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Mechanical tests and finite element models for bone holding power of tibial locking screws

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Abstract

Objective. To investigate the bone holding power of tibial locking screws.

Design. The bone holding power was assessed by mechanical testing and finite element analysis.

Background. Screw loosening might threaten fracture fixation and bone healing.

Methods. In mechanical tests, six types of different tibial locking screws were inserted into low-density polyurethane foam tubes, which simulated osteoporotic bone. The screws were pushed out of the foam bone by an axial load, and the maximal pushout load was recorded. In finite element analysis, three-dimensional finite element models with a nonlinear contact interface between the screws and the bones were created to simulate the mechanical testing. The total strain energy of the bone and total reaction force of the screws were recorded. The contribution of the design factors was analyzed by the Taguchi method.

Results. In the mechanical tests, foam bone was stripped by the screw threads without screw deformation. The testing results were closely related to those of finite element analysis. The Taguchi analysis showed that the descending order of contribution of the design factors was outer diameter, pitch, half angle, and inner diameter. Root radius and thread width had minimal effects.

Conclusions. The bone holding power of the screws could be reliably assessed by finite element models, which could analyze the effects of all the design factors independently and were potentially applicable to screws with irregular thread patterns.

Relevance

The finite element models built in this study may help manufacturers in evaluating new designs of locking screws and assist surgeons in selecting suitable devices for patients with severe osteoporosis.

Keywords: Finite element analysis; Holding power; Tibial screw

1. Introduction

Interlocking nailing has been effectively used to treat tibial shaft fractures because of its advantages of minimal tissue injury and high fixation stability (Brumback, 1996), but mechanical failure of the locking screws may result in loss of fracture fixation and impairment of fracture healing (Brumback, 1996; Westmoreland et al., 1995). Modification of the screw design to improve mechanical strength, however, may jeopardize the bone holding power (Krag et al., 1986; Lin et al., 2001; Willett et al., 1993), especially in bones with severe osteoporosis (Kwok et al., 1996; Leggon et al., 1993; Okuyama et al., 1993). Loosening and back-out of the locking screws may lead to loss of fracture fixation or impairment of the fracture healing. The bone holding power and its relationship to the geometry and dimensions of the screws have been extensively investigated on different kinds of screws, but the results related to the effects of the design parameters on the bone holding power have varied (Chapman et al., 1996; DeCoster et al., 1990; Halsey et al., 1992; Krag et al., 1986; Kwok et al., 1996; Leggon et al., 1993; Lin et al., 2001; Liu et al., 1995; Thompson et al., 1997; Willett et al., 1993). The finite element method—a powerful tool for computing the stress and strain inside an arbitrary structure—can be

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used to investigate this problem rigorously. This method with its advantage of avoiding the experimental errors and the confounding effects of inter-specimen variation can cover as wide a range as desired and can determine the real effects of each design factor independently (Dar et al., 2002).

In this study, the bone holding power of tibial locking screws was assessed by straight axial pushout tests. Pushout strength correlated to the maximal screw striping torque can be a good measure of holding power (Lin et al., 2001). Then finite element models were developed, and the analytical results were correlated to those of the mechanical tests. The applicability of the finite element models was confirmed by changing the loading conditions, material properties, and interface properties. Then the contribution to bone holding power of each design factor of the screws was analyzed systematically by the Taguchi robust design method (Dar et al., 2002).

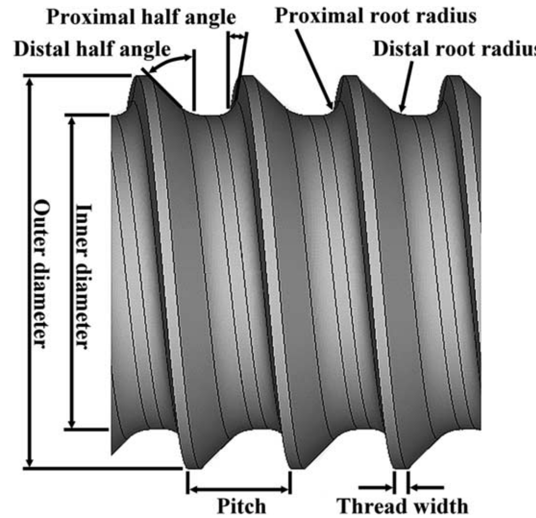

Fig. 1. Schematic diagram of a locking screw.

2. Methods

2.1. Structures of the tested screws

Five types of commercially available fully threaded tibial locking screws—Synthes (Synthes, Paoli, PA, USA), Howmedica (Howmedica, Rutherford, NJ, USA), Richards type I, Richards type II (Richards, Memphis, TN, USA), Osteo AG (Osteo, Selzach, Switzerland), and one type of specially designed, both-ends-threaded screw—were tested in this study. The design rationale of the both-ends-threaded screw was to use a smooth shank in the middle to improve the mechanical strength. The proximal threads, which are larger than the distal threads, could achieve better bone purchase at the near cortex and did not jeopardize the strength of the nail. All the screws were made from 316L stainless steel, and the dimensions of these locking screws were measured with a Surface Roundness RA-100 (Mitutoyo, Kawasaki, Japan) including the outer diameter, inner diameter, root radius, pitch, half angle, and thread width (Fig. 1) (Table 1). All of the locking screws had a self-tapping tip, and their length was about 50 mm.

Table 1
Geometry and mechanical properties of six locking screws

Geometry and mechanical properties	Synthes	Howmedica	Richards type I	Richards type II	Osteo AG	Both-ends-threaded
Outer diameter (mm)	4.88	4.46	4.5	4.96	4.96	4.48[a] 6.04[b]
Inner diameter (mm)	4.32	3.80	3.71	3.96	3.52	3.59[a] 4.97[b]
Proximal root radius (mm)	0.3	0.4	0.1	0.23	0.2	0.1
Distal root radius (mm)	0.3	0.4	0.4	0.43	1	0.1
Pitch (mm)	2.75	1.48	1.26	1.29	1.74	1.50
Proximal half angle (°)	30	22.5	10	10	10	40
Distal half angle (°)	30	67.5	45	45	35	30
Thread depth (mm)	0.28	0.33	0.395	0.5	0.72	0.445[a] 0.535[b]
Thread width (mm)	0.5	0.2	0.3	0.15	0.1	0.17
Calculated shear area (mm^2)	85.62	88.05	96.22	112.72	115.08	114.16
Pushout strength (N) in density of 0.5 g/cm^3	494 (47)	503 (65)	585 (56)	644 (31)	673 (63)	690 (42)
Pushout strength (N) in density of 0.25 g/cm^3	160 (22)	182 (55)	197 (23)	234 (28)	225 (25)	256 (22)
Total strain energy (10^{-3} J)	39.04	39.92	41.76	44.02	43.24	45.88
Total reaction force (N)	7.84	8.00	8.38	8.82	8.68	9.12

Values are expressed as mean (SD).
[a] Distal threads.
[b] Proximal threads.

2.2. Mechanical tests of bone holding power

Two kinds of cylindrical tubes made from polyurethane foam (Bayer, Leverkusen, Germany) with different densities were used for the mechanical tests. The first had a density of 0.25 g/cm^3 and the other had a density of 0.5 g/cm^3 with additional fiber reinforcement. The tubes of foam bone had an outer diameter of 40 mm and inner diameter of 30 mm. The measured compressive moduli of the foam bones were 0.04 and 0.36 GPa, respectively. We used a foam bone with a relatively low density and modulus, close to that of the cancellous bone (Hayes, 1991), to simulate the cortex at a metaphyseal region with severe osteoporosis. The locking screws were inserted through the center of the cylindrical foam bone at 30-mm intervals to prevent interference between neighboring screws. For fair comparison, the pilot hole was 3.5 mm in diameter for all the screws, and the screws were inserted without tapping until the screw cap abutted against the surface of the foam bone. Then the screws were axially loaded at the screw tip and pushed out of the foam bone by the actuator of the material testing machine (Bionix 858, MTS Corporation, Minneapolis, MN) (Fig. 2). Pushout tests have two key advantages over pullout tests: less bending moment when the screws are loaded and a simpler testing setup. The loading mode was displacement control with a loading rate of 2.5 mm/min. The experiment was terminated when the displacement of the actuator reached 5 mm, and the maximal load was recorded as the pushout strength. The tests were performed on six new screws of each type. After the tests, the foam bones were carefully inspected and the locking screws were rechecked for any possible deformation.

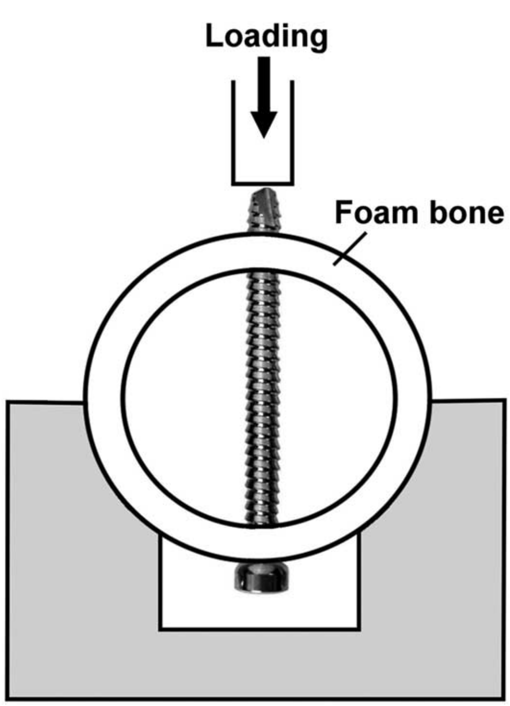

Fig. 2. Configuration of testing set-up.

2.3. Predicted relative pushout strength

According to the description of mechanical fasteners in *Machinery's Handbook* (Oberg et al., 1996), if the nut is made of a material with lower strength than that of the screw, then when the screws are axially loaded, stripping of the nut, which may take place before the screw breaks, can be predicted by shear areas of the threads. The shear areas of the nuts can be calculated by the mathematical formula: $\pi D[0.5p + \tan(30°)(D - d)/2]n$, where D = outer diameter of the screws; L = length of the screws engaged in the cortices; p = pitch; d = inner diameter; n = the number of threads per unit length ($n = L/p$). Here, 30° are the fixed half angle of the screw thread. This formula, rewritten as: $\pi DL \times [0.5 + 0.57735(D - d)/(2p)]$ has also been used to predict the holding power of different orthopedic screws (Asnis et al., 1996; Brown et al., 2000; Lin et al., 2001). In this study, the shear area of the bone by each type of tibial locking screw was calculated accordingly. For the both-ends-threaded screws, the shear area of each cortex was computed separately and summed.

2.4. Finite element analysis

Three-dimensional finite element models were established with the use of commercial software ANSYS 5.7 (Canonsburg, PA, USA). The computer used was an Intel Pentium IV-2.53 GHz with 1 Gb RAM. The three-dimensional models were built according to the measured geometries of the locking screws. Surface models were first generated by helical sweep of a predetermined thread with Ansys Parametric Design Language (APDL). Then the surface models were transformed to three-dimensional models by subtraction from a solid cylinder with the use of Boolean operation. To reduce the computational time, the finite element models of the screw anchoring in the cortex were established by inserting a 4-mm-long locking screw at the center of a round plate of bone with a thickness of 3 mm and an outer diameter of 20 mm (Fig. 3). The material of the locking screws was stainless steel with an elastic modulus of 230 GPa. The cortical bone made from an isotropic material with an elastic modulus of 0.36 GPa was intended to simulate osteoporosis. The Poisson's ratio was 0.3 for both locking screws and bones. The locking screw was opposed to the bone with a nonlinear contact interface without any frictional force. The contact layers between the locking screws and the bones were free-meshed, and the rest of the models were map-meshed using high-order 20-node brick elements of SOLID 95, which allowed various element shapes and compatible

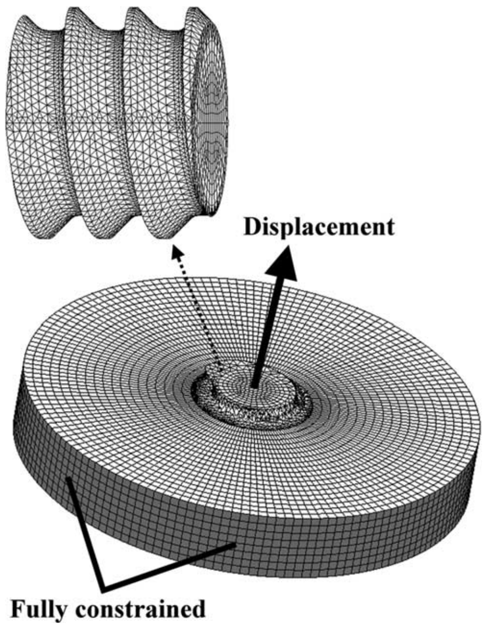

Fig. 3. The boundary condition and loading condition of the finite element models and the configuration of the screw (dash arrow). A displacement (solid arrow) was given to the screw inserted at the middle of the bone and the outer edge of the bone (dark area) was fully constrained.

deformable surfaces for a curved boundary. The element size was 0.4 mm for mapped mesh and 0.2 mm for free mesh. Surface-to-surface contact elements were used for contact simulation. The contact surfaces of the locking screws were meshed with CONTA 174, and the contact surfaces of the bone were meshed with TARGE 170. Surface-to-surface contact elements with contact checking at the face integration points could be used for higher-order quadrilateral elements with midside nodes (ANSYS Incorporated, 2003). A displacement of 0.01 mm was applied to the cross-section surface of one end of the screws, and only axial displacement of the screws was allowed. The peripheral margin of the bone was fully constrained (Fig. 3) and the solution was determined by Precondition Conjugate Gradient (PCG) solver.

The post-processing analysis included calculation of the total strain energy of the bone and total reaction force of the screw. The total strain energy was defined as the summation of the strain energy of the elements of the bone, and the total reaction force was defined as the summation of the reaction force of the nodes over the screw surface with pre-applied displacement. For the both-ends-threaded screw, the total strain energy and the reaction force of the proximal threads and the distal threads were computed separately and the values were summed. For the fully threaded screws, the values were doubled to reflect anchorage of the screw threads in two cortices. The applicability of the finite element models was examined by changing the loading condition (0.01, 0.1 and 0.3 mm), the elastic modulus of the bone (0.36 GPa, 5 GP and 10 GP), and the friction coefficient between the screws and the bones (0, 0.13, 0.27). The results of the finite element analyses were correlated to those of the mechanical tests by linear regression.

2.5. Factorial analysis by Taguchi method

Six design factors of fully threaded screws were studied: (A) outer diameter, (B) inner diameter, (C) root radius, (D) pitch, (E) half angle, and (F) thread width. The chosen range of design factors was equally divided into three discrete levels, which covered the most com-

Table 2
The L18 orthogonal array and the total strain energy transformed into a signal-to-noise (S/N) ratio

Run	Outer diameter (mm)	Inner diameter (mm)	Root radius (mm)	Pitch (mm)	Half angle (°)	Thread width (mm)	S/N ratio
1	4.5	3.52	0.1	1.9	20	0.1	−33.868
2	4.5	3.82	0.25	2.45	30	0.3	−34.385
3	4.5	4.12	0.4	3	40	0.5	−35.592
4	4.75	3.52	0.1	2.45	30	0.5	−33.945
5	4.75	3.82	0.25	3	40	0.1	−34.559
6	4.75	4.12	0.4	1.9	20	0.3	−33.645
7	5	3.52	0.25	1.9	40	0.3	−33.551
8	5	3.82	0.4	2.45	20	0.5	−33.484
9	5	4.12	0.1	3	30	0.1	−33.979
10	4.5	3.52	0.4	3	30	0.3	−34.602
11	4.5	3.82	0.1	1.9	40	0.5	−34.287
12	4.5	4.12	0.25	2.45	20	0.1	−34.370
13	4.75	3.52	0.25	3	20	0.5	−34.055
14	4.75	3.82	0.4	1.9	30	0.1	−33.704
15	4.75	4.12	0.1	2.45	40	0.3	−34.365
16	5	3.52	0.4	2.45	40	0.1	−33.791
17	5	3.82	0.1	3	20	0.3	−33.746
18	5	4.12	0.25	1.9	30	0.5	−33.400

monly used ranges for tibial locking screws. Each factor had two degrees of freedom. Consequently, there were overall 12 degrees of freedom, and accordingly an L18 orthogonal array with 17 degrees of freedom was chosen. This orthogonal array required 18 runs of finite element analyses based on 18 design parameter combinations. The results of the finite element analysis were transformed into a the-higher-the-better signal-to-noise ratio, $S/N = -10\log(y_i^{-2})$ (y_i: the result of the ith study) (Table 2). Analysis of the variance (ANOVA) was used to investigate the significance and contribution of each design parameter to the bone holding power of the screws (Fowlkes and Creveling, 1995).

The ANOVA process began with calculating the total sum of squares of deviation about the mean: $SS_{\mathrm{T}} \sum_{i=1}^{n}(S/N_i - \overline{S/N})^2$ (n: number of experiments, S/N_i: the S/N of the ith study, $\overline{S/N}$: overall mean of S/N). For each design parameter, the sum of the squares of deviation about the mean was $SS_P = \sum_{i=1}^{n} N_{Pi}(\overline{S/N}_{Pi} - \overline{S/N})^2$ (P: design parameter from A to F, n: number of discrete levels, N_{Pi}: number of experiments at each level of each parameter, $\overline{S/N}_{Pi}$: mean of S/N at each level of each parameter), and the mean square of deviation was $MS_P = SS_P/$factor degree of freedom (2 in this study). The sum of the squares of the error was $SS_{\mathrm{E}} = SS_{\mathrm{T}} - SS_{\mathrm{A}} - SS_{\mathrm{B}} - SS_{\mathrm{C}} - SS_{\mathrm{D}} - SS_{\mathrm{E}} - SS_{\mathrm{F}}$ and the mean square of the error was $MS_{\mathrm{E}} = SS_{\mathrm{E}}/$factor degree of freedom. The F value of ANOVA for each parameter was $F = MS_P/MS_{\mathrm{E}}$ and the percentage contribution of each factor could be computed as $SS_P/SS_{\mathrm{T}} \times 100\%$.

3. Results

3.1. Mechanical tests and the relative pushout strength

In the pushout tests, as the screws were loaded, the load increased linearly with the displacement and dropped abruptly while the foam bone was stripped. The displacement of the screws at the ultimate load was less than 2 mm in all the screws. All failures occurred in the foam bone and the structure of the screws was preserved. The screws were pushed out of the foam bone by shearing a cylinder of the foam material surrounding the threads. The pullout strength of the screws was consistently higher in the foam bone with higher density. The order of the pushout strength from high to low was both-ends-threaded screw, Osteo AG, Richards type II, Richards type I, Howmedica, and Synthes in the foam bone with a density of 0.5 g/cm^3. The order was similar in the foam bone with a density of 0.25 g/cm^3 (Table 1). The computed shear area of the bone was closely related to the pushout strength measured in the mechanical tests with a high correlation coefficient of 0.98 in the foam bone with a density of 0.5 g/cm^3 and 0.94 in the foam bone with a density of 0.25 g/cm^3 (Table 1).

3.2. Finite element models

Total element number of the finite element models ranged from 70,000 to 320,000. Total node number ranged from 170,000 to 500,000, and the computer solution time ranged from 5 to 50 h. Because of the numerical instability caused by inadequate element size, the regions of thread roots were remeshed by increasing the mesh density. The local element size was decreased from 0.2 to 0.03 mm, and the solutions were considered converged when the difference of the total strain energy or total reaction force between two neighboring models was less than 3%. The total strain energy of the bones showed perfect parallel relationship with the total reaction force of the screws. The results of the finite element analysis, including both total strain energy and total reaction force, were very closely related to the push-out strength of the screws in the mechanical tests with the correlation coefficient of 0.96 for the foam bone with a density of 0.5 g/cm^3 and 0.99 in the foam bone with a density of 0.25 g/cm^3 (Table 1).

In the applicability study of the finite element models (Table 3), increasing the pre-applied displacement might increase the absolute values of total strain energy and total reaction force, but the correlation coefficient of the results between finite element analysis and mechanical tests was minimally affected. In contrast, increasing the elastic modulus of bone or the frictional coefficient between the bone and the screw might also increase the total strain energy and the total reaction force, but these might decrease the correlation coefficient of the results between finite element analysis and mechanical tests and also the parallel relationship between total strain energy and total reaction force.

3.3. Factorial analysis by Taguchi method

As shown in the S/N graph in Taguchi factorial analysis (Fig. 4), increasing the outer diameter or decreasing the inner diameter, pitch, and half angle could significantly increase the bone holding power. The outer diameter had the highest contribution (46.40%) to the holding power of the screw, and then the descending order of contribution was pitch (29.01%), half angle (16.39%), and inner diameter (4.52%). The effects of root radius and the thread width were minimal (Table 4). The sum of the contribution of each design parameter approximated 100%, indicating that these six parameters could explain almost the entire change of pushout strength of the screws. Verification run with optimal levels of each design factor for the highest bone holding power showed that the total strain energy of the screw was 22.6×10^{-3} J, which was very close to that (21.8×10^{-3} J) computed by the predictive equation: $\overline{S/N} + \sum_{i=1}^{n}(\overline{S/N}_i - \overline{S/N})$ ($\overline{S/N}$: overall mean of S/N, n: number of design parameters, $\overline{S/N_i}$: mean S/N of each

Table 3
The effects of changing the pre-applied displacement, elastic modulus, and friction coefficient on the results of total strain energy (10^{-3} J) and their relationship to the pushout strength in the foam bone with a density of 0.5 g/cm^3 and the total reaction force

Displacement (mm)	Synthes	Howmedica	Richards type I	Richards type II	Osteo AG	Both-ends-threaded	$r1$	$r2$
0.01	39.04	39.92	41.76	44.02	43.24	45.88	0.96	1
0.1	3865	3979	4164	4388	4312	4542	0.96	1
0.3	34297	35599	37306	39323	38622	40710	0.96	1
Elastic modulus (GPa)								
0.36	39.04	39.92	41.76	44.02	43.24	45.88	0.96	1
5	533.1	546.1	608.6	599.2	578.3	625.3	0.82	0.87
10	1049.8	1074.6	1195.7	1174.4	1116.4	1226.9	0.76	0.86
Frictional coefficient								
0	39.04	39.92	41.76	44.02	43.24	45.88	0.96	1
0.13	39.33	40.12	44.70	44.19	43.42	40.98	0.88	0.86
0.27	40.22	40.51	44.99	44.46	43.78	41.38	0.88	0.83

$r1$ = correlation coefficient between total strain energy and pushout strength;
$r2$ = correlation coefficient between total strain energy and total reaction force.

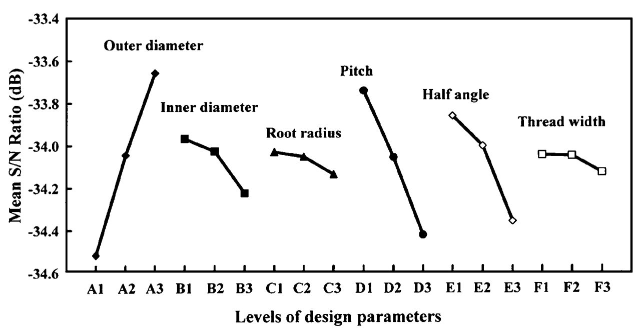

Fig. 4. Signal-to-noise graph of the total strain energy at different levels of each design parameter.

design parameter at the optimal level), confirming the linear model with minimal interaction.

4. Discussion

The bone holding power of different kinds of screws has been widely investigated mechanically using cadaver bones (Krag et al., 1986; Kwok et al., 1996; Okuyama et al., 1993; Willett et al., 1993), animal bones (Halsey et al., 1992; Leggon et al., 1993; Liu et al., 1995; Schatzker et al., 1975), and synthetic bones (Asnis et al., 1996; Brown et al., 2000; DeCoster et al., 1990; Lin et al., 2001; Thompson et al., 1997) Synthetic bone has the advantages of less individual variation, more consistent test results, greater availability, and easier specimen handling (Asnis et al., 1996; Lin et al., 2001; Thompson et al., 1997) by either pullout or pushout tests. Theoretically, for axial loading pushout tests should be equal to pullout tests because of identical loading directions. Although synthetic bone can simulate the situation of real bone, the relationships among different screws were more useful than the absolute values of the experimental data (Brown et al., 2000; Lin et al., 2001). Besides screw geometry, the absolute values of pushout strength in vivo might be further affected by the mechanical properties of the bone and also the size of the pilot holes (DeCoster et al., 1990; Halsey et al., 1992; Lin et al., 2001; Okuyama et al., 1993). Increasing the density of the bone or decreasing the size of the pilot hole could increase the bone holding power. In the present study, both the density and the compressive

Table 4
ANOVA table for total strain energy

Factor	Sum of squares	Degrees of freedom	Mean square	F value	Contribution (%)
Outer diameter	2.22	2	1.11	48.63	46.40
Inner diameter	0.22	2	0.11	4.74	4.52
Root radius	0.04	2	0.02	0.80	0.77
Pitch	1.39	2	0.69	30.41	29.01
Half angle	0.78	2	0.39	17.18	16.39
Thread width	0.03	2	0.01	0.56	0.53
Error	0.11	5	0.02	–	2.38
Total	4.79	17	–	–	100

modulus of the foam bone were much lower than those of normal cortical bone. These characteristics represented the worst-case scenario—a patient presenting with severe osteoporosis, in which case the bone could not hold the screws firmly. Consequently, in all the mechanical tests, the failure was cylinder shear of the foam bone by screw threads with no deformation of the screws. This finding was compatible with reports in the literature that screw loosening almost always occurs by stripping of the internal threads of the host materials (Asnis et al., 1996; Lin et al., 2001).

From a design point of view, the finite element method can appreciably save the expense, time, and effort of repeated mechanical tests. This study showed that the analytical results of the finite element models of the tibial locking screws were closely related to those of mechanical tests for both foam bones with different density. The linear relationship between total strain energy of the bone and total reaction force of the screw in the finite element analysis was compatible with the linear relationship between the load and the displacement before stripping of the foam bone in mechanical tests. However, the results of finite element models were subject to different loading conditions, the material property of the bone, and the frictional coefficient between the screw and the bone. Thus the applicability of the models should be examined if these factors were varied. The current study showed that varying pre-applied displacements did not affect the applicability of the models. By contrast, increasing the elastic modulus of the cortex or the friction coefficient might decrease the applicability. Not only the relationship between the results of finite element analyses and mechanical tests but also the linear relationship between total strain energy and total reaction force was compromised. The applicability was more affected with increasing elastic modulus because such an increase could result in a substantial screw deformation that was not compatible with the findings in the mechanical tests. In this study, a pre-applied displacement of 0.01 mm was used to lessen the computational time. However, an overly large pre-applied displacement on the screws might break up the contact elements and lead to no solution.

Similar to other studies (Asnis et al., 1996; Brown et al., 2000; Lin et al., 2001), the present study showed that the shear area of the bone calculated by the mathematical formula was closely related to the pushout strength determined by mechanical testing. As described in the *Machinery's Handbook* (Oberg et al., 1996), the basic theory of this mathematical formula was based on the presumption of a machine screw with symmetric threads, the same space between adjacent threads as that occupied by the threads and a fixed half angle of 30°. These presumptions were obviously not applicable to the locking screws with asymmetric threads and unequal space. Nevertheless, with its emphasis on the effects of outer diameter and pitch, this mathematical formula could still achieve a close relationship. The formula, however, had the disadvantage of including limited design factors and could only be applied to screws with homogeneous geometry. In contrast, the finite element model could examine the effects of all the design factors independently and was potentially applicable to screws with irregular thread patterns.

The Taguchi fractional analysis is a powerful statistical tool to fairly assess the relative importance of screw design factors while reducing experimental efforts (Dar et al., 2002). With an L18 orthogonal array, only 18 runs of the analyses were sufficient, instead of the 3^6 runs required in a full factorial design. The effects of each design factor can be assessed independently, especially in situations with interactions among the design factors (Fowlkes and Creveling, 1995). Furthermore, the L18 orthogonal array can evenly distribute the interaction over all the columns and give the most realistic effects of the factors. The factorial statistics showed the descending order of the contribution of the design factors was outer diameter, pitch, half angle, and inner diameter. The root radius and the thread width had negligible effects. Although the importance of these design factors is sensitive to the parameter space chosen (Dar et al., 2002), in this study, realistic ranges were used and this could yield a comprehensive assessment of the relative contribution of the design factors in real conditions. The finding of the factorial analysis confirmed the previously reported results of dominant influence of the outer diameter on the bone holding power (Kwok et al., 1996; Lin et al., 2001; Thompson et al., 1997). By contrast, the reported effects of inner diameter or pitch on the bone holding power are more widely varied (Halsey et al., 1992; Krag et al., 1986). This inconsistency might be caused by using human or animal bones with high inter-specimen variation (Chapman et al., 1996; Thompson et al., 1997), insufficient sample size (Krag et al., 1986; Westmoreland et al., 2002), small difference of screw design (Thompson et al., 1997), or lack of isolation of the individual design factor (Asnis et al., 1996). As for thread profile, the previous studies did not demonstrate significant difference of pullout strength between buttress threads and "V" threads (Halsey et al., 1992; Krag et al., 1986). However, the magnitude of the half angle of the threads has never been specified and its effect on the bone holding power has never been reported. The finite element models in the present study revealed that the proximal half angle contributed significantly to the bone holding power. The screws with smaller half angle could resist the pushout force more effectively because of more vertical edge of threads and more bone incorporated between the threads.

The present study had potential limitations. Although clinically screw loosening might be caused by a turning back of the screws, pushout testing did reveal the strength of fixation and could be a good measure of holding power (Lin et al., 2001; Westmoreland et al., 2002). Clinically, toggling of the bone fragment might also generate substantial pullout force on the locking screws and lead to screw loosening. The effects of the prestress caused by the discrepancy between the size of the pilot hole and the inner diameter of the screw were not investigated in the present study. However, these effects were supposed to be minute because of the low density and modulus of the bone. The close relationship between results of finite element analyses and mechanical tests further supported this supposition. Although the effects of the design factors might vary in situations with different bone properties (Asnis et al., 1996; Westmoreland et al., 2002), the relationship of the bone holding power among the locking screws in either mathematical models or mechanical tests in this study represented only situations with osteoporosis, in which locking screws tended to loosen. Comparison of finite element models with experimental data is always crucial. Adjustment of a model to try to make its results match experimental results should be judiciously done.

In conclusion, the bone holding power of the locking screws was closely related to their geometry and dimension. The finite element model predicted the relative bone holding power of the screws best in osteoporotic bone conditions. It could analyze the effects of each design factor independently and could be used for design optimization of the different kinds of orthopedic screws. This model may assist manufacturers in evaluating their screw designs and assist surgeons in selecting suitable devices, especially for patients with severe osteoporosis.

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