Introduction

The most common knee surgery is anterior cruciate ligament (ACL) reconstruction. It produces early return to sport and good clinical outcomes [1], [2], [3], [4], [5], [6], [7]. The outcomes are affected by various factors, such as type of grafts, graft fixation methods, tunnel orientations, graft diameters, and rehabilitation program. The most common graft is Bone-Patellar Tendon-Bone (BPTB), hamstring tendon (HT), and quadriceps tendon (QT) grafts [8]. These grafts are comparable both in their biomechanical properties and clinical outcomes, although different morbidities in their respective harvesting sites [4], [7], [9]. Other graft, such as peroneus longus tendon (PLT) graft, is being studied [10], [11], [12], [13].

Grafts are ultimately integrated into the bone tunnels by either screws, cross-pins, or cortical suspension devices. Cortical suspension fixations have been demonstrated to possess superior biomechanical properties to both screws and cross-pins [14]. A fixed-loop button was commonly used as cortical suspension device on the femoral side. Although they provide desirable biomechanical properties, it needs more drilling on femoral tunnel that may disturb graft integration and widen the tunnel size. Therefore, adjustable loop cortical suspension devices have been designed for easier loop length calculation and integration of the grafts in the femoral tunnel. However, concerns have been raised regarding adjustable loop loosening due to cyclic loading in experimental studies. The loosening was not found in fixed loop devices, and potentially results in knee laxity postoperatively [15], [16].

There have been only seven publications that studies about ACL reconstruction clinical outcomes using adjustable loop devices. These studies consistently show that adjustable loop devices and other femoral fixation methods bear similar functional outcomes, as evaluated by the International Knee Documentation Committee (IKDC) score, Tegner-Lysholm score, and other criteria [16], [17], [18], [19], [20], [21]. Loop loosening...
did not significantly differ, neither in radiographs nor clinically [18], [19], [20]. However, Tunnel widening which was a drawback in fixed loop fixation was not decreased in adjustable loop fixation [17].

Hop tests were designed as one of the performance test for determining patients’ readiness for return to sport after ACL reconstruction. There indeed has been much debate in return to sport criteria, but hop tests have been the most widely studied performance test because of its simplicity and reproducibility [22], [23], [24].

The purpose of this study was to evaluate the functional outcomes and hop tests in patients with post-operative ACL reconstruction with adjustable loop button fixation for femoral site fixation after 2-years of follow-up. The post-operative functional outcomes would be compared to the preoperative. This study hypothesized that there would be a significant increase of functional outcomes.

Methods

We conducted a single-centered retrospective study in patients diagnosed with ACL rupture from January to July 2017. All patients that included in this study, completed informed consent forms, and underwent ACL reconstruction surgery with adjustable loop button fixation and PLT as the graft.

ACL rupture diagnosis was established by history taking, physical examination, and MRI examination. The inclusion criteria were patients with chronic ACL total rupture without any additional ligament injury around knee joint. Exclusion criteria, there should be any history of lower limb fracture, multiple ligament injury, and concomitant with meniscus rupture. All patients who met the inclusion and exclusion criteria will be contacted, in which they would receive informed consent forms within the duration of sample collection. Theoretically, minimum sample needed could be calculated as follows:

\[
N = \frac{(Z_\alpha + Z_\beta)^2}{E/SD^2}
\]

N = minimum sample size
\(Z_\alpha\) = normal standard deviation for \(\alpha\)
\(Z_\beta\) = normal standard deviation for \(\beta\)
E = size effect
SD = standard deviation in results

By choosing \(\alpha = 0.05\), \(\beta = 0.20\), E = 0.60 and SD = 1.00, the value of N will be 21.80. Thus, the minimum sample size needed in this study is 22. The functional outcomes were reported as preoperative and 2-years post-operative Tegner-Lysholm score, Modified Cincinnati score, and IKDC. The results of the 6 months post-operative hop tests would also be recorded. This study was approved by Medical Ethics Committee with IRB number KE/FK/0148/EC/2019.

Surgical procedure

All of ACL reconstruction surgery was done by single orthopedic surgeon. SR did all of the procedure. In ipsilateral leg, surgeon used an open tendon stripper to harvest peroneus longus tendon. Through anteromedial portal, femoral drill guide was inserted. Femoral drill guide was placed at ACL foot print on the medial wall of lateral femoral condyle. Guide pin was ensured in accurate intra-articular position. Surgeon was created a full-length 6 mm wide femoral tunnel using outside-in approach. ACL tibial drill guide was inserted through anteromedial portal to create the tibial tunnel. Tibial drill guide was placed at the center of the ACL tibial stump. A 6-mm tibial tunnel was created under direct visualization using a low-speed drilling method. Number 2 Vicryl suture was used to calculate the ACL length from proximal femoral tunnel to distal tibial tunnel. The harvested peroneus longus tendon was marked according to the ACL length measurement.

Rehabilitation program

Figure 1: Adjustable-loop suspensory fixation device

Femoral stabilization was fixed using an adjustable-loop suspensory fixation (ALSF) device (GraftMax™ Button, Conmed, USA [Figures 1 and 2]). The suture guide was pulled until all the graft suture had passed the femoral skin. The graft was fastened with bioabsorbable screw at tibial site with 90° knee flexion and posterior drawer of the tibia. There were no additional securing knots over the ALSF. The remaining graft was sutured with fascia. Surgeon closed and the operation were done.

Figure 2: Hamstring graft with adjustable-Loop Suspensory Fixation device

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After surgery was finished, patients were passed the ACL rehabilitation program. The operated knee was positioned in extension position soon after surgery. Knee flexion was exercised progressively until 3-weeks post-operative to achieve 90° flexion position. Patients were allowed to mobilize with partial weight bearing for first 3-weeks post-operative. Full weight bearing was allowed to patients after 3-weeks post-operative. At 2 months after surgery, the patients were allowed to jog. Patients were tested the Lachmann test, anterior drawer test, serial hop test, and knee functional outcome at 6 months follow-up. After patients passed the test, they were allowed to return to sport activity.

Patient outcomes

Patients were interviewed and examined 2 years after the ACL reconstruction for the functional outcomes by an experienced sports clinician who did not participate in the surgery. The assessment was done using IKDC, Cincinnati, and Tegner-Lysholm score which were adjusted to a scale of 100. Hop tests were evaluated on 6 month after the surgery.

Statistical analysis

Statistical Package for the Social Sciences (SPSS) program version 25.0 (IBM Corporation, USA) was utilized to calculate for the statistical analysis. For each scores of the functional outcomes, the results were expressed in means and standard deviations. The normality data distribution was evaluated using Kolmogorov–Smirnov test to check for their distribution normality, and it is found that only IKDC pretest data have a normal distribution (p = 0.200). Therefore, Wilcoxon Signed-Rank test was used to assess significant differences between pre-operative and 2-years post-operative IKDC score, Tegner-Lysholm score, and Cincinnati score.

Results

In total, there were 47 patients enrolled in this study. The baseline information of the patients is presented in Table 1. Median value of the age was 22 years, with 40 male subjects (85.1%) and seven female subjects (14.9%). The identifiable cause of ACL rupture was related to sports 38 (80.9%) subjects, such as basketball, volleyball, and football, or accidents 9 (19.1%) subjects. Median Body Mass Index (BMI) was found to be 25.0.

Results of pre-operative and 2-years post-operative functional outcomes are shown in Table 2. The IKDC score, Tegner-Lysholm score, and Cincinnati score yielded statistically significant differences (p < 0.001) between their pre- and post-operative score. The median of the hop tests was 92, 94, 94, and 95 for the single, triple, cross over, and timed tests, respectively, as shown in Table 3.

Discussion

In the present study, we found that all functional outcomes are significantly different between pre-operative and post-operative subjects. In addition, the median postoperative Tegner-Lysholm, IKDC, and Cincinnati scores were more than 95.0. The Tegner-Lysholm score median was 98.0, which was higher than the excellent cutoff (>90 according to Mitsou et al.) and the Cincinnati score median was 95.0, which was also higher than the excellent cutoff (>80 according to Bentley et al.) [25], [26]. On the other hand, IKDC score is a subjective scoring system that might be affected by gender and factors; hence, it is more difficult to make the cutoffs [27]. However, we believed that median score of 95.6 could be inferred as an excellent score as well.
These findings indicated that ACL reconstruction using adjustable loop device and PLT would have favorable functional outcomes.

Adjustable loop fixation method was introduced in 2012. There are lot of ongoing researches regarding its utilization. However, these studies mainly focused on common used autografts such as BPTB, HT, and QT grafts. Study of PLT graft and an adjustable loop fixation usage concurrently was conducted by Khajotia et al. [28]. In their study, they included 25 patients and used ALSF device by TightRope RT (Arthrex) for the femoral site fixation. Their method of PLT graft harvesting and ACL reconstruction was similar to us. Functional outcomes were assessed using IKDC score in 6 months follow-up and the mean result was 83.53. Our study resulted in better IKDC score at 95.6 in longer period of follow-up. The longer follow-up period could be explained by stronger integration of the grafts in the femoral tunnel. Ranjan et al. stated that the IKDC score was higher in 2 years rather than 6 months of follow-up [21]. There was no function deterioration of the ankle joint when compared to the normal ankle [28]. However, these might be attributable to the small sample size used in these studies [28].

There are few studies that assessed the clinical outcomes of the adjustable loop fixation. Boutsaidis et al. studied a total of 272 patients who had undergone ACL reconstruction with either adjustable loop fixation (Pullup XL, SBM) or bioabsorbable screw fixation with approximately 2 year of follow-up [20]. Post-operative IKDC score was significantly higher in adjustable loop group compared to the screw group. Although the average IKDC score was not stated, 81.6% of the subjects was Graded A (normal) postoperatively. It concluded that the operation yielded favorable results.

Ranjan et al. compared 2 types of suspensory fixations, the adjustable loop (TightRope RT, Arthrex) and fixed loop (Endobutton CL Ultra, Smith and Nephew) in 102 patients [21]. The study concluded that the functional outcomes of both suspensory fixations using IKDC and Tegner-Lysholm scores showed no significant different in 2-years follow-up. Average IKDC scores for the adjustable and fixed loop were 84.3 and 85.2, respectively. Our study resulted in higher post-operative average IKDC score 95.6. This difference might be caused by different type of graft. We used PLT autograft while Ranjan et al. used HT autograft. The previous studies comparing PLT and other more common used autograft resulted in similar functional outcomes [10], [12], [13]. Thus, other factors might have contributed to this difference such as observer errors in evaluating functional outcomes and small sampling size. Sundararajan et al. observed a relatively low average 78.4 in IKDC score and 87.25 in Tegner-Lysholm score after 2-years follow-up of ACL reconstruction in patients with adjustable loop fixation (TightRope RT, Arthrex) [17]. Study by Ranjan et al. showed that the functional outcomes of adjustable loop and fixed loop (Endobutton CL Ultra, Smith and Nephew) groups were not significant different.

Hops tests are easily performed and widely used tool for assessing patients' readiness to return to sport including psychological readiness. Patients were performed four common forms of hop tests: The single one-leg, triple one-leg, crossover one-leg, and 6-m timed hop test at 6 months after ACL reconstruction. Systematic review by Hegedus et al. concluded that physical performance tests, including hop tests, should be used with caution [22]. Return to sport criteria decision was developed: include other performance-based test and patient-reported measurement of knee function. These criteria are still lack of consensus [29], [30]. Nawasreh et al. found that at 12 and 24 months follow-up, hop test as outcome predictor was consistent [29]. The 6-m hop test combined with single hop test was indicated a half of the outcome variation at 24 months after ACL reconstruction. Based on good hop tests result, our study might be predicted to have higher subjects for returning to sport.

This study has several limitations. This study did not compare the method of fixation using adjustable loop fixation to other methods such as fixed-loop, and screw. This study had few subjects. Greater number of subjects will provide a more reliable result. This study did not include return to sport analysis, although we included the hop tests results.

Conclusion

ACL reconstruction with adjustable loop fixation (GraftMax™ Button, CONMED) on the femoral site had excellent functional outcomes in 2-years of follow-up with excellent serial hop test.

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