



Primary ankle ligament augmentation versus modified Brostrom-Gould procedure: a 2-year randomized controlled trial

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Abstract

Background: More than 20% of patients develop chronic instability following appropriate management of an ‘ankle sprain’. There is little research comparing surgical techniques. ‘Anatomical’ procedures, such as the modified Brostrom-Gould (MBG), are generally preferred. However, not all patients are suitable for this procedure. Augmentation of a primary repair using a synthetic ligament, such as the ligament augmentation reconstruction system (LARS), is another ‘anatomic’ option. Our objective was to compare the clinical outcome following the MBG with that following the LARS technique using a prospective randomized clinical trial.

Methods: Patients who satisfied the study criteria were randomly allocated to undergo the LARS procedure or the MBG procedure. All patients followed a similar rehabilitation programme. Patients completed the foot and ankle outcome score (FAOS) before surgery, and then at 1 year and 2 years following surgery. Statistical analysis was used to compare the groups ($P < 0.05$).

Results: Forty-one patients took part in the study, 21 were randomized to the LARS group and 20 to the MBG group. The LARS group had a significantly better improvement in the total FAOS at both 1 year (25.5 standard error (SE) 3.8 versus 16.0 SE 3.3) and 2 years (27.1 SE 4.5 versus 15.8 SE 4.9) post-surgery.

Conclusion: Primary repair combined with LARS results in better patient-scored clinical outcome, at 2 years post-surgery, than the MBG procedure. Although longer follow-up is required, the LARS procedure may be considered as an alternative, especially in those patients for whom the MBG is relatively contra-indicated.

Introduction

‘Ankle sprains’ are common sports-related injuries and usually involve the lateral ligament complex.¹ Most patients make a full functional recovery. However, more than 25% of cases develop chronic instability.² Chronic instability is associated with chondral injuries to the talus,^{3,4} and may predict early-onset osteoarthritis.⁵ Surgery is indicated when non-operative treatment has failed. There has been a general trend away from the non-anatomical procedures, on account of their increased risk of complications and adverse effects on the biomechanics of the ankle and hindfoot, in favour of the ‘anatomic’ procedures.^{6–12} The modified Brostrom-Gould (MBG) is commonly regarded as the treatment of choice, owing to its relative simplicity and safety.^{13–15} However, it is not suitable for

all patients, including patients with long-standing instability and those of larger body mass.^{16,17} If the inferior extensor retinaculum (IER) is included in the reconstruction, it can adversely affect hindfoot biomechanics.¹⁸

Alternative anatomical procedures include reconstruction using autologous graft, but this bears the risk of graft site morbidity.^{19–21}

Synthetic grafts, such as the ligament augmentation reconstruction system (LARS), may be used in an extra-articular location to augment a primary repair, without the risks of polyethylene synovitis seen with their use inside joints, such as the knee.²²

The goal of the current study was to compare the clinical outcome following the MBG procedure, with that of the LARS procedure, for chronic lateral ankle instability.

Table 1 Inclusion and exclusion criteria for patient enrollment in this study

| Inclusion criteria | Exclusion criteria |
|---|------------------------|
| Chronic instability (>3 months) of ATFL and CFL | Previous ankle surgery |
| Medically fit | MBG contra-indicated |
| Physically active | Ankle fracture |
| Failed non-operative treatment | Diastasis |
| Skeletally mature | MCL laxity |
| Signed, informed consent | >90 kg body mass |

ATFL, anterior talofibular ligament; CFL, calcaneofibular ligament; MBG, modified Brostrom-Gould; MCL, medial collateral ligament.

Table 2 Rehabilitation programme used for all patients following ankle stabilization surgery

| Time period post-surgery | Rehabilitation instructions |
|--------------------------|---|
| 0–7 days | Nil weight bearing, elevation, ROM for toes, knee and hip |
| 1–6 weeks | Air-cast stirrup brace worn when mobilizing and allowed to WBAT with brace on. Allow to perform active, passive and resisted ROM work in dorsi-plantar flexion and eversion-pronation (no inversion-supination movements). Can swim when wounds healed, with brace on, and cycle on a stationary bike against light resistance. |
| 6–12 weeks | Wean off the brace for WBAT, can progress active, passive and resisted ROM in all directions, with the exception of no passive inversion-supination movements. Can begin balance and proprioceptive work, and running when the strength and balance are symmetrical. |
| After 12 weeks | Can begin sport-specific drills and skills. Return to sport when function is similar to that of the opposite uninjured ankle. |

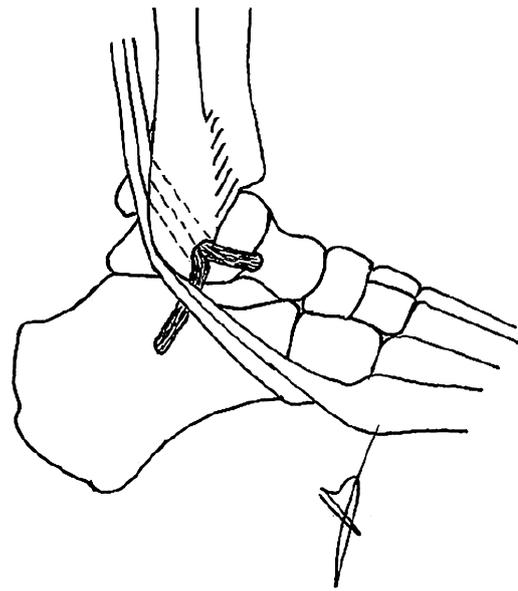
ROM, range of motion; WBAT, weight bear as tolerable.

Methods

Patients presenting to the main author satisfying the inclusion criteria in Table 1 were invited to take part in the study. Patients were regarded as physically active if they took part in physical activity at least twice per week. Appropriate non-operative treatment included avoidance of all physical activities requiring twisting and/or pivoting, in addition to a physiotherapist-supervised strengthening, balance and proprioceptive programme. Patients were informed of the rationale behind the study and were prepared to undergo either the MBG or the LARS procedure. Randomization was performed using a single toss of a coin. All patients followed a similar rehabilitation programme, as detailed in Table 2. Ethical approval was granted by the hospital's Quality, Safety and Ethics Committee.

Surgical techniques

All surgery was performed by the main author. For the MBG procedure, three double-armed suture anchors (3.5 mm Twin-Fix suture anchors, Smith and Nephew Inc., Andover, MA, USA) were used to secure the anterolateral capsuloligamentous structures to the distal fibula. The extra-capsular calcaneofibular ligament (CFL) was also repaired and the IER included in the repair.

**Fig. 1.** Diagram showing the final positioning of the ligament augmentation reconstruction system.

The LARS AC 30 DB (LARS, Surgical Implants and Devices, Arc-sur-Tille, France) synthetic ligament was used for the LARS procedure. The anterior talofibular ligament (ATFL) limb of the ligament was attached to its distal insertion site adjacent to the articular surface of the talus using a 4.75-mm suture anchor (BioComposite SwiveLock, Arthrex Inc., Naples, FL, USA). From here, the ligament runs in an extra-capsular position proximally to the fibular tunnel. The CFL limb was attached to its insertion site on the lateral side of the os calcis using a similar anchor, and from here runs in an extra-capsular location deep to the peroneal tendons and capsule, to the fibular tunnel. A 5-mm diameter tunnel is drilled in the fibula starting where the ATFL and CFL attachments overlap, aiming proximally and posteriorly within the centre of the fibula, penetrating both cortices and at least 25 mm long. The two limbs of the LARS are then pulled (as a loop) superiorly along the fibular tunnel, tensioned individually and then secured using a third 4.75 mm SwiveLock. The excess loop is then cut flush with the posterior surface of the fibula. A repair of the lateral collateral ligament (LCL) complex is performed using absorbable suture (1-vicryl) with imbrication of the attenuated structure, before closing the wound in layers. Figure 1 shows the final position of the LARS.

Post-operative management

All patients were placed in a dorsal back slab until 7–10 days post-surgery. At the first post-operative check, the patient was placed in a subtalar stabilizing brace and was allowed to weight bear as tolerable. The rehabilitation protocol aimed to return patients to full activity within 3–4 months of surgery and is detailed in Table 2.

Outcomes of interest

The foot and ankle outcome score (FAOS) is a patient-scored questionnaire, validated for the use with ankle lateral ligament injury.²³ Patients completed this questionnaire at presentation, and again 12 and 24 months post-surgery. The changes in the scores were compared using statistical

analysis ($P < 0.05$). Analyses were performed using the parametric *t*-test and the non-parametric Mann–Whitney U-test.

Details of all complications were documented.

Power analysis

Using a significance level of 5%, a power of 80% and a standard deviation of 5 units for the total FAOS, the total sample size required was calculated to be 38 or 19 patients per group.

Results

Forty-one patients were enrolled in the study from April 2009 to May 2010. There were 21 patients in the LARS group, 11 male and 10 female, mean age 26.1 years (range 16–43). There were 20 patients in the MBG group, 10 male and 10 female, mean age 24.0 years (range 16–41). Table 3 summarizes the FAOS in the two groups at baseline, 1 and 2 years post-surgery. Table 4 summarizes the changes in the scores and results of the statistical analysis comparing the groups. The LARS group had a significantly better improvement in the total FAOS at both 1 year (25.5 standard error (SE) 3.8 versus 16.0 SE 3.3) and 2 years (27.1 SE 4.5 versus 15.8 SE 4.9) post-surgery. This was also seen within each of the subscales of the FAOS. There were no outliers in either group, in terms of total FAOS or subscales of the FAOS.

Complications

One patient in the LARS complained of irritation of the peroneal tendons by the fibular suture anchor, necessitating removal of the anchor at 6 months post-surgery. Another patient developed a superficial wound infection that required wound debridement and a period of intravenous antibiotics.

Table 3 Foot and ankle outcome score results for LARS group and MBG group, SE in parentheses

| | | LARS | MBG |
|----------|----------|-------------|------------|
| Pain | Baseline | 71.4 (5.8) | 64.6 (6.6) |
| | 1 year | 89.7 (6.1) | 75.3 (2.6) |
| | 2 years | 91.0 (5.7) | 78.4 (5.0) |
| Symptoms | Baseline | 69.6 (5.3) | 65.7 (6.7) |
| | 1 year | 91.4 (5.3) | 78.0 (6.1) |
| | 2 years | 95.1 (4.5) | 78.1 (6.3) |
| ADLs | Baseline | 69.3 (13.2) | 62.3 (4.8) |
| | 1 year | 94.2 (3.4) | 79.4 (6.1) |
| | 2 years | 94.5 (4.2) | 80.1 (8.2) |
| Sport | Baseline | 61.8 (6.0) | 57.4 (4.7) |
| | 1 year | 94.6 (3.9) | 78.1 (4.8) |
| | 2 years | 94.9 (4.0) | 74.6 (6.5) |
| QoL | Baseline | 62.4 (9.8) | 61.0 (7.0) |
| | 1 year | 92.2 (3.3) | 80.0 (5.3) |
| | 2 years | 94.3 (3.6) | 79.0 (5.6) |
| Total | Baseline | 66.9 (3.9) | 62.2 (3.5) |
| | 1 year | 92.4 (2.5) | 78.2 (3.4) |
| | 2 years | 94.0 (3.0) | 78 (5.2) |

ADLs, activities of daily living; LARS, ligament augmentation reconstruction system; MBG, modified Brostrom-Gould; QoL, quality of life; SE, standard error.

In the MBG group, the only complication was a pseudoaneurysm, requiring surgical excision.

Discussion

This study found that physically active patients with chronic lateral ligament instability of the ankle have a superior clinical outcome following a LARS augmentation of a primary repair, compared with a MBG procedure, up to 2 years following surgery.

Over the last few decades, ‘anatomic’ procedures such as the MBG have emerged as the preferred procedure for chronic lateral ligament instability of the ankle. There are a relatively large number of patients for whom the MBG is associated with a poorer outcome. This includes patients with generalized ligamentous laxity or joint hypermobility, long-standing lateral ligament instability and failed previous surgery,^{16,17,24,25} as well as patients with adverse hindfoot biomechanics and high-demand athletes.^{26–28}

Despite the relative popularity of the MBG procedure, there is a paucity of high-level scientific research. Most of the studies are relatively short-case series only.^{7,16,29,30} A meta-analysis was unable to assist the surgeon in choosing the best surgical option for chronic lateral instability of the ankle.³¹

Three long-term studies support the relative safety and clinical effectiveness of the MBG procedure. Maffulli *et al.* performed an 8.7-year (range 5–13 years) follow-up of 38 out of 42 patients who had undergone an isolated ATFL repair. Although they concluded that the procedure was ‘effective’, they reported less than 60% return to previous level of sport and almost 40% of patients had radiographic evidence of either development or progression of osteoarthritis.¹⁵ Lee *et al.* retrospectively reviewed 30 of 38 patients who underwent an ATFL imbrication reinforced with the IER.¹⁴ Patients were reviewed a mean of 10.6 years (range 16–35 years) following surgery. The authors concluded that the long-term results were good to excellent in most cases, with no control group. The longest published follow-up study is that of Bell *et al.* who published a case series of 32 ankles in 31 patients.¹³ Only 23 ankles in 22 patients could be followed-up using a single numeric evaluation (FAOS questionnaire), an average of 26.3 years (range 24.6–27.9 years) following a Brostrom, or similar procedure. There was neither a baseline measurement nor control group in this study, and the data from approximately one-third of patients were not available, making these results hard to evaluate.

Although a safe procedure, a number of concerns have been raised concerning the MBG, such as the strength of the repair achieved following imbrication of tissues that have already been damaged,^{24,29,32–35} the difficulty in repairing the CFL which is extracapsular in location²⁰ and the effect that inclusion of the IER has on the biomechanics of the hindfoot.¹⁸

Attempts have been made to improve the strength of the anatomical reconstruction using an appropriately positioned autograft. Sugimoto *et al.* described a case series of 13 patients who were followed-up for 26.5 months after an anatomic reconstructive procedure using a bone-patellar tendon graft.²⁰ They described their results as ‘good’ with a low risk of complications. The use of the central third of the patellar tendon for other procedures such as anterior cruciate ligament (ACL) reconstruction has been associated

Table 4 Changes in FAOS over the 2-year follow-up period for LARS group and MBG group and results of statistical comparison of the two groups, SE in parentheses

| | Time period (year) | LARS | MBG | t-test | Mann-Whitney U-test |
|----------|--------------------|-------------|------------|--------|------------------------|
| | | | | | Inter-group comparison |
| Pain | 0-1 | 18.3 (8.9) | 10.8 (7.2) | 0.005* | 0.004* |
| | 0-2 | 19.6 (8.8) | 13.8 (7.9) | 0.032* | 0.037* |
| | 1-2 | 1.3 (3.2) | 3.1 (4.0) | 0.138 | 0.021* |
| Symptoms | 0-1 | 21.8 (5.1) | 12.4 (6.5) | 0.001* | 0.001* |
| | 0-2 | 25.6 (5.4) | 12.4 (5.9) | 0.001* | 0.001* |
| | 1-2 | 3.8 (4.4) | 0 (3.5) | 0.005* | 0.006* |
| ADLs | 0-1 | 24.9 (12.8) | 17.1 (7.0) | 0.021* | 0.039* |
| | 0-2 | 25.2 (12.8) | 17.8 (8.8) | 0.037* | 0.047* |
| | 1-2 | 0.3 (1.6) | 0.7 (4.0) | 0.701 | 0.979 |
| Sport | 0-1 | 32.7 (7.2) | 20.7 (5.4) | 0.001* | 0.001* |
| | 0-2 | 33.0 (6.8) | 17.2 (6.5) | 0.001* | 0.001* |
| | 1-2 | 0.3 (1.9) | -3.5 (3.5) | 0.001* | 0.001* |
| QoL | 0-1 | 29.8 (9.1) | 19.7 (7.0) | 0.001* | 0.001* |
| | 0-2 | 31.9 (9.1) | 18 (7.1) | 0.001* | 0.001* |
| | 1-2 | 2.1 (3.3) | -1.0 (4.3) | 0.014* | 0.008* |
| Total | 0-1 | 25.5 (3.8) | 16 (3.3) | 0.001* | 0.001* |
| | 0-2 | 27.1 (4.5) | 15.8 (4.9) | 0.001* | 0.001* |
| | 1-2 | 1.6 (1.2) | -0.2 (2.4) | 0.006* | 0.001* |

*Statistically significant. ADLs, activities of daily living; FAOS, foot and ankle outcome score; LARS, ligament augmentation reconstruction system; MBG, modified Brostrom-Gould; QoL, quality of life; SE, standard error.

with anterior knee pain, and pain on kneeling, for up to 2 years following surgery.³⁶⁻⁴⁰ Strength deficits in the quadriceps have been reported following harvesting of either the patellar tendon or the quadriceps tendon.⁴¹

Potential graft site morbidity has driven the search for a graft devoid of such complications. Allograft use for ACL reconstructions has been associated with a higher failure rate.⁴² A synthetic ligament could obviate any such problems but unfortunately the use of synthetic ligaments for ACL reconstruction was abandoned because of the risk of synovitis and osteoarthritis.^{22,43,44}

A third generation polyethylene ligament was designed in an attempt to solve the problems associated with its predecessors. However, a report has appeared in the literature of polyethylene synovitis following the use of the LARS ligament for ACL reconstruction.⁴⁵ The LARS was specifically designed as an isometric scaffold to allow the remnants of the natural ligament to heal. During ACL reconstruction, preservation of natural ligament remnants and isometric position of the LARS are both challenging and contentious. During LCL reconstruction of the ankle, the remnants of the LCL complex are easy to preserve and the isometric attachment points are more readily found. The ankle joint is more constrained than the knee and less reliant on soft tissues. This synthetic device may be more suitable for ankle LCL reconstruction, and if placed in an extra-capsular location, free of the risks of polyethylene synovitis.

This study has a number of weaknesses. Only 41 patients (but of adequate power); blinding was not possible (LARS procedure required two additional incision); and follow-up is only 2 years. Patients weighing more than 90 kg were excluded from the study, which reduces the generalizability of the results. However, because

the MBG is relatively contra-indicated in larger patients, including such patients in the study may have biased the study against the MBG procedure. For similar reasons, a period of 3 months was used to define chronic instability, rather than a longer period, which might have otherwise biased the study against the MBG procedure. With these limitations in mind, the current study has demonstrated the clinically superior outcome following the extra-capsular use of LARS for primary ankle LCL reconstruction, relative to the MBG. Further research is required to determine if the LARS procedure is cost-effective, free of longer-term complications and its precise absolute, or relative, indications and contra-indications.

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