

Performance of IMN Screws

3 | Reduced play compared to competition

Background

This study was designed to investigate the influence of different angular stable locking solutions for the distal tibia on the torsional and bending play of the nail-bone construct.

Material

Non-angular stable constructs

3 screws – double ML* and single AP** locking

- T2 Standard Tibial Nail with 5mm Locking Screws, Fully Threaded [Stryker]
- Expert Tibial Nail with 5mm Locking Screws [DepuySynthes]

Angular stable constructs

2 screws – double ML* locking

- T2 Alpha Tibial Nail with 5mm Advanced Locking Screws of IMN Screws System [Stryker]
- Expert Tibial Nail with ASLS5 of Angular Stable Locking System [DepuySynthes]

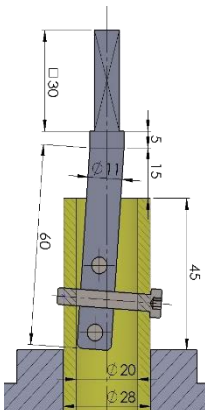
Method

Nail sample preparation [6]:

- Nails were cut at the distal part and an 8mm square was manufactured to clamp the distal nail ends in the test machine.
- Nail diameters: 11mm

Fixation of distal nail ends in bone model [6]:

- Cotton hard tissue (HGW2375.4, Krüger & Sohn GmbH, 84030 Landshut), cylindrical shape
- Locking according to operative techniques of manufacturers



Test procedure [6]:

- Servo-hydraulic test machine: Instron 8874
- Loading: torsional and bending in frontal plane
- Output: stiffness and play (mean \pm standard deviation)
- Sample size $n = 5$ (exception: $n = 4$ for ASLS5 group with Expert Tibial Nail)

Abbreviations: * medio-lateral, ** antero-posterior

References:

[6] Report "WST Model Part B.1 - Generic model of a human long bone treated with a dummy of an intramedullary nail", internal document: Institute of Biomechanics, Trauma Center Murnau, 2019.

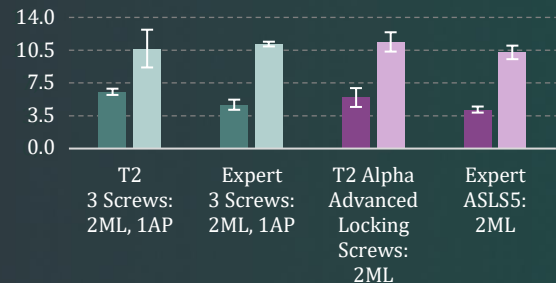
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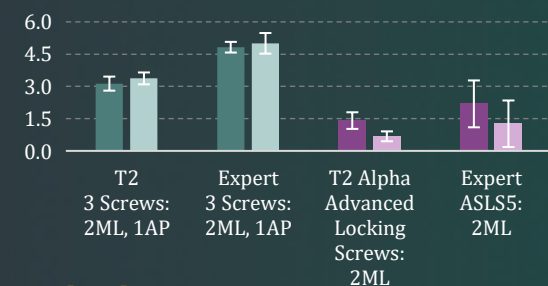
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Results

- Torsional (left of the two bars in Nm/°) and bending (right of the two bars in Nmm/°) stiffness results (mean \pm standard deviation) [6]:



- Torsional (left of the two bars) and bending (right of the two bars) play results in ° (mean \pm standard deviation) [6]:



Conclusions

- No statistically significant differences in bending stiffness were detected. The T2 construct with 3 screws and the T2 Alpha construct with 2 Advanced Locking Screws showed a higher torsional stiffness compared to their respective Expert counterpart ($p \leq 0.035$). [6]
- The T2 Alpha construct with 2 Advanced Locking Screws showed the overall lowest torsional and bending play among all tested constructs and a statistically significant decrease compared to both non-angular stable constructs with 3 screws ($p \leq 0.009$). [6]

Performance of IMN Screws

4 | Equal or better bicortical insertion behavior

Background

During surgery, locking screws typically need to be inserted through two cortical layers of human bone. An insertion test was conducted to measure and compare the maximum torque during insertion of locking and angular stable locking screws.

Material

5mm screws (reference)

- Locking Screws, Fully Threaded [T2, Stryker]

5mm angular stable screws

- Advanced Locking Screws [IMN Screws System, Stryker]

Method

- Bicortical model (“sandwich” construct): 35mm Sawbone insert surrounded by two 4mm Renshape disks
 - Cortical bone simulated by Renshape BM5166 [Schurg]
 - Inner cancellous bone simulated by polyurethane foam, cellular rigid, 12.5 pcf, #1522-10 [Sawbones]
 - Nail embedded into cancellous bone
 - Holes pre-drilled according to operative technique
- Procedure: Insertion with a constant rotation (30rpm) under a constant axial load (31N) on the drill and screw test stand (see pictures in the right upper corner)
- Output: Highest torque required to insert the screw into the “sandwich” construct with the embedded nail
- Sample size n = 6 (exception: n = 5 for reference)



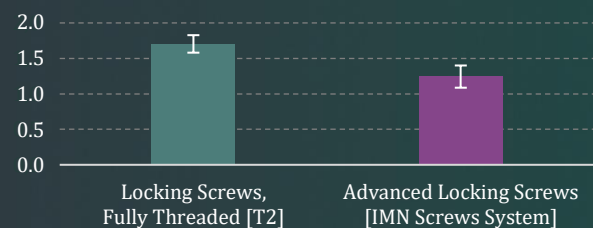
Locking Screw (reference)



Advanced Locking Screw

Results

- Insertion torque results (mean \pm standard deviation) in Nm [7]:



Conclusions

- With over-drilling of the near cortex, Stryker's Advanced Locking Screws showed an equal or lower insertion torque compared to the Locking Screws, Fully Threaded [T2] ($p = 0.031$). [7]
- Even though Stryker's Advanced Locking Screws are guided by the internal threads of the T2 Alpha nails, no increased insertion torque could be measured.

References:

[7] Test report 170118CG1 (A0030043): internal documents, Stryker's Trauma & Extremities division, 2018.

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