Performance of IMN Screws

1 | Increased fatigue strength

Background

Intramedullary nailing systems are designed to provide temporary fracture fixation until bony healing occurs.
Sufficient fatigue strength is a prerequisite to reduce the risk of implant failure and thus primarily screw breakage [1, 2] in case of overload.
This paper compares the fatigue strength of 5mm locking screws and 5mm angular stable or fixed angle screws of different intramedullary nailing systems. More stable implant constructs may lead to increased loads on locking screws. Therefore, angular stable screws are typically designed to provide a higher fatigue strength. Stryker's Advanced Locking Screws of the IMN Screws System are designed with oversized threads that engage with the internal threads of the T2 Alpha nails while maintaining bicortical purchase. Advanced Locking Screws may be preferred in instances when axial stability is desired.

Material

5mm locking screws

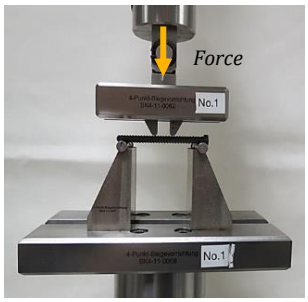
- Locking Screw, Fully Threaded [T2, Stryker]
- Locking Screw [IMN Screws System, Stryker]
- Internal Hex Captured Screw [Trigen, Smith & Nephew]
- Double Lead Thread Screw [Phoenix, Biomet]

5mm angular stable or fixed angle screws

- Advanced Locking Screw used with T2 Alpha Nailing Systems [IMN Screws System, Stryker]
- ASLS5 [Angular Stable Locking System, DepuySynthes]
- Cortical Screw Fixed Angle [Natural Nail System, Zimmer]

Method

- Dynamic 4-point bending testing according to ASTM F1264-16.
- Loading: sinusoidal load applied for 500,000 cycles representing a healing period of three months with a safety factor of 2.

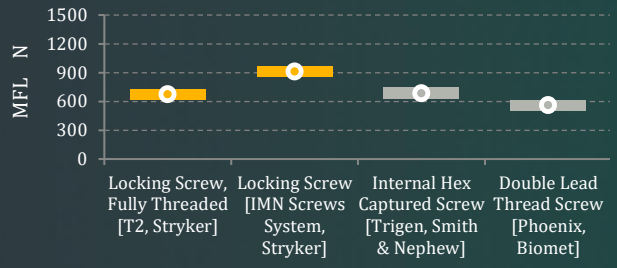


- Output: fatigue strength expressed as median fatigue limit (MFL) in N; maximum load at which 50% of the tested samples survive 500,000 load cycles without failure.
- Sample size n = 6.

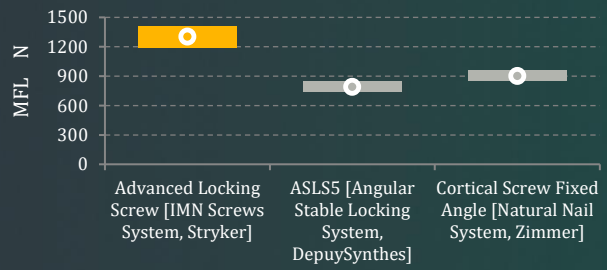
Results

- Failure mode: Screw breakage in the region of the highest bending moment. [3]
- Results are presented in high-low plots: The circle in the box represents the MFL. The box represents the 95% confidence interval of the MFL. [3]

5mm locking screws



5mm angular stable / fixed angle screws



Conclusions

- Stryker's Advanced Locking Screws showed an increased fatigue strength compared to different 5mm locking screws and angular stable or fixed angle screws. The analysis was supported by statistical techniques. [3]

References:
[1] Rether JR, et al. Experiences with a helical femoral nail (LFN®). A multicenter study. Unfallchirurg. 2013 Jul;116(7):582-8.
[2] Hutson JJ, et al. Mechanical failures of intramedullary tibial nails applied without reaming. Clin Orthop Relat Res. 1995 Jun;(315):129-37.
[3] Test reports 080611CG2 (A0003696), 260117CG2 (A0023253), 170118CG1 (A0030043): internal documents, Stryker's Trauma & Extremities division, 2014, 2017, 2018.

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Performance of IMN Screws

2 | Reduced play by angular stable locking

Background

This study was designed to investigate the influence of angular stable locking using Stryker's Advanced Locking Screws on the stiffness and play of the nail-bone construct.

Material

5mm screws (reference)

- Locking Screws, Fully Threaded [T2, Stryker]

5mm angular stable screws

- Advanced Locking Screws used with T2 Alpha Nailing Systems [IMN Screws System, Stryker]

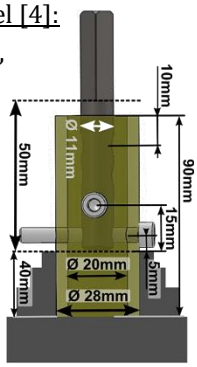
Method

Nail model and tested locking configuration [4]:

- Nail diameter: 11mm
- Number of screws: 2
- Angle between screws: 90° (simulated AP/ML* locking)
- Nail hole diameter: 5.1mm

Fixation of nail model in bone model [4]:

- Cotton hard tissue (HGW2375.4, Krüger & Sohn GmbH, 84030 Landshut), cylindrical shape
- Outer and inner diameter: 28mm and 20mm
- Holes for locking screws pre-drilled according to operative technique [5]

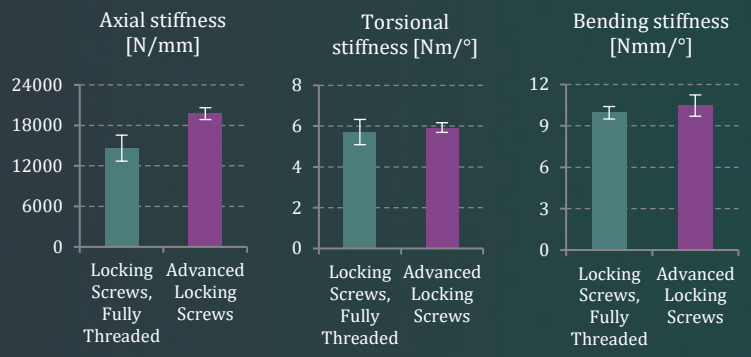


Test procedure [4]:

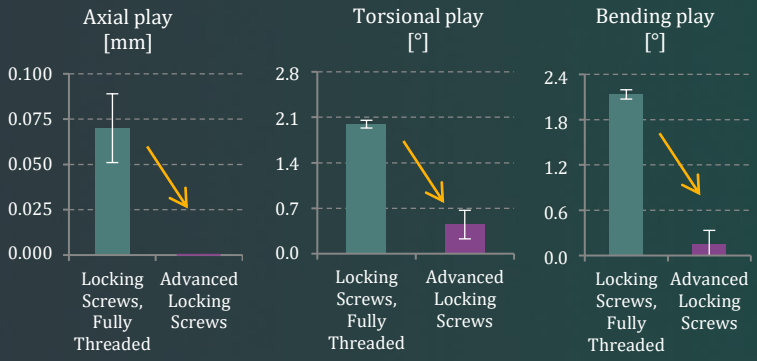
- Servo-hydraulic test machine: Instron 8874
- Loading: axial, torsional and bending
- Output: stiffness and play which defines the movement between nail and screws
- Sample size n = 5

Results

- Axial, torsional and bending stiffness results (mean ± standard deviation) [4]:



- Axial, torsional and bending play results (mean ± standard deviation) [4]:



Conclusions

- The usage of Stryker's Advanced Locking Screws did not affect torsional and bending stiffness, whereas axial stiffness was increased compared to the Locking Screws, Fully Threaded [T2] ($p = 0.001$). [4]
- The usage of Stryker's Advanced Locking Screws resulted in a negligibly low, not measurable axial play and significantly decreased both torsional and bending play compared to the Locking Screws, Fully Threaded [T2] ($p < 0.001$). [4]

Abbreviations: * antero-posterior/medio-lateral

References:
[4] Report "WST Model Part A.2 - Generic model of a human long bone treated with a dummy of an intramedullary nail", internal document: Institute of Biomechanics, Trauma Center Murnau, 2019.
[5] Operative technique: T2 Alpha Tibia Nailing System, T2-ST-20, Rev 3, 02-2019.

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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

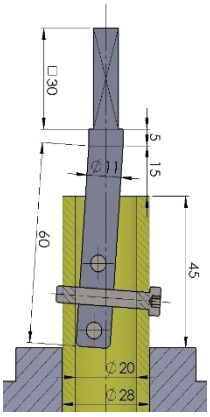
- T2 Standard Tibial Nail with 5mm Locking Screws, Fully Threaded [Stryker]
- Expert Tibial Nail with 5mm Locking Screws [DepuySynthes]

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]:

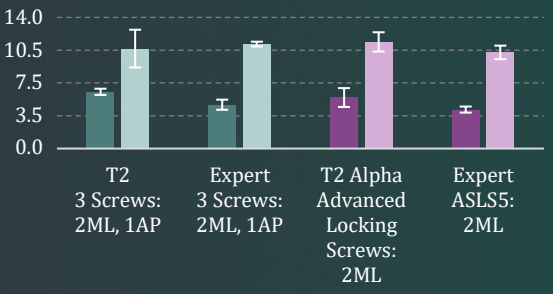
- Cotton hard tissue (HGW2375.4, Krüger & Sohn GmbH, 84030 Landshut), cylindrical shape
- Locking according to operative techniques of manufacturers

Test procedure [6]:

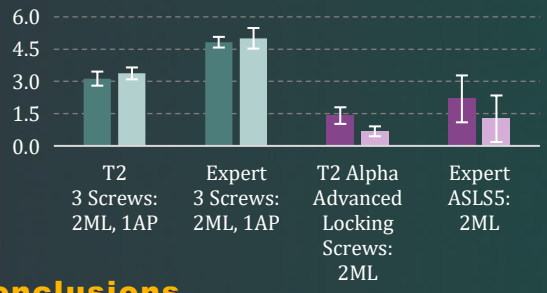
- Servo-hydraulic test machine: Instron 8874
- Loading: torsional and bending in frontal plane
- Output: stiffness and play (mean ± standard deviation)
- Sample size n = 5 (exception: n = 4 for ASLS5 group with Expert Tibial Nail)

Results

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



- Torsional (left of the two bars) and bending (right of the two bars) play results in ° (mean ± 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]

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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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]

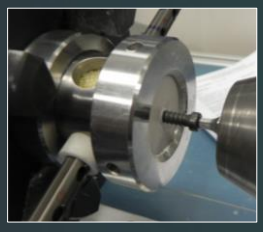
5mm angular stable screws

- Advanced Locking Screws [IMN Screws System, Stryker]

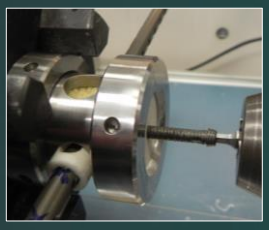
Method

- 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)



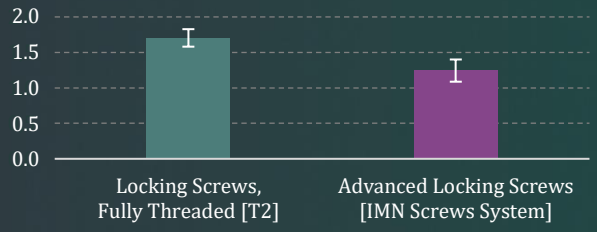
Locking Screw (reference)



Advanced Locking Screw

Results

- Insertion torque results (mean ± 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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