

Performance of Eba One - Standard and Long nail

Background

Global prevalence of osteoporosis and fragility fractures is increasing due to the aging population. Proximal femoral fractures are among the most common orthopedic conditions in elderly that significantly cause health deterioration and mortality. [1]

Nowadays, intramedullary nail is the gold standard of treatment for lateral proximal femur fractures. [2]

This study aimed at verifying that the Eba One nail has sufficient mechanical properties, such as fatigue bending strength and static torsional stiffness, in order to avoid implant breakage. [3]

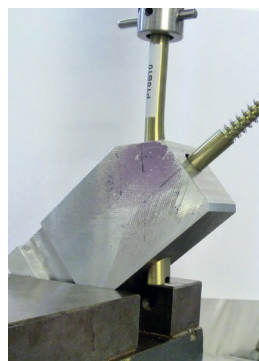
All the test have been conducted following the ASTM F1264 which is «Test Method for Intramedullary Fixation devices». [4]

Material

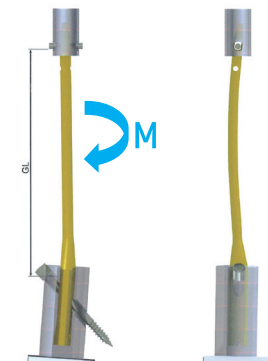
- $\varnothing$ 10/11 mm Standard Nail [Citieffe, Eba One]
- $\varnothing$ 10/11 mm Long Nail [Citieffe, Eba One]
- $\varnothing$ 10/11 mm Trochanteric Nail 180 [Stryker, Gamma3™]
- $\varnothing$ 10/11 mm Long nail R1.5 [Stryker, Gamma3™]

Method

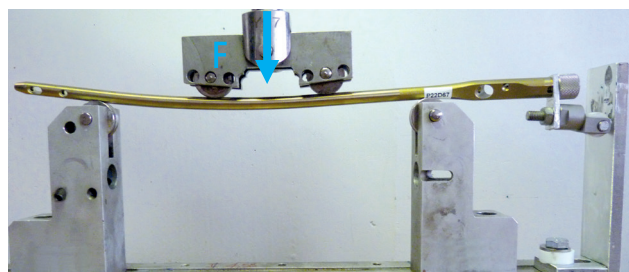
- ASTM F1264 Annex A1 - Static Four-Point Bend Test Method
- ASTM F1264 Annex A2 - Static Torsion Test Method
- ASTM F1264 Annex A3 - Bending Fatigue Test Method
- Loading conditions: 1 million cycles representing a 1-year healing period.
- Sample size $n = 3$



ASTM F1264
Annex A2



ASTM F1264
Annex A2



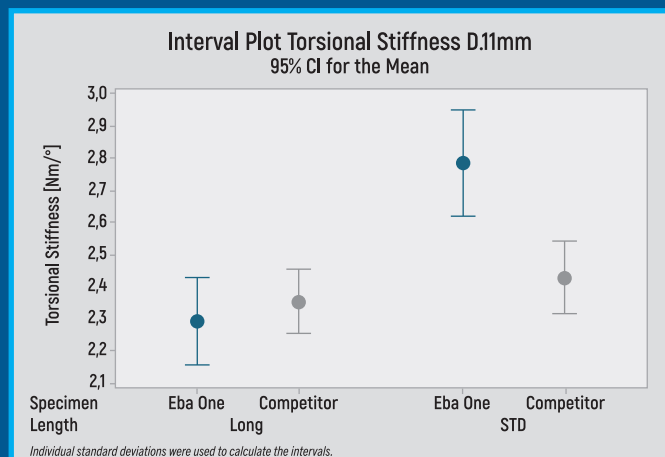
ASTM F1264
Annex A3

References

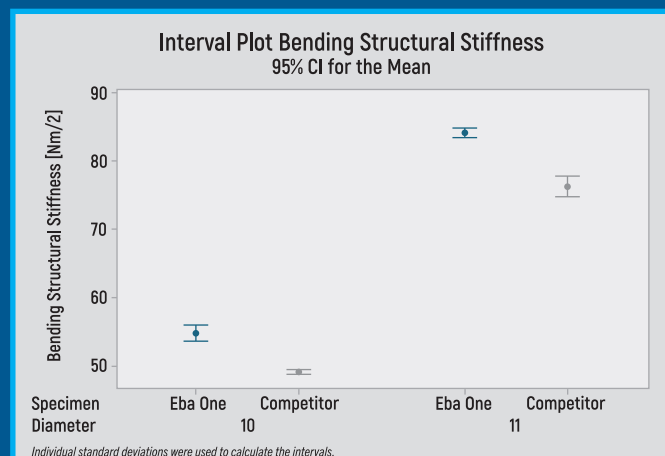
1. Baghdadi S, Kiyani M, Kalantar SH, et al. Mortality following proximal femoral fractures in elderly patients: a large retrospective cohort study of incidence and risk factors. *BMC Musculoskelet Disord.* 2023;24(1):693.
2. Cleveland M, Bosworth DM, Thompson FR, Wilson HJ, Ishizuka T [1959] A ten-year analysis of intertrochanteric fractures of the femur. *J Bone Joint Surg Am* 41[8], 1399-1408.
3. Johnson NA, Uzoigwe C, Venkatesan M, et al. Risk factors for intramedullary nail breakage in proximal femoral fractures: a 10-year retrospective review. *Ann R Coll Surg Engl.* 2017;99(2):145-150.
4. Test Reports R18A22 , R18A37 , RP031 , RP032 , RP033 , RP034: *internal documents, Citieffe*, 2018.

Results

- ASTM F1264 Annex A2 - Static Torsion Test Method



- ASTM F1264 Annex A1 - Static Four-Point Bend Test Method



Conclusions

- Following the ASTM F1264 Annex A2: the $\varnothing$ 11 mm Eba One STD nail showed increased Torsional Stiffness compared to the competition.
- Following the ASTM F1264 Annexes A1 and A3: the $\varnothing$ 10-11 mm Eba One Long showed increased Bending Structural Stiffness compared to the competition.

Performance of Eba One - Lag screw

Background

Global prevalence of osteoporosis and fragility fractures is increasing due to the aging population. Proximal femoral fractures are among the most common orthopedic conditions in elderly that significantly cause health deterioration and mortality.[1]

Nowadays, intramedullary nail is the gold standard of treatment for lateral proximal femur fractures. [2]

One of the most dangerous post-operative complications that can occur when treating fractures with this method is the medial migration of the lag screw. [3,4,5,6]

This study aims at investigating the stability and safety of the Eba One lag screw compared to the one of a competition nailing system.

The test have been conducted following the ASTM F453, ASTM F1839, and the Medial Migration Set Screw Failure Test. [7]

Material

- Lag Screw [Citieffe, Eba One]
- Lag Screw [Stryker, Gamma3™]

Method

- ASTM F543 Annex A2 - Test Method for Driving Torque of Medical Bone Screws;
- ASTM F543 Annex A3 - Test Method for Determining the Axial Pullout Load of Medical Bone Screws;
- ASTM F1839 - Specification for uniform material test block: 15PCF foam density to reproduce head femoral bone [8];
- Medial Migration: Set Screw Failure Test;
- Sample size n = 3.



ASTM F543
Annex A2



Set Screw Failure Test
Set Up



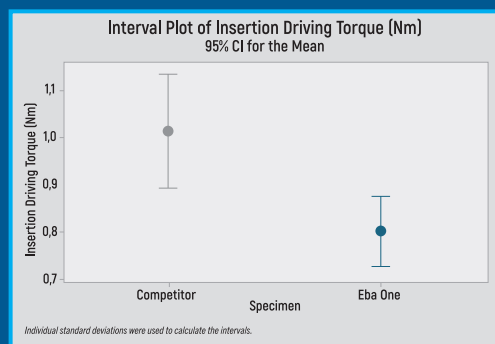
ASTM F543
Annex A3

References

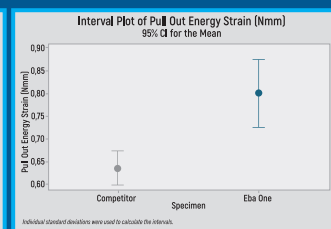
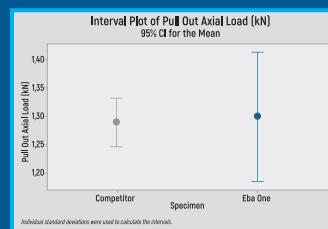
1. Baghdadi S, Kiyani M, Kalantar SH, et al. Mortality following proximal femoral fractures in elderly patients: a large retrospective cohort study of incidence and risk factors. *BMC Musculoskelet Disord.* 2023;24(1):693.
2. Cleveland M, Bosworth DM, Thompson FR, Wilson HJ, Ishizuka T (1959) A ten-year analysis of intertrochanteric fractures of the femur. *J Bone Joint Surg Am* 41(8), 1399-1408.
3. Schipper IB, Steyerberg EW, Castelein RM, et al. Treatment of unstable trochanteric fractures. Randomised comparison of the gamma nail and the proximal femoral nail. *J Bone Joint Surg Br.* 2004;86(1):86-94.
4. Takasago T, Goto T, Toki S, et al. Intrapelvic migration of the lag screw in intramedullary nailing. *Case Rep Orthop.* 2014;2014:519045.
5. Thein E, De Cannière A, Burn A, Borens O. Medial migration of lag screw after gamma nailing. *Injury.* 2014;45(8):1275-1279.
6. Chapman T, Zmistowski B, Krieg J, Stake S, Jones CM, Levicoff E. Helical Blade Versus Screw Fixation in the Treatment of Hip Fractures With Cephalomedullary Devices: Incidence of Failure and Atypical "Medial Cutout". *J Orthop Trauma.* 2018;32(8):397-402.
7. Test Reports R18A21, R18A24: internal documents, Citieffe, 2018.
8. Al-Munajjed AA, Hammer J, Mayr E, Nerlich M, Lenich A. Biomechanical characterisation of osteosyntheses for proximal femur fractures: helical blade versus screw. *Stud Health Technol Inform.* 2008;133:1-10.
9. Varghese V, Saravana Kumar G, Krishnan V. Effect of various factors on pull out strength of pedicle screw in normal and osteoporotic cancellous bone models. *Med Eng Phys.* 2017;40:28-38.

Results

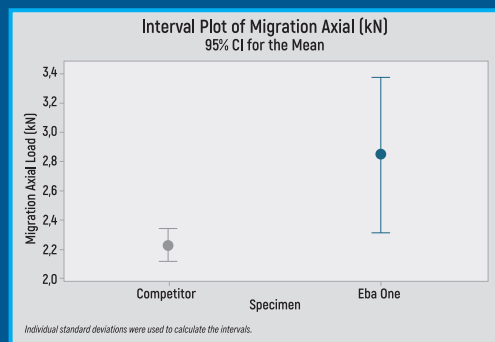
- ASTM F543 Annex A2 – Insertion Driving Torque of Medical Bone Screws



- ASTM F543 Annex A3 – Axial Pullout Load of Medical Bone Screws



- Medial Migration Set Screw Failure Test



Conclusions

- ASTM F543 Annex A2: the Eba One lag screw showed a decreased Insertion Driving Torque compared to the competitor* showing less overheating and less possibility of bone necrosis. [* Significantly different: p-value < 0,05]
- Following the ASTM F543 Annex A3:
 - The Eba One Lag screw showed equal Axial Pull Out Load compared to the competitor*. [* Not Significantly different: p-value > 0,05]
 - The Eba One Lag screw showed an increased Strain Energy [9] compared to the competitor** showing an increased stability of the implant given by the characteristics of the lag screw. [** Significantly different: p-value < 0,05]
- Following the Medial Migration Set Screw Failure test: the load required to break the Eba One set screw is bigger compared to the one required to break the set screw of the competitor* reflecting a lower risk of the lag screw medial migration into the pelvis. [* Significantly different: p-value < 0,05]

Background

Global prevalence of osteoporosis and fragility fractures is increasing due to the aging population. Proximal femoral fractures are among the most common orthopedic conditions in elderly that significantly cause health deterioration and mortality. [1]

Nowadays, intramedullary nail is the gold standard of treatment for lateral proximal femur fractures. [2]

This study investigates the fatigue strength, torsional properties and the axial pull out load of $\varnothing$ 5.2 mm Eba One cortical screw compared to the one of a competition nailing system.

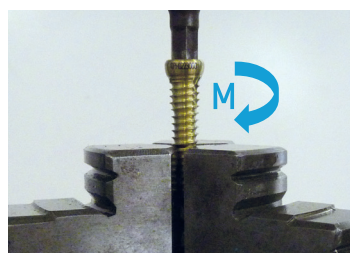
All the test have been conducted following the ASTM F453 which is «Test Methods for Metallic Medical Bone Screws». [3]

Material

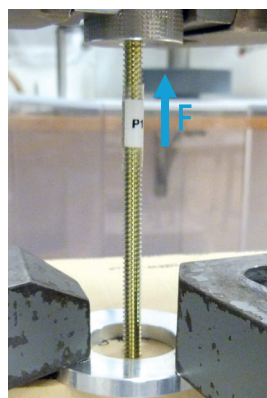
- $\varnothing$ 5.2 mm Cortical Screw [Citieffe, Eba One]
- $\varnothing$ 5 mm Cortical Screw [Stryker, Gamma3™]

Method

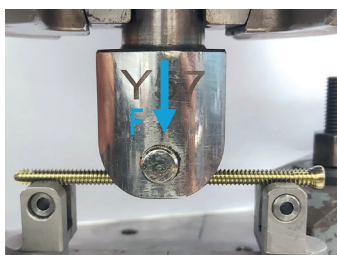
- ASTM F543 Annex A1 - Test Method for Determining the Torsional Properties of Metallic Bone Screws;
- ASTM F1264 Annex A4 - Test Method for Bending Fatigue of IMFD Locking Screws;
- ASTM F543 Annex A3 - Test Method for Determining the Axial Pullout Load of Medical Bone Screws;
- Sample size $n = 5$.



ASTM F543
Annex A1



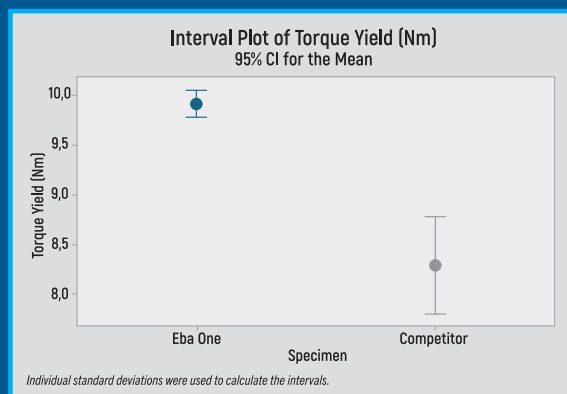
ASTM F543
Annex A3



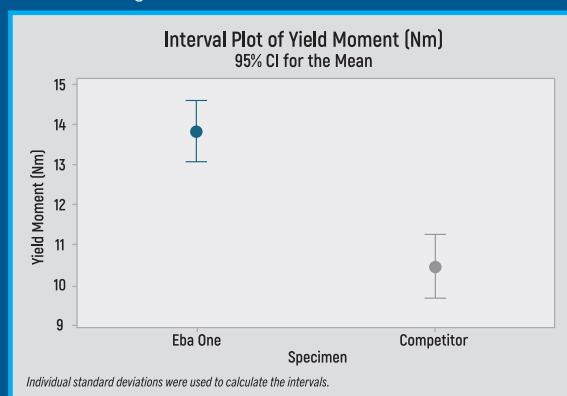
ASTM F1264
Annex A4

Results

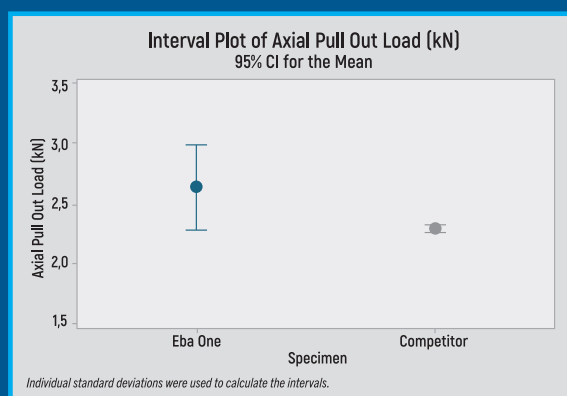
- ASTM F543 Annex A1 - Static Torsion Test Method



- ASTM F1264 Annex A4 - Test Method for Bending Fatigue of IMFD Locking Screws



- ASTM F543 Annex A3 - Axial Pullout Test Meth



Conclusions

- Following the ASTM F541 Annex A1: the Eba One cortical screw has an increased Torque Yield compared to competition.
- Following the ASTM F1264 Annex A4: the Eba One cortical screw showed an increased Yield Moment compared to competition.
- Following the ASTM F543 Annex A3: the Eba One cortical screw has an increased Axial Pull Out Load compared to competition.

References

1. Baghdadi S, Kiyani M, Kalantar SH, et al. Mortality following proximal femoral fractures in elderly patients: a large retrospective cohort study of incidence and risk factors. *BMC Musculoskelet Disord.* 2023;24(1):693.
2. Cleveland M, Bosworth DM, Thompson FR, Wilson HJ, Ishizuka T (1959) A ten-year analysis of intertrochanteric fractures of the femur. *J Bone Joint Surg Am.* 41(8), 1399-1408.
3. Test Reports R18A19, R18A18, R18A11, R18A09, R18A20: internal documents, Citieffe, 2018.