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Is Titanium Alloy Stronger than Stainless Steel as the Material for Locked Nails and Screws?

ABSTRACT

Objectives: The purpose of this biomechanical study was to compare the mechanical properties of locked nails and screws made from either stainless steel or titanium alloy.

Methods: The specially designed locked nails and screws with the same structures were made from either stainless steel or titanium alloy. The structural factors investigated included inner diameter and root radius for locking screws and outer diameter and nail hole size for locked nails. The mechanical properties investigated included bending stiffness, strength, and fatigue life. Finite element models were used to simulate the mechanical tests and compute the stress concentration factors.

Results: Increasing the root radius and the inner diameter could effectively increase the fatigue strength of the locking screws. Fatigue strength increased more in titanium than in stainless steel screws, especially when the inner diameter was increased. In contrast, the titanium locked nails were much weaker than their stainless steel counterparts. Finite element models could closely predict the results of the biomechanical tests with a correlation coefficient that ranged from -0.58 to -0.84 for screws and was -0.98 for nails. The stress concentration factors ranged from 1 to 1.81 for screws and from 3.06 to 4.17 for nails.

Conclusions: With larger root radius and inner diameter, titanium locking screws could provide much stronger fatigue strength than stainless steel counterparts. However, titanium locked nails might lose their advantages of superior mechanical strength because of high notch sensitivity and this limitation should be a critical concern clinically. Finite element analyses could be reliably used in research and development of locked nails and locking screws.

Key Words: mechanical properties, titanium, stainless steel, locked nailing

INTRODUCTION

Locked intramedullary nailing has become the most widely accepted treatment method for lower extremity long bone fractures.[1] It has the advantage of minimal tissue injury and high fixation stability. The most commonly used materials for conventional locked nailing systems is stainless steel. Even so, the use of a titanium alloy has been advocated lately[2] because of its excellent combination of better biocompatibility, corrosion resistance, fewer resultant artifacts on computer tomographic scans and magnetic resonance images, and mechanical properties.[3,4] However, the greatest concern about the titanium alloy, as compared with stainless steel, is its material property of notch sensitivity, which may substantially decrease the fatigue strength, leading to a higher risk of implant breakage and failure of the fixation.[3,5] This notch sensitivity effect is especially prominent at the regions with abrupt geometrical change, such as the thread valley of the locking screws or the screw hole of the nail.

Few studies have compared the mechanical properties of the locked nail systems made from titanium alloy or stainless steel.[6] In the present study, the locking screws and the locked nails were specially manufactured with either titanium alloy or stainless steel with the same geometry and dimensions. The mechanical properties, including the stiffness, yielding strength, and fatigue strength, were compared. The hypothesis was that the titanium implants should better resist fatigue breakage, which is the most commonly seen failure mechanism for fracture fixators. However, in situations with high notch effect, the fatigue strength of the titanium implants might be compromised. The other hypothesis was that finite element analyses could reliably predict the results of mechanical tests and be used to assess the severity of the notch effect.

MATERIALS AND METHODS

Structures of the Tested Nails and Screws

The specially designed locking screws and locked nails were made (United, Taipei, Taiwan) from either stainless steel according to the specification of ASTM (American Standard of Tested Materials) F138 Grade 2.2 or titanium alloy (Ti6Al4V) according to the specification of ASTM F136-96 (Carpenter Technology, Reading, PA). The stainless steel had a yield strength of 786 MPa and an elongation rate of 26%. Titanium alloy had a yield strength of 795 MPa and an elongation rate of 10%. Because it has been shown that the determining factors for the fatigue strength are inner diameter and the root radius of the threads,[7] the locking screws manufactured in the present study had two different inner diameters, 3.8 and 4.1 mm, and three different root radii: 0.1, 0.3, and 0.5 mm (Table 1) (Fig. 1A). The other structures of the screws were exactly the same, and the length was 55 mm for all. Two smooth bolts without threads were used as controls. For locked nails (Table 2), metal tubes with a fixed length of 110 mm and a round hole at the center were used to reflect the worst case clinical scenario. Use of this design could also reduce the effects of confounding factors, such as the location and number of holes, the distance between the holes, etc. The metal tubes had two different outer diameters, 11 mm and 12 mm, and three different hole diameters, 4.5, 5, and 5.5 mm for 11-mm nails and 5, 5.5, and 6 mm for 12-mm nails (Fig. 1B). The wall thickness was 1.5 mm for all nails. To increase the nail rigidity, one additional type of titanium nail (Nail-t in Table 2) with a wall thickness of 3 mm, outer diameter of 11 cm, and nail hole diameter of 4.5 mm was made for further comparison.

Biomechanical Tests

Screws

High molecular weight polyethylene tubes with an outer diameter of 50 mm and an inner diameter of 40 mm were used for tests (Fig. 2A). The screws were inserted through the center of the tubes until the screw cap abutted against the tube wall. To simulate clinical conditions, the screws were compressed at the middle by a cylindrical nail with an outer diameter of 12 mm and wall thickness of 1.5 mm. At first, static-loading tests were conducted with a ramp-type load on six samples of each type of screw with a loading rate of 1 mm/min in a displacement control mode using a materials testing machine (Bionix 858, MTS Corporation, Minneapolis, MN). The loading continued until the screws had permanent angular deformation. The load–deformation curves were generated with the data acquisition rate of 100 Hz. The slope of the most linear part was measured as the bending stiffness. The 0.2% offset yielding strength was measured according to the ASTM designation F 1264 standard. Then, with the same testing setup, dynamic loading tests were conducted with a 10-Hz cyclic sinusoidal loading on six new screws of each type with a fatigue rated load cell. The maximal load (750 N) was 90% of the yielding strength of the weakest screw, and the stress ratio was 5-10%. With this loading, low-cycle fatigue failure was expected. The tests were terminated when the displacement of the actuator was beyond 2 mm and the crack on the screws was visible or when the fatigue life was more than 10^6 cycles. The cycle–displacement curve and the number of cycles to failure were recorded. The cyclic stiffness was measured on the slope of the load–deformation curve in cyclic-loading tests when the screw deformation was stabilized. For screws that did not fail in the cyclic loading tests with the maximal load of 750 N at one million cycles, the maximal load was increased to 950 N, and the tests were repeated using six new screws.

Nails

Standardized four-point bending tests (ASTM designation F 1264) were conducted to test the locked nails (Fig. 2B). The nail hole was at the plane of loading to represent the worst case scenarios. Both ends of the nails were simply supported by two metal rollers, and two-point loads were applied through two other metal rollers with the same span between the supporting and loading rollers. Nail rotation during cyclic loading was prevented by two bars inserted in the slots at the nail ends. Initially, the nails were statically loaded until yielding, and then were dynamically loaded with a maximal load of 3000 N under the same testing set-up until either nail breakage or one million cycles was reached. The bending stiffness, yielding strength, cyclic stiffness, and the fatigue life were measured by means similar to those used for the screws.

Failure Analysis

A failure analysis, which included implant surface examination, material analysis, fractographic examination, metallographic examination, and hardness tests,[8] was performed on the failed cracked nails and screws.

Finite Element Analysis

The finite element analyses were conducted with the use of commercial software ANSYS 8.0 (Canonsburg, PA). Three-dimensional screw (Fig. 3A) and nail models (Fig. 3B) with the same structures as those in biomechanical tests were first generated with CAD software (SolidWorks 2007, Concord, MA) and then imported into ANSYS program for analysis. The locking screws were surrounded at each end by a polyethylene cuff with an outer diameter of 7 mm and a width of 5 mm (Fig. 3A). The Young’s modulus was 230 GPa for stainless steel, 110 GPa for titanium, and 2.6 GPa for polyethylene. The Poisson’s ratio was 0.3 for all materials. The core of the locking screws was map meshed, and the surface including screw threads with curved boundaries was free-meshed with high order 20-node hexahedral elements. Similarly, the polyethylene cuff was also map-meshed except for the layer surrounding the screws. Surface-to-surface contact elements were used for the interface between the locking screw and polyethylene. The overall element size was 0.4 mm. To simulate the loading in mechanical tests, a two-point load with 200 N (250N for screws that did not fail under 750 N) (mean load of the fatigue tests) at each point was applied to the middle of the screws. The lower half of the surface of both bone cuffs was fully constrained to simulate the boundary condition of biomechanical tests. Axial rotation of the screws was not allowed. The finite element analyses of locked nails were similarly performed (Fig. 3B). Both ends of the nails with a length of 110 mm were supported by two rollers made of stainless steel with contact elements on the interfaces between them. To simulate the loading in mechanical tests, a two-point load with 825 N at each point (mean load of the fatigue tests) was applied at the middle of the nails. In both screw and nail models, the mesh was refined in areas with peak stress by increase of mesh density, and numerical convergence was confirmed if the change in the results of sequential analysis was less than 3%. After processing, the maximal tensile stress of the locking screws and nails was recorded. For computation of the stress concentration factor of locking screws, the maximal stress of the threaded screws was divided by that of the smooth bolts with the same inner diameter. For nails, the stress concentration factor was computed by dividing the maximal stress of the nails with a hole by that of the nails without a hole.

Statistical Analysis

In the biomechanical tests, Student’s t-tests were used to compare the stainless steel implants with their titanium counterparts. Linear regression analysis was used to correlate the results of finite element analyses correlated to those of the biomechanical tests. The significance level was defined as $p < 0.05$.

RESULTS

Biomechanical Tests

Screws

In static loading tests, the load-deformation curve was linear initially and had a yielding at about 2.0 mm displacement for titanium screws and 1.5 mm for stainless steel screws. For multi-cyclic tests, the screws cracked at either one of the two points contacting the nail. The titanium screws had a shorter crack propagation phase than stainless steel ones. The multi-cyclic stiffness was consistently higher than bending stiffness in both types of screws (Table 3). The titanium screws had lower bending stiffness and multi-cyclic stiffness than their stainless steel counterparts, but only multi-cyclic stiffness was significantly lower. The difference of the yielding strength between the titanium screws and their stainless steel counterparts was not statistically significant. For fatigue strength, all the titanium screws were significantly stronger than their stainless steel counterparts. The increase in the fatigue life of titanium screws as the root radius or inner diameter increased was higher than that of their stainless steel counterparts. Although stiffness, yielding strength, and fatigue life tended to be higher as the root radius increased, the increase of fatigue life was the most remarkable, especially for titanium screws. This increase of fatigue life was disproportionately higher in titanium screws with larger inner diameter. The standard variation of fatigue life of the titanium screws was obviously higher than that of their stainless steel counterparts.

Nails

The nails failed at the middle of the nail hole in both yielding and multi-cyclic tests. The failure pattern was similar to that of the locking screws. The bending stiffness of the titanium nails was about 60% to 70% of that of their stainless steel counterparts (Table 4). Again, multi-cyclic stiffness was consistently higher than the bending stiffness in both types of nails. The difference between the titanium nails and their stainless steel counterparts was also larger in multi-cyclic stiffness than bending stiffness. The yielding strength of the titanium nails was significantly higher than that of their stainless steel counterparts. Surprisingly, the fatigue life of the titanium nails was consistently lower than that of their stainless steel counterparts, about only one third. The difference between the fatigue life of titanium nails and that of their stainless steel counterparts was not much affected by the diameter of the nails and nail holes. The stiffness, yielding strength, and fatigue life of the titanium nails were substantially increased as the thickness of the nail wall was increased from 1.5 mm to 3.0 mm. However, the stiffness and fatigue life were still lower in titanium nails than in their stainless steel counterparts.

The failure analysis revealed both the stainless steel and titanium alloy complied with the requirements of ASTM F138 and ASTM F136-96, respectively. The hardness of the metals was within the acceptable range for orthopedic alloys.

Finite Element Analysis

For locking screws, total element number of the finite element models ranged from 141 thousands to 310 thousands. Total node number ranged from 229 thousands to 409 thousands, and the computer solution time ranged from 6 to 18 hours under the Microsoft Windows XP system. For nails, total element number of the finite element models ranged from 106 thousands to 111 thousands. Total node number ranged from 165 thousands to 174 thousands, and the computer solution time ranged from 6 to 10 hours. The point with maximal tensile stress was at the valley of the thread on the undersurface at the middle of the screws. The maximal tensile stress was closely correlated to the logarithm of the fatigue life measured in the mechanical tests. In stainless steel screws, the correlation coefficient was -0.83 ($p<0.01$) (Table 3). In titanium screws, the correlation coefficient was -0.84 for the tests with a maximal load of 750 N ($p<0.01$) and -0.58 for tests with a maximal load of 950 N ($p=0.013$). The nails had a higher correlation coefficient than did locking screws, -0.98 ($p<0.01$) for both stainless steel and titanium (Table 4). In screws, the stress concentration factor increased, ranging from 1 to 1.81 as the inner diameter and root radius decreased. The stress concentration factor of the nails increased as the nail diameter decreased and the nail hole diameter increased. It ranged from 3.06 to 4.17 and was higher than that of the locking screws.

DISCUSSION

The present study illustrated that the fatigue strength of titanium screws was higher than that of their stainless steel counterparts, especially when the root radius and the inner diameter were increased. In contrast, the titanium locked nails were much weaker than their stainless steel counterparts because of higher stress concentration effect caused by the nail hole. Doubling the thickness of the titanium nail wall could substantially increase the fatigue strength, but it was still lower than that of the stainless steel nails.

The purpose of the locked nailing system is to provide sufficient fixation stability for fracture union. At the very least, the implants should remain intact until fracture union is achieved. Otherwise, if the implant fails, the fracture fixation can be lost and the deformity may recur, resulting in the failure of the surgical intervention.[8,9] Although the optimal implant has not yet been developed, improvement of the implant design and selection of appropriate materials are part of the refining process and should be thoroughly investigated. It is well known that titanium has a special material property of notch sensitivity,[3,4] which indicates the sensitivity of a material to stress concentrations. Devices made from materials with notch sensitivity may lose fatigue strength drastically and fail early at the regions with high stress concentration. In a previous biomechanical study comparing the fatigue strength of spinal transpedicle screw devices made of either titanium or stainless steel with identical structures, Chen et al.[4] demonstrated a higher strength in titanium devices with a structure with lower stress concentration effects. Conversely, the titanium devices might be weaker if the structure had higher stress concentration effects. This notch sensitivity effect, which dramatically affected the fatigue strength of the titanium devices, was scarcely studied in the fracture fixators. It has been reported that titanium plates might carry a higher risk of implant failure as compared with stainless steel ones and thus were not recommended for use in high stress conditions.[10] In contrast, in a biomechanical study conducted by Antekeier et al.,[6] titanium nails were found to have a higher fatigue strength than stainless steel nails. In that study, however, the devices had different structures. In the present study, the geometry and dimension of the screws or nails were identical and the comparison was fair. It has been reported that the increasing the root radius and inner diameter could increase the fatigue strength of the stainless steel locking screws.[7] The contributions of the root radius and inner diameter were 27.8% and 63.8%, respectively. As shown in this study, the increase in fatigue life brought about by increasing the root radius or inner diameter was more prominent in titanium screws, and the contribution of the inner diameter was even greater than that of the root radius. For screw design consideration, the root radius has minimal effects on the pullout strength,[11] and could be as large as possible. In contrast, increasing the inner diameter may decrease the pullout strength, thus optimization studies based on the trade-off of the bending strength and pullout strength are warranted. On the other hand, the bending stiffness and the yielding strength were minimally affected by root radius in both kinds of screws. In the present study, titanium screws had higher yielding strength and lower bending stiffness than their stainless steel counterparts, but the differences did not reach significant levels. However, the difference between the multicyclic stiffness of titanium screws and stainless steel screws was larger and could reach statistical significance. The multicyclic stiffness tended to be higher than the static bending stiffness because of the higher loading rate.

For both titanium and stainless steel locked nails, the fatigue life was longer when the outer diameter was larger and the nail hole was smaller. However, inverse to the locking screws, fatigue life of the titanium nails was consistently shorter than that of the stainless steel counterparts. This finding could be explained by the high stress concentration effect in locked nails. The stress concentration factors computed by the finite element analyses ranged from 3.06 to 4.17 in locked nails as compared with 1 to 1.8 in locking screws. Higher stress concentration effects might decrease the fatigue life of titanium nails with their higher notch sensitivity. The outer finish on the nail rarely contributes significantly to preventing this type of notch failure at the nail holes. Doubling the thickness of the titanium nail wall could increase its fatigue life and bending stiffness, but these values were still lower than in stainless steel nails that were only half as thick. Nails with lower stiffness could be inserted with more ease during operation, but the effects of lower stiffness on fracture healing need further clinical studies.

Finite element analysis, a powerful tool for computing the stress and strain inside an arbitrary complex structure, can be effectively used in investigating the mechanical performance of the locked nail and screws with complex thread patterns. In the current study, the maximal tensile stress in finite element analyses was closely related to the logarithm of the fatigue life in mechanical tests with high correlation coefficients. Still, in screws the point with maximal tensile stress did not correspond to the failure point in cyclic loading tests because of the uneven contact between the nails and screws. This might explain the lower correlation coefficients in screws than in locked nails with simpler structures. Some investigators demonstrated that higher stress concentration effects could reduce the fatigue strength of titanium spinal transpedicle fixators.[4,12] However, their studies did not provide the real value of stress concentration effects. In the present study, finite element analysis could compute the stress concentration factors and assess the notch effects of the implant design quantitatively. The finite element models can appreciably save the expense, time, and effort involved in repeated implant manufacture and mechanical tests.

The present study had potential drawbacks. First, only limited types of screws and nails were studied, and so the study could only demonstrate the trend of the influence of the studied design variables. Short nails with one nail hole at the middle might not represent real clinical conditions. However, this model could investigate the pure hole effect (irrespective of the position or number of holes) on the mechanical property of the nails and simulate the worse case scenarios in bending tests. A second drawback is that the devices were tested with only one loading rate. The fatigue life especially in the titanium screws might vary under different deformation quantities and loading rates.[13] Conditions with other deformation quantities and loading rates need to be studied. However, low cycle fatigue failure in the present study represented the worse case scenario in situations with unstable fracture fixation and are also the most commonly seen clinical failure patterns.[7] Finally, the present study still could not answer how high the stress concentration factor was when the titanium devices began to lose their advantages of high fatigue strength. Actually, stress concentration effects might not be the sole factor that determines the severity of notch sensitivity. Other geometrical factors, such as the diameter of the implants, might also play significant roles.

In conclusion, with larger root radius and inner diameter, titanium locking screws could provide much stronger fatigue strength than stainless steel counterparts. In contrast, the titanium locked nails might lose their advantages of superior mechanical strength because of high notch sensitivity. This should be a critical concern before use of titanium nails becomes widespread clinically. Finite element analysis could reliably predict the fatigue life of the implants and had the further advantage of assessing the severity of notch sensitivity quantitatively.

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LEGENDS

Figure 1. Geometry and dimension of (A) locking screws and (B) locked nails.

Figure 2. Testing setup of (A) locking screws and (B) locked nails. Arrows indicate loading direction.

Figure 3. Finite element models of (A) locking screws and (B) locked nails. Arrows indicate loading direction.

Is Titanium Alloy Stronger than Stainless Steel as the Material for Locked Nails and Screws?

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The devices described in this manuscript are for experimental use and are not FDA approved or commercially available in the United States.

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Figure 1

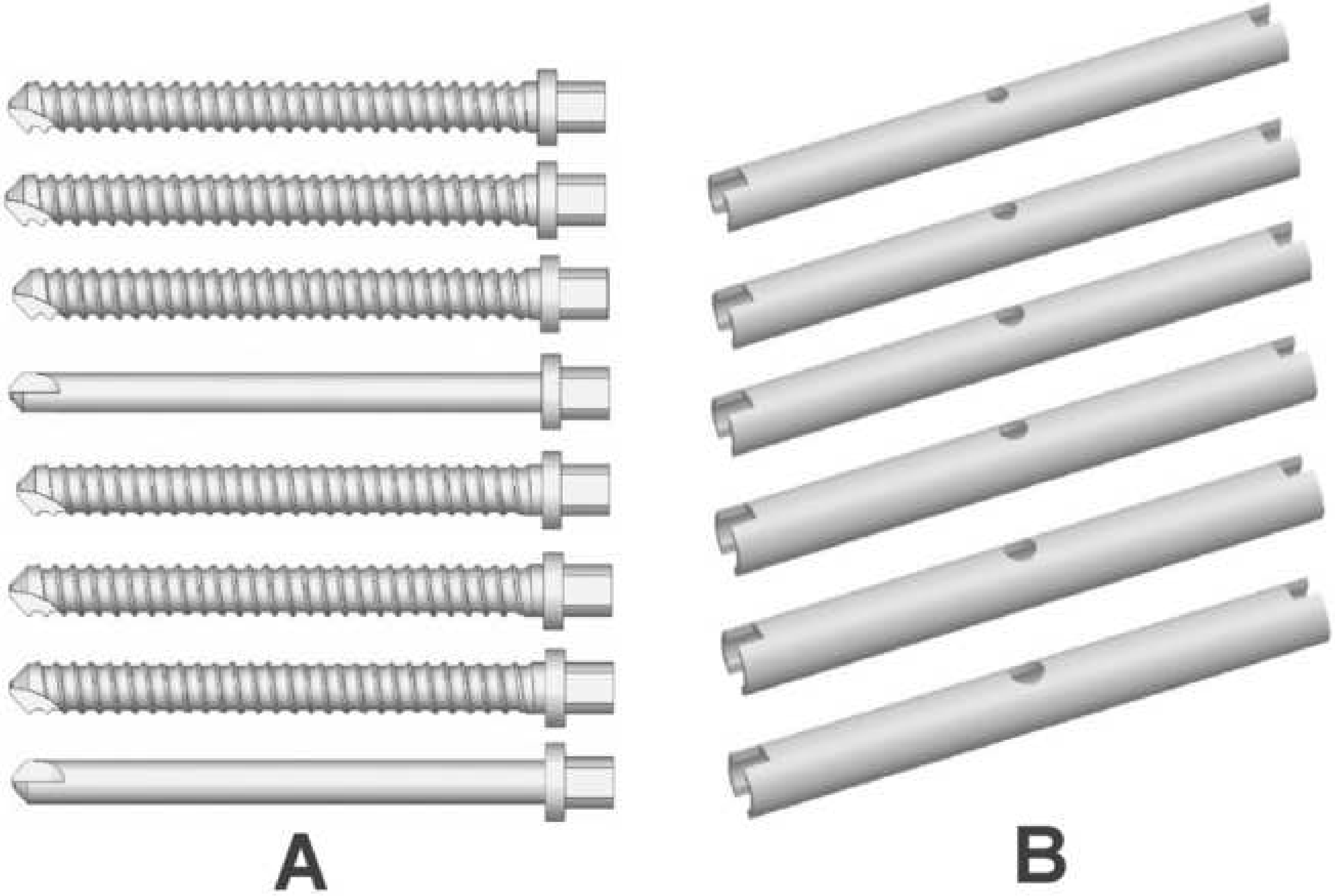

Figure 2

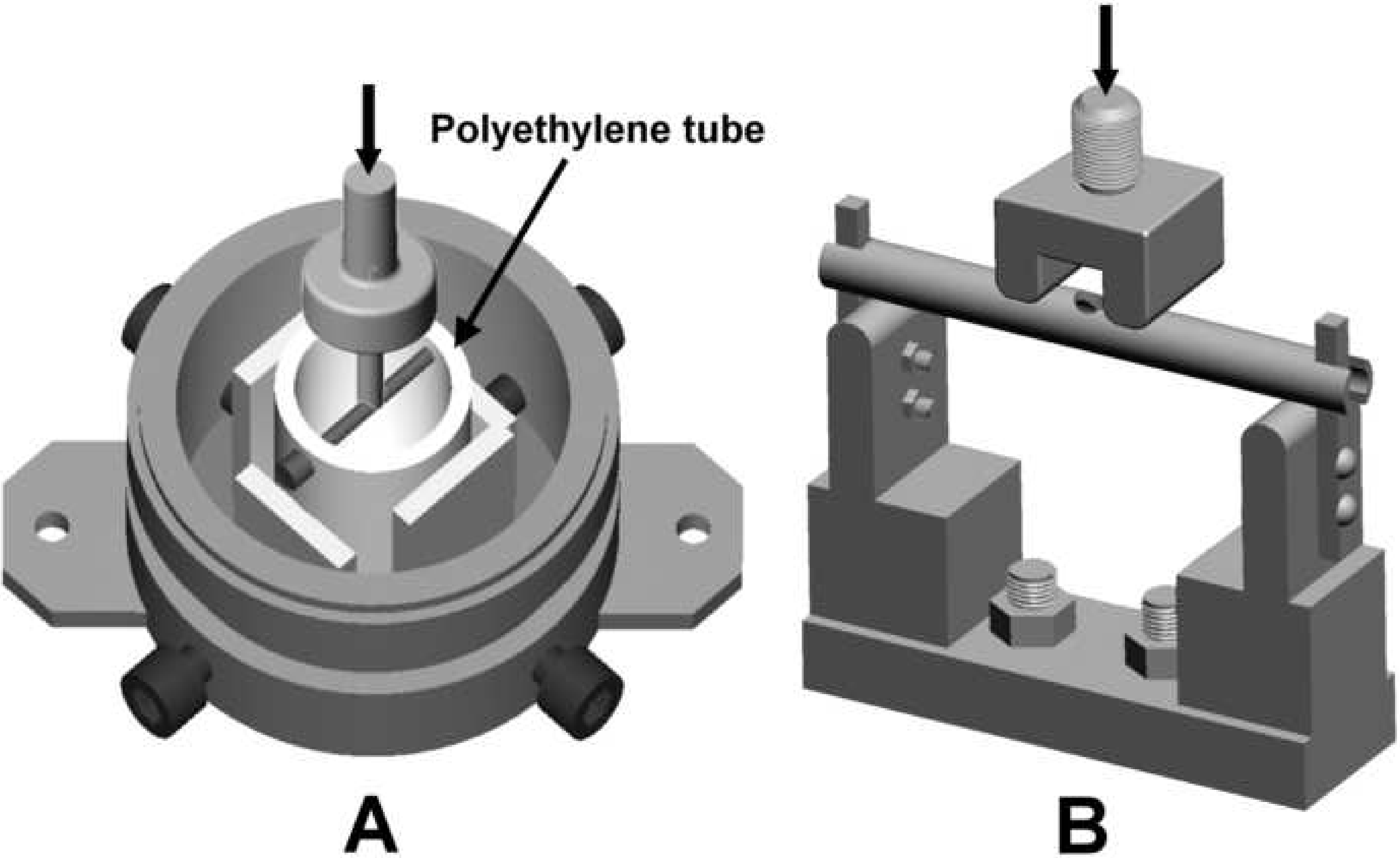

Figure 3

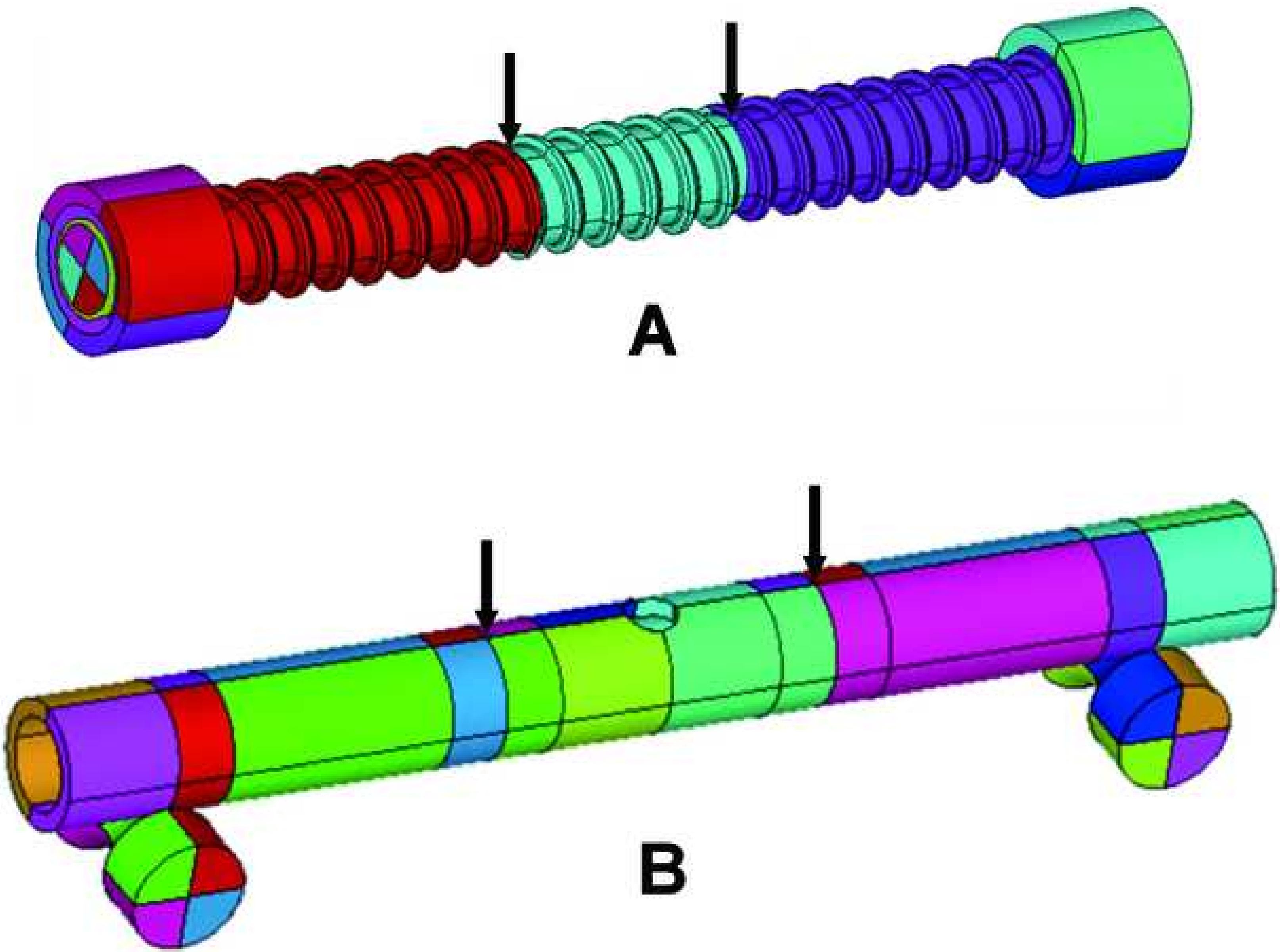

Table 1

TABLE 1. Geometry and Dimensions of Locking Screws

Design variable	**Screw type**							
	Screw 1	**Screw 2**	**Screw 3**	**Screw 4**	**Screw 5**	**Screw 6**	**Screw 7**	**Screw 8**
Outer diameter	4.9	4.9	4.9	4.9	4.9	4.9	4.9	4.9
Inner diameter (mm)	3.8	3.8	3.8	3.8	4.1	4.1	4.1	4.1
Proximal root radius (mm)	0.1	0.3	0.5	-	0.1	0.3	0.5	-
Distal root radius (mm)	0.8	0.8	0.8	-	0.8	0.8	0.8	-
Pitch (mm)	1.81	1.81	1.81	-	1.81	1.81	1.81	-
Proximal half angle (º)	45	45	45	-	45	45	45	-
Distal half angle (º)	15	15	15	-	15	15	15	-
Thread width (mm)	0.3	0.3	0.3	-	0.3	0.3	0.3	-

Table 2

TABLE 2. Geometry and Dimensions of Locked Nails

Design variable	Nail type						
	Nail-1	**Nail-2**	**Nail-3**	**Nail-4**	**Nail-5**	**Nail-6**	**Nail-t**
Outer diameter	11	11	11	12	12	12	11
Inner diameter (mm)	8	8	8	9	9	9	5
Wall thickness (mm)	1.5	1.5	1.5	1.5	1.5	1.5	3
Diameter of nail hole (mm)	4.5	5.0	5.5	5.5	6.0	6.5	4.5

Nail-t: additional titanium nail with wall thickness of 3 mm.

Table 3

TABLE 3. Results of Mechanical Tests and Finite Element Analyses of Locking Screws

Screw type	Bending stiffness (N/mm)	Yielding strength (N)	Fatigue life 750-50 N (10^3 cycles)	Fatigue life 950-50 N (10^3 cycles)	Multi-cyclic stiffness (N/mm)	Maximal tensile stress (MPa)	Stress concentration factor
SS-1	710±27	871±36	12.3±0.3*	–	[illegible]	1173.5	1.81
TS-1	692±35	886±27	16.8±4.6	–	[illegible]	1015.5	1.75
SS-2	713±19	897±49	16.2±3.8*	–	[illegible]	901.5	1.39
TS-2	706±60	923±58	29.3±12.8	–	[illegible]	781.5	1.34
SS-3	842±116	920±83	25.4±2.8*	–	[illegible]	835.5	1.29
TS-3	772±46	1039±90	48.3±22.6	–	[illegible]	710	1.25
SS-4	666±75	830±55	174±110*	–	[illegible]	648	1
TS-4	652±20	841±51	>1000	152.3±55.9	[illegible]	581.5/736.5	1
SS-5	887±10	993±131	42.6±6.9*	–	[illegible]	926	1.75
TS-5	865±80	1084±102	>1000	159.1±214	[illegible]	813/1029.8	1.67
SS-6	948±10	1016±75	44.9±14*	–	[illegible]	730	1.38
TS-6	907±85	1148±88	>1000	545.7±498	[illegible]	650/823.3	1.34
SS-7	979±113	1032±130	47.1±10*	–	[illegible]	679	1.28
TS-7	909±62	1100±88	>1000	>1000	[illegible]	597.5/756.8	1.23
SS-8	807±47	1035±90	>1000	149.6±55.5*	[illegible]	530.5/672	1
TS-8	798±19	1065±104	>1000	>1000	[illegible]	486/615.6	1

SS: stainless steel screw; TS: titanium screw; values expressed as mean±standard deviation; *statistically significant difference between SS and TS; /: stress under 200 N/ stress under 250 N.

Table 4

TABLE 4. Results of Mechanical Tests and Finite Element Analyses of Locked Nails

Nail type	Bending stiffness (N/mm)	Yielding strength (N)	Fatigue life (10^3 cycles)	Multi-cyclic stiffness (N/mm)	Maximal tensile stress (MPa)	Stress concentration factor
SN-1	5123±486*	4918±251*	27.2±2.72*	5909±169*	1049.7	3.14
TN-1	3310±311	4962±402	6.95±0.74	3978±85	1047.7	3.15
SN-2	4859±413*	4003±182*	17.7±1.27*	5761±191*	1128.1	3.37
TN-2	3298±276	4352±398	5.88±0.32	3854±76	1126.5	3.39
SN-3	4753±319*	3814±183*	14.7±1.27*	5625±134*	1238.3	3.70
TN-3	3014±231	4124±377	4.17±0.45	3675±64	1237.2	3.72
SN-4	6335±534*	5411±201*	45.2±2.22*	7372±180*	922.1	3.24
TN-4	4194±341	5701±412	12.16±0.84	4934±80	920.3	3.27
SN-5	5879±547*	4854±201	31.6±1.73*	6930±204*	1010.1	3.55
TN-5	3862±232	5073±488	9.85±0.87	4718±85	1008.2	3.60
SN-6	5462±421*	4188±167	21.6±3.26*	6620±208*	1095.9	4.13
TN-6	3546±231	4381±411	7.08±0.88	4351±79	1093.9	4.17
SN-1	5123±486*	4918±251*	27.2±2.72*	5909±169*	1049.7	3.14
TN-t	4331±189	5542±411	18.8±2.5	4584±39	766.9	3.06

SN: stainless steel nail; TN: titanium nail; values express as mean±standard deviation; * statistically significant difference between SN and TN.