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Research Article

All-Inside Bioinductive Collagen Implant Augmentation for the Repair of Myotendinous Rotator Cuff Tears: Surgical Technique and Report of Preliminary Results

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Abstract

Purpose: The purpose of this study is to assess the short-term results and describe tips to prevent complications during the implant.

Methods: Between April 2021 and April 2022, 6 patients with myotendinous junction (MTJ) rotator cuff tears were treated with arthroscopic placement of Bio-inductive Collagen Implant by a single surgeon. Patients were followed up to 6 months. All were evaluated preoperatively and postoperatively by use of Visual Analogic Scale (VAS), Constant shoulder score and American Shoulder and Elbow Surgeons (ASES) Score.

Results: At a mean follow-up of 6 months. All the patients were satisfied with the procedure. Although we do not have enough patients to make statistical difference, there was an improvement in the constant shoulder score, VAS and ASES scores, also there is an improved articular range in forward flexion, internal rotation, and external rotation. All the patients had full incorporation of the graft into the native tissue as documented in postoperative resonance imaging.

Conclusion: Our study supports Bio-inductive Collagen Implant as a viable solution for surgical salvage in select cases of MTJ rotator cuff pathology. This treatment option may provide patients with decreased pain and increased function as an associated gesture on arthroscopic repair of MTJ rotator cuff tears.

Level of Evidence: Level IV, therapeutic case series.

Keywords: Shoulder; Myotendinous Junction Tears; Rotator Cuff; Regeneten; Bio-Inductive Collagen Implant; Shoulder Arthroscopy

Introduction

The myotendinous junction (MTJ) represents the weakest point in the myotendinous unit because this junction has less capacity for energy absorption than either muscle or tendon [1]. Medial tears of the rotator cuff that occur at the MTJ can occur primarily (without prior surgery or type 1), or secondarily after previous rotator cuff repair (secondary or type 2 failures) [2]. Evidence suggests that retears or failure heal can be attributed to intrinsic biological factors of the healing environment, such as hypo- vascularity and compromised tissue quality [3,4].

Rupture of the MTJ usually affects the infraspinatus muscle [2,5,6] but can also affect the supraspinatus muscle [6,7].

Millett., *et al.* Described three typical patterns of MTJ ruptures

- Type A Tears Primary medial cuff tears
- Type B Tears Chronic Medial Cuff Tears with Adequate Muscle Quality and Insufficient Tendon Length.
- Type C Chronic Medial Cuff Tears with Poor Muscle Quality or Tear Extension [2].

Type B ruptures suppose a challenge for the surgeon due to the unavailability of a solid and reliable structure to support the suture as is the tendon, in its place we find fragile muscular fibers and less resistant to traction. Even though there is not yet defined which is the best material, preliminary biomechanics studies suggest that

augmentation can be an effective method for massive or retracted ruptures of the rotator cuff [8-13].

One emerging approach for rotator cuff repair augmentation is to use a highly porous collagen bio- inductive implant (REGENETEN; Smith and Nephew, Andover, MA). Although the implant's mechanism of action is not fully understood, it has been shown that it induces tissue ingrowth and new host tissue formation on the bursal surface [14,15].

The decision to repair the rotator cuff depends on many patient-dependent variables such as symptoms, comorbidities, physical demands, and treatment expectations, among others. Although the findings on physical examination of a MTJ tear are similar to the most common rotator cuff tears, there are many pathophysiological factors that pose a challenge to its repair, including the time since rupture, the degree of retraction, fat infiltration, the quality of tissue in the medial stump and the amount of remaining tendon in the lateral area, the quality of bone in the glenoid cavity and in the major tuberosity, tendon morphology and in case of secondary tears the number of suture anchors in the previous repair.

There has been recent publications about MTJ repair and open augmentation [6,16] but to our knowledge, there are no published studies regarding "All-Inside" arthroscopic treatment of MTJ ruptures of the rotator cuff with bioinductive collagen implant augmentation.

The purpose of this study is to show our early results of MTJ reparation with bioinductive collagen implant augmentation all-inside arthroscopy. Specifically: describe the functional results through the VAS, constant and ASES scales and the MRI findings before to the treatment and compare it to 3 months after the surgery.

Materials and Methods

Approval is requested by the scientific committee of UMIVALE ACTIVA, and informed consent is requested from all patients before the enrollment into the study.

A series of 6 patients with MTJ rotator cuff were identified by MRI, with an age range between 35 and60 years of both sexes.

Inclusion criteria

Partial or total rupture of SE and Infraspinatus (IE). All patients underwent a preoperative evaluation of the visual analogue scale (VAS), the American Shoulder and Elbow Surgeons (ASES) test [17] and the Constant test [18]. All the repairs were performed by a single surgeon (OYa) from April 2021 to April 2022.Post-operative-evaluation of patients was performed at 2 weeks, 4 weeks, and 3 months by use of VAS, constant and ASES scores and physical examination; tendon integrity is assessed by MRI at 4 months of injury.

Prior to surgery, all patients underwent conservative treatment including Sick leave, oral NSAIDs, rehabilitative treatment, and platelet-rich plasma (PRP) infiltrations.

5 patients are female and 1 male, the average age of the patients is 47 years and the time from the first visit to the specialist to surgical treatment was 5 months. The average time of onset of symptoms to surgery is 36 months, although this value is affected by a patient who took 10 years to perform surgery. The median of 18 months is then taken as the value.

4 shoulders were left and 2 were right. Corresponding to 3 dominant and 3 non-dominant. All patients were operated at the "Hospital inter mutual of Levante" in charge of the mutual Umivale Activa; 3 of them being an accident at work and 3 coming from common contingency.

The length of the rupture was measured in preoperative MRI, from anterior to posterior and the average was 11.3 mm (range from 7 to 22 mm). Two patients had previously undergone surgery.

Preoperative evaluation

Patients are evaluated by the surgeon and pre-operative questionnaires are conducted including VAS, Constant and ASES. A measurement of the articular ranges is carried out: anterior flexion, abduction, external rotation, and internal rotation. All patients underwent two preoperative MRIs to assess the progress of the tear and measure the length of the tear.

Surgical technique

All patients were operated on in lateral decubitus, under general anesthesia and axial traction of 5 Kg, with arthroscopic technique.

Case	Sex	Age	Dominance	Shoulder	AW/CC	Reintervention	Start	First visit to specialist
1	F	35	Right	Right	CC		2012	27/5/21
2	F	45	Right	Left	AW		7 months	25/1/22
3	F	38	Right	Left	AW		1 year	22/2/22
4	F	60	Right	Left	AW	1 (2019)	2 years	10/3/22
5	F	49	Left	Left	CC		6 months	16/12/21
6	M	57	Right	Right	CC	1 (2018)	4 years	20/5/22

Table 1

Case	1º RM	RM pre-Op	Result pre-Op	Surgery	Discharge	Control MR	Result post Op
1	20/15/12	20/4/21	22mm Lineal	11/6/21	10/11/21	9/11/21	Tendon integrity
2	2/7/21	9/11/21	10 mm lineal	24/2/22	26/7/22	10/05/22	Tendon integrity
3	17/6/21	27/1/22	7mm lineal	4/3/22	15/07/22	12/04/22	Tendon integrity
4	24/8/21	13/12/21	7mm lineal	1/4/22	26/07/22	15/03/22	Tendon integrity
5	1/12/21	11/3/22	10mm lineal	22/4/22	On Rehab	28/06/22	Tendon integrity
6	16/1/19	10/4/22	12 x 13mm	10/6/22	On Rehab	26/07/22	Tendon integrity

Table 2

A posterior portal is performed (more medial than usual), from where the camera is inserted. Then a lateral working portal is done to make a large bursectomy and acromioplasty. The tear is identified, and the adhesions are debrided then is measured in both AP and Sagittal plane. Accessory portals are made (more medial than usual). The augmentation, which will be carried out through an enlarged lateral portal, where the implant of bioinductive collagen implant (REGENETEN; Smith and Nephew, Andover, MA). Is passed and unfurled, then the medial area of the implant is fixed to the tendon with resorbable staples with the help of a cannula through the Neviaser portal. Subsequently, the implant applicator is removed, and the bone anchor is proceeded with one or two staples that fix the implant to the bone in the lateral area (covering the area of the repair with the implant. Finally, the remaining fixation is made in the anterior and posterior area.

Tenotomy of the biceps is performed in all patients due to tears and inflammation of the biceps.

Post-surgical treatment consists of the use of sling for 4 weeks, and then passive mobilization exercises with the help of a rehabilitator. Active mobility begins at 6 weeks at 8 weeks, rotator cuff strengthening exercises are initiated.

Key steps during implantation

- Make all the arthroscopic procedures prior to the implantation, such as acromioplasty, distal clavicle excision or biceps tenotomy/tenodesis.
- Make anterior and posterior portals a little more medial for an efficient angle of attack during implantation.
- Perform broad bursectomy and acromioplasty to be able to place anchors the most perpendicular way possible.
- Place a cannula in the lateral portal, where the implant will enter. Be sure to have the footprint and the greater trochanter correctly prepared with shaver to avoid soft tissue interposition.
- Make sure to have a correct view from the posterior portal before deploying the implant through the lateral portal
- During the placement start at medial part, direct the implant to the Neviaser portal, towards the Axis of the soft tissue anchors.
- Help yourself with a forceps when removing the implant gun.
- Place the bone anchors through the lateral portal, it can be sufficient with 2 or 3 anchors.
- Do not over-strain the implant because it may tear.
- Do not under-strain the implant as it may be protuberant making a subacromial impigement

- During the first implants, it is advisable to be accompanied by an experienced arthroscopist.

Figure 1: During arthroscopy on lateral decubitus, the anterior and posterior portals are more medial than usual, and it is always necessary a Neviaser portal.

Postoperative evaluation

Patients are evaluated by the surgeon at 2 and 4 weeks, and 3 months after the injury. Post-operative questionnaires are conducted that include VAS, Constant and ASES. A measurement of the articular ranges is carried out: anterior flexion, abduction, external rotation, and internal rotation. All patients underwent a post-IQ MRI from three to six months after injury to assess the integrity of the repair.

Results

Patients showed improvement in VAS, Constant and ASES at 3 months.

The joint balance improved markedly in all the arches.

MRI at 3-6 months were reviewed by the authors and validated by an experienced radiologist and showed tendon integrity in 100% of cases, there were no signs of inflammatory reaction, or foreign body reactions.

Case	EVA preOp	EVA 3 m	Constant preOp	Constant 3 m	Ases PreOp	Ases 3 m
1	8	2	51	90	14	28
2	7	2	52	87	15	25
3	8	2	49	85	14	27
4	9	4	55	80	16	25
5	7	3	52	85	15	47
6	8	4	51	87	16	25

Table 3

Case	Flexion pre	Flexion post	Abduction pre	Abduction post	Internal rotation pre	Internal rotation post	External rotation pre	External rotation post
1	90	165	90	175	30	60	50	75
2	80	170	75	150	20	70	60	85
3	100	150	90	140	30	65	50	80
4	70	120	70	120	30	45	40	50
5	90	130	90	165	20	65	60	80
6	100	155	90	140	20	55	50	75

Table 4

Figure 2

As complications, 3 patients showed Acromioclavicular arthritis that were resolved with physiotherapy; 1 patient had adhesive capsulitis and is still recovering with rehabilitation. There have been no adverse effects associated with the implantation of Regeneten®.

Discussion

Myotendinous junction tears cannot be repaired by traditional suture and fail with conservative treatment.

To solve these problems, much research has been done on biological augmentation devices [6,9,10,14,21,22], which are responsible for meeting the physiological demands of the tendon and ensuring the mechanical properties of the repair.

The uses of bio-inductive implants indications are evolving. At present the main indication for the senior surgeon is MTJ rupture, but they can be used in patients with high re-tear risk, such as massive rupture, revision repair, poor quality tendon tissue or with co-morbidities such as diabetes, smoking history, or autoimmune disease.

Biopsies of collagen implants retrieved from human rotator cuff repair subjects revealed cellular incorporation, tissue formation and maturation, implant resorption, and biocompatibility [15,23].

MRI findings support that this bio-inductive collagen implant induces new tendon-like tissue formation and creates an environment conductive to the healing of partial-thickness cuff tears [24,25]. We think longer-term evaluation will be necessary to assess the durability of these results, also there is also the need of making new studies with a bigger study population.

Conclusions

This study supports the hypothesis that this Bio-inductive Collagen implant is a viable solution for surgical salvage when combined with rotator cuff repair in select cases of symptomatic myotendinous joint rotator cuff tears. This treatment option may provide patients with decreased pain and increased function and articular range despite a previously rotator cuff tear. The ability to heal MTJ rotator cuff defects, represents a new way to guarantee the success in the repair of these difficult to treat lesions.

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