Biomechanical Performance of Asnis Micro Cannulated Screws

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Summary

Introduction: The biomechanical performance of the Asnis Micro cannulated screw system was compared to similar products from Vilex and Synthes. Materials & Methods: The screw insertion performance, interfragmentary compression ability, pull-out strength and bending strength were determined and compared. Results & Conclusions: The tests conducted on the new Asnis Micro cannulated screws demonstrated equal or better biomechanical performance compared to Synthes and Vilex.

1. Introduction

Stryker has developed a new cannulated screw system indicated for trauma and reconstructive treatments in the foot. As an example of a foot application a hallux valgus correction is shown in Figure 1. To demonstrate mechanical product strength, the new cannulated screws were compared to Synthes and Vilex cannulated screws used in the same application. (See Table 1)

![Figure 1: Asnis Micro cannulated screws](image)

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Material</th>
<th>Screw Dimensions in [mm]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stryker®</td>
<td>Ti6Al4V</td>
<td>Ø2.0x20/5 Ø2.0x20/9 Ø2.0x24/6</td>
</tr>
<tr>
<td>Vilex®</td>
<td>Ti6Al4V</td>
<td>Ø2.0x20/6 Ø2.0x24/6</td>
</tr>
<tr>
<td>Synthes®</td>
<td>316L</td>
<td>Ø2.4x30/6</td>
</tr>
<tr>
<td>Stryker®</td>
<td>Ti6Al4V</td>
<td>Ø3.0x28/12 Ø3.0x30/6 Ø3.0x40/8</td>
</tr>
<tr>
<td>Synthes®</td>
<td>Ti6Al7Nb</td>
<td>Ø3.0x28/12 Ø3.0x30/6 Ø3.0x40/8</td>
</tr>
</tbody>
</table>

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

2. Materials

Test Set-up

For testing two different bone simulation materials (BSM) were used:

- a) Cancellous bone: Polyurethane foam grade 15 meeting the specification acc. ASTM F1839 [2], [3].
- b) Cortical bone: RenShape® Blockmaterial BM 5166 (Huntsman Advanced Materials (UK) Limited; Duxford, Cambridge, England CB2 4QA) [4].

Bone simulation materials (BSM) offer mechanical properties in the same order of magnitude as human bone but with much less spreading.

Note: These materials are not absolutely identical to real bone, but allow for a relative comparison of the tested implants.

3. Methods

3.1 Screw Insertion Torque

Purpose

To determine screw insertion torque in cancellous and cortical BSM.

To compare it against the screw shear-off torque, cf. section 3.2.

To compare it against the screw strip-off torque, cf. section 3.3.

Definitions

The insertion torque is the torque needed for introducing the screw into BSM to a pre-defined depth. The lower the insertion torque the easier the insertion of the screw.

The greater the difference between insertion torque and shear-off torque the less likely the chance of screw thread stripping out of poor bone upon screw insertion and tightening.

Additionally, the greater the difference between insertion torque and strip-off torque the less likely the chance of screw thread stripping out of poor bone upon screw insertion and tightening.

Test Method

Screw insertion was performed using the dedicated guide wire. The torque needed for screw insertion was determined for 6mm insertion depth in cancellous BSM and for 2mm in cortical BSM [1], [9], [10] & [11]. For test set-up, see Figure 2.

![Figure 2: Test set-up to determine screw insertion torque.](image)

3.2 Shear-Off Torque

Purpose

To determine the applicable torque until screw fails by shearing off the head or the thread.

Test Method

The screw was fixed at the threaded part keeping at least one thread exposed [1]. Torque was then applied until breakage of the screw [8], [11] by

![Figure 3: Test set-up to determine screw shear-off torque.](image)
The information contained in this document is intended for healthcare professionals only.
means of a torsion test machine. The test set-up is depicted in Figure 3.

3.3 Strip-Off Torque

Purpose
To determine the applicable torque until screw thread strips out of cancellous BSM.

Test Method
Screw insertion was performed over a guide wire followed by tightening until strip-off. A washer prevented the screw head from sinking in the BSM [6], [11]. The test set-up is shown in Figure 4.

Definitions
Maximum measured strip-off torque until screw strip-off in cancellous bone. The higher the compression force, the higher the capability to apply interfragmentary lag forces.

Test Method
The screw was inserted over a guide wire. The dedicated washer prevents the screw head from sinking in the BSM. To apply compression force, the screw was tightened until strip-off/pull-out [6], [11]. For test set-up, see Figure 5.

3.4 Interfragmentary Compression Ability

Purpose
To determine the applicable interfragmentary compression force in cancellous bone.

Definitions
Maximum measured interfragmentary compression force until screw strip-off in cancellous bone. The higher the compression force, the higher the capability to apply interfragmentary lag forces.

Test Method
The screw was inserted over a guide wire. The dedicated washer prevents the screw head from sinking in the BSM. To apply compression force, the screw was tightened until strip-off/pull-out [6], [11]. For test set-up, see Figure 5.

3.5 Pull-Out Strength

Purpose
To determine the axial holding strength of the screw in cancellous BSM.

Definitions
The pull-out strength is the resistance against axial screw back out of the bone. The higher the pull-out strength, the higher the capability to resist lag forces.

Test Method
The first five millimeters of the screw were inserted in cancellous BSM and then pulled out [1], [5], [11]. For test set-up, see Figure 6.

4. Results

4.1 Results Torsional Properties
To represent the screw insertion behavior via cortical into cancellous bone, the cortical and cancellous insertion torque bar charts in the following figures were added together and are shown as a sum in one column.

Comparing the difference between the insertion torque and the strip-off or the shear-off torque permits an assessment of mechanical characteristics.

The Asnis Micro screws are designed as cancellous bone screws but also may be inserted through the cortex. Therefore, insertion tests in cortical BSM also were performed.

Ø2.0mm Screws
The compared screws showed statistically equivalent insertion torque in cancellous BSM, but in cortical BSM the Asnis Micro screw demonstrated a significantly lower insertion torque (student t-test, p≤0.05). Both screws showed a high resistance against screw breakage during insertion into cortical plus cancellous BSM (shear-off torque is at least seven times as high as insertion torque). For both screws the strip-off torque is at the same level and also much lower than the shear-off torque. That means in case of screw over-tightening in cancellous bone, the screws can over-wind without breakage. The Asnis Micro screw showed significantly higher shear-off torque than the Vilex screw (student t-test, p<0.05).

Ø3.0mm Screws
The Asnis Micro and Synthes screws showed similar levels of insertion torque. The shear-off torque is at least four times as high as insertion torque for both screws and demonstrates resistance against screw breakage. Asnis Micro showed slightly higher strip-off torque than Synthes and compared to the insertion torque, a higher degree at strip-off resistance. Both screws have a large difference between shear-off torque and strip-off torque which means a high degree of resistance against screw breakage in case of screw over-tightening (shear-off torque is at least nine times higher than strip-off torque). The Asnis Micro screw showed significantly higher shear-off torque than the Synthes screws (student t-test, p<0.05).
4.2 Interfragmentary Compression Ability
Asnis Micro Ø2.0 showed slightly lower interfragmentary compression force than Vilex, but the results are of similar scale. The Ø3.0mm screws showed equal compression force.

4.3 Pull-Out Strength
Both Asnis Micro screws showed excellent pull-out strength, which are significantly higher than both Vilex and Synthes (student t-test, p≤0.05).

4.4 Cantilever Bending Strength
The Asnis Micro screws Ø2.0 showed significantly higher bending strength compared to Vilex (student t-test, p≤0.05) while the Asnis Micro screws Ø3.0 showed equal strength to Synthes. As expected the Synthes Ø2.4mm screw strength is located between the strength values of the other two screw diameters.

5. Summary and Conclusion
The tests conducted on the new Asnis Micro cannulated screws demonstrated equal or better mechanical performance compared to similar products from Vilex and Synthes.

- The low insertion torque/high shear-off torque of Asnis Micro screws as compared to both Vilex and Synthes demonstrates easy screw insertion and a high degree of resistance against screw shear-off during insertion in high strength cortical plus cancellous bone.
- The high strip-off results of Asnis Micro (Zero with a slash sign) Ø3.0 screws compared to Synthes indicates a higher resistance to stripping and breakage.
- The interfragmentary compression force of the Asnis Micro screws is at the same range as both the Synthes and Vilex screws.
- The significantly higher pull-out strength of the Asnis Micro screws as compared to Vilex and Synthes provides evidence for excellent axial holding strength and back out resistance.
- Asnis Micro provides two screw diameters Ø2.0 and Ø3.0 permitting control over the mechanical properties of the osteosynthesis performed. Choosing a Ø3.0 screw instead of Ø2.0 may enhance the mechanical strength by approximately 50% (e.g. shear-off strength +63%, bending strength +31%, interfragmentary compression +53%).

6. References
A surgeon must always rely on his or her own professional clinical judgment when deciding to use which products and/or techniques on individual patients. Stryker is not dispensing medical advice and recommends that surgeons be trained in orthopaedic surgeries before performing any surgeries.

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