



Intramedullary Rods

Clinical Performance
and Related
Laboratory Testing

Harvey/Daniels/Games
EDITORS



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Intramedullary Rods: Clinical Performance and Related Laboratory Testing

J. Paul Harvey, Jr., A. U. Daniels, and Robert F. Games, editors



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The quality of the papers in this publication reflects not only the obvious efforts of the authors and the technical editor(s), but also the work of these peer reviewers. The ASTM Committee on Publications acknowledges with appreciation their dedication and contribution of time and effort on behalf of ASTM.

Foreword

The papers in this publication, *Intramedullary Rods: Clinical Performance and Related Laboratory Testing*, were presented at the symposium on Femoral Intramedullary Rods: Clinical Performance and Related Laboratory Testing held 12-13 May 1987 in Cincinnati, Ohio. The symposium was sponsored by ASTM Committee F-4 on Medical and Surgical Materials and Devices and the Committee on Biomedical Engineering of the American Academy of Orthopedic Surgeons. J. P. Harvey, Jr., USC School of Medicine, A. U. Daniels, University of Utah, and R. F. Games, Richards Medical Company, Inc., presided as symposium chairmen and are editors of this publication.

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Overview

The symposium as an informal meeting for discussion has its obvious usefulness for the symposiast, but, as an excuse for multiple publication, quite another view may be taken of it. Also, if every symposiast were a Dr. Samuel Johnson, perhaps the intercalated discussions at a symposium might strike more fire and distil less mutual admiration. Symposia, like hard liquor, should be taken in reasonable measure, at appropriate intervals.

Sir F. M. R. Walshe [1888-1979]
 Perspectives in Biology and Medicine
 2:197, 1959

Times change and activities change. The ASTM Committee F-4 on Medical and Surgical Materials and Devices has long used design standards, but with the markedly increased use of internal fixation devices for fractures and the joint replacement implants all members agree performance standards have become necessary. Designs vary, and aside from copying nature, one need not be concerned about a design as long as the device can be inserted into the body easily and maintained there without creating unusual forces on surrounding anatomical structures or preventing muscles from performing normal function. The materials used for construction of the device should not cause unusual biological responses or preferably any biological response whatsoever. However, we are concerned that implants provide function as close to normal physiology as possible. Function has become everything; design, other than as it effects function, does not need to be standardized.

To write a standard for a device we need to find out from the user the application of the device and the problems associated with this application. We must have information from the general interest participants—the engineers and the biologists who are interested in materials, the strength of materials, design capabilities of material, and response of tissue to implant material. We also must have information from the manufacturers describing the problems and difficulties in manufacturing devices. We also need to know the cost of providing specific characteristics in the device. Putting this information together allows us to see the factors and functions which should be standardized. We must also learn how to test for these functions. Also, stimulating people from many disciplines to work together on one problem usually necessitates our specifying definitions and specific terms for use so all can speak the same language when talking to one another about a single problem.

This book consists of the papers presented at the ASTM Symposium on Femoral Intramedullary Rods: Clinical Performance and Related Laboratory Testing. The discussion of each paper was of value to the symposiast. The last afternoon of the symposium we did not present papers but attempted to begin writing standards for intramedullary rods, having all participants help in specifying definitions and in deciding what functions could be standardized. We have had subsequent meetings of F-4 Section on Intramedullary Rods. However, at the date of this printing we have not yet had consensus for standards on intramedullary rods or testing for functions of rods. But we are very far forward compared to our position when the symposium was held. Our discussions and presentations have struck much fire and opened new concerns and problems and controversy in clinical performance and related laboratory testing.

We feel this approach of holding a symposium on a topic and having the participants attempt before the end of the symposium to write standards was very successful. This book represents

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the basis for the discussion, the controversy, and the standards (when written). We feel that we will try again to use the same format. Our next attempt will be a symposium on Spinal Devices. Like hard liquor our symposia will be presented in reasonable measure at appropriate intervals.

J. Paul Harvey, Jr.

USC School of Medicine, Los Angeles, CA
90003; symposium cochairman and coeditor.

A. U. Daniels,¹ Norman R. Bayne,¹ and Aaron A. Hofmann¹

Mechanical Properties of Küntscher Nail Sections

REFERENCE: Daniels, A. U., Bayne, N. R., and Hofmann, A. A., “**Mechanical Properties of Küntscher Nail Sections**,” *Intramedullary Rods: Clinical Performance and Related Laboratory Testing*, ASTM STP 1008, J. P. Harvey, Jr., A. U. Daniels, and R. F. Games, Eds., American Society for Testing and Materials, Philadelphia, 1989, pp. 3-9.

ABSTRACT: The purpose of this study was fourfold: determine the section rigidity in torsion and bending of three commonly used sizes of Küntscher-type nails obtained from a single source; compare the results with calculated values based on section geometry and material properties; determine the effect of a transverse hole (intended to accommodate a locking device) on section properties; and determine the effect of simulated-use cyclic loading on properties of sections with transverse holes. Because rods of this design are slotted and asymmetrical in cross section, bending tests were performed in two orientations, 0 deg (slot-down) and 90 deg (slot rotated 90 deg from the slot-down position).

We found that the change from an 11-mm to a 15-mm rod diameter increased rod stiffness and strength by about a factor of two, except in the 90-deg orientation, where closure of the rod open section under load markedly reduced strength and stiffness for all rod sizes. Neither the transverse holes nor cyclic load exposure had a marked effect on section properties. In torsion, measured stiffness essentially equaled calculated stiffness. There was not a similar equality in measured and calculated stiffness in bending because the point loading in the actual tests produce much different effects on open sections than the pure bending moments used in the calculations.

We also concluded that ASTM F 383 needs to be modified to incorporate a more conventional use of terminology for structural stiffness or rigidity and strength, and a method for measuring deflections that recognizes the problem of open sections. It also seems appropriate to modify the gripping method for torsion tests to include the use of mechanical chucks.

KEY WORDS: intramedullary nail, Küntscher, rigidity, strength, test method

Basic information on mechanical properties of femoral intramedullary rods is necessary to further our understanding of the manner in which these devices stabilize fractures. The role of these properties in rod design and performance has been outlined recently by Donald and Pope [1]. Also, Johnson and Tencer [2] have reported that there is substantial variation in geometry and mechanical properties among intramedullary rods of the same nominal size and design produced by different manufacturers.

In this study, our purpose was fourfold: to determine the section rigidity in torsion and bending of three commonly used sizes of Küntscher-type nails obtained from a single source; to compare the results with calculated values based on section geometry and material properties; to determine the effect of a transverse hole (intended to accommodate a locking device) on section properties; and to determine the effect of simulated-use cyclic loading on properties of sections with transverse holes. We found that our testing also raised questions concerning the standard test method used, and these are also discussed.

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Materials and Methods

Test specimens were straight sections of standard 11, 13, and 15-mm Küntscher-type stainless steel nail stock (Howmedica, Inc., Rutherford, NJ). Torsion tests were performed according to the ASTM Standard Practice for Static Bend and Torsion Testing of Intramedullary Rods (F 383), with two exceptions. First, the gage length used was 229 mm rather than 254 mm. Then, rather than inserting the ends of the rods into "blocks of suitable material" as suggested in the standard, the ends were gripped externally in standard chucks for torsion testing supplied with the test machine (Model 1125, Instron Corp., Canton, MA), as shown in Fig. 1.

For comparison with measured values, torsional stiffness was calculated using the following expression

$$T = D \times B^3 \times C \times G/3L$$

where

T = torsional moment required for a specified torsional deflection,

D = angle of torsional deflection (1 deg),

B = wall thickness of nail section (1.7 mm for 11- and 13-mm, 1.8 for 15),

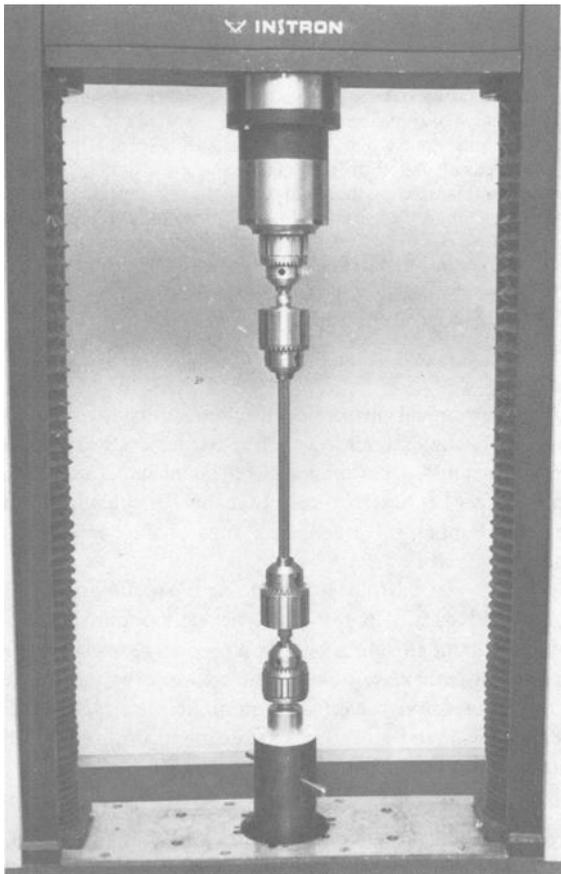


FIG. 1—Test configuration for torsional testing of intramedullary rods.

C = circumference around cloverleaf portions of the nail (mm),
 G = shear modulus of 316L stainless steel (77 GPa), and
 L = gage length (229 mm).

Bending tests also were performed according to ASTM F 383, except that a standard bending test fixture (Fig. 2) supplied with the test machine was used. This fixture had loading and supporting points which were sections of non-rotating cylinders rather than rollers as suggested by the standard.

Tests were performed with and without 5-mm transverse holes, and bending tests were performed with the open slot at both 0 and 90 deg with respect to the loading direction (Fig. 3). Tests on specimens with transverse holes were repeated after placing the sections in simulated bones (polymeric tubes with section properties similar to the human femur), adding a Schanz screw for transverse stabilization, and exposing the preparations to 300 000 cycles of four-point bending at twice the peak moment [3] expected during normal-level walking ($98 \text{ N} \cdot \text{m} \times 2 = 196 \text{ N} \cdot \text{m}$).

For comparison with measured values, structural elastic-range bending stiffness was calcu-

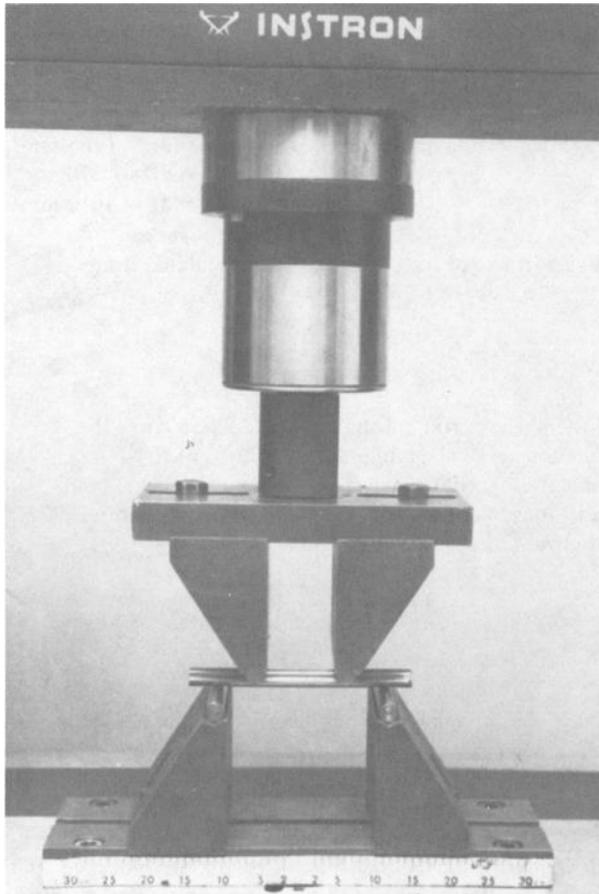


FIG. 2—Test configuration for bend testing of intramedullary rods. A rod is shown in the 0-deg orientation.

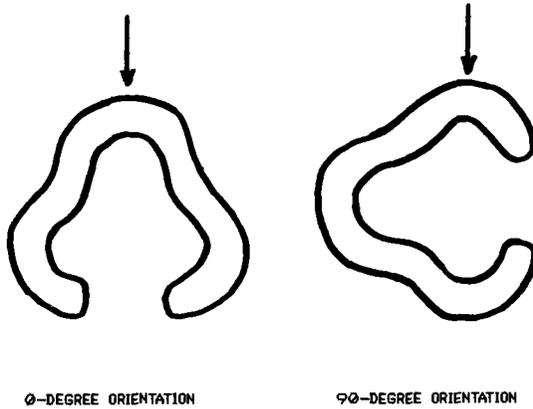


FIG. 3—Rod section orientations used in the bending tests.

lated by first determining the area moments of inertia, I , of the rod cross sections using standard geometric methods. The values determined were as follows:

0-deg testing orientation:	I (11-mm rod) = 248 mm ⁴
	I (13-mm rod) = 662 mm ⁴
	I (15-mm rod) = 1276 mm ⁴
90-deg testing orientation:	I (11-mm rod) = 185 mm ⁴
	I (13-mm rod) = 570 mm ⁴
	I (15-mm rod) = 1010 mm ⁴

Then, the bending stiffness of the specimens was calculated from

$$F/y = 6EI/X$$

where

F/y = slope of the linear portion of the force/deflection curve,

E = elastic modulus of 316L stainless steel (200 GPa),

I = area moment of inertial of the cross section (see above), and

X = a constant whose value depend on configuration of fixtures (277×10^3 mm³ for this test configuration).

Results and Discussion

Torsional Rigidity

ASTM F 383 torsional rigidity includes only elastic deformation and is the torque required to produce an angular deflection of 1 deg. Results are shown in Fig. 4. Mean test values were 19, 26, and 42 N·cm for the 11, 13, and 15-mm intact nail sections. For the intact sections, the differences between calculated and measured torsional rigidities were less than 10%, and the effects of both transverse holes and cyclic loading on torsional rigidity were negligible. Gripping the specimens with chucks is much easier than insertion into blocks as suggested by the standard, and the close agreement between measured and calculated rigidities suggests that the gripping method is an appropriate one.

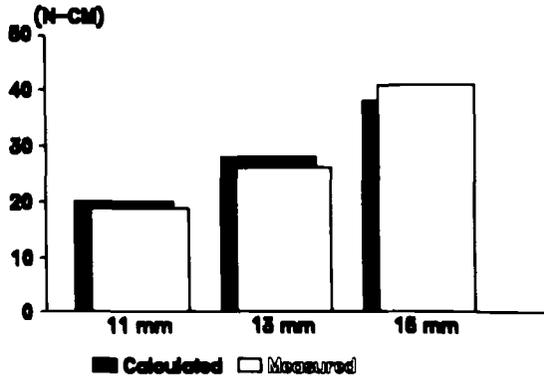


FIG. 4—Results of torsional rigidity test on 11, 13, and 15-mm diameter rods.

Elastic-Range Bending Stiffness

The ASTM F 383 standard defines a parameter called “bending rigidity,” which is the bending moment required to produce a permanent deflection of 0.13 mm divided by the total deflection produced by this bending moment. Thus, ASTM F 383 “bending rigidity” includes both elastic and plastic deformation and is actually a measurement of rod structural strength in bending. In mechanics, the terms “rigidity” and “stiffness” are conventionally reserved for measurements of material or structural elastic modulus. ASTM F 383 makes no provision for defining or reporting such a parameter, even though it is elastic range bending stiffness that could be expected in great measure (along with the torsional rigidity discussed in the previous section) to determine the intrinsic fracture stabilization that a rod can provide, barring slippage at the rod/bone interface. Therefore, we chose to measure and report the actual “elastic-range bending stiffness” which is the slope of the linear portion of the load/deflection curve recorded in performing the bending test.

As shown in Figs. 5 and 6, measured *elastic-range bending stiffness* was substantially less than calculated for the largest diameter rod, especially in the 90-deg orientation. This was attributable to the simplicity of the method used for calculating stiffness of an open section and the additional deflection due to the rod section closing under load in the 90-deg orientation.

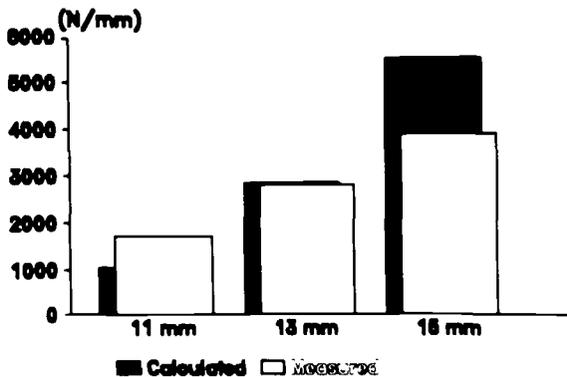


FIG. 5—Results of bending stiffness tests for 0-deg orientation.

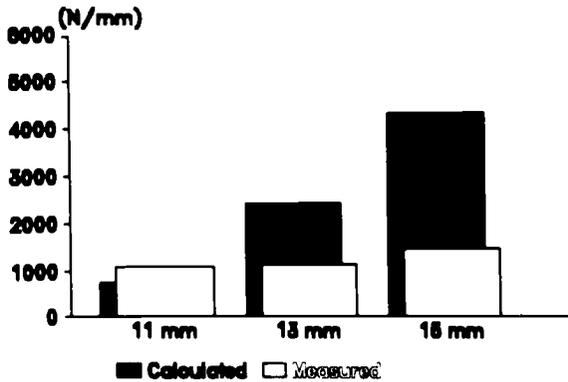


FIG. 6—Results of bending stiffness tests for 90-deg orientation.

Bending Strength

In keeping with conventional mechanics terminology, we have chosen to refer to ASTM F 383 “bending rigidity” as *bending strength* as discussed above. As shown in Figs. 7 and 8, the bending strengths for the three sizes of rods were 30, 50, and 68 kN·m/m, respectively, at 0-deg orientation and 19, 21, and 27 kN·m/m at 90 deg. The effect of the transverse hole on bending strength was negligible except for the 11-mm nail section, where there was a 15% decrease for the 90-deg orientation (which is the less clinically significant of the two orientations). The result is logical since transverse holes have the largest effect on area moment of inertia of the rod cross section for the smallest diameter rod, oriented so that the portions of the section through which the hole passes are farthest from the neutral axis in bending.

Exposure to cyclic loading did produce some plastic deformation of the screw holes, but no fatigue cracks large enough to be detected with a low-power optical microscope. Bending strength was not significantly affected, except for a possible *increase* for 13- and 15-mm nails tested in the 0-deg orientation. Perhaps a small amount of cold working occurred during cycling, producing this effect.

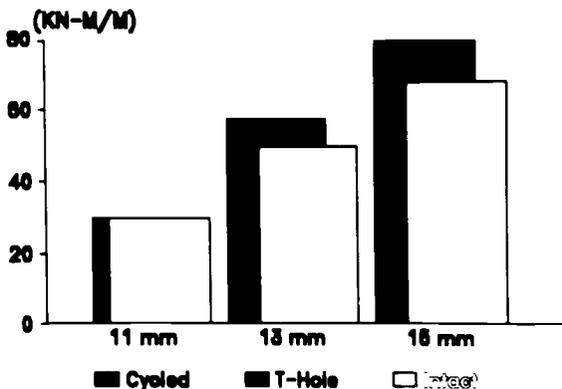


FIG. 7—Results of bending strength tests for 0-deg orientation.

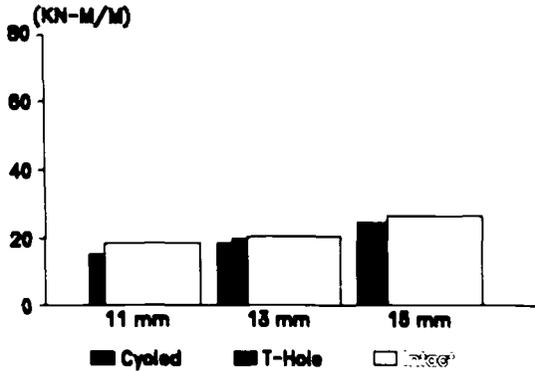


FIG. 8—Results of bending strength tests for 90-deg orientation.

Conclusions

1. The change from an 11- to 15-mm rod diameter increased rod stiffness and strength by about a factor of two, except in the 90-deg orientation, where closure of the rod open section under load markedly reduced strength and stiffness for all rod sizes.
2. Neither the transverse holes nor cyclic load exposure had a marked effect on section properties.
3. In torsion, measured stiffness essentially equaled calculated stiffness.
4. There was not a similar equality in measured and calculated stiffness in bending because the point loading in the actual tests produce much different effects on open sections than the pure bending moments used in the calculations.
5. ASTM F 383 needs to be modified to incorporate a more conventional use of terminology for structural stiffness or rigidity and strength as well as a method for measuring deflections that recognizes the problem of open sections. It also seems appropriate to modify the gripping method for torsion tests to include the use of mechanical chucks.

Acknowledgment

Donation of intramedullary rod sections by Howmedica, Inc., and partial support from the U.S. Veterans Administration's Rehabilitation Research and Development Service are gratefully acknowledged.

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- [2] Johnson, K. and Tencer, A. F., "Mechanical and Geometric Properties of Commercially Available Cloverleaf Intramedullary Rods," *Transactions. Orthopedic Research Society*, Vol. 8, 1983, p. 226.
- [3] Paul, J. P., "The Biomechanics of the Hip Joint and its Clinical Relevance," *Proceedings*, Royal Society of Medicine, Vol. 59, 1966, pp. 943-948.

Calculation and Experimental Analysis of Forces and Stresses in Intramedullary Nail Models

REFERENCE: Baumgart, F. and Becker, H. J., "Calculation and Experimental Analysis of Forces and Stresses in Intramedullary Nail Models," *Intramedullary Rods: Clinical Performance and Related Laboratory Testing, ASTM STP 1008*, J. P. Harvey, Jr., A. U. Daniels, and R. F. Games, Eds., American Society for Testing and Materials, Philadelphia, 1989, pp. 10-19.

ABSTRACT: One open cylindrical tube made from shape memory alloy of 55% nickel and 45% titanium (NiTi) was tested. The activated total radial force was measured between rigid plates, when the tube was heated by hot water. Three NiTi tubes of 10-mm length were inserted into biomechanical equivalent aluminum tubes and heated in order to measure the deformation of the model tubes. Photoelastic tests were performed on three NiTi tube specimens, 2.5 mm in length, which had been inserted into biomechanical equivalent Araldite disks of 10-mm thickness. All tests were evaluated by combining the results with calculations on slender circular rings and were transmitted to natural bone tubes. The results show activated stresses between 15 and 30 N/mm² in real bone and therefore no dangerous stress states.

KEY WORDS: osteosynthesis, biomechanics, design, intramedullary nails, shape memory alloys

A nickel-titanium memory alloy (NiTi) of 55% nickel and 45% titanium and its shape memory effect (SME) can be used for different kinds of orthopedic implants such as wires, staples, and plates. Because intramedullary nails made of NiTi have some distinct advantages, their use has been proposed by some authors [1,2]. The memory effect of the NiTi alloy can be measured by about 6% linear strain. The behavior of a memory implant with "high" transition temperature range $A_s - A_f$ in principle is indicated in Fig. 1.

Recently used stainless steel nails need very high forces for implantation and removal. In the case of a memory nail following the principle shown in Fig. 1, the forces can be reduced drastically. The heat supply can be provided by injection of hot water or by insertion of a silicon heater into the nail, which results in the temperature of the nail becoming higher than the temperature of the surrounding tissue.

For intramedullary nails using fixation by SME (Fig. 2), an important question is whether or not the activated radial force generated by the nail can lead to dangerous stress states in the hollow tube of the natural bone. Because the dimensions of an NiTi nail are prescribed by the functional load to have sufficient stiffness and strength, the force activated by SME is also determined and cannot be chosen freely. The goal of this investigation was to show that the bone cannot be overloaded by the expanding NiTi nail.

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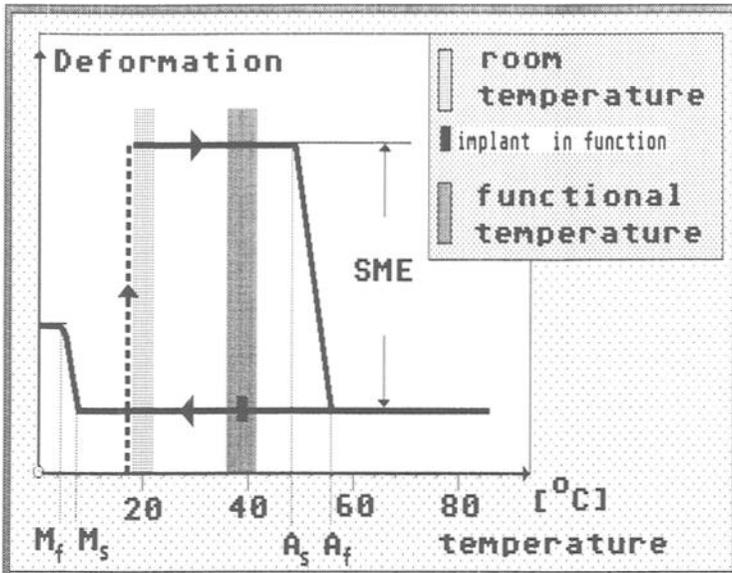


FIG. 1—Principle of memory implants.

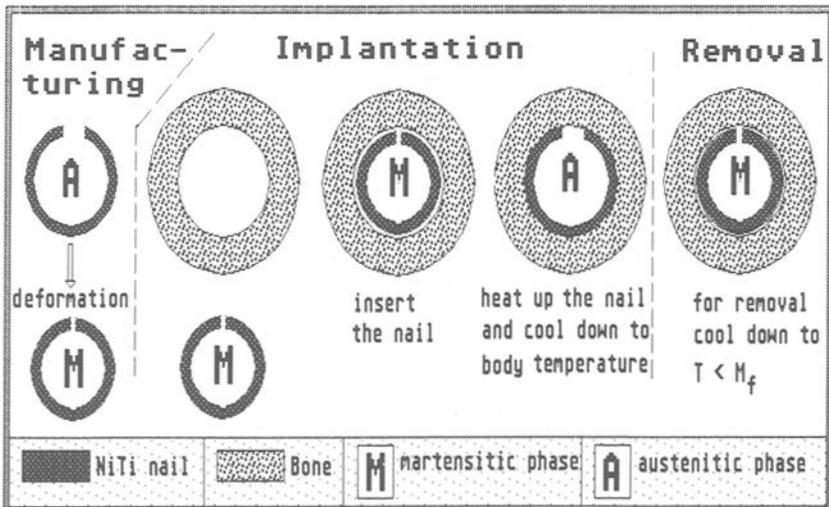


FIG. 2—Handling of intramedullary NiTi nail.

Materials and Methods

Dimension of a Well-Designed NiTi Nail

Biehl et al. [3] have shown by measurements on different stainless steel nails the static fracture bending moments (Table 1). During heating, NiTi can activate a flow stress of about 500 N/mm² ($T > A_f$). The same value can be used as an upper limit of the allowable stress for design of a NiTi nail. Because this value is lower than that of stainless steel, an increase of wall

TABLE 1—Fracture bending tests (after Ref 3).

Nail Type	Fracture Bending Moment, Ncm		
	Nail Diameter 8 mm	Nail Diameter 9 mm	Nail Diameter 10 mm
Ortopedia (Küntscher)	8470	9060	12750
OSTEO	4410	5430	5100
AO	4710

thickness for NiTi nails is necessary. The estimated dimensions for a fracture bending moment of 5000 Ncm are

$$d = 11 \text{ mm} \quad s = 1.5 \text{ mm}$$

Methods for Estimation of Expanding Forces and of Stress Distribution During Heating

If an NiTi nail is used as proposed in Fig. 2, it activates, by expansion, compressive stresses on the inner contour of the bone tube. Three tests were carried out:

1. Measurement of the expanding force (Fig. 3).
2. Test of 10-mm-long specimens of NiTi nail in aluminum tubes with biomechanical equivalent stiffness to bone tubes; control of diameters d_1 and d_2 (Fig. 4) of the aluminum tubes after heating.
3. Test of 2.5, 5, and 10-mm-long specimens of NiTi nails in three biomechanical equivalent Araldite tubes and observation of photoelastic reaction.

Design of Equivalent Aluminum Tubes

The mean values for the dimensions of human femurs have been reported by Sadakane et al. [4]. For the present investigation, three typical bone tubes were used. The dimensions and material properties are given in Table 2. The Poisson number of all the materials was chosen to be $\nu = 0.3$.

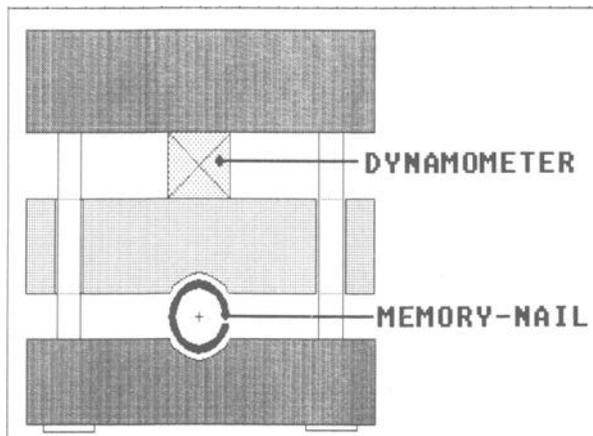


FIG. 3—Measurement of expanding force.

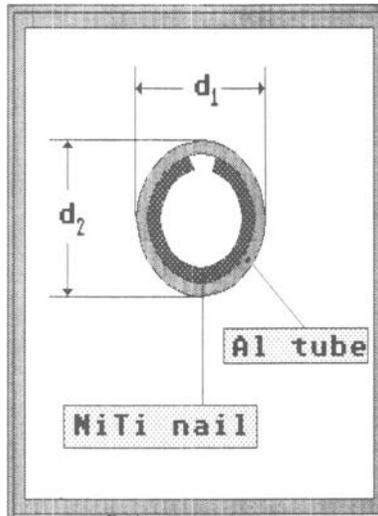


FIG. 4—Test model.

TABLE 2—Base values for calculations.

	Bone Tubes		Material Properties	Modulus of Elasticity, E , kN/mm^2
	Inner Diameter, d_i , mm	Wall Thickness, s , mm		
No. 1	11	5	bone (cortical)	17
No. 2	12	6	aluminum	70
No. 3	13	7	Araldite	3.4

The *equivalence* of two tubes, made from different materials but with the same inside diameter, is defined as follows (Fig. 5) [5]:

Both tubes have the same radial displacement w when loaded by the same internal pressure p .

The well-known pressure displacement relation for thick-walled elastic tubes is used and leads to the design formula

$$D = d_i \sqrt{\frac{A + 1}{A - 1}} \tag{1}$$

where

$$A = \frac{E_M}{E_B} \left[\frac{1 + (d_i/d_o)^2}{1 - (d_i/d_o)^2} + \nu_B \right] - \nu_M \tag{2}$$

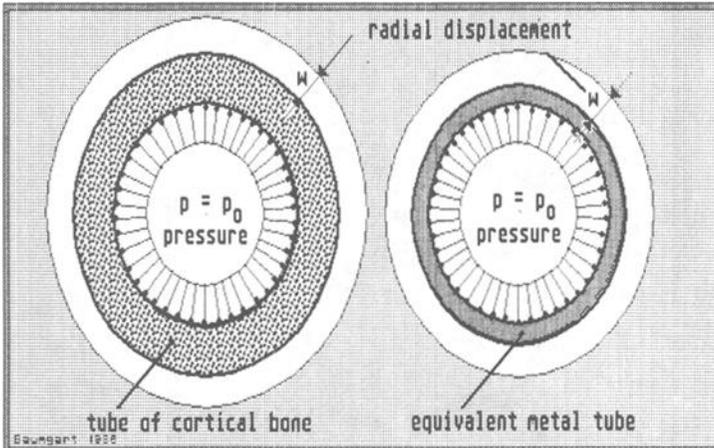


FIG. 5—Model for equivalent design.

and

- E_M = modulus of elasticity of model,
- E_B = modulus of elasticity of bone,
- d_i = inner diameter of both tubes,
- d_a = outer diameter of bone tube,
- D = outer diameter of model tube, and
- $\nu_B = \nu_M = \nu$ = Poisson numbers.

The results of the calculation are given in Table 3.

Design of Equivalent Araldite Disks

The calculation of an equivalent Araldite disk follows Eqs 1 and 2. But from the small modulus of Araldite results, $A < 1$. Therefore, an equivalent Araldite tube of the same length is not possible, and neither is it possible with $D \rightarrow \infty$. The stiffness of Araldite is not sufficient. For this reason, the length of the NiTi tubes is reduced to 2.5 mm to reduce the activated radial pressure. A is then estimated by

$$A = \frac{E_M \ell_M}{E_B \ell} \left[\frac{1 + (d_i/d_a)^2}{1 - (d_i/d_a)^2} + \nu_B \right] - \nu_M$$

where $\ell_M = 10$ mm and $\ell = 2.5$ mm, which means that the stiffness of the Araldite tube is increased to about 4 times the real value. D follows from Eq 1. The results are given in Table 4.

TABLE 3—Calculation of equivalent aluminum tubes.

	Dimension			
	d_i , mm	d_a , mm	D_{calc} , mm	D_{used} , mm
Tube No. 1	11	21	12.46	12.5
Tube No. 2	12	24	13.67	13.7
Tube No. 3	13	27	14.88	14.9

TABLE 4—Calculation of equivalent Araldite tubes.

	d_i , mm	d_o , mm	A , l	D , mm
Tube No. 1	11	21	1.3450	28.7
Tube No. 2	12	24	1.2733	34.6
Tube No. 3	13	27	1.2229	41.1

Tests

All of the models were heated in a temperature-controlled bath of fluid (water, glycerine). Maximum temperature was 70°C.

Results and Discussion

Test A: Expanding Force at Rigid Fixation

The expanding force of a memory nail ($d = 11$ mm, $s = 1.5$ mm, $\ell = 200$ mm) was estimated to $P = 7000$ N, which is equivalent to a specific expanding force of 35 N/mm. The bending stress in the nail, activated by SME, is calculated to be about 500 N/mm². This is in good agreement with the results of Johnson [6].

Test B: Expanding Force in Equivalent Aluminum Tubes

The displacements u and w in two orthogonal radial directions on the outside of three aluminum tubes caused by the SME of the NiTi tubes have been measured (Fig. 4). A slender ring shows the following displacements u and w by loading with a specific radial force q :

$$2w = 0.137 \frac{qR^3}{EJ} = c_w \times q$$

and

$$2u = 0.149 \frac{qR^3}{EJ} = c_u \times q$$

(For q , u , w , R , see Fig. 6. $E = 70$ kN/mm² for aluminum, and $J = s^3/12$ is the specific moment of inertia of the ring). Because estimation of q from the test results and by these formulas is redundant, control of the model was possible. A mean value of

$$q = 49.8 \text{ N/mm}$$

has been estimated. The standard deviation of 11% is relatively small and shows the validity of the mechanical model.

Test C: Stress State in Equivalent Araldite Tubes

Figure 7 shows the NiTi tubes (2.5, 5, and 10 mm in length) and the three equivalent Araldite tubes. All these tubes have been investigated in photoelastic tests. The NiTi nails were heated by the glycerine bath. Figure 8 shows the isochromatics in the disk at a start temperature of 0°C. Figure 9 illustrates the same disk with a 10-mm-long NiTi nail after heating to 60°C, and

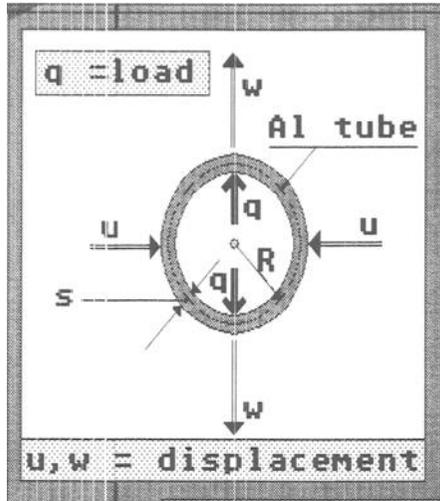


FIG. 6—Model for calculation.

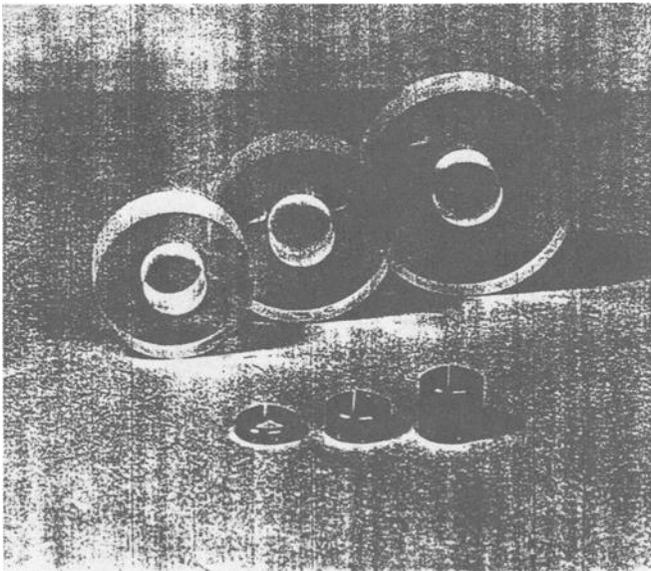


FIG. 7—Equivalent Araldite disks and NiTi tube specimens (11 mm).

Fig. 10 shows the same disk after cooling down to 37°C. From Figs. 9 and 10 it is clear that *the stress state does not decrease after cooling down to body temperature, and is still present as long as the bone resists against the activated forces. Furthermore, the stress distribution shows two concentrations, one near the gap of the NiTi nail and the other on the opposite side, which means that the mechanical model of Test B is very close to the reality.*

The photoelastic test was not yet evaluated quantitatively; therefore additional information for the expanding force is not available.

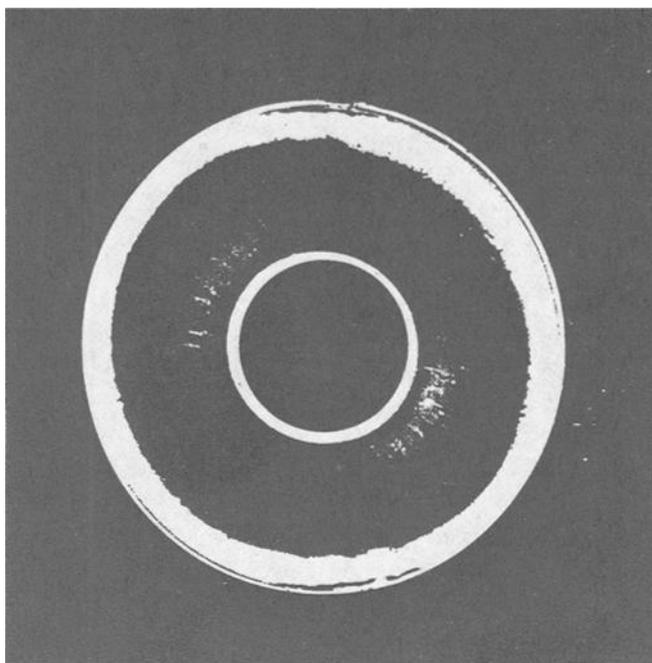


FIG. 8—Araldite disk, outside diameter 35 mm, inside diameter 12 mm, 0°C.

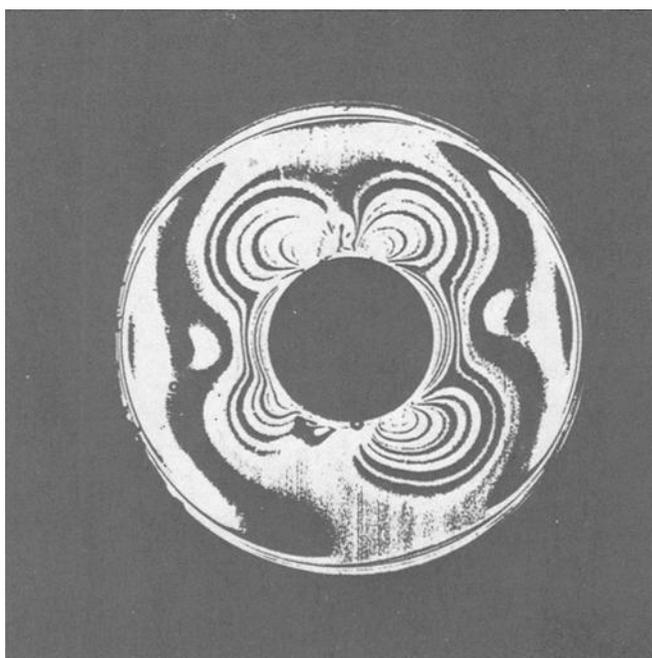


FIG. 9—Araldite disk, outside diameter 35 mm, with NiTi nail, +60°C.

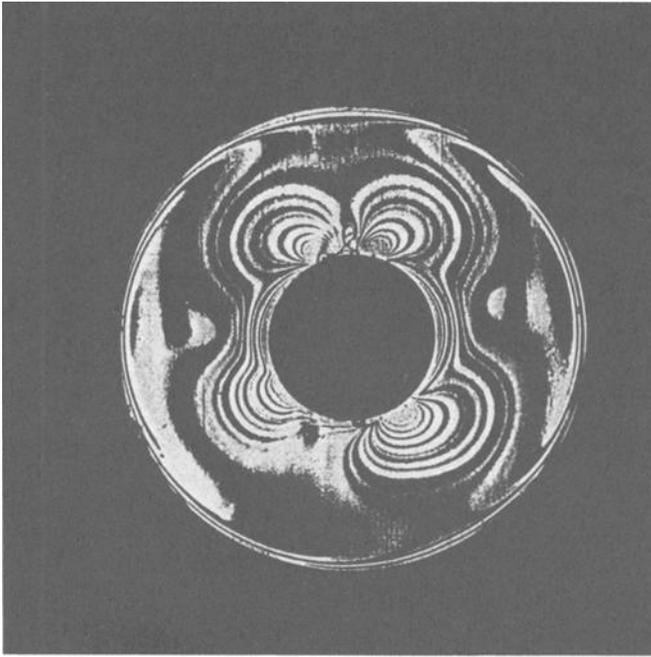


FIG. 10—Araldite disk, outside diameter 35 mm, with NiTi nail, +37°C.

Calculation of Stresses in Bone Model

Calculations using the bending theory of circular beams assuming two opposite radial forces of $q = 50 \text{ N/mm}$ on the inside of the bone tubes show bending stresses of maximum 22 N/mm^2 (tension) and minimum 31 N/mm^2 (compression). These stresses are very low in comparison with the fracture stress of the cortex of about 121 N/mm^2 (see Ref 7).

Conclusions

Combined calculations and experimental investigations on short intramedullary nail models have shown that the assumed models are in agreement with the tests and *are useful for pre-calculations*. We conclude that *well-designed NiTi nails cannot activate dangerous stress states in bone by SME only*.

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Testing Method for Evaluating Bending Stiffness and Torsional Stability of Femurs Implanted with Intramedullary Nails

REFERENCE: Butts, M. K., Bechtold, J. E., Hoeltzel, D. A., Kyle, R. F., and Gustilo, R. B., "Testing Method for Evaluating Bending Stiffness and Torsional Stability of Femurs Implanted with Intramedullary Nails," *Intramedullary Rods: Clinical Performance and Related Laboratory Testing*, ASTM STP 1008, J. P. Harvey, Jr., A. U. Daniels, and R. F. Games, Eds., American Society for Testing and Materials, Philadelphia, 1989, pp. 20-25.

ABSTRACT: A testing method to evaluate the performance of intramedullary (IM) nails in stabilizing femur fractures and to compare the effects of different design features is presented in this study. Techniques are described for preparing specimens, creating fractures, potting bones for testing with electrohydraulic materials testing machine, testing in bending and torsion, and measuring flexural stiffness and torsional stability. Flexural stiffness is calculated from the moment versus deflection curve. The femur is rotated to 10 deg from neutral, and the torque generated at this forced rotation is recorded. The torque is then released by rotating the femur back to the neutral position, and the angle at which the torque returns to zero is recorded as the springback angle. The springback angle indicates the amount of slippage between the intramedullary nail and bone, or their relative stability in torsion.

KEY WORDS: intramedullary nail, testing method, bending stiffness, torsional stability, springback angle

Intramedullary nails were developed to stabilize fractured bones by acting as an internal splint, while allowing both early mobilization of adjacent joints and weight bearing. Initially, the indications for the use of an intramedullary nail were a transverse, midshaft fracture with inherent stability from interdigitating fragments. Newer intramedullary nails have been developed which will stabilize more comminuted fractures as well as those in the proximal and distal shaft regions.

Intramedullary nails must stabilize a fractured bone against a combination of axial compressive, bending, and torsional loads, depending on the severity of the fracture and the amount of bone loss.

Traditional intramedullary nails are most effective for fractures with inherent stability and little bone loss, since they do not resist torsional loading particularly well. Newer intramedullary nails, which provide positive interlock with the proximal and distal fragments, have been specif-

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ically designed to resist torsional loading and axial collapse in the absence of interdigitating fracture fragments.

Different designs for providing the positive interlock with the nail and the bone fragments have been developed, and quantification of the effectiveness of each of the nail designs will aid the clinician in selecting a type of intramedullary nail.

A protocol has been developed in the authors' Minneapolis laboratory to evaluate the bending and torsional performance of femoral and tibial intramedullary rods. Portions of the technique are described in Bechtold et al. [1] and Thimsen et al. [2]. Results of testing of intramedullary rods using this technique are presented in a companion paper in this volume, by Bechtold et al. [3].

Objective

The objective of this paper is to describe test methodology which has been developed in this laboratory to evaluate the performance of different designs of intramedullary nails implanted in femurs, with respect to their stiffness in bending and stability in torsion. The effect of the amount of bone loss on intramedullary nail performance will also be considered. A comparison of interlocking nails using these tests is presented in a separate paper [3].

Methods

In this study, the performance of an intramedullary nail which has been implanted into a femur is to be evaluated. First, the cadaver specimens and their preparation will be discussed; then the experimental methods for evaluating the intramedullary nails in bending, torsion, and axial pushout will be presented.

Femur Specimen Selection

Either fresh or formalin-fixed femurs are suitable for this study, although fresh femurs are preferred. Fresh femur specimens are more difficult to obtain for testing, but they most closely approximate the bones within which the intramedullary nails must actually function.

The material properties of formalin-fixed and fresh cancellous bone differ in that formalin-fixed cancellous bone is much weaker and softer than fresh cancellous bone. This difference is important if the interlocking mechanism relies on the integrity of the cancellous bone stock, as for an intramedullary nail with distal cancellous locking fins.

A synthetic femur model which satisfactorily reproduces the geometry of a human femur, its material properties, and their anatomic variation, would be useful as a standard bone model for comparative evaluations. Such standard femurs have been reported [4] and may be suitable for comparative evaluations of intramedullary nails.

Since neither synthetic femur models nor fresh femurs were available to this laboratory in sufficient numbers for statistical evaluations, we have used formalin-fixed femurs, cognizant of their drawbacks as discussed above.

Specimen Preparation

Radiographs—Standard anterior-posterior and medial-lateral planar radiographs are obtained for each femur. The correct size of intramedullary nail for each femur is determined from these radiographs, using clinical size guidelines and appropriate scale factors.

Fixture Potting—A self-curing material (Dental diestone) is used to pot the femurs into aluminum fixtures (cubes), which will attach the femurs to the materials testing machine. Dental

diestone is an inexpensive powder which is mixed with water until it has a doughy consistency, and then hardens in 10 to 20 min, depending on the amount of water added.

First, the distal condyles are potted. The distal femur shaft is left free if distal interlocking screws are to be inserted later.

Transverse Fractures—Reproducible transverse midshaft fractures are then created with a hand saw or electric bandsaw. This produces a fracture with no interdigitating fragments which would influence the stability provided by the intramedullary nail.

To model bone loss or comminution, segments of bone can be sequentially removed from the midshaft region. As an example, first the freshly fractured bone can be tested. Then, to model mild comminution or bone loss, the same bone with 3.0 cm of the bone shaft removed at the isthmus would be tested. To model additional bone loss, a femur with 6.0 cm removed would be tested. Finally, to model severe bone loss or comminution, a femur with 9.0 cm removed would be tested.

Reaming—A starting hole is created proximally, and the femur is reamed using a flexible reamer. The correct intramedullary nail is inserted according to standard surgical techniques, taking care to keep fracture fragments anatomically aligned.

The distal fixture is attached to the materials testing machine, and the proximal end of the femur is potted in Dental diestone in aluminum fixture cube. Proper bone alignment while potting is maintained with the load frame of the materials testing machine.

Specimen Testing

Four-Point Bending—Femurs and intramedullary nails must resist bending forces during the gait cycle. The performance of the bone/intramedullary nail structure in bending could be characterized by the flexural stiffness of the bone with implanted intramedullary nail, under four-point bending.

The femurs are tested in four-point bending on an MTS electrohydraulic materials testing machine. The bending moment is applied on the posterior-medial aspect of the femur with a moment arm of 6.2 cm. The bending moment is applied in approximately the same anatomic location for each femur tested, if all the femurs tested are roughly the same length, Fig. 1.

The femur is loosely clamped at the outer two supports to prevent longitudinal rotation of the femur during bending. This is necessary because the anterior curvature of the femur and its irregular shape cause the femur to rotate in its supports when being loaded.

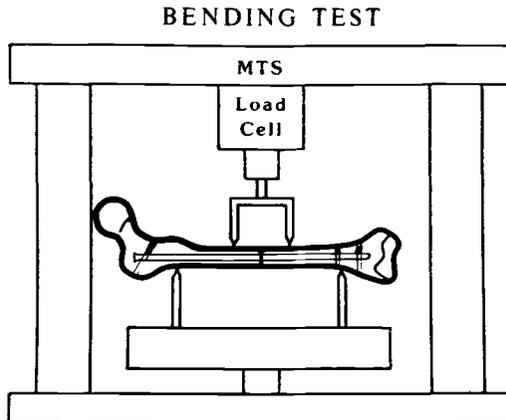


FIG. 1—Apparatus to test femur with implanted intramedullary nail in four-point bending.

A midshaft displacement of 0.32 cm is applied, and moment (load) versus midshaft displacement is recorded on an analog X-Y recorder. The displacement limit of 0.32 cm is arbitrary, but in the past it has been sufficient to create a linear moment/deflection relationship and does not permanently bend the intramedullary nail. The flexural stiffness is calculated as the slope of the moment vs. deformation curve.

Torsional Testing—Femurs must also resist torsional forces during the gait cycle and activities of daily living. Torsional forces are particularly large when the patient rises from a chair or climbs stairs. As mentioned previously, it is this torsional loading which the traditional intramedullary nails were poor at resisting. A testing technique which examines the performance of intramedullary nails in resisting torsion was developed.

The torsional testing consists of two parts. First, the distal fragment is externally rotated 10 deg with respect to the proximal fragment. The maximum torque generated at this forced rotation is measured. This torque will represent the amount of resistance to torsional loading which the intramedullary nail imparts to the fractured femur, Fig. 2.

The extent of rotation to apply to the femur was chosen to be 10 deg to provide a severe loading case for better differentiation of torsional characteristics among the intramedullary nails tested.

The torque is then removed by internally rotating the distal fragment. The amount of rotation of the distal fragment, or springback, which is necessary for the torque to return to zero, is measured, Fig. 3.

The springback angle is an indication of the amount of slippage between the intramedullary nail and bone during torsional loading. Thus, a large springback angle represents a case in which an intramedullary nail maintained contact and stability throughout the torsional loading and then returned to its original position. A small springback angle represents a case where an intramedullary nail provided poor resistance to the severe forced rotation and allowed the proximal and distal fragments to slip relative to each other.

Push-Through Test—In the final test, the ease with which the intramedullary nail could penetrate the distal femoral condyles due to direct axial load is measured. Because penetration of

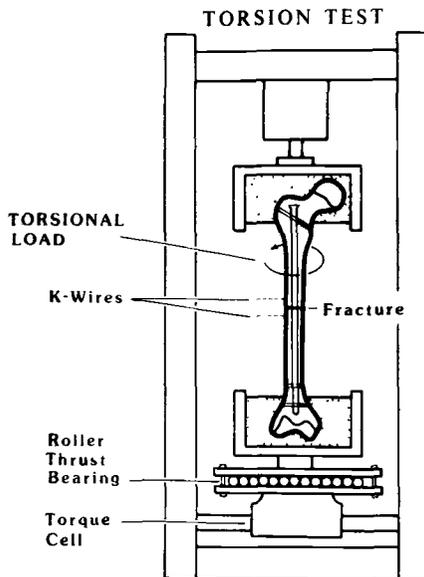


FIG. 2—Apparatus to test femur with implanted intramedullary nail in torsion.

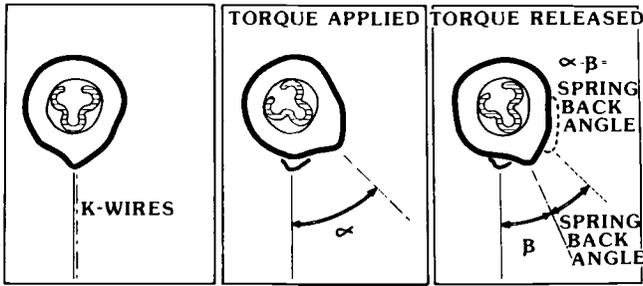


FIG. 3—Measurement of springback angle.

the femoral articulating surface can lead to serious, late complications and degenerative changes in the cartilage and bone, this should be avoided.

The distal femoral condyles are freed of dental diestone. A rim of diestone is left, however, which stabilizes the distal fragment and resists the force of the intramedullary nail being pushed distally.

The intramedullary nail is directly attached to the load frame of the materials testing machine, and is loaded in the distal direction. The load at which the intramedullary nail pushes through the condyles, or at which the condyles crack, is measured.

Discussion

A simple test methodology has been developed to compare different intramedullary nails with regards to

- (a) their bending stiffness,
- (b) the amount of torque which can be generated at 10 deg of forced rotation,
- (c) the amount of springback upon release of torque (or slipping between nail and bone), and
- (d) the amount of load required to push the intramedullary nail through the distal femoral condyles.

A comparison of bending stiffness (a) tends to evaluate primarily the nail geometry and cross-sectional properties, since the fractured bone will contribute little to the bending stiffness of the structure.

The remaining comparisons will evaluate the effects of different design features of the different intramedullary nails tested, with regards to their resistance to torsional and axial loading.

The performance of an intramedullary nail which relies on cancellous fixation will be underrated when implanted in formalin-fixed femurs, since the cancellous bone is weakened by fixation in formalin. The performance may be especially underrated in the torsion and push-through tests. Comparative evaluations rather than absolute evaluations may be more appropriate when formalin-fixed femurs are being used.

The testing procedure outlined in this paper is simple and can be directly adapted to other bones such as the tibia and humerus.

Acknowledgments

This testing procedure has been developed during various research projects, with the aid of D. Thimsen, J. Nagano, F. D. Simon, D. Mesna, J. M. Schaffhausen, and R. S. Hammett, Jr.

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Lance L. Bear,¹ James J. Hamilton,² Abdul A. Sukere,¹ Gary Lynch,³ and James A. Davidson³

Testing of Intramedullary Nails Using Physiological Loading

REFERENCE: Bear, L. L., Hamilton, J. J., Sukere, A. A., Lynch, G., and Davidson, J. A., "Testing of Intramedullary Nails Using Physiological Loading," *Intramedullary Rods: Clinical Performance and Related Laboratory Testing, ASTM STP 1008*, J. P. Harvey, Jr., A. U. Daniels, and R. F. Games, Eds., American Society for Testing and Materials, Philadelphia, 1989, pp. 26-33.

ABSTRACT: The increased interest in using intramedullary nails for fixation of long bone fractures has created a need for more in-depth laboratory testing of these devices. Until recently, most testing has addressed bending strength, bending rigidity, and torsional strength as separate properties. In actuality, bending and torsion are applied simultaneously to an implanted intramedullary nail. This study presents a technique for mimicking physiological loading incurred by an intramedullary nail during walking gait and the results of tests performed using this method.

KEY WORDS: intramedullary nail, physiological loading, walking gait, static fixation, dynamic fixation, rosette strain gage, axial strain, shear strain

Failure of intramedullary nails is not an uncommon event and is usually defined by breakage of the nail or loosening of the nail during service. There are many possibilities for this potential failure, including poor surgical technique, careless manufacturing processes, patient compliance, and inadequate nail design. If failure occurs, bone deformities and damage may result unless corrective measures are taken.

In order to discover why an intramedullary nail fails *in vivo*, it is necessary to examine the type of loading the nail experiences. The majority of the test results available examine bending and torsional properties separately to obtain data such as bending and torsional rigidity and strength [1]. While these type of tests give the strength of the nail in different modes of loading, little indication is given about likely location and modes of failure *in vivo*.

In vivo nails are subject to complex loading. Ligaments and tendons apply compression and torque to bones depending on their location and direction of action. Then, of course, body weight causes compression of the bones. These loads are directly transmitted to an intramedullary nail when implanted.

Abductor, flexor, rotator, and extensor muscle groups work to produce locomotion. Since these muscle groups work in cycles, every point in a gait cycle is composed of different loading patterns [2]. Body weight also causes complex loading of the femur due to its geometry. Since the femur bows forward and the femoral head is located off center and back at an angle, body weight alone causes bending in two planes and torsion as well as compression.

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Resultant loads acting on the femur have been resolved into X and Y components of force by Paul [2]. The reactions are given in X and Y forces varying with time during a normal gait cycle. These factors were not determined by summing the individual loads applied by all of the ligaments and tendons, but by examining the leg as a free body and by resolving the forces from the ground reactions up the limb.

The actual effect of this type of loading on an intramedullary nail has not been investigated. Considering the bone-nail contact areas, interaction of elastic and visco-elastic materials and a complex mode of loading, the problem becomes greatly complicated. It should be noted that not only does the overall loading vary, but so does each component during the walking cycle. The following test method makes an attempt to simulate this type of loading and examines the resulting axial and shear strains experienced by an implanted intramedullary nail.

Testing Method

Figure 1 shows that the maximum loading on the femur occurs between Positions 2 and 40. This is the time that the foot is in contact with the walking surface. The maximum resultant force occurs between Positions 26 and 39. The maximum loading on the femur can be examined by focusing on these 14 points. These data were collected for a male weighing approximately 67.5 kg (150 lb). The loading cycle, in general, is independent of body weight and should be proportional for any individual.

The X and Y components of these 14 points were resolved into a resultant force and an angle of application. A loading fixture was then designed that could support the femur as it is located in the human body and apply the resultant force through the required angle. The femoral head

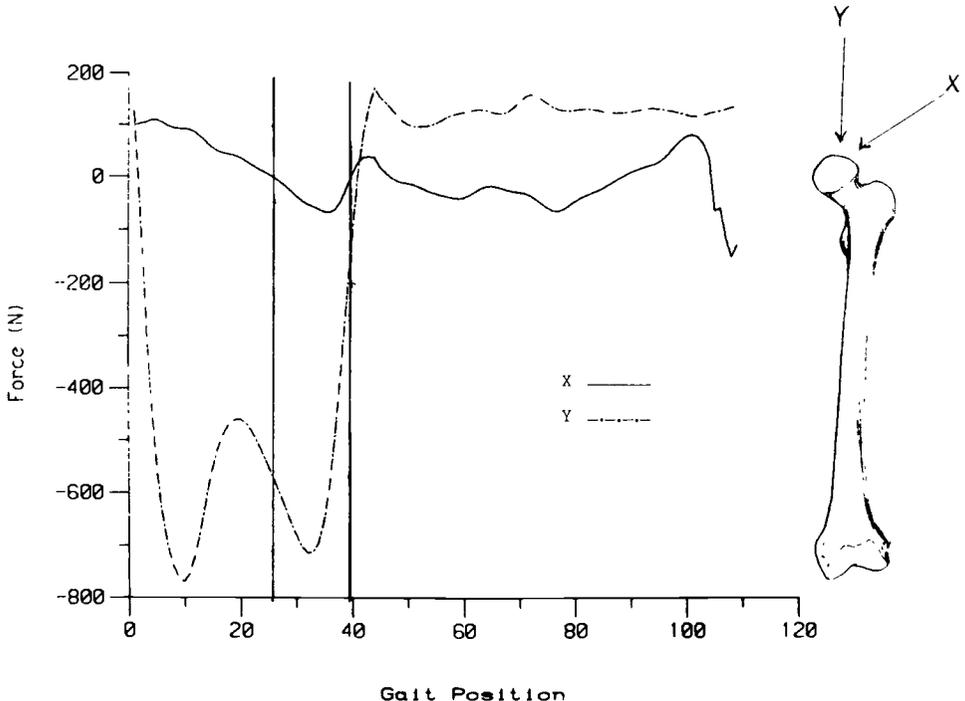


FIG. 1— X and Y reaction forces at the hip during a complete gait cycle, focusing on the area of loading in this study.

receptacle is essentially a cup filled with automotive body putty molded to the femoral ball; this cup is tilted by a steel wedge that is moved in or out by a lead screw.

The distal end of the femur was placed in a steel cup filled with sand. The proximal and distal fixtures were secured to the compression plates of a Tinus-Olsen compression testing machine. The head receptacle was bolted to the top plate, and the knee receptacle was clamped to the bottom plate. The femur was positioned so that if a plumb line were hung from the midpoint of the shaft at the proximal end, it would strike the midpoint of the shaft at the distal end.

Embalmed femurs were used because fresh bones were not available. The bones were maintained at room temperature and were kept wrapped in plastic whenever testing was not in progress to preserve moisture content.

To record loading incurred by the nail rosette, strain gages were placed on the inner wall of the nail. Gages were placed on the posterior wall of the nonslotted nail and on the anterior wall of the slotted nail. The nail was then inserted into the femur and loaded in the testing apparatus. All 14 loading positions were investigated, and the strains were recorded. This procedure was performed for five cases:

1. No screws, no break in bone.
2. Screws, no break in bone.
3. No screws, break in bone.
4. Screws, break in bone.
5. Screws, section of bone removed.

These five cases represented the most common situations in which intramedullary nails are used. Cases 1 and 2 represent dynamic and static fixation in a healed bone. Cases 3 and 4 represent dynamic and static fixation of a fracture located in the center one third of the shaft. Case 5 represents static fixation of a femur with multiple fractures or bone loss.

Testing Procedure

A Grosse-Kempff interlocking nail and a Russell-Taylor interlocking nail were instrumented with 45-deg/2-mm length rosette strain gages. These gages were placed approximately 8.5 cm apart inside 14-mm by 42-cm nails. Three-metre lead wires were attached to the gages at the factory so soldering was not necessary inside the nails. M-bond cyanocrylate cement was used to adhere the gages. After the glue had cured for 24 h, the lead wires were also glued inside the nail to avoid accidental tearing of the gages. All gages were then checked with an ohmmeter to insure that no damage had occurred to the gages. The lead wires were labeled and tied in a bundle where they passed through the slot at the end of the slotted nail. The wires were passed through the unused screw holes on the nonslotted nail.

The instrumented nails and femurs were taken to an orthopaedic surgeon for insertion. Axial Gages 1 through 5 were connected to a Budd ten-channel strain indicator, and the instrument was zeroed and balanced. The medullary canals of the femurs were drilled and reamed per protocol and the nails inserted. In order for us to locate the nails in proper position, a small amount of the bone had to be removed to allow clearance for the wires at the top of the bone. The strains in the axis of the nails were then recorded. An X-ray machine was used to examine the nails for proper location and good bony contact. Holes were then drilled for the screws, but they were not inserted.

The bones were returned to the laboratory for testing. One specimen was placed in the loading fixture and the load cell was zeroed. Gage wires 1 through 3 were attached to a Vishay/Ellis 21 ten-channel strain indicator, and Gages 4 and 5 were connected to a Budd ten-channel strain indicator. Both instruments were zeroed and balanced.

Testing was performed by adjusting the angle of the femoral head receptacle and then applying the corresponding load. Strains were then recorded for all the gages. The load was relaxed and the process was repeated for the 14 positions in sequence. After this test, the femur was

removed from the testing machine and the three screws were inserted. The femur was again placed in the loading apparatus and the load cell and strain gages were zeroed and balanced. The test was run again with the screws in place.

The bone was returned to the orthopaedic surgeon for cuts to be located to simulate a fracture. An X-ray machine was again used to examine the bone to locate the best area to simulate a fracture. The bone was cut with a reciprocating saw in a location where good bony contact existed above and below the cut. Marks were made to indicate the point for the cuts to be made for the last test.

The bone was then tested as before with and without the screws in place. Bone was removed by cutting the femur at the location of the marks made prior and the section of bone between the cuts broken out. The screws were left in and the entire test run again. This procedure was done for both of the nails mentioned.

Results and Discussion

Before any of the data are presented, it must be noted that all five strain gages were placed on the inner anterior wall of the slotted nail and on the inner posterior wall of the nonslotted nail. Because of this, corresponding strain readings from each nail are opposite in sign. This is seen in all of the following graphs. The trend and magnitude of the data rather than the direction of deviation from zero should be examined when comparing.

Figure 2 compares the axial strain incurred by both the slotted and nonslotted nails after insertion into intact femurs. These strain readings were taken immediately after the nails were driven in and their locations checked. These data show that the curvature of the nail does not match the curvature of the shaft of the femur. Obviously high strains are generated not only in bending, but also in torsion and compression of the nail. Considering this and the data found, it is very possible that damage to the bone or nail could occur upon insertion. This concept was examined by Tencer et al. [3]. By investigating pullout forces of the nail and hoop stresses on

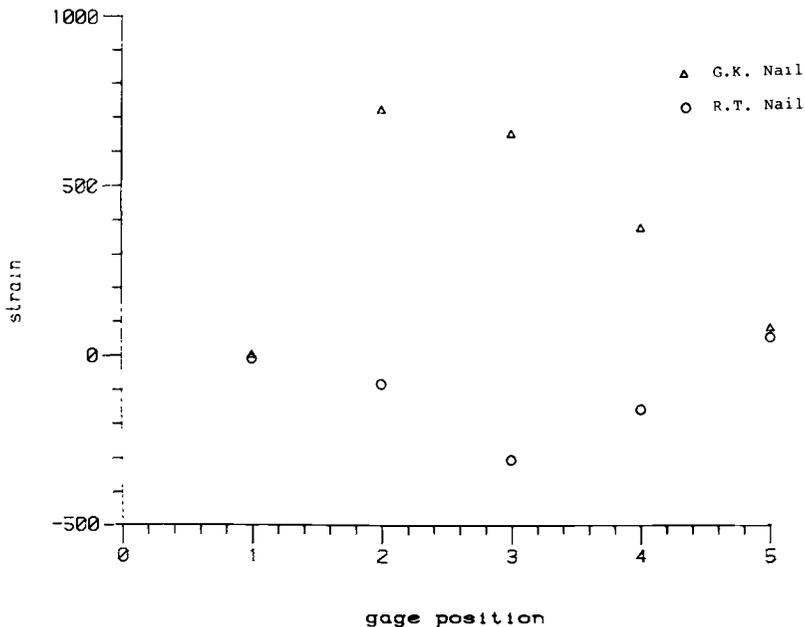


FIG. 2—Axial strain upon insertion of both Grosse-Kempf and Russel-Taylor nails.

the bone after insertion of the nail, they found that proper reaming and location of the starting hole in the top of the femur is essential to effective and safe nail usage. Possibly this finding can be taken further in standardization of curvature and rigidities of intramedullary nails along with refinement of insertion techniques.

Figures 3 and 4 show the shear strain at loading Position 8 in the slotted and nonslotted nails respectively. The shear strain in all the strain gages for the five cases of nail configuration examined in this study are shown. Position 8 is the gait loading position chosen from the 14 examined because it has the highest resultant force. The shear strain in these plots show how torsional loading is transferred to an implanted intramedullary nail. In every test, Gages 1 and 5 were barely affected. The maximum loading on the nail always occurred at the point where the cut was made in the bone; Gage 4 in Fig. 3 and Gage 2 in Fig. 4. The reason for the strain rise at the fracture site is that at this point the nail does not have the added rigidity of the bone. Therefore, this point is the weakest in the system and experiences the most deflection. Also, the screws in Cases 2, 4, and 5 help transfer the load to the nail. Without the screws, as in Cases 1 and 3, the nail is loaded only by the frictional contact of the bone. This transfer of load to the nail by the screws helps to distribute the load more evenly over the nail. The nonslotted nail seems to display this more than the slotted nail. Possibly the slotted nail "gripped" the bone more than the nonslotted nail, keeping the loading more localized even after the screws were inserted. It was observed that after the testing of Cases 1 through 4, the nonslotted nail was loose in the canal of the femur while the slotted nail remained tight.

Figures 5 and 6 are plots of axial strain at loading position 8 in the slotted and nonslotted nails, respectively. Again, axial strain is shown for all five of the strain gages for the five nail usages examined. This parameter shows how bending is transmitted to the implanted nail. As with torsion, Gages 1 and 5 experienced the least amount of deformation and the gage located

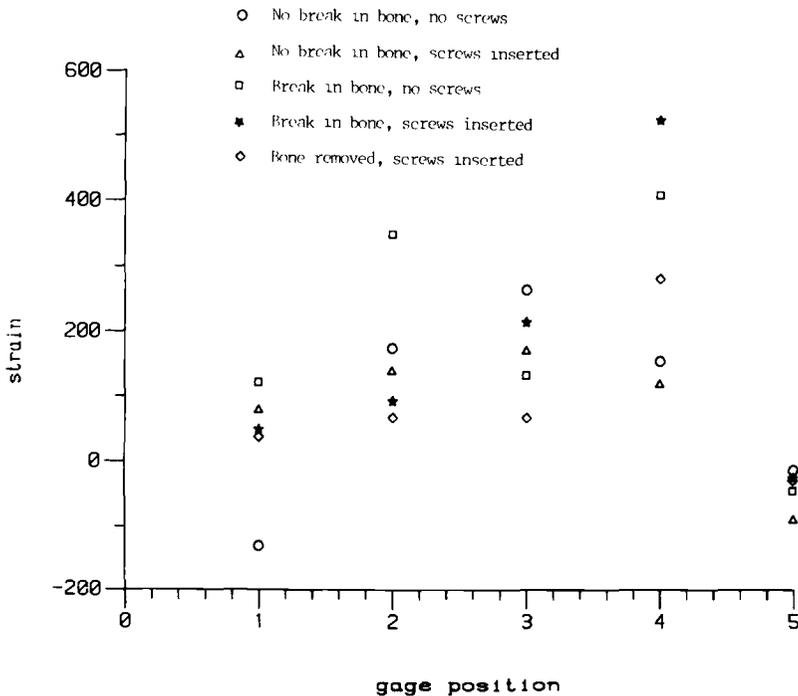


FIG. 3—Shear strain incurred by all strain gages at gait loading position 8 for Grosse-Kempf nail.

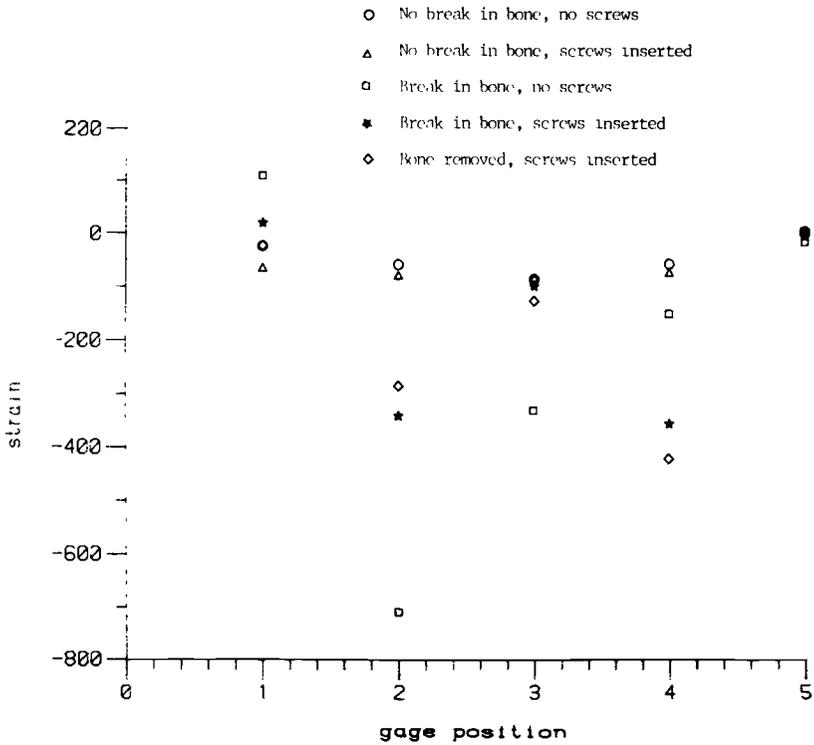


FIG. 4—Shear strain incurred by all strain gages at gait loading position 8 for Russel-Taylor nail.

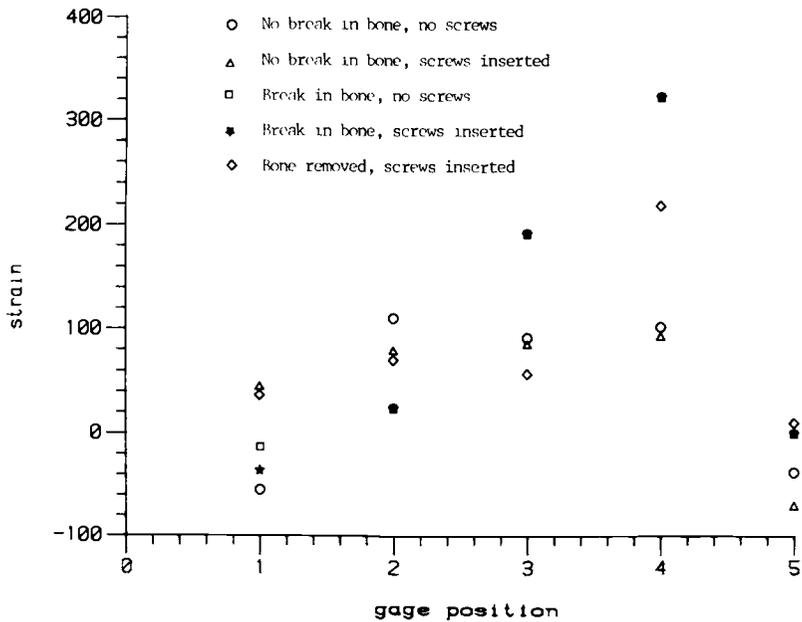


FIG. 5—Axial strain incurred by all strain gages at gait loading position 8 for Grosse-Kempf nail.

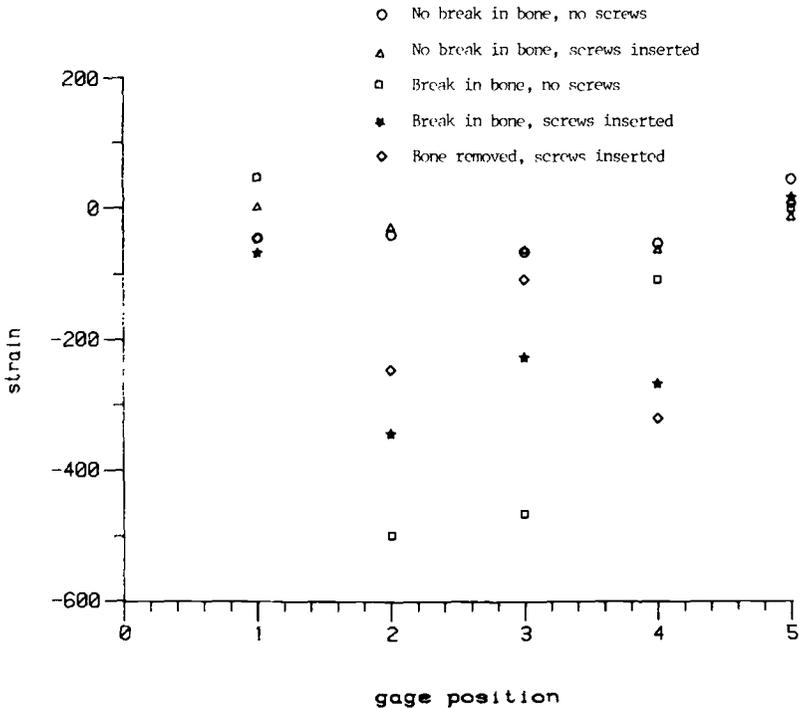


FIG. 6—Axial strain incurred by all strain gages at gait loading position 8 for Russel-Taylor nail.

at the point of the cut in the bone experienced the most. Cases 3 and 4 strain the nail the most. Note that the slotted nail experienced overall more shear strain while the nonslotted nail experienced relatively the same in both torsion and bending. This is easily explained by the low shear stiffness of the open section. Attention must be given to this torsional component for it is suspected that rotations of up to 30 deg can occur at the fracture sight when static fixation is used. This rotation may cause callus buildup at the fracture site.

Figure 7 is a plot of axial strain in the nonslotted nail for the break in bone Case 1, with screws in place showing all 14 gait loading positions. Plots were made of both axial and shear strain for both nails in all five nail configuration cases. All of the plots had basically the same trend. A good representation of this trend is shown in Fig. 7. Gages 1 and 5 show little change, while Gages 2, 3, and 4 reach a maximum at about loading Position 7 or 8 and then progress back to zero. As in the preceding figures, the highest strains throughout the loading cycle occurred in the gage closest to the cut in the bone for Cases 3 and 4. Cases 1 and 2 loaded the nail considerably less than Cases 3 and 4, and Case 5 fell just below Cases 3 and 4. It is easy to see by examining all of the plots that the screws help to distribute the loading more evenly over the nail in every case in which they were used.

Conclusion

This testing scheme has shown that different combination of bone fractures and nail fixation techniques transfer bending and torsional loading to intramedullary nails in varying ways. During one gait cycle, an intramedullary nail experiences a wide range of torsion and bending loads that constantly alter the principle stress and its direction of action. Realizing that fatigue is sensitive to loading modes and that these nails are exposed to complex loading modes over long

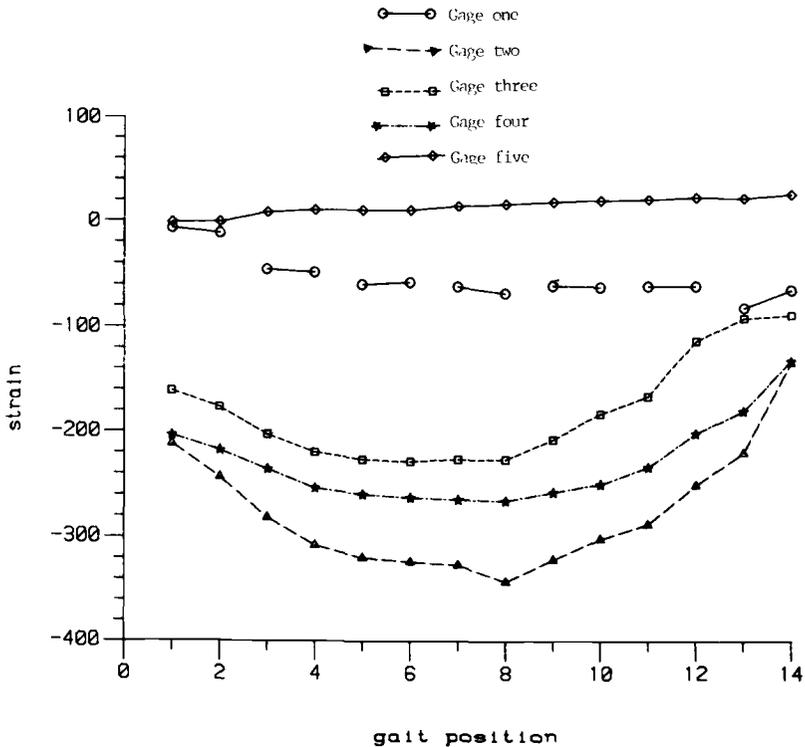


FIG. 7—Axial strain given by all five gages during a gait loading cycle for Russel-Taylor nail.

periods of time, fatigue testing in a physiological type of loading and environmental system should be examined. This would show how the nail reacts to failure and how it fails, possibly yielding new insight into intramedullary nail fixation techniques and nail design.

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Modeling the Insertion of a Zickel Rod into the Femur

REFERENCE: Hoffman, A. H., Daly, A., Olivieri, S. A., and Tarquinio, T. A., "Modeling the Insertion of a Zickel Rod into the Femur," *Intramedullary Rods: Clinical Performance and Related Laboratory Testing, ASTM STP 1008*, J. P. Harvey, Jr., A. U. Daniels, and R. F. Games, Eds., American Society for Testing and Materials, Philadelphia, 1989, pp. 34-43.

ABSTRACT: A computer-aided design (CAD) system was used to model the insertion of a Zickel rod into a femur. Results show that although the shape of the rod and the intramedullary canal match closely in the fully inserted position, a considerable geometric mismatch can occur during rod insertion. The location of the starting hole and the valgus bend at the proximal end of the rod shaft can combine to create high stresses in the trochanteric region. High stresses can also occur during insertion between the canal and the distal posterior rod surface. These phenomena are the likely causes of the intraoperative complications of trochanteric fracture and the difficulty experienced in readjusting the anteversion once a rod has been inserted. Redesign of the distal end of the rod could reduce the difficulty in readjusting the anteversion.

KEY WORDS: intramedullary rods, Zickel rod, femur fractures, subtrochanteric fractures, geometric modeling, computer-aided design

Intramedullary rods are a well-accepted tool for the treatment of femur fractures. In this application, intramedullary rods have proven to be less prone to fatigue failure than other implants such as bone plates. However, subtrochanteric fractures of the femur have proven to be very difficult to manage. These fractures involve the proximal shaft just below the trochanters of the femur and combine the management problems of both areas. Typical subtrochanteric fractures are shown in Fig. 1. The subtrochanteric region of the femur is subjected to large stresses due to bending moments and the direct forces caused by body weight and musculature [1]. Rybicki et al. [2] used the finite-element method to examine the effect of muscle forces on resulting stresses during one-legged stance. More recently, Vichnin and Batterman [3] used a more sophisticated finite-element model to perform a stress analysis of the proximal femur.

Zickel [4] recognized that standard intramedullary rods permit varus angulation in the higher subtrochanteric fractures because of inadequate fixation of the proximal fragment. The medullary canal is wide in this area, and often there is severe comminution. These problems led him to develop a new intramedullary rod which would fix both the proximal and distal fracture fragments and maintain reduction of the fracture. The device he developed bears his name.

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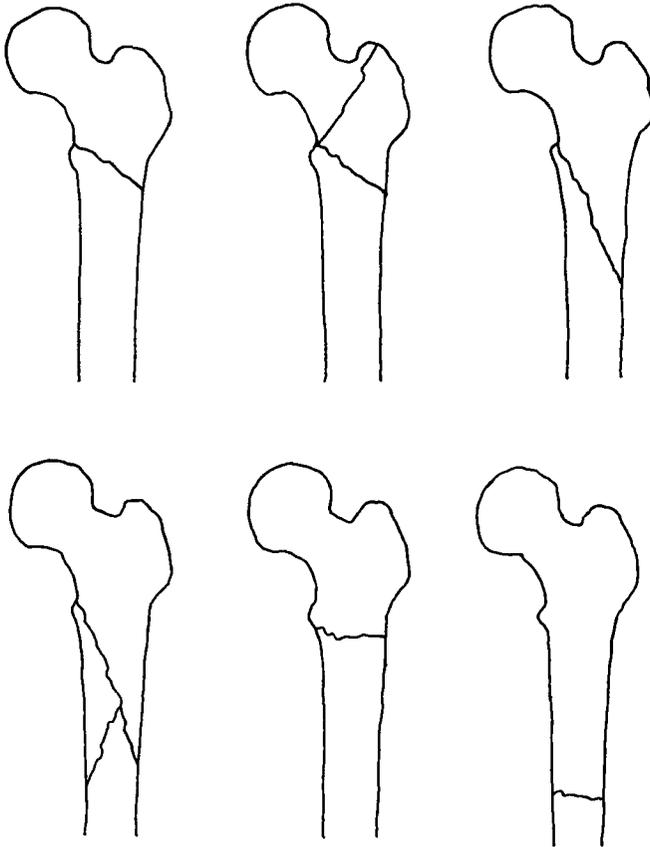


FIG. 1—*Subtrochanteric fractures.*

The Zickel rod (Howmedica, Rutherford, New Jersey) is a tapered rod with an essentially square cross section and a tunnel through the larger proximal end to receive a triflanged cross nail (Fig. 2). The cross nail is held in position by a set screw. The rod is angulated and curved in two spatial planes in an attempt to match the spatial curve of the femoral intramedullary canal. The proximal end of the rod is wider and has a valgus angulation to help maintain the valgus reduction of fractures. Due to the different spatial curvature, different rods are required for the left and right femurs. The rod also comes in three sizes (11, 13, and 15 mm). Recently, a rod with a slightly modified geometry (Zickel II) has been introduced. The original Zickel rod was used in our work.

In the operating procedure, the intramedullary canal of the proximal and distal fragments are reamed to accommodate the appropriately sized rod. The proximal femur must be progressively reamed to 17 mm to accommodate the larger proximal end of the rod. The rod is then introduced into the reamed hole and driven into the distal shaft while maintaining the correct anteversion of the cross nail slot. After the rod is inserted, the cross nail position is determined using a wire inserted through a tunnel locator. If the position is correct, a hole is reamed and the cross nail is driven into the neck and head of the femur.

The Zickel rod achieves its fixation from the cross nail and by an interference (friction) fit with the reamed intramedullary canal. Under-reaming the canal can lead to bursting, particularly in the trochanteric region. Overreaming can compromise the integrity of the fixation. Due

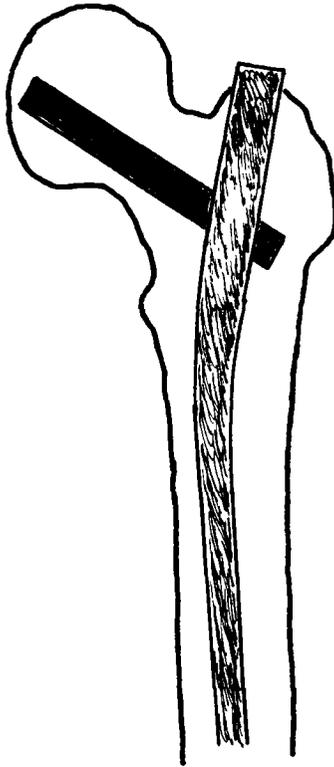


FIG. 2—Zickel rod and cross nail.

to the complex geometric curvatures of the rod and intramedullary canal, the interference encountered during rod insertion may differ from that obtained in the fully inserted position.

Since its introduction in the mid-1960's, the Zickel rod has been extensively used in the treatment of subtrochanteric fractures. The majority of reports [5-8] indicate that its use has been highly successful: rod failure is very rare [6]. The Zickel rod has been shown to exhibit greater torsional rigidity than other fracture-implant systems used to treat subtrochanteric fractures of femur [9].

However, use of the Zickel rod is not without its intraoperative complications. Thomas and Villar [5] have suggested that, due to technical difficulties, its use should be reserved for surgeons of reasonable experience. The following two intraoperative complications are not uncommon.

1. Comminution (fracture) of the greater trochanter [5-7]. Zickel [6] has attributed this to underreaming of the trochanteric fragment, failure to maintain the stability of the fragment during reaming, and failure to maintain alignment of the proximal and distal fragments during rod insertion. Thomas and Villar [5] have noted the effect of the unforgiving geometry of the rod. They state that if the rod is inserted in the incorrect rotational alignment, the valgus offset of the proximal part may act like a wedge and split the bone.

2. Difficulty in inserting the cross nail into the femoral neck at the correct degree of anteversion [5, 7]. An incorrect anteversion angle can result from misaligning the rod prior to insertion or rotation of the rod during insertion. A misalignment of this type can cause the cross nail to penetrate the neck or head of the femur. This problem can be revealed by X-rays of the guide

wire prior to reaming the hole for the cross nail. When a rotation problem occurs, the rod must be extracted, rotated, and reinserted. However, the shape of the cross section often encourages the rod to follow its original path when it is reinserted. Reaming the canal to a larger diameter will alleviate this problem, but it may also compromise the mechanical stability of the implant.

Zickel rods are also used in the fixation of pathological fractures of the femur [10, 11] and for the prophylactic stabilization of impending pathological fractures [12]. During prophylactic stabilization, there are no fragments to displace during rod insertion and special precautions must be taken to accommodate the geometry of the rod.

Removal of the rod also requires that the intact, healed femur accommodate the geometry of the rod. Recently, Yelton and Low [13] have reported femoral fractures incurred during late removal of the rod. They state that the configuration of the rod appeared to be a significant factor producing this complication.

The biomechanical factors affecting fracture stability and femoral bursting have been investigated for many other types of intramedullary rods [14]. There appear to be no published reports which investigate the geometric parameters associated with the use of the Zickel rod. In our work, we have used a computer-aided design (CAD) system to develop geometric models of a typical femur and a Zickel rod. The graphics software was then used to combine these models and to analyze the insertion of the rod into the femur. Images of the insertion could be viewed from any spatial position, thereby allowing points of interference and geometric mismatch to be clearly identified.

Methods

Measuring the Shape of the Femur and Rod

A plastic anatomical replica of a left femur and a 13-mm left Zickel rod were used. The data describing the external geometry of the femur were developed by placing a pointer in the tool holder of a vertical milling machine with a digital tool-positioning readout. The femur was clamped to the machine table such that the condyles rested on the table and the long axis of the bone was aligned with the direction of table travel. The anteversion is the angle between the table and the femoral neck. The pointer was used to digitize the surface outline at 2.54-cm intervals along the long axis of the bone. A similar procedure was used to generate the geometric data describing the shape of the Zickel rod.

Development of the Geometric Models on the CAD System

The coordinate points describing the surfaces of the femur and rod were used to construct three-dimensional models on a ComputerVision Designer IV Interactive Graphics System. Once the coordinate data were entered, a basic outline of the shape was visible on the screen. The CAD system software was used to fit a polynomial curve, called a B-spline, to the set of points depicting each cross section. Axial B-splines were then added to develop a wire mesh outline of each of the shapes. The computer software was then used to fit surfaces to the B-spline wire mesh. This created a solid model for which centroid calculations could be performed. The centroids were calculated using groups of elements. Due to the nature of this study, the geometry of the shaft, trochanters, and neck of the femur were developed in greater detail than other portions of the bone.

Modeling Rod Insertion into the Femur

It was assumed that the center of the intramedullary canal coincided with the centroidal curve of the femur. As described later, the fact that the centroidal curve of the femur closely

corresponds to that of the rod in the fully inserted position supports this assumption. An arc was fit to each set of centroidal data, and the center of curvature and the primary radius of curvature were determined.

After both models had been constructed, the model of the rod was overlaid (merged) onto the model of the bone. This procedure required that a common coordinate system be developed. This coordinate system was established by merging the models with the rod in the fully inserted position and then rotating the rod about the three bone axes so that the best fit between the centroid curves was obtained. This fit was further verified by viewing the model from the proximal end of the femur to ensure that the cross nail had the proper degree of anteversion.

Starting from the fully inserted position, the rod was backed out of the bone while the rod maintained the anteverted angle of the cross nail. The graphics software allowed the images to be viewed from any position in space. The anterior view, lateral view, and view from the proximal end of the femur were analyzed in detail for the rod fully inserted and at three intermediate insertion positions.

Results

The radius of curvature of the bone is approximately 230 cm, while that of the rod is 94 cm. Although this seems to be a large difference in curvature, the relatively small angles of arc subtended allow for a relatively good fit in the fully inserted position. Figures 3 to 6 show the rod 30%, 60%, 75%, and 100% (fully) inserted. The outline of the rod in the fully inserted position appears in Figs. 3 to 5 and corresponds to the location of the reamed hole that would yield the desired fully inserted position.

Ideally, the rod geometry and the reamed intramedullary canal should closely correspond at all phases of rod insertion. Figures 4 and 5 show that considerable rod/bone interference (geometric mismatch) will occur during rod insertion unless alleviated by additional reaming of the bone. At 30% insertion (Fig. 3), interference is just beginning in both the anterior and lateral views. By 60% insertion, (Fig. 4) considerable interference is observed in both views. In the

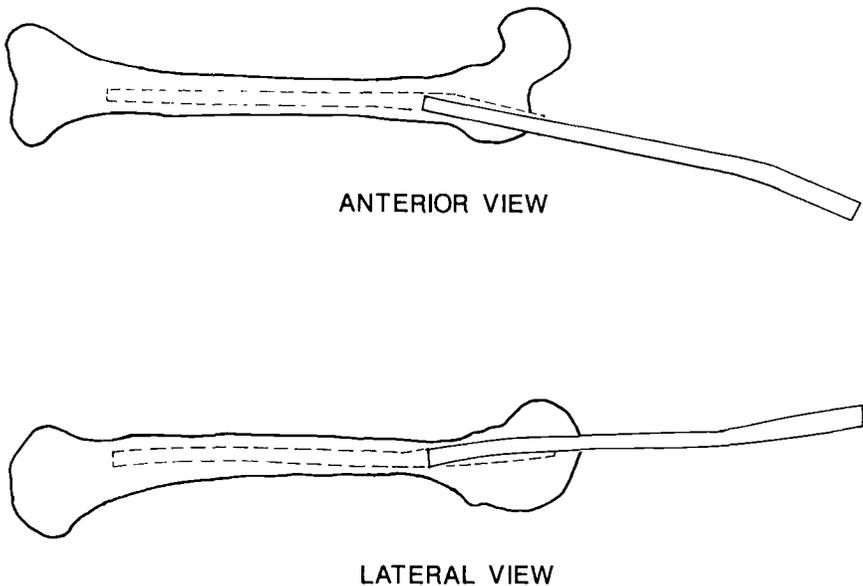
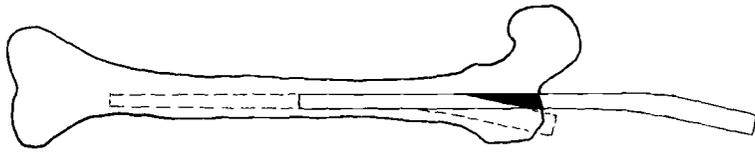
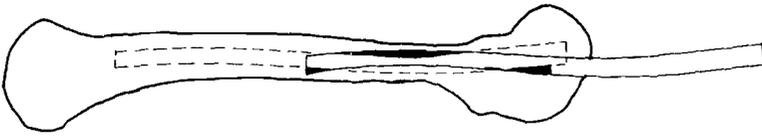


FIG. 3—Rod 30% inserted into femur.



ANTERIOR VIEW



LATERAL VIEW

FIG. 4—Rod 60% inserted into femur. Shaded areas represent regions of potential interference.



ANTERIOR VIEW



LATERAL VIEW

FIG. 5—Rod 75% inserted into femur. Shaded areas represent regions of potential interference.

anterior view, the proximal trochanteric region experiences severe interference because of the mismatch between the valgus proximal bend of the hole needed to accommodate the rod in the fully inserted position and the relatively straight distal rod shaft. In the lateral view, there is a mismatch between the relatively small radius of curvature of the distal end of the rod and the large curvature of the intramedullary canal. At 75% insertion, the mismatch in the anterior view is essentially unchanged, while the mismatch between the centroid curvatures has in-

creased in the lateral view. In the fully inserted position (Fig. 6), the cross nail is properly oriented along the neck of the femur, and the only remaining mismatch is at the distal end of the rod in the lateral view. The distal end of the rod is anterior to the centroidal curve of the bone.

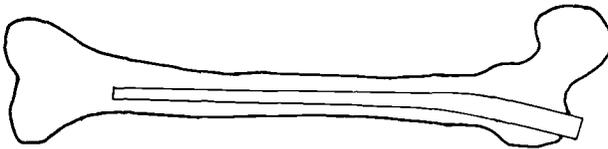
There was a difference in anteversion between the femur and the rod. The femur anteversion was 10 deg, which is a typical value [15]. There is no built-in anteversion in the rod (the Zickel II rod has a 6-deg anteversion). Therefore, the femur anteversion must be accommodated by rotating the rod about its long axis.

Discussion

The Zickel rod uses a complex geometry with spatial curvature in two planes in an attempt to match the complex shape of the intramedullary canal in the femur. Our results show that although the spatial curves of the rod and the femur match rather well in the fully inserted position (Fig. 6), a considerable geometric mismatch occurs during the insertion and extraction of the rod from about 30% insertion until near full insertion. The geometric mismatch may manifest itself clinically in a number of ways. Four possible ways are outlined below.

1. The intramedullary canal can be over-reamed to eliminate the potential interference.
2. If the mismatch is severe and not alleviated by additional reaming, then insertion of the rod could result in bursting of the femur.
3. The starting hole location could be shifted to eliminate some of the interference that occurs during rod insertion.
4. In fractures, some angulation between the proximal and distal fragments may occur during rod insertion and thereby reduce the geometric mismatch.

When viewed anteriorly, the valgus bend at the proximal end of the rod has the potential to cause severe interference. Figures 4 and 5 show that considerable interference will be encountered during insertion if the canal is reamed to fit the rod in its fully inserted position. In addition, in the lateral view, the rod bears against the posterior region of the starting hole. It should



ANTERIOR VIEW



LATERAL VIEW

FIG. 6—Rod fully inserted into femur.

be noted that except for the valgus bend at the proximal end, the rod is almost straight in the anterior view. Thus the interference in the anterior view over the initial 75% of insertion can be almost entirely eliminated by moving the starting hole medially to the position shown in Fig. 7. However, this hole will not accommodate the proximal valgus bend in the rod. Fully inserting the rod into this hole will cause considerable stresses in the trochanteric region, which could lead to comminution. Trochanteric fracture is not an uncommon intraoperative complication [5-7]. Overreaming could reduce the stresses in this region. However, Thomas and Villar [5] state that even if the proximal fragment has been overreamed (to 18 mm), comminution of the greater trochanter can still occur.

In the prophylactic stabilization of pathological femurs without fractures, it is important that the already weakened bone not be severely stressed by the rod. This problem is overcome by providing an entrance slot as shown in Fig. 7 [12] to accommodate the valgus bend in the rod.

In the clinical setting with fractured femurs, it is likely that some angulation occurs between the proximal and distal fragments during insertion to accommodate the geometric incompatibility of the rod and the reamed hole. This would effectively reduce the interference shown in Figs. 4 and 5.

If the bone heals firmly around the rod, then removing the rod can cause considerable stresses to occur in the subtrochanteric region. For example, assuming that the bone heals firmly around the rod in the fully inserted position (Fig. 6), then extracting the rod (Figs. 3 to 5) would cause severe bending stresses on the lateral surface of the subtrochanteric region. Yelton and Low [13] have recently reported four cases of subtrochanteric fracture during removal of a Zickel rod. Two of these fractures occurred through stress raisers (screw holes). They attribute these fractures to the shape of the rod. Although they refrain from recommending it, they indicate that the forces that occur during extraction could be reduced by removing some bone immediately medial and posterior to the proximal end of the rod. This would be in the general area within the dashed lines in Fig. 7.

The lateral views of Figs. 4 and 5 show that the mismatch between the rod and intramedullary canal occurs at the distal end of the rod. As the rod is inserted, the distal end bears on the

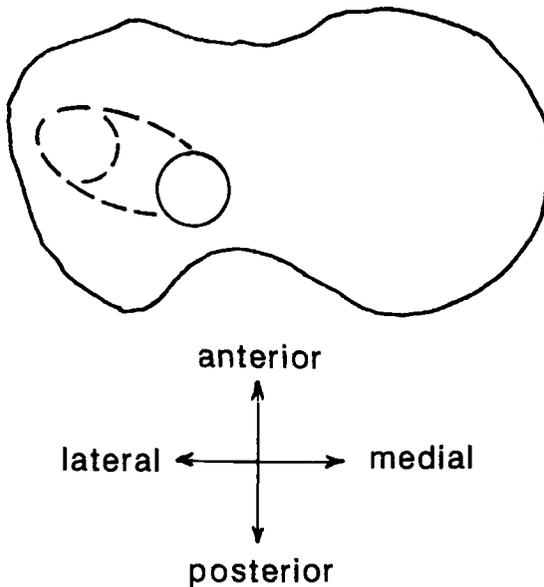


FIG. 7—Starting hole location (solid circle) which would eliminate most of the interference up to the valgus bend in the rod. An entrance slot (dashed lines) is recommended in prophylactic uses [12].

posterior surface of the canal, the middle of the inserted portion bears on the anterior wall, and the proximal end bears on the posterior wall of the starting hole. Thus the distal posterior surface of the rod "guides" it down the intramedullary canal. If the stresses caused by this contact are sufficient to permanently deform the corresponding surface of the canal, then a track will be created. If the initially achieved anteversion is not correct and the rod must be removed and rotated through a small angle, then upon reinsertion this track will tend to seat the rod in its original position. If the distal 2 cm of the rod was round instead of essentially square, then the preferential tracking of the rod could be reduced. The newer Zickel II rod still maintains an essentially square cross section and thus can not be expected to alleviate this problem. When fully inserted, the distal end of the rod lies anterior to the centroidal curve of the bone in the lateral view. Thus the rod/bone interference shifts from the posterior to the anterior surface of the rod as the rod nears full insertion.

Conclusions

A computer-aided design system has been used to model the insertion of a Zickel rod into the femur. Results show that the location of the starting hole and the valgus bend of the proximal rod shaft can combine to create high stresses in the trochanteric region that could lead to additional fractures during rod insertion. In addition, the geometry of the rod can create large bending stresses in the subtrochanteric region when extracting it from a healed femur. This may explain the subtrochanteric fractures that have been reported during rod extraction.

Interference between the distal posterior surface of the rod and the intramedullary canal during insertion may be sufficiently high to cause a tracking groove in the canal. A groove of this type would complicate extracting the rod and reinserting it to obtain a better degree of anteversion. The effect of the groove could be eliminated if the distal end of the rod were round.

Depending on the starting hole location, more interference may be present during rod insertion than exists when the rod is fully inserted. Thus the "tightness of fit" felt during rod insertion may not be an accurate indicator of the degree of fixation that is ultimately achieved.

Acknowledgment

We wish to thank Professor Kenneth Scott and the staff of the Computer Aided Design Laboratory at Worcester Polytechnic Institute for their assistance.

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Mechanics of Distal Locking in Intramedullary Rods: Comparison in Osteoporotic and Normal Femurs

REFERENCE: Latta, L., Zych, G. A., Greenberg, P., and Milne, T., "Mechanics of Distal Locking in Intramedullary Rods: Comparison in Osteoporotic and Normal Femurs," *Intramedullary Rods: Clinical Performance and Related Laboratory Testing, ASTM STP 1008*, J. P. Harvey, Jr., A. U. Daniels, and R. F. Games, Eds., American Society for Testing and Materials, Philadelphia, 1989, pp. 44-52.

ABSTRACT: The pseudostatic torsional stiffness and strength of fixation of two types of distal locking intramedullary nails was measured in embalmed human femora which were graded for osteoporosis. Cortical distal locking (Grosse-Kempf) was stronger than cancellous distal locking (Brooker-Wills) rods in both normal and osteoporotic femora. There was also a significant loss in strength of fixation for osteoporotic versus normal bones with either type of fixation, but the difference was more pronounced with cancellous fixation.

Cyclic testing to ± 20 deg internal and external rotation showed no difference in loosening between cortical and cancellous locking in normal bones. But in osteoporotic bone, loosening was proportional to degree of osteoporosis with cancellous locking and was significantly greater than with cortical locking. There was no significant difference in loosening for cortical locking rods in normal versus osteoporotic bone.

KEY WORDS: intramedullary rods, distal femoral locking, static torsion, stiffness, strength, cyclic torsion, loosening

The indications for intramedullary (IM) nailing for fractures of the femur have expanded considerably with the advent of proximal and distal locking systems [1-3]. Two common types of fractures of the distal femur have been impossible to manage with conventional IM nails: comminution with high-energy trauma in young individuals, and long oblique diaphyseal/metaphyseal fractures from low-energy trauma in elderly patients. Of these, the latter type of fracture has provided the biggest problem for conventional open reduction with internal fixation (ORIF) [1,4,5,6], but also has very high morbidity with conservative management [7].

Closed nailing is an attractive alternative for both types because of the reduced operative trauma compared with ORIF [1] or reduced periods of bed rest compared with traction [7]. However, the quality of fixation in each case may be very different depending upon the type of distal locking mechanism and the quality of bone. Also, the type of fixation which is best for the young trauma patient with normal bone quality may not be the best for the elderly patient with osteoporosis.

A number of mechanical studies have addressed the issues of stability, stiffness, and loosening.

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ing in locked and unlocked IM systems [8-15], but no studies have addressed these issues in osteoporotic versus normal bone.

Purpose

The purpose of this study was to quantify the differences of mechanical fixation for two commonly used types of distal locking IM nails: Grosse-Kempf (GK) and Brooker-Wills (BW) in normal and osteoporotic bone of the distal human femur.

Methods

One hundred ten human cadaveric femurs were X-rayed proximally and distally for grading of bone quality. A grade of I to IV was assigned to each distal radiograph based upon the trabecular patterns noted on the frontal view (AP). Grade IV was assigned if both columns of trabeculae from the medial and lateral condyles appeared normal (were continuous to the cortex) and a dense pattern of trabeculae coupled them together centrally. Grade III was assigned if the columns were intact, but the central, coupling trabeculae were absent. Grade II was given to distal femurs which had only one column intact (the medial column always disappeared first). Grade I was given to those which had no columns intact. Grades I and II consistently had markedly thinned cortices compared to Grades III and IV. For the 110 bones, gradings of three independent observers were compared to establish repeatability and accuracy of the technique. Singh Indices were assigned to each proximal radiograph independently.

All distal femurs were cut distal to the isthmus so that fixation was only accomplished by the distal locking mechanism of the nails. Eight distal femurs, four of Grade I and four of Grade IV, were fixed with GK and BW nails. Each was rotated to failure at a constant rate of 5 deg/s with a constant axial load of 1700 N while torque was recorded.

Strength of fixation in torsional loading has proven to be an unphysiological condition, since rotation to 45 deg and more is almost completely elastic in normal bone [13], far beyond "clinical failure." Thus, most studies have looked at stiffness [12-14] or loosening [8-11] for small displacements (≤ 30 deg) as measures of performance.

In an effort to test parameters related more closely to clinical failure criteria, we fixed 32 distal femurs, eight each of Grades I, II, III, and IV, with GK and BW nails for cyclic torque testing. Reversing cyclic rotation of ± 20 deg was applied for 25 cycles at a rate of 0.5 Hz with axial load proportional to the torque. Axial load was combined with torsion in all tests because it has been shown to significantly affect the behavior of locking mechanisms in IM nails [13,14].

Torque was applied to each femur by a cam mechanism mounted on the load cell of an MTS, hydraulically controlled testing machine. The distal femur was clamped in a vise and mounted on a table attached to the ram of the MTS. The ram raised and lowered the femur and the rod into the cam at a constant rate of displacement. The cam engaged a rod mounted perpendicular to the IM nail axis through the proximal locking holes. Thus the proximal end of the nail remained free (slots were not restricted from shearing displacements), and the full length of the nail was essentially free to rotate from the proximal to distal locking mechanisms (since there was no fixation through the isthmus). Since the cam was designed to rotate the cross rod ± 20 deg, the torque was proportional to the rigidity of the nail/fixation system. To isolate the rigidity of the fixation from that of the nail, each nail was measured for torsional rigidity in the same setup without the bone so that the nail compliance could be subtracted from the system compliance to estimate the fixation compliance. The fixation stiffness was calculated from the fixation compliance.

The cam engaged the cross rod at two places, equidistant from the nail center to apply a force couple to the cross rod and thus a torque to the IM nail. The cam surfaces were machined at a

45-deg angle to the direction of displacement, and the separation of the two cam surfaces was 15 cm. Therefore, the cam exerted a torque of 0.15 N·m and an axial load of 1 N for each newton of measured axial load on the cam. This proportion of torque : axial load was constant for loading or unloading, internal or external rotation except for alterations by the cam friction (Fig. 1).

Springback angle, axial load, and torque were measured for each cycle in external and internal rotation. The hysteresis of the first and 25th cycles were measured from the X-Y plots of each specimen.

Results

Singh Index and the distal femur grades demonstrated a similar trend but not a statistically significant correlation. Comparison of independent grading showed <5% discrepancy between observers and observations. There was a significant loss of trabecula as well as cortical thinning for Grades I and II versus III and IV (Fig. 2).

Strength tests demonstrated significant differences between Grade I and IV bones (Fig. 3) and significant differences between cortical and cancellous locking mechanisms (Fig. 4). However, the test proved to be of no clinical significance since a rotation of at least 120 deg was required to obtain mechanical failure in all specimens. The residual plastic deformation in the nails after the strength tests ranged from 20 to 180 deg.

In cyclic tests there was a significant difference in loosening for Grade I versus II versus III and IV for BW. Grade III and IV for BW and Grades I, II, III, and IV for GK were not significantly different (Fig. 5). Therefore, for comparison of springback angles, all GK grades were combined; and for BW, Grades III and IV were combined and considered to be normal

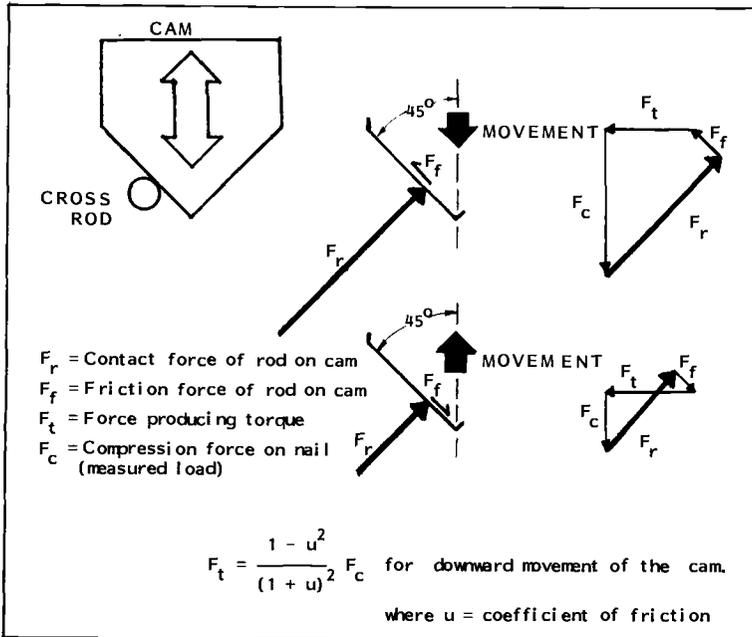


FIG. 1—The cam placed a combined compression and torque load on the nail by exerting both vertical and horizontal force components on the cross rod in the proximal end of the nail. Proportion of vertical to horizontal load was altered by frictional resistance of cam.

bone. There was a significant loss of springback in Grade I and II BW from 1 to 25 cycles (Fig. 5). This loss was significantly greater than for normal (Grade III/IV) bones (Fig. 6). There was only a slight loss (insignificant) in springback from 1 to 25 cycles in BW grade III/IV and GK. There was no significant difference in springback angle for BW versus GK in normal bone. In osteoporotic bone, GK had significantly greater springback than BW (Fig. 7).

The stiffness of GK fixation was significantly greater than BW for all grades. There was only a slight loss in system stiffness for osteoporotic versus normal grades for BW and no differences for GK. But calculated fixation stiffnesses showed significant decreases from Grades III/IV to Grade II and to Grade I with BW (Table 1).

Hysteresis loss from 1 to 25 cycles was significantly greater for BW Grade I compared to all other grades and fixation types. All the others were not significantly different (Table 1).

Discussion

The patterns of trabecular loss with osteoporosis were quite consistent. Like the Singh Index for the proximal femur, the grading system devised for this study correlated well the measured values reflecting the strength of the bone. Since reading bone density on clinical radiographs does not produce consistent results, reading trabecular patterns is a more clinically useful tool. More documentation and a clinical correlation will be necessary to prove the usefulness of this system, but at this stage it does look promising.

Strength tests proved to be of no clinical significance, which correlates well with other studies [13]. It was important in this study to determine whether strength in torsion would be of clinical significance in osteoporotic bone. Since it was not in Grade I bones, there was no point to test strength in Grade II bones. And since these tests destroyed the nails, there was no reason to test large numbers of specimens—the goals were accomplished in a few tests.

Most authors have tested torsion at fixed rotational displacements of 15 deg or less [8-12], but others have shown that rotations up to 45 deg are almost completely elastic. We chose ± 20 deg because it was predicted to be not too severe for normal bone and because it would provide a severe enough test for osteoporotic bone to create some measurable loosening. Since the loosening in normal bone was about 1% after the first cycle and <5% after the 25th cycle for both nails, this assumption was felt to be reasonable.

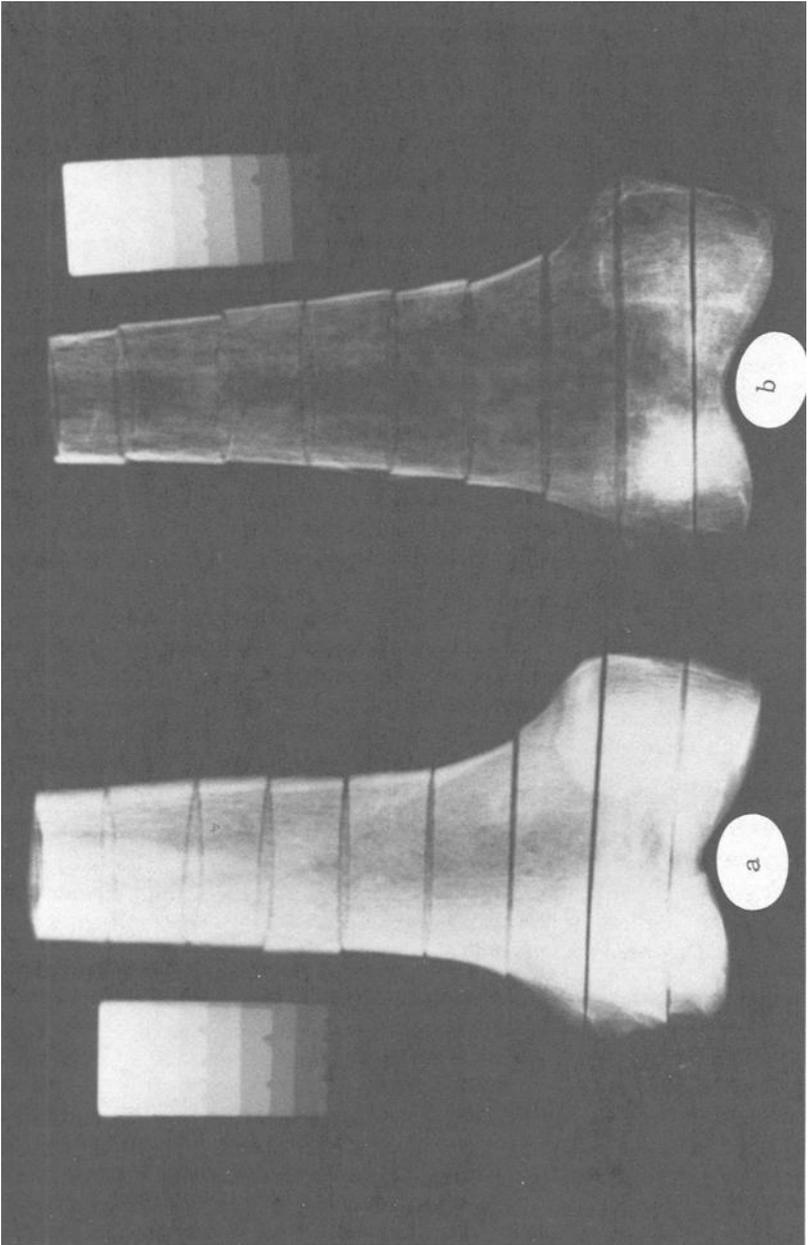
Most of the compliance of the system was in the nail for both of the systems tested. But the BW nail was far more compliant than the GW (0.129 N·m/0 for BW, versus 0.260 N·m/0 for GW). Thus the torque applied to each fixation system was different, though the rotation was the same. This is somewhat unfair since the more compliant BW nail placed only about 40% as much torque on the distal locking mechanism as did the GW. But with functional activity (particular gait), the loading is probably more displacement-dependent than it is torque-dependent. This may have been the reasoning of other investigators, since most studies have also used displacement-driven tests [8-15].

Conclusion

Fixation in osteoporotic bone is weaker than in normal bone for both BW and GK (Fig. 3). Loosening in osteoporotic bone is significantly greater for BW fixation compared with normal bone, but not for GK (Fig. 6). Loosening of GK and BW fixation in normal bone is comparable, but GK is significantly less than BW in osteoporotic bone (Fig. 7).

Acknowledgments

This work was supported by Biomet, Howmedica, Richards, and the University of Miami Orthopaedic Biomechanics Laboratory at Mt. Sinai Medical Center, Miami Beach, Florida.



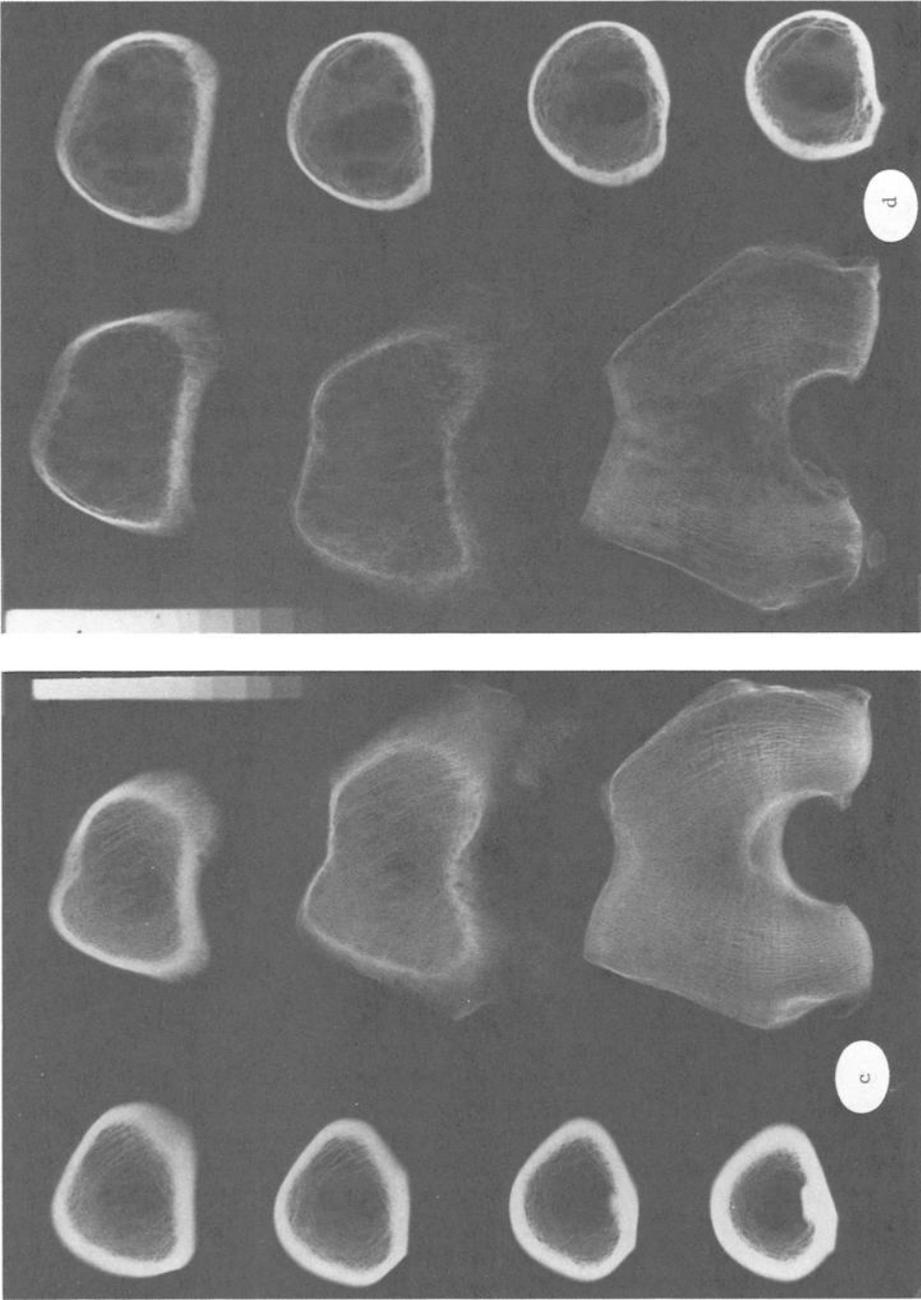


FIG. 2—A Grade IV (a) normal and a Grade I [(b) osteoporotic] distal femur were each sliced into serial, axial cross sections to demonstrate loss of central trabeculae and cortical thinning of the typical osteoporotic pattern [compare cross sections in (c) and (d)].

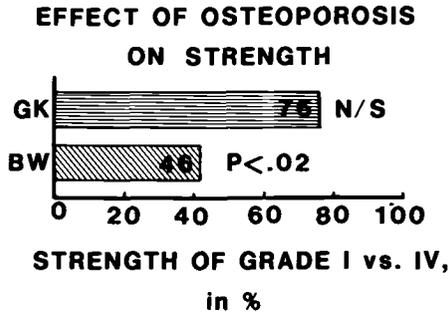


FIG. 3—Osteoporosis reduced ultimate torque to failure of the bone significantly, by student's t-test, for both cancellous and cortical fixation.

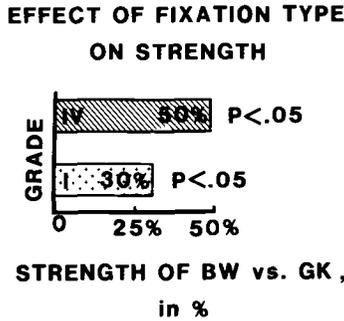


FIG. 4—Cortical fixation had significantly greater ultimate torque than cancellous, by student's t-test, for both normal and osteoporotic bone, but difference was more pronounced in osteoporotic bone.

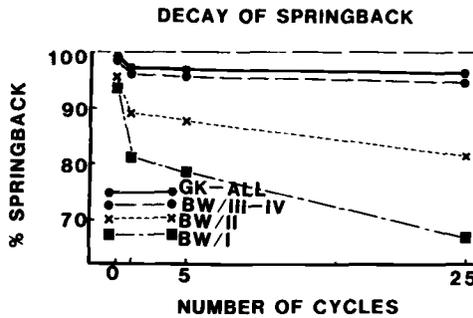


FIG. 5—Decay of springback was significant from 1 to 25 cycles only in cancellous locked Grade I and II bones. Difference was significant between Grades I and II at 1, 5, and 25 cycles.

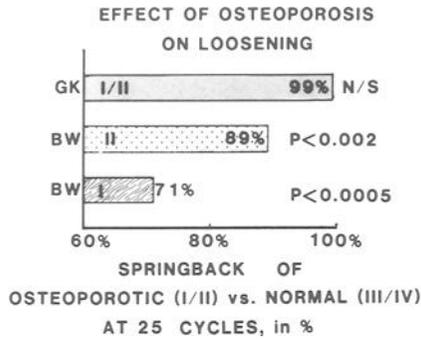


FIG. 6—By student's *t*-test, loosening in osteoporotic bone was significantly greater than in normal bone for cancellous but not for cortical fixation.

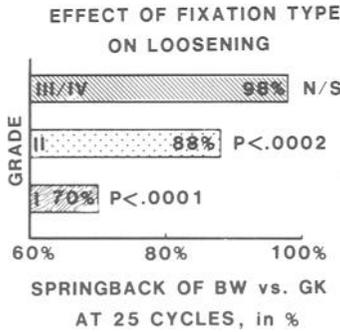


FIG. 7—By student's *t*-test, loosening was significantly different for cortical versus cancellous fixation only in osteoporotic bone.

TABLE 1—Summary of stiffness and hysteresis calculations.

Group	System Stiffness, N·m/0	Fixation Stiffness, N·m/0 (±SD)	Loss of Hysteresis, % (±SD)
GK I-IV	0.225	0.594 (±0.020)	19.5 (±9.6)
BW III-IV	0.091	0.313 (±0.010)	11.6 (±6.4)
BW II	0.082	0.224 (±0.018)	17.3 (±10.9)
BW I	0.071	0.156 (±0.007)	35.4 (±14.3)

NOTE: SD = standard deviation.

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A Method to Evaluate Motion at the Bone Fracture Interface on Intramedullary Nailing

REFERENCE: Lynch, G. E. and Davidson, J. A., "A Method to Evaluate Motion at the Bone Fracture Interface on Intramedullary Nailing," *Intramedullary Rods: Clinical Performance and Related Laboratory Testing, ASTM STP 1008*, J. P. Harvey, Jr., A. U. Daniels, and R. F. Games, Eds., American Society for Testing and Materials, Philadelphia, 1989, pp. 53-59.

ABSTRACT: Two methods were used to evaluate motion at the fracture site in cadaver femurs stabilized with intramedullary (IM) nails. Both bending stability at the fracture site and torsional stability of slotted and unslotted IM nails were evaluated. The first method was to manually measure the rotational stability of the device itself. The second method characterized the fracture displacement in a femur under anatomical load. Both slotted and nonslotted stainless-steel IM nails were fixed statically (proximal and distal screw fixation) in identical cadaver femurs. The distal end of each femur was fixed in epoxy and a circumferential saw cut carefully made at the mid-shaft location. The load was physiologically applied at a 12-deg angle anteriorly in the anterior-posterior plane. Displacements at the fracture site were recorded as a function of the applied load.

Results showed the bending displacement for both types of IM nails to be essentially zero. This was expected because both ends of the nails were fixed and because the opposing fracture surfaces on the medial side of the femur loaded against each other. However, the rotational displacement for the slotted nail was significantly greater than that of the unslotted nail. This was consistent with bench tests, which showed a similar trend in the rotational stiffness.

KEY WORDS: intramedullary nails, fixation, bone, interfaces, stability, motion

It is well known that stability at a fracture site is necessary to promote healing in long-bone fractures. Intramedullary (IM) nails, used to stabilize long-bone fractures, have historically contained a longitudinal slot, originally designed to allow a slight closure of the nail during insertion. Recent studies have shown that the slot compromises the torsional stability of the nail and allows the nail to twist during insertion [1]. The increased stiffness of nonslotted nails reduces these problems. In addition, the absence of the slot most likely reduces the relative amount of motion at the fracture site and thus may better promote healing. Mechanical testing performed on slotted versus unslotted nails has verified the increased bending and torsional stiffness of unslotted nails [1]. However, since these effects as related to motion are not well documented, the subject study was performed.

Materials

Slotted and nonslotted stainless steel IM nails, 13-mm diameter by 44-cm length, were obtained from two manufacturers along with the appropriate fixation screws (Table 1). All prod-

¹Research laboratory manager and director of materials research, respectively, Richards Medical Company, Memphis, TN 38116.

TABLE 1—*Intramedullary nails tested.*

Type	Diameter, mm	Length, cm	Alloy	Manufacturer
Russell-Taylor	13	44	316 Stainless Steel (ASTM F 138) Grade 2	Richards Medical Company Memphis, TN
Grosse-Kempf	13	44	316 Stainless Steel (ASTM F 138) Grade 2	Howmedica Rutherford, NJ

ucts tested were received new and in their original packages. The appropriate instrumentation and surgical procedures were also used in conjunction with the respective surgical technique manuals.

Two average-sized cadaver femurs (left) were procured for testing. Both femurs were essentially identical in size and bone quality as determined from radiographs.

Procedure

Bench Tests

A test fixture was designed and fabricated to test IM nails for rotational stiffness. Figure 1 is a schematic of the test setup. The IM rod was attached between two Jacobs drill chucks. The chuck jaws gripped the rod at the screw holes so that the holes did not affect the test results. A torque sensing transducer was attached to one chuck and mounted on a sliding table. A linear rotary potentiometer was attached to the opposing chuck. Both transducers were amplified, calibrated, and connected to an X-Y plotter to provide a graph of torque versus rotation. A 44.5-N weight was attached to one chuck via a 15.2-cm lever arm to apply torsional force. One chuck was offset 7 deg to allow for the curvature of the rods.

The test was performed by inserting the IM nail into the chucks. The plotter recorded the applied torque as the load was slowly applied. Figure 2 is a photograph of the test machine with an intramedullary rod in place.

Cadaver Tests

The IM nails were implanted into the cadaver femurs to simulate statically locked fixation. A photograph of this test setup is shown in Fig. 3. Recent studies have determined that static

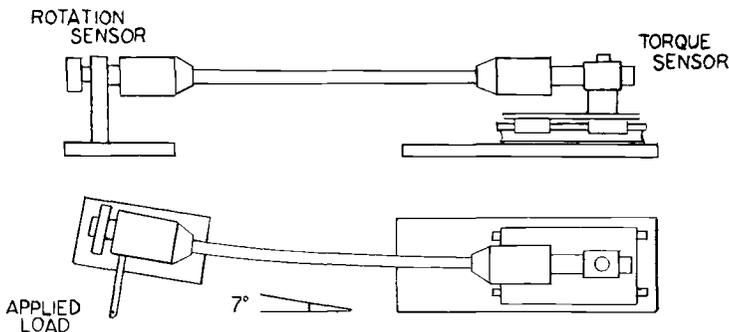


FIG. 1—*Bench test setup.*

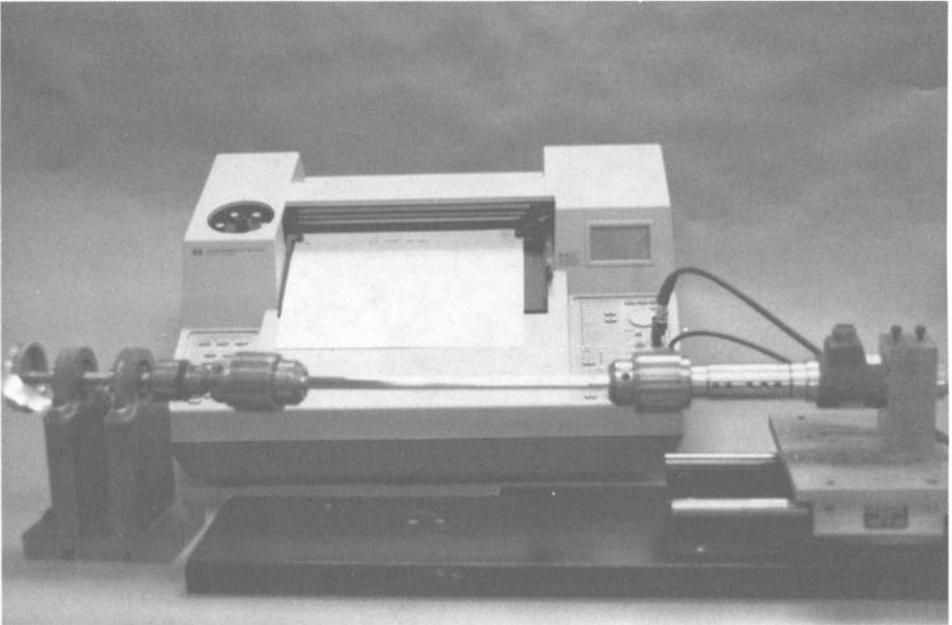


FIG. 2—Test machine with IM rod in place.

locking significantly increases torsional and compressive rigidity in the absence of bone contact at the fracture site and in some circumstances with bone contact [2]. Both femurs were prepared identically by reaming the canals to 14-mm diameter. Both nails were inserted using the appropriate surgical technique and instrumentation. Proximal and distal fixation screws were used to provide static locking. The distal end of each femur was fixed in epoxy 7.5 cm deep. The level of epoxy was 1 mm above the top distal fixation screw.

Circumferential saw cuts (1-mm blade) were carefully made at the mid-shaft location. These cuts were representative of smooth transverse osteotomies, as shown in Fig. 4. Longitudinal marks were made at the fracture site to measure rotational displacement ΔR during loading. The load was physiologically applied at a 12-deg angle in the medial-lateral plane relative to the femur axis and at a 13-deg angle anteriorly in the anterior-posterior plane. The bending displacement ΔB was determined from the amount of opening of the fracture gap during loading on the lateral side of the femur. These measurements were made manually using dial calipers. Both types of measurements are illustrated in Fig. 5.

Results

Bench Test

Results of the bench test, in which the IM rods were tested individually, showed the unslotted rod to be five times more resistant to torsional force than the slotted rod. Figure 6 is a graph from the *X-Y* plotter showing typical torque versus rotation response of both types of nails.

Cadaver Test

The bending displacement, ΔB , at the fracture site on the femur subjected to anatomical loading was essentially zero for both types of intramedullary rods. This was not surprising since



FIG. 3—*Cadaver test setup.*

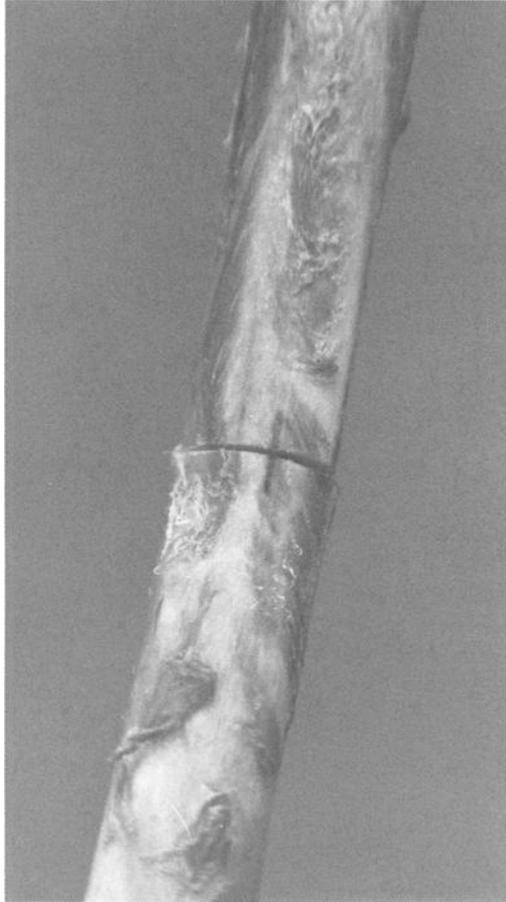


FIG. 4—*Osteotomy site with longitudinal marks for measuring rotational displacement.*

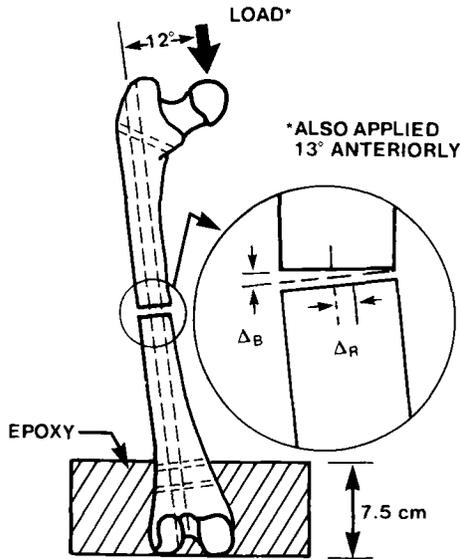


FIG. 5—Test setup with the cadaver femur and displacement locations.

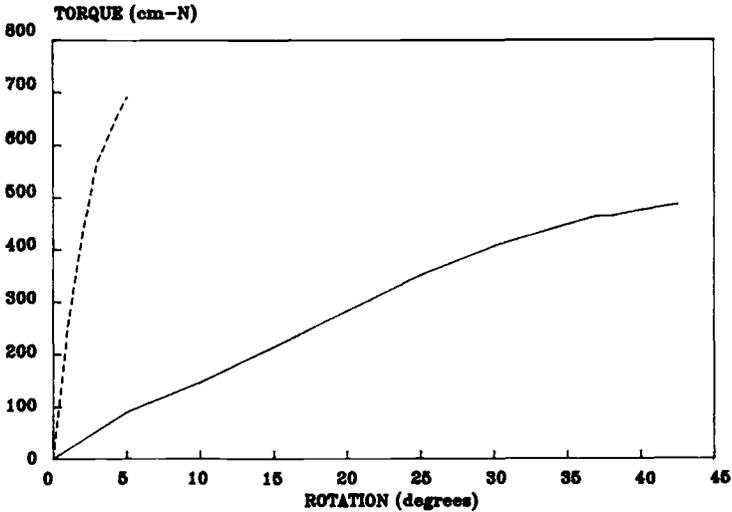


FIG. 6—Torque versus rotation in the bench test: (— slotted; - - - - - non-slotted).

both ends of the nail were fixed and the opposing fractures surfaces on the medial side of the femur loaded against each other.

The rotational displacement ΔR , for the slotted nail was significantly greater than that for the unslotted nail. Figure 7 plots the manual measurements, showing applied load versus angular displacement. At a load of 445 N, for example, the rotational displacement of the slotted nail was 3.33 mm, while that of the unslotted nail was only 0.53 mm—more than six times more resistant to rotation.

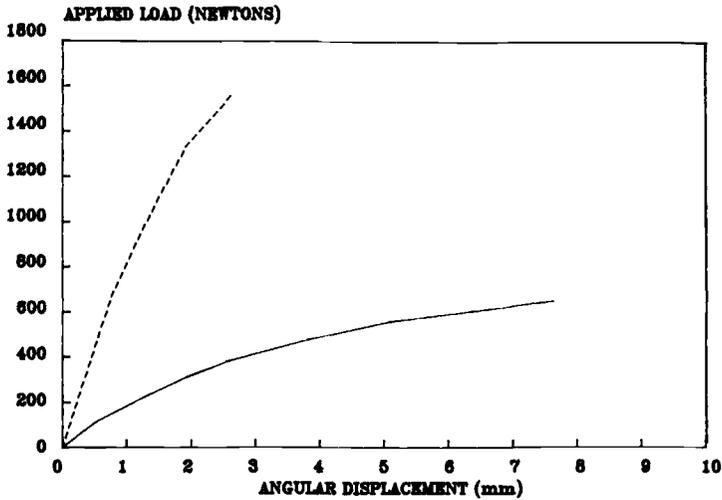


FIG. 7—Applied load versus angular rotation in the cadaver femur test: (—) slotted; (---) non-slotted).

Discussion

Because both ends of the nail were fixed and because, during loading, the opposing fracture surfaces on the medial side of the femurs loaded against each other, it is not surprising that the bending displacement was essentially zero for both types of nails. If the fracture gap were large, the slotted nail would be expected to allow greater bending displacement to occur.

In comparing rotational stability in Figs. 6 and 7, it is obvious that the trends in relative stiffness given in the bench tests were indicative of actual cadaver responses. The slope of the curves representing the non-slotted nails was essentially identical in both tests. However, the slotted nail was slightly stiffer in the cadaver test. Most likely, the interference fit between the canal wall and the rod contributes slightly to the torsional rigidity of the nail.

Summary

Although there is negligible difference in bending displacement at a tight fracture site between slotted and unslotted statically fixed IM nails in a femur, a significant increase in rotational displacement occurs with a slotted IM nail under physiological loading. It is expected that the reduced tendency for displacement (motion) at the fracture site in an unslotted IM nail results in better conditions for fracture healing.

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Comparison of Interlocking and Noninterlocking Intramedullary Nails in Bending and Torsion

REFERENCE: Bechtold, J. E., Schaffhausen, J. M., Kyle, R. F., and Gustilo, R. B., "Comparison of Interlocking and Noninterlocking Intramedullary Nails in Bending and Torsion," *Intramedullary Rods: Clinical Performance and Related Laboratory Testing*, ASTM STP 1008, J. P. Harvey, Jr., A. U. Daniels, and R. F. Games, Eds., American Society for Testing and Materials, Philadelphia, 1989, pp. 60-64.

ABSTRACT: Two types of interlocking intramedullary (IM) nails and a noninterlocked IM nail were tested in bending and torsion, to compare their flexural stiffness, and torsional stability in a femoral fracture model. A Grosse-Kempf IM nail with proximal and distal cortical interlocking screws, a Brooker-Wills IM nail with proximal interlocking screw and distal cancellous interlocking fins, and a Grosse-Kempf IM nail with no interlocking screws were tested. All IM nails had similar flexural stiffnesses. The interlocked Grosse-Kempf IM nail was most stable in torsion, followed by the interlocked Brooker-Wills IM nail. The noninterlocked Grosse-Kempf IM nail was least stable in torsion.

KEY WORDS: intramedullary nail, interlocked intramedullary nail, bending stiffness, torsional stability, Grosse-Kempf, Brooker-Wills

Intramedullary (IM) nails have not generally been indicated for fractures in the proximal or distal thirds of the femur, since the widened proximal and distal portions of the intramedullary canal do not provide the snug contact region between the IM nail and bone necessary for stabilization. Fractures with severe comminution also lack a snug contact region between the IM nail and bone.

Interlocking IM nails were developed to provide positive fixation when the fractured bone lacks a large enough contact region. An interlocking IM nail differs from a traditional IM nail in that an interlocking IM nail has direct transcortical or cancellous fixation at either or both metaphyseal regions of the fractured bone.

An interlocked IM nail can prevent shortening in cases of severe comminution, and allow earlier patient mobilization than alternative treatments, especially for the patient with multiple fractures, thus extending the clinical indications for intramedullary nails.

Different mechanisms for interlocking with the bone have been developed, with their own advantages and disadvantages. In one design, transcortical fixation screws are inserted from one cortex through a hole in the IM nail, and through the opposite cortex. The proximal screw is usually oblique (depending on the manufacturer), while the distal screws are transverse. Various combinations of proximal and distal transfixion screws can be used, depending on the type

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and location of the fracture. The advantage of transcortical fixation screws is that the interlocking mechanism is through relatively strong cortical bone. Their disadvantage is that it is difficult to locate the distal fixation holes in the IM nail to drill the bone correctly, without additional radiation exposure to the patient and surgeon.

Another mechanism for interlocking incorporates an oblique proximal transcortical fixation screw, with distal tri-fins with cancellous interlock. The advantage of distal tri-fins is that no additional radiation exposure is required for the distal fixation mechanism, since the fins are remotely deployed proximally through a direct linkage. The disadvantage is that the fixation is in the relatively weaker cancellous bone.

The relative performance of interlocking IM nails as a function of the number and location of transcortical fixation screws and of distal tri-fins is the subject of this study. Interlocking IM nail performance as a function of bone loss is also investigated.

Portions of this study have been presented previously [1,2].

Objective

This work compares the bending stiffness and stability under torsional loading of two different designs of interlocking intramedullary nails (Grosse-Kempf and Brooker-Wills), and a representative noninterlocked IM nail (Grosse-Kempf with no cortical transfixion screws). In addition, the effect of bone loss or comminution is studied for the Grosse-Kempf IM nail.

The Grosse-Kempf IM nail has cortical transfixion screws distally and proximally, with the proximal screw at an oblique angle. The Brooker-Wills IM nail has an oblique cortical transfixion screw proximally and tri-fins with cancellous fixation distally. The tri-fins are deployed from above by a direct linkage.

Methods

Uniform transverse fractures were created in unpaired formalin fixed human femora. Properly sized Grosse-Kempf IM nails were inserted in eleven femora and Brooker-Wills IM nails in twelve femora.

The Grosse-Kempf IM nail was tested in the following configurations:

1. with no transfixion pins (representing a noninterlocked Kuentscher-type nail),
2. with one proximal and two distal transfixion pins,
3. with only the proximal and second distal screws,
4. with only the proximal and first distal screws,
5. with only the proximal screw,
6. with all three screws, and 3 cm of bone removed at midshaft,
7. with all three screws, and 6 cm of bone removed at midshaft, and
8. with all three screws, and 9 cm of bone removed at midshaft.

The Brooker-Wills IM nail was tested:

1. with one proximal transfixion pin and with distal fins deployed.

The femora were tested in four-point bending on an MTS electrohydraulic materials testing machine. The bending moment was applied on the posterior-medial aspect of the femur with a constant moment arm of 6.2 cm. The femur was clamped at the outer supports to prevent rotation during bending. A midshaft displacement of 0.32 cm was applied, and moment (load) versus midshaft displacement was recorded on an analog X-Y recorder. The flexural stiffness is calculated at the slope of the moment versus deformation curve.

The torsional testing consisted of two parts. First, the distal fragment was externally rotated 10 deg, and maximum torque at this rotation was measured. Then, the distal fragment was

rotated back to release the torque, and the amount of rotation, or springback, was measured. The springback angle is an indication of the amount of slippage between the IM nail and bone during rotational loading.

This testing method is described more fully in the Butts et al. paper, which appears elsewhere in this volume [3].

Results

Comparison of Type of Interlocking Mechanism

Four-Point Bending—The average flexural stiffness of the noninterlocked IM nail was 235 N/mm, the stiffness of the fully interlocked Grosse-Kempf IM nail (one proximal and two distal transcortical fixation screws) was 259 N/mm, and the stiffness of the Brooker-Wills nail was 207 N/mm (Table 1).

There was no significant difference in the flexural stiffness in four-point bending for either interlocking mechanism (3 transfixion screws versus proximal screw and distal fin) or for the noninterlocked IM nail versus IM nail interlocked with distal fins. The fully interlocked Grosse-Kempf IM nail with three transfixion screws showed a statistically higher flexural stiffness than the noninterlocked nail (Table 2).

Torsion—The average maximum torque at 10 deg of forced rotation for the noninterlocked IM nail was 59 N-cm, the maximum torque for the fully interlocked Grosse-Kempf IM nail (three transfixion screws) was 253 N-cm, and the maximum torque for the Brooker-Wills IM nail was 122 N-cm (Table 1).

The differences in maximum torque were statistically significant between all IM nails (Table 2). The IM nail with transcortical fixation screws developed the largest torque, followed by the IM nail with distal fins and then the noninterlocked nail.

Springback Angle—The average springback angle between the 10 deg forced rotation at maximum torque and the position when the torque was reduced to zero was 0.9 deg for the noninterlocked IM nail, 8.4 deg for the fully interlocked Grosse-Kempf IM nail, and 6.1 deg for the Brooker-Wills IM nail (Table 1).

TABLE 1—Mean values.

	4-POINT BENDING STIFFNESS (N/mm)		MAXIMUM TORQUE (N-cm)		SPRINGBACK ANGLE (DEG)	
	MEAN	S. D.	MEAN	S. D.	MEAN	S. D.
BROOKER-WILLS (n=12)	207	54.1	122	61.2	6.1	2.5
GROSSE-KEMPF (n=11)	259	111.0	253	59.1	8.4	1.5
NON-INTERLOCKED (n=11)	235	91.2	58	39.4	0.9	1.4

TABLE 2—Statistical significance.

	4-POINT BENDING STIFFNESS	MAXIMUM TORQUE	SPRINGBACK ANGLE
Brooker-Wills vs. Grosse-Kempf	NOT Sig. T=1.4/p=1.6	Sig. Diff. T=5.2/p<.001	Sig. Diff. T=2.7/p=.01
Brooker-Wills vs. Non-Interlock	NOT Sig. T=.89/p=.38	Sig. Diff. T=2.9/p=.01	Sig. Diff. T=6.0/p<.001
Grosse-Kempf vs. Non-Interlock	Sig. Diff. T=2.7/p=.02	Sig. Diff. T=14.0/p<E ⁻⁶	Sig. Diff. T=12.0/p<E ⁻⁶

The differences in springback angle were statistically significant between all IM nails (Table 2) and followed the same trend as maximum torque. The IM nail with transcortical fixation screws exhibited the largest springback angle, followed by the IM nail with distal fins and then the noninterlocked nail.

Comparison of Number and Location of Fixation Screws

Four-Point Bending—There was no statistical difference between the Grosse-Kempf nail in fully interlocked configuration (No. 2, with one proximal and two distal transcortical fixation screws), and the Grosse-Kempf in partially interlocked configurations (Nos. 3, 4, 5), Table 3.

Maximum Torque—There was no statistical difference in the maximum torque developed at the forced 10 deg rotation between the Grosse-Kempf nail in fully interlocked configuration (No. 2), and the Grosse-Kempf nail with one proximal and at least one distal screw (Nos. 3 and 4). The Grosse-Kempf nail with one proximal and no distal screws (No. 5) developed statistically less torque than any configuration with proximal and distal screws (Nos. 2, 3, 4), and showed no statistical difference from the torque developed with no interlocking mechanism (No. 1), Table 3.

Springback Angle—There was no statistical difference in the springback angle (from the forced 10 deg of rotation and maximum torque to zero torque), between the Grosse-Kempf nail with any configuration of proximal and distal screws (Nos. 2, 3, 4). The Grosse-Kempf nail with one proximal and no distal screws (No. 5) showed a statistically smaller springback angle than any configuration with both proximal and distal screws (Nos. 2, 3, 4) and showed no statistical difference from the springback angle with no interlocking mechanism (No. 1), Table 3.

Comparison of Fully Interlocked Grosse-Kempf with Different Amounts of Bone Loss

There was no statistical difference in either the flexural stiffness, maximum torque, or springback angle, between the fully interlocked Grosse-Kempf IM nail with 3, 6, or 9 cm of

TABLE 3—Grosse-Kempf mean values.

	4-POINT BENDING STIFFNESS (N/mm)		MAXIMUM TORQUE (N-cm)		SPRINGBACK ANGLE (Deg.)	
	MEAN	S.D.	MEAN	S.D.	MEAN	S.D.
1) NON-INTERLOCKED (n=11)	235	91.2	58	39	0.9	1.4
2) FULLY INTERLOCKED (n=11)	259	111	253	60	8.4	1.5
3) PROXIMAL & SECOND DISTAL SCREWS (n=11)	267	98.4	221	54	8.0	1.89
4) PROXIMAL & FIRST DISTAL SCREWS (n=11)	262	101	226	54	8.0	1.7
5) PROXIMAL SCREW ONLY (n=11)	256	98.8	53.2	48	1.0	1.8
6) ALL 3 SCREWS, 3cm BONE REMOVED (n=11)	203	70.6	221	27	8.7	1.6
7) ALL 3 SCREWS, 6cm BONE REMOVED (n=10)	179	90.2	207	23	9.0	1.5
8) ALL 3 SCREWS, 9cm BONE REMOVED (n=9)	158	97.7	187	20.1	9.3	1.1

bone loss (Nos. 6, 7, 8), Table 3. The bone with 9 cm of the shaft removed, however, had slightly less flexural stiffness, and smaller maximum torque than that with 3 cm of shaft removed.

Discussion

All IM nails and configurations tested showed flexural stiffnesses in the same relative range. All IM nails tested were slotted, cloverleaf in cross section, and of stainless steel, so it is reasonable to expect that their stiffness in bending will be similar. A bending test of an intramedullary nail in a fractured bone will test primarily the IM nail.

The differences in torsion and springback between the Brooker-Wills and Grosse-Kempf interlocking IM nails may be attributable to the fixation quality distally. The Brooker-Wills has cancellous fixation distally, and the Grosse-Kempf has cortical fixation.

Higher values of torsional resistance may be anticipated *in vivo* with the Brooker-Wills nail since the cancellous bone in the femora tested was weakened by formalin fixation. These results should be interpreted only as a relative comparison of the interlocking mechanisms.

As expected, both types of interlocking nails were more stable in torsion and had larger springback angles than the noninterlocked Grosse-Kempf.

The fully interlocked Grosse-Kempf IM nail behaved similarly to the partially interlocked Grosse-Kempf, with one proximal and one distal fixation screw. The second distal fixation screw does not improve the static quality of support to the fractured bone, but may improve the dynamic performance in a fatigue loading situation (walking).

The fully interlocked Grosse-Kempf IM nail was able to maintain stability even with severe bone loss (up to 9 cm of midshaft bone removed). A similar study has not yet been performed with the Brooker-Wills nail.

Acknowledgment

We would like to acknowledge Howmedica and Biomet for supplying the intramedullary nails tested.

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Stability of Subtrochanteric Femoral Fractures Fixed with Interlocking Intramedullary Rods

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ABSTRACT: A variety of designs of interlocking intramedullary rods has been developed in recent years for fixation of otherwise unstable femoral fractures. In this study, plastic model femurs with either stable transverse subtrochanteric osteotomies or unstable subtrochanteric defects were used to compare the rotational stiffness provided by different types of intramedullary rods. Simultaneous axial, bending, and torsional loading was applied to examine the effect of rod-bone and fracture surface interaction on rotational stiffness. For the stable transverse fracture, increasing the axial load from 150 to 1000 N increased the rotational stiffness as much as 5.7 times (Zickel nail). Thus, a large component of the resistance to rotation was due to interaction of the fracture surfaces. In contrast, with the unstable segmental defect, rotational stiffness was primarily dependent on the inherent torsional stiffness of the implant. For example, the fracture fixed with a double-interlocked tubular titanium rod was about seven times stiffer in rotation than fractures fixed with slotted-cloverleaf intramedullary rods. Close comparison of these experimentally measured characteristics with actual clinical performance will be necessary to identify the optimum design features for interlocking intramedullary devices.

KEY WORDS: axial mode, bending mode, fixation technique, interlocking, plastic model, reproducibility, resistant, rotation, slotted cloverleaf, stability, stable fracture, stiffness, subtrochanteric fracture, torsional mode, unstable fracture

Intramedullary rods have been used for fixation of stable femoral fractures with great clinical success for several decades. Recent years have seen the application of intramedullary fixation techniques to more complex, unstable fractures through the development of interlocking devices. With many of the devices currently in use, interlocking has been achieved by the addition of screws or blades proximally and distally, with the rods essentially unchanged from the slotted-cloverleaf designs originally developed for use with relatively stable fractures (without interlocking). The question is posed whether this represents the optimum design for use with com-

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plex comminuted fractures that are unstable in the axial, bending, and rotational modes and, therefore, depend relatively more on the rigidity of the intramedullary rod to achieve stability.

Optimizing the design of interlocking intramedullary (IM) rods requires the development of a reliable and reproducible laboratory test method to evaluate and compare the stability and strength of the fixation achieved. The numerous prior studies of the mechanical characteristics of IM rods published in the literature have typically involved the use of cadaver femora loaded in servo-hydraulic test machines. One major difficulty of these studies has been the need to collect a sufficient number of cadaver femora of a reasonably consistent size and bone quality to permit a statistically meaningful number of experiments. In the study reported here, we employed plastic model femurs, produced using silicone molds of a representative human femur, to evaluate the mechanical stability of a variety of bone-implant combinations. These synthetic femurs could be produced with uniform geometry and material properties. Although, as will be discussed, the mechanical properties of the plastic model femur were only an approximation of those of human bone, this limitation was more than offset by the advantage of improved uniformity between tests.

Previous investigations of the rigidity and strength of femurs with simulated fractures fixed with intramedullary devices have typically included a second major limitation in that the axial, bending, or torsional modes were evaluated *independently* of each other, a practice which limits the clinical applicability of the results. In the study reported here, the stability of subtrochanteric fractures fixed with ordinary and interlocking intramedullary rods was evaluated under *simultaneous* axial, bending, and torsional loading, a model more representative of the loading on the femur during gait. By this procedure, the influence on torsional stability of the bending of the rod within the canal and of the interaction of the fracture surfaces was assessed.

Materials and Methods

Plastic Bone Model

Plastic model femurs have been used in an earlier study of femoral neck fracture fixation [1] and in an ongoing investigation of micromotion of noncemented total hip prostheses [2]. A detailed set of instructions for producing the master silicone molds and for fabricating the plastic femurs is available from the first author (H. McKellop) by written request.

The completed plastic femurs had a "cancellous" core of urethane foam surrounded by a fiberglass-reinforced epoxy shell "cortex." As fabricated, the cancellous core of the model bone extended throughout the medullary cavity, obviously a nonphysiological situation. However, since this material was reamed out prior to insertion of the rods, it did not effect the resultant mechanical properties of the implant-bone assembly.

The elastic modulus of the urethane foam was about 100 MPa, a value in the range that has been measured for the intertrochanteric cancellous bone of the human femur [3]. The epoxy cortex had an elastic modulus about 7 GPa, that is, from one-third to one-half that of human cortical bone [4]. However, it should be pointed out that the femur-implant assembly was essentially a composite structure with the metal component having a modulus either 100 GPa (titanium alloy) or 200 GPa (stainless steel). The behavior of a composite structure with component moduli in the ratio 200/7 may not be that different from a composite beam with the ratio 200/20. Nevertheless, the differences in material properties between the synthetic bone and human bone should be considered when experimental results are interpreted.

Intramedullary Devices Evaluated

Table 1 lists the devices evaluated in this study. Two noninterlocking implants (Ender pins, Sampson rod) and one with proximal interlocking only (Zickel nail) were included. This was done to provide a broader perspective of the nature of the stability achieved with the different

TABLE 1—*Devices evaluated in this study.*

Device	Size (Length, Diameter)	Manufacturer	Reamer Diameter, mm	Type
1. Enders-type (EN)	42 cm, 4.5 mm	Biomet Warsaw, IN	15	five total, inserted combination of "C" shape and "S" shape; stainless steel
2. Sampson Rod (SR)	40 cm, 15 mm	3M Minneapolis, MN	17	round rod with sharp external flutes, no interlocking; stain- less steel
3. Zickel Nail (ZN)	30 cm, 15 mm	Howmedica Rutherford, NJ	17	square solid cross section, 90-mm- long proximal interlocking nail; cobalt-chromium molybdenum alloy
4. Biomet Interlocking (BI)	42 cm, 15 mm	Biomet Warsaw, IN	15	Kuntscher-type slotted cloverleaf with proximal and distal interlocking screws; stainless steel
5. Grosse-Kempf (GK)	42 cm, 15 mm	Howmedica Rutherford, NJ	16	cloverleaf cross sec- tion, slotted all but proximal 2 cm, proximal and distal interlocking screws; stainless steel
6. Brooker-Wills (BW)	42 cm, 15 mm	Biomet Warsaw, IN	16	cloverleaf cross sec- tion, fully slotted, proximal interlock- ing screw, distal interlocking blades; stainless steel
7. Williams Y-nail (WY)	42 cm, 15 mm	Biomet Warsaw, IN	16	cloverleaf cross sec- tion, fully slotted, proximal U-nail through neck and head, distal inter- locking screws; stainless steel
8. Russel-Taylor (RS)	42 cm, 15 mm	Richards Memphis, TN	16.5	tubular nonslotted, proximal and distal interlocking screws; stainless steel
9. Titanium alloy tubular (TA)	42 cm, 14 mm	Prototype	15	tubular nonslotted, proximal and distal interlocking screws; titanium alloy

designs and to allow comparison of the results obtained in the laboratory with the published clinical performance of these devices.

Insertion of Rods

The individual rods were inserted following the manufacturer's instructions as closely as possible. The rod sizes were selected to provide the closest appropriate fit to the model bone. Most of the rods were nominally 15 mm in diameter. The prototype titanium tubular device was available only in 14 mm diameter. However, since this was a double-interlocked, nonslotted design, it is not likely that the difference of 1 mm on the diameter had significant effect on the comparison with the much more flexible nonslotted devices. The diameters to which the intramedullary canals were reamed was as indicated in the manufacturer's instructions (Table 1).

Testing Protocol

After reaming and insertion of the rods, the *proximal* transfixation was inserted where provided. With a saw, a complete transverse osteotomy was then cut 3 cm distal to the lesser trochanter. This was done in an alignment jig to ensure reproducibility between specimens. Full-length X-rays were taken to document placement of the device in the femur. The implant-stabilized femur was then mounted in an MTS servo-hydraulic test machine by potting the distal end in an adjustable mount (Fig. 1). The long axis of the bone was aligned parallel to the load axis of the MTS. Axial load was applied to the femoral head through a load cup which was free to translate in the M-L plane but was restricted in the A-P direction. The lower (distal) mount was bolted to a thrust bearing-plate, which was in turn connected to a calibrated bar, such that torque could be applied about the long axis of the femur while simultaneous axial load was applied to the femoral head. The offset of the femoral head resulted in simultaneous axial, bending, and torsional loading to the femur.

The load program was carried out in the following sequence:

1. Axial load to 150 N.
2. Torsional load to 20 Nm or 45 deg, whichever came first. This was alternated externally and then internally through six complete cycles. The axial load, axial displacement of the femoral head, torsional load, and rotational displacements were each continuously recorded using electronic transducers.
3. The axial load was increased to 1000 N and the torsional loading repeated.
4. The load was removed, and a second transverse osteotomy was cut 3 cm distal to the first, and the resulting free fragment was removed, producing a completely unstable fracture. Distal transfixation was applied where provided.
5. The torsional stabilities were again measured first with 150 N and then with 1000 N axial load.

A final X-ray was taken to document collapse or bending of the assembly.

Results

Insertion of Rods

The manufacturer's instructions were followed as closely as possible for the various devices. Some details are noted below.

1. Enders Nails: The canal was reamed in retrograde fashion to 15 mm (to simulate the physiologic intramedullary canal). We were able to implant three nails without difficulty via a distal medial cortical approach. The final two nails resisted all attempts at placement via this portal. Therefore, two holes were drilled in the femoral head and the nails were implanted in antero-

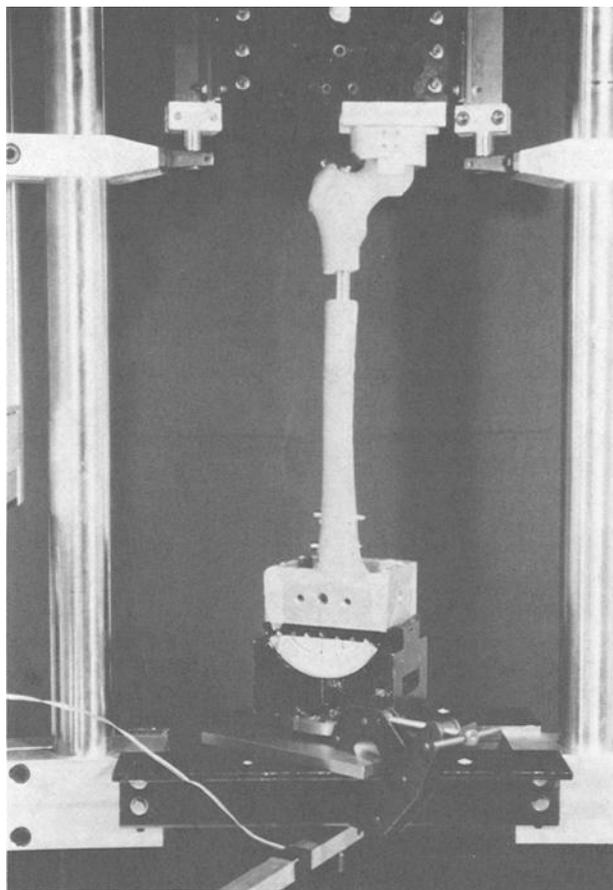


FIG. 1—Synthetic femur with 3-cm subtrochanteric osteotomy stabilized with an interlocking intramedullary rod (Biomet Interlocking). Axial load was applied to the femoral head parallel to the shaft, with the load fixture free to slide in the medial-lateral direction. Torsional load was applied about the long axis of the bone using the calibrated bar attached to a thrust bearing in the lower mount.

grade fashion until X-ray revealed good position within the distal medullary canal (Fig. 2a). The entry sites and the distal canal were filled with bone cement to provide distal fixation for the nails (equivalent to the nails passing through and being anchored by the medial femoral cortex).

2. Sampson Rod: The canal was reamed to 17 mm, 2 mm over the nominal diameter of the rod. The first femur fractured when the rod was driven into place. Implantation was successful on the second attempt. However, the proximal fragment was noted to rotate freely about the device when no axial load was applied (Fig. 2b).

3. Zickel Nail: As with the Sampson rod, the canal was reamed to 17 mm, 2 mm over implant diameter. The greater trochanter fragmented on the first three attempts at insertion even though the manufacturer's recommended approach (slightly lateral to pyriformis fossa) was used. The crosspiece was placed though a window in the base of the greater trochanter and driven into the cancellous bone of the femoral head. X-ray verified good position of the device (Fig. 2c).

4. Brooker-Wills Nail: The canal was reamed to 16 mm, 1 mm over the rod diameter, and the

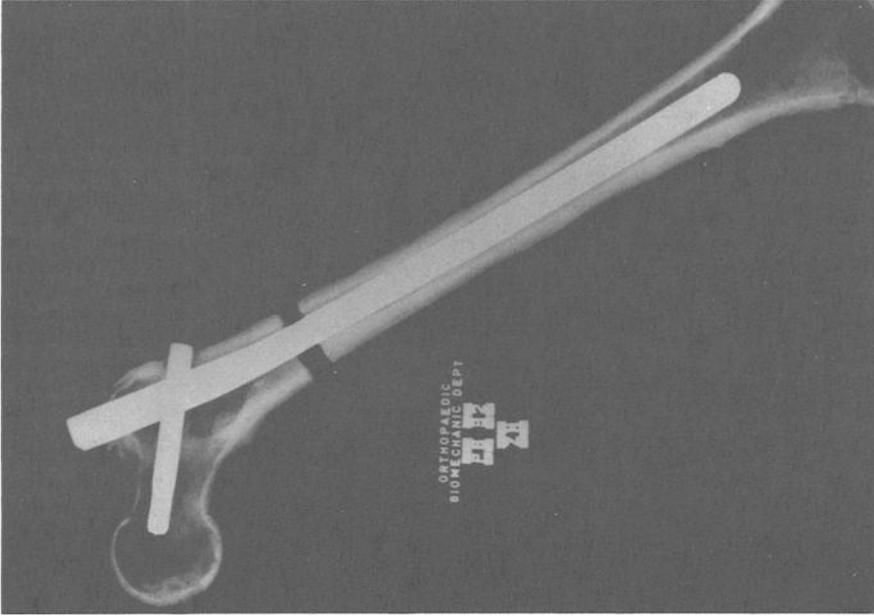


FIG. 2b—Placement of Sampson rod.

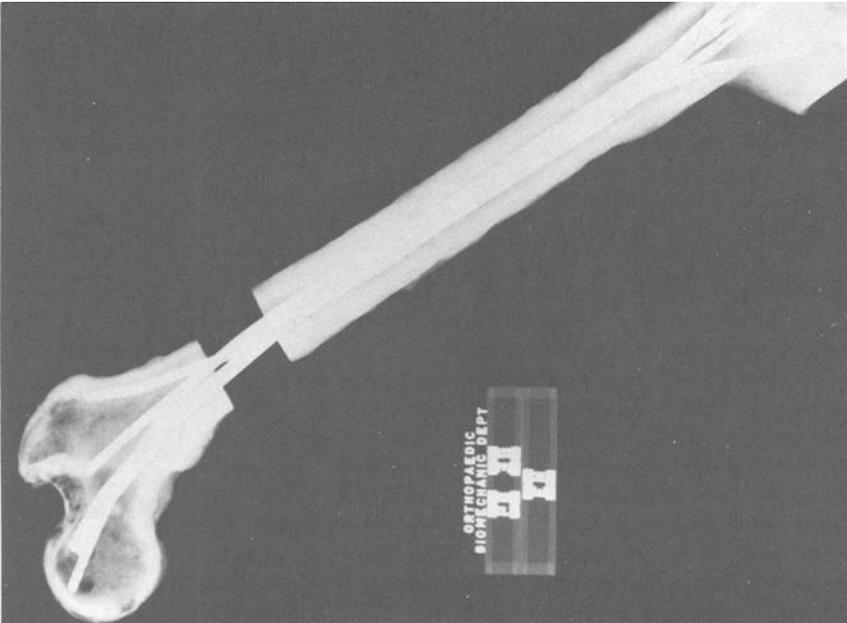


FIG. 2a—Radiograph showing details of the placement of the intramedullary rods. Five Ender s-type nails in a synthetic femur with unstable osteotomy.

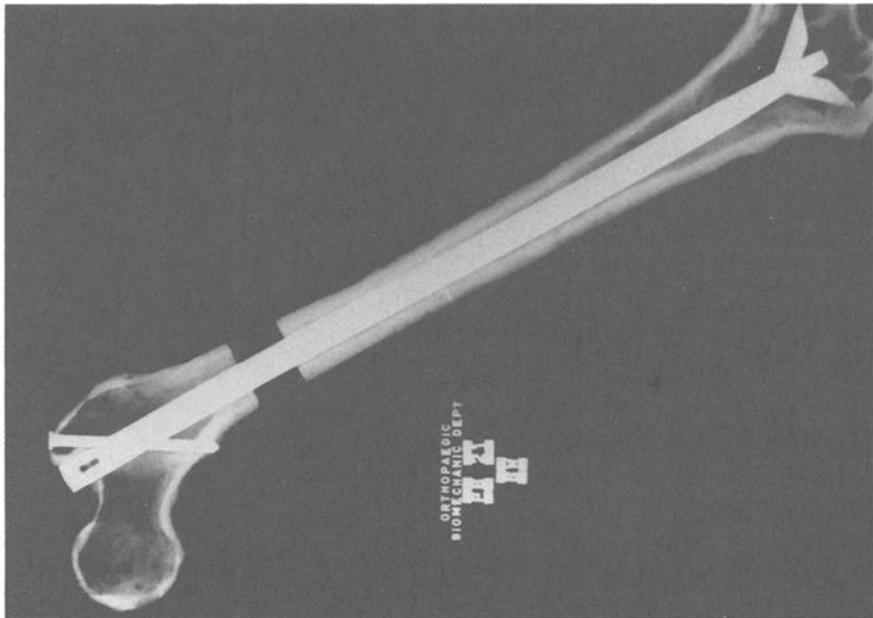


FIG. 2d—Placement of Brooker-Wills nail.

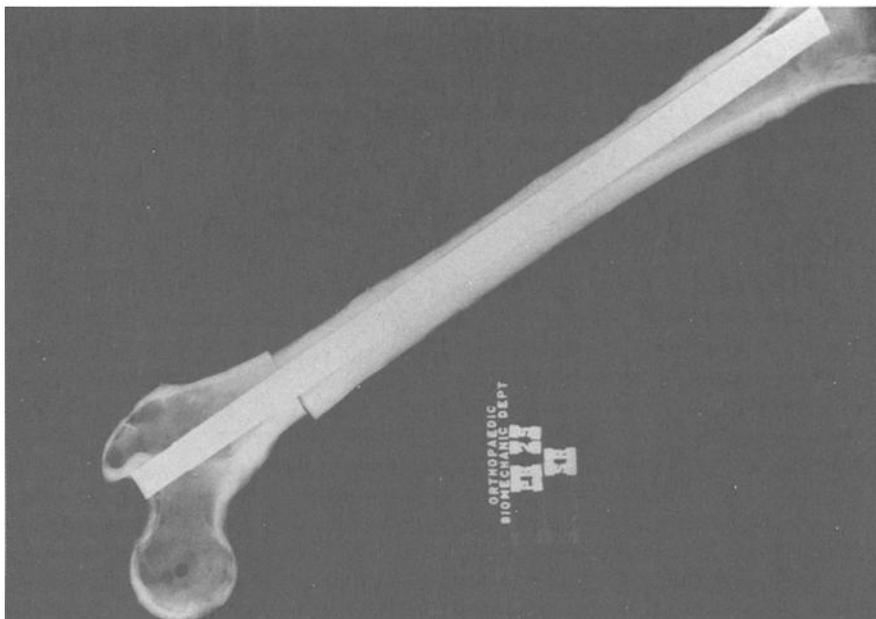


FIG. 2c—Placement of Zickel nail, stable osteotomy.

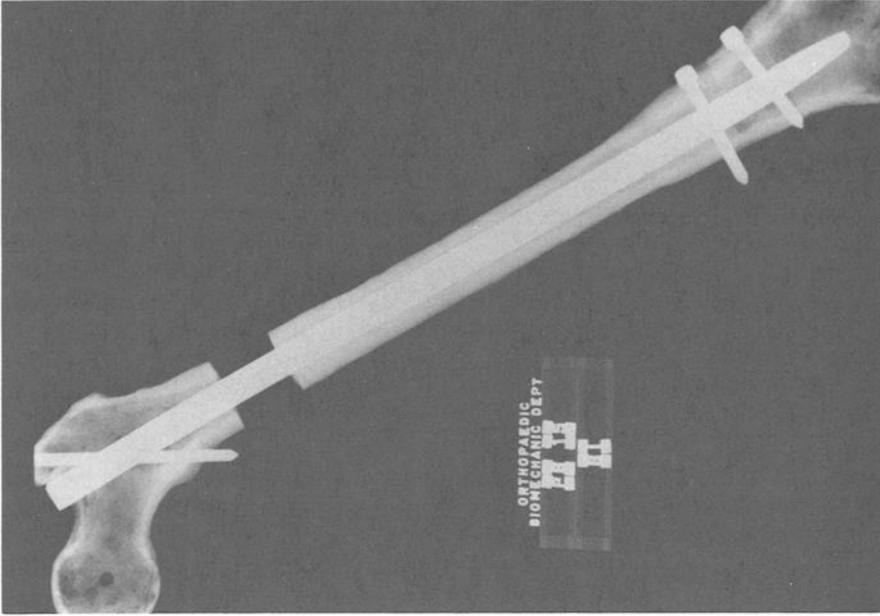


FIG. 2f—Placement of Biomet interlocking nail.

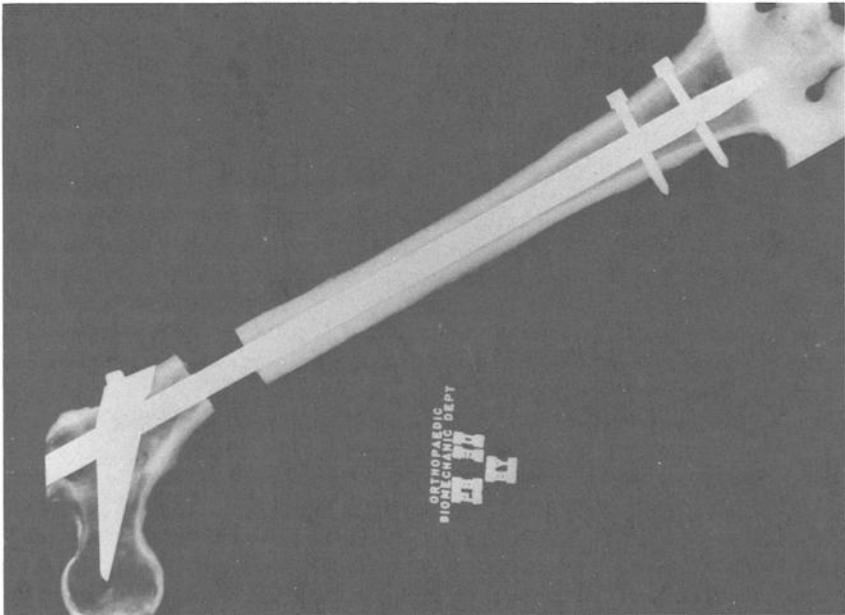


FIG. 2e—Placement of Williams "Y" nail.

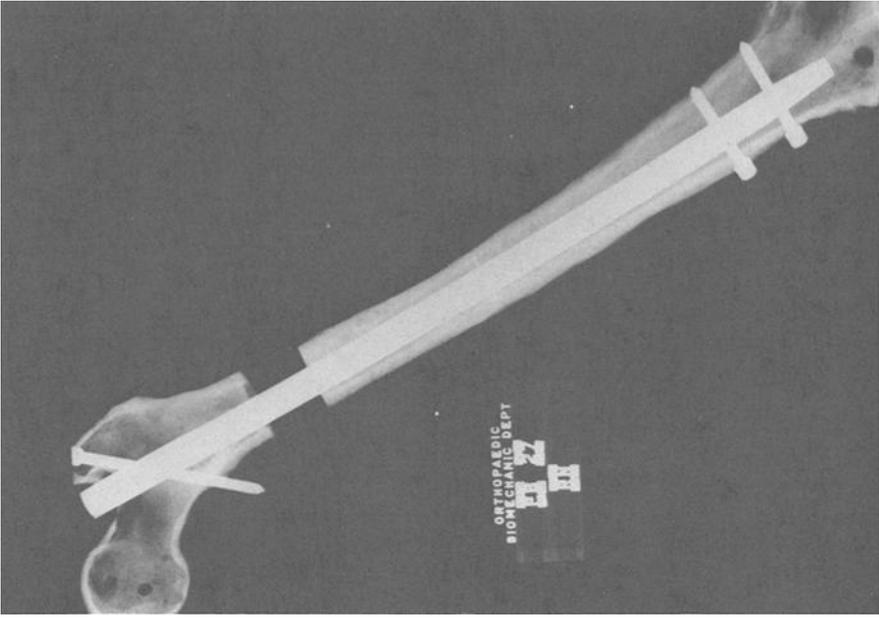


FIG. 2h—Placement of Russell-Taylor nail.

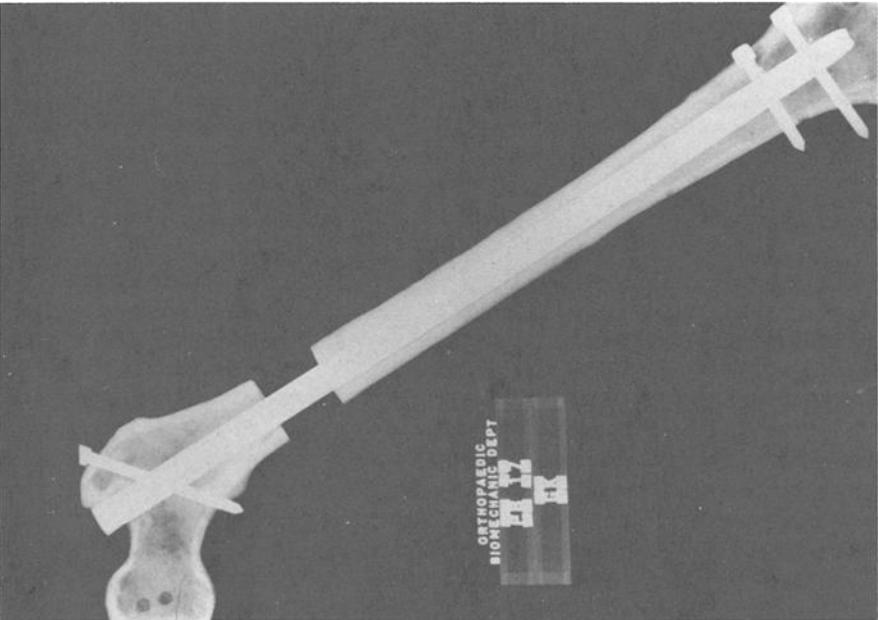


FIG. 2g—Placement of Grosse-Kempj nail.

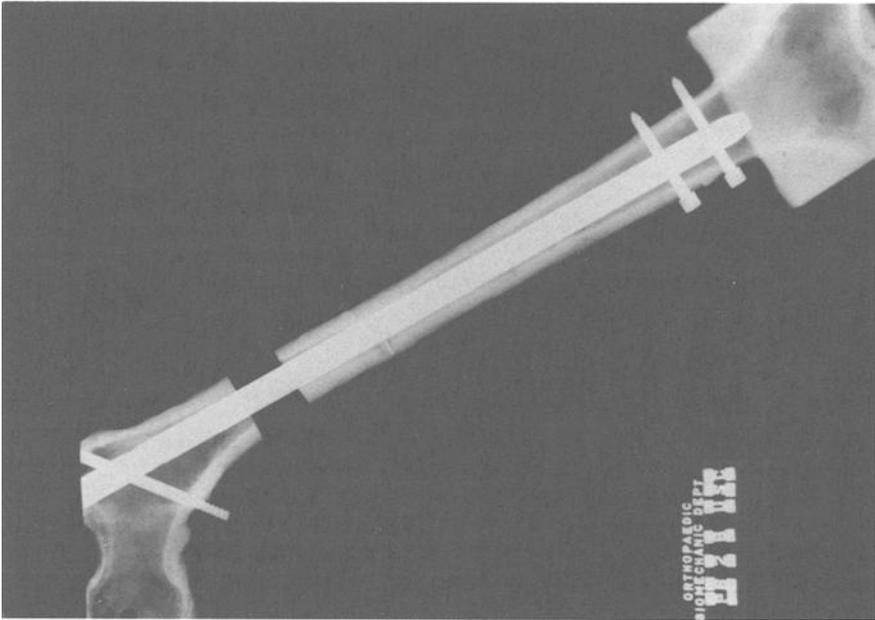


FIG. 2i—Placement of Prototype tubular titanium alloy nail.

device was implanted in the standard fashion. Proximal locking was placed for the stable fracture model. For the unstable fracture, the double-bladed insert was passed through the implant canal and the blades were deployed into the cancellous bone of the femoral condyles (Fig. 2d).

5. Williams Y-Nail: Before insertion of the intramedullary component, the canal was reamed to 16 mm. A 1½ by 3 cm defect was then cut in the lateral cortex of the greater trochanter and the Y-portion of the nail driven through cancellous bone of the neck into the femoral head. Good positioning was verified by X-ray. The slotted cloverleaf rod was then advanced through the orifice in the Y-component distally into the medullary canal (Fig. 2e). The Y-portion of the device was tightened into place with the screw provided for this purpose. The intramedullary nail had a cloverleaf cross section, but with the slot on the lateral side rather than anterior, as is typical of Kuntscher-type nails.

6. Locking Intramedullary Nails: Similar implantation protocol was used for the Biomet Interlocking, Grosse-Kempf, Russel-Taylor and titanium alloy prototype interlocking systems. The canal was reamed 1 mm over the nominal diameter of the implant with the Grosse-Kempf and titanium alloy nails, 1½ mm over for the Russel-Taylor and 0 mm over for the Biomet Interlocking. These devices had very similar appearance on X-ray (Fig. 2f, g, h, i).

Stiffness Measurements

The torsional stiffnesses of the implant-stabilized femurs are compared in Fig. 3 for the single transverse osteotomy (stable fracture) and in Fig. 4 for the segmental defect (unstable fracture).

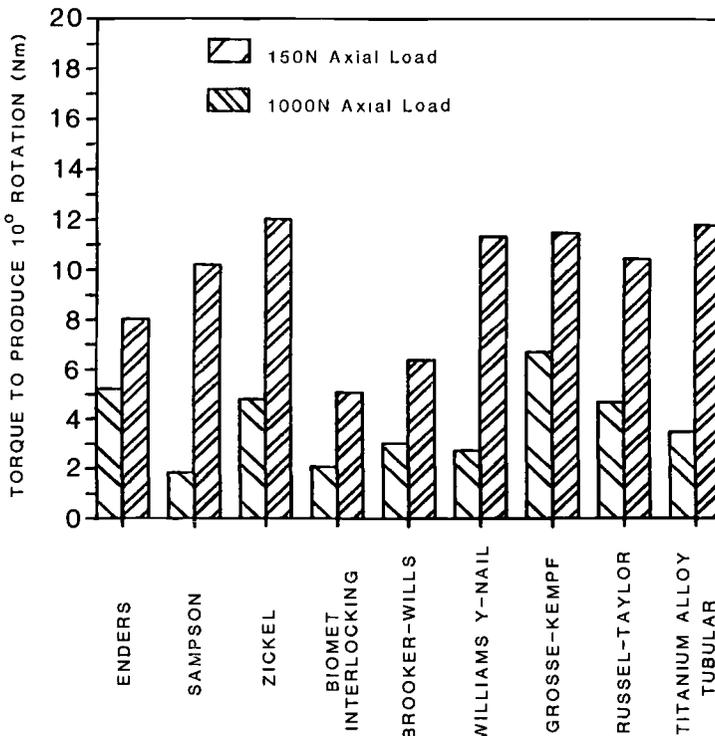


FIG. 3—Rotational stiffnesses of stable subtrochanteric osteotomies fixed with intramedullary nails at low (150 N) and high (1000 N) axial load. Ender-type nails and Sampson rod were noninterlocking; the remaining nails had proximal interlocking only applied with this osteotomy.

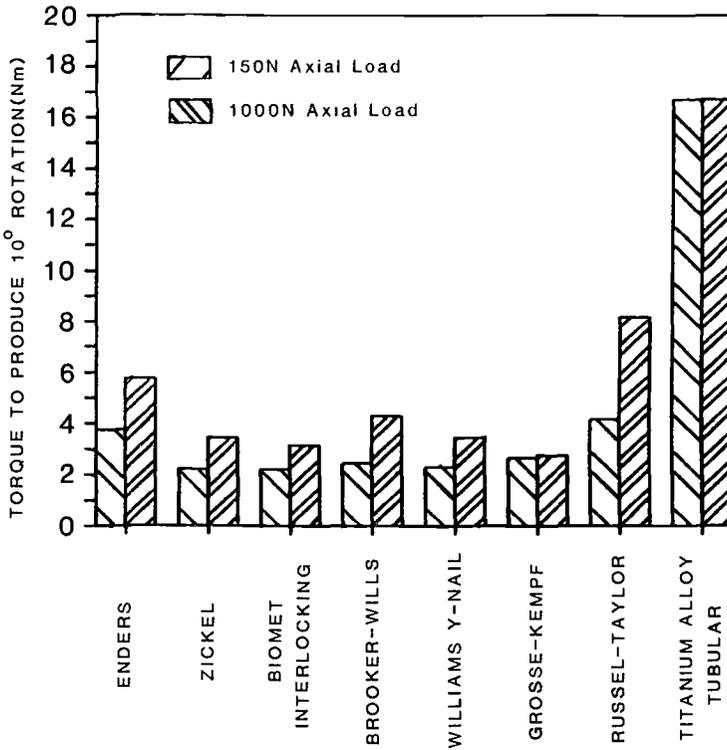


FIG. 4—Rotation stiffnesses of unstable, 3-cm subtrochanteric osteotomies fixed with intramedullary nails. The Ender-type nails were not interlocking; and Zickel nail had proximal interlocking only. The remaining nails had both proximal and distal interlocking applied.

The Sampson rod was not evaluated with the segmental defect since, with no proximal or distal interlocking, the fracture simply collapsed 3 cm. Each graph shows the torsional stiffness at both 150 N and 1000 N axial load.

Discussion

The loading on the femur used in this study consisted of an axial load through the center of the femoral head and parallel to the shaft. Although numerous studies have shown that the resultant force on the femoral head during gait is inclined at 10 to 15 deg to the shaft (that is, directed toward the center of the knee), this load does not necessarily produce the most physiological stress and displacement conditions for the entire femur. Rohlman and colleagues [5] used strain gage and finite-element analysis techniques to study the stress and displacement distributions on the femur (with a hip prosthesis inserted) for four load cases: (a) a single load through the femoral head parallel to the shaft; (b) a single load through the head but inclined toward the knee; (c) an inclined-head load with simultaneous abductor force at the greater trochanter; and (d) an inclined-head force with abductor force and tensor fascia lata force acting simultaneously. The stresses and displacements were surprisingly similar for Cases (a) and (d), with the exception of the stress distributions near the muscle attachments on the greater trochanter. Load Cases (b) and (c) produced an unphysiologically high bending moment in the proximal femur. Thus, if Load Case (d) was considered to be the most physiological, then Load

Case (a), the single load parallel to the shaft, was clearly preferable to either (b) or (c). Since (a) was relatively easy to apply and was reproducible among experiments, it was selected as the standard load case for our study.

The stable and unstable fracture models used in this study, that is, a simple transverse osteotomy 3 cm distal to the lesser trochanter followed by a second transverse osteotomy 3 cm distal to the first, with the fragment removed, was previously used by Tencer and colleagues [6] in their study of stabilization of subtrochanteric fractures. Clearly, there are many other possible fracture orientations, such as 45-deg oblique, that would have very different mechanical characteristics. As Tencer and colleagues stated, the two transverse osteotomies used in this study provided the opportunity to examine axial and rotational stability in two extremes, that is, completely stable with significant bone load sharing and completely unstable with only the rod providing axial and rotational rigidity. It was felt that these two cases were sufficient to provide a useful comparison between the different devices. Other fracture shapes could be evaluated using the techniques outlined in this report.

Some general trends were readily apparent in comparing the effect of low or high axial load on the rotational stability of the fractures. With the stable fracture (Fig. 2), although there was no systematic difference *between* the different designs, the effect on rotational stiffness of the increase in axial load was readily apparent with any given design. Rotational stiffnesses increased by as much as 5.8 times (for the Sampson rod) over that with simultaneous low axial load. This result emphasized the need to measure rotational stiffnesses with physiological axial and bending loads applied and with interaction of the fracture fragments. The lowest rotational stiffness at high load occurred with the Brooker-Wills and Biomet Interlocking designs, two slotted-cloverleaf rods with essentially identical rod dimensions.

Differences in the rotational stiffness between the different designs were much more apparent with the *unstable* segmental fracture (Fig. 3). The slotted rods typically allowed more rotation than the unslotted, double-interlocking designs. The unslotted Zickel nail, with proximal interlocking only, behaved much like the slotted-cloverleaf nails that had both proximal and distal interlocking (BI, GK, BW, WY). Thus, although the solid Zickel nail was inherently stiffer in rotation than the slotted designs, the lack of distal fixation allowed a similar amount of rotation of the bone segments. The five Ender pins provided rotational stiffness somewhat greater than the slotted designs. The rotational stiffness of the tubular titanium nonslotted design was four to five times greater than that of the slotted designs and was essentially unchanged going from low to high axial load.

The rotational stiffness of the Russel-Taylor rod, also a closed-section tubular design, was somewhat greater than that of the slotted designs but considerably below that of the tubular titanium rod. This was unexpected since the inherent rotational stiffnesses of the two devices were comparable. However, during testing it was apparent that much of the rotational motion of the bone with the Russel-Taylor rod occurred because there was a relatively large amount of clearance between the proximal screws and the screw holes in the rod (screw = 6.3 mm, hole = 6.9 mm). This permitted several degrees of rotation of the bone segments before the rod resisted motion. In contrast, the smaller screw-hole clearance in the tubular titanium rod (screw = 6.2 mm, hole = 6.36 mm) permitted very little motion. Thus, stiffness in rotation (as well as in other modes) was a function of the tightness of fit of the devices connecting the bone to the rod, as well as inherent stiffness of the rod.

Four of the devices evaluated in this study were also included in the earlier study by Tencer and colleagues [6] using the identical fracture model but with cadaver femurs rather than plastic model bones. Tencer and colleagues measured rotational stiffness with no axial load applied, thus minimizing the interfragmentary friction at the fracture site. In contrast, rotational stiffness in our study was measured with either 150 N or 1000 N axial load applied, thereby jamming the fracture fragments together (no distal interlocking was used with the single transverse fracture to permit collapse of the fragments. The effect of these differences in experimental format

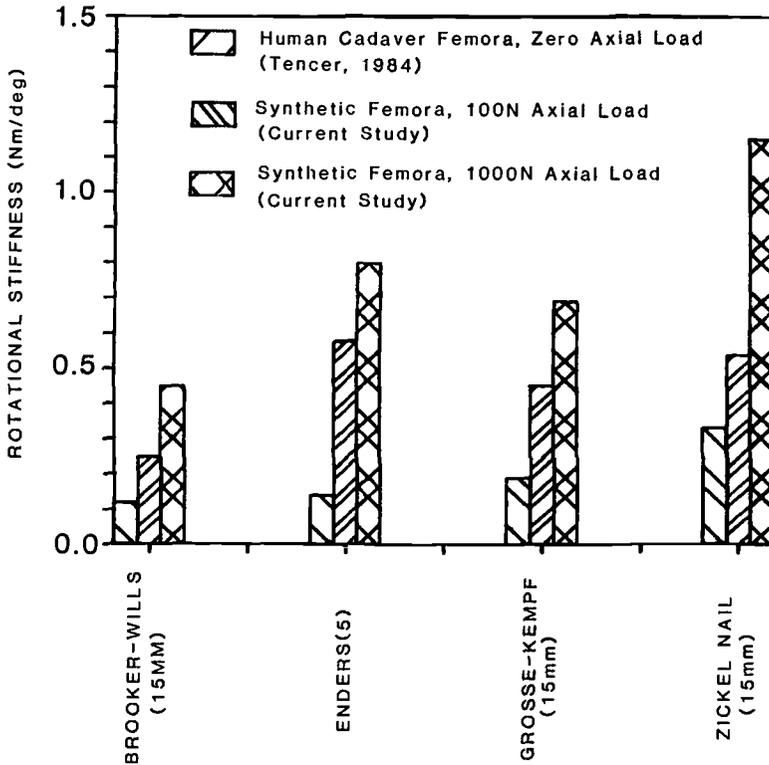


FIG. 5—Comparison of the rotational stiffnesses of four devices as tested in cadaver femora by Tencer and colleagues [6] with no axial loading and in the current study using synthetic femurs with either 150 N or 1000 N simultaneous axial loading.

is illustrated by Fig. 4, where the rotational stiffnesses are plotted as Newton-meters per degree of rotation. The relative rotational stiffnesses of the different devices were strongly effected by the axial loading on the femur. The rotational stiffnesses with 150 N axial load were greater than those measured by Tencer and colleagues by ratios ranging from 1.6 (Zickel) to 4.1 (Ender pins). At 1000 N, axial load these ratios increased to 3.5 (Zickel) and 5.7 (Ender pins).

Conclusion

The above discussion has emphasized only some of the trends that were apparent in the results of the experiments. Much more detailed information regarding the mechanics of the individual devices could be derived from a detailed analysis of the complete torque-displacement graphs for each component. However, there is currently no agreement as to the amount of stiffness (or, conversely, flexibility) that will best promote fracture healing in clinical use. The universal design tradeoff for skeletal fixation devices in general also applies to intramedullary rods. That is, a too-rigid device might result in stress-shielding of the bone or may hold the fracture surfaces apart and predispose the fracture to nonunion. On the other hand, too much flexibility might permit unacceptable amounts of angular or rotational deformity, or might permit excessive motion at the fracture surfaces leading to nonunion and pseudarthrosis. Laboratory studies such as those reported here can eliminate obviously unacceptable devices and can compare the remaining designs on a quantitative basis. The final determination of the optimum

mechanical design parameters can be achieved only through a close comparison of the laboratory results with the clinical performance of the specific designs.

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Initial Mechanical Stability of Three Distally Locked Intramedullary Nail Systems

REFERENCE: Daniels, A. U., Hofmann, A. A., West, H. S., and Morgan, J. M., "Initial Mechanical Stability of Three Distally Locked Intramedullary Nail Systems," *Intramedullary Rods: Clinical Performance and Related Laboratory Testing, ASTM STP 1008*, J. P. Harvey, Jr., A. U. Daniels, and R. F. Games, Eds., American Society for Testing and Materials, Philadelphia, 1989, pp. 80-86.

ABSTRACT: Both the initial torsional stability and axial compressive fixation strength were compared using human cadaver femoral specimens, for three intramedullary nail systems incorporating distal transverse locking: the Grosse-Kempf (GK), Brooker-Wills (BW), and an experimental system referred to informally as the Utah Nail (UN). Unlike the GK system, the BW and UN devices utilize internally deployed distal fixation components to provide transverse stabilization without the need for either mechanical aiming devices or distal incisions for placement of components. The experimental UN system provided greater stabilization and strength than the BW but less than the GK, especially with respect to strength. The UN system has been used successfully in a small number of clinical cases, and it is not yet clear what levels of stabilization and strength are needed in various clinical situations.

KEY WORDS: femur, intramedullary nail, fracture stabilization, internal fixation

Transversely locked intramedullary nails are valuable in the treatment of more complex long-bone fractures, because they provide additional axial and torsional stability compared to conventional nails alone [1]. However, where distal placement of transverse pins or screws is required, locking systems, such as the Grosse-Kempf (GK), which employ aiming devices are more difficult and time-consuming to use, due to the limits of accuracy which are encountered with the aiming devices [2]. A clinical example of distal locking with the GK system is shown in Fig. 1.

The Brooker-Wills (BW) system eliminates the need for a distal aiming device by incorporating an internally deployed device to provide transverse locking. However, questions have been raised as to whether or not this device provides stabilization comparable to that which can be achieved with the GK using distal pins deployed with an aiming device. In this study, we compared axial and torsional stabilization provided by these two systems and a third set of experimental components, referred to informally as the "Utah nail" (UN) and consisting of a standard commercially available cloverleaf rod and Ender pin, both modified slightly so that the pin serves as an internally deployed distal locking device. The distal locking components employed by the three fixation systems which were compared in this study are shown in Fig. 2.

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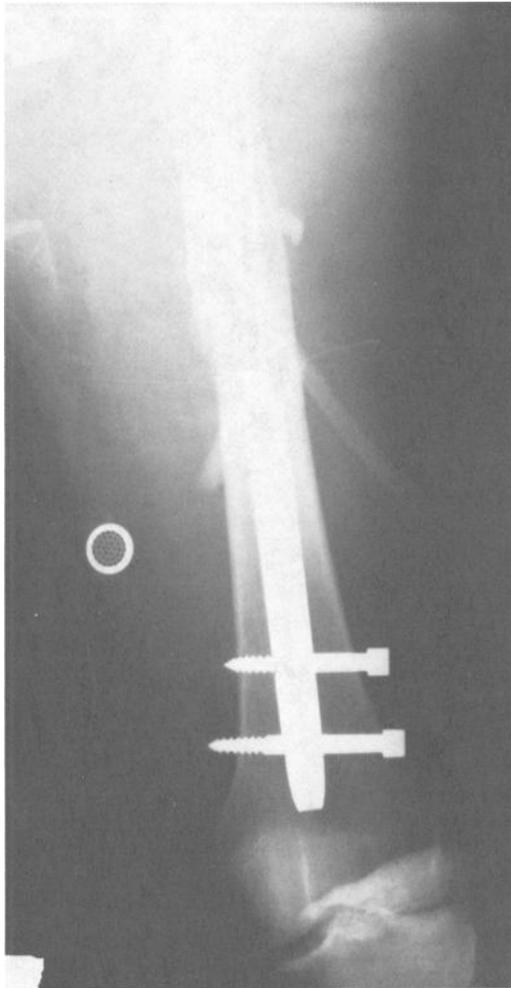


FIG. 1—Example of distal locking achieved with the Grosse-Kempf intramedullary system.

Materials and Methods

Torsional stiffness of fixation is a measure of the stability which an intramedullary fixation system provides. Strength of fixation in axial compression strength indicates whether a system will maintain fixation under patient loads occurring either in leg lifts or ambulation. Accordingly, simulated in-use torsional stiffness of fixation and axial compressive fixation strength of 15-mm-diameter cloverleaf rods with locking systems were determined, using either eight or nine fresh frozen and thawed cadaver femurs per nail. The tests were planned so that for a given nail system, tests of matching contralateral femurs were divided approximately equally between the other two nail systems to minimize the effects of biologic variation on test method precision. GK and BW systems were installed using the methods described in product literature, and techniques used for the UN were generally similar.

Nails were press-fit distally into cancellous bone, allowing no initial cortical contact. The

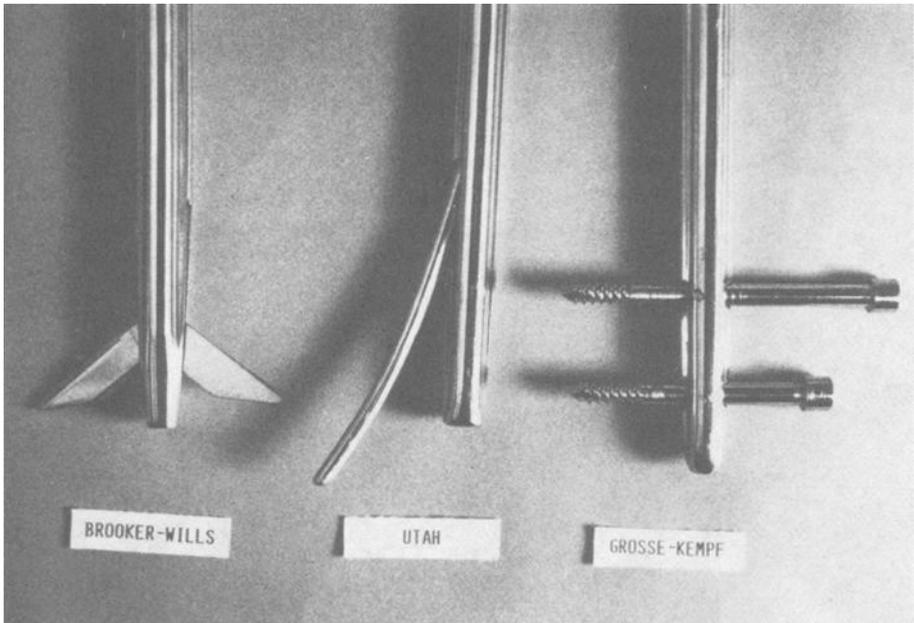


FIG. 2—The three distal locking systems compared in this study. Brooker-Wills and Utah systems incorporate internally deployed components for distal interlocking. Torsional load at 20 deg rotational displacement.

absence of cortical contact was confirmed radiographically, because such contact would substantially and artificially augment the stiffness and strength of fixation. To assess system torsional stiffness, rod/bone specimens with the locking mechanisms deployed were subjected to three loading cycles between plus and minus 50 kg·cm of applied torque. Torsional stiffness was determined and reported as the average torsional moment required to produce 20 deg of rotational displacement during the cyclic loading. For system axial compressive strength, loading at 10 mm/min was applied, with axial force recorded until either 5 mm of axial displacement had occurred or the load reached 500 kgf.

Additional tests (three femurs per nail) were performed with matched distal-third femoral specimens to determine the relative contributions of the rods alone and the locking devices alone to both torsional stiffness and axial compressive strength. This was accomplished for torsional stiffness as follows. First, *without* the locking devices deployed, the specimens were subjected to torsional loads in both directions until permanent angular displacement occurred, noting the torque required to produce 20 deg of displacement. Now, with the rods offering no intrinsic resistance to rotation, the locking devices were deployed and the original cyclic loading tests were repeated to determine the torsional stiffness provided by the locking devices alone.

Relative contributions to axial compressive strength were determined similarly. First, *without* the locking devices deployed, the specimens were taken to 5 mm of axial displacement as described above. The force value recorded was then that for axial compressive strength of fixation provided by the rod alone. The rod was then extracted back to its original position, and the locking device was employed. Then, the test was repeated to 5 mm displacement or 500 kgf. Since the contribution of the rod alone had been eliminated in the first part of the test, the force value recorded in the second part of the test was for the locking device alone.

Results

As shown in Fig. 3, the distal interlock devices supplied most of the torsional stability in the BW and GK systems, while the contributions of the nail and locking device to stability were more equal in the UN system. The UN was intermediate in performance between the BW and GK, providing 30% less stiffness in torsion than the GK, but 27% more than the BW.

Results of the tests to determine the strength of fixation in axial compression are presented in Fig. 4. As shown, the GK system did not migrate 5 mm before reaching 500 kgf. Both other systems provided much less fixation strength than the GK: each migrated 5 mm at less than 200 kgf, with the UN registering 23% more fixation strength than the BW. In the tests to determine relative contributions of system components, the least axial support was provided by the BW rod alone, probably due to its more pointed distal tip.

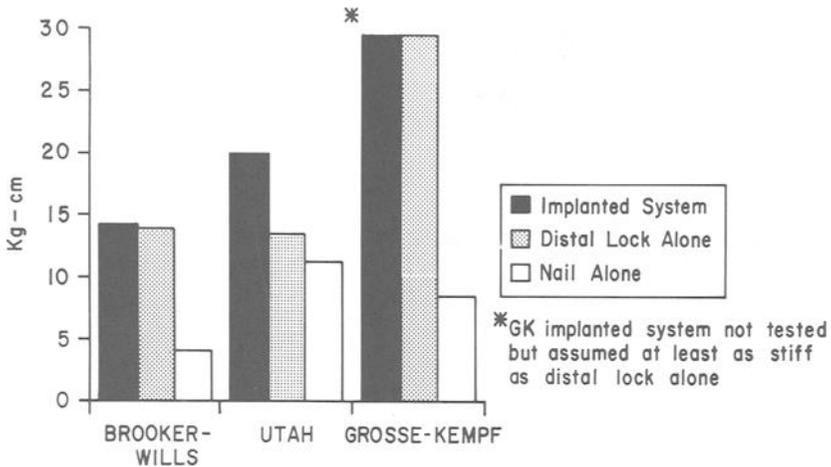


FIG. 3—Results for torsional stiffness tests, designed to provide a measure of the relative stability of fixation with the three distal locking systems.

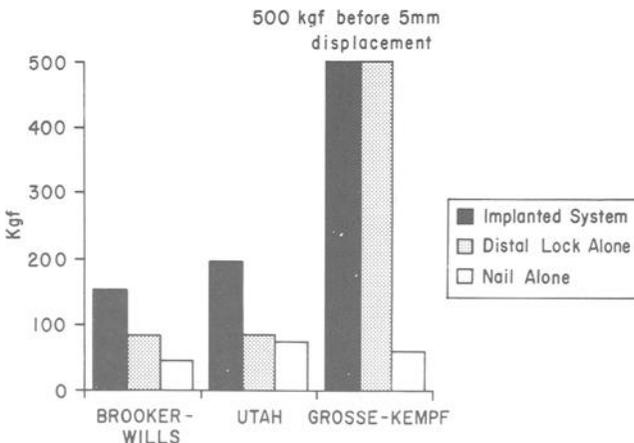


FIG. 4—Results for axial compression tests, designed to provide a measure of the relative strength of fixation achieved with the three distal locking systems. Axial load at 5 mm displacement.

Discussion

The UN system has worked satisfactorily when used in a small number of clinical cases on a physician-prescribed basis. An example is shown in Fig. 5. Patient WD, a 22-year-old male, sustained a closed, comminuted fracture of the distal left femur in a motorcycle accident (Fig. 5a). Antero-posterior and mediolateral views of the immediate postoperative fixation achieved

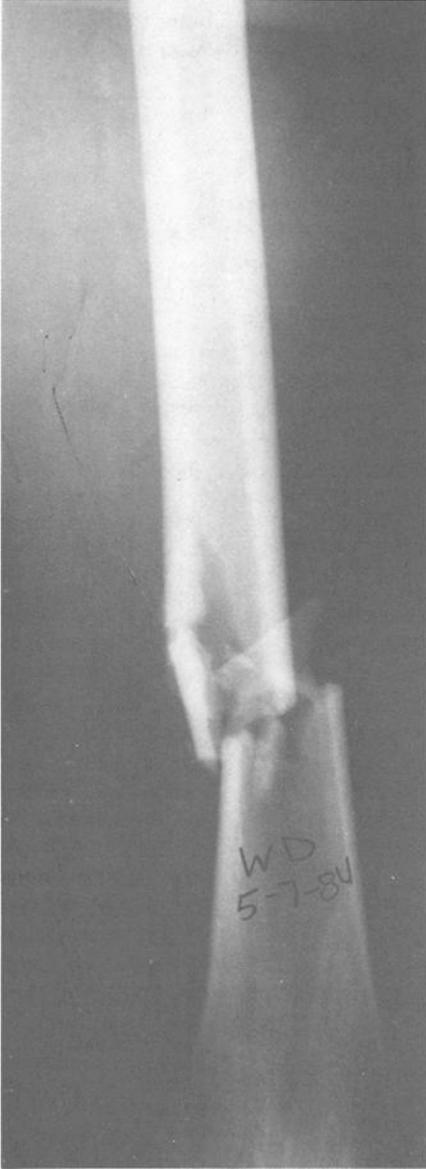


FIG. 5a—Closed, comminuted fracture of the distal left femur, sustained by a 22-year-old male patient (WD) in a motorcycle accident.

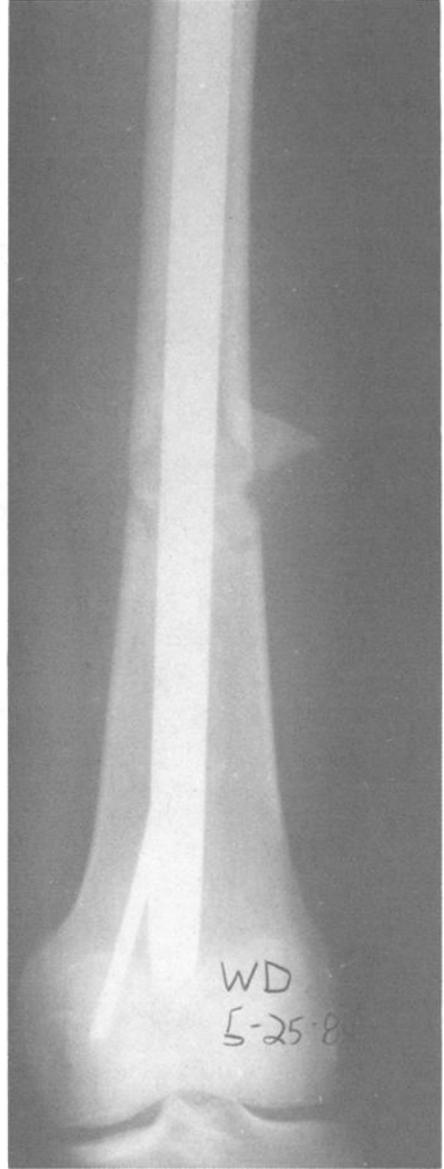


FIG. 5b—Antero-posterior view of immediate post-operative femoral fracture stabilization in patient WD with the UN system.

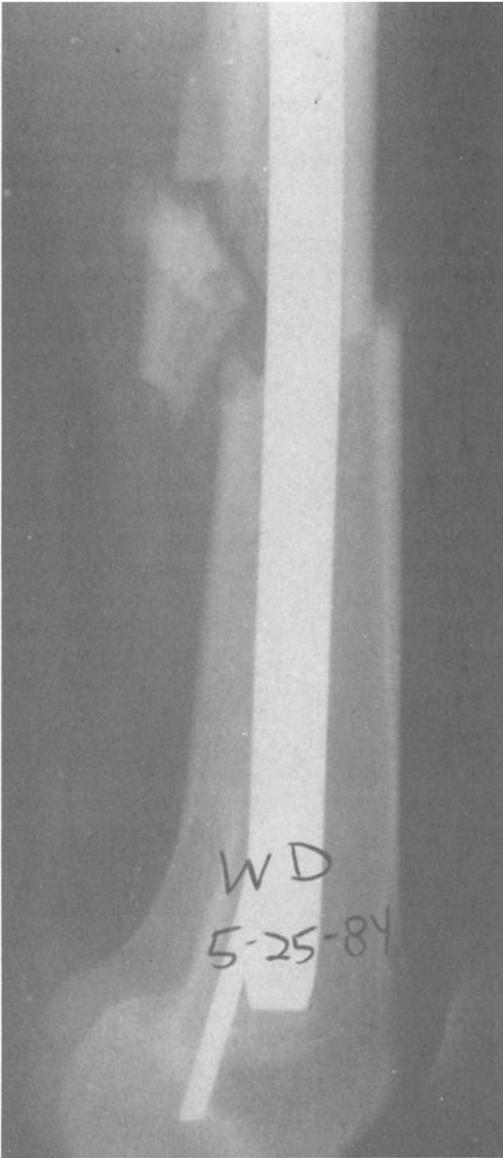


FIG. 5c—Medio-lateral view of immediate post-operative femoral fracture stabilization in patient WD with the UN system.



FIG. 5d—Femoral fracture healing in patient WD after removal of the UN intramedullary components at 15 months after surgery.

with the UN system are shown in Figs. 5b and 5c. The patient was allowed to become full weight-bearing at four months after surgery, and Figure 5d shows the result when the rod was removed at 15 months.

The GK system clearly provided superior stability and strength of fixation in the laboratory tests reported here. However, as illustrated by the clinical case described above, the question of

how much stability is required clinically is still largely unanswered, and the difficulties encountered in distal placement of transverse devices discourage the use of the GK technique. In the laboratory tests, the UN provided better stabilization than the BW system, and both of these latter systems may be used far more easily and quickly than the GK. Continued clinical experience will indicate in which cases these more easily deployed systems are sufficient.

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Biomechanical Variables Affecting Stability and Stresses in the Fractured Femur During Intramedullary Nailing

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ABSTRACT: Closed intramedullary nailing is an accepted method of treatment for femoral shaft fractures. Technical complications of this procedure include fracture instability, which may result in nail migration and malrotation, and femoral bursting during nail insertion. These complications were investigated in terms of geometric and mechanical parameters of the bone-implant system. Mechanical test results indicate that nails of the same nominal size from different manufacturers possess more than a twofold difference in flexural rigidity and a threefold difference in torsional modulus. These differences are due to variations on the cross-sectional shape and wall thickness. Measurements in insertion force and hoop stress in cadaver femora were significantly different for most of the nails tested due to differences in mechanical and geometric properties. Insertion forces in the distal fracture component were consistently lower than those in the proximal fracture component and decreased linearly with component length. Increasing the reamed diameter in the distal component 1 mm over the nail size decreased the insertion forces significantly. The most significant variable affecting femoral bursting was found to be the placement of the starting hole. Anterior offset from the neutral axis of the canal by more than 6.0 mm consistently resulted in excessive hoop stresses and femoral bursting. Case reports are presented to illustrate these biomechanical principles clinically.

KEY WORDS: intramedullary nailing, fracture stability, femoral bursting

Closed intramedullary fixation is a widely accepted and well-documented method of management of femoral shaft fractures [1-8]. The operative procedure is safe, can be performed rapidly, and does not further disrupt the periosteal blood supply at the fracture site [9,10]. Intramedullary fixation allows early joint motion and weight-bearing which, in fact, may stimulate callus formation and thus union, through controlled motion and compression of the fracture [2,4,5,10,11].

As a result of their large size, position within the medullary canal of the bone, and increased flexural rigidity, these implants are not prone to fatigue failure [12], as are bone plates [13-15]. Since the implant is a load-sharing device, it prevents the stress protection of bone that is commonly seen with the plate fixation [16-18]. Therefore, it is generally agreed that, when indicated, closed intramedullary fixation is the procedure of choice over plating for femoral shaft fractures.

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Complications of closed intramedullary fixation of femoral shaft fractures include bursting of the proximal fracture component during insertion of the nail [11, 19-23] and inadequate fixation of the fracture [14, 19, 23, 24]. This may result in proximal migration of the nail, malrotation of the fracture components, or axial shortening of the femur. These complications may result in delayed union, malunion, or shortening of the extremity, or may necessitate premature removal of the nail [25].

Over the past 30 years, the literature indicates a downward trend in the occurrence of complications resulting from intramedullary nail fixation of fractures (Table 1). However, a number of procedures which yield unsatisfactory results continue to occur. The purpose of this study was to identify the effect of starting hole position, length of the major proximal and distal fracture fragment, reamed diameter and nail type on fracture stability, and femoral bursting during the closed insertion of an intramedullary nail for a femoral shaft fracture. These data are correlated with several examples of clinical complications seen in our institution following this procedure.

Materials and Methods

Intramedullary Nails Used

Standard cloverleaf intramedullary nails of 15.0-mm nominal diameter, as designated by ASTM standards [26], and 420-mm long were obtained from five different manufacturers:

- A Orthopaedic Equipment Co, Bourbon, IN,
- B DePuy, Warsaw, IN,
- C Howmedica, Rutherford, NJ,
- D Zimmer, Warsaw, IN, and
- E Synthes (USA), Paoli, PA.

All nails are currently available for sale and use in the United States. In the presentation of results, the plots are coded as given above.

Geometric Measurements of Nails

The anterior-posterior (AP) curvature of each nail was quantified by measuring the elevation of the nail midpoint above its end points using a height gage. Further nail cross-sectional properties, including the section area centroid location and moment of inertia about the *X*- and *Y*-axes through the centroid, were determined using an angular profilometer. This device determines the polar coordinates of any point on the external surface of a section through measurement of the angular position and radius magnitude of that position. Measurements were made by fixing a short segment of nail with negligible curvature to a rotating shaft coupled to a single-turn angular potentiometer.⁴ A linearly variable differential transformer⁵ (LVDT) was mounted

TABLE 1—*Published statistics regarding complications.*

Investigator	Year	Series Size	Complications, %
Dencker [19]	1964	459	14.0
Hansen [11]	1979	300	9.7
Winqvist [8]	1984	520	5.2

⁴Model A040, Markite Corp., New York, NY.

⁵Linear variable differential transformer, Model 100-DC-D, Shaevitz Engineering, Pennsauken, NJ.

with its axis perpendicular to the longitudinal axis of the specimen to measure the radial distance of the external surface of the specimen for any angular position. The polar coordinates of the external surface of each nail could then be digitized using an LSI 11/23 minicomputer.⁶ The program SLICE [20] was used to calculate the geometric properties of each section. System accuracy was determined using standard cylindrical sections. Measurements of cross-sectional area were found to be accurate within 1.6%, and the section moment of inertia through the centroid, within 2.6%. Wall thickness was determined from caliper measurements on the nail specimens used for the cross sectional studies. The wall thickness was assumed constant throughout the nail.

Mechanical Property Measurements of Nails

Flexural rigidity values of the nails were determined in two planes (AP and ML [medial-lateral]) with reference to the anatomical orientation of the implant. Four-point bending loads (positioned 5.5 cm from nail center) were applied in a compression tester with the load measured by a load cell⁷ and the displacement of the load plunger by an LVDT.⁸ The nails were supported with one end free and the other end in a pinned support to allow rotation in the plane of the applied bending load. Torsional properties of the nails were determined using a torsion tester with one end of the nail fixed to a torque cell⁹ and the other end to a shaft free to rotate and coupled to a rotational variable differential transformer.¹⁰ Data was recorded on an X-Y recorder.¹¹ In all cases, load-deflection curves were repeated at least twice to ensure that no slippage occurred in the specimen clamping mechanism and that the nails were not loaded into their plastic range. Reproducibility of the mechanical data was better than 6.7% for retested nails. The flexural and torsional rigidities of the implants were determined using standard beam deflection equations for four-point bending and torsional loading with input data from the experimental load-deflection curves.

Preparation of Specimens

Fresh cadaver femora were obtained at autopsy from adult males between the ages of 20 and 55 years. Each femur was radiographed and discarded if evidence of osteoporosis or other pathology was noted. Accepted femoral specimens were stripped of soft tissue and sectioned transversely at the mid-diaphysis to create a proximal and distal femoral component. Each component was covered with a wet towel and wrapped in plastic to maintain a moist environment for the duration of the project. The specimens were stored at -20°C when not in use.

A neutral location for the starting hole in the proximal femoral component was identified such that the center of the starting hole was aligned with the middle of the medullary canal in both ML (Fig. 1) and AP (Fig. 2) planes. Each specimen was reamed using standard flexible reamers (OEC) passed over a 3-mm guide rod as defined in the surgical procedure [27].

The proximal femoral components were then potted in a thin ring of polyester resin molded around the trochanteric region just under the femoral head (Fig. 3). Distal components were supported by embedding the femoral condyles in the same potting material. This provided support against compressive loading during experimental nail insertion, while not interfering with the generated stress distribution within the bone.

⁶Digital Equipment Corp., Maynard, MA.

⁷Model 3132, Lebow Associates, Goleta, CA.

⁸Model 1000DCD, Shaevitz Engineering, Pennsauken, NJ.

⁹Model 2021, Lebow Associates, Goleta, CA.

¹⁰Model R30D, Shaevitz Engineering, Pennsauken, NJ.

¹¹Model 7064A, Hewlett Packard, Palo Alto, CA.



FIG. 1—Lateral view of proximal femur; black line represents neutral axis for starting hole.

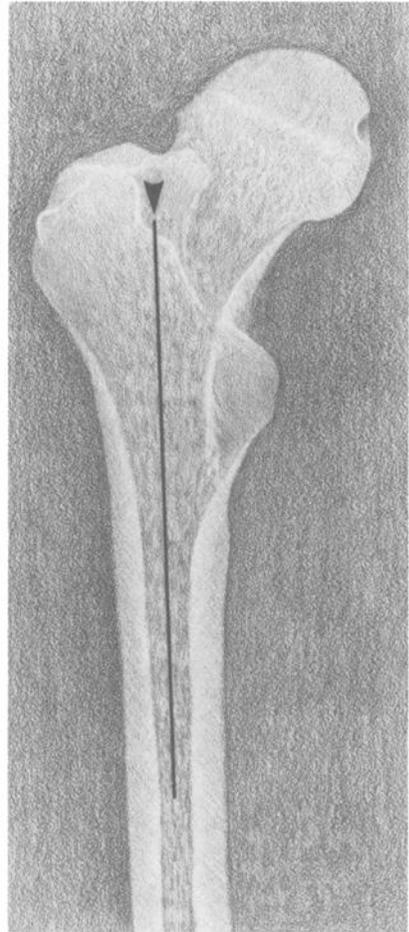


FIG. 2—Anterior view of proximal femur; black line represents neutral axis for starting hole.

Variables Measured

For the purposes of this study, axial push-out force was considered a quantitative indicator of fracture stability, since this is a measure of the frictional force generated between the surface of the nail and the bone. Axial push-out force was defined in terms of the axial load required to initiate axial motion at the nail-bone interface of a fully inserted nail. This was determined by mounting each specimen in a screw-driven mechanical testing machine¹² and inserting the respective nails at a fixed ratio of 100 mm/min. Axial insertion force was recorded during the insertion phase on a strip chart recorder. The push-out force was measured as the insertion force when the nail was level with the greater trochanter.

To determine hoop stress (the circumferential stresses generated in the femur) and thus an indication of the potential for femoral bursting during nail insertion, proximal femoral compo-

¹²Model 1000, Instron Corp., Canton, MA.

nents were instrumented with a 45-deg strain gage rosette¹³ bonded to the distal diaphysis of the proximal component, 30 deg from the AP plane of the femur on the anterior-medial aspect (Fig. 3).

Strain gages were bonded in accordance with accepted practices as described by Hayes and others [18,28,29]. Hoop stresses were then calculated via an anisotropic analysis as outlined by Carter and others [30-35].

Experimental Sequence

In proximal femoral components, the effect of four parameters was evaluated; reamed diameter, nail type, femoral component length, and starting hole location. All testing was performed using 15.5 mm as the reamed diameter for proximal components, which is standard clinical practice [27,28,36] when a 15-mm-diameter nail is used.

Experiments with the nails of five different manufacturers involved insertion of the nails in a random sequence into each of the nine specimens used in this part of the experiment. In most cases, the first nail insertion was repeated at the end of the experiment to confirm the reproducibility of the tests. The same nine femora were then used to determine the effect of proximal femoral component length. Nail Type B (DePuy), which consistently showed the highest insertion forces, was repeatedly inserted as the proximal femoral component was progressively shortened in 1-cm increments. This continued until insertion forces were not measurable. The location of the strain gage rosette resulted in its removal upon sectioning of the proximal femoral component; therefore, no strains were recorded during this phase of the study.

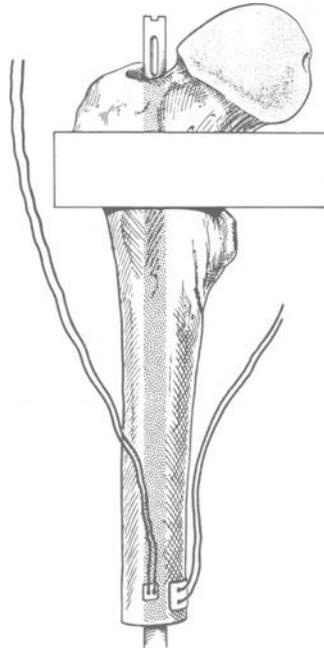


FIG. 3—A proximal specimen (potted) with a strain rosette applied.

¹³EA-06-060WR-120, Micro Measurements, Raleigh, NC.

To identify the effect of starting hole location on insertion forces and hoop stresses, 13 additional proximal specimens were prepared. All experiments were performed in a manner identical to that described above with one exception: The location of the starting hole was offset in various directions from the neutral position. Again, only nail Type B was used in these experiments.

Distal femoral components were tested in a similar manner. However, strains were not monitored since clinical experience [15,31], supported by experimental evidence presented here, indicated that insertion forces and hoop stresses are lower in the distal femoral component than in the proximal component.

Since the curvature of the medullary canal of the proximal femoral component proved to be an important parameter, the shape of the canal was quantified after all experiments were completed. Positive casts were made of the medullary canal with fast-setting polymethylmethacrylate. The offset of the proximal starting hole with respect to the axes of the canal was confirmed and could then be evaluated by measurement from the molded casts.

Results

Geometric Properties of the Nails

The moments of inertia of the nail cross sections about the *X*-axis (neutral axis for AP bending) with the origin at the centroid of the area were calculated for five nails of 14-mm nominal size. The values, shown in Table 2, were the average results of three measurement trials, with a repeatability within $\pm 2\%$ for each nail. The nails, whose cross-sectional profiles are shown in Fig. 4, were found to have significant differences in moment of inertia values. For example, the cross-sectional moment, *IY*, of Nail Type E was only 72% of that of Nail Type D. Moments of inertia of other nails were also less than that of Nail Type D, which had the largest flexural and torsional rigidity. Moments of other nails were greater than that of Nail Type E which, except for ML bending, had the lowest rigidities.

As illustrated in Fig. 4 and Table 2, wall thickness, a parameter not directly specified by the ASTM Specification for Cloverleaf Intramedullary Pins (F 339-71), varies between 1.0 mm (Nail E) and 2.0 mm (Nail D).

Mechanical Properties of Nails

Results illustrated in Fig. 5 indicate that except for Nail A in ML bending, the flexural rigidities increase with nail size in both AP and ML planes. Large differences in flexural rigidities between implants were noted, particularly in the ML plane. For example, Nail D (nominal size 15 mm) was found to have a ML flexural rigidity of $0.1866 \times 10^3 \text{ Nm}^2$ compared with $0.0567 \times 10^3 \text{ Nm}^2$ for Nail A (15-mm diameter), more than a twofold difference. The change in flexural rigidity with nominal size also varies between nails. Considering ML bending rigidities, illus-

TABLE 2—*Geometric properties of the nails.*

Nail Type	Wall Thickness, mm	Cross-Sectional Area, mm ²	IX, mm ⁴	IY, mm ⁴
A	1.40	48.37	807.02	791.99
B	1.30	47.42	820.21	818.29
C	1.50	51.27	788.89	857.62
D	2.00	63.77	837.09	929.92
E	1.00	36.85	644.39	669.55

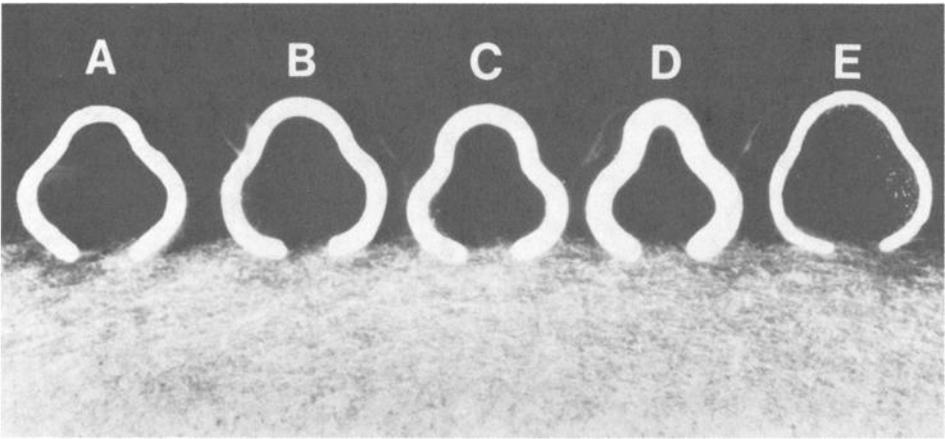


FIG. 4—Cross-sectional view of the five nails tested (A = OEC, B = DePuy, C = Howmedica, D = Zimmer, E = Synthes).

trated in Fig. 5a, as Nail C increases from 12- to 16-mm nominal size, the flexural rigidity increases from $0.0536 \times 10^3 \text{ Nm}^2$ to $0.1860 \times 10^3 \text{ Nm}^2$, while for Nail A the change is from $0.0586 \times 10^3 \text{ Nm}^2$ to $0.0761 \times 10^3 \text{ Nm}^2$ over the same range of sizes, a much smaller and also nonuniform increase.

Torsional moduli of intramedullary nails, as shown in Fig. 5c, varied considerably. For example, the torsional modulus of Nail D, 14-mm nominal size, was $0.0450 \text{ Nm}^2/\text{deg}$, which compared with that of Nail E, 14-mm size, at $0.0140 \text{ Nm}^2/\text{deg}$ is 3.22 times as large. As in the other modes, the implant torsional rigidity increased with diameter, although the magnitude of the changes varied for different nails.

Measurements of the elevation of the midpoint of the nails above their ends, as an indication of their AP curvature, showed large variations. Nail D (14-mm diameter, 420 mm long) with an elevation of 9.9 mm had the most curvature, while Nail E (14-mm diameter, 420 mm long) was the flattest at only 4.58 mm.

Reproducibility of Technique

Axial push-out force as a function of insertion depth was recorded for five consecutive trials in one proximal specimen using a single nail (Fig. 6). Note that the forces generated in Trials 3, 4, and 5 are virtually identical, but below those values recorded in Trials 1 and 2. These differences are explained by the self-reaming effect of the nail during repeated insertion. This illustrates that the insertion force converges to a reproducible profile although the actual push-out force is 35% larger than those forces reported here. These results indicate that valid comparisons can be made between different nails, since the self-reaming effect disappears after the third trial. Since the effect of self-reaming is to significantly reduce push-out force and hoop strain values, the hoop stress data generated as a function of starting hole position were taken from the first insertion trial only.

Effect of Reamed Diameter

Altering the medullary canal by reaming significantly affected the axial forces necessary to insert the nail. In the proximal components, forces dropped an order of magnitude with just a

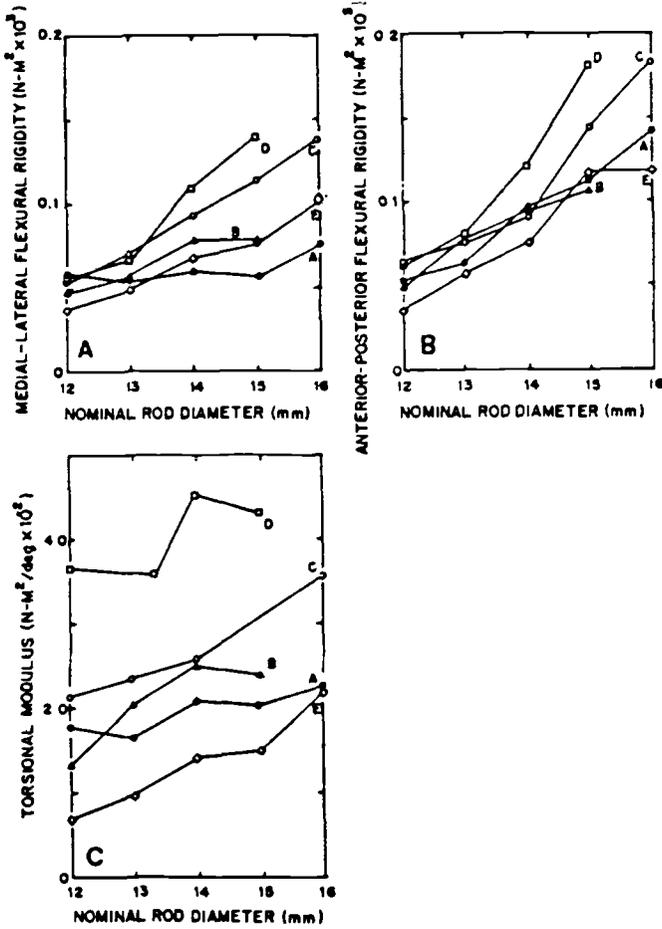


FIG. 5—Mechanical properties of five types of intramedullary nails of five nominal diameters. (a) Medial-lateral flexural rigidity; (b) anterior-posterior flexural rigidity; (c) torsional rigidity.

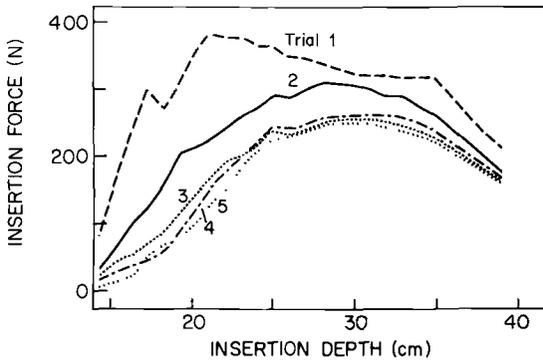


FIG. 6—Insertion force versus insertion depth for five consecutive trials.

1-mm increase in the canal diameter over the nominal diameter of the nail. In the distal components (Fig. 7), reaming the medullary canal only 0.5 mm larger than the nominal size of the nail resulted in a significant drop of the axial push-out forces. Therefore, reaming to different diameters appears to be the only method of adjusting fracture stability distally, given a particular fracture location and nail type.

Effect of Insertion Depth on Push-out Force and Hoop Stress as a Function of Nail Type

Figure 8 illustrates changes in the insertion force as a function of nail type and insertion depth in the proximal femur for a typical proximal femoral component. Note the different force profiles generated by nails of the same diameter but from different manufacturers. This is due to large differences in the mechanical and geometric properties among the different nails. Nail Type B (DePuy), and to a lesser extent A (OEC), have a characteristic which might be expected of a fairly stiff flat nail. The insertion force increases steadily and the nail deforms as it is inserted. Nail D (Zimmer), which is the stiffest and most curve nail, generated the highest hoop stresses (Fig. 9) and axial forces during insertion in the proximal component, but the lowest push-out force when fully inserted, indicating a potential for femoral bursting during insertion as well as instability after insertion. This instability occurs because the nail conforms more closely to the bow of the medullary canal than the other nails, due to its large anterior curvature.

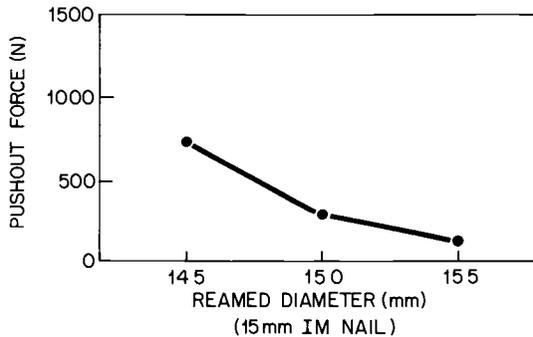


FIG. 7—Push-out force versus reamed diameter (distal component).

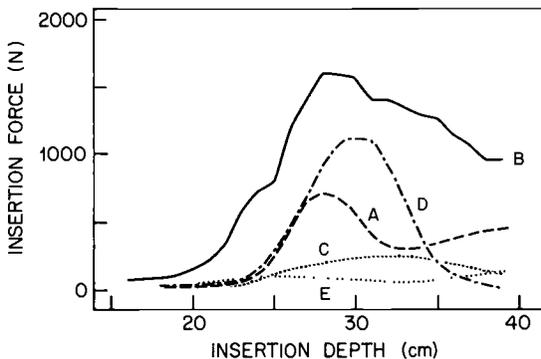


FIG. 8—Insertion force versus insertion depth with respect to nail type.

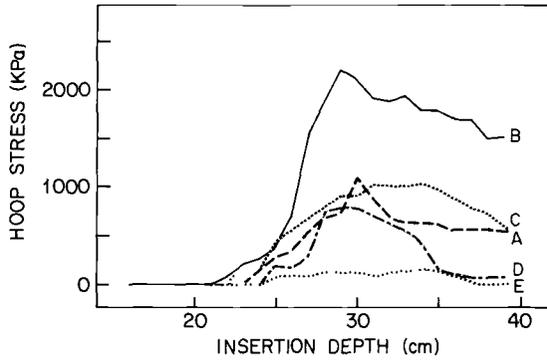


FIG. 9—Hoop stress versus insertion depth with respect to nail type.

More force is required to deform the nail and allow passage into the medullary canal, but results in less three-point bending when the nail is fully inserted. Comparison of Figs. 8 and 9 clearly demonstrates the correlation between high insertion forces and high hoop stresses.

Figure 10 shows the mean value of push-out forces for each nail type in the proximal and distal femoral components. In both cases, Nail B generated the highest frictional forces, while Nail E generated the lowest. Distally, fracture stability was found to be highly dependent on the femoral component length and curvature, changing rapidly with insertion depth of the nail. Statistically significant differences in the mean push-out force for different nails were noted between nails B and D ($p < 0.05$) and B and E ($p < 0.01$) in the proximal component, and between Nails B and A ($p < 0.05$) and B and E ($p < 0.001$) in the distal component.

Effect of Femoral Component Length

The effect of femoral component length on push-out force was determined using Nail B (Fig. 11). The decrease in push-out force with decreasing femoral component length resulted from reduced deformation of the nail, which must bend less to conform to the shape of the medullary canal. These results indicate that even in short proximal components, sufficiently high nail

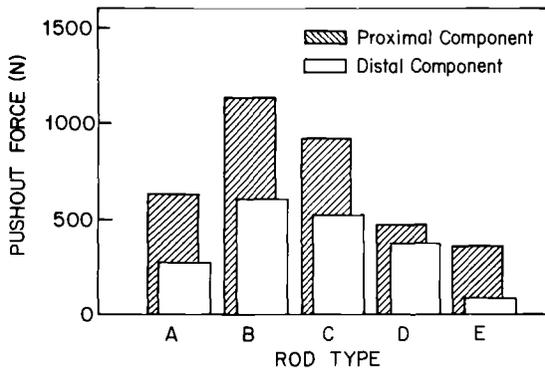


FIG. 10—Push-out force versus nail type.

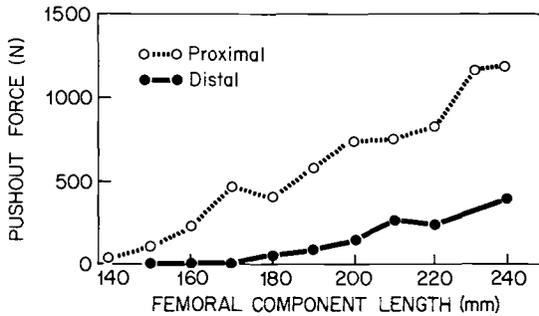


FIG. 11—Push-out force versus fracture component length.

retention forces can be generated. The majority of fracture instability appears to occur distally, since the axial push-out forces are significantly reduced and eventually vanish with decreasing femoral component length. This is due to the narrow isthmus region of the femur, which is only several centimeters in length: the nail can not maintain a frictional hold on the distal femoral component.

Effect of Starting Hole Location

To illustrate the effect of starting hole position, Fig. 12 presents a two-dimensional view of the proximal aspect of the femur sectioned through the head, neck and greater trochanter. This maps starting hole locations into areas of common hoop stresses ($\pm 10\%$) generated distally in the proximal femoral component when Nail B was inserted using a particular starting hole.

The results show an anterior region (> 100 kPa), bounded by a nearly medial-lateral contour, in which femoral bursting was consistently experienced in six specimens. The reason for this is clear upon examination of the casts taken from these test specimens (Fig. 13). The medullary canal, with anterior placement of the starting hole, has an S-shaped profile which requires bending of the nail to allow it to pass into the canal. As the curved nail is passed down the canal, the femur, as well as the nail, must deform transiently to allow passage of the relatively stiff nail down the canal. Thus, hoop stress is generated in the proximal femoral component, resulting in

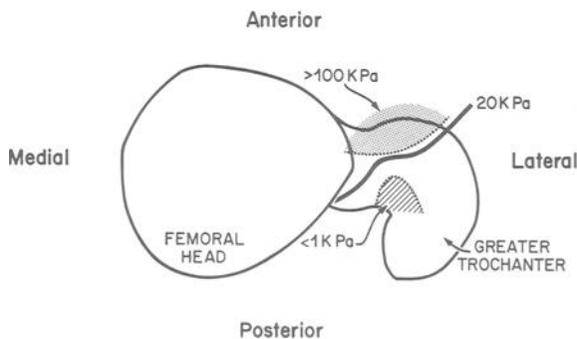


FIG. 12—Coronal view of proximal femur with a map of areas of common hoop stresses that are generated distally.

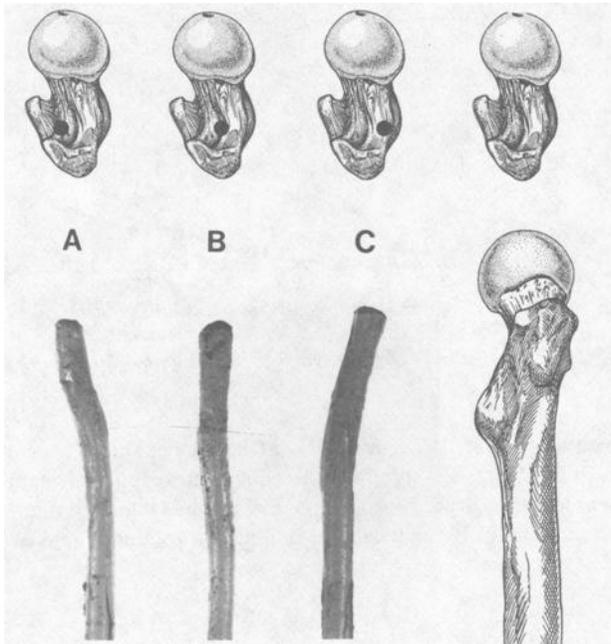


FIG. 13—Molded casts of medullary canal following removal of intramedullary nail. Cast A demonstrates a posterior starting position, B is neutral, and C illustrates an anterior starting position.

lifting off of the anterior cortex and thus bursting and subsequent instability. This mode of femoral bursting is illustrated in Fig. 14.

Medial or lateral offset of the start hole, if not combined with anterior offset, resulted in reduced stresses and push-out forces. Posterior placement with little medial or lateral deviation produced the lowest stresses. A contour, running anterior-lateral to posterior-medial, represents the locus of points in which acceptably high push-out forces were observed while the generated hoop stresses were within acceptable limits. This is considered a favorable situation.

Clinical Examples of Femoral Bursting

The following cases are selected to represent examples of the mechanical difficulties and subsequent complications that can be encountered with closed intramedullary nail fixation of femoral shaft fractures. All clinical examples shown demonstrate femoral bursting.

On the postoperative X-rays, dotted lines indicate the intramedullary canal, while arrows indicate the center of the intramedullary canal and the center of the intramedullary nail. A difference between these two arrows can be measured both on the AP and lateral X-ray projection accounting for routine X-ray magnification.

Case A is of a 28-year-old white female who sustained a closed femoral shaft fracture without apparent undisplaced fracture lines (Fig. 15a). This fracture would be amenable to treatment by closed intramedullary nail fixation. The procedure was undertaken and resulted in comminution of both the proximal and distal fracture components, rendering the fracture unstable. Review of the postoperative X-rays reveals the starting point or the center of the intramedullary nail to be displaced anteriorly 15 mm and laterally 11 mm (Figs. 15b and 15c).

Case B is of a 26-year-old male who sustained a closed transverse fracture of the proximal

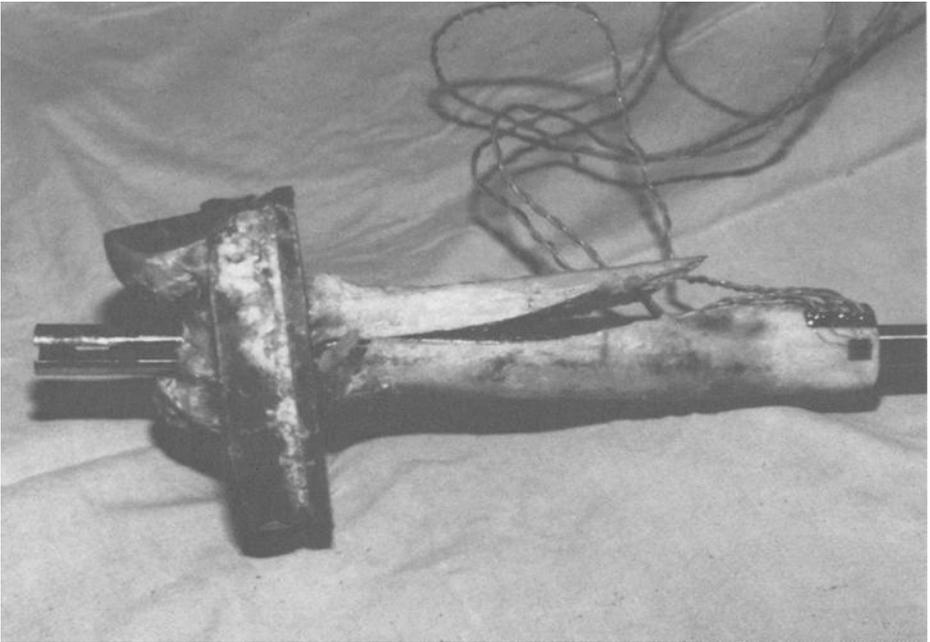


FIG. 14—Typical appearance of a proximal femur that burst during intramedullary nail insertion.

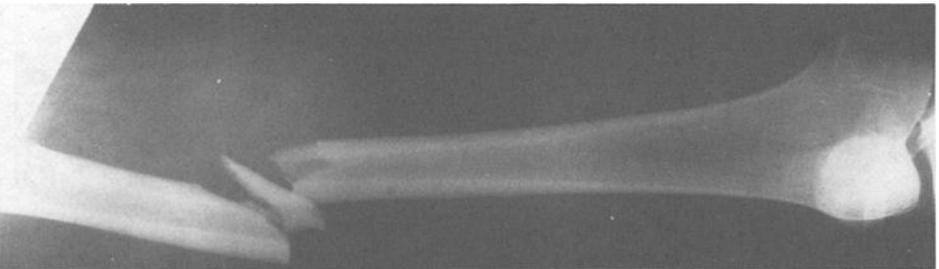


FIG. 15a—Case A: preoperative X-ray.

femoral shaft (Fig. 16a). The patient was positioned in the supine position on the fracture table. During operative insertion of a closed intramedullary nail, comminution of the proximal fragment occurred by means of elevation of the anterior cortex. A review of the postoperative X-rays reveals the starting position to be displaced anteriorly 8 mm (Figs. 16b and 16c). The fracture shortened 3 cm and healed.

Case C is a 26-year-old female who sustained a closed, short oblique fracture of her midshaft femur (Fig. 17a). Following closed intramedullary nailing, it was noted that her leg had shortened over 4.0 cm. Review of her X-rays reveals a starting position for the nail which is displaced 15 mm posterior from the normal position (Figs. 17b and 17c) and significantly outside of the region of low hoop stresses seen in the laboratory. In this posterior area, stresses generated distally are high for similar reasons as in the case of an anterior starting hole location. It ap-

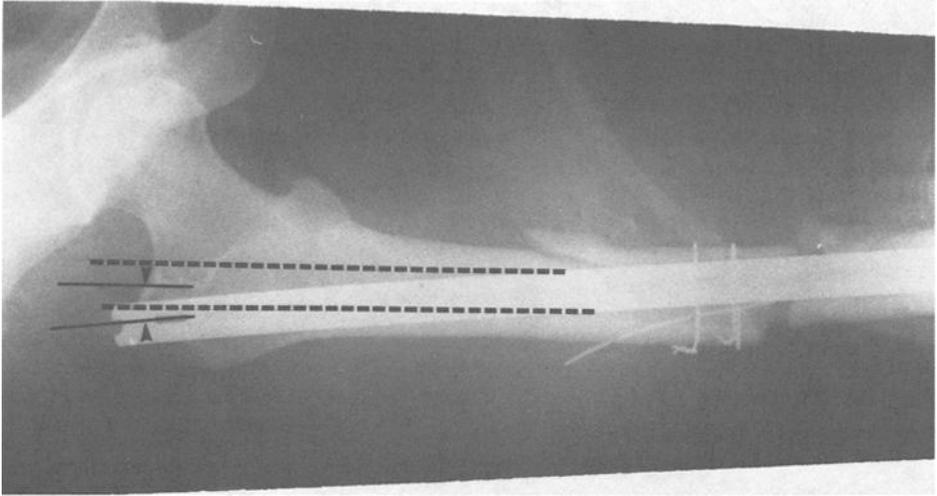


FIG. 15b—Case A: AP X-ray. Dotted lines outline intramedullary canal; arrows indicate center of canal and center of nail.

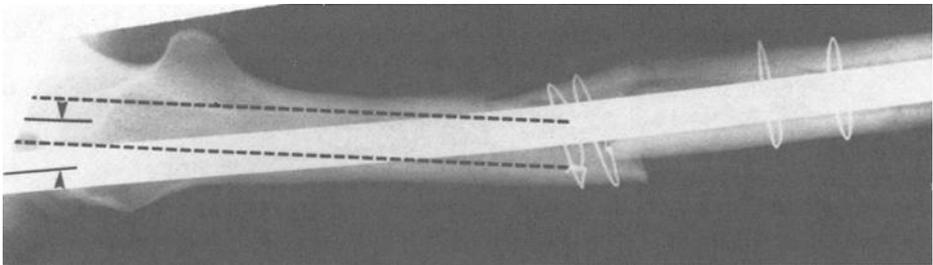


FIG. 15c—Case A: lateral X-ray. Dotted lines outline intramedullary canal; arrows indicate center of canal and center of nail.

pears that this position caused the relatively stiff nail to transverse across the medullary canal and comminute the anterior cortex during nail insertion.

Case D is of a 34-year-old female with multiple injuries including bilateral femoral shaft fractures (Fig. 18a). Immediately following closed intramedullary nailing, comminution and shortening was noted in the right femur. Review of the X-rays reveals that starting point in the right femur to be displaced 10 mm anteriorly and 2 mm laterally (Figs. 18b and 18c).

Figure 19 illustrates the cross section of the proximal femur that was shown earlier in the paper. The abnormal starting positions of these described cases are mapped on this cross section and are distinctly mapped into areas experimentally shown to correspond to the generation of high hoop stresses upon insertion of the intramedullary nail. These cases further confirm the validity of the laboratory experiments.

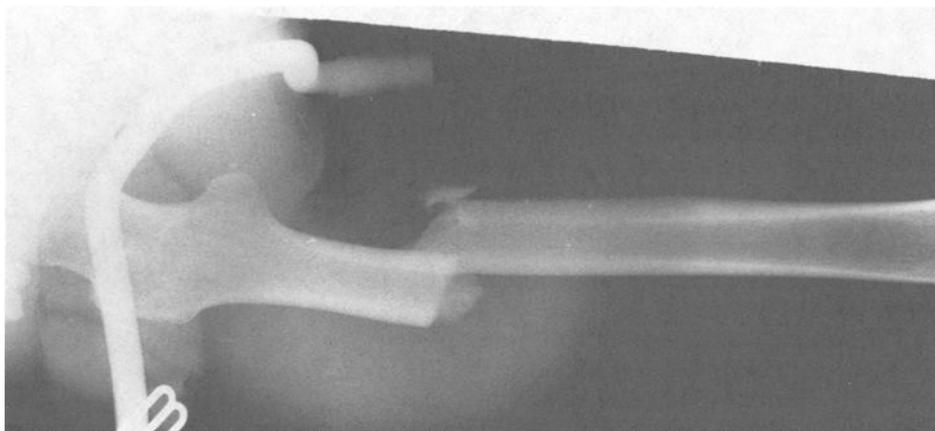


FIG. 16a—Case B: preoperative X-ray.

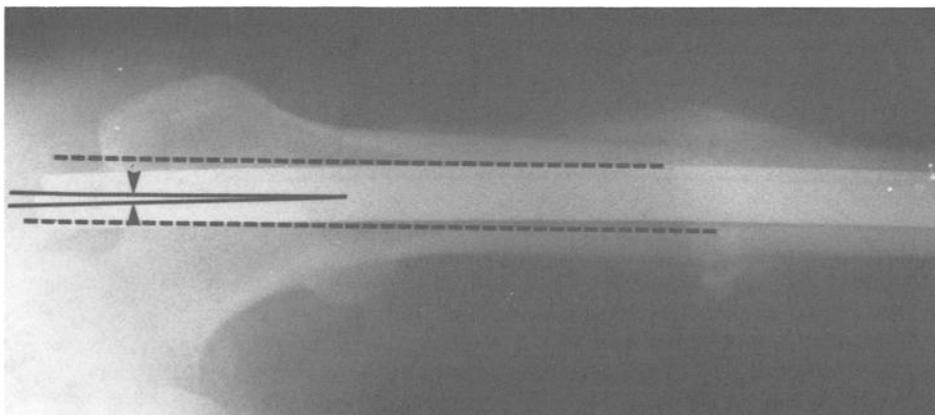


FIG. 16b—Case B: AP X-ray. Dotted lines outline intramedullary canal; arrows indicate center of canal and center of nail.

Discussion

Few reports of the mechanical properties of intramedullary rods have been produced [17,37,38] and of those, only the data of Soto-Hall and McCloy [39] and Martens et al. [38] can be directly compared with the data generated in the present tests. The tests of Soto-Hall and McCloy [39] were performed on small-diameter nails; however, they reported a flexural rigidity value of $0.181 \times 10^3 \text{ Nm}^2$ ($18.5 \times 10^4 \text{ kg cm}^2$) for a 13-mm nail of unspecified type tested in four-point bending. That value is larger than the values derived in these tests, which ranged from $0.0579 \times 10^3 \text{ Nm}^2$ to $0.080 \times 10^3 \text{ Nm}^2$ for 13-mm nails. Martens et al. [38] reported a torsional modulus of $0.0273 \text{ Nm}^2/\text{deg}$ ($1.6 \times 10^3 \text{ kg cm}^2/\text{rad}$) for a 13-mm diameter rod, which compared with a range of values of $0.00949 \text{ Nm}^2/\text{deg}$ to $0.0356 \text{ Nm}^2/\text{deg}$ measured here. In

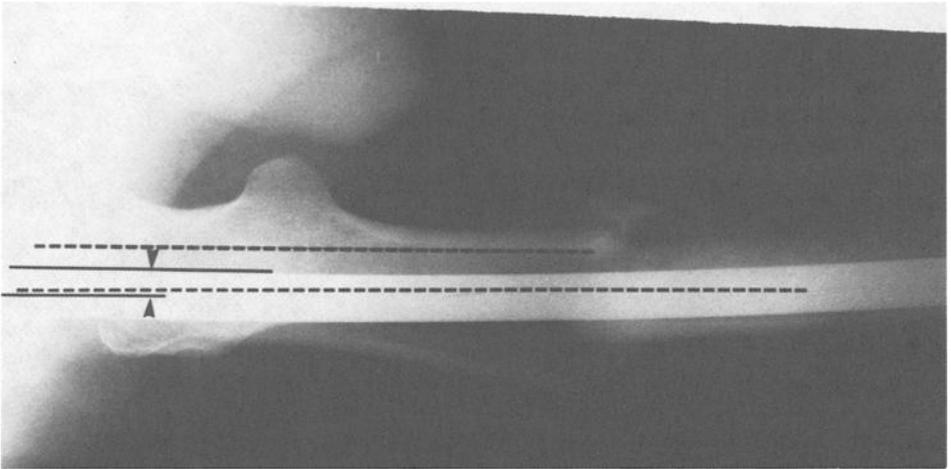


FIG. 16c—Case B: lateral X-ray. Dotted lines outline intramedullary canal; arrows indicate center of canal and center of nail.

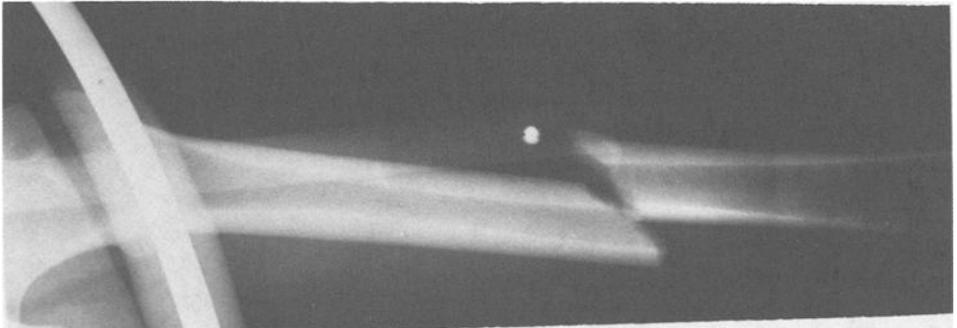


FIG. 17a—Case C: preoperative X-ray.

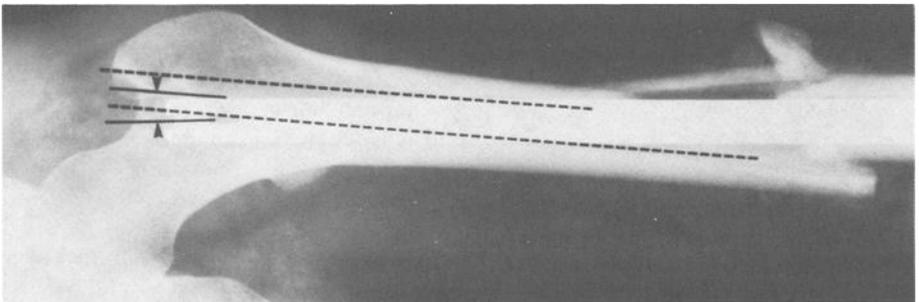


FIG. 17b—Case C: AP X-ray. Dotted lines outline intramedullary canal; arrows indicate center of canal and center of nail.

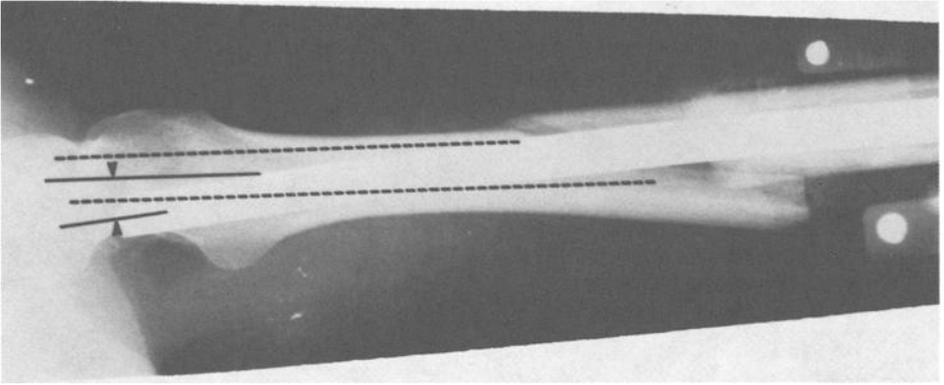


FIG. 17c—Case C: lateral X-ray. Dotted lines outline intramedullary canal: arrows indicate center of canal and center of nail.



FIG. 18a—Case D: preoperative X-ray.

addition, as a further check on the flexural rigidity values derived from experimental tests, they were compared with the product of the measured cross-sectional moment of inertia and the elastic modulus (Stainless 316L, $E = 21 \times 10^4 \text{ Nm}^2$). Results showed that the product of the section moment of inertia elastic modulus was within $\pm 12.5\%$ for all 4-mm nails in both bending modes, compared with flexural rigidity values derived from the load-deflection experiments. Considering that an error of 0.1 mm in the measurement of the wall thickness of the nail could produce a 7.73% error in the value of the calculated flexural rigidity, these bounds of agreement are felt to be acceptable.

It can be argued that during weight-bearing, bending is a significant load on the mid-diaphyseal region of the femur [34], and that bending of the nail probably increases the frictional forces at the nail-bone interface enhancing fracture stability. Since physiological loading conditions are so variable, we have chosen here to measure the minimum frictional forces, generated solely by the nail and femur geometry without the complicating influence of anatomical loads.

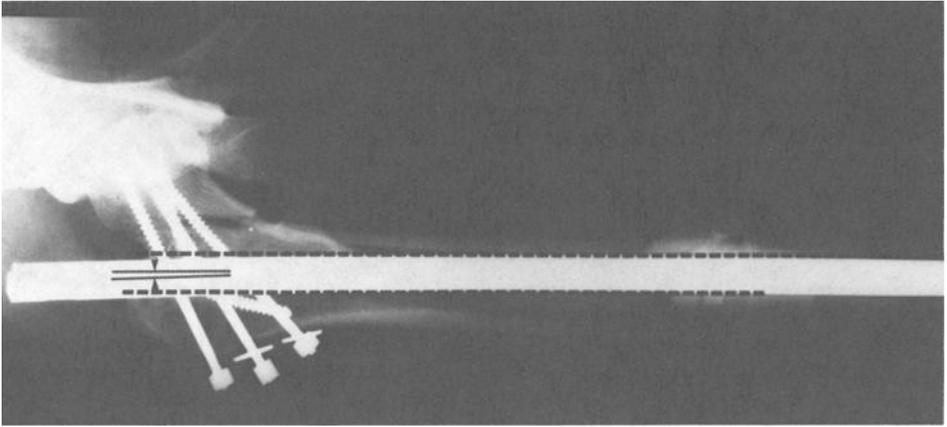


FIG. 18b—Case D: AP X-ray. Dotted lines outline intramedullary canal; arrows indicate center of canal and center of nail.

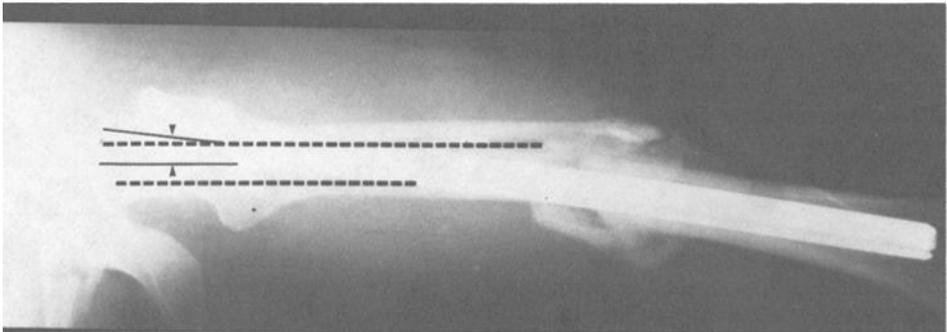


FIG. 18c—Case D: lateral X-ray. Dotted lines outline intramedullary canal; arrows indicate center of canal and center of nail.

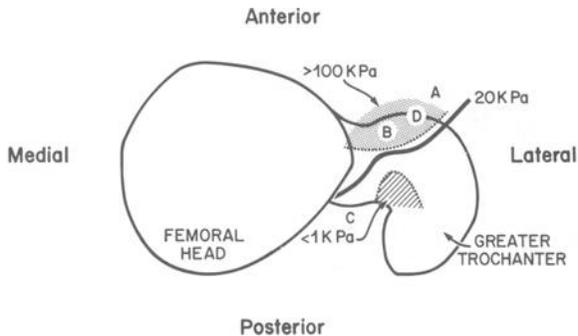


FIG. 19—Hoop stress map of proximal femur showing starting points of Cases A, B, C, and D.

Since torsional instability, nail migration, and leg shortening [1,3,9,22] most likely occur during intervals where minimum frictional forces are generated, we felt that the study of this worst case was the most justifiable.

It should not be interpreted from these data that the nails providing high push-out forces are necessarily superior to those producing lower forces. High push-out forces may result in high hoop stresses and a greater potential for cracking of the femur. In fact, as demonstrated, nail type is but one of several variables that affect push-out force and hoop stress generation. It is more important that the surgeon understand the characteristics of the nail (stiff or flexible, flat or curved, undersized) and tailor his or her technique accordingly (ream diameter, starting hole position).

Conclusions

The following conclusions can be summarized from this study:

1. Intramedullary nails of the same nominal size but from different manufacturers, although governed by ASTM Standard F 339-71, were found to have different shapes and cross-sectional thickness. These differences resulted in a more than twofold variation in flexural rigidity and in a threefold variation in torsional rigidity of the implants.
2. Variations in geometric and structural parameters of the nails produce varying push-out when inserted into cadaver femora. In particular, the most undersized (in terms of cross-sectional diameter) and flexible nail, Type E, produced the lowest push-out forces, while the most rigid nail flexurally, Type D, produced lower push-out forces than would have been expected, possibly because its greater curvature allowed it to conform more closely to the AP bow of the femur. The greatest push-out forces were generated by Nail Type B.
3. Push-out forces drop rapidly in both distal and proximal femoral components at fracture component lengths less than about 200 mm, although the forces are significantly higher in proximal components due to the distortion of the medullary canal by offsetting the starting hole. The low forces generated in the distal components give rise to concern about producing adequate distal fracture component control, especially in more distal fractures, below the isthmus region.
4. Reaming the medullary canal only 0.5 mm larger than the nominal size of the nail results in a drop of the push-out force to nearly zero in the distal femoral component.
5. Because of the possibility of offsetting the starting hole, this procedure could be used to stabilize fractures more proximal than those located in the mid-diaphyseal region, but not those more distal, if the fracture pattern is transverse.
6. Placement of the starting hole 6 mm or more anterior to the medial-lateral axis of the medullary canal resulted in consistent cracking of the femoral component. Posterior placement reduced stresses and push-out forces significantly. Medial placement of the starting hole raised stresses and force, but not to the same magnitudes as anterior placement.

Acknowledgments

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The Role of Medullary Reaming in Closed Nailing of Femur Fractures

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ABSTRACT: This study compares results of unreamed Schneider intramedullary nailings with reamed Küntscher intramedullary nailings. Eighty consecutive closed intramedullary roddings of femoral shaft fractures performed at Parkland Memorial Hospital, Dallas, were reviewed. In the first 40 cases, straight, narrow Schneider or Küntscher rods with an average diameter of 10 mm were inserted following closed reduction. No reaming maneuvers and no effort to attain rigid cortical contact with either fracture fragment were made. In the next 40 cases, the standard Küntscher technique with reaming and cortical impingement of the nail on both fragments was employed using Küntscher nails of an average diameter of 13 mm. All patients were followed to fracture union. Analysis of patient and fracture variables (such as anatomic location and degree of comminution) showed no significant differences in the two groups. While both groups demonstrated multiple minor complications, including slight shortening, mild angulation, and variable degrees of malrotation, major complications were significantly greater in the nonrigid rod group. They included one nonunion, three implant failures, and several cases with unacceptable shortening.

Medullary reaming allows the use of stronger rods, improves stable osteosynthesis by permitting cortical contact with the nail, minimizes postoperative shortening, and stimulates healing by depositing morselized bone reamings in the fracture of hematoma. The versatility of the closed technique is markedly enhanced by routine reaming.

KEY WORDS: medullary reaming, femur fracture, intramedullary nailing, Küntscher nail, Schneider nail

Intramedullary rodding is now accepted as an excellent treatment for many adult femoral shaft fractures. Küntscher's original enthusiasm for the technique for fixation of transverse and short oblique fractures of the proximal and midshaft femur seems justified since many authors have reported high rates of fracture union associated with low incidences of complications [1-12]. Over the past several decades, controversy has centered on the necessity and desirability of specific technical aspects of the Küntscher nailing procedure [4, 7, 8, 10, 13].

One major point of disagreement is the need for routine medullary reaming. Küntscher modified his original unreamed technique in the early 1950's by introducing the use of flexible reamers and larger diameter nails. He theorized two major advantages from this innovation: first, with endosteal reaming, wider and stronger nails standardly could be inserted, minimizing the

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risk of implant failure; second, the wider cloverleaf nail would permit elastic impingement of the nail on the proximal and distal fragments, thereby enhancing fracture stabilization. Others have suggested further advantages of reaming, including increased nail-to-bone surface contact, providing improved torsional control, and delivery of autologous cortical-cancellous bone graft to the fracture site [2].

Many fracture surgeons continue to rely on a nonreamed system, by which the rod acts solely as an internal splint [7,13,14]. These authors report results comparable with those of the reamed method while avoiding the reported disadvantages of reaming. Among possible disadvantages are destruction of endosteal blood supply, cortical thinning and decreased end-to-end surface contact, and pulmonary embolus as a result of reaming that may force marrow elements into the intravascular space. To our knowledge, a valid comparison of the reamed and nonreamed series has not been presented to date. Variations in fracture locations, fracture patterns, implants, surgical techniques, and evaluation criteria make any attempt at statistical comparison of individual reported series difficult to interpret.

Between 1977 and 1980, at Parkland Memorial Hospital in Dallas, Texas, a standardized technique of closed intramedullary rodding of femur fractures was employed. The original technique involved internal splinting with straight Schneider rods without reaming. In 1979, this system was modified to the more rigid Küntscher system employing routine reaming and wider, pre-bent cloverleaf nails. This change was instituted to permit expanded application of the closed technique to more complex fracture patterns of the proximal and distal femoral shaft. The purpose of the present study was to compare the results of our series of Schneider roddings with our initial results from Küntscher nailing to determine if the introduction of routine reaming was beneficial.

Materials and Methods

Approximately 360 adult femoral shaft fractures were seen at Parkland Memorial Hospital in Dallas, Texas, between 1977 and 1980. Early in this period, transverse and short oblique fractures of the femoral shaft which were minimally or moderately comminuted were treated with a straight Schneider rod without prior reaming. Fractures of the distal third and the subtrochanteric region were standardly treated with open reduction and internal fixation, while comminuted midshaft fractures were managed by roller traction and cast braces. Fifty-five patients were treated with Schneider rodding without prior reaming. Seven of these patients required an open reduction with retrograde nailing and, thus, were excluded from the study. Eleven patients were lost to follow-up, leaving a total of 37 patients with 39 fractures which had been internally splinted with a Schneider rod. Beginning in 1979, routine intramedullary reaming and Küntscher rods were utilized. Thirty-nine patients treated in this fashion with 41 fractures have had sufficient long-term follow-up to be included in this review.

There were 31 males and 6 females in the nonreamed group, with an average age of 25 years, ranging from 19 to 65 years. In the Küntscher group there were 26 males and 13 females, and these patients had a median age of 26 years with a range of 14 to 87 years. Seventy-nine fractures were secondary to major trauma. There was one pathologic fracture of an osteoporotic femur in a paraplegic that was treated with a Schneider rod without reaming.

Fracture location was categorized by proximal, middle, and distal thirds of the shaft (Fig. 1). There were five proximal third fractures, 34 middle third fractures, and no distal third fractures in the nonreamed Schneider group. In the Küntscher group there were 11 proximal, 24 middle, and 6 distal third fractures. Each group had two patients with bilateral femur fractures. The basic fracture pattern was either transverse or short oblique in nearly all cases. There was one segment fracture established with a Küntscher rod.

The degree of fracture comminution was graded as minimal, moderate, or severe (Fig. 2). A fracture with no radiographically evident comminution or small fragments of less than a centi-

SCHNEIDER

KÜNTSCHER

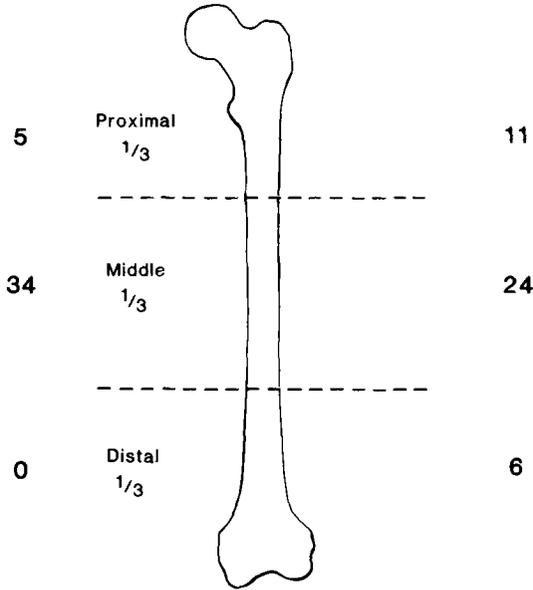


FIG. 1—Location of fractures in both groups.

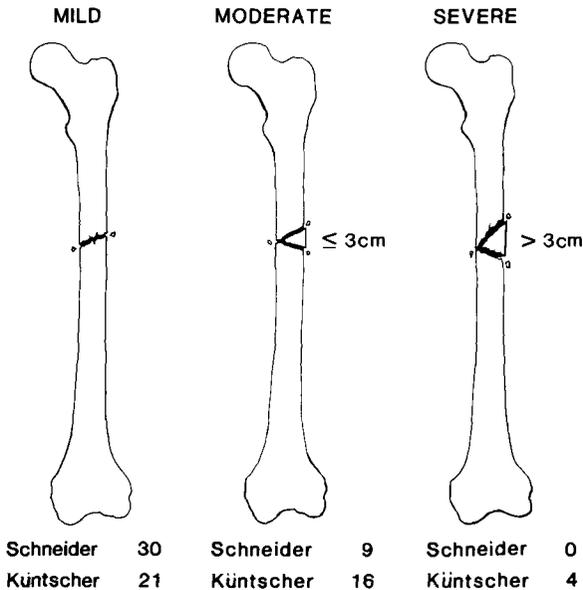


FIG. 2—Degree of fracture comminution was graded as minimal, moderate, or severe. A fracture with no radiographically evident comminution or small fragments of less than 1 cm in length was classified as minimally comminuted. Moderate fracture comminution involved fractures with a single butterfly fragment up to 3 cm in length. Fractures with butterfly fragments greater than 3 cm in length or with multiple fragments at fracture site were described as severely comminuted.

meter in length was classified as minimally comminuted. Moderate fracture comminution involved fractures with a single butterfly fragment up to 3 cm in length. Fractures with butterfly fragments greater than 3 cm in length or with multiple fragments at the fracture site were described as severely comminuted. There were no severely comminuted fractures, 9 moderately comminuted fractures, and 30 minimally comminuted fractures in the Schneider rod group. Comminution in the Küntscher group was classified as 4 severe, 16 moderate, and 21 minimal (Fig. 2).

Four open fractures, all in the Schneider rod group, were treated by closed rodding. These Grade I open injuries were initially irrigated and debrided. Following delayed primary closure, closed rodding was accomplished at seven to ten days after injury.

Ipsilateral lower extremity injuries were frequent in both groups. These included fractures of the tibia, patella, ankle, acetabulum, and hemipelvis. Open knee injuries with osteochondral fractures as well as knee ligament injuries also occurred. One patient with a severe Grade III open tibia fracture has undergone a below-the-knee amputation.

The length of time from fracture to definitive surgery ranged from hours to three weeks, and the average length of the between injury and rodding was seven days. Skeletal traction of 30 to 40 lb (13 to 18 kg) through a proximal tibial pin was used to ensure preoperative overdistracted at the fracture site in all cases.

Operative Technique

All procedures were performed on a Maquet fracture table with the patient in the lateral decubitus position. The ability to obtain a closed reduction in all planes was then confirmed by fluoroscopy. Following closed reduction, the trochanteric (piriformis) fossa was exposed through a 6 to 10-cm muscle-splitting incision which extended proximally from the greater trochanter. After the medullary canal was entered at the trochanteric fossa with a sharp awl, the narrow self-broaching nail was then inserted. The nails had been preoperatively selected based on standard radiographs with a tube to film distance of 1 m. The isthmal width and the distance from the greater trochanter to the proximal pole of the patella were measured, and the rod was selected. The rod was driven across the fracture site under fluoroscopic control. No attempt was made to secure cortical impingement of the rod on either the proximal or distal fragment. The rod was considered to serve only as an internal splint.

The latter half of the patients in this series were managed in a similar fashion except for the use of routine reaming and, thus, larger cannulated Küntscher nails. After satisfactory closed reduction of the fracture and placement of the trochanteric entrance hole, a guide rod was passed across the fracture site. Flexible reamers were then used to widen the medullary canal. Exact rod diameter was determined at surgery by the resistance in both fragments to the passage of the reamers. The diameters of rods were generally 12 to 13 mm for females and 13 to 15 mm for males. Proper rod length was determined at the time of surgery by measuring the length of the bulb tipped guide rod from the tip of the trochanter to the old distal femoral epiphyseal scar. Reaming was continued until cortical contact of the nail extended 2 to 3 cm on both sides of the fracture. In distal fractures, cortical contact with endosteal surface of the distal fragment was not always possible. Pre-bent, tapered-tip Küntscher nails were uniformly used.

Postoperative supplemental external immobilization was left to the discretion of the operating surgeon. Most postoperative casts or braces were utilized for treatment of associated ipsilateral limb injuries. However, in 14 patients treated with narrow Schneider rods, an adjustable plastic thigh cuff was used to improve muscle function and to protect the fracture during peak loading. Three patients in the nonreamed Schneider group required a cast brace for supplemental rotatory control of the fracture. All patients were allowed full weight-bearing as tolerated unless the fracture pattern was prone to shortening on the rod or there was an associated ex-

tremity injury which precluded early function of the limb. All patients were followed to fracture union and the completion of their rehabilitation.

Results

The postoperative course was similar for the two groups. Most patients without significant associated injuries were capable of ambulating with crutches within the first postoperative week. The period to independent ambulation and hospital discharge varied among both groups. The average time to full weight-bearing without aids was approximately six weeks in the Küntscher nail series and ten weeks in the Schneider group. The median time to radiographic evidence of bridging callus was however essentially equal at eight to nine weeks. There was no significant difference in either appearance of bridging callus or time to full weight-bearing between those patients who underwent immediate closed rodding and those for whom the procedure was delayed for greater than ten days. The return of knee motion and quadriceps function was nearly identical in the two groups. The major determinant of persistent loss of knee motion and quadriceps weakness at the time of final follow-up was the presence or absence of major ipsilateral limb injuries. Severely comminuted patellar fractures which required patellectomy and open tibia fractures necessitating prolonged external immobilization were particularly associated with the inability to return to preinjury employment was noted in the nonreamed and reamed groups.

Minor complications were common in both groups. Postoperative femoral shortening on the rod occurred in twelve cases (nine Schneider cases and three Küntscher nailings). In all cases except two, the shortening was 1 cm or less, and resulted in no limp or disability. A 1.5-cm shortening in a 15-year-old girl with a distal third fracture treated with a reamed Küntscher nail resulted in a mild, short-leg limp. Another patient, a 20-year-old male treated with a 9-mm Schneider nail experienced shortening of 2 cm. Angulations in the varus/valgus and anterior/posterior (AP) planes of less than five (5) deg were noted on the post-operative radiographs in multiple cases, especially in the Schneider series. No long-term problems have arisen from these minor degrees of malalignment. Malrotation of greater than 15 deg occurred in one Küntscher case. Failure of the operating surgeon in this case to confirm proper leg and foot position on the Maquet table led to nailing of a proximal third fracture in 25 deg of external rotation. This 18-year-old male continued to walk with a marked external rotation deformity of the leg one year after his injury. Complaints of pain at the proximal tip of the rod were frequent in both groups.

Major complications of implant failure and nonunion occurred exclusively in the nonreamed Schneider series. These included three cases of implant bending and fracture angulation. All were in young adult males whose thick femoral cortices and narrow isthmi prevented the use of Schneider rods of greater than 8 to 10 mm in diameter.

In Case 1, a 23-year-old white male was involved in a motor vehicle accident in which he sustained a closed midthird femur fracture with moderate comminution. He underwent rodding ten days postinjury with an 8-mm Schneider rod. At surgery, despite proper trochanteric hole placement, the rod impinged on the lateral cortex proximally and developed a 9-deg bend in varus as well as a 16-deg anterior bow. Postoperatively the patient was treated in a cast brace and began partial weight-bearing. He was noted to have 20 deg anterior bow in his femur with an 18-deg bend in the rod at one month. The varus angulation had increased to an unacceptable 12 deg in the rod and 17 deg at the fracture site. The rod was removed and the patient treated in a cast brace until healing at four months with 3 deg varus, 10 deg anterior bow, and 2 cm of shortening.

In Case 2, a 20-year-old black male presented with a minimally comminuted fracture at the junction of the proximal and midshaft femur. He was treated by closed rodding using a 9-mm Schneider rod without reaming. At surgery, the implant bent 16 deg, resulting in 16-deg angulation at the fracture site. Attempts to straighten the rod one week later resulted in slight im-

provement of fracture angulation, but during the manipulation, a medial butterfly fragment displaced. Progressive angulation to 15 deg of varus subsequently occurred, and his rod was also extracted. He healed his fracture in 15 weeks in 9 deg varus and 2 cm of shortening with cast brace treatment.

The third case of implant bending occurred with a 10-mm rod in a moderately comminuted midshaft fracture. Implant and fracture site bending measuring 7 deg of varus at the time of fracture healing resulted in no significant functional or cosmetic impairment.

One fracture failed to unite in the 80 roddings. A 43-year-old white male sustained a closed midthird femur fracture which was moderately comminuted. A closed reduction and intramedullary rodding without reaming with a 10-mm Schneider rod was undertaken eight days after injury. He was allowed to bear weight postoperatively as tolerated in a thigh lacer. Follow-up examinations revealed implant loosening and a hypertrophic nonunion. He was treated at 18 months with repeat Schneider rodding using a larger diameter rod and autogenous bone graft. His nonunion has persisted at two years after the second procedure.

There were no superficial or deep-wound infections in either group. There were three documented cases of mild pulmonary embolism. Routine arterial blood gases and examination of urine for fat were not performed. Clinically significant fat embolism requiring support did not occur in either series.

Discussion

Due to their load-sharing properties, intramedullary rods are ideal for stabilization of adult femoral shaft fractures. Nearly all large series of femoral roddings report excellent success rates in achieving union and full functional recovery of the extremity [4, 7-10, 13, 14, 15]. While the concept receives almost universal acceptance, controversy surrounds various technical aspects of the procedure. Specific areas of disagreement include the value of an open versus closed technique, the timing of the surgical procedure, and the relative advantages and risks of routine reaming of the medullary canal.

The goal with any intramedullary device should be rigid stabilization of the fracture. Küntscher hypothesized that reaming of the canal and use of a wide-diameter nail would assure elastic impairment of the nail on both the proximal and distal fragments [4]. In practice, however, fixation is more often achieved by multiplied contact points of the nail on the undulating endosteal surfaces. Reaming tends to increase the number and surface area of these contact points. Fracture stability must be secured in three planes: varus-valgus, anterior-posterior, and rotation. Noncomminuted midshaft fractures which are anatomically reduced with interdigitation of the fracture fragments can satisfactorily be controlled in all planes with an intramedullary splint. The single case of nonunion following Schneider rodding in this series was in a moderately comminuted mid-shaft fracture where rotatory forces were not adequately neutralized. This deficiency in rotatory stabilization with an intramedullary splint would be of greater clinical importance with more distally located fractures. The addition of flutes to a round nail has been used to increase the torsional stability of intramedullary nails [15]. It has been determined experimentally that a fluted nail is significantly more rigid at all diameters than a Schneider or Küntscher nail [15].

The relative stability of a Schneider rod without prior reaming and a larger, more rigid Küntscher nail is reflected in this series in the period to full weight-bearing. The median time to full weight-bearing was ten weeks for the Schneider group, while it took only six weeks for patients in the Küntscher group to bear weight fully. The larger Küntscher rods provide greater strength inherent to their size, and improved stabilization due to increased surface area contact. Rigid nailing minimizes postoperative microscopic motion at the fracture site, thus encouraging earlier functional recovery. The use of supplemental external fixation with a plastic thigh cuff

assisted in postoperative limb rehabilitation following intramedullary splinting, but still did not provide stabilization to match the more rigid Küntscher nail.

The insertion of larger nails following reaming similarly aids in attaining an anatomic reduction. By filling the medullary canal with the nail, an "interference fit" is achieved (Fig. 3). An anatomic reduction assures maximal cortical contact between the major fracture fragments and, thus, reduces the risks of the fracture telescoping on the nail. The incidence of postoperative shortening of the femur was higher in the Schneider rod group even though no distal fractures, where the risk of shortening is higher, were treated by this form of splinting. Oblique fractures are especially prone to shortening unless the canal is adequately filled by the intramedullary rod.

Implant failure was encountered exclusively in the nonreamed group. The strength of any type of intramedullary rod, whether solid or hollow, increases exponentially with its diameter [4,16,17]. Küntscher recognized the increased strength of larger rods and considered it as a prime justification for routine reaming [4]. Laurence has shown that the 13-mm Küntscher nail is fully twice as strong in bending as an 11-mm nail [17]. Ong, reporting on 101 diaphyseal fractures treated with closed rodding without reaming, noted angulation, rotatory instability, and nail breakage when nails with diameters of less than 9 mm were used [9]. Allen et al. have introduced the concept of "the working length" of a nail [16], which is defined as the length of the nail crossing the fracture site between the areas of contact in the proximal and distal frag-

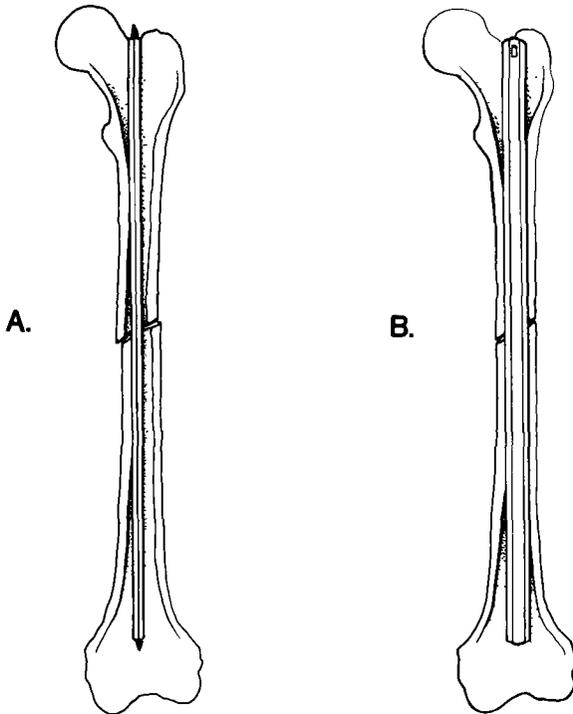


FIG. 3—(a) *Schneider nail fails to achieve a stable construct without reaming.* (b) *Kuntscher nail is able to achieve a stable "interference fit" secondary to medullary reaming.*

ments. In comminuted fractures, the working length can be several centimeters. The resistance of the nail to bending is inversely proportional to the square of the working length. The use of a narrow rod in Case 1, in which the working length was approximately 2 cm, resulted in plastic deformation of the rod. In Case 2, the displacement of a medial butterfly resulted in an increase in the working length, with subsequent increased angulation.

Since wider nails resist bending as well as torsional forces better than thin rods, an obvious solution to implant failure is to routinely use only larger rods. However, due to wide variations in the medullary diameter, cortical thickness, and anterior bow of the femurs in this young patient population, the widest rod which could be inserted without reaming was 12 mm. Attempts to use larger rods without reaming may result in nail incarceration at the isthmus or cortical penetration of the nail. The introduction of routine flexible reaming permitted nails of an *average* diameter of 13 mm to be easily inserted.

Reaming results in the production of a large quantity of morselized bone chips. Many of these bone fragments are deposited in the fracture hematoma during passage of the flexible reamers and in the hip musculature during extraction of the reamers. The role of this morselized autograft in promoting callus formation is unknown. Some authors hypothesize an actual harmful effect of the tissue and recommend its routine irrigation from the fracture site [7,18]. Chapman has recently demonstrated that segmental defects in the femur can be successfully treated with closed nailing, utilizing the morselized reamings to supplement autogenous cancellous graft [19]. Because of the potential bone-inductive effect of the reamings, a modification in the standard techniques have been introduced at our institution soon after completion of this report. The morselized cortical bone is now collected during the reaming maneuver and inserted into the fracture hematoma through a chest tube passed into the proximal fragment. Preliminary results suggest that the time to fracture union is decreased and that the size of the fracture callus increased when the bone reamings are utilized. Histologic evidence from a single autopsy case similarly supports the concept that the morselized chips have a strong bone inductive effect.

In addition to improving fracture reduction, minimizing shortening, preventing implant failure, and depositing bone graft at the fracture site, routine reaming also greatly increases the versatility of the closed nailing technique. In the nonreamed series there were only five proximal third fractures and no distal third fractures. The reamed group included eleven proximal and six distal fractures. During the period of the nonreamed group study, seven patients underwent open femoral rodding. Three of these patients underwent open rodding because their fractures could not be reduced closed on the Maquet fracture table. Proximal third fractures can be especially difficult to reduce because of the deforming muscle forces. The use of the reamed system aids in the initial reduction in two ways. First, the bulb tip guide can be bent at the tip assisting in its passage across fracture sites which have minor translatory displacement of the fragments. The sequential use of larger flexible reamers over this guidepin will gradually aid in reduction, which is completed by the passage of the larger cloverleaf nail. A second means by which this system can assist in reduction is the use of a short, 10 to 11-mm Küntscher rod in the reamed proximal fragment to lever the proximal fragment into alignment with the distal fragment. Once the proximal fragment is levered into satisfactory position, the guidepin can then be inserted through the rod and into the distal fragment. The larger number of proximal and distal fractures treated with the Küntscher system in this series reflects the expanded indications for the closed technique as a result of the increased safety, intraoperative control, and fracture stabilization offered by the reamed system. The use of a nonreamed system for proximal and distal fractures, comminuted fractures, segmental fractures, and long oblique fractures would likely increase the frequency of major complications. The reaming system improves the surgical success and does aid the surgeon in his intramedullary fixation of more difficult fracture patterns. The advent of reamed intramedullary nailing utilizing proximal and distal interlocking

screws is the logical extension of the reamed nailing techniques as it applies to the most difficult fracture patterns [3, 13, 15, 20].

The theoretical disadvantages of reaming of the intramedullary canal during femoral nailing have been summarized by Levy [21]. These include destruction of the medullary blood supply, thinning of the cortex, widespread injury to the endosteum, increased chance of fat embolization and infection, as well as a significantly prolonged operative time [21]. In this series, as well as others in which a reamed system has been used, complications resulting from these theoretical disadvantages have not arisen [1, 3].

Reaming does destroy the nutrient artery and its branches in the diaphysis, resulting in extensive cortical necrosis. The cortex is then revascularized by widespread proliferation of extraosseous and periosteal blood vessels as well as the remaining vessels in the rich cancellous bone of the metaphysis. This process, however, takes a long time, with empty osteocytic lacunae being present up to eleven months postinjury [7]. Many investigators have noted the tremendous subperiosteal osteogenesis which occurs after reaming. Trueta and Cavadias felt that bone-marrow ischemia was the initiating factor [22]. Danckwardt-Lilliestrom found that extensive fat embolization in cortical vessels results in apparent cortical ischemia and stimulates periosteal new bone formation. They postulated that increased pressure during the reaming procedure forced the marrow contents into the cortical blood vessels. When the medullary cavity of rabbit tibia were suctioned during the reaming procedure, there was much less fat embolism and cortical necrosis and the fractures healed with less periosteal proliferation. The human femur with its abundant soft tissue envelope will rapidly revascularize after reaming, although necrotic cortical segments may not be replaced for long periods of time. This is especially true when violation of the soft tissues is obviated by the open technique.

Additional trauma to a femur already damaged by fracture and thinning of the cortex with weakening of the bone have been mentioned by Levy as additional theoretical disadvantages of the reamed system [5]. Papineau reported prolonged healing times and an increased incidence of refracture in a series of patients treated with reaming and a large Küntscher nail, compared with his results with a small Küntscher rod inserted without reaming and augmented with autogenous bone graft [23]. In this series, there was no statistically significant difference in healing times in the reamed and nonreamed groups. Adherence to Hansen's recommendation to ream above 17 mm only in osteoporotic femurs in elderly patients will minimize the problem of excessive cortical thinning.

There were no clinically detectable cases of fat embolism in this series. Hansen noted 23 cases in 300 femurs treated with the reamed Küntscher system. All cases of fat embolism occurred, however, between the time of injury and definitive fracture care. None of his cases were exacerbated by the reaming procedure [21].

The reported low infection rate following closed nailing was confirmed in this series, in which there were no superficial or deep infections. Once the technical aspects of the procedure have been mastered, most femoral shaft fractures can be nailed in under two hours of anesthesia time.

The versatile reamed system can be applied to nearly all diaphyseal fractures of the femur. Only minor technical modifications in the procedure are necessary to assure satisfactory stabilization of the more complex fracture patterns. The advantages of rapid mobilization, decreased short-term and long-term morbidity, and substantial savings in health-care dollars greatly outweigh the theoretical disadvantages of the closed nailing system with routine reaming.

Conclusion

Femoral nailing is a demanding technique. The use of reaming increases those demands, and careful attention must be paid to details. Good results can be obtained in simple transverse and short oblique fractures of the midthird of the femoral shaft with the nonreamed technique.

Medullary reaming and the use of a wide nail are mandatory in the treatment of severely comminuted fractures and fractures of the proximal and distal aspects of the shaft. Both techniques, if they are to be successful, require diligent attention to detail from the time of patient arrival in the emergency department to the time of fracture union.

Doctor Küntscher wrote in 1945:

I consider enlargement of the medullary canal diameter by reaming one of the greatest advances in the field of intramedullary surgery [17].

Based on this study of 76 patients with 80 femoral fractures, we concur.

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The Brooker-Wills Femoral Nail: Technical Difficulties and Their Avoidance

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ABSTRACT: Eighty-seven femur fractures treated with the Brooker-Wills distal fin deployment interlocking nail were analyzed for intraoperative technical problems. Only unstable fractures located distal to the lesser trochanter and proximal to a level 5 cm proximal to the distal epiphyseal scar were included. Seventeen fractures were subtrochanteric, 19 were comminuted diaphyseal, and 51 were subisthmal. The majority (73) were locked proximally and distally. Of the 87 procedures, 33 technical difficulties occurred in 24 cases, for an overall rate of 29%. These ranged from problems with fin deployment and proximal screw insertion to bending of the nail itself. Patient position and proper technique were significantly correlated with the incidence of technical difficulties.

Postoperative complications were few, with one angulatory malunion, five nonunions, two unacceptable shortenings, and no deep wound infections. Average healing time was 12 weeks. The nail functioned well in regard to fracture healing, which was not affected by the technical difficulties. A significant learning curve for nail insertion was demonstrated. The authors concluded that most of the problems encountered could be avoided by strict adherence to suggested technical details and lateral patient positioning.

KEY WORDS: femur, intramedullary nail, Brooker-Wills, technical difficulties

The problems of shortening, malrotation, and angulation in the unstable femoral shaft fracture have recently been addressed by the use of interlocking intramedullary nails. The indications for intramedullary nailing alone without external support or traction postoperatively have been expanded to those fractures proximal and distal to the isthmus with Grade III and IV comminution [1-7]. With this greater flexibility has come a set of complications and technical difficulties unique to interlocking nails.

Most interlocking nails have a single proximal locking screw and one of two basic forms of distal interlock. While many systems use two distal cross screws [3,4], the Brooker-Wills interlocking femoral nail uses a set of fins deployed from inside the nail itself to achieve distal fixation without the need for an incision in the distal lateral thigh.

This paper is a retrospective review of 87 Brooker-Wills femoral nailings with special attention to the intraoperative technical problems and their avoidance.

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Materials and Methods

Eighty-four patients with 87 unstable femur fractures were treated with the Brooker-Wills femoral nail. Sixty-four nailings were in males and 23 in females. Average age was 36 years, with a range from 15 to 84 years.

Fifty-six patients were involved in motor vehicle accidents, 16 suffered gunshot wounds, and 9 patients received their fracture from a fall. Two nails were used in conjunction with intramedullary shortening procedures, and one fracture occurred during removal of a Zickel nail. Six of the total 87 nailings were prior nonunions; the rest were acute fractures.

All fractures were located between the lesser trochanter and distal epiphyseal scar. Seventeen were subtrochanteric, 19 were diaphyseal, and 51 were subisthmal in location. All were unstable according to the classification of Winquist and Hansen [7]. Sixty fractures were closed and 27 were open. Using the classification system of open fractures proposed by Gustilo [6], 6 were Grade I, 6 were Grade II, and 15 were Grade III. All open fractures were managed by irrigation and debridement. The Grade I injuries were closed primarily, and the Grade II and III open injuries were closed in a delayed fashion. The open fractures were nailed after wound stabilization.

Associated injuries included 12 closed head injuries, 6 significant abdominal injuries, 9 chest wounds, 5 pelvic fractures, 3 contralateral hip fractures, 4 knee dislocations, 10 ipsilateral tibia fractures, 5 ipsilateral ankle or foot fractures, and 24 upper extremity and contralateral lower extremity fractures. Two patients sustained severe burn injuries.

The first 50 nails were inserted using the original instrumentation, and all subsequent nails were inserted using the revised instrumentation [9]. Seventy-three femurs were nailed in the static mode, eight with proximal fixation only, four with distal fins only, and two with no interlocking due to technical problems of insertion of the fixation devices (Table 1).

The average delay from acute injury to nailing was 5.9 days. Over the period of study the delay before nailing decreased. The first 50 patients were nailed an average of 7.4 days after injury, and the subsequent 34 patients were nailed an average of 3.7 days after injury.

Forty-one procedures were performed in the supine position and 46 in the lateral position. Thirteen fractures required open reduction and the remaining 74 nailings were performed in a closed fashion. The open procedures were performed for the following reasons: removal of plate and grafting (one), bone graft and cerclage wire supplementation (two), bone grafting alone (two), cerclage wiring (two), and inability to reduce the fracture by closed technique (six). Only one of these thirteen open procedures was performed in the second half of the series.

Preoperative Planning

Once the patients are stabilized in the trauma emergency room and their associated injuries recognized, a plan of care is formulated. Intramedullary fixation of the femur fracture is given a high priority in order to avoid the complications of recumbency in the polytraumatized patients.

TABLE 1—*Interlocking modes of the 87 nails.*

Interlocking Mode	Number
Static	73
Dynamic	14
Proximal	8
Distal	4
None	2

Skeletal traction is placed in the emergency room to maintain soft tissue and bony length, thus facilitating fracture reduction during the nailing procedure. If severe comminution is present, the contralateral femur is X-rayed preoperatively in order to determine the proper nail length required for the fractured limb. Unless otherwise contraindicated, all patients are prophylactically treated for deep vein thrombosis to minimize the incidence of pulmonary embolus.

Operative Procedure

If thoracic and other associated injuries allow, the lateral position is preferred. In our experience, the lateral position will give the best visualization of the proximal nail for distal fin insertion. In positioning the patient, care is taken to insure that the entire femur can be visualized under fluoroscopy and that an appropriate reduction can be obtained. In some proximal fractures, a reduction is very difficult due to flexion of the proximal fragment; in these cases, the surgeon may elect to use a small-diameter Kuntscher nail in the proximal fragment to reduce the fracture and pass the guide wire.

Placement of the skin incision, entrance into the medullary canal through the piriformis fossa and reaming once the guide wire is passed across the fracture site is performed as described by Winquist and Hansen [7,10]. The proper nail length is either determined preoperatively by contralateral femur X-ray or intraoperatively by subtracting the remaining length of guide wire exposed proximal to the greater trochanter tip from the total guide wire length. The femoral canal is reamed to a diameter 1.0 to 1.5 mm greater than the planned diameter of the chosen nail.

The selected nail is mounted on the driving guide, placed into the femur over the guide wire, and driven across the fracture site under fluoroscopic guidance. Care is taken to avoid abutting the distal fragment, which can cause increased comminution. The driving insert fits beyond the nail's proximal screw holes to avoid bending the nail at these holes during insertion. The proximal tip of the nail is positioned at the level of the greater trochanter. The distal end of the nail is positioned at the distal epiphyseal scar for subisthmal fractures and at the superior pole of the patella for subtrochanteric fractures.

When the nail is 2 cm short of complete insertion, we change to the proximal drill guide insert to complete insertion and allow for predrilling of the proximal cross-screw hole. The hole is drilled and the screw is inserted. The screw is then retracted under fluoroscopy until its tip lies at the lateral hole in the nail: this may help avoid migration of the nail during fin insertion. Changing the guide insert prior to complete insertion allows visual confirmation of proper guide placement, a difficult task if the nail is already completely inserted.

Excellent exposure of the proximal nail tip is required for ease of fin insertion. The appropriate length fins are attached to the fin driver and placed into the nail. They are inserted with hand pressure only and are deployed under visualization with fluoroscopy. Gentle twisting of the fin inserter may be required to deploy the fins. If cortical penetration occurs (Fig. 1), the fins should be withdrawn and left incompletely deployed. The proximal cross-screw is then placed across the nail. Final position of the entire device is checked under fluoroscopy prior to skin closure.

Postoperatively, the patient is graduated from toe-touch gait with crutches to full weight-bearing at a rate dependent upon fracture severity, healing on X-ray, and physical examination.

Results

Seventy-six of the 84 patients were available for follow-up evaluation. One patient had died of widespread carcinoma and seven were lost to follow-up. The range of follow-up was 8 to 48 months.



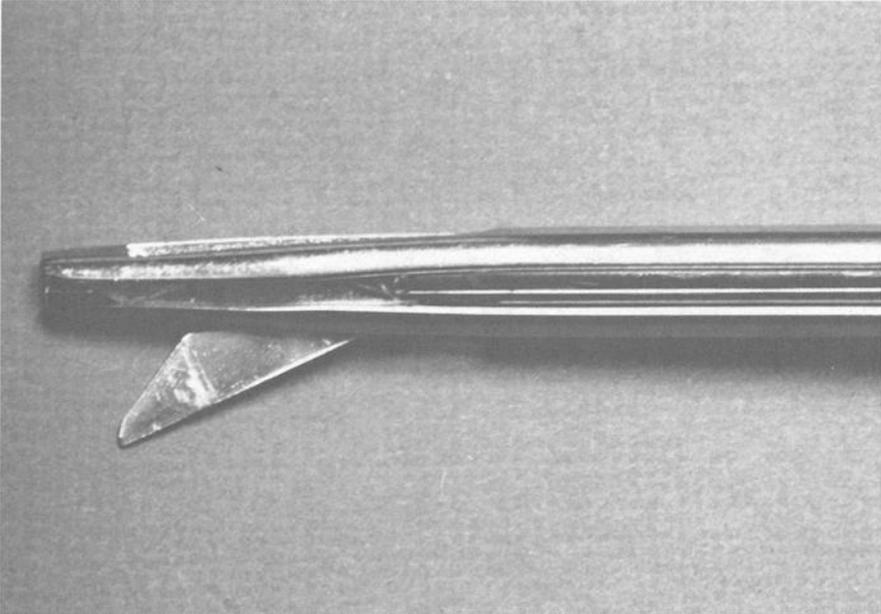
FIG. 1—*Fin protruding from bone cortex.*

Thirty-three technical difficulties were encountered in 24 of the 84 patients (29%). The distal fins failed to deploy in eleven patients. The fins were improperly oriented in five patients. Seven instances of proximal nail bending were encountered, and inability to place the proximal screw properly occurred in six patients. The nail itself migrated distally in four patients during fin insertion (Table 2).

Failure of the distal fins to deploy occurred in 12.6% of the patients. In three of these eleven cases, the fins eventually deployed properly. Back and forth gentle coaxing was the method of choice to obtain deployment. Three patients had persistent absence of fin deployment and distal fixation could not be obtained. Five patients had only one fin deploy. In these cases of unilateral fin deployment, one fin went out its slot and the other continued straight down the nail axis (Fig. 2). Forceful attempts to deploy this fin resulted in increased risk of distal nail migration. We concluded that the fin inserter should be pulled back a short distance and deployment reattempted. If multiple passes fail to deploy the fins, they should be extracted and inspected for bending (Fig. 3). A new set of fins may be needed.

TABLE 2—*Technical difficulties encountered in insertion of the 87 nails.*

Technical Difficulties	Number (%)
Failure of fin deployment	11 (12.6)
Improper fin orientation	5 (5.7)
Proximal nail bending	7 (8.0)
Proximal screw misplacement	6 (6.9)
Nail migration distally	4 (4.6)

FIG. 2—*Single fin deployed.*

Improper orientation of the fins was encountered in five cases. This was due to insertion parallel instead of perpendicular to the slot in the nail and was recognized in four instances (Fig. 4). In the fifth case, the fin inserter was driven with a mallet and the entire nail inadvertently penetrated into the knee joint. Improper insertion of the fins is best avoided by adequate visualization of the proximal tip of the nail, which was more difficult with the patient in the supine position.

In four cases the nail migrated distally during fin insertion. Two of these cases resulted in protrusion of the nail into the knee (Fig. 5). Both of these cases were in osteoporotic females with comminuted distal third fractures. Traction was used to treat both cases, and one patient subsequently was placed into a cast brace. Although one developed a nonunion, both finally healed with 2 cm of shortening.

In six cases, either the proximal screw could not be inserted or it missed the nail. Four were prior to the development of the new instrumentation. The nail guide had been removed in all six cases for fin insertion prior to predrilling the proximal screw hole. After removing this nail

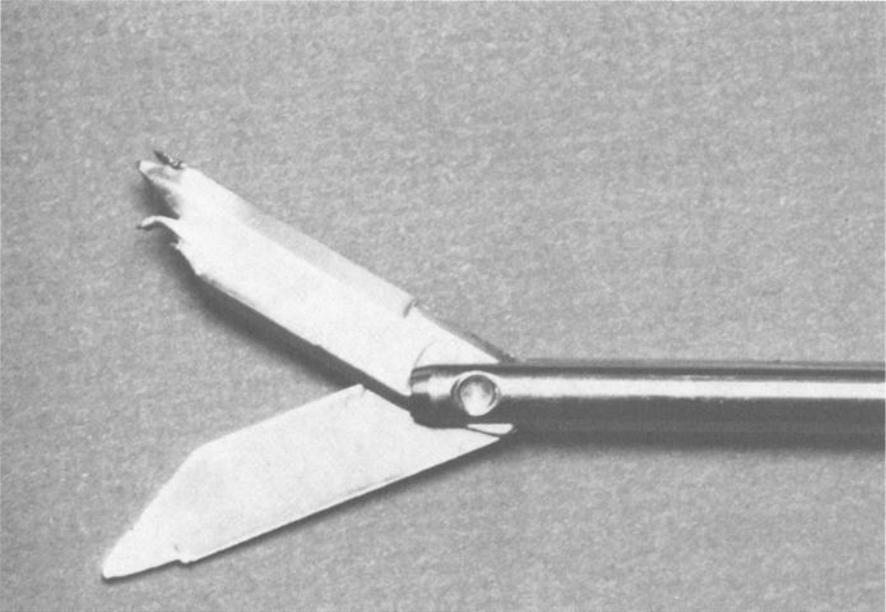


FIG. 3—*Bent fins.*

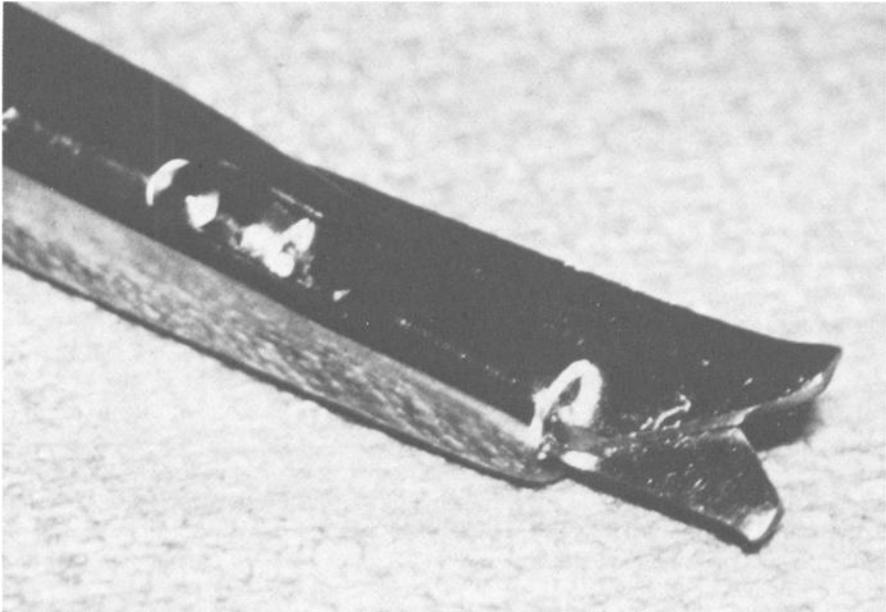


FIG. 4—*Improperly oriented fins.*

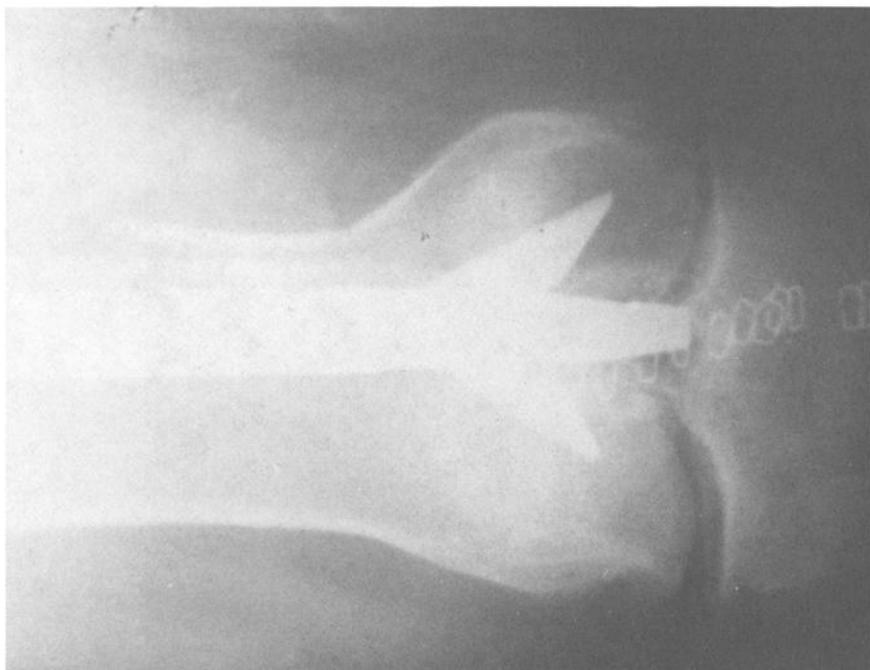


FIG. 5—*Protrusion of nail into knee joint.*

guide to insert the fins, reseating it was difficult. This in turn caused difficulty drilling the proximal screw holes. One case required a second procedure for reinsertion of the proximal screw due to unacceptable shortening.

The proximal tip of the nail was bent intraoperatively in seven cases (Fig. 6). Three of these cases occurred with the original instrumentation. The other four were bent while driving the nail the last few centimeters using the short insert for drilling the proximal screw hole. This shorter insert was placed into the nail before complete insertion to be sure it was well seated while the proximal tip of the nail was easily visualized. All seven cases occurred with the patient in the supine position. Both new and old instrumentation sets often abutted against the pelvis in the supine position unless the leg was adequately adducted.

Forty-six cases were done in the lateral and 41 in the supine position. In the 41 supine cases, 20 technical difficulties occurred and during the 46 lateral cases, 13 technical difficulties occurred. The average operative time for the supine position was 3.01 h and 2.11 h for the lateral position. Estimated blood loss (EBL) was 590 and 419 mL for the supine and lateral positions, respectively (Table 3).

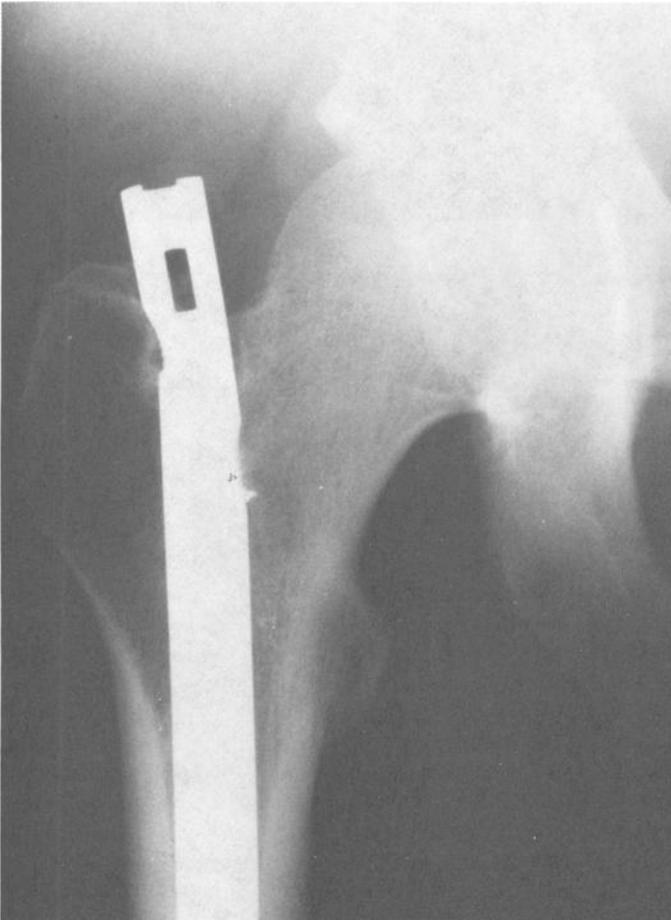


FIG. 6—Bent proximal nail.

TABLE 3—Position of patient for surgery, $p = 0.05$.

	Supine	Lateral
Total number of procedures	41	46
Technical difficulties	20	13
Average EBL, mL	590	419
Average operative time, h	3.01	2.11

Adverse clinical effects were noted in only 2 of the 24 patients who had technical difficulties during the operative procedure. These were the two cases of knee penetration by the nail. Both of these cases healed 2 cm short, and one developed a nonunion. Postoperative complications included labial edema (two), shortening greater than 1 cm (five), knee range of motion less than 120 deg (two), transient nerve palsy (four), superficial wound infection (two), hematoma (one), and heterotopic bone formation (one). None of these postoperative complications were related to the intraoperative complications already discussed except for two of the cases of shortening.

Healing was defined as X-ray evidence of bridging callous and a painless clinical examination with full weight-bearing. Five of the 76 patients at follow-up had nonunions. All of these five were closed injuries. Three of the five nonunions resulted from uneventful closed nailings of subisthmal comminuted fractures. One was a case of knee penetration, and the last was an open nailing during a procedure that had been delayed for associated injuries. All five patients had prolonged non-weight-bearing status postoperatively due to associated injuries or technical difficulties.

Discussion

The effectiveness of intramedullary nailing in femoral shaft fractures has been clearly defined throughout the orthopedic literature [11, 12]. The subgroup of unstable femoral shaft fractures as defined by Winquist [7] may be best treated with interlocking femoral nails in many cases. The advantage of controlling rotation, length, and alignment without the use of external support in the unstable condition has also been well documented [14]. Along with these advantages of interlocking femoral nailing, many possible pitfalls specific to the interlocking process have developed [13].

White [6] reports a 12.8% incidence of intraoperative technical problems using the Brooker-Wills nail. These problems included difficulty deploying the distal fins (3.5%), difficulty inserting the proximal screw (3.5%), two bent nails at the proximal screw holes and a fragmented greater trochanter. Two of White's patients required open reduction to pass the guide wire. This overall incidence of technical difficulties is significantly lower than ours (29%), although the types of problems encountered were similar. White indicated the presence of a learning curve during his series by stating that with experience, the technical problems were minimized. A similar experience was noted by Hanks [2], who reported a greater than 50% decrease in technical difficulties between the first half and second half in his series of 50 patients. Winquist [7] reported a preference for the lateral position for insertion of interlocking nails with distal screw fixation. He felt that this lowered intraoperative difficulties. White reported the use of the supine and lateral positions with almost equal frequency, 48.4% and 51.6%, respectively. His indications for selection of position were based on fracture location, body habitus, available equipment, and surgeon preference. He did not offer an analysis of technical difficulties related to patient position. Browner [13] reviewed the advantages of each position and related the ease of positioning, fracture reduction, and distal screw placement as advantages of the supine posi-

tion. The drawback of this position was obtaining entry into the proximal femur for guide wire placement. He reported a method for establishing this entry portal in the supine position.

In our series, a significant difference was noted in technical difficulties related to patient position. The supine position was associated with a higher incidence of technical difficulties. Our EBL (419 versus 590 mL) and the operative time (2.11 versus 3.01 h) were less for the lateral position. In our experience, the lateral position allowed better trochanteric exposure by allowing more hip flexion and soft tissue retraction from the proximal nail tip. This in turn reduced the difficulty of proximal screw guide and distal fin insertion. Thus, when the patient's associated injuries allow, we would recommend the lateral position when the Brooker-Wills nail is chosen. If the supine position must be used, special attention should be directed to trochanteric exposure.

White reported a 3.5% incidence of difficulty placing the proximal screw as opposed to our 6.9%. The proximal screw should always be placed to avoid shortening by collapse of the distal fins. With the proximal screw in place, only 4 mm of collapse can occur through the nail itself.

Accuracy of proximal screw placement is dependent upon the drill guide being properly seated on the nail. A sharp drill bit should be used to avoid excessive manual force during drilling, which can angulate the bit away from the proximal hole axis, causing the surgeon to miss the nail. Significant difficulty seating the drill guide was experienced if the nail had been fully inserted. We have found that changing the inserts with the nail about 2 cm short of full insertion facilitates that process. However, this may have defeated the purpose of redesigning the driving insert and may have been responsible for continued proximal nail bending during nail insertion in the supine position. When the nail has been seated and the proximal screw hole drilled, the screw was inserted and then removed until its tip barely contacted the lateral hole in the nail. Then, following fin deployment, the screw was placed back across the nail. This method was also described by Browner [13]. The use of excessive force to deploy the fins may cause the nail to move distally, malaligning the predrilled proximal screw holes, and should be avoided.

Our rate of postoperative complications and the final results after healing were comparable to other interlocking nail studies [1-7,14,15]. Even with our high technical difficulty rate during surgery, the patients generally healed in nearly anatomic alignment and had excellent range of motion. In further comparison with other interlocking nail systems, the Brooker-Wills nail avoids an incision at the distal lateral thigh. It can also be hypothesized that the amount of X-ray exposure to the surgeon's hands may be decreased, especially if one is using the free-hand technique to insert the distal screws in other systems.

Conclusions

Intramedullary interlocking nailing of the femur is a technically demanding procedure. Most of the technical problems unique to the Brooker-Wills distal fin deployment system can be minimized by adhering to the general principles of closed intramedullary nailing and the specific recommendations stated in this paper and by other authors [2,6,13]. Excellent clinical results can be expected using this system, especially in severe femoral fractures of unstable configuration.

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Distal Locking for Unstable Femoral Fractures: Is It Necessary? A Preliminary Report

REFERENCE: Behrens, F. and Johnson, J., "Distal Locking for Unstable Femoral Fractures: Is It Necessary? A Preliminary Report," *Intramedullary Rods: Clinical Performance and Related Laboratory Testing, ASTM STP 1008*, J. P. Harvey, Jr., A. U. Daniels, and R. F. Games, Eds., American Society for Testing and Materials, Philadelphia, 1989, pp. 130-136.

ABSTRACT: This is a preliminary report of a randomized-surgeon trial. This trial was carried out to determine if nail impaction into the distal femoral metaphysis (IMP) was as effective as distal locking (LOC) in preventing shortening and malalignments in unstable femoral fractures. Fourteen fractures were treated with IMP and 30 with LOC. The two groups had similar demographic, injury, and treatment characteristics and did not significantly differ in healing times, shortening, and rotational or angulatory deformities. There was a slight increase in complications in the LOC group. We concluded that distal nail impaction is an attractive alternative to distal locking with screws or deployable wings. It appears to be safer and has a lower complication rate.

KEY WORDS: unstable femoral fractures, interlocking nailing, nail impaction

Since the pioneering work of Gerhard Küntscher [1,2] in the 1940's, intramedullary nailing has become the most effective method of stabilizing femoral shaft fractures. When compared with nonoperative techniques, this method provides easier nursing care, earlier patient mobilization, a lower rate of complications, increased knee motion, and in the multiply-injured patient, lower mortality rates and a shortened hospital stay [3]. Traditional open or closed intramedullary nailing is most effective for the stabilization of stable fractures of the femoral diaphysis, but is not applicable to long spiral or oblique breaks, metaphyseal fractures, and lesions involving segmental comminution and bone loss [4,5]. Recently, several newer nail designs that interlock bone and nail [6-8] or deploy wings from within the nail [9,10] have been developed to prevent angulatory and rotatory malalignment and axial collapse in unstable fractures. While generally successful [4,8,10,11], the distal locking mechanisms have caused such difficulties as prolonged operating and fluoroscopy time, inability to localize the distal locking holes, missed locking, screw pullout, fixation of the distal fragment in rotatory and angulatory malalignment, penetration of the wing mechanism into the joint, difficulties removing the wing mechanism, excessive shortening, and injuries to the superficial femoral vessels [6-8,10,11,17].

Rationale

Clinical and experimental observations in the early 1980's led us to believe that the impaction of a femoral nail into the dense cancellous bone of the distal femoral metaphysis would provide

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sufficient axial stability to prevent shortening. Because in the past, rotatory problems have been rare and distal locking appears ineffective for the prevention of angulatory deformities, distal impaction could possibly avoid the need for distal locking and the many problems it may cause.

We also noted that nails inserted into the distal femoral metaphysis rarely migrated beyond the level where a vigorously impacted 3-mm guidewire with a 4-mm ballpoint tip had come to a halt. We therefore decided to use strong impaction of the guidewire as a "probe" to determine the ability of the distal femoral metaphysis to resist further nail impaction. For proximal locking, we would continue to use the standard interlocking screws.

To test this hypothesis objectively, we used the design of a modified randomized-surgeon clinical trial [12,13].

Material and Methods

Between August 1982 and July 1986, we treated 44 unstable femoral fractures [4] in 43 patients. All such fractures assigned to one surgeon were exclusively stabilized with a proximal locking screw and distal impaction (IMP). This group consisted of 14 fractures. There were twelve males (85.7%) and two females (14.3%). The median age was 27 years (range: 16 to 87 years). The unstable fractures assigned to the other surgeons were all treated by one proximal and either one or two distal interlocking screws or deploying wings (LOC). A total of 30 fractures were treated with this method. The average age of the patients was 24 years (range: 16 to 45 years). There were 24 males (82.8%) and 5 females (17.2%).

There were 13 closed fractures and one open Type 3B fracture [14] in the IMP group. The LOC group consisted of 21 closed, 3 open Type 1, 4 open Type 2, and 2 open Type 3B fractures [14]. According to the Winquist-Hansen classification, the IMP group contained two obliques, two Type 2 comminuted, eight Type 3 comminuted, and two Type 4 comminuted fractures, while the LOC group consisted of one transverse, two oblique, two segmental transverse, three Type 2 comminuted, eleven Type 3 comminuted, and eleven Type 4 comminuted fractures. In the IMP group, five fractures were located in the proximal third and nine in the middle third of the femur. In the LOC group, there were 8 proximal, 13 middle, and 9 distal fractures. Comminution exceeding two thirds of the bony circumference occurred in 50% of the IMP fractures and in 66.7% of the LOC fractures.

In the IMP group, 57.2% of the fractures were caused by motor vehicle accidents, 21.5% by pedestrian versus automobile accidents, 14.3% by motorcycle accidents, and 7.2% by falls. In the LOC group, the motor vehicle accidents made up 63%, the motorcycle accidents 26.7%, pedestrian versus automobile accidents 13.3%, work-related accidents 3.3%, and snowmobile-related accidents 3.3% of the fractures.

In the IMP group, 13 fractures (85.7%) had associated injuries and 12 (78.6%) skeletal injuries elsewhere. The IMP group contained eleven head and neck injuries, six upper extremity injuries, two contralateral lower extremity injuries, and ten ipsilateral lower extremity lesions. In addition, there were three abdominal, five chest, one central vessel, and one lumbar spine injury without loss of neurological function. In the LOC group 28 of the 30 fractures (93.3%) had associated injuries, and in 20 (66.7%) there were additional skeletal lesions. There were 23 head and neck injuries, 14 upper extremity injuries, 14 contralateral lower extremity injuries, and 24 ipsilateral lower extremity injuries. In addition, there were eight abdominal lesions, eight chest injuries, two genitourinary injuries, two lumbar spine injuries without neurological loss, and one thoracic spine injury with decreased neurological function, as well as a major central vessel injury.

In all patients, the nails were inserted within 15 days of injury. The mean time from nailing to injury was 4.7 days (range: 1 to 15 days) in the IMP group and six days (range: 0 to 12 days) in the LOC group. Fractures which were not immediately nailed were temporarily stabilized in distal femoral or proximal tibial pin traction.

For all fractures, intramedullary nailing was carried out on a fracture table. With the exception of five patients in the LOC group, all were placed in the supine position. Positioning of the patient, draping, reduction of the fractures, and approach to the greater trochanter was carried out in the standard fashion [4,9-11]. In the IMP group, we used nine Grosse-Kempf and five OEC-Küntscher interlocking nails. Seating of the guidewire and nail placement was as described earlier under "Rationale," while proximal locking occurred with the help of the aiming devices provided by the manufacturers. In the LOC group, we used eight OEC-Küntscher, 17 Grosse-Kempf, and five Brooker-Wills nails. In this group, distal locking was carried out with distal fins in five fractures, two locking screws in 20 fractures, and one locking screw in five fractures.

After discharge, all patients were followed at regular intervals in the outpatient clinic until the fractures were healed.

Results

Demographic characteristics of the IMP and LOC patients were statistically equivalent ($p = <0.05$). The fracture characteristics in both groups were similar with the exception that the LOC group had a higher percentage of open fractures and these involved the distal third of the femur. In the IMP group, there were slightly fewer patients with more than 66% comminution of the bony circumference, but according to the two-tailed T-test, none of these differences were significant ($p = <0.05\%$) [15,16].

All patients were followed until healed and reexamined between nine months and three years nine months after the injury. No patient died, and none was lost to follow-up. The operating time for the stabilization of isolated femoral fractures varied by less than one minute between the two groups. The mean operating time for the IMP group was 161.5 min (range: 105 to 245 min) and for the LOC group 162.1 min (range: 90 to 250 min). For isolated femoral fractures, the average blood replacement was 763 cc in the IMP group and 695 cc in the LOC group. Mean hospital stay for the IMP group was 16.6 days (range: 4 to 50 days), and for the LOC group 32 days (range: 4 to 201 days).

Because assessing healing times according to radiographic criteria is most difficult, we equated the time to full, unsupported weight-bearing with healing time. Full, unsupported weight-bearing occurred in the IMP group after a mean of 97.6 days (range: 40 to 157 days), and in the LOC group after 131 days (range: 13 to 487 days). The differences in healing times between IMP and LOC groups were statistically insignificant. This held true when considering treatment groups (IMP versus LOC) in association with the degree of comminution [15,16].

Proximal dynamization was carried out in one IMP patient at 116 days. In the LOC group, 9 out of 30 fractures were distally dynamized after a mean of 102 days (range: 37 to 219 days).

Reviewing the radiographs immediately after intramedullary nailing, we found that in the IMP group there were seven fractures which were distracted from 2 to 11 mm, and one that was short by 2 mm. In the LOC group, there were five fractures which were distracted from 3 to 9 mm and nine that were short between 3 to 9 mm. At the time of healing, leg length was assessed with wood blocks or scanograms or both. Leg length discrepancies in excess of 5 mm were found in three patients. One patient in the IMP group was 13 mm long, while in the LOC group one patient shortened by 2.5 cm and another one by 8 mm. There were no malrotations in excess of 10 deg, and no varus or valgus deformities exceeding 5 deg. Statistical assessment with analysis of variance (ANOVA) showed there were no real differences in leg length discrepancies between the two treatment groups. This held true when considering treatment groups (IMP versus LOC) in association with the degree of comminution [15,16].

There were few intraoperative complications. Open reductions were needed for one fracture in the IMP group and three in the LOC group. Once the fractures were reduced and the guidewires passed the fracture site, the muscle sleeve was closed and the reaming and nailing process

continued. A 9-mm frontal cutting reaming head got stuck in a thin medullary canal and had to be removed openly. One nail each in the IMP and the LOC groups broke through the more proximal of the distal locking holes. In the IMP group, the nail breakage occurred after the fracture had healed. Three distal locking screws backed out and were removed. There was one deep infection in the LOC group. After debridement and renailling, this resolved without further drainage.

Discussion

The introduction of interlocking nails is without doubt the greatest advance that has occurred in the management of femoral fractures during the past two decades. It has extended the indications from stable diaphyseal fractures to unstable, and comminuted lesions from a level just distal to the lesser trochanter to the supracondylar area of the distal femur. Previously, such lesions were treated in traction or by a combination of intramedullary nailing and circlage wiring. Both methods either interfered with postoperative care or led to a significantly higher complication rate in the form of postoperative infections and healing complications [3,4]. Interlocking nailing possibly has become most beneficial for the multiply-injured patients who have the highest incidence of unstable fracture patterns. In these patients, early intramedullary femoral stabilization has significantly decreased mortality rates, multisystem organ failures, and hospital stays [3].

While changes in nail design and the development of reliable targeting devices have made proximal interlocking a fast and reliable procedure, distal interlocking with screws or deployable wings has been responsible for complication rates between 10% and 20% [7,10,11,17]. Since to date no reliable distal targeting devices have been developed, most surgeons are exposed to considerable radiation during distal screw insertion. Reoperations for backed-out and therefore ineffective distal screws or wings deployed into the knee joint are not rare [8,10,11,17]. More importantly, injuries to the superficial femoral vessels in the adductor canal can be limb-threatening [17]. While such injuries are rare, the inconsistent course of the superficial femoral vessels and their close adherence to the medial femoral cortex make it unlikely that they can be avoided with certainty.

We felt that nail impaction into the metaphyseal bone of the distal femur (Fig. 1), if reliable and consistent, could solve most of the problems encountered with distal interlocking and wing deployment (Fig. 2). We tested the feasibility and limitations of this approach with a randomized-surgeon trial [12], whereby the patients assigned to one of the surgeons were exclusively treated with distal impaction while the remaining patients were managed with distal interlocking screws or, in five instances, wing deployment. The principal features of this trial design are that the choice of treatment method cannot be influenced by surgeon or patient and that each surgeon involved in the trial only performs the procedure that he considers most appropriate and with which he feels technically most comfortable [12]. To further increase the validity of the study, the data were collected and evaluated by an independent investigator (J.J.).

Statistical comparison of the two treatment groups showed they did not significantly differ with respect to demographic, injury, and treatment characteristics. While the LOC group contained more Type 4 fractures, it did not statistically differ in the amount of bony comminution and, therefore, instability from the IMP group. We hoped to show that distal impaction would reduce operating time and possibly blood loss, but found that in our setting they were almost identical to the LOC group. There was a significant decrease in the hospital stay for the LOC group, but this may be related to a slight reduction in the percentage of multiply-injured patients. Although the time to full, unsupported weight-bearing, which we designated as the healing time, was by about 25% shorter in the IMP group, this difference again was not statistically significant. For both treatment groups, the rate of significant shortening, rotational and alignment deformities were less than in previous reports about interlocking nailing of the femur

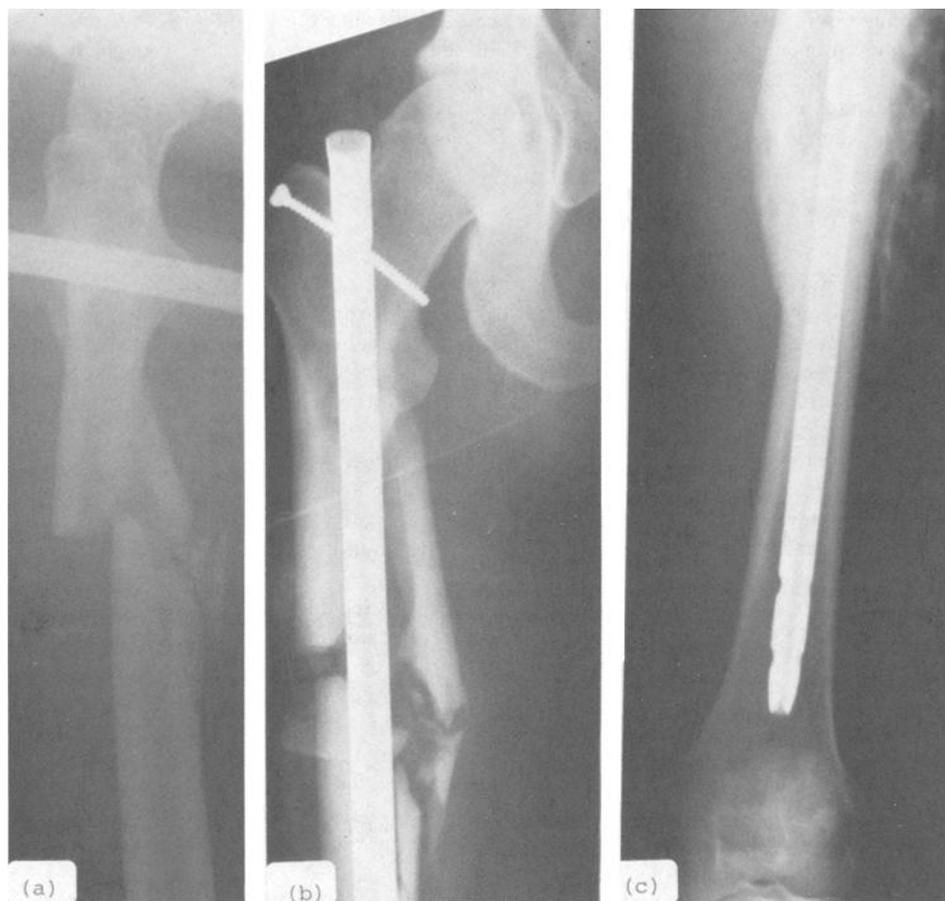


FIG. 1—(a) Type 3 comminuted fracture of proximal femur. (b) After closed intramedullary nailing with 11 mm of lengthening; proximal interlocking with AO screw and distal impaction. (c) Healed fracture one year after injury.

[8,10,11]. The absence of significant length and alignment differences between the two treatment groups shows conclusively that they are equivalent. Within the limits of this preliminary report, we therefore conclude that distal impaction of femoral nails in conjunction with proximal screw interlocking can be used as an alternative to distal wing deployment or distal screw interlocking. The method does not have significant disadvantages. It appears to be safer and will probably cause, in most hands, less intra- and postoperative complications. While entirely empirical, firm distal impaction of the 3-mm guidewire with a 4-mm ballpoint tip appears to be an excellent means to assess the capability of the distal femoral metaphysis to resist further nail impaction during the early healing period.

All IMP patients began walking with crutches and 130 Newton toe-touching and then progressed to full, unsupported weight-bearing as radiographic signs of callus formation appeared and as their sense of security increased. To decrease the danger of rotational deformity, the wearing at night of a derotation boot during the first ten days is recommended. In the IMP



FIG. 2—(a) Anterior-posterior view of closed Type 3 fracture of the femoral diaphysis (comminuted diaphyseal fracture). (b) Early after closed interlocking nailing; backing out of most distal screw. (c) Healed fracture ten months after injury; dynamization through removal of distal interlocking screws at three months.

group, all fractures with the exception of one healed readily without dynamization. One fracture which showed signs of delayed union at three months proceeded promptly to consolidation after removal of the proximal locking screw.

Although the oldest patient in the IMP group was an 87-year-old man with moderate osteoporosis, the method should be used with caution under these circumstances, particularly if the patient is unwilling or incapable of adhering to an early partial weight-bearing regime. Due to the danger of rotational deformity, the method is contraindicated after closed femoral osteotomies or shortening.

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Intramedullary Fixation of Unstable Trochanteric Fractures of the Hip

REFERENCE: Henry, S. L., Koenig, T., Rosenberg, S. and Seligson, D., "Intramedullary Fixation of Unstable Trochanteric Fractures of the Hip," *Intramedullary Rods: Clinical Performance and Related Laboratory Testing, ASTM STP 1008*, J. P. Harvey, Jr., A. U. Daniels, and R. F. Games, Eds., American Society for Testing and Materials, Philadelphia, 1989, pp. 137-151.

ABSTRACT: The Küntscher Y-nail is a two-piece intramedullary device used in the management of unstable trochanteric fractures. The Y-nail consists of a Küntscher intramedullary nail and a fenestrated femoral neck component. This device offers distinct biomechanical and clinical advantages when compared with the compression hip screw, blade-plate device, or other intramedullary fixation.

This retrospective study evaluated 137 patients with unstable fractures of the hip. Results were evaluated by specific criteria: pain, extremity shortening, range of motion, deformity, and ambulatory status. Management with the Y-nail resulted in 36% excellent, 44% good, 16% fair, and a 4% poor result. Clinical experience with this technique resulted in a short operative time, limited blood loss, decreased soft tissue trauma, and early patient ambulation.

The Küntscher Y-nail may provide a favorable alternative to other methods used for stabilization of fractures of the proximal femur.

KEY WORDS: Küntscher Y-nail, intramedullary fixation hip, unstable hip fractures, intertrochanteric fractures

Over the past three decades, improvements in health care for the elderly have increased the chances of survival and allowed the benefits of operative treatment to be applied to precariously ill patients with multiple medical problems. Yesterday's standard, the Jewett nail, has been mostly replaced by the compression hip screw for the management of unstable trochanteric fractures. Intramedullary nails, including the Zickel nail and Enders' and Harris nails, and prosthetic replacement are less frequently selected for the management of these unstable fractures. The compression hip screw is perhaps the most commonly used device today, but it continues to have an appreciable risk of complications in unstable fractures in osteoporotic bone [1,2]. The procedure can be prolonged with excessive blood loss. Anatomic reduction and fixation often fails, and displacement osteotomy frequently results in a significant deformity and shortening [1,3]. Techniques utilizing an anatomic reduction and interfragmental screws, blade plate fixation, or Enders' condyloccephalic nailing are not reliable in the management of unstable fractures.

Therefore, we turned to Küntscher's Y-nail, an appliance in use for more than 40 years by Küntscher and his pupils. The subject of this paper is the biomechanical rationale, surgical indications, and clinical results of Küntscher Y-nailing for trochanteric fracture.

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Biomechanics

Intramedullary fixation of the proximal femur provides specific biomechanical advantages over nail-plate devices. This is due in part to the extension of the fracture into the medial cortex in Part 3 and 4 fractures and the loss of inherent stability. As loading occurs in unstable fractures, compression forces are applied across the most medial femoral cortex. A bending moment occurs which is the product of loading force F and distance d between the line of force and the most medial point of bone-to-bone contact [4]. In stable fractures, the lesser trochanter acts as a buttress, reducing distance d between the medial bone-to-bone apposition and the perpendicular line of force. In unstable fractures, loss of this medial buttress moves the fulcrum laterally, which in turn increases the bending moment and the risk of failure.

Unstable fractures treated with rigid nail-plate devices have large bending moments at the nail-plate junction, hence the risk of device breakage. Sliding nails and screws are similarly subjected to large bending moments. With fracture impaction, the sliding devices allow medial collapse and reduction of the moment arm. Intramedullary devices (such as the Ender nail, Zickel nail, and Küntscher Y-nail) may themselves serve as the fulcrum in unstable fractures. Reduction of distance d by placement into the intramedullary canal reduces the moment 30% to 40% and thus lessens the risk of device failure (Fig. 1).

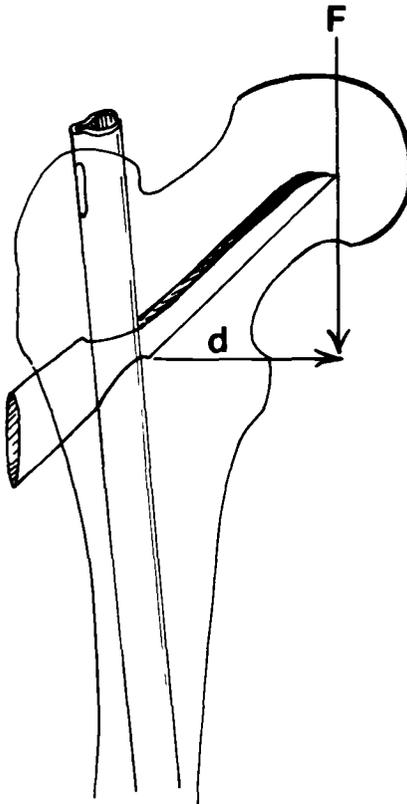


FIG. 1—Intramedullary fixation reduces d and the bending moment $F \times d$ when compared with nail-plate devices.

As the fracture is allowed to collapse, the bone-to-bone apposition reduces the device loading. Devices which allow fracture settling have a lower failure rate [2]. The compression hip screw [5], Pugh nail [6], Massie nail [7], and similar devices allow fragment collapse with a decreased femoral head to lateral cortex distance. Fracture settling also occurs with the Küntscher Y-nail. With cyclic loading, the fenestrated femoral neck component may "walk" down the intramedullary nail until cortical apposition occurs, resulting in a more stable configuration. Further loading locks the Y-nail at 135 deg and prevents varus deformity of the femoral neck.

Shape and functional design of the implant within the femoral head are significant factors affecting articular penetration and cutout. The implant's design should maximize surface cross-sectional area to increase friction and retard motion through osteoporotic bone. The compression hip screw is round and tends to separate the bone trabecula. The Y-nail is trough-shaped; bone collects in the trough, increasing the surface area and resistance and decreasing the risk of cutout.

Indications

Stable intertrochanteric fractures may be managed equally well by all of the commonly used instrumentation, including the Y-nail. The Y-nail, however, may provide more stable fixation in unstable intertrochanteric, subtrochanteric, and combined inter- and subtrochanteric fractures. It is also useful in the management of pathologic fractures and as a salvage procedure where primary fixation with another appliance has failed.

The Y-nail is particularly indicated for reverse oblique fractures of the intertrochanteric region (Fig. 2) and as an alternate procedure for appropriate ipsilateral femoral shaft and intertrochanteric fractures (Fig. 3).

Operative Technique

Küntscher Y-nailing is best performed on a standard fracture table with biplanar fluoroscopy. The patient is placed in a supine position with the thorax rolled to the uninjured side and the ipsilateral arm supported over the chest on a padded anesthesia screen. The contralateral lower extremity may be stabilized by "well-leg traction" or supported by a sling with the hip and knee in flexion.

Unstable trochanteric fractures of the hip are most commonly reduced with traction and 15 to 20 deg of internal rotation. In those instances in which the greater trochanter lies with the proximal fragment, external rotation may be necessary for proper reduction. Once reduction is achieved, placement of the image intensifier and draping should not prevent midline adduction of the injured leg during the operation.

The instrumentation consists of two components: the femoral neck component and the straight cloverleaf intramedullary nail. The femoral neck component of the Küntscher Y-nail ranges in length from 80 to 120 mm in 10-mm increments and is available with fenestration for either a 10-mm or a 12-mm intramedullary nail. Prior to insertion of the Y-nail, the components should be assembled to ensure that the femoral neck and intramedullary nail will engage and lock. If not, a plate-bending press is used to flatten the proximal flare of the intramedullary (IM) nail and to prevent distal migration. Caution should be exercised not to mismatch 10- and 12-mm components.

To estimate the length of the femoral neck component, place the implant on the anterior aspect of the hip and check the placement with fluoroscopy. The component should lie between the center of the femoral head and the subchondral plate. An equally useful method employs a K-wire to determine the proper depth into the femoral head. A 1.5 to 2.0-cm distance between the articular surface of the femoral head and the component tip is recommended to allow for impaction.

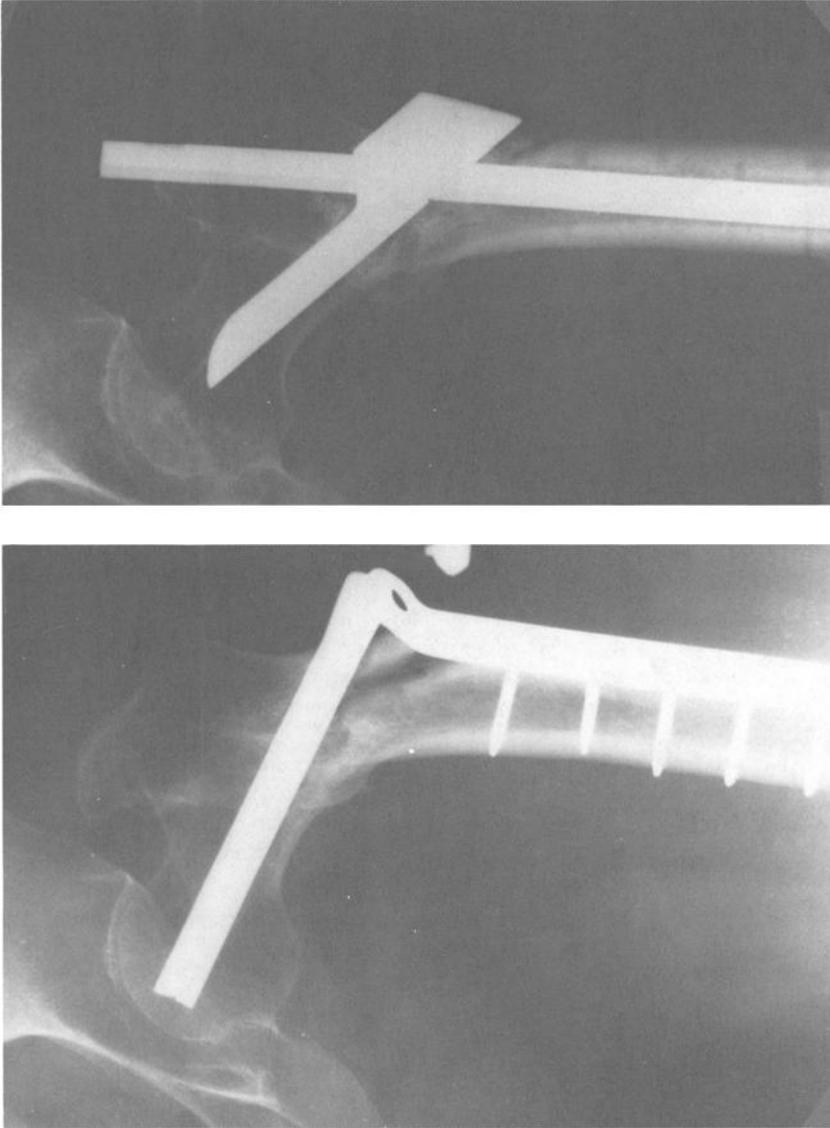


FIG. 2—(left) Reverse oblique intertrochanteric and subtrochanteric fractures are extremely unstable and are at risk for failure when treated with rigid or sliding devices. (right) After this revision with the Y-nail (1967), patient had a successful union, and elective removal of the instrumentation. (1972).



FIG. 3—27-year-old-female with ipsilateral subtrochanteric and femoral shaft fracture. Caution should be exercised with transverse subtrochanteric fractures and femurs with large canals, since the Y-nail may not provide adequate rotational stability.

Instrumentation should include the standard Küntscher IM nailing tray and several specialized Y-nail instruments (Fig. 4).

A 10-cm lateral incision is made beginning two fingerbreadths distal to the tip of the greater trochanter. The fascia lata and vastus lateralis muscle are incised separately and elevated. A K-wire is placed through the lateral cortex and into the inferior aspect of the femoral neck at an angle of 135 deg. A large cannulated drill (1.25 cm) or conical burr can be passed over the guide pin to ream the lateral cortex. Rongeurs are used to enlarge the cortical defect, using the base of the cervical component as a template. On occasion, a comminuted fracture will extend into the cortical window: no special adjustments are necessary since this has not affected the end clinical results. After the superior and inferior borders of the drilled cortex have been enlarged with a rongeur, the femoral neck component is inserted with the Y-nail driver. A cannulated driver is now available to allow placement of the femoral neck component over the guide wire (Fig. 5). The original Y-nail instrumentation requires removal of the guide wire from the femoral neck prior to the component insertion.

With the hip in internal rotation, the correct plane of the driver should be parallel to the floor. Under fluoroscopic imaging, the femoral neck component is driven to within 1.5 to 2.0 cm from the articular surface. The cervical component should be slightly inferior within the femo-

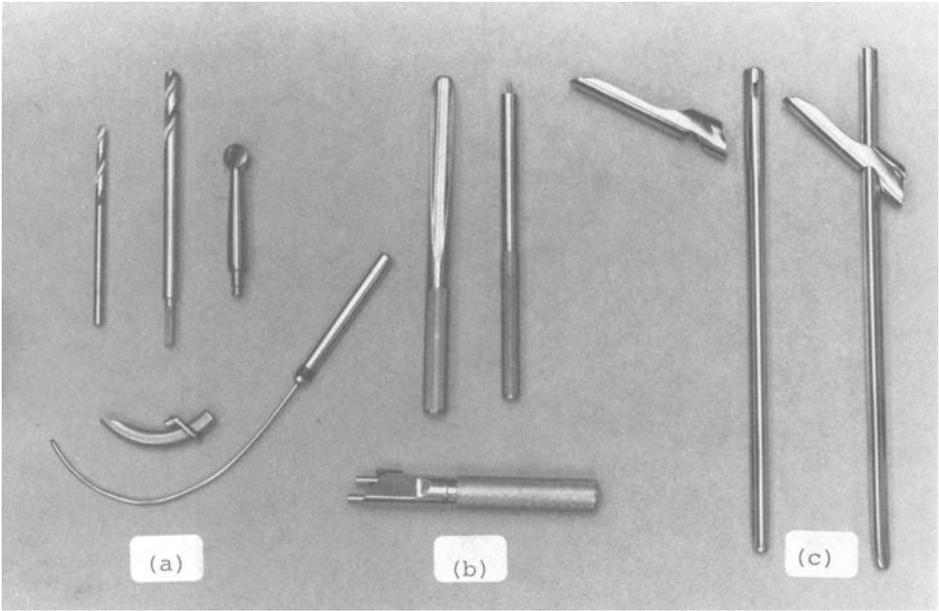


FIG. 4—*Y-nail instrumentation: (a) cortical drills and conical reamer, optional curved guide, curved guide wire; (b) channel guide, intramedullary nail driver, femoral neck component driver; (c) disassembled and assembled Küntscher Y-nail.*

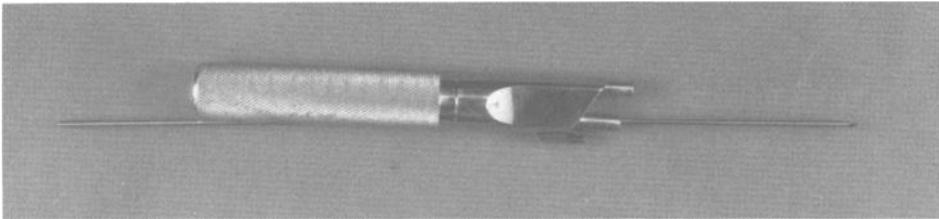


FIG. 5—*Cannulation of driver allows placement of femoral neck component over guide wire, ensuring more accurate placement.*

ral head, as viewed on the anterior-posterior (AP) projection (Fig. 6), and centered in the femoral head and neck, as viewed on the lateral projection.

The femoral neck component should be seated until the fenestration for the longitudinal nail is centered over the IM canal. The final position of the femoral neck component is dependent to a great extent upon the entry site of the intramedullary nail (Fig. 7). A lateral entry site in the greater trochanter tends to back the femoral neck nail out laterally and out of proper position within the femoral head. An entry site which is too medial advances the femoral neck nail toward the articular surface and may penetrate the head.

A 7-cm curved guide may be used to assist direction of the curved guide wire. Often this small guide becomes obstructed with bone and may impede passage of the curved guide wire through the greater trochanter. In the elderly osteoporotic patient, the curved guide wire can be passed

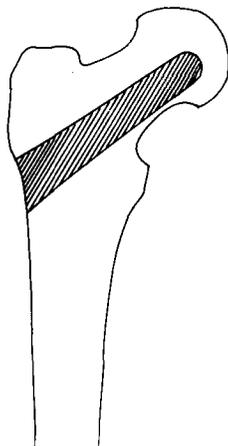


FIG. 6—*Proper placement of Y-nail in inferior aspect of femoral neck and head. Placement of femoral neck component 1.5 to 2 cm from articular surface allows for minimal impaction and avoids complications.*

freehand (without use of the curved guide) with minimal resistance. The curved guide wire is advanced through the soft tissue until it becomes palpable. A 2-cm incision is made over the guide wire as it tents the skin. The intramedullary nail or hole enlarger is passed over the guide wire to the greater trochanter. The straight Küntscher nail is then driven down through the proximal border of the greater trochanter as the curved guide wire is slowly removed.

In young patients with exceedingly hard bone, placement of the curved guide wire through the greater trochanter may be extremely difficult. In these patients, a standard IM nailing approach can be made. A hole enlarger or reamer awl may be necessary before placement of the intramedullary nail. An optional step may include passage of a standard intramedullary guide wire through the trochanteric hole and femoral neck component and down the shaft. This serves as another method to ensure proper placement of the intramedullary nail through the femoral neck component (Fig. 8). Reaming is not necessary unless the patient has an ipsilateral shaft fracture or an extremely narrow intramedullary canal.

The positions of the guide and intramedullary nail are checked with AP and lateral fluoroscopy. Driving the intramedullary nail is facilitated by directing the femoral neck nail driver toward the knee. This maneuver places the femoral neck and head in valgus and unlocks the two components. As the nail is advanced, it should be visible through the base of the femoral neck component. The slot in the medullary nail should face medially, and its progress should be monitored by the image intensifier as it is driven distally. After the nail is seated and the components engaged, the base of the femoral neck nail may protrude 2 to 4 mm through the lateral cortical window. This is a common finding but is rarely of clinical importance. After wound irrigation the extremity traction is released and the incisions are closed. Suction catheters are placed deep to the fascia lata and a compression dressing is applied; a trochanteric roll helps control bleeding. The drains then are removed after 24 to 48 h. Full weight-bearing as tolerated is started on the parallel bars on the first postoperative day.

Clinical Series

This is a combined retrospective study of 137 consecutive patients stabilized with the Küntscher Y-nail in Louisville, Kentucky, and Pittsburg, Pennsylvania, between 1967 and 1986. Ninety-six females and 41 males were evaluated. Mean follow-up was 40 months (range, 6

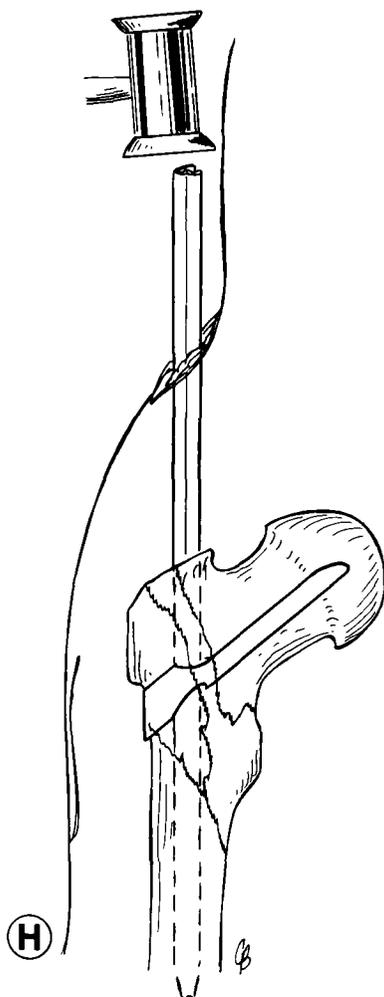


FIG. 7—Entry for intramedullary nail should be centered over femoral canal and fenestration of femoral neck component.

months to 18 years). Mean age was 76 years, with a range of 25 to 99 years. Twenty-three patients were lost to follow-up, including 18 patients who died prior to the minimum six-month follow-up appointment.

Early fracture fixation and postoperative mobilization were attempted. The mean time from admission to surgery was two days (range, 6 h to 12 days). Eleven patients (8%) underwent fracture stabilization within 12 h of admission. In 86 patients (63%), internal fixation was performed between 12 and 48 h, and 40 patients (29%) had surgery after 48 h. The average operative time was 83 min (range, 30 to 160), with a mean blood loss of 340 cc (range, 100 to 1000 cc). Most patients were in a chair on the first postoperative day and ambulating by the third postoperative day. Hospitalization averaged 15.5 days (range, 6 to 55 days).

The mechanism of injury in 122 patients (89%) was either a fall or a motor vehicle accident.

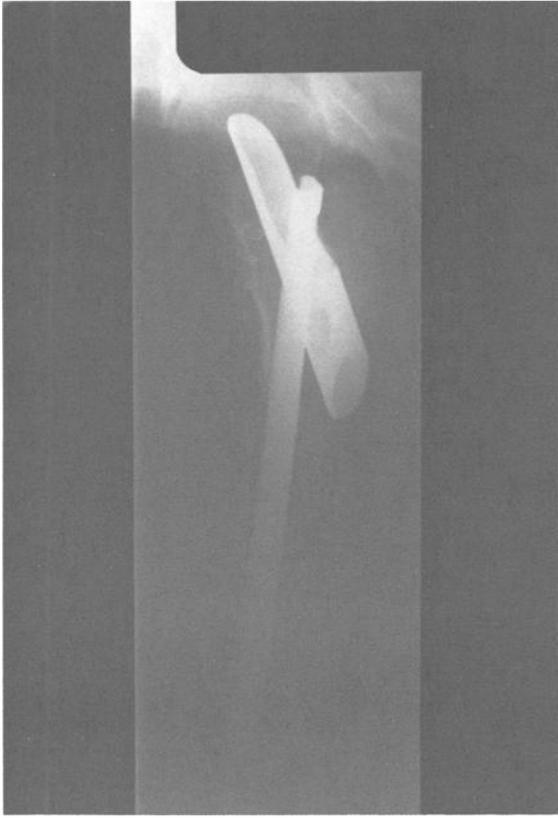


FIG. 8—Intramedullary nail was passed anterior to femoral neck component. Intramedullary nail should be visible through base of the neck component where it passes through fenestration.

Seven patients (5%) had pathologic fractures, and eight patients (6%) had failed primary osteosynthesis.

Fractures were classified as intertrochanteric, subtrochanteric, and combined intersubtrochanteric. Fractures were categorized by Evan's classification [8] and were considered unstable with comminution of (1) the medial calcar, (2) the subtrochanteric region, (3) the posterolateral aspect of the greater trochanter, or (4) if the fracture line extended in a reverse and oblique manner (Fig. 9).

Thirty-seven patients (27%) sustained stable intertrochanteric fractures. Eighty-five (62%) had unstable intertrochanteric fractures as defined by Evan's classification; 70 Evan's unstable Type I and six Evan's unstable Type II (reverse oblique). The series also includes six patients (4%) with subtrochanteric fractures and nine patients (7%) with basilar femoral neck fractures.

Results

Results were evaluated by clinical and radiographic criteria: pain, extremity shortening, range of motion, residual varus-valgus deformity, and return to the pre-fracture ambulatory

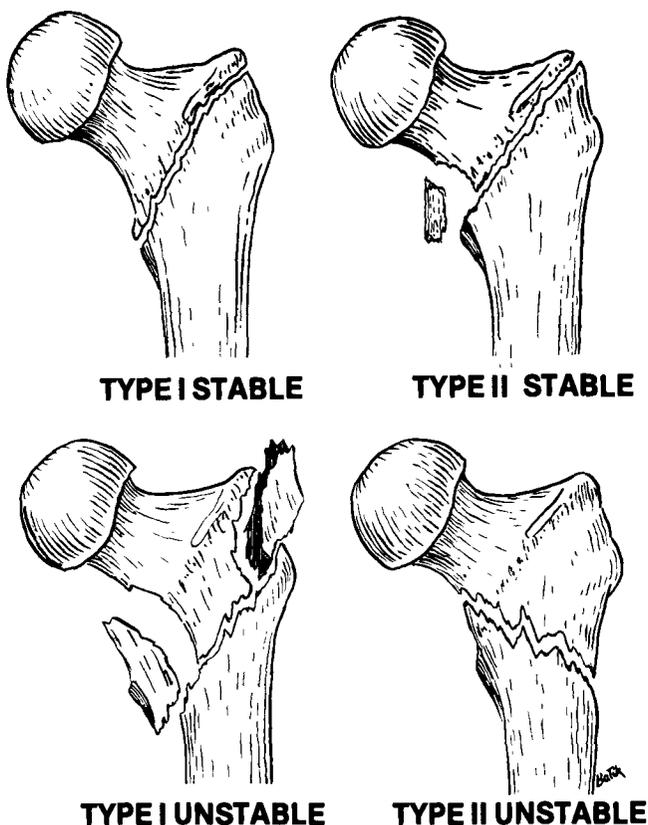


FIG. 9—Fractures were considered unstable if medial cortical buttress was comminuted or associated with a large posterolateral fragment of the greater trochanter or both. Reverse oblique fracture was also considered unstable and associated with a high failure rate when treated with compression hip screw or nail plate devices.

status. An *excellent* result was defined by having no pain, no shortening, a full range of motion, absence of a varus or valgus deformity, and return to the same ambulatory status prior to the fracture. A *good* result was characterized with minimal pain, less than 1 cm of shortening, good range of motion, and the ability to ambulate independently with or without a cane. Patients with a *fair* result complained of mild pain, shortening between 1.0 and 2.5 cm, mildly restricted range of motion, and ambulation restricted to use of a walker. *Poor* results were characterized by having moderate to severe pain, greater than 2.5 cm of shortening, varus deformity, and marked restriction of ambulation.

Thirty-six percent of the fractures stabilized with the Y-nail had excellent results (Figs. 10 and 11). Of the remaining patients, 44% had good results, 16% fair, and 4% poor.

Complications

Seven patients (5%) had protrusion of the cervical component through the femoral head (Fig. 12). Two patients were revised and a third refused revision when it was recommended. The remaining four patients had minimal femoral head penetration of 0 to 2 mm and were asymp-



FIG. 10—(a) Unstable intertrochanteric fracture in an 86-year-old male. Note segmental loss of medial femoral cortex. **(b)** Following discharge, this patient failed to return to our clinics until postoperative Week 7. He was full weight-bearing, and early callus formation was noted on X-ray. Patient returned to clinic requesting removal of skin staples.



FIG. 11—Patient was full weight-bearing and ambulating independently without walker or cane. Patient was asymptomatic with weight-bearing; however, he did have mild tenderness with palpation over trochanter.

tomatic. Since we modified the operative technique to restrict the device insertion to 1.5 to 2.0 cm from the articular surface, the complication has not been experienced.

Migration of the intramedullary nail either proximally or distally occurred in three patients (2%) (Fig. 13). Two of these patients were revised; one had an excellent result, the second had a fair result. Component failure and breakage was reported in one patient who had a 10-cm penetration through the femoral head. Healing occurred, but the femoral neck component broke at 18 months. After nail extraction, the patient ambulated with assistance of a walker with minimal pain.

Limb shortening greater than 1 cm was noted in 15 patients. The mean extremity shortening was 1.8 cm with a range of 1.25 to 4.4 cm. Three patients had minimal external rotation deformities, but without clinical significance (mean 11 deg, range 8 to 12 deg). Two patients had deep vein thrombosis, and three patients developed infection (two superficial and one deep).

Discussion

In 1969, Fischer [9] reported excellent results with 324 cases of peritrochanteric fractures stabilized with the Küntscher Y-nail over a 20-year period. The Y-nail provided better stability than plate-screw devices, allowed weightbearing on the first postoperative day, shortened hospitalization, and decreased operative time (by 40 min). Fischer also managed ipsilateral trochanteric and femoral shaft fractures, pathologic fractures, and failed screw-plate fixation with the Y-nail.

Cuthbert and Howat [10] managed 91 patients with the Y-nail. This case series included 76

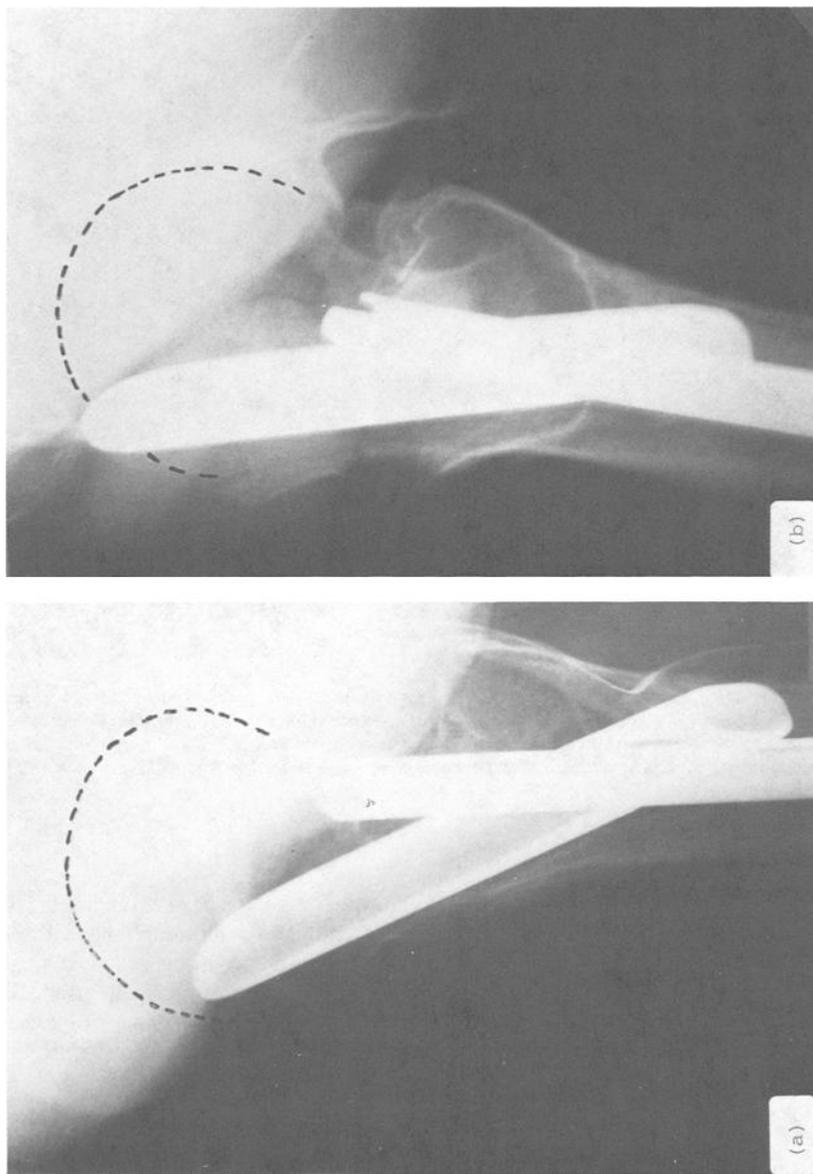


FIG. 12—(a) Postoperative lateral X-ray of an unstable intertrochanteric fracture (89 YOWM). Note anterior placement within 4 mm from articular surface. **(b)** After fracture impaction the femoral neck component penetrated the femoral head by 4 to 5 mm. This patient was not revised and went on to union without symptoms.

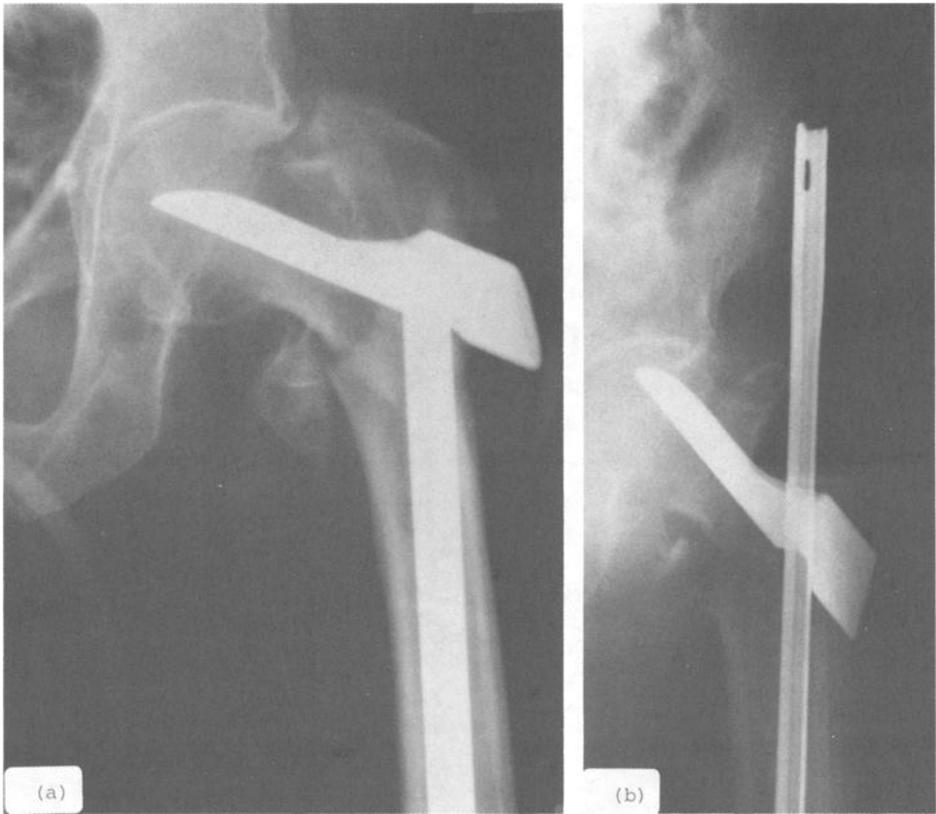


FIG. 13—(a) Progressive distal migration was followed for four postoperative days until disengagement of the two components occurred. Examination of the implant after revision revealed an implant defect as the cause. (b) Proximal migration of intramedullary nail has rarely occurred and is best treated by brief anesthesia and gently tamping of the IM nail distally. This complication has occurred with the use of long IM nails.

unstable intertrochanteric and 15 subtrochanteric fractures. Eight failures were reported. Five of the eight failures resulted from distal migration of the longitudinal nail through the fenestration of the femoral neck component. Subsequently, these authors began using a flanged longitudinal nail that prevented additional disengagements. Severe osteoporosis was responsible for one nail disengagement, and the two remaining failures were attributed to poor surgical placement. Of these failures, only one required revision. The other seven patients healed with protected weight bearing. There were no nonunions reported.

In a 1983 report of a large retrospective study, Maatz et al. [11] recommended full weight-bearing immediately following surgery. In this series, two femoral neck component breakages occurred. Both patients underwent revision, and healing occurred without further problems. Distal intramedullary nail migration did not occur; however, three cases of proximal migration were reported. All three were revised by making a 2-cm stab incision and advancing the longitudinal nail distally until engagement with the femoral neck component occurred. All healed without further incident. Favorable results have also been experienced by Standenat [12], Nather [13], and Hempel [14].

In 1985, Kernohan et al. [15] reported a series of 105 cases in which Y-nails were used, including 50 pathologic fractures. Supplemental use of cement for stabilization produced good results. Weight-bearing was delayed for two weeks in this patient group. Kernohan also revised 18 cases with failed blade plate fixation with the Küntscher Y-nail.

Malrotation is a complication of Y-nailing that has been reported in most large series [10,11,15]. The malrotation usually is an external rotation deformity that rarely is of any clinical significance. Excessive rotation can be corrected by manipulation if it is detected prior to impaction and callus consolidation.

In summary, our experience with the Küntscher Y-nail shows that this simple interlocking intramedullary appliance is a reliable method for stabilizing comminuted intertrochanteric fractures in the elderly.

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Intramedullary Nailing of Femoral Shaft Fractures Using the Hansen-Street Nail

REFERENCE: Stein, D., Proano, F., Johanson, P., Stryker, W., and Kim, W., "Intramedullary Nailing of Femoral Shaft Fractures Using the Hansen-Street Nail," *Intramedullary Rods: Clinical Performance and Related Laboratory Testing, ASTM STP 1008*, J. P. Harvey, Jr., A. U. Daniels, and R. F. Games, Eds., American Society for Testing and Materials, Philadelphia, 1989, pp. 152-153.

ABSTRACT: This is a retrospective study of 211 consecutive femoral shaft fractures treated with intramedullary nailing using the solid, diamond-shaped Hansen-Street nail. The pre-bent nail was inserted into the broached femoral canal with the aid of image fluoroscopy and with closed reduction in 168 cases, with an average operating time of 1.7 h and blood loss of 75 cc. Open technique was performed in 43 cases. The average follow-up was 13.7 months; there were no nonunions. The time to bony union by bridging callus was 4.1 months. Length stability correlated with the degree of comminution and the fracture site location. Shortening greater than 2 cm was found in 1.4% of the cases. Malrotation greater than 10 deg occurred in 2.1% and infection in 1.8% of patients. The Hansen-Street nail provides a simple and versatile bone-implant complex and is somewhat unique in affording some rotational control by the press fit of the diamond-shaped nail in the prebroached medullary canal. This end-result study reveals gratifying clinical results without sacrificing the medullary contents and some endosteal cortex, which results from intramedullary reaming.

KEY WORDS: femoral nailing, femoral fracture, intramedullary nailing, Hansen-Street nail

The Hansen-Street nail provides a simple and versatile bone-implant complex as well as substantial rotational control by the press fit of the diamond-shaped nail in the prebroached medullary canal. By avoiding mechanical reaming, this system minimizes endosteal disruption. Recent studies [1] have indicated that as much as two thirds of the inner cortex of the femur becomes avascular with reaming. Also with less direct contact of the implant and inner cortex, the medullary circulation has the capacity to regenerate more rapidly, as pointed out by Rhinelandt in his studies [2]. Reamed nails carry a nonunion rate of up to 2% for closed fractures and up to 18% for open fractures [3]. The Hansen-Street nail system requires no reaming and, in this series of femoral shaft fractures, brought about 100% bony union.

Technique

All intramedullary nailings are performed using a fully adjustable fracture table. Most procedures are undertaken with the patient in the lateral decubitus position for facilitating the approach. However, the supine technique offers the advantage of less valgus deformity caused by

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the bowing which results from gravitational effects. Posterior bowing which may occur in the supine position is in the plane of function of the knee joint and, therefore, less troublesome. In addition, if the knee is kept rotated slightly toward the floor, external rotatory deformity due to the patients tendency to roll forward in the lateral position can be avoided [4]. Image fluoroscopy and a reduction attempt prior to draping is mandatory. A standard approach to the piriformis fossa is performed.

The Hansen-Street nail system is simple in that reaming the femoral canal is not required. Instead, a broach is inserted into the medullary canal of the femur and carefully driven down the shaft and across the fracture site. An appropriately sized and bent diamond-shaped nail is then driven down the femur and across the fracture with the aid of image fluoroscopy. Traction is released after the nail is well into the distal fragment in order to impact the bone ends. The nail is then driven to the physal scar or to the superior pole of the patella. When open reduction is necessary, a lateral approach to the femur is utilized.

Results/Conclusions

Closed reduction was performed in 168 cases, with an average operating time of 1.7 h and blood loss of 75 cc. Open technique was performed in 43 cases. The average follow-up was 13.7 months, and there were no nonunions. The time to bony union by bridging callus was 4.1 months. Length stability correlated with the degree of comminution and the fracture site location. Shortening greater than 2 cm was found in 1.4% of the cases. Malrotation greater than 10 deg occurred in 2.1% and infection in 1.8% of patients.

Implant failure was seen in two patients (1.8%). In one case, the threaded end of the nail used for engaging the insertion device fractured off the nail after insertion. The fracture healed without complications, and the patient was lost to follow-up. Two months after the operation, the other patient explored the limits of nail-bending yield strength by jumping from a wall at a height of 6 ft (2 m). The resultant impact loading caused bending of the implant to 45 deg (valgus). The patient was taken to the operating suite, where the nail was straightened under anesthesia, removed, and replaced with a new implant. His fracture healed without further complications.

This study reveals gratifying clinical results and indicates that this system has the capacity to treat the vast majority of femoral shaft fractures with complications quite comparable to reamed nails. The Hansen-Street nail is simple, inexpensive, and easy to use and brings about bony union without sacrificing the medullary contents and some endosteal cortex, which results from intramedullary reaming.

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Intramedullary Nailing for Treatment of Diaphysial Nonunions of the Femur

REFERENCE: Gualtieri, G., Gualtieri, I., Gagliardi, S., and Hendriks, M., "Intramedullary Nailing for Treatment of Diaphysial Nonunions of the Femur," *Intramedullary Rods: Clinical Performance and Related Laboratory Testing, ASTM STP 1008*, J. P. Harvey, Jr., A. U. Daniels, and R. F. Games, Eds., American Society for Testing and Materials, Philadelphia, 1989, pp. 154-160.

ABSTRACT: Küntscher nailing was performed on 55 noninfected pseudoarthroses of the femur. Of these, 16 had previously been submitted to conservative treatment while 39 had undergone surgery. Closed intramedullary nailing was used in 24 cases, a half-closed technique in 23 cases, and open intramedullary nailing in 8 cases. The union rate was 100%. The average time from surgery to radiographic consolidation was three months. Complications included two infections.

KEY WORDS: nonunion, Küntscher, nailing, femur

Pseudoarthrosis is one of the causes of the unsuccessful treatment of fractures, whether treated by surgical or conservative means [1,2]. Our experiences show that nonunion of the femoral shaft has become more frequent in recent years, when plates for the fixation of fractures have still been widely used. This invasive method does not require postoperative external immobilization, but involves higher risks of infection, delayed consolidation, and pseudoarthrosis.

The results obtained with intramedullary fixation utilizing the Küntscher nail in noninfected pseudoarthroses of the femoral shaft are reported here [3-5].

Materials and Methods

Fifty-five cases of nonunion of the femoral shaft were treated surgically between the years 1968 and 1984. Of these, 16 had previously been submitted to conservative treatment, while 39 had undergone surgery: 12 intramedullary nailings (2 Ender, 9 Küntscher, 1 Rush); 27 osteosyntheses with plates or screws or both. Average age of the 55 patients (16 female, 39 male) was 29.6 years, ranging from 15 to 78. There was a predilection for nonunion on the left side (32 left, 23 right). The average time from the initial fracture was 17.8 months, with a minimum of 6 and a maximum of 144 months. All cases had removal of their implants at surgery, except two cases, in which plates had been removed previously.

We divided the noninfected pseudoarthroses into two groups:

- (a) Pseudoarthroses following conservative treatment and secondary to insufficient fracture reduction, too short immobilization period, gap between the fracture ends, or bone loss due to exposure.

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- (b) Pseudoarthroses following surgical treatment and secondary to insufficient stability of fixation, bone necrosis due to excessive stripping of the periosteum, or secondary to application of inadequate implants.

In all cases, Küntscher's well-known operation technique was performed. Depending on previous treatment and type of pseudoarthrosis we adopt one of the following:

1. Insertion by the closed technique. The classical method for recent fractures is performed. This procedure is preferred whenever possible. It can also be applied in nonunions following bad intramedullary fixation (too thin or too short nails, insufficient reaming, etc.) and in case of inadequate implants: Rush, Ender, etc. [6-11].
2. Insertion by the half-closed technique, that is, a small surgical exposure of the femoral shaft just sufficient for removal of the initial hardware, without any stripping of the periosteum and exposure of the site of nonunion. Subsequently, closed Küntscher nailing was done.
3. Open nailing was performed in those cases of pseudoarthrosis where closed reduction on the fracture table (Wittmoser's table) was impossible. Fragment isolation was kept to a minimum, just sufficient to ensure alignment.

Only a short segment of the medullary cavity was opened to allow the introduction of a guide-wire. Surrounding fibrous tissue as well as newly formed bone tissue was not removed. All the nonunions of the middle-third, hypertrophic, and atrophic ones have been treated as described above, provided that bone loss was not massive, which would have meant excessive bone shortening.

The clinical series was subdivided into three groups according to surgical technique used:

1. Osteosynthesis by the closed technique. Twenty-four reduced pseudoarthroses: fourteen following conservative treatment, eight following intramedullary nailings (two Ender, five Küntscher, one Rush), and two following osteosynthesis with a plate which had been previously removed (Fig. 1).
2. Osteosynthesis by the half-closed technique. Twenty-three reduced pseudoarthroses, all following fixation with plates or screws or both (Fig. 2).
3. Osteosynthesis by the open technique. Eight nonreduced pseudoarthroses: two following conservative treatment, two following fixation with plates, and two with a Küntscher nail (Fig. 3).

Cast-brace immobilization was generally not necessary: a plaster spica extended on the trunk and including the whole thigh for a period of 30 days was applied in only 12 cases. Weight-bearing was allowed after 21 days in cases where treatment had been closed and after 40 to 80 days in the other patients.

Results

The average time from surgery to bone union determined radiographically was three months (range 1.5 to 10 months). The radiographic consolidation in the nonunions treated by the closed technique was obtained in less time than in the others (Fig. 4). The range of movement of the knee never decreased in comparison with preoperative values. The range of movement increased in 24 patients by 20 to 30 deg. At the end of treatment the range of flexion was:

- (a) above 90 deg in 29 cases,
- (b) 90 to 60 deg in 19 cases, and
- (c) less than 60 deg in 7 cases.

Limb shortening from 0.01 to 0.02 m occurred in only four patients while malrotation was not observed.

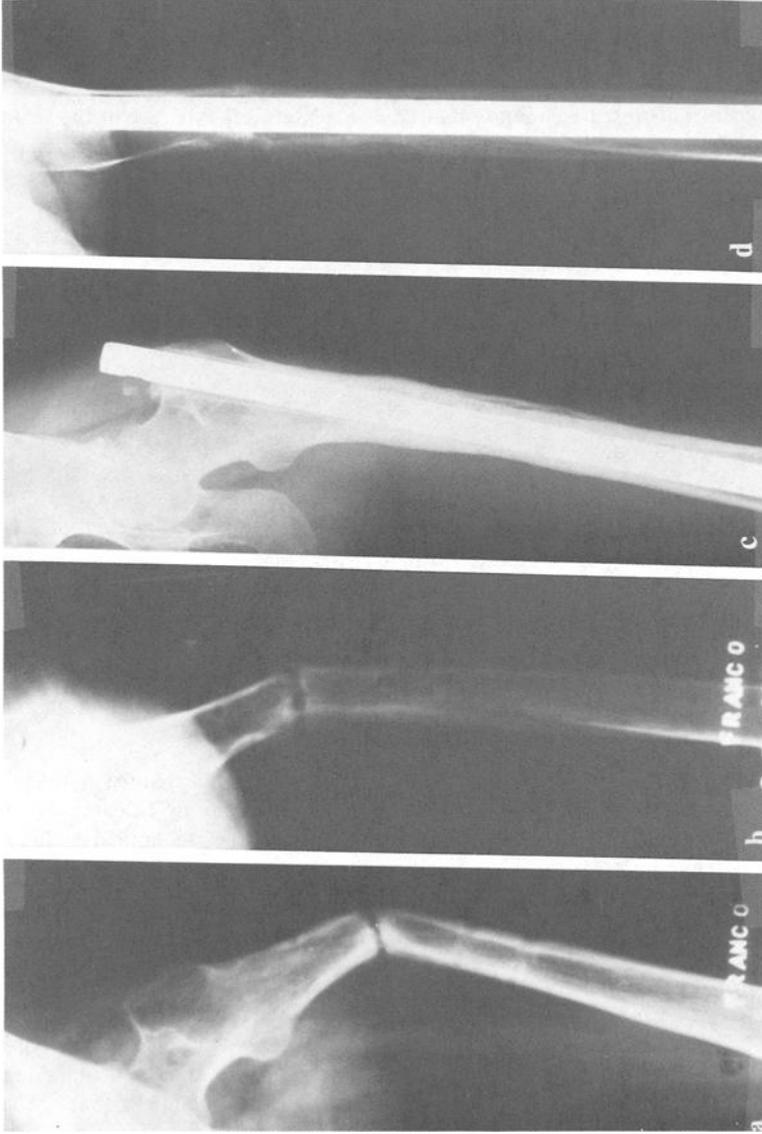


FIG. 1—Osteosynthesis by the closed technique. An 18-year-old woman sustained a fracture of the left femur, which was stabilized with a plate. At nine months post-surgery, the implants were removed and a cast-brace was applied (a, b). The bone has united one and a half months after the osteosynthesis by the closed technique with a Küntscher nail (c, d).

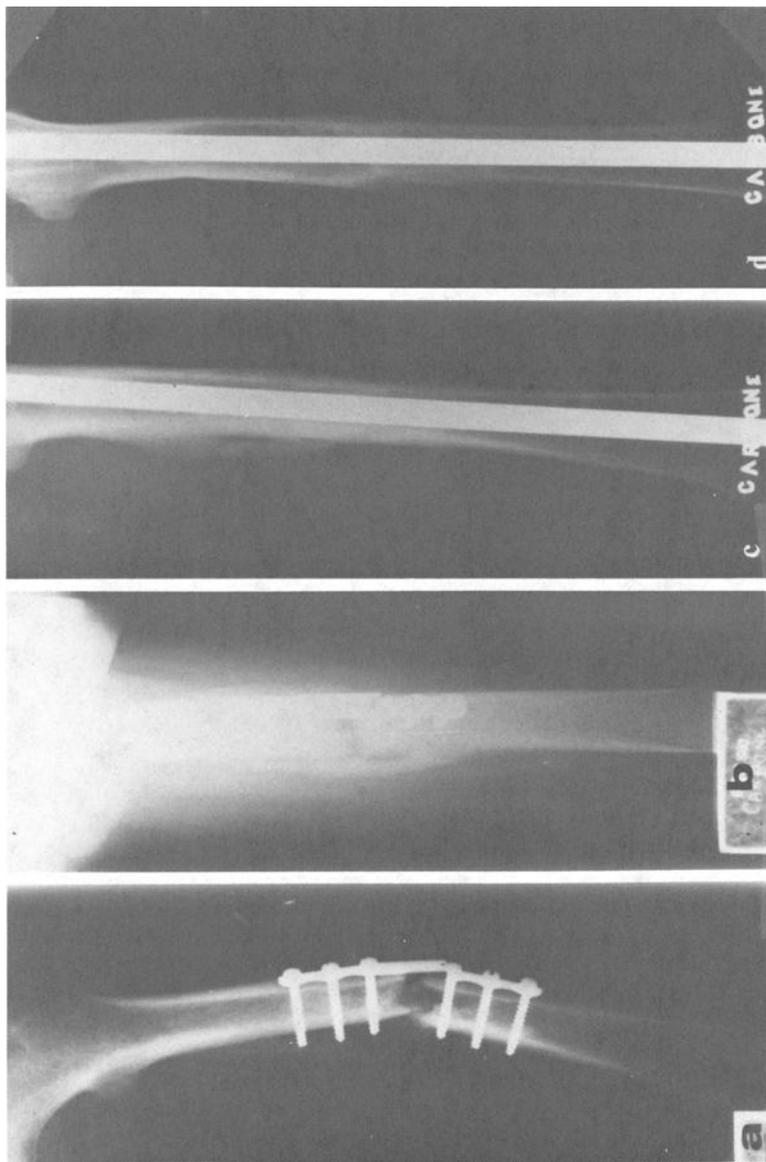


FIG. 2—Osteosynthesis by the half-closed technique: Pseudoarthrosis of one year's duration in a 16-year-old male who sustained a fracture of the femur, which was stabilized with a plate (a, b). Three months after intramedullary nailing by the half-closed technique, the bone has united (c, d).



FIG. 3—Osteosynthesis by the open technique: A 19-year-old woman sustained a fracture of the left femur, which was treated initially with a cast-brace. At four months post-surgery, the fracture was stabilized elsewhere with screws and autoplasmic bone grafting (a, b). Appearance at five months after intramedullary nailing by the open technique (c, d).



FIG. 4—Osteosynthesis by the closed technique: Nonunion of six months' duration in a 28-year-old man. The fracture had been treated elsewhere with a cast-brace. Anteroposterior and lateral radiographs before surgery (a, b) and two months after intramedullary nailing by the closed technique (c, d), showing osseous union.

Postoperative Complications

Two patients treated by an open technique had infections, one of whom recovered after a short time without removal of the implant. The other case was an osteitis which was resolved after removal of the nail, allowing for healing of the pseudoarthrosis.

Discussion

We prefer Küntscher nailing if possible without bone grafting rather than the "classical" approach of the site of nonunion including removal of the fibrous scar tissue, regularizing of the fracture ends, opening of the medullary cavity, and alignment followed by auto- or homoplastic bone grafting and osteosynthesis with a plate.

We reserved this treatment for nonunions of the medial shaft of the femur, an area contained between two imaginary levels passing as follows: one 0.07 m below the upper border of the greater trochanter of the femur and the other 0.07 m above the joint line of the knee [12].

Consolidation took place in all cases, generally with a solid and regular callus; in some cases the callus was exuberant. In our opinion, reaming of the medullary canal is an essential step in this type of surgery [13]. Our long experience with Küntscher nailing in the treatment of fractures of the femoral shaft, which always includes reaming of the cavity, has shown that this procedure does not compromise the vitality of the fracture ends. Indeed, reaming removes the fibrous tissue between bone fragments and medullary canal, allowing the nail to fit snugly within the cavity. A nail which fits snugly above and below the site of nonunion improves the stability of intramedullary fixation. Furthermore, the nail maintains the openness of the medullary cavity, a condition which is essential to healing.

Conclusions

In our opinion, Küntscher nailing, when indicated, is by far the best method to treat noninfected pseudoarthroses of the femoral shaft. The operation is not difficult to perform and minimizes risk of infection and other complications. Generally there is no need for external immobilization, thus early weight-bearing is allowed. As a result, functional recovery is more rapid, at times preceding the biological union of pseudoarthrosis.

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Ender Nail Fixation in Fractures of the Proximal Femur

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ABSTRACT: Between 1980 and 1984, a study to assess the usefulness of Ender nail fixation in the treatment of fractures of the proximal femur was conducted at the University of Tennessee Memorial Hospital. Data were recorded regarding shortening, malunion, knee pain, loss of reduction, nonunion, and pin problems. Assessment of operative time, blood loss, length of hospital stay, auxiliary fixation, and other parameters was made. This study, the first to utilize data from a large (225 cases), consecutive series of flexible nailings done by a small number of surgeons (the three authors), clearly demonstrated the advantages of Ender nailing in peritrochanteric fractures: fracture stability, decreased operative trauma, very low infection rate, and very low nonunion rate. The complication rate decreased significantly as the surgeons gained more expertise, emphasizing the importance of precision and experience in placing the Ender nails.

KEY WORDS: Ender nailing, intertrochanteric fractures, intramedullary nailing, peritrochanteric fractures, subtrochanteric fractures

Extracapsular fractures of the hip remain one of the major problems in current orthopedic practice because of high morbidity and mortality. These patients are generally older, sicker, and less tolerant of intervention than almost any other patient group. At the same time, they require rapid mobilization to prevent potentially fatal complications from recumbency. It is well known that the risk of atelectasis, pneumonia, urinary sepsis, thrombophlebitis, pulmonary embolus, and decubitus ulcers is increased at bed rest, particularly in the elderly. In theory, Ender nailing of these fractures makes good biomechanical sense; however, a high complication rate has been cited. The authors believe that the complication rate can be kept acceptably low, allowing applications of this intramedullary system to the fixation of peritrochanteric fractures of the femur. A 225-case experience will be presented.

Mechanics and Principles: Rationale

Several goals must be met by any fixation system to provide the optimum results in peritrochanteric hip fractures:

1. The bone device complex must provide strength and stability. Ender nails are intramedullary devices and are, therefore, load sharing rather than load bearing. No side plate or screws

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are required for fixation. There is considerable decrease in the bending force on the device at the fracture site because of the location near the bending axis.

2. Controlled axial sliding must be allowed to occur. The fracture must be able to impact, while alignment of the fracture fragments is maintained.

3. Insertion of the device should be as rapid and as atraumatic as possible. Less dissection of tissue in general and no dissection of muscle is required for insertion of Enders nails. No periosteal stripping or devitalization of bone occurs at or near the fracture site. Once the technique is learned well, operative time is relatively short. Blood loss is less due to the remote site of operative intervention.

Methods and Materials

The series was compiled over four years (1980 to 1984) at The University of Tennessee Hospital in Knoxville, Tennessee, where 225 consecutive peritrochanteric fractures were studied. All operative procedures and follow-up examinations were performed by the three authors. All published American series during this time (and previously) have been done in orthopedic training programs while multiple surgeons and often residents performed the cases. The patient profiles and fracture types/severities are similar to other hip-fracture series. Fractures occurred in females twice as often as in males. The majority of patients were osteoporitic; average patient age was 72 years. Forty-two percent had associated medical problems. Eighty percent of the fractures were intertrochanteric, and 20% were subtrochanteric. Fifty-four percent of the fractures were unstable and accounted for the overwhelming majority of post-op complications. Four to eleven nails were used. Ordinarily, three to four nails were used to cross the fracture and enter the femoral head. The remainder were stacking nails to fill the canal, provide interference fit, and prevent backing out. Traction was used while in bed in 3% of the patients. They were mobilized without traction bed-to-chair during the day. Average hospital stay was 17 days. Eighty-three percent of the patients were followed for six months; 58% were followed for one year or more. All were followed to union when possible.

Fracture Classification

Gaping I (20%)

This is a simple fracture due to external rotation (Fig. 1). The periosteal hinge remains intact posteriorly, and there is little loss of position. The fracture is readily reduced by internal rotation, and the nails seem to guide themselves with little effort.

Gaping II (10%)

This is also secondary to external rotation (Fig. 2). It has a significant posterior fragment, but the periosteal hinge remains intact. Reduction is usually by simple internal rotation. Care must be taken that the nails do not exit the posterior comminution as they are passed across the fracture.

Gaping III (25%)

This type is still an external rotation injury, but forces are more severe (Fig. 3). Portions of the greater and lesser trochanters may be off, and the shaft is invariably displaced laterally and migrated proximally by muscle pull. Reduction here may require disimpacting the fracture by shaking it or by the Ledbetter maneuver. After the fragments are disimpacted, they are reduced by traction, internal rotation, and abduction. It may be necessary to support behind the hip to

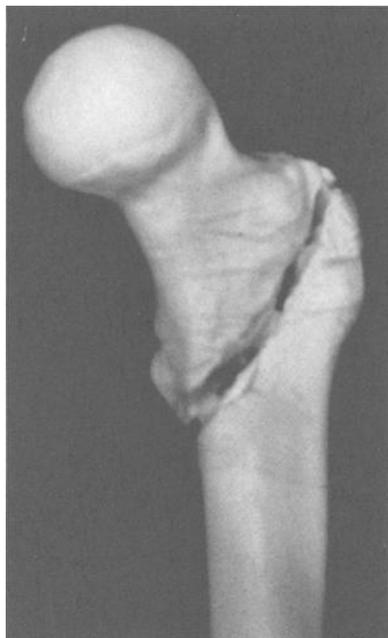


FIG. 1a—*Gaping I fracture, anterior-posterior.*



FIG. 1b—*Gaping I fracture, lateral.*

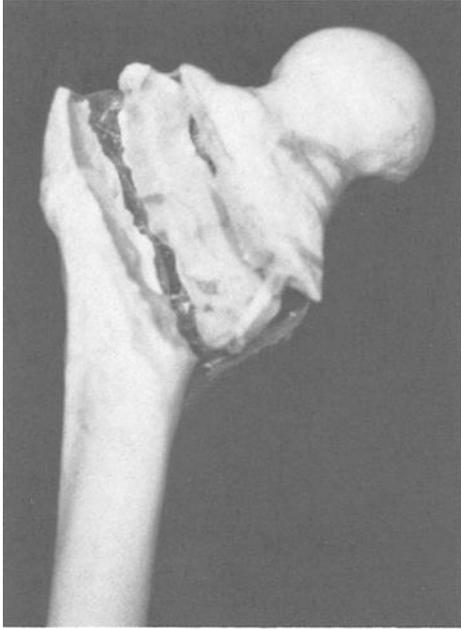


FIG. 2a—*Gaping II fracture, anterior-posterior.*



FIG. 2b—*Gaping II fracture, lateral.*

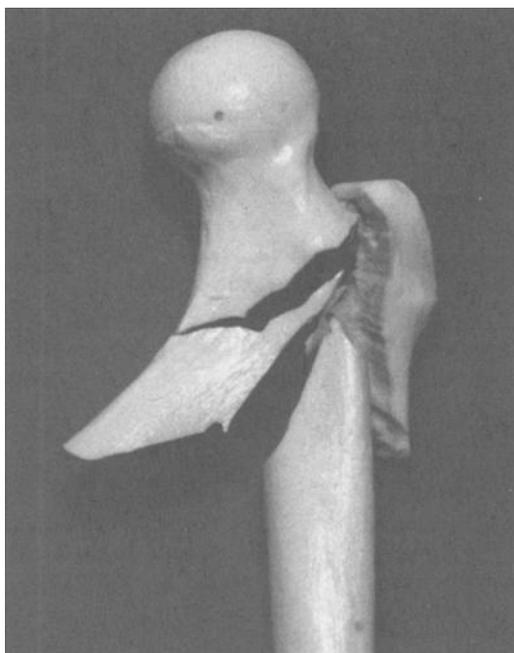


FIG. 3a—*Gaping III fracture, anterior-posterior.*



FIG. 3b—*Gaping III fracture, lateral.*

remove posterior sags. Once the fracture is adequately reduced in valgus and the fragments are impacted, it is usually stable. If shortening is too great to be tolerated, then traction may be needed. This has not been necessary in our experience and is certainly no more of a problem than the shortening that accompanies the medial displacement osteotomy.

Impacted (25%)

In this type of fracture, the head and neck fragment is simply pressed into the intertrochanteric cancellous bone (Fig. 4). There may be some additional comminution. The reduction is by traction and abduction trying to gain a valgus angulation. The fracture should be stable in this position after fixation. If the impacted calcar area is not adequately reduced, the pins can be very difficult to get to traverse the fracture site, having a tendency to come out onto the medial side of the neck fragment.

Subtrochanteric Stable (5%)

This is a transverse or short oblique fracture without much comminution. It usually results from bending forces and may be little or greatly displaced. The reduction may be somewhat difficult if the traction and extension does not work well. The pull of the iliopsoas muscle and gluteals tend to flex, abduct, and externally rotate the proximal fragment. The surgeon simply has to follow the proximal fragment with the distal fragment. It is also sometimes helpful to use the tip end of the nail to manipulate the proximal fragment into alignment. Once the fragment is aligned properly, advance at least one more nail into the head from a medial position. Then place two nails into the greater trochanter using a similar portal on the latter side to control rotation. Once repaired in this way, the patient can usually be encouraged to bear weight to pain tolerance. Accurate reduction of rotation is very important in these fractures.

Subtrochanteric Unstable (15%)

Into this heading falls a significant number of comminuted, spiral, long oblique, and other fractures. They may occur in the elderly with very poor bone and little trauma or in the young with severe degrees of trauma. The reduction must be improvised by careful attention to the fracture pattern and individualized to each case. Our main goal in treatment was to skewer the head and neck fragment onto the end of the shaft fragment in good alignment and rotation. Careful attention must be paid to length because there can be considerable shortening. These patients were not allowed to bear weight on the injured limb. These are unstable fractures by any method of treatment until callus formation has provided a medial buttress. It is our belief that the minimal trauma and maintenance of the fracture hematoma do as much or more to aid the healing of these fractures than the plating and bone grafting we had formerly used. It may occasionally be necessary to keep the patient in traction for two or three weeks until the fracture is more stable, but this has not been our experience.

Results

Average operative time including unstable subtrochanteric fractures was 42 min. Blood loss averaged 170 cc. The vast majority of patients treated with the technique described above did very well: 84% of fractures healed with excellent or good anatomical and functional result. Functional return to walking was achieved by 98% of patients who walked prior to the hip fractures. Knee pain and stiffness occurred in less than 5% after three months. The complication rate was noted to decrease drastically as experience was gained in the use of this technique. For this reason, the results have been placed into three groups: Group A represents the first 50



FIG. 4a—*Impacted fracture, anterior-posterior.*

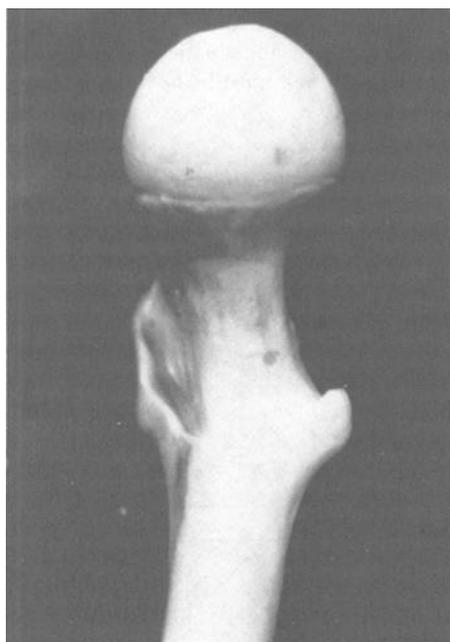


FIG. 4b—*Impacted fracture, lateral.*

patients; Group B represents the next 175 patients; and Group C, a combination of Groups A and B, therefore represents the entire patient population studied.

Complications were seen to fall into three major types. Pins being prominent at the knee caused knee pain and stiffness in some patients, although not all patients with prominent pins complained of pain or and decreased range of motion clinically (Fig. 5). In the first 50 patients (Group A), this complication occurred in 14% of the cases, whereas in the next 175 cases (Group B) it was seen only 5% of the time. Pins perforating the femoral head can be a source of hip pain even after healing, but again, not all patients with protruding pins are symptomatic (Fig. 6). In the first 50 cases, (Group A), 10% of the patients were noted to have pins protruding proximally. Ordinarily, only a single pin protruded, leaving the remaining pins in place. This decreased to 4% in the next 175 cases (Group B). Loss of fracture reduction occurred in 4% of the patients early in the series and dropped to 3% in the last 175 cases (Fig. 7). Significant malunion including external rotation deformities did not occur. There were no cases of deep-wound infection, osteomyelitis, or bending or breakage of the nails.

Discussion

There are several factors that lead to the decreased complication rate. First, the basic principles essential to all intramedullary nailing techniques were more clearly understood with time. Second, technique modification developed with repetitive "hands-on" experience. Attention to detail is critical. The key points include the following.

1. *Meticulous attention to reduction* is of paramount importance. Valgus must be restored or even increased. Restoration of femoral neck anteversion is necessary to prevent external rotation and malunion.
2. *Perfect entry portal location* must be made posterior and above the medial femoral condyle (Fig. 8).
3. *Correct nail length* must first be estimated by C-arm image but, finally, perfect length must be critically determined during the procedure.
4. *Nails must be custom fit* for each individual patient at the proximal end as well as at the knee (Fig. 9). The proximal end of the nail must be bent into increased varus as well as into

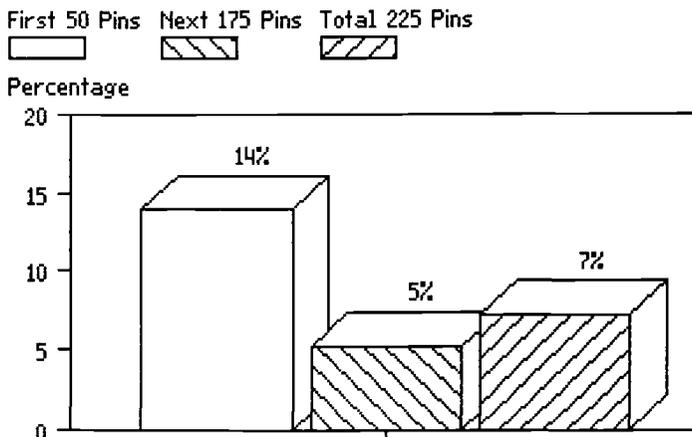


FIG. 5—Pins prominent at knee.

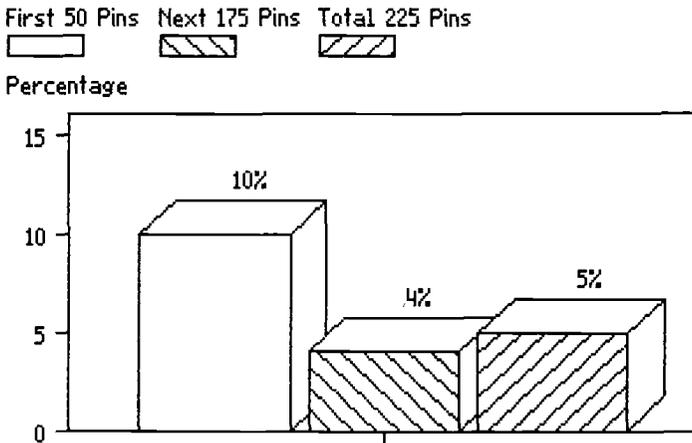


FIG. 6—Pins protruding proximally.

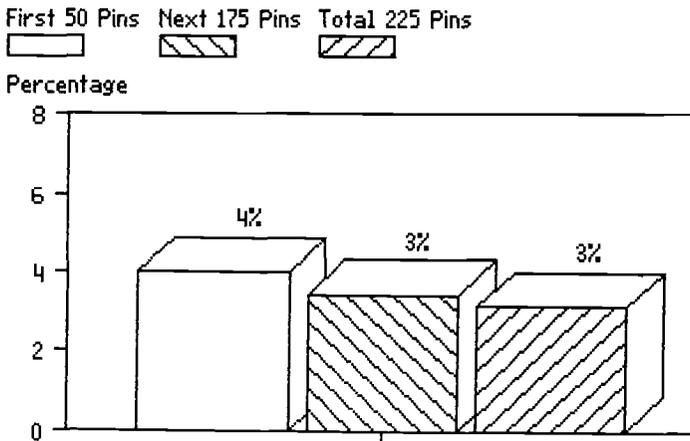


FIG. 7—Loss of reduction.

anteversion. The distal end of the nail at the knee must be straightened, and the insertion eye must be bent posteriorly.

5. *The nails must be inserted into good quality bone* in the subchondral area of the weight-bearing femoral head. At least one nail should be 1 cm from the subchondral plane in both AP and lateral C-arm views (Fig. 10).

6. *Traction must be released* during the procedure and the fracture impacted after several nails have been passed.

7. *Additional nails should be fanned out in the femoral head* to get at least four or more nails across the fracture (Fig. 11).

8. *The femoral canal must be filled with additional nails* to achieve an interference fit to avoid nail backout.

9. *At the conclusion of the procedure, an ideal knee profile must be present* with the nail eyelet countersunk or in some cases slightly inside the intramedullary canal.

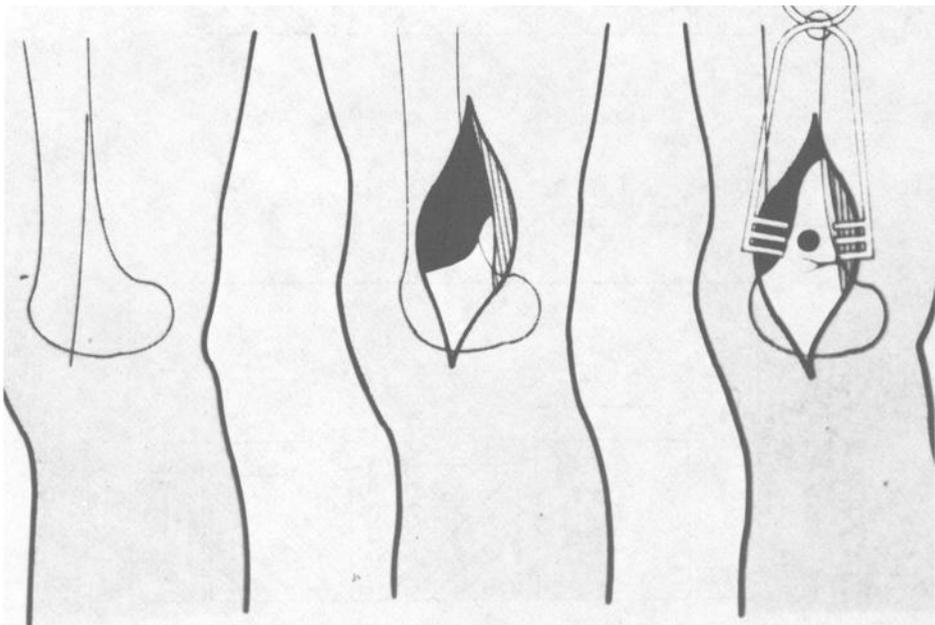


FIG. 8—*Skin incision and entry portal.*

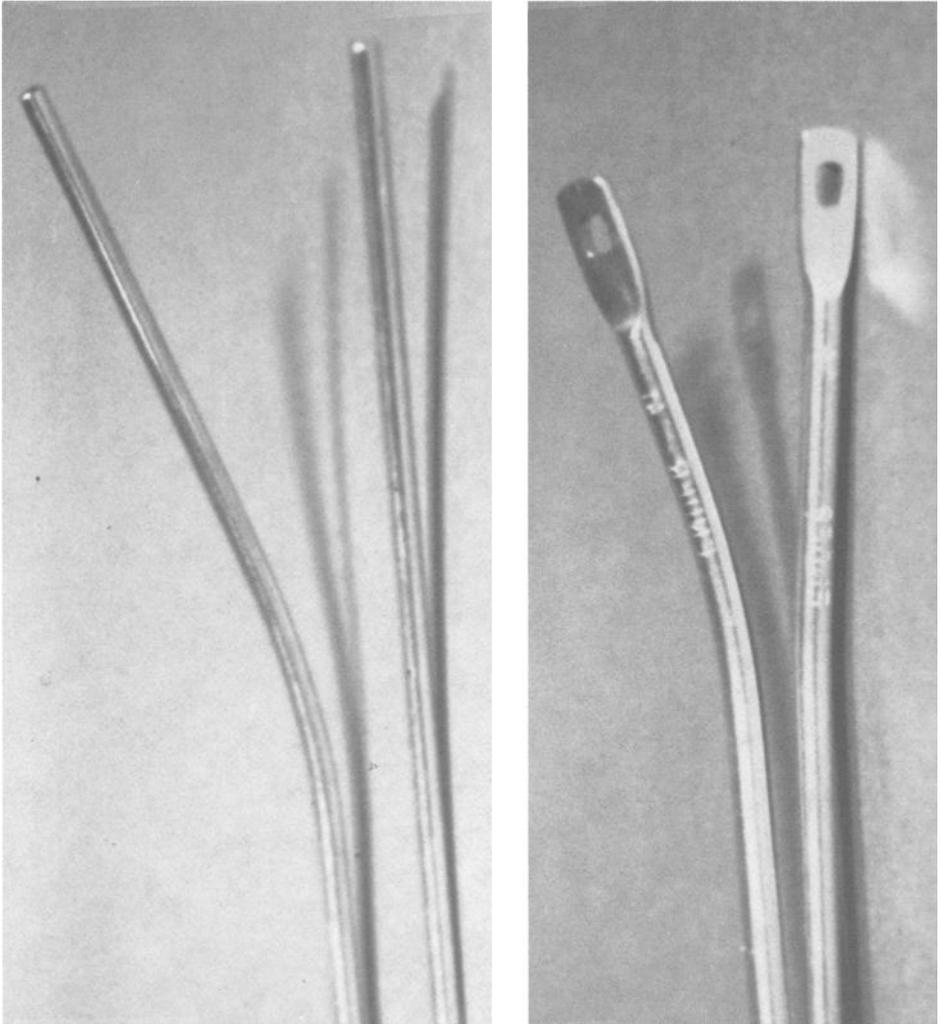


FIG. 9—Custom bending of nail: (left) proximal end; (right) distal end.



FIG. 10—*Insertion of nails to subcondral bone.*



FIG. 11—*Fanning of nails in femoral head.*

10. *The femoral head shaft and knee must be carefully checked using C-arm with adequate visualization, proving that the Ender nailing has been satisfactory.*

Conclusions

The Ender nailing technique is not difficult, but does require case repetition and experience to master. Meticulous attention to detail yields the potential benefits of this procedure without the problems. The data suggest that several published series in the United States show poor statistical results because they encompass the initial experience of many surgeons. The poor results represent the low end of the learning curve rather than any inherent weakness in the technique. Certain technical modifications have rendered this a useful tool in the treatment of a difficult fracture.

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Rush Pin Intramedullary Fixation of Transverse Diaphyseal Femoral Fractures

REFERENCE: Brueckmann, F. R., "Rush Pin Intramedullary Fixation of Transverse Diaphyseal Femoral Fractures," *Intramedullary Rods: Clinical Performance and Related Laboratory Testing*. ASTM STP 1008, J. P. Harvey, Jr., A. U. Daniels, and R. F. Games, Eds., American Society for Testing and Materials, Philadelphia, 1989, pp. 175-180.

ABSTRACT: The Indiana series is a series collected from 27 different surgeons, of 387 transverse diaphyseal femoral fractures, similarly classified and treated with nonreamed, 6.35-mm (1/4 in.) precurved Rush pins, is reported. Insertion sites are the lateral femoral condyle or greater trochanter. Reduction prior to surgery is accomplished with a special extension table with a knee support. Ninety percent of the fractures were pinned by closed technique. Open fractures occurred in 4.6% of the patients and were treated similarly. No persisting infection or nonunion was detected. Malalignment in external rotation or valgus or both was present in 1.3% of patients. Healing to painless weight-bearing is usually between ten and twelve weeks.

KEY WORDS: femoral fractures, fracture fixation intramedullary, bone nails, Rush pins

Interest in Rush pin fixation of femur fractures dates back to 1961 with D. S. Blackwell and the present author. The exceptional results of the technique in fracture care stimulated us to teach residents and staff. The Indiana series consists of patients of 27 different orthopedic surgeons in various cities in Indiana and others who understand and practice the technique and who have contributed their results under a standard reporting system.

Clinical Materials

Three hundred and eighty-seven cases of diaphyseal fractures are reported, classified according to AO method at 32-A3.2, being transverse fracture in the middle diaphysis. Twelve of the patients had bilateral fractures. Age range was between 4 and 89 years, with the predominance between 15 and 30 years of age and with men the most frequent patients. The left side was the predominant side of injury. Motorcycle and automobile accidents accounted for 88% of the fractures. Open fractures of Grade I and Grade II were present in 4.6% of the patients, and 2.3% of the patients had pathologic fractures. Associated injuries to the face, cranium, chest and abdomen, and additional other fractures were present in 40% of the patients.

Methods

The Rush pin (Berivon Company) is a work-hardened 316L stainless steel pin which, because of its high-yield strength and low modulus of elasticity, is very resilient and thus adaptable to fracture treatment.

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Preoperative treatment has varied since 1968 with the recognition of the advantages of early surgery to improve the post-fracture period and reduce pulmonary embolism, adult respiratory distress syndrome (ARDS), and to allow the other medical and surgical specialties to more easily care for the patient unencumbered by traction or cast. Skeletal traction for one week changed to Buck's traction overnight in planning to leave the femur shortened until surgery. The current plan is immediate internal fixation of all long bone fractures, usually in conjunction with neurosurgery, thoracic surgery, and with the assistance of abdominal vascular and urologic surgeons.

Early surgery within a few hours of admission has been found to reduce the difficulty for fracture reduction and is the primary time for treatment.

Antibiotics are used in 85% of the patients prophylactically and 8% therapeutically. The 4.6% of the patients with open Grade I and Grade II fractures were treated by debridement and internal fixation with the wound packed open at the present time. Early in the series, debridement, skeletal traction and, later, pinning were done, but experience has shown that these treatments make no difference to the infection rate.

The operative treatment has varied little with the exception of the surgery time, which has been markedly reduced by the use of an appropriate fracture table, which facilitates reduction, and by image intensification for viewing the fracture in surgery.

The fracture table (Berivon Company, Meridian, Mississippi) with the knee support has made reduction simple by providing the same vector forces on the fractured femur as those provided in Russell's traction in the supine position. Reduction, or the ability to reduce the fracture, is paramount to ease of internal fixation treatment.

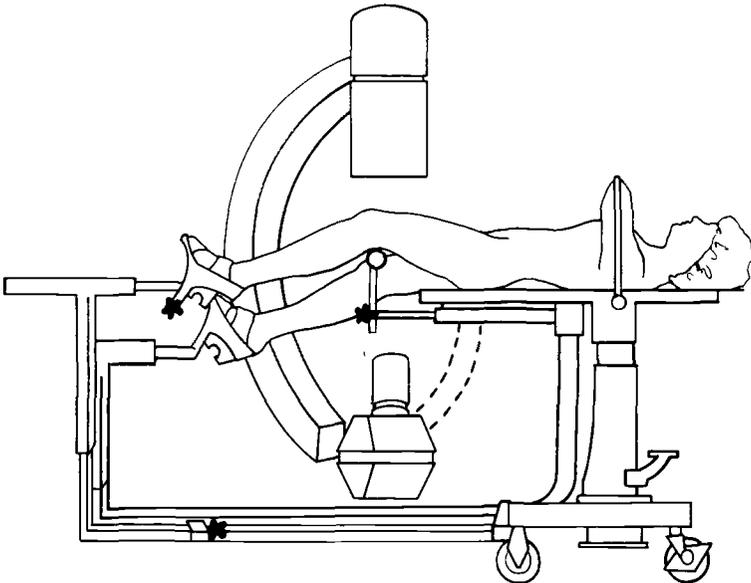


FIG. 1—Extension table with adjustable counter support which creates vector forces for reduction.

I have modified the knee counter support for bilateral femoral fractures so that the femurs are at different levels when seen from the lateral view and are thus divergent. Lateral X-rays with the image intensifier allow for no change in the draping while fixing the femurs either singly or jointly.

The concept of holding the fracture with a precurved pin, bent to the diameter of the medullary canal to provide rotational and fracture stability, is essential to this technique [1]. The length of the 6.35-mm ($1/4$ in.), work-hardened resilient pin is from the insertion site to the cancellus bone of the lateral femoral condyle or the greater trochanter.

Awl insertion sites are either the lateral greater trochanter or the anterior half of the lateral femoral condyle. The greater trochanter is used when the fracture is closer to the proximal end of the diaphysis because it allows the pin, when inserted into the fracture site, to be used as a lever to help reduce the fracture. The precurved pin, with its sled runner point, allows the pin itself to be rotated to reduce the fracture. The awl insertion angle is the most unforgiving portion of the surgery and should ultimately be 30 deg to the long axis of the femoral shaft. Awl

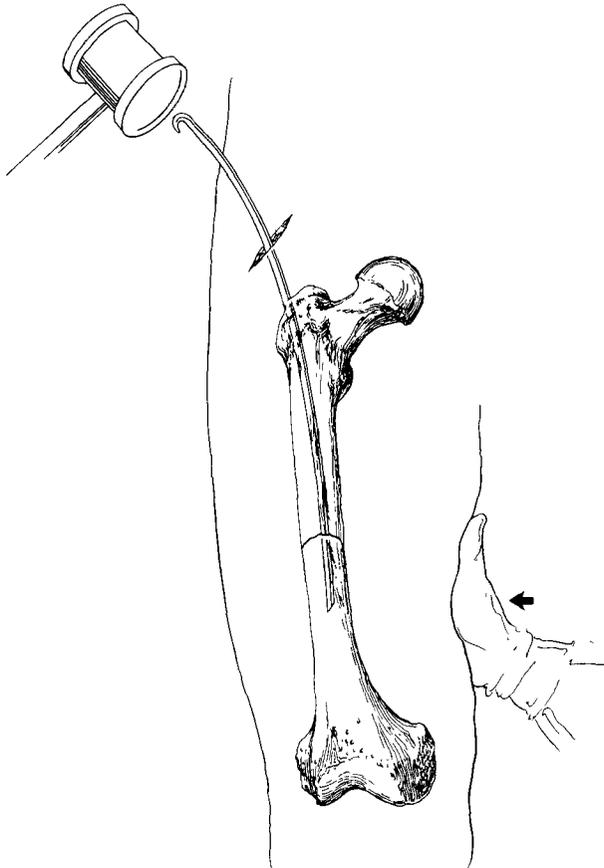


FIG. 2—Curved pin inserted in the greater trochanter.

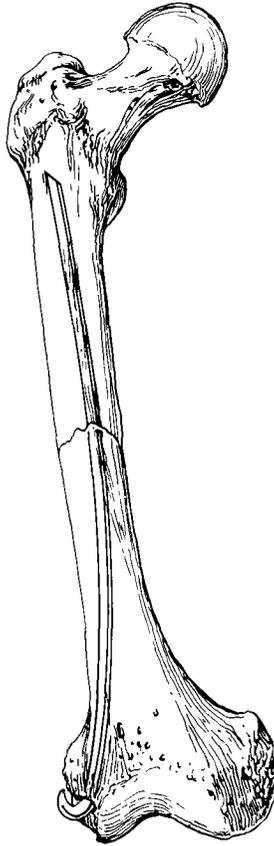


FIG. 3—*Curved pin inserted in the lateral femoral condyle.*

insertion at the lateral femoral condyle must be in line with the proximal femoral shaft and is thus in the anterior third of the condyle.

No attempt should be made to conform to the anterior bow of the femur.

Open treatment of the fractures by the semi-open or finger reduction technique, which was used in 5.4% of the patients when the fractures could not be reduced closed, means that for a total of 10% open fractures, actually 4.6% of the fractures were compound or open fractures to start with.

The usual anesthesia time was less than an hour in uncomplicated, single-fracture patients.

Postoperative management is dependent upon the overall condition of the patient. No cast or bracing is needed; in fact, it is generally a detriment. Ideally, an anterior plaster splint is applied while the knee lies over the counter-support after surgery is over, and then the lower extremity is elevated to the overhead bar of the fracture bed until the patient is more comfortable and thigh swelling is decreased. When the anterior splint is removed, the patient, by sitting on the side of the bed, immediately has 80 to 90% knee motion, and quadriceps exercises can be begun. Crutch training with toe touching is advised. Initiating any formal physical therapy in single-fracture patients has rarely been necessary. Anti-embolism hose, elastic bandages, or aspirin have been generally used for prophylaxis of embolism, but no protocol has been standard.

Young patients have been advised to have their Rush pins removed approximately one year post-surgery.

Results

Follow-up has been good, with 5% followed less than ten months post-surgery. Three people died in the hospital with multiple injuries; three died in long-term follow-up, presumably due to metastatic disease and disability.

Healing time to painless weight-bearing is usually between ten and twelve weeks and did not correlate with disappearance of the fracture line on X-ray. The physician seldom removed the pin at that time, even in young people, but waited until radiographic remodeling was seen. Seventy-eight percent of the pins were removed by two years post-fracture.



FIG. 4—Mid-shaft fracture 11 months after closed pinning with curved, 6.25-mm pin.

Complications

No non-union or persistent infections have been found in our series of 387 patients, with follow-up between 11 and 18 months, but slow healing has been present in 2.6%. This did not result in pin failure or a second surgery of bone grafting.

Malalignment of less than 20 deg in external rotation or 10 deg of valgus or both has been a problem in 1.3% of patients.

Opening the fracture site by the semi-open technique or with the Grade I or II open fractures did not cause infection or non-union.

No peroneal nerve palsies were reported, but neither were they seriously looked for.

Embolism or ARDS was seen in 3% of the cases, but did not affect the outcome at final review. The management of those with the disease was greatly facilitated, since the patients could be moved from the bed as necessary.

Discussion

Since pin fixation in shaft fractures of the humerus and tibia utilizes the same instruments and basic techniques [3] and since fractures of the condylar ends of these bones and other bones use the same instruments, but different techniques [2], proficient use of basic techniques carry over to a shorter "learning curve." Fewer instruments and pin inventory reduce hospital expense.

Conclusion

The Indiana series of nonreamed, 0.35-mm (1/4 in.) Rush pin fixation of diaphyseal transverse femur fractures has had excellent results in the hands of Indiana orthopedic surgeons properly using the technique. As with all surgical techniques, attention to detail in surgery and postoperative care is essential for maximizing results. Its use in polytrauma, bilateral femoral fractures, and open fractures specifically highlights its unique position for rapid, effective fixation with minimal disturbance of bone healing.

Acknowledgments

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Mechanical Complications Following Interlocking Femoral Nailing

REFERENCE: Wiss, D. A. and Brien, W., "Mechanical Complications Following Interlocking Femoral Nailing," *Intramedullary Rods: Clinical Performance and Related Laboratory Testing, ASTM STP 1008*, J. P. Harvey, Jr., A. U. Daniels, and R. F. Games, Eds., American Society for Testing and Materials, Philadelphia, 1989, pp. 181-189.

ABSTRACT: Two hundred and sixty-two fractures of the femoral shaft were treated with the Grosse-Kempf interlocking nail. Mechanical complications occurred in 26 cases (10%): There were five broken nails (2%), four bent nails (1.5%), four proximal screw failures (1.5%), and thirteen major torsional deformations of the nails (5%). Four of the five broken nails were in previously open fractures and were associated with nonunion of the fracture. Two of the nails broke at the junction of the proximal threaded conical portion and the slot in the nail, one occurred at the nonunion site, and two occurred through the proximal of the two distal screw holes. Eccentric portals of entry led to nail deformation in two patients, and additional trauma led to bending in two other patients. There were four failures of the proximal interlocking screw; three of the four broken screws occurred in comminuted subtrochanteric femur fractures treated with static locked nails. Minor degrees of torsional deformation of the nail were seen in up to 50% of the cases. However, major torsional deformation was seen in only 13 patients (5%). Mechanical complications following locked nailing appear to be acceptably low. Their enormous clinical efficacy appears to justify their continued use.

KEY WORDS: fractures, fixation, intramedullary

Readily available information on closed nailing procedures, together with the widespread availability of image intensification, has made closed intramedullary nailing the treatment of choice for most simple diaphyseal fractures of the femoral shaft in adults. Nearly 50 years of worldwide experience with femoral nailing has shown it to be a safe, reliable, and cost-effective method of treatment. With the introduction of locking nails into the United States in the 1980's, the indications for closed femoral nailing have expanded significantly [1,2]. Closed femoral nailing can now be performed in patients who previously would have required an open reduction or traction and casting to manage their femur fracture.

Deformation and mechanical failure of intramedullary nails is an uncommon but well-recognized complication [3]. The marked increase in the number of femoral nailings done in our hospital, together with the increased mechanical demands placed on the interlocking nails, has led to an increased number of complications. The purpose of this paper is to review the mechanical complications following Grosse-Kempf interlocking nailing of complex fractures of the femur.

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Materials and Methods

In a prospective study, 406 patients with 408 comminuted or rotationally unstable fractures of the femur were treated with the Grosse-Kempf interlocking femoral nail between 1983 and 1986. Adequate clinical and radiographic follow-up were available in 260 patients with 262 fractures. There were 220 males and 40 females with an average age of 31 years. The fracture was on the right side in 141 and on the left side in 121. The vast majority of fractures were the result of high-energy trauma secondary to motor-vehicle or motorcycle accidents (Table 1). One hundred and eighty-eight fractures (72%) were closed and seventy-four (18%) were open. While most of the fractures were located in the middle third of the femur, a significant number of injuries were either proximal or distal (Table 2). Fracture comminution was graded and classified according to the method of Winquist and Hansen (Table 3). Of the 262 nailings, 189 patients were static locked, 34 were proximal dynamic locked, 27 were distal dynamic locked, and 12 were "reversed" locked.

Results

Two hundred and sixty patients with 262 fractures were followed until fracture union. Follow-up ranged from 5 to 34 months, with an average follow-up of 13.5 months. Closed femoral nailing was achieved in 90% of the cases. The average surgical time, including setup on the

TABLE 1—*Mechanism of Injury.*

Trauma	Patients, %
Motor vehicle	35
Motorcycle	27
Gunshot wounds	14
Pedestrian versus automobile	11
Fall	10
Other	3

TABLE 2—*Fracture location.*

Location	Patients, %
Proximal third	25
Middle third	48
Distal third	15
Segmental	12

TABLE 3—*Fracture comminution.*

Fracture	Patients, %
Grade I	11
Grade II	16
Grade III	31
Grade IV	39

fracture table, was 2 h 58 min. Blood loss averaged 390 mL per case. There was an average of eleven pre-operative days and nine post-operative days.

Fracture union was defined as the period between operation and full weight-bearing without external support and a radiographically healed fracture. The average time to bridging callus was 8.3 weeks and to cortical bridging was 23.1 weeks. Two hundred and fifty-five (97%) fractures united, and there were seven (3%) nonunions. Six of the seven nonunions healed following renailing, and one healed following cancellous bone grafting. Only eight (3%) fractures had shortening greater than 1 cm, while ten (4%) fractures were lengthened more than 1 cm. The most common complication was angulation. Twenty-six fractures (10%) had varus or valgus between 5 and 10 deg, while in ten fractures (4%) varus-valgus angulation between 11 and 20 deg was noted. Apex anterior or posterior angulation between 5 and 10 deg occurred in 24 patients (9%) and between 11 and 20 deg in ten fractures (4%). There were four wound infections: two incisional, one late deep infection, and one bullet-tract infection. All resolved with either incision and drainage or local wound care, in conjunction with high-dose intravenous antibiotics.

Mechanical Complications

Mechanical complications occurred in 26 cases (10%): There were five broken nails, four bent nails, four proximal screw failures, and thirteen major torsional deformities of the nail. Of the five broken nails, four were statically locked for highly comminuted fractures and were never "dynamized." Four of the five broken nails were in previously open fractures and were associated with nonunion of the fracture. Two of the nails broke at the junction of the proximal threaded conical portion and the slot in the nail, one occurred at the nonunion site in a middle third shaft fracture, and two occurred at the proximal of the two distal screw holes. All five fractures healed following removal of the broken implant and renailing with a larger nail (Fig. 1).

In four patients, the nail bent. Eccentric portals of entry led to nail deformation in two patients, and additional trauma led to bending in two other patients. All four fractures healed without further surgery, although one patient has a 15-deg varus deformity (Fig. 2).

There were four failures of the proximal interlocking screw. Three of the four broken screws occurred in comminuted proximal third (subtrochanteric) femur fractures treated with static locked nails. Three of the four patients walked early without external support before there was bridging callus. Two patients healed without problems; however, in the other two patients, deformity developed. In one patient 12 mm of shortening occurred, and in the other patient 10 deg of external rotation was noted (Fig. 3).

Minor degrees of torsional deformation of the nail were seen in up to 50% of the cases. However, major torsional deformation was seen in 13 patients (5%), making distal screw insertion ever more difficult.

Discussion

Improvements in implant manufacturing as well as a better understanding of the biomechanics of intramedullary nailing have made mechanical complications following intramedullary nailing an uncommon event. This is due in part to the fact that intramedullary nails are weight-sharing implants rather than weight-bearing devices, as are plates and screws [4]. Unfortunately, no quantitative information is available on the load sharing that occurs between an implanted medullary nail and a newly fractured or healing femur [5]. Comminuted fractures fixed with an interlocking nail, however, share some of the mechanical characteristics of both nails and plates and screws. In complex fractures where direct contact between the bone ends does



FIG. 1—Breakage of a statically locked Grosse-Kempf femoral nail 14 months following injury. The fracture has failed to unite.

not exist secondary to fracture comminution, tremendous stress is transferred to the nail and locking screws [6, 7].

The "working length" of an intramedullary nail is defined as that portion of the nail crossing the fracture site between two areas of contact proximally and distally. The "working length" of the nail plays a major role in both the strength and rigidity of the fixation. This is important because rigidity in torsion is inversely proportional to the working length. Doubling the working length halves the rigidity in torsion. On the other hand, stiffness in bending is inversely proportional to the square of its working length. A nail with a working length of 5 mm is 16 times as rigid in bending as a nail with a working length of 20 mm [8].

Deformation of a reamed intramedullary nail is produced by mechanical bending of the nail within the medullary canal as the limb is loaded on movement or weight-bearing [3]. Clinically, this has been attributed to small-diameter nails, fracture comminution, premature weight-bearing, and abnormal stresses across the fracture site. The resistance of a nail to bending is determined by several factors, including the elastic properties of the materials, the length of the



FIG. 2—Nail deformation in the distal tip of the nail following a second accident three months after initial nailing.

implant, and the cross-sectional diameter and geometry. Nail failure occurs in one of three patterns: plastic failure, brittle failure, or fatigue failure. The most common pattern is fatigue failure caused by repetitive cyclical loading in bending and torsion [8].

Actual breakage of the nail can be divided into two types. Early breakage of the nail is almost always the result of an undersized nail used in the management of a comminuted fracture. Late breakage can be divided into two subtypes. In one, the failure is remote from the fracture site and has little effect on the stability of fixation or the healing of the fracture [5]. The second late failure pattern is breakage associated with delayed union or nonunion of the fracture itself. In this circumstance, failure usually occurs in the weak areas of the nail. In our series, two implants broke at the junction of the cylindrical and slotted portion of the nail. One occurred at the nonunion site in the middle third of the femur and two occurred at the proximal of the two distal screw holes. Of the five nonunions, four cases were previously open fractures which failed to unite despite adequate nailing. In the remaining case, a mentally disturbed patient with a distal comminuted gunshot fracture broke through the proximal of the two distal screw holes at eight weeks when he walked without support. All five patients healed their fracture following

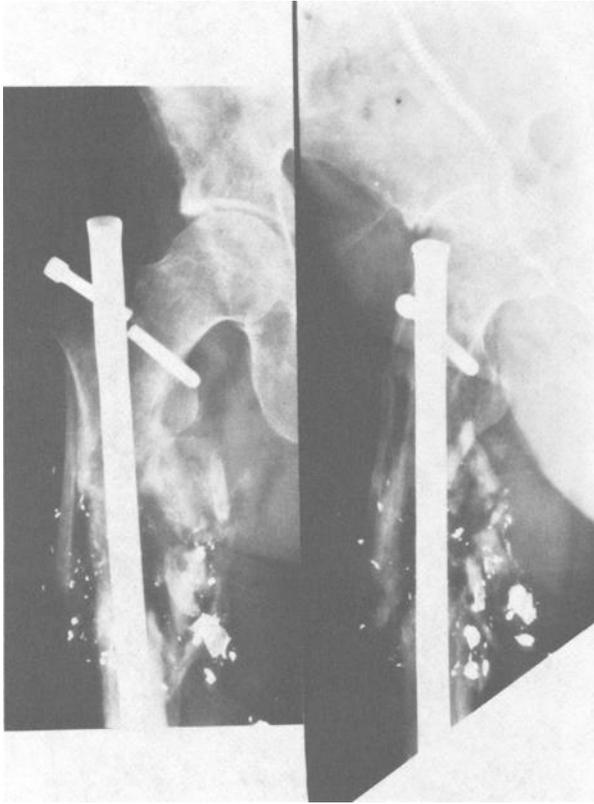


FIG. 3—Proximal screw failure ten weeks following static nailing of a comminuted subtrochanteric fracture.

removal of the implant, re-reaming, and insertion of a larger nail. Removal of the distal broken segment of the nail should be done closed, using specially designed hook extractors.

Deformation of the nail secondary to plastic failure of the stainless steel occurred in four patients. Two were the direct result of faulty portals of entry. Abnormal starting portals, particularly those which are located too far anteriorly, result in increased hoop stresses leading to eccentric reaming, iatrogenic comminution, or nail deformation [9]. If this complication is to be avoided, confirmation of the correct starting point in the piriformis fossa using the image intensifier is essential.

Two other patients bent their nails in a subsequent accident. These were minor in nature and were more a radiographic curiosity than a clinical problem. This unusual problem could be minimized by nail removal following fracture union. However, most trauma authorities recommend leaving an intramedullary nail in place for at least 18 months. Obviously, repeat trauma within a year and half of nailing leading to nail deformities or breakage cannot be controlled.

There were four failures of the fully threaded proximal interlocking screw. All occurred in subtrochanteric femur fractures. Three of the four cases had been statically locked and in the remaining case dynamically locked proximally. Biomechanical studies have shown that the subtrochanteric region is an area of high stress concentration [6, 7, 10]. Enormous demands are placed on the nail and proximal screw, particularly in very proximal comminuted fractures

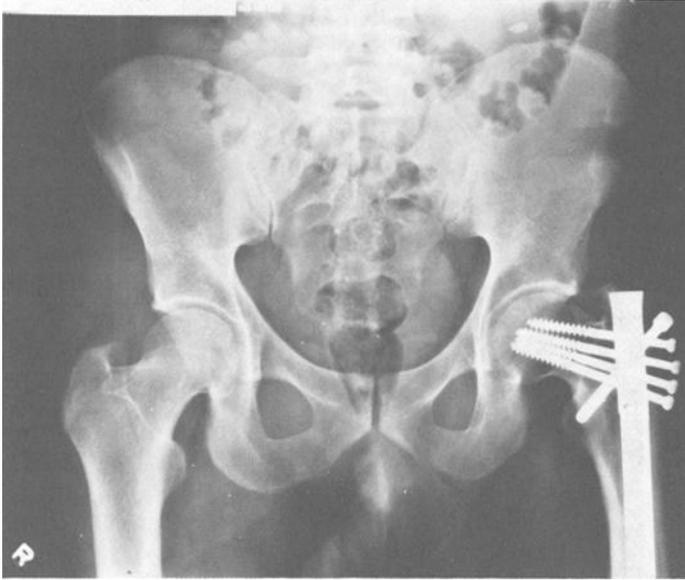


FIG. 4—Late failure of a Grosse-Kempf nail at the junction of the conical and slotted portion of the nail.

which require a static lock. Bending, torsional, and shear stresses led to fatigue failure of the proximal screw in these four patients. In two patients, screw breakage occurred late but had no effect on the fracture outcome. In two other patients, failure occurred early (eight and ten weeks), leading to increased external rotation and shortening, respectively. Newer nail designs which direct two larger proximal screws into the head and neck of the femur might reduce this complication.

Minor degrees of torsional deformity of the nail were noted in nearly half of the patients in the series. This is due to the inherent torsional weakness of the slotted Grosse-Kempf nail. Allen et al. [8] have shown that a closed-section cylindrical nail has a torsional moment of inertia 50 times greater than an equivalent open-section (slotted) nail. It is worth reemphasizing that torsional rigidity of a slotted nail is inversely proportional to the working length: as the working length of the nail increases, rigidity in torsion decreases significantly. Since the most common indication for a locked nail is a comminuted length unstable fracture, long working lengths are the rule rather than the exception. In this series, three fourths of the fractures were statically locked and two thirds of those fractures had Winquist-Hansen Grade III or IV comminution. The torsional weakness is of course offset in part by the addition of locking screws. In 13 patients, significant torsional deformation of the nail occurred, making distal screw insertion difficult. In many of these cases, the limitations of the rotational excursion of the C-arm image intensifier required complete repositioning of the image to facilitate screw insertion. In other cases, the screws had to be placed through the quadriceps mechanism, jeopardizing knee motion. Torsional deformation of a slotted interlocking nail has been the major obstacle to the development of a nail-mounted external targeting device for distal transfixing screws. One solution to this problem has been the design and implementation of closed-section locking nails. However, due to their increased stiffness in bending and torsion, they have the theoretical disadvantage of stress shielding and may minimize callus formation.

In conclusion, mechanical complications following locked nailing appear to be acceptably low (Table 4) [11,12]. The enormous clinical efficacy of locking nails appears to justify their



FIG. 5—Perforation of the cortex during nail insertion in a massively obese patient.

TABLE 4—Mechanical complication rates.

Complication	Patients, %
Minor torsional deformity	50
Major torsional deformity	5
Broken nails	2
Bent nails	1.5
Proximal screw failure	1.5
Distal screw failure	<1

continued use. In view of the low breakage rate, these failures do not represent a major clinical problem. However, nail breakage following closed nailing must be assumed to be associated with a delayed union or nonunion until proven otherwise. The risk appears to be greatest for comminuted subtrochanteric fractures treated with statically locked nails. Newer nail designs are expected to reduce mechanical complication even further.

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