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Superficial Medial Collateral Ligament Augmented Repair Versus Reconstruction: A Multicenter Randomized Controlled Trial

Abstract

Background: Although previous studies have reported good short-term results for superficial medial collateral ligament (sMCL) reconstruction, whether an augmented MCL repair compared to a sMCL reconstruction technique are clinically equivalent still remains unclear.

Purpose/Hypothesis: The purpose of this study was to compare clinical outcomes between randomized groups who underwent sMCL augmentation repair versus sMCL autograft reconstruction. The hypothesis was that there would be no significant differences in objective or subjective outcomes between both groups.

Study Design: Randomized controlled equivalence trial; Level of evidence, 1.

Methods: Patients were prospectively enrolled from 2013 to 2019 from 3 different centers. Grade III sMCL injuries were confirmed by stress radiography. Patients were randomized to an anatomic sMCL reconstruction versus an augmented repair with surgical treatment determined after examination under anesthesia confirmed sMCL incompetence. Post-operative visits occurred at 6 weeks and 6 months for repeat evaluation and repeat stress radiography at final follow-up. Patient reported outcome measures (PROMs) were obtained preoperatively and post-operatively at 6 months, 1 year, and at final follow-up. The primary outcome measure was side-to-side difference on valgus stress radiographs at a minimum of 1-year follow-up. The two one-sided t-test (TOST) procedure was used to test clinical equivalence for side-to-side difference in valgus gapping, and the Mann-Whitney U-test was used to compare postoperative PROMs between groups.

Results: Fifty-four patients were prospectively enrolled into this study. Fifty patients had 6-month stress radiograph data, while 40 patients had one year postoperative valgus stress radiograph data. The average overall patient age was 38.0 years (standard deviation (SD = 14.2 years), and the body mass index was 25.0 (SD = 3.6). Preoperative valgus stress radiographs demonstrated 3.74 mm (SD = 1.1 mm) of increased side-to-side gapping overall, while it was 4.10 mm (SD = 1.46 mm) in the MCL augmentation group and 3.42 mm (SD = 0.55) in the MCL reconstruction patients. Postoperative valgus stress radiographs at an average of 6 months were obtained in 50 patients after surgery were 0.21 mm (SD = 0.81 mm) for the MCL augmentation patients and 0.19 mm (SD = 0.67 mm) for the MCL reconstruction patients (p = 0.940). At final follow-up (minimum 1-year), Lysholm scores were significantly higher in the reconstruction group (median 90, inter-quartile range 83 – 99) compared to the repair group (median 80, IQR 67 - 92; p=0.031). Final IKDC scores were also significantly higher for the reconstruction group (median 85, IQR 68 - 89) compared to the repair group (median 72, IQR 60 - 78; p=0.039). Postoperative Tegner scores were not significantly different between the repair group (median 5, IQR 3.5 - 6) and the reconstruction group (median 5.5, IQR 4 - 7; p=0.123). Patient satisfaction was also not significantly different between the repair (median 7.5, IQR 5.75 – 9.25) and reconstruction groups (median 9, IQR 7 - 10; p=0.184).

Conclusion: This study found that there was no difference in objective outcomes between a sMCL augmentation repair versus a complete sMCL reconstruction at one year postoperatively, indicating equivalence between these two procedures. Patient reported clinical outcomes favored the reconstruction over a repair. In addition, this study demonstrated that anatomic-

based treatment of MCL tears with an early knee motion program had a very low risk of graft attenuation and also a low risk of arthrofibrosis.

INTRODUCTION

The medial knee structures, primarily comprised of the superficial medial collateral ligament (sMCL), deep medial collateral ligament (dMCL), and posterior oblique ligament (POL), are the most commonly injured knee ligaments.[8] Although the injury prevalence is high, recommendations for treatment differ when nonoperative treatment fails or surgical treatment is required.[1, 9] Anatomically imprecise graft placement and suboptimal reconstruction graft fixation methods can lead to graft over-constraint or graft loosening. Studies have attempted to optimize the surgical technique for the medial knee structures by providing thorough descriptions of the quantitative anatomy and biomechanics of the sMCL, dMCL and POL.[2, 3, 8, 18] These findings stress the importance of an anatomic restoration of all injured medial knee structures so that the native kinematic relationships within the knee can be fully re-established.[1] In this regard, stress radiographs have been reported to be an invaluable tool, with an increased side-to-side medial compartment gapping difference of 3.2 mm for an isolated sMCL tear and ≥ 9.8 mm for a complete sMCL, deep MCL and POL tear.[7]

A previous biomechanical study has validated both an anatomic sMCL augmentation repair and reconstruction technique.[19] Although previous studies have reported good short-term results for a complete MCL and POL reconstruction, whether an isolated MCL augmentation repair and reconstruction techniques are equivalent, when the POL does not require a reconstruction, still remains unclear.[5, 6, 10, 12, 15] Therefore, the purpose of this study

was to compare clinical outcomes between randomized groups who underwent sMCL augmentation repair versus sMCL autograft reconstruction. The hypothesis was that there would be no significant differences in objective or subjective outcomes between both groups.

Methods

Trial Design

This was a multi-center randomized controlled trial. The three participating institutions and respective surgeons include: The Steadman Clinic (R.F.L.), Vail, CO, USA; University of Oslo (L.E.), Oslo, Norway; and Aarhus University Hospital (M.L.), Aarhus, Denmark. The eligibility criteria for inclusion included: > 18 years of age, grade III MCL tear, combined ACL and MCL tears, and clinical and radiographic examination occurring within 12 months of MCL injury. Patients were excluded by the following: < 18 years of age, BMI $\geq$ 40 kg/m^2, previous sMCL injury on either knee, or if the involved knee had a previous history of knee ligamentous surgery, alignment surgery, knee dislocation, complete POL tear, or multi-ligamentous pathology at time of MCL injury (with the exception of ACL injury).

All patients were randomly placed into one of two groups: anatomic sMCL reconstruction or anatomic sMCL augmented repair. A stratified permuted block randomization was arranged prior to commencement of the trial by the coordinating site. Blocks of size 6 were used – each containing 3 reconstruction and 3 augmented repair assignments to achieve an approximate 1:1 allocation ratio between groups. Site was the only stratification factor. The randomly assigned surgical technique was revealed to the treating surgeon after the exam under anesthesia, prior surgery, and following completion of informed consent.

Clinical and Radiographic Diagnosis

The clinical examination for the extent of a medial knee injury consisted of the valgus stress test applied at full extension and at 20° of knee flexion to subjectively estimate medial compartment gapping. Assessment of anteromedial rotation by the anteromedial drawer and dial tests were also performed to assess the potential for additional injury to the POL and dMCL.

Isolated grade III MCL injuries were objectively verified using valgus stress radiographs and magnetic resonance imaging (MRI). At 20° of knee flexion, the degree of medial compartment gapping was measured relative to the uninjured contralateral knee, with grade III injuries typically indicated by an increase of 3.2 mm, with concomitant complete injuries to the POL and dMCL indicated by a relative increase of 9.8 mm.[7] MRI was also utilized for diagnosis, with previous data reporting an accuracy of 87% for medial knee injuries.[20]

Anatomic sMCL Reconstruction

An anteromedial incision was made along the medial aspect of the knee, beginning from medial to the patella and extending distally over the midportion of the tibia 7 to 8 cm distal to the joint line. After identification of the distal sMCL tibial attachment, an open-ended hamstring stripper was used for proximal harvest of the semitendinosus tendon, followed by release from its tibial attachment. The ends of the graft were then whip-stitched with braided polypropylene No. 2 sutures (FiberWire, Arthrex Inc., Naples, FL). Within the pes anserine bursa, the distal tibial attachment of the sMCL was identified approximately 6 cm distal to the joint line.[8] An

eyelet pin was then transversely drilled through the attachment site across the tibia, and was over-reamed with a 7 mm reamer to a depth of 25 mm. The femoral attachment of the sMCL was then identified, approximately 3.2 mm proximal and 4.8 mm posterior to the medial epicondyle.[8] When Identification of the medial epicondyle was not obvious, the attachment was found by locating the adductor tubercle distal to the attachment of the adductor magnus tendon, and then identifying the medial epicondyle which is by measuring approximately 12.6 mm distal and 8.3 mm anterior from the adductor tubercle. A tunnel was then created, first by drilling an eyelet pin anterolaterally across the femur, followed by over-reaming of a 7 mm reamer to a depth of 30 mm. A 7 x 20 mm cannulated bioabsorbable screw (BIOSURE PK, Smith & Nephew, Andover, MA); was then used to secure the femoral attachment of the sMCL. The graft was then passed under the sartorius fascia, pulled into the tibial tunnel using an eyelet passing pin, and fixed at its distal tibial insertion; while securing the graft, the knee was positioned in 20° of flexion and neutral rotation with application of a varus reduction force. The proximal soft tissue tibial attachment of the sMCL was then restored 12 mm distal to the medial joint line, directly over the anterodistal attachment of the anterior arm of the semimembranosus, using a double-loaded suture anchor.

Anatomic sMCL Augmented Repair

The procedure was begun likewise as before, in addition to the proximal harvesting of the hamstring tendons, but the distal attachments were left intact on the tibia. The semitendinosus tendon was then anchored to the tibia 6 cm distal to the joint line based on its native distal tibial attachment, using 2 double loaded suture anchors, and the underlying

remnant of the distal aspect of the sMCL was sutured together at this location. The MCL tendon graft was then passed proximally under the sartorius fascia to the sMCL femoral attachment, approximately 3.2 mm proximal and 4.8 mm posterior to the medial epicondyle.[8] An eyelet pin was then placed anterolaterally across the femur at the femoral attachment of the sMCL, and was over reamed with a 7 mm reamer to a depth of 30 mm. The semitendinosus graft was then aligned at the femoral origin of the sMCL, and the ends of the graft were then whip-stitched with braided polypropylene No. 2 sutures (FiberWire); excess graft was removed following preparation. The graft was pulled into the tunnel and secured with a 7 x 20 mm cannulated bioabsorbable screw (BIOSURE PK); the knee was positioned in 20° of flexion and neutral rotation with application of a varus reduction force. Finally, the proximal tibial attachment of the sMCL was secured using a double-loaded suture anchor (Figure 1).[10]

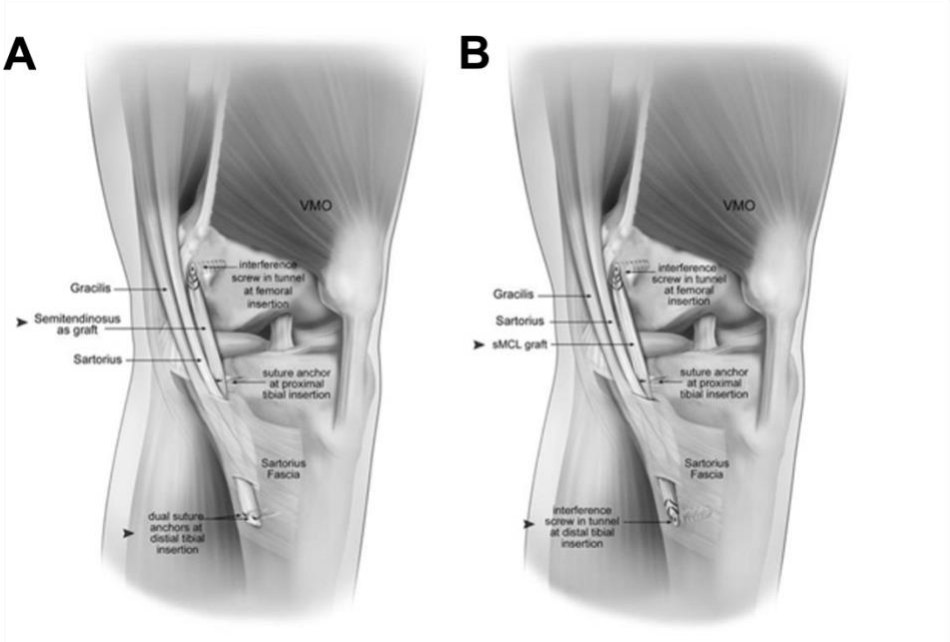

Figure 1. Illustration of randomized surgical techniques. A) Anatomic superficial MCL repair versus B) anatomic superficial MCL reconstruction.

Postoperative Rehabilitation

Physical therapy was initiated on postoperative day one, along with early range-of-motion (ROM) to reduce the chance of intraarticular adhesions or quadriceps atrophy. Patients were kept non-weightbearing for the first 6 weeks, to avoid disturbance to reconstruction graft healing. For the first two weeks postoperatively, patients were allowed to perform exercises of quadriceps setting, straight-leg raises (with bracing), knee flexion to 90 degrees, and hip extension and abduction exercises, following which progressive knee flexion was allowed to increase to full ROM as tolerated. At six weeks postoperatively, weightbearing exercises were initiated including gait training, closed kinetic chain exercises, and leg presses (only to 70° of knee flexion). Lower-extremity strength training and proprioception typically were allowed around 16 to 20 weeks postoperatively, assuming patients were progressing accordingly, and return to full activity was allowed dependent upon activity-specific functional tests and objective evidence of healing on valgus stress radiographs.[7, 8]

Data Collection

Upon initial visitation, baseline outcome measures were completed by patients who were issued a baseline questionnaire evaluation. Patients were asked to return to clinic at 6 weeks postoperatively for a physical examination, and at 6 months postoperatively for clinical and radiographic examinations. Clinical examination included: knee ROM, valgus stress test in extension and 30° of flexion, dial test, anteromedial drawer test, Lachman test, pivot shift test, and posterior drawer test. Radiographic examination consisted of bilateral valgus stress radiographs. Patients were issued postoperative follow-up questionnaires at the time points of

6 months, 1 year, and each year thereafter. The primary patient-reported outcomes used for this study were: International Knee Documentation Committee (IKDC) score, Lysholm score, the Tegner activity scale, and a numeric rating scale patient satisfaction question (1 – 10 where 10 represents 'very satisfied').

Statistical Analysis

The primary hypothesis of this clinical trial was clinical equivalence in side-to-side difference (SSD) in gapping on valgus stress radiograph between MCL augmented repair and MCL reconstruction groups. The two one-side t-test method (TOST) was used to formally test the null hypothesis of a clinically relevant difference, versus the alternative hypothesis of a clinical equivalence with respect to clinically meaningful threshold of SSD valgus gapping. To aid in interpretation of the TOST, a 90% confidence interval for the mean difference – which corresponds to a significance level of $\alpha = 0.05$ – was presented graphically.[4]

For the secondary endpoint of patient reported outcome measures (PROMs) IKDC, Lysholm, Tegner activity scale, and patient satisfaction, furthest follow-up that was obtained at least 1-year post-surgically was analyzed. Non-parametric statistical tests were performed including the Mann-Whitney U-test (MWU) for independent samples group comparisons, and the Wilcoxon signed-rank (WSR) test for paired samples comparisons. Fisher's exact test (FET) was used to compare the treatment groups with respect to binary or categorical variables. As a further analysis of the postoperative PROM scores, clinical equivalence was assessed by performing a bootstrapping procedure to estimate the 90% confidence intervals for the between-group difference median PROM score.[13] In-text summary statistics were reported

using the following formats: Mean ± Standard Deviation, Median (1st Quartile – 3rd Quartile), or Estimate [Confidence Interval]. All graphs and analyses were completed with the statistical package R version 4.0.3 (R Development Core Team, Vienna, Austria with additional package *equivalence*).[16]

Power and Sample Size Calculation

An a priori power analysis was performed for the primary endpoint equivalence test. Relevant parameters for this calculation included the margin of clinical equivalence (δ), the between-patient within group standard deviation of valgus gapping (s), the observed reconstruction vs augmented repair difference (m), the type-1 error rate (α) and the required statistical power (1-β). The margin of clinical equivalence was set at δ=2.0 mm based on the 2000 IKDC objective knee examination grading guidelines which defined a side-to-side difference in valgus gapping of 0-2 mm as normal. The standard deviation of valgus gapping measurements was estimated conservatively to be s=2.35 mm based on a prior in vitro biomechanical study.[7] We chose an anticipated observed mean group difference of m=0.25mm. The type-1 error rate was set at α=0.05. It was calculated that 52 subjects were necessary to achieve 80% statistical power.

Results

Fifty-four patients were prospectively enrolled between December 2013 and May 2019. Fifty patients (93%) had complete 6-month valgus stress radiograph exam, while 40 patients (74%) had complete 12-month postoperative valgus stress radiograph exam (Figure 2). The mean patient age was 38.0 ± 14.2 years, and the mean body mass index was 25.0 ± 3.6 kg/m^2. A

thorough summary of demographic, patient detail, baseline exam and preoperative patient-reported outcome measures are presented in Table 1. In the Appendix, Table 2 further summarizes these baseline characteristics by site.

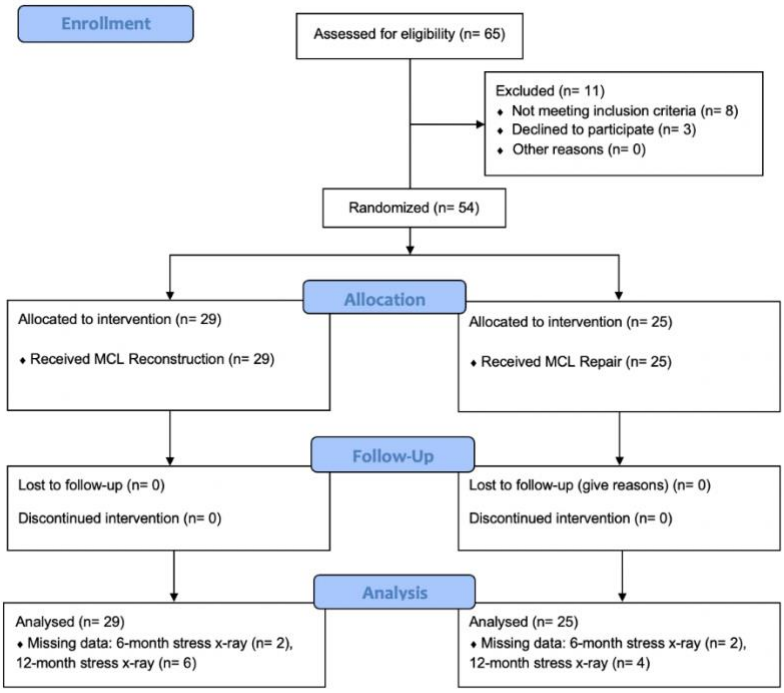

Figure 2. CONSORT flow diagram illustrating the grouping and flow of all patients assessed for eligibility and enrollment in this randomized controlled trial.

Table 1. Comparison of baseline covariates between MCL Treatment Groups†

	Recon	**Repair**
	No. 29	**No. 25**
Age	32.0 (23.0 - 40.0)	43.0 (27.0 - 57.0)
Sex		
F	13 (44.8%)	11 (44.0%)
M	16 (55.2%)	14 (56.0%)
Site		
Denmark	10 (34.5%)	8 (32.0%)
Oslo	1 (3.4%)	0 (0.0%)
Vail	18 (62.1%)	17 (68.0%)
Body Mass Index	24.9 (22.3 - 26.8)	24.6 (23.1 - 25.8)
Time Inj-Surg (wks.)	14.3 (3.8 - 28.0)	5.8 (2.4 - 21.0)
Chronicity		
Acute	9 (31.0%)	14 (56.0%)

Chronic	20 (69.0%)	11 (44.0%)
ACL Reconstruction		
N	5 (17.2%)	6 (24.0%)
Y	24 (82.8%)	19 (76.0%)
Valgus Gapping (SSD)	3.4 (3.0 - 3.5)	3.6 (3.1 - 4.4)
ROM Ext Uninjured (EUA)	-1.0 (-3.0 - 0.0)	-2.0 (-2.0 - 0.0)
ROM Flex Uninjured (EUA)	135.0 (135.0 - 140.0)	135.0 (135.0 - 140.0)
ROM Ext Injured (EUA)	-1.0 (-3.0 - 0.0)	-2.0 (-3.0 - 0.0)
ROM Flex Injured (EUA)	135.0 (135.0 - 140.0)	135.0 (135.0 - 140.0)
Valgus 0 deg (EUA)		
0	0 (0.0%)	1 (4.0%)
1	11 (37.9%)	5 (20.0%)
2	10 (34.5%)	7 (28.0%)
3	8 (27.6%)	12 (48.0%)
Valgus 30 deg (EUA)		
2	4 (13.8%)	2 (8.0%)
3	25 (86.2%)	23 (92.0%)
Dial Test (EUA)		
0	15 (51.7%)	8 (32.0%)
1	3 (10.3%)	6 (24.0%)
2	4 (13.8%)	1 (4.0%)
3	7 (24.1%)	10 (40.0%)
AM Drawer (EUA)		
0	3 (10.3%)	2 (8.0%)
1	4 (13.8%)	4 (16.0%)
2	13 (44.8%)	10 (40.0%)
3	9 (31.0%)	9 (36.0%)
Lachman (EUA)		
0	4 (13.8%)	5 (20.0%)
1	3 (10.3%)	0 (0.0%)
2	11 (37.9%)	13 (52.0%)
3	11 (37.9%)	7 (28.0%)
Pivot Shift (EUA)		
0	5 (17.2%)	4 (16.7%)
1	3 (10.3%)	5 (20.8%)
2	14 (48.3%)	7 (29.2%)
3	7 (24.1%)	8 (33.3%)
Heel Height Injured (EUA)	1.0 (0.0 - 3.0)	1.0 (1.0 - 3.0)
Heel Height Uninjured (EUA)	1.0 (0.0 - 3.0)	1.0 (0.8 - 2.0)

Baseline IKDC	53.4 (41.3 - 64.4)	53.4 (41.3 - 62.5)
Baseline Lysholm	67.0 (44.8 - 78.2)	55.0 (45.2 - 68.5)
Baseline Tegner	4.0 (2.5 - 5.8)	4.0 (2.8 - 4.0)

† data presented as count (%) or median (1st quartile - 3rd quartile)

†† p values correspond to the Mann-Whitney U-test or Fisher's exact test

Note: EUA = exam under anesthesia, SSD = side-to-side difference, AM = anteromedial, ROM = range of motion, Flex = flexion, Ext = extension, Inj=injury

Preoperative valgus stress radiographs demonstrated a mean of 3.7 ± 1.1 mm of increased side-to-side difference (SSD) overall; subgroup analysis revealed 4.1 ± 1.4 mm versus 3.4 ± 0.5 mm of increased SSD valgus stress in the MCL augmentation group and in the MCL reconstruction group, respectively. Six-month postoperative valgus stress radiographs were obtained in 50 patients. At 6 months, the mean SSD was 0.20 ± 0.74 mm for all patients, 0.21 ± 0.81 mm for the MCL augmentation patients, and 0.19 ± 0.67 mm for the MCL reconstruction patients. Twelve-month postoperative valgus stress radiographs were obtained in 40 patients. At 12 months, the mean SSD was 0.32 ± 0.72 mm for all patients, 0.30 ± 0.75 mm for the MCL augmentation patients, and 0.33 ± 0.71 mm for the MCL reconstruction patients. The two one-sided t-test (TOST) procedure found a between-group mean difference in SSD of valgus gapping of 0.02 mm (90% confidence interval [-0.34, 0.37]; $p<0.001$) at 6-months following surgery and -0.03 mm (90% confidence interval [-0.42, 0.37]; $p<0.001$) at 12-months following surgery. Both confidence intervals fell comfortably within the a priori specified margin of clinical equivalence of ± 2 mm (Figure 3). Further, the average difference in SSD valgus gapping between MCL augmentation and MCL reconstruction patients, at both 6 and 12 months postoperatively, was shown to be within ± 0.5 mm with a 5% significance level.

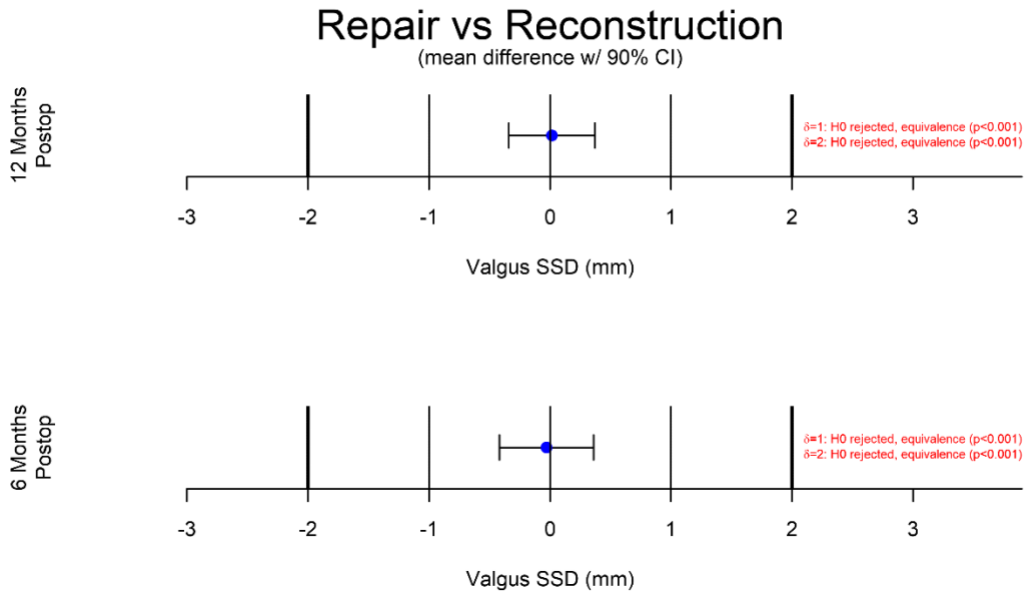

Figure 3. Equivalence plot between MCL Augmentation Repair versus MCL Reconstruction patients for side-to-side difference (SSD) in valgus stress radiographs at 6 and 12 months postoperatively (CI: confidence intervals).

Patient Reported Outcomes

At baseline, the augmented repair group had lower Lysholm scores (median 55, IQR 45 - 69) than the reconstruction group (median 67, IQR 45 - 78) (Table 1), which may be considered clinically relevant. Conversely, baseline IKDC scores for the repair group (median 53, IQR 41 - 63) versus the reconstruction group (median 53, IQR 41 - 64; MWU p=0.649) were not substantially different.

At final follow-up (minimum 1-year), Lysholm scores were significantly higher in the reconstruction group (median 90, IQR 83 - 99) compared to the repair group (median 80, IQR 67 - 92; MWU p=0.031). Final IKDC scores were also significantly higher for the reconstruction group (median 85, IQR 68 - 89) compared to the repair group (median 72, IQR 60 - 72; MWU p=0.039). Postoperative Tegner scores were not significantly different between the repair

group (median 5, IQR 3.5 - 6) and the reconstruction group (median 5.5 IQR 4 - 7; MWU p=0.123). Patient satisfaction was also not significantly different between the repair (median 7.5, IQR 5.8 - 9.3) and reconstruction groups (median 9.0 IQR 7 - 10; MWU p=0.184). Overall, the average time to final follow-up for the repair group (29.3 ± 16.3 months), versus the reconstruction group (30.0 ± 14.5 months), was not deemed to be a confounder between groups (p=0.425). Figure 4 demonstrates the between-group difference in median PROM scores at final follow-up, along with 90% bootstrap estimated confidence intervals, and can be used to interpret clinical difference/equivalence of patient-reported outcomes.

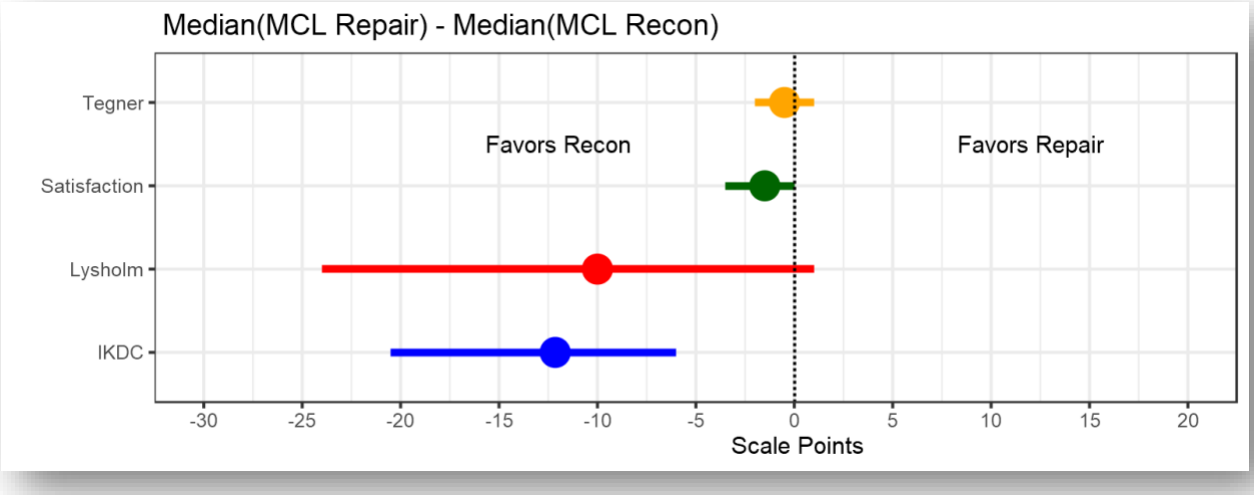

Figure 4. Between-group comparison of patient reported outcomes scores at final follow-up. Dots represent the difference in group medians, while the error bars represent the 90% bootstrap estimated confidence intervals for the difference in medians.

Complications & Failures

There were no reported cases of deep venous thrombosis, infection, or arthrofibrosis in any patient in either group. There were no reported MCL graft ruptures in either the

augmentation or reconstruction group as indicated from objective valgus stress radiographs (i.e., ≥ 3.2 mm) and subjective physical examination at 12 months postoperatively. Additionally, at final follow-up, there were no identified ACL reconstruction graft ruptures for those patients with concomitant procedures (80% of total sample).

Discussion

The most important finding of this study was that there was no difference in objective outcomes between a sMCL augmentation repair versus a complete sMCL reconstruction at one year postoperatively. These results indicate equivalence with no inferiority between sMCL augmentation repair and sMCL reconstruction. Patient reported outcomes appeared to favor the reconstruction over the repair. In addition, this study demonstrated that anatomic-based treatment of MCL tears with an early knee motion program had a no evidence of graft attenuation based upon objective valgus stress data and no evidence of arthrofibrosis at 12-months postoperatively.

This study focused on sMCL tear patients with either an intact POL or a capsular POL avulsion that could be repaired. Thus, it did not analyze patients who may have required a complete medial knee reconstruction. Previously, LaPrade and Wijdicks[10] reviewed 28 patients that all underwent single stage anatomic reconstructions of the posteromedial corner, including the sMCL and POL, and coinciding reconstruction of the cruciate ligaments. They reported significant increases in subjective IKDC scores (76.2 postoperative vs. 43.5 preoperative) and resolution of side-to-side medial instability at two years postoperative in all study patients. LaPrade and Wijdicks also reported improvements in valgus stress radiographs: 6.2 mm average

of medial compartment gapping on preoperative bilateral valgus stress radiographs compared to 1.3 mm average of gapping of on postoperative stress radiographs in side-to-side medial compartment gapping.[10] In addition, in one of the largest studies on MCL and POL reconstructions by Lind et al.[12], 50 patients who were followed for a minimum of two years had a 98% normal or nearly normal (grade A or B) IKDC score for medial knee stability and an overall IKDC score of 74% for grade A or B. All patients were similarly operated on with semitendinosus autografts, but the pes tendons were left attached distally along the anteromedial tibia and were not rerouted to the distal MCL tibial attachment for the distal MCL tibia attachment and they were placed into one femoral tunnel for the MCL and POL attachment. However, their technique has now been modified to attach the distal MCL tibial attachment via suture anchors similar to the present study.[11]

This study objectively validated the previous biomechanical findings that distal tibial MCL graft fixation can be either with suture anchors (leaving the semitendinosus graft intact) or via a tunnel and interference screw fixation. This is important because the distal tibial fixation of the MCL is its strongest overall attachment.[17] While free autografts and allografts require a distal MCL tibial tunnel, anchor fixation has some advantages, so it is important to have this validated as a fixation method. Anchor fixation can avoid the possibility of tunnel convergence with a posterior cruciate ligament reconstruction tunnel and avoids the risk of graft damage by interference screw fixation in this particularly hard cortical bone of the tibia at this location.[14] Additionally, the subjective outcomes between the sMCL reconstruction and the augmented repair group demonstrated significantly improved outcomes for the reconstruction over the repair group for the Lysholm Knee Score and the IKDC Subjective Knee form. However, some

caution should be used in interpreting this data because the baseline repair group Lysholm data was clinically relevantly lower between groups.

We recognize some limitations to this study. Despite implementing a block randomization approach to surgical treatment assignment, there were several potentially impactful baseline differences between the augmented repair and reconstruction groups. The repair group was substantially older, was operated on more acutely on average, and reported lower average preoperative Lysholm scores. While these group distinctions did not appear to have an impact on the primary postoperative valgus gapping endpoint, it remains unclear whether these differential characteristics persisted to cause the lower patient-reported health status of the augmented repair group. Although the primary outcome was the amount of objective side-to-side difference on valgus stress radiographs for MCL surgical patients, the study sample included combined ACL and MCL injuries. Combined ACL/MCL injuries may represent confounding variables when evaluating PROs, yet this does not introduce variability when evaluating our primary outcome of medial knee laxity as determined by valgus stress radiographs. Additionally, it is recognized that one enrollment center contributed only a single study patient which can be attributed to the pre-determined inclusion/exclusion criteria, patient/surgeon shared decision-making, and inherent societal differences between countries. The disparate number of patients enrolled from each site is an inherent limitation of international, multi-center randomized controlled trials which may partially limit the generalizability and external validity of the results.

Conclusion

This study found that there was no difference in objective outcomes between a sMCL augmentation repair versus a complete sMCL reconstruction at one year postoperatively, indicating equivalence between these two procedures. Patient reported clinical outcomes favored the reconstruction over a repair. In addition, this study demonstrated that anatomic-based treatment of MCL tears with an early knee motion program had a very low risk of graft attenuation and also a low risk of arthrofibrosis.

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Appendix:

Table A2

Comparison of baseline covariates between sites.[†]

	Blinded No. 18	**Blinded No. 1**	**Blinded No. 35**
Age	25.5 (23.0 - 32.8)	18.0 (18.0 - 18.0)	43.0 (31.0 - 57.0)
Sex			
F	6 (33.3%)	0 (0.0%)	18 (51.4%)
M	12 (66.7%)	1 (100.0%)	17 (48.6%)
MCL Group			
Recon	10 (55.6%)	1 (100.0%)	18 (51.4%)
Repair	8 (44.4%)	0 (0.0%)	17 (48.6%)
Body Mass Index	24.8 (23.7 - 27.1)	24.8 (24.8 - 24.8)	24.9 (21.7 - 25.8)
Time Inj-Surg (wks.)	25.3 (17.6 - 59.3)	51.0 (51.0 - 51.0)	3.8 (2.1 - 10.0)
Chronicity			
Acute	0 (0.0%)	0 (0.0%)	23 (65.7%)
Chronic	18 (100.0%)	1 (100.0%)	12 (34.3%)
ACL Reconstruction			
N	2 (11.1%)	0 (0.0%)	9 (25.7%)
Y	16 (88.9%)	1 (100.0%)	26 (74.3%)
Valgus Gapping (SSD)	3.4 (3.1 - 3.6)	2.9 (2.9 - 2.9)	3.5 (3.0 - 4.2)
ROM Ext Uninjured (EUA)	0.0 (0.0 - 5.0)	-5.0 (-5.0 - -5.0)	-2.0 (-3.0 - -1.5)
ROM Flex Uninjured (EUA)	140.0 (140.0 - 140.0)	135.0 (135.0 - 135.0)	135.0 (135.0 - 137.5)
ROM Ext Injured (EUA)	0.0 (0.0 - 5.0)	-5.0 (-5.0 - -5.0)	-3.0 (-4.5 - -1.5)
ROM Flex Injured (EUA)	140.0 (131.2 - 140.0)	135.0 (135.0 - 135.0)	135.0 (135.0 - 135.0)

Valgus 0 deg (EUA)			
0	1 (5.6%)	0 (0.0%)	0 (0.0%)
1	13 (72.2%)	0 (0.0%)	3 (8.6%)
2	4 (22.2%)	1 (100.0%)	12 (34.3%)
3	0 (0.0%)	0 (0.0%)	20 (57.1%)
Valgus 30 deg (EUA)			
2	6 (33.3%)	0 (0.0%)	0 (0.0%)
3	12 (66.7%)	1 (100.0%)	35 (100.0%)
Dial Test (EUA)			
0	18 (100.0%)	1 (100.0%)	4 (11.4%)
1	0 (0.0%)	0 (0.0%)	9 (25.7%)
2	0 (0.0%)	0 (0.0%)	5 (14.3%)
3	0 (0.0%)	0 (0.0%)	17 (48.6%)
AM Drawer (EUA)			
0	2 (11.1%)	0 (0.0%)	3 (8.6%)
1	2 (11.1%)	0 (0.0%)	6 (17.1%)
2	12 (66.7%)	1 (100.0%)	10 (28.6%)
3	2 (11.1%)	0 (0.0%)	16 (45.7%)
Lachman (EUA)			
0	2 (11.1%)	0 (0.0%)	7 (20.0%)
1	3 (16.7%)	0 (0.0%)	0 (0.0%)
2	10 (55.6%)	1 (100.0%)	13 (37.1%)
3	3 (16.7%)	0 (0.0%)	15 (42.9%)
Pivot Shift (EUA)			
0	2 (11.8%)	0 (0.0%)	7 (20.0%)
1	7 (41.2%)	1 (100.0%)	0 (0.0%)
2	8 (47.1%)	0 (0.0%)	13 (37.1%)
3	0 (0.0%)	0 (0.0%)	15 (42.9%)
Heel Height Injured (EUA)	1.0 (1.0 - 1.4)	6.0 (6.0 - 6.0)	1.0 (-2.0 - 3.0)
Heel Height Uninjured (EUA)	1.0 (1.0 - 1.0)	6.0 (6.0 - 6.0)	1.0 (-1.5 - 3.0)
Baseline IKDC	53.4 (46.9 - 65.1)	64.4 (64.4 - 64.4)	43.6 (35.6 - 61.5)
Baseline Lysholm	71.0 (58.8 - 77.5)	67.0 (67.0 - 67.0)	54.0 (42.0 - 69.5)
Baseline Tegner	4.0 (2.2 - 4.0)	7.0 (7.0 - 7.0)	7.0 (4.5 - 7.5)

† data presented as count (%) or median (1^{st} quartile - 3^{rd} quartile)

†† p values correspond to the Kruskal-Wallis ANOVA or Fisher's exact test

Note: EUA = exam under anesthesia, SSD = side-to-side difference, AM = anteromedial, ROM = range of motion, Flex = flexion, Ext = extension