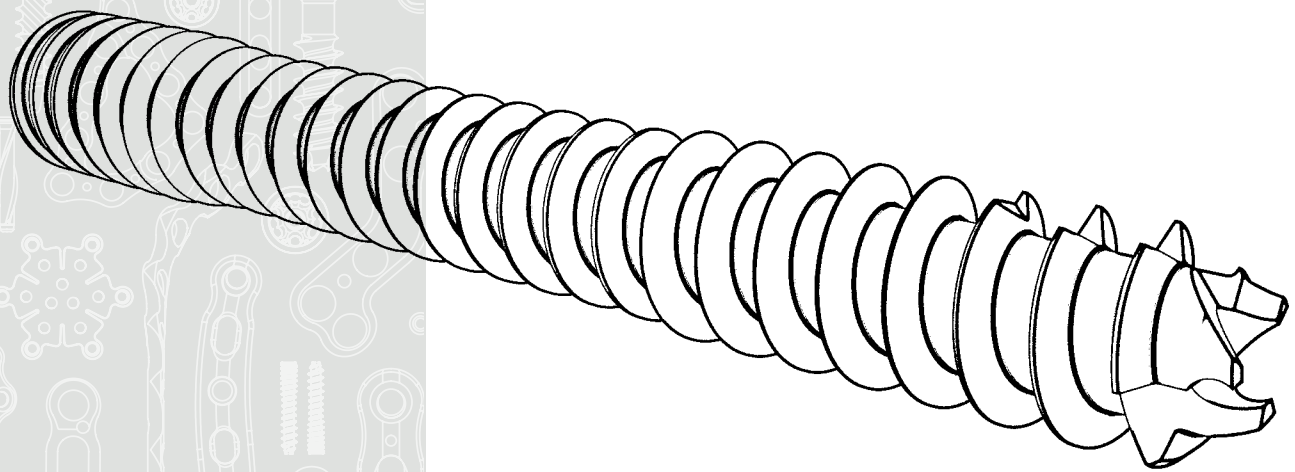


Compression and Insertion Torque Comparison between Acumed Acutrak® 2 Mini and Arthrex 3.5 mm Mini Compression FT Headless Compression Screws

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Compression and Insertion Torque Comparison of Acumed to Arthrex Headless Compression Screws

Objective:

Determine and compare the fracture site compression force and insertion torque profiles of Acumed's Acutrak 2[®] Mini and Arthrex's 3.5 mm Mini Compression FT (fully threaded) Headless Compression Screws in a synthetic bone model with three different simulated fracture locations.

Materials & Methods:

Testing was performed using an Admet 8610 testing machine (Norwood, MA) with a dual FUTEK (Irvine, CA) load cell configuration (Figure 2). In order to assess the performance characteristics of the Acumed Acutrak 2[®] Mini and the Arthrex 3.5 mm Mini Compression FT screws in varying clinical settings, two 30 lb/ft³ (PCF) Sawbones foam blocks (Vashon Island, WA) were used as a bone surrogate to represent proximal, midline, and distal fracture fragments (Figure 1a, 1b, and 1c). Proximal fracture fragments had a 10 mm upper foam block, midline fracture fragments had a 14 mm upper foam block, and distal fracture fragments had an 18 mm upper foam block. In all test configurations, a 2-mm simulated fracture gap separated the upper from the lower foam blocks, which were 25 mm thick. For both Acumed and Arthrex headless compression screws, five (5) 30 mm long screws (P/N AT2-M30 and AR- 8730-30H, respectively) were used. Each of the five screws was used twice

in each fracture location scenario, for a total of 10 insertions per screw type and fracture location. A load cell was secured to the base of the test machine and the lower foam block was attached to the load cell. This load cell was used to measure fracture site compression force between the two blocks during screw insertion. A second torque cell was attached to the screwdriver (2.0 mm hex for Acumed and T10 Hexalobe for Arthrex) and measured the screw's insertion torque profile during insertion.

The foam blocks were drilled according to the manufacturers' recommendations^{1,2} and the screws were inserted flush to the top of the upper foam block using the appropriate driver (Figure 2). Guide wires were not used, as the machine controlled location and alignment during insertion. For all test samples, the compressive force at the fracture site and insertion torque on the screwdriver were measured and recorded continuously throughout the insertion of the screw.

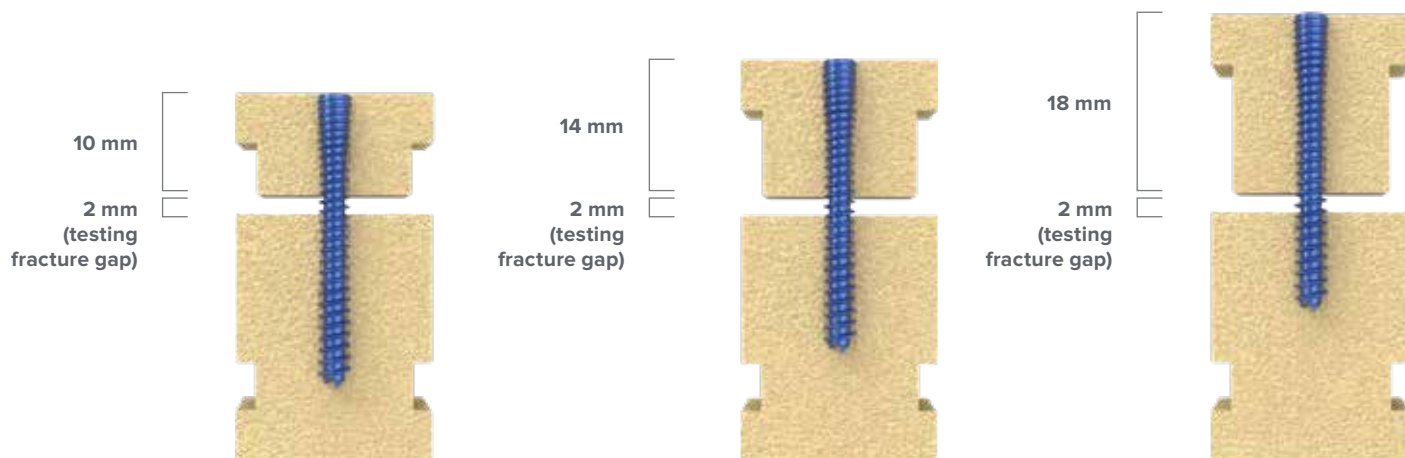
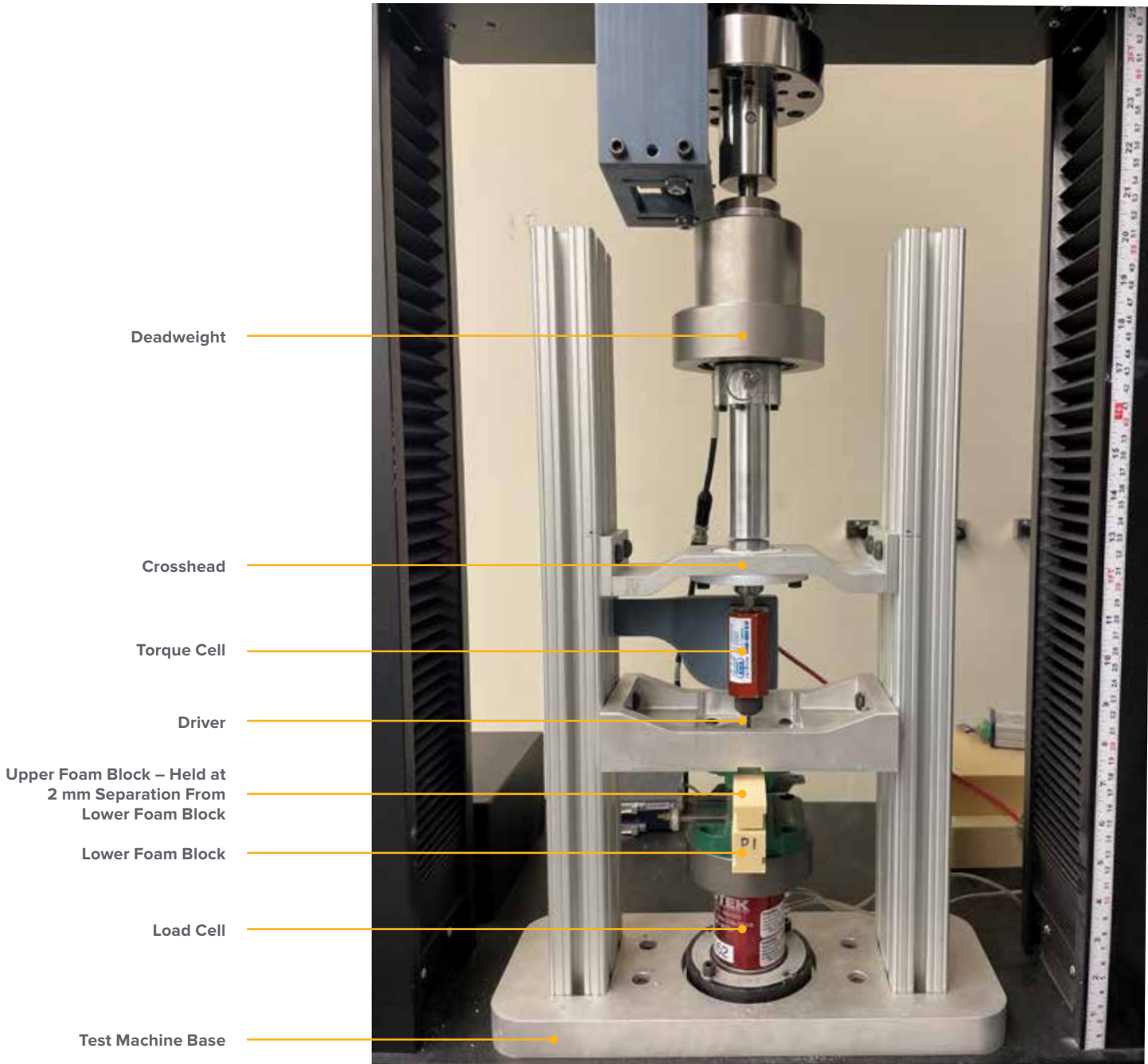


Figure 1a-Proximal

Figure 1b-Midline

Figure 1c-Distal

Figure 2



Results:

In the proximal and midline fracture locations, the Acutrak 2® Mini screw had a higher average maximum fracture site compression force at final screw seating, while in the distal fracture location both screws achieved similar final compression.

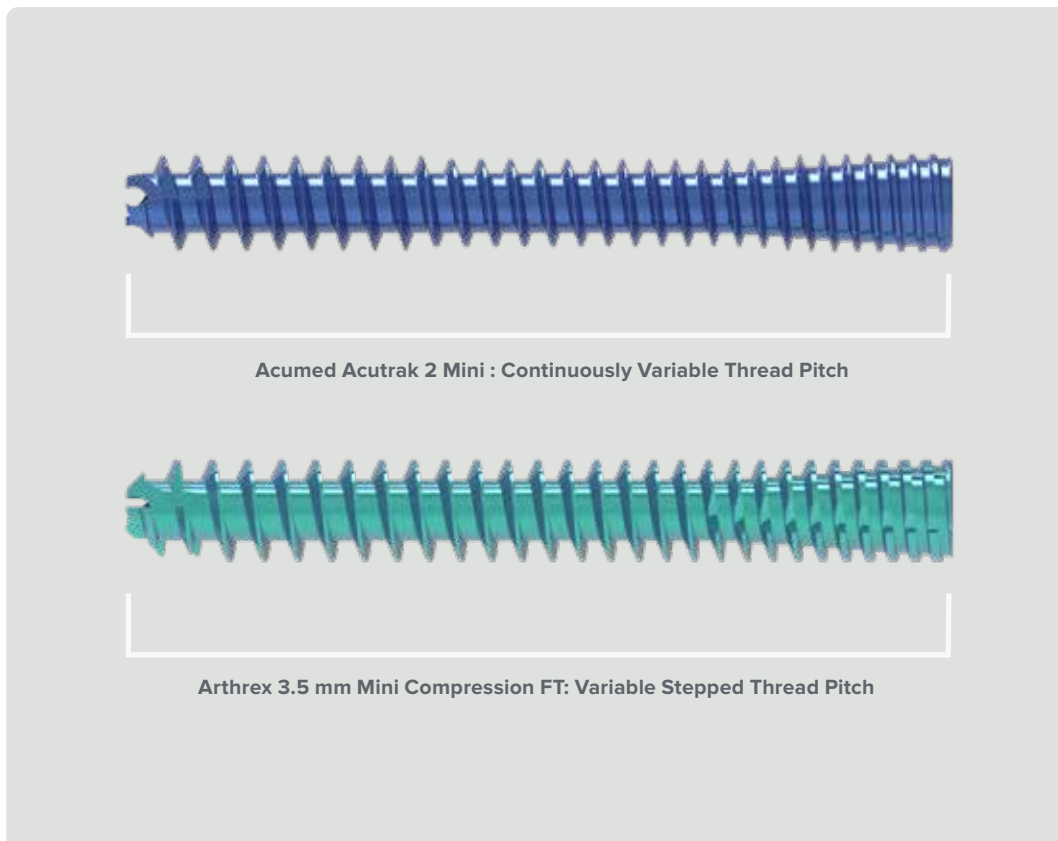
In the case of the simulated proximal fracture location, the Acutrak 2 Mini achieved its maximum compression force before dropping 9% at final screw seating (Figure 3). Similarly, the Arthrex 3.5 mm Mini Compression FT screw achieved maximum compression force before dropping by 60% at final screw seating.

For the simulated midline fracture location, the Acutrak 2 Mini screw showed an increasing fracture site compression force throughout insertion of the screw (Figure 4). Similar to the proximal fracture, the Arthrex 3.5 mm Mini Compression FT screw achieved maximum compression force before dropping by 13% at final screw seating.

Finally, for the simulated distal fracture location, both the Acutrak 2 Mini screw and the Arthrex 3.5 mm Mini Compression FT screw showed an increasing fracture site compression force throughout insertion of the screw (Figure 5).

For the simulated proximal fracture location, the Acutrak 2 Mini screw showed an increase in driver insertion torque over the final 15% of screw insertion depth while fracture site compression peaked at around 70% of insertion depth, then plateaued and dropped by 9% before final seating (Figure 6).

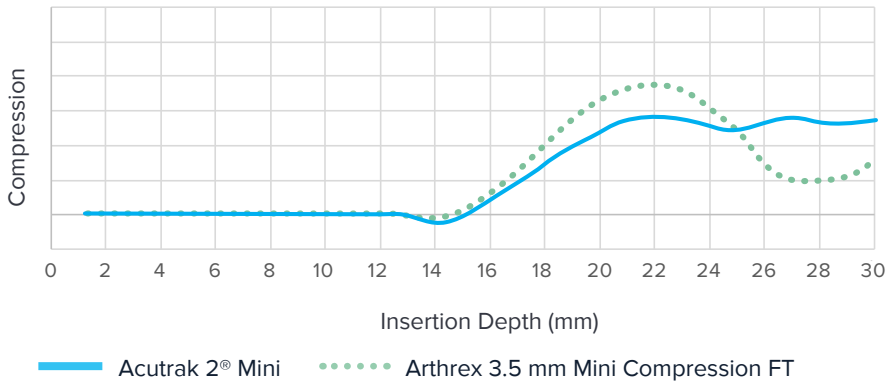
The Arthrex 3.5 mm Mini Compression FT screw in the simulated proximal fracture location showed a general increase in driver insertion torque with increasing fracture site compression force up to approximately 70% of screw insertion depth, after which the insertion torque continued to increase, while the fracture site compression decreased by 60% by the time the screw was fully seated (Figure 7).



Fracture Site Compression Force Profiles for Proximal Fracture

Average Compression Profile – 30 mm Screw Length

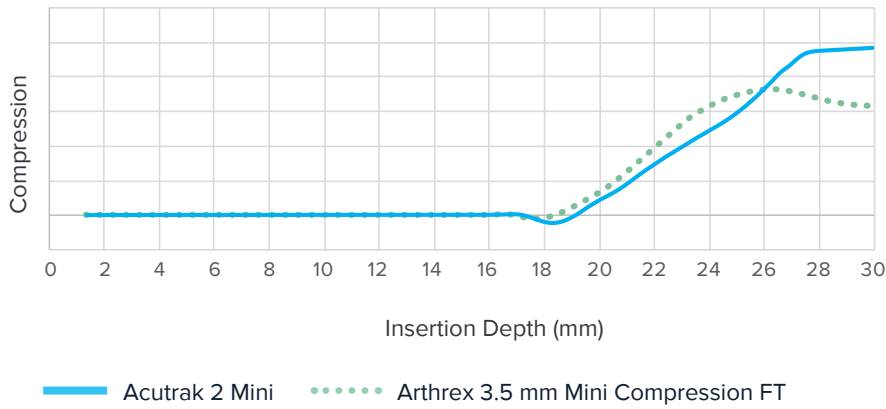
Figure 3



Fracture Site Compression Force Profiles for Midline Fracture

Average Compression Profile – 30 mm Screw Length

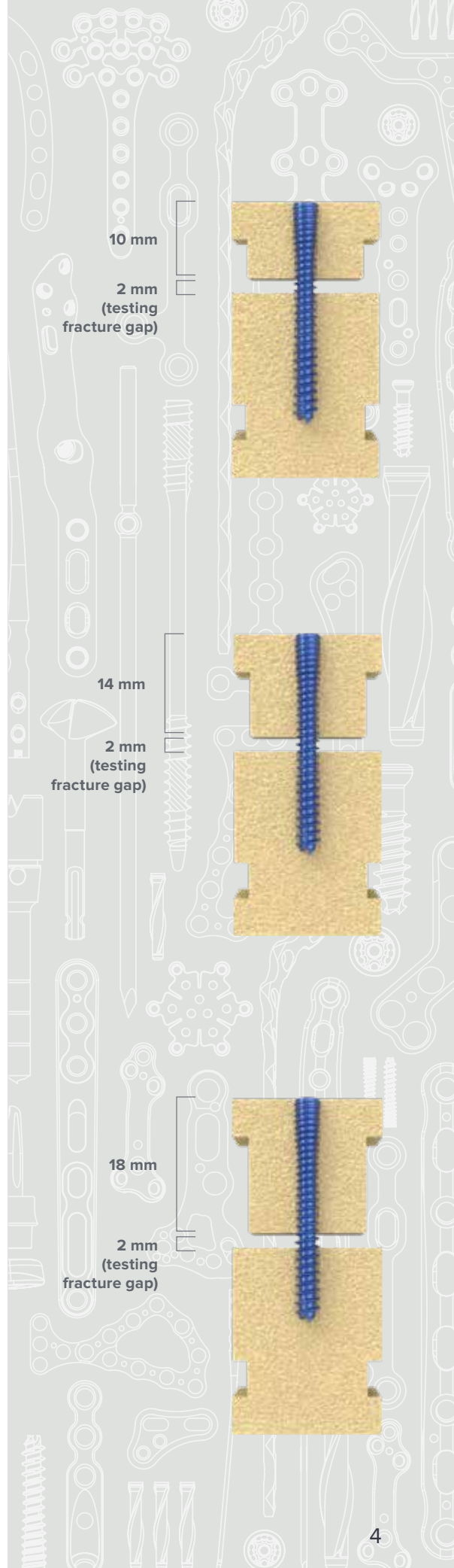
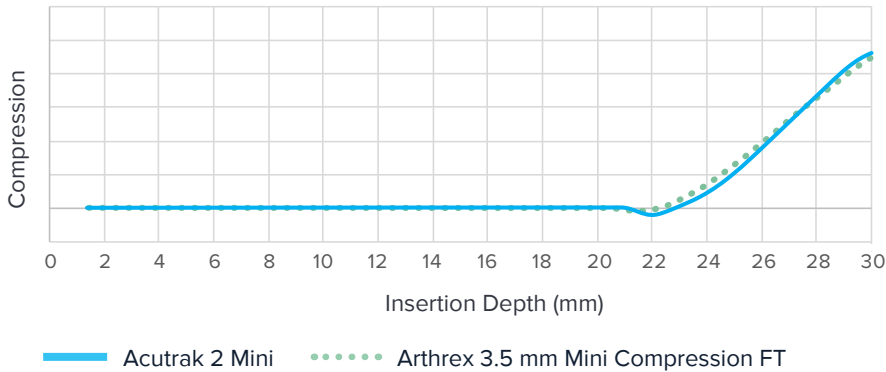
Figure 4



Fracture Site Compression Force Profiles for Distal Fracture

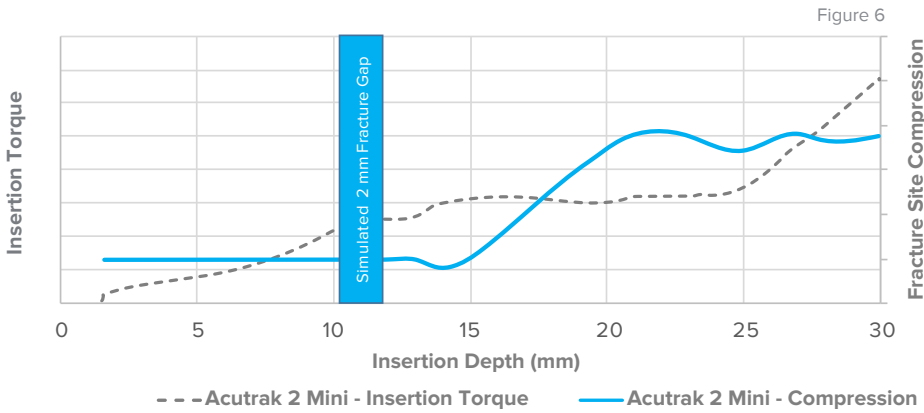
Average Compression Profile – 30 mm Screw Length

Figure 5



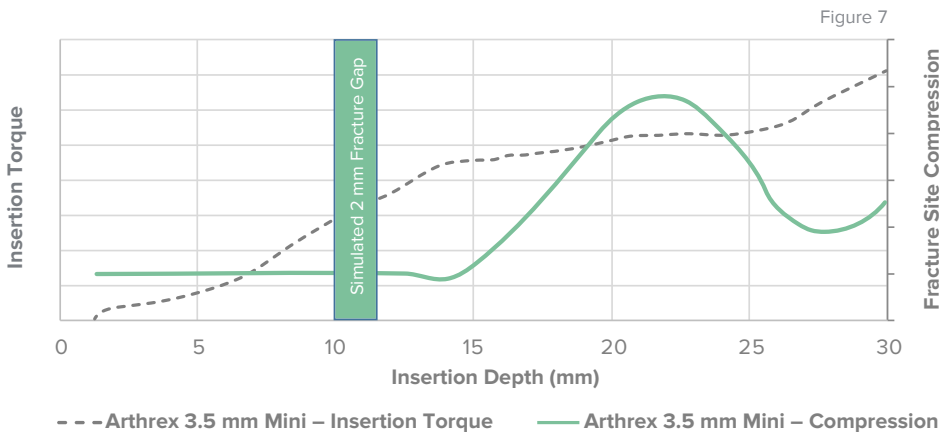
Acumed Screw Insertion Torque & Compression Force Profile for Proximal Fracture

Average Driver Insertion Torque – Acutrak 2® Mini x 30 mm Long



Arthrex Screw Insertion Torque & Compression Force Profile for Proximal Fracture

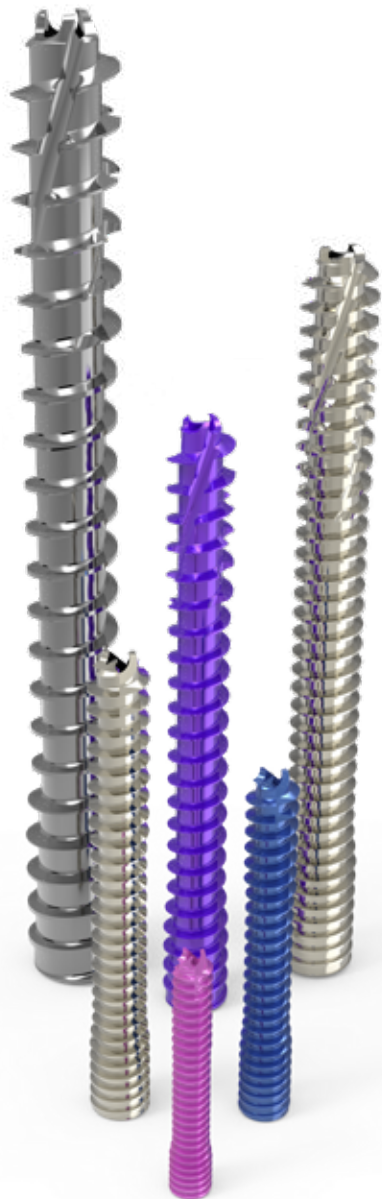
Average Driver Insertion Torque – Arthrex 3.5 mm Mini Compression FT x 30 mm Long



Conclusion:

- ▶ Compared to the Arthrex 3.5 mm Mini Compression FT screw, the continuously variable thread pitch technology of the Acutrak 2 Mini screw resulted in greater fracture site compression force upon final screw insertion in both proximal and midline fracture locations.
- ▶ In the simulated proximal fracture location, the Arthrex 3.5 mm Mini Compression FT screw showed a 60% loss of maximum fracture site compression force upon final screw insertion, despite driver insertion torque continuing to increase. In contrast, the Acutrak 2 Mini screw lost 9% of compression before final seating.

Note: A surgeon's selection of a headless compression screw system should be based on how much compression is required for the particular clinical application and any other device features or benefits that may be helpful to the surgeon. While bench testing may not always be indicative of clinical results, this study demonstrates that the final compression when the screw is fully seated may not necessarily be the peak compression achieved during screw insertion. Furthermore, the study indicates that in the proximal fracture models, the insertion torque, which some users may rely on for feedback, may not correlate to interfragmentary compression.



Acutrak 2® Headless Compression Screw System

Since its introduction in 1994, Acutrak® Headless Compression Screw technology has revolutionized the way surgeons treat fractures, fusions, and osteotomies. The Acutrak 2 is the next generation in fully threaded headless fixation, offering larger guide wires, larger hex drivers, and a tapered end. Long term surgeon feedback has helped develop this continuously variable fully threaded headless implant with instrumentation designed to simplify the surgical technique. The Acutrak 2 family is composed of 68 unique screw size options to fit a wide variety of applications throughout the body, from 2 mm x 8 mm up to 7.5 mm x 120 mm.

Data on file (TR-011335 & TR-011374), Hillsboro OR 2022

References:

1. SPF00-02-K Surgical Technique Acumed Acutrak 2 Headless Compression Screw System; 2022.
2. LB1-0487-EN_G Brochure Arthrex Compression FT Screw System; 2021.
3. TR-011335 Insertion and Compression Testing of Headless Compression Screws – Test Method Development and Validation; 2022.
4. TR-011374, Insertion and Compression Testing of Headless Compression Screws – Comparison of Different Screw Designs, 2022.



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