# RESEARCH



# Single-bundle ACL combined with ALL reconstruction yields comparable outcomes in patients with varied anatomical risk factors for ACL graft failure

Wei-Lun Peng<sup>1</sup>, Yi-Jou Chen<sup>2</sup>, Yu-Chieh Hung<sup>2</sup>, Chin-Shan Ho<sup>3</sup>, Chih-Hao Chiu<sup>2,4</sup>, Alvin Chao-Yu Chen<sup>2,4</sup>, Yi-Sheng Chan<sup>4,5</sup>, Kuo-Yao Hsu<sup>4,6</sup> and Cheng-Pang Yang<sup>2,3,4\*</sup>

# Abstract

**Background** Anterior cruciate ligament (ACL) graft failure is influenced by factors such as meniscal tears and tibial plateau slope. Combined anterior cruciate ligament (ACL) and anterolateral ligament (ALL) reconstruction has reduced failure rates; however, its efficacy in high-risk patients remains unclear. This study hypothesized that combined ACL and ALL reconstruction would yield similar clinical outcomes in patients with varying risks of ACL failure.

**Patients and methods** A total of 76 patients who underwent primary single-bundle ACL reconstruction combined with ALL reconstruction between June 2018 and June 2021 were included. The medial tibial slope (MTS), lateral tibial slope (LTS), and anterior tibial translation (ATT) were measured using magnetic resonance imaging and plain radiography of the knee joint. The meniscal lesions were assessed during surgery. Preoperative clinical assessments and final follow-up were conducted using patient-reported outcome measurements (PROMs), including the International Knee Documentation Committee (IKDC) evaluation, Lysholm knee scoring scale, and Tegner Activity scale. PROMs were collected at least two years postoperatively.

**Results** The average follow-up was  $32.5 \pm 7.4$  months. There were no significant differences in postoperative IKDC score, Lysholm score, or Tegner activity score between patients with or without medial meniscus injury (p=0.155, 0.914, and 0.042, respectively), with or without lateral meniscus injury (p=0.737, 0.569, and 0.942, respectively), medial tibial slope > 12° or ≤ 12° (p=0.290, 0.496, and 0.988, respectively), or lateral tibial slope > 7.4° or ≤ 7.4° (p=0.213, 0.625, and 0.922, respectively). No significant correlations were found between anterior tibial translation and postoperative IKDC (R=-0.058, p=0.365), Lysholm (R=-0.017, p=0.459), or Tegner activity scores (R=-0.147, p=0.189).

**Conclusion** Our study demonstrates that single-bundle ACL reconstruction combined with ALL reconstruction provides reliable and comparable clinical outcomes in patients with high-risk factors for ACL graft failure, such as increased tibial slope or meniscal injury. Our results suggest that the indications for ALL reconstruction may be expanded to include patients with a high tibial slope or meniscal injury, because these factors have been shown to contribute to increased rotational instability and high rates of ACL graft failure. Future prospective randomized controlled trials with large patient cohorts and long follow-up periods are needed to validate these findings and establish clear guidelines for patient selection and surgical decision-making.

\*Correspondence: Cheng-Pang Yang ronnie80097@gmail.com Full list of author information is available at the end of the article



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# Level of evidence Level 3.

**Keywords** Single bundle ACL combined with ALL reconstruction, ACL graft failure, Lateral meniscus injury, Medial meniscus injury, High tibial slope, Anterior tibial translation

# Introduction

Several risk factors for anterior cruciate ligament (ACL) graft failure have been identified. Previous research demonstrated that single-bundle ACL has a graft failure rate of 1.4–18%, [1–3] with only 65% of patients returning to their pre-injury level, and 55% resuming competitive sports [4–7].

Furthermore, the presence of a posterior third medial or lateral meniscal tear (including posterior meniscus root and ramp injuries) during surgery has been associated with an increased risk of high-grade pivot shift (2.6 and 1.8 times higher odds, respectively) and subsequent repeat ACL injury [8]. In patients with multiple ACL failures, the lateral and medial tibial plateau slopes were significantly high [9-11]. A case-control study identified a higher hazard ratio for ACL graft rupture among patients with a medial posterior tibial slope > 12° on radiographs [12]. Previous studies also showed that the most accurate predictor of ACL failure was a lateral tibial slope>7.4° as measured on MRI, which has a sensitivity of 88% and a specificity of 84% [13, 14]. Additionally, several studies have indicated that excessive anterior tibial translation (ATT) are a predictive risk factor for primary ACL reconstruction failure [15-17]. A recent study showed that the ATT of the lateral compartment was significantly larger in patients with an impaired anterolateral ligament (ALL) than in those with an intact ALL. We concluded that an impaired ALL increases the ATT of the lateral compartment after acute ACL injuries, with a flatter lateral femoral condyle and a steeper lateral tibial plateau in the sagittal plane being predictors of a further increase in ATT [18].

Biomechanical studies have demonstrated that the ALL functions as a secondary stabilizer of the ACL, resisting anterior tibial translation and internal tibial rotation [19, 20]. It has also been shown that concurrent reconstruction of the ACL and ALL significantly reduces internal rotation and axial plane tibial translation compared to isolated ACLR in the presence of ALL deficiency [19, 21].

Nonetheless, the impact of single-bundle ACL combined with ALL reconstruction on the high tibial slope in patients with meniscal injury, who carry a higher risk of primary ACL failure, remains unknown.

This approach, which considers both ligamentous and osseous factors, is crucial for optimizing surgical outcomes and reducing the risk of ACL graft failures [23–25].

The primary objective of this study was to evaluate the clinical outcomes of patients who underwent single-bundle ACL reconstruction combined with ALL reconstruction, focusing on those with higher risk factors for ACL graft failure such as an increased tibial slope and meniscal injury. The secondary objectives were to compare the clinical results between patients with higher and lower ACL failure risks and assess the impact of anatomical characteristics on surgical outcomes. We hypothesized that single-bundle ACL reconstruction combined with ALL reconstruction would yield comparable clinical outcomes between patients with higher and lower ACL failure risks, despite the presence of risk factors such as high tibial slope or meniscal injury. This study aimed to provide further insights into the indications for combined ACL and ALL reconstruction, particularly in patients with high-risk anatomical features, ultimately contributing to improved surgical decision-making and patient outcomes.

# **Materials and methods**

# **Patient enrollment**

This single-institution, single-surgeon, retrospective study involved 86 patients with ACL rupture who underwent single-bundle ACL reconstruction combined with ALL reconstruction from June 2018 to June 2021. We excluded patients aged > 50 years and those with a followup period of less than 2 years. Patients were excluded from the study if they underwent any of the following: revision surgery, multi ligamentous injuries, meniscal deficiency requiring transplantation, cartilage lesions treated with concomitant cartilage procedures, or ipsilateral knee surgery.

One patient was lost of follow-up, resulting in a total of 76 patients for analysis.

# **Radiological assessment**

We measured the medial tibial slope (MTS), lateral tibial slope (LTS), and anterior tibial translation (ATT) using magnetic resonance, as all patients underwent preoperative MRI and plain radiography of the knee joints.

#### Surgical technique

Single-bundle ACL combined with ALL reconstruction was performed using the method designed by Sonnery-Cottet, which included three additional incisions to allow graft insertion for ALL reconstruction: proximal and posterior to the lateral epicondyle of the femur, 1 cm posterior to Gerdy's tubercle, and 1 cm anterior to the head of the fibula. These locations corresponded to the anatomical positions of the anterolateral ligament. The graft for this method was a hamstring autograft, with the ACL reconstructed using a tripled semitendinosus tendon, and the ALL reconstructed using a gracilis tendon graft sutured to the tripled semitendinosus tendon [22]. The meniscus injury were repaired, if present. The tunnel positions were uploaded as shown in Figure 1.

Postoperatively, patients followed different rehabilitation paths based on their surgical details. Those without meniscus repair started with no brace, immediate continuous passive motion (CPM), and crutches for two weeks before transitioning to full weight bearing.

In contrast, meniscal repair patients wear a Range of Motion (ROM) brace for six weeks, limit flexion to  $0^{\circ}$ - $60^{\circ}$  for four weeks, and then allow full range of motion. They used crutches for partial weight-bearing during the first four weeks.

All patients progressed to jogging at three months, sprinting and competitive exercises at six months, and full sports activities by nine months, marking the end of rehabilitation and return to preinjury function.

# **Clinical and functional evaluation**

Preoperative clinical assessments and final follow-up were conducted using patient-reported outcome measures (PROMs), including the International Knee Documentation Committee (IKDC) evaluation, Tegner activity scale, [26] and Lysholm score [27]. Internal tibial rotation was determined manually using the pivot shift test and any pain at the ALL attachment sites was recorded.

Subgroup analyses were conducted by dividing the cohort into different groups based on the slope angle. Previous studies have demonstrated that a higher hazard ratio for ACL graft rupture was identified in patients with a medial posterior tibial slope > 12° on X-ray [12], and the most accurate predictor of ACL failure was a lateral tibial slope > 7.4° measured on MRI [13, 14].

In addition, we compared postoperative outcomes between patients with and without medial/lateral meniscal injury, as both factors were found to be associated with ACL graft failure in prior studies [8, 28, 29]. Finally, we evaluated the correlation between clinical outcomes and preoperative anterior tibial translation as measured on MRI [14, 17].

# Statistical analysis

Data were analyzed using SPSS Statistics (version 25.0). Armonk, NY: IBM Corp). We compared two independent samples using the Mann-Whitney U test, with a cutoff significance value of P < 0.05. Correlations between the MTS and outcomes, LTS and outcomes, and anterior tibial translation and outcomes were calculated using the Pearson Correlation Coefficient.

# Results

# **Patient demographics**

Demographic data are presented in Table 1; radiographic assessments, in Table 2; and clinical assessments, in Table 3. All patients were followed up for a minimum of 2 years. One patient experienced graft failure in a traffic accident, and revision surgery was performed 1 year after the primary reconstruction.

# Medial meniscus injury versus no medial meniscus injury

Seventy-six patients were included in this total of 76 patients. Among the 24 patients with a medial meniscal injury, the IKDC score averaged 76.6, the Lysholm score was 91.2, and the Tegner activity score was 6.5. In contrast, among the 52 patients without a medial meniscal injury, the IKDC score averaged 71.8, Lysholm score 91.1, and Tegner activity score 5.6. The *P* value for the IKDC score, Lysholm score, and Tegner activity score between the two groups were 0.155, 0.914, and 0.042, respectively. No significant differences were found in IKDC or Lysholm scores between the two groups; however, the Tegner activity score was significantly higher in patients with medial meniscal injury. Table 4 presents the results of the study.

#### Lateral meniscus injury versus no lateral meniscus injury

Among the 32 patients with a lateral meniscal injury, the average IKDC score was 73.8, the Lysholm score was 92.3, and the Tegner activity score was 5.8. Among the 44 patients without a lateral meniscal injury, the IKDC score averaged 73.0, Lysholm score was 90.2, and Tegner activity score was 5.9. The P value for the IKDC score between the two groups was 0.737 for the Lysholm score, and 0.569 and 0.942, respectively. There were no significant differences in the IKDC, Lysholm, and Tegner activity scores between the two groups. Table 5 presents the results.

#### Correlation of medial tibial slope and subjective outcomes

The correlation between the medial tibial slope (MTS) and subjective outcomes (including IKDC score, Lysholm score, and Tegner activity score) was evaluated using the Pearson Correlation Coefficient. The *R*-value of the MTS with IKDC score was 0.124 (P=0.229), with a Lysholm score of 0.206 (P=0.108), and with the Tegner score, it was 0.046 (P=0.391). No correlations were found between MTS and IKDC, Lysholm, or Tegner activity scores. The results are shown in Figs. 2, 3 and 4.

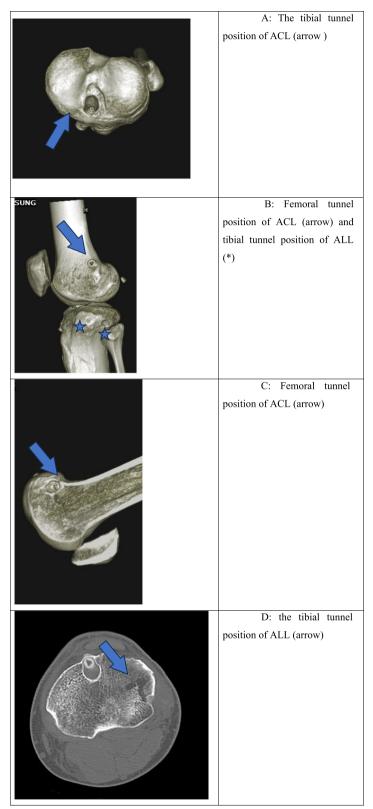


Fig. 1 A The tibial tunnel position of ACL (arrow). B Femoral tunnel position of ACL (arrow) and tibial tunnel position of ALL (\*). C Femoral tunnel position of ACL (arrow). D the tibial tunnel position of ALL (arrow)

 Table 1
 Demographic data for all patients

Variable	Value
Follow up (months)	32.5±7.4
Sex (Male)	56 (73.7%)
Age (Year)	29.6±8.3
BMI (kg/ m <sup>2</sup> )	25.2±3.6
Comorbidities (Obesity)	8 (10.5%)
Professional athletes	8 (10.5%)
Graft failure	1 (1.3%)

Table 2	Radiographic	assessment for	all patients
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Variable	Value
Meniscus injury	
Medial	24 (31.6%)
Lateral	32 (42.1%)
X ray- Medial tibial slope (°)	11.4±3.3
MRI	
Medial tibial slope (°)	4.5±3.9
Lateral tibial slope (°)	$3.9 \pm 3.7$
Anterior tibial translation (°)	$2.4 \pm 3.5$

Table 3 Clinical assessment (function data) for all patients

Variable	Value
Pivot shift (Before operation)	
Grade 0	0
Grade 1	0
Grade 2	20
Grade 3	56
Pivot shift (After operation)	
Grade 0	74(97.3%)
Grade 1	2
Grade 2	0
Grade 3	0
Complication	
Superficial wound infection	2
hemoarthrosis	3
Lateral knee pain	1

**Table 4**Comparison of PROM between injured and intactmedial meniscus groups

	MM injured (24)	MM intact (52)	P value
IKDC score	76.6±8.4	71.8±10.2	0.155
Lysholm score	91.2±7.6	91.1±9.4	0.914
Tegner activity score	$6.5 \pm 1.2$	5.6±1.0	0.042

0.942

meniscus groups. (preop proms)			
	LM injured (32)	LM intact (44)	P value
IKDC score	73.8±10.1	73.0±9.8	0.737
Lysholm score	92.3±7.8	$90.2 \pm 9.5$	0.569

59 + 12

58 + 13

Tegner activity score

 Table 5
 Comparison of PROM between injured and intact lateral

Among the 36 patients with a medial tibial slope > 12°, the IKDC score averaged 75.4, Lysholm score was 92.6, and Tegner activity score was 5.9. Conversely, among the 40 patients with a medial tibial slope  $\leq$  12°, the IKDC score averaged 71.4, the Lysholm score was 89.8, and the Tegner activity score was 5.8.

The P values for the IKDC score between these two groups were 0.290, 0.496 for the Lysholm score, and 0.988 for the Tegner activity score. No significant differences were found in the IKDC, Lysholm, and Tegner activity scores between the two groups. Table 6 presents the results.

# Lateral tibial slope and subjective outcomes

The correlation of the lateral tibial slope (LTS) with subjective outcomes, including IKDC, Lysholm, and Tegner activity scores, was evaluated using the Pearson Correlation Coefficient. The *R*-values of LTS with the IKDC, Lysholm, and Tegner scores were 0.061 (P=0.357), 0.103 (P=0.268), and 0.266 (P=0.054), respectively. There were no significant correlations between the LTS and the IKDC, Lysholm, or Tegner activity scores. The results are shown in Figs. 5, 6 and 7.

In the subgroup of 12 patients with a lateral tibial slope >7.4°, the average IKDC score was 78.3, Lysholm score was 93.2, and Tegner activity score was 5.8. Among the 64 patients with a lateral tibial slope  $\leq$ 7.4°, the average IKDC score was 72.4, the Lysholm score was 90.7, and the Tegner activity score was 5.9. The *P* value for the IKDC score between these two groups was 0.213 for the Lysholm score, and 0.625 and 0.922, respectively. No significant differences were found in the IKDC, Lysholm, or Tegner activity scores between the two groups. Table 7 presents the results.

# Correlation of anterior tibial translation and subjective outcomes

None of the patients in our study had an anterior tibial translation (ATT) > 10 mm. Thus, we measured the correlation between ATT and subjective outcomes, including IKDC, Lysholm, and Tegner activity scores, using the Pearson Correlation Coefficient. The *R*-values of ATT with the IKDC, Lysholm, and Tegner scores were -0.058 (P=0.365), -0.017 (P=0.459), and -0.147 (P=0.189),

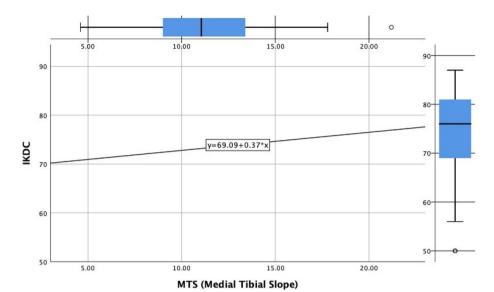


Fig. 2 The Pearson Correlation Coefficient between MTS (medial tibial slope) and IKDC score, R = 0.124 (P = 0.229)

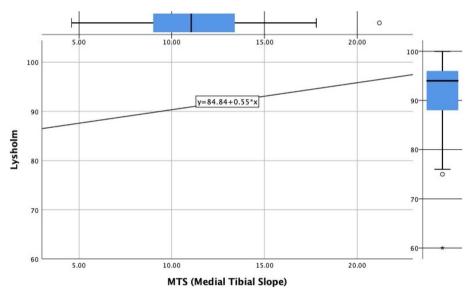


Fig. 3 The Pearson Correlation Coefficient between MTS (medial tibial slope) and Lysholm score, R = 0.206 (P = 0.108))

respectively. There were no significant correlations between ATT and IKDC, Lysholm, or Tegner activity scores. The results were listed in Figs. 8, 9 and 10.

# Discussion

Our study found that single-bundle ACL combined with ALL reconstruction yielded similar clinical outcomes among patients with high and low ACL failure risks, including those with medial or lateral meniscus injuries and increased posterior tibial slopes. One patient (1.3%) experienced graft failure within the 2-year follow-up period and 97.3% had a grade 0 pivot shift on postoperative physical examination. Furthermore, there were no significant differences in IKDC, Lysholm, and Tegner activity scores between patients with or without lateral meniscus injuries, higher or lower medial tibial slope, and higher or lower lateral tibial slope. Furthermore, no significant correlations were found between anterior tibial translation and postoperative PROMS.

Previous research has demonstrated that single-bundle ACL reconstruction may result in less favorable clinical outcomes in patients with high risk factors such as

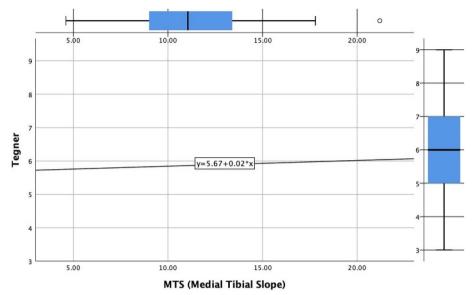


Fig. 4 The Pearson Correlation Coefficient between MTS (medial tibial slope) and Tegner score, R = 0.046 (P = 0.391)

**Table 6** (preop proms). Comparison of PROM between medial tibial slope >  $12^{\circ}$  and medial tibial slope  $\leq 12^{\circ}$  groups

	MTS > 12° (36)	$MTS{\leq}12^{\circ}(40)$	P value
IKDC score	$75.4 \pm 7.7$	71.4±11.2	0.290
Lysholm score	92.6±7.1	89.8±10.1	0.496
Tegner activity score	$5.9 \pm 1.2$	$5.8 \pm 1.2$	0.988

medial meniscus injury, lateral meniscus injury, and increased posterior tibial slope. These factors are associated with a high-grade pivot shift and greater instability, which can result in repeated ACL reconstruction failures [8-11, 30-33].

Surgical indications for single-bundle ACL combined with ALL reconstruction included factors such as grade

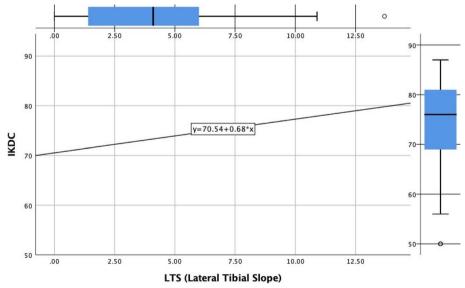


Fig. 5 The Pearson Correlation Coefficient between LTS (lateral tibial slope) and IKDC score, R = 0.061 (P = 0.357)

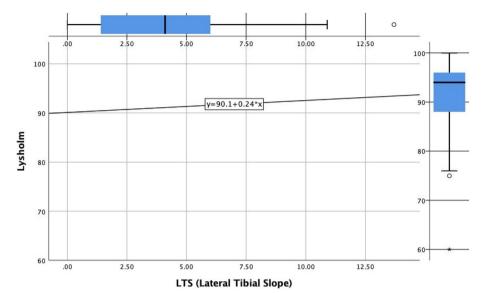


Fig. 6 The Pearson Correlation Coefficient between LTS (lateral tibial slope) and Lysholm score, R = 0.103 (P = 0.268)

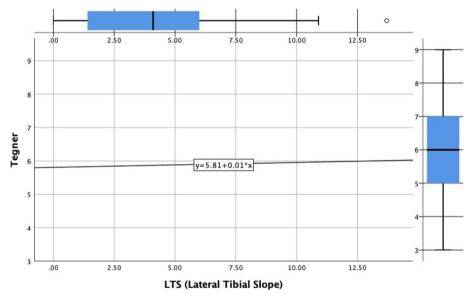
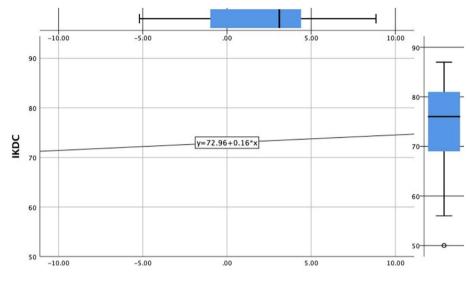


Fig. 7 The Pearson Correlation Coefficient between LTS (lateral tibial slope) and Tegner score, R = 0.266 (P = 0.054)

Table 7 (preop proms). Comparison of PROM between later	al
tibial slope > 7.4° and lateral tibial slope $\leq$ 7.4° groups	

	LTS > 7.4° (12)	LTS $\leq$ 7.4° (64)	P value
IKDC score	78.3±4.0	72.4±10.3	0.213
Lysholm score	$93.2 \pm 6.9$	$90.7 \pm 9.1$	0.625
Tegner activity score	$5.8 \pm 1.0$	$5.9 \pm 1.3$	0.922

III pivot shift, associated Segond fracture, chronic ACL rupture, high levels of sporting activity, participation in pivoting sports, age  $\leq 25$  years, preoperative side-to-side laxity >7 mm, lateral femoral notch sign on plain radiographs, and revision ACL reconstruction [4]. Recent literatures also suggests that the lateral extra-articular procedure (LEAP) should be performed in skeletally



**ATT (Anterior Tibial Translation)** 

Fig. 8 The Pearson Correlation Coefficient between ATT (anterior tibial translation) and IKDC score, R=-0.058 (P=0.365)

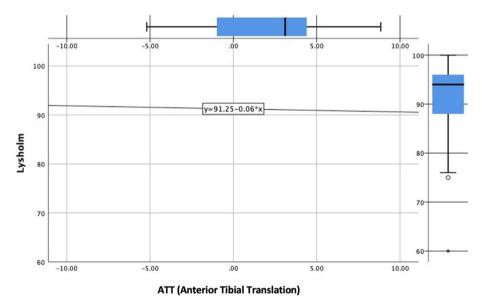


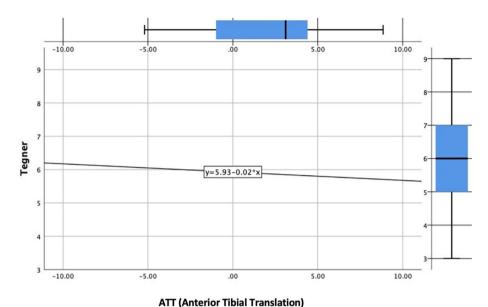
Fig. 9 The Pearson Correlation Coefficient between ATT (anterior tibial translation) and Lysholm score, R=-0.017 (P=0.459)

immature adolescent patients and professional athletes [34–36]. A recent study by Hopper et al. investigated the risk factors of ACL graft failure in professional athletes. The authors found that athletes who underwent isolated ACLR had a significantly higher graft failure rate than those who underwent combined ACLR and LEAP (15.5% vs. 6.0%, p=0.0105). Additionally, athletes aged 21 years or younger were at a higher risk of graft failure compared to older athletes (13.8% vs 6.6%, p=0.0290). Multivariate analysis revealed that athletes undergoing isolated ACLR

had more than a twofold risk of ACL graft rupture (HR 2.678, 95% CI 1.173–4.837, p=0.0164) than those undergoing combined ACLR and LEAP [34].

However, their studies did not list any anatomical parameters as indications.

Researches conducted by Batty et al. and Parkinson et al. suggested that meniscal injuries, specifically in the posterior third, increase the odds of a high-grade pivot shift and can be predictive of graft failure in singlebundle ACL reconstruction [8, 28, 29]. On the other



**Fig. 10** The Pearson Correlation Coefficient between ATT (anterior tibial translation) and Lysholm score, R = -0.147 (P = 0.189)

hand, our study indicates that when patients undergo ACL combined with ALL reconstruction, outcomes are not influenced by the presence or absence of meniscus injury.

Studies by Grassi et al. and Ni et al. demonstrated a connection between higher tibial plateau slopes and an increased risk of ACL reconstruction failure [9, 16, 37]. Tanaka et al. found that patients who failed ACL reconstruction had significantly greater anterior displacement of the lateral plateau compared to patients with acute ACL injuries, suggesting that excessive anterior tibial subluxation of the lateral compartment can be indicative of ACL reconstruction failure [15].

In our study, patients who underwent single-bundle ACL reconstruction combined with ALL reconstruction exhibited no significant differences in outcomes based on the presence or absence of medial meniscal injuries, lateral meniscal injuries, or variations in the medial or lateral tibial slope. These findings support our hypothesis that single-bundle ACL combined with ALL reconstruction can yield similar clinical outcomes in patients with different levels of ACL failure risk. Our results may provide the possibility of considering these preoperative characteristics as indications for ACL reconstruction combined with ALL reconstruction; however more research is needed to support this.

A growing body of literature has examined the outcomes of combined ACL and ALL reconstruction, suggesting that more parameters should be explored in future studies focusing on combined ACL+ALL and ALL reconstruction [20, 21, 34, 38, 39].

In terms of the Tegner activity score (TAS), patients with medial meniscus (MM) injuries exhibited significantly superior scores than those without medial meniscus (non-MM) injuries. To clarify this finding, we recalculated the TAS to compare the change from preinjury to post-surgery ( $\Delta$ TAS). There was no significant difference in TAS between patients with and without meniscal injuries (p = 0.343). Looking at the pre-injury data, the TAS score for patients with MM injuries was 7.17, compared to 6.65 for patients without MM injuries. The higher pre-injury TAS score in the MM injury group may explain the superior post-surgical TAS score observed in these patients.

# Limitations

Despite providing valuable insights, this study has several limitations that should be considered. First, its retrospective, non-randomized design limits the conclusiveness regarding the superiority of ACL reconstruction combined with ALL reconstruction over ACL reconstruction alone owing to the absence of a control group. Additionally, the lack of preoperative and postoperative KT1000 or KT2000 arthrometer measurements precludes a more objective evaluation of ACL ligament strength. These measurements may have contributed a robust quantitative aspect to our findings. Third, the follow-up period of 2–3 years, although adequate for preliminary conclusions, may not fully capture the long-term outcomes of surgical interventions.

Another limitation of our study was the relatively small sample size of each comparison group; therefore, the study may have been underpowered to detect significant differences in clinical outcomes between the compared groups. Future research with larger sample sizes is needed to confirm our findings and further investigate the potential impact of these anatomical factors on the outcomes of combined ACL and ALL reconstruction."

This study was conducted by a single surgeon to maintain consistency in surgical technique, focusing on the impact of combined ACL and ALL reconstruction across different patient groups. Although this approach ensures procedural uniformity, it also introduces limitations regarding the generalizability of the outcomes. The combined ACL and ALL reconstruction technique, which is technically more demanding, may yield varying results when performed by less experienced surgeons. Future studies involving multiple surgeons with varying levels of expertise may provide a broader perspective on the reproducibility and general applicability of these findings.

# Conclusion

Our findings suggest that single-bundle ACL combined with ALL reconstruction can yield similar clinical outcomes in patients with a higher risk of ACL graft failure during primary surgery. Future studies should focus on combined ACL+ALL and ALL reconstruction in patients with varying anatomical differences. These findings may broaden the indications for ACL-combined ALL reconstruction in primary ACL reconstruction.

#### Code availability

Not applicable

#### Authors' contributions

C.-P.Y., K.-Y.H: Conceived and planned the case report. Supervised and revised the manuscript. Alvin C.-Y.C.,Y.-S., C., C.-H.Chiu. contributed to data acquisition. P.-W.L.: wrote the manuscript. Y.-J, C., Y.-C.H.: collected PROMS data. C.-S.H.: statistical analysis. All authors have read and agreed to the published version of the manuscript.

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#### Availability of data and materials

The dataset supporting the conclusions of this article is available from the corresponding author on reasonable request.

### Declarations

#### Ethics approval and consent to participate

This level 3 retrospective therapeutic trial was approved by the Institutional Review Board of the Chang Gung Medical Foundation Institutional Review Board (202300134B0).. All methods were performed in accordance with relevant guidelines and regulations. Patient consent was waived because of ethical clearance from the Linkou Chang Gung Memorial Hospital when anonymized clinical data were used for retrospective analysis.

#### **Consent for publication**

Not applicable.

#### **Competing interests**

The authors declare no competing interests.

#### Author details

<sup>1</sup>Department of Orthopedic Surgery, MacKay Memorial Hospital, Taipei City, Taiwan. <sup>2</sup>Department of Orthopedic Surgery, Linkou Chang Gung Memorial Hospital, Taoyuan City 333, Taiwan. <sup>3</sup>Graduate Institute of Sports Science, National Taiwan Sport University, Taoyuan, Taiwan. <sup>4</sup>Comprehensive Sports Medicine Center, Taoyuan Chang Gung Memorial Hospital, Taoyuan City 333, Taiwan. <sup>5</sup>Department of Orthopedic Surgery, Keelung Chang Gung Memorial Hospital, Keelung City 204, Taiwan. <sup>6</sup>Department of Orthopedic Surgery, Tucheng Hospital, Ministry of Health and Welfare, New Taipei City, Taiwan.

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