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Soft Tissue Fixation to Bone

A Biomechanical Analysis of Spiked Washers

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ABSTRACT

The initial fixation strengths of two spiked-washer designs were evaluated using human femurs and fascia lata tissue. Fascia lata was attached to the femur using the fixation devices, and then each femur-washer-fascia lata complex was loaded in tension to failure. Load-elongation curves were recorded, the initial failure load, initial failure displacement, stiffness, ultimate load, and ultimate displacement were determined for each test, and failure modes were recorded. Results indicated that the 6-spike design provided superior initial fixation strength in the 19-mm diameter size. This washer design was then compared with two commercially available fixation devices: the spiked AO washer and soft tissue fixation plate. Fixation provided by the prototypal washer design was not different in most instances from that provided by the AO fixation devices. Based on these results, important design characteristics for soft tissue spiked washers are identified and discussed.

Injuries to the ligaments and tendons of the knee are common, and often require special devices to reattach the injured tissue to the bone. Additionally, knee ligament reconstruction procedures implement specialized tools and equipment to attach replacement tissues to bone. For these procedures to be successful, the fixation must provide sufficient initial fixation strength during the postoperative period, must not interfere with the soft tissue healing, and must either be biocompatible for long-term use or be easily removable. The spiked washer for soft tissue has been used in recent years to fulfill these requirements.[3,4,8,9]

Despite the popularity of these fixation devices, biomechanical data on the efficacy of soft tissue washers are limited. Several studies have examined the performance of devices such as staples.[1,2,5,6,9] Case reports have advocated the use of washers for repair of ligaments of the knee and ankle.[4,8] Another study examined fixation to a metallic surface using the spiked AO washer and soft tissue fixation plate.[3] The only study of the performance of washers in attaching soft tissue to bone was conducted by Robertson et al.[9] They compared the immediate fixation strengths of several suture techniques, staples, a spiked washer, and a spiked plate for soft tissue. In each case, attachment to cancellous bone was made with a 6.5-mm cancellous screw. Cyclic loading was performed, and results showed that the spiked washer and the spiked plate for soft tissue provided the most secure fixations overall, and that one of the staple designs provided the worst fixation. To our knowledge, no work has yet been done to compare the initial fixation strengths of different spiked washer designs for soft tissue.

The purposes of this study were 1) to assess the effect of two prototypal washer designs on the structural characteristics of a femur-washer-fascia lata complex, 2) to compare the initial fixation strength of the best prototypal design with that of presently used soft tissue fixation washers, and 3) to determine important washer design considerations for the effective fixation of soft tissue with minimal tissue necrosis.

MATERIALS AND METHODS

Biomechanical studies

Washer designs. Two prototypal washer designs were evaluated biomechanically, and then the superior prototype was compared with two currently used fixation devices: the AO polyacetal resin spiked washer and the AO soft tissue fixation plate (Synthes Ltd., Paoli, PA). The two prototypal washer designs were fabricated from titanium. These designs differed in the number of spikes (3 or 6), the number and location of smaller posts or ridges or both, and the size of the shoulder around the spikes (Fig. 1). The

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spikes on the 3-spike washer were situated on raised posts of larger diameter than the spike itself. The flat area formed by the wider diameter post is the post shoulder. Smaller, rounded spikes of approximately 1 mm in height were positioned over the remaining surface area of the washer. The spikes on the 6-spike washer were positioned on the tops of ridges that followed the circumference of the washer for approximately 40°. The height of the ridges was 1.3 mm. Ridges of decreasing height were present toward the center of the washer. For each of the two prototypes, 13-, 16-, and 19-mm diameter washers were machined and tested. For descriptive purposes in the paper, these designs are referred to as either the "3-spike" or "6-spike" design.

The AO soft tissue washer and plate are commercially available soft tissue fixation devices (Synthes Ltd.) (Fig. 2). The soft tissue washer is manufactured from polyacetal resin and is approximately 13.7 mm in diameter. It has 8 spikes positioned around its periphery and mounted on tops of posts of 1.6-mm height and 2.4-mm diameter. The soft tissue plate is machined from 316-L stainless steel and consists of an array of 24 cone-shaped spikes of 3-mm height. Unlike the washers, the plate is rectangular in cross-section, and screw attachment is achieved at the far end of the device.

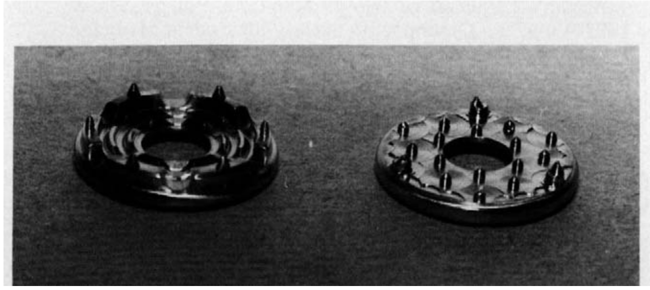

Figure 1. The two prototypal washer designs (16-mm diameter) used in the mechanical tests.

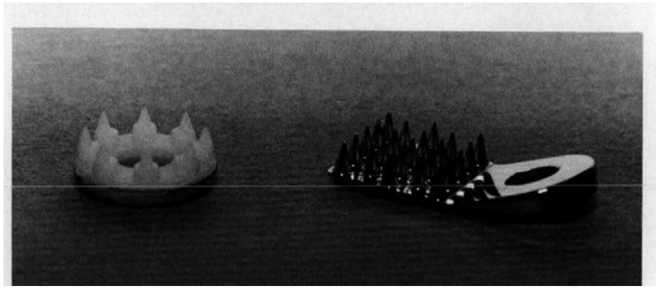

Figure 2. The AO washer and soft tissue plate.

Effective surface area. The effective surface area of each washer design and size was calculated. For the round washers, the effective surface area was computed using the inside and outside diameters of the washer, whereas for the soft tissue plate a square cross-section was assumed. The effective surface area should be related to the structural properties because it represents the area of contact at the tissue-bone interface.

Biomechanical testing. To assess the initial fixation strength of the washers, biomechanical tests were performed with human fascia lata attached to the distal portion of the femur using each fixation device. Six fresh human distal femurs were obtained and cleaned of all soft tissues. Specimens were then placed in airtight plastic bags and frozen at −17.7°C until the day of testing. Before testing, each femur was allowed to thaw to room temperature. The femurs were potted in a cylinder with molten fusible No. 158 low-melting alloy (Affiliated Metals, Salt Lake City, UT).

Human fascia lata that had been sterilized with ethylene oxide and preserved by lyophilization (rapid freezing and dehydration under high vacuum) was used as the soft tissue in all biomechanical tests. This tissue was chosen for its relatively constant thickness, homogeneity, and availability. The fascia lata was reconstituted in distilled water for at least 24 hours before use and was cut into strips slightly wider than the particular attachment device to be tested. Cuts were always made in a direction parallel to the fiber orientation of the tissue. The thickness of the tissues was measured at several locations along the length using digital calipers.

The fascia lata strips were attached either to the lateral or to the medial surfaces of each femur using the selected fixation devices. Each washer was tested once on each femur, and care was taken to assure that the test locations had a similar quality of bone. Because there were two prototypes, three different diameters, and two AO fixation devices, eight devices were tested on each femur. To reduce any possible effect of differing attachment site bone quality on the biomechanical parameters, fixation methods were assigned randomly to a test location on the femur. The bone surface was prepared by removing the periosteum and providing a flat surface to ensure proper fixation at the periphery of each attachment device. Fully threaded cancellous bone screws (diameter, 6.5; length, 35.0 mm) were used for all tests. Screw holes (diameter, 3.2 mm) were drilled into the bone surface. Each hole was tapped to 6.5 mm deep. Small slits were made in the fascia lata strips, and then the screw was passed through the attachment device and threaded through the slit in the fascia lata. A 9/64-inch hex driver wrench was used to tighten the screws to "two-finger tightness" (approximately 5 inch-pounds of torque) to imitate the clinical procedures used with the screws. An experiment with the screws and a torque wrench demonstrated that the difference between repeated efforts of a single individual to tighten the screw to two-finger tightness differed, at most, by ±1 inch-pound. The same individual tightened all screws in the study. To prevent the tissue from wrapping around the screw as it was tightened, the tissue was held in proper orientation against the femur by limiting rotation of the attachment device. When attaching the AO soft tissue plate, special wrenches were used to contour the device to the bone and thus assure equal penetration of all spikes.

The potted femurs were fastened vertically in a test fixture bolted to the base plate of a materials testing machine. The fixture was positioned so that the soft tissue would be pulled vertically and yet tangential to the surface of the femur (Fig. 3). The free end of the fascia lata was clamped between specially designed soft tissue clamps. Care was

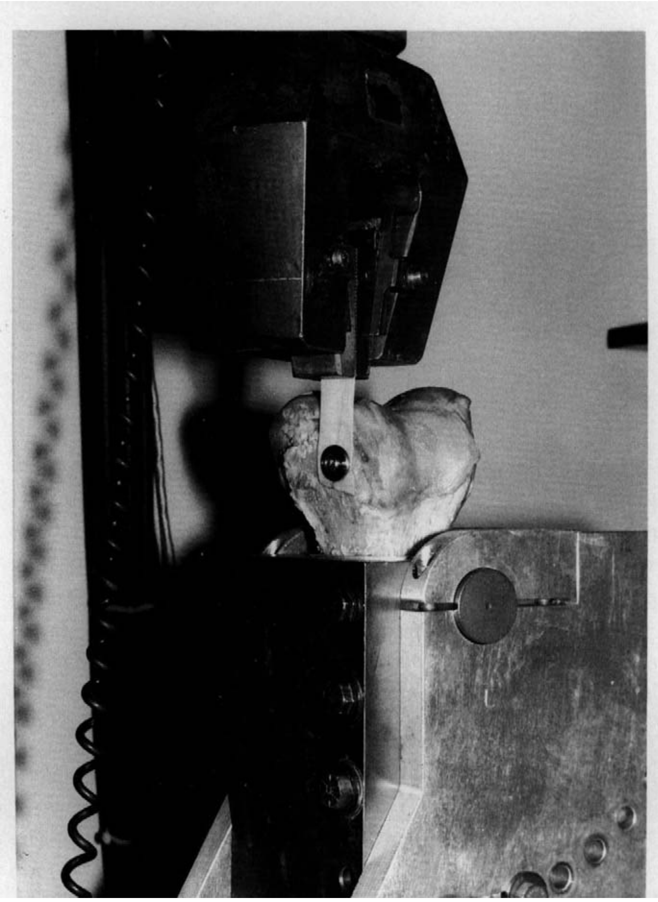

Figure 3. The test setup used for evaluation of the structural properties of the femur-washer-fascia lata complex.

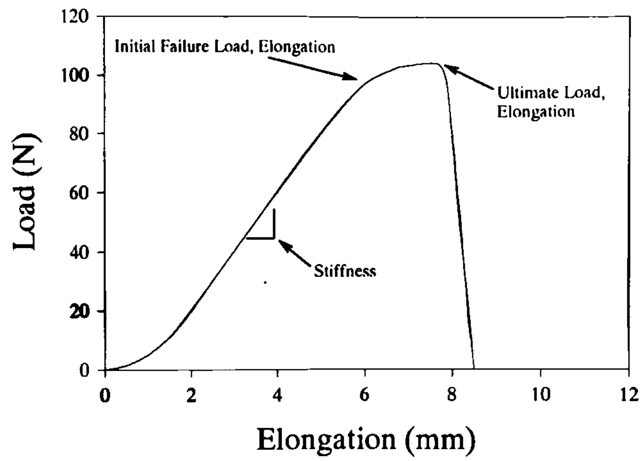

Figure 4. A representative load-elongation curve of a femur-washer-fascia lata complex shows how the various structural parameters were defined.

taken to ensure that, for each test, the distance from the center of the washer attachment to the clamped end was the same for all tests, and that the tissue was clamped so that equal loading would occur across its width. The zero-load length of the femur-washer-fascia lata complex was determined by consecutively applying and removing a small tare load. A preload of 2.0 N was applied to the femur-washer-fascia lata complex, and three preconditioning cycles were performed between 0 and 1 mm of elongation at an extension rate of 0.5 mm/sec. This was followed immediately by destructive testing at 0.5 mm/sec. Actuator displacement and applied load were recorded to define initial failure load (load at which the load-elongation curve began to become nonlinear), initial failure elongation, ultimate load, ultimate elongation, and stiffness (Fig. 4). The location on the femur, failure mode, and tissue quality were recorded for each test.

Statistical analysis. The effect of prototypal washer design on the biomechanical properties of the femur-washer-fascia lata complex was assessed for each washer diameter using a one-way analysis of variance (ANOVA). Complete block design (repeated-measures ANOVA) was used to account for the different test locations on the femur that were used. Comparisons between different washer diameters were not made because of the difference in size of fascia lata strips used for different washer sizes. The "most effective" of the two prototypes was then compared with the AO spiked washer and soft tissue fixation plate, again using the ANOVA with complete block design. A one-way ANOVA with completely randomized design was performed to assess any differences in tissue thickness between groups. When significance was measured by any of the ANOVA statistics, subsequent independent t-tests between different levels of the factor were performed. Significance levels for the ANOVA and t-test were set at $P \leq 0.05$.

RESULTS

Although all the fascia lata specimens had relatively constant thickness, there were small differences between samples. The ANOVA indicated that there was no effect of experimental group on the thickness of the fascia lata used ($P > 0.5$). All specimens showed a similar failure mode in which the fascia lata pulled from beneath the washer or plate and was shredded into small strips by the penetrating spikes or post shoulders (Fig. 5).

Prototypal washer designs

Stiffness. The stiffness of the femur-washer-fascia lata complex was determined from the load-elongation curve in the most linear portion before initial failure began (Fig. 4). The stiffness for the 19-mm 6-spike design was significantly greater than that for the 19-mm 3-spike design ($P < 0.02$) (Table 1).

Initial failure load and elongation. The initial failure load was determined to be the best indicator of fixation strength (Table 1). Clinically, any displacement of the tendon from the fixation site would indicate failure of the repair. At the initial failure load, soft tissue was still in intimate contact with the bone, whereas toward the ultimate failure load the soft tissue began to pull from beneath the washer or plate. The initial failure load of the 6-spike group (98.6 ± 34.9 N) was significantly greater than that of the

3-spike group (148.9 ± 42.8 N) in the 19-mm size ($P < 0.05$). No significant differences in the initial failure elongation between washer designs could be demonstrated ($P > 0.25$ for all cases).

Ultimate load and ultimate elongation. Ultimate load was defined as the maximum load sustained by the femur-washer-fascia lata complex during the destructive tests (Table 1). No significant differences were detected between the ultimate loads of the 3- and 6-spike washers for either the 13- or 16-mm sizes (P = 0.12 and 0.34, respectively). The ultimate load of the 19-mm 3-spike washer was significantly less than that of the 6-spike washer ($P < 0.02$). There were no significant differences in the ultimate elongations between the two designs ($P > 0.25$ in all cases).

"Best" prototypal washer versus AO washer and soft tissue plate

Based on the biomechanical results, the 6-spike washer was identified as providing superior initial fixation. To assess which size (diameter) of the 6-spike washer design should be compared with the AO washer and plate, the effective surface areas of the three sizes of the 6-spike washer and the AO devices were computed (Table 2). It was concluded that the 19-mm washer should not be compared with the AO designs, because of the large difference in effective surface area, but that both the 13- and 16-mm washers were of comparable size. To avoid comparing again the 13- and 16-mm sizes of the prototypal design with each other, two separate one-way ANOVAs were performed: one compared the 16-mm 6-spike AO washer and plate, while the other compared the 13-mm 6-spike AO washer and plate.

The 13-mm 6-spike washer versus AO washer versus AO plate. No significant differences were seen in the initial failure load, initial failure elongation, or stiffness in these fixation devices, although in the case of the initial failure load the AO washer was close to being significantly greater than the 13-mm 6-spike prototype (P = 0.07) (Table 3). There was a significant effect of washer type on ultimate load with the AO washer having the largest ultimate load ($P < 0.02$). For the ultimate elongation, the AO washer had the largest value, and the AO plate had the smallest value ($P < 0.02$).

The 16-mm 6-spike washer versus AO washer versus AO plate. No significant differences were seen in the initial failure load, initial failure elongation, stiffness, or ultimate load in these fixation devices (Table 3). The AO plate had a significantly smaller ultimate elongation than both the prototype and the AO washer ($P < 0.02$). The AO washer had a significantly greater ultimate load and elongation than the soft tissue plate ($P < 0.03$ and 0.01, respectively).

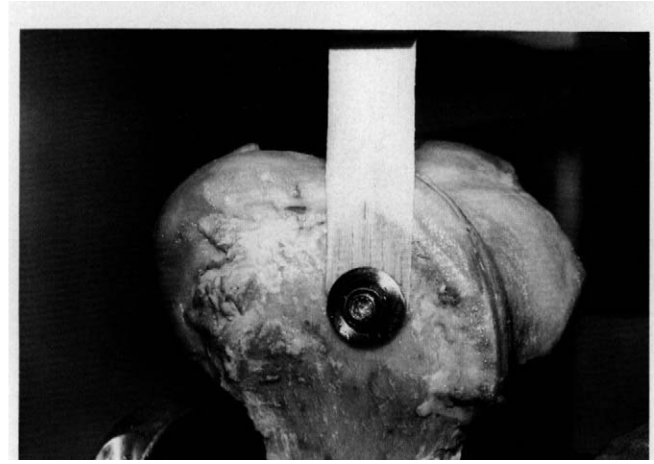

Figure 5. Mode of failure for fascia lata fixation. In all cases the fascia lata shredded from beneath the fixation device.

DISCUSSION

Although there were no demonstrable differences in the washer designs for the 13- and 16-mm sizes, the 19-mm 6-spike design provided a larger initial failure load, stiffness, and ultimate load than the 19-mm 3-spike design. There are several possibilities for the lack of significant differences in the smaller sizes. In the smaller sizes, magnitudes of the experimentally measured parameters were smaller; therefore, experimental errors represented a larger percentage of the value. The results might also be explained by the differences in the material (stress-strain) properties of the fascia lata between specimens used in testing. These differences would affect the structural measurements that were taken. Increasingly larger tissue samples were used with larger washer sizes, and it is possible that the effect of the differing material properties was large enough to mask the effect of the different washer designs.

Based on the relative performance of the 3-spike and 6-spike washer designs, several important design considerations can be presented. The 6-spike design provided su-

TABLE 1
Data for the mechanical tests using the prototype washer designs (mean ± standard deviation)

Washer type: Diameter (mm)	Washer type: Spikes (No.)	Thickness (mm)	Initial failure load (N)	Initial failure elongation (mm)	Stiffness (N/mm)	Ultimate load (N)	Ultimate elongation (mm)
13	3	0.56 ± 0.11	62.7 ± 21.3	4.1 ± 1.2	25.1 ± 9.9	83.1 ± 21.6	6.9 ± 3.0
13	6	0.55 ± 0.09	87.2 ± 51.9	5.6 ± 3.0	23.4 ± 6.6	113.6 ± 43.8	7.8 ± 2.6
16	3	0.56 ± 0.12	104.8 ± 52.2	4.6 ± 2.3	32.1 ± 7.6	126.1 ± 33.6	7.2 ± 2.1
16	6	0.59 ± 0.13	81.2 ± 20.4	5.0 ± 1.7	25.4 ± 11.7	110.1 ± 20.5	8.4 ± 1.9
19	3	0.59 ± 0.09	98.6 ± 34.9	5.6 ± 2.0	27.3 ± 11.3	119.3 ± 35.9	8.7 ± 2.8
19	6	0.59 ± 0.15	148.9 ± 42.8[a]	5.3 ± 1.7	44.8 ± 9.0[a]	185.8 ± 21.4[a]	8.6 ± 2.6

[a] Significant difference between the washer designs was noted.

TABLE 2
Effective surface areas of the washer designs used in this study (mm^2)

13-mm, 3-spike	16-mm, 3-spike	19-mm, 3-spike	13-mm, 6-spike	16-mm, 6-spike	19-mm, 6-spike	AO washer	AO plate
108.6	175.7	261.5	108.6	175.7	261.5	122.4	144.0

TABLE 3
Comparison of the 6-spike prototype design with the AO washer and AO soft tissue plate

Washer type	Initial failure load (N)	Initial failure elongation (mm)	Stiffness (N/mm)	Ultimate load (N)	Ultimate elongation (mm)
13-mm, 3-spike	62.7 ± 21.3	4.1 ± 1.2	25.1 ± 9.9	83.1 ± 21.6	6.9 ± 3.0
13-mm, 6-spike	87.2 ± 51.9	5.6 ± 3.0	23.4 ± 6.6	113.6 ± 43.8	7.8 ± 2.6
AO washer	103.2 ± 47.6	6.3 ± 3.1	28.7 ± 16.1	119.3 ± 35.6	7.8 ± 2.6
AO plate	90.6 ± 16.0	5.0 ± 2.2	30.5 ± 10.6	94.1 ± 15.7	5.3 ± 2.1

perior initial fixation in the 19-mm diameter size. We believe the important design features responsible for the difference are the texture of the undersurface along with the design, number, and position of the spikes.

Spikes should be positioned near the periphery of the washer to take advantage of the entire washer surface area. A rough washer undersurface like that used in the 6-spike design will provide an improved frictional hold on the fascia lata; however, this type of design feature may have a tendency to produce pressure necrosis. An ongoing histologic study in our laboratory is addressing the in vivo response of soft tissue to washer fixation.

When attaching the different fixation devices to bone, several problems with the designs became evident. 1) When tightening the AO spiked washer against hard bone, the spikes bent and were smashed, indicating plastic failure of the polymeric washer material, which compromised the function of both the spike and the post shoulder. 2) The AO spiked plate had to be bent during attachment so that the spikes farthest from the screw attachment would seat as deeply as those closest to the screw. 3) Post shoulders on the 6-spike prototypal washer design were too long and thin, and they sometimes cut through the fascia lata.

We believe that the most important washer design feature is the spike. With the exception of the soft tissue plate, the basic spike design on all the washers tested was one in which the spike was situated on a raised post of wider diameter than the spike itself. The flat area created by the wider diameter post is the post shoulder, and it serves two purposes: 1) limiting the penetration of the spike into the bone, and 2) tightly compressing the soft tissue beneath it. Although the vascularity of the tissue directly beneath the shoulders will be compromised, the tissue between the posts should experience very little compression.[7] The total post shoulder surface area on the AO spiked washer was large in comparison with the prototypal designs, and this may explain its superior performance. On the other hand, the spikes on the AO plate had no shoulders, which explains the performance of the AO plate being equivalent to or worse than the 6-spike prototype and the AO washer, despite its much larger effective surface area.

Not only should spiked washers be available in different diameters, but washers with different post heights should be available for tissue of different thickness. The post should be slightly shorter than the thickness of the tissue to be attached. If a spiked washer with too short a post is used to attach a thick piece of tissue, pressure necrosis would likely result. Conversely, if a washer with posts that are too tall is used to attach thin tissue, the tissue would not be in contact with the undersurface of the washer. The size of the washer should be determined by the width of the tissue.

Based on the information about washer design gleaned from this study, a new prototype has been designed and manufactured. The effects of this fixation device on tissue fixation currently are being evaluated in an in vivo model. It is hoped that information gained from this work will lead to improved soft tissue washer designs that provide better initial fixation and less tissue necrosis than the models presently available.

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