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Original Article

Proximal humeral fractures treated with a low-profile plate with enhanced fixation properties

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ABSTRACT

Background: Our purpose was to evaluate the clinical and radiographic outcomes of proximal humeral fractures treated with a new generation plating system and compare results with a meta-analysis of recent literature.

Methods: Between 2014 and 2017, 93 patients (18 males, 75 females) with proximal humerus fractures were treated with open reduction and internal fixation (ORIF) using a Pantera® Plate. These low-profile plates are anatomically shaped and include "cross-elements" that form a three-dimensional scaffold in bone to enhance fixation stability. According to Neer classification, there were 24 two-part fractures, 49 three-part fractures and 20 four-part fractures (4 with dislocated heads). X-rays and Constant Shoulder Scores (CSS) were used to evaluate healing, complications, and clinical outcomes. Results were compared with a meta-analysis of similar studies reported in literature over the last 10 years.

Results: Eighty-three patients with a minimum follow-up of 2 years had a mean CSS of 72 (53–90) graded as excellent for 23 patients (28%), good for 35 (42%), fair for 14 (17%), and poor for 11 (13%). Fractures healed without complication in 75 (91%) patients. Eight (9%) complications were observed, i.e., three avascular necrosis of the humeral head, one case of implant loosening, two cases of subacromial impingement and two superficial infections. There was no significant correlation between Neer fracture stage and patient outcome ($p = 0.257$). Compared to the literature, this method had a lower complication grade ($p = 0.03$), though it did not significantly differ in its clinical outcomes ($p = 0.08$).

Conclusions: The investigated plating system includes design features that can potentially increase utility for ORIF of proximal humeral fractures. While the complication profile was signficantly less than reported in the literature for standard proximal humerus plates, clinical outcomes were similar. Further studies will be required to better understand the role of plate design on treatment of these challenging fractures.

Level of evidence: IV, therapeutic study.

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1. Introduction

Proximal humerus fractures account for about 5% of fractures and are the third most common fracture due to osteoporosis [1]. These fractures have a typical bimodal incidence, i.e., in young patients they are caused by high-energy trauma and are mostly broken down and multi-segmented (one-third of cases); in elderly patients they are caused by low-energy trauma (two-thirds of cases) [1,2]. An effective classification of this kind of injury is challenging [3] and the treatment of these fractures is still much debated [4]. It is largely accepted that each case must be assessed individually, because the sole classification of the fracture is not enough to establish a treatment. In fact, it is mandatory to take into

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account other parameters, like age, functional demands of the patient, bone quality, rotator cuff function, and especially the integrity of the vascular system to estimate the risk of necrosis of the humeral head [5,6] which is the main complication in this particular kind of fracture and requires specific surgical intervention. This wide range of options provides an equally wide set of data from literature, and the results from each individual study are very rarely replicated in subsequent trials. The gold standard for osteosynthesis in 3- or 4-part proximal humerus fractures according to Neer's classification is the use of open reduction and internal fixation (ORIF) with plates and screws [7].

The purpose of this study was to evaluate clinical and radiographic outcomes of proximal humerus fractures treated with a new generation low-profile plate and to use a meta-analytical approach to compare the results with those from several recent studies that treated this pattern of fracture with plate and screws through ORIF. Our hypothesis was that good and excellent results would be obtained with an anatomic design, minimizing the potential for failure of fixation.

2. Materials and methods

2.1. Patients

This retrospective study was approved by the IRBs of the authors' affiliated institutions.

From January 2014 to December 2017, we treated 93 patients (18 males, 75 females) of average age of 70 years (27–90), who were diagnosed with fracture of the proximal humerus with indication to surgery. We utilized the Neer classification to stage the fractures. Inclusion criteria were: age 18–100 years and a recent fracture [8]. Exclusion criteria were patients with life-threatening polytrauma, dementia, life expectancy less than 6 months, or pathological fractures. All patients were completely informed, in a clear and comprehensive way, of surgery and possible conservative alternatives. Patients were treated according to the ethical standards of the Helsinki Declaration, and were invited to read, understand, and sign the informed consent form.

Patients were evaluated with anteroposterior and lateral radiographs pre- and post-surgery to observe the stability of the fixation and the fracture healing as well as documenta by complications. Objective quality of life and shoulder function were measured by Constant Shoulder Score (CSS) [9] and categorized as "Excellent" (86–100), "Good" (71–85), "Fair" (56–70), and "Poor" (<56). Shoulder range of motion was also reported.

2.2. Description of plates and screws

The design of the Pantera® Proximal Humerus Fracture Fixation Plate System (Toby Orthopaedics, Inc., Miami, FL USA) was based on measurements taken from Asian humeri while the screw positioning was based on published CT-derived bone density studies of the proximal humerus. The Ti6Al4V ELI system includes plates (thickness: 2.8 mm, length: 73–220 mm), 3.5 mm cortical locking (length: 10–45 mm) and nonlocking (length: 10–40 mm) screws, 5.28 mm threaded posts (length 30–50 mm), and 1.98 mm threaded cross-elements (length: 20–35 mm) (Fig. 1a and b) [10]. The anatomical (left and right versions) plates help address displacement of the humeral head posteriorly. Proximal suture clips provide additional fixation of the tuberosities and facilitating rotator cuff repair. The plates include both locking and nonlocking holes for the cortical screws and can accommodate up to three threaded posts. The posts are large humeral head screws each containing three threaded cross-holes (or two in the case of the shortest post) to allow passage of the cross elements. The central cross-hole is

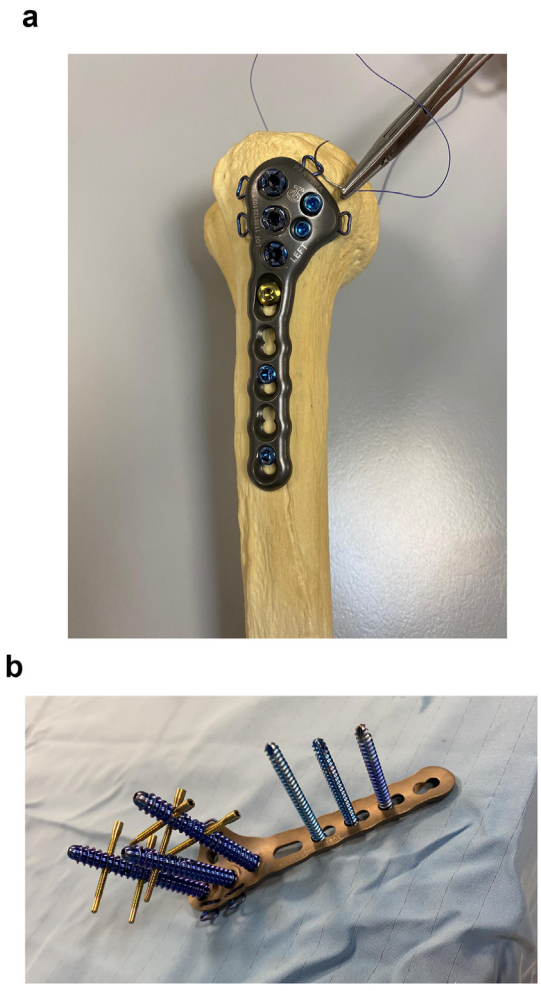

Fig. 1. a, b Pantera® thickness is 2.8 mm and its anatomical (left- and right-version) profile helps address displacement of the humeral head posteriorly and its proximal suture clips provide additional bony fixation of the tuberosities and facilitate rotator cuff repair (a). Cross element fixation creates an internal scaffold within the trabecular bone (b).

rotated 30° from the plane described by the proximal and distal cross-holes, similarly the axes of the two cross-holes of the shortest cross-element in the series are offset by 30° with respect to each other. A drill guide is used to index with the proximal aspect of the post to permit passage through and engagement with the cross-elements. The cross-elements create an internal fixation scaffold within the trabecular bone. The application of the cross-elements to fix the lesser tuberosity is entirely extra-articular. They stabilize the subscapularis pull and allow a three-dimensional fixation, minimizing loss of reduction and protrusion through the articular surface of the humeral head.

2.3. Operative technique

All operations were conducted in the beach chair position. A deltopectoral approach was elected as it was considered to be the best approach to allow appropriate fracture reduction and fixation of proximal humeral fractures [11]. After soft tissue dissection and good fracture site exposure, we identified the humeral ascendant circumflex artery to protect it. Once a satisfactory reduction was obtained, we re-established the anatomical relationship between the articular surface and the humeral shaft by restoring both its angular alignment and retroversion. Following this, a Pantera®

Plate of appropriate size was positioned at the fracture site (Fig. 1a and b). The authors prefer to place it immediately posterior to the intertubercular groove and approximately 1.5–2.0 cm distal to the insertion of the supraspinatus to avoid impingement with the acromion. First, a K-wire is drilled into the central post hole coinciding with the center line of the humeral head. The design of this plate offers suture clips to assist the reduction and fixation of the comminuted bone of the tuberosities and to repair associated soft tissue lesions, such as rotator cuff tears. The comminuted greater tuberosity is brought under the proximal and posterior buttress of the plate. At this point, fixation of the shaft can aid complete reduction of the buttress-like humeral head (with the tuberosities) to the shaft. If the medial calcar is fractured, it is possible to use a more distal screw hole for the purposes of initial diaphyseal fixation (and to achieve the desired buttress reduction). The calcar may then be lagged to the construct through the oblong screw hole. At least one cortical locking screw must be placed into one of the distal holes on the plate. Once the optimal fracture reduction, proper position of the plate, and distal fixation have been accomplished, it is possible to proceed with the definitive proximal fracture fixation filling all three post holes using K-wire as a guide. At this time, discretionally, with the shoulder in slight extension abduction, slight external rotation and with the guide device assembled, cross-elements can be applied in order to minimize loss of reduction and protrusion through the articular surface of the humeral head (Fig. 2a–c). Fluoroscopy images with anterior-posterior and axillary views should be used throughout and at the end of the fixation to check metalwork position. When good fixation is achieved, the procedure should be completed with abundant lavage, accurate final haemostasis, and closure in layers (Fig. 3a–c).

2.4. Post-operative rehabilitation

All patients underwent the same postoperative rehabilitation protocol that included immobilization support, pendulum exercises, gently assisted passive motion and avoidance of external rotations up to 30 days. Proper rehabilitative therapy started about 5 weeks post-surgery and continued until a suitable functional recovery was achieved.

X-Ray controls were planned at 1, 3, 6, 12 months and then annually. Fracture healing was radiologically assessed by examination of callus size, cortical continuity, and progressive loss of the fracture line.

2.5. Review of the literature and statistical analysis

In order to compare our results to those from other studies, we used the electronic database PubMed to review the literature of the last 10 years of studies regarding surgical treatment of proximal humeral fractures. Inclusion criteria for comparison with other

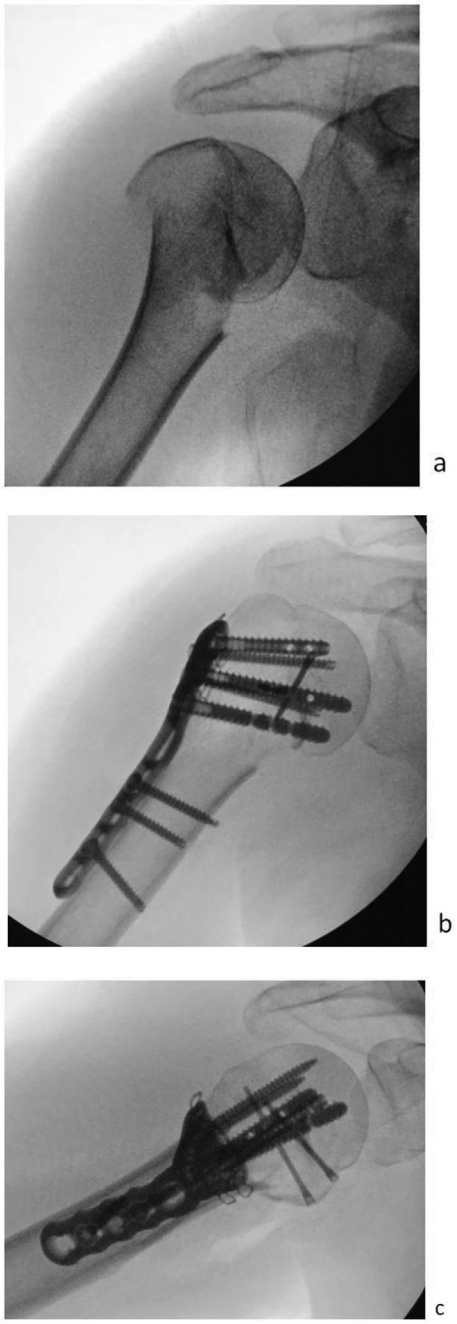

Fig. 3. (a, b, c) X-Ray control pre- and post-surgery.

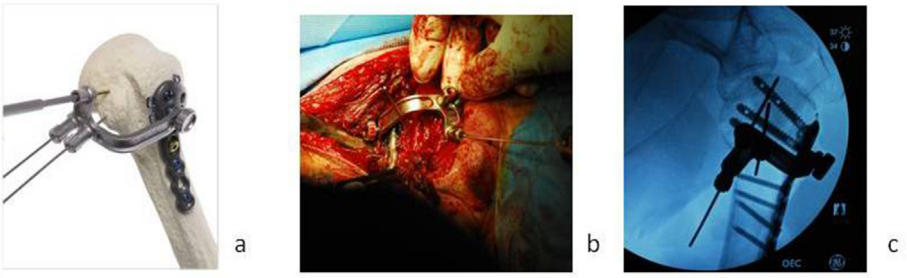

Fig. 2. (a, b, c) The application of the cross elements to fix the lesser tuberosity is entirely extra-articular. They stabilize the subscapularis pull and allow a three dimensional fixation, minimizing loss of reduction and protrusion through the articular surface of the humeral head.

case-series were: 1) proximal humeral fractures treated with plate and screws (ORIF); 2) clinical outcomes evaluated with Constant Shoulder Score; and 3) complications reported. Descriptive analysis was based on reporting mean and standard deviation (SD) for continuous variables and percentages for categorical variables. For papers that didn't report the SD, we obtained it from the absolute value of CSS and the minimum and maximum results [12]. The association between Neer fracture stage and patient outcomes (CSS) was analyzed with one-way ANOVA. The results of the current study were compared with those in the literature through a meta-analysis performed with chi-square test to test for significantly different proportions of complications, and a t-test to test for significantly different clinical outcomes. i.e., CSS. Both fixed and random-effects meta-analysis were used to pool estimates of proportions with 95%CI across studies. The heterogeneity among included studies was measured using Q tests and the I^2 statistic to assess the extent of the inconsistency. A probability value of $p < 0.05$ and $I^2 > 50\%$ indicated the existence of significant heterogeneity. All statistical analysis were performed with SAS System version 9.4 (SAS, Cary, NC USA) and MedCalc version 19.1.3 (MedCalc Software Ltd., Belgium) software.

3. Results

3.1. Patient outcomes

At a minimum follow-up of 2 years (24–36 months) we lost 10 patients (11%). The main characteristics of the sample are shown in Table 1. Of 83 patients that we were able to check, fractures healed without complication in 75 (90.4%) of the cases, with good formation of bone callus as documented by X-Ray controls with a mean time for radiological union of 12 weeks (8–20 weeks). There were eight complications (9.6%), including three cases (3.6%) of avascular necrosis of the humeral head and one case (1.2%) of screw cut-out where cross-elements were not used. These four cases were treated with surgical hardware removal and patients underwent replacement with hemiarthroplasty or reverse total shoulder arthroplasty, as needed. In addition, two patients (2.4%) reported persistent pain consistent subacromial impingement, while two (2.4%) other patients that were under steroid therapy reported superficial infection and were treated with surgical curettage and antibiotics. We did not find a significant association between Neer fractures stage and patient outcome (CSS) (one-way ANOVA; $p = 0.257$; $f = 1.381$). The mean CSS was 74 ± 8 (range 58–90) for Neer II ($n = 21$), 73 ± 8.25 (range 57–90) for Neer III ($n = 45$), and 70 ± 8.75 (53–88) for Neer IV ($n = 17$). The mean CSS for the entire population ($n = 83$) was 72 ± 10.8 (range 53–90) with satisfactory results as follows: 23 (27.7%) excellent, 35 (42.2%) good, 14 (16.9%) fair, and 11 (13.3%) poor. Average active shoulder flexion was 124° (range 90–180) and active shoulder abduction was 112° (80–168).

3.2. Literature reviewed and statistical results

During the last 10 years only nine case series met our three inclusion criteria (Table 2). An external observer performed a meta-analysis of reported complications (Fig. 4), showing that 19.65% of patients had complications (95%CI: 14.653 to 25.179) (inconsistency of the sample for random effects: 47.45%). This percentage of complications is significantly greater than the percentage following our surgical method (9.64%, ci 4.254 to 18.111) ($p = 0.0297$). However, our clinical results (CSS 72 ± 10.8) were not significantly different from the pooled mean of CSS reported in literature (75 ± 15.8) (t-test; $p = 0.0807$).

4. Discussion

The main finding of this study is that a low-profile, anatomically shaped plate with an enhanced fixation design can allow good clinical and radiographic outcomes in the treatment of proximal humeral fractures of all Neer stages. The ability of this plate to provide a stable fixation is critical.

While debate exists about the best surgical option for proximal humeral fractures [13,14], many authors agree that an effective osteosynthesis requires careful handling of the fragments in comminuted fractures and an equally prudent approach to the vascular structures that surround the head of the humerus [15–18]. We focused on the plate characteristics, allowing us to perform a more suitable reduction of the fracture, especially displaced and/or dislocated fractures, while avoiding damage to the humeral head. The plate is equipped with angular stability screws for proximal and posterior support and utilizes cross-elements that enter the bone through the lesser tuberosity with an extra-capsular and extra-articular trajectory (Figs. 1b and 2a). An important benefit of the cross-elements is the fixation of the lesser tuberosity, i.e., a well-fixed lesser tuberosity provides an additional mechanical buttress to the thin comminuted cortical bone of the tuberosities. In addition, stabilization of the lesser tuberosity may play a role in the restoration of functional internal rotation. While the mechanical support afforded by the cross-elements can withstand forces tending to collapse the humeral head [19,20], the plate also provides an excellent low-profile buttress to the greater tuberosity proximally and posteriorly. Suture clips on the plate provide points of attachment for the rotator cuff inserts to reduce the chance of a late sub-acromial impingement. All these characteristics allow a three-dimensional mechanical reconstruction of the humeral head, safeguarding the three columns, i.e., the first column (greater tuberosity) is stabilized directly by this plate as would be the case with other lateral plates; the second column, consisting of the lesser tuberosity, is stabilized with the adjustable cross-elements; and the third column, the medial calcar, is also supported by the cross-elements. Recently, Gonzalez- Hernandez et al. [10] conducted a high level biomechanical study of the pullout

Table 1
Sample divided according to Neer classification.

Sample	Gender	Age (yo)	Neer score	Follow-Up (months)	Notes
21 (25%)	16 f; 5 m	min 62 max 89	II	min 26 max 36	
45 (54%)	37 f; 8 m	min 53 max 90	III	min 24 max 36	
17 (21%)	15 f; 2 m	min 27 max 90	IV	min 25 max 34	4 patients with dislocation of humeral head

"f" = female; "m" = males; "yo" = years old.

Table 2
Results reported from case series over the last 10 years that treated proximal humeral fractures with ORIF and followed up clinical outcomes with Constant Shoulder Score (CSS).[9]

Case series	Sample	Mean age	Complications	Neer Classification			CSS score	SD	excellent	good	fair	poor
				II	III	IV						
Current trial	83	70	8	21	45	17	72 (53–90)	10.8	23	35	14	11
Kumar (2014)[23]	49	38	8	8	15	26	79 (50–100)	14.5	25	13	6	5
Patil (2012)[24]	44	57	4		16	28	80 (40–100)	17.4	7	27	6	2
Gönç (2017)[25]	31	58	7	4	14	13	70 (48–86)	11.0	–	–	–	–
Shen (2019)[22]	6	54	0	4	2		87 (83–92)	10.3	–	–	–	–
Vijayvargiya (2016)[26]	26	46	4	5	12	9	73 (67–82)	4.7	6	8	10	2
Fattoretto (2016)[27]	55	63	7		16	39	62 (16–97)	23.4	–	–	–	–
Falez (2015)[28]	74	68	20	–			71 (28–100)	20.8	–	–	–	–
Erasmo (2014)[29]	82	56	23	7	40	35	75 (42–92)	14.5	8	52	17	5
Dietrich (2014)[30]	72	52	18	–			86 (82–91)	3.2	–	–	–	–

"SD" = standard deviation; "-" = value not specified by Authors.

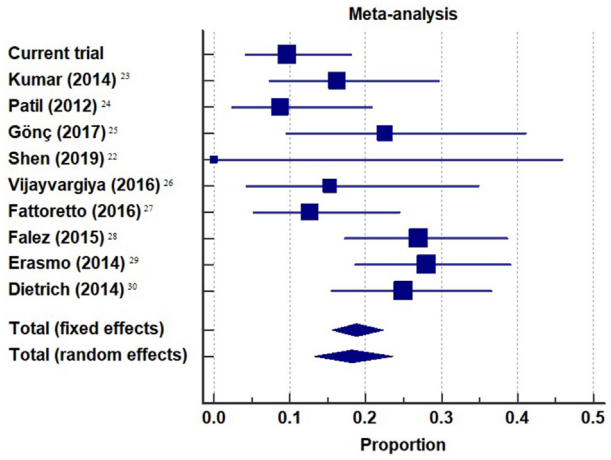

Fig. 4. Meta-analysis of complications reported in literature. Inconsistency (I^2): 47.45% (ci: 0.0–75.9%). Total proportions of complication (random effects): 19.649% (ci: 14.653 to 25.179).

characteristics of Pantera posts with and without cross-elements from a synthetic bone substrate that simulated osteoporotic bone. Relative to posts without cross-elements, the use of one and two cross-elements increased the peak load by 29% and 87% and increased the work to peak load by 126% and 343%, respectively. As such, the authors concluded that the use of the cross elements provides a profound biomechanical advantage to enhance the fixation properties.

Jabran et al. [21] performed a systematic review of biomechanical analyses of plating systems for proximal humerus fractures with the greatest body of data regarding the Proximal Humeral Internal Locking System (PHILOS, DePuy Synthes, West Chester, PA, USA). These are mono-axial locking plates available in both stainless steel and titanium configurations allowing two choices of modulus of elasticity. A long variant (up to 290 mm) exists for fractures extending to the humeral shaft or without medial support. The PHILOS plates are not anatomical as separate left and right versions are not included. Although Jabran et al. [21] consider these plates to have relatively low thickness, the maximum thickness of the long plates is 3.7 mm. Overall, the PHILOS plates demonstrated better mechanical performance than nonlocking plates. Despite this, the authors stated that clinical studies have reported a significant number of complications due to screw perforation of the humeral head. Like the PHILOS plates, the Pantera system is also a locking plate system. However, the Pantera system differs in that it is lower profile (2.8 mm vs. 3.7 mm maximum), is available in a single material (titanium alloy), the longest plate in the series is 220 mm versus 290 mm, and the system includes threaded posts and cross-elements to create a three-dimensional scaffold to enhance purchase in soft, cancellous bone. It is this last feature that extends the concept of locking plates a clinically signficant step further.

Shen et al. [22] described 6 shoulder posterior dislocations associated with proximal humeral fractures, citing zero complications and a CSS of 87 (83–92). Kumar et al. [23] showed a CSS of 79 (50–100) on a sample of 49 young patients (mean age 38 years) reporting 8 complications (16%). Patil et al. [24] prospectively treated 44 patients, with a mean age of 57.5 years, and a mean CSS of 80 (40–100), showing 4 (9%) complications. Gönç et al. [25] treated 31 patients through minimally invasive plate osteosynthesis (MIPO), assessing clinical outcomes at 1-year follow-up and showing 7 complications (22.6%) and an average 70 ± 11.5 CSS for patients with or without varus progression. In 2016, both Vijayvargiya et al. [26] and Fattoretto et al. [27] reported results of 2-, 3- and 4- Neer stage fractures treated with ORIF through two different approaches, i.e., Vijayvargiya prospectively showed the lower mean CSS for a deltoid splitting approach (67.5) and the greater for a delto-pectoral approach (82), while Fattoretto retrospectively reported an overall CSS of 61.93 ± 18.59 (16.5–97). In our review, only Falez et al. [28] reported a prospective multicenter study, citing 20 (27%) complications in 74 patients treated with MIPO using an antero-lateral approach in two different orthopaedic departments, showing a CSS of 71 (28–100). Finally, in 2014, both Erasmo et al. [29] and Dietrich et al. [30] reported more than 25% complications in a relatively young patient-series (mean age 56 and 52, respectively). The average CSS of 82 patients that Erasmo reported was 75, while Dietrich investigated the return-to-work ability in 72 patients showing an average CSS 86.

All these cited studies utilized the PHILOS plating system, a tool that lacks some of the features of the Pantera® Plate, such as cross elements and the ability to attach multiple soft tissue sutures using the suture clips rationally positioned on the proximal perimeter of the plate.

The current authors support the hypothesis of the study, and in fact the results show only two cases (2.4%) that developed subacromial impingement and just one (1.2%) case of screw cut-out. Other clinical studies of the use of this low-profile anatomical plate are not yet available. Related complications are significantly fewer, and we think that the good trend of clinical outcomes, actually at the edge of statistical significance, could still improve with a larger sample size. Comparing our data with others from similiar studies, we found that our results were remarkable. In particular, radiographic union was achieved in 90.4% with complications observed in 9.6%. The mean CSS on the entire series was

72 ± 10.8 with values for Neer II, III, and IV being statistically equivalent.

The main limitations of the current study were the limited number of patients and their retrospective evaluation with risk factors that may be present but were not measured; moreover, the selection of patients may have been biased, making generalization of results difficult. We did not carry out a systematic review of literature as we only compared our results with those of other studies that treated the same pattern fractures and assessed the outcomes with the same functional scoring system. These results require further randomized comparative studies in order to establish if the differences between Pantera® Plate and other plates are significant.

Another limitation of the current study is represented by the fact we were unable to statistically compare the fracture pattern of our case series with that of the current literature as only four authors [23,25,26,29] described the fracture pattern according to the "Neer classification" in their studies.

In conclusion, our study shows that the Pantera® plate is well-suited to provide stable fixation for the treatment of proximal humeral fractures, and the results obtained are encouraging. While functional outcomes were similar to those obtained by others utilizing the PHILOS plating system, the complication profile was significantly reduced. Further studies would help establish if our data was due to the specific features of the plate used, and if so, compare the results in a larger meta-analysis that includes other well-established surgical options for ORIF of proximal humeral fractures.

Declaration of competing interest

None.

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