Objective laxity and subjective outcomes are more influenced by meniscal treatment than anterior cruciate ligament reconstruction technique at minimum 2 years of follow-up

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ABSTRACT

Objective: The purposes of this study were: (1) to compare three different surgical techniques for anterior cruciate ligament (ACL) reconstruction at a minimum 2 years of follow-up in terms of objective laxity and patient-reported outcomes; (2) to inspect the role of meniscal tears and treatment alongside with ACL reconstruction.

Methods: 59 patients were randomly assigned to one of the three reconstruction groups according to the ACL reconstruction technique: Double Bundle, Single Bundle, Single Bundle with Lateral Plasty. Autologous hamstring tendons were used in all the ACL reconstruction techniques. Objective laxity tests and KOOS were collected before surgery as a baseline and at a minimum of 2 years of follow-up and compared through a Repeated measure ANOVA. Secondary analysis to evaluate the effect of meniscal treatment on laxity reduction and scores improvement was also conducted using ANOVA. Three laxity evaluations were performed: anterior/posterior displacement at 30° of knee flexion (AP 30), anterior/posterior displacement at 90° of knee flexion (AP 90), and pivot-shift test.

Results: Objective laxity and KOOS showed statistically significant improvement at follow-up in all three groups (p < 0.0001) without differences among the techniques. A higher AP 30 (mean difference 2.4 mm, p = 0.0333, ES = 0.66) was found at baseline for the patients with irreparable medial meniscal tear compared to the patients with isolated ACL tear; a statistically significant difference in pain score at two-year follow-up was found between patients who underwent lateral meniscectomy and patients with either meniscal repair (mean difference 6.9 ± 12.5) or isolated ACL tear (mean difference 6.8 ± 16.1); patients with reparable meniscal tear had a statistically significant pain score improvement compared to the patients who underwent medial and lateral meniscectomy (mean difference of 9.5 ± 14.53 and 23.4 ± 19.2 respectively).

Conclusion: Comparable objective laxity and subjective outcomes were found among the three ACL reconstruction techniques at a minimum of 2 years of follow-up. The presence of irreparable medial meniscal tear increased pre-operative laxity (AP 30, mean difference 2.4 ± 3.6 mm). Patients with meniscal repair presented higher pain relief between baseline and follow-up compared with patients undergoing medial or lateral meniscectomy (mean difference of 9.5 ± 14.53 and 23.4 ± 19.2, respectively).
What are the new findings?

- No difference in laxity evaluation and clinical outcomes was found among the three different ACL reconstruction techniques at a minimum of 2 years of follow-up
- The presence of irreparable medial meniscal tear increased pre-operative laxity (AP 30, mean difference 2.4 ± 3.6 mm)
- Patients with meniscal repair presented higher pain relief between baseline and follow-up compared with patients undergoing meniscectomy or isolated ACL reconstruction (Cohen’s d from 0.66 to 1.21)

Introduction

The single bundle (SB) reconstruction represents the standard treatment of the anterior cruciate ligament (ACL) tear. Although the results of the SB are satisfactory and reliable, persistent rotational laxity with a feeling of instability and patient dissatisfaction are reported in the literature [1]. The concept of anatomic reconstruction has been therefore introduced in an attempt to solve these issues and with the aim of restoring the ACL to its native features. Such a concept is either applied to SB or alternative techniques. First is the double-bundle (DB) reconstruction, which is aimed to anatomically recreate both the bundles of the native ACL [2]. Second, a combined intra-articular reconstruction and lateral extra-articular tenodesis (SBLP) [3,4], which interest was renewed after the anatomical redefinition of the Anterolateral Ligament (ALL) [4]. Biomechanical studies have shown superior results in terms of knee stability for DB and SBLP reconstruction compared to SB technique [4-6]. Anyway, clear evidence of differences in clinical outcomes between these different techniques is lacking [4,7,8].

Furthermore, ACL injuries are frequently associated with meniscal tears [9], and the biomechanical interdependence between ACL and meniscus should always be considered when performing ACL reconstruction. In particular, the medial and the lateral meniscus have been reported to function as critical secondary knee stabilisers in anteroposterior translation and pivot shift (PS) test, respectively [10,11]. Previous in-vitro and in-vivo studies with surgical navigation systems reported increased knee laxity and tibial contact pressure in the presence of concurrent ACL injury and medial meniscectomy; increased osteoarthritis at long-term follow-up was also observed [3,12,13]. Hence, clarifying the role of meniscal tears and their management in the setting of ACL reconstruction is crucial in accurately restoring the knee kinematics and improving functional results.

Therefore, the purpose of the present study was to compare three different surgical techniques (SB, DB and SBLP) for ACL reconstruction at a minimum of 2 years of follow-up with laxity assessment and KOOS sub-items and to explore the role of meniscal treatment in ACL reconstruction at a minimum of 2 years of follow-up. It was hypothesised that, at follow-up, (1) ACL reconstruction with the SBLP technique would obtain better control of laxity and higher KOOS score than the other two techniques and that (2) a higher residual laxity would be present in patients who had undergone partial meniscectomy.

Methods

The present study represents the secondary analysis of a larger prospective study aimed at investigating the outcomes of ACL reconstruction. For the specific purposes of the present study, a cohort of 98 patients enrolled between 2011 and 2017 was investigated to compare three different surgical techniques for ACL reconstruction with both patient-reported outcomes and objective laxity assessment. Patients were randomly assigned to one of the three groups. Simple randomization was performed using the sealed opaque envelope technique. The inclusion criteria of the prospective study were consistent throughout the whole period: ACL deficiency with or without a medial or lateral meniscal tear; age between 18 and 65 years; no concomitant other ligamentous injuries; no previous knee surgery. Both clinical outcomes and objective laxity assessment were collected before surgery as a baseline and at a minimum of 24 months of follow-up. A single surgeon (X.X.) performed all the laxity assessments. A complete kinematic and score assessment was also required for eligibility in this secondary analysis: patients with incomplete kinematic data of the injured or contralateral limb or incomplete score data at baseline or follow-up were excluded from the study. MRI was obtained for each patient. The presence of concomitant injuries was defined at baseline on MRI examination and was confirmed with the arthroscopic view during the surgery.

Based on the surgical technique used for the ACL reconstruction, the patients were divided into 3 groups:

- Single-Bundle Group (SB);
- Single-Bundle Lateral Plasty Group (SBLP);
- Non-anatomic Double-Bundle Group (DB).

One single expert surgeon (S.Z.) performed the surgical procedures in all patients using autologous hamstring tendons. All three techniques were described in detail in previous studies [3,14,15].

Testing protocol

In order to evaluate clinical knee laxity, three evaluations were performed:

- Anterior/posterior displacement at 30° of knee flexion (AP 30) through KT-1000 at manual maximum (KT-MM) force (primary outcome);
- Anterior/posterior displacement at 90° of knee flexion (AP 90) through Rolimeter (secondary outcome);
- Posterior acceleration of lateral tibial compartment during a tibial reduction in the PS [16] through KiRA device (Orthokey, Florence, Italy) (secondary outcome).

The reliability of all laxity tests performed at maximum force was evaluated in previous studies [17]. The examiner was the same during the whole set of tests and was blinded to the allocated surgical treatment and patients’ meniscal status. The Knee Injury and Osteoarthritis Outcome Score (KOOS) was also assessed (secondary outcome): the sub-items of Pain, Symptoms, Activity of Daily Living (ADL), Sport, Quality of Life (QoL) were calculated at both Baseline and follow-up [18].

Statistical analysis

Data were analyzed offline in MATLAB (The MathWorks Inc, Natick, Massachusetts, USA). All the clinical laxity data were expressed as a side-to-side difference between the injured and the contralateral limb. The KOOS results were expressed as the difference between baseline and follow-up for each sub-item. The Kolmogorov–Smirnov test was used to verify the normal distribution of the data. Since the normal distribution was confirmed for all the data, normal-distributed continuous variables were presented as mean and standard deviation (SD). Categorical variables were presented as sample size and percentages. The Repeated measure ANOVA test was performed to assess the between-group differences of continuous variables along with the two times assessment, while the two-tailed Student’s t-test was used to compare each group with one another. The effect of the ACL reconstruction technique (named “Group”) and the effect of the meniscal treatment (named “Meniscus”) were assessed in the repeated measure ANOVA model. Differences between the groups were considered statistically significant if p < 0.05. The partial eta squared (η2) was reported alongside the p-value and was considered small, medium, and
large for values of 0.01, 0.06, and 0.14, respectively [19]. P-values were adjusted using the Dunn-Sidak post-hoc correction for multiple comparisons with unequal group sizes. For the single group post-hoc comparisons, the Cohen’s d was reported alongside the p-value and the effect size was considered small, medium, and large for values of 0.2, 0.5, and 0.8, respectively [19]. Minimum clinically important difference (MCID) was computed for the group comparisons as 0.5 × Standard deviation of the difference [20–22] and compared to the actual difference detected. An a-priori power analysis was performed in G*Power (v3.1, Brunsbüttel, Germany). A repeated measure ANOVA with a within-between factor interaction test was used. A medium partial eta squared of 0.06, a number of groups, and a type I error of 0.05, were considered. A minimum of 14 subjects per group was therefore required to obtain adequate statistical power. All statistical analyses were performed in MATLAB.

**Ethics**

All the patients signed informed consent forms before enrollment, and the research study was approved by the Institutional Review Board (IRB approval: Prot.Gen. 0013202 of April 19th 2013).

**Results**

From the original cohort, 39 patients were excluded for the incompleteness of clinical or kinematic data in one of the two evaluations. Overall, 59 patients (48 men and 11 women) with a mean age of 25.8 ± 8.8 years fulfilled all the inclusion criteria and were included in the final analysis (Supplementary material – Appendix A1). No patient underwent reoperation at the involved or contralateral knee. No other clinically significant complications were reported by the patients at the follow-up visit. The complete demographic data were reported in Table 1. The ACL reconstruction technique—SB, SBLP, DB—and the meniscal treatment undergone by the patients—medial meniscus repair (MR), partial meniscectomy (MM), partial lateral meniscectomy (LM), isolated ACL tear (intact menisci, IM)—were reported.

**Clinical laxity evaluation**

Regarding the AP 30 evaluated with KT-MM (Table 2), the side-to-side difference between injured and contralateral limbs significantly decreased between baseline and follow-up for each group (p < 0.0001, large effect size). At follow-up, the side-to-side difference was lower than 2 mm for all the groups. The laxity reduction between baseline and follow-up was 3.4 ± 0.0 [95% CI 1.7–5.1] mm, 2.4 ± 0.5 [95% CI 0.6–4.2] mm, and 3.5 ± 0.9 [95% CI 1.9–5.1] mm for the DB, SB, and SBLP groups respectively. No statistically significant differences were found among the three groups in terms of laxity reduction (p > 0.05).

Regarding the AP 90 evaluated with Rolimeter (Table 2), the side-to-side difference showed a statistically significant decrease between baseline and follow-up for each group (p < 0.0001, large effect size). At follow-up, the side-to-side difference was lower than 0.5 mm at follow-up.
for all the groups. The laxity reduction between baseline and follow-up was 2.4 ± 2.2 [95% CI 1.5–3.3] mm, 3.7 ± 3.1 [95% CI 2.0–5.4] mm, and 2.2 ± 2.0 [95% CI 1.4–3.0] mm for the DB, SB, and SBLP groups respectively. No statistically significant differences were found among the three groups in terms of laxity reduction (p > 0.05).

Regarding the PS evaluation with KIRA (Table 2), the side-to-side difference of posterior acceleration of the lateral tibial compartment showed a statistically significant decrease between baseline and follow-up for each group (p < 0.0001, large effect size). At follow-up, the residual difference was less than 0.5 m/s² for all the groups. The laxity reduction between baseline and follow-up was 1.7 ± 1.5 [95% CI 0.9–2.5] mm, 2.6 ± 1.5 [95% CI 1.7–3.5] mm, and 1.5 ± 1.3 [95% CI 1.0–2.0] mm for the DB, SB, and SBLP groups respectively. No statistically significant differences were found among the three groups in terms of laxity reduction (Time*Group p > 0.05).

Subjective outcome evaluation

All the sub-items of the KOOS improved significantly at follow-up (p < 0.0001). All the time comparisons showed a large effect ($\eta^2_p = 0.14$), except for KOOS-ADL ($\eta^2_p = 0.02$, small effect). For all the ACL reconstruction groups, the greatest improvement was observed in KOOS-QoL (35.4 ± 26.7 in DB group, 43.1 ± 19.7 in SBLP group, 49.8 ± 17.3 in SB group) and in KOOS-Sport (36.2 ± 35.2 in DB group, 41.3 ± 25.6 in SBLP group, 43.9 ± 22.5 in SB group).

The smallest improvement was observed in KOOS-ADL for SBLP and DB groups (10.5 ± 12.9 and 8.7 ± 9.5, respectively) and in KOOS-Symptoms for the SB group (12.0 ± 13.1).

No statistical differences were found among the three groups in terms of score improvement (Time*Group p > 0.05) (Table 2).

Meniscus treatment evaluation

Regarding the clinical laxity, a significantly higher AP 30 was observed only at baseline for the patients who underwent medial meniscectomy compared to those with the isolated ACL tear (p = 0.0333, Cohen’s d = 0.66, mean difference 2.4 ± 3.6 mm) (Table 3). No statistical differences were found at follow-up and for the other laxity parameters. Full laxity and clinical outcome assessment according to the meniscal status was reported in Supplementary Material – Appendix A2.

Regarding the KOOS score, a significant difference in the Pain sub-item at follow-up was observed between patients who underwent lateral meniscectomy and patients with either meniscal repair (p = 0.0290, Cohen’s d = 0.55, mean difference 6.9 ± 12.5 mm) or isolated ACL tear (p = 0.0331, Cohen’s d = 0.42, mean difference 6.8 ± 16.1 mm lower than MCID 8.1 mm). The patients who underwent meniscal repair also had a significant score improvement between baseline and follow-up compared to each of the other three groups (Cohen’s d from 0.66 to 1.21, Table 3).

Discussion

The main finding of the current study was that there were no significant differences between the three ACL reconstruction surgical techniques analyzed in reducing the knee laxity or in KOOS improvement evaluated at a minimum of 2 years of follow-up. On the other side, the analysis by meniscal status showed higher pre-operative AP 30 laxity (mean difference 2.4 ± 3.6) in patients with irreparable meniscal tears compared to ones with isolated ACL rupture. Moreover, while the lateral meniscectomy was associated with higher pain at follow-up evaluation compared to ones who underwent meniscal repair or isolated ACL reconstruction (mean difference of 6.9 ± 12.5 and 6.8 ± 16.1, respectively), patients who underwent meniscal repair had a significant improvement in pain KOOS sub-item between baseline and follow-up compared to the patients who underwent medial and lateral meniscectomy (mean difference of 9.5 ± 14.53 and 23.4 ± 19.2, respectively).

Since the concept of anatomical reconstruction was introduced aiming to obtain a reconstruction more similar to the native ACL, previous studies of single versus double-bundle reconstruction often include different techniques of reconstruction. Moreover, the surgical techniques proposed are often poorly described and defined [7]. Several biomechanical and clinical studies have compared the DB with the SB technique, and the results were controversial. A meta-analysis by van Eck et al. argued that DB would reduce dynamic AP and rotational laxity compared to SB, whereas Lysholm and Cincinnati knee scores would be similar [7]. Lee et al. [5] showed that DB reduced AP and rotational laxity significantly more than SB during intra-operative evaluation, without significant differences between the two techniques provided in laxity or patient-reported outcomes at 2 years of follow-up. Furthermore, several studies reported no differences in laxity or patient-reported outcomes measurement between an anatomical SB and a DB technique at a minimum of 2 years of follow-up [23–25], in line with the findings of the current work.

After the recent anatomical definition of ALL [4], attention has returned to the lateral extra-articular procedures with the aim of addressing knee laxity better. In vivo studies, in which intra-operative evaluation was provided, reported that SBLP was superior in controlling internal rotation and AP tibial translation compared to SB [26] and DB [27]. In a recent intra-operative evaluation, the same three techniques performed in the current study were compared, finding significantly superior results in terms of controlling AP 90 in the SBLP group [15]. Nevertheless, in the current study, the differences provided in the intra-operative evaluation [15] were not confirmed after 2 years of follow-up. These findings are in contrast with results presented in previous studies, in which a significantly better control of laxity was reported in a patient who underwent an SBLP procedure compared with isolated intra-articular techniques [28].

Table 3
Significant multiple comparisons among meniscus treatments.

| Antero-posterior displacement at 30° (KT-MM) | KOOS – Pain |
|--------------------------------------------|-------------|
| Baseline mean difference (mm) Cohen’s d p-value | Baseline mean difference Cohen’s d p-value | Follow-up mean difference Cohen’s d p-value | Difference mean difference Cohen’s d p-value |
| IM vs MR 0.4 ± 3.0 0.12 n.s. | 8.7 ± 19.7 0.44 0.0421* | 0.1 ± 11.9 0.01 n.s. | 8.7 ± 14.9 0.59 n.s. |
| IM vs MM 2.4 ± 3.6 0.66 0.0333* | 0.6 ± 23.1 0.03 n.s. | 1.4 ± 17.3 0.08 n.s. | 0.8 ± 12.3 0.07 n.s. |
| IM vs LM 0.8 ± 6.0 0.14 n.s. | 7.9 ± 25.4 0.31 n.s. | 6.8 ± 16.1 0.42 0.0331* | 14.6 ± 17.3 0.85 0.0087* |
| MR vs MM 2.0 ± 3.9 0.52 n.s. | 8.1 ± 20.9 0.39 n.s. | 1.5 ± 16.6 0.09 n.s. | 9.5 ± 14.5 0.66 0.0385* |
| MR vs LM 0.5 ± 6.1 0.08 n.s. | 16.5 ± 20.1 0.82 0.0055* | 6.9 ± 12.5 0.55 0.0290* | 23.4 ± 19.2 1.21 0.0093* |
| MM vs LM 1.5 ± 6.5 0.23 n.s. | 8.4 ± 23.2 0.36 n.s. | 5.4 ± 20.6 0.26 n.s. | 13.8 ± 18.6 0.74 0.011* |

Note: Either objective laxity or subjective outcome results were reported only for the time frame (baseline or follow-up) where statistically significant differences were found; MR = Medial Meniscus Repair; MM = Medial Meniscectomy; LM = Lateral Meniscectomy; IM = Intact Menisci; “Difference” means follow-up – baseline score difference; n.s. = not significant; * = statistically significant.
In the current study, since no differences were found in terms of laxity reduction or KOOS subitems between the analyzed ACL reconstruction surgical techniques, the effect of meniscal status and treatment was investigated. Patients who underwent medial meniscectomy presented a significantly higher AP 30 compared to the isolated ACL group at baseline (mean difference 2.4 mm, ES = 0.66). This finding is in line with the literature: the critical role of the medial meniscus in restraining uniplanar anterior load in the ACL-deficient knee was underlined in previous cadaveric studies, with the most significant effect when the posterior horn was involved [10,29]. Moreover, in a recent in vivo intra-operative evaluation of ACL injured patients, a significantly greater AP 30 and 90 were founded in the patients with a medial meniscal tear, subsequently treated with meniscectomy, compared with the intact menisci group [11]. Dejour et al. analyzed a clinical series of ACL-injured knees and reported a significantly higher AP at 20° of flexion measured on stress radiographs in patients with medial meniscal lesions [30].

Furthermore, in the current study, a significantly higher pain (lower KOOS—Pain score) was reported by the patients who underwent lateral meniscectomy compared with patients who underwent isolated ACL reconstruction or associated meniscal repair (mean difference of 6.8 ± 6.1 and 6.9 ± 12.5 respectively). Moreover, the group of patients who underwent a meniscal repair showed a significantly higher pain relief (greater KOOS—Pain score improvement) between the baseline and follow-up evaluation compared to patients who underwent medial and lateral meniscectomy (mean difference of 9.5 ± 14.53 and 23.4 ± 19.2 respectively). The higher pain relief in the patients who underwent meniscal repair could be explained by their higher pain report at baseline, which achieves the same score as the meniscus-intact group at follow-up evaluation. These findings are in line with the results of previous studies, in which good to excellent clinical outcomes and absence of the symptoms were reported in most of the patients who underwent meniscal repair [31,32]. In particular, the concomitant ACL reconstruction was identified as a prognostic factor correlating with a better chance of a successful repair and a lower re-operation rate [32]. These results, included those of the current study, endorse the repair, whenever possible, of the meniscal tear in association with ACL reconstruction to better restore knee kinematics and to achieve higher pain relief.

Therefore, the key findings of the current study are: the application of anatomical principles in the setting of ACL reconstruction, such as the respect of the native femoral insertion or the restoration of the two functional bundles or even the reconstruction of the ACL with an extra-articular procedure, permitted to obtain satisfactory results without significant differences between three distinct techniques; when a meniscal tear is associated, it should be addressed preserving the great amount of the meniscus possible. Patients should be aware of the risks derived from a diagnosis of concomitant ACL and meniscus injury in order to shape their expectations of the surgery and rehabilitation process.

This study has several limitations. The strict inclusion criteria and the multiple devices used for the quantitative assessment made through were responsible for the low number of patients included and for the exclusions, especially in the LM group. Because of the limited sample size, it was not possible to conduct a multi-factorial data comparison by including ACL surgical techniques and meniscus treatment simultaneously, and the differences across meniscal groups could be underpowered. However, the MR group consisted of patients with only medial meniscus tears, and this allowed a direct clinical comparison between the two different treatments. A further limitation is represented by the laxity evaluation, which was performed manually during the tests. Nevertheless, all the clinical evaluations were performed by the same senior surgeon, who had already demonstrated high reliability in manual assessment [17]. Another limitation is the lack of standardisation of meniscal tears and partial meniscectomy. Anyway, in common clinical practice, the standardisation of the amount of meniscus resected would have been highly unethical. Furthermore, such a lack of standardisation usually performed in daily clinical practice more than in previous in-vitro settings.

Conclusion
No significant differences were found between the three different ACL reconstruction techniques (SB, DB and SBLP) in outcomes at a minimum of 2 years of follow-up. Meniscus status and its surgical treatment influenced both kinematics and subjective outcomes in the setting of ACL reconstruction: the patients with a medial meniscal tear, subsequently treated with meniscectomy, presented higher pre-operative AP laxity at 30° of flexion compared with isolated ACL patients. Furthermore, the patients who underwent meniscal repair presented significantly higher pain relief compared with each of the other groups at 2-year follow-up.

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Declaration of competing interest
All authors have nothing to disclose.

Appendix A. Supplementary data
Supplementary data to this article can be found online at https://doi.org/10.1016/j.jisako.2022.04.006.

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