

Retrospective Study

Use of Ligament Advanced Reinforcement System tube in stabilization of proximal humeral endoprotheses

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Abstract

AIM: To review outcomes following usage of the Ligament Advanced Reinforcement System (LARS®) in shoulder tumors.

METHODS: Medical records of nineteen patients (19 shoulders) that underwent tumor excisional procedure and reconstruction with the LARS synthetic fabric, were retrospectively reviewed.

RESULTS: Patients' median age was 58 years old, while the median length of resection was 110 mm (range 60-210 mm). Compared to immediate post-operative radiographs, the prosthesis mean end-point position migrated superiorly at a mean follow up period of 26 mo ($P = 0.002$). No statistical significant correlations between the prosthesis head size ($P = 0.87$); the implant stem body length ($P = 0.949$); and the length of resection ($P = 0.125$) with the position of the head, were found at last follow up. Two cases of radiological dislocation were noted but only one was clinically symptomatic. A minor superficial wound dehiscence, healed without surgery, occurred. There was no

evidence of aseptic loosening either, and no prosthetic failure.

CONCLUSION: LARS[®] use ensured stability of the shoulder following endoprosthetic reconstruction in most patients.

Key words: Proximal humeral endoprotheses; Ligament Advanced Reinforcement System

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Core tip: Endoprosthetic replacement of the proximal humerus for tumor resection offers predictable outcome. In an attempt to optimize functional scores, the use of Ligament Advanced Reinforcement System (LARS) tubes was facilitated. Our retrospective analysis revealed that LARS was not associated with specific complications. Its ability to ensure shoulder stability was good, albeit not perfect. Superior migration of the humeral head was common over time.

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INTRODUCTION

Latest advances in the diagnosis and management of neoplastic diseases, conferring prolonged life expectancy, have resulted in limb-salvage surgery as the main treatment choice for patients with bone and soft tissues sarcomas^[1-4]. Endoprotheses use has increased over the last 30 years with the overall 5-year survival rate rising from 20% to 85%^[1,3,5].

The upper extremity neoplasms are a third less common than lower extremity ones^[6]. Metastatic Bone Disease (MBD) is the most common cause of destructive bone lesions in adults, with the humerus as the second most common site, following the femur^[7-9]. The proximal humerus (PH) is also the third most common region for osteosarcoma^[6]. Even though limb-sparing surgery is the treatment of choice for 95% of tumors of the shoulder girdle, significant functional loss may follow^[10]. Since the first reported operation, a partial scapulectomy for an aneurysmal tumor of the subscapular artery performed by Liston^[11] in 1819, many surgical techniques have been described. Tumors of the PH should always meet the following values: (1) oncological principles of resection; (2) reconstruction of the missing segment; and (3) soft tissue reconstruction^[10]. The success of any technique is established upon the ability to achieve a long disease-free survival, and a stable and functional shoulder

joint. This may be impeded by complications such as aseptic or septic loosening, infection and mechanical failure^[11,12]. Recently, a new classification of these complications has been proposed with soft tissue and joint instability referred to as Type 1 failure^[13]. An unstable joint may lead to pain, discomfort, distress and inability to benefit from maximal usage of the hand and elbow. Stability relies primarily on the soft tissue envelope which includes: Labrum, joint capsule, rotator cuff and surrounding muscles. Maintaining joint stability can be rather challenging after the extensive resection of these structures, and albeit fundamental, ability to reattach soft tissues to the implant remains limited^[13-15]. Although various implant suspension methods using tapes, wires or tendons have been described^[16-21], the incidence of instability or dislocation has rarely been studied.

Capsuloplasty is achieved through reconstruction of the shoulder capsule with synthetic or collagenic tissue to secure stability. A previous study reported a 4.3% incidence of cranial subluxation of the proximal or total humerus prosthesis with synthetic Trevira[®] use^[2]. The Ligament Advanced Reinforcement System (LARS[®], Arc-sur-Tille, France), an artificial fabric made of polyethylene terephthalate, presents a great capacity for cellular and connective tissue properties both in the *in vitro* and *in vivo* studies^[22,23]. It has been used mainly for knee ligament augmentation or replacement^[24-27]. Our purpose was to report the results of the LARS[®] tube in the stabilization of proximal humeral endoprosthetic replacement for tumors, and to categorize any potential risk associated with its use.

MATERIALS AND METHODS

We retrospectively reviewed the medical records of 19 consecutive patients who underwent proximal humeral replacement, either due to sarcoma or to metastatic disease, followed by soft tissue reconstruction with LARS[®] synthetic fabric (LARS, Arc sur Tille, France). All procedures were performed by a single surgeon (RT). Implants were all Modular Replacement System of PH (MRS PH) (Stryker Orthopaedics Kalamazoo, Michigan, United States) (Figure 1). Extra articular resection was performed in one case only. Patients were operated through a standard deltopectoral approach with en bloc resection of the biopsy tract when applicable. According to the length of resection and soft tissue invasion, muscles and tendons were excised or detached from their bony attachment. Resection of the deltoid muscle may have differed based on the primary diagnosis. Joint capsule and rotator cuff tendons were sectioned at joint line level, and the labrum was preserved in all intra-articular resections. The axillary nerve was sacrificed in 2 cases. Surgical margins were assessed intraoperatively by pathologists. Reaming of the humeral medullary canal was performed and stem size was selected based on line to line sizing (French paradox)^[21,28]. Implants were selected with respect to the length of resection and the humeral head size,

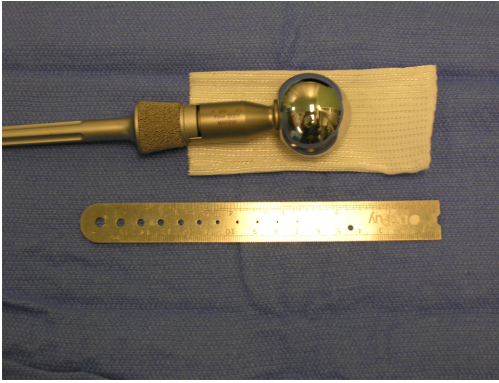


Figure 1 The prosthesis used was the Modular Replacement System of Proximal Humerus (Stryker Orthopaedics Kalamazoo, Michigan, United States).



Figure 2 Proper preparation of the Ligament Advanced Reinforcement System tubing that was cut the appropriate length to properly cover the head and body but short of covering the porous surface of the implant immediately adjacent to the host humerus.

Table 1 Classification of humerus head implant position

1 > 50% inferior migration of Prosthesis H.Head
2 < 50% inferior migration of Prosthesis H.Head
3 = Centralized
4 < 50% superior migration of Prosthesis H.Head
5 > 50% superior migration of Prosthesis H.Head
6 = Unstable

either 40 or 44 mm. Proper cementation of the definitive construct was then performed ensuring the expected 40-45 degrees of retroversion of the head. The LARS® tube was cut the appropriate length to properly cover the head and body but short of covering the porous surface of the implant immediately adjacent to the host humerus (Figure 2). The fabric was secured to the implant with #5 Ethibond® sutures. The proximal end of the tube fabric was spitted open allowing suturing to the remaining glenoid capsule and labrum in a circumferential manner figure of eight with #2 Ethibond® sutures (Figures 3 and 4). This usually led to an initial passive range of motion approximating 50 degrees of abduction and flexion and 40 degrees of internal and external rotation. No anchors were used. Shoulder stability was evaluated by pulling the arm longitudinally from the scapula and found stable in all directions. Severed tendons and muscles were reattached to the fabric with non resorbable sutures when possible. Postoperatively, the upper extremity was left into an arm and cuff sling for 6 wk, to allow for scarring, after which it was discarded. Active and passive ranging of the elbow and hand was encouraged right after surgery. Particular attention was paid to the stability of the implant and the existence of any identifiable adverse effect of the LARS fabric. Digitized radiographs were obtained with patient in standing position and without any arm support.

Two independent reviewers performed a double-blind evaluation of the Anteroposterior (AP) views of the digitized radiographs. An object of known size was used as a marker to identify any magnification error. In order to evaluate the position of the prosthesis and the

glenohumeral translation in the follow-up period, the percentage of the prosthesis head in correlation with the glenoid center, and with the superior and inferior glenoid rims, was assessed (Figure 5). The difference in distances between the midline from the glenoid center, and the midline from the center of the head of the prosthesis, was estimated and classified as shown in Table 1. Additionally, shoulder stability was evaluated by reviewing clinical notes. Functional assessment was based on the 1987 Musculoskeletal Tumor Society functional scoring system (MSTS)^[29] collected prospectively preoperatively and at 3, 6, 12, 24 and 36 mo after surgery^[29]. The analysis was performed by means of statistical software package (IBM SPSS v.19.0) statistical package. This study was approved by the hospital ethics committee. Study comprised 19 shoulders from 19 patients that underwent endoprosthetic replacement of the proximal humerus. Bone sarcoma made for 10 cases and metastatic disease for 9.

RESULTS

Ten patients were male. The median age was 58 years old (range: 23 to 77 years). Fifteen patients were right handed, three were left handed and one described himself as ambidextrous. Resection involved the right side in only 10 patients. Two thirds of cases (68%) presented with pathological fractures, and four patients had received neoadjuvant and adjuvant chemotherapy. Patients' characteristics are listed in Table 2. Following appropriate and individualized oncological pre-operative management, they underwent proximal humeral replacement and soft tissue reconstruction using the LARS synthetic fabric. The median length of resection was 110 mm (range 60-210 mm). The median humerus head size was 44 mm (range 35-50 mm), however, in 2 cases head size could not be measured due to the extent of bony destruction. In 9 patients the 40 mm modular head implant was selected and the rest received the 44 mm prosthesis. The implant body median length was 60 mm (range 40-140 mm). Utilizing the LARS

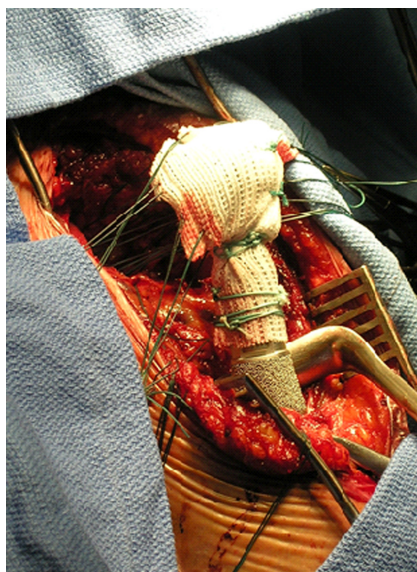


Figure 3 Suturing the remaining glenoid capsule and labrum with the proximal end of the fabric.

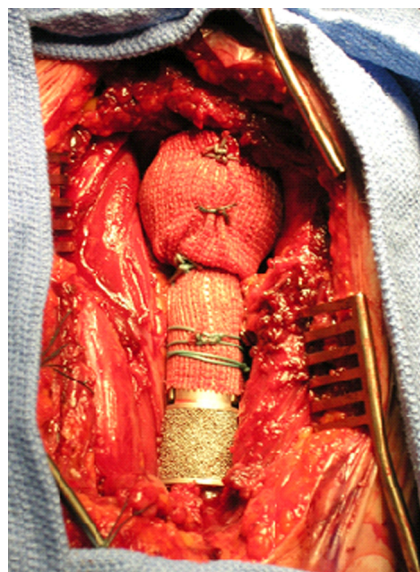


Figure 4 Final position of the proximal humeral endoprosthesis.

Table 2 Patients characteristics

Patient	Sex	Age	Diagnosis	Lesion side
1	Male	43	Ewing sarcoma	R
2	Male	58	Telangiectatic osteogenic sarcoma	R
3	Female	31	Chondrosarcoma	L
4	Female	53	Metastatic carcinoma renal cell primary	R
5	Male	67	Metastatic lung primary	L
6	Female	51	Metastatic lung primary adenocarcinoma	R
7	Male	64	Chondrosarcoma	L
8	Female	63	Metastatic thyroid	L
9	Female	52	Chondrosarcoma	R
10	Female	64	Metastatic clear cell renal	L
11	Male	23	Ewing sarcoma	L
12	Male	54	Metastatic renal cell carcinoma	R
13	Female	61	Metastatic breast	R
14	Male	70	Metastatic renal	L
15	Female	51	Metastatic undifferentiated sarcoma of bone	L
16	Female	68	Chondrosarcoma	L
17	Male	66	Metastatic clear cell renal	R
18	Male	77	Metastatic lung adenocarcinoma	R
19	Male	52	Multiple myeloma	R

L: Left; R: Right.

tube allowed the deltoid to be reattached in 9 patients and the pectoralis major and long head of the biceps (or what was left of it) in 8 patients. Primary closure was achieved for all patients with no need for flap mobilization. No significant neurological deficit affecting elbow and hand function was identified. No local recurrence was detected as per clinical examination and radiological evaluation. Although mechanical loosening was not found, one patient complained of discomfort relating to gross instability. No identifiable adverse local tissue reactions were noted and there was no sign of delayed wound healing, even in patients who had

undergone preoperative radiotherapy. A single case of minor superficial wound dehiscence, requiring minor care, occurred in the perioperative period. Radiological follow-up ranged from 14 to 2400 d (mean = 418 d). The overall follow-up period ranged from 14 to 2400 d (mean = 806 d).

Based on the proposed classification for head positioning with respect to the glenoid, statistical analysis revealed a mean post-operative starting position of 2.63 (from 3 = centralized head in the glenoid). The prosthesis mean final position was 3.68 (as 4 means < 50% superior migration). The prosthesis mean end-position tended to migrate more superiorly, at a mean follow up period of 26 mo ($P = 0.002$) (Figure 6). Inter observer reliability with respect to interpretation of the radiographs was very strong (kappa = 0.929 $P < 0.01$), thus, strength of agreement was almost perfect according to the Landis and Koch criteria^[30]. During the follow up period, 2 prostheses were considered radiographically dislocated, but only one was symptomatically unstable and dislocated, requiring further surgical stabilization. No statistical significant correlation was found between the head size of the prosthesis used ($P = 0.87$); the size of the implant stem body height ($P = 0.949$); the length of resection ($P = 0.125$), and the position of the head at last follow up.

The functional results were described based on the functional rating system of the Musculoskeletal Tumor Society and the Toronto Extremity Salvage Score (TESS)^[29,31,32]. Mean preoperative MSTs and TESS scores were 15.2 and 62.9, while the postoperative mean scores were 15.5 and 65 respectively. There was no correlation between preoperative MSTs score and end-function.

DISCUSSION

Endoprosthetic replacement of the PH offers a pre-

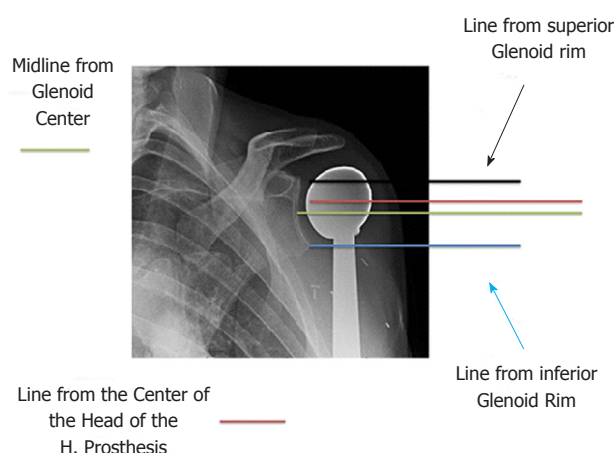


Figure 5 Radiological assessment of humerus head implant position.

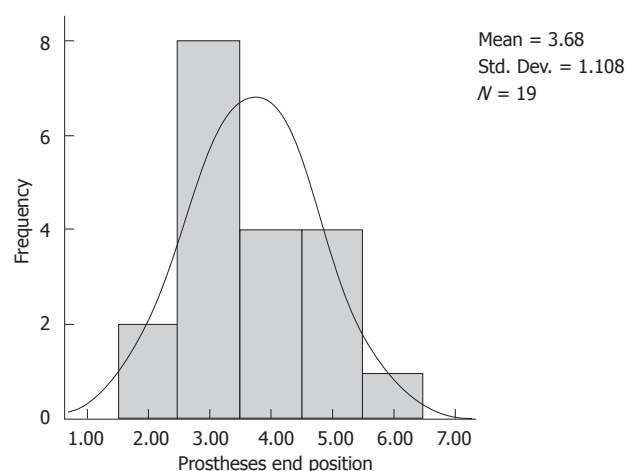


Figure 6 Prosthesis end position.

dictable outcome, with acceptable cosmetic and complication rates, albeit the functional results are limited by the lack of active mobility and strength. It is a durable construct however, stability remains a challenge.

Since the first endoprosthetic PH replacement by Pean in 1893, with a platinum and rubber alloy implant, many different procedures have been described^[33]. Sacrificing the rotator cuff and the deltoid in favor of oncological wider margins, and symptomatic instability with painful impingement on the subacromial arch, have been challenging potential complications^[15]. Several authors have advocated capsuloplasty, using a mesh-like fabric aiming at providing a more stable prosthesis by fixing the prosthesis to the glenoid, and allowing the reattachment of the surrounding muscles and tendons^[16,34,35]. Capsuloplasty, using Dacron aortic graft and Trevira Tubes, has been studied and reports support its usage^[34]. The common features that characterize these fabrics are biocompatibility and porosity that encourage tissue ingrowth, and strength that reduces shearing forces. By using Dacron aortic graft, authors have reported a decrease in symptomatic instability with no increase in infection or reoperation rates^[34]. Improvement of post-operative shoulder function was demonstrated and thought to be related to reattachment of the rotator cuff to Trevira tubes around the prosthesis^[36]. Histopathological examination of the soft tissue surrounding Trevira tubes revealed ingrowth of fibrous tissues and no foreign body granuloma or inflammatory process^[36]. LARS[®] was used to reconstruct soft tissue around four knees and three proximal femurs after tumor resection, and was found to be effective in improving stability and providing muscle attachment^[22].

Being a retrospective study and having a heterogenic small sample size of patients are among the few study weaknesses followed by the fact that there was not a control group of patients without LARS to compare with. We identified two cases with dislocation (10.4%), although only one was symptomatically unstable. Follow up period was relatively short and it is possible that further proximal migration of the implant may be noted after a longer follow up period. However, migration

tended to occur early on and then stabilized. Moreover, our classification proposal may have been thought to be among our study's weaknesses as it has never been described before. There was no other complication of significance including deep infection. Our work is among the few studies reporting about LARS for stabilization of proximal humeral prostheses. Some studies reported instability ranging between 0% and 11% using other types of fabric or techniques^[16,34,36]. A recent series of interscapulothoracic resection for shoulder tumors found no difference in stability whether LARS was used or not^[37]. Our study differs from others as we recorded progressive migration of the implant over time^[38]. We found that most implants migrated superiorly and anteriorly. Implants stable in their end position were found to be without measurable clinical effect. Our only symptomatic patient had gross instability on every attempt at active shoulder motion.

Our study, as others, supports the reconstruction of the shoulder capsule as an effective way of minimizing symptomatic instability. It is unclear which, if any material would be superior to another. It remains unclear in other studies if there was a progressive superior and anterior migration of the implant over time, but it certainly could not be prevented with the LARS[®] and the suturing technique utilized here. Nevertheless, it resulted in a stable construct in 18 of the 19 cases and provided adequate function of the elbow and hand. Even in cases when there may be some migration, the consequences for stability and overall function would be of minor clinical relevance.

COMMENTS

Background

Malignant tumors or metastasis of proximal humerus may cause significant loss of function. Endoprosthetic replacement is the most common way to reconstruct the resected bony part following limb salvage procedure, provide normal use of the hand and elbow and optimize the shoulder's postoperative functional outcome.

Research frontiers

Shoulder implant instability leads to pain, discomfort, and inability to benefit of the

functional outcomes of the procedure. Maintaining joint stability is challenging.

Innovations and breakthroughs

Use of the LARS® tube in the stabilization of proximal humeral endoprosthetic replacement for tumors and identification of any potential risk associated with its use.

Applications

Literature has advocated the use of various types of tissue, including synthetic or xenograft, to help reconstruct a new capsule over the proximal humeral endoprotheses and maintain the proper positioning and stability. This retrospective analysis revealed that facilitation of LARS tubes in the endoprosthetic replacement of the proximal humerus was not associated with specific complications and proved to provide good, although not perfect, shoulder stability. Longer length of follow up would be needed to confirm that proximal and anterior migration does not progress.

Terminology

LARS is an abbreviation for Ligament Advanced Reinforcement System. TESS is an abbreviation for toronto extremity salvage score. MSTs is an abbreviation for musculoskeletal tumor society score.

Peer-review

This article is very good.

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