

# DePuy Synthes 2.7 mm VA LCP® Clavicle Plate System Reengineered to Reduce Prominence

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## Abstract

### Background

Clavicle fractures are common in adult and adolescent patients, and displaced fractures are typically treated using an open reduction internal fixation (ORIF) approach. In several cases, though, surgeons are called upon to perform a hardware removal procedure, since poorly fitting plates may lead to discomfort, tissue irritation and other complications. The DePuy Synthes 2.7 mm Variable Angle (VA) LCP® Clavicle Plate System was therefore designed to treat simple and complex fractures with low implant prominence.<sup>1</sup>

### Methods and Results

The plates were compared to plates of existing clavicle systems (Stryker VariAx 2 Clavicle System and Acumed Clavicle Plating System) in two steps. All plates were digitally fitted on a broad population of clavicle bones from the DePuy Synthes Human Bone Database, which contains more than 600 clavicles of different patient ages, gender, and ethnicities, using the proprietary software *Trauma Development Tool 2.0* (Synthes Innomedic GmbH, Germany). In the second step, the resulting bone-plate models were analyzed by a

proprietary algorithm<sup>2</sup> that measured the overall plate prominence, i.e., the plate-to-bone conformity.

### Results and Conclusion

The results of the study revealed that the DePuy Synthes 2.7 mm VA LCP Clavicle Plate System demonstrates a lower prominence and a greater plate-to-bone conformity compared to the Stryker VariAx® 2 Clavicle Locking Plate System and Acumed Locking Clavicle Plating System. The 2.7 mm VA LCP Clavicle Lateral Plates show at least 7.6% lower prominence when compared to the Acumed Superior Distal Clavicle Plate, and the 2.7 mm VA LCP Clavicle Shaft Plates show at least 14.5% lower prominence when compared to the Acumed Superior Midshaft Locking Clavicle Plates. When analyzed against Stryker Superior Midshaft and Lateral Plates, the 2.7 mm VA LCP Clavicle Lateral Plates are at least 16.6% less prominent than the Stryker Superior Lateral Plates, and the 2.7 mm VA LCP Clavicle Shaft Plates are at least 19.8% less prominent than the Stryker Superior Midshaft Plates.<sup>1</sup>

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## Introduction and Objective

Clavicle fractures are considered common, accounting for nearly 5% of all fractures in adults and adolescents (male patients under 30 and over 70 years of age making up the majority of those who sustain clavicle fractures) and may reach 15% of all fractures in children.<sup>3-5</sup>

Orthopedic referral is indicated for fracture displacement, comminution, and shortening.<sup>6-8</sup> In those cases where operative treatment is considered, plate fixation is chosen most frequently compared to other forms of ORIF, since it provides immediate, rigid stabilization.<sup>9</sup> Recently, it has become evident that one of the most common complications, when treating clavicle fractures operatively, is the need for hardware removal due to irritation caused

by prominent implants.<sup>9</sup> A US administrative claims database analysis from 2012-2016 found that among patients treated operatively for clavicle fracture, 83% had a reoperation.<sup>10</sup>

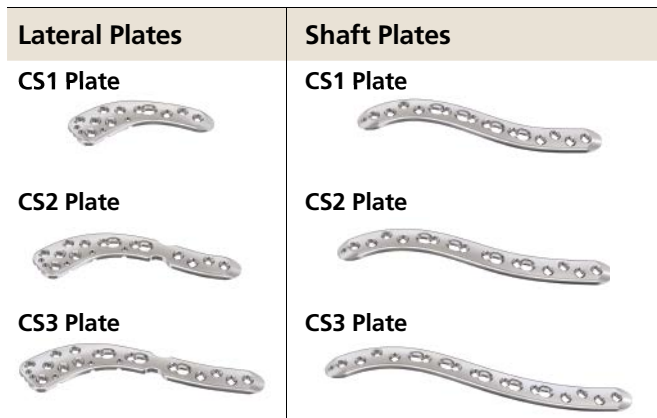
The need for low profile, well-fitting plates becomes even more imperative for the midshaft region of the clavicle, where only a thin layer of soft tissue covers the bone and patients can easily palpate the implant. This implant prominence contributes significantly to overall patient discomfort and dissatisfaction.<sup>11</sup> The DePuy Synthes 2.7 mm VA LCP Clavicle Plate System is designed to treat simple and complex fractures including malunions and nonunions by providing low profile plates that are engineered to reduce prominence through enhanced plate-to-bone fit.<sup>1</sup>

## Materials and Methods

In order to compare the 2.7 mm VA LCP Clavicle Plates against selected comparator plates, all plates in scope were fitted on a broad clavicle bone population using the proprietary software *Trauma Development Tool* (TDT 2.0, Synthes Innomedic GmbH, Germany). The resulting plate-bone models were analyzed with a proprietary algorithm in MATLAB (R2015b; MathWorks, Natick, MA, USA) that measured the overall plate prominence, representing the volume a plate adds to a bone, including the space between the underside of the plate and the top surface of the bone.<sup>2</sup>

### Plate selection

The DePuy Synthes (DPS) 2.7 mm VA LCP Clavicle Plate System includes Lateral and Shaft Plates that are available in 3 sizes corresponding to clavicle size (CS); CS1, designed for small bone populations; CS2, designed for medium bone populations; and CS3, designed for large bone populations (see Figure 1). For each plate shape of the 2.7 mm VA LCP Clavicle Plate System, a comparator plate of equivalent length and fracture scope (i.e., treatment of fracture, having sufficient screws for fixation) was defined, following the corresponding surgical technique guides of their manufacturer. The plates were selected from the Stryker VariAx 2 Clavicle Locking Plate System and the Acumed Clavicle Locking Plating System.



**Figure 1** Available DePuy Synthes 2.7 mm VA LCP Clavicle Lateral and Shaft Plates in their different sizes.

### Bone Population

Three bone populations were generated from the database of digital clavicles available in the DePuy Synthes Human Bone Database. These population groups were defined according to the axial bone length (L): Small Population L<133 mm, Medium Population L 134 mm–155 mm, and Large Population L>156 mm. These three population groups consisted of 124 bones. To fairly compare the plates to one another, the bones used in these three population groups were randomly selected from the bone database after excluding the 350 bones used to initially develop the plate shape.<sup>14</sup> The small, medium, and large bone populations were generated so that a dedicated population was available to assess fit and prominence for each plate size available in the 2.7 mm VA LCP Clavicle System. From all the analyzed bones, approximately 3% were identified as anatomical outliers and were excluded from the analyzed results.<sup>12-13</sup>

Notes: The three-dimensional (3D) models of the comparator products were generated using point clouds from 3D scans of the marketed implants. For this direct product comparison, screws were not included to limit the result variability due to the different fixation options that each manufacturer provides. Furthermore, the screw holes were suppressed in the 3D models to facilitate the fitting algorithm (see Figure 2), since the hole geometry does not impact the prominence calculation. Long plates were acquired and digitized from Stryker (item number 628207) and Acumed (item number 70-0112). Shorter Stryker plates (item numbers 628203, 628204, and 628205) and shorter Acumed plates (item number 70-0117) were generated using the 3D models of the longer plate with the corresponding shape and subtracting the required plate segment, to achieve the correct plate length and shape.



**Figure 2** Examples of 3D models with suppressed holes (Lateral Plates are shown).

## Results

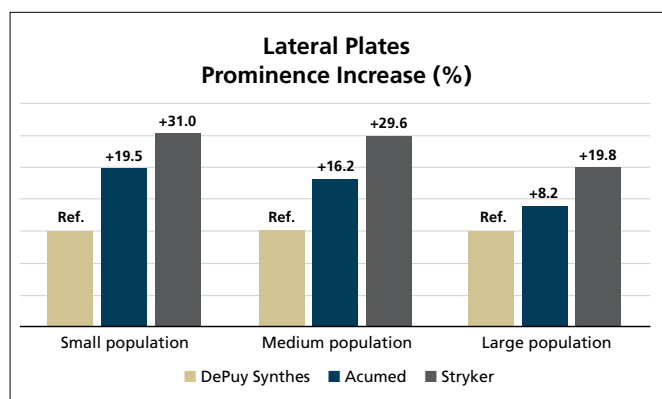
### Lateral Plates

The following table (see Table 1) lists the resulting prominence values for the Lateral Plates in prominence increase (percentage) with respect to the 2.7 mm VA LCP Clavicle Plate, Lateral. The results are grouped per target bone population and if a plate has not been fitted for a specific population, "N/A" is noted.

| Plate   | Plate Prominence Increase Relative to the DePuy Synthes Plates |                   |                  |
|---|--|-------------------|------------------|
|   | Small Population   | Medium Population | Large Population |
| DePuy Synthes, 2.7 mm VA LCP Clavicle Plate, Lateral, CS1, Left               | Ref.   | N/A               | N/A              |
| DePuy Synthes, 2.7 mm VA LCP Clavicle Plate, Lateral, CS2, Left               | N/A  | Ref.              | N/A              |
| DePuy Synthes, 2.7 mm VA LCP Clavicle Plate, Lateral, CS3, Left               | N/A  | N/A               | Ref.             |
| Acumed, Superior Distal Clavicle Locking Plate, 3.5 mm, 9-Hole, Left, 68 mm   | +19.5%   | N/A               | N/A              |
| Acumed, Superior Distal Clavicle Locking Plate, 3.5 mm, 12-Hole, Left, 101 mm | N/A  | +16.2%            | +8.2%            |
| Stryker, Superior Lateral Plate, 3-Hole, Left, 74 mm                          | +31.0%   | N/A               | N/A              |
| Stryker, Superior Lateral Plate, 4-Hole, Left, 86 mm                          | N/A  | +29.6%            | N/A              |
| Stryker, Superior Lateral Plate, 5-Hole, Left, 98 mm                          | N/A  | N/A               | +19.8%           |

**Table 1** Calculated plate prominence for small, medium, and large bone populations with the plates intended to treat lateral clavicle fractures.<sup>1</sup> Reference plate for increase values.

The analysis showed that all 2.7 mm VA LCP Clavicle Plates, Lateral have a statistically significantly lower prominence [ $P$ -value<0.007 for the Mann-Whitney test in Minitab® 18 (Version 18.1, Minitab Inc.)] when directly compared to each of the selected comparator plates.<sup>12</sup> The chart below (Figure 3) quantifies the increase in the prominence values of the comparator plates when both are compared to the 2.7 mm VA LCP Clavicle Plates, Lateral.



**Figure 3** Difference of the plate prominence expressed in percentage, using the DePuy Synthes (DPS) 2.7 mm VA LCP Clavicle Plate, Shaft, as reference.

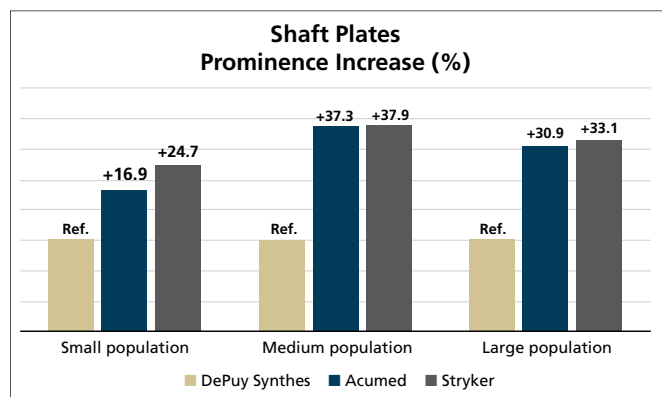
### Shaft Plates

As with the Lateral Plates, the same analysis was conducted with the plates that are intended to treat midshaft fractures of the clavicle. The lowest prominence value resulting from the computed options of each comparator are used for comparison with the 2.7 mm VA LCP Clavicle Plate, Shaft (underlined in Table 2 below).

| Plate  | Plate Prominence Increase Relative to the DePuy Synthes Plates |                   |                  |
|--|--|-------------------|------------------|
|  | Small Population   | Medium Population | Large Population |
| DePuy Synthes, 2.7 mm VA LCP Clavicle Plate, Shaft, CS1, Left                                | Ref.   | N/A               | N/A              |
| DePuy Synthes, 2.7 mm VA LCP Clavicle Plate, Shaft, CS2, Left                                | N/A  | Ref.              | N/A              |
| DePuy Synthes, 2.7 mm VA LCP Clavicle Plate, Shaft, CS3, Left                                | N/A  | N/A               | Ref.             |
| Stryker, Superior Midshaft, Decreased Curvature, Standard Plate, 8-Hole, Left, 99 mm         | +29.3%   | N/A               | N/A              |
| Stryker, Superior Midshaft, Decreased Curvature, Bridge Plate, 6-Hole, Left, 99 mm           | <u>+24.7%</u>  | N/A               | N/A              |
| Stryker, Superior Midshaft, Increased Curvature, Standard Plate, 8-Hole, Left, 97 mm         | +32.4%   | N/A               | N/A              |
| Stryker, Superior Midshaft, Decreased Curvature, Standard Plate, 10-Hole, Left, 120 mm       | N/A  | +40.6%            | +33.9%           |
| Stryker, Superior Midshaft, Decreased Curvature, Bridge Plate, 8-Hole, Left, 122 mm          | N/A  | <u>+37.9%</u>     | <u>+33.1%</u>    |
| Stryker, Superior Midshaft, Increased Curvature, Standard Plate, 10-Hole, Left, 120 mm       | N/A  | +40.8%            | +33.9%           |
| Acumed, Superior Midshaft Clavicle Locking Plate, Narrow-Profile, 8-Hole, Large, Left, 96 mm | <u>+16.9%</u>  | N/A               | N/A              |
| Acumed, Superior Midshaft Clavicle Locking Plate, Low-Profile, 8-Hole, Medium, Left, 94 mm   | +31.8%   | N/A               | N/A              |
| Acumed, Superior Midshaft Clavicle Locking Plate, Low-Profile, 10-Hole, Left, 121 mm         | N/A  | <u>+37.3%</u>     | <u>+30.9%</u>    |

**Table 2** Calculated plate prominence for small, medium, and large bone populations with the plates intended to treat midshaft clavicle fractures.<sup>1</sup> Percentage values reflect comparison to DePuy Synthes reference (Ref.) plate in table above.

The analysis showed that all 2.7 mm VA LCP Clavicle Plates, Shaft have statistically significantly lower prominence [ $P$ -value<0.001, for the Mann-Whitney test in Minitab® 18 (Version 18.1, Minitab Inc.)] compared directly to each of the selected comparator plates.<sup>13</sup> The chart below (Figure 4), quantifies the increase in the prominence values of comparator plates when both are compared to the 2.7 mm VA LCP Clavicle Plates, Shaft.



**Figure 4** Difference of the prominence expressed in percentage, using the DePuy Synthes (DPS) 2.7 mm VA LCP Clavicle Plate, Shaft, as reference.

## Discussion

The DePuy Synthes 2.7 mm VA LCP Clavicle Plate System incorporates multiple plate designs. In addition to the 2.7 mm VA LCP Clavicle Plate, Lateral, and the 2.7 mm VA LCP Clavicle Plate, Shaft, a Shaft Extra Long (XL) design is available for extended fracture patterns in large clavicles. The design of the Shaft XL plate (see Figure 5) is based on the plate shape of the Shaft CS3 plate, which was developed for large clavicles. The only difference is that the Shaft XL plate extends medially to a length of 144 mm, whereas the Shaft CS3 plate is 124 mm long. All required shape parameters are the same for the Shaft and Shaft XL plates, following equivalent shape and fit enhancements. A Medial plate (see Figure 5) is also available in the 2.7 mm VA LCP Clavicle Plate System to address fractures of the medial end of the clavicle. Since Stryker and Acumed do not feature such a dedicated product, a direct prominence comparison was not possible.



**Figure 5** VA LCP Clavicle Shaft Plate Extra Long (XL) [left image] and VA LCP Clavicle Medial Plate (available in one size only) [right image].

## Conclusion

The Shaft and Lateral Plates of the DePuy Synthes 2.7 mm VA LCP Clavicle Plate System were shown to have statistically significant lower overall plate prominence in relation to the direct comparator plates for the corresponding clavicle bone population groups. In summary, the 2.7 mm VA LCP Clavicle Lateral Plates have at least 7.6% lower prominence when compared to Acumed Superior Distal Clavicle Plate and 16.6% lower prominence compared to Stryker Superior Lateral Plate. The 2.7 mm VA LCP Clavicle Shaft Plates have at least 14.5% lower prominence when compared to Acumed Superior Midshaft Clavicle Locking Plates and 19.8% lower prominence when compared to Stryker Superior Midshaft Plates (Increased and Decreased Curvatures).

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