



The Effect of ACL Graft Size on Post-operative Knee Extension

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Abstract

Introduction: Understanding factors that cause loss of extension post Anterior Cruciate Ligament (ACL) reconstruction may assist surgeons in preventing this problem. The aim of this clinical trial is to determine the effect of reconstructed ACL graft size on postoperative range of motion in ACL reconstruction in human subjects.

Methods: This therapeutic comparative cohort study consisted of a retrospective analysis of prospectively collected data. Participants either received an autologous double bundle ACL graft (Control) or a combined autologous/synthetic graft (Hybrid), which increased graft cross-sectional area. Femoral notch width was measured preoperatively by Magnetic Resonance Imaging. Range of motion was determined using goniometry at two years post reconstruction. Stepwise logistic regression and bivariate correlation was used to analyse data.

Results: 54 participants were included in analysis, 22 Control and 32 Hybrid. Hybrid group had a significantly larger reconstructed graft cross-sectional area (\times (Hybrid)= 71 ± 9.30 mm²; \times (Control)= 59 ± 12.26 mm², $t=4.76$, $p<0.05$). Mean notch size was smaller in Control group (1.83 ± 0.18 cm) compared to Hybrid group (1.91 ± 0.27 cm). Hybrid group had significantly fewer cases of postoperative knee extension loss ($\chi^2=3.90$, $p<0.05$), defined as loss of passive range $\geq 3^\circ$ at 2 years post-surgery. Increased graft cross-sectional area was not a significant predictor of loss of extension. There was also no relationship between notch width and extension range of movement. ($r=0.01$, $p=0.80$).

Conclusion: A 20% increase in ACL graft cross-sectional area was not a significant predictor of postoperative extension loss.

Keywords: Morphology; Chi-square analysis; Cadaveric anatomy; Magnetic resonance imaging

Introduction

Graft size is an important factor in determining a satisfactory outcome in anterior cruciate ligament reconstruction (ACLR). Optimal graft size is yet to be accurately defined in the literature although grafts larger than 7 mm have been found to have lower failure rates and an inverse correlation between ACL graft size and anterior-posterior tibio-femoral translation [1-3]. Furthermore, grafts with larger cross-sectional area have superior patient reported outcomes [4]. This body of literature indicates the mechanical and clinical benefit of increasing graft size when performing ACLR.

Grafts that are too large, however, may cause graft-notch mismatch leading to graft impingement, loss of extension (LOE) or failure [3,4]. Literature reports mean graft diameter used of a four-strand hamstring (HS) graft to between 7.5 ± 0.7 mm for females and 7.9 ± 0.9 mm for males [5]. Significant morphological variation exists between hamstring size across the population therefore a portion of the population may have insufficient hamstring tendon to create a sufficient ACL graft [1,5,6]. Grafts may be increased in size by tripling or quadrupling under harvested hamstrings, adding or selecting large sized allografts or augmenting the autograft with a prosthetic ligament. Oversized grafts, however, may increase the risk of graft notch mismatch, subsequent impingement, LOE and the need for primary or delayed notch plasty.

Graft selection and configuration largely determines the morphological and mechanical features of the reconstructed ACL graft. Early single stranded hamstring grafts have been shown to be inferior to both the native ACL and the central one third patellar tendon graft in terms of both maximal tensile load and cross sectional area [7,8]. To increase hamstring graft size surgeons have doubled, tripled or quadrupled a single or combination of hamstring tendons. This technique has been shown to achieve graft dimensions and mechanical properties superior to the native ACL and other commonly used ACLR

graft options [9]. Upsizing the graft may also compensate for the proposed increase in failure of the implanted graft during early graft maturation [10].

The use of allograft in ACLR has also been studied. It is shown, in a caprine study, that allograft in ACLR significantly reduced cross-sectional area when compared to patellar tendon autograft at 6 months post reconstruction [11]. It could be hypothesised that this reduction in size may confer a commensurate reduction in graft strength also found those receiving autograft ACLR were twice as likely to suffer from LOE when compared to those receiving allograft [12].

Presently, the extent to which an ACL graft can be upsized before causing LOE problems is unknown. While the effects of varying graft sizes are reported in the literature there is a paucity of prospective clinical studies that assess the effect of graft size on LOE. To our knowledge no comparative study between two defined graft sizes in human ACLR has been published previously.

Between August 2008 to October 2010 the senior surgeon conducting this study changed his practice from offering patients a standard four-strand hamstring double bundle autograft to offering the same graft with a prosthetic LARS graft augment (Ligament Augmentation & Reconstruction System 133 L0130605, Arc Sur Tille, France). This added approximately 9 mm² cross-sectional area to the total graft bundle. This represented an average increase of approximately 20% to the cross-sectional area of the graft. The objective of this graft construct

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Received June 02, 2019; Accepted June 19, 2019; Published June 25, 2019

Citation: Sheldon M (2019) The Effect of ACL Graft Size on Post-operative Knee Extension. J Trauma Treat 8: 447.

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was to take advantage of the initial stiffness and strength of the LARS graft whilst the native autograft was undergoing early revascularisation and ligamentisation in order to facilitate safe accelerated rehabilitation (running in two months, Return To Sport (RTS) in 4-6 months) whilst minimising the risk of graft stretch and early failure.

The aim of this observational prospective cohort study was to compare knee LOE at two years post ACLR in a Control group of patients who received a four-strand HS ACLR against a treatment group (HYBRID) who received a combined HS/LARS graft. The relationship between patient age and MRI measured intercondylar notch size on LOE was also assessed. It was hypothesised that the Hybrid group would have higher rates of LOE due to increased graft size.

Methods

Study participants

Between August 2008 and October 2010, 147 patients prospectively identified as eligible for enrolment. 88 of the 147 participants identified as eligible met exclusion criteria or did not consent for participation. 59 participants were included in the study and underwent primary ACLR. Exclusion criteria included patients with open growth plates, previous surgery including ACLR to either knee, varus thrust gait, requiring of a concomitant ligament surgery or having a compensable injury. One participant was excluded from analysis as no data was available for the area of their replacement graft. An additional four participants were excluded from analysis as they were lost to follow up and as a result no LOE records were available. This resulted in a total of 54 participants analysed within the study (Figure 1).

Informed consent was obtained from all individual participants included in the study. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Study parameters

This observational study was designed to investigate patients returning for testing as part of a larger cohort study to evaluate the clinical outcomes of the Hybrid graft configuration [13]. It was a retrospective analysis of prospectively collected data. Data collected included gender, age at the time of surgery, side of injury, size of intercondylar notch and post-operative ROM (both flexion and extension). Primary outcome was LOE at 2 years.

Graft types

Patients were offered two ACL graft configurations: four-strand hamstring (4SHS) (Control) or 4SHS with an added prosthetic ligament (Hybrid). Patients were invited to choose their preferred graft based on a standard pre-operative consultation and information. Of the 59 consented participants, 34 chose Hybrid and 25 chose Control grafts.

Graft Type 1 (Control):

- Double bundle hamstring autograft graft
- Anteromedial Bundle (AMB)-doubled semitendinosus
- Posterolateral Bundle (PLB)-doubled gracilis

Graft Type 2 (Hybrid):

- Double Bundle hamstring autograft graft with LARS augment

- AMB-doubled semitendinosus and a synthetic LARS Ligament Reinforcer 133 (L0130605, LARS®, Ligament Augmentation & Reconstruction System, Arc Sur Tille, France).
- PLB-doubled gracilis
- The inclusion of a LARS augment added between 8.4 mm² – 12 mm² to the cross-sectional area (LARS was doubled in all patients). This represented an average increase of 20% to the total graft area

Surgical technique

All patients underwent primary double bundle hamstring ACL reconstruction by the senior surgeon. Examination under anaesthesia was performed to confirm the clinical diagnosis and MRI findings. Physical examination included Lachmann, anterior drawer and pivot shift tests. Under high tourniquet the limb was positioned at 90 degrees with thigh side-post and foot roll bar. All meniscal and chondral surgical intervention was performed during the same operation, prior to ACLR.

The tendons were harvested through a 3 cm transverse incision centred 1 cm proximal to the maximal bulge of the pes anserinus. The individual tendons were slung through a 20 closed loop endobutton with the tails whip-stitched to themselves using 1 vicryl suture over the distal 3 cm. The diameters were measured in 1 mm increments with tubular sizers and then were pre-tensioned using the Acuflex Graftmaster™ (Smith & Nephew, Inc., Andover, MA, USA) at 20 lb.

All patients received an ACL stump remnant retention technique preserving all stable tibial ACL remnant tissue. The AMB position was marked and drilled at the 10:30 clock position (left knee) 5 mm off the back wall of the notch at 90° flexion. The postero-lateral bundle (PLB) position was marked and drilled 8 mm distal and posterior to the AMB position approximately 5 mm off the articular cartilage. Existing bundle footprints were used to confirm tunnel position. The femoral tunnels were prepared for endobutton fixation drilling through an accessory inferior-central medial portal with the knee in hyper flexion. The viewing portal was routinely the lateral portal throughout the procedure unless vision was difficult in which case accessory medial portal was used. The tibial tunnel positions were placed within the tibial footprint using the preserved remnant envelope as a guide. The AMB position was identified drilling to an elbow target jig set at 60°, positioned in the centre of the stump 8 mm from the anterior margin of the remnant, drilling start point 1 cm medial to the tibial tubercle. The PLB was drilled to the jig placed at the postero-lateral margin of the tibial footprint drilling start point on the tibia at the anterior margin of the medial collateral ligament. The PLB graft was placed before the AMB. Both grafts were tensioned manually through 15 knee cycles. Graft was tensioned in flexion (AMB 45°, PLB 20°).

ACL graft type and size was determined by referring to the patients' intra-operative records. The diameters were measured in 1 mm increments with tubular sizers using the Acuflex Graftmaster™ (Smith & Nephew, Inc., Andover, MA, USA). Standard geometric calculation was used to convert this measurement to a cross sectional area calculation in millimetres square. The total area of the Control and Hybrid grafts was calculated by the addition of the AMB and PLB. Patient data included gender, age at the time of surgery, side of injury and post-operative ROM (both flexion and extension).

Range of motion

LOE was defined as loss of passive range $\geq 3^\circ$ at a minimum of 2 years post-surgery. This measurement was compared to an anatomical 0° . Failure to achieve full range was inferred if manipulation under anaesthetic or arthroscopic notchplasty was performed prior to two years post-surgery. A single, blinded experienced physiotherapist took ROM measurements with the patient in supine position with heel support using goniometry. The anatomical landmarks used were the prominence of the external surface of the greater trochanter, the lateral epicondyle of the femur and the distal apex of the lateral malleolus [14].

Rehabilitation and follow up

The Control and Hybrid groups underwent different rehabilitation regimes. Details of rehabilitation regimes can be found. Follow up consisted of clinical consultation at 2 years at which point LOE measurements were taken (Figure 2).

MRI measures

Magnetic resonance imaging (MRI) was used to determine the width of the intercondylar notch. The images were obtained prior to surgery on a 1.5T MRI (GE medical systems LX platform, Milwaukee, Wis) utilising a dedicated 8 channel knee coil. The image used for the measurements was from a coronal T2 fat suppressed sequence (TR 4000 ms, TE 85 ms) with a FOV of 14 cm, slice thickness of 3 mm with a slice gap of 1 mm and a 256×192 matrix. Notch width was measured at the point where the ACL and PCL intersect which approximately represents the mid-point of the tibial spine. Establishing a common point of reference allowed for the standardisation of measurement between patients. Linear measurements were calculated by generating a line from the apex of the lateral meniscus to the apex of the medial meniscus (Figure 3). Line B was then drawn from the highest point in the roof of the intercondylar notch to line A. Line C represents the width of the notch and was obtained by measuring the distance between the two femoral condyles at the point which bisects line B and runs parallel to line A. Notch width was measured from the inner surface of the identified cortical bone; a method of measurement that is accurate when compared to corresponding cadaveric anatomy [15]. Notch width was not objectively measured intra-operatively.

Data management and analysis

Data were gathered and statistically analysed using Statistical Package for the Social Sciences 21.0 for Windows (SPSS, Chicago, IL). LOE is a dichotomous variable and therefore logistic regression was used to compare groups. The level of significance was set at $p < 0.05$. The statistician for the University of Notre Dame assisted in all areas of statistical analysis on behalf of the study group.

Group	Age		Gender	Side	
	Mean	St. Dev	% Male	Left	Right
Control (N=22)	26.9	11.3	50.0	12	10
Hybrid (N=32)	31.3	11.3	62.5	16	16

Table 1: Age, gender and side of operation (left/right) separated by group type (Control/Hybrid) for all 54 patients included in the final analysis.

Group	No. LOE	LOE (%)	Notch Size		Graft Area	
			Mean	St. Dev	Mean	St. Dev
Control (N=22)	7	31.0%	1.8	0.2	58.6	11.3
Hybrid (N=32)	4	12.5%	1.9	0.3	71.1	9.4

Table 2: Extension loss, notch size and graft area (mm^2) statistics separated by group type (Control/Hybrid) for all 54 patients included in the final analysis.

Results

Descriptive and comparative statistics

Demographic data on the 54 patients included in the analysis can be found in Table 1. Participants were aged 15-57 at the time of ACLR. Mean age was 26 in the Control group and 31 in the Hybrid group. The Control group was 50% male and the Hybrid group 62% male. Chi-Square analysis indicates that there were no significant differences between the Control and Hybrid groups with regards to the side of operation (left/right; $\chi^2(1)=0.11$, $p=0.74$) or gender ($\chi^2(1)=0.83$, $p=0.36$). Similarly, there was no difference between the two groups with regards to age ($t(52)=-1.41$, $p=0.17$).

There was no difference between the two groups with regards to Notch Size ($t(45)=-0.81$, $p=0.42$). However, the Hybrid group did receive a significantly larger area of reconstructed graft ($t(52)=-4.41$, $p < 0.001$) consistent with the surgical technique received. Eleven of the 54 participants (20.4%) were found to have study defined LOE, 7 (31.0%) in the Control group and 4 (12.5%) in the Hybrid group. These results are displayed in Table 2.

A total of five participants required notchplasty to correct their extension deficit and two patients experienced frank graft rupture. Contrary to initial predictions, Chi-square analysis demonstrated that the Hybrid group had significantly fewer cases of post-operative knee extension loss ($\chi^2(1)=3.90$, $p < 0.05$, $N=55$).

Logistic regression analysis

Logistic regression was used to establish the predictive power of treatment group, age and total area (entered simultaneously as a single level model) (Table 3). Nine of the 25 participants in the Control group failed to have sagittal MRI views. As a result this variable could not be included in regression analyses without substantial loss of validity. We instead used bivariate correlation to determine notch width effect on LOE.

Analysis revealed that surgical group (Wald=3.88, $p=0.049$) was a significant predictor of LOE with the variable's Beta weight ($\beta=-1.86$) indicating that those in the Control group were 6.45 times more likely (odds ratio) to experience extension loss than those receiving the Hybrid graft. Age of the patient at the time of surgery was also found to be predictive of LOE (Wald=4.04, $p=0.04$) with the odds of experiencing extension loss being 1.07 for every year of age ($\beta=0.07$). The mean age of those with LOE was 34 years compared to the mean age of those with full available range of 25 years, supporting the above finding that older age was associated with a greater incidence of LOE. Notably, total graft area was not found to be predictive of LOE

Variable	β	S.E.	Wald	df	Significance	Exp (B)
Group	1.86	0.95	3.88	1	$p=0.05$	6.45
Age	0.07	0.03	4.04	1	$p=0.04$	1.07
Graft Size	0.02	0.04	0.22	1	$p=0.64$	1.02
Constant	-1.82	2.11	0.74	1	$p=0.39$	0.16

Table 3: Logistic regression output including Beta weights, standard error, Wald statistics, significance and odds ratios, for three predictors of extension loss following ACL reconstruction.

Group	Original n	Missing Data n			Final n
		Graft Area	Notch Width	Extension Loss	
Control	25	1	7	2	22
Hybrid	34	0	2	2	32
Total	59	1	9	4	54

Table 4: Number of patients with missing data across a range of variables relevant for logistic regression.

(Wald=0.22, p=0.64). While individual variables reached significance, the overall model only approached significance according to the block chi-square statistic ($\chi^2(3)=7.74$, p=0.05); demonstrating a Cox & Snell pseudo R2 of 0.13 and a Nagelkerke pseudo R2 of 0.21 (suggesting the complete model accounts for about 21% of the total variance of factors

leading to extension loss). The model tested here, including three predictors (age, graft size and group) correctly predicts the existence (or non-existence) of extension loss in 83.3% of the patients in the present study (an increase of 3.7% predictive accuracy over a null model with no predictors).

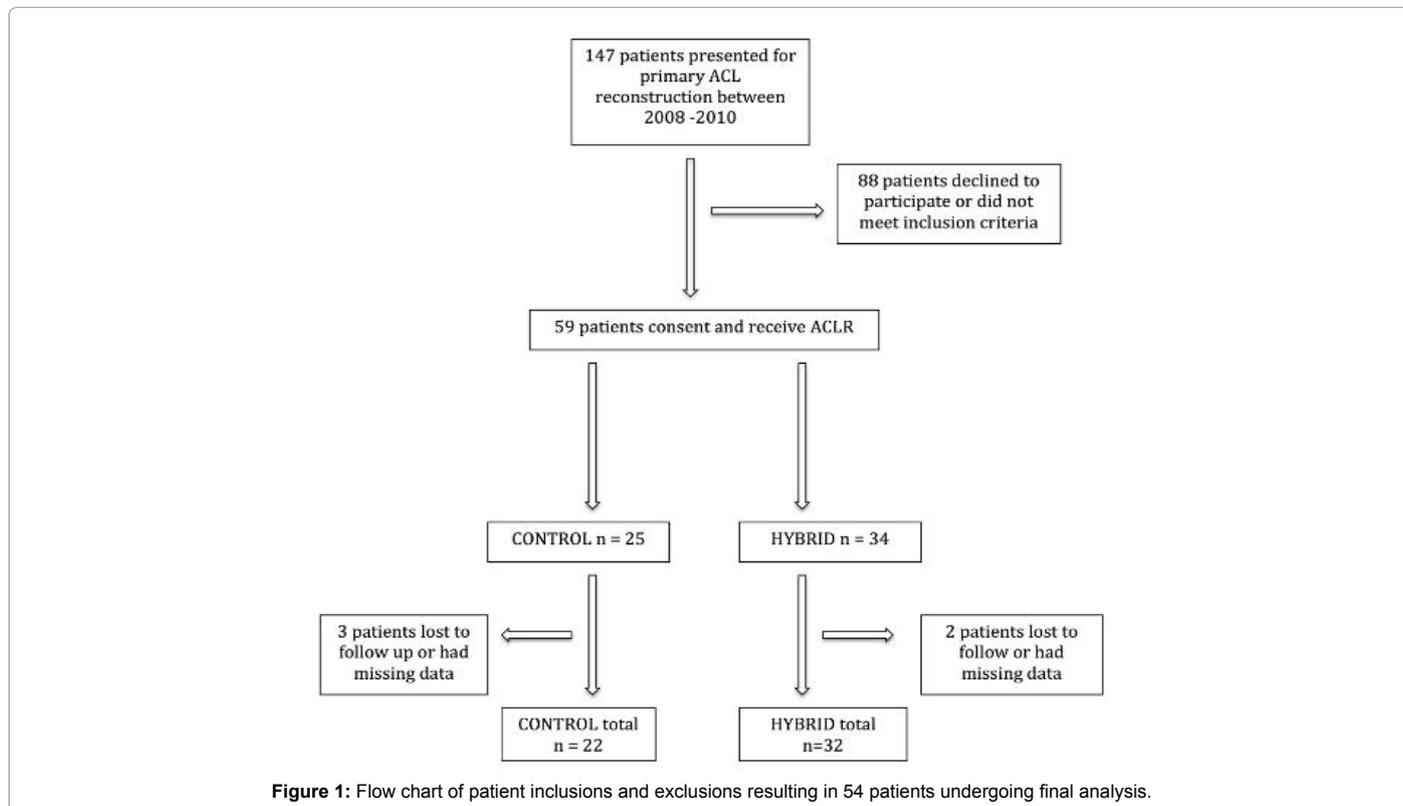


Figure 1: Flow chart of patient inclusions and exclusions resulting in 54 patients undergoing final analysis.

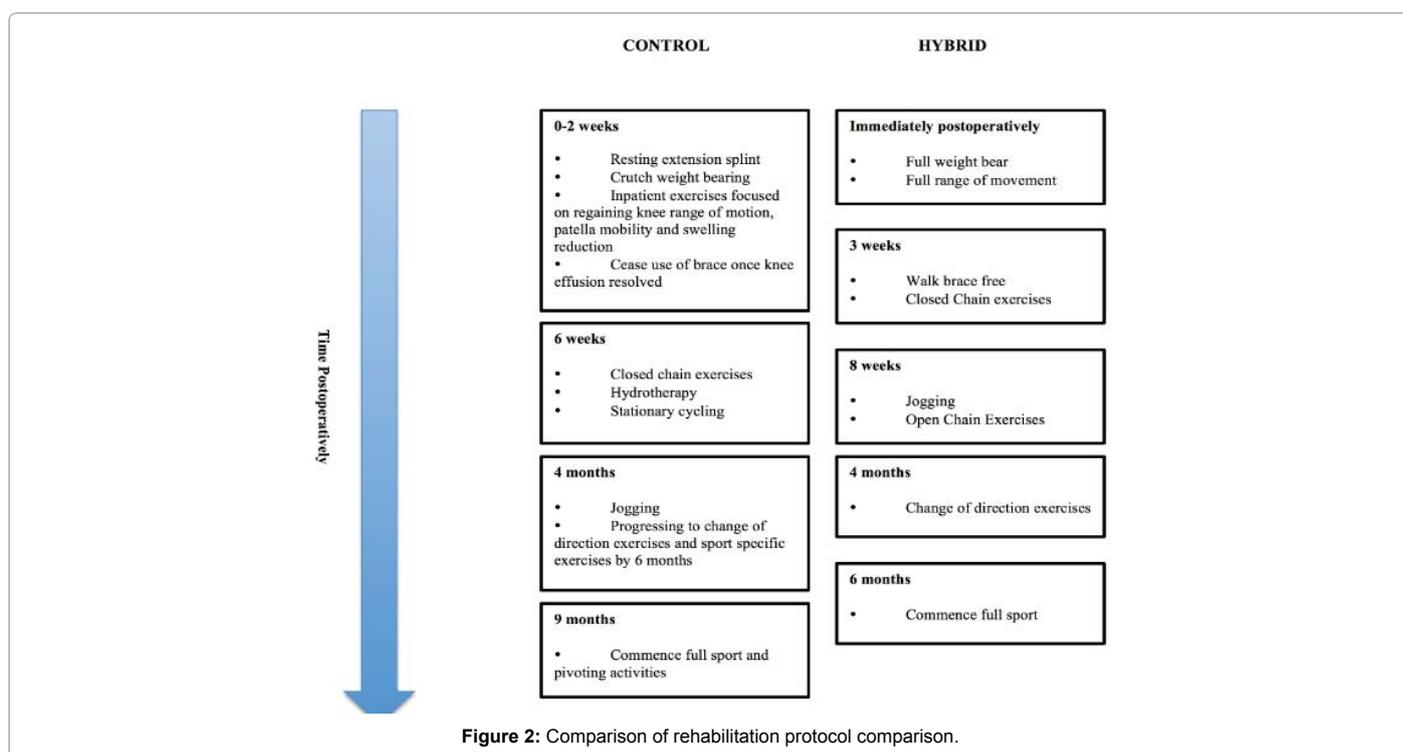


Figure 2: Comparison of rehabilitation protocol comparison.



Figure 3: Coronal MRI showing the method of measuring intercondylar width. Line A is drawn from the lateral meniscus to the apex of the medial meniscus. Line B was drawn from the highest point in the roof of the intercondylar notch to line A. Line (notch width) drawn at the point which bisects line B and runs parallel to line A.

While Notch Width was not able to be included in the present analysis as a result of missing data, nonparametric Spearman's correlation indicates that Notch Size was not significantly related to extension loss ($r(50) = -0.16$, $p = 0.29$). The number of patients with missing data is found in Table 4.

Discussion

The results in this study indicate no apparent relationship between a 20% increase in the reconstructed ACL graft cross-sectional area and the incidence of postoperative extension loss. Despite Hybrid group having a larger reconstructed graft, logistic regression analysis revealed the Hybrid group had significantly fewer cases of post-operative knee extension loss. This finding does not provide support for our initial hypothesis that the Hybrid group would be more likely to experience LOE and is contrary to the widely accepted paradigm. Regression analysis also indicated older age was associated with a greater incidence of LOE, in the sampled population. Bivariate correlation analysis revealed no relationship between notch width and LOE. The results of the current study suggest increasing four strand hamstring grafts by 20% may be safely performed to create larger, stronger grafts, which may decrease the rate of graft failure.

A number of studies have investigated the clinical effect of increasing graft size during ACLR. Biomechanical studies have found a direct correlation between graft size and both resistance to stretch and ultimate load to failure [9,16,17]. The use of larger sized grafts has been advocated to reduce the risk of graft rupture [16-18]. Additionally, a significant correlation between larger graft size and superior patient reported outcomes [18,19]. Which employed a similar Hybrid configuration to the current study using LARS graft to augment short (<15 cm length) or undersized (3-4 mm diameter) semitendinosis grafts. Improved knee function scores were demonstrated with no increase in risk of ligament rupture. Joint kinematics of ACL reconstructed knees with graft sizes between 5-9 mm. Here, increased ACL graft size was associated with substantially greater joint stability and decreased

articular cartilage contact pressures [20]. A similar inverse correlation between ACL graft size and anterior-posterior tibio-femoral translation was found [2,3]. This body of literature is compelling for the use of increased graft size for improved stability and decreased graft failure. To our knowledge previous studies evaluating graft size effect on LOE have consisted of case series only, and therefore this study represents the first comparative cohort study that investigates effect of graft size on LOE.

There is evidence published to suggest grafts can be excessively large. According to a caprine study, larger grafts were found to be associated with a greater incidence of LOE [3]. This indicates a need for balance between utilizing a graft with sufficient cross-sectional area to withstand the forces subjected on the ACL while concurrently ensuring the graft is thin enough to allow unhindered ROM. The current study suggests that it may be possible to increase the size of the ACL graft safely without exposing patients to a greater risk of LOE. As described in results, augmenting the autologous graft with LARS effectively increased the total graft area between 8.4 mm^2 - 12 mm^2 (approximately 20% increase in cross-sectional area for a graft 7 mm diameter). This increase may fall below a critical threshold where graft-notch mismatch does not occur. In the current study the graft size was increased by adding a 9 mm^2 LARS ligament, however upsizing could alternatively be performed by tripling/quadrupling hamstrings, by adding allograft or synthetic ligament. The results of this study suggest this can be achieved without precipitating LOE. This is particularly relevant to women, adolescents and shorter statured patients who are more likely to have undersized harvest tendons [15,21].

In this study, a narrow notch size was not found to be a predictor of LOE. Previous studies indicate a narrow notch size may be associated with graft impingement and consequent LOE [22-24]. On intra-operative identification of unfavourable notch morphology, notch plasty can be performed to prevent impingement [25,26]. This procedure however can lead to graft failure, abnormal graft forces, increased anterior knee laxity and adversely affect articular cartilage consistent with early degenerative disease [25-27]. Notch plasty also removes osseous landmarks required for accurate tunnel positioning and can cause possible regrowth/overgrowth of the notch in the long term [28]. This literature reflects the importance of choosing appropriate graft size to avoid notch impingement and therefore may alleviate the need for notch plasty.

The current study suggests older patients are at significantly greater risk of LOE. This finding was supported but refuted by the several other studies in the literature reviewed [12,29-31]. It is hypothesised that older patients may be less motivated to return to high-level sport and therefore less likely to participate in rehabilitation programs aimed at regaining ROM. Alternatively, age-related connective tissue changes including decreased elastic properties of ligaments may account for the results seen in the current study [32].

Overall extension loss in the current study was 21.8% at two years. The literature shows significant variation in the reported incidence of LOE, ranging between 2-25% [12,31,33]. The discrepancy in reported results may be attributed to inconsistencies in definition of LOE between trials and thus is not consistently reported. The current study defines LOE as a restriction in range of $\geq 3^\circ$ which is more stringent than previous studies [12,31]. This may account for the relatively high incidence of LOE in the observed population. An additional point of discrepancy between studies is the variability of follow up, ranging between four weeks and one year [12,31,33]. A final source of inconsistency is whether previous studies chose to measure LOE

against an anatomical 0° or the ROM in the contralateral knee. The anatomical 0° method adopted by the current study fails to account for patients who have up to 6° of physiological hyperextension [34]. However, anatomical 0° was chosen in this study as it more accurately reflects a deficit that is likely to confer function loss.

Limitations

A notable limitation of the study was the heterogeneity in management between the two treatment groups with regard to the difference in tensioning technique and the difference in rehabilitation protocols. Hybrid grafts were tensioned in full extension whilst the Control grafts were tensioned at 45° (AMB) and 20° (PLB) of flexion. The impact of altering tensioning patterns has been shown to affect post-operative knee kinematics and may have contributed to the observed differences in extension deficits between groups [35]. The rehabilitation protocols applied to the Hybrid and Control groups were set as part of a larger cohort study designed to evaluate the clinical outcomes of the Hybrid graft configuration (Figure 2). Superior initial strength of the synthetic bundles of the Hybrid grafts allowed for aggressive early rehabilitation. The differing rehabilitation protocols may have had an effect on the incidence of LOE. Intrinsic selection bias may have been introduced due to patient selection of graft type. As an observational study randomisation of graft type was not within the scope of the study. Generalizability and reliability of results is limited by the small sample size, from a single institution.

Conclusion

In the studied population there was no evidence to suggest a 20% increase in the size of the reconstructed ACL graft or the size of the intercondylar notch influenced postoperative extension loss. Younger patients and patients who chose and received a Hybrid graft were less likely to suffer postoperative LOE.

Competing Interests

The authors declare that they have no competing interests.

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