学位論文

The stability of total talar prosthesis- How stable to dislocation? Cadaveric study

（人工距骨の安定性―脱臼への耐性は如何ほどか？ カダバ研究）

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The Stability of Total Talar Prosthesis

- How stable to Dislocation? Cadaveric Study -

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Running title: The stability of TTP ankle

ABSTRACT

Aim**:** The aim of this study was to characterize ankle stability of Total Talar Prosthesis (TTP) and to determine the effect of implant sizes on stability as well as the resistance to TTP dislocation. Methods: Twelve below-knee cadaveric specimens were divided into two groups. Group 1 received a size matched implant and Group 2 received downsized implant by five percent. The stability assessment under fluoroscopy was performed for each cadaver in its native state. Following TTP insertion process, each then underwent evaluation of the TTP ankle stability. The stability of pre and post TTP was compared. 1) Anterior drawer distance. 2) Talar tilt angle under varus and valgus stress 3) Subtalar tilt angle under varus stress was measured. Finally, the dislocation test was performed using the aforementioned testing conditions, then the stress force was slowly increased from 0 to 350 N, during which time it was observed on fluoroscopy all the time. Results: Compared to pre TTP ankles, varus and anterior drawer stress showed significant instability ($p <0.001$ to 0.031). Only anterior drawer stress in smaller sized implants showed significant instability when compared to identical sized implants ($p = 0.008$). No dislocation was seen under varus, valgus, and subtalar stress. However, anterior dislocation was observed in all cases of smaller size implant group ($p = 0.045$). Conclusion: TTP implant was stable under valgus and subtalar stress. However, clinicians should pay attention to anterior instability. Notably, downsized implants should be considered carefully to minimize the chance for anterior dislocation.

Level of Evidence: Ⅳ, Biomechanical cadaveric study

KEYWORDS: Total talar prosthesis, Ankle stability, Talar necrosis, Talar comminuted fracture

INTRODUCTION

Talar osteonecrosis is a challenging and often frustrating condition to treat (Figure 1a) [1-3]. Traditionally, treatment options include ankle arthrodesis and talectomy, but each has inherent limitations. Previous studies found that the non-union rate with ankle arthrodesis is about 20%[4,5] . Moreover, arthrodesis eliminates ankle motion and pseudarthrosis may develop[6]. Talectomy with or without arthrodesis can result in non-union, pseudoarthrosis, leg-length discrepancy and varus deformity[7,11,12].

Total Talar Prosthesis (TTP) can be a good alternative for managing talar necrosis and comminuted fractures of talus (Figure 1b)[8,9]. It can restore the function of the ankle joint without an associated leg-length discrepancy[9,10]. The use of TTP custom made implants made with 3D printing based on the CT imaging of contralateral talus have shown to restore near normal anatomic alignment in the setting of osteonecrosis[1] (Figure 2). Previous clinical studies reported good clinical outcomes and prosthetic stability in clinical manual stress during follow up period despite the implant not being stabilized by ligament reattachment or alternative devices[9,10]. It remains unknown, however, how stable an implant is against dislocation nor how implant sizing might affect stability of the ankle. This is particularly relevant because there exists the occasional temptation to insert a smaller sized implant due to greater ease of introduction as well as an occasional preference for downsizing when talar collapse exists. Better understanding the implications of such tradeoffs may lead to more optimized treatment algorithms for patients who are candidates for TTP, and would also provide improved understanding of tibiotalar and subtalar joint biomechanics following TTP. The primary aim of this study, therefore, was to detect stability of the ankle after TTP replacement. Secondarily, we wanted to determine the effect of implant size on overall ankle stability as well as the force required to render a freshly implanted ankle unstable. Our hypothesis was that there would be a significant instability in the TTP implanted state, to a greater degree when these implants are knowingly downsized.

Materials and Methods:

Specimen preparation

Twelve nonpaired fresh-frozen, below-knee amputated cadaveric specimens were used. No specimen had signs of ankle osteoarthritis or previous trauma based on pre-sectioning radiographic evaluation (OrthoScan FD Pulse C-Arm, OrthoScan, Scottsdale, AZ). Soft tissues were maintained to simulate in vivo conditions. Before testing, specimens were thawed at room temperature 24 hours prior to the start of the experiment. Intact specimens were randomized into two groups of six specimens. In Group 1, the TTP implant identical to the size of the cadaveric talar bone was used. In Group 2, the TTP implant 5% smaller in height compared to the actual cadaveric talus size was used. The second group with smaller sized implant was envisioned to simulate real clinical cases with talus collapse due to avascular necrosis of talus. In the clinical realm, the TTP implant is made from the contralateral healthy talar images, thus it is entails to order smaller sized implant in cases of talar collapse to avoid difficult insertion case due to implant size mismatch. Prior to the experiment, no differences were found between two groups in terms of specimen age, gender, and laterality (Table 2).

Implant preparation

Prior to the experiment, CT images of twelve cadavers were performed (SOMATOM Dual Source CT scan, Siemens®, Munich, Germany). The field of view was set to 250mm centered on the talus and slice pitch was within 2mm. The Digital Imaging and Communications in Medicine (DICOM) images obtained from the CT scan were then manually processed for segmentation of the talus using the 3D Slicer open source software (Slicer 4.10). Six cadaveric CT images were segmented to create TTP implant identical to the original size and the other six implants were segmented 5% small height than the original size of the talus, which all other dimensions remained the same as original talus shape. Finally, the segmented talus was scaled and smoothed to replicate cartilage surface using Meshmixer (Meshmixer 3.0). The implant were 3D printed using Full Cure 720 plastic coated with Tungsten which allows implant to clearly visible under fluoroscopy.

TTP operation procedure

In all twelve cadavers, the steps to insert the TTP implant was carried out as previously described by Taniguchi et. al[9]. Using the anterior approach, a 6-8 cm incision was made at the level of talus. The talus was then shattered carefully with oscillating bone saw while protecting surrounding structure from damage and removed piece by piece in the order of head, neck and body part of the talus. All ligaments attached to the talus were dissected at the same time. After removing the talus completely, the implant was inserted manually and the joint capsule was repaired as much as possible and the skin was sutured. The identical sized implant was inserted to 6 cadavers as an identical sized group and the 5% smaller height TTP implant was inserted to 6 cadavers as a smaller sized group.

Experimental procedure

The experiment was carried out according to following three steps (Table 1). In the first step, every 12 cadaver's stabilities were measured as a pre TTP intact state. In the 2nd step, TTP implant was inserted in each cadaver according to the surgical method described above. Then the stability was measured again as a TTP state in each group. All steps were evaluated using fluoroscopy. The details of the measurement method are as follows.

Fluoroscopic measurements

All specimens were stressed using the Telos device (Telos Stress Device GA-Ⅲ/E, Telos GmbH®, Laubscher, Holstein, Switzerland)) and fluoroscopic images were obtained. (Figure 3). In the both 1st pre TTP intact and 2nd TTP implantation stage, four fluoroscopic measurements were performed:

1. Talar tilt angle: The talar tilt angle was measured by applying an incremental varus and valgus force of 10, 30, 50 and 150 Newton (N) (Figure 4 and 5).
2. Anterior drawer distance: The anterior drawer distance was measured by applying an incremental force of 10, 30, 50, 150N with ankle in neutral, 45 degree plantar flexed and 10 degree dorsiflexed position (Figure 6).
3. Subtalar joint tilt: The subtalar joint tilt was measured under 30 degrees of internal rotation and by applying an incremental varus force of 10, 30, 50, 150N. The measurement point was set to the tilt of posterior talocalcaneal joint surface. (Figure 7)

Finally, dislocation test was performed for all twelve TTP state cadaveric specimens as a 3rd step. We examined whether the ankle would dislocate by applying an increasing force from 0N to 350 N under varus, valgus, subtalar stress and anterior drawer stress. The 350N was the maximum force that could be applied using the Telos stress device. When dislocated, the amount of applied force to the ankle was recorded. A radiopaque coin was placed adjacent to and at the level of the medial joint line to allow for scaling and adjustments for magnification on the images. Images were uploaded and analyzed using Image J software (version 1.8.0, National Institutes of Health, Bethesda, MD).

Statistical analysis

All measurements were reported as mean and standard deviation (SD) in degree or millimeter (mm). To detect the difference in baseline demographic characteristics of the cadaveric groups and ankle stability in intact state between identical size group and small size group, as well as to compare the stability difference after implant insertion between two groups, a Man-Whitney U test was used. A paired T test was used to detect the difference of stability between intact state and TTP implanted state in both the groups. We then compared the frequency of dislocation between the two groups using chi-squire test. In this study a p-value < 0.05 was considered as statistically significant. Data analyses were performed using Studio R statistical software.

RESULTS

The stability of TTP state

Compared to the pre TTP intact state, the talar tilt angle under varus stress of 50N and150N showed significant instability after identical size prosthesis was implanted (p-values ranging from 0.025 to 0.031; Figure 8a). In the smaller sized implant group, the talar tilt angle under all forces of varus stress showed significant instability (p-values ranging from 0.008 to 0.031; Figure 8a). Under anterior stress, anterior drawer distance in all ankle positions under 150N showed significant instability after identical and small size prosthesis was implanted (p-values ranging from <0.001 to 0.027; Figure 8b, 8c, 8d). Furthermore, destabilization of the tibiotalar articulation was evident at 30N force in the smaller sized group when subjected to the anterior drawer test in plantar flexion ankle position (p = 0.007; Figure 8d). In contrast, there was no difference in stability among the both sized implant group when subjected to valgus stress or subtalar joint tilt between the pre and post implanted state (Figure 8e, 8f).

The effect of implant size

The anterior drawer distance measurement performed in dorsiflexion position in the small sized implant group was larger than the anterior drawer distance for those performed in the identical sized implant group under 150N (p = 0.008; Figure 8c), corresponding to a higher risk of instability. In contrast, there was no difference in varus, valgus, or subtalar tilt measurements between the two implant groups (p-values ranging from 0.09 to 1.0; Figure 8a, 8e, 8f). In addition, all cases of small sized implant group dislocated while performing anterior drawer dislocation test. Comparatively, three prostheses were dislocated among identical sized implant groups when subjected to the anterior drawer dislocation test (Table 3). It should also be noted that the force required to dislocate the tibiotalar joint while performing anterior drawer stress was the largest for the dorsiflexion position, followed by neutral position and plantarflexed position (Table 3). Moreover, no dislocation was observed while performing varus, valgus stress, or subtalar tilt, even at a maximum force of 350 N.

DISCUSSION

This study found that ankles having undergone TTP implantation demonstrate significant increments in talar tilt angle under varus stress and anterior drawer distance under anterior drawer stress regardless of implant size when compared to the pre TTP intact state.

Further, dislocation was observed only under anterior drawer stress. In terms of the effect of implant size, the risk of anterior instability and dislocation was more increased with the smaller sized implant, but no difference was observed in other stress directions between both sized implant group.

Unlike the result of varus stress, valgus stress had no impact on the talar tilt angle post implantation. Arguably, such results make anatomical sense because lateral ligaments such as the anterior talofibular ligament inherently designed to oppose varus and anterior translation are no longer attached following TTP. Conversely, however, TTP also results in detachment of portions of the deltoid ligament complex, although fibers of the superficial deltoid serve that remain intact appear to still serve as a medial stabilizer to act against any valgus directed force. In addition, the absence of valgus and varus dislocation when subjected up to 350N of force, despite the increase in talar tilt angle, could stem from a fact that the intact syndesmotic ligaments along with medial and lateral malleolus acts as a buttress and prevent frank dislocation.

Potential anterior instability has emerged as the major biomechanical concern following TTP implantation. Our study highlighted that TTP replaced ankles show obvious instability in the sagittal plane under anterior drawer stress, with the largest values noted during plantarflexion. Interestingly, dislocation of the implant was only observed when subjected to anterior drawer stress in both implant groups. A previous study by Ando et al[10] postulated that total talar replacement surgery carries a theoretical risk of anterior instability of the prosthesis because the anterior talofibular and deep deltoid ligaments are divided during the procedure. Thus, in the immediate postoperative period in vivo, the risk of anterior instability is the highest until soft tissues heal with scarring. Moreover, the heightened instability in plantarflexion suggests that increased care in maintaining ideal ankle position during the early postsurgical period must be strongly considered. In our clinical practice, TTP ankles are usually immobilized for three weeks after surgery[13]. The findings of our study further strengthen our postoperative management protocol and suggest that an immobilization protocol until reasonable soft tissue healing is achieved seems most appropriate.

One major concern surrounding the use of TTPs has been the more easily inserted but undersized implant, which may result in subtalar instability. Abramson et al[14] showed that the hindfoot varus is seen in three postoperative patients across a case series of eight patients treated with undersized TTP implant. They proposed that overstuffing can be prevented through undersizing of implants by 2.5%, but that this would also alter the kinematics and mobility of the subtalar joint. In contrast, this study showed that when implanted with either undersized or matched size implants, the subtalar joint remains stable. Such findings could relate to the fact that stress forces tend to concentrate at the tibiotalar joint rather than subtalar joint due to inherent anatomical shape of the ankle joint – dome and mortise. In addition, as the implant is not stabilized with any ligaments, the congruity of the joint has a direct effect on stability against all stress forces. Moreover, in our study, the implants were customized and 3D printed thus leading to high joint congruity and good stability. These findings may, however, differ in the presence of commercially available TTP implants.

The impact of implant size selection on postoperative ankle stability is unknown. In the event of talar collapse due to avascular necrosis, joint space may narrowing may render same size implantation challenging. As implants become increasingly customized based on contralateral imaging of a host's normal talus, the need to evolve and have available specific size ranges to compensate for anatomy is likely to also evolve. Notably, our study found that undersized implants carried a risk of anterior dislocation in early postoperative period, presumably due to joint ligamentocapsular release during anterior exposure. These data also suggest that when implants can be inserted too easily it should raise concern about joint instability in the early postsurgical period. Consideration could be given to more limited release of the joint capsule with concomitant use of an external fixator for sufficient joint space creation. Future clinical studies using undersized TTP implants with eyelets that allow for ankle ligament reconstruction may further expand sizing options during TTR to better address these tradeoffs.

This study has a few limitations that should be considered. First, study implants were comprised of a plastic material that obviously differs from currently clinical used components comprised of alumina ceramic. Differences in implant material stiffness and friction may have had the potential to cause variations in stress and load response. However, we reproduced the same shape as each individual talus by 3D printing, so we were able to set up our study to simulate the actual clinical TTP situation. Secondly, there is a possibility of some ligaments or soft tissues getting stretched out while carrying out the dislocation test. Prior studies have highlighted the heightened risk of anterior instability of the prosthesis after the total talar replacement surgery[10]. Therefore, at the end of the dislocation session, we conducted an anterior drawer dislocation test to prevent the soft tissue from stretching. However, multiple testing condition may have a residual effect on the ligaments and soft tissue. Lastly, only cross sectional imaging in form of CT scan was used to reproduce customized 3D implants. Although CT may underestimate the true dimensions of the talus to be replaced, addition of MRI evaluation and calculation of mean dimensions of the talus may also aid in more accurate approximation of the talar dimension in the years ahead.

Conclusion

Under valgus and subtalar stress, TTP implantation appears capable of sufficiently resist instability. Anterior and varus instability, however, seems more common in the early postoperative period, so postoperative immobilization makes sense in terms of getting stability with soft tissue healing. Importantly, our data also suggest that the choice of small implants should be considered carefully to avoid the potential for anterior dislocation.

Conflict of Interest

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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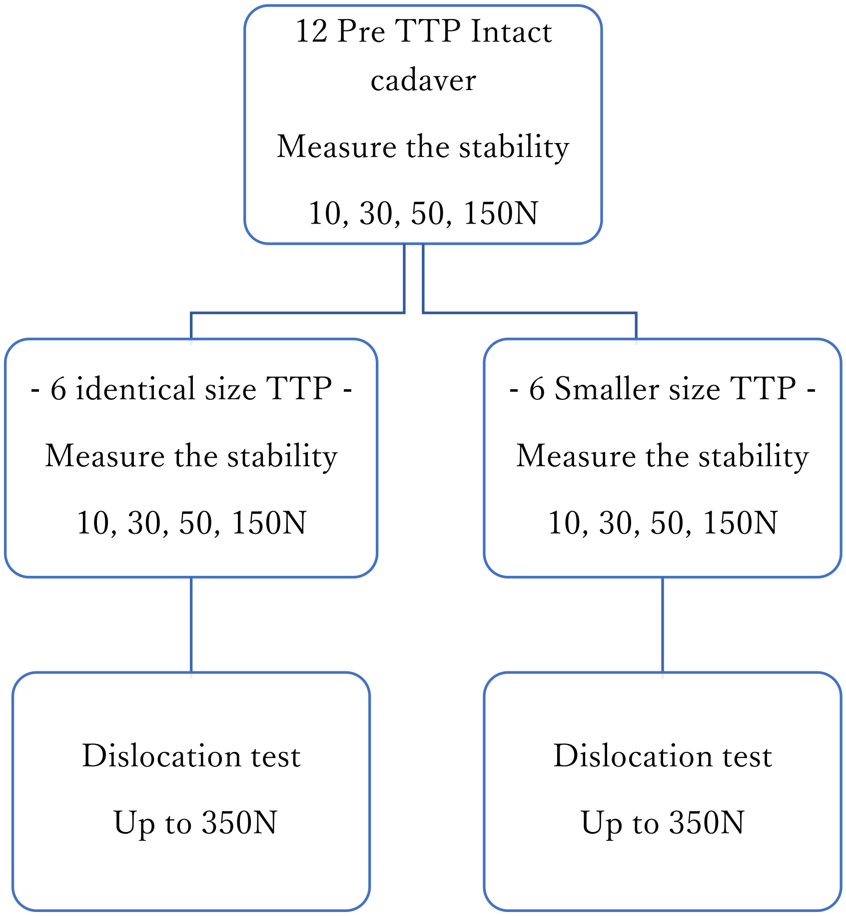

Table1: The flow chart of the experiment.

Figure

Figure 1a: The left foot X ray lateral view of talar necrosis.

Figure 1b: The left foot X ray lateral view after inserted Total talar prosthesis implant.

Figure 2: Total talar prosthesis implant.

	Identical N=6	**Smaller N=6**	**P value**
Mean age (± SD)	56.07 ± 1.83	56.33 ± 12.09	1.0
Sex (Male / Female)	5 / 1	5 / 1	1.0
Side (Rt / Lt)	1 / 5	0 / 6	0.30

Table 2. Demographic data of cadaver

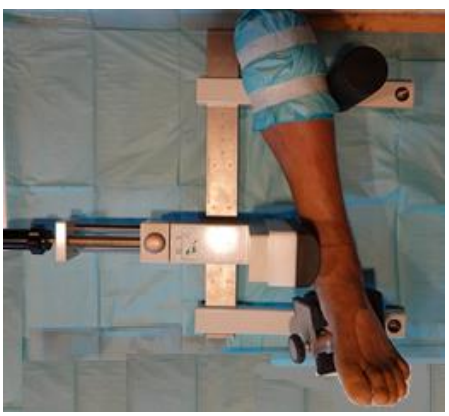

Figure 3: The setting up of Cadaver specimen under Telos stress device.

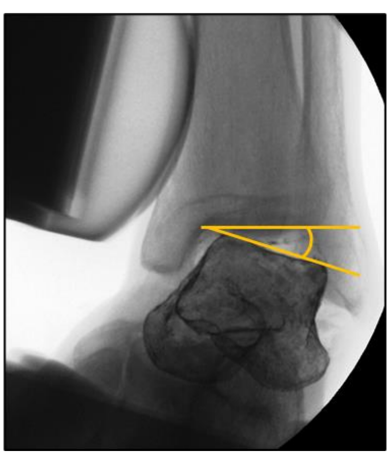

Figure 4: Talar tilt angle of left ankle under varus stress.

Figure 5: Talar tilt angle of left ankle under valgus stress.

Figure 6: Anterior drawer distance of left ankle under anterior drawer stress.

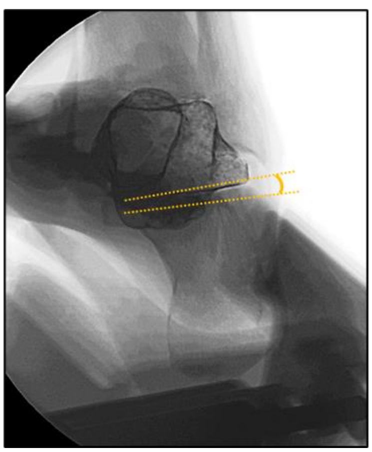

Figure 7: Subtalar tilt angle of left ankle under varus stress.

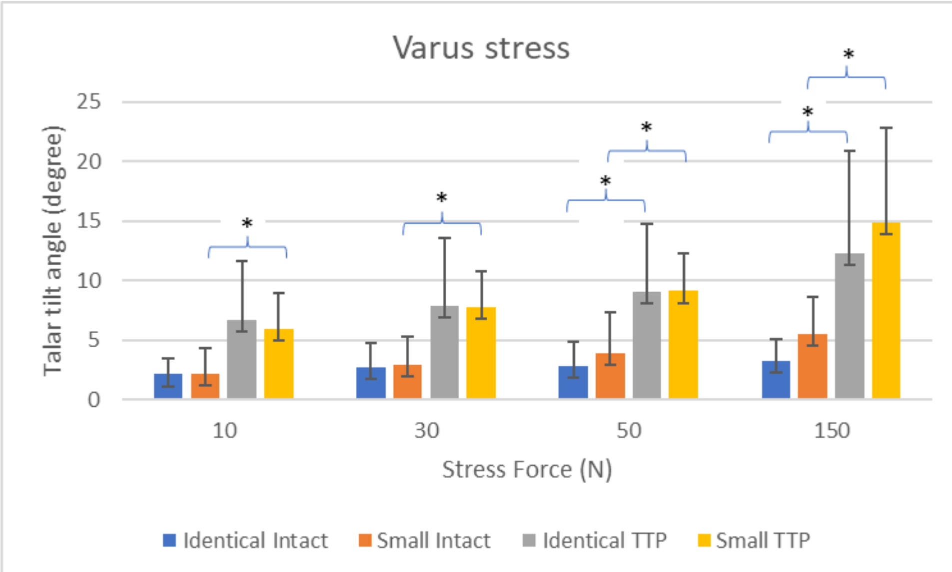

Figure 8a. The stability comparison between the pre and post TTP implant group under varus stress. Data are mean degree of talar tilt angle and error bar means standard deviation. Asterisks denote significant p-value.

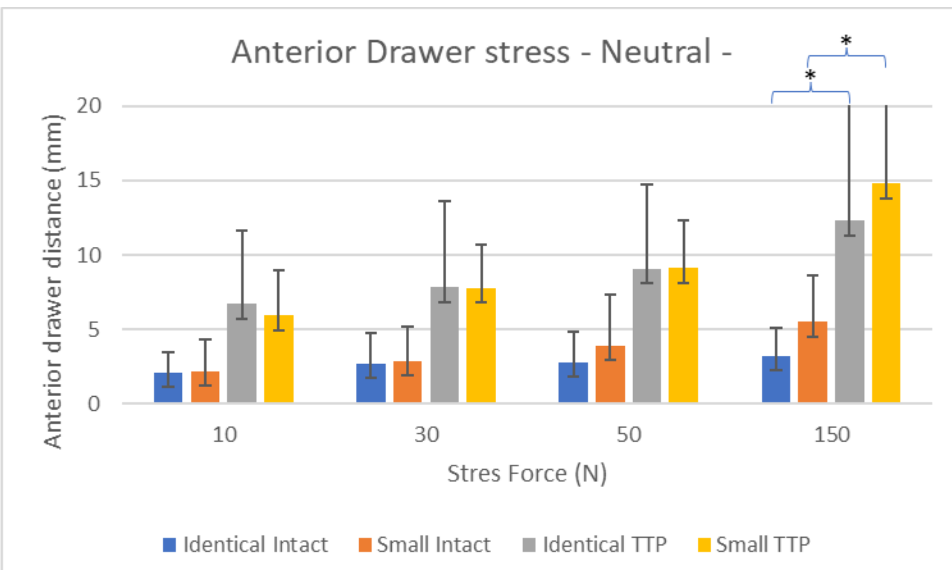

Figure 8b. The stability comparison between the pre and post TTP implant group under anterior drawer stress in the neutral ankle position. Data are mean millimeter of anterior drawer distance and error bar means standard deviation. Asterisks denote significant p-value.

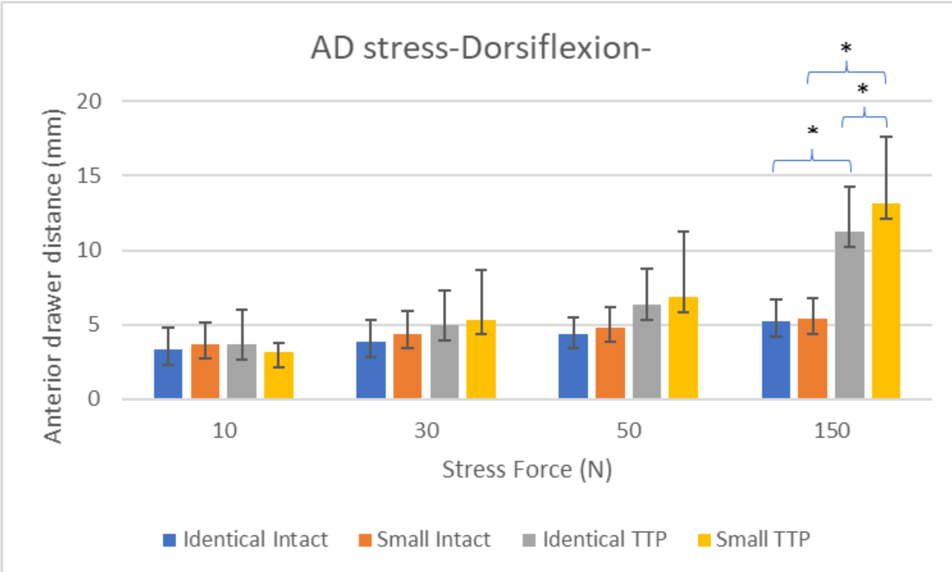

Figure 8c. The stability comparison between the pre and post TTP implant group under anterior drawer stress in the dorsiflexion ankle position. Data are mean millimeter of anterior drawer distance and error bar means standard deviation. Asterisks denote significant p-value.

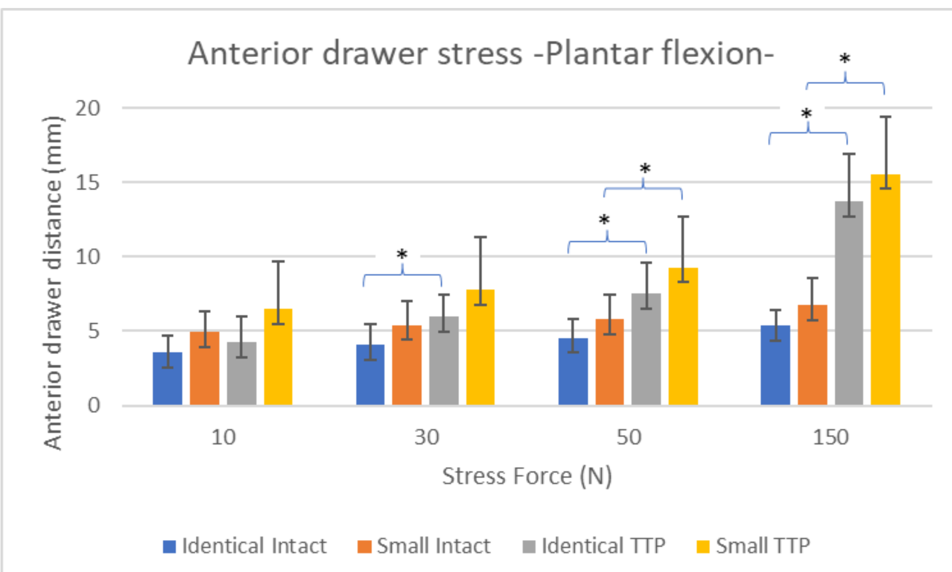

Figure 8d. The stability comparison between the pre and post TTP implant group under anterior drawer stress in the plantar flexion ankle position. Data are mean millimeter of anterior drawer distance and error bar means standard deviation. Asterisks denote significant p-value.

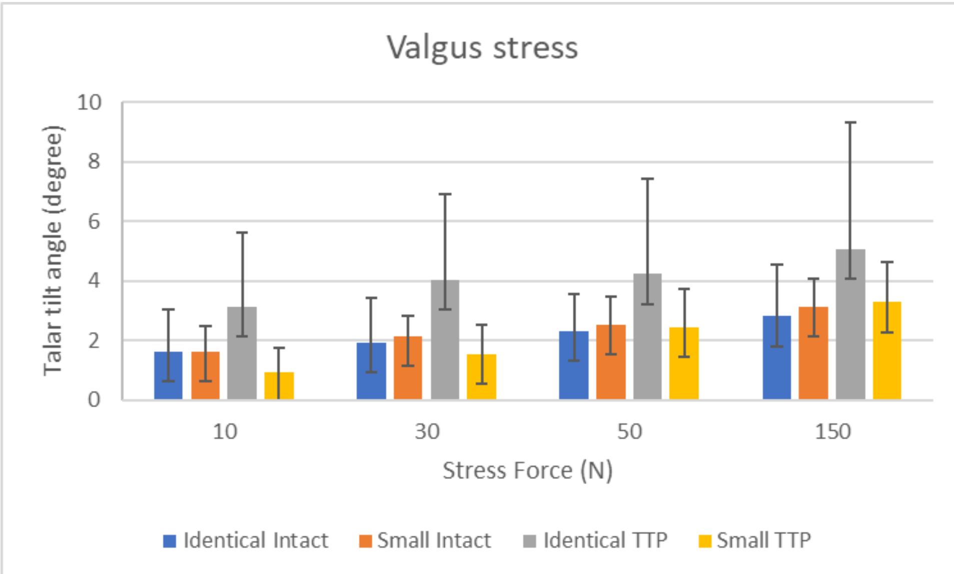

Figure 8e. The stability comparison between the pre and post TTP implant group under valgus stress. Data are mean degree of talar tilt angle and error bar means standard deviation.

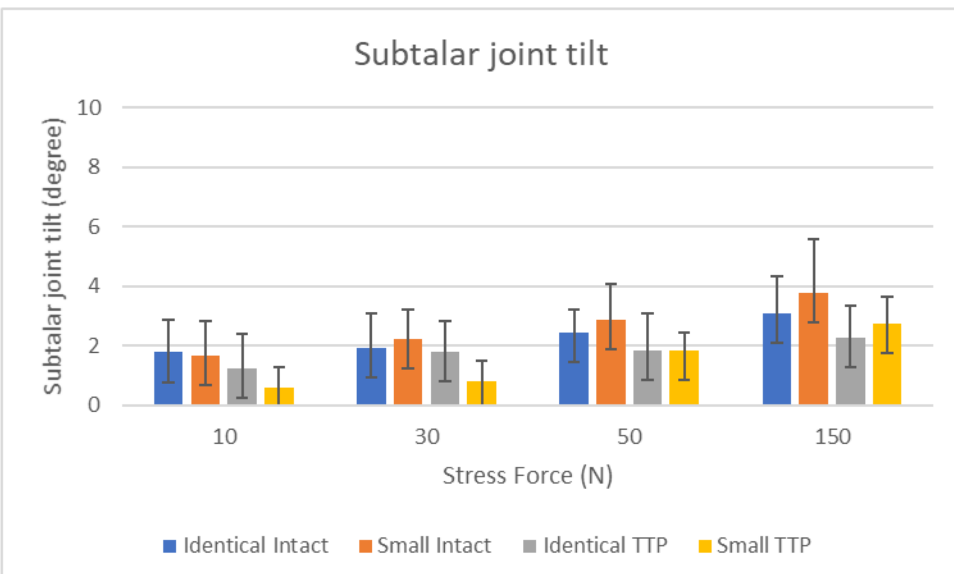

Figure 8f. The stability comparison between the pre and post TTP implant group under varus stress. Data are mean degree of posterior subtalar joint tilt and error bar means standard deviation.

Anterior drawer stress		Identical N=6	Small N=6	P value
Dislocation case		3	6	0.045
	Neutral	200.0±86.60	291.67±73.60	-
	Dorsiflexion	280.0±60.83	305.0±78.42	-
	Plantar flexion	143.33±11.55	280.0±77.46	-

Table3. The result of Dislocation test. Data are number of anterior dislocation and mean newton force when dislocated ± standard deviation.

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