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Evaluation of a Biodegradable Synthetic Matrix for Lateral Ankle Ligament Surgical Repair Augmentation: An Open Label Controlled Multicenter Retrospective Review

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ABSTRACT

Background: The modified Broström procedure is widely accepted to address surgical treatment of chronic lateral ankle instability. Augmentation of the anterior talofibular ligament has become popular in an effort to improve outcomes over modified Broström alone. The purpose of this study was to evaluate outcomes of surgery using a modified Broström alone versus a modified Broström augmented with a synthetic polycaprolactone based-polyurethane urea matrix.

Methods: Retrospective chart review and prospective satisfaction surveys were performed in patients that had undergone Broström alone (MB) or a modified Brostrom with synthetic graft augmentation (PUUR). In the retrospective chart review, patient demographics, healing progression, complications, safety and the postoperative rehabilitation timeline were analyzed. VAS was used to assess pain before surgery and at follow-up visits. Patients 12 months post-surgery were contacted to complete surveys assessing long term stability and patient satisfaction.

Results: There was no difference in VAS between groups before surgery. PUUR patients demonstrated significantly lower VAS at 2-, 6-, and 12-week clinic follow-up visits compared to MB alone. Time to transition to unrestricted full weight bearing (FWB) after surgery was significantly faster in PUUR patients (9.04 ± 0.34 wks vs. 11.4 ± 1.79 wks; P = .047). Procedure specific adverse events were similar between the MB and PUUR groups (3.2% and 4.2%, respectively; p = 0.83).

Conclusion: Our results suggest that augmentation using a synthetic, woven PUUR matrix may lead to reduced early postoperative pain and an earlier transition to unrestricted FWB in patients recovering from chronic lateral ankle instability.

Level of Evidence: III

Keywords: Broström Repair; Lateral Ankle Instability; ATFL

Introduction

Ankle sprains account for up to 40% of all athletic injuries, and 85% of ankle injuries involve the lateral ligamentous complex [1]. Initial patient treatment is conservative, but continued ligament laxity may require surgical intervention. Chronic recurrent lateral ankle instability occurs after 10% to 20% of acute ankle sprains [2]. Although multiple surgical procedures for anterior talofibular ligament (ATFL) repair or ligament reconstruction are well described, the modified Broström repair technique is most widely utilized [3,4]. Yet, reoperation rates have been reported as high as 14% following surgical repair [5]. Lateral ligament repair can be performed alone or with augmentation. For patients with poor tissue quality, medical comorbidities and complex repairs, the use of autograft, allograft, or synthetic augmentation devices may improve healing. Early tissue necrosis and resorption of avascular tissue grafts can lead to loss of biomechanical properties and ultimate load to failure [6-8]. Several synthetic grafts have been developed as alternatives to auto- or allograft replacements. Soft tissue augmentation devices have historically been designed with a rigid structure unmatched to the elastic modulus of the targeted musculoskeletal tissues [3,9]. A degradable biomaterial matrix woven from wet-spun fibers of polycaprolactone based-polyurethane urea (PUUR) provides an augmentation device closer to the elastic modulus of ligament. PUUR textile strips (Artelon Flexband®, Marietta, GA), have been reported for numerous orthopedic soft tissue reconstructive applications [9-13]. PUUR elastomers have an extensive safety record and are widely used biomaterials in catheters, vascular prosthesis, and artificial hearts due to their adaptable mechanical properties and documented biocompatibility [14-17]. The biomechanical properties of PUUR and the woven textile nature create manufacturing adaptability to optimize tensile properties to mimic native tissue. This improves functional kinematics by providing resistance to stress relaxation and creep while decreasing stress shielding.

Although PUUR has been used in >60,000 cases to date in the reconstruction of soft tissues throughout the body, a direct comparison of lateral ankle ligament repair, with and without PUUR augmentation, has not been previously conducted. The purpose of this study was to perform a retrospective medical chart review to assess the safety and efficacy determined by clinical evaluation, VAS, and physical therapy milestones in patients undergoing a modified Broström procedure with and without PUUR augmentation. In addition, patients enrolled in the retrospective study were contacted to complete a longer-term patient outcome and satisfaction survey following at least 1-year post-operative.

Methods

Patient Identification

Following appropriate ethics approval, a retrospective review of patients diagnosed with chronic lateral ankle instability who underwent a modified Broström procedure either alone (MB) or with PUUR augmentation (PUUR) between January 2018 and June 2022 was conducted. Patients that had surgery performed by any of the nine participating foot and ankle surgeons and had postoperative hospital or ASC safety and efficacy data were evaluated for eligibility. All study surgeons performed both augmented and non-augmented repairs. At all participating study institutions, consecutive chart review was performed to identify patients who met all of the inclusion and none of the exclusion criteria (Table 1). 226 patients met study qualifications (MB = 83, PUUR = 143). Data was extracted from both written and electronic medical records. Physician and patient reported outcomes and revision rates were established via chart review from patient scheduled and unscheduled follow up clinic visits. Clinical post-surgical follow up for this procedure typically concludes at 12 weeks, therefore, to collect longer-term outcome measures outside of the clinical follow up window, we attempted to contact all patients via phone at a minimum of one year post operative and asked to complete a satisfaction and functional survey.

Table 1: Study Selection Criteria.

Inclusion Criteria
Patients aged 18 – 75 at the time of surgery
Patients diagnosed with lateral ankle instability by physician clinical assessment
Patients who underwent surgical ATFL repair with or without PUUR augmentation (does not require and isolated repair)
Exclusion Criteria
Significant secondary procedures, including significant OCD lesions and/or significant microfracture of the talus or tibia that warrant modification of the typical lateral ligament repair post-operative protocol
Any concomitant orthopedic procedure that extended the post-operative rehabilitation beyond the routinely prescribed post-op protocol following ATFL repair
Patients undergoing a calcaneal osteotomy
Patients with less than 6-weeks follow-up
Patients with incomplete medical records
Patients who were workers compensation cases
Patients with a history of infection of the ankle predating the ankle repair procedure
Any orthopedic issue outside the ankle that, in the determination of the investigator, may impede functional endpoint measurements

Surgical Technique

PUUR used in the study consisted of strips of varying size (0.3-0.5cm X 8-32cm). For patients that underwent augmentation with the PUUR matrix, the modified Broström procedure was performed first followed by tensioning of the PUUR device anchored on either end via bone tunnels (Figure 1). Using the provided kit, guide wires were placed into the anterior fibula and into extra-articular talus body/neck junction. Bone tunnels were created and the PUUR graft was inserted into the talus first. The modified Brostrom procedure was completed and the PUUR graft was placed overtop or superficial to the repair and inserted into the fibula bone tunnel. Additional procedures such as synovectomy and arthroscopy were commonly performed as needed. A summary of additional procedures in each group is presented (Table 2).

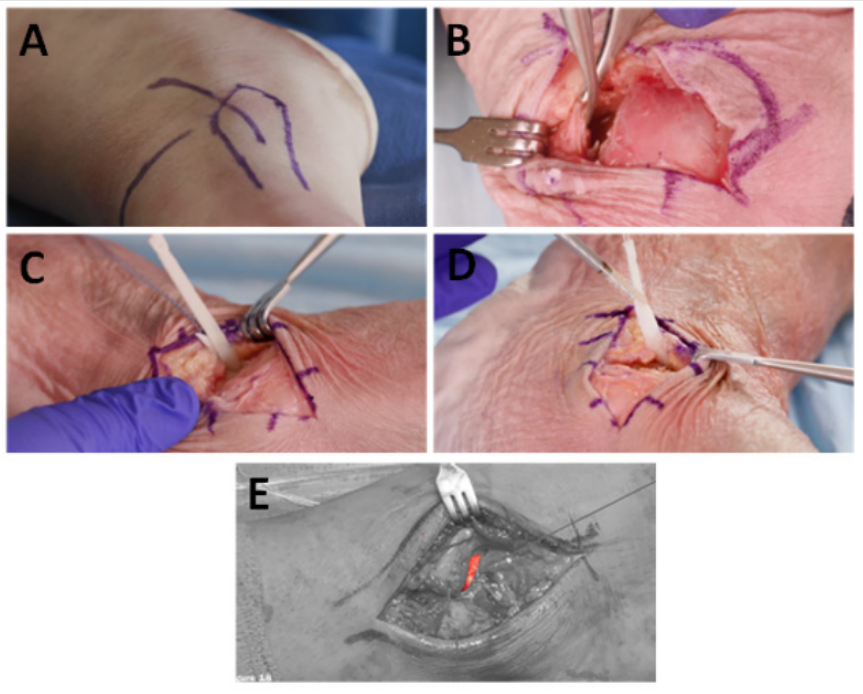

Figure 1: PUUR augmented surgical technique.

A. Compared to a traditional Broström, the incision for PUUR augmentation should be extended by 1cm both proximally and distally. Curving the distal incision anteriorly is helpful to gain greater exposure to the talus.

B. After exposure and takedown of the ankle capsule, the lateral portion of the talus is exposed, and the insertion of the ATFL just off the anterior cartilage border of the lateral talar process is visualized.

C. The PUUR matrix is inserted into the talus using a provided FLEXBAND ANCHOR.

D. The PUUR matrix is next anchored to the fibula using a provided FLEXBAND ANCHOR.

E. Final placement of the PUUR matrix is completed and the incision is closed.

Table 2: Concomitant Procedures.

Additional Procedure	n	Control (%)	PUUR (%)
Ankle arthroscopy	136	36 (43.4%)	100 (68.5%)
Partial excision, talus or fibula	103	14 (16.9%)	89 (62.2%)
Synovectomy	77	14 (16.9%)	63 (44.1%)
Repair of ruptured collateral ligaments	57	15 (34.9%)	42 (29.4%)
Tenodesis, synovectomy, and/or tendon debridement	47	22 (51.2%)	25 (17.4%)
Tenolysis (flexor or extensor tendon)	31	0 (0.0%)	31 (21.7%)
Deltoid/spring ligament repairs	12	7 (8.4%)	5 (3.5%)
Calcaneal fibular ligament repair	12	3 (7.0%)	9 (6.3%)
Osteotomy	11	6 (13.9%)	5 (3.5%)

Characteristics and Outcome Assessments

Patient demographics, diagnosis, and injury history including previous treatments for the index ankle were collected. Clinical evaluations included physician's assessment of healing progression measured by typical patient post-op examination (i.e. wound healing, stability measurements, ROM, swelling, etc). Visual analog scale (VAS) for pain (collected at 2 of 4 participating institutions) was recorded prior to surgery and at 2-, 6-, and 12-week post-surgical visits. Only patients with baseline VAS and VAS at least two follow-up visits were included in VAS analysis. Safety data was assessed by collecting adverse events and complications. While all adverse events were collected, events relating to procedure specific outcomes, including delayed wound healing, wound infection, neuritis, and peri-implant osteolysis were analyzed in greater detail. Complications defined by patients necessitating a return to the operating room were also reported and classified as relating to product, procedure, or neither.

Postoperative rehabilitation milestones including non-weight bearing duration, time to physical therapy initiation, total physical therapy duration, and time to transition from boot to brace with ultimate unrestricted full weight bearing (FWB) were analyzed. Given the multi-center study design, the post-operative rehabilitation programs were not standardized across study sites, however, the approach was similar for all sites and the following summary represents an aggregate protocol. From immediate post-operative: non-weight bearing (NWB; 0-4wks), transition to CAM boot with weight bearing as tolerated (WBAT) and transition to PT initiation (2-6wks), transition out of CAM boot to lace-up brace and progression to FWB (6-10 weeks), sport-specific activity initiation (10-12wks) and return to play (RTP; 12+wks). Progression throughout each stage was determined by the physician and collected from the clinical medical records. Identified patients who were at least 1-year post-operative were solicited by phone, and if willing, consented for participation in phone surveys. Ultimately, 46/143 (32.2%) of PUUR patients and 40/83 (48.2%) of MB patients completed the survey which measured residual pain, instability, any additional procedures including revision surgery, quality of life ratings, and overall satisfaction.

Statistical Analysis

All data were recorded in Microsoft Excel (2011, Microsoft Corp., Redmond, WA). The data are presented as frequencies, means, standard errors, ranges, and percentages. All outcomes for the study were defined as the average change in the outcome from baseline. At each timepoint (2-, 6- and 12-weeks post-operative), the mean change from baseline in both groups was evaluated. Where comparisons were possible, scores were analyzed using a student's t test; a P-value of less than .05 was considered significant. For the comparison of proportions, Chi-square test was used, and a P-value of less than .05 was considered significant.

Results

Patient Characteristics

A total of 226 patients who underwent an MB procedure alone (n=83) or with PUUR augmentation (n=143) were enrolled in the study. There were no differences in patient pre-operative demographics between the two groups (Table 3). Significantly more PUUR patients underwent concomitant procedures at the time of their ATFL repair compared to the MB group (99.3%; 142/143 vs. 80.1%; 67/83; P < .0001). The type and distribution of the most common concomitant procedures between both groups are provided in Table 2. Physician assessment of healing progression was similar between the two groups at the 2-, 6- and 12-week clinical follow-up visits.

Table 3: Patient Demographics.

	Control	PUUR	P-values
Gender	N = 83	N = 143	
Male	27 (32.53%)	46 (32.17%)	
Female	56 (67.47%)	97 (67.83%)	
Age	41.84 ± 1.63	41.78 ± 1.22	0.9735
BMI	33.27 ± 0.81	32.16 ± 0.69	0.3129
Ethnicity			
Caucasian	59 (71.08%)	112 (78.32%)	
African American	6 (7.23%)	8 (5.59%)	
Hispanic	2 (2.41%)	6 (4.20%)	
Asian	1 (1.20%)	1 (0.70%)	
Not Specified	15 (18.07%)	16 (11.19%)	
Non-isolated Repair	67 (80.7%)	142 (99.3%)	0.0000

VAS

VAS was collected before surgery and at each follow-up visit from patients at 2 of the 4 study sites. Preoperatively, there was no significant difference in pain between groups (MB 6.39, PUUR 5.54, P = 0.08). PUUR augmented patients (n=44) demonstrated significantly lower VAS scores compared to MB alone (n=33) at the 2 (4.68 ± 0.35 vs. 6.26 ±0.37, P< .001), 6 (2.95 ± 0.32 vs. 5.42 ± 0.50, P<.0001) and 12 (2.75 ± 0.26 vs. 4.77 ± 0.41, P<.0001) week post-operative visits (Figure 2). At 6- and 12-week postoperative visits, the mean VAS was significantly reduced compared to baseline in both groups.

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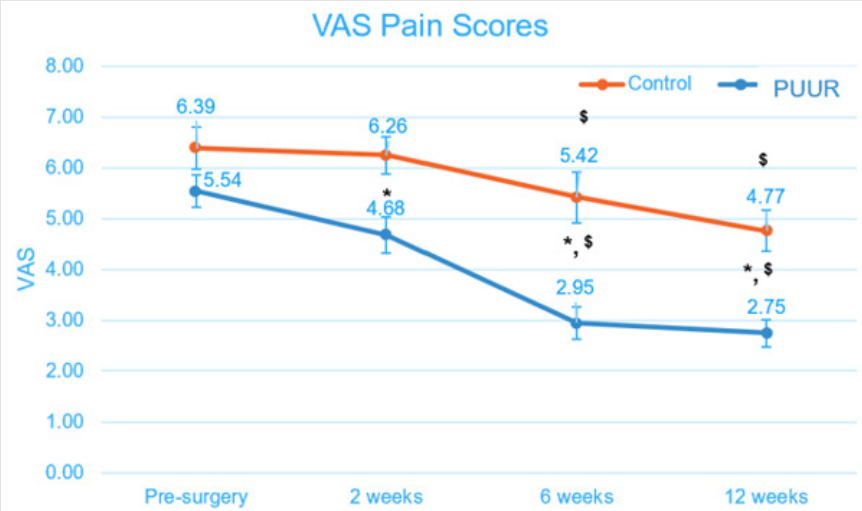

	Control (n)	PUUR (n)
Pre-surgery	33	44
2 weeks	31	42
6 weeks	26	36
12 weeks	30	38

Figure 2: VAS. VAS pain scores were collected at baseline (before surgery), 2-, 6-, and 12-week follow up visits. Baseline VAS was similar between groups. Average VAS scores were significantly reduced in PUUR augmented patients compared to MB alone at all follow-up visits. Both groups show significant changes from pre-surgical baseline scores at both 6 and 12 weeks. *p <0.05 vs. MB along; $p< 0.05 vs. baseline.

Adverse Events and Complications

Complications: There were 9 reported complications, 3 in the MB group (3.6%) and 6 (4.2%) in the PUUR group (p = 0.83). No complications were reported as product related. There were 2 revisions (2.40%) in the MB group and 1 revision (0.70%) in the PUUR group. The PUUR revision patient sustained a significant ankle repeat injury following a serious fall approximately 1-year post-surgery. This required a revision of the lateral ligament repair with PUUR matrix along with peroneal tenosynovectomy, 1st metatarsal dorsiflexion osteotomy, and ankle arthroscopy with synovectomy. One revision in the MB group occurred 10 days postoperative from reportedly chronic neuropathic pain requiring repeat surgical evaluation with ankle arthroscopic debridement, lateral ankle ligament assessment, and peroneal synovectomy. The second isolated MB group revision was disclosed by the patient in a follow-up call and had occurred outside of the study site of care, requiring anchor removal with soft tissue repair. There were 5 remaining complications in the PUUR group. One patient experienced a deep wound infection requiring irrigation and debridement and antibiotics. Another patient fell down a flight of stairs sustaining a bimalleolar ankle fracture. A separate patient presented with peroneal tendon split tear and underwent peroneal tenolysis. A diabetic patient underwent partial first metatarsal excision, FHL tenolysis and sesamoid excision due to a great toe ulceration. The final patient underwent a tibial osteotomy and open talar osteochondral treatment for a progressive lesion. No cases of implant failure, periimplant fracture, or foreign body reaction were observed. The final complication in the MB group was a patient that required gastrocnemius recession with associated ankle arthrotomy and posterior capsular release.

Adverse Events: Adverse events were collected from all enrolled patients. A total of 53 adverse events (22.1% of patients) occurred. The most common adverse events were delayed wound healing (n = 19 patients)neuritis (n = 7 patients), and superficial wound infection (n = 6 patients). Delayed wound healing occurred in a similar number of patients in both groups (PUUR = 10 vs. MB = 9) and was correlated with a significant increase in BMI (P=.020). Neuritis occurred in 4 MB and 3 PUUR patient. Superficial wound infection did not occur in any MB patients and occurred in 6 PUUR patients, though no deep infection developed. Amongst the remaining [21] additional adverse events, all were classified as either mild or moderate and no adverse events were related to the PUUR device. There were no serious adverse events reported in either group.

Postoperative Rehabilitation: A summary of the major post-operative rehabilitation milestones collected with the number of subjects with evaluable data for each milestone is presented in Table 4. Early PT milestones were similar between groups. Non-weightbearing duration after surgery was similar (PUUR: 4.0 ± 0.1 wks. vs. MB: 3.7 ± 0.2 wks). Similarly, there was no difference in the mean time to physical therapy initiation (PUUR 5.03 ± 0.19 weeks vs. MB 4.96 ± 0.26 weeks); or total physical therapy duration (PUUR 10.1 ± 0.93 weeks vs. MB 11.2 ± 3.2 weeks). However, the time to unrestricted FWB in commercial footwear with or without bracing for patients in the PUUR augmented group was significantly faster compared to MB alone. PUUR augmented patients transitioned to normal footwear an average of 2.4 weeks faster than MB patients (9.04 ± 0.34 wks vs. 11.4 ± 1.79 wks. P = .047).

Table 4: Post-operative Rehabilitation Milestone Summary.

Post-op Rehab	Control	n	PUUR	n	p-value
NWB duration (wks)	3.7 ± 0.18	68	4.0 ± 0.12	135	0.12
Time to PT entry (days)	34.7 ± 1.80	42	35.2 ± 1.29	128	0.849
PT duration (days)	78.3 ± 22.3	12	70.7 ± 6.49	70	0.68
Time to unrestricted FWB (days)	79.5 ± 12.5	53	63.3 ± 2.43	101	0.047*

Note: (*p< 0.05 between PUUR and MB alone groups).

Patient Survey: In an effort to gain longer term follow up data, best attempts were made to contact all patients that were at least 12 months postoperative to assess residual ankle pain, instability, additional procedures, revisions, quality of life, and overall procedure satisfaction. Patients that provided consent completed the short satisfaction survey. Mean follow-up was 20.8 ± 0.87 months for PUUR patients (n = 46) and 32.5 ± 2.76 months for MB patients (n = 40) (Table 5). Although this is a limited patient response, and clearly does not represent a lost-to-follow up population, this is not surprising given our requests to complete the patient survey were unsolicited and unexpected by these patients. There was a significant difference in both the number of responders (p = 0.02) and length of follow up (p<0.0001) between study groups. Overall, there were no significant differences in answers to survey questions between groups. Patient satisfaction on a ten-point scale with 0 representing not satisfied and 10 representing very satisfied was rated high in both groups (PUUR = 8.5 vs. MB = 8.9; P = .305). Similarly, most patients indicated they would repeat the procedure and would recommend the surgery to a family member. Approximately 50% of patients in both groups reported some degree of occasional pain, though there was no difference in severity between groups. Residual ankle instability was similar across groups (PUUR 26.1% and MB = 20%). A single isolated MB patient reported having a revision surgery outside of the care of a study surgeon.

Table 5: Patient Satisfaction Survey.

	Control	**PUUR**	**p-value**
# of respondents	40	46	P = 0.02
Mean follow-up	32.5 ± 2.76 mos	20.8 ± 0.87 mos	<0.0001
How satisfied were you with your treatment for lateral ankle instability? (out of 10)	8.90	8.46	0.291
How likely would you be to have this procedure done again? (out of 10)	8.62	7.48	0.151
Would you recommend this procedure to a family member? (% Yes)	95%	89.1%	0.321
Do you still suffer from residual chronic pain or ankle instability (% Yes)	55%	52.2%	0.793
IF YES, is your pain Less than before your surgery The same as before your surgery More than before your surgery	 3 0 5	 3 4 5	0.301
What is your average level of daily pain in the ankle that you had surgery?	4.5	4.5	1.00
Do you have residual surgical ankle instability? (% Yes)	20%	26.1%	0.505
Have you had any additional medical procedures or treatments on your surgery ankle? (% Yes)	17.5%	15.2%	0.256

Discussion

This is the first controlled study to assess the safety and clinical efficacy of a PUUR matrix woven textile for ATFL augmentation during modified Broström repair. Pain scores for both groups were significantly decreased from preoperative levels through 12-weeks follow-up (PUUR: 5.5 to 2.35 and MB: 6.4 to 3.29). However, pain in the PUUR group was significantly lower at all follow-up clinical visits (2, 6, 12 weeks) compared to isolated MB group which may be more notable given the greater complexities of the surgical procedures in the augmentation group. The range of patient reported pre-to post-op changes in VAS scores (approximately 6 – 2) over similar time points is consistent with previous publications. In a similar ATFL repair study, Kulwin et al., did not report a comparative decrease in early postoperative pain between patients that underwent MB alone vs. MB patients augmented with suture tape [18]. This discrepancy could be due to differences in study design, surgical procedure, or device used in augmentation. In their report of isolated ATFL repair with augmentation, Xu et al. also reported decreases in pain from pre-surgery in patients undergoing MB with or without suture tape augmentation, but no difference in pain between the 2 groups [19]. A potential benefit of ATFL augmentation is accelerating the postoperative recovery period due to the additional biomechanical support. While there was no difference in NWB duration between MB and PUUR groups, PUUR augmentation led to a statistically significant reduction in time to unrestricted FWB in commercial footwear. As experience with the augmentation device became more evident, the study surgeons began to further expedite the post-operative rehabilitation program with their augmented patients.

There were 2 revisions in the isolated MB group, and 1 in the PUUR augmentation group (2.40% vs 0.70%, respectively). This is similar compared to published results that report revision rates following modified Brostrom procedures at 1.2% [19]. Overall, there were no differences in adverse events between PUUR and MB alone groups. The majority of adverse events noted in both groups were secondary to delayed wound healing (MB = 10% and PUUR = 6.3%). A subgroup analysis demonstrated patients from both groups experiencing delayed wound healing had a significantly higher BMI, which is known to correlate with delayed wound healing [20,21]. All AEs were classified as mild to moderate, and no AEs were considered related to the study device. The safety profile of the PUUR device is similar to that reported by Kelly et al., who reported an overall AE rate of 12.4% (13/105 patients) with PUUR incorporation in various foot and ankle reconstructive procedures. ATFL augmentation during the MB procedure is thought to relieve the injured ligament from excessive stress-strain forces during early to mid-phase healing process. Giza et al. reported PUUR augmented repairs increased ultimate load to failure by 150%, and prevented creep compared to control samples [22]. The resorbable PUUR matrix maintains 90% of its initial strength through the first year of implantation, and then degrades slowly by hydrolysis over a period of up to seven years [23]. In addition to strength, PUUR tensile properties have been demonstrated to alter mechanically driven biological signals and to orchestrate local cell populations during the remodeling process [24] allowing the matrix to promote tissue maturation by promoting cell recruitment, extracellular matrix deposition and angiogenesis [11,25-28].

There are clear limitations within this study given the retrospective nature of the study design. The availability of data was limited to what was present within the medical records both in amount and type (outcome measures) available for collection. In particular, the postoperative rehabilitation evaluation may be confounded by the patients completing therapy at different sites. Despite the constraints of retrospective study designs, the true value is to gather real world evidence of the use of products in everyday clinical practice outside the scope of a rigorously designed protocol that may considerably narrow both practical clinical product application and the participating patient population. A prospective, randomized, controlled trial with validated functional outcome measurements, standardized post-op rehabilitation protocols and lengthier follow-up is ongoing. The results of this study will further enhance the ability to detect any notable differences with augmentation.

Conclusion

This is the first study to directly compare MB with and without PUUR augmentation. PUUR augmentation of the lateral ligamentous complex during ankle instability surgery decreased recovery pain and allowed quicker return to FWB, compared to MB alone. The PUUR matrix was safe with no difference in adverse events compared to a control group. This study shows early results suggesting PUUR augmentation may create the potential to expedite and improve patient outcomes post-operatively compared to modified Broström alone.

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