



Cohort Study

Functional outcome of implant-free bone-patellar tendon autograft versus hamstring autograft in arthroscopic anterior cruciate ligament reconstruction: A prospective study

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ABSTRACT

Introduction: The use of implant in anterior cruciate ligament (ACL) reconstruction has been associated with several drawbacks including graft injury, implant osteolysis, implant migration and soft tissue irritation. Implant-free ACL reconstruction surgery offers additional benefits of cost-effective, improved graft incorporation and ease of revision surgery. Our study aimed to compare the functional outcome of ACL reconstruction by using bone-patellar tendon autograft with press-fit fixation technique and hamstring autografts with implant.

Methods: A prospective cohort study design was used. Between March 2013 and March 2014, 12 patients underwent patella tendon-bone graft fixated by press-fit fixation technique (implant-free), while 24 patients underwent ACL reconstruction using implant-fixated hamstring tendon graft. Objective functional outcome was measured by using rolimeter, and subjective functional outcome was measured according to the functional score of IKDC, Tegner-Lysholm and KOOS.

Results: Both techniques have shown no significant difference in terms of functional outcome, whether assessed by rolimeter measurement, IKDC score, Tegner-Lysholm, KOOS score between implant group and implant-free group, preoperatively and postoperatively.

Discussion: Our study results are in line with several other studies with various follow-up time and systematic review. With the right technique, graft harvesting of patella tendon-tibial tuberosity bone block can be successfully performed, and associated donor site morbidity can be avoided.

Conclusion: Patients who underwent ACL reconstruction using implant-free technique by press-fit fixation had comparable outcome with ACL reconstruction with implant, objectively and subjectively. This technique should be further revisited and reevaluated.

1. Introduction

Total rupture of anterior cruciate ligament (ACL) is frequently lead to a functional knee disability. The annual incidence of unilateral ACL rupture in the general population varies from 0.01 to 0.08% and 1.5–1.7% in sports active population [1]. In the United States, it is reported that more than 100,000 patients underwent ACL reconstruction in 1996 [2]. Rupture of ACL affects knee stability, which may cause the symptom of giving way, increased risk of meniscal injuries, as well as

early onset of joint degeneration [3].

The most common method of treatment for ACL rupture is surgical reconstruction. The goal is to restore the stability of the knee, as well as to prevent the early onset of osteoarthritis caused by joint instability. The decision regarding graft choice and fixation method remains controversial. The use of implant for ACL graft fixation has been associated with several problems and complications, such as graft injury, implant osteolysis, implant migration and soft tissue irritation. On the other hand, implant-free ACL surgery offers additional benefits of lower

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cost, improved graft incorporation and ease of revision surgery [4].

Our study compares the short term functional outcome of patients undergoing ACL reconstruction using patella tendon-bone graft fixated by press-fit fixation technique (implant-free) with ACL reconstruction using implant-fixated hamstring tendon graft. Despite known possible postoperative complications known to bone-patellar tendon autografts such as infection, graft failure or patella fracture, we hypothesize that, with good aseptic measure, proper intraoperative technique and good postoperative management, the implant-free method would give comparable functional outcome with hamstring autograft reconstruction method.

2. Methods

2.1. Patient recruitment

This study was conducted at Gatot Soebroto Army Hospital, Jakarta by using prospective cohort study design. Between March 2013 and March 2014, 36 patients diagnosed with total rupture of ACL on a single knee were recruited for the study. The diagnosis was made based on clinical examination and MRI radiography. The samples were randomized and allocated into two groups: ACL reconstruction using patella tendon-bone graft fixated by press-fit fixation technique (implant-free group) and ACL reconstruction using implant-fixated hamstring tendon graft (implant-treated group).

All surgery was conducted by a single senior orthopaedic surgeon. Both techniques use the same femoral and tibial tunnel placement. Subjects with hyperlaxity according to Beighton hypermobility score and previous history of knee surgery were excluded. All patients received the same post-operative instructions, care and physiotherapy regimens.

This study is registered at [ClinicalTrials.gov](https://clinicaltrials.gov) with registration ID: NCT04123834 (<https://clinicaltrials.gov/ct2/show/NCT04123834?term=NCT04123834>). This study received ethical approval from the Ethical Clearance Committee board of Universitas Indonesia – Cipto Mangunkusumo Hospital (No. 651/H2.F1/ETIK/2013). All patients were consented to be included in the study and publication of the results. The work is reported in line with the STROCCS criteria [5].

2.2. Surgical technique

Our study used the modified press-fit graft fixation technique described by Edgar Michael T Eufemio from Philippine. A midline skin incision was made that extends from the inferior pole of patella up to proximal tibial tuberosity. Patella tendon with tibial tuberosity bone block was harvested, the patella bone was left intact. The tendon was then fixed together with non-absorbable suture. Schematic of the procedure is illustrated in Fig. 1.

The knee was fully flexed and a femoral tunnel was drilled. The bone plug was prepared into a cone shape with the length equal to the femoral tunnel length. The diameter of the femoral tunnel was 1 mm smaller than the bone plug diameter to ensure the press-fit mechanism. The ACL insertion at tibia was determined, a tunnel was made. The bone block was inserted into the femoral tunnel and the patella tendon was inserted through the tibial tunnel. A small hole was drilled by using a 2.0 K-wire at the distal opening of tibial tunnel. Fixation of the end of tendon graft was made into the hole by using polyester non-absorbable suture (Fig. 2). Fixation was made by manual tensioning, double knots and posterior drawer position to ensure tight fixation. The wound was sutured layer by layer until the cutaneous layer.

2.3. Data gathering and analysis

Anterior knee laxity was assessed by measuring anterior translation at 30° of flexion with a rolimeter and comparing it with the contralateral knee. Functional outcome was evaluated by using the subjective

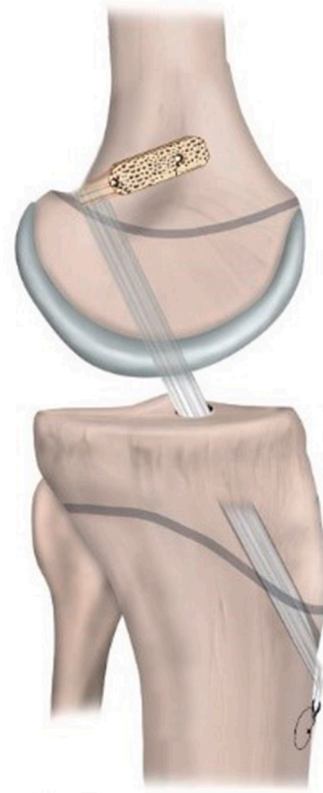


Fig. 1. Schematic of the implant-free press-fit ACL reconstruction.

International Knee Documentation Committee (IKDC) score, Tegner-Lysholm Score, and Knee Injury and Osteoarthritis Outcome (KOOS). The scores were measured preoperatively, as well as at 1, 3, and 6 months after surgery.

Data were analyzed using the IBM® SPSS® Statistics 18 for Mac. Chi-square Test and Fisher's Exact Test were applied for statistical analysis by two tailed-assessment. Paired T-test, Mann-Whitney U/Wilcoxon sum rank, and McNemar test were used for continuous numeric data. A p-value of less than 0.05 was considered statistically significant for all analyses.

3. Results

3.1. Subject characteristics

A total of 37 subjects were included in this study. Groups assignments were randomly allocated. Twelve subjects were included in the implant-free group, while 25 subjects were in the implant-treated group. In the implant-treated group, there was 1 dropped-out patient due to re-rupture of ACL before the time of follow-up was complete.

The causes of ACL injury in this study were varied, including stepping on the wrong foot, traffic accident, soccer, volleyball. The most frequent cause of injury in implant-free group was stepping on the wrong foot (33%), while in implant group was soccer (67%).

3.2. Functional outcome

There was no significant difference between implant-free group and implant group in rolimeter measurement, either at the time before surgery or at 6 months after surgery ($p = 0.075$).

Turning to other measurements, no significant differences were observed between implant-free and implant group in terms of IKDC Score, Tegner-Lysholm Knee Scoring Scale, or KOOS. These results were found at the time before surgery, 1 month, 3 months, or 6 months after

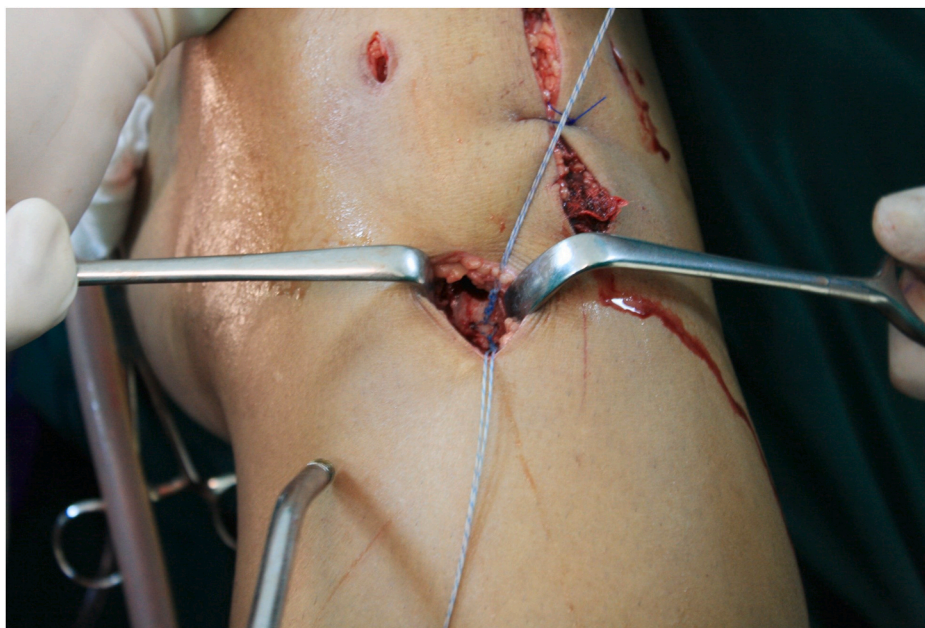


Fig. 2. Fixation of the tendon graft into the distal of tibia tunnel by suture knots.

surgery ($p > 0.05$). Details for the results of the IKDC Score, Tegner-Lysholm Knee Scoring Scale, or KOOS were described in Table 1, Table 2, and Table 3, respectively.

4. Discussion

In this study, the median age of the subjects was 28 (range: 25–36) years old. This finding is similar to a large retrospective cohort study conducted by Mei et al. [6], in which the majority ACL patients was 26 years old. Another study also found younger patient age who suffered ACL injury, which was athletes [7]. This condition appeared as a result of trauma or sports injury on younger age patient [8,9]. Additionally, Mei et al. [6] found that 80% of male non-athletes developed ACL injury from basketball and soccer games.

In this study, males are accounted for 97.22% of the total subjects. This result is similar to a previous epidemiological study conducted by Koulouvaris et al. [8] which showed that females did not have an increased risk ACL injury. This might be due to participation and frequency in sports activities of men and boys are far more than those of women and girls, usually. Thus, the incidence of ACL injury in male is higher than that in female in this study. Mei et al. [6] found that non-athlete males were 3 times of females for developing ACL injury. Men and are boys are more interested in highly competitive and contact sports games, for example, soccer, basketball, skateboarding [10], while women and girls are more likely to participate in aerobics, badminton,

table tennis, swimming and other single or non-contact games [11]. However, numerous studies suggested that the majority of the subjects are mostly female. Prodromos et al. [12] suggested on their meta-analysis that female subjects had a roughly 3 times higher incidence of ACL rupture than male subjects. Whereas, two studies reported that the incidence of ACL rupture in female subjects was 8–9 times greater than in male subjects [12,13]. However, Collins et al. [14] suggested that males were more likely to have an ACL injury reconstructed than females. Several factors have been proposed to account for this variation in ACL injury rates, including general joint laxity, increased quadriceps angle, increased posterior tibial slope, decreased notch width, smaller ACL cross-sectional area, hormonal factors, and the tendency for female athletes to land with their knees with inadequate flexion and in a position of valgus and external rotation [15].

The main factor leading to ACL injury is a sports injury, accounting for 87% and 83% for the implant and implant-free group, respectively. The most frequent sports game which caused ACL injury in this study was soccer, in which similar with the study conducted by Miyasaka et al. [16] Other sports that are the main causes include basketball, gymnastics and rugby.

Duration from initial injury to the operating table considered one of the prognostic factors in ACL injury. Previous studies have shown that the time elapsed from injury to ACL reconstruction is correlated with secondary meniscal tears due to knee instability and increased risk of osteoarthritis [17,18]. Gupta et al. [17] in their prospective

Table 1
IKDC score of the subjects.

IKDC Score	Overall Patient N = 36	Implant-free Group N ₁ = 12	Implant Group N ₂ = 24	p-value	Mean Difference (95% CI)	Power‡	Data Normality§
Pre-operative	40.89 (18.614)	34.38 (13.952)	44.15 (20.023)	0.140	-9.78 (-22.91-3.36)		p ₁ = 0.436 p ₂ = 0.224
Post-operative							
1 Month	24.22 (8.185)	24.03 (6.547)	24.31 (9.023)	0.923	-0.29 (-6.25-5.68)	0.928	p ₁ = 0.778 p ₂ = 0.584
3 Months	52.81 (8.641)	54.89 (6.803)	51.77 (9.386)	0.314	3.12 (-3.08-9.33)	0.996	p ₁ = 0.852 p ₂ = 0.419
6 Months	70.92 (10.361)	73.47 (10.473)	69.65 (10.286)	0.303	3.82 (-3.61-11.26)	0.929	p ₁ = 0.066 p ₂ = 0.177

Results are presented in mean (±SD).

Table 2
Tegner activity level scale of the subjects.

Tegner Scale	Overall Patient N = 36	Implant-free Group N ₁ = 12	Implant Group N ₂ = 24	p-value	Median Difference (95% CI)	Power [‡]	Data Normality [§]
Pre-operative	50.00 (27.25–63.75)	29.00 (18.25–61.75)	54.00 (36.50–63.75)	0.224	–14.5 (–30.0–7.00)		p ₁ = 0.322 p ₂ = 0.297
Post-operative							
1 Months	51.00 (38.50–62.75)	52.50 (49.00–62.75)	44.00 (34.75–62.50)	0.097	8.00 (–1.0–18.0)	0.940	p ₁ = 0.059 p ₂ = 0.077
3 Months	80.50 (70.00–88.00)	84.50 (74.25–88.75)	76.50 (66.25–87.50)	0.280	5.0 (–5.0–16.0)	0.945	p ₁ = 0.053 p ₂ = 0.393
6 Months	95.00 (90.00–100.00)	95.00 (87.00–100.00)	95.00 (90.00–100.00)	0.989	0.0 (–5.0–5.0)	0.405	p ₁ = 0.001 p ₂ = 0.018

Results are presented in median (inter-quartile range) for abnormal data distribution, with millimeter unit measurement.

Table 3
KOOS (Knee injury and Osteoarthritis Outcome Score) score of the subjects.

KOOS	Overall Patient N = 36	Implant-free Group N ₁ = 12	Implant Group N ₂ = 24	p-value	Median Difference (95% CI)	Power [‡]	Data Normality [§]
Pre-operative	60.10 (47.00–71.10)	53.85 (40.05–70.18)	63.10 (50.60–72.75)	0.456	–7.15 (–20.20–8.90)		.587 .059
Post-operative							
1 Month	44.90 (32.55–59.50)	46.10 (42.88–61.00)	44.30 (29.65–57.13)	0.311	4.75 (–4.80–16.60)	0.853	.211 .162
3 Months	78.00 (67.15–84.35)	77.70 (70.20–83.60)	78.00 (66.25–84.50)	0.960	0.00 (–6.50–8.30)	0.804	.208 .082
6 Months	88.40 (83.60–92.45)	90.20 (81.13–90.95)	88.10 (84.65–93.35)	0.999	0.00 (–5.90–4.80)	0.631	.012 .029

Results are presented in median (inter-quartile range) for abnormal data distribution, with millimeter unit measurement.

observational study analyzed more than 400 patients who delayed ACL reconstruction up to 18 years after injury. They found that surgical delay beyond 6 months was significantly associated with damage to the medial meniscus.

Our study found that the overall incidence of associated meniscal injury was 36% for lateral and 22.2% for lateral and medial meniscal injuries, respectively. Although this incidence between lateral and medial meniscus was not statistically significant, it is different from the study by Servin et al. [19] who found that the associated meniscal injury was higher for medial meniscus. They also found that some patient also had a bilateral meniscal tear. The most common tear location was the posterior horn of the medial meniscus, followed by tear involving the whole medial meniscus. Older age, male sex, increased body mass index, and prolonged onset of injury were significant factors for the development of medial meniscus tears. A retrospective study by Papastergiou et al. [18] evaluated the prevalence of ACL injury-associated meniscus tear in 451 patients. They concluded that in subjects with ACL rupture, the prevalence of meniscal tears specifically medial meniscus tears requiring treatment was increased with time, especially at 3 months after injury [18]. They also suggested that reconstruction surgery should be carried out within 3 months after injury in order to prevent secondary meniscal tears [18]. In our study, 16 (44.4%) of 36 subjects had a meniscal injury. Various mechanisms affect the frequency of medial and lateral meniscal tears, including lower limb alignment, load distribution, and delay of intervention. Various mechanisms are affecting the frequency of medial and lateral meniscal tears. They are lower limb alignment, load distribution, and delay of intervention. Biomechanically, the medial meniscus is a secondary stabilizer of the knee against anterior displacement of the tibia in the ACL-injured knee and is subjected to anteroposterior shear forces. On the other hand, the more mobile lateral meniscus is less likely to undergo these shear stresses. This may account for the high incidence of medial meniscus tears in most of the studies. Our study did not meet this usual finding. However, our finding corresponded with the study by Senga et al. who found that percentage of associated lateral meniscal tear was higher

than the medial meniscal tear [20]. This may be due to the previous finding that acute ACL injury was associated with more lateral meniscal tears, while chronic ACL deficiency was associated with more medial meniscal tears. This might explain that most of our cases were acute ACL injuries.

Our data suggest that there was no significant difference in functional outcome whether assessed by rolimeter measurement, IKDC score, Tegner-Lysholm, KOOS score between implant group and implant-free group. This is in line with a study conducted by Wipfler et al. [21] which found that no significant difference in functional outcome after 9 years of follow up. Besides, several studies have shown that implant-free technique with press-fit fixation gives strong stability to the knee and has a satisfactory result [21–24]. A systematic review by van Rhijn et al. [25] concluded that either bone-patellar tendon or hamstring autograft can be selected as the graft for ACL reconstruction due to their similar clinical outcomes. However, specific consideration merits attention, in which ACL reconstruction using bone-patellar tendon is more likely to result in statically stable knee, but is also associated with more complications and osteoarthritis in the future [25, 26]. Bone patellar tendon graft has long been the gold standard for patients with strong functional demand, however, it has a higher risk of complications including extension stiffness and anterior pain. Donor-site morbidity and especially the risk of anterior pain and discomfort kneeling are less observed with hamstring graft choice. Studies recommend the use of hamstring graft for ACL reconstruction in growing children, due to the risk of donor-site growth disorders (tibial tuberosity epiphyseal plate fusion, and risk of *genu recurvatum* induced by the transphyseal tunnel bone-plugs [27].

Harvesting of bone-patellar tendon can result in donor site morbidity and associated postoperative anterior knee pain, patellar fracture or patellar tendon tear, and the potential for graft construct mismatch [27]. However, in our study, no complication associated with bone-patellar graft harvesting occurred. This finding suggested that with the right technique, donor site morbidity associated with bone-patellar bone graft harvesting can be avoided, and its harvesting process could be

successfully performed.

This study is the first prospective study that evaluated implant-free technique with press-fit fixation compared to implant technique with hamstring autograft in Indonesia. Short duration of the follow-up period is the main limitation of our study. Additionally, post op rehabilitation of the patient in both group was not even, and the study did not investigate objective knee function, such as knee range of movement and muscle power. Study with longer follow-up period, same rehabilitation protocol, additional data such as graft tension, range of movement and muscle power would be needed.

5. Conclusion and summary

In conclusion, patients who underwent ACL reconstruction using patella tendon-bone graft fixated by press-fit fixation technique (implant-free) had comparable outcome with ACL reconstruction using implant-fixated hamstring tendon graft, objectively and subjectively. This technique should be further revisited and reevaluated. Further studies with longer follow up duration are required to determine full knee functional capacity comprehensively.

Declaration of competing interest

All authors declare no conflict of interest.

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Author AL, MB, IS YY conceived and designed the study, performed all examinations, acquired, analyzed and interpreted the patient data, and draft the publication work. Author AL also serves as the corresponding author. Author AM analyzed and interpreted the patient data, and draft the publication work. All authors read and approved the final manuscript.

LIST OF ABBREVIATIONS

ACL	Anterior cruciate ligament
MRI	Magnetic resonance imaging
IKDC	International Knee Documentation committee
KOOS	Knee Injury and Osteoarthritis Outcome

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.amsu.2021.102184>.

Provenance and peer review

Not commissioned, externally peer-reviewed.

Ethical approval

This study received ethical approval from the Ethical Clearance Committee board of Universitas Indonesia – Cipto Mangunkusumo Hospital (No. 651/H2.F1/ETIK/2013). All patients were consented to be included in the study and publication of the results.

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Author contribution

Author AL, MB, IS YY conceived and designed the study, performed all examinations, acquired, analysed and interpreted the patient data, and draft the publication work. Author AL also serves as the corresponding author. Author AM analysed and interpreted the patient data, and draft the publication work. All authors read and approved the final manuscript.

Registration of research studies

Name of the registry: ClinicalTrials.gov.

Unique Identifying number or registration ID: NCT04123834.

Hyperlink to your specific registration (must be publicly accessible and will be checked): <https://clinicaltrials.gov/ct2/show/NCT04123834?term=NCT04123834&draw=2&rank=1>.

Guarantor

Author AL and MB accept full responsibility for the work and/or the conduct of the study, had access to the data, and controlled the decision to publish.

Consent

All patients were consented to be included in the study and publication of the results.

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