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Supplement

Labral reconstruction with polyurethane implant

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ABSTRACT

Surgical treatment of labral injuries has shifted from debridement to preservation over the past decades. Primary repair and secondary augmentation or reconstruction techniques are aimed at restoring the labral seal and preserving or improving contact mechanics. Currently, the standard of care for non-repairable tears favours the use of auto- or allografts. As an alternative, we present our initial experience using a synthetic, off-the-shelf polyurethane scaffold for augmentation and reconstruction of segmental labral tissue loss or irreparable labral damage. Three patients aged 37–44 (two male, one female) with femoroacetabular impingement without associated dysplasia (Wiberg $>25°$) or osteoarthritis (Tönnis <2) were included in this series. Labral reconstruction (one case) and augmentation (two cases) were performed using a synthetic polyurethane scaffold developed for meniscal substitution (Actifit®, Orteq Ltd, London, UK) and adapted to the hip. Clinical results were analysed with patient-reported outcomes (PROMs) using non-arthritic hip score (NAHS) and daily live activities hip outcome score (DLA HOS) and magnetic resonance images (MRI) at 2- and 4-year follow-up. Clinically improvement was seen in all PROMs at 4 years. The NAHS scores improved from 57.7 to 82.3 (50.9% improvement) and HOS from 59 to 79.3 (35.3% improvement). Last follow-up MRIs confirmed the presence of the scaffold; however, the scaffold signal was still hyperintense compared to native labrum. There was no shrinkage in any scaffold and no progression to hip osteoarthritis seen. Reconstruction or augmentation of segmental labral defects with a polyurethane scaffold may be an effective procedure. At 4 years after implantation, our small cases series resulted in improved hip joint function, reduced pain and scaffold preservation on follow-up imaging.

INTRODUCTION

The acetabular labrum plays a major role in hip joint kinetics. It increases the contact area between femur and acetabulum [1] and provides important function as a fluid seal that improves lubrication, and as a joint stabilizer that increases contact surface area and acetabular volume resulting in a reduction of contact pressures in the femoroacetabular joint [2, 3]. These are key elements in the maintenance and function of the hip over time.

Surgical treatment of labral injuries has shifted from debridement to preservation surgery over the past decades [4, 5]. Primary repair and secondary reconstruction techniques in femoro-acetabular impingement (FAI) are aimed at restoring the labral seal and preserving or improving contact mechanics which is associated with improved results [6, 7]. Labral repair techniques have shown better clinical outcomes, lower revision rate and less long-term progression to osteoarthritis than labral resection [8–10]. The majority of labral tears can be addressed through primary repair techniques [11]. However, degenerative, hypoplastic or calcified labral tissue and previous debridement or failed repair, may not be amenable to repair and require augmentation or reconstruction techniques to restore the labral seal [12, 13].

Labral reconstruction has recently become popular and multiple techniques using autografts or allografts reporting

good outcomes at medium to long term have been described [5, 8, 13, 14]. However, both grafts types are not exempt from complications. Autografts have the disadvantage of donor site morbidity inadequate graft sizing or morphology [15].

Allografts require procurement from a tissue bank, presents a potential risk of immune reaction and infectious diseases transmission, and have shown a later integration [13, 16, 17].

As an alternative to procedures using human tissues, we present our initial experience with a biodegradable, synthetic scaffold originally developed for symptomatic meniscal tissue restoration (Actifit®, Orteq Ltd, London, UK). Its length is 6 cm so it is just suitable for segmental reconstruction but not for a circumferential one. Study approval was obtained from the local ethics committee (N° 2018/8109/I, Parc de Salut Mar). To the best of our knowledge, this technique has not been previously described and reports the surgical approach for labral augmentation and reconstruction with a polyurethane labral scaffold along with first-in-man clinical outcomes and radiological findings at 4-year follow-up.

CASE DESCRIPTIONS

Three patients, two male aged 40 and 37 and one female aged 44, were included in this study. All subjects were evaluated and treated by the senior surgeon, with long-term experience in hip arthroscopy. Patients were assessed pre-operatively and at 2- and 4-year follow-up with patient-reported outcome measures (PROMs) using the non-arthritic hip score (NAHS) and the daily live activities hip outcome score (DLA HOS). A 1.5 T magnetic resonance imaging (MRI) was carried out and compared at 2- and 4-year follow-up to assess the status of the labral substitute and the progression of hip osteoarthritis.

Surgical technique

Hip arthroscopic was performed with the patient placed in the supine position on a traction table. The hip joint is distracted, and portal placement was performed according to the standard hip arthroscopy protocol previously described using standard anterolateral (AL), mid-anterior distal and distal anterolateral portals [18]. An image intensifier to evaluate distraction and to guide accurate portal placement was utilized. When necessary, acetabuloplasty was undertaken according to pre-operative planning. Bony debridement was performed to achieve a healthy and suitable bony attachment. In the case of a residual small healthy labrum, labral augmentation was considered; however, if an irreparable labrum was present, labral substitution was undertaken Two bone anchors were placed just posterior to healthy labral margins. In Case 1, an additional bone anchor was placed in the middle of the defect. The defect was then measured with a flexible plastic ruler and a polyurethane scaffold substitute was prepared using a Medial Actifit (Actifit®, Orteq Ltd, London, UK), as seen in Fig. 1 with resection of lateral scaffold wall until an 8 mm width and an oversized defect length of 0.5 cm was achieved.

Attachment of the scaffold was achieved with sliding knots outside the patient (Fig. 2) and slipped inside the joint using a cannula or a half pipe cannula, sliding the most lateral knot first followed by the medial knot (Fig. 3). Secondary suture anchors over the length of the scaffold were placed at a distance of 10 mm with trans-scaffold sutures affixed to bone or trans-scaffold sutures attached to the native labrum in case of augmentation.

Traction was released and a T-capsulotomy was performed for femoral cam resection when present. An impingement test at 90° flexion was performed to confirm the absence of impingement.

Subject presentations

Subject 1

Subject 1 was a 40-year-old man with groin pain-related to mixed FAI in his right hip. He had a positive impingement test, decompression manoeuvre and dynamic internal rotation test, while FABER test was negative. X-rays showed an Alfa angle of 60° at 45° Dunn view and cross over sign with a Wiberg angle of 30° on a pelvic AP view. No signs of osteoarthritis with joint space >2 mm and Tönnis 0 of OA classification. Pre-operative NAHS was 42 and DLA HOS 47.

Surgery was scheduled for labral repair and femoro-acetabular osteoplasty but finally debridement of anterolateral labrum was performed because of irreparable labrum due to tear and frayed tissue. Three months later, surgery was carried out because of persistent groin pain and instability which still required the use of crutches. A 3-mm depth acetabuloplasty of the anterior wall and an osteoplasty of the residual cam was performed. The labral defect was confirmed between 12 and 2 o'clock in the anterior wall and reconstructed with a labral scaffold of 4 cm in length.

Subject 2

Subject 2 was a 44-year-old woman who was referred because of groin pain in her right hip related to sport and work activities (nurse). FAI was suspected after physical examination that included positive impingement test, decompression manoeuvre and dynamic impingement test. Pincer type FAI was confirmed by cross over sign on X-ray. Wiberg angle >25° and Tönnis osteoartrhitis

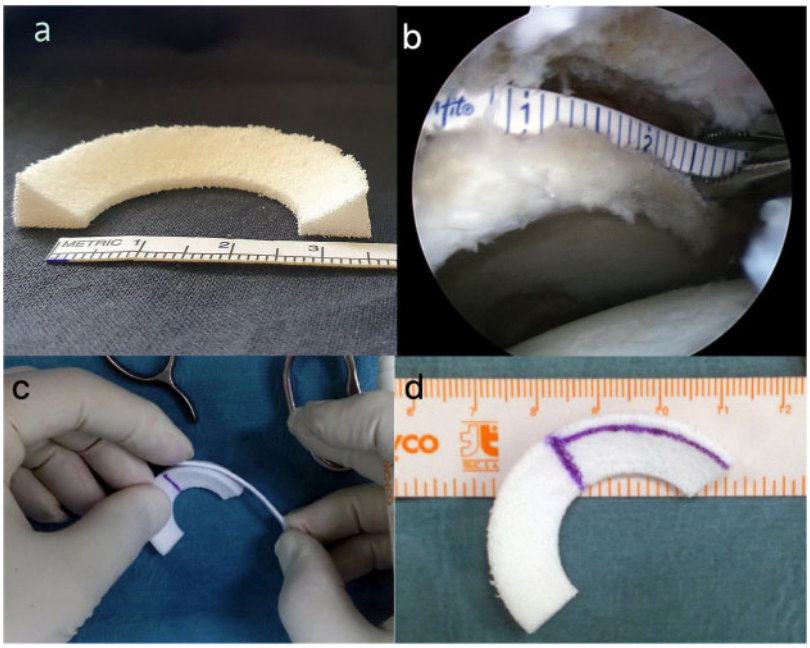

Fig. 1. Preparation of labral scaffold from medial meniscal polyurethane substitute (subject 2). (**a**) Scaffold, with 6 cm length and 1 cm height. (**b**) Measurement of labral length defect with a plastic flexible ruler. (**c**) Using the plastic ruler on the scaffold to mark desired length. (**d**) Scaffold prepared to be cut.

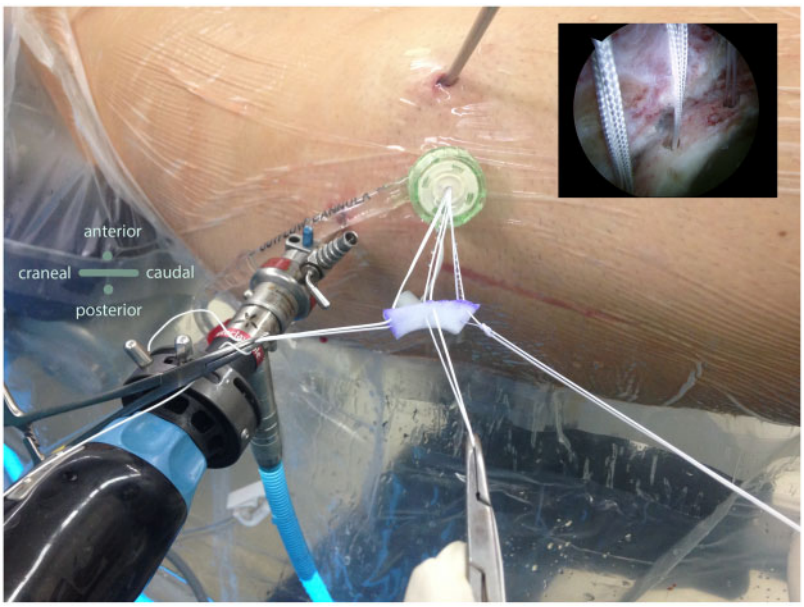

Fig. 2. Right hip of subject 1 with scaffold prepared for introduction. Three bone anchors were previously placed covering the defect. On the corner the arthroscopic view from anterolateral portal.

classification of 1 confirmed lack of dysplasia or advanced osteoarthritis. MRI showed normal cartilage and femoral head sphericity. After an unsuccessful course of physiotherapy hip arthroscopy was carried out in 2010 where pincer resection and a labral reattachment was performed. A small anterior labrum of 3 mm in width was noted and a lack of labral seal seen at final assessment after traction release by the intraoperative impingement test. Due to persistent pain and functional limitation for activities of daily living, revision surgery was planned using a labral augmentation.

Surgery was performed in February 2015 and a hypoplastic and frayed labrum of <3 mm height, attached to the bone rim was confirmed as well as healthy hyaline cartilage in both acetabular and femoral sides. Labral augmentation was carried out with a 3.5-cm length polyurethane scaffold to cover the area where detachment and acetabuloplasty was previously performed (Fig. 4). The rest of the labral structure was also hypoplastic but without fraying, so we decided not to include in the augmentation.

Subject 3

Subject 3 was a 37-year-old man referred because of groin pain related to physical activity. The subject described groin pain and there was a positive impingement test, decompression manoeuvre, dynamic internal rotation test and negative FABER test. X-ray showed an Alfa angle of 58° at 45° Dunn view and Wiberg angle of 30° on pelvic AP view, as well as Tönnis 0 at osteoarthritis classification. MRI showed a labral tear at the anterior wall with a small labrum. Pre-operative NAHS was 85 and DLA HOS 75.

Surgery was performed in December 2016. A hypolastic anterior labrum was confirmed by a measurement of 2–3 mm labral height as well as limited torn labrum between 12 and 1 o'clock in the anterior wall. Labral augmentation was performed just for torn labrum with a labral scaffold of 3.5 cm length attached with three suture anchors.

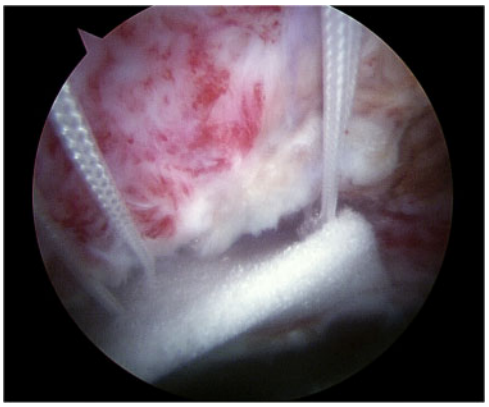

Fig. 3. Right hip of subject 1 from anterolateral portal were scaffold is placed sliding the knot of medial bone anchor.

Post-operative rehabilitation

A standard post-operative rehabilitation programme for labral reconstruction was used. Weight bearing was restricted to 50% body weight for 3 weeks. Post-operative day 1, patients began supervised physical therapy with progressive continuous passive motion, with circumduction movements to increase motion and prevent adhesions. Active movements and strength mainly of pelvi-trocantheric muscles was initiated at 3 weeks post-operative, and a normal gait pattern was established. Heterotopic ossification prophylaxis was routinely administered, using indomethacin for 3 weeks. Advanced rehabilitation began 3 months after surgery with sport readaptation and progressive

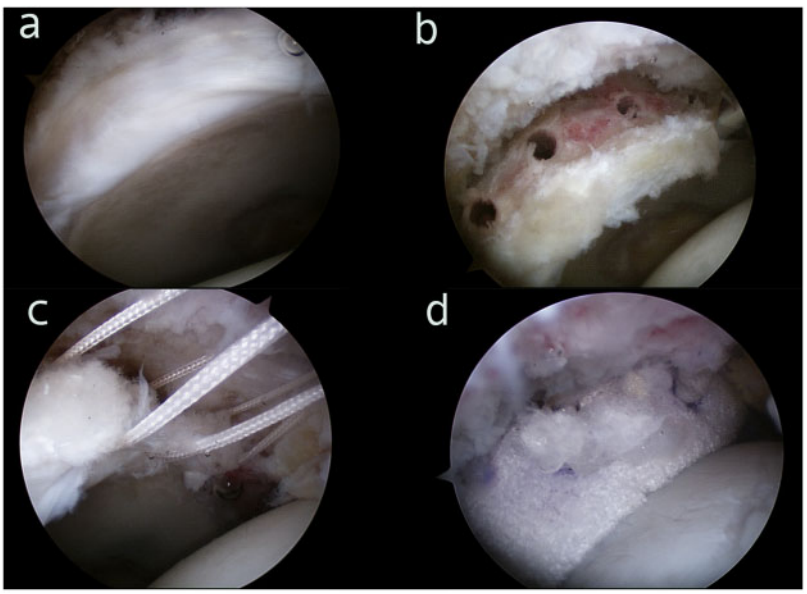

Fig. 4. Right hip of subject 2 view from anterolateral portal. (**a**) Hypoplastic labrum, without original triangular shape. (**b**) Holes on acetabular rim, prepared for insertion of bone anchors. Note the remaining labrum is preserved. (**c**) Bone anchors [3] in place and involving the remaining labrum. (**d**) After traction release, contacto of scaffold with femoral head during impingement test.

increase in joint impact. Return to play and high impact sports were not recommended for 6–8 months.

RESULTS

There were no surgical complications in any case and post-operative rehabilitation had a normal course, similar to patients with labral reconstruction by other techniques.

Outcomes

Clinical outcomes measured by PROM's showed improvement of NAHS nab DLA HOS at 4 years post-operative (Table I). The NAHS score improved from an average of 57.7–82.3 (50.9% improvement, 17.6–78.6) and the HOS from 59 to 79.3 (35.3% improvement, 23.6–48.9).

MRI

Last follow-up MRIs confirmed the presence of the scaffold; however, the scaffold signal was not equal to the native labrum. Hyperintensity in T1 images was present at 2- and 4-year follow-up, but there was no shrinkage in any scaffold and no progression to hip osteoarthritis seen on the 2-or 4-year MRIs (Fig. 5).

DISCUSSION

The most relevant finding of this study was the improvement in PROMs and radiological results at 4-year follow-up in a small series of patients treated with a synthetic polyurethane scaffold using a segmental labrum augmentation or reconstruction technique.

The use of this polyurethane implant for reconstruction of knee menisci was developed more than 15 years ago for treatment of symptomatic, segmental meniscus insufficiencies. This biodegradable synthetic implant has an interconnected macroporous structure allowing for blood vessels ingrowth and a new tissue regeneration. Scaffold integration in the hip joint can be expected due to the abundant vascular supply of the acetabulum bone bed after debridement and bone refreshment or resect in addition to the surrounding vascularization. Since the hip is not subjected to the same compressive and shear forces as in the knee, comparable results may be achieved.

A number of studies have shown good to excellent results following implantation of this scaffold in the knee. A recently European multicentre study has shown good clinical and radiological results, with a survival of 87.5% after 5 years of follow-up [19]. Schuttler *et al.* [20] showed that good short-term results of their clinical series were maintained up to a mid-term follow-up of 4 years. MRI images showed no significant changes in the articular cartilage over the follow-up period. More recently Butt *et al.* [21] re-confirmed good short-term follow-up in his case series at 2 years. Their MRI results imply that meniscal scaffolds may have a chondroprotective effect on the articular cartilage and a slowing of the progression of osteoarthritis.

In this study, MRI results demonstrated correct positioning and sizing of the scaffold at 1- and 4-year follow-up. Other studies have reported good MRI results of polyurethane scaffolds in the knee. Verdonk *et al.* [22] confirmed the appearance of tissue ingrowth on DCE-MRI at 3 months post-operative in 81.4% of the patients. Efe *et al.* [23] reported a stable appearance of the scaffold and host tissue at 6 and 12 months post-operative. The lack of progression to OA with the use of a scaffold was confirmed by Bulgheroni *et al.* [24], Schuttler *et al.* [20] and Haspl *et al.* [25].

Key advantages of segmental labral reconstruction with a synthetic off-the-shelf scaffold may include *ad hoc* availability compared to allograft limitations [26], a faster operative time through concurrent scaffold preparation instead of tissue harvesting or allograft preparation, no donor-site morbidity, a potentially reduced infection rate, and avoidance of disease transmission. Further economic advantages may become apparent with future commercialization of this scaffold in the hip. With further development of this technique, hip joint preservation surgery may be enhanced with the use of synthetic scaffolds which may lead towards a lower total hip arthroplasty (THA) conversion rate due to failed allograft reconstruction. Maldonado

Table I. Clinical outcomes (PROMs) at 4-year follow-up

PROMs	*NAHS Pre-operative*	*NAHS Post-operative*	*HOS Pre-operative*	*HOS Post-operative*
Subject 1	42	**75**	47	**70**
Subject 2	46	**72**	55	**68**
Subject 3	85	**100**	75	**100**

bold are the results of the postoperative scores.

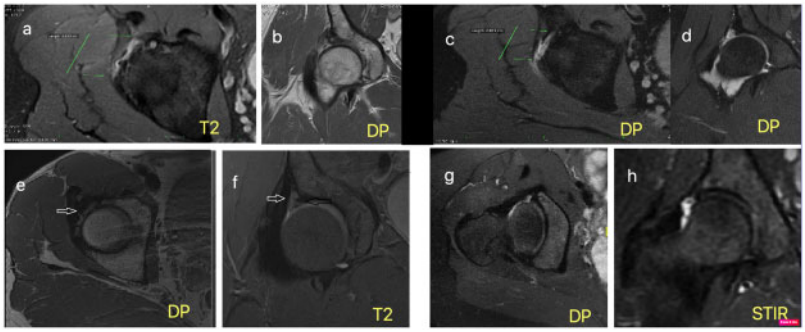

Fig. 5. MR follow-up of the three cases. (**a** and **b**) Pre-operative axial and sagital views of subject 1, with a labral defect marked with green arrows of 2.8 cm. (**c** and **d**) Final follow-up with labral reconstruction. Note that the scaffold is hyperintense in DP sequences. (**e** and **f**) Final follow-up of subject 3 with labral augmentation. White arrow points scaffold and black arrow points residual native labrum. Native labrum is hypointense while scaffold remains isointense at DP and T2 sequences. (**g** and **h**) MR at 4-year follow-up where the scaffold is hyperintense at STIR and DP sequences.

[27] reported a conversion to THA rate of 17.6% with complications of 21.4% at 30 months following allograft labrum reconstruction.

Limitations of autograft tissue include a reduced survivorship of 70% at 5 years and 61% at 10 years, with a mean survival time of 9 years with revision or THA as the endpoint. Nine percent of the hips underwent revision arthroscopy and 27% underwent THA [28].

Reconstruction of larger defects is more feasible with the scaffold than some other techniques such as autologous capsule tissue or indirect head of the rectus tendon reconstruction that allow only up to 1 cm defect size [8]. Scaffolds are easy to manoeuvre due to their strong consistency allowing for the retaining of sutures until integration and growth of new labral tissue. The 8 mm thickness and adaptable length with its easy manipulation allows treatment of any segmental labral injury of less than 6 cm length. The triangular shape of the implant is similar to the labral anatomy compared to the cylindrical as the tubulised fascia lata grafts. This shape allows a good insertion at the base of the triangle and a correct apposition on the femoral head, thus restoring the labral seal, as observed intraoperatively when reducing the hip after segmental labral reconstruction in this case series.

A recently performed biomechanical cadaveric study on reconstruction of the hip labrum with a polyurethane scaffold has been completed. Contact and peak stresses were restored to normal following segmental labral reconstruction with the scaffold. In comparison to partial labrectomy, reconstruction with the scaffold significantly decreased contact pressure [29].

The indications for labral augmentation and/or reconstruction with a polyurethane implant could possible be the same as those described in the literature for other types of labral grafts: labral pathology, refractory to conservative treatment, presenting labral tissue insufficient for repair, a hypoplastic labrum <3 mm or a revision surgery for previous labral debridement. Contraindications include a pre-operative joint space ≤ 2 mm or advanced degenerative joint disease; therefore, the same as for preservation surgery [12, 15].

The main limitation of this study is the small sample size. A histological study demonstrating growth of new labral tissue inside the implant would have been helpful; however, none of the patients needed reoperation. The promising histological description of early vascularization of an allograft at 8 weeks after labral allograft reconstruction [17] suggest the high integration capacity that occurs in labral reconstruction due to the double vascular supply received from the capsule and the cancellous bone from the acetabular rim. For this reason and due to the histological findings in meniscal reconstruction surgery, scaffold integration and formation of labrum-like tissue may be encouraged in the hip. Augmentation was limited to the frayed or manipulated labrum for pincer resection, but not extended to the complete hypoplastic labrum, and that can be the cause of a suboptimal results at PROM evaluation, with a clear improvement but not arriving to the 80s or 90s expected at NAHS and HOS evaluation.

CONCLUSION

Reconstruction or augmentation of segmental labral defect with a synthetic off-the-shelf polyurethane scaffold may be an effective alternative to autograft or allograft tissue in patients with a non-repairable labrum in femoro-acetabular impingement. At 4 years after implantation, our small cases series resulted in improved hip joint function, reduced pain and scaffold preservation on follow-up imaging. A larger

prospective cohort study is needed to confirm our early findings.

CONFLICT OF INTEREST STATEMENT

There are no conflicts of interest in this study.

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