Asnis III Biomechanical Performances
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Summary
The biomechanical performance of the Asnis III system was determined in a comprehensive test program. Clinically relevant tests to determine screw insertion behavior and pull out resistance in addition to data about guide wire stiffness and screw friction were included. Asnis III cannulated screws as well as competitor products were tested. In all tests the Asnis III proved to have highly effective and potentially better biomechanical performance than other competitors. These results support the success of the Asnis III development process with the goal to create a functional and simplified cannulated screw system with excellent biomechanical properties.

Introduction
The Asnis III system was designed to optimize surgical outcomes while offering simple procedures. At the same time it shall be designed to ensure highly effective biomechanical performance. The biomechanical performance of this design was determined by a review of the in vitro testing done with Asnis III and competitor products for benchmarking.

Material and Method
A comprehensive test program including Asnis III product range and competitor products was completed [1]. The following sections present the most significant tests and corresponding results. The implants referred to in the tests are listed in Table 1.

<table>
<thead>
<tr>
<th>Screw Type</th>
<th>Manufacturer</th>
<th>Brand</th>
<th>Material / Anodization type</th>
<th>Thread Diam.</th>
<th>Thread Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small Ø</td>
<td>Partially Threaded</td>
<td>Synthes CSS</td>
<td>Ti / III</td>
<td>4.5mm</td>
<td>15mm</td>
</tr>
<tr>
<td></td>
<td>Fully Threaded</td>
<td>Stryker Asnis III Ti / II</td>
<td>5.0mm</td>
<td>15mm</td>
<td></td>
</tr>
<tr>
<td>Large Ø</td>
<td>Partially Threaded</td>
<td>Synthes CSS</td>
<td>Ti / III</td>
<td>4.5mm</td>
<td>40mm</td>
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<tr>
<td></td>
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<td>Stryker Asnis III Ti / II</td>
<td>5.0mm</td>
<td>40mm</td>
<td></td>
</tr>
<tr>
<td>Largest Ø</td>
<td>Partially Threaded</td>
<td>Depuy ACE Ti / II</td>
<td>StSt</td>
<td>8.0mm</td>
<td>20mm</td>
</tr>
<tr>
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<td>Partially Threaded</td>
<td>Stryker Asnis III Ti / II</td>
<td>8.0mm</td>
<td>25mm</td>
<td></td>
</tr>
</tbody>
</table>

Table 1: Implants tested (Ti: Titanium Alloy, StSt: Stainless Steel, II / III: Anodization Type II / III).

Tests were principally performed according to an ASTM medical screw testing standard [2]. For most tests Bone Simulation Material (BSM) blocks made of polyurethane foam, grade 15pcf, were used instead of human bone [3]. This common BSM offers mechanical properties in the range of human spongy bone with consistent material properties [4].

Screw Insertion Behavior
Using the Test Set Up as shown in Figure 1, the screw insertion behavior was determined by measuring:
- Screw Insertion Torque
- Screw Strip Out Torque
- Screw Deformation Torque

![Figure 1: Test set ups for insertion tests](image)

Based on this data, safety factors were calculated for:
- Screw Strip Out
- Screw Deformation
A **Statistical analysis** was performed using the Student t-test with a significance level α=0.05.

**Note:** The safety factors are the more important values as they put the absolute values measured in relation to each other and therefore provide a direct measure for safety during screw insertion.

**Insertion Torque**

**Definition:** The *Insertion Torque* is defined as the maximum torque measured before reaching the seating point.

**Clinical Significance:** The lower the Insertion Torque the higher the safety against undesired bone fragment rotation during screw insertion.

**Method:** While acquiring torque the screw was inserted in Bone Simulation Material as depicted in Figure 1.

![Figure 2: Insertion Torque in mean value ± standard deviation. An * indicates a significant difference.](image1)

**Results:** Asnis III insertion torques were either equal or better than competitor products, see Figure 2.

**Strip Out Torque**

**Definition:** The *Strip Out Torque* is defined as the maximum torque measured before the screw to the bone thread connection is destroyed.

**Clinical Significance:** The greater the difference between Insertion Torque and Strip Out Torque the less likely the chance of screw thread stripping out of osteoporotic bone upon screw insertion and tightening.

**Method:** After seating the screw in the Bone Simulation Material the screw was further tightened until the screw thread stripped out.

**Results:** Asnis III strip out torques were equal to or better than competitor products, compare Figure 3.

![Figure 3: Strip Out Torque in mean value ± standard deviation. An * indicates a significant difference.](image2)

**Screw Deformation Torque**

**Definition:** The *Deformation Torque* is defined as the torque where plastic screw deformation occurs.

**Clinical Significance:** The greater the difference between Insertion Torque and Deformation Torque the higher the in vivo safety against screw deformation during insertion into good quality bone.

**Method:** Fixing the screw tip in a clamping device (Figure 1) the screw is tightened until screw deformation starts. The torque required to start permanent deformation is recorded.

![Figure 4: Screw Deformation Torque in mean value ± standard deviation. An * indicates a significant difference.](image3)

**Results:** Asnis III screw deformation torques were better than competitor products for the small and the largest screw diameters as shown in Figure 4.

**Strip Out Safety**

**Definition:** The *Strip Out Safety Factor* is defined as the ratio between Screw Strip Out Torque and Screw Insertion Torque.

**Clinical Significance:** The greater the difference between Insertion Torque and Strip Out Torque the less likely the chance of screw thread stripping out...
of osteoporotic bone upon screw insertion and tightening.

Figure 5: Strip Out Safety Factor = 1 means no safety against thread strip out.

**Results:** Figure 5 demonstrates Asnis III Strip Out Safety Factors to be up to 50% higher than competitor products.

**Screw Deformation Safety**

**Definition:** The Screw Deformation Safety Factor is defined as the ratio between Screw Deformation Torque and Screw Insertion Torque.

**Clinical Significance:** Screw Deformation Safety means the greater the difference between Insertion Torque and Deformation Torque the higher the in vivo safety against screw deformation during insertion into good quality bone.

Figure 6: Screw Deformation Safety Factor = 1 means no safety against screw deformation.

**Results:** Figure 6 shows Asnis III Safety Factors to be up to 37% higher than competitor products.

**Summary**

The results show Asnis III insertion torques to be on the same level or up to 25% lower than competitor products (Figure 2). This demonstrates the excellent cutting and tapping behavior of the Asnis III cannulated screw.

The values obtained for safety against strip out and screw deformation prove Asnis III to be ahead of the competition: Asnis III safety factors are up to 50% higher than in competitor products (Figure 5). These results suggest that Asnis III screws may enable easier and safer insertion than competitor products.

**Screw Pull Out Behavior**

Interfragmentary pull forces are one of the major biomechanical loads putting primary reposition and further stability at fracture site at risk.

The purpose of this test was to determine the axial holding strength of screws in bone when an axial pull force is applied as depicted in Figure 7.

**Definition:** The maximum pull force during testing is defined as the Pull Out Strength.

**Clinical Significance:** The higher the Pull Out Strength, the higher is the capability to resist lag forces.

Figure 7: Test set up to determine Pull Out Strength.

Figure 8: Pull Out Strength in mean value ± standard deviation. An * indicates a significant difference (α=0.05).

**Results:** The results presented in Figure 8 prove that Asnis III Pull Out Strength is higher than competitor results for small and large diameter screws.
Guide Wire Bending Stiffness

Exact guide wire placement facilitates easier bone fragment reposition and screw placement during surgery. The guide wire bending stiffness is the crucial factor for this.

The Guide Wire Bending Stiffness is defined as the resistance against elastic deformation under application of a bending load and behaves proportional to the 4th power of the wire diameter as visualized in Figure 9.

Clinical Significance: The higher the Guide Wire Bending Stiffness the easier the bone fragment reposition and the less likely jamming and malpositioning during drilling and screw insertion.

Figure 9: Guide Wire Bending Stiffness is proportional to the 4th power of the wire diameter.

Results: Asnis III Guide Wire Bending Stiffness is equal or higher than competitor products for both, small and large diameter screws (Figure 9). For small diameter screws the Asnis III Guide Wire Bending Stiffness is more than two times higher than the competitor value.

Summary: The stiffness feature hints Asnis III to allow easy and safe fragment repositioning and screw placement.

Anodization Type II

Anodization Type II is a unique electrochemical treatment which modifies the surface structure of Titanium by embedding hard oxides in the surface area. Anodization Type II has been shown to [5][6]:

- Reduce friction coefficient
- Enhance implant fatigue strength

Limitations

The materials list represents the screws available at time of testing. Since then the repertory of screw diameters may have increased.

References

[1] Test data on file at Stryker Trauma AG, Selzach, Switzerland – test reference № S00028, S00035, S00036, S00053, S01006 & V09167
[6] A. Baumann & N. Zander; White Paper: Ti6Al4V with Anodization Type II: Biological Behaviour and Biomechanical Effects; March 2005; DOT GmbH, Rostock, Germany; Stryker Trauma GmbH, Schönkirchen, Germany