Ligament Augmentation Reconstruction System (LARS) for Ankle Lateral Ligament Reconstruction in Higher-Risk Patients

A 5-Year Prospective Cohort Study

Mark D. Porter,*[†] DSc, Aleksandra Trajkovska,[‡] MChD, BNurs, BMedSci (Hons), and Ekavi Georgousopoulou,[§] PhD

Investigation performed at Barton Private Hospital, Barton, ACT Health Directorate, Australia

Background: The modified Broström-Gould (MBG) procedure is the gold standard for patients with chronic ankle instability (CAI), but it is relatively contraindicated for patients with higher body weight or generalized ligamentous laxity (GLL). The use of the ligament augmentation reconstruction system (LARS) is an alternative.

Hypothesis: It was hypothesized that clinical outcomes would be similar in patients with increased body weight (>90 kg) or GLL, relative to controls.

Study Design: Cohort study; Level of evidence, 2.

Methods: A total of 66 patients satisfying the inclusion criteria were invited to participate and were divided into 3 groups: controls (no risk factors for inferior clinical outcome), patients with body weight >90 kg, and patients with GLL (Beighton score, \geq 5 of 9). All patients underwent imbrication of the lateral collateral ligament complex augmented with the LARS. Primary outcomes of interest were Tegner activity scale (TAS) and Foot and Ankle Outcome Score (FAOS) subscale scores. Secondary outcomes were recurrence of ankle instability, the need for further surgery, and/or complications. Patients were reviewed at 2 and 5 years postoperatively, and outcomes between groups were compared using repeated-measures analysis of variance.

Results: Complete data were available for 63 patients (21 patients in each group). TAS improved in all groups from preoperatively to 2 years and 5 years postoperatively (P < .001 for all). Relative to the controls, the TAS scores were lower in the >90-kg group at 2 years and 5 years (P < .001 for both periods), while the GLL group had similar scores to controls at both postoperative periods. Both the >90-kg and the GLL groups showed no significant difference in improvement on any FAOS subscale scores relative to the controls, at both 2 and 5 years postoperatively. There were no recurrences, repeat surgeries, or major complications.

Conclusion: Relative to controls, patients with body weight >90 kg or GLL had similar FAOSs, and TAS scores were lower in the >90-kg group, at 2 and 5 years, after the use of the LARS to augment lateral collateral ligament imbrication for CAI. Use of the LARS in this manner is a viable option in patients for whom the MBG procedure is relatively contraindicated.

Keywords: ankle instability; LARS ligament; BMI; GLL

Ankle sprains are among the most common musculoskeletal injuries, accounting for up to 40% of injuries among physically active individuals.^{10-12,18,19,37,45,52,58} Most are acute in nature, and the majority involve the lateral ligament complex (LCL).³ Injuries to the LCL complex most commonly involve the anterior talofibular ligament (ATFL) and the calcaneofibular ligament (CFL), with the incidence being 7 per 1000 persons per year.^{21,35}

Although most ankle sprains completely heal with appropriate nonoperative management, up to 40% of those who sustain them develop chronic ankle instability (CAI).^{7,55} CAI has been associated with many long-term sequelae, such as altered ankle kinematics,⁴⁶ chondral injuries,^{48,57} and early-onset osteoarthrosis of the ankle joint.^{20,48,54} For these reasons, surgical repair of the ruptured LCL complex is indicated when nonoperative management has failed.^{1,4}

Although contentious, several studies have revealed that individuals with higher body weight and body mass index and those with generalized ligamentous laxity (GLL) are at increased risk of ankle sprains.^{2,5,6,43,55} GLL is

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 TABLE 1

 Inclusion and Exclusion Criteria for Patient Enrollment^a

Inclusion Criteria	Exclusion Criteria	
 Chronic instability (>3 mo and <24 mo) of ATFL and CFL confirmed with MRI and physical findings, after an ankle sprain Medically fit for general anesthetic Physically active Failed nonoperative treatment Skeletally mature Signed informed consent 	 Previous ankle surgery Ankle fracture or diastasis Chronic recurrent instability for >24 mo Rheumatological or connective tissue disease 	

^aATFL, anterior talofibular ligament; CFL, calcaneofibular ligament; MRI, magnetic resonance imaging.

characterized by abnormally increased range of motion (ROM) at multiple joints compared with that of the general population and is related to conditions with abnormal collagen laxity such as Marfan syndrome.⁵⁹ The prevalence is between 5% and 15% of the population, and most cases have no known genetic aberrancy.²³ The increased laxity is a contributing factor to increased risk of CAI after acute injury and the risk of recurrence after ligament reconstruction.¹⁸

The modified Broström-Gould (MBG) procedure has evolved as the surgical treatment of choice for chronic lateral ligament instability of the ankle.^{8,28,29,40} There are concerns about the strength of this procedure for some patients, particularly those with GLL, increased body mass, and long-standing instability, as well as those who participate in competition at an elite level.^{38,55,60} Alternative procedures have reconstructed the LCL complex using an autologous graft, but this is associated with the risk of graft-site morbidity.^{12,25} Another option is to augment an imbrication of the LCL complex using a synthetic ligament. The ligament augmentation reconstruction system (LARS) device made of polyethylene terephthalate (PET; Corin Group) has been used in this manner and has the advantages of a biological repair of native ligaments, protected by a strong synthetic ligament during the reparative phase.^{40,41}

A recent randomized controlled trial (RCT) with 5-year follow-up found that the use of the LARS resulted in higher patient-scored outcomes and activity levels with lower recurrence rates relative to the MBG procedure, in physically active patients with CAI.⁴¹ That study excluded patients who were regarded to be at a higher risk of failure after the MBG procedure, including body weight >90 kg, GLL, failed previous ankle reconstructions, and long-standing chronic instability. The authors of that paper chose these exclusion criteria to avoid biasing the study in favor of the LARS procedure.

Given that the LARS has been demonstrated to have superior results in patients without these risk factors, the objective of our research was to determine if the LARS has similar outcomes when used in patients with a higher risk of failure (ie, body weight >90 kg or GLL). Our null hypothesis was that the outcomes would be similar even in the presence of these risk factors.

METHODS

Study Design and Population

After receiving approval from the hospital ethics committee, we conducted a prospective cohort clinical study. The supervising author (M.D.P.), a subspecialist sports orthopaedic surgeon, performed all procedures. Patients evaluated by the surgeon who satisfied the inclusion and exclusion criteria in Table 1 were invited to participate in the study. All patients had a sports-related traumatic onset of ankle instability. The diagnosis of disruption of the ATFL and CFL was confirmed by magnetic resonance imaging and physical assessment. The physical signs were a grade 3 talar tilt test and grade 3 anterior drawer test.

Patients were regarded as physically active if they took part in recreational or competitive physical activity at least 3 times per week. All patients were informed of the rationale behind the study, and all consented to undergo the LARS procedure. All patients followed the same rehabilitation program after surgery (Table 2). Patients were informed that if they opted not to take part in the study, this would not result in any change to the treatment provided.

Treatment Group Allocation

Patients were divided into 3 groups. Those who had no known risk factors for recurrence, weighed < 90 kg, and did

^{*}Address correspondence to Mark D. Porter, DSc, Canberra Orthopaedics and Sports Medicine, Suite 2, 19 Napier Close, Deakin, ACT 2600, Australia (email: mdporter@iinet.net.au).

[†]Canberra Orthopaedics and Sports Medicine, Deakin, Australian Capital Territory, Australia.

[‡]Canberra Hospital, Garran, Australian Capital Territory, Australia.

[§]ACT Health Directorate, Australian Capital Territory, Australia.

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Ethical approval for this study was obtained from Barton Private Hospital (reference No. BPH EC O2).

TABLE 2	
Rehabilitation Protocol for All Patients After Ankle Stabilization Surgery	ı

Time After Surgery	Rehabilitation Instructions			
0-7 d	No weightbearing, elevation, or ROM for toes, knee, and hip.			
1-6 wk	WBAT with fracture boot. Allowed to perform active, passive, and resisted ROM work in dorsiflexion and plantarflexion and eversion-pronation (no inversion-supination movements). Can swim when wounds heal, and remove the boot to use a stationary bike with light resistance.			
7-12 wk	Wean off the boot for WBAT. Can progress to active, passive, and resisted ROM in all directions (but no passive inversion- supination movements). Can begin balance and proprioceptive work and running when strength and balance are symmetrical.			

^aROM, range of motion; WBAT, weightbearing as tolerated.

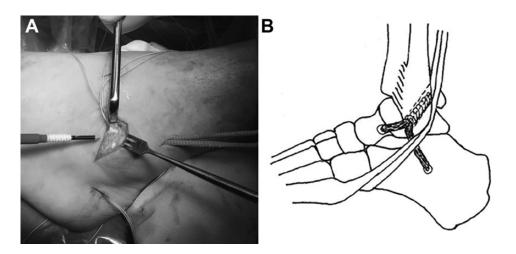


Figure 1. The surgical technique performed using the Ligament Augmentation Reconstruction System (LARS). (A) Intraoperative photograph showing the LARS in situ, before final tensioning and fixation. (B) Final positioning of the LARS, which is cut flush with the posterior surface of the fibula.

not have GLL (Beighton score, ≤ 4 of 9) were allocated to the control group; patients with increased body weight were placed in the >90-kg group, and those with a Beighton score ≥ 5 were placed in the GLL group. None of the patients in the study had both GLL and body weight >90 kg.

Surgical Technique

All procedures were performed with the patient under a general anesthetic, in a supine position, with a sandbag under the ipsilateral pelvis and an inflated tourniquet. Examination under anesthesia and arthroscopy were performed before the stabilization. The LARS procedure was performed as described in the literature and shown in Figure 1.^{40,41} An anterolateral approach was used to approach and divide the anterolateral capsuloligamentous structures to expose the anterior surface of the lateral malleolus. A 5-mm fibular tunnel was drilled posterosuperiorly from a point 5 mm proximal to the tip of the malleolus and angled in such a manner that it was at least 20 mm in length before it passed through the posterior cortex of the fibula.

We used the LAC 20 LARS ligament (Corin Group), which was a straight, porous, cordlike ligament made of

interlocked PET fibers. The diameter was 4 mm and compressible. The looped end of the folded ligament was passed from distal to proximal along the 5-mm fibular tunnel. The looped end was retrieved via the proximal 1-cm skin incision. The CFL limb was passed from the distal end of the fibular tunnel, deep to the peroneal tendons and sheath, and was retrieved via the distal 1-cm skin incision. Using this incision, the CFL limb was secured in a 4.5-mm bone tunnel at its insertion site using a 4.75-mm suture anchor (BioComposite SwiveLock; Arthrex). The ATFL limb was passed from the fibular tunnel, superficial to the capsuloligamentous structures and fixed in a 4.5-mm bone tunnel at its distal attachment using a similar 4.75-mm suture anchor. Traction on either side of the looped end of the LARS ligament allowed the tension of the ATFL and CFL limbs to be adjusted independently, until the anterior drawer and talar tilt were corrected. Before final fixation with a third SwiveLock in the fibular tunnel, the surgeon checked that the LCL reconstruction had not been overtensioned and did not restrict the passive ROM in the ankle joint. The capsuloligamentous structures were then closed, maintaining the LARS in an extracapsular position and double-breasting the attenuated tissues.

At the end of the procedure, all patients were placed in a removable fracture boot. They were asked to remain nonweightbearing but encouraged to perform active postoperative ROM work for the toes, knee, and hip. As prophylaxis against deep venous thrombosis, all patients were placed on subcutaneous enoxaparin 40 mg daily between surgery and the first postoperative review. They were also asked to remove the fracture boot to perform active ROM in dorsiflexion and plantarflexion as tolerable. At the first postoperative review, the wound was checked, and thereafter patients were allowed to begin weightbearing as tolerable in the fracture boot. The rehabilitation program detailed in Table 2 was commenced under the supervision of the treating physical therapist. The rehabilitation protocol aimed to return patients to full activity within 4 months of surgery.

Primary Outcomes of Interest

The primary outcomes of interest were Tegner activity scale (TAS) and Foot and Ankle Outcome Score (FAOS). Both outcome measures were emailed to patients and returned to the supervising author. Patients completed the FAOS before undergoing surgery and then again at 2 years and 5 years after surgery. This is a patient-scored questionnaire validated for use in ankle lateral ligament injury.⁴⁴ It consists of 5 domains that are scored out of a possible maximum of 100 points (higher values represent better clinical outcomes), from which an average score, or total, is computed. The FAOS domains are pain, other symptoms, activities of daily living, sports/recreational activities, and overall quality of life.

TAS scores were recorded based on preinjury status, then again immediately before surgery (0 years), and then at 2 and 5 years after surgery. The TAS is a numerical scale with values from 0 to 10 representing specific activities. Values of 10 represent the highest activity level (eg, one of the codes of football at an elite level) and 0 the lowest (no sports activities and unable to do even sedentary work). It has a minimal detectable value of 1.

Secondary Outcomes of Interest

Secondary outcomes were recurrence of ankle instability, need for further surgery, and/or complications. Patients were routinely asked to report any complications to the surgeon. All complications requiring more than normal postoperative care, including readmission to the hospital, infection, further surgery, thromboembolism, nerve injury, or recurrence of instability, were recorded in the patient's notes over the 5-year period. Patients were asked again to document any complications that had occurred and report these at the same time as completing the FAOS and TAS questionnaires.

Statistical Analysis

A power analysis was performed based on prior research performed on the use of the LARS ligament, with documented recurrence rates and range of values for FAOS and TAS.²⁶ With an SD of 5 points for the total FAOS, 19 patients were required in each group to achieve a power of 80% with 95% significance. If 1 point is regarded as clinically important, then to detect a significant difference between the mean TAS, 20 patients were required in each group.

Repeated-measures analysis of variance was performed to compare the control group with the high-risk groups (>90-kg and GLL) regarding changes in FAOS subscales at 0, 2, and 5 years after surgery, and changes in the TAS at preinjury and 0, 2, and 5 years after surgery. FAOS for each subscale was then adjusted for age and sex, and TAS was adjusted for preinjury scores, age, and sex. Changes were compared between and within groups, with P < .05regarded as significant.

Data entry was performed in Microsoft Excel, and statistical analysis was conducted using SPSS Version 26 (IBM).

RESULTS

Patient Characteristics

A total of 66 patients underwent lateral ankle stabilization using LARS between April 2009 and May 2011. No patients refused to take part in the study. Three patients were lost to follow-up, all in the >90-kg group, and their data were not included for analysis. These patients had changed postal address and internet address and/or had moved overseas. To the best of our knowledge, none of these patients had further ankle instability and/or surgery or any significant complications. Thus, 63 patients were enrolled in the study (21 patients in each group).

Table 3 summarizes general patient characteristics overall and by group. Although the male:female ratio was relatively equivalent for the control group, it was 1:1.6 for the GLL group and 3.2:1 for the >90-kg group. There was no significant difference in preinjury TAS scores between either high-risk group relative to the control group (Table 3).

TAS and FAOS Outcomes

Patients in all 3 study groups saw significant improvements in TAS scores from preoperatively to 2 years after surgery, and this improvement was maintained at 5 years after surgery (P < .001 for all). There was no difference between the GLL and control groups at 2 and 5 years postoperatively (P = .18 and .14, respectively). The improvement in TAS scores was significantly lower in the >90-kg group at 2 and 5 years relative to the controls (P = .02 and .03, respectively). The comparison of TAS scores between the control group and the high-risk groups indicated significant differences at both 2 years and 5 years postoperatively (P < .001 for both). These results were unaltered after adjustments made for preinjury scores, age, and sex (P < .001) (Table 4).

There were no significant differences in any FAOS subscale between either high-risk group when compared with

Patient Characteristics ^a						
			High-Risk Groups			
Characteristic	Total, $N = 63$	Control Group, $n = 21$	$\overline{\text{GLL}}, n = 21$	>90 kg, n = 21		
Age Sex	26.87 ± 8.49	26.14 ± 8.55	25.14 ± 7.38	29.33 ± 9.44		
Male	34 (54)	10 (48)	8 (38)	16 (76)		
Female	29 (46)	11 (52)	13 (62)	5 (24)		
BMI	26.43 ± 4.31	25.00 ± 4.09	23.18 ± 2.69	30.12 ± 2.97		
Preinjury TAS	8.33 ± 1.0	8.67 ± 0.86	8.19 ± 1.08^b	8.14 ± 1.06^c		

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^aData are reported as mean ± SD or n (%). BMI, body mass index; GLL, generalized ligamentous laxity; TAS, Tegner activity scale. ${}^{b}P = .12$ versus control group.

 $^{c}P = .07$ versus control group.

TABLE 4
Comparison of Postoperative TAS and FAOS Results Between the Control Group and High-Risk Groups ^a

	High-Risk Groups				D (1)10111
	Control Group	GLL	>90 kg	P (High-Risk vs Control)	$P_{ m adjusted}~(m ANOVA, m Overall~Comparison)^b$
TAS					<.001 ^e
Preinjury	8.67 ± 0.856	8.19 ± 1.08	8.14 ± 1.06	.183	
0 y	4.33 ± 0.856	4.52 ± 0.814	3.95 ± 1.12	.142	
2 y	8.71 ± 0.717	8.62 ± 0.921	7.52 ± 0.981	<.001	
5 y	8.29 ± 1.02	8.71 ± 0.717	7.57 ± 0.978	<.001	
FAOS subscale					
Pain					.918
0 y	73.6 ± 6.52	75.8 ± 5.37	74.4 ± 6.90	.541	
2 y	91.0 ± 5.67	90.3 ± 5.44	91.0 ± 5.61	.911	
5 y	90.1 ± 4.47	89.1 ± 4.63	89.6 ± 4.63	.815	
Symptoms					.985
0 y	70.6 ± 7.15	72.1 ± 6.10	71.3 ± 7.48	.789	
2 y	94.5 ± 4.08	93.9 ± 4.35	94.3 ± 3.97	.884	
5 y	93.0 ± 3.98	92.3 ± 3.76	93.1 ± 3.85	.770	
ADL					.574
0 y	69.4 ± 12.0	71.0 ± 10.4	69.3 ± 13.2	.879	
2 y	94.6 ± 4.24	93.9 ± 3.89	94.1 ± 3.87	.851	
5 y	96.0 ± 2.33	96.3 ± 2.65	95.4 ± 2.64	.549	
Sport					.711
0 y	63.0 ± 5.59	63.2 ± 5.59	62.6 ± 7.37	.954	
2 y	94.9 ± 4.02	94.1 ± 4.03	94.3 ± 4.12	.819	
5 y	95.8 ± 3.52	94.8 ± 3.77	95.4 ± 3.80	.651	
QoL					.652
0 y	62.6 ± 9.83	64.1 ± 9.56	63.0 ± 10.3	.888	
2 y	93.7 ± 3.54	93.6 ± 3.70	94.3 ± 3.59	.795	
5 y	94.7 ± 3.23	93.5 ± 3.20	94.3 ± 3.23	.501	

^aData are reported as mean ± SD. ADL, activities of daily living; ANOVA; analysis of variance; FAOS, Foot and Ankle Outcome Score; GLL, generalized ligamentous laxity; LARS, ligament augmentation reconstruction system; QoL, quality of life; TAS, Tegner activity scale.

^bAdjusted for age and sex.

^cTAS adjusted for preinjury scores, age, and sex.

the control group at 0, 2, or 5 years after surgery (Table 4). No significant differences were found on any subscale, even with adjustments for age and sex, between either high-risk group when compared with the control group.

Secondary Outcomes of Interest

Over the 5-year period, no patient reported recurrent instability, nor were there any complications requiring additional surgery or admission to the hospital. There were only 5 complications recorded in the study population. These included 3 cases of superficial wound infection that responded to a course of oral antibiotics, 2 in the >90-kg group and 1 in the control group. There was 1 case of deep venous thrombosis in the >90-kg group and 1 case in the control group, and both responded to oral anticoagulants.

DISCUSSION

The findings in this study demonstrated that physically active patients with GLL or body weight >90 kg had similar outcomes in terms of the FAOS when compared with the control group at the 5-year follow-up. However, only the GLL group had similar TAS scores. This outcome persisted when adjustments were made for age and sex among all groups. Therefore, we accept our null hypothesis. There were no clinical failures in any of the patients. The study was not adequately powered to compare the low incidence of complications between the groups, with an 8% risk overall for any complication.

Patients with body mass >90 kg are relatively common in sports such as tackle football. Patients with ligamentous laxity may be disproportionately represented in certain sporting activities, such as gymnastics, swimming, and dance. Such patients have been found to be more susceptible to ankle sprains with recurrent instability and the subsequent development of CAI.^{5,6,43} Ankle instability in these 2 groups is predominantly mechanical because of anatomical defects such as arthrokinematic changes, ligamentous tear, and/or degenerative pathological laxity.^{26,27,34} However, there may also be an element of functional instability that was not measured in this study.¹⁴

The ultimate goal of surgery for treatment of CAI is to restore normal hindfoot biomechanics,⁴² and the anatomic MBG procedure remains the gold standard.^{30,36} However, several studies have shown poorer outcomes after the MBG procedure for patients with a high body weight and/or GLL, even if the interior extensor retinaculum is included,²⁹ rendering these conditions relative contraindications.^{24,28,29,38,39,60} Other factors attributable to poorer outcomes include repair strength achieved after imbrication of tissues that have already been damaged^{1,17,25,33,56} and the difficulty in repairing the extracapsular CFL.⁴⁷ Waldrop et al⁵⁶ has shown that the initial mechanical properties of the ligaments in the standard Broström repair were 50% weaker than those of native ATFL immediately after repair.

Alternative surgical procedures for these higher-risk patients include the nonanatomic reconstructive procedures, but these have been gradually replaced with anatomic ligament reconstruction procedures. However, there is morbidity associated with harvesting the autologous graft, while the use of allografts increases costs and there is the risk of disease transmission. The use of the synthetic LARS is an alternative without the associated risks of graft harvesting.

Originally used for the reconstruction of the anterior cruciate ligament, the LARS may be more suited to use as an extracapsular augmentation device. When used to augment an imbrication of the LCL complex of the ankle, the synthetic graft is placed extracapsularly, thereby avoiding the potential occurrence of polyethylene synovitis, as has occurred with reconstruction of the anterior cruciate ligament of the knee.^{13,15,31,51} The ankle joint is more constrained by bone anatomy than the knee and is less reliant on extra-articular soft tissues than the knee joint, rendering this synthetic device potentially more suitable for ankle LCL reconstruction. This may be even more important in patients with GLL given the already increased ROM compared with normal, across multiple joints.^{5,6}

There is a paucity of published level 1 studies investigating the use of synthetic ankle ligaments. A recent metaanalysis performed by Lei et al³² attempted to compare the use of artificial ligaments with the MBG procedure for ankle instability. Their study concluded that there was no evidence that the LARS technique improved the clinical outcome relative to the MBG procedure for lateral ankle instability, on the basis of the data from what they described as 4 different RCTs.³² The paper pooled the results of techniques that used synthetic ligament irrespective of the design of the ligament or which components of the LCL complex were reconstructed. Two studies included in the meta-analysis were published by Porter et al.^{40,41} Both of these RCTs used the PET LARS device to augment both the ATFL and the CFL and found a superior outcome relative to the MBG procedure at the 2-year and 5-year follow-up visits. The other 2 studies were by Ulku et al⁵³ and Cho et al,⁹ and both used an internal brace device (InternalBrace; Arthrex). This internal brace device consists of a braided ultra-high molecular weight polyethylene/polyester suture tape with knotless bone anchors. The paper by Cho et al⁹ was in fact an uncontrolled case series rather than an RCT, and all patients were women and weighed <70 kg. The Ulku et al paper was an RCT, but all patients underwent either an ATFL repair or augmentation of the ATFL only. The results of the meta-analysis are not applicable to patients who undergo a reconstruction of both the ATFL and the CFL using the LARS and who are male and/or weigh >70 kg.

The LARS is a strong synthetic ligament with an ultimate tensile load of 1000 N, 49 and it acts a scaffold for the ingrowth of collagen tissue.⁵¹ The LARS induces biointegration and ultimately incorporates the remnants of the native ligament itself, thereby facilitating healing. With biomechanical behavior of the ankle joint being nonlinear and dependent on the magnitude of the load applied,⁵⁰ this is of particular importance in those with high body weight, as any excess weight negatively affects healing ability because of increases in mass moment of inertia on the talocrural joint.^{3,16,43} Although coated with collagen, there is no published evidence that the internal brace device stimulates ingrowth of fibrous tissue in vivo, and although stronger than native tissue, its ultimate tensile load is less than that of the LARS.²² Hence, there are some salient differences between the 2 devices, and pooling the data from the use of the 2 devices may not be appropriate.

This study has several limitations. Although the data at 5 years are consistent with an excellent clinical outcome in these patients, longer-term studies are required to fully evaluate the role of the LARS in patients with CAI. The study is not an RCT design, but the goal was to compare the outcome after the same surgical procedure in different patient groups. Patients were sequentially enrolled in the study, and none refused to take part. The study did not investigate the potential role of functional instability as a confounding factor. The small sample size in each group reduces the generalizability of the results, but the power analysis demonstrated that it was large enough to answer the hypothesis. In common with the MBG procedure, the internal brace procedure, and many ligament reconstruction techniques, the surgeon cannot be sure that the final tension in the reconstruction is the same in all patients. However, the LARS technique used allows the tension to be adjusted before final fixation to avoid overconstraint of the ankle joint. Although the patient-scored outcomes used in this study have been validated for use in lateral ankle instability, the scoring remains subjective in nature. However, there is no practical valid objective imaging modality or other technique to measure functional instability of the ankle. Any additional radiation exposure or expense when clinically unnecessary was deemed an unacceptable departure from standard treatment of patients for ethics approval. The outcome after the ankle lateral ligament reconstruction is also influenced by the level of physical activity, and all 3 groups had similar levels of activity. Sex may be a confounding factor. The GLL group had a higher percentage of women, and the >90-kg group had a higher percentage of men relative to the control group. The study was not powerful enough to compare the incidence of complications in the treatment groups.

CONCLUSION

The findings of the current study demonstrated that patients weighing >90 kg or those with GLL have similar excellent clinical outcomes compared with patients without these risk factors, in terms of the TAS and FAOS when reviewed 5 years after lateral ankle reconstruction using the LARS, with a low risk of recurrence or significant complications. The use of the LARS may be specifically indicated for these patients.

REFERENCES

- 1. Ahlgren O, Larsson S. Reconstruction for lateral ligament injuries of the ankle. *J Bone Joint Surg Br.* 1989;71(2):300-303.
- Albensi RJ, Nyland J, Caborn DNM. The relationship of body weight and clinical foot and ankle measurements to the heel forces of forward and backward walking. J Athl Train. 1999;34(4):328-333.
- 3. Al-Mohrej OA, Al-Kenani NS. Acute ankle sprain: conservative or surgical approach? *EFORT open Rev.* 2017;1(2):34-44.
- Bell SJ, Mologne TS, Sitler DF, Cox JS. Twenty-six-year results after Broström procedure for chronic lateral ankle instability. *Am J Sports Med.* 2006;34(6):975-978.

- Beynnon BD, Murphy DF, Alosa DM. Predictive factors for lateral ankle sprains: a literature review. J Athl Train. 2002;37(4):376-380.
- Bin Abd Razak HR, Bin Ali N, Howe TS. Generalized ligamentous laxity may be a predisposing factor for musculoskeletal injuries. *J Sci Med Sport*. 2014;17(5):474-478.
- Chan KW, Ding BC, Mroczek KJ. Acute and chronic lateral ankle instability in the athlete. *Bull NYU Hosp Jt Dis.* 2011;69(1):17-26.
- Cho BK, Kim YM, Kim DS, Choi ES, Shon HC, Park KJ. Outcomes of the modified Brostrom procedure using suture anchors for chronic lateral ankle instability—a prospective, randomized comparison between single and double suture anchors. *J Foot Ankle Surg.* 2013;52(1):9-15.
- Cho BK, Park KJ, Kim SW, Lee HJ, Choi SM. Minimal invasive suturetape augmentation for chronic ankle instability. *Foot Ankle Int.* 2015; 36(11):1330-1338.
- Colville MR. Surgical treatment of the unstable ankle. J Am Acad Orthop Surg. 1998;6(6):368-377.
- Cumps E, Verhagen E, Meeusen R. Prospective epidemiological study of basketball injuries during one competitive season: ankle sprains and overuse knee injuries. *J Sports Sci Med.* 2007;6(2): 204-211.
- Fong DTP, Hong Y, Chan LK, Yung PSH, Chan KM. A systematic review on ankle injury and ankle sprain in sports. *Sports Med.* 2007; 37(1):73-94.
- Foster TE, Wolfe BL, Ryan S, Silvestri L, Kaye EK. Does the graft source really matter in the outcome of patients undergoing anterior cruciate ligament reconstruction? An evaluation of autograft versus allograft reconstruction results: a systematic review. *Am J Sports Med.* 2010;38(1):189-199.
- 14. Freeman MA. Instability of the foot after injuries to the lateral ligament of the ankle. *J Bone Joint Surg Br.* 1965;47(4):669-677.
- Glezos CM, Waller A, Bourke HE, Salmon LJ, Pinczewski LA. Disabling synovitis associated with LARS artificial ligament use in anterior cruciate ligament reconstruction: a case report. *Am J Sports Med*. 2012;40(5):1167-1171.
- Gómez JE, Ross SK, Calmbach WL, Kimmel RB, Schmidt DR, Dhanda R. Body fatness and increased injury rates in high school football linemen. *Clin J Sport Med.* 1998;8(2):115-120.
- Gould N, Seligson D, Gassman J. Early and late repair of lateral ligament of the ankle. *Foot Ankle*. 1980;1(2):84-89.
- Gribble PA, Bleakley CM, Caulfield BM, et al. Evidence review for the 2016 International Ankle Consortium consensus statement on the prevalence, impact and long-term consequences of lateral ankle sprains. *Br J Sports Med*. 2016;50(24):1496-1505.
- Gulbrandsen M, Hartigan DE, Patel KA, Makovicka JL, Tummala SV, Chhabra A. Ten-year epidemiology of ankle injuries in men's and women's collegiate soccer players. *J Athl Train*. 2019;54(8):881-888.
- Harrington KD. Degenerative arthritis of the ankle secondary to longstanding lateral ligament instability. *J Bone Joint Surg Am.* 1979;61: 354-361.
- Hølmer P, Søndergaard L, Konradsen L, Nielsen PT, Jørgensen LN. Epidemiology of sprains in the lateral ankle and foot. *Foot Ankle Int*. 1994;15(2):72-74.
- Hong CK, Hsu KL, Kuan FC, et al. The biomechanical properties of a high-tensile strength tape for tendon graft fixation using the Krackow configuration. Arthrosc Sport Med Rehabil. 2020;2(4):e347-e351.
- Juul-Kristensen B, Røgind H, Jensen DV, Remvig L. Inter-examiner reproducibility of tests and criteria for generalized joint hypermobility and benign joint hypermobility syndrome. *Rheumatology*. 2007; 46(12):1835-1841.
- Karlsson J, Bergsten T, Lansinger O, Peterson L. Reconstruction of the lateral ligaments of the ankle for chronic lateral instability. *J Bone Joint Surg Am.* 1988;70(4):581-588.
- Karlsson J, Eriksson BI, Bergsten T, Rudholm O, Swärd L. Comparison of two anatomic reconstructions for chronic lateral instability of the ankle joint. *Am J Sports Med.* 1997;25(1):48-53.
- Kim JS, Young KW, Cho HK, Lim SM, Park YU, Lee KT. Concomitant syndesmotic instability and medial ankle instability are risk factors for

unsatisfactory outcomes in patients with chronic ankle instability. *Arthroscopy* 2015;31(8):1548-1556.

- Knupp M, Lang TH, Zwicky L, Lötscher P, Hintermann B. Chronic ankle instability (medial and lateral). *Clin Sports Med.* 2015;34(4): 679-688.
- Krips R, van Dijk CN, Halasi PT, et al. Long-term outcome of anatomical reconstruction versus tenodesis for the treatment of chronic anterolateral instability of the ankle joint: a multicenter study. *Foot Ankle Int.* 2001;22(5):415-421.
- Kura H, Ishii S, Luo ZP, et al. Kinematic change of the ankle and anklesubtalar joint complex of the foot treated by Brostrom-Gould procedure. J Jpn Orthop Assoc. 2001;75:S575.
- Lee KT, Park YU, Kim JS, Kim JB, Kim KC, Kang SK. Long-term results after modified Brostrom procedure without calcaneo-fibular ligament reconstruction. *Foot Ankle Int*. 2011;32(2):153-157.
- Legnani C, Ventura A, Terzaghi C, Borgo E, Albisetti W.Anterior cruciate ligament reconstruction with synthetic grafts. A review of literature. *Int Orthop.* 2010;34(4):465-471.
- Lei T, Qian H, Lei P, Hu Y. Lateral augmentation reconstruction system versus modified Brostrom-Gould procedure: a meta-analysis of RCTs. *Foot Ankle Surg.* 2021;27(3):263-270.
- Liu SH, Jacobson KE. A new operation for chronic lateral ankle instability. J Bone Joint Surg Br. 1995;77(1):55-59.
- Lohrer H, Nauck T, Gehring D, Wissler S, Braag B, Gollhofer A. Differences between mechanically stable and unstable chronic ankle instability subgroups when examined by arthrometer and FAAM-G. *J Orthop Surg Res.* 2015;10(1):32.
- Lynch SA, Renström PAFH. Treatment of acute lateral ankle ligament rupture in the athlete: conservative versus surgical treatment. Sports Med. 1999;27(1):61-71.
- Maffulli N, Del Buono A, Maffulli GD, et al. Isolated anterior talofibular ligament Broström repair for chronic lateral ankle instability: 9-year follow-up. *Am J Sports Med.* 2013;41(4):858-864.
- McKay GD, Goldie PA, Payne WR, Oakes BW. Ankle injuries in basketball: injury rate and risk factors. *Br J Sports Med*. 2001;35(2): 103-108.
- Park KH, Lee JW, Suh JW, Shin MH, Choi WJ. Generalized ligamentous laxity is an independent predictor of poor outcomes after the modified Broström procedure for chronic lateral ankle instability. *Am J Sports Med.* 2016;44(11):2975-2983.
- Petrera M, Dwyer T, Theodoropoulos JS, Ogilvie-Harris DJ. Short- to medium-term outcomes after a modified Broström repair for lateral ankle instability with immediate postoperative weightbearing. *Am J Sports Med*. 2014;42(7):1542-1548.
- 40. Porter M, Shadbolt B, Stuart R. Primary ankle ligament augmentation versus modified Brostrom-Gould procedure: a 2-year randomized controlled trial. *ANZ J Surg.* 2015;85(1-2):44-48.
- Porter M, Shadbolt B, Ye X, Stuart R. Ankle lateral ligament augmentation versus the modified Broström-Gould procedure: a 5-year randomized controlled trial. Am J Sports Med. 2019;47(3):659-666.
- Prisk VR, Imhauser CW, O'Loughlin PF, Kennedy JG. Lateral ligament repair and reconstruction restore neither contact mechanics of the ankle joint nor motion patterns of the hindfoot. *J Bone Joint Surg Am.* 2010;92(14):2375-2386.
- Rooney BD, Derrick TR. Joint contact loading in forefoot and rearfoot strike patterns during running. J Biomech. 2013;46(13):2201-2206.

- Roos EM, Brandsson S, Karlsson J. Validation of the Foot and Ankle Outcome Score for ankle ligament reconstruction. *Foot Ankle Int.* 2001;22(10):788-794.
- Roos KG, Kerr ZY, Mauntel TC, Djoko A, Dompier TP, Wikstrom EA. The epidemiology of lateral ligament complex ankle sprains in National Collegiate Athletic Association sports. *Am J Sports Med*. 2017;45(1):201-209.
- Son SJ, Kim H, Seeley MK, Hopkins JT. Altered walking neuromechanics in patients with chronic ankle instability. J Athl Train. 2019;54(6): 684-697.
- 47. Sugimoto K, Takakura Y, Kumai T, Iwai M, Tanaka Y. Reconstruction of the lateral ankle ligaments with bone-patellar tendon graft in patients with chronic ankle instability: a preliminary report. *Am J Sports Med*. 2002;30(3):340-346.
- Sugimoto K, Takakura Y, Okahashi K, Samoto N, Kawate K, Iwai M. Chondral injuries of the ankle with recurrent lateral instability: an arthroscopic study. *J Bone Joint Surg Am*. 2009;91(1):99-106.
- Tarbrizian M, Leroy-Gallisot A, Yahia L. Technical report: evaluation of synthetic LARS knee ligaments. Biomechanics and Biomaterials Research Group. École Polytechnique Montréal. 1996;1-34.
- Tohyama H, Beynnon BD, Pope MH, Haugh LD, Renström PA. Laxity and flexibility of the ankle following reconstruction with the Chrisman-Snook procedure. J Orthop Res. 1997;15(5):707-711.
- Trieb K, Blahovec H, Brand G, Sabeti M, Dominkus M, Kotz R. In vivo and in vitro cellular ingrowth into a new generation of artificial ligaments. *Eur Surg Res*. 2004;36(3):148-151.
- 52. Tummala SV, Hartigan DE, Makovicka JL, Patel KA, Chhabra A. 10-year epidemiology of ankle injuries in men's and women's collegiate basketball. *Orthop J Sports Med*. 2018;6(11):2325957118805400.
- Ulku TK, Kocaoglu B, Tok O, Irgit K, Nalbantoglu U. Arthroscopic suture-tape internal bracing is safe as arthroscopic modified Broström repair in the treatment of chronic ankle instability. *Knee Surg Sports Traumatol Arthrosc.* 2020;28(1):227-232.
- Valderrabano V, Hintermann B, Horisberger M, Tak SF. Ligamentous post-traumatic ankle osteoarthritis. *Am J Sports Med*. 2006;34(4): 612-620.
- Vuurberg G, Altink N, Rajai M, Blankevoort L, Kerkoffs G. Weight, BMI and stability are associated with lateral ankle sprain and chronic ankle instability: a meta-analysis. *J ISAKOS* 2019;4:313:327.
- Waldrop NE III, Wijdicks CA, Jansson KS, LaPrade RF, Clanton TO. Anatomic suture anchor versus the Broström technique for anterior talofibular ligament repair: a biomechanical comparison. *Am J Sports Med.* 2012;40(11):2590-2596.
- Wang DY, Jiao C, Ao YF, et al. Risk factors for osteochondral lesions and osteophytes in chronic lateral ankle instability: a case series of 1169 patients. Orthop J Sports Med. 2020;8(5):2325967120922821.
- Waterman BR, Owens BD, Davey S, Zacchilli MA, Belmont PJ. The epidemiology of ankle sprains in the United States. *J Bone Joint Surg Am.* 2010;92(13):2279-2284.
- Wolf JM, Cameron KL, Owens BD. Impact of joint laxity and hypermobility on the musculoskeletal system. J Am Acad Orthop Surg. 2011;19(8):463-471.
- 60. Yeo ED, Park JY, Kim JH, Lee YK. Comparison of outcomes in patients with generalized ligamentous laxity and without generalized laxity in the arthroscopic modified Broström operation for chronic lateral ankle instability. *Foot Ankle Int.* 2017;38(12):1318-1323.