Biomechanical Performance of Headless Compression Screws: Fixos Ø4.0, 5.0 & 7.0 mm compared to Synthes Ø4.5 & 6.5 mm HCS

M. Vallotton, A. Torcasio PhD
Stryker Trauma AG, Selzach, Switzerland

Abstract

Introduction: The screw biomechanical performance plays a crucial role on the early interfragmentary stability and, in turn, on the fracture healing outcome. To assess the biomechanical performance of the headless compression screws Fixos 4.0, 5.0 & 7.0 mm, interfragmentry compression force and pull-out strength were determined and compared to the Synthes 4.5 & 6.5 mm HCS. Materials & Method: Interfragmentary compression force and pull-out strength were determined in a synthetic bone material. Results: The interfragmentary compression force generated by the Fixos screws was higher than the force of the Synthes HCS (by 47%, 75% and 72%, for group Ø4.0-4.5, Ø4.5-5.0 and Ø6.5-7.0 mm, respectively). In addition, the pull-out strength associated to Fixos screws was higher than the pull-out strength of the Synthes HCS by 27% and 9%, for group Ø4.5-5.0 and Ø6.5-7.0 mm, respectively. For group Ø4.0-4.5 mm, the pull-out strength of Fixos screw was 9% lower. Discussion and conclusion: These results demonstrate improved biomechanical performance (i.e. better interfragmentary stability) of the Fixos screws compared to the similar size Synthes HCS with exception of the pull-out strength in the smallest tested screws. However, the smaller diameter of the Ø4.0mm Fixos screw may be more appropriate for certain situations.

1 Introduction

Headless compression screws (HCS) represent a well-known solution allowing for compression and stability of small bone fractures without causing problems related to screw head prominence (i.e. tissue irritation). Recently, new second generation HCS have been introduced with the purpose of offering optimized screw placement (i.e. cannulated version), extending the indication for use to all small bones and articular fractures as well as offering enhanced biomechanical performance. Specifically, it is generally believed that the screw biomechanical performance plays a crucial role on the early interfragmentary stability and, in turn, on the fracture healing outcome [1]-[6]. During the early phase of the healing process, compression forces and pull-out strength of the screw should be sufficiently high for preventing micromotion at the fracture site to occur, which would result into fibrous tissue formation or non-union. Together with a reduced incidence of non-union, early internal fixation would also include early mobilization and reduced pain for the patient [7], [8].

In this study the biomechanical performance of the last generation headless compression screws Fixos Ø4.0, 5.0 & 7.0 mm from Stryker was assessed and compared to Synthes HCS.

2 Material

Two types of Headless Compression Screws (HCS) were compared: The Stryker Fixos Ø4.0, 5.0 & 7.0 mm and the Synthes HCS (Figure 1, Table 1).

Figure 1: Headless Compression Screws used for testing arranged from top to bottom in pairs: Ø4.0-4.5, 4.5-5.0, 6.5-7.0 mm; Fixos (top) and Synthes HCS (bottom).
<table>
<thead>
<tr>
<th>Size</th>
<th>Description</th>
<th>Dimensions [mm]</th>
<th>Material</th>
</tr>
</thead>
<tbody>
<tr>
<td>ø4.0-4.5</td>
<td>Fixos</td>
<td>Ø4.0x 40/ 13</td>
<td>Titanium</td>
</tr>
<tr>
<td></td>
<td>Synthes HCS</td>
<td>Ø4.5x 40/ 16</td>
<td>Titanium</td>
</tr>
<tr>
<td>ø4.5-5.0</td>
<td>Fixos</td>
<td>Ø5.0x 50/ 17</td>
<td>Titanium</td>
</tr>
<tr>
<td></td>
<td>Synthes HCS</td>
<td>Ø4.5x 50/ 20</td>
<td>Titanium</td>
</tr>
<tr>
<td>ø6.5-7.0</td>
<td>Fixos</td>
<td>Ø7.0x 90/ 16</td>
<td>Titanium</td>
</tr>
<tr>
<td></td>
<td>Synthes HCS</td>
<td>Ø6.5x 90/ 16</td>
<td>Titanium</td>
</tr>
</tbody>
</table>

Table 1: Headless Compression Screws used for testing. Dimensions display screw diameter x screw length / thread length

3 Method

3.1 Compression force

3.1.1 Purpose and Significance

Headless compression screws are intended to generate an interfragmentary compression in order to provide stability of a fracture, osteotomy or arthrodesis. Under certain conditions (e.g. in good quality bone and stable fragmentary reduction) high compression forces may be beneficial.

For headless compression screws an interfragmentary displacement of 1-2mm might be of interest to obtain safe fragment reduction. The calculated maximum gap reductions for the Fixos screws are (head is flush with the bone):

- Ø4.0mm: 1.4 mm gap reduction
- Ø5.0mm: 1.7 mm gap reduction
- Ø7.0mm: 2.1 mm gap reduction

3.1.2 Biomechanical Model and Test Method

The selected biomechanical model aimed for determination of compression forces in a comparative measurement strategy. As bone simulation material (BSM) the well-established solid rigid polyurethane foam (ASTM F1839 [9]) with a density of 0.32g/cc was taken. Due to its uniformity it allowed for result comparison without requiring a large sample size like required with e.g. cadaver bone.

The screws were inserted over the corresponding K-Wire. No predrilling and no countersinking were performed as for the Synthes HCS the latter step is optional. The screws were then inserted manually. Attention was paid to apply a constant rotational speed. The generated compression force was measured until until a significant decrease of the force was recorded indicating failure. In this position both screw types were countersinked (Figure 2).

Figure 2: Biomechanical model of interfragmentary bone compression measurement: a) Test setup schematically illustrated. b) Experimental test setup. c) Fixos: Final screw position (head countersinked). d) Synthes HCS: Final screw position (head countersinked).

The maximum measured compression force during insertion was evaluated and subject of the statistical analysis. For that the test groups were compared using the Mann-Whitney U Test with a significance level of 95%. At least six samples per group were tested.
3.2 Pull-out strength

3.2.1 Purpose and Significance

Headless Compression Screws are intended to maintain interfragmentary compression when subjected to in-vivo loads during bony fusion. In order to maintain this compression force the pull-out strength of the threads is essential. Under certain conditions (e.g. compromised bone stock or non-compliant patient) high pull-out strength may be beneficial.

3.2.2 Biomechanical Model and Test Method

The selected biomechanical model aimed for determination of screw pull-out strength in a comparative measurement strategy. As a bone simulation material (BSM), the well-established solid rigid polyurethane foam (ASTM F1839 [9]) with a density of 0.32g/cc was taken. Due to its uniformity it allowed for result comparison without requiring a large sample size like required with e.g. cadaver bone.

First, the screw shaft was inserted over the corresponding K-Wire into fragment 1, (Figure 3). No predrilling for screw shaft and head was performed as for the Synthes HCS the latter step is optional. Then, the assembly was brought together with fragment 2 into which the screw shaft was inserted. Finally the screw was tightened in the fixture while compressing the fragments until the screw head reached the following position (Figure 3):

- Fixos: No head prominence, flush with the bone surface
- Synthes HCS: No head prominence, countersinked with dedicated instrumentation (red mark on sleeve)

Note that in these positions the screw shaft threads were completely inserted in fragment 2.

For determination of the pull-out strength an axial force was applied with constant displacement rate of 5 mm/min until either the screw head of the screw shaft pulled-out the material.

The maximum measured force during the tests was defined as pull-out strength and subjected to the statistical analysis. Specifically, differences between the tested groups were assessed using a Mann-Whitney U Test with a significance level of 95%. At least six samples per group were tested.

![Figure 3: Biomechanical model of head and shaft screw pull-out strength measurement: a) Schematic illustration of the test setup. b) Experimental test setup. c) Fixos: screw head position after interfragmentary compression (head flush with bone). d) Synthes HCS: screw head position after interfragmentary compression (head countersinking according to surgical technique).](image-url)
4 Results

4.1 Ø4.0-4.5mm Screws

4.1.1 Compression force

There was a statistical significant difference between the two Ø4.0-4.5mm groups (p= 0.002). The compression force of the Fixos screw was +47% higher than the force of the Synthes HCS (Figure 4, [10]):

Figure 4: Compression force results of tested Ø4.0-4.5mm headless compression screws

4.1.2 Pull-out strength

There was a statistical significant difference between the two Ø4.0-4.5mm groups (p= 0.014). The pull-out strength of the Fixos screw was -9% lower than the force of the Synthes screws (Figure 5, [11]).

Figure 5: Pull-out strength of tested Ø4.0-4.5mm headless compression screws

As failure mode both screw types showed screw head pull-out.

4.2 Ø4.5-5.0mm Screws

4.2.1 Compression force

There was a statistical significant difference between the two Ø4.0-4.5mm groups (p= 0.003). The compression force of the Fixos screw was +75% higher than the force of the Synthes HCS (Figure 6, [10]):

Figure 6: Compression force results of tested Ø4.5-5mm headless compression screws [10]

4.2.2 Pull-out strength

There was a statistical significant difference between the two Ø4.5-5.0 mm groups (p= 0.002). The pull-out strength of the Fixos screw was +27% higher than the force of the Synthes HCS screws (Figure 7, [11]).

Figure 7: Pull-out strength of tested Ø4.5-5.0mm headless compression screws

As failure mode both screw types showed screw head pull-out.
4.3 Ø6.5-7.0mm Screws

4.3.1 Compression force

There was a statistical significant difference between the two Ø6.5-7.0mm groups (p= 0.002). The compression force of the Fixos screw was +72% higher than the force of the Synthes HCS (Figure 8, [10]):

![Figure 8: Compression force results of tested Ø6.5-7mm headless compression screws](image)

4.3.2 Pull-out strength

There was a statistical significant difference between the two Ø6.5-7.0mm groups (p= 0.002). The pull-out strength of the Fixos screw was +9% higher than the force of the Synthes HCS (Figure 9, [11]):

![Figure 9: Pull-out strength of tested Ø6.5-7.0mm headless compression screws](image)

As failure mode the Fixos screw showed shaft pull-out while the Synthes HCS showed head pull-out.

5 Discussion

Aim of this study was to evaluate the biomechanical performance of the headless compression screws Fixos compared to a competitor device. We found that the interfragmentary compression force generated by the Fixos screws was higher than the force of the Synthes HCS (by 47%, 75% and 72%, for group Ø4.0-4.5, Ø4.5-5.0 and Ø6.5-7.0mm, respectively). In addition, the pull-out strength associated to Fixos screws was higher than the pull-out strength of the Synthes HCS by 27% and 9%, for group Ø4.5-5.0 and Ø6.5-7.0mm, respectively. For group Ø4.0-4.5mm, the pull-out strength of Fixos screw was 9% lower compared to Synthes HCS.

With the exception of the pull-out strength in the smallest tested screws, these results demonstrate improved biomechanical performance of the Fixos screw compared to similar size compression screws Synthes HCS. Furthermore, these findings may suggest the Fixos screw to represent a good solution allowing for high inter-fragmentary stability and, in turn, may allow for a more favorable fracture healing outcome. Interfragmentary stability is related to several factors such as the type of the fracture, quality of the bone involved and quality of fracture reduction. Although fracture geometry and bone quality cannot be controlled, quality of fracture reduction may be enhanced by providing adequate compression at the fracture surface [12].

As a first limitation of this study, the comparison of the screws’ performances was evaluated in a specific synthetic bone density. Earlier studies have demonstrated that the microstructural properties (i.e. porosity) and tissue modulus of cancellous bone are highly variable and this has a great influence on the maximum achievable compression force [1], [13]. Second, the synthetic bone simulation material has almost uniform spherical pores while human cancellous bone is characterized by a more complex microstructure which might affect maximum compression force and pull-out strength as well. Third, the study doesn’t provide any information on the fatigue mechanical behavior: cyclic loading might cause reduced screw mechanical performance over time.
6 Conclusion

These results demonstrate improved biomechanical performance (i.e. better interfragmentary stability) of the Fixos screws compared to similar size headless compression screws Synthes HCS with exception of the pull-out strength in the smallest tested screws.

Concerning this difference (pull-out strength -9% for Fixos), the comparison of the Ø4.0mm Fixos screw versus the bigger Synthes Ø4.5mm screw may be caused by the difference of the diameter. However, the smaller diameter of the Ø4.0mm Fixos screw may be more appropriate for certain situations while providing a +47% higher compression force than the Ø4.5mm Synthes HCS.

7 References


[10] Internal Report № BML 13-394, 2013, Stryker Trauma AG, Selzach, Switzerland


Publisher: Stryker Trauma AG
Selzach, Switzerland

Content ID: FIX-WP-2 Rev. 1

A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate the breadth of Stryker product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.