行政院國家科學委員會補助專題研究計畫成果報告

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一、中文摘要

在本論文我們測試一種自己設計無鏍紋之鏍絲的彎折強度及骨咬合強度，並且和四種市面上的脛骨鎖定鏍絲比較，Synthese、Howmedic、Richard 及 Osteo，測試彎折強度，我們把鏍絲穿入一個高分子量塑鋼管內，並在鏍絲中央施予一三點彎折力量，然後以材料試驗機來測試其彎折強度，再施予疲乏壓力以測試其疲乏壽命，然後在人工骨上植入鏍絲，在鏍絲頂端施以推出的力量，來測量鏍絲之咬合強度，分別用不同密度及人工骨以不同尺寸之預鑽孔，另外再測量鏍絲旋壞強度，鏍絲推出力量之測試，鏍絲彎折強度為旋壞強度之百分之六十，實驗結果顯示鏍絲之降伏強度和疲乏之壽命和鏍絲內徑非常相關，旋壞強度可以可靠的預測推出強度，高密度人工骨以小預鑽孔可以增加鏍絲之咬合強度，我們設計之無鏍紋鏍絲有最高之疲乏壽命及不錯之咬合強度。

關鍵詞：彎折強度、骨咬合強度、三點彎折測試

Abstract

The bending strength and holding power of one specially designed tibial locking device, a unthreaded bolt, were studied and compared with four types of commercially available tibial interlocking screws: Synthes, Howmedica, Richard, and Osteo. To test bending strength, the devices were inserted into a high molecular weight polyethylene tube and loaded at their midpoint by a materials testing machine to simulate a three-point bending test. Single loading yielding strength and cyclic loading fatigue life then were measured. To test holding power, the devices were inserted into tubes made of polyurethane foam and their tips were loaded axially to measure push-out strength. The devices were tested with two different densities of foam materials and two different sizes of pilot holes. Stripping torque of the screws were measured first. Then push-out tests were performed with each screw inserted with a tightness equal to 60% of its stripping torque. Test results showed that the yielding strength and the fatigue life, were closely related to the inner diameter of the screws. The stripping torque could predict the push-out strength reliably. All tested devices showed greater holding power in the foam with the higher density and with the smaller pilot holes. The unthreaded bolt had the highest fatigue strength but only fair holding power.

Key words: Holding power, Bending strength, Three-point bending test

二、緣由與目的

Interlocking nailing with the advantages of minimal tissue injury and stable fracture fixation has been well accepted for treatment of tibial shaft fractures.[1,3,9] However, it is potentially complicated with failure of the hardware around the nail aperture.[9,11,15,21] For tibial locking screws, bending is the main load causing implant failure. For a fully threaded screw, increasing the inner diameter to increase its bending strength may decrease its holding power, but increasing the outer diameter to increase the holding power may jeopardize the nail's strength.[8,13,17,19]

To improve the mechanical performance of locking screws, one new device different from conventional fully threaded screws were manufactured in the authors' institute. It was an unthreaded bolt with an oblique set screw on the bolt cap to hold bone. In this study, the bending strength (yielding strength and fatigue life) and push-out strength of these two screws were tested and compared with those of commercially available tibial locking screws.

三、結果與討論

Tests of bending strength

In the single loading tests, all of the devices consistently yielded at the middle and the load-deformation curve had an obvious yielding around the point of 1-mm deformation. The yielding strength of the devices was closely related to their inner diameter with a correlation coefficient of 0.93 (Table 2). The yielding strength of the unthreaded bolt was significantly higher than that of the Osteo screw and significantly lower than that of the Synthes and the both-ends-threaded screws, but did not differ significantly from that of the Howmedica or Richard screw (Table 2). For cyclic loading tests, the maximal load used for testing was 31.5 Nm, the minimal 1.75 Nm. The fatigue crack occurred without visible plastic deformation at the middle of the four threaded screws. In all screws, the cracks began at the valley of the thread. The unthreaded bolt, as well as its set screw, sustained a cyclic loading of more than 10^6 cycles and had a fatigue life significantly longer than that of any other device tested. The fatigue life of the devices was also closely related to their inner diameter (correlation coefficient = 0.92).

Tests of holding power

All holding power failures occurred in the polyurethane foam bones. The stripping torque, and push-out strength of the locking devices are shown in Figures 3 and 4. For threaded screws, these values were consistently higher in those tests in which the higher density foam and smaller pilot holes were used. For each of the four sets of tests, the correlation between stripping torque and push-out strength was very high (correlation coefficients = 0.96, 0.98, 0.95, and 0.98). Although the unthreaded bolt had the lowest push-out strength among all the devices, not all of the differences between its score and that of the other devices were statistically significant. The two sizes of pilot holes had no significant effect on the bolt’s push-out strength (p=0.21 and 0.72, respectively).

In distal tibial fractures under single axial loading, Russell-Taylor nails consistently failed at the proximal of two distal nail apertures, but the Synthes nail failed at either the nail aperture or locking screws.[11] There has been a design dilemma between the strength of the screw and the strength of the nail around the nail aperture.[8,19] Increasing the screw strength by increasing the screw diameter necessitates a larger nail aperture and may jeopardize the strength of the nail. Another dilemma is between the strength and the holding power of the screws.[13,17,19] The current study showed that the unthreaded bolt increased the fatigue strength tremendously, but the holding power provided by the oblique set screw was less than that of the threaded screws.

The physiological loading condition of tibial locking screws is still undetermined. Hutson et al[11] found that three-point bending could reflect the real loading condition of the locking screws in tibial fractures. They found that the failure patterns of the screws were consistent with their clinical observations of this implant in use. In the present study, yielding consistently occurred at the middle of the devices, and the yielding strength was closely related to the inner diameter of the screw. For cyclic loading, all of the screws cracked at the middle without visible plastic deformation, a typical feature of fatigue fracture. The failure consistently occurred at the stress concentration sites.[8,12] Mechanically, the fatigue strength is strongly affected by the inner diameter of the screws.[8]

The bone holding power of screws can be assessed by either insertion torque or pullout strength, but pullout tests are more commonly used for measuring holding power for osteosynthesis bone screws,[2,4,5,17,20] external fixator pins,[6,10] and spinal transpedicle screws.[7,14,18] The loosening mechanism of the locking screws of the interlocking nails might be either a turning-back or a pull-out of the screws. Most of the reported pullout tests have been performed with the screws inserted half way into the bone. For this study, the authors decided the screws should be tested with a tightness like that encountered in surgical practice. Additionally, pushout test is considered similar to pullout test, because they are both axial loading in the same direction. The authors first measured the stripping torque when the screws were tightened against the bone, and then the push-out tests were performed with the screws tightened up to 60% of the stripping torque. In this study, the push-out strength of the screws was closely related to the stripping torque.

It has been intended to simulate the holding power of threaded screws by numerical analysis. There are several mathematical formulas for calculating the pullout strength of fully threaded screws.[4,17,20] Chapman et al[4] demonstrated a good correlation between the pullout strength of cancellous screws and the formula of D[0.5 + 0.57735 (D - d)/p] (D, outer diameter; d, inner diameter; p, pitch). According to this formula, the ratios of the calculated strength for the four commercially-available screws in the order of Osteo, Richard, Howmedica, and Synthes were 1: 0.84: 0.72: 0.74. For testings with 3.5 mm pilot holes in two foams with different densities, the ratios of the testing results in this study were 1: 0.88: 0.81: 0.71 and 1: 0.87: 0.75: 0.73, respectively. The formula of Chapman et al closely predicted the push-out strength with correlation coefficients of 0.91 and 0.99, respectively. A modification of the pitch or thread profile[10] may not effectively change the mechanical behaviors of the locking screw. Meanwhile, the inner diameter and outer diameter of the screws, however, are both limited by the diameter of the locking nail. Taken together, these circumstances suggest that new designs intended to improve mechanical behaviors should be different from fully threaded screws and move toward something like the special devices studied in this report.

It has been shown in previous studies that pullout tests of screws performed on cadaver bones,[6,7,14,18,22] animal bones,[10] or synthetic bones may have great individual variation.[2,4,5,6,8] Synthetic bones have the advantages of less individual variation and more consistent testing results.[4,6] Because locking screws tend to slip out more in osteoporotic bones than in dense cortical bones clinically,[16,18] a foam material with a density lower than that of cortical bone was used in this study to simulate the worst-case scenario of osteoporotic bones. The results of this study support previous findings that the insertion torque and the push-out strength of the screws were higher in denser foams.[2,4,5,18,22] The holding power of the screws was consistently higher when inserted with a small pilot hole than when inserted with a large one.[10] In the present study, this difference in holding power was greater in the denser foam. Evans et al[6] reported that the holding power of the screws began to decrease when the ratio between the diameter of the pilot hole and outer diameter of the screw was larger than 0.93.

The unthreaded bolt, had the longest fatigue life among all devices, suggesting elimination of threads could greatly enhance fatigue life. The unthreaded bolt with its small diameter and good fatigue strength was an ideal design for small locked nails, but its bone holding power was low compared to the threaded screws. However, this deficiency may not be a serious problem for locked nailing because a loosened screw can still maintain locking stability.[8] Additionally, the authors observed that the holding power of the unthreaded bolt was not affected by the size of the pilot holes. The set screw of the unthreaded bolt had the advantage of providing a certain holding power on bones with an excessively large pilot hole resulting from osteoporosis or technique errors, a situation in which other screws might completely lose their bone holding power.

In conclusion, four screws currently used for locked nailing tended to fail under high loading, especially under cyclic loading.

Without bony apposition at the fracture site, weight-bearing should be protected to prevent mechanical failure. The unthreaded bolt developed could produce very high fatigue strength but its holding power was only fair. Further research on the locking screws with high holding power as well as high fatigue strength was warranted.

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Table 1. Dimensions of the locking devices. (Unit: mm)

	Synthes	Howmedica	Richard	Osteo	Unthreaded
Inner diameter	4.32	3.97	3.71	3.52	4.0
Outer diameter	4.88	4.46	4.50	4.96	4.0
Pitch	2.75	1.48	1.26	1.74	-

All values are means with a standard deviation < 0.05 mm.

Table 2. Yielding strength and fatigue life of the locking devices.

	Synthes	Howmedica	Richard	Osteo	Unthreaded
Yielding strength	64.9 ± 4.7	48.8 ± 2.8	48.2 ± 3.6	34.9 ± 3.1	48.3 ± 1.6
Fatigue life	111 ± 21.3	28.7 ± 7.9	18.1 ± 4.0	10.2 ± 4.6	> 1000

Values are expressed as mean ± SD. The unit of yielding strength: Nm.
The unit of fatigue life: 1000 cycles.