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Original article

Reliability of open architecture anchors in biocomposite material: medium term clinical and MRI evaluation. Our experience

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Summary. *Objectives*: Comparing radiologic bone ingrowth and the clinical outcomes of an open-construct (PEEK) (polyether ether ketone) suture anchor with those of a bio-composite suture anchor (glycolic polylactic acid anchors, beta-tricalcium phosphate and calcium sulphate) in patients with arthroscopic rotator cuff repair. *Methods*: From August 2017 to January 2019, 33 patients of both sexes, aged between 44 and 78 years underwent arthroscopic rotator cuff repair for tears considered repairable with an extension not exceeding 4 cm. The bioabsorbable anchors used comprised glycolic polylactic acid/beta-tricalcium phosphate/calcium sulphate, and the non-absorbable anchors in polyetheretherketone (PEEK). All patients underwent MRI evaluation at 12 months postoperatively to determine complications and identify any re-tear. *Results*: Clinical scores showed an improvement from both clinical and functional point of view. There were no statistically significant changes compared to the physical examination. On radiographs, mobilizations, anchor pull-outs or other complications did not occur in each group. *Conclusions:* Shoulder function improved after complete repair of the rotator cuff and similar clinical results were achieved regardless of the material and shape of the suture anchor. The bioabsorbable anchors in innovative open architecture material seem to have results comparable to peek anchors. Unfortunately, further studies are needed to define the advantages in using one material compared to the other. (www.actabiomedica.it)

Key words: open architecture anchors, shoulder, rotator cuff, tear, tendon repair, arthroscopy.

Summary

The advent of modern suture anchor technology has not only revolutionized arthroscopic treatment options for management of complex shoulder pathology, but also engendered a scientific research of innovative materials to identify the ultimate composition and design. What began as an open procedure with trans-osseous suture fixation has evolved dramatically with the widespread adoption of an arthroscopic, anchor-based technique for rotator cuff repair. The open architecture anchors have an exclusive design that allows to reduce the material between the tendon and the bone, favouring the entry of blood into

the anchor. This should allow new bone ingrowth within the central canal within 12 weeks after implantation as evidenced in preclinical studies (1, 2). Furthermore, the reduction in the amount of material implanted in the shoulder compared to traditional anchors with a solid core should make an eventual surgical revision easier. Third generation anchors were made using PLLA (poly-L-lactic acid), PDLA (poly-D-lactic acid) or PEEK (polyetheretherketone) as base material. Some components are added to third generation anchors such as tricalcium beta-phosphate and calcium sulphate to obtain new bio-composite materials with greater osteoconductive properties. Although suture anchors are one of the most important advances in rotator cuff arthroscopic repair, their design and composition continue to improve. The goal of these changes is to facilitate bone formation and repair strength to achieve better clinical results and fewer complications.

Introduction

Tendon injuries of the rotator cuff are very common. Wear and tear is the most common mechanism of the tendon failure, related to the aging process of the individual. For this reason, this pathology shows a significant increase after the age of 50 years, although it is increasingly common to diagnose these lesions even in people under the age of 40 years, certainly due to the attention that patients begin to place on painful shoulders, as well as the technological improvement of diagnostic tools. The incidence of rotator cuff injury varies from 5% to 40%, and of course the prevalence increases with age up to 51% in patients over the age 80 of years (3). An epidemiological study by Yamamoto et al. have highlighted, an incidence of 20% of asymptomatic lesions in the population under study (4). The absence of symptoms was correlated with an involvement of the non-dominant side, with the negativity of subacromial impingement signs and with the presence of good functionality of the deltoid and periscapular muscles. Among the four anatomical elements of the so-called rotator cuff, the tendon most often affected by the rupture is the supraspinatus. Recent studies have highlighted how sex and associated pathologies, in particular metabolic and endocrine ones, can play a significant role in the progression of the tendon lesion. In fact, female sex appears to be more affected and moreover women seem to have less functional recovery after post-surgical rehabilitation. It also appears that thyroid diseases (5) represent a risk factor in the development of atraumatic lesions as well as diabetes and dyslipidaemias.

A full comprehensive classification of all the complex anatomical and clinical variables related to rotator cuff tears is not yet available. This classification help the surgeon to understand the characteristics of the lesion and to repair it as evidenced in some clinical studies (6). Among the systems that evaluate the size of the lesion, one of the most commonly used is that developed by DeOrio and Cofield (7). They classified the ruptures of the anterior-posterior part of the tendon, worn by the humeral head, measuring them during the surgery. The system detects small breaks if they are < 1 cm, medium if they are between 1 and 3 cm, massive if they are > 5 cm in thickness.

Obviously the treatment changes according to the type of lesion, so it ranges from simple infiltrative therapy (8) to surgical treatment (arthroscopic and non-arthroscopic) (9). Moreover, a systematic observation of MRI parameters could help the surgeon to predict the impossibility to obtain complete repair of rotator cuff tear (RCT) and to consider different surgical approach, as shown in other studies (10, 11, 12). Although suture anchors are one of the most important advances in rotator cuff arthroscopy, their design and composition continues to improve; first generation anchors (metal anchors) allowed good fixation, but several complications, including implant loosening and migration with secondary joint damage. The second generation anchors (in polyglycolic acid) resulted in a rapid dissolution after about 4 weeks with loss of stability. Those of the third generation were made using PLLA (poly-L-lactic acid), PDLA (poly-D-lactic acid) or PEEK (polyetheretherketone) as base material. Components are sometimes added to third generation anchors (13, 14, 15) such as tricalcium beta-phosphate and calcium sulphate, to obtain new bio-composite materials with greater osteoconductive properties (Table 1).

Table 1. Composition third generation anchors used in the study

PLGA Co-glycolic poly-L-lactic acid (65%)	β-tricalcium phosphate (15%)	Calcium sulphate (20%)
Has a long history of clinical use[16]	Longer-term (18 months) absorption profile for sustained bone formation[18]	Shorter-term (4-12 weeks) absorption profile for enhanced early bone formation and calcium release[20]
Degradation rate faster than PLLA[17]. Comprised of natural products: lactic acid and glycolic acid	Osteoconductive (physical) – Serves as a scaffold to allow for bone ingrowth[19]	Osteoconductive (biochemical) – Associated with increased levels of local growth factors[21]

Table 2. Study demographic data

	Group A	Group B	p
n° patients	15	18	
μAge ± SD (min-max), yr	67,13 ± 11,99 (60-78)	58,16 ± 8,20 (44-72)	p = 0,0162
Sex (male)	7 (46,67%)	11 (61,11%)	p = 0,494
Affected side = dominant side	12 (80%)	15 (83,33%)	p = 1
Constant pre-op ± SD	61,14 ± 15,6	53,6 ± 13,13	p = 0,162
ASES pre-op ± SD	48,46 ± 16,16	49,51 ± 10,84	p = 0,838

Legend: SD = standard deviation.

Materials and Methods

This retrospective cohort study covers the period from August 2017 to January 2019, 33 patients of both sexes (18 men and 15 women), aged between 44 and 78, were eligible for the inclusion criteria, with a RCT considered repairable at the preoperative assessment and with an extension not exceeding 4 cm measuring in preoperative-MRI. These patients were asked about the dominant limb and the side affected by the RCT. The patients were divided into 2 groups: 18 repairs have been done with glycolic polylactic acid anchors, beta-tricalcium phosphate and calcium sulphate (group B), and 15 repairs with non-absorbable peek anchors (group A); demographic data are reported in Table 2. Patients were administered internationally validated clinical-functional scales (Constant Score and ASES Score) (22, 23) in the preoperative and 12 months of follow-up, in addition to an accurate physical examination (grading of abduction, elevation, internal and external rotation). MRI checks were performed on all patients after 12 months of follow-up to evaluate any failures according to the assessment proposed by Sugaya et al. (24) (Table 3), degree of osteolysis and reabsorption (25) (Table 4, 5).

Table 3. Criteria developed by Sugaya et al. to evaluate tendon healing

	Sugaya classification
Type 1	Sufficient thickness, homogeneous tendon (low signal on T2 images)
Type 2	Sufficient thickness, partial high-intensity from within the tendon
Type 3	Inufficient thickness, without discontinuity
Type 4	Minor discontinuity on more than one slice, suggesting a small tear
Type 5	Major discontinuity suggesting a moderate or large tear

Table 4. Resorption grades of the anchors

Grading	**Anchor resorption**
Grade 1	Clearly visible
Grade 2	Visible
Grade 3	Barely visible, partially oedematous bleaching
Grade 4	Complete resorption

Statistical analysis

Descriptive analysis was performed to characterize the study population.

Chi-square, Mann-Whitney U test, T-student or Fisher's exact test were used to compare groups, as appropriate. A $p < 0.05$ was considered statistically significant in all analyses. All analysis were perfomed using STATA software version 13 (StataCorp, College Station, TX).

Results

In the international scores there was an improvement from both clinical and functional point of view in both patient groups with a comparable trend between groups A and B. There were no statistically significant changes compared to the physical examination. All of the 33 patients achieved 12-month follow-up: 18 of them performed repair with glycolic polylactic acid, beta-tricalcium phosphate and calcium sulphate (Figure 1), and 15 of them with peek anchor (Figure 2). To MRI, according to the Sugaya classification, group A registered 3 type 1, 12 type 2 and 3 type 3; in group B there are 2 type 1, 11 type 2 and 2 type 3 (Table 6).

On MRI, mobilizations, anchor pull-outs or other complications did not occur in group A and B (Table 7).

Discussion

The study showed that the degree of bone growth in PEEK anchors was comparable to that of anchors with biocomposite material in the healing phases. Shoulder function improved after complete repair of the rotator cuff, regardless of material. The complication rate on postoperative magnetic resonance imaging and, in particular, the re-rupture rate at 12 months did not show significant differences between the 2 groups. Recently, materials have been made to increase biocompatibility and reduce bone-related complications. Kim et al. (26, 27) suggested that both the regulation of polymer properties and the integration of osteoconductive material improved biocompatibility and revealed that biocomposite suture anchors reduced the extent of cyst formation around anchors and osteolysis.

The criteria for an ideal bioabsorbable implant are different; as evidenced by the study of Speer and Warren (28) and that of Milewski et al. (29), a good suture anchor must firstly provide adequate initial fixation force to adhere the soft tissues to the bone and maintain satisfactory strength over time to promote the mechanical integrity of the tissues themselves; it must be made with completely safe materials

Table 5. Grading of osteolysis reaction of the anchors

Grading	Anchor osteolysis
Grade 0	without fluid signal
Grade 1	with a punctual fluid signal within the anchor area
Grade 2	with separable sections of anchor material and fluid accumulation at the tip of the anchor

Table 7. Results of our analysis (2)

Open architecture anchors in biocomposite material Follow-up 1y	
Grading of the resorption (min-max) (1-4)	82% grade 3 18% grade 2
Grade of osteolysis (min-max) (0-2)	88% grade 0 12% grade 1

Table 6. Clinical and radiological results (1)

		Group A	Group B	
		Follow-up 1y	Follow-up 1y	
μ Constant Score post-op ± SD		94,64 ± 4,43	95 ± 4.251	p = 0,829
μ ASES Score post-op ± SD		96± 1,7	95,83 ± 4,27	p = 0,893
Sugaya class (post-op)	Type 1 (%)	13,3	16,7	
	Type 2 (%)	73,3	66,7	
	Type 3 (%)	13,3	16,7	

Legend: SD = standard deviation.

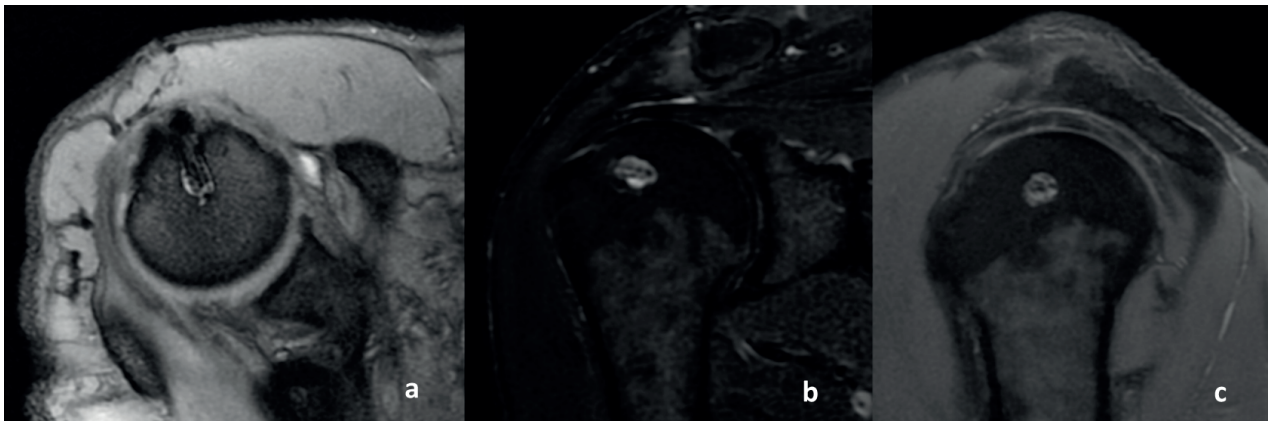

Figure 1. Open architecture anchor, 1 year. Right shoulder: T2 Axial (a), STIR Cor (b), FS T2 Sag (c) sequences.

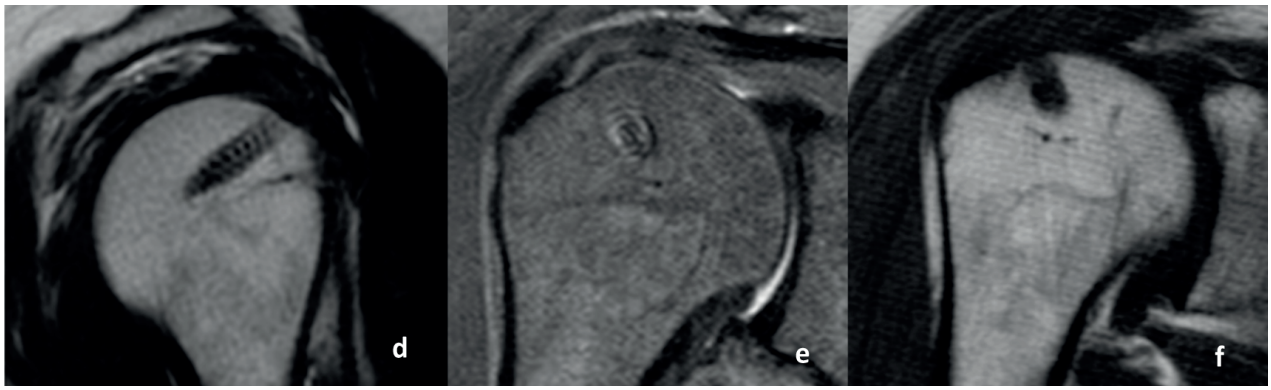

Figure 2. Peek anchor, 1 year. Right shoulder: FS T2 Sag (d), STIR Cor (e), FS T1 Cor (f) sequences.

(no toxicity, antigenicity, pyrogenic or carcinogenic activity); it must not be bioabsorbed too slowly to avoid potential breakage and migration of the anchor; finally, it must be completely replaced by the bone. However, due to the nature of the biodegradable material, bone growth in the anchor requires a prolonged period of time. As the work of Barber et al. suggests (30), the anchors in biocomposite material are completely degraded after 3 years from implantation. Certainly, the already demonstrated potential advantages of open architecture anchors should not be underestimated (they avoid the use of metal, good biocompatibility, good resistance, rapid re-absorption, advantage in case of overhauls, low complications intended as pull outs, foreign body reactions, synovitis, anchor fragmentation, bone cysts, osteolysis). In a study by Chahla J. et al. (31) open architecture anchors led to higher bone growth surrounding the anchor and greater total bone mineral mass within the anchor due to its larger volume.

Limitations

This study has certain limitations. We used limited number of patients. However, measurements taken from the MRI imaging and all the clinical evaluations were done by different examiner; furthermore, the pre and post operative MRI, where the measurements were done, were not performed in a single centre and by the same radiologist; lastly, group B patients are on average younger than group A patients.

Conclusion

Shoulder function improved after complete repair of the rotator cuff and similar clinical results were achieved regardless of the material and shape of the suture anchor. The anchors in innovative open architecture material in glycolic polylactic acid, tricalcium beta-phosphate and calcium sulphate seem to have results comparable to peek anchors, in terms of medium-term clinical-functional results and medium-term imaging. Certainly further studies are needed to define the advantages in using one material compared to the other.

Conflict of interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article

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