Fatigue Strength of Medial Column Plates

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Abstract

Introduction: The use of plate systems represents a well-recognized technique for obtaining an effective compression, reduction and stabilization of the medial column of the foot. In this study, the in vitro fatigue strength of NCM (Medial Column Fusion) plates was determined and compared to a competitor’s equivalent foot system. Material: Two plates were investigated: Stryker VariAx 2 NCM Plate and Wright Medical Darco RPS Plate. Method: The fatigue strength of the plates was evaluated by dynamic loading in a four-point bending setup. Results: The Stryker NCM Plate showed + 121.3% higher strength compared to the Wright Medical plate (p=0.001) Conclusion: This biomechanical study provides valuable data on the in vitro fatigue strength of NCM plates. The Stryker VariAx 2 NCM Plate showed superior fatigue strength with respect to a competitor product tested under the same conditions and used in the same anatomical region.

1 Introduction

Medial column fusion represents a well-recognized technique for correcting mid-foot deformities, such as Charcot and flatfoot deformities [1], [2], [3]. Nowadays, plates which closely match bone foot anatomy are available on the market which may be used for obtaining an effective compression, reduction and stabilization of the medial column of the foot. Nevertheless, investigations are needed in order to determine to what extent these systems are sufficiently strong to withstand the repetitive loads associated to active motion.

In this study, the in vitro fatigue strength of such plating systems was determined and compared.

2 Material & Method

The following two plates were investigated: Stryker VariAx 2 NCM Plate with 3.5mm VariAx 2 non-locking screws and Wright Medical Darco RPS 8-hole Plate with 3.5mm Darco non-locking screws (Table 1, Figure 1).

For all plates the fatigue strength was determined by dynamic loading in a four-point bending according to ASTM F382 [4] and statistically compared.

Table 1: Description of the tested plates [5], [6], [8]
The plates were fixated to extension blocks simulating simplified anatomical geometry of the medial column of the foot (Figure 2).

![Figure 2: VariAx 2 Medial Column Fusion Plate construct assembly.](image)

The construct was mounted on a four point bending set-up with a loading roller distance $L_1$ of 100 mm and a support roller distance of 150 mm (Figure 3).

![Figure 3: Four-point bending test setup used for medial column plates based on ASTM F382 [4].](image)

A dynamic load ($F$) was applied with an electrodynamic test machine (Instron ElectroPuls E3000) at 6 Hz for 500,000 cycles, until 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 [4], [9] 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 $\alpha = 0.05$.

3 Results

The Stryker NCM Plate showed + 121.3% higher strength compared to the Darco RPS Plate ($p=0.001$) (Figure 4).

![Figure 4: Four point bending fatigue strength of medial column 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 NCM Plate. We found the Stryker Plate to show substantially higher fatigue strength compared to the competitor device. These results suggest that Stryker VariAx 2 NCM Plate may withstand higher repetitive loads and may be less likely to fail compared to the here tested competitor product. A higher fatigue strength may be beneficial in case of delayed unions.

This study aimed for characterizing the implant’s strength 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 [10].
In addition to the enhanced mechanical performance, the VariAx 2 NCM Plate shows also improved design characteristics with respect to the competitor device: left/right specific pre-bent plates are offered to allow the surgeon to closely match bone foot anatomy [8] while the competitor device is universal with no anatomical twist [6].

5 Conclusion

This biomechanical study provides valuable data on the in vitro fatigue strength of the Stryker VariAx 2 NCM Plate. The Stryker VariAx 2 NCM Plate showed superior fatigue strength with respect to a competitor product tested under the same conditions and used in the same anatomical region.

6 References


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