Compression Performance of Headless Compression Screws:

DePuy Synthes CCHS versus Acumed® Acutrak® 2 and Arthrex® Compression FT

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Abstract

Introduction: Previous studies[6-7] have evaluated the compression performance of Ø3.5mm Acumed Acutrak 2 and Arthrex Compression FT fully threaded headless compression screws. In those studies, compression was measured in a mechanical test where proximal and distal foam blocks were rigidly fixed together as screws were inserted. The study described in this paper is intended to reevaluate compression performance of those devices and the DePuy Synthes Cannulated Compression Headless Screws (CCHS) allowing for translation between the proximal and distal foam blocks, which is a more reliable model, accounting for screw cutting performance during insertion.

Purpose: The objective of this study was to compare the interfragmentary compression generated by Ø3.5mm x 30mm headless compression screws. The following screws were tested: DePuy Synthes Cannulated Compression Headless Screws (CCHS, Short and Long Thread), Acumed Acutrak 2, and Arthrex Compression FT.

Materials And Methods: Ø3.5mm x 30mm headless compression screws were inserted to 30mm depth (flush) into 30 pounds per cubic foot (pcf) foam using a proximal and distal foam block to simulate an osteotomy/fracture. Procedure A was a pass/fail study (for as many as n=3 of each screw) to determine if screws could generate interfragmentary compression, and was performed per the Acutrak 2 surgical technique,[2] using only a countersink to prepare the bone. In Procedure B, n=10 of each screw were tested with a hole prepared using both the countersink and drill bit. The test fixture allowed the blocks to translate, and interfragmentary compression and insertion depth were measured. Test specimens and setup were chosen to closely match the Acumed and Arthrex studies.[6-7]

Results: In Procedure A, CCHS Short and Long Thread successfully generated interfragmentary compression, while Acumed Acutrak 2 left a gap between the proximal and distal blocks when fully seated with no interfragmentary compression. Arthrex screws were not tested in Procedure A due to technique requirements for drill use.

In Procedure B, CCHS Short Thread generated noninferior compression (p<0.001) to Acumed Acutrak 2, and superior compression (p<0.001) to Arthrex Compression FT. CCHS Long Thread generated superior compression (p<0.001) to both Acumed Acutrak 2 and Arthrex Compression FT.

Discussion And Conclusion: The Acumed Acutrak 2 was unable to generate interfragmentary compression using its required technique[2,4,5] for hole preparation with a countersink (Procedure A), whereas the DePuy Synthes CCHS successfully generated compression. In a predrilled and countersunk condition (Procedure B), the DePuy Synthes CCHS either generates non-inferior or superior compression to Acumed Acutrak 2 and Arthrex Compression FT.

Introduction

Headless compression screws are a common solution to generate interfragmentary compression and stable fixation while limiting proximal screw prominence.

Acumed and Arthrex have released the results of similar studies[6-7] comparing the compression performance of their Ø3.5mm fully threaded headless compression screws. In both test setups, the foam blocks were rigidly held, representing fully constrained proximal and distal bone fragments. A rigidly fixed test method does not account for the cutting performance of a screw because, in a less rigid construct, the screw may push the distal block away as it drills/taps into it, potentially compromising the reduction.

This study allows for translation between foam blocks and, as a result, accounts for cutting efficiency of the screw's tip as it relates to interfragmentary compression. The DePuy Synthes Cannulated Compression Headless Screws (CCHS) were tested against the Acumed Acutrak 2 and Arthrex Compression FT screws.

Purpose

The objective of this study was to determine the interfragmentary compression generated in a non-rigidly constrained test setup when the proximal end of the screw is flush with the bone analog for the following Ø3.5mm x 30mm screws:

- DePuy Synthes CCHS Short Thread
- DePuy Synthes CCHS Long Thread
- Acumed Acutrak 2
- Arthrex Compression FT

Materials and Methods

Four headless compression screws were compared: DePuy Synthes CCHS Short Thread, DePuy Synthes CCHS Long Thread, Acumed Acutrak 2, and Arthrex Compression FT, shown in Figure 1 and listed in Table 1. All screws were Ø3.5mm x 30mm length and were inserted using the appropriate guide wires, drill bits, countersinks, and screwdrivers.[1-5] Up to n=3 of each screw were tested under Procedure A, and n=10 of each screw in Procedure B.

30 pcf foam blocks per ASTM F1839-08[9] were prepared with a predrilled hole at each guide wire's nominal diameter to minimize wire deflection during insertion. Constructs consisted of a 14mm-thick proximal foam block and a 40mm-thick distal block.

All compressive load was transferred between blocks by a load cell resting on a post machined into the distal block as shown in Figure 2. The test setup started with no initial fracture/osteotomy gap between the foam blocks to simulate full reduction achieved prior to screw insertion.

Table 1 Headless Compression Screws Tested.

Product*	Part Number
DePuy Synthes Ø3.5 CCHS Short Thread	04.333.330
DePuy Synthes Ø3.5 CCHS Long Thread	04.334.330
Acumed Acutrak 2 Mini (Ø3.5)	AT2-M30-S
Arthrex Compression FT Mini (Ø3.5)	AR-8730-30H

*It is assumed that the sterile and nonsterile part for each screw are mechanically equivalent.

Figure 1 Representative screws tested (left to right): DePuy Synthes CCHS Short Thread, DePuy Synthes CCHS Long Thread, Acumed Acutrak 2, Arthrex Compression FT.

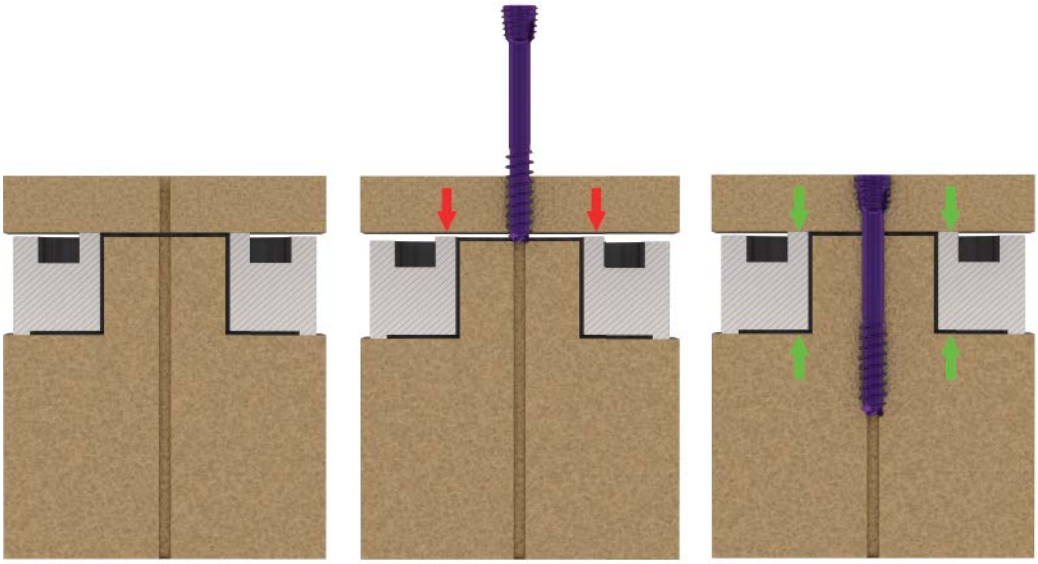

Figure 2 Midline fracture setup with no initial fracture gap (left), screw cutting into distal block and generating a gap (middle), and fully inserted screw (right). Load cell shown in silver.

Screw insertion was performed using methods based on ASTM F543-17 Annex A2[8] with a fixture allowing for translation between the proximal and distal blocks. The proximal block fixture translated along smooth steel rods using plastic bushings, and the distal block was fixed to the test frame carriage. Screw advancement (displacement/insertion depth) and interfragmentary compression were recorded. Representative test setup photographs can be found in Figure 3. Screws were inserted to 30mm depth, resulting in the proximal end flush to the proximal foam surface (full depth).

Procedure A: Countersink Only

To match Acumed's required technique,[2,4,5] the proximal blocks in Procedure A were prepared with a countersink. Specimens were assessed in a pass/fail manner for up to n=3 of each of the CCHS (Short and Long Thread) and Acutrak 2 screws. The Arthrex screw was not included in this procedure because its technique requires the use of both a long drill (full depth drilling) and a countersink.[3]

A specimen was deemed to pass if it could insert and generate interfragmentary compression. A specimen failed if it could not tap into the foam or generate interfragmentary compression at full depth. If a specimen failed to insert, no additional specimens of that screw type were tested, and the study shifted to Procedure B.

Procedure B: Drill and Countersink

Test blocks were prepared with the appropriate drill bit and countersink for each screw type. Screws (n=10 of each type) were inserted to full depth, and interfragmentary compression (N) generated was used for statistical analysis.

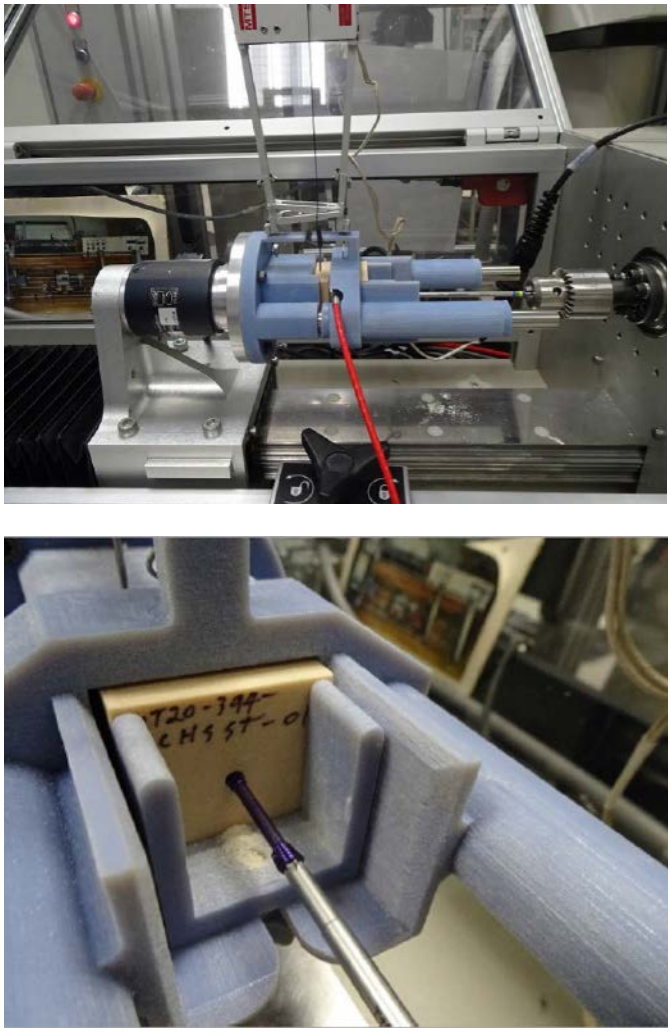

Figure 3 Representative test setup fixture (top); representative test setup screw pre-insertion (bottom).

Results

Procedure A: Countersink Only

Both CCHS screws (Short and Long Thread) successfully inserted and generated interfragmentary compression, while Acutrak 2 failed to generate interfragmentary compression,[11] shown in Table 2.

Table 2 Procedure A Test Results.

Screw†	Pass/Fail
DePuy Synthes Ø3.5 CCHS Short Thread	All 3 Screws Passed
DePuy Synthes Ø3.5 CCHS Long Thread	All 3 Screws Passed
Acumed Acutrak 2 Mini	Failed to Insert

†Arthrex Compression FT was not tested in Procedure A because its required technique includes drill and countersink.[3]

During insertion, the Acutrak 2 screw drove an interfragmentary gap between the proximal and distal foam blocks. Once it reached full depth, shown in Figure 4, the Acutrak 2 screw was unable to close that interfragmentary gap. Figure 5 shows the post-test result for the Acutrak 2 specimen tested in Procedure A. The post machined into the distal block is visible, and the load cell not in contact with the distal block. As a result, compressive load is not transferred between proximal and distal blocks.

Because the Acutrak 2 screw could not close the fracture gap it created, and did not complete its function of generating interfragmentary compression, this test run was deemed a failure, and the test advanced to Procedure B.

Figure 4 Post-test Acumed Acutrak 2 specimen fully inserted, the proximal end flush with the foam surface.

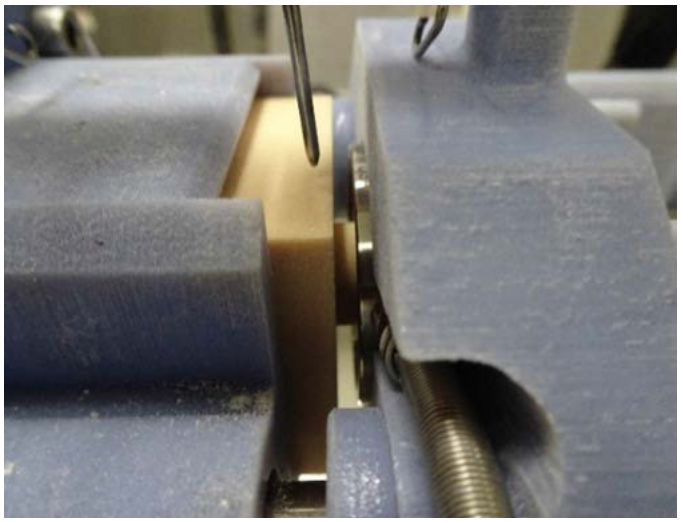

Figure 5 Post-test Acumed Acutrak 2 specimen with a gap between distal block (on left) and donut load cell (on right).

Procedure B: Drill and Countersink

Table 3 shows the mean compression generated at full depth for each screw,[11] shown graphically in Figure 6.

Table 3 Mean Compression Test Results

Screw (sample size n=10)	Compression (N) Mean±Std.Dev.
DePuy Synthes Ø3.5 CCHS Short Thread	262 ± 35.3
DePuy Synthes Ø3.5 CCHS Long Thread	296 ± 30.1
Acumed Acutrak 2 Mini	248 ± 14.8
Arthrex Compression FT Mini	128 ± 22.5

The partially threaded CCHS (Long and Short Thread) generated the highest observed mean compression, while the fully threaded Acutrak 2 and Arthrex Compression FT generated the lowest mean compression values.

A hypothesis test was performed for each comparison at a 90% confidence level to determine if the interfragmentary compression generated by the CCHS screw when flush with the bone surface (full depth) was non-inferior to that of the competitive devices with a non-inferiority margin (zone of indifference) of 5% (δ).[10]

$$H_O: \mu_{subject} \leq \mu_{predicate} - \delta$$
$$H_A: \mu_{subject} > \mu_{predicate} - \delta$$

If the non-inferiority test returned a significant result, a superiority test at a 90% confidence level was subsequently run.[10]

$$H_O: \mu_{subject} \leq \mu_{predicate}$$
$$H_A: \mu_{subject} > \mu_{predicate}$$

Table 4 Summarized Statistical Results.

Screw (sample size n=10)	Statistical Conclusion[11]
CCHS Short Thread vs Acutrak 2	Noninferior p=0.023
CCHS Short Thread vs Arthrex FT	Superior p<0.001
CCHS Long Thread vs Acutrak 2	Superior p<0.001
CCHS Long Thread vs Arthrex FT	Superior p<0.001

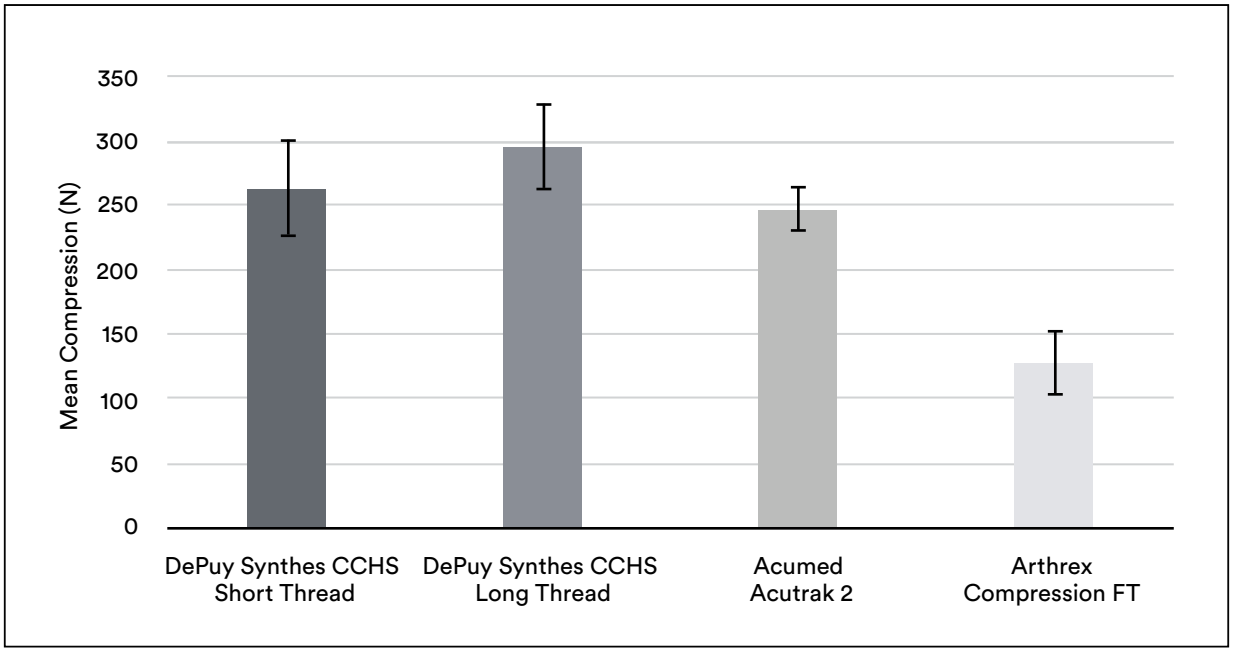

Figure 6 Compression Test Results (Mean±Standard Deviation) from Table 3.

Discussion

Procedure A: Countersink Only

Using Acumed's required countersinking technique for their Acutrak 2 screws and simulating the test conditions from their published study,[6] this study showed that the Acumed Acutrak 2 screw could not generate interfragmentary compression when the foam blocks were able to translate. On the contrary, the CCHS Short and Long Thread were able to successfully insert and generate compression.

As the screw cuts/taps into the distal block, its cutting tip may create a gap between the blocks. Once the thread has purchase in both blocks, the screw should be able to close that gap and generate interfragmentary compression. Headless compression screws generate compression based on the design of the screw, and its accompanying preparation technique. This study shows that in this test condition, the required technique for the Acutrak 2 screw is insufficient to generate compression when the screw is inserted flush to the foam surface.

Surgeons should be aware of any potential shortcomings of the implant they choose. While Acumed recommends the long drill for use in harder bone per their Technique Guide, bone quality may not be known prior to screw insertion. In the extremities, where there is little available bone, care should be taken to ensure that the screw will generate the intended compression.

Procedure B: Drill & Countersink

The results of this study indicate that the interfragmentary compression generated by the CCHS Short Thread is non-inferior to Acumed Acutrak 2 and superior to Arthrex Compression FT, and that the CCHS Long Thread is superior to both Acumed Acutrak 2 and Arthrex Compression FT.

The data presented herein demonstrate the mean compression generated by each of these screws at a particular fracture/osteotomy gap relative to the screw length.

Conclusion

In a non-predrilled condition, the Acumed Acutrak 2 screw failed to generate compression across the fracture.

In a predrilled condition, the DePuy Synthes CCHS Short Thread generates similar compression to the Acumed Acutrak 2 screw, and superior compression to the Arthrex Compression FT screw. Additionally, the CCHS Long Thread generates superior compression to both the Acumed Acutrak 2 and Arthrex Compression FT screws.

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‡Bench testing may not be indicative of clinical performance.

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