Mechanical Performance of the DePuy Synthes 2.7 mm VA LCP® Clavicle Plate System

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Introduction

The DePuy Synthes 2.7 mm Variable Angle (VA) LCP® Clavicle Plate System is designed to treat simple and complex fractures with low construct prominence.[1] This system features thinner plates with enhanced shapes that match the bow and the contour of the clavicle[1,2] for low construct prominence and enhanced plate-to-bone fit.* The 2.7 mm VA LCP Clavicle Plates are thinner[3] and accommodate smaller screws than established DePuy Synthes superior clavicle systems, therefore raising the question on their mechanical performance in comparison to those systems. In this paper, the mechanical performance of the 2.7 mm VA LCP Clavicle Plates is presented and discussed in comparison to the performance of the 3.5 mm LCP® Superior Clavicle Plates and the 3.5 mm LCP® Reconstruction Plates.

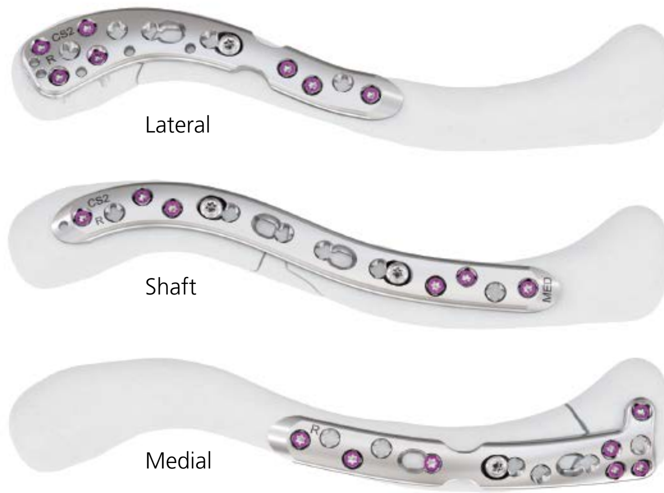

Figure 1 Different plate types of the 2.7 mm VA LCP Clavicle Plates System: Lateral, Shaft, and Medial plates.

DePuy Synthes 2.7 mm VA LCP Clavicle Plates

The 2.7 mm VA LCP Clavicle Plates are available in three different types: lateral, shaft, and medial (see Figure 1). Each plate type addresses fractures in the corresponding region of the clavicle, as described in detail within the surgical technique.[4] All screw holes in all plates accept 2.7 mm screws and the surgeon can determine the best combination of 2.7 mm cortex, 2.7 mm metaphyseal, and/or 2.7 mm VA locking screws needed for fixation. If a combination of VA locking, cortex (see Figure 1), or metaphyseal screws are used, it is recommended to insert cortex or metaphyseal screws first, next to the fracture. This pulls the plate to the bone to ensure that the plate sits flush on the clavicle. This reduction of the plate-to-bone fit is beneficial for the overall hardware prominence and the overall construct stability through better load sharing,[5] especially in configurations where a high implant load is expected.

The recommended construct configuration consists of at least one (cortex or metaphyseal) screw for plate-to-bone reduction and a total of four 2.7 mm screws placed bicortically per main fracture fragment (Figure 1). Please note that for fractures in the medial clavicle, monocortical screw placement in the most medial screw holes should be considered to prevent perforation of neurovascular structures or the sternoclavicular joint.

*Compared to Stryker VariAx 2 Clavicle System and Acumed Clavicle System.

The use of a smaller† screw size in the 2.7 mm VA LCP Clavicle Plates enables a staggered screw hole positioning in the plate shaft design (see Figure 1). The staggered screw hole positioning increases screw density compared to a plate of the same length with in-line screw holes.[6] Moreover, the staggered screw holes have predefined converging hole angulation (i.e., toward the middle of the bone), which is designed to increase resistance to pull-out.† According to Denard et al. 2011,[5] a staggered screw pattern provides better construct stability by creating a biplanar fixation. These authors studied the strength of planar (i.e., in-line screw holes) and biplanar (i.e., staggered screw holes) fixation in diaphyseal fractures with unicortical and bicortical screws. In non-osteoporotic bone, biplanar fixation was shown to be 42% stronger when bicortical screws were used. These results further support the recommended construct configuration with bicortical screw fixation.

Mechanical Performance[8]

The mechanical performance of plate and screw constructs was extensively assessed during the development of the 2.7 mm VA LCP Clavicle Plate System, and relevant results are presented in this section for comparison with established DePuy Synthes systems.

†Compared to the established larger 3.5 mm LCP® Superior Clavicle Plates System.

Plate Constructs

The selected systems that were compared to the 2.7 mm VA LCP Clavicle Plate System were the 3.5 mm LCP Superior Clavicle Plates (i.e., plates without extension) and the 3.5 mm LCP Reconstruction Plates. One plate construct was defined for each system and was tested in both materials offered: stainless steel 316L (SSt) and titanium (TiCp or TAN depending on the system). The selected plate and screw constructs are shown in Figure 2 for the stainless steel material option. The same construct configurations were used for the titanium material option.

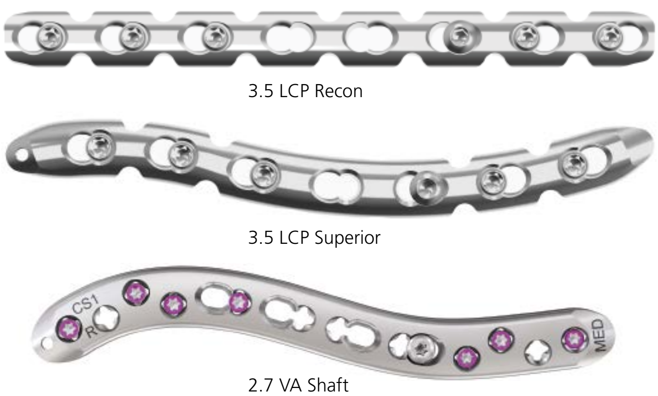

Figure 2 Plate and screw construct configurations used for mechanical testing. Stainless steel material option shown. The lateral end of the plates is shown on the left side of the picture.

These construct configurations were selected to follow the recommended screw configuration of the VA LCP Clavicle Plates as previously described, as well as the recommendation in the AO Manual for Fracture Management,[7] which states to insert at least three screws per main fragment for the 3.5 mm LCP Plate Systems. Note that only one cortex screw was used in the screw configuration for the 2.7 VA Shaft to represent the least amount of cortex screws. The same configuration was used for the comparison plates. Therefore, the three tested construct configurations were (see Figure 2):

- **3.5 LCP Recon:** a 3.5 mm LCP Reconstruction Plate, 8 holes fixated with 3 x 3.5 mm Locking Screws on the lateral side, and with 1 x 3.5 mm Cortex Screw and 2 x 3.5 mm Locking Screws on the medial side.
- **3.5 LCP Superior:** a 3.5 mm LCP Superior Clavicle Plate, 7 holes fixated with 3 x 3.5 mm Locking Screws on the lateral side, and with 1 x 3.5 mm Cortex Screw and 2 x 3.5 mm Locking Screws on the medial side.
- **2.7 VA Shaft:** a 2.7 mm VA LCP Clavicle Plate Shaft CS1 fixated with 4 x 2.7 mm VA Locking Screws on the lateral side, and with 1 x 2.7 mm Cortex Screw and 3 x 2.7 mm VA Locking Screws on the medial side.

Mechanical Test Method

Plate and screw constructs were tested with static load-to-failure tests and cyclic tests to quantify the construct strength (i.e., the maximal force reached) and the construct fatigue strength (i.e., the maximal force withstanding 1,000,000 cycles). These mechanical tests were carried out at the DePuy Synthes Test Lab in Oberdorf (BL, Switzerland). Static load-to-failure tests were performed following a monotonic loading on Zwick Z/100 Universal testing machines (see Figure 3). Cyclic fatigue tests were performed on Walter & Bai Servo hydraulic testing machines.

Plates were assembled with the defined screw configuration on dedicated fixtures with a mating surface to the corresponding plate made of DuraForm®-HST Composite material. These fixtures were designed with a 20 mm gap between the lateral and medial blocks to simulate the worst-case scenario of a large fracture gap (e.g., for comminuted fractures) where the plate bridges the fracture with no load-sharing with the bone. The plate position and orientation on these fixtures were defined through specific lever arms (i.e., defined distances between screws, the plate, and the blocks) such that an equivalent loading condition for all tested plates was achieved. The gap location was defined according to the scope of the plates as described in the corresponding surgical techniques.[4]

Figure 3 Exemplary test setup for the 3.5 LCP Superior Plate (SSt).

AO Foundation is a third-party medically guided, not-for-profit organization led by an international group of surgeons specialized in the treatment of trauma and disorders of the musculoskeletal system.

For each construct, six specimens were tested in load-to-failure and 15 specimens in cyclic conditions. The construct fatigue strength was calculated according to ISO 12107:2012(E) for 1,000,000 cycles. Mean and standard deviation values of construct strength and construct fatigue strength were computed for each construct test. The statistical analysis was performed in Minitab Statistical Software (Minitab 18; Minitab Inc., State College, PA, USA), where constructs were compared with a two-sample t-test with 90% confidence and a significance level of 0.1.

Mechanical Test Results[8]

The strength of the 3.5 LCP Recon constructs, the 3.5 LCP Superior constructs, and the 2.7 VA Shaft constructs are summarized in Figures 4a and 4b. For stainless steel, the 2.7 VA Shaft constructs (318.0 N±5.3 N) showed statistically significant superior strength compared to the 3.5 LCP Superior constructs (305.7 N±3.4 N, *P*-value=0.001) and the 3.5 LCP Recon constructs (104.3 N±2.5 N, *P*-value<0.001).

For titanium, the 2.7 VA Shaft constructs (290.8 N±2.7 N) showed statistically significant superior strength compared to the 3.5 LCP Superior constructs, (278.5 N±9.2 N, *P*-value=0.013) and the 3.5 LCP Recon constructs (180.8 N±2.0 N, *P*-value<0.001).

The fatigue strength of the 3.5 LCP Recon constructs, the 3.5 LCP Superior constructs, and the 2.7 VA Shaft constructs are summarized in Figures 5a and 5b. For stainless steel, the 2.7 VA Shaft constructs (167.4 N±14.7 N) showed statistically significant superior fatigue strength compared to the 3.5 LCP Superior constructs (140.5 N±8.2 N, *P*-value<0.001) and the 3.5 LCP Recon constructs (85.0 N±2.7 N, *P*-value<0.001). For titanium, the 2.7 VA Shaft constructs (176.6 N±8.2 N) showed statistically significant superior fatigue strength compared to the 3.5 LCP Superior constructs (129.5 N±5.9 N, *P*-value<0.001) and the 3.5 LCP Recon constructs (117.2 N±3.3 N, *P*-value<0.001).

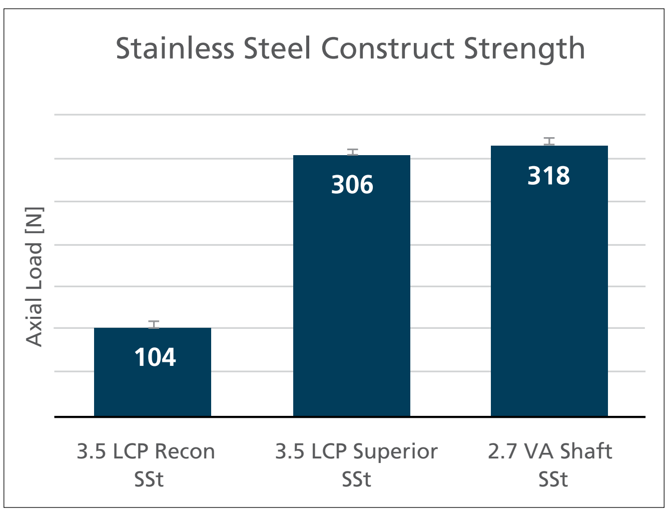

Figure 4a Construct strength results for static load-to-failure tests.

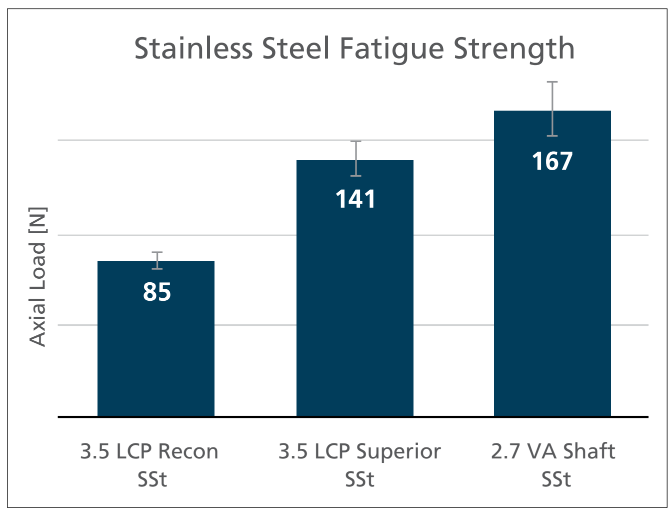

Figure 5a Construct fatigue strength results for cyclic tests (at 1,000,000 cycles).

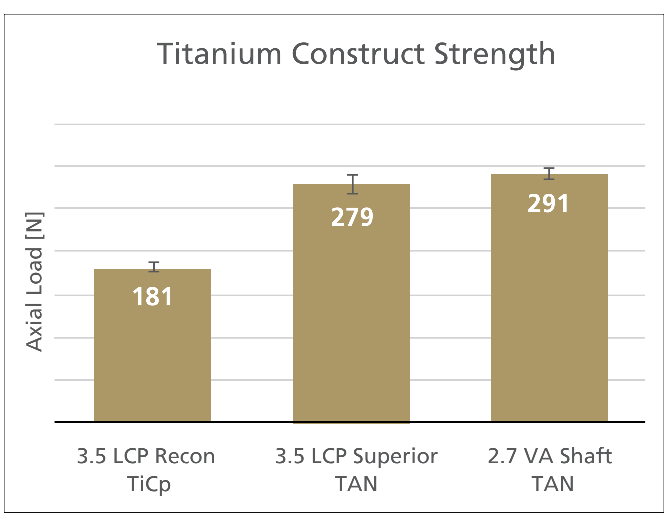

Figure 4b Construct strength results for static load-to-failure tests.

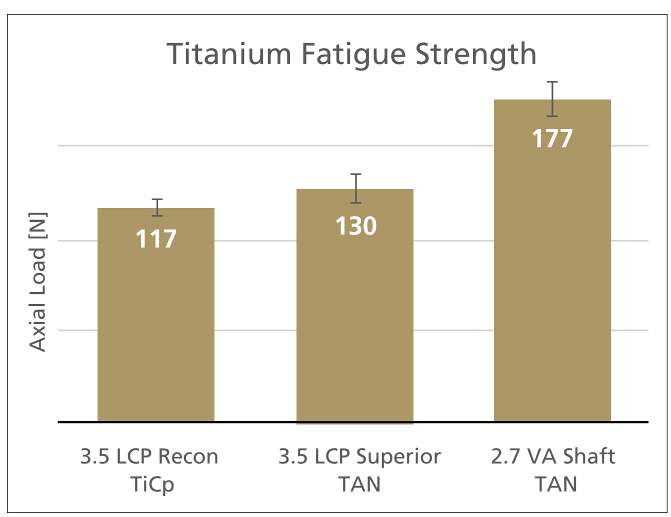

Figure 5b Construct fatigue strength results for cyclic tests (at 1,000,000 cycles).

Mechanical Test Conclusion

The presented mechanical performance tests demonstrated that the 2.7 VA Shaft Plates constructs are stronger than the 3.5 LCP Recon Plate constructs and the 3.5 LCP Superior Plate constructs, for both materials (stainless steel and titanium). The relative considerably lower strength seen for the 3.5 LCP Recon Plate constructs is a result of the 3.5 LCP Recon Plate being manufactured from a different raw material that is malleable and contourable. For stainless steel, the 3.5 LCP Recon Plates are manufactured from annealed raw material, whereas the 3.5 LCP Superior Plates and the 2.7 VA Shaft Plates are manufactured from cold-worked raw material. For titanium, the 3.5 LCP Recon Plates are manufactured from commercially pure titanium (TiCp), whereas the 3.5 LCP Superior Plates and the 2.7 VA Shaft plates are manufactured from titanium alloy (TAN).

Additional mechanical tests were performed with the 2.7 mm VA LCP Clavicle Plates, both lateral and medial, using the same test method.[8] All results were compared to the same established DePuy Synthes plates: the 3.5 LCP Superior Clavicle Plates and the 3.5 mm LCP Recon Plates (see Figure 2). Lateral plate constructs showed higher construct static strength and higher construct fatigue strength compared to the 3.5 mm LCP Recon Plates. Compared to the 3.5 mm LCP Superior Clavicle Plates, the lateral plate constructs showed higher construct static strength and equivalent construct fatigue strength. Medial plate constructs showed higher construct static strength and higher construct fatigue strength compared to both established 3.5 mm DePuy Synthes plates. Therefore, the following can be concluded on the mechanical performance of the system:

- The 2.7 mm VA LCP Clavicle Plates have higher construct static strength than the 3.5 mm LCP Superior Clavicle Plates.[1,8]
- The 2.7 mm VA LCP Clavicle Plates have equivalent construct fatigue strength compared to the 3.5 mm LCP Superior Clavicle Plates.[1,8]
- The 2.7 mm VA LCP Clavicle Plates are stronger than the DePuy Synthes 3.5 mm LCP Recon Plates.[9]

Summary and Conclusion

The 2.7 mm VA LCP Clavicle Plate System is reimagined to reduce prominence with thinner and lower profile plates‡ and smaller 2.7 mm screws, while delivering comparable strength to the 3.5 mm LCP Superior Clavicle Plates and higher strength than the 3.5 mm LCP Reconstruction Plates.[8] These plates also include VA combi holes to pull the plate to the bone, next to the fracture, for better load sharing between the plate, screws, and the bone, as well as providing staggered VA screw holes with predefined hole angulation to increase pull-out resistance.[6] The performed mechanical tests showed that the 2.7 mm VA LCP Clavicle Plates have higher construct static strength and equivalent construct fatigue strength compared to the DePuy Synthes 3.5 mm LCP Superior Clavicle Plates when tested, based on the recommended screw configuration for each system.

‡Compared to Stryker VariAx 2 Clavicle System, Acumed Clavicle System, and DePuy Synthes 3.5 LCP® Clavicle System.

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