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Original Research

No differences in objective knee laxity measurements or patient-reported outcome measures between fixed- and adjustable-loop suspensory fixation in anterior cruciate ligament reconstruction: 1-year results from the GAP study, a prospective, double-blinded, randomized trial

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ABSTRACT

Introduction: Suspensory fixation is one of the most common graft fixation methods in anterior cruciate ligament (ACL) reconstruction and can be performed using either a fixed-loop device or an adjustable-loop device. There has, however, been a paucity of comparative clinical data and a clear need for an adequately powered, double-blinded, randomized study to determine whether there is any difference in objective knee laxity between these fixation methods. The G-Lok Against ProCinch (GAP) study was designed to address this need.

Methods: In a single-center, two-surgeon series, 164 patients were recruited and randomized to receive a hamstring autograft ACL reconstruction using either a fixed-loop or adjustable-loop femoral fixation (Stryker G-Lock or ProCinch, respectively). Patients and assessors were blinded. Knee laxity was the primary outcome measure, and measurements were taken using the GNRB (Genourob, Laval, France) knee arthrometer set at 150 N and 200 N. Measurements were taken from the operated leg and compared to the contralateral leg. Patient-reported outcome measures (PROMs) were collected at baseline, 6 months, and 12 months, and a linear regression analysis was undertaken.

Results: At 1 year, 121 patients (62% male; mean age: 31 years, standard deviation [SD]: 9.8) had complete knee laxity assessments. Of these, 58 received the fixed-loop fixation and 63 the adjustable-loop device. At 150 N, the operated-knee laxity in the fixed-loop group was 5.51 mm (SD: 1.40; 95% confidence interval [CI]: 5.14–5.87) versus 5.61 mm (SD: 1.39; 95% CI: 5.26–5.96) in the adjustable-loop group (P = 0.68). At 200 N, the operated-knee laxity in the fixed-loop group was 6.94 mm (SD: 1.54; 95% CI: 6.53–7.34) versus 7.02 mm (SD: 1.53; 95% CI: 6.63–7.40) in the adjustable-loop group (P = 0.77). There was no statistically significant difference in the between-knee laxity measurements or PROMs (Tegner Activity Scale score, International Knee Documentation Committee [IKDC] Subjective Knee Evaluation Form, Lysholm Knee Scoring Scale score, or any of the Knee injury and Osteoarthritis Outcome Score [KOOS] domains) between the groups.

Conclusion: The GAP study is the first to compare knee laxity measurements between these two graft fixation devices in a randomized and blinded study. No statistically significant differences were observed in absolute or relative (operated vs. non-operated) knee laxity measurements or PROMs. These important new findings should inform surgeons and patients when considering graft fixation choice in ACL reconstruction. This study also provides new reference data for the operated and non-operated knees of patients following hamstring autograft ACL reconstruction.

Level of evidence: I, prospective, double-blinded, randomized controlled trial.

Trial registration: NCT03184922 (*ClinicalTrials.gov*)

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What are the new findings?

- There were no statistically significant differences in absolute or relative knee laxity measures for fixed- versus adjusted-loop femoral fixation
- There were no statistically significant differences in patient-reported outcome measures between the fixation methods
- Important new reference data for knee laxity measures following hamstring anterior cruciate ligament reconstruction are reported versus the contralateral non-operated knee

INTRODUCTION

Anterior cruciate ligament (ACL) rupture is a common injury, and approximately 13,000 people undergo ACL reconstruction in the National Health Service in the United Kingdom (UK) each year [1]. Rehabilitation after this type of surgery has become more aggressive over the years, with early full weight-bearing, range-of-motion, and strengthening exercises beginning soon after surgery. Failure of an ACL reconstruction is a devastating complication for patients, and around 3% of patients undergo revision surgery within 5 years of their index procedure [2]. The definition of failure is inconsistent across the literature, ranging from subjective functional instability to objective side-to-side laxity differences and may include hardware failure or graft re-rupture. Truly objective measurement requires mechanical assessment devices such as the GNRB (Genourob, Laval, France) or KT-1000 (MEDmetric, San Diego, CA, USA) [3].

Topics of continued debate in ACL reconstruction are the choice of graft used and the surgical implantation technique. While consensus is lacking, hamstring autograft is the most frequently used graft, accounting for over 90% of cases in UK and Swedish registries [4,5]. Various methods exist for fixing the graft in the femoral tunnel, but the most commonly used in the UK is a suspensory fixation (77% of cases) following by interference screw fixation (17%) [4]. No matter the technique used, it is important to preserve the initial stability of the graft while healing of the graft to the surrounding bony tunnel occurs, and this may be particularly important in the first 12 weeks [6].

While suspensory fixation is a long-established and proven technique, this has commonly been done using a “fixed-loop” device to suspend the graft in the femoral tunnel, usually in combination with an interference screw in the tibia. More recently, “adjustable-loop” devices have been developed for femoral fixation and/or double-suspensory fixation in the tibia also. Theoretical advantages of adjustable-loop devices include precise graft length determination and, with double-suspensory techniques, the construction of shorter, stiffer grafts [7]. Additionally, adjustable-loop systems may reduce inventory requirements compared to fixed-loop devices. While industry-supported biomechanical studies are encouraging and support the comparative failure strength for fixed- versus adjustable-loop devices in cyclic testing that simulates daily life, concerns remain for clinical practice, particularly regarding potential slippage of adjustable-loop devices during cyclical loading and its impact on graft fixation integrity [8].

We hypothesized that patients undergoing autograft hamstring ACL reconstruction using an adjustable-length femoral suspensory device would demonstrate equivalent objective knee laxity and patient-reported outcomes compared to those receiving a standard fixed-length device. To test this hypothesis, the primary aim of this randomized clinical study was to directly compare the objective knee laxity measurements between these two fixation methods. A secondary aim was to compare patient-reported outcome measures (PROMs) and to monitor for complications, including graft failure, between the two fixation methods.

MATERIALS AND METHODS

This was a two-group, double-blinded, randomized controlled trial comparing two suspensory femoral fixation devices in ACL reconstruction. The study was reviewed by the Wales Research Ethics Committee (REC) and granted a favorable opinion (REC reference: 17/WA/0169). The full trial protocol is available on request from the senior author.

One arm of the study was randomized to femoral graft fixation with a fixed-length suspensory loop device and the other to femoral graft fixation with an adjustable suspensory loop. Standardized tibial fixation with an interference screw was used in all patients.

Participants

Patients aged 16 years or older presenting with an isolated ACL-deficient knee were eligible. Exclusion criteria included urgent meniscal repair (locked knee), multi-ligament injuries, significant pre-existing degenerative changes (defined as radiographic evidence of Kellgren-Lawrence grade 3 or above), previous ipsilateral knee surgery, and neuromuscular or neurosensory deficiencies. Eligible patients were identified by the clinical team and consented by a research nurse.

Recruiting centers

All patients were recruited at the Princess Elizabeth Orthopaedic Centre (PEOC), Exeter, United Kingdom. All ACL reconstructions were performed by two consultant orthopedic surgeons, each performing 75–100 ACL reconstruction procedures per year.

Randomization and masking

An online random assignment generator (www.graphpad.com) produced the confidential schedule held by the study co-ordinator. Allocation details were sealed in opaque, sequentially numbered envelopes, opened by theater staff only during the procedure. Personnel who enrolled patients and obtained consent did not have access to the allocation sequence. Allocation was concealed until after consent was obtained and the patient was in theater. The data analysts were blinded to group allocation until after the analysis protocol was finalized and agreed.

Interventions

Patients were randomized to hamstring ACL reconstruction using either (1) a fixed-length suspensory loop (G-Lok, Stryker Corp.) or (2) an adjustable-length suspensory loop (ProCinch, Stryker Corp.) for femoral fixation. Tibial fixation for all participants was done with an appropriately sized interference screw (usual care).

The operative technique for each ACL reconstruction was otherwise the standard technique (with femoral tunnel drilling via the anteromedial portal). Patients were discharged home on the same day following physiotherapy assessments and advice and were allowed to fully weight-bear as comfortable using walking aids for the initial 2-week period. Patients with a concurrent meniscal repair were placed into a range-of-motion brace with restricted flexion for 6 weeks and advised to avoid deep flexion and pivoting for the first 4 months. Patients were reviewed at 2 days after surgery for a wound check and were instructed on closed kinetic chain knee exercises, range-of-motion exercises, cryotherapy, and began their formal ACL rehabilitation program from 2 to 3 weeks after surgery. All patients were followed up in clinic at

2 weeks, 6 weeks, 3 months, 6 months, and 1 year post-operatively. Besides the GNRB measurements described later, all patients followed standardized institutional post-operative protocols following their ACL reconstruction.

Outcomes

The primary outcome was objective anterior knee laxity at 1 year using the GNRB arthrometer at 134 N [9,10]. Measurements at 134 N are considered a reliable, sensitive measure of ACL integrity [9,10]. Secondary outcomes were GNRB anterior knee laxity measurements at 3 months and 6 months. Laxity was measured at the international standard force of 134 N (3, 6, and 12 months) and additionally at 150 N (6 and 12 months) and 200 N (12 months) when these forced were safer to test, following graft ligamentization and maturation. Measurements were performed by a blinded specialist physiotherapist. Laxity was measured in both knees to enable the use of the contralateral, uninjured knee as a control. Failure was defined as a >3-mm side-to-side difference or an absolute laxity >10 mm. These thresholds were based upon work done by Alford and Bach [11]. The secondary outcome measures were the GNRB measurements at 3 months and 6 months post-operatively and graft failure (if applicable). PROMs (Tegner Activity Scale score, Knee injury and Osteoarthritis Outcome Score [KOOS], International Knee Documentation Committee [IKDC], and Lysholm knee scoring scale) were collected at baseline, 6, and 12 months.

Sample size

The null hypothesis was for no difference between the mean laxity between the fixation devices. While there is no agreement on the minimum clinically important difference (MCID) for between-knee differences in knee laxity, based on a combination of the work of Alford and Bach, and the means and standard deviation (SD) figures reported by Lanzetti et al. an MCID of 3.6 mm (i.e., 0.6 mm over the upper satisfactory between-knee difference of 3.0 mm) was selected [11,12]. Applying a probability (power) 0.90, a type I error rate of 5% (significance), and an SD of 1.0, it was therefore calculated that recruitment of 60 cases in each group was necessary [12]. Including an adjustment of 20% to account for patients lost to follow-up increased this number in each group to 75, and the total target sample size to 150 cases to support a minimum final sample of 120 cases. Study follow-up was affected by clinical restrictions due to the COVID-19 pandemic, and, therefore, due to the resultant loss of follow-up data, an approved amendment subsequently increased recruitment numbers to 164 participants.

Patient involvement

Patients were consulted during the design of the study. The nature of the GNRB assessments was highlighted in the patient information. It was stressed by our patient representatives that the patients needed to be fully informed of the commitment required should they agree to take part, and this information was included in the patient information. Patients were consulted on both the design and wording of the information leaflet, and consent form and all suggested changes were implemented.

Statistical analysis

The analysis protocol was finalized and agreed before unblinding the study data. Statistical testing was undertaken at the 5%, two-sided, significance level. Stata v18.0 (StataCorp, College Station, Texas, USA) was used to perform all analyses. Statistical analysis of all outcomes was undertaken on an intention-to-treat basis. Baseline demographic information was summarized with descriptive statistics and analyzed for between-group differences with a chi-squared test for categorical data (sex and concurrent procedures) and a two-sided t-test for continuous data (age and GNRB laxity). For patient-reported outcomes, a linear regression analysis was performed to compare scores between the two intervention groups. A sensitivity analysis adjusting for baseline values as covariates was also performed to confirm that conclusions were unchanged. Shapiro-Wilk tests were performed on all continuous outcome variables to assess normality of distribution. Where non-normality was detected, confirmatory non-parametric tests (Wilcoxon rank-sum) were also performed. Cohen's d effect sizes with 95% confidence intervals (CIs) were calculated for all between-group laxity comparisons. An attrition bias analysis was performed comparing baseline characteristics between 12-month completers and non-completers using t-tests and chi-squared tests. All randomized participants with available data at each time point were analyzed in their allocated group; there were zero crossovers between treatment arms.

RESULTS

Of 164 recruited patients (Aug 2017–Aug 2022), 82 (50%) were randomized to the fixed-loop and 82 (50%) to the adjustable-loop group (Fig. 1). There were no significant between-group differences in baseline demographic characteristics or concurrent procedures (Table 1).

Three months

At 3 months, 102 patients (59% male; mean age: 30.8 years, SD: 9.9) had complete knee laxity assessments. Of these, 48 received the fixed-loop fixation and 54 the adjustable-loop device. Overall, 134-N knee laxity was greater in the operated-knee (mean: 5.58 mm; 95% CI: 5.26–5.89) than in the contralateral knee (mean: 4.22 mm; 95% CI: 3.95–4.49; $P < 0.05$), a difference of 1.35 mm (SD: 1.43; 95% CI: 1.07–1.63; $P < 0.05$) (Table 2).

Absolute operated-knee laxity did not differ between interventions (Fig. 2). At 134 N, laxity in the fixed-loop group was 5.56 mm (SD: 1.72; 95% CI: 5.06–6.06) versus 5.59 mm (SD: 1.53; 95% CI: 5.18–6.01) in the adjustable-loop group ($P = 0.91$). Relative between-knee laxity also did not differ (134 N: mean: 1.36 mm; 95% CI: 0.94–1.78 versus mean: 1.35 mm; 95% CI: 0.95–1.74; $P = 0.96$) (Table 2; Fig. 3).

Six Months

At 6 months, 108 patients (62% male; mean age: 30.8 years, SD: 10.0) had complete knee laxity assessments. Of these, 49 received the fixed-loop fixation and 59 the adjustable-loop device. Overall, 134-N knee laxity was greater in the operated-knee (mean: 5.38 mm; 95% CI: 5.12–5.64) than in the contralateral knee (mean: 4.05 mm; 95% CI: 3.82–4.27; $P < 0.05$). This corresponded to a between-knee difference of 1.34 mm (SD: 1.26; 95% CI: 1.09–1.58; $P < 0.05$). Including all patients, knee laxity measurements at 150 N were greater in the operated-knee (mean: 5.96 mm; 95% CI: 5.69–6.23) than in the contralateral knee (mean: 4.56 mm; 95% CI: 4.33–4.79; $P < 0.05$). This corresponded to a between-knee difference of 1.40 mm (SD: 1.34; 95% CI: 1.15–1.66; $P < 0.05$).

There was no statistically significant difference in the absolute operated-knee laxity measurements between the interventions (Figure 2). At 134 N, the operated-knee laxity in the fixed-loop group was 5.31 mm (SD: 1.22; 95% CI: 4.96–5.66) versus 5.44 mm (SD: 1.49; 95% CI: 5.05–5.83) in the adjustable-loop group ($P = 0.63$). At 150 N, the operated-knee laxity in the fixed-loop group was 5.92 mm (SD: 1.25; 95% CI: 5.56–6.28) versus 5.99 mm (SD: 1.54; 95% CI: 5.59–6.39) in the adjustable-loop group ($P = 0.81$) (Table 2).

There was also no statistically significant difference by intervention for the relative, between-knee, laxity measurements for patients receiving the fixed-loop versus adjustable-loop device at either 134 N (mean: 1.32 mm; 95% CI: 1.00–1.64 versus mean 1.35 mm; 95% CI: 0.99–1.71; $P = 0.90$) or 150 N (mean: 1.38 mm; 95% CI: 1.06–1.71 versus mean 1.42 mm; 95% CI: 1.03–1.81; $P = 0.88$) (Table 2; Figure 3).

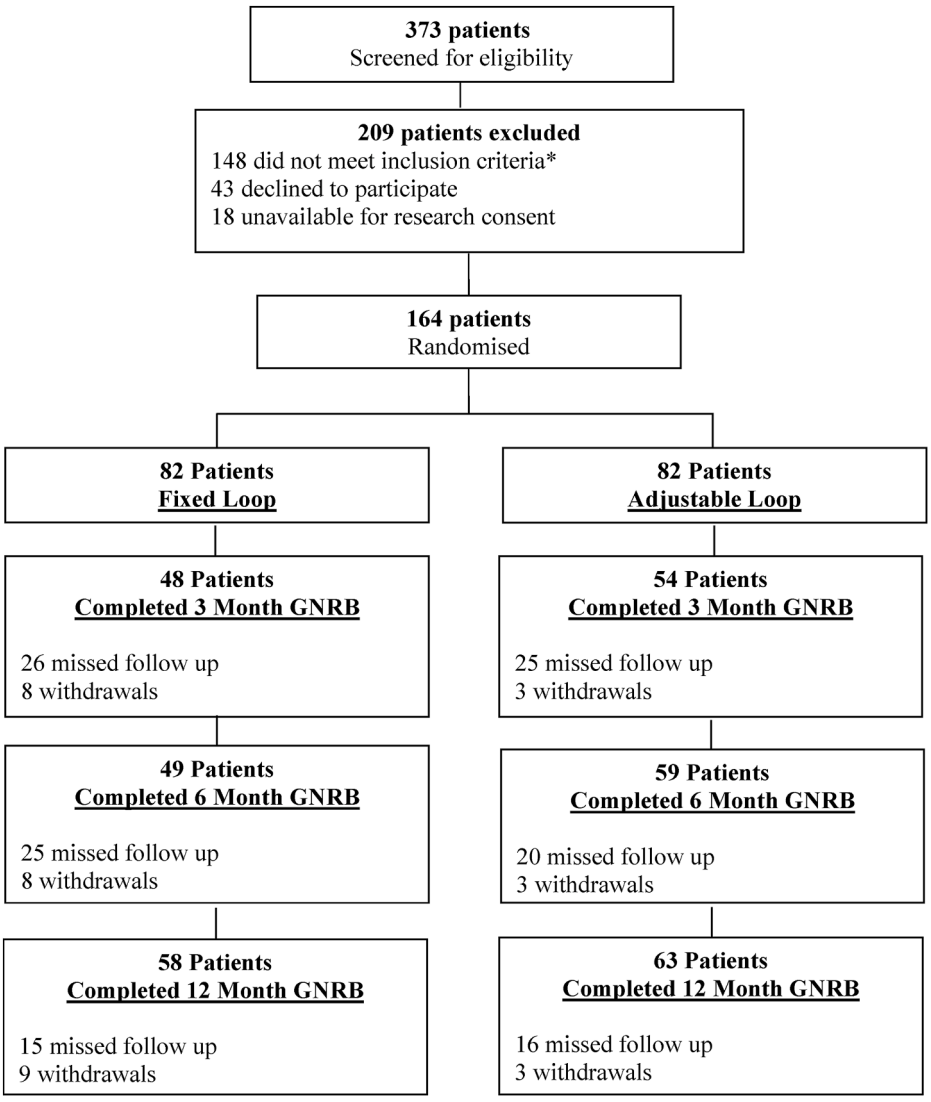


Fig. 1. Participant flow chart.

Table 1
Demographics.

	Fixed loop (n = 82)	Adjustable loop (n = 82)	P value
Sex			
Male	57 (69.5%)	49 (59.8%)	0.191
Female	25 (30.5%)	33 (40.2%)	0.191
Age at randomization	29.2 (9.97)	30.8 (9.15)	0.291
Concurrent procedures			
PMM	12 (14.6%)	10 (12.2%)	0.647
PLM	2 (2.4%)	2 (2.4%)	1.000
MMR	30 (36.6%)	31 (37.8%)	0.872
LMR	15 (18.3%)	17 (20.7%)	0.694
LET	4 (4.9%)	7 (8.5%)	0.349

Data are presented as n (%) or mean (SD); PMM = partial medial meniscectomy; PLM = partial lateral meniscectomy; MMR = medial meniscal repair; LMR = lateral meniscal repair; LET = lateral extra-articular tenodesis.

There were no statistically significant differences in any PROM at 6 months (Table 3). The mean Tegner activity level was 3.41 (SD: 1.50) in the fixed-loop group versus 3.77 (SD: 1.18) in the adjustable-loop group (P = 0.159). Mean KOOS subscale scores were comparable between the fixed-loop vs adjustable-loop groups: Symptoms 73.41 (SD: 16.90) versus 75.05 (SD: 14.70; P = 0.575), Pain 82.43 (SD: 13.80) versus 82.46 (SD: 13.59; P = 0.991), Activities of Daily Living 89.98 (SD: 13.37) versus 91.05 (SD: 12.32; P = 0.652), Sport 66.53 (SD: 20.95) versus 64.73 (SD: 20.57; P = 0.643), and Quality of Life 50.69 (SD: 20.34) versus 55.04 (SD: 19.60; P = 0.244). The IKDC score was 68.95 (SD: 14.94) versus 70.10 (SD: 15.36; P = 0.685) and the Lysholm score was 81.57 (SD: 13.86) versus 82.25 (SD: 12.36; P = 0.782). Both groups reported the expected improvements from baseline across all PROMs.

Twelve months

At 1 year, 121 patients (62% male; mean age: 31 years, SD: 9.8) had complete knee laxity assessments. Of these, 58 received the fixed-loop fixation and 63 the adjustable-loop device. Overall, 134-N knee laxity was greater in the operated-knee (mean: 5.04 mm; 95% CI: 4.78–5.29) than in the contralateral knee (mean: 3.93 mm; 95% CI: 3.72–4.13; P < 0.05). This corresponded to a between-knee difference of 1.11 mm (SD: 1.29; 95% CI: 0.88–1.34; P < 0.05). Knee laxity at 150 N was greater in the operated-knee (mean: 5.56 mm; 95% CI: 5.30–5.81) than in the contralateral knee (mean: 4.45 mm; 95% CI: 4.24–4.66; P < 0.05). This corresponded to a between-knee difference of 1.11 mm (SD: 1.29; 95% CI: 0.88–1.34; P < 0.05). At 200 N, including all patients, the operated-knee laxity was 6.98 mm (SD: 1.53; 95% CI: 6.70–7.25) and the contralateral knee laxity was 5.86 mm (SD: 1.28; 95% CI: 5.63–6.09; P < 0.05). This corresponded to a between-knee difference of 1.12 mm (SD: 1.38; 95% CI: 0.87–1.37; P < 0.05) which is below the pre-defined threshold for an important difference.

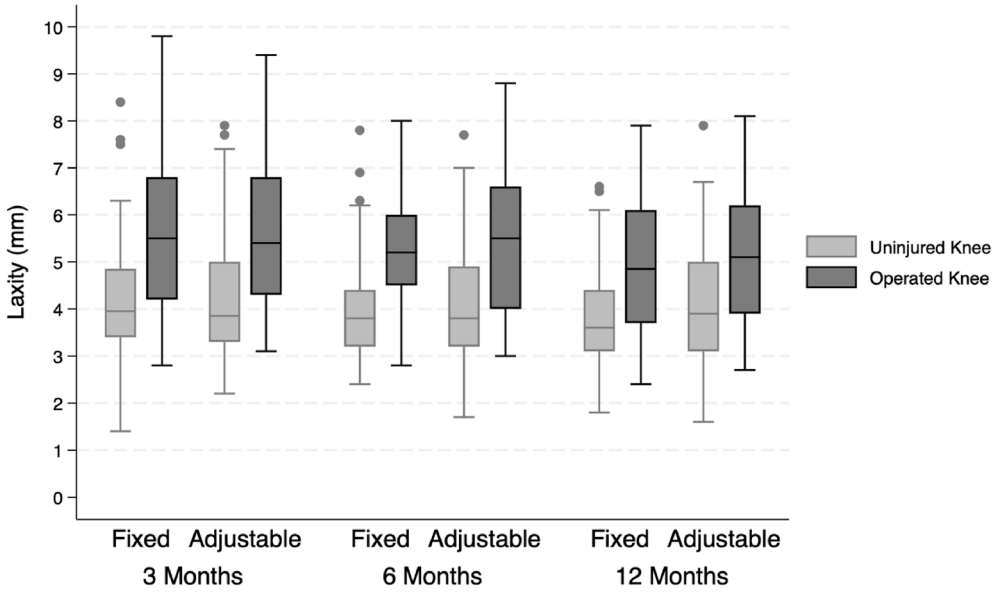


Fig. 2. Absolute knee laxity measurements (uninjured versus operated knee) by intervention over time (134-N GNRB measurements).

Table 2
Absolute and relative GNRB measurements by intervention.

3 months (n = 102)		Fixed loop	Adjustable loop	P value
		n = 48	n = 54	
Absolute laxity	134 N	5.56 (5.06–6.06)	5.59 (5.18–6.01)	0.91
Relative laxity	134 N	1.36 (0.94–1.78)	1.35 (0.95–1.74)	0.96
6 months *(n=108)*		*n=49*	*n=59*	
Absolute laxity	134 N	5.31 (4.96–5.66)	5.44 (5.05–5.83)	0.63
	150 N	5.92 (5.56–6.28)	5.99 (5.59–6.39)	0.81
Relative laxity	134 N	1.32 (1.00–1.64)	1.35 (0.99–1.71)	0.90
	150 N	1.38 (1.06–1.71)	1.42 (1.03–1.81)	0.88
12 months *(n=121)*		*n=58*	*n=63*	
Absolute laxity	134 N	4.99 (4.62–5.36)	5.09 (4.74–5.44)	0.69
	150 N	5.51 (5.13–5.87)	5.61 (5.26–5.96)	0.68
	200 N	6.94 (6.53–7.34)	7.02 (6.63–7.40)	0.78
Relative laxity	134 N	1.20 (0.89–1.51)	1.04 (0.68–1.39)	0.50
	150 N	1.23 (0.93–1.52)	1.00 (0.64–1.36)	0.33
	200 N	1.26 (0.93–1.58)	0.99 (0.61–1.37)	0.29

Data are presented as mean (95% confidence interval); relative laxity measurements = operated knee vs. contralateral uninjured knee.

There was no statistically significant difference in the absolute operated-knee laxity measurements between the interventions (Fig. 2). At 134 N, the operated-knee laxity in the fixed-loop group was 4.99 mm (SD: 1.42; 95% CI: 4.62–5.36) versus 5.09 mm (SD: 1.40; 95% CI: 4.74–5.44) in the adjustable-loop group (P = 0.69). At 150 N, the operated-knee laxity in the fixed-loop group was 5.51 mm (SD: 1.40; 95% CI: 5.13–5.87) versus 5.61 mm (SD: 1.39; 95% CI: 5.26–5.96) in the adjustable-loop group (P = 0.68). At 200 N, the operated-knee laxity in the fixed-loop group was 6.94 mm (SD: 1.54; 95% CI: 6.53–7.34) versus 7.02 mm (SD: 1.53; 95% CI: 6.63–7.40) in the adjustable-loop group (P = 0.78) (Table 2).

There was also no statistically significant difference by intervention for the relative, between-knee, laxity measurements for patients receiving the fixed-loop versus adjustable-loop device at 134 N (mean: 1.20 mm; 95% CI: 0.89–1.51 versus mean: 1.04 mm; 95% CI: 0.68–1.39; P = 0.50), 150 N (mean: 1.23 mm; 95% CI: 0.93–1.52 versus mean: 1.00 mm; 95% CI: 0.64–1.36; P = 0.33), or at 200 N (mean: 1.26 mm; 95% CI: 0.93–1.58 versus mean: 0.99 mm; 95% CI: 0.61–1.37; P = 0.29) (Table 2; Figure 3).

There was further improvement in all PROMs at 12 months, with no statistically significant differences between the interventions (Table 3). The mean Tegner activity level was 4.80 (SD: 1.93) in the fixed-loop group versus 5.16 (SD: 1.68) in the adjustable-loop group (P = 0.297). Mean KOOS subscale scores were comparable: Symptoms 79.59 (SD: 15.06) versus 83.48 (SD: 11.45; P = 0.127), Pain 87.63 (SD: 11.36) versus 90.38 (SD: 8.89; P = 0.158), Activities of Daily Living 94.35 (SD: 8.41) versus 96.36 (SD: 5.07; P = 0.129), Sport 79.20 (SD: 17.98) versus 79.69 (SD: 16.39; P = 0.880), and Quality of Life 62.61 (SD: 19.75) versus 67.30 (SD: 19.11; P = 0.204). The IKDC score was 77.87 (SD: 16.01) versus 80.78 (SD: 12.93; P = 0.289), and the Lysholm score was 86.04 (SD: 11.53) versus 88.95 (SD: 8.25; P = 0.128).

Cohen's d effect sizes for all between-group laxity comparisons were negligible to small, with all 95% CIs crossing zero. At 12 months, effect sizes for absolute laxity ranged from d = −0.05 to d = −0.08 and for relative (between-knee) laxity from d = 0.12 to d = 0.19, confirming the functional equivalence of the two fixation methods.

Return-to-activity analysis using the Tegner Activity Scale showed that the mean pre-injury Tegner score was 6.7 (SD: 1.9) in the fixed-loop group and 6.9 (SD: 2.2) in the adjustable-loop group. At 12 months, 28% (30/107) of patients returned to their pre-injury Tegner activity level, with no statistically significant difference between groups (P = 0.624). Furthermore, 52% (56/107) of patients were within one Tegner level of their pre-injury score (P = 0.381).

An attrition-bias analysis comparing 12-month completers (n = 121) with non-completers (n = 43) showed that non-completers were significantly younger (mean: 26.6 years, SD: 7.9 versus 31.2 years, SD: 9.8; P = 0.008). There were no statistically significant differences in sex (P = 0.234), intervention group allocation (P = 0.375), or concurrent procedures (partial medial meniscectomy P = 0.149, PLM P = 0.227, medial meniscal repair P = 0.142, lateral meniscal repair P = 0.861, lateral extra-articular tenodesis P = 0.530). No supplementary loss-to-follow-up data were recorded.

Adverse events

One patient experienced a graft failure in the adjustable loop group following a twisting injury during rehabilitation at four months. Radiographs showed increased posterior tibial slope, and this was subsequently managed with an osteotomy, with the patient responding well and opting not to undergo revision ACL surgery. The patient withdrew from the study following this re-injury and is not included in the reported analyses.

Table 3
Patient reported outcome measures (PROMs).

PROM	Month	Fixed loop	Adjustable loop	P value
Tegner	Baseline	6.73 (6.29–7.18; SD: 1.87)	6.87 (6.37–7.37; SD: 2.21)	0.684
Tegner	0	2.57 (2.19–2.95; SD: 1.60)	2.75 (2.41–3.09; SD: 1.50)	0.489
Tegner	6	3.41 (3.06–3.77; SD: 1.50)	3.77 (3.50–4.03; SD: 1.18)	0.159
Tegner	12	4.80 (4.35–5.26; SD: 1.93)	5.16 (4.78–5.54; SD 1.68)	0.297
KOOS symptoms	0	62.01 (57.68–66.33; SD: 18.27)	62.34 (58.08–66.60; SD: 18.77)	0.913
KOOS symptoms	6	73.41 (69.41–77.41; SD: 16.90)	75.05 (71.72–78.39; SD: 14.70)	0.575
KOOS symptoms	12	79.59 (76.03–83.16; SD: 15.06)	83.48 (80.88–86.08; SD: 11.45)	0.127
KOOS pain	0	65.59 (61.59–69.60; SD: 16.94)	65.62 (61.34–69.91; SD: 18.87)	0.992
KOOS pain	6	82.43 (79.17–85.70; SD: 13.80)	82.46 (79.38–85.55; SD: 13.59)	0.991
KOOS pain	12	87.63 (84.94–90.32; SD: 11.36)	90.38 (88.36–92.40; SD: 8.89)	0.158
KOOS Activities of Daily living	0	74.45 (70.11–78.79; SD: 18.33)	75.03 (70.58–79.48; SD: 19.61)	0.853
KOOS Activities of Daily living	6	89.98 (86.81–93.14; SD: 13.37)	91.05 (88.26–93.85; SD: 12.32)	0.652
KOOS Activities of Daily living	12	94.35 (92.36–96.35; SD: 8.41)	96.36 (95.21–97.51; SD: 5.07)	0.129
KOOS sport	0	34.61 (28.48–40.74; SD: 25.91)	40.87 (35.10–46.63; SD: 25.39)	0.147
KOOS sport	6	66.53 (61.57–71.49; SD: 20.95)	64.73 (60.06–69.40; SD: 20.57)	0.643
KOOS sport	12	79.20 (74.94–83.45; SD: 17.98)	79.69 (75.97–83.41; SD: 16.39)	0.880
KOOS Quality of Life	0	24.59 (20.44–28.74; SD: 17.54)	29.19 (25.19–33.20; SD: 17.66)	0.117
KOOS Quality of Life	6	50.69 (45.88–55.51; SD: 20.34)	55.04 (50.59–59.49; SD: 19.60)	0.244
KOOS Quality of Life	12	62.61 (57.94–67.29; SD: 19.75)	67.30 (62.96–71.64; SD: 19.11)	0.204
IKDC	0	45.14 (41.55–48.73; SD: 15.17)	47.73 (43.94–51.52; SD: 16.70)	0.335
IKDC	6	68.95 (65.42–72.49; SD: 14.94)	70.10 (66.61–73.58; SD: 15.36)	0.685
IKDC	12	77.87 (74.08–81.66; SD: 16.01)	80.78 (77.85–83.72; SD: 12.93)	0.289
Lysholm	0	58.94 (54.99–62.90; SD: 16.71)	58.57 (54.06–63.08; SD: 19.88)	0.904
Lysholm	6	81.57 (78.29–84.85; SD: 13.86)	82.25 (79.44–85.05; SD: 12.36)	0.782
Lysholm	12	86.04 (83.31–88.77; SD: 11.53)	88.95 (87.07–90.82; SD: 8.25)	0.128

Data are presented as mean (95% confidence interval); KOOS = Knee injury and Osteoarthritis Outcome Score; IKDC = International Knee Documentation Committee Subjective Knee Evaluation Form; SD = standard deviation.

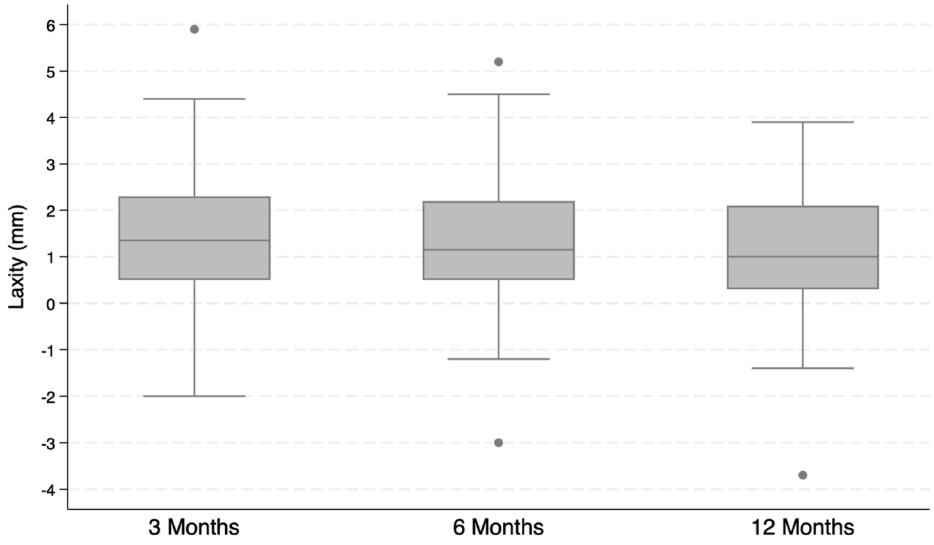


Fig. 3. Relative laxity measurements (operated knee versus uninjured knee) over time (134-N GNRB measurements).

DISCUSSION

Principal findings

Our study shows that there was no statistically significant difference in objective knee laxity measurements, or PROMs, for a fixed-loop versus adjustable loop device used for suspensory fixation of a hamstring autograft in the femur for ACL reconstruction. Our study also provides important normative reference data for knee laxity measurements in the normal versus operated knee in a large series of patients.

Comparison with previous studies

Adjustable-loop devices have theoretical advantages over fixed-loop devices in terms of more precise adjustment and placement of grafts, and reductions in theater inventory. With their introduction, however, there have been concerns about "slippage" of the devices during cyclical loading, and therefore, in preparation for this study, a biomechanical study of the adjustable- and fixed-loop devices was done; no clinically significant elongation of the constructs was detected [8]. Furthermore, systematic reviews of clinical studies identified no clinical study reporting any significant difference between patient groups in terms of knee stability, outcome scores, or graft failure but highlighted the need for better quality evidence—further supporting the design and conduct of the GAP study—including the need for the collection of objective knee laxity data [13,14].

Several other biomechanical studies have compared the strength and lengthening of fixed- versus adjustable-loop devices in a laboratory environment [13,15–17]. While some studies noted clinically significant lengthening of adjustable loops under cyclic loading, ultimate failure loads consistently exceeded the forces expected during early post-operative rehabilitation [15–17]. Crucially, these laboratory

assessments utilizing mechanical testing devices or animal bone models cannot fully replicate the *in vivo* conditions of human tissue, underscoring the necessity of the clinical data presented here.

As described earlier, multiple studies comparing fixed- and adjustable-loop devices have been reported [13]. While, at varying time intervals of follow-up, no significant differences were reported in these studies in terms of knee laxity, patient-reported outcome, or graft failures, a recent meta-analysis expressed concerns about the quality of these studies in terms of small study numbers, incomplete follow-up, and the risk of methodological bias from primarily non-randomized study designs [14]. Our study is the largest prospective study and, to our knowledge, the only adequately powered randomized clinical trial of a fixed-loop versus adjustable-loop device. Nevertheless, our findings are consistent with these previous clinical studies in finding no statistically significant difference between the fixed-loop and adjustable-loop device groups.

Our finding of a 1- to 1.3-mm side-to-side difference in reconstructed knees is comparable to studies using quadriceps or patellar tendon grafts [18,19]. These findings provide important reference data for hamstring autograft ACL reconstruction, although it should be noted that differences in graft preparation, construct stiffness, fixation methods, and tunnel preparation may limit direct comparisons across different graft types.

No statistically significant differences were observed in PROMs between the groups at any of the time points. Similarly, no difference in PROMs between fixed- and adjustable-loop techniques has been reported in any previous study [20,21]. The absolute values records were comparable to other high-quality studies of ACL reconstructions, including for patients undergoing ACL reconstruction as part of the recent ACL-SNNAP and DOSTAR trials [22,23].

Strengths and limitations

Our study is strengthened by being a single-center study and by the double-blind (patients and assessor) nature of the study design. To our knowledge, our study is this largest prospective study and the largest randomized study of a fixed-loop versus adjustable-loop device.

With the key concern with the adjustable-loop devices being slippage and therefore laxity, the GAP study was designed with objective knee laxity (as measured with the GNRB device) as the primary outcome measure. Objective outcome data are reported using the validated GNRB device [9]. Measurements at 134 N (the primary outcome measure utilized) have been shown previously to be both well tolerated and to be the most sensitive indicator of ACL integrity [10]. Laxity measurements at 134 N, 150 N, and 200 N were collected at later time points in the study. These measurements were designed to replicate the forces of real-life rehabilitation and function.

Follow-up of post–ACL reconstruction patients can be challenging, but 74% of recruited patients completed their follow-up to the primary endpoint of the study and the potential for attrition bias cannot be completely excluded. This proportion is still comparable to other large studies of ACL injury and reconstruction, for example, 78% of patients completed follow-up in the ACL-SNNAP study [22]. Analysis of attrition in our study showed that non-completers were significantly younger than completers ($P = 0.008$), although there were no differences in sex, intervention group, or concurrent procedures. This age-related attrition may limit the generalizability of findings to younger patients. Importantly, dropout was balanced between intervention groups ($P = 0.375$), reducing the risk of differential attrition bias.

As a single-center, two-surgeon study, using a single graft type (hamstring autograft) and standardized tibial fixation (interference screw), the results may not be generalizable to other graft types, fixation constructs, or surgical techniques. Long-term rates of revision surgery following ACL reconstruction are reported to be up to approximately 3% over 5 years, but long-term follow-up was not the intended design of this study which instead evaluated the primary fixation method over the period of time where graft incorporation would be anticipated to be complete [2,24]. None of the recruited patients sustained a re-rupture of their graft during the period of follow-up.

Conclusion

This randomized study found no significant difference in objective knee laxity or patient-reported outcomes between fixed-loop and adjustable-loop femoral fixation devices. These findings support the short-term equivalence of adjustable-loop devices in terms of knee laxity and patient-reported outcomes for hamstring autograft ACL reconstruction at 1-year follow-up.

Author contributions

S.A.: analyzed data, wrote and edited the manuscript.
A.N.: recruited patients, collected data, edited the manuscript.
S.M.: recruited patients, edited the manuscript.
V.M.: concept, design, methodology, recruited patients, edited the manuscript.

Transparency declaration

The senior author (V.M.) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

Data sharing

Additional data may be available on request.

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Declaration of competing interests

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Vipul Mandalia reports was provided by Royal Devon and Exeter Hospital. Vipul Mandalia reports a relationship with Royal Devon and Exeter Hospital that includes: employment. No additional relationship or activities If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jisako.2026.101123.

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