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Original Article

Outcomes evaluation of locking plate osteosynthesis in displaced fractures of the proximal humerus

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ABSTRACT

Objective: To evaluate functional outcomes, radiographic findings and complications of proximal humeral fractures treated with locking plates and to determine prognostic factors for successful clinical outcomes.

Methods: Forty patients undergoing internal fixation of fractures of the proximal humerus with the Philos® plate were included in the study. The surgeries were performed between 2004 and 2011 and the patients underwent radiographic and clinical evaluation, by Constant–Murley and Dash score. Outcomes were analyzed by use of multivariate regression with several different variables.

Results: Patients were on average of 61.8 ± 16.28 years, and most were female (70%). The Constant–Murley score was 72.03 ± 14.01 and Dash score was 24.96 ± 19.99 . The postoperative radiographs showed a head-shaft angle of $135.43^\circ \pm 11.82$. Regression analysis showed that the patient's age and the Hertel classification influenced the Constant–Murley scale ($p = 0.0049$ and 0.012 , respectively). Other prognostic criteria such as Neer and AO classification, head-shaft angle, the presence of metaphyseal comminution and extension of the humeral metaphyseal fragment showed no effect on prognosis. Complications occurred in four patients (10%).

Conclusion: The fixation with the Philos® plate provided good clinical and radiographic results in fractures of the proximal humerus, with a low complication rate. Patient's age and Hertel classification were defined as prognostic factors that led to worse functional outcomes.

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Avaliação do resultado do tratamento cirúrgico das fraturas desviadas do terço proximal do úmero com placa pré-moldada com parafusos bloqueados

R E S U M O

Palavras-chave:

Fraturas do úmero
Fixação interna de fraturas
Resultado de tratamento

Objetivo: Avaliar os resultados clínicos e radiográficos e as complicações das fraturas do terço proximal do úmero tratadas com a placa Philos® e correlacionar esses resultados com critérios prognósticos.

Métodos: Foram estudados 40 pacientes submetidos a osteossíntese de fraturas do terço proximal do úmero com a placa Philos®. As cirurgias foram feitas entre 2004 e 2011 e os pacientes foram submetidos a avaliação funcional (escalas de Constant-Murley e Dash [Disability of Arm-Shoulder-Hand]) e radiográfica. Os resultados funcionais foram correlacionados com variáveis clínicas e radiográficas por meio de regressão múltipla.

Resultados: Os pacientes apresentavam em média $61,8 \pm 16,28$ anos e a maioria era do sexo feminino (70%). Observamos pontuação de $72,03 \pm 14,01$ pela escala de Constant-Murley e $24,96 \pm 19,99$ pela de Dash. A radiografia pós-operatória evidenciou um ângulo cabeça-diáfise de $135,43^\circ \pm 11,82$. A análise por regressão demonstrou que a idade do paciente e a classificação de Hertel exercem influência direta na escala de Constant-Murley ($p = 0,0049$ e $0,012$, respectivamente). Outros critérios prognósticos, como a classificação de Neer e AO, o ângulo cabeça-diáfise, a presença de cominuição metafisária e a extensão do fragmento metafisário não demonstraram influência no prognóstico em nossa amostra. Complicações ocorreram em quatro pacientes (10%).

Conclusão: A osteossíntese com a placa Philos® proporcionou, em nossa amostra, bons resultados clínicos e radiográficos, com baixo índice de complicações. A idade do paciente e a classificação de Hertel foram demonstradas como fatores preditores do resultado funcional.

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Introduction

Fractures of the proximal third of the humerus account for around 4–5% of all fractures and are the second commonest types in the upper limbs.¹ Their incidence increases with age and women are affected up to twice as often as men. Just as with other fractures relating to osteoporosis, the incidence of fractures of the proximal third of the humerus presents an increasing trend.¹ In elderly patients, the proximal third of the humerus is commonly osteoporotic, which makes it difficult to fix and stabilize using traditional plates and screws.^{2,3} Several techniques have been described for treating these fractures, including fixation with a plate and screws, laminar plate, intramedullary nail, percutaneous pins or tension band, or using partial arthroplasty.^{4–6} Premolded plates with locking screws are considered to be the main implants for increasing the mechanical stability of these fractures.⁵ Several clinical studies have shown good results in relation to shoulder function and consolidation with this type of implant.^{7–9} Clinical and intraoperative variables have been described as prognostic criteria for these fractures, including: age, fracture classification, adequacy of reduction and plate positioning.^{10–13}

The complication rate from using these synthesis materials is high and may result both from the fracture pattern^{14,15} and from the surgical technique.⁷ In a recent systematic review, Sproul et al.⁷ demonstrated a complication rate of 49% among 514 patients, with a reoperation rate of 14%.

The aim of this study was to evaluate the clinical and radiographic results and complications from fractures of the proximal third of the humerus treated with the Philos® plate and correlate these results with prognostic criteria.

Methods

Between 2004 and 2011, 86 patients underwent operations to treat displaced fractures of the proximal third of the humerus, which were fixed using a fixed-angle premolded plate and proximal screws made by Philos® (Synthes®). The operations were performed by five different surgeons with experience in surgical treatment for these fractures. These patients were invited to make a return visit between August 2011 and July 2012, and 40 of them came for reassessment (40 shoulders). The other patients did not come because of death, change of telephone number or refusal to participate in the investigation. The displacement parameters for indicating surgery were based on the Neer criteria, with displacement greater than 45° or 1 cm between the fragments (or 0.5 cm for the displacement of the tubercles). Patients over the age of 18 years with fractures presenting fewer than 30 days of evolution were included. Patients who did not come for the reassessment, those with clinical follow-up of less than 6 months, fractures affecting only the greater or lesser tubercle, pathological fractures, dislocated fractures and cases with previous infection in the shoulder affected were not included in the analysis.

Intervention

The procedures were performed under general anesthesia in association with interscalene block, and antimicrobial prophylaxis consisting of first-generation cephalosporin was used for 24 h.

The patients were positioned in horizontal dorsal decubitus, with the dorsum elevated at 30°. A deltopectoral access route was used. The tendons of the supraspinatus, infraspinatus and subscapularis were repaired using nonabsorbable suturing thread in order to aid in reducing and fixing the tubercles. After the reduction, radioscopy was used to confirm that the fragments had been adequately positioned. Provisional fixation using steel wires was then performed. The Philos® plate was positioned around 1 cm laterally to the bicipital groove, and its height was observed by means of radioscopy. The repair wires of the tendons were passed through holes in the plate. After the fracture had been reduced and the plate had been adequately positioned, definitive fixation was performed, with locking screws inserted proximally (minimum of five)¹⁶ and cortical or locking screws distally (minimum of three). Following this, knots were made in the cuff repair threads.

After the operation, the patients were kept using a sling for four weeks. Active movements of the elbow, wrist and fingers were started during the immediate postoperative period. Passive movement of the shoulder was started on the 14th day after the operation, which allowed flexion of up to 90°, external rotation and abduction as tolerated, with swinging exercises. After the end of the fourth week, assisted and free active movements were started in all planes. Strengthening was started after the fracture had consolidated.

Outcomes

The patients were evaluated clinically by means of the Constant-Murley¹⁷ and DASH¹⁸ functional scales.

Radiographs were performed preoperatively in accordance with the trauma series. After the operation, the following views were produced: anteroposterior with 30° of external rotation, lateral in the plane of the scapula and lateral axillary. The primary outcome was the Constant-Murley evaluation. The secondary outcomes were the DASH functional scale, the head-shaft angle and the presence of complications. Computed tomography was required for eight patients.

In addition to the outcomes, the following variables were evaluated:

Factors intrinsic to the patient: gender, age and dominant side.

Factors relating to the injury: side affected, fracture mechanism, fracture classification (Neer,¹⁹ Hertel et al.¹⁴ and AO²⁰), extent of the metaphyseal fragment of the humeral head, displacement of the medial fragment of the head in relation to the lower shaft of less than 2 mm, position of the displacement of the head (varus or valgus), head-shaft angle (anteroposterior radiographic view) (Fig. 1) and presence of metaphyseal comminution.



Fig. 1 – Head-shaft angle of 80°, which demonstrates varus displacement.

Factor relating to the intervention: time elapsed between the trauma and the surgical treatment.

Postoperative radiographic criteria: head-shaft angle, height of the plate in relation to the top of the humeral head (Fig. 2A), height of the tuberosity in relation to the top of the humeral head (Fig. 2B), distance between the anteroinferior border of the anatomical neck and the shaft, and presence of an inferomedial screw (Fig. 3A and B).

Clinical and radiographic complications were evaluated: postoperative infection, loosening of the synthesis material, osteonecrosis, pseudarthrosis, secondary displacement of the fracture, loosening of the screws, protrusion of screws into the joint and secondary arthrosis. The need for a new surgical procedure to treat complications or to remove the synthesis material was recorded.

Statistical analysis

The data were assessed with regard to normality of distribution by means of the Shapiro-Wilk test. The parametric data were presented as means and standard deviations; nonparametric data as medians and percentiles; and categorical data as absolute values and percentages. The Wilcoxon test was used to make comparisons between two related quantitative



Fig. 2 - (A) Height of the tuberosity in relation to the top of the humeral head. The values are considered to be negative when the tuberosity is below the top of the head; (B) height of the plate in relation to the top of the humeral head.

variables, and the Mann-Whitney *U* test to make comparisons between two unpaired quantitative variables.

The variables identified as potential predictors for the results from the Constant and DASH scales were evaluated in univariable mode by means of linear regression and were then subjected to multiple regression analysis. All the factors were inserted in an initial model and then the factors that presented lower association ($p > 0.05$) were excluded from the model, which maintained clinical sense.

The significance level of 5% was used. The Stata® statistical software (version 10.0) was used for the descriptive analysis, and SPSS 19.0 for Windows was used for the regressions.

Results

The patients' mean age at the time of fracture occurrence was 61.8 ± 16.28 years. The right side was affected in 22 cases (55%) and the dominant side in 25 (62.5%). Fractures were more prevalent among females, with 28 cases (70%).

The median length of time between the fracture and the osteosynthesis was 8.5 days (p25% 5; p75% 14).

The most prevalent trauma mechanism was a fall to the ground, with 26 cases (65%). Falls from a height were responsible for seven fractures (17.5%), while motorcycle accidents accounted for two (5%). Other causes occurred in five cases (12.5%).

Five patients (12.5%) presented associated fractures. Two patients (5%) had rotator cuff tears, which were observed during the operation and completely repair.

According to the Neer classification, 22 patients (55%) presented fractures in three parts, 16 (40%) in two parts and only two (5%) in four parts. Patterns 1 (13 cases, 32.5%) and 7 (12

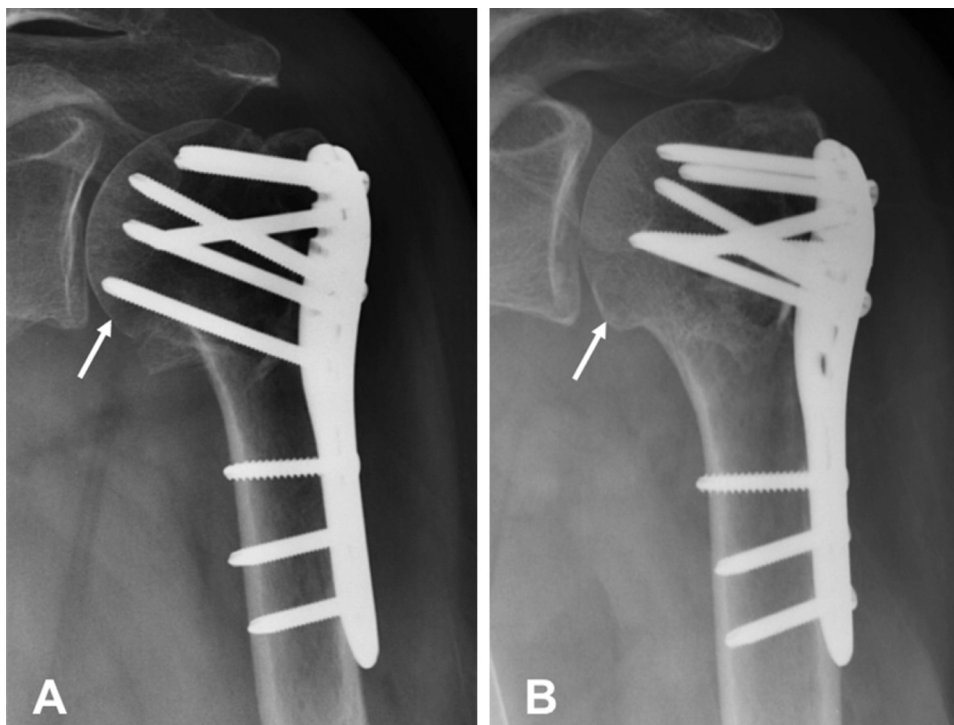


Fig. 3 - (A) Presence of the inferomedial screw (arrow) and (B) absence of inferomedial screw.

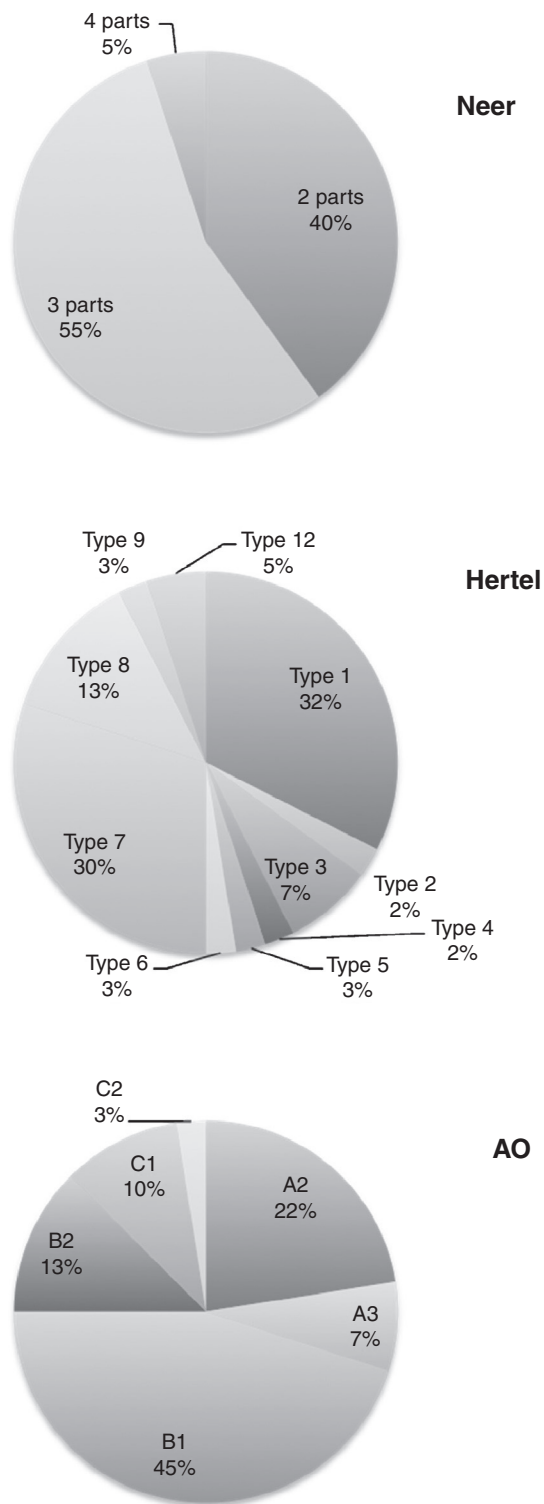


Fig. 4 – Percentage distribution of the fractures according to the Neer, Hertel and AO classifications.

cases, 30%) were the most prevalent types according to the Hertel classification. Subtype 11-B1 predominated in the AO classification, with 18 cases (45%). Five cases (12.5%) were classified as type C. The complete analysis of the types of fractures according to these three classifications can be seen in Fig. 4.

The analysis of the preoperative radiographs showed the cephalic fracture had metaphyseal extent of a median of 12 mm (p25% 8 mm; p75% 20 mm). Fourteen cases (35%) presented metaphyseal extent of 8 mm or less. Twelve cases (30%) presented significant displacement between the humeral head and the diaphysis, with signs of a medial periosteal lesion. Six cases (15%) presented an association between a medial periosteal lesion and a metaphyseal fragment less than or equal to 8 mm. None of these cases presented a type C fracture in the AO classification.

Nineteen cases (47.5%) presented valgus displacement of the head and 16 (40%), varus. Four patients (10%) did not present any displacement of the head (only of the tubercle) and one (2.5%) had a translation without angular displacement. Metaphyseal comminution was present in seven cases (17.5%).

The postoperative radiographs showed a head-shaft angle of $135.43^\circ \pm 11.82$. Medial metaphyseal support was observed in 38 cases (95%). The height of the greater tubercle in relation to the top of the humeral head was $-5.03 \text{ mm} \pm 5.30$. The distance between the medial border of the head and the metaphysis was $13.09 \text{ mm} \pm 6.32$. The top of the plate was at a mean distance of $15.97 \text{ mm} \pm 6.97$ from the most proximal portion of the greater tubercle. In 32 cases (80%), inferomedial screws were inserted. In no case was the plate positioned outside of the acceptable patterns (Fig. 5A-C).

Functional assessment on the patients was done after a median interval of 21 months after the surgery (p25% 12; p75% 32.5). The patients presented results of 72.03 ± 14.01 points according to the Constant-Murley scale and 24.96 ± 19.99 according to the DASH scale (Fig. 6A-C).

Regression analysis of the influence of the different prognostic criteria demonstrated that the patient's age and Hertel classification had a direct influence on the result from the Constant assessment ($p = 0.0049$ and 0.012 , respectively). Other prognostic criteria, such as the Neer and AO classifications, the head-shaft angle, the presence of metaphyseal comminution and the extent of the metaphyseal fragment, did not show any influence on the prognosis, as determined using the functional scales, in our sample.

Four patients (10%) presented complications: secondary displacement of the fracture (Fig. 7A and B), osteonecrosis, screw positioned intra-articularly and postoperative stiffness. The patients with secondary displacement and osteonecrosis presented secondary protrusion of the screws intra-articularly. Four patients (10%) underwent reoperation. One patient (2.5%) presented loss of the reduction of the greater tubercle, with proximal retraction of 1 cm. No occurrences of infection, loosening of the synthesis material or secondary arthrosis was observed.

Discussion

Osteosynthesis of fractures of the proximal third of the humerus using premolded plates with locking screws produces satisfactory results. Through a systematic review on 514 patients, Sproul et al.⁷ found that the mean score was 74 points according to the Constant scale and 27 points on the DASH

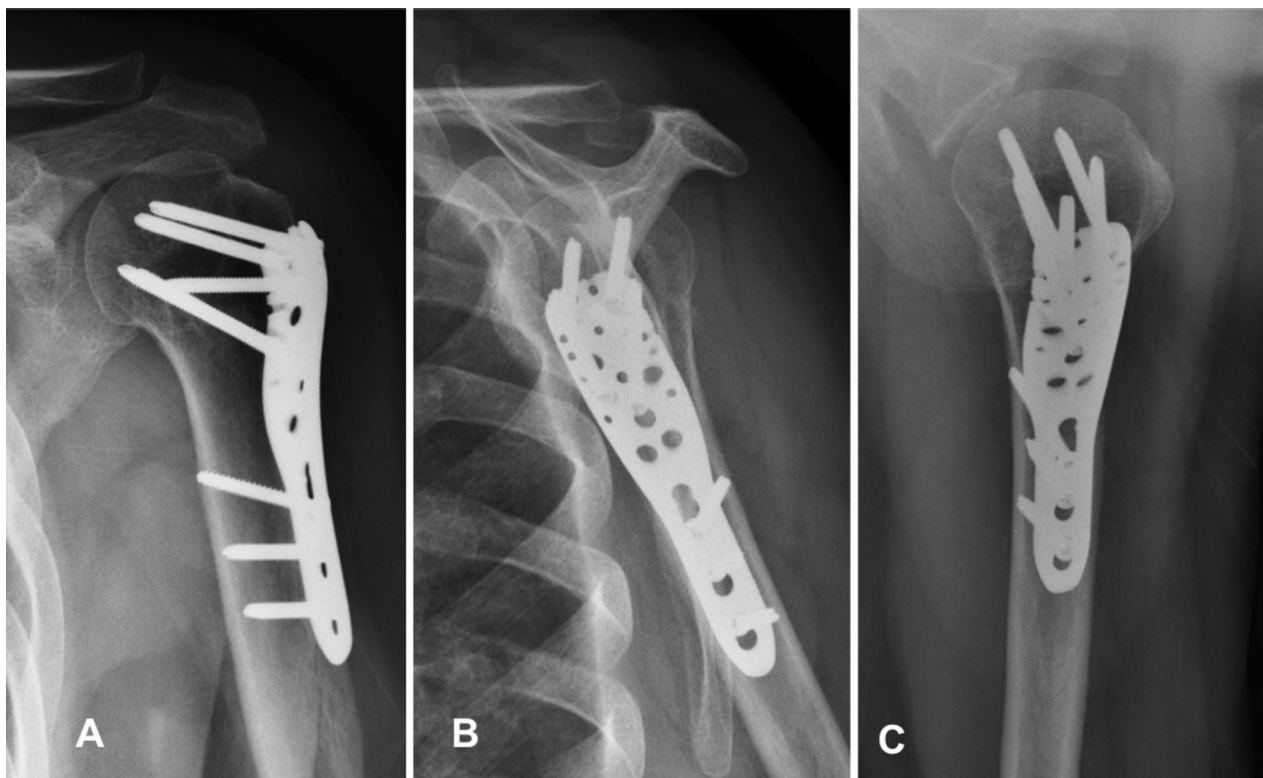


Fig. 5 – Radiographic evaluation of a case with a well-positioned plate and adequately reduced fracture. (A) Anteroposterior; (B) lateral; (C) axillary.

scale. Our study showed similar results, with 72.03 and 24.96 points, respectively.

Several variables relating to the patient, type of fracture and surgical technique have been studied as prognostic factors for these fractures.¹⁰⁻¹³

Patient's age is a parameter that has an influence on the final result.¹² Our study demonstrated that patients who were more elderly presented worse results according to the Constant and DASH scales. Other factors that we studied in relation to our patients did not show any influence on the regression model used.

Among the classification evaluated in our study, only the one described by Hertel et al.¹⁴ demonstrated any influence on the clinical result.

The classification or binary descriptive system described by Hertel et al.¹⁴ consists of identifying the morphology of the fracture by investigating the following fracture lines: (1) between the greater tubercle and the humeral head; (2) between the greater tubercle and the shaft; (3) between the lesser tubercle and the head; (4) between the lesser tubercle and the shaft; and (5) between the greater tubercle and the lesser tubercle. Based on identifying these traits, 12 types of fracture can be determined. In addition to subtypes, the authors suggest that other factors leading to a poor prognosis should be added to the classification. The most important are the extent of the medial metaphyseal fragment of the head and the posteromedial periosteal lesion, indicated by a displacement greater than 2 mm between the head and the proximal fragment of the shaft. The combination of a metaphyseal

fragment smaller than 8 mm or a medial periosteal lesion and involvement of the anatomical neck demonstrates that there is a 97% risk of ischemia of the humeral head. The initial displacement of the fracture and even the presence of dislocation of the head were described by the authors as criteria of lesser importance for the prognosis. In our study, the binary descriptive classification was a determining factor for the clinical result ($p=0.0049$). In the study by Hertel et al.,¹⁴ the risk of ischemia was determined, which does not directly imply that osteonecrosis will occur and does not necessarily determine a worse clinical result. In our study, four cases (10%) were classified in the worst types of the Hertel classification (types 2, 9, 10, 11 and 12). Only one case presented osteonecrosis, and this did not present the criteria associated with a poor prognosis. We were unable to find a correlation between the clinical results and the presence of a metaphyseal fragment smaller than 8 mm or a medial periosteal lesion.

The AO classification was shown by Harderman et al.²¹ to be a prognostic factor for the clinical result and presence of complications. On the contrary, Sudkamp et al.¹² did not find any influence from this classification on the functional result, but demonstrated a relationship between the Neer classification and complications. In our study, we did not find any direct relationship between the clinical result and the Neer and AO classifications. The lack of representation of these classifications in the regression model used may be explained by the low incidence of fracture patterns of greater complexity in our series (only two cases of fractures in the Neer category of four parts and five cases in AO type C).

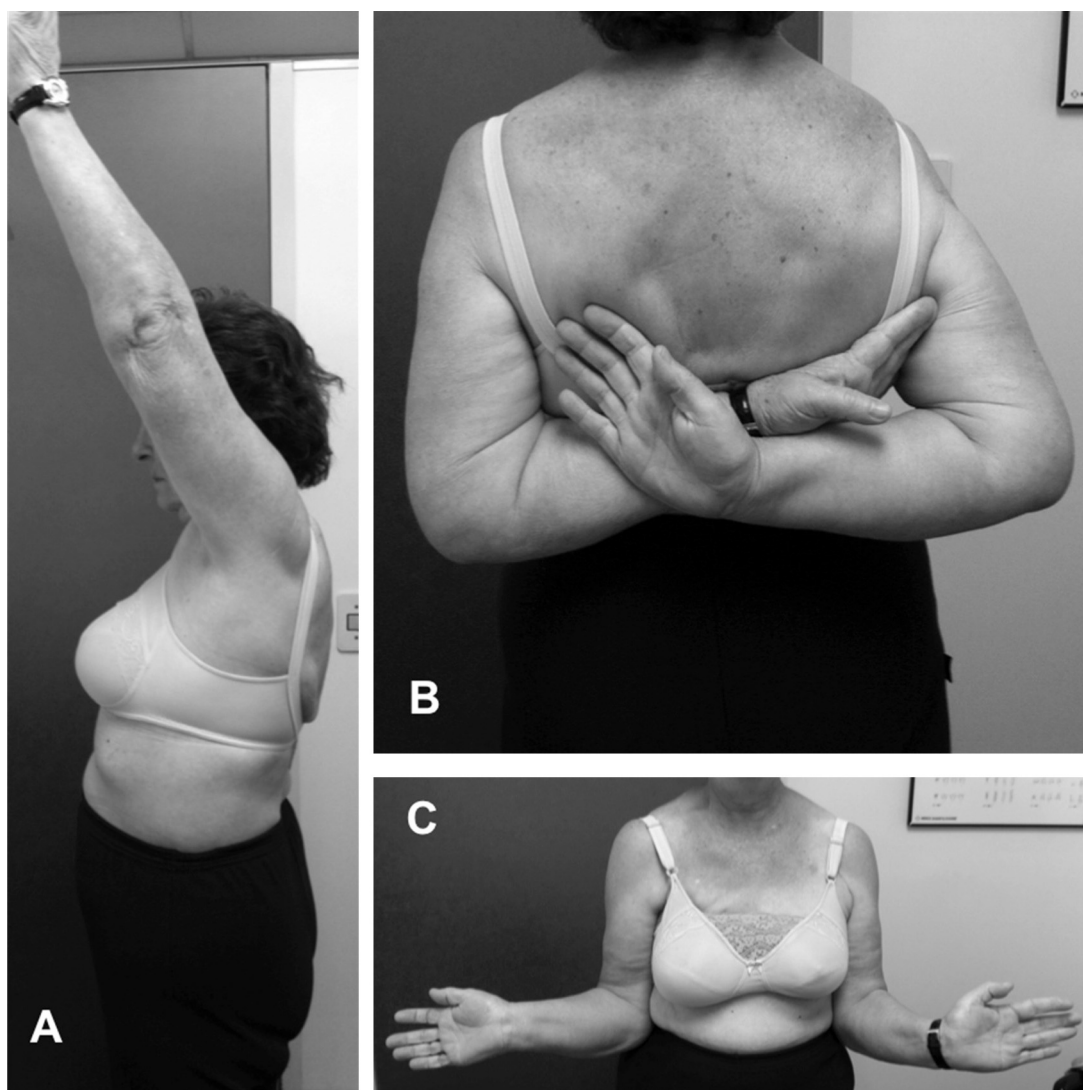


Fig. 6 – Functional evaluation on a patient 12 months after the operation. (A) Elevation; (B) internal rotation; (C) external rotation.

Metaphyseal comminution,²² varus or valgus pattern of head displacement¹¹ and head-shaft angle¹³ have been indicated as important in determining the prognosis for fractures. However, we did not observe any correlation between these variables and the clinical results from our study.

Adequate reduction of the fracture is essential for achieving a good clinical result from fixation of fractures of the proximal third of the humerus.^{10,12} Several reduction parameters have been described,^{14,23-25} and rigorous observance of these is important for obtaining good results. Lack of medial metaphyseal support for the head may lead to early loss of the reduction and penetration of the joint by the screws, particularly in cases with metaphyseal comminution and primary varus displacement. Owsley et al.²⁶ demonstrated that the incidence of varus deformity was 25% and that screw cut-out occurred in 23% of the cases of this fracture pattern. In our study, only one patient (2.5%) presented secondary loss of reduction.

Factors relating to the positioning of the plate and screws may also influence the clinical results.^{15,24,27-29} The most frequent complications described from osteosynthesis using a locking plate relate to perforation of the humeral head caused by the proximal screws, and to impact secondary to high positioning of the plate.²⁵⁻²⁷

The mean values for the reduction parameters in our study were within the normal patterns. The plate was adequately positioned in all the cases (Fig. 6A-C). In one case, a screw that was too long was inserted and it remained inside the joint: it had to be removed. In 80% of the cases, at least one screw was inserted in the inferomedial region, which was reported by Zhang et al.²⁴ as important for maintaining the reduction in complex fractures. There was no correlation between the reduction and plate positioning parameters and the functional scales, or in relation to the presence of complications.

In a systematic review, Sproul et al.⁷ showed that the complication rate was 49%. Our sample showed a considerably

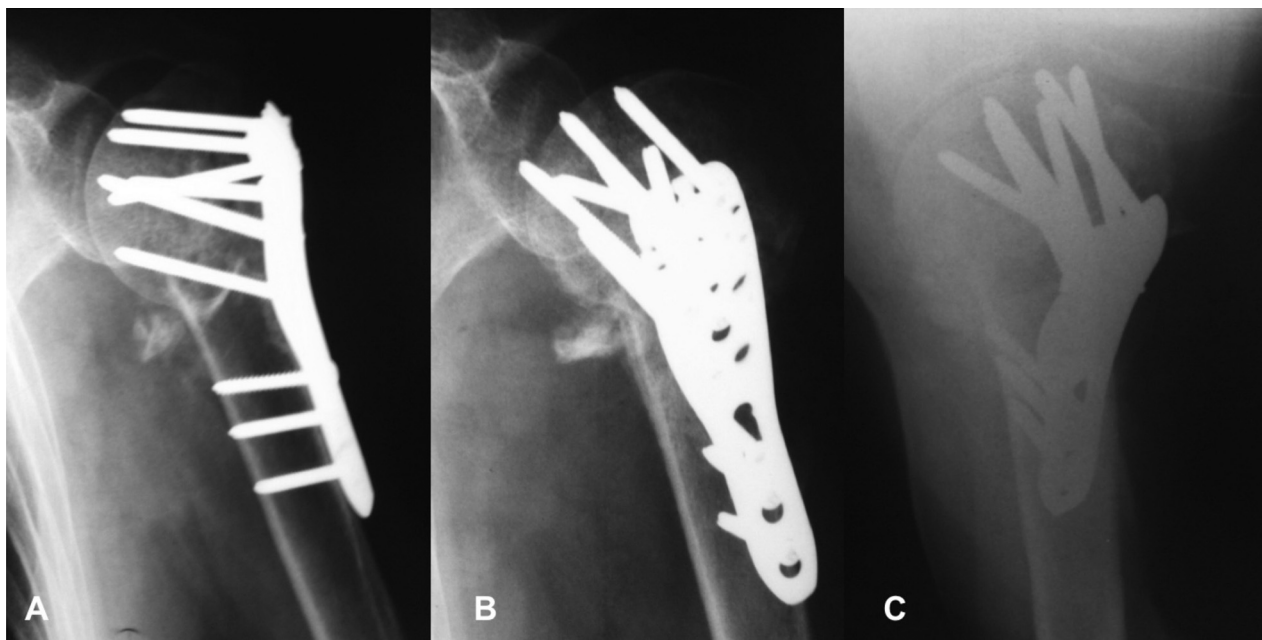


Fig. 7 – Radiographic evaluation of a case with secondary varus collapse and protrusion of screws into the joint. (A) Anteroposterior; (B) lateral; (C) axillary.

smaller rate (10%). We believe that our low incidence was related to rigor in applying the principles of reduction and adequate positioning of the plate and screws. The small number of complex fractures or fractures with factors giving a poor prognosis also contributed toward this picture.

Our study presents certain limitations. Multivariable regression analysis enables control over and assessment of different prognostic criteria and diminishes the bias of confounding factors.¹² Furthermore, it may quantify their association with the final outcome. However, the size of our sample limited the assessment of many variables and may have generated a type II (beta) error due to insufficient study power. Another limitation is that the length of postoperative follow-up varied between the patients, which made comparative analysis difficult. In addition, seven cases (17.5%) presented lengths of follow-up of less than one year. If these patients were excluded, the mean follow-up would become 25.4 months.

As positive points, our study presented a homogenous sample of patients who underwent operations using a standardized technique, following the principles of reduction and plate positioning. The evaluation on the radiographic prognostic criteria was standardized and done by an evaluator who was blinded in relation to the patients' follow-up. Our study draws attention to the need to carefully assess different prognostic factors relating to fractures of the proximal third of the humerus.

Conclusion

Osteosynthesis of fractures of the proximal third of the humerus using a Philos® plate provided good clinical and radiographic results from our sample, with a low complication

rate. The patient's age and Hertel classification were shown to be predictive factors regarding the functional result.

Conflicts of interest

The authors declare no conflicts of interest.

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