Abstract

Introduction: The use of plate systems represents a well-recognized technique for the internal fixation of fractures in the foot, i.e. talar neck and navicular fractures. Aim of this study was to investigate the in vitro fatigue strength of Talar Neck Plate and Navicular Plate systems. Material: Four plates were investigated: Stryker VariAx 2 Talar Neck plates, Biomet ALPS Talar Neck plates, Stryker VariAx 2 Navicular Plates and Synthes VA-LCP navicular plates. Method: The fatigue strength of the plates was evaluated by dynamic loading in a four-point bending setup. Results: The Stryker Talar Neck Plate showed + 69.2% higher strength compared to the Biomet plate (p=0.001). The Stryker Navicular Plate showed + 97.1 % higher strength compared to the Synthes plate (p=0.001). Conclusion: This biomechanical study provides valuable data on the in vitro fatigue strength of the Stryker VariAx 2 Talar Neck Plate and VariAx 2 Navicular Plate. The Stryker VariAx 2 Plates showed superior fatigue strength with respect to competitor products tested under the same conditions and used in the same anatomical regions.

1 Introduction

Foot injuries, such as talar neck and navicular fractures, are being seen with increasing frequency at trauma centers as a consequence of high energy trauma [1] [2]. Treatment of these injuries may be quite challenging as outcomes may often be compromised by complications, including post-traumatic arthritis, avascular necrosis, malunion and nonunion [2][3].

Among the different techniques used for the internal fixation of these fractures, the use of plate systems which closely match the natural bone anatomy represents a well-recognized technique for obtaining an effective reduction. Nevertheless, investigations are still needed in order to determine to what extent these systems are sufficiently strong to withstand the repetitive loads associated to active motion. This might be more relevant in case of poor bony support, either fracture-related or caused by delayed unions/non unions, where the risk of implant failure due to repetitive stress in use is higher.

In this study, the in vitro fatigue strength of such plates was determined and compared to competitor’s equivalent foot systems.

2 Material & Method

The following four plates were investigated: Stryker VariAx 2 Talar Neck plates with 2.7mm VariAx 2 non-locking screws, Biomet ALPS Talar Neck plates with 2.5mm ALPS non-locking screws, Stryker VariAx 2 Navicular Plates with 2.7mm VariAx 2 non-locking screws and Synthes VA-LCP navicular plates with 2.4mm Synthes non-locking screws (Table 1, Figure 1).

Figure 1: Top to bottom: 1) Stryker VariAx 2 Talar Neck plate [4], 2) Biomet ALPS Talar Neck plate [4] [5], 3) Stryker VariAx 2 Navicular Plate [6], 4) Synthes VA-LCP Navicular Plate [6] [7].
Table 1: Description of the tested plates

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Plate Type</th>
<th>Material plate</th>
<th>Ref N°</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stryker</td>
<td>VariAx 2 Talar Neck, 2.7mm screws</td>
<td>Titanium Grade 2 [8]</td>
<td>626880</td>
</tr>
<tr>
<td>Biomet</td>
<td>ALPS Talar neck, 2.5mm screws</td>
<td>Ti6Al4V [9]</td>
<td>8240-75-001</td>
</tr>
<tr>
<td>Stryker</td>
<td>VariAx 2 Navicular, 2.7mm screws</td>
<td>Titanium Grade 2 [8]</td>
<td>626882</td>
</tr>
<tr>
<td>Synthes</td>
<td>VA-LCP Navicular, 2.4mm screws</td>
<td>Ti6Al7Nb [10]</td>
<td>04.211.220</td>
</tr>
</tbody>
</table>

For all plates the fatigue strength was determined and statistically compared by dynamic loading in a four-point bending according to ASTM F382 [11].

The ends of each talar neck and navicular plate were fixated to two extension blocks simulating simplified anatomical geometry of the talus and the navicular bone, respectively. A 4 and 7 mm gap was created between the two blocks to simulate the worst case fracture for talus and navicular bone, respectively (Figure 2).

All the constructs were mounted on a four point bending set-up with a loading roller distance L1 of 70 mm and a support roller distance L2 of 130 mm (Figure 3).

A dynamic load F was applied with an electrodynamic test machine (Instron ElectroPuls E3000) at 6 Hz for 500,000 cycles, run-out level (the specified number of loading cycles is reached), or until failure (defined as plate breakage). In case of failure the next sample was tested at a decreased load. In case of run-out the next sample was tested at an increased load. With this method, described by Little [11][12], the median fatigue limit (MFL), a 50% probability of surviving 500,000 load cycles, was determined for at each plate type (n=6). This fatigue strength values were statistically compared by Student’s t-test with a significance level of α = 0.05.

![Figure 2](image1.png)  
![Figure 3](image2.png)

Figure 2: 1) Talar neck plates fixated to bone simulation material blocks; 2) Navicular plates fixated to bone simulation blocks.

Figure 3: Four-point bending test setup used for talar neck plates (left) and navicular plates (right) based on ASTM F382 [11].
3 Results

The Stryker Talar Neck Plate showed + 69.2% higher strength compared to the Biomet plate (p=0.001) (Figure 4).

![Figure 4: Four point bending fatigue strength of Talar Neck Plates illustrated in high-low plot. The box represents the 95% confidence interval of the median fatigue limit. The circle within the box represents the median fatigue limit or 50% survival rate at this load level.](image)

The Stryker Navicular Plate showed + 97.1% higher strength compared to the Synthes plate (p=0.001) (Figure 5).

![Figure 5: Four point bending fatigue strength of Talar Neck Plates illustrated in high-low plot. The box represents the 95% confidence interval of the median fatigue limit. The circle within the box represents the median fatigue limit or 50% survival rate at this load level.](image)

4 Discussion

Aim of this study was to assess the in vitro fatigue strength of the newly developed Stryker VariAx 2 Talar Neck Plates and VariAx 2 Navicular Plates. We found the Stryker Plates to show substantially higher fatigue strength compared to the competitor devices. These results suggest that Stryker VariAx 2 Talar Neck and Navicular Plates may withstand higher repetitive loads and may be less likely to fail compared to the here tested competitor products even in case of missing bony support. In addition, the improved fatigue mechanical performance may be beneficial in case of delayed unions.

This study aimed at characterizing the implants in a reproducible in vitro environment, hence, not attempting to characterize the performance of the implants in a physiologic milieu. As a consequence, the differences in fatigue strength can be associated to plate geometry, material, and manufacturing processes only. In vivo other factors such as post-operative treatment, plate fixation technique, bone quality, and the environment of implantation may have a major influence [13].

5 Conclusion

This biomechanical study provides valuable data on the in vitro fatigue strength of the Stryker VariAx 2 Talar Neck Plate and VariAx 2 Navicular Plate. The Stryker VariAx 2 Plates showed superior fatigue strength with respect to competitor products tested under the same conditions and used in the same anatomical region.
6 References


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