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Constrained or unconstrained shoulder replacement for musculoskeletal tumor resections?

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Background: Many options exist for reconstructing the shoulder after large bony resections of the proximal humerus. One of the more widely used is endoprosthetic replacement. Proximal migration of unconstrained hemiarthroplasty articulations may cause difficulties particularly in the setting of loss of the rotator cuff and/or deltoid musculature. To attempt to overcome these issues, a fixed-fulcrum constrained reverse shoulder replacement option may be considered.

Methods: A retrospective review of prospectively collected data from the Queensland Bone and Soft Tissue Sarcoma Service was undertaken to compare the function, implant survivorship, and reoperation rate of constrained reverse and unconstrained hemiarthroplasty-type endoprostheses in patients with tumors.

Results: We retrospectively reviewed data on 41 consecutive proximal or total humeral endoprosthetic replacements undertaken between January 2003 and July 2018. One patient was excluded as lost to follow-up prior to 24 months. There were 21 unconstrained implants and 19 constrained shoulder replacements (Stanmore Modular Endoprosthesis Tumour System with Bayley-Walker articulation). Proximal migration of the unconstrained hemiarthroplasty articulation occurred in 8 patients (38%), and dislocation or failure of the constrained mechanism occurred in 5 (26%). Reoperation for implant-related issues was required in 5 patients in the constrained group and none in the unconstrained group. Of the 18 patients alive at the time of review, 12 provided functional scores. The mean follow-up period for surviving patients was 4.2 years (standard deviation, 2.7 years), with a minimum of 2 years' follow-up. Functional scores were similar between the 2 groups.

Conclusion: Constrained reverse prostheses were associated with a higher reoperation rate in this series without any functional benefit compared with unconstrained hemiarthroplasty-type articulations. We favor the use of unconstrained hemiarthroplasty-type endoprostheses for reconstruction after resection of destructive lesions of the proximal humerus.

Level of evidence: Level III; Retrospective Cohort Comparison; Treatment Study

Keywords: Shoulder replacement; Bayley-Walker; oncology; endoprosthesis; proximal humeral replacement

The surgical treatment of primary bone sarcomas and metastatic lesions of the proximal humerus is often limb-salvage surgery with resection of a variable length of the humerus. The clinical challenge is to reconstruct a stable and functional shoulder joint in the presence of rotator

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cuff detachment and, frequently, deltoid dysfunction or resection. Treatment options include osteoarticular allograft, allograft-prosthesis composite, allograft arthrodesis, autograft with clavicula pro humero, extracorporeal irradiation and reimplantation, or the use of a custom or modular endoprosthesis.[1,9,11,17,19,22] Potential advantages of endoprosthetic replacement include the immediate availability of modular systems, a low reported complication rate, and more rapid rehabilitation when not having to await bone union.[5] The intention of hemiarthroplasty is to primarily act as a functional spacer; however, newer designs have afforded reverse articulating reconstruction.

Current implant options include custom or modular implants with hemiarthroplasty, reverse shoulder, and constrained articulations. Unconstrained hemiarthroplasty-type endoprostheses have been reported to develop superior migration, thereby prompting concerns regarding acromial wear, pain, and functionality.[6,8] The reported rates of proximal migration in unconstrained endoprostheses range from 10% to 76%.[3-5,10,13,18] However, in the majority of these studies, proximal migration was not clearly defined. Proximal migration in the setting of humeral endoprostheses has been defined as an acromiohumeral interval of less than 5 mm measured on an anteroposterior (AP) shoulder radiograph.[5] A 5-mm proximal migration interval was first defined in 1970 in the diagnosis of rotator cuff tears in native shoulders on AP radiographs.[24] Proximal humeral ''escape'' has been defined as migration of the prosthesis superior to the level of the acromion.[10,11] To overcome these perceived issues, a fixed-fulcrum constrained reverse shoulder replacement can be considered.

The Bayley-Walker prosthesis has been available since 1973[7] and used on a customized basis in the tumor setting since 1994.[2] The Modular Endoprosthesis Tumour System (METS; Stanmore Implants Worldwide, Elstree, UK) has been available since 2001. The Bayley-Walker articulation was incorporated as an option into its modular proximal humeral replacement system in 2006.[10] Biomechanically, the Bayley-Walker prosthesis is a reverse-polarity fixed-fulcrum total shoulder replacement.[12] The reverse polarity allows medialization of the center of rotation, which permits enhancement of deltoid function and improved stability of the moment arm. The head within a glenosphere affords a highly constrained design that aims to prevent subluxation of the prosthesis. The glenoid component is a hydroxyapatite-coated helical tapered screw that maximizes bending and torsional fixation.[10]

The aims of this study were to review and identify the function and survivorship of the constrained Stanmore METS–Bayley-Walker proximal humeral replacement and to compare this with other unconstrained hemiarthroplasty proximal humeral replacements in a single-center musculoskeletal oncology unit.

Materials and methods

This was a single-center, longitudinal, retrospective cohort study conducted at a large tertiary referral center in Queensland, Australia. We identified 41 patients from the Queensland Bone and Soft Tissue Sarcoma Service database who had undergone proximal humeral resection and endoprosthetic replacement for a benign aggressive or malignant bone tumor between January 2003 and July 2018. One patient was excluded as lost to follow-up prior to 24 months postoperatively. This radiologic and functional outcome study examined unconstrained and constrained endoprostheses. Demographic and treatment information was collected. In addition, we collected complication and reoperation data, as well as functional scoring using the Musculoskeletal Tumor Society (MSTS) scoring system, Toronto Extremity Salvage Score (TESS), and Short Form 12 (SF-12). The choice of prosthesis varied over the study period owing to surgeon preference and the desire to reduce prosthetic costs and try to improve functional outcomes. A shift toward a constrained reverse-type prosthesis using the newer Bayley-Walker articulation occurred after 2006. This article provides a comparison of the unconstrained prosthesis and constrained reverse prosthesis.

Surgery was performed by the 2 senior authors (S.M.M.S. and I.C.D.) in all 40 patients. With the patient in the beach-chair position, a deltopectoral approach was used and included excision of the biopsy tract in the anteromedial deltoid region. Preoperative planning with plain radiographs, computed tomography, and magnetic resonance imaging determined the resection length. The preplanned length of the proximal humerus required for oncologic treatment was resected, and the deltoid muscle insertion was preserved if possible. All stems were cemented with the use of antibiotic-impregnated cement. The humeral component was routinely positioned in 30° of retroversion. A glenoid component was inserted only in the constrained group. Detached rotator cuff muscles were reattached to the prosthesis with nonabsorbable sutures through holes in the prosthesis. A Trevira tube (Mutars; Implantcast, Buxtehude, Germany) or Prolene polypropylene hernia repair mesh (Ethicon; Somerville, NJ, USA) was incorporated to aid in the reattachment of soft-tissue structures in all cases. Deltoid resection was required in 2 unconstrained cases (1 total humeral replacement). There were 2 cases of planned axillary nerve resection (1 constrained and 1 unconstrained) and no cases of unplanned axillary nerve injury. Complete deltoid detachment and reattachment were performed in 5 unconstrained (1 total humeral replacement) and 5 constrained cases. Partial deltoid detachment was performed in 11 unconstrained and 13 constrained cases. Two unconstrained cases had no partial deltoid insertion detachment.

Routine postoperative management included a broad arm sling for 6 weeks. Active range-of-motion exercises of the wrist and elbow were allowed with physiotherapy supervision. Shoulder therapy routinely comprised initial active-assisted range of motion, followed by active shoulder movements at 6 weeks postoperatively. Postoperative routine follow-up in patients with metastatic disease included clinical review at 6 weeks, 3 months, 12 months, and 24 months and then as survival allowed. In patients with primary malignancy, routine follow-up took place every 3 months for the first 2 years, followed by every 6 months until 5 years and, finally, yearly. Plain radiographs were taken at every routine outpatient review to assess stability and the position

of the implant (Figs. 1 and 2). At the latest clinical follow-up, assessment of function via the MSTS score, TESS, and SF-12 score for patient satisfaction was conducted. The questionnaires were administered verbally by us with prior ethical approval and patient consent.

Results

Forty patients underwent proximal (37) or total humeral (3) replacement. The median age at the time of surgery was 54.1 years (interquartile range [IQR], 20.8 years). The median age was 55.5 years (IQR, 28.2 years) in the constrained group and 52.8 years (IQR, 18.5 years) in the unconstrained group. The mean age of patients presenting with metastatic disease was 62.4 years (standard deviation [SD], 11.4 years), and that of patients with primary disease was 44.0 years (standard deviation, 17.2 years). Of the patients, 25 (63%) were men. Surgery was performed on the dominant limb in 7 of the 19 patients who received a constrained prosthesis (37%). In contrast, in the unconstrained group, 12 of the 21 patients (57%) underwent surgery on the dominant arm. The indication for operative intervention was predominantly metastatic disease, followed by primary sarcoma, hematologic malignancy, or benign aggressive bone tumor (Table I). Five resections were undertaken in the setting of an acute pathologic fracture, comprising metastatic renal cell carcinoma (2), giant cell tumor (1), chondroblastoma (1), and metastatic melanoma (1). All operations were primary procedures and were not performed for failure of previous fixation or for arthroplasty revision.

There were 21 unconstrained and 19 constrained humeral prostheses. All constrained implants were METS modular proximal humeral replacements incorporating the Bayley-Walker articulation with a locking ring (Stanmore Implants Worldwide). The unconstrained implants used were as follows: HMRS (Stryker, Kalamazoo, MI, USA) in 12 cases (including 1 total humeral replacement); Global (DePuy Synthes, Warsaw, IN, USA) in 5; Mutars in 2 (total humeral replacements in both); Cofield (Smith & Nephew, London, UK) in 1; and METS with a hemiarthroplasty articulation (Stanmore Implants Worldwide) in 1. The mean resection length was 147.2 mm (SD, 69.5 mm). When total humeral resection patients (3 in unconstrained group) were excluded, the mean resection length decreased to 140.3 mm (SD, 31.1 mm) in the constrained group and 121.0 mm (SD, 45.7 mm) in the unconstrained group.

The 40 patients were followed up for a minimum of 24 months or as allowed by survival. The mean follow-up period was 3.4 years (SD, 3.1 years). Patients with metastatic disease showed a mean follow-up period of 3.0 years (SD, 3.0 years) vs. 5.2 years (SD, 3.3 years) for those with nonmetastatic disease. The mean follow-up period was 3.5 years (SD, 3.2 years) in the constrained group and 3.3 years (SD, 2.9 years) in the unconstrained group. Of the 40 patients, 22 had died by the time of this review. The mean time from the date of surgery to death was 2.6 years (SD, 3.2 years) (2.5 years for both constrained and unconstrained cases). Twelve patients (30%) died within 12 months of

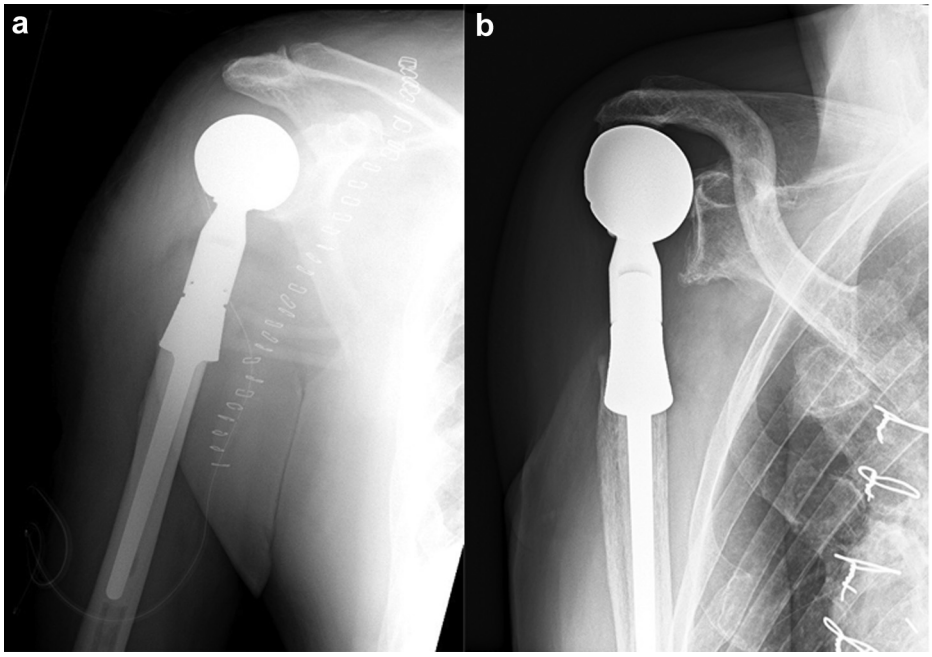

Figure 1 (**a**) Radiograph in a 65-year-old male patient who underwent placement of an unconstrained hemiarthroplasty (MRS [Stryker, Kalamazoo, MI, USA] modular hemiarthroplasty) for chondrosarcoma in 2009. (**b**) Radiograph showing proximal migration of the unconstrained hemiarthroplasty in the same patient at 9 years postoperatively.

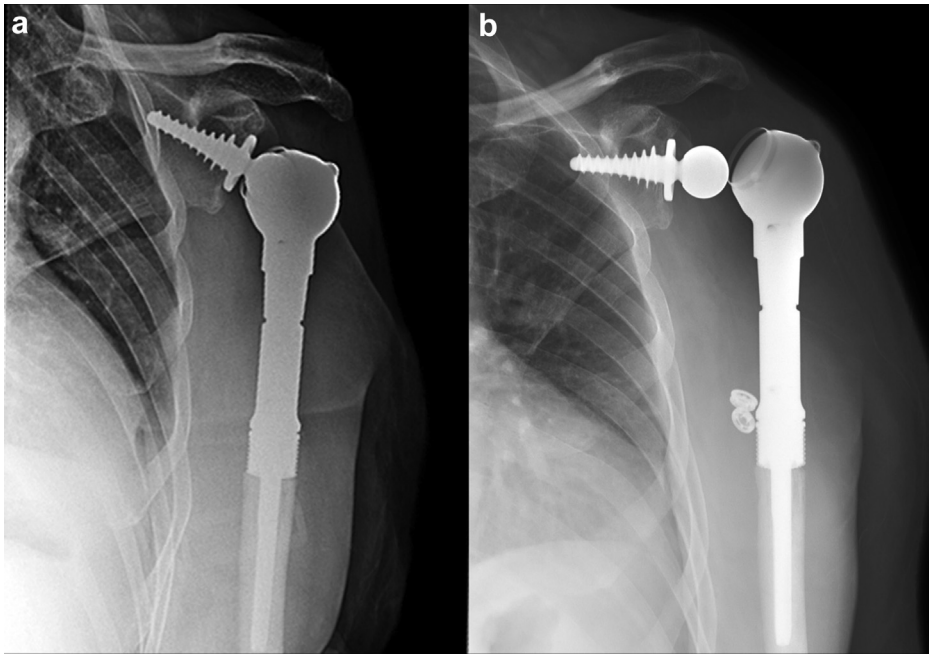

Figure 2 (**a**) Radiograph in a 70-year-old male patient who underwent placement of a constrained reverse Bayley-Walker prosthesis for chondrosarcoma resection. (**b**) Radiograph of the same patient showing dislocation of the Bayley-Walker prosthesis with the locking ring intact at 5 months postoperatively.

shoulder surgery, and an additional 7 patients (48%) died within 5 years.

Seventeen patients (42%) underwent neoadjuvant and adjuvant chemotherapy. Ten patients (25%) received postoperative radiotherapy. Local recurrences developed in 2 patients (a dedifferentiated chondrosarcoma and an osteosarcoma). Both patients proceeded to undergo forequarter amputation (1 with a Bayley-Walker prosthesis and 1 with a total humeral endoprosthesis). No infections occurred. There were no cases of aseptic loosening of either the humeral or glenoid component.

Of the 18 patients alive in this study, 6 declined to participate at the time of our retrospective review. The remaining 12 patients underwent functional assessments using the MSTS score, TESS, and SF-12 score (Table II). The 12 patients comprised 7 constrained and 5 unconstrained cases (including 1 total humeral prosthesis). The mean follow-up period of these 12 patients was 4.8 years (SD, 2.8 years). No difference in handedness was found between the unconstrained and constrained groups.

In the unconstrained prosthesis group, 8 of 21 patients (33%) experienced radiologic proximal migration. Proximal migration was defined as an acromiohumeral interval of less than 5 mm on an AP shoulder radiograph (Fig. 1, *b*). Among the patients deemed to have proximally migrated implants, the implant remained contained beneath the acromion in 6 and migrated superior to the acromion in 2. Proximal migration was either asymptomatic or had minimal symptoms that did not warrant surgical intervention. It was often found incidentally on routine radiographic follow-up. No reoperations for proximal migration were performed in our cohort.

Table I Histologic diagnoses of patients undergoing proximal or total humeral replacement

Diagnosis	All patients, n	Constrained, n	Unconstrained, n
Metastatic disease	19 (renal cell carcinoma in 8)	8	11
Chondrosarcoma	7	4	3
Osteosarcoma	4	1	3
Lymphoma or myeloma	3		3
Giant cell tumor of bone	2	2	
Leiomyosarcoma	2	2	
Pleomorphic sarcoma	1	1	
Angiosarcoma	1		1
Chondroblastoma	1	1	

Table II Patient functional scores using MSTS, TESS, and SF-12 scoring systems

	Mean (CI)	SD	Min	Max
MSTS score, %				
Constrained (n = 7)	60.4 (±3.8)	10.1	46.7	66.7
Unconstrained (n = 5)	43.3 (±7.8)	17.5	20.0	63.3
TESS, %				
Constrained (n = 7)	64.1 (±5.5)	14.5	44.2	87.2
Unconstrained (n = 5)	61.7 (±8.1)	18.1	43.6	81.9
SF-12 physical health composite score				
Constrained (n = 7)	43.3 (±3.6)	9.5	31.8	60.1
Unconstrained (n = 5)	40.4 (±4.3)	9.5	24.9	49.8
SF-12 mental health composite score				
Constrained (n = 7)	42.5 (±5.1)	13.4	25.6	61.2
Unconstrained (n = 5)	42.5 (±7.0)	15.6	38.1	58.2

MSTS, Musculoskeletal Tumor Society; *TESS*, Toronto Extremity Salvage Score; *SF-12*, Short Form 12; *SD*, standard deviation; *Min*, minimum; *Max*, maximum; *CI*, confidence interval.

In the constrained prosthesis group, 5 of 19 patients (26%) experienced a mechanical failure of the constraint mechanism (Fig. 2, *b*). This led to 8 additional surgical procedures. In 4 of these 5 patients, the humeral component dislocated from the glenoid component with the locking ring intact. In the remaining patient, the polyethylene component of the proximal humeral segment detached from the proximal humerus and remained attached to the glenoid component. These failures occurred at an average of 12.6 months (range, 1-27 months) after surgery. In 3 patients, dislocation occurred twice. One patient declined further surgery, and dislocation remained. This patient's implant proximally migrated but he had clinically acceptable function and was able to return to his previous occupation. The 2 other patients underwent subsequent revision surgery and, at the time of this review, showed no dislocation. There were no cases of dislocation in patients with deltoid detachment or axillary nerve resection in the constrained group.

On analysis of the 12 patients able to provide functional scores, no difference in function was found between the constrained and unconstrained prostheses using the MSTS score, TESS, and SF-12 score (Table II). The role of the SF-12 in this study was to control for general health; the scores confirmed that the 2 groups were comparable.

Discussion

During the study period, there was a change in clinical practice, with an increase in the use of constrained endoprostheses because of concerns regarding the functional outcomes, proximal migration, and stability of unconstrained prostheses. Published results regarding the Bayley-Walker constrained articulation used in the METS modular proximal humeral replacement are limited. Long-term outcomes have not been reported. A design-center review published by Griffiths et al[10] evaluated 68 Bayley-Walker prostheses. The reported dislocation rate was 25.9%. Closed reduction was attempted in all patients but was unsuccessful. Open reduction of the dislocated prosthesis was performed in only 4 patients, whereas in the remaining 10, the dislocation was left untreated. A design change was reported during the study period, with the last 4 patients receiving an implant with a metal locking O-ring incorporated into the implant to limit dislocation. None of these patients reportedly dislocated at a relatively short mean follow-up of 14.5 months. Griffiths et al predicted improved performance and a reduced dislocation rate with the newly designed locking ring.

Our series used this locking-ring construct, but despite this technical modification, dislocations still occurred. Of the 5 dislocations in our series, 4 occurred with the locking ring still intact, indicating that the locking ring has not solved the issue of dislocation (Fig. 2, *b*).

Maclean et al[12] reported on a series of 8 Bayley-Walker prostheses in 2017 with a mean follow-up period of 49 months. None of these 8 cases were reported to have a dislocation. The mean MSTS score was 60.0%, and the mean TESS was 62.7%. The reported functional scores are similar to those found in our study (60.4% and 64.1%, respectively). The authors concluded that the implant provided excellent medium-term survivorship and pain relief.

We consider that the fixed-fulcrum constrained reverse implant dislocates because of biomechanical factors. The permitted range of motion appears restrictive, and it is likely that repeated impingement leads to the polyethylene deformation and eventual dislocation even with the locking ring intact. The addition of a locking O-ring, in an attempt to prevent this complication, has not achieved success in eliminating this problem.

The reported rates of proximal migration in unconstrained prostheses range from 10% to 76%.[3-5,10,13-16,18,21,23] Cannon

et al,[5] using the same 5-mm AP radiograph definition of proximal migration as in our study, reported proximal humeral migration in 22 of 76 patients (29%) with unconstrained prostheses. Our series showed a comparable radiographic proximal migration rate of 38%. There were no reoperations for implant-related issues in our unconstrained group. The reported reoperation rate for proximal migration or dislocation in unconstrained endoprostheses is 0%-19%.[5,11,13-16,21] The data suggest that proximal migration is a known phenomenon that rarely requires reoperation. We acknowledge that the decision to reoperate is clinician driven and may lead to bias in reported results. This is a potentially significant limitation.

Evaluation of function in shoulder endoprostheses has been reported in several studies using the MSTS, TESS, and SF-12 scoring systems. There are a number of case series with differing prostheses and resection lengths, thereby making relevant comparison a challenge. The MSTS score for unconstrained endoprostheses has a reported range of 63%-90%,[3,5,10,11,14,15,17,20,21,25] and the TESS has a range of 72%-82%.[11,14,20] In constrained prostheses, the MSTS ranges from 60% to 77.7%[10,12] and the TESS ranges from 62.7% to 77.2%.[10,12] In the literature, there are no comparative studies that have evaluated unconstrained and constrained prostheses. Our study demonstrated no difference in functional scores using the MSTS, TESS, or SF-12 scoring system.

This study reports on a consecutive series of patients from a single center specializing in orthopedic oncologic surgery. The study limitations include the retrospective nature of the review. In addition, multiple types of unconstrained hemiarthroplasty were used; however, we expect similar function with each hemiarthroplasty articulation. We acknowledge a shift toward the increased use of a newer design of constrained implant toward the end of the study period. The uptake of a new implant can have a confounding influence on results; however, the results obtained by the experienced oncology surgeons in our series are similar to those reported by the design center. Only a relatively small number of patients provided functional scores, and it is acknowledged that greater numbers may potentially alter those results. Although death is a competing risk factor, we consider that the results from this series remain relevant in terms of comfort and function for the expected life span of this cohort. In addition, there was variation in proximal humeral resection lengths. Finally, the functional scores and measurements of proximal migration were obtained by us, leading to potential assessment bias.

Conclusion

We reviewed our consecutive series of endoprosthetic proximal and total humeral replacements performed to reconstruct skeletal defects created by tumor resection surgery. The use of a constrained reverse articulation did not result in a demonstrable improvement in function. It did lead to a high dislocation and reoperation rate. The reported modification to the implant design has not, in our experience, been effective in reducing a concerning rate of implant failure. We advise caution in the use of this constrained reverse implant and favor unconstrained endoprostheses for shoulder resection surgery.

Disclaimer

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