Chapter 10
Massive and Irreparable Rotator Cuff Tears

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Abstract When primary repair of a massive rotator cuff tear is impossible, the lesion is called an irreparable rotator cuff tear. Treating irreparable rotator cuff tears is difficult as a result of the less satisfactory results and a higher retear rate. In addition, if massive rotator cuff rupture is left untreated, this complication frequently leads to cuff tear arthroplasty. Therefore, is would be helpful to change the concept of treatment from tissue repair and/or reconstruction to tissue regeneration. For tissue regeneration, the use of a scaffold is necessary. Based on the results of this experimental study, we concluded that the PGA sheet scaffold material allows for the regeneration of the tendon-to-tendon as well as tendon-to-bone interface in an animal model.

Based on the findings of the experimental study, we performed patch graft repair with a polyglycolic acid (PGA) sheet, an artificial biomaterial, for irreparable rotator cuff tear cases and successfully improved the results of repair for irreparable rotator cuff tears in terms of postoperative pain control and short-term outcomes. PGA sheets are a possible artificial scaffold material for promoting tendon regeneration in rotator cuff repair.

Keywords Rotator cuff • Massive and irreparable tear • Artificial material • Polyglycolic acid • Regeneration

10.1 Introduction

The management of massive rotator cuff tears is thought to be challenging because of the less satisfactory results and higher retear rate. In addition, if left untreated, massive rotator cuff rupture frequently leads to cuff tear arthroplasty [1]. Even when this complication is treated with total shoulder arthroplasty, shoulder pain and elevation disturbances frequently persist. In fact, there is a recent trend to

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K. Tamai et al. (eds.), *Advances in Shoulder Surgery*,
DOI 10.1007/978-4-431-55988-7_10

treat difficult cases using reverse total shoulder arthroplasty; however, this procedure is very invasive [2]. Therefore, various surgical techniques, including musculotendinous transfer [3–5] and patch grafts with autologous fascia lata [6] or artificial materials [7], have been used for the treatment of irreparable tears. However, the application of musculotendinous transfers necessitates the sacrifice of normal tissue and does not result in anatomic reconstruction unless rotator cuff repair is also performed. Furthermore, patch grafts made using fascia lata tend to degrade from normal wear and stretching [7], and those made using nonabsorbable artificial materials become mechanically weaker over time as a result of foreign-body reactions and/or infection. Hence, new strategies for the treatment of irreparable rotator cuff tears must be developed. The development of a tissue-engineering technique [8] offers a promising future for musculoskeletal tissue repair, and many studies have reported success in tendon engineering both in vitro [9, 10] and in vivo [11–13].

Based on the results of an experimental study, we performed a clinical study using a sophisticated artificial material. We hypothesized that it would be better to repair defects of the rotator cuff according to the patch graft technique using a polyglycolic acid (PGA) sheet without sacrificing the autologous tissues, such as the fascia lata, and employing a minimally invasive operative procedure using an arthroscopic patch graft. The purpose of this study was to investigate the short-term clinical results of arthroscopic PGA sheet patch graft repair for irreparable rotator cuff tears based on the concept of tissue regeneration.

10.2 Materials and Methods

We defined irreparable rotator cuff tears as those that, because of their size and retraction, cannot be repaired primarily to the site of insertion onto the tuberosity, despite conventional techniques of mobilization and soft tissue release. This study involved 75 patients selected from 436 patients who were evaluated in the shoulder surgery section of our department for shoulder pain in the years 2012–2013. The study was performed according to our hospital ethics committee guidelines and approved by our hospital ethics committee. All subjects [28 women and 47 men, with a mean age of 65.7 years (range, 57–77 years)] were diagnosed with irreparable rotator cuff tears. The patients were assigned to receive surgical treatment using repair with a PGA sheet (Neoveil, Gunze, Japan) patch graft (PGA group, 37 patients) or a fascia lata patch graft (PG group, 38 patients). Informed consent was obtained from all participants. The kind of patch to be used was selected randomly, and the patients were treated by the same surgical team. The exclusion criteria were as follows: (1) osteoarthritis of the glenohumeral joint; (2) inflammatory arthritis or any rheumatic condition; (3) labral lesions requiring additional procedures, such as type 2 superior labrum anterior posterior or Bankart lesions; (4) biceps lesions requiring tenodesis; and (5) injuries of the contralateral shoulder. The surgical procedure was performed arthroscopically in all patients. Partial

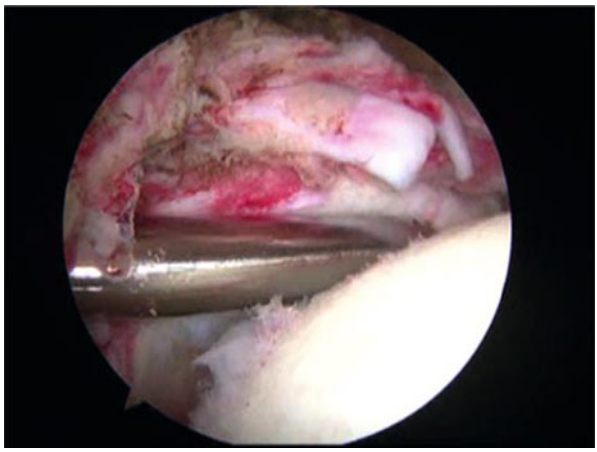

Fig. 10.1 Arthroscopic findings. The irreparable rotator cuff injury was found arthroscopically

bursectomy, minimal acromioplasty, and adhesion release were performed. The size of the defect was measured, and a graft of the same size as the defect was made using a PGA sheet (PGA group) or the fascia lata (PG group). The graft was placed underneath and overlapped with the edge of the torn tendon at a width of more than 5 mm to protect against superior migration of the humeral head. The sutures on the graft were passed through the tendon and tied up on the tendon surface. The fascia lata was harvested from the lateral side of the thigh just distal to the great trochanter. The footprint was prepared with a rasp, and two or three suture anchors were used in a single-row fashion (Figs. 10.1 and 10.2).

All patients followed the same rehabilitation regimen, which included the use of a rigid brace for 3 weeks and passive movement exercises under the supervision of a physical therapist for an additional 5 weeks. Active movement exercises were commenced at 3 weeks with limitation of the elevation angle. A strengthening exercise program was started at 12 weeks postoperatively.

The patients were clinically evaluated preoperatively and at 1, 3, 6, and 12 months postoperatively. The Japanese Orthopaedic Association (JOA) shoulder rating scale was used to evaluate the subjects preoperatively and at 12 months postoperatively. A magnetic resonance imaging (MRI) examination was performed at 1 year postoperatively in all patients. The intensity of the grafted patch was graded as high-, iso-, or low intensity, and the patients were classified into high-intensity, iso-intensity, and low-intensity groups.

Patients whose grafted patch contained a large amount of high-intensity areas were assigned to the high-intensity group, those with a large amount of iso-intensity areas in the grafted patch were assigned to the iso-intensity group, and those with a large amount of low-intensity areas in the grafted patch were assigned to the low-intensity group. High-intensity areas were thought to contain poorly matured tissues and low-intensity areas were considered to contain well-matured tissues. The rate obtained comparing the high-intensity group and the other groups was

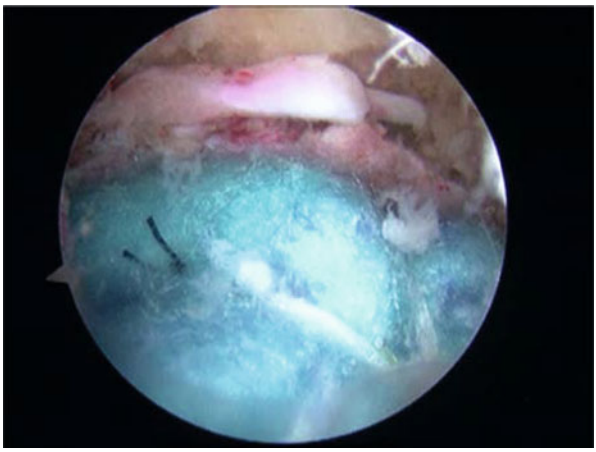

Fig. 10.2 Arthroscopic finding. Arthroscopic polyglycolic acid (PGSA) sheet patch graft was performed for an irreparable rotator cuff injury

defined as the high-intensity rate. No second-look arthroscopic surgeries or biopsies were performed.

Statistical analysis was conducted using the Mann–Whitney *U* test among the treatment groups. When comparing the pre–post treatments, the paired *t* test was performed. When comparing high-intensity rates, the Pearson chi-square test was used. A *p* value less than 0.05 was considered as being statistically significant.

10.3 Results

The follow-up analysis showed that each group benefited from the surgical treatment of irreparable rotator cuff tears. The mean JOA scores improved from 54.9 ± 1.1 points preoperatively to 90.7 ± 1.0 points at the 12-month follow-up ($p < 0.01$) in the PGA group and from 52.6 ± 1.5 points preoperatively to 91.7 ± 1.2 points at the 12-month follow-up ($p < 0.01$) in the PG group (Table 10.1). For the factor of pain, the mean scores improved from 15.8 ± 2.1 points preoperatively to 26.7 ± 1.1 points at the 12-month follow-up ($p < 0.01$) in the PGA group and from 14.7 ± 1.8 points preoperatively to 25.6 ± 1.4 points at the 12-month follow-up ($p < 0.01$) in the PG group. For the factor of function, the mean scores improved from 11.6 ± 2.2 points preoperatively to 17.6 ± 1.3 points at the 12-month follow-up ($p < 0.01$) in the PGA group and from 12.5 ± 1.4 points preoperatively to 16.8 ± 1.5 points at the 12-month follow-up ($p < 0.01$) in the PG group.

The MRI findings at 1 year showed a low-intensity rate of 51.4 % (19/37 patients), an iso-intensity rate of 35.1 % (13/37 patients), and a high-intensity rate of 13.5 % (5/37 patients) in the PGA group, and a low-intensity rate of 39.5 % (15/38 patients), iso-intensity rate of 28.9 % (11/38 patients), and high-intensity rate of 31.6 % (12/38 patients) in the PG group (Table 10.2). The MRI findings at 1 year

Table 10.1 The Japanese Orthopaedic Association (JOA) score of each group (points)

	Before surgery	12 months after surgery
PGA group	54.9 ± 1.1	90.7 ± 1.0*
PG group	52.6 ± 1.5	91.7 ± 1.2*

Mean JOA scores improved from 54.9 ± 1.1 points preoperatively to 90.7 ± 1.0 points at 12-month follow-up ($p < 0.01$) in the polyglycolic acid (PGA) group and from 52.6 ± 1.5 points preoperatively to 91.7 ± 1.2 points at 12-month follow-up ($p < 0.01$) in the patch graft (PG) group
*$p < 0.01$

Table 10.2 Magnetic resonance imaging (MRI) findings

	Low-intensity group	Iso-intensity group	High-intensity group
PGA group	51.4 % (19/37 patients)	35.1 % (13/37 patients)	13.5 % (5/37 patients)*
PG group	39.5 % (15/38 patients)	28.9 % (11/38 patients)	31.6 % (12/38 patients)*

MRI findings at 1 year showed a low-intensity group of 51.4 % (19/37 patients) and an iso-intensity group of 35.1 % (13/37 patients), a high-intensity group of 13.5 % (5/37 patients) in the PGA group, and a low-intensity group of 39.5 % (15/38 patients), an iso-intensity group of 28.9 % (11/38 patients), and a high-intensity group of 31.6 % (12/38 patients) in the patch graft (PG) group
The high-intensity rate was significantly lower for the PGA group ($p = 0.001$)
*$p = 0.001$

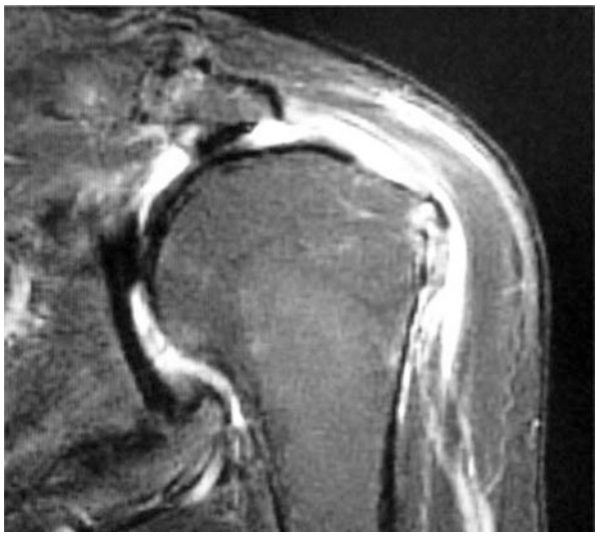

Fig. 10.3 Magnetic resonance imaging (MRI) finding before surgery

showed a high-intensity rate of 13.3 % (4/30 patients) in the PGA group and 31.2 % (10/32 patients) in the PG group (Figs. 10.3, 10.4). The high-intensity rate was significantly lower in the PGA group ($p = 0.001$). The type of implanted patch was the only factor affecting the retear rate. No major complications occurred, and no adverse events related to patch application were noted, including local inflammation, fibrosis, or subacromial adhesions affecting the joint function.

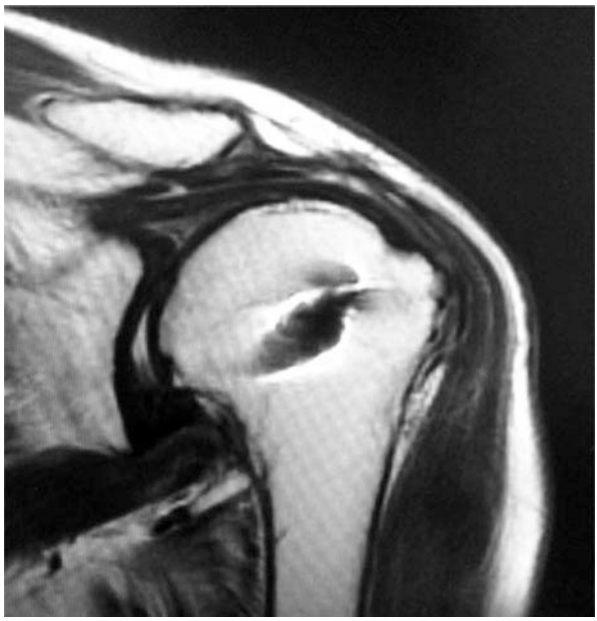

Fig. 10.4 Magnetic resonance imaging finding 1 year after surgery

10.4 Discussion

Rotator cuff tears represent the most common cause of shoulder pain in patients older than 60 years. Surgical repair of rotator cuff tears has become a common procedure with good clinical results [14–17]. However, failure of repair for massive rotator cuff tears occurs in 20 % to 68 % of patients, depending on tear size, patient age, degree of muscle atrophy, muscle fatty degeneration, and chronicity [18–24]. In addition, the high retear rates after surgery can be attributed to the quality of the residual tendon and healing capacity of the residual tendons. Native rotator cuff enthesis is characterized by complex morphological structures and involves direct insertion. The complex morphological structure of bone tendon insertion is difficult to repair. When primary repair of a massive rotator cuff tear is impossible, the lesion is called an irreparable rotator cuff tear. Treating irreparable rotator cuff tears is difficult for many reasons. Patients with irreparable rotator cuff tears may present with a variety of manifestations, such as no or mild symptoms, or may be completely disabled and in severe pain. The true incidence of irreparable rotator cuff tears is not known; however, anatomic studies of cadavers and imaging studies of asymptomatic patients have demonstrated rotator cuff tears in 30 % to 50 % of older patients, especially in those older than 70 years [25–27]. Tempelhof et al. [28] studied 411 asymptomatic individuals and found that 38 % of those older than 70 years had full-thickness rotator cuff tears. Rotator cuff tears with an increased degree of fatty infiltration and muscle atrophy, in association with a high-riding humeral head to the acromion, are at high risk of becoming irreparable. Goutallier

et al. [22] used computed tomography (CT)scans to evaluate fatty infiltration, although magnetic resonance imaging (MRI) is probably more sensitive [17]. Irreparable rotator cuff tears occur in two physiologically distinct patient groups; however, they can be present in all age and activity groups. Most often, these tears occur in physiologically older, lower-demand patients (older than 70 years, and usually female) who are asymptomatic until a minor trauma creates symptoms. The second group consists of physiologically younger, more active patients, often in the sixth decade of life, who present with dramatic symptoms of pain and disability after an acute event or with a history of rotator cuff surgery or chronic rotator cuff injury. When the patient complains of symptoms of pain and disability, operative treatment should be considered. However, the development of a retear after surgical repair of a massive rotator cuff tear is an unsatisfactory result. Several factors, such as patient age, preoperative tear size, degree of muscular atrophy, degree of fatty infiltration of the cuff muscle, surgical technique, and inappropriate rehabilitation, have been demonstrated to be associated with tendon retears [29–32]. Generally, when massive rotator cuff tears are successfully repaired, excellent clinical results may be achieved and joint degeneration may be halted or at least markedly decelerated [33]. Trappey and Gartsman [34] insisted that a low-tension environment is critical for rotator cuff healing. Other biomechanical studies have demonstrated that the elements needed for the successful repair of rotator cuff tears are strong fixation [35], a high interface pressure, and a wide interface area between the tendon and bone [36], as well as minimizing the concentration of stress inside the tendon [37]. In cases of arthroscopic repair of massive rotator cuff tears, achieving effective anatomic repair is difficult because the repair construct is under inevitably undue tension even after adequate release. Therefore, the retear rate of massive rotator cuff tears is generally higher than that of smaller rotator cuff tears. Recent studies have demonstrated that the postoperative healing rate after arthroscopic repair of massive rotator cuff tears is 47 % to 94 % [23, 29, 38, 39].

Based on these reports, we considered that it would be better to change the concept of treatment from tissue repair and/or reconstruction to tissue regeneration. For tissue regeneration, a scaffold is necessary. We subsequently performed an experimental study for the purpose of selecting the optimal scaffold material to promote the regeneration of structures within the articular joint as a pilot study.

We selected three biomaterials for our pilot study—polytetrafluoroethylene (PTFE), poly-L-lactate-epsilon-caprolactone (PLC), and polyglycolic acid (PGA) sheets—that were used in clinical applications with different absorption speeds. We sutured these synthetic biomaterials to the surface of the medial joint capsules using 3-0 nylon sutures in the bilateral knee joints of 27 Japanese white rabbits weighing 3.0–3.4 kg (Japan SLC, Hamamatsu, Japan) and evaluated the histological findings. PTFE, a nonabsorbable synthetic material, is used in clinically vascular surgery for reconstruction of large vessels, including the heart and abdominal wall, and, indeed, for covering irreparable tears of the rotator cuff [3]. PLC, an absorbable material, is very flexible with a rubber-like elasticity to facilitate a complete recovery and is known to degrade very slowly depending on the hydrophilicity of each monomeric unit. This PLC sheet has been used for the dura mater [40] and blood vessels in

experimental studies [41] and clinical applications [42]. PGA, which is known to degrade rapidly, is biocompatible and has been approved for human clinical applications [43]. PLC, PGA, and their copolymers have received great interest in the tissue-engineering field [44]. In our pilot studies, we confirmed that the PGA sheet hydrolyzes most rapidly, exhibiting a potential for producing abundant fibrous tissue with fewer foreign-body reactions. Subsequently, we examined which scaffold is adequate for regeneration of the rotator cuff between PGA and PLC and confirmed that the PGA sheet is more suitable. We did not consider the PTFE sheet to be suitable for tendon regeneration because it caused a substantial foreign-body reaction in the pilot study and fibrous cells did not infiltrate into the PTFE fibers. Moreover, polyglyconate is the strongest absorbable monofilament available [45]. Many experimental studies employing tissue engineering techniques have been performed using PGA [10, 46–50]. Polyglycolic acid sheets are used in thoracic surgery in various clinical applications and have been approved by the Ministry of Health and Welfare as a medical tool. We therefore considered it reasonable to use PGA sheets in clinical applications for tissue engineering (Fig. 10.5).

We subsequently performed an experimental study of patch grafts to compare the validity of the biomaterials, PGA and PLC sheets, using an irreparable rotator cuff injury model in rabbits.

As to the PLC group, on a gross examination, the remaining PLC scaffold sheets were covered with thin scar-like tissue at all time points. A histological examination of the tissues in the PLC group 4 weeks after surgery revealed the gross presence of PLC fibers. Randomly oriented fibroblasts and fibers with a small diameter exhibiting minimal wave formation surrounded by trabecular bone were found around the scaffolds at the tendon insertion sites. There was also infiltration of granulation tissue and blood vessels between the PLC fibers, and the interface was bridged by loose connective tissue. Some chondrocytes were seen, although they were not arranged along the long axis (Fig. 10.6). At 16 weeks after surgery, the PLC sheet grossly remained, and many multinuclear cells indicating a foreign-body

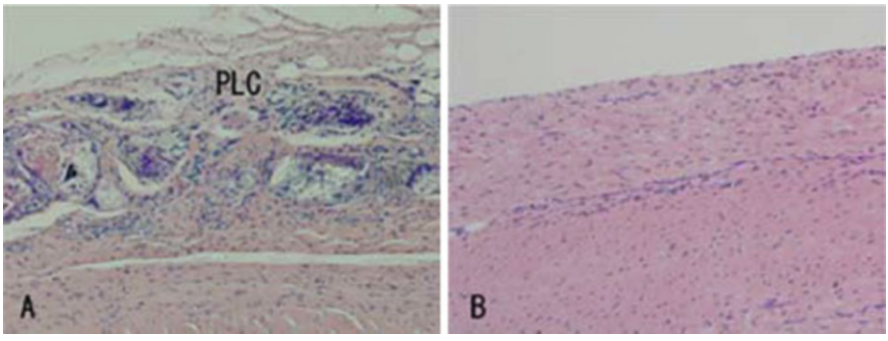

Fig. 10.5 Micrographs of specimens of the surface of the capsules of the knee joints 24 weeks after surgery with the poly-L-lactate-epsilon-caprolactone (PLC) sheet (**a**) and PGA sheet (**b**). Hematoxylin and eosin, ×100. (From Yokoya et al. [50])

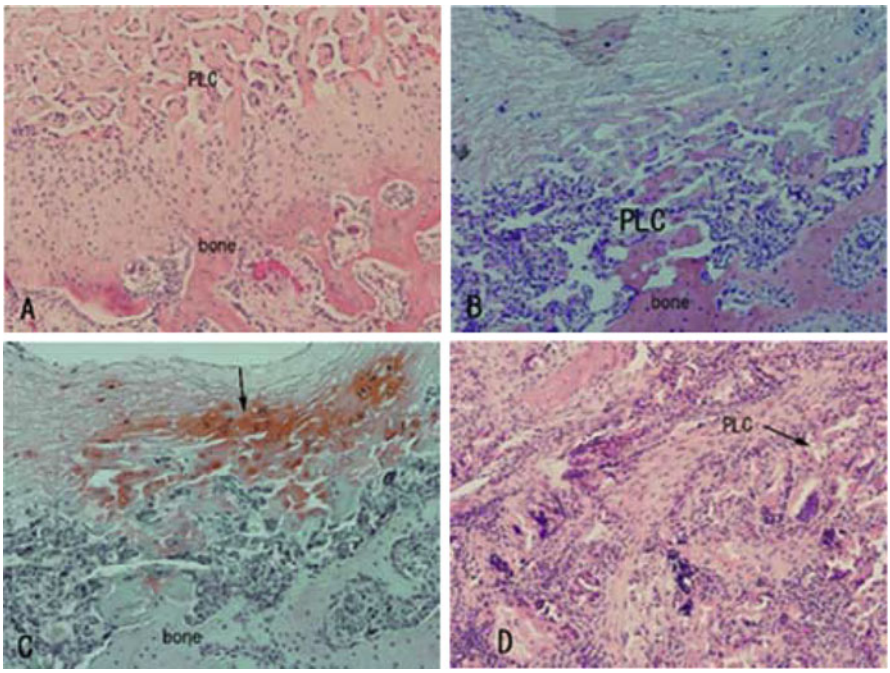

Fig. 10.6 Micrographs of specimens in PLC group. (**a**) At the PLC–bone interface at 4 weeks after the operation: *PLC* PLC scaffold, *bone* trabecular bone. Hematoxylin and eosin, ×100. (**b**) At the PLC–bone interface at 16 weeks: *PLC* PLC scaffold, *bone* trabecular bone. Hematoxylin and eosin, ×100. (**c**) At the PLC–bone interface at 16 weeks: *arrow* metachromasia indicating proteoglycan, *bone* trabecular bone. Safranin-O, ×100. (**d**) At the tendon proper at 16 weeks: *PLC* remaining PLC fibers. Hematoxylin and eosin, ×100. (From Yokoya et al. [50])

reaction were noted around the sheet. Although the conjunction area between the PLC fibers and trabecular bone was increased, the cell and fiber arrangement at the sites of tendon insertion was irregular. Some chondrocytes were scattered, and metachromasia was found around the chondrocytes on Safranin-O staining, thus indicating that the tissue contained proteoglycan. In the tendon proper, even at 4 and 16 weeks after surgery, the regenerated tendon-like tissue did not show good continuity between the PLC fibers and the proximal tendon edge, the border being quite clear, except for a small region. A few fibroblasts were found; however, they were highly scattered and many vessels were seen in the newly regenerated tendon at all time periods. Furthermore, significant foreign-body reactions were observed around the fiber areas at 8 and 16 weeks.

As to the PGA group, on a gross examination, the PGA sheets were covered with thick scar-like tissue on the implanted scaffold at 4 weeks after surgery. At 16 weeks, the PGA fibers were substituted with tendon-like scar tissue at the area of tendon insertion. A histological examination of the tissues in the PGA group 4 weeks after surgery revealed that the PGA fibers were partially degraded into

small fragments, and extensive foreign-body reactions were detectable around the fragments of the PGA fibers. The tendon insertion site consisted of predominantly immature fibrous tissue aligned along the load axis (Fig. 10.7). At 8 weeks, most of the fibrous tissue was parallel to the long axis, although some direct collagen fibers were observed. At 16 weeks after surgery, tendon-to-bone healing was seen with the formation of continuous tissues, indicating the creation of parallel collagen fiber continuity between the tendon and bone with collagen fibers noted along the long axis. Fibrocartilage interface tissue stained with Safranin-O metachromasia, indicating the proteoglycan content, was partially found in smaller amounts than normal, although these amounts were larger than that seen in the PLC group. The PGA fibers were completely degraded, and no foreign-body reactions were seen at any sites at this time point. A histological examination of the tendon proper site 4 weeks after surgery revealed that the PGA-repaired areas exhibited a layer of inflammatory cells on the surface of the suture material. The volume, density, and crimp pattern of these bands appeared to increase gradually in both groups by 8 and 16 weeks. Some treated repair tissues at 16 weeks had densely packed, highly

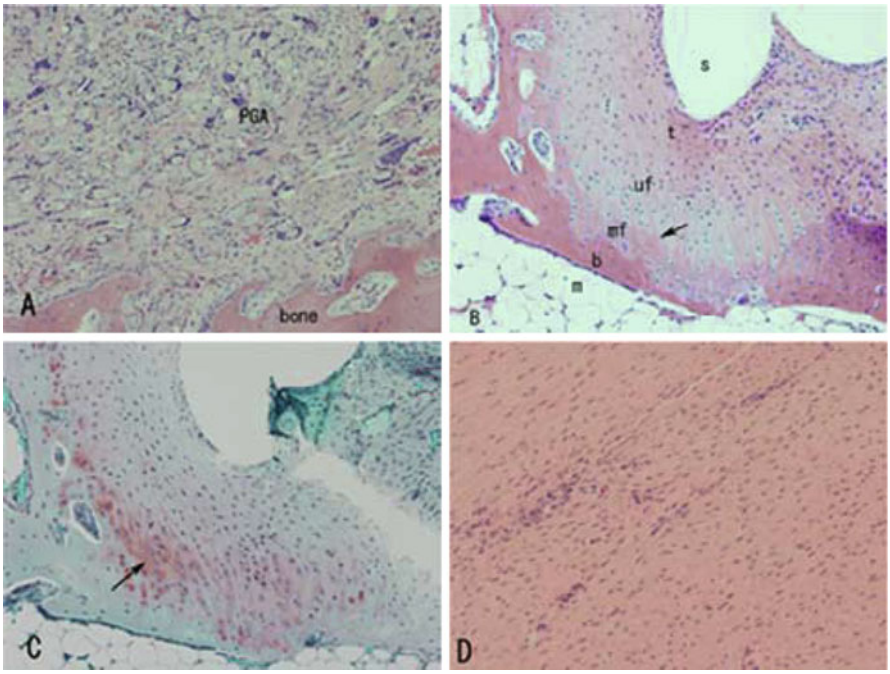

Fig. 10.7 Micrographs of specimens in PGA group. (**a**) At the PGA–bone interface at 4 weeks after the operation: *PGA* PGA fibers, *bone* trabecular bone. Hematoxylin and eosin, ×100. (**b**) At the PGA–bone interface at 16 weeks: *s* suture tract, *t* tendon, *uf* unmineralized fibrocartilage, *mf* mineralized fibrocartilage, *b* bone, *m* bone marrow, *arrow* tide mark. Hematoxylin and eosin, ×100. (**c**) At the PGA–bone interface at 16 weeks: *arrow* metachromasia indicating proteoglycan. Safranin-O, ×100. (**d**) At the PGA–tendon interface at 16 weeks. Hematoxylin and eosin, ×100. (From Yokoya et al. [50])

crimped fibers; these fibers were grouped in bundles along the axis of the tensile load.

Implants consisting of PGA sheets, a rapidly absorbable material, were used to replace completely resected infraspinatus tendon insertion sites in 33 adult Japanese white rabbits, and a well-arranged fibrocartilage layer was found at the regenerated tendon insertion sites; however, the sites of tendon insertion were mainly regenerated by type III collagen [51]. From the results of this experimental study, we concluded that the PGA sheet scaffold material allows for the regeneration of the tendon-to-tendon as well as the tendon-to-bone interface in an animal model. The PGA sheet is therefore a possible alternative scaffold material for tendon regeneration in cases of rotator cuff repair.

We hypothesized that it would be better to repair defects of the rotator cuff clinically according to the patch graft technique using a polyglycolic acid (PGA) sheet without sacrificing the autologous tissue, such as the fascia lata, and selecting a minimally invasive operative procedure, arthroscopic patch grafting.

Although some research has been reported regarding the regeneration of tendon insertion sites, these sites were regenerated with autologous tissues [52, 53], not artificial biomaterials. The tissue-engineering approach using biodegradable three-dimensional scaffolds offers more potential options for the treatment of severe tendon lesions. However, no studies have previously reported the regeneration of tendon insertion sites using artificial biomaterials [53–55]. Three-dimensional scaffolds should be biocompatible, highly porous, and biodegradable. The scaffold should permit cell invasion and easy attachment of cells and should provide an environment that is suitable for cell proliferation and differentiation. The cells must be allowed to secrete their own extracellular matrix components, promoting the formation of a tissue-like organization, while the scaffold itself tends to degrade as it synchronizes the organization of the extracellular matrix [56]. Polytetrafluoroethylene (PTFE), used as an artificial biomaterial for irreparable massive rotator cuff tears [7, 55], poly-L-lactate-epsilon-caprolactone (PLC), a synthetic scaffold possessing adequate flexibility, retractility, and a late absorbable speed [40, 41, 44], and polyglycolic acid (PGA), which shows relatively fast degradation and is the strongest absorbable monofilament available [45], are some of the most commonly used artificial biomaterials in experimental studies. Among them, PGA, which enhances cell–cell interactions at high cell densities and stimulates extracellular matrix production [12], appears to have the desired characteristics.

Tissue-engineering techniques using a biodegradable scaffold offer potential alternatives for recreating valid tendon-to-tendon and tendon-to-bone interfaces. In the present study, implants consisting of PGA sheets, a rapidly absorbable material, were used to replace completely resected infraspinatus tendon insertion sites in 33 adult Japanese white rabbits, and a well-arranged fibrocartilage layer was found at the regenerated tendon insertion sites. Based on the results of this experimental study, we concluded that the PGA sheet scaffold material allows for the regeneration of the tendon-to-tendon and tendon-to-bone interface in an animal

model. PGA sheets are a possible alternative scaffold material for tendon regeneration in the setting of rotator cuff repair.

Based on these experimental data, we investigated the clinical results of arthroscopic PGA sheet patch grafts for irreparable rotator cuff tears. The results showed that the application of a patch graft with a PGA sheet, an artificial biomaterial, can improve the results of repair of irreparable rotator cuff tears in terms of postoperative pain control and short-term outcomes. The use of patches, either biological or artificial biomaterials, has been advocated to reduce the high-intensity rate, as supported by the rationale that collagenous scaffolds may improve tendon resiliency after repair, even if these materials are typically absorbed within a few weeks after implantation [57].

On the one hand, biological patches are mechanically weak [58] and rapidly resorbed upon implantation. On the other hand, biological patches provide a suitable environment for tissue repair [59, 60], whereas artificial biomaterials are biologically inert and thought to not provide the regenerative stimuli that support the healing process. Theoretically, the ideal patch for rotator cuff repair should combine the features of both biological and artificial biomaterial patches, serving as an inductive template to carry signals supporting tissue regeneration [60]. The quality of tendons has considerable limitations regarding torn rotator cuff tendons.

In an effort to augment the deficient rotator cuff tissue, and at the same time maintain the anatomic integrity of the shoulder, some surgeons incorporate biological tissue scaffolds into the cuff deficiency [61–64]. A porcine submucosa subintestinal graft, named Restore (DePuy, Warsaw, IN, USA), was found to increase pain and lead to poor tendon healing. Its clinical outcome in humans is in contrast to that seen in many preclinical animal studies, which suggests that the Restore graft may not be suitable for human rotator cuff repair [65].

The GraftJacket (Wright Medical Group, Memphis, TN, USA) is derived from the human dermis and is used as an interpositional graft in cases of massive and irreparable rotator cuff tears. Improvement in the UCLA (University of California Los Angeles) shoulder scores at the 2-year follow-up has been demonstrated. Furthermore, magnetic resonance has indicated tissue incorporation into the graft [66].

Synthetic scaffolds include polytetrafluoroethylene (PTFE) felts and polyester grafts. PTFE was found to improve pain scores in 30 patients with massive rotator cuff tears [63]. In particular, Teflon grafts (PTFE graft) provided satisfactory functional results and strength in 23 of 25 patients, again patients with massive rotator cuff tears, whereas Gore-Tex grafts (PTFE graft) improved the mean JOA score in 27 patients from 57.7 to 88.7 [66], and Dacron grafts (polyester) improved the Constant score in 15 of 17 patients. The Leeds–Keio graft (polyester) used in subscapular transposition augmentation shows superior clinical results to those obtained with augmentation grafts [64].

The chemical and physical properties of synthetic grafts can be controlled, although the trade-off is a lack of biocompatibility, which usually makes the graft nonabsorbable. In addition, a high rate of immune and inflammatory responses has been reported [67]. For these reasons, the PGA sheet may be an ideal patch, being

absorbable and regenerative at this point. However, the satisfactory results reported here, as well as the extensive clinical experience and successful outcomes, prompt further studies.

The limitations of this study include the following: (1) the retrospective design, requiring further randomized prospective studies to ultimately assess the value of patch grafts in rotator cuff repair; (2) the lack of an a priori power analysis; and (3) the fact that no second-look arthroscopic surgeries or biopsies of the repair tissue were performed.

10.5 Conclusion

The 2-year clinical results of irreparable rotator cuff tears repair using arthroscopic patch grafts with a PGA sheet demonstrated an improved shoulder function and significantly lower high-intensity rate, compared with that observed in patients treated with a fascia lata patch. PGA sheets, an absorbable artificial biomaterial, may be an ideal patch, being absorbable and regenerative at this point.

The satisfactory results reported here, as well as the extensive clinical experience and successful outcomes, prompt further studies.

Conflicts of Interest The authors, their families, and any research foundations with which they are affiliated did not receive any financial payments or other benefits from any commercial entity related to the subject matter of this article.

Acknowledgments We are grateful to Brian Quinn for his critical reading of the manuscript.

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