Bio-inductive implant for rotator cuff repair: our experience and technical notes

Gian Mario Micheloni, Gianpaolo Salmaso, Gino Zecchinato, Stefano Giaretta, Elia Barison, Alberto Momoli

Orthopedic and Traumatology Unit - Ospedale San Bortolo - Vicenza (Italy) - AULSS8 Berica.

Summary. The treatment of chonic large and partial rotator cuff tears represents a common challenge for orthopedic surgeons. Numerous treatments were suggested but the best is still controversial. Into this field the use of an augment for rotator cuff repair aims to protect the tension of the suture in the postoperative phase and to facilitate the biological healing process. In our institution we treated 4 patients (3 males and 1 female) with rotator cuff tear with bio-inductive implant. All patients presented with a postero-superior rotator cuff tear: 3 patients with a type C-III tear according to Snyder classification and 1 patient with partial articular tear with significant degeneration and poor tendon quality (type A-III tear according to Snyder classification). The final outcome is highly satisfying intraoperatively and the postoperative protocol reflects our normal postoperative protocol following to rotator cuff repair. No complications occurred at 6 months follow-up. The use of the bio-inductive implant in the arthroscopic rotator cuff repair resulted easy, rapid and reproducible. Although no current scientific evidences regarding such implants exist, in selected cases and with the correct indications, the use of bio-inductive implant could represent an effective aid and an option in case of complex rotator cuff tears. (www.actabiomedica.it)

Key Words: bio-inductive implant; patch; rotator cuff tear; rotator cuff repair

Introduction

The treatment of rotator cuff tears represents a common challenge for orthopedic surgeons (1).

The great outcomes and the population median age determined a constant increase of surgical repairs in the last years (2). The orthopedic surgeon, more and more frequently, faces with the surgical treatment of chronic large size lesions in patients with muscle atrophy, thus with a high-risk of failure. Re-ruptures occur mainly because of mechanical factors such as excessive tension of the sutured margins and insufficient biological repair capacity related to patient's age (3).

An additional critical aspect is represented by partial tears, in particular partial articular supraspinatus tendon avulsion (PASTA), with poor tendon quality and difficult to assess if the lesion is fixable and when (4).

There is also a grey zone in the rotator cuff lesions classification in which the best surgical treatment remains uncertain. Numerous treatments were suggested for third-degree complete tears (C) according to Snyder classification (5), and nowadays they are still object of research with modest clinical outcomes (6-7). Furthermore, there is no large consensus regarding the best surgical treatment for partial tears (A) (8-10).

This study aims to analyze our preliminary experience together with the technical aspects in the first 4 patients treated with bio-inductive implants and rotator cuff repair in patients with such type of tendon tears.

Materials and Methods

We treated 4 patients (3 males and 1 female, average age 64 years old) with rotator cuff tear with bioinductive implant of Regeneten® (Smith and Nephew plc, Watford, Hertfordshire UK) at San Bortolo Hospital in Vicenza (Italy).

All patients presented with a postero-superior rotator cuff tear: 3 patients with a type C-III tear according to Snyder classification and 1 patient with partial articular tear with significant degeneration and poor tendon quality (type A-III tear according to Snyder classification).

A shoulder brace with arm abduction for 2 weeks (maintained for additional 2 weeks only at night) was placed at the end of surgical procedure in all patients. Passive physical therapy exercises were started 3 weeks from surgery and active physical therapy was begun on the 5th week, avoiding forced adduction to 90 degrees until the 6th week.

No short-term neurological complications, general or surgical wound infections occurred.

Technical notes

Patients were positioned in lateral decubitus position; standard approach was used to evaluate intra-articular space of the upper portion of the subscapularis tendon, of the insertion of the long head of the biceps tendon and of the supraspinatus tendon.

All patients were affected by pain and tendinitis of the long head of the biceps tendon, therefore tenotomy was performed. The integrity of the subscapularis tendon and the stability of the mobilization were settled with specific arthroscopic instruments.

Supraspinatus tendon lesion (A-III according to Snyder classification) was noted in one case.

At the level of the subacromial region (Figure 1), after accurate preparation of the footprint with shoulder rotating milling cutters, the rotator cuff was repaired with suture techniques: in case of C-III tear (according to Snyder classification) 2 ThRevo® anchors (Conmed, Largo, Florida, United States) were placed (Figure 2), whereas in case of A-III tear (according to Snyder classification) no tear completion

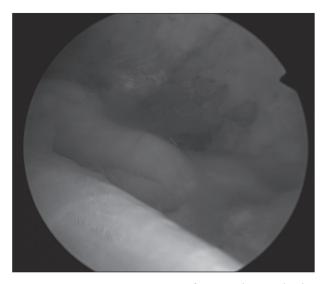


Figure 1. intraoperative assessment of supscapularis tendon lesion (subacromial view)

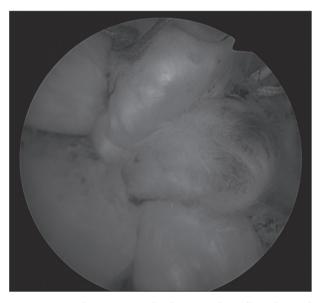


Figure 2. Tendon suture with Threvo anchors (lateral portal view)

and suture technique were performed due to the poor tendon quality.

Thus, a Regeneten[®] bio-inductive implant was placed in all patients, following the technique described by the manufacturing company.

A small distal enlargment of the lateral portal could be necessary to allow the implant insertion, parallel to the tendon.

The bio-inductive implant was fixed with absorbable anchors in the medial portion and with Peek anchors in the lateral portion at the level of the greater tuberosity.

Neviaser portal for arthroscopic placement of medial anchors was preferred and used.

The implant resulted stable for extra-and intrarotation movements in all patients at the end of the placement (Figures 3-4).

All patients underwent subacromial bursectomy and decompression.

Discussion

The tendon suture techniques described for the treatment of large rotator cuff tears are various, al-though the clinical outcomes and the rate of re-rup-ture still remain non-optimal (3,11,12).

The orthopedic surgeon is usually forced to a large release, traction of the ruptured tendon and medialization of the footprint in order to obtain an acceptable result in case of ruptured tendon retraction. Hence, the clinical outcome is modest, with a high risk of failure and recurrence of the lesion (3,13,14).

The use of an absorbable arthroscopic subacromial spacer with subjective good outcomes is also described for the worst cases in which the suture technique is not possible to be utilized, even though this type of procedure is usually recommended in patients with less functional demands (15) or with comorbidity when a complete repair is not possible or a long physical therapy course isn't tolerate (16).

The use of an augment for rotator cuff repair aims to protect the tension of the suture in the postoperative phase and to facilitate the biological healing process. For this reason, within the years numberless scaffold (17-20) were described and used, both synthetic, especially with mechanical features, and biological (allografts and xenografts), with the additional goal to stimulate the potential healing process (21). Currently, because of the scarce number of scientific studies with a high level of evidences, there is no consensus regarding the augment with the best clinical outcomes. Less recent xenografts were related to cases with significant inflammatory reaction and therefore their use was limited. More recent versions did not show such adverse reaction and the allograft,



Figure 3. Final result of bio-inductive implant postioning (posterior portal view)

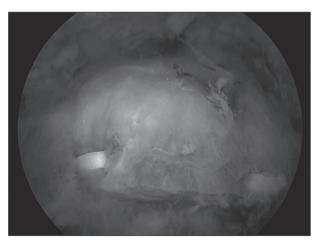


Figure 4. Final result of bio-inductive implant postioning (lateral portal view)

xenograft and synthetic implants results appear to be comparable (22).

The augment could result in a precious aid for the orthopedic surgeon also in cases of partial articular supraspinatus tendon avulsion (PASTA) to support the healing of the rotator cuff. The use of the augment would result interesting specifically in patients with poor tendon quality, avoiding the debridement and the completion of the lesion.

In our cases the use of the bio-inductive implant resulted simple and rapid, increasing the complete duration of the surgical procedure of approximately ten minutes. In all probability, the duration could decrease as the learning curve progresses. In our opinion the placement of the lateral portal is fundamental to obtain a good outcome, since it permits the access of the instruments to place the implant in parallel with the direction of the tendon fibers.

Furthermore, the use of Neviaser portal, recommended by us, offers the operator the tangential positioning of the absorbable anchors, resulting more functional and practical, instead of using the accessory lateral portal recommended by the manufacturing company.

Lastly, in our opinion, it is important to familiarize with the size of the implant (available in medium and large sizes) in order to guarantee the lateral fixation with the Peek anchors at the level of the greater tuberosity.

For this reason we recommend to use a sterile needle as marker, determining accurately the bone compactness below the tendon.

The final outcome is highly satisfying intraoperatively and the implant fixation with absorbable and Peek anchors is well-adhered to the underlying tendon.

The postoperative protocol reflects our normal postoperative protocol following to rotator cuff repair.

No complications occurred during first six weeks of follow-up. It would result interesting to assess the long-term clinical scores and the diagnostic assessments (ultrasound or MRI study) of the implant integration with the native tendon.

Conclusions

The use of the bio-inductive implant in the arthroscopic rotator cuff repair resulted easy, rapid and reproducible. In our opinion, it is indicated as a support in large lesions and in partial articular lesions with significant tissue degeneration of the rotator cuff. The absence of early complications, though the limited number of cases, results to be encouraging also considering the possible use in the daily practice.

Although no current scientific evidences regarding such implants exist, in selected cases and with the correct indications, the use of bio-inductive implant could represent an effective aid and an option in case of complex rotator cuff tears. **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

References

- 1.Audenaert E, Nuffel VJ, Schepens A, Verhelst M, Verdonk R. Reconstruction of massive rotator cuff lesions with a synthetic interposition graft: a prospective study of 41 patients. Knee Surg Sports Traumatology Arthrosc. 2006;14(4):360–4.
- 2.Avanzi P, Dei Giudici L, Capone A, Cardoni G, Lunardi G, Foti G et al. Prospective randomized controlled trial for patch augmentation in rotator cuff repair: 24-month outcomes. J Shoulder Elbow Surg.2019;28(10):1918-1927.
- 3.Galatz LM, Ball CM, Teefey SA, Middleton WD, Yamaguchi K. The outcome and repair integrity of completely arthroscopically repaired large and massive rotator cuff tears. J Bone Joint Surg Am. 2004;86-A(2):219–24.
- 4.Bernazzani M, McMartin T, Garbis N. Repairing PASTA Lesions Without Violation of the Rotator Cuff. Arthrosc Tech. 2020 Jun 9;9(7):e883-e887.
- Snyder S. Arthroscopic Classification of Rotator Cuff Lesions and Surgical Decision Making. Philadelphia: Lippincott Williams & Wilkins; 2002.
- 6.Millstein ES, Snyder SJ. Arthroscopic evaluation and management of rotator cuff tears. Orthop Clin North Am. 2003;34(4):507-520.
- Davidson J, Burkhart S. The geometric classification of rotator cuff tears: a system linking tear pattern to treatment and prognosis. Arthroscopy. 2010:26(3):417-424.
- 8.Sun L, Zhang Q, Ge HA, Sun Y, Cheng B. Which is the best repair of articular-sided rotator cuff tears: A metaanalysis. J Orthop Surg Res. 2015;10:84.
- 9.Deutsch A. Arthroscopic repair of partial-thickness tears of the rotator cuff. J Shoulder Elbow Surg. 2007;16:193-201.
- 10.Castricini R, La Camera F, De Gori M, Orlando N, De Benedetto M, Galasso O et al. Functional outcomes and repair integrity after arthroscopic repair of partial articular supraspinatus tendon avulsion. Arch Orthop Trauma Surg. 2018;139:369-375.
- 11.Park JY, Lhee SH, Oh KS, Moon SG, Hwang JT. Clinical and ultrasonographic outcomes of arthroscopic suture bridge repair for massive rotator cuff tear. Arthroscopy. 2013:29(2):280-289.
- 12.Di Benedetto ED, Di Benedetto P, Fiocchi A, Beltrame A, Causero A. Partial repair in irreparable rotator cuff tear: our experience in long-term follow-up. Acta Biomed. 2017;88(4S):69-74.
- 13.Bishop J, Klepps S, Lo IK, Bird J, Gladstone JN, Flatow EL. Cuff integrity after arthroscopic versus open rotator cuff repair: a prospective study. J Shoulder Elbow Surg. 2006;15:290e9.

- 14.Sugaya H, Maeda K, Matsuki K, Moriishi J. Repair integrity and functional outcome after arthroscopic double-row rotator cuff repair. A prospective outcome study. J Bone Joint Surg Am. 2007;89:953e60.
- 15.Ricci M, Vecchini E, Bonfante E, Micheloni GM, Berti M, Schenal G et al. A clinical and radiological study of biodegradable subacromial spacer in the treatment of massive irreparable rotator cuff tears. Acta Biomed. 2017;88(4S):75-80.
- 16.Stewart RK, Kaplin L, Parada SA, Graves BR, Verma NN, Waterman BR. Outcomes of subacromial balloon spacer implantation for massive and irreparable rotator cuff tears: a systematic review. Orthop J Sports Med. 2019:7(10), 2325967119875717.
- 17.Derwin KA, Badylak SF, Steinmann SP, Iannotti JP. Extracellular matrix scaffold devices for rotator cuff repair. J Shoulder Elb Surg. 2010;19(3):467–76.
- 18.Chalmers PN, Frank RM, Gupta AK, Yanke AB, Trenhaile SW, Romeo AA et al.All-arthroscopic patch augmentation of amassive rotator cuff tear: surgical technique. Arthrosc Techniques. 2013;2(4):e447–51.
- 19.Flury M, Rickenbacher D, Jung C, Schneider MM, Endell D, Audigé L. Porcine dermis patch augmentation of supraspinatus tendon repairs: a pilot study assessing tendon integrity and shoulder function 2 years after arthro-

scopic repair in patients aged 60 years or older. Arthroscopy. 2018;34(1):24–37.

- 20.Karuppaiah K, Sinha J. Scaffolds in the management of massive rotator cuff tears: current concepts and literature review. EFORT open reviews. 2019;4(9): 557-566.
- 21.Chalmers PN, Tashjian RZ. Patch Augmentation in Rotator Cuff Repair. Curr Rev Musculoskelet Med. 2020;13(5)561-571.
- 22.McIntyre LF, Bishai SK, Brown III PB, Bushnell BD, Trenhaile SW. Patient-reported outcomes after use of a bioabsorbable collagen implant to treat partial and full-thickness rotator cuff tears. Arthroscopy. 2019;35(8):2262-2271.

Received: 10 October 2020

Accepted: 20 November 2020

Correspondence:

Gian Mario Micheloni

Orthopedic and Traumatologic Unit - Ospedale San Bortolo

Vicenza - AULSS8 Berica

Tel: 00390444752823

E-mail: gianmario.micheloni@gmail.com