Biomechanical Performance of Cannulated Compression Screws: Fixos Ø4.0, 5.0 & 7.0 mm compared to Asnis III

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Abstract

Introduction: The biomechanical screw performance plays a crucial role on the early interfragmentary stability and, in turn, on the fracture healing outcome. Therefore, this study compares the biomechanical performance of the cannulated headless compression screws Fixos Ø4.0, 5.0 & 7.0 mm to the standard cannulated compression screws Asnis III. 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 ASNIS III screws (by 54%, 47% and 95%, for group Ø4.0, 5.0 & 6.5-7.0 mm, respectively). The pull-out strength associated to Fixos screws was higher than the pull-out strength of the ASNIS III screws (by 18%, 29% and 39%, for group Ø4.0, 5.0 & 6.5-7.0 mm, respectively). Discussion and conclusion: Asnis III is a proven cannulated screw system with more than ten years market experience. In terms of compression force and pull-out strength the Fixos screws demonstrated superior biomechanical performance which may allow for enhanced interfragmentary stability.

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 optimizing screw placement (i.e. cannulated version), extending the indication for use to all small bones and articular fractures as well as allowing for 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].

Purpose of this study was to evaluate the biomechanical performance, in terms of compression force and pull-out strength, of the last generation headless compression screws Fixos 4.0, 5.0 & 7.0 mm from Stryker when compared to proven conventional cannulated compression screws.

2 Material

Two types of cannulated compression screws were compared: the Stryker Fixos Ø4.0, 5.0 & 7.0 mm screws and the Stryker Asnis III Cannulated Compression Screw (Figure 1, Table 1).

Figure 1: Cannulated compression screws used for testing arranged from top to bottom in pairs: Ø4.0, 5.0 & 6.5-7.0 mm; Fixos screws with threaded head, Asnis III screws with spherical head.
Biomechanical performance of Fixos Ø4.0, 5.0 & 7.0 mm compared to ASNIS III

<table>
<thead>
<tr>
<th>Size</th>
<th>Description</th>
<th>Dimensions [mm]</th>
<th>Material</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ø4.0</td>
<td>Fixos REF 658040</td>
<td>Ø4.0 x 40/ 13</td>
<td>Titanium</td>
</tr>
<tr>
<td></td>
<td>Asnis III REF 604640</td>
<td>Ø4.0 x 40/ 13</td>
<td>Titanium</td>
</tr>
<tr>
<td>Ø5.0</td>
<td>Fixos REF 658150</td>
<td>Ø5.0 x 50/ 17</td>
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<td>Asnis III REF 601650</td>
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<tr>
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<td>Fixos REF 658390</td>
<td>Ø7.0 x 90/ 16</td>
<td>Titanium</td>
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<tr>
<td></td>
<td>Asnis III REF 602690</td>
<td>Ø6.5 x 90/ 20</td>
<td>Titanium</td>
</tr>
</tbody>
</table>

Table 1: Cannulated compression screws used for testing. Dimensions display screw diameter x screw length / thread length

3 Methods

3.1 Compression force

3.1.1 Purpose and Significance

Cannulated 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 cannulated screws (HCS) like the Fixos 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: 2.1mm 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 Asnis III Screw 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 the screw head reached the following positions (Figure 2):

- Fixos: no head prominence, flush with the bone surface
- Asnis III: Spherical part inserted completely but leaving the cylindrical head part prominent

Figure 2: Biomechanical model of interfragmentary bone compression measurement: a) Test setup schematically illustrated. b) Experimental test setup. c) Fixos: Final screw position (head flush with bone. d) Asnis III: Final screw position leaving cylindrical head part prominent

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

Cannulated 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 might 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 and no countersinking were performed as for the Asnis III Screw 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
- Asnis III: Spherical part inserted completely leaving upper head part prominent.

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.
4 Results

4.1 Ø4.0mm Screws

4.1.1 Compression force

There was a statistical significant difference between the two Ø4.0mm groups (p= 0.002). The compression force of the Fixos screw was +54% higher than the force of the Asnis III screws (Figure 4, [10]):

![Figure 4: Compression force results of tested Ø4.0mm Cannulated Compression screws](image)

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

4.1.2 Pull-out strength

There was a statistical significant difference between the two Ø4.0mm groups (p= 0.002). The pull-out strength of the Fixos screw was +18% higher than the strength of the Asnis III screws (Figure 5, [11]).

![Figure 5: Pull-out strength of tested Ø4.0mm Cannulated Compression screws](image)

4.2 Ø5.0mm Screws

4.2.1 Compression force

There was a statistical significant difference between the two Ø5.0mm groups (p= 0.002). The compression force of the Fixos screw was +47% higher than the force of the Asnis III screws (Figure 6, [10]):

![Figure 6: Compression force results of tested Ø5.0mm Cannulated Compression screws](image)

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

4.2.2 Pull-out strength

There was a statistical significant difference between the two Ø5.0 mm groups (p= 0.003). The pull-out strength of the Fixos screw was +29% higher than the strength of the Asnis III screws (Figure 7, [11]).

![Figure 7: Pull-out strength of tested Ø5.0mm Cannulated Compression screws](image)

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= 0.005). The compression force of the Fixos screw was +95% higher than the force of the Asnis III screws (Figure 8, [10]):

![Figure 8: Compression force results of tested Ø6.5-7.0mm Cannulated 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 +39% higher than the strength of the Asnis III screws (Figure 9, [11]):

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

As failure mode the Fixos screw showed shaft pull-out while the Asnis III screw showed head pull-out.

5 Discussion

Aim of this study was to evaluate the biomechanical performance of the headless cannulated compression screws (Fixos) compared to the well-established conventional headed cannulated compression screws (Asnis III). Asnis III is a proven cannulated screw system which has been successfully used in clinics for more than ten years [12]. We found that the interfragmentary compression force generated by the Fixos screws was higher than the force of the Asnis III screws (by 54%, 47% and 95%, for groups Ø4.0, 5.0 & 6.5-7.0 mm, respectively). In addition, the pull-out strength associated to Fixos screws was higher than the pull-out strength of the Asnis III screws (by 18%, 29% and 39%, for groups Ø4.0, 5.0 & Ø6.5-7.0 mm, respectively). These results demonstrate enhanced biomechanical performance of the Fixos screws compared to similar size clinically successful cannulated compression screws Asnis III. Such enhancements are shown to be more relevant with increasing the screw size.

These findings may suggest the Fixos screws offer an additional solution allowing for high interfragmentary stability. 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 [13].

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][14]. 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 may cause reduced screw mechanical performance over time.

Concerning the comparison of the Ø6.5mm Asnis III screw versus the bigger Fixos Ø7.0mm screw both the differences of compression force (+95% for Fixos) and pull-out strength (+39 for Fixos) are mainly caused by the difference of the diameter. However, the smaller diameter of the Asnis III screw may be more appropriate for certain situations.

6 Conclusion

The Asnis III screws demonstrated with more than ten years market experience good clinical results and patient safety. In terms of compression force and pull-out strength the Fixos screws demonstrated enhanced biomechanical performance which may allow for enhanced interfragmentary stability.

7 References

[10] Internal Report № BML 13-394, 2013, Stryker Trauma AG, Selzach, Switzerland
[12] FDA Premarket Notification, 510(k) № K000080, April 2000, Food and Drug Administration, USA

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