

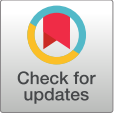
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Research Article

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REVERSE SHOULDER ARTHROPLASTY FOR PROXIMAL HUMERUS FRACTURES: CLINICAL AND RADIOLOGICAL COMPARISON OF INLAY AND ONLAY DESIGN PROSTHESES

PROKSİMAL HUMERUS KIRIKLARINDA TERS OMUZ ARTROPLASTİSİ: INLAY VE ONLAY TASARIM PROTEZLERİN KLİNİK VE RADYOLOJİK SONUÇLARININ KARŞILAŞTIRILMASI



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Abstract

Objective: Proximal humeral fractures (PHFs) are common among the elderly with numerous treatment options. Especially for complex fractures, reverse shoulder arthroplasty (RSA) has become a popular treatment alternative. However, effects of different RSA designs in the setting of PHFs have not been clarified yet. The purpose of this study was to compare the clinical and radiological outcomes of inlay (medialized) and onlay (lateralized) design RSAs performed for PHFs.

Material and Methods: A retrospective evaluation was conducted on patients who underwent RSA for PHF between December 2016 and September 2023. The patients were divided into two study groups based on the prosthetic design: Group I (inlay) and Group II (onlay). Clinical and radiological outcome data of the final follow-up visits were compared between the study groups. The clinical outcome measures included the pain score (visual analogue scale – VAS), simple shoulder test (SST), and subjective shoulder value (SSV). Tuberosity healing was evaluated using follow-up radiographs.

Results: A total of 74 patients were included in the study. There were 26 patients in group I and 48 patients in group II. The mean age of the patients was 72.4±7.2 years, and the mean follow-up duration was 51.2±25.4 months. The tuberosity healing rate was

Öz

Amaç: Proksimal humerus kırıkları (PHK) yaşlı popülasyonda sık görülen ve çok çeşitli tedavi seçenekleri olan kırıklardır. Özellikle kompleks kırıklarda ters omuz artroplastisi (TOA) popüler bir tedavi seçeneği haline gelmiştir. Ancak PHK'daki uygulamalarda farklı TOA tasarımlarının klinik sonuçlara etkisi halen netleştirilememiştir. Bu çalışmada PHK durumunda uygulanan TOA'de inlay (medialize) ve onlay (lateralize) protez tasarımlarının klinik ve radyolojik sonuçlarını karşılaştırmak amaçlanmıştır.

Gereç ve Yöntemler: Aralık 2016-Eylül 2023 tarihleri arasında PHK tanısıyla TOA uygulanan hastalar retrospektif olarak incelenmiştir. Grup I (inlay) ve grup II (onlay) olmak üzere kullanılan protezin tasarımına göre iki çalışma grubu oluşturulmuştur. Çalışma grupları, son klinik değerlendirmede elde edilen radyolojik görüntüleme ve klinik sonuçlarına göre karşılaştırılmıştır. Klinik sonuçların değerlendirilmesinde ağrı skoru (görsel ağrı skalası-VAS), basit omuz testi (SST) ve subjektif omuz değeri (SSV) kullanılmıştır. Tüberkül iyileşmesinin değerlendirilmesinde ise direkt radyografi görüntülerinden faydalanılmıştır.

Bulgular: Çalışmaya 74 hasta dahil edilmiştir. Grup I'de 26, grup II'de ise 48 hasta bulunmaktadır. Hastaların ortalama yaşı 72,4±7,2 yıl ve ortalama takip süresi ise 51,2±25,4 ay olarak bulunmuştur. Tüberkül kaynama oranı grup I'de daha yüksek olmakla birlikte



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higher in group I; however, the difference showed no significance (61.5% vs 54.2%, $p>0.05$). The two study groups were comparable in terms of clinical outcomes ($p>0.05$).

Conclusion: The findings of this study showed that, despite the absence of tuberosity healing in nearly half of the patients, both prosthetic designs resulted in satisfactory clinical outcomes. Although the inlay design group had a higher rate of tuberosity healing, the difference was not statistically significant, and further research is needed to confirm any potential superiority.

Keywords Proximal humerus fracture · reverse shoulder arthroplasty · tuberosity healing

aradaki farkın istatistiksel olarak anlamlı olmadığı görülmüştür (%61,5 vs %54,2, $p>0,05$). İki çalışma grubu arasında klinik sonuçlar açısından anlamlı fark görülmemiştir ($p>0,05$).

Sonuç: Bu çalışmada hastaların yaklaşık yarısında tüberkül iyileşmesi sağlanamadığı halde klinik sonuçlarda tatmin edici seviyede bir ilerleme elde edildiği görülmüştür. Inlay tasarım protezlerde tüberkül iyileşme oranları daha yüksek olmakla birlikte aradaki farkın anlamlı olmadığı görülmüştür. Bu tasarımın tüberkül iyileşmesi açısından olası üstünlüğünün gösterilmesi için ileri çalışmalara ihtiyaç vardır.

Anahtar Kelimeler Proksimal humerus kırığı · ters omuz artroplastisi · tüberkül iyileşmesi

INTRODUCTION

With a variety of conservative and surgical treatment options, the management of proximal humeral fractures (PHF), one of the most prevalent osteoporotic fractures in the elderly, remains contentious. Due to the low bone density, poor bone microstructure, high rate of comorbidity, and increased risk of falling in this population, the incidence of complex PHF patterns and subsequent need for surgery is markedly high (1, 2). Reverse shoulder arthroplasty (RSA), hemiarthroplasty, and internal fixation are among the surgical procedures that have been documented for treating PHFs (3). Due to previous findings reporting superior outcomes of RSA in the acute setting compared with delayed treatment of PHFs, RSA has grown in popularity as the main treatment option for PHF in the elderly (4, 5).

The Grammont design has constituted the main biomechanical principles of the RSA procedure; yet it was not deprived of certain disadvantages, such as scapular notching (6). For this reason, newer designs were developed, which led to lateralization with lower neck-shaft angle (NSA), a larger glenosphere diameter, or onlay humeral components. Biomechanical studies suggested that lateralization improves range of motion by increasing the tension in the rotator cuff muscles and by lengthening the deltoid. It was also reported that lateralization could decrease incidence of scapular notching by avoiding the contact between the glenoid neck and the humeral tray (6, 7). These advantages have been described well for cuff tear arthropathy. However, the effects of different RSA designs in the treatment of PHFs have not been clearly defined yet. The current data on this topic are controversial due to the heterogeneous cohort characteristics and study designs. This study aims to compare the effects of the RSA design on clinical outcomes and tuberosity healing. We hypothesized that an onlay (lateralized) humeral component would be disadvantageous compared to the inlay (medialized) humeral component in the setting of PHF; since tuberosity repair would be more difficult and tense, which

eventually would lead to unsuccessful tuberosity healing and inferior clinical outcomes.

MATERIAL AND METHODS

This retrospective case-control study was conducted at a single university hospital serving as a referral center for shoulder disorders. The study protocol received approval from the appropriate local ethics board (Date: 25.12.2024, No: 23), and written consent was obtained from all participating patients. The research was carried out in compliance with the principles outlined in the Declaration of Helsinki.

Data from the medical records of all patients with PHF diagnosis who underwent RSA surgery between December 2016 and September 2023 were assessed. Patients were diagnosed through preoperative radiographs and computed tomography (CT) scans. The senior author determined the fracture pattern, classification, and the decision to perform RSA. The inclusion criteria consisted of the following: (1) availability of follow-up data for a minimum of 12 months, (2) presence of head-split type PHFs, 3- and 4-part displaced PHFs, or shoulder fracture-dislocations, (3) time to surgery from injury being less than 4 weeks, (4) RSA intervention using an inlay or onlay design prosthesis with the same surgical approach (deltopectoral approach). The exclusion criteria were: (1) delayed surgery (later than 4 weeks), (2) revision surgery, (3) history of any surgery to the affected shoulder, (4) history of any neurological or rheumatoid condition.

A total of 74 patients were included in the final analysis of this study. Group I consisted of 26 patients treated with an inlay (medialized) design prosthesis, whereas Group II included 48 patients who received an onlay (lateralized) design prosthesis (Figure 1). Each study group comprised two distinct designs. The Lima SMR Reverse (LimaCorporate, Udine, Italy) and Delta Xtend (DePuy Orthopaedics, Warsaw, IN, USA) were used as inlay design prostheses in group I. The Biomet Comprehensive Shoulder System (Biomet, Warsaw, IN, USA) and Next Shoulder

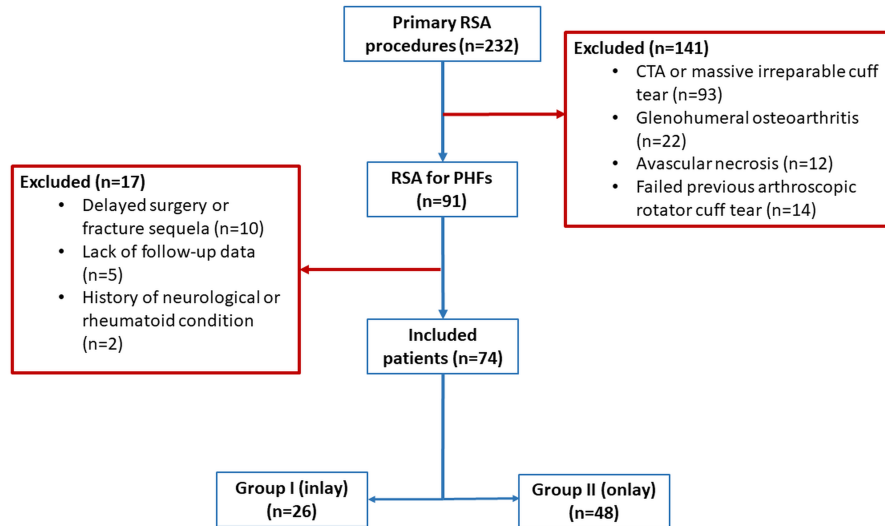


Figure 1. Patient selection flow chart of the study.

RSA: reverse shoulder arthroplasty, CTA: cuff tear arthropathy, PHF: proximal humeral fracture

Solutions (Next, Ankara, Turkey) were used as onlay design prostheses in group II.

All procedures were conducted by the senior author under general anaesthesia, supplemented with an interscalene nerve block, while the patients were positioned in the beach-chair position. The deltopectoral approach was preferred in all patients. There were minor differences in tuberosity detection due to the differences in the fracture pattern. An osteotome was used to separate the lesser and greater tuberosity fracture fragments, and the tuberosities were then secured using No.2 braided non-absorbable Ethibond sutures (Ethicon, Johnson & Johnson). The head fragment was removed and kept for potential use as an autograft source. A standard surgical technique and instrumentation were performed according to the technical instructions of the manufacturing companies. Two holes were drilled into the humeral diaphysis and two No. 2 braided, non-absorbable Ethibond sutures were passed through these holes before insertion of the humeral stem. One loop-suture in “nice-knot” manner was passed through each tuberosity fragment. Following the reduction of the prosthesis, tuberosity fragments were reduced and fixed to the neck of the prosthesis. Then, the tuberosity repair was completed tying the sutures between the tuberosities and finally fixing the tuberosities to the humeral diaphysis using the sutures passing through the holes on the humeral diaphysis. The humeral head fragment was used as a source of autograft to fill the remaining gaps between the tuberosities if needed.

All patients adhered to the identical conventional rehabilitation program and were monitored by the same physiotherapist, who had expertise in shoulder rehabilitation.

Immobilization with an arm sling in 30° of abduction and neutral rotation was applied to all patients for 4 weeks following surgery to allow tuberosity healing. Immediate active wrist and elbow motion was allowed postoperatively. At the postoperative 4th week, passive and active-assistive range of motion exercises were initiated, respecting the pain-free motion limits with gradually increasing intensity. Active range of motion exercises were allowed starting from the 6th week. Deltoid, rotator cuff and periscapular strengthening exercises and shoulder proprioception exercises were initiated at the 10th postoperative week depending on the recovery level of each individual.

All post-operative clinical evaluations were conducted by a single author at 2 weeks, 4 weeks, 3 months, 6 months, 12 months, and annually thereafter. Clinical outcome measures comprised pain score (visual analogue scale – VAS, where 0 signifies no pain and 10 denotes maximum pain), subjective shoulder value (SSV, with 0 points representing the worst outcome and 100 points the best outcome), and simple shoulder test (SST, where 0 points indicate the worst outcome and 100 points indicate the best outcome). SST is a diagnostic questionnaire that was previously translated to Turkish and showed high reliability and validity and good correlation with shoulder function, muscle strength, and the DASH (Disabilities of Arm, Shoulder, and Hand) questionnaire (8). Data from the final clinical follow-up visit were used in the final analysis.

In each follow-up visit, true anteroposterior and axial radiographs of the shoulders were obtained, and tuberosity healing was assessed. Radiological assessments were performed by two independent surgeons and then confirmed

by the senior author. A displacement of >1cm of the tuberosity fragment from the humeral diaphysis or the absence of tuberosity (osteolysis) in the 2 radiographic projections were categorized as tuberosity nonunion.

Statistical analysis

Descriptive statistical methods used to analyse the study data were mean, median, range, standard deviation, and percentage. The normality of the distribution was assessed using histograms, the Kolmogorov-Smirnov test, and the Shapiro-Wilk test. The chi-square test was used for the comparison of categorical data. Quantitative variables were analyzed using an unpaired samples t-test for normally distributed data and the Mann-Whitney U test for non-normally distributed data. All statistical analyses were conducted using GraphPad Prism Software for Windows (Version 9.3.0, San Diego, California, USA), with a significance level established at $p=0.05$.

RESULTS

There were 58 (78.4%) female and 16 (21.6%) male patients. The mean age of the patients was 72.4 ± 7.2 years, and the mean follow-up duration was 51.2 ± 25.4 months. At the final follow-up visit, both study groups showed satisfactory outcomes in terms of all clinical outcome measures. Group I (inlay design) showed superior pain outcome (2.1 ± 2.4 vs 2.3 ± 2.4), superior SST outcome (75.6 ± 22.9 vs 71.7 ± 21.4), and superior SSV outcome (77.1 ± 17.7 vs 74.6 ± 17.8); however, these differences were not statistically significant ($p > 0.05$). Results of clinical outcome measures were resumed in Table 1 (Figure 2).

Table 1. Results of the clinical outcome measures. (Data are interpreted as mean $\pm$ standard deviation.

Outcome measure	Group I (n=26)	Group II (n=48)	p value
Pain score (VAS)	2.1 ± 2.4	2.3 ± 2.4	0.73 ^a
SST	75.6 ± 22.9	71.7 ± 21.4	0.39 ^a
SSV	77.1 ± 17.7	74.6 ± 17.8	0.71 ^a

VAS: Visual analogue scale, SSV: Subjective shoulder value, SST: Simple shoulder test, ^a: Mann-Whitney U test

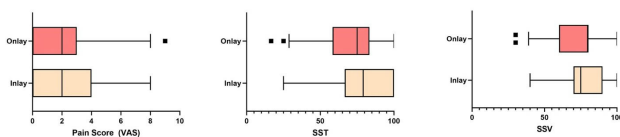


Figure 2. Graphs illustrating the mean clinical outcome scores of the study groups.

VAS: visual analog scale, SST: simple shoulder test, SSV: subjective shoulder value

Table 2. Distribution of tuberosity healing rates of the two study groups

	Group I (n=26)	Group II (n=48)	p value
Healed/not healed tuberosity	16 (61.5)/10 (38.5)	26 (54.2)/22 (45.8)	0.54 ^a

Data are interpreted as frequency (percentage). ^a: chi-square test

DISCUSSION

The present study introduced the clinical and radiological outcomes of inlay and onlay design RSAs performed for the treatment of PHFs. The most important finding of this study is that even though almost half of the patients failed to achieve a successful tuberosity healing, both designs showed satisfactory clinical outcomes. Secondly, unlike our hypothesis, the findings of this study were insufficient to put forward the superiority of the inlay design RSA for PHF since no significant difference was observed in terms of both clinical and radiological outcomes between the two designs.

The majority of previous studies comparing inlay and onlay RSA designs performed for different indications reported comparable results between the two designs (9-13). However, onlay design and lower NSA have been suggested to provide higher external rotation, extension, abduction, and lower scapular notching rates in biomechanical studies due to increased posterior rotator cuff tensioning and deltoid muscle lever arm (7, 10, 14). For a rarer indication of RSA performed in glenohumeral osteoarthritis without rotator cuff tear, no difference was reported between inlay and onlay designs in terms of functional outcomes and complication rates (15).

Despite the presumed advantages of humeral lateralization such as less scapular notching, better deltoid wrapping and efficiency in the case of cuff tear arthropathy where the tuberosities are intact, RSA for PHF relies on different fundamentals. Outcomes of RSA for fracture have been reported to be less reliable than cuff-deficient shoulder (16-18), and tuberosity healing has been identified as the major factor affecting functional outcomes in RSA surgery for PHFs (19, 20). In a recent meta-analysis, the overall rate of tuberosity union was reported to be 68% (21), which was consistent with our findings. Previous reports indicated increased range of motion, lower complication rates, and longer prosthesis survival when anatomical tuberosity healing was achieved (22, 23). A prior biomechanical research stated a notable reduction in the joint reaction forces in the shoulder in instances of tuberosity non-union (24). Therefore, current knowledge recommends that anatomical and stable fixation of the tuberosities should be obtained in RSA for fracture. However, findings of the present study showed that even though in almost half of the patients tuberosity healing could not be achieved, good clinical outcomes and high patient satisfaction

were obtained. This situation raises the idea that tuberosity healing might not be as important as it was thought to be, or that other contributing factors might also be quite important in order to obtain good clinical outcomes. However, it is not yet possible to draw such a conclusion from our findings, and further research with higher evidence is still needed.

The prosthetic features of different RSA designs have variable biomechanical and kinematical impacts for tuberosity healing in the setting of PHF. There are several previous studies reporting the results of different prosthetic designs. However, to our knowledge, the current study is the first to compare the effects of two RSA designs in a single cohort. Mattiassich et al. reported a 72% tuberosity union rate in 32 patients using a traditional Grammont design prosthesis with an inlay humeral stem and 155° NSA (25). Similarly, Torrens et al. reported a tuberosity union rate of 68% with the same prosthesis (26). Comparable tuberosity union rates have also been reported with onlay designs to an inlay RSA design. In their study with 51 patients, Grubhofer et al. reported an overall tuberosity union rate of 81% using an onlay design with a 135° NSA fracture stem. In our study, the tuberosity union rate was slightly higher in the inlay design group (61.5% vs 54.2%) without significant difference. An inlay design would probably be more advantageous due to the easier and more anatomical reduction of tuberosities, less tension during tuberosity repair, and the higher likelihood of tuberosity union. However, the findings of our study were not sufficient to support such an inference and indicated the need for further studies.

Fracture-specific stems have recently been developed to improve the chances of tuberosity union. Metaphyseal windows for grafting, hydroxyapatite or porous covering of the stem, lateral flange for proper tuberosity location, and calcar holes for suture passage are some of the several alterations found in fracture stems. The goal of these changes is to improve the osteointegration between the prosthesis and tuberosities (20). NSA has also been reported to be an important factor for tuberosity healing. A previous biomechanical study comparing RSA designs with 135° and 155° reported that a more stable tuberosity fixation is possible with an anatomical NSA of 135°, which allowed the exact anatomical positioning of the tuberosities (27). Accordingly, in a systematic review by O'Sullivan et al., the authors indicated

that the highest tuberosity union rate was achieved with an anatomical 135° NSA (28). To increase the efficiency of RSA for fracture and to obtain better clinical outcomes, efforts to develop newer prosthetic designs and modifications of current designs continue intensively today.

This study has several limitations. The retrospective nature of the study represents a primary limitation that may have introduced potential selection and assessment bias. Post-hoc power analysis for the comparison of tuberosity healing rates between inlay and onlay prostheses (64.5% vs 54.2%) demonstrated a power of 15.1%, indicating a limited ability to detect a statistically significant difference between the groups. This low power is primarily attributed to the relatively small sample size and the modest observed effect size. While our findings show a trend towards higher tuberosity healing rates in the inlay group, the study was not adequately powered to confirm this difference with statistical significance. Since this study focuses on a considerably specific topic, conducting a study with sufficient power requires an almost infeasible sample size for a single-center study. Secondly, compared to previous reports, the current study has a considerably larger cohort size, which highlights its importance. However, future research with a larger patient cohort is warranted to further investigate the potential impact of prosthesis design on tuberosity healing outcomes in RSA for PHF. Another limitation to note is the absence of interobserver and intraobserver reliability testing for radiological evaluations. All radiological evaluations were conducted following consensus among the observers and confirmation by the senior author. This study represents the first-ever comparison of various RSA designs in this context. Consequently, it contributes significantly to the existing literature. However, it is evident that further research is needed on this topic to clarify the effects of different RSA designs conducted in the setting of a PHF.

CONCLUSION

Our findings demonstrated that RSA is an effective treatment for complex PHFs in the elderly, and that satisfactory clinical outcomes might be achieved regardless of the prosthetic design used as long as an appropriate surgical technique and close clinical follow-up are performed. While inlay RSA showed a slightly higher tuberosity healing rate, the difference was not statistically significant. Further research with larger samples is needed to determine any clinical advantage.



Ethics Committee Approval Ethics committee approval was received for this study from the ethics committee of Bezmialem Vakıf University (Date: 25.12.2024, No: 23).

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Conflict of Interest The authors have no conflict of interest to declare.

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