Mechanical Comparison of Headless Compression Screw Cutting Performance:

DePuy Synthes CCHS vs. Stryker® Fixos®/Fixos 2 & Acumed® Acutrak® 2

Gregory Maino – DePuy Synthes Trauma, West Chester, PA, USA

ABSTRACT

INTRODUCTION: Headless compression screws that are claimed as self-drilling/tapping can vary greatly in both their design and functionality. The tip design of any self-drilling/tapping screw is intended to reduce the need for the user to predrill before inserting the screw, achieved by reducing the axial force needed for the screw to self-tap. This study compared the cutting performance of the DePuy Synthes Cannulated Compression Headless Screws (CCHS) to Stryker Fixos/Fixos 2 screws and Acumed's Acutrak 2 Micro. Cutting performance is characterized as the axial load required for a screw to self-tap (linearly advancing at a rate equivalent to one pitch per revolution).* In this context, a screw with superior cutting performance is one that requires less axial force to insert.

MATERIALS AND METHODS: Axial load required for screws to self-tap into foam bone simulant over a guide wire was determined using methods based upon those described in ASTM F543 Annex A2 and Annex A4.

RESULTS: In all comparisons (Ø2.5, 4.0, 6.5, and 7.5 mm CCHS), it has been demonstrated with >99% observed confidence (p-value<0.01) that CCHS require less axial load to self-tap than the Fixos/Fixos 2 screws (Ø2.5, 4.0, 7.0 mm) and the Acutrak 2 Micro screw (Ø2.5 mm).

DISCUSSION: In the design of a self-drilling screw intended to function as a cutting tool, cutting efficiency and predictable chip evacuation are desirable traits. The DePuy Synthes CCHS implants have a positive rake angle at their cutting tip, while generic headless compression screws feature a neutral rake angle. The cutting tip differentiates the CCHS implants from generic headless compression screws and contributes to the superior cutting performance of the DePuy Synthes CCHS.

CONCLUSION: This study demonstrates that DePuy Synthes CCHS have superior cutting performance when compared to Stryker Fixos/Fixos 2 screws and Acumed Acutrak 2 Micro of comparable size when inserted into the same medium.

*This definition of self-tapping is maintained throughout this paper.

INTRODUCTION

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

Self-drilling/tapping[1-6] headless compression screws are designed so that they can be inserted without preparing the bone with a drill bit or tap. Tip designs between screws vary greatly, affecting a screw's cutting performance during insertion. A screw with a more efficient cutting tip will require less axial load to insert. Alternatively, a screw with poor cutting performance requires the surgeon to apply greater axial load during insertion and may require the surgeon to predrill.

This comparative study assessed the mechanical cutting performance of headless compression screws from DePuy Synthes, Stryker, and Acumed, which have similar indications.[1-6] Cutting performance for this study is characterized as the axial load required for the screw to self-tap (linearly advancing at a rate equivalent to one pitch per revolution). A screw with superior cutting performance requires less load to self-tap.

MATERIALS

Three headless compression screw systems were compared: DePuy Synthes CCHS, Stryker Fixos/Fixos 2, and Acumed Acutrak 2 Micro. Figure 1 shows representative screws from each system, and Table 1 shows the parts tested. For the purpose of this study, screw length did not play a role, as cutting tip and distal thread geometry dictate self-drilling and self-tapping.

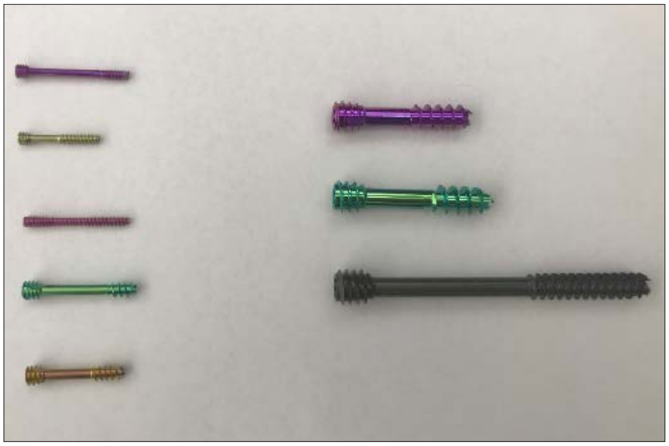

Figure 1: Representative screws tested, shown in order from Table 1, from top left to bottom right

Table 1: Headless compression screws tested

Group	Product†	Foam Density
1 (Ø2.5)	**DePuy Synthes Ø2.5 CCHS** REF: 04.333.128	40 pounds/ft^3 (pcf)
	Stryker Fixos Ø2.5 REF: SV20	
	Acumed Acutrak 2 Micro REF: AT2-C18S, AT2-C22S, AT2-C24S, AT2-C26S, AT2-C28S, AT2-C30S	
2 (Ø4.0)	**DePuy Synthes Ø4.0 CCHS** REF: 04.333.428	20 pcf
	Stryker Fixos Ø4.0 REF: MV24A and MV60A	
3 (Ø6.5–Ø7.5)	**DePuy Synthes Ø6.5 CCHS** REF: 04.333.735	20 pcf
	DePuy Synthes Ø7.5 CCHS REF: 04.333.840	
	Stryker Fixos 2 Ø7.0 REF: 658580	

†It was assumed that the sterile part for all competitive devices was mechanically equivalent to the non-sterile part.

METHODS

Screw insertion testing was performed using methods based upon ASTM F543 Annex A4 (for Groups 1 and 2) and A2 (modified for Group 3). Screws were inserted over the appropriate diameter guide wire per each screw's surgical technique.

Foam blocks (per ASTM F1839[8]) were prepared with a predrilled hole at the guide wire's nominal diameter to minimize wire deflection during insertion. Foam density used for each group is shown in Table 1, and insertion depth was constant within each group (11 mm for Groups 1 and 2, and 19 mm for Group 3).

Tests were performed independent of one another, and while test conditions within a group were consistent (i.e. all 2.5 screws ran under the same conditions), conditions across groups were not (e.g. foam density differed between 2.5 and 4.0 groups).

Prior to testing, distal threads of Stryker and Acumed screws were inspected for their pitch, and these values were recorded. Because all devices in scope are self-drilling/tapping,[1-6] all screws were inserted without the use of a predrill. Non–pre-drilled foam truly evaluates the screw's ability to self-drill and self-tap. Representative test images can be found in Figure 3.

For Groups 1 and 2, the axial load was increased at a rate of 2N/s by the electromechanical test frame until the screw reached a predefined depth. The displacement rate of each sample was analyzed to determine the axial load at which the screw began to advance at a rate equivalent to one thread pitch per revolution (self-tap).

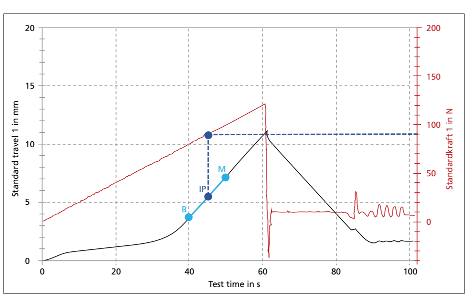

Figure 2: Example output data for Groups 1 and 2. Slope calculated between points B and M to find the inflection point (IP) at which the displacement equals the pitch rate. The corresponding load at that point is the load required for the screw to self-tap.

For Group 3, screws were inserted at discrete axial loads to a predefined depth. The displacement rate was analyzed to determine if a specimen successfully self-tapped. Consecutive specimens used a step-stair method based upon ASTM STP 731.[9] If a test specimen did not self-tap before the predefined depth, the axial load for the next specimen was increased by the step size. If the specimen self-tapped, the axial load for the next test specimen was lowered by the step size.

Loading was performed using discrete weights, and axial load for the purpose of analysis was reported in kilogram-force (kgf). The mean load reported was calculated as the median fatigue limit as described in ASTM STP 731.

Figure 3: Representative test setup per ASTM F543 A4 (top); representative test setup per ASTM F543 A2 (middle); Representative post-test specimen (bottom)

RESULTS

Results of the testing are listed in Table 2 and shown graphically in Figures 4 through 6.

Table 2: Test results

Group	Product (Sample Size)	Axial Load (Mean±Std. Dev.)[10]
Group 1	**Ø2.5 CCHS** (n=15)	29.4±5.62 N
	Ø2.5 Stryker Fixos (n=15)	49.5±2.54 N
	Acumed Acutrak 2 Micro (n=15)	77.3±4.52 N
Group 2	**Ø4.0 CCHS** (n=14)	13.7±1.11 N
	Ø4.0 Stryker Fixos (n=11)	16.7±1.17 N
Group 3	**Ø6.5 CCHS** (n=6; per ASTM STP 731)	38.1±2.56 N
	Ø7.5 CCHS (n=6; per ASTM STP 731)	39.9±2.56 N
	Ø7.0 Stryker Fixos 2 (n=6; per ASTM STP 731)	47.9±2.56 N

The null and alternative hypotheses were assessed for each comparison to determine if the axial load required for the CCHS to self-tap was less than that of the competitive devices.

$$H_0: \mu_{subject} \geq \mu_{predicate}$$

$$H_A: \mu_{subject} < \mu_{predicate}$$

The results of this testing demonstrate with statistical significance >99% (*p*-value<0.01)[10] for all comparisons per Table 1 that the DePuy Synthes Cannulated Compression Headless Screws require less axial load to advance at their distal thread pitch.

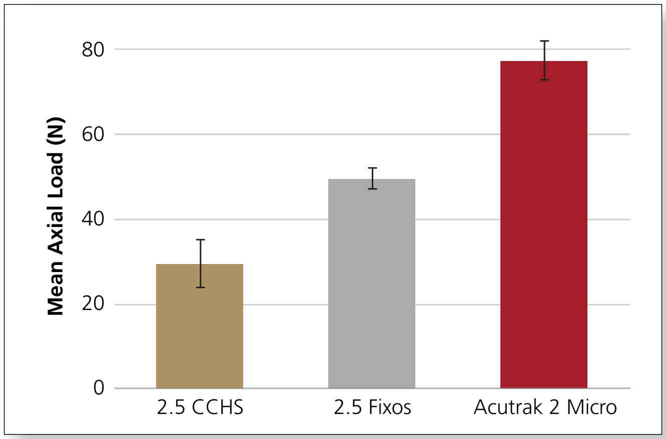

Figure 4: Group 1 – Ø2.5 mm CCHS vs Ø2.5 mm Stryker Fixos and Acumed Acutrak 2 Micro into 40 pcf foam

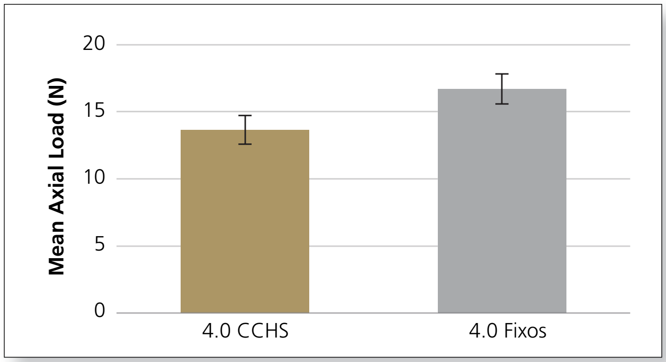

Figure 5: Group 2 – Ø4.0 mm CCHS vs Ø4.0 mm Stryker Fixos into 20 pcf foam

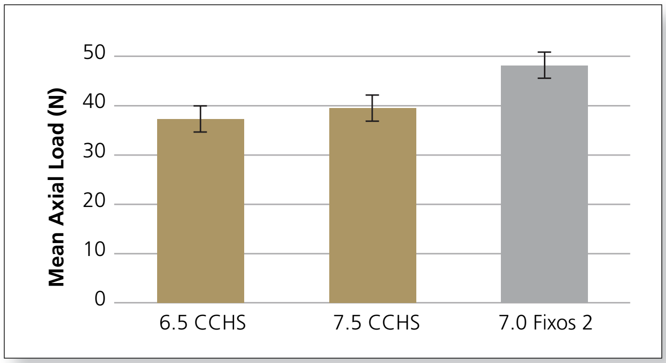

Figure 6: Group 3 – Ø6.5 mm CCHS and Ø7.5mm CCHS vs Ø7.0 mm Stryker Fixos 2 into 20 pcf foam. Because DePuy Synthes does not offer an exact diametric match, the neighboring diameters were both tested for comparison.

DISCUSSION

The tip of a self-drilling screw is intended to reduce the need for the user to predrill before inserting the screw by reducing the force required for the screw to self-tap. Cutting performance of the self-drilling feature plays a significant role in the ability for the screw to self-tap.

One feature that distinguishes the DePuy Synthes CCHS screw is that the cutting tip has a positive rake angle, while generic headless compression screws feature neutral rake angles, as shown in Figure 7.

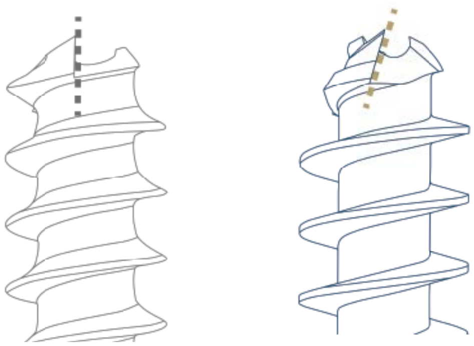

Figure 7: Generic cutting tip (left) with neutral rake angle vs CCHS cutting tip (right) with positive rake angle.

The improved cutting tip on the DePuy Synthes CCHS bites into the surface, and the positive rake angle, combined with the primary and secondary relief surfaces, allow for chip evacuation directed away from the hole. The critical features of the cutting tip are shown in Figure 8. In contrast, neutral rake angles, common in self-drilling bone screws, scrape along the surface until they bore a hole. Chip evacuation from a neutral rake angle cutting surface is unpredictable, allowing for chips to go both into and out of the hole being cut. The cutting tip on the DePuy Synthes CCHS differentiates the screw family from generic headless compression screws by providing superior cutting performace as the results of this comparative study suggest.

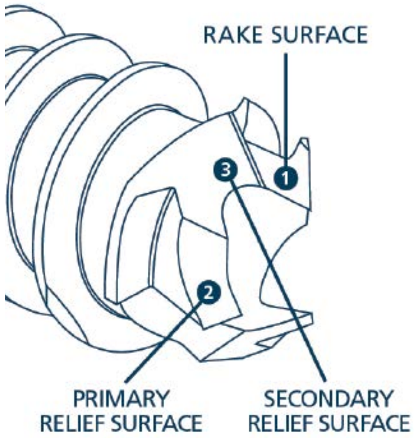

Figure 8: CCHS cutting tip design

Conclusion

The results of this testing demonstrate with statistical significance >99% (p-value<0.01‡) for all comparisons that the DePuy Synthes Cannulated Compression Headless Screws (CCHS) require less axial load to self-tap than Stryker Fixos/Fixos 2 and Acumed's Acutrak 2 Micro.[9]

DePuy Synthes Cannulated Compression Headless Screws, by the definition of self-tapping defined within this paper, have superior cutting performance when compared to the Stryker and Acumed headless screws.

While bench testing may not be indicative of clinical performance, these statistically significant findings are compelling and suggest superior performance in similar mechanical conditions. Therefore, a DePuy Synthes CCHS may require a surgeon to apply less force for the screws to self-tap into bone.

Cutting performance as described reduces screw insertion force and minimizes the need to predrill for CCHS as compared to competitive headless compression screws.[10-11]

‡Minitab reported p-value to three decimal places as p=0.000 for all comparisons. p-value is reported throughout this document as p<0.01.

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[§]Bench testing may not be indicative of clinical performance.