

# Clinical and radiological outcomes with PEEK suture anchors used in rotator cuff repair: our experience confirm that a perianchor fluid signal on RM does not affect clinical outcome at one year of follow up

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**Abstract.** *Introduction / objectives:* Osteolytic-type reactions of the perianchor bone which in magnetic resonance are manifested as hyperintensity of the signal in T2 images are reported in many studies. The doubt that this reaction of the bone could result in a loss of pull-out in the short and medium term and that it could therefore negatively affect tendon healing is the subject of an increasing number of studies. An osteolytic type signal around absorbable anchors can be explained by the metabolic processes in progress foreseen by the very nature of the material used, however this type of signal is also recognized around sutured implants or made of notoriously inert material. The objective of the present study is to evaluate and compare to the literature data the clinical and radiological results of a group of patients who underwent arthroscopic suture of a rotator cuff tear using polyetherketone (PEEK) suture anchors. *Materials and methods:* Twenty patients, aged between 44 and 73 years, who underwent arthroscopic repair of the rotator cuff for lesions smaller than 4 cm considered reparable between August 2017 and January 2019, were enrolled in the present study. Patients were evaluated clinically with clinical examination, Constant scale and ASES scale pre and post surgery. MRI either pre and post operation at one year were evaluated to obtain data about tendon healing and evaluate bone reaction to PEEK anchors. *Results:* The mean lesion size was 16.8 mm +/- 7.8 mm and the mean tendon retraction was 15.6 mm +/- 14.9 mm. The mean increase in Constant and ASES scores at the one year-follow up was respectively 36.8 (p<0.01) and 47.2 (p<0.01). MRI analysis showed a tendon signal according to Sugaya classification of type 1 in the 25% of patients, type 2 in the 60% of cases and type 3 in the remaining 15%. Osteolysis was grade 0 in 65%, grade 1 in 30% and grade 2 in 5% of cases. No anchors pull out or mobilization were reported. *Conclusions:* The presence of a T2 hyperintense signal osteolysis like on MRI control using PEEK anchors for the suture of rotator cuff lesions does not find correlation with the final clinical result of the procedure. Indeed, both patients with a major degree of osteolysis and those with degree 0 had an improvement both in terms of clinical and scores evaluation and in terms of tendon healing according to Sugaya's score found in our cohort. (www.actabiomedica.it)

**Keywords:** polyetherketone (PEEK) suture anchors, shoulder, rotator cuff tear, tendon repair, arthroscopy.

## Introduction

Rotator cuff tears are by far the most common cause of shoulder dysfunction and pain. The incidence

of rotator cuff injury varies from 5% to 40%. The prevalence increases with age up to 51% in patients older than 80 years (1).

Arthroscopic rotator cuff repair is being performed more and more frequently as a response to the growing quality of life needed by patients who, even at older ages, no longer wish to desist from an active life. The principles, techniques and instrumentation have evolved to obtain better results, and surgeons have increasingly favored the arthroscopic approach.

Although the repair of the rotator cuff tendons often results in excellent clinical outcome with the abolition of pain and the recovery of shoulder function however, several studies reported a failure rate in tendon healing between 13% and 94% of patients (2).

It seems reasonable that achieving biomechanical stability of the suture is essential for the biological healing of the tendon. Therefore the force vectors that run through it need to be absorbed by anchor and sutures. The ideal anchor must optimize the fixation of the suture to the bone in the short and medium term, must obtain a stable fixation of the suture to the tendon, and must ensure the restoration of the anatomical footprint of the rotator cuff on the humerus. (3)

Several studies have provided indications on how to perform arthroscopic repairs in both small and massive lesions. (4).

A systematic observation of MR images could help the surgeon to predict the impossibility to obtain an optimal repair of rotator cuff tear (RCT) and to consider different surgical approach, as shown in literature (5, 6, 7).

Suture anchors are one of the most important devices in rotator cuff arthroscopic repair, their design and composition continues to improve and different surgical acts can be associated to glean the final result (8).

The introduction of suture anchors has revolutionized many surgical approaches in the field of orthopedics by allowing the fast and more efficient fixation of the tendon to the bone in both open and arthroscopic surgery. The evolution in design and materials over time has followed the impulse to meet the ever-changing needs of the surgeon and overcome the already patented implants with new solutions that could improve biomechanical aspects and the biocompatibility of the products for a better clinical result even in forecast of possible further operations to those joints. (9)

Recently, both bioabsorbable and non-resorbable non-metallic materials have received considerable attention (10) because of the lower incidence of revision surgeries caused by intolerance to metal fixation implants due to migration or metallosis, better quality in post-surgical imaging, and because they facilitate the surgeon in case of revision, as they can be attacked with metal burs, or if they have been resorbed without excessive osteolysis, they are not an obstacle in subsequent surgical procedures such as a new repair of the rupture of the rotator cuff or prosthetic shoulder in the long-term failure of a rotator cuff tear repair. (11)

Polymers such as PEEK is a solid, not metallic, plastic-like material. Plastic is made up of a small repeating unit, or monomer: these pieces are covalently linked to form a macromolecular chain. Although the rigid covalent bonds keep the monomers together, the chains are held together by the physical interaction of different components, the polymer chains can move relative to one another without breaking the covalent bonds, allowing the polymers to deform without breaking. Polymers can be distinguished according to their properties of interaction with the organism into: bioabsorbable and biostable, being PEEK included in the latter group.

PEEK is a rigid semi-crystalline thermoplastic polyethylene with excellent mechanical properties. It offers the advantages of not interfering with postoperative imaging and of a stable fixation without the complications associated with the degrading polymer as in the case with polylactic acid implants (12, 13).

PEEK implants in animals demonstrated no acute inflammatory response and only mild chronic inflammation. (14.) Its main problem was the poor osteointegration capacity, as it happens for metals. In animals, PEEK showed direct bone contact in some areas but also the presence of cartilage-like areas and fibrous interfaces. This poor bone-implant interface is explained by the fact that the inertia and hydrophobicity of the PEEK surface hinder cell adhesion proteins (15,16)

## Materials and methods

In this retrospective cohort study, a group of patients who underwent rotator cuff arthroscopic

repair from August 2017 to January 2019 was analysed. Patients underwent regular clinical and magnetic resonance imaging follow up until one year after the operation.

Twenty patients of both sexes (11 men and 9 women), aged between 44 and 73 years, were enrolled.

The inclusion criteria were:

1. a rotator cuff tear considered repairable on preoperative evaluation;
2. a lesion of an extension of no more than 4 cm measured on the preoperative MRI and confirmed intraoperatively;
3. patients' consent to regular follow up, included a one-year follow up MRI

The anchors used in the study were fully threaded non-absorbable polyetheretherketone (PEEK) suture anchor (TWINFIX™, Smith & Nephew):

All patients underwent arthroscopic rotator cuff reconstruction, by the same senior surgeon in the same center. All procedures were followed by a recovery phase with multiple orthopedic and physiatric re-evaluations, all patients were provided with personalized information on rehabilitation methods.

During the preoperative assessment and at the one-year postoperative assessment, there were administered to patients internationally validated clinical-functional scales: the Constant (17) and ASES (18, 19) rating scales.

After approximately 12 months of follow-up (mean follow-up 12.7 months +/- 1.8), MRI scans were performed on all patients who agreed to participate in the study.

Multiple parameters were considered in the MRI evaluation to assess any failures in the reconstruction of the rotator cuff.

We evaluate the possible pull-out of the anchor, the radiological signs of tendon healing according to Sugaya et al classification. (20) As described in the following table:

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

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

The degree of osteolysis was also analyzed and classified according to Kim et al. (21).

**Table II.** Grades of perianchor fluid collection on T2-weighted MRI scans Grade Criteria as suggested by Kim et al. (21)

Grade 0	No fluid signal
Grade 1	Minimal fluid collection
Grade 2	Local fluid collection
Grade 3	Fluid collection around the whole length of the anchor at a diameter less than twice the diameter of the anchor
Grade 4	A diameter exceeding the grade 3 limit

A descriptive statistical analysis was performed to characterize the study population and Chi-square, T-student and Fisher tests were used as appropriate to compare groups. A  $p < 0.05$  was considered statistically significant in all analyzes. Microsoft Excel for Windows was used throughout the statistical study.

## Results

The mean lesion size was 16.8mm +/- 7.8mm and the mean tendon retraction was 15.6mm +/- 14.9mm. The pre-operation and one-year follow up functional scales ASES and Constant results are reported in table III:

Both the Constant scale and the ASES increased for all patients. On average, the increase in the Constant scale was 36.8 and for the ASES was 47.23. Analyzing these results through Student's T test we found

Table III.

Patients	Constant PRE-surgery	Constant POST-surgery	ASES PRE- surgery	ASES POST- surgery	Number of anchors	Sugaya			Osteolysis 0-1-2-3-4
						Type 1 Type 3	Type 2 Type 4	Type 5	
1	49	94	46,6	94,9	1	2		0	
2	89	94	48,3	94,9	1	1		0	
3	69	98	54	100	1	2		1	
4	54	94	47	94,9	1	3		0	
5	53	96	48,3	96,6	2	2		1	
6	51,5	98	79,9	96,6	1	2		0	
7	82	92	64,9	93,3	1	1		0	
8	53	93	53	94,9	3	2		0	
9	69	92	54	94,9	1	2		1	
10	53,5	81	63,3	94,9	2	2		2	
11	59	96	43,3	96,6	3	1		0	
12	48	98	55	100	3	3		0	
13	82	98	55	98,3	1	2		0	
14	36	96	28,3	94,9	2	3		0	
15	45	96	38,3	96,6	2	1		1	
16	62	98	13,3	98,3	1	2		1	
17	72	96	41,6	96,6	2	1		0	
18	38	94	48,3	94,9	1	2		0	
19	43	96	41,6	96,6	2	1		1	
20	48	92	55	94,9	2	2		0	
Mean	57,8	94,6	48,95	96,18					
SD	14,6	3,7	13,3	1,8					

that the increase in these scores was statistically significant ( $p < 0.01$ ).

Tendon healing according to Sugaya score and the osteolysis data according to Kim are reported respectively in table IV and V (Table IV).

Table IV. MRI evaluation following Sugaya classification

Sugaya grade	Patients	
Sugaya 1	5	25%
Sugaya 2	12	60%
Sugaya 3	3	15%
Sugaya 4	0	0%
Sugaya 5	0	0%

Table V. MRI evaluation following Kim et al. classification

Osteolysis Grade	Patients	
0	13	65%
1	6	30%
2	1	5%
3	0	0%
4	0	0%

No cases with Sugaya grade greater than 3 and osteolysis detected around the PEEK higher than grade 2 were detected.

Pull-out of the suture anchor or its mobilization were not found in any patients.

After one year of follow up no infections or need for revision surgery were reported.

## Discussion

Implants in plastic polymeric materials or bio-composites are increasingly used in orthopedics due to their biocompatibility and excellent biomechanical properties that guarantee adequate clinical safety (22)

The data from this study show that after arthroscopic repair of the rotator cuff using PEEK anchors, the functional results clinically detected and the healing of the tendon, analyzed through a one-year MRI study, are similar to those reported in the literature even in the presence of areas of osteolysis around the implant (23, 24, 25). The function of the shoulder improved, by analyzing the different evaluation scales, after the repair of the rotator cuff regardless of the presence or absence of osteolysis around the anchors in a statistically significant way.

Speer et al. (26) already in 1996 identified 4 important criteria that must be met for an implant to be used during shoulder arthroscopy:

1. The implant must have an initial fixation force to give stable compression to the soft tissues against the bone.
2. The property of the material and the degradation time of the implant must allow satisfactory strength and stability while the tissues are in the restarting phase and are regaining mechanical integrity.
3. The implant must not degrade too slowly to avoid the complications of metal implants.
4. Implant materials must not cause toxicity, antigenic response or carcinogenicity.

Biocomposite materials are the ones that currently come closest to these standards. The anchors built in PEEK, although not in resorbable material, possess all the other afore mentioned characteristics.

Osteolysis and cyst formation worsen the local situation in rotator cuff repair as they can promote pull-out and bone deficiency could make revision surgery more difficult. (27)

Osteolysis around suture anchors is a well-known phenomena that has been studied since the introduction of this type of implant because the presence of fluid around the threads of the anchor could affect its

tightness in terms of both pull out and stability during tendon healing.

In a prospective study Jae-Hoo Lee et al. (23) have implanted in the same shoulder of patients treated arthroscopically for rotator cuff repair a bioabsorbable anchor in biocomposite material and an anchor of similar architecture in PEEK and subsequently analyzed the functional results through serial and periodic collection of functional scales ASES and a radiological follow-up in MRI. The design of this study has the ability to eliminate the interpersonal bias due to the individual biological abilities of each patient in dealing with the presence of foreign bodies such as suture anchors. Furthermore it also allows for a simultaneous evaluation in MRI of the results between 2 different types of materials for the realization of suture anchors. Their study highlights that biocomposite anchors has a statistically significant tendency to form higher degrees of fluid collection around itself, however the PEEK anchors also formed osteolysis in their experience, regardless of the clinical outcome that did not showed significant changes. In their study, with a 3 and 6 months follow up MRI, it is also possible to see how this phenomenon evolves over time.

Kim S. Et al. (24) conducted a study comparing 4 types of non-metallic anchors: two biocomposed models with different percentage presence of PLLA, all-suture anchors and one PEEK model. They have implanted anchors of different types in the same patient and have performed a follow up through MRI about one year after surgery. They conclude that a peri-anchor fluid signal expressing osteolysis was detected for all models used in the study, including those in PEEK, but without any influence on the final clinical results and on the tendon integrity, regardless the size of the osteolytic area that varies between the different implants.

Also in our series, the observed degree of osteolysis and resorption did not find any correlation with the clinical results which, by analyzing the ASES and Constant scores, improved in a comparable way regardless of the degree of osteolysis.

Furthermore, in our case series we have treated mainly small sized lesions with a 1 to 3 anchors while in the literature at least 2 anchors and sometimes the double row technique was performed. It is possible

that the greater density of anchors within the bone causes more pronounced inflammatory reactions, also simply due to their spatial proximity, giving signals of more pronounced osteolysis MRI (grade 3 and 4) that were not detected in our analysis.

This study has several limitations, first of all the sample size of the cohort examined is limited. The detection of the functional scales was not performed by the same person in the pre and postoperative period. MRI scans were not performed in the same radiology center with the same equipment.

## Conclusions

The presence of a T2 hyperintense signal osteolysis like on MRI control using PEEK anchors for the suture of rotator cuff lesions does not find correlation with the final clinical result of the procedure. Indeed, both patients with a major degree of osteolysis and those with degree 0 had an improvement both in terms of clinical and scores evaluation and in terms of tendon healing according to Sugaya's score found in our cohort.

**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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