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ORIGINAL STUDY

Early complications from the use of porcine dermal collagen implants (Permacol™) as bridging constructs in the repair of massive rotator cuff tears A report of 4 cases

J. Agustin SOLER, Sam GIDWANI, Mark J. CURTIS

From Kingston Hospital, Kingston upon Thames, Surrey, United Kingdom

The repair of massive rotator cuff tears can be very challenging. Different surgical techniques are described in the literature, including debridement of the cuff with subacromial decompression, attempts at direct partial repair, various tendon transfers, shoulder hemiarthroplasty, reversed shoulder arthroplasty and allograft augmentation. Following favourable published evidence of the use of porcine dermal collagen implants, Permacol™ (Tissue Science Laboratories, Hampshire, UK, now known as Collagen Repair Patch™, Zimmer, Warsaw, Ind) as a bridging device to repair massive defects, we used it in four of our patients. However, we have seen with great concern that in all four cases, the grafts failed between 3-6 months after a promising early postoperative period. We report on these 4 cases giving clinical, radiographic and histological findings.

We conclude that although Permacol™ has many obvious advantages, it should not be used to bridge irreparable massive rotator cuff tears.

Keywords : rotator cuff tear ; repair ; Permacol ; porcine dermal collagen.

INTRODUCTION

Massive rotator cuff tears are often debilitating and painful, and their treatment remains a challenge. Several techniques are described in the literature, including debridement of the cuff with subacromial decompression, attempts at direct partial repair, various tendon transfers, shoulder hemiarthroplasty, reversed shoulder arthroplasty and allograft augmentation (*11*). More recently there has been increasing interest in the potential role of human, bovine and porcine-derived implants, of either small intestinal or dermal origin (*14*), as augmentation or even bridging devices when direct repair is impossible. Animal studies have demonstrated that such implants may in fact enhance rotator cuff healing (*4*). However there is little data available on the complications or limitations of these products.

Permacol™ is a recently introduced porcine-derived implant, engineered for use in soft tissue repair and reconstruction throughout the human body (*5*). It is produced from porcine dermal collagen, and its architecture is very close to that of human tissue. According to the manufacturers, as it is not a reconstituted form of collagen, its three

■ J. Agustin Soler, MD, Research & Clinical Fellow in Orthopaedics.
University College Hospital, London.
■ Sam Gidwani, MD, Specialist Registrar in Orthopaedics.
■ Mark J. Curtis, MD, Consultant Orthopaedic Surgeon.
Kingston Hospital, Kingston upon Thames.
Correspondence : J. Agustin Soler, Flat 6, Cambridge Court, Cambridge Road, Kingston upon Thames, Surrey, KT1 3LX, United Kingdom. E-mail : agustinsoler@cortado.com.

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dimensional architecture is more likely to be maintained (*6*). Indeed, in its production process, it has been chemically cross-linked with hexamethylene diisocyanate to make it more resistant to enzymes responsible for the breakdown and resorption of implanted collagen. It is sterilized by gamma-irradiation.

We have used Permacol™ (Tissue Science Laboratories, Hampshire, UK, now known as Collagen Repair Patch™, Zimmer, Warsaw, Ind) implants to augment repairs of supraspinatus tears in a group of 20 patients. In four of these twenty patients there was a significant residual defect after attempted convergence repair, and we therefore used the Permacol implants in these selected cases as a *bridging* device. In these four patients, the repairs failed within 6 months, and in two some form of revision surgery was required. We present the clinical, imaging and histological findings from these cases. To the best of our knowledge, this is the first report of failure of this particular implant used for bridging irreparable defects.

CASE SERIES

Our cohort of 4 patients underwent rotator cuff repair by the same Consultant Orthopaedic Shoulder Surgeon during a 2 year period (2003-2005). There were three females and one male. The mean age was 76 (range 71-82 years). They all presented with pain, weakness to the rotator cuff and decreased range of motion. In three of the cases the diagnosis was degenerative tear of the rotator cuff. The fourth case had a history of traumatic rupture of the rotator cuff 3 months previously (table I).

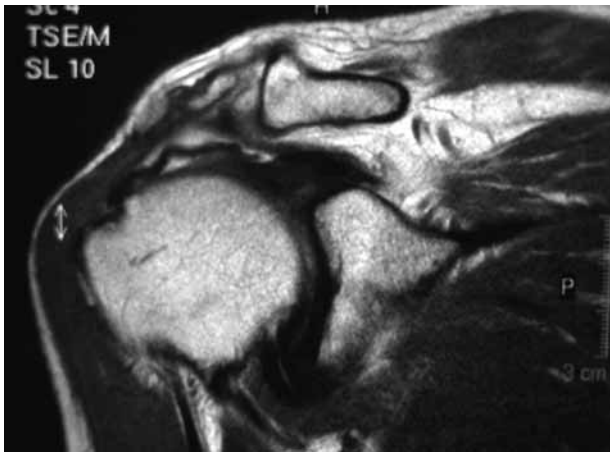
All patients underwent subacromial decompression, if it had not been previously carried out. The

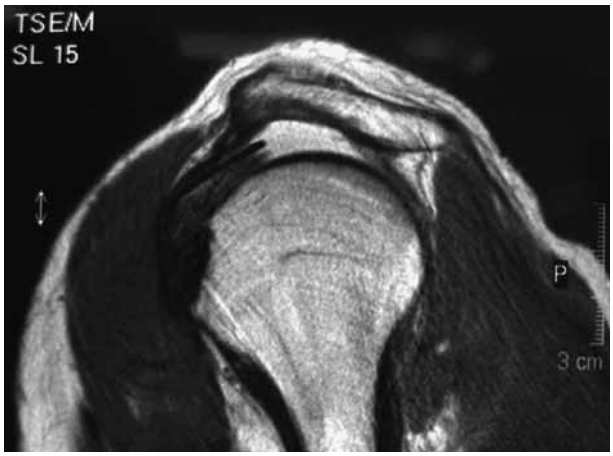
Table I. — A summary of the case histories of the four patients

Patient	Age/Sex	Previous procedures	Symptoms prior to Permacol graft	Approach used	Time to failure post-op	Symptoms of failure	Further surgery
1	82/F	Subacromial steroid injection only	Gradual increase in pain and night pain over 3-6 months. No trauma.	Superior bra-strap incision, OSD and excision ACJ	3 months	Reduced range and strength, increased pain	No
2	76/M	Subacromial steroid injection only	Fall 3 months before leading to acute pain and weakness. Previous minor impingement symptoms.	ASD, deltoid split used for cuff repair (‘mini-open’)	6 months	Reduced range and strength, increased pain	No
3	75/F	ASD & excision ACJ 6 months before, tear diagnosed	Continuing pain, weakness and night pain over 6 months.	Superior bra-strap incision, OSD and excision ACJ	3 months	Pain, catching and weakness	Delta shoulder replacement (good result)
4	71/F	OSD, excision of ACJ & S/Sp repair 8 yrs before	Fall 6 months before leading to acute pain and weakness.	Superior bra-strap incision reused	3 months	Inflammation and pain*	Delta shoulder replacement (good result)

* Ultrasound guided aspiration carried out to exclude infective cause.

Abbreviations : ASD : Arthroscopic Subacromial Decompression ; OSD : Open Subacromial Decompression ; ACJ : Acromioclavicular joint ; S/Sp : Supraspinatus.





Figs. 1 & 2. — Coronal and sagittal T2 MRI scans of the shoulder of Patient 2 showing pooling of fluid in the subdeltoid bursa and loss of integrity of the Permacol™ graft.

combination of subacromial decompression and rotator cuff repair was achieved either using arthroscopic decompression combined with a mini-open repair via a deltoid split approach or through a bra-strap incision, with a Rockwood 2-step acromioplasty and subperiosteal elevation of the deltoid.

In each of the four cases, there was a residual defect following a convergence cuff repair and therefore, a Permacol™ graft was used to bridge the defect *(2)*. The Permacol™ patch was sutured in place using Bio-Corkscrew suture anchors and #2 FiberWire® suture material (Arthrex, Naples, Florida, USA).

Following a good postoperative recovery between 3 to 6 months, with improvements in range of movement and pain, all four patients who had their defects bridged with a Permacol™ graft showed signs and symptoms of a recurrent rotator cuff tear. In all cases there were signs of inflammation, which were so florid in patient 4 that an ultrasound-guided aspiration was needed to exclude an infective aetiology. Indeed, the microbiology report was negative for infection.

MRI studies were conducted in all four patients (fig 1&2). In each case the MRI scan showed inflammatory change, resorption of the graft and significant fluid pooling in the subdeltoid bursa. There was also evidence of loss of continuity of the remaining graft material.

Two of the four cases proceeded to have Delta CTA™ reverse total shoulder replacements (DePuy, Johnson & Johnson, USA). During the operations, it was noted that the Permacol™ implant had disintegrated and was unrecognisable. All that was found was a mass of collagenous debris. Again, microscopy and culture of this material did not reveal any evidence of infection. Histological analysis of the debris confirmed necrotic fibrinous material on a background of chronic inflammation (fig 3).

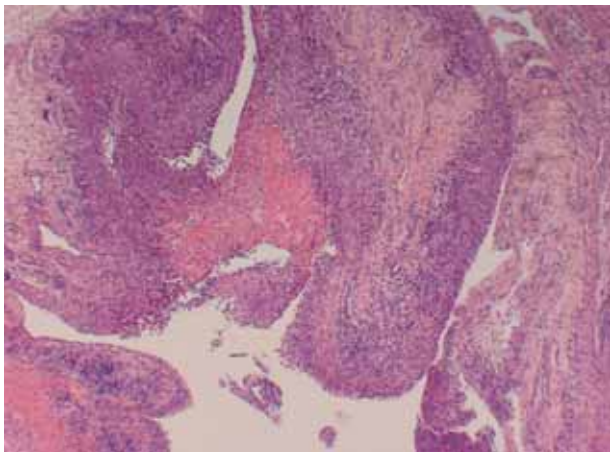


Fig. 3. — Histological specimen demonstrates significant numbers of chronic inflammatory cells and no recognisable remnants of the porcine collagen-derived graft.

With regards to the other 16 patients who received the implant as an augment to the rotator cuff repair, none have experienced similar complications or early failure of their repairs to date.

DISCUSSION

The ideal implant in the context of rotator cuff repair would be a biologically inert material that does not degrade or lose its tensile strength inside the body, or one that allows sufficient ingrowth of host cells to allow healing of the cuff tendon before it loses its strength.

Various grafts can be used in rotator cuff repair to supplement or augment a repair (*8, 11, 12, 14*). Animal studies of porcine-derived implants, albeit of small intestinal origin, have been encouraging : tissue ingrowth without any evidence of foreign body or immune-mediated reactions has been demonstrated when grafts were used to repair tears in the infraspinatus tendon of adult dogs (*3*). However a recent study looking at the histological response to five commercially available bioscaffolds in rats, including Permacol™, demonstrated very distinct host tissue responses and rates of degradation (*4*). This coincides with work that has shown significant differences between four of these bioscaffolds (not including Permacol™), both in terms of their biomechanical properties and DNA content (*15*). It was particularly interesting to note that all the bioscaffolds tested had a modulus of elasticity one order of magnitude less than that of normal canine infraspinatus tendon.

When faced with an irreparable tear or defect in the rotator cuff, one may consider the use of a graft to bridge the defect. In a study by Neviaser *et al* (*13*), all but 2 of 16 patients with massive rotator cuff tears treated with freeze-dried allografts to bridge the defect had good or excellent results (*13*). They also reported a definite decrease or absence of nocturnal pain in all 16 patients.

With specific reference to the implant which we have used, a previous medium-term study suggested that Permacol™ could be safely and effectively used to *bridge* irreparable defects in the rotator cuff, a concept that has also been suggested by Zimmer (*7*). Ten patients were followed for 12 months and experienced a significant improvement in symptoms and Constant score, without obvious complications (*14*).

However, there have also been a few reports of less satisfactory results. A case of localised inferior orbital fibrosis associated with Permacol™ has been reported in the context of orbital blowout fracture repair (*2*). Upon exploring the orbit, gross fibrosis of the inferior rectus muscle was noted. Biopsy of the area revealed chronic granulomatous inflammation suggestive of foreign body reaction. A randomized controlled trial of trapeziectomy alone or with interposition of Permacol™ implants had to be terminated prematurely because of apparent inflammatory reactions to the implant in 6 of 13 patients (*1*).

All the cases of early failure that we report occurred when this implant was used as a bridging device to repair rotator cuff defects, seeing the promising results of published work. However, after a short period of promising postoperative recovery, the patients again began experiencing pain and weakness of the operated shoulder. Imaging investigations including USS and MRI demonstrated partial or full rupture with breakdown of the implant, inflammatory changes and effusions, all supporting the fact that the implants had failed.

In one of the cases that underwent a further surgical procedure, a mass of collagenous debris was noted. This was presumed to be the liquefying collagen implant as there were no other signs of the implant. Histological examination revealed necro-inflammatory exudate admixed with fibrinous material and chronic synovitis. Interestingly, there has been another recent and similar report of porcine small intestine submucosal implants (as opposed to the porcine dermal collagen used in this study) in rotator cuff repairs causing non-specific inflammatory reactions with early failure of the repair (*10*).

In our series of patients, when used as a bridging device rather than simply for augmentation of a repair, this implant was associated with an inflammatory response that ultimately weakened and compromised the repair. All four patients experienced a worsening of symptoms. While it is

not possible to definitively establish the reason for this failure, it may be related to greater exposure to the joint and synovial structures, and possibly also to the greater forces that may be transmitted through such a graft when used to bridge a defect and not simply to augment a repair.

In conclusion, while the use of Permacol™ has many obvious advantages, we do not advocate using it to bridge irreparable defects. We have stopped using this implant to bridge rotator cuff repairs until more information from larger studies becomes available.

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