Evaluation of a New Device for the Reattachment of the Achilles Tendon

Jill S. Kawalec-Carroll, PhD

Ohio College of Podiatric Medicine
6000 Rockside Woods Blvd.
Independence, OH 44131

Specific Aims:

The objective of this study was to evaluate the performance of a new device for the reattachment of the Achilles tendon. The new device consisted of a plate and two screws. The specific aims of the study were as follows:

1. To compare the maximum load to failure obtained with plate fixation to that observed with suture anchor fixation in cadaveric limbs. It was hypothesized that the maximum load sustained by the reattachment prior to failure would be greater for the plate than that for a suture anchor currently on the market.

2. To modify the plate and screw designs, based on the results of testing in cadaveric limbs, in order to prevent the screws from pulling through the plate. Simulated tendons and foam blocks were used for testing. It was hypothesized that the modified design would prevent or reduce the screws from pulling through the plate, without a reduction in the maximum load to failure.

3. To determine the pull-out strength of the plate reattachment device via direct loading of the plate. Foam blocks were used for testing. It was hypothesized that the pull-out strength of the plates would be greater than the maximum loads obtained during simulated clinical loading, since the only mode of failure would be device failure (as opposed to tendon failure).

Cadaveric Limbs:

Materials and Methods:

Five matched pairs of fresh frozen lower limb specimens were used in this study. The demographics for the donors are shown in Table 1. Dissection was performed on each limb to expose the posterior portion of the calcaneus and to isolate the Achilles tendon. The Achilles tendon was then detached at the calcaneus and reattached for testing. For each matched pair, a plate (original design) was used to reattach the tendon in the left limb, while a suture anchor (Arthrex Bio-Suture Tak, Mini, 2.4 mm with one 2-0 FiberWire and two needles (Item #AR-1322BNF)) was used to reattach the tendon in the right limb. The Achilles tendon was then horizontally transected approximately 4 inches proximal to the point of calcaneal reattachment, to allow for the clamping of the tendon for loading.

Table 1: Donor Demographics

Specimen (L/R)	Gender	Race	Age (years)	Height	Weight (lbs)
Foot A/Foot F	Female	Caucasian	72	5'9"	100
Foot B/Foot G	Male	Hispanic	87	5'10"	150
Foot C/Foot H	Female	Caucasian	44	5'2"	156
Foot E/Foot J	Female	Caucasian	74	5'4"	86
Foot I/Foot D	Female	Caucasian	70	4'11"	126

A computer-controlled MTS 858 Mini Bionix biomechanical test system was used to apply a tensile load to the Achilles tendon in a direction perpendicular to the calcaneus, in order to simulate clinical loading. For each limb, a hole approximately 0.2 inches in diameter was drilled through the calcaneus in a lateral-to-medial direction. The foot was then placed on a flat platform that was attached to the load cell of the test system. A threaded rod approximately 0.2 inches in diameter was passed through the hole previously drilled into the calcaneus, and the rod was then secured to the load cell via vertical brackets attached to the flat platform on either side of the foot. The proximal end of the Achilles tendon was grasped with a clamp that was attached to the actuator piston rod of the test system. The tendon was then loaded in tension at a rate of 0.236 inches/second until failure occurred, as indicated visually by either device failure or soft tissue failure, and mechanically by a sudden drop in load. Load (lbf) and displacement (inches) were recorded, and the maximum load to failure was determined. The failure mechanism was also noted.

Statistical analysis was conducted to determine if there was a statistically significant difference in maximum load to failure between the plate and suture anchor reattachment. The two-tailed student's t-test was used for analysis, and significance was defined as $p<0.05$.

Results and Discussion:

The maximum load to failure and the failure mechanism for each sample are shown in Table 2. The maximum loads to failure obtained with the plate reattachment were consistently greater than those measured with the suture anchor reattachment. The most common mode of failure observed for the plate reattachment was device failure, with the screws pulling through the plate (3 out of 5 samples, or 60%). This can be corrected with a slight modification of the plate and screw design. Failure of the tendon was observed in two of the five samples with the plate reattachment (40%). Device failure was the mechanism most often observed with reattachment via the suture anchor (4 out of 5 samples, or 80%). In these cases, the suture tore from the anchor. In one of the samples with suture anchor reattachment, the suture tore through the tendon (20%). It is important to note that, while device failure was the most often cause of failure for both reattachment devices, the plate/screw construct failed at a higher load than the suture anchor.

Table 2: Maximum Load to Failure and Failure Mechanism – Cadaveric Limbs

Sample	Max Load (lbf)	Failure Mechanism
Plate and Screws		
Foot A	28.18	Device Failure (right screw pulled through plate)
Foot B	52.45	Device Failure (right screw pulled through plate)
Foot C	55.78	Soft Tissue Failure (tendon failed)
Foot E	45.25	Device Failure (both screws pulled through plate)
Foot I	38.40	Soft Tissue Failure (tendon failed)
Suture Anchor		
Foot F	10.11	Device Failure (suture strength – suture tore from anchor)
Foot G	14.67	Device Failure (suture strength – suture tore from anchor)
Foot H	14.41	Device Failure (suture strength – suture tore from anchor)
Foot J	25.31	Device Failure (suture strength – suture tore from anchor)
Foot D	13.11	Soft Tissue Failure (suture pulled through tendon)

The average maximum loads to failure for the reattachment devices are shown in Figure 1. The average maximum load to failure measured with the plate reattachment (44.01 ± 11.10 lbf) was approximately 3 times greater than that measured with the suture anchor reattachment (15.52 ± 5.76 lbf). This difference was statistically significant ($p<0.001$, power = 0.994).

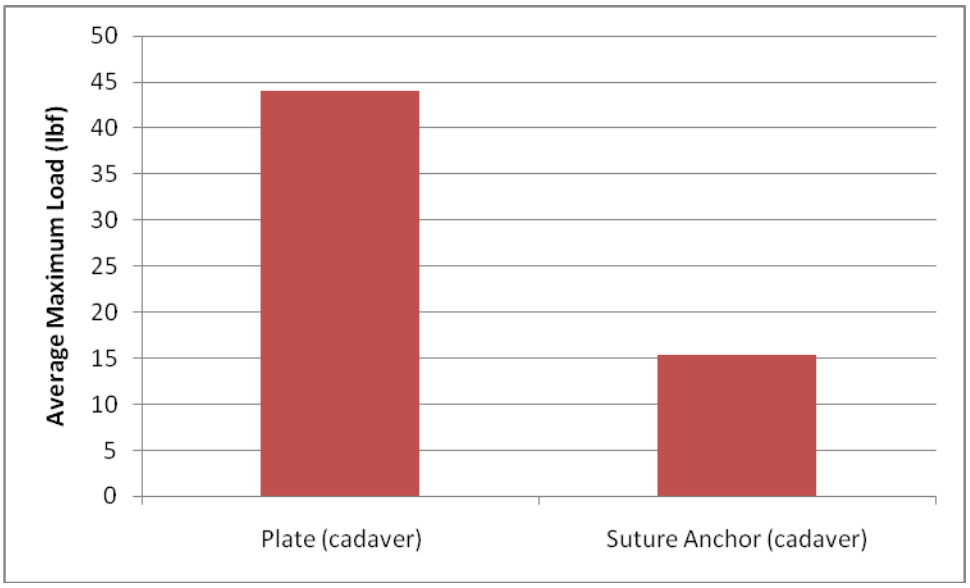

Figure 1: Average Maximum Load to Failure – Cadaveric Limbs

Simulated Tendon:

Materials and Methods:

Based on the results from testing in cadaveric limbs, the plate and screw design was modified to prevent the screws from pulling through the plate. The maximum load to failure obtained with the modified design was evaluated using a simulated tendon and foam block. A total of four blocks and simulated tendons were used for testing.

The simulated tendon was attached to the block with the plate. A hole approximately 0.2 inches in diameter was drilled through the block. The block was then placed on a flat platform that was attached to the load cell of the test system. A threaded rod approximately 0.2 inches in diameter was passed through the hole in the block and then secured to the load cell via vertical brackets attached to the flat platform on either side of the block. The simulated tendon was grasped with a clamp approximately 4 inches from the point of attachment to the block. Using the MTS biomechanical test system, the simulated tendon was loaded in tension at a rate of 0.236 inches/second until failure of either the simulated tendon or the plate. Load (lbf) and displacement (inches) were recorded, and the maximum load to failure was determined.

Statistical analysis was conducted to determine if there were statistically significant differences in the maximum load to failure between the modified plate reattachment using the simulated tendon and foam block, plate reattachment using cadaveric limbs, and suture anchor reattachment using cadaveric limbs. The one-way ANOVA was used for analysis. Pairwise multiple comparison procedures were performed using the Holm-Sidak method. Significance was defined as $p<0.05$.

Results and Discussion:

The maximum loads to failure sustained by the modified plate for each sample are shown in Table 3, while the average maximum loads to failure for the three constructs tested thus far are shown in Figure 2. The average maximum load to failure for the modified plate reattachment was 44.71 ± 8.08 lbf. This is not significantly different ($p<0.907$) from that observed with the original plate design in cadaveric limbs (44.01 ± 11.10 lbf). In contrast, the average maximum load to failure measured with the modified plate reattachment using the simulated tendon was significantly greater ($p<0.001$) than that found with suture anchor reattachment in cadaveric limbs. The power of the performed analysis was 0.998. It should be noted that caution should be used when comparing results with the simulated tendon and foam block to those with the cadaveric limbs, due to the different materials used for the "tendon" and "calcaneus".

Table 3: Maximum Load to Failure – Simulated Tendon

Sample	Maximum Load (lbf)
Block A	33.60
Block B	46.45
Block C	45.84
Block D	52.95

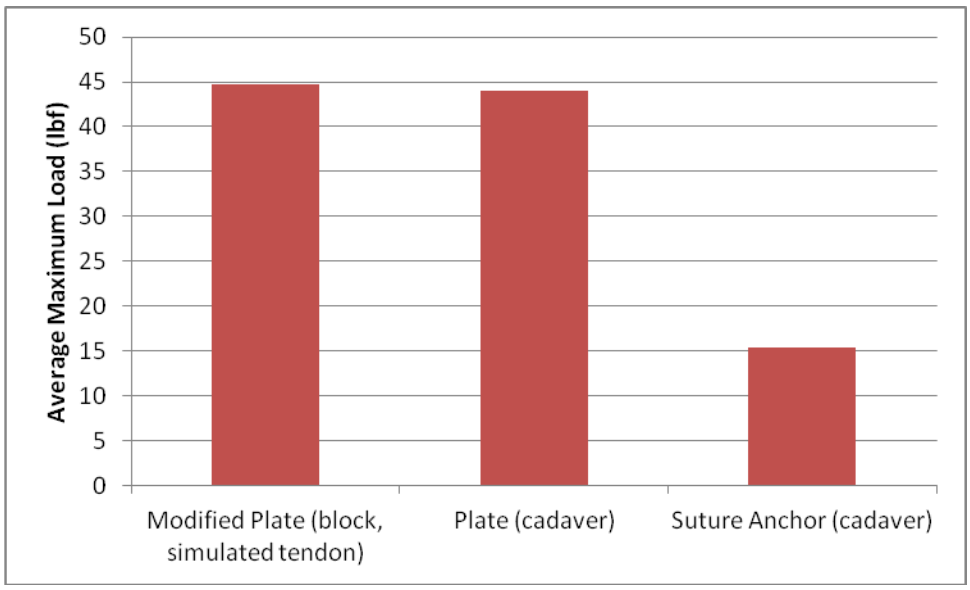

Figure 2: Average Maximum Load to Failure – Simulated Tendon/Foam Block and Cadaveric Limbs

Direct Loading:

Materials and Methods:

The pull-out strength of the modified plate and screw design was tested via direct tensile loading, using foam blocks. Six blocks were used for testing.

The L-shaped end of a Senn retractor was attached to the block with the plate. A hole approximately 0.2 inches in diameter was drilled through the block. The block was then placed on a flat platform that was attached to the load cell of the test system. A threaded rod approximately 0.2 inches in diameter was passed through the hole in the block and then secured to the load cell via vertical brackets attached to the flat platform on either side of the block. The handle of the retractor was grasped with a clamp. Using the MTS biomechanical test system, a tensile force was applied to the retractor at a rate of 0.236 inches/second until the plate pulled away from the block and fixation failed. Load (lbf) and displacement (inches) were recorded, and the maximum load to failure was determined.

Statistical analysis was conducted to determine if there were statistically significant differences in the average maximum load to failure between the direct loading of the plate using a foam block, plate reattachment using the simulated tendon and foam block, plate reattachment using cadaveric limbs, and suture anchor reattachment using cadaveric limbs. The one-way ANOVA was used for analysis. Pairwise multiple comparison procedures were performed using the Holm-Sidak method. Significance was defined as $p<0.05$.

Results and Discussion:

The maximum loads to failure sustained by the modified plate for each sample are shown in Table 4, while the average maximum loads to failure for all four groups tested are shown in Figure 3. The average maximum load to failure was 94.47 ± 16.37 lbf.

This is significantly greater ($p<0.001$) than the average maximum loads to failure observed for all other groups: plate reattachment in cadaveric limbs, suture anchor reattachment in cadaveric limbs, and modified plate reattachment using simulated tendon and foam block. The power of the performed test was 1.000. Caution should be used when comparing results with the foam block to those with the cadaveric limbs, due to the different materials used for the "tendon" and "calcaneus".

Table 4: Maximum Load to Failure – Direct Loading

Sample	Maximum Load (lbf)
Block E	80.05
Block F	93.13
Block G	108.95
Block H	89.12
Block I	76.93
Block J	118.65

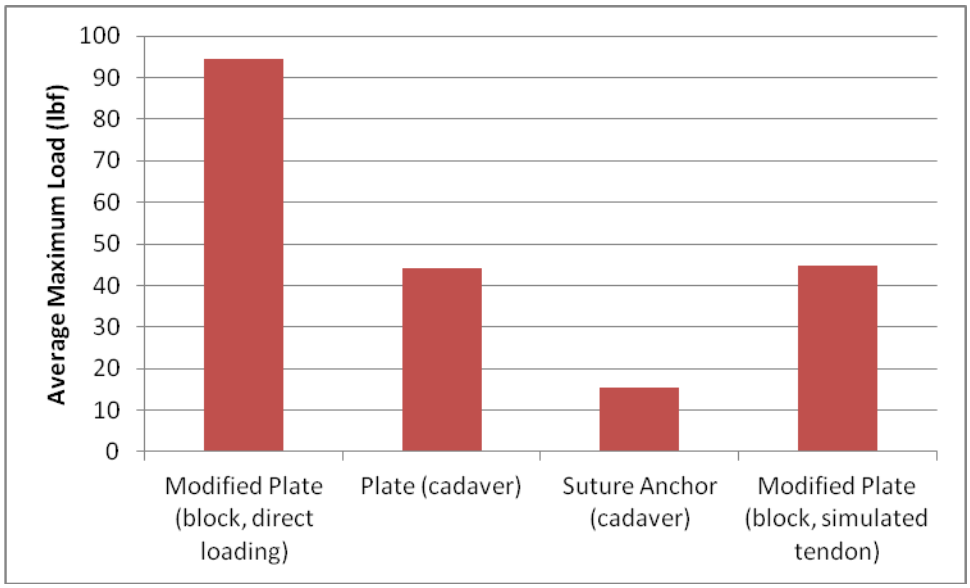

Figure 3: Average Maximum Loads – Direct Loading/Foam Block, Cadaveric Limbs, and Simulated Tendon/Foam Block

Conclusions

In conclusion, the reattachment of the Achilles tendon with a novel plate-and-screw design failed at a higher load compared to reattachment with a commercially-available suture anchor. While device failure was observed with the original plate-and-screw design, a minor modification improved the performance of the device. In clinical applications, it can be expected that reattachment of the Achilles tendon with the plate examined in this study will be superior to that obtained with suture anchors.