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Patient Selection for Biodegradable Subacromial Spacer Implantation

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Abstract

Objectives: This study reports on cases of implanted biodegradable subacromial spacer (InSpace Balloon) in irreparable rotator cuff tears and aims to give guidelines for patient selection for implantation of subacromial spacer. We measured GH distance, range and strength of abduction and VAS, TCS and ASES scores of 29 patients before a surgery and after the implantation of subacromial spacer. History of previous shoulder surgeries (first *vs*. revision), condition of subscapularis (intact or irreparable *vs*. reparable) and condition of Long Head of the Biceps tendon (LHB), (tenotomy vs. tenodesis, previous tenotomy or rupture), and the need for subacromial decompression during surgery (yes *vs*. no) are considered in a sex-specific manner. Inferential statistics exposed factors that significantly influence the outcome of an operation. Additionally, we discuss radiologically and intraoperatively assessed condition of GH and AC arthrosis and the size of implanted balloon.

Patients: Our study included 29 patients (17 males, 12 females) that were treated in Orthopedic Hospital of Valdoltra (Slovenia) between January 2016 and October 2017. In all patients, we implanted biodegradable subacromial spacer (InSpace Balloon).

Methods: Statistical analysis was performed in R using WRS2 package [Mair, P., and Wilcox, R (2018). WRS2: Wilcox robust estimation and testing] for robust inferential statistics with no assumption of normality and homoscedasticity. The outcome of a surgery was assessed by GH distance, abduction range and strength, and VAS, TCS and ASES scores before and after implementation of a subacromial spacer.

Results: Abduction range of motion, strength, VAS, TCS and ASES scores showed significant differences in their values before and after the surgery. GH distance decreased from 8.6 before to 8.1 after the surgery, but the difference was not significant. Patients were further split into groups with respect to their gender and factors that we hypothesized to be influential on the outcome of the surgery. Condition of subscapularis tendon, history of previous shoulder surgeries and the need for subacromial decompression during surgery showed significant influence on the outcome of a surgery; on the other hand, data does not provide support for the influence of the condition of subscapularis tendon.

Conclusion: Implantation of subacromial spacer is a safe and effective method for treatment of irreparable rotator cuff tears. Condition of subscapularis tendon, history of previous shoulder surgeries and the need for subacromial decompression should be considered before the surgery in a sex-specific manner as they significantly influence the outcome of the surgery with respect to various criteria. These factors could potentially be used to predict the outcome of the surgery, provide guidelines and implement a decision support system for patient selection for implantation of subacromial spacer. Overall, implantation of subacromial spacer in irreparable rotator cuff tears showed very good results with high patient satisfaction and pain relief.

Keywords: Irreparable rotator cuff tear; Subacromial spacer; RC; CS

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Introduction

The best surgical solution for irreparable Rotator Cuff (RC) tear is still a challenge. Massive irreparable RC tears are defined as tears ≥ 5 cm and/or two or more completely torn tendons involved. There are many options for repair (subacromial decompression and debridement, partial tendon repair, tendon transfer, reverse prosthesis…) but there are no definitive guidelines concerning the preferred method [1]. Every technique is not suitable for each and every patient

and patient expectations regarding outcome are different according to age, sex, and occupation and sport activities. In patients with irreparable RC tear some surgeons recommend reverse shoulder arthroplasty even in the absence of glenohumeral arthritis [2-4]. One option is implantation of biodegradable subacromial spacer (Inspace balloon) between the acromion and humeral head. Its effect by increasing Constant Score (CS), Range of Motion (ROM) and action on pain relief is known. Fast and non demanding operation gives comparable results to other more complex surgical interventions [5,6]. Patient's inclusion criteria for the implantation of subacromial spacer are still under debate. With this article we tried to predict the most appropriate patient selection for implantation of subacromial spacer in irreparable rotator cuff tears.

Materials and Methods

Study design

The study was approved by the hospital Ethical Committee. It was designed as a single center, prospective study to assess the best patient selection for implantation of subacromial spacer. All patients were voluntary included in the study. All subjects had persistent pain and functional disability for at least five months, had failure of conservative therapy and had imaging confirmation of RC tear by either CT or MR arthrography. All patients had at least one cycle of physiotherapy preoperatively and in 45% (13/29) of patients implantation of subacromial spacer was a revision procedure. Exclusion criteria included significant shoulder osteoarthritis (≥ grade III in the Hamada classification), shoulder infection or systemic immunosuppression. Final confirmation of RC tear, tendon involvement and reducibility was made during surgery. Condition of subscapularis tendon, Long Head of Biceps (LHB) tendon, glenohumeral arthrosis and the need for subacromial decompression was also assessed during surgery. The size of implanted balloon was measured. Patient's pain, range of motion, activities of daily living and shoulder strength were evaluated using Constant Score (CS) and ASES score before and after surgery at 3 and 6 months follow up. All patients had X-ray of affected shoulder in AP and Y projections preoperatively and postoperatively. Acromiohumeral distance, AC arthrosis and glenohumeral arthrosis according to Hamada classification were measured on X-ray.

Surgical technique

The implantation was performed utilizing arthroscopic shoulder procedure with the patient in general anesthesia and interscalene block in lateral decubitus position. All procedures were done by two experienced shoulder surgeons. At least 3 arthroscopic portals (posterior, anterior and lateral) were used for removal of subacromial bursa and debridement of the tear. In cases of massive immobile tear and poor quality tissue a decision was made to insert the subacromial spacer. The subacromial biodegradable spacer is a biocompatible and biodegradable balloon made of copolymer poly (L-lactide-co-ε-caprolactone). It is arthroscopically implanted between acromion and humeral head. Some authors use fluoroscopy-guided insertion technique with patient in local anesthesia. In all shoulders the concomitant pathology was addressed if needed. To select the appropriate spacer size the subacromial space was measured using an arthroscopic probe between lateral acromion and 1 cm to 2 cm medial to glenoid rim at 12.00 o'clock position. Spacer was introduced through the lateral portal and inflated with saline solution as recommended by the manufacturer. After initial over inflation there was a small backflow of saline solution into syringe until the final volume was achieved. 3 small (40 mm × 50 mm) (10%), 18 medium (50 mm × 60 mm) (62%) and 8 large (60 mm × 70 mm) (28%) spacers were implanted all together. At the end of the procedure the shoulder was taken through a full range of motion to confirm the stability and proper placement of the implant. Last arthroscopic check was performed to verify that the spacer is in the right position and does not interfere with normal shoulder function. Postoperatively the arm was put in a sling for two weeks. During this two weeks forward flexion and abduction movements were limited to no more than 60^0, less if painful. Strengthening exercises were allowed after three months.

Patients

Our study included 29 patients (17 males, 12 females) with a mean (range) age 63.9 (53 to 78) years in males and 68.6 (50 to 85) years in females (Figure 1). Patients were treated in Orthopedic Hospital of Valdoltra (Slovenia) between January 2016 and October 2017. Surgeries were performed by a single surgeon. The median follow-up time was 8.9 (6 to 18) months. In all patients, we implanted biodegradable subacromial spacer (In Space Balloon). The indication for surgery was irreparable rotator cuff, intact or reparable subscapularis and absence or mild glenohumeral arthrosis (Hamada I-II). Patients with osteoarthritis ≥ grade III in the Hamada classification were excluded. Figure 2 shows distribution of patient's parameters that potentially influence the outcome of an operation, separately for each sex. Significant differences in distributions were observed for the history of previous shoulder surgeries (SurNum),

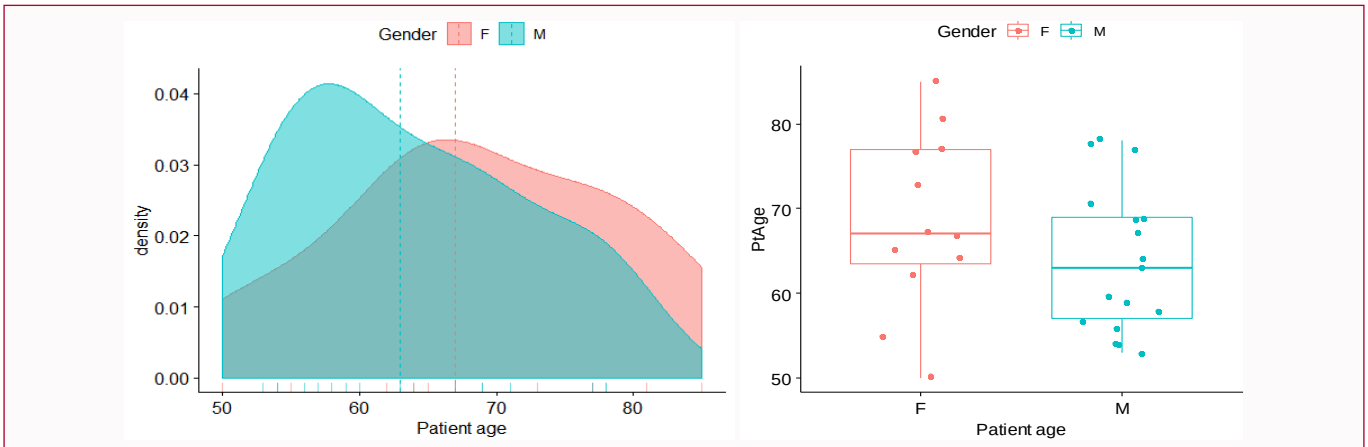

Figure 1: Distribution of patients' gender and age.

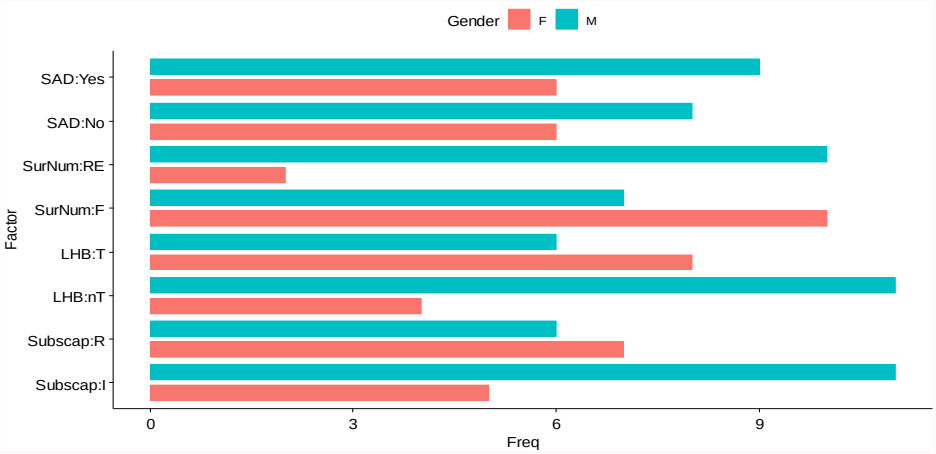

Figure 2: Distribution of patients according to parameters that may influence the outcome of subacromial spacer implantation.
Red: Female; Blue: Male; SubScap: Condition of Subscapularis (I: Intact or Irreparable, R: Reparable); LHB: Condition of Subscapularis Tendon (T: Tenotomy, nT: Tenodesis, previous Tenotomy or Rupture); SurNum: History of Previous Shoulder Surgeries (F: First, RE: Revision); SAD: The Need for Subacromial Decompression during Surgery (No, Yes)

Table 1: GH distance, range and strength of abduction and VAS, TCS and ASES scores of 29 patients before a surgery and after the implantation of subacromial spacer.

Outcome	Surgery	Min	Max	Mean	SD	Median	IQR	p-value
GH distance	Before	0	18	8.6	3.9	8.9	4.3	0.454
	After	1	14	8.1	3.4	7.6	3.7	
ASES	Before	10	57	28	12.8	25	13.3	0.00000829
	After	12	93	58.2	23.2	59.9	31.6	
TCS	Before	8	53	28.4	13.1	25	13	0.0000337
	After	8	86	50.5	23.7	57	34	
VAS	Before	4	10	7	1.3	7	2	0.0000119
	After	0	8	3	2.5	3	5	
Abduction range	Before	60	180	84.6	33.7	60	30	0.0014
	After	60	180	122.1	48.3	120	97.5	
Abduction strength	Before	0	4	1.8	1.4	2	3	0.0764
	After	0	7	2.9	2.3	2.5	2.9	

condition of subscapularis (SubScap) and (LHB) tendon between both sexes.

Statistical analysis

Statistical analysis was performed in R using WRS2 package [Mair, P., and Wilcox, R (2018). WRS2: Wilcox robust estimation and testing] for robust inferential statistics with no assumption of normality and homoscedasticity. The outcome of a surgery was assessed by GH distance, abduction range of motion, strength, VAS, TCS and ASES scores before and after implantation of a subacromial spacer. The following inferential models were used to estimate the statistical significance at confidence level $\alpha=0.05$.

- A robust repeated measurements ANOVA using function rmANOVA was used to model within-subject effects (measurements before and after the surgery) and to estimate the statistical significance of a between-subject effect of a surgery.

- A mixed-effect linear regression model and between-within subjects ANOVA on the trimmed means using function bwtrim was used to model within-subject effects and to estimate the statistical significance of between-subject effects of a surgery, gender-related differences and their interaction.

- Furthermore, a mixed-effect linear regression model was used to model within-subject effects and between-subject effects of a surgery, individual factor of influence (SurNum, Subscap, LHB, SAD) and their interaction.

- A similar model was used to estimate the statistical significance of factors of influences in a gender-specific manner by combining the levels of individual factors and gender. For both models, the statistical significance of the effects was estimated using function bwtrim.

Results

Our study included 29 patients (17 males, 12 females) treated in our institution between January 2016 and October 2017. The mean patients' age was 65 (50 to 85) years. The median follow-up time was 8.9 (6 to 18) months. In all patients, a biodegradable subacromial spacer (InSpace Balloon) was implanted arthroscopically. The mean duration of symptoms prior to surgery was 24 (5 to 108) months with failure of conservative treatment. None of the patients required revision operation and there were none complications related to

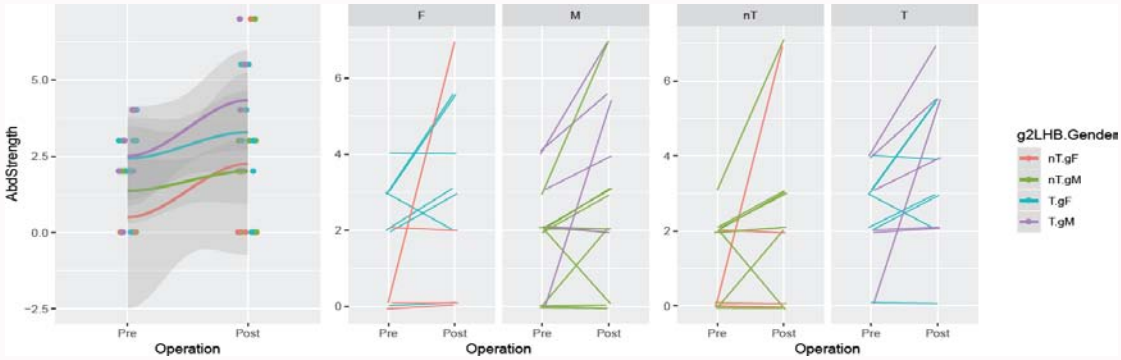

Figure 3: Abduction strength before and after the surgery. Mean (left) and individual profiles separated by gender (middle) and condition of subscapularis tendon (right).
nT/T: Tenodesis, previous tenotomy or rupture/tenotomy; F/M: Female/Male

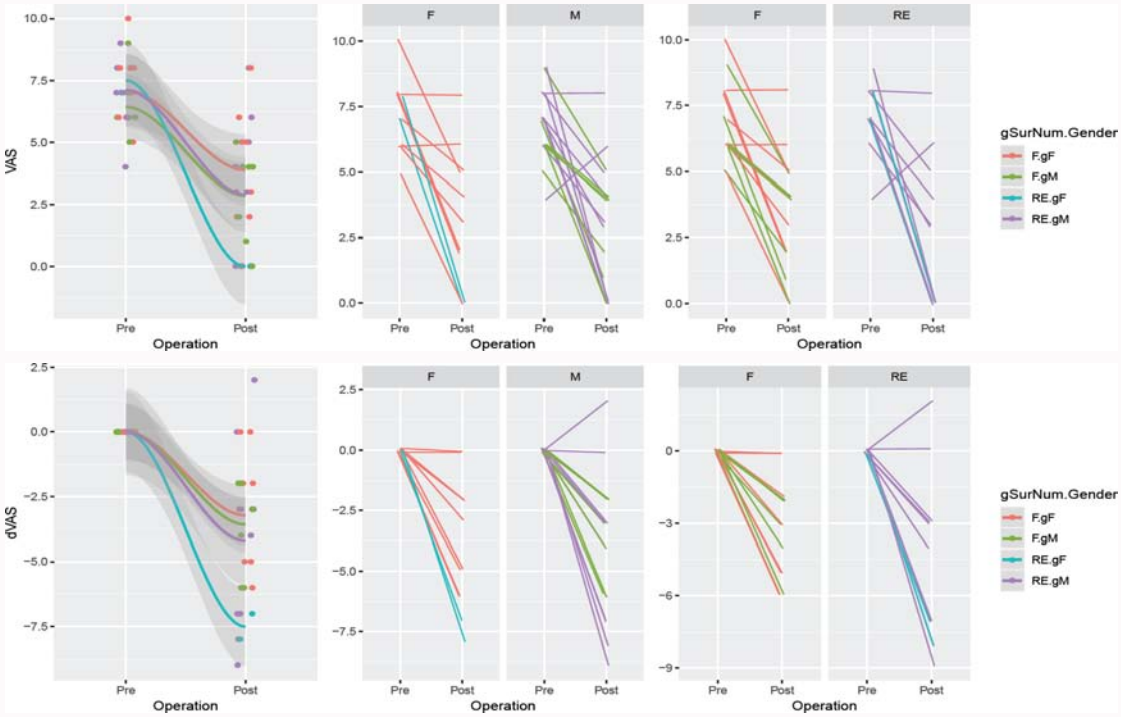

Figure 4: VAS scores before and after the surgery (top) and their differences between post- and pre-operation (bottom). Mean (left) and individual profiles separated by gender (middle) and history of previous surgeries (right). F/RE: First/Revision Surgery; F/M: Female/Male

surgery. All patients successfully concluded the study. The surgical implantation of subacromial spacer was judged as fast and non-demanding procedure by the surgeons.

Intraoperative associated lesions

During arthroscopy all the concomitant pathology was addressed if needed. In 13 cases (45%) subscapularis tendon was also repaired. In 14 cases (48%) biceps tenotomy was performed and in 1 case (3%) biceps tenodesis. In other cases biceps was already ruptured, tenotomised or tenodised. In 15 cases (52%) subacromial decompression was performed. In 13 cases (45%) implantation of subacromial spacer was a revision procedure.

Radiographic results

In 18 patients (62%) there was increase of acromiohumeral distance on X-ray after surgery and in 11 patients (38%) there was decrease of the same distance. On average there was decrease of acromiohumeral distance for 0.5 mm from 8.6 mm prior to surgery to 8.1 mm after surgery. Condition of the LHB tendon (ruptured, tenodised), condition of subscapularis tendon (intact, ruptured), type of surgery (primary or revision procedure) and concomitant subacromial decompression during surgery did not significantly influence on acromiohumeral distance postoperatively. X-ray measurements were done by a single shoulder surgeon.

Statistical analysis

Abduction range and strength, VAS, TCS and ASES scores showed significant differences in their values before and after the surgery (Table 1); no significant gender-specific effects or surgery-gender interactions were observed. The mean ASES score before surgery was 28.0 and after surgery 58.2. The mean TCS score before surgery was 28.4 and after surgery 50.5. The mean decrease of pain according to VAS score was from 7.0 before to 3.0 after surgery. We found increase in range of abduction (from 84.6 to 122.1 degrees) and

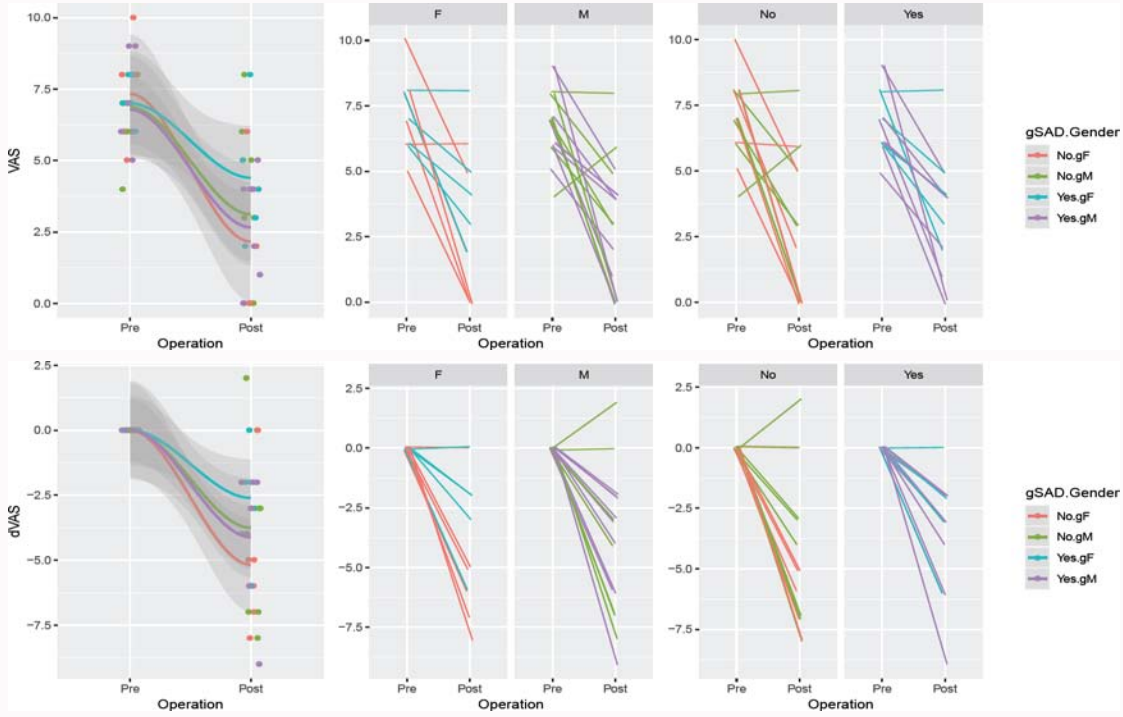

Figure 5: VAS scores before and after the surgery (top) and their differences between post- and pre-operation (bottom). Mean (left) and individual profiles separated by gender (middle) and the need for subacromial decompression (right).
No/Yes: The need for subacromial decompression; F/M: Female/Male.

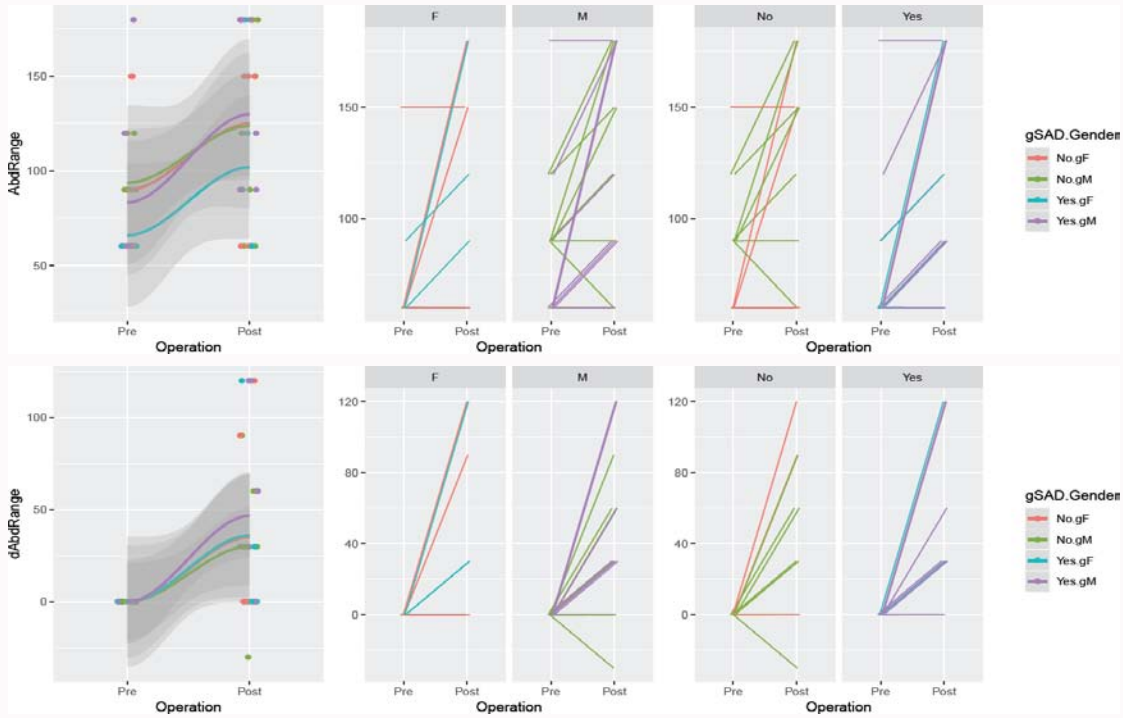

Figure 6: Abduction range before and after the surgery (top) and their differences between post- and pre-operation (bottom). Mean (left) and individual profiles separated by gender (middle) and the need for subacromial decompression (right).
No/Yes: The need for subacromial decompression; F/M: Female/Male

increase in strength of abduction (from 1.8 kg to 2.9 kg) after surgery. GH distance decreased from 8.6 before to 8.1 after the surgery, but the difference was not significant. Patients were further split into groups with respect to their gender and factors that we hypothesized to be influential on the outcome of the surgery. Condition of subscapularis tendon, history of previous shoulder surgeries and the need for subacromial decompression during surgery showed significant influence on the outcome of a surgery; on the other hand,

data does not provide support for the influence of the condition of subscapularis.

Condition of subscapularis tendon

Condition of subscapularis tendon significantly influences abduction strength in a non-gender specific manner. Abduction strength was overall (i.e. pre- and post-operationally) higher if tenotomy was performed in comparison with a group of patients with tenodesis, previous tenotomy or rupture (Figure 3). Interestingly, though not significant, improvement in abduction strength was most prominent for males if tenotomy was performed (1.83) as well as for females if no tenotomy was performed (1.75) in comparison to males w/o tenotomy (0.63) and females with tenotomy (0.86).

History of previous shoulder surgeries

History of previous shoulder surgeries exposed significant gender-specific influence on VAS score. The decrease of VAS was most prominent for the group of females after a revision surgery (mean score difference of 7.5), while 4.2 was recorded for males in comparison to 3.2 and 3.6 after a first surgery for females and males, respectively (Figure 4).

The need for subacromial decompression

The need for subacromial decompression exposed significant non-gender-specific influence on VAS score (Figure 5). The decrease of VAS after a surgery with no need for subacromial decompression (4.36) was significantly larger in comparison to surgeries requiring a decompression (3.57). Important (though not statistically significant) sex-specific differences were also observed (Figure 5 bottom left): A prominent influence of subacromial decompression on VAS score was observed in females (decompression decreases VAS from 5.17 to 2.6), but not in males (decompression increases VAS from 3.75 to 4.11). The need for subacromial decompression also exposed significant non-gender-specific influence on abduction range (Figure 6). The increase of abduction range after a surgery with subacromial decompression was significantly larger (42.9) in comparison to surgeries requiring no decompression (32.1). Important (though not statistically significant) sex-specific differences were also observed (Figure 6 bottom left): Subacromial decompression prominently increases abduction range in males (from 30 to 46.7), but not in females (from 35 to 36).

Discussion

RC tears are one of the most frequent pathologies in the shoulder and incidence increases with age. After 60 years of age every second person has a torn RC. Tears can spread from partial to full thickness. The severity of a tear is not in direct correlation with patient symptoms and clinical exam. Painless and normally functioning shoulder can be present in association with massive irreparable RC tear. On the other hand small partial avulsion of the RC tendon (PASTA) may have important functional implications and dramatically affect the patient's quality of life [7-10]. When tendon retraction and its dimension makes repair impossible we talk about irreparable tear. The tear cannot be repaired even if we use intraoperative tissue mobilization and release techniques [11]. Predicting the RC tear reparability and healing rate is crucial for preoperative patient selection and operative technique. Primarily imaging characteristics can partially predict RC tear reparability. Patte classification of tendon retraction, Goutallier CT classification of fatty muscular degeneration and Thomazeau MRI muscle belly atrophy classification are the most common used ones [9,10]. Some MRI and CT irreparable tears may be amenable to completely or at least partially repair with correct surgical technique. According to some authors approximately 90% of primary apparently irreparable RC tears can be repaired with good release and appropriate surgical technique [8]. Even if we are able to reach the footprint of such torn tendon we have to take in account possible biological cause of repair failure such as: Fatty muscle infiltration, previous operations, surface of tendon to bone contact, grade of chondral tendon metaplasia, neoangiogenetic tendon potential, and age of patient and smoking habits. According to this information's we should change the concept of reparability to concept of 'appropriateness of repair' [12].

What surgical options we have today to deal with irreparable RC tears?

- Debridement, subacromial decompression and tenotomy of long head of biceps tendon
- Partial repair
- Superior capsule reconstruction
- Latissimus dorsi transfer
- Reverse shoulder replacement
- Subacromial biodegradable spacer-InSpace balloon

Debridement, subacromial decompression and tenotomy of long head of biceps tendon.

Tear margin can be a source of pain. Chronic inflammatory cells, dystrophic calcifications and other inflammatory reactions sequela is seen on tendon tear margin. Removal of this tissue may decrease pain [13]. Subacromial decompression is indicated when we have a protrusion of lower bone surface that can irritate or damage underlying tendons. Acromioplasty, with resection of coracoacromial ligament, alters the coracoacromial arch and may cause upper ward migration of the humeral head. Decompression must not be a standard procedure in irreparable RC debridement [14]. Flattened, degenerated and inflamed biceps tendon is often seen in patients with massive RC tears. This can be a cause of pain. Patients with chronic RC tears who had a spontaneous rupture of Long Head of Biceps Tendon (LHB) had pain relief. Walch made a study on 307 patients with RC tears where he observed improvement in constant score from 49 to 68 after biceps tenotomy. 87% of patients were satisfied or very satisfied after that procedure [15]. Debridement, subacromial decompression and tenotomy of long head of biceps tendon may reduce pain without improving strength and function of the shoulder. Despite the generally good clinical results, significant narrowing of the acromiohumeral distance and a progression of radiologic osteoarthritis after surgery have been described. The results reported in some studies must be interpreted with caution [16].

Partial RC tear repair

The procedure that involves the restoration of the cables involved in force transmission and force couples around the shoulder was first introduced by Burkhart et al. in 1993 [17]. He introduced the biomechanical concept of "suspension bridge" in the rotator cuff and hypothesis of the functional RC which led to the rationale for partial repair of the RC tear. In massive RC tears where a complete RC repair is not possible a partial balanced rotator cuff repair is the goal. In this situation it is important to restore the anterior and posterior rotator cable attachments which are the upper subscapularis tendon and the infraspinatus tendon [18]. These two tendons must be restored to

achieve balance between the transverse couples of the shoulder. The vast majority of irreparable RC tears have an anterior and/or posterior extension that affects the transverse couples [19]. In partial RC tear repair has to include all of subscapularis tendon as well as inferior half of infraspinatus as a minimum. If this is achieved a stable fulcrum and balanced transverse forces for physiologic shoulder kinematics are restored. Biceps tenotomy and acromioplasty are usually performed as well [19]. Burkhart obtained an improvement of forward flexion, strength and improved UCLA score in his series of 14 patients [17]. Duralde and Blair had similar results and improvement of the ASES score [20].

Superior capsular reconstruction

The shoulder capsule is an important static stabilizer of the glenohumeral joint [21]. Because it attaches to a large area of greater tuberosity, it is often concomitantly torn with rotator cuff tears [22]. Superior capsular defects increase glenohumeral translation in all directions [21]. Superior capsular reconstruction works by providing the glenohumeral joint with a passive constraint to superior humeral-head translation and improve shoulder kinematics by anatomically replacing the superior capsule, optimizing the otherwise dysfunctional rotator cuff force. It has been shown that reconstruction of a superior capsule with a collagen graft attached medially to the superior glenoid and laterally to the greater tuberosity, restores superior translation to physiological conditions [23]. For repair it is possible to use fascia lata autograft or a human acellular dermal patch allograft. Despite its rapid growth in popularity and several biomechanical studies evaluating the technique, clinical outcome literature for superior capsular reconstruction remains limited to date. It may be a reasonable treatment option in younger patients with irreparable posterosuperior rotator cuff tears wishing to avoid tendon transfer or reverse total shoulder arthroplasty [24].

Latissimus dorsi transfer

Latissimus Dorsi Tendon Transfer (LDTT) was first introduced by Gerber et al in 1988 [25]. The procedure involves transfer of latissimus dorsi tendon from its insertion on anteromedial humeral neck to the greater tuberosity. This transposition converts muscle's internal rotation and extension forces into external rotation and flexion forces and optimizes the deltoid muscle's function about the shoulder joint [26]. It has been shown that LDTT decrease pain and restore elevation and external rotation in patients with posterosuperior rotator cuff tears with loss of supraspinatus and infraspinatus function [27,28]. For the LDTT it is required that the subscapularis tendon is intact or reparable, that deltoid function is normal and there is limited or absent omarthrosis [29,30]. At the beginning this was open procedure and as arthroscopic skills and techniques have advanced, arthroscopic-assisted LDTT is more frequently used [30,31]. The procedure can now also be done as fully arthroscopically. With arthroscopic-assisted LDTT there is less damage to deltoid muscle with less postoperative pain and quicker rehabilitation and the procedure is warranted as safe and with low risk of complications [32,33]. According to Valenti et al. the results of LDTT were significantly better according to range of motion and strength when this procedure was combined with partial repair of infraspinatus [34].

Reverse shoulder replacement

The Reverse Shoulder Arthroplasty (RSA) is an arthroplasty where by medialization and distalization of glenohumeral joint's center of rotation the tension and strength of deltoid muscle is increased. It is proven that this procedure can restore shoulder function [35-37]. Arthroplasty is an option for treating patients with irreparable RC tears. In the last decade the number of RSA increased exponentially. Instability, infection, humeral loosening and glenoid loosening are the main reasons for revision. Revision rate is between 10% to 50%, depending on the surgeon experience. At 15 years the survival rate for RSA is between 70% to 80% [38]. RSA is still a salvage procedure for younger patients due to high risk of complications and failure [39,40].

Subacromial biodegradable spacer-InSpace balloon

Patients with massive RC tears sometimes progressively develop the ability to compensate functional deficit of the shoulder without any intervention [41]. With introduction of Inspace balloon in subacromial space normal shoulder biomechanics is enabled by restoring normal gliding of glenohumeral joint. There is also decrease of pain. Patients can rapidly adopt this 'compensatory behavior'. With this behavior they develop chronic compensated and asymptomatic shoulder with RC tear that is sustained also after biodegradation of the spacer. It should biodegrade over a period of 12 months [42-45]. In rabbits the formation of mature connective tissue around the spacer with no signs of active inflammation was seen [5]. Normal function of subscapularis is crucial for good outcome after balloon insertion. Ruptured subscapularis, even only his upper third, alters biomechanics of the shoulder by antero-superior subluxations of the humeral head due to dysfunction of RC cable significantly [46-49]. Upper part of subscapularis enhances abduction. On the axial plane it balances the activity of infraspinatus and teres minor. On the coronal plane it opposes the upward migration caused by deltoid contraction [50]. Intact or reparable subscapularis is important in shoulder biomechanics and together with restoration of normal gliding and pain reduction, associated with Inspace implantation, increases active shoulder ROM. Severe dysfunction of external rotators also creates a disbalance between anterior and posterior RC. That is why absence or dysfunction of infraspinatus and teres minor, with positive Hornblower sign, is a contraindication to balloon insertion. As known from previous studies pseudoparalysis is also a contraindication for subacromial spacer insertion [45]. Deltoid is the most important muscle for glenohumeral motion in RC deficient shoulder. In case of massive RCT, with loss of stabilization and centralization activity of the cuff, deltoid contraction may lead to anteriosuperior humeral head translation and subluxation [51]. With subacromial spacer, due to restoration of normal gliding and decrease of pain, with functional subscapularis and teres minor, we create a fulcrum on which the deltoid can lever to elevate the arm. According to the manufacturer of the subacromial spacer InSpaceTM Balloon System (Orthospace, Caesarea, Israel) the indications for insertion are massive irreparable RC tear, intact or reparable subscapularis, absence or mild GH arthrosis (Hamada I-II), negative Hornblower sign with absence of complete insufficiency of external rotators, absence of pseudo paralysis, intact coracoacromial ligament, absence of allergy to material, absence of infection, intact axillary nerve and deltoid sufficiency and no high demand patients due to low strength increase.

Our results

In our study there was significant increase in ASES and TCS score, increase in range of abduction and strength of abduction and decrease of pain according to VAS score after surgery. In more than half of the procedures subacromial decompression was also performed (52%). In these procedures we did only bony decompression without a release of Coraco-Acromial (CA) ligament. On average there was increase of ASES and TCS scores in both subgroups (with and

without decompression) and the difference before and after surgery was statistically significant. In recent studies it has been shown that balloon insertion alone comparing to debridement and subacromial decompression in massive RC tears achieved better improvement in ASES and TCS score at 22 months follow up [43]. We inserted subacromial balloon to all of our patients and we added subacromial decompression in more than half of the cases. In our study average follow up time was only 8, 9 (4 to 18) months. Maybe at longer follow up there would be a difference between patients with and without subacromial decompression regarding ASES and TCS score. To date there are not any long term studies comparing balloon insertion alone to balloon insertion with debridement and subacromial decompression in massive RC tears. Regarding acromiohumeral distance measurements on X-ray before and at last follow up we found a decrease of acromiohumeral distance for 0.5 mm on average in both subgroups but the difference was not statistically significant. Implantation of spacer helps to keep the humeral head centered during dynamic movements and opposes static superior or anterosuperior migration of the humeral head [45]. CA ligament also passively restricts upward displacement of the humeral head [52-54]. Implantation of balloon in patients after subacromial decompression and release of CA ligament may lead to anterosuperior subluxation of glenohumeral joint, loss of central fulcrum of the joint and inefficiency of the spacer. In such patients we could expect worse results. In our study we did not release CA ligament and this might be a reason why we had comparable results between this subgroups. In almost half of the procedures (48%) biceps tenotomy was performed and in 1 case (3%) biceps tenodesis. In other cases biceps was already ruptured, tenotomised or tenodised. Maman et al. [44] showed that LHB tenotomy in association with spacer implantation for massive RC tears did not influence the final functional outcome comparing to spacer implantation alone [44]. In our study there was average increase of ASES and TCS score in both subgroups and the difference before and after surgery was statistically significant. Deranlot et al. [55] in his study showed that mean acromiohumeral distance significantly decreased from 8.2 mm to 6.2 mm and preoperative spontaneous rupture of LHB did not influence significantly on acromiohumeral distance postoperatively with arthroscopic implantation of a biodegradable subacromial spacer at three years follow up. [55] In our study there was also average decrease of acromiohumeral distance according to X-ray measurements although our average measured distances (0.5 mm) were smaller than those measured by Deranlot et al. [55] (2.1 mm). Comparing subgroups of patients with tenotomy during surgery and patients who already had tenotomy, tenodesis or spontaneous rupture there was on average small decrease of acromiohumeral distance in patients with tenotomy and very small increase in the other subgroup but the difference was not statistically significant. Our follow up time was shorter and maybe we could expect some different measurements at longer follow up. The images were taken by different radiological technicians with probability of different X-ray angles during imaging but the cause might also be surgeon's inexperience regarding X-ray readings. In almost half of the procedures (45%) subscapularis tendon was also repaired. In other cases subscapularis tendon was intact. We already know that intact or reparable subscapularis is important in shoulder biomechanics and together with restoration of normal gliding and pain reduction, associated with Inspace implantation, increases active shoulder ROM. Other important aspects of subscapularis integrity were described earlier. In these subgroups of patients we found statistically significant difference before and after surgery according to ASES score in both subgroups and according to TCS score in a group of intact subscapularis. But we found marginally significant difference according to TCS score in a subgroup of repaired subscapularis. TCS score mainly consists of measurements of shoulder movements and ASES score on measuring patients difficulties using his hand in daily living. Perhaps this different type of measurements according to both functional scores influenced on final result. Maybe this difference would become also statistically significant with longer follow up time after good healing of subscapularis, better motion and better strength of the shoulder. In this subgroup of patients we also find small average decrease of acromiohumeral distance but the difference was not statistically significant. In our study in 45% of patients implantation of subacromial spacer was a revision procedure. There is a lot of articles about revision shoulder procedures having worse outcome results than primary one. In a retrospective study done by Shields et al. patients with previous rotator cuff repair had lower functional and subjective outcome scores after RTSA compared with patients with no history of shoulder surgery who undergo RTSA [56]. In our study there was average increase of ASES and TCS score in both subgroups and the difference before and after surgery was statistically significant. We also found bigger decrease of acromiohumeral distance postoperatively in patients with primary surgery comparing to a revision procedure. In a revision procedure there was actually no difference in acromiohumeral distance before and after surgery. This might be because there is already some humeral head upward migration before surgery and lesser depression of humeral head could be achieved with subacromial spacer insertion. Castricini et al. [46] showed an improvement in TCS score from 35.5 to 69.5 points with arthroscopically assisted transfer of the LDT for the posterosuperior RC tear. These results are comparable to ours with improvement from 28.5 to 50.5 point postoperatively. Indications for LDTT are also deficit of ER with positive Lag sign which is a contraindication for implantation of subacromial spacer. With LDTT patients feel increasing strength of the shoulder [47]. In our study the increase of strength after the implantation of silastic implant was minimal (from 1.75 kg to 2.86 kg). We also found increase in range of abduction (from 84, 64 to 122, 14 degrees). Preoperative range of motion is important aspect in patient selection. With better preoperative range of motion we can expect better postoperative range of motion. The mean decrease of pain according to VAS score was from 6.96 before to 3 after surgery.

Limitations

There are some limitations of our study. This is a retrospective and single center study with limited number of patients. There is also a very short follow up time. Maybe with longer follow up time and higher number of patients results would be different. Indication for subacromial spacer implantation was determined by the surgeon by inability to perform RC tear repair even with intraoperative tissue mobilization and release techniques. Both surgeons are experienced in shoulder surgery but we have to take into account surgeon's bias in decision making. Clinical data assessment was performed by two surgeons and radiological data and X-ray measurements were done by a surgeon and not radiologist. Images were taken by different radiological technicians with probability of different X-ray angles during imaging. This could all be a reason for different measures of acromiohumeral distance before and after surgery. In almost half of our patients (13/29) implantation of subacromial spacer was a revision procedure which could also influence the final functional outcome.

Conclusion

Implantation of subacromial spacer is a safe and effective method for treatment of irreparable rotator cuff tears. According to our study the best candidates for subacromial spacer implantation are patients with massive irreparable RC tear without significant osteoarthritis (Hamada II or less) and intact subscapularis. Patients with reparable subscapularis might have some problems with small deficit of range motion after surgery. The condition of LHB tendon is not relevant for the final outcome. Subacromial decompression as a concomitant procedure is not necessary and we do recommend to implant subacromial spacer also in a revision surgery. Respecting all limitations we believe that implantation of subacromial spacer gives very good results with high patient satisfaction and pain relief.

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