Are Commercially-available Precontoured Anatomical Clavicle Plating Systems Offering the Purported Superior Optimum Fitting to the Clavicle? A Cadaveric Analysis and Review of Literature

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Abstract: PURPOSE The indication for operative treatment of displaced midshaft clavicle fractures remains controversial. However, if plate fixation is considered, implant prominence and skin irritation are the most common causes for re-operation. Low profile implants as well as closely contouring plates to the individual anatomy may reduce these complications. The aim of this study was to compare the fitting accuracy and implant prominence of 3.5mm pelvic reconstruction plates (PRP) with pre-contoured anatomical clavicle plates (PACP) for midshaft clavicle fractures. METHODS Three-dimensional data of the largest, median and smallest male and female clavicle of an existing database of 89 cadaveric clavicles were included for analysis. A three-dimensional model of a commercially available PACP was used for digitally positioning of the plate on the segmented clavicles. Three-dimensional printouts of each clavicle were produced and the 3.5mm reconstruction plates were manually bent and positioned by the senior author. Computed tomography scans and three-dimensional reconstructions were then obtained to digitally compare the fitting accuracy and implant prominence. RESULTS Pelvic reconstruction plates offered superior fitting accuracy and lower implant prominence compared to PACP. The largest difference in implant prominence was observed in large sized female clavicles and measured 3.6mm. CONCLUSION Both, the less costly PRP plates and commercially available PACP for midshaft fractures of the clavicle demonstrated a clinically acceptable fitting accuracy. The manually bent pelvic-reconstruction plates demonstrated reduced implant prominence with superior fitting. Hypothetically this might contribute to a reduced rate of reoperation.

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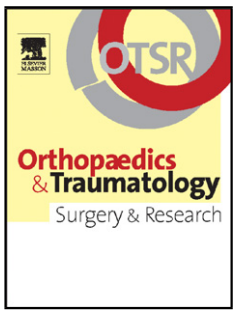

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Original article

Are Commercially-available Precontoured Anatomical Clavicle Plating Systems Offering the Purported Superior Optimum Fitting to the Clavicle? A Cadaveric Analysis and Review of Literature

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Abstract

Purpose: The indication for operative treatment of displaced midshaft clavicle fractures remains controversial. However, if plate fixation is considered, implant prominence and skin irritation are the most common causes for re-operation. Low profile implants as well as closely contouring plates to the individual anatomy may reduce these complications. The aim of this study was to compare the fitting accuracy and implant prominence of 3.5mm pelvic reconstruction plates (PRP) with pre-contoured anatomical clavicle plates (PACP) for midshaft clavicle fractures.

Methods: Three-dimensional data of the largest, median and smallest male and female clavicle of an existing database of 89 cadaveric clavicles were included for analysis. A three-dimensional model of a commercially available PACP was used for digitally positioning of the plate on the segmented clavicles. Three-dimensional printouts of each clavicle were produced and the 3.5mm reconstruction plates were manually bent and positioned by the senior author. Computed tomography scans and three-dimensional reconstructions were then obtained to digitally compare the fitting accuracy and implant prominence.

Results: Pelvic reconstruction plates offered superior fitting accuracy and lower implant prominence compared to PACP. The largest difference in implant prominence was observed in large sized female clavicles and measured 3.6 mm.

Conclusion: Both, the less costly PRP plates and commercially available PACP for midshaft fractures of the clavicle demonstrated a clinically acceptable fitting accuracy. The manually bent pelvic-reconstruction plates demonstrated reduced implant prominence with superior fitting. Hypothetically this might contribute to a reduced rate of reoperation.

Level of evidence: Level IV cadaveric study
Key words: clavicle, fracture, midshaft, reconstruction plate, three-dimensional

Introduction

Clavicle fractures are common, accounting for 3 to 5% of fractures in adults and 10% to 15% of fractures in children and show a bimodal distribution peaking in young male patients of less than 30 years and elderly patients of over 70 years. [1-3] Sixty-nine to 82% of those fractures occur in the middle third of the clavicle, primarily in young adults as a result of a direct force applied to the shoulder, typically during high energy trauma. [1, 3-5] Historically, both, displaced and non-displaced fractures of the middle third of the clavicle have rarely been treated with open reduction and internal fixation (ORIF). This non-operative treatment approach has historically been reasoned with a remarkably low non-union rate of non-displaced fractures of less than one percent [6-9], a higher non-union rate after ORIF [9, 6] and finally a high level of patient satisfaction after non-operative treatment. [7, 8] In contrast, more recently conducted prospective observations raised considerable doubt whether these results, mainly reported in the nineteen sixties to nineteen eighties of the past century are still applicable today. In a randomized multicenter trial comparing non-operative treatment with plate fixation, the Canadian Orthopedic Trauma Society reported a lower rate of non- and malunion, a shorter time until union, a significantly better functional outcome but high complication and reoperation rates of 18% and 38% in the operative group, respectively. [10] Shortening over 20 mm [11] may be considered as an indication for surgery, with smoking, comminution and overall displacement as independent risk factors for nonunion. [12] However, if operative treatment for midshaft fractures of the clavicle is considered, plate fixation provides immediate, rigid stabilization and is biomechanically favorable compared to intramedullary fixation with flexible devices. [13] Various models of pre-contoured anatomical plating (PACP) systems are currently offered by implant manufacturers purporting high fitting accuracy and low implant prominence without the need of further customization. These plating systems are costly, and require large amounts of stock to accommodate for anatomic variations of the clavicle. Nevertheless, frequently reported plate related complications include irritation as a result of a prominent implant. [14] These complications may be reduced using low profile pelvic reconstruction plates (PRP) contoured closely to the patient's individual anatomy. [15]

The aim of this cadaveric study was to compare the fitting accuracy and implant prominence of commercially available pre-contoured 3.5 mm anatomical plates (PACP) to manually bent 3.5 mm pelvic reconstruction plates (PRP) for management of midshaft fractures of the clavicle.

Materials & Methods

The data of six clavicles were obtained from an existing data set of full body computed tomographic (CT) scans of 89 cadavers provided by the Institute of Forensic Medicine, University of Zurich, Switzerland. For final analysis we included the three-dimensional data of the largest, the median and the smallest male and female clavicle defined by length, volume and surface. Inclusion criteria were CT scans including the entire clavicle of both sides and the absence of radiographic signs of trauma or other pathology. Data were acquired with a Siemens Emotion 6® and a Siemens Somatom Definition Flash® CT scanner, respectively. The in-plane (xy-) resolution of a CT scan ranged between 0.9 mm x 0.9 mm and 1.27 mm x 1.27 mm. The slice thickness varied from 0.5 mm to 0.6 mm. Segmentation of the CT data was performed in an automatic fashion using a previously described segmentation algorithm.

[16] Bilateral three-dimensional triangular surface models were generated for each clavicle using the marching cube algorithm. [17]
Three-dimensional data of the PACP with a profile height of three millimeters were provided by the plate manufacturer (*Arthrex Inc., Naples FL, USA*). All available plate shapes were positioned on the superior aspect of the clavicle using the CASPA planning software (*Balgrist Computer Assisted Research and Development AG, Zurich, Switzerland*) and the plate with the best fit defined as the highest fitting accuracy was compared to the pelvic-reconstruction plate.
For positioning of the 3.5 mm eight-hole PRP with a profile height of 2.7 mm (*Synthes Inc., Westchester PA, USA*) a three-dimensional printout of each clavicle was produced by laser sinter rapid prototyping. The plates were manually bent by the senior author until the subjective best fit was achieved. The time until subjective best fit was achieved was recorded. Computed tomography scans and three-dimensional reconstruction were then obtained as described above with the plates correctly positioned on the three-dimensional printouts. Best fit was defined as the smallest bone-plate distance after adequate positioning of the plate on the superior aspect of the clavicle. [13] Fitting accuracy was defined as the average plate to bone distance. Implant prominence was defined as the sum of the maximal plate to bone distance and the profile height of the implant. The distance between the bone and the implants was measured from bone- to implant surface using the polygons of the three-dimensional models.
Local ethics committee approval was obtained.

Statistical Analysis
Statistical analysis was performed using the SPSS software (*Statistical Package for the Social Sciences version 21.0, SPSS Inc., Chicago, IL, USA*). A two-tailed Kolmogorov–Smirnov test was used to evaluate the normality of distribution of continuous variables. Means of normally distributed variables were compared using Students T-test. Results were expressed as mean ± standard deviation (SD) or range as applicable. A p-value of <0.05 was considered to be statistically significant. The difference in fitting accuracy was calculated using points of measurement recorded from the three-dimensional planning tool.

Results
The average fitting accuracy of PRP and the PACP was 0.67 mm (*range: 0.05 to 2.90 mm*) and 1.1 mm (*range: 0.04 to 4.03 mm*), respectively. (Figure 1)
For the three male clavicles, the average fitting accuracy of the PACP for the smallest, median and largest clavicle were 0.99 mm, 1.08 mm, and 0.86 mm, and for the PRP 0.78 mm, 0.67 mm and 0.71 mm, respectively. For the three female clavicles, the average fitting accuracy of the PACP were 1.03 mm, 0.67 mm, and 1.24 mm, and for the PRP 0.59 mm, 0.61 mm, and 0.63 mm, respectively. (Figure 2) The difference in fitting accuracy between the PRP and PACP was significant for all plate sizes in male and female clavicles. (*Table 1*) (Table 2) The calculated implant prominence is illustrated in Table 3. The largest difference in implant prominence was observed in large sized female clavicles and measured +3.6 mm for the PACP compared to the PRP.
The average bending time for the reconstruction plates was six minutes (range: 1 - 12 minutes).
Discussion
Plate fixation is regarded as the procedure of choice for ORIF of open or severely displaced midshaft fractures of the clavicle.[18, 19] Established fixation techniques vary considerably

regarding plate positioning (superiorly, antero-inferiorly) and implant selection (i.e 3.5mm locking compression plates, PACP or PRP). However, the rate of implant related complications remains high.[10, 20, 21] Implant prominence and skin irritation are the most commonly reported complications following plate fixation and also represent the most common indications for reoperation.[14] While antero-inferior plate placement may reduce implant prominence and has the advantage of instrumentation away from infraclavicular neurovascular structures, placing the plate at the superior aspect provides significantly higher fracture rigidity and stiffness. A superiorly mounted construct withstands the force applied by the weight of the of the hanging arm working as a tension band and is, in contrast to antero-inferiorly placed constructs, not exposed to cantilever bending forces.[13, 22, 23] [24] Pelvic reconstruction plates are designed to be contoured easily and as such have a low bending stiffness and there are studies reporting a higher incidence of construct failure of reconstruction plates mounted antero-inferiorly in midshaft clavicle fractures.[25] As a consequence in our institution, if PRP are used we place them on the superior aspect of the clavicle and therefore did the same in this study.

However, given the variation in anatomy and morphology of the clavicle, achieving an appropriate plate shape to yield to a decent fit for the bone is challenging. There are several reports evaluating the clinical outcome of different plate models and plating techniques.[26-28] Straight non-contoured plates, PACP and low profile PRP, initially developed for fixation of pelvic fractures, provide rigid fixation and facilitate early rehabilitation as well as pain reduction for acute midshaft clavicle fractures.[13] While the feasibility of straight 3.5mm locking compression plates for midshaft fractures of the clavicle has been demonstrated [29] plate prominence and reoperation rate as a result of skin irritation is significantly higher compared to PACP and individually contoured PRP.[26, 15]

Pre-contoured anatomical plates based on statistic standard models of the clavicle have been developed to avoid the need for excessive contouring and reduce implant prominence. As a result of the intra- and inter-individual variation of the clavicle in length, diameter, cross section and degree of bowing, many commercially available plating systems require a wide variety of plate options to accommodate for anatomic variations.[30, 29, 31] Hence, considering costs of different plating systems, the 3.5 mm PRP do not only provide the advantage of a lower price compared to the PACP used in this study (187 USD vs. 390 USD) but also drastically reduce the amount of required stock. Further, even though anatomic plate systems are developed to accurately fit the shape of a wide variety of clavicles, in our experience in most cases contouring is still needed.[32] In this study the average bending time for an experienced surgeon for contouring the PRP was 6 minutes. The additional time required for bending of the plates has however to be set against the additional costs for the plate itself and the additional amount of required stock.

Whilst providing similar average fitting accuracy, in our study, the implant prominence of the PACP was larger compared to the manually-contoured PRP in particular on the lateral aspect of larger female clavicles. This finding is supported in current literature where worse fit of PACP was observed in this patient group.[28] As a result of the immediate subcutaneous location of the clavicle, even small differences in implant prominence of superiorly placed plates may contribute to plate related complications and therefore, higher reoperation rates.

This study compared the fitting accuracy and implant prominence of a superiorly placed, commercially available pre-contoured 3.5 mm midshaft clavicle plate with a manually bent low-profile 3.5 mm pelvic reconstruction plate.

The main limitation of this study is the lack of comparison to other currently available plating systems. Therefore, the here presented results may only be applicable to the described implants. Further, the thickness of the subcutaneous fat layer, another important factor influencing the need for revision surgery as a result of implant prominence was not subject of the current analysis.

In conclusion, low-profile PRP fitted closely to the patient's individual anatomy and may hypothetically reduce plate prominence and the risk of implant removal. The main advantages are the lower crude costs, simple handling of the stock and the universal applicability to a wide variety of anatomic variants. Commercially available PACP demonstrated a similar but slightly lower fitting accuracy and higher implant prominence for most clavicle sizes. Here, the main advantage of PACP is the theoretically shorter operation time, but at the price of higher implant cost and required amount of implants stocked.

Tables

Table 1: Fitting accuracy of male clavicles

Size	PRP *(mean, SD)*	PACP *(mean, SD)*	*p-value*
*Small**	0.78 ± 0.45	0.99 ± 0.58	<0.001
*Median**	0.67 ± 0.39	1.08 ± 0.64	<0.001
*Large**	0.71 ± 0.34	0.99 ± 0.55	<0.001

** millimeters; PRP: pelvic reconstruction plate; PACP: pre-contoured anatomical clavicle plate*

Table 2: Fitting accuracy of female clavicles

Size	PRP *(mean, SD)*	PACP *(mean, SD)*	*p-value*
*Small**	0.59 ± 0.29	1.03 ± 0.46	<0.001
*Median**	0.61 ± 0.24	0.67 ± 0.39	<0.001
*Large**	0.63 ± 0.30	1.24 ± 0.62	<0.001

** millimeters; PRP: pelvic reconstruction plate; PACP: pre-contoured anatomical clavicle plate*

Table 3: Implant prominence

SIze	Male			Female		
	PRP	PACP	Δ	PRP	PACP	Δ
*Small**	*5.39*	*6.70*	*1.31*	*5.07*	*5.65*	*0.58*
*Median**	*5.60*	*7.07*	*1.47*	*4.53*	*5.82*	*1.29*
*Large**	*4.90*	*6.18*	*1.28*	*4.60*	*8.20*	*3.6*

** millimeters; PRP: pelvic reconstruction plate; PACP: pre-contoured anatomical clavicle plate*

Conflict of Interest and Founding Source

David Ephraim Bauer, Hingsammer A, Schenk P, Vlachopoulos L, Fürnstahl P, Meyer DC have nothing to disclose. (generated with the ICMJE form for disclosure)

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Figure Legends

Fig. 1*: Fitting accuracy of A) 3.5 mm Recon-plate B) Pre-contoured plate; *Distance in millimeters*

Fig. 2*: Fitting accuracy, whiskers illustrate implant prominence*

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