

Original Article

# Randomized controlled trial comparing clinical and functional outcomes of bone-patellar tendon-bone and hamstring tendon autografts in ACL reconstruction

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## ABSTRACT

**Objectives:** The purpose of this randomized trial was to compare the clinical and functional outcomes of anterior cruciate ligament reconstruction (ACLR) using hamstring tendon (HT) and bone-patellar tendon-bone (BTB) autografts.

**Materials and Methods:** Thirty-eight patients with isolated ACL injuries were randomized to undergo ACLR using either HT ( $n = 19$ ) or BTB ( $n = 19$ ) autografts. All procedures were performed using an anatomic single-bundle arthroscopic technique. Patients were evaluated preoperatively and at 12 months postoperatively using the International Knee Documentation Committee (IKDC) score, rolimeter testing, Lachman and pivot-shift tests, single-leg hop test, and range of motion.

**Results:** Both groups demonstrated significant post-operative improvement across all parameters. The mean IKDC score was  $82.6 \pm 6.3$  in the HT group and  $83.2 \pm 5.9$  in the BTB group. No significant differences were observed between groups in terms of knee stability, hop test performance, or return-to-sport rates. No complications or graft failures occurred during follow-up.

**Conclusion:** ACLR using either HT or BTB autografts provided comparable clinical and functional outcomes at 1-year follow-up. Graft choice should be individualized based on patient characteristics and surgeon preference.

**Keywords:** Anterior cruciate ligament, Autograft, Bone-patellar tendon-bone, Hamstring tendon, Reconstruction

## INTRODUCTION

Anterior cruciate ligament (ACL) injury is one of the most common and functionally disabling knee injuries encountered in orthopedic practice, particularly among young and physically active individuals.<sup>[1]</sup> The ACL plays a vital role in maintaining knee stability by resisting anterior tibial translation (ATT) and providing rotational control.<sup>[2]</sup> Untreated ACL injuries are strongly associated with functional instability, meniscal tears, chondral damage, and the development of early post-traumatic osteoarthritis.<sup>[3]</sup> Surgical reconstruction remains the gold standard treatment for symptomatic ACL deficiency in active patients, aiming to restore knee kinematics, allow safe return to sports, and prevent further intra-articular damage.<sup>[4]</sup> Among the various graft choices, the two most commonly used autografts are the bone-patellar tendon-bone (BTB) and the hamstring tendon (HT). Each graft has distinct biomechanical and clinical characteristics influencing surgeon preference and patient outcomes.<sup>[5]</sup>

BTB grafts are often considered the “gold standard” due to rigid bone-to-bone fixation and faster healing at the tunnel interfaces, but they are associated with donor-site morbidity, including anterior knee pain and kneeling discomfort.<sup>[6]</sup> HT grafts provide lower donor-site morbidity and reduced anterior knee pain but may have slower graft incorporation and higher laxity in some athletic populations.<sup>[7]</sup> Several recent systematic reviews and randomized studies have debated the superiority of one graft over the other, with most concluding that no definitive consensus exists regarding clinical outcomes or return-to-sport rates.<sup>[8-10]</sup> Moreover, recent publications have expanded the debate by introducing quadriceps tendon and other grafts as alternatives, highlighting the need for further high-quality randomized controlled trials (RCTs) that directly compare BTB and HT autografts in modern surgical settings.<sup>[11,12]</sup> In light of this ongoing debate, and given the limited RCT data from the Middle Eastern population, we designed this

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prospective RCT to compare the clinical and functional outcomes of ACL reconstruction using HT versus BTB autografts. We hypothesized that both grafts would yield equivalent stability and functional results at 1-year follow-up, allowing for an evidence-based approach to personalized graft selection.

## MATERIALS AND METHODS

### Study design and setting

This study was a prospective RCT conducted at Kasr Al-Ainy Medical School Hospital, Cairo University, Egypt, between February 2020 and March 2022. The study was approved by the institutional review board, and written informed consent was obtained from all patients before participation in the study. The trial adhered to the ethical standards of the Declaration of Helsinki and was conducted and reported in accordance with the CONSORT 2010 guidelines.<sup>[13]</sup>

### Patient selection

A total of 40 patients presenting with isolated ACL rupture were assessed for eligibility. After applying inclusion and exclusion criteria, 38 patients were enrolled in the study and randomized equally into two groups: 19 patients underwent ACL reconstruction using HT autografts, and 19 patients received BTB autografts.

### Inclusion criteria

Patient age between 18 and 55 years, symptomatic, magnetic resonance imaging-confirmed complete ACL tear, no radiological evidence of osteoarthritis > grade II (Kellgren-Lawrence), normal contralateral knee, and patient willingness and ability to comply with rehabilitation and follow-up.

### Exclusion criteria

Patients with multiligamentous knee injury, previous surgery on the affected knee, contralateral knee pathology, systemic disease affecting healing (e.g., diabetes, rheumatoid arthritis), and active infection or open wounds.

### Randomization and blinding

Randomization was performed using a sealed opaque envelope technique immediately before surgery to ensure allocation concealment. Group allocation was blinded from both the patient and the independent senior physiotherapist who performed post-operative outcome assessments, thereby ensuring blinded evaluation. A CONSORT flow diagram summarizing the patient enrollment, allocation, follow-up, and analysis is presented in the Results section.

### Surgical techniques

All procedures were performed arthroscopically under spinal or general anesthesia by senior orthopedic consultants trained in sports surgery. Standard diagnostic arthroscopy

was first conducted to confirm ACL rupture and rule out any additional intra-articular injuries.

### HT group

The semitendinosus and gracilis tendons were harvested through a small oblique incision over the pes anserinus. After tendon debridement and preparation, tendons were quadrupled and secured using whipstitch sutures. Anatomic single-bundle ACL reconstruction was performed. The femoral tunnel was drilled through the anteromedial portal with the knee in deep flexion (120°). Both femoral and tibial fixation were achieved using bioabsorbable interference screws.

### Patellar tendon group (BTB)

A central-third BTB graft measuring approximately 10 mm wide and 25 mm long, with tibial and patellar bone plugs, was harvested through a longitudinal midline incision. Bone ends were shaped into trapezoids for anatomical fit. Tunnel placement was done similarly to the HT group. Bone-to-bone fixation was achieved using biodegradable interference screws of appropriate diameter. Special care was taken to minimize donor site morbidity. All patients underwent the same arthroscopic technique for femoral and tibial tunnel preparation, graft passage, and tensioning.

### Post-operative rehabilitation

A standardized rehabilitation protocol was followed in both groups, designed in accordance with current evidence-based guidelines:<sup>[14,15]</sup>

- Day 1–7: Isometric quadriceps activation, cryotherapy, and passive range of motion (ROM) 0–90°
- Week 2–6: Progressive weight bearing with crutches; closed-chain exercises; proprioception training
- Month 3: Jogging and low-impact sports-specific drills if quadriceps strength  $\geq 80\%$  of contralateral limb
- Month 6–8: Return to full sport allowed if hop test and strength assessments  $\geq 90\%$  symmetric.

Patients were reviewed at 1, 3, 6, and 12 months postoperatively. Primary and secondary outcomes were recorded at baseline and at the 12-month follow-up for analysis.

### Statistical analysis and data interpretation

#### Sample size

Sample size was calculated using Power Analysis and the Sample Size software program version 15.0.5 for Windows (2017) using the results published by Baur *et al.*<sup>[16]</sup> with the post-operative clinical and functional outcome was assessed by the Tegner activity scale as the primary outcome. Patients were allocated into two groups: Group I (BTB group) and Group II (HT group). The null hypothesis was considered as the presence of a difference between both treatment modalities regarding the total post-operative

Tegner activity scale (non-inferiority study). A sample size of 15 patients in each group was needed to achieve 90% power ( $1-\beta$ ) in the proposed study using a one-sided two-sample unequal-variance t-test with a margin of non-inferiority of 1.0 and significance level  $\alpha$  of 5%. Four patients dropped out, so 19 patients were enrolled in each group.

### Data analysis

Data analysis was performed by the Statistical Package for the Social Sciences (SPSS) software, version 25 (SPSS Inc., PASW Statistics for Windows version 25. Chicago: SPSS Inc.). Qualitative data were described using numbers and percent. Quantitative data were described using median (minimum and maximum) for non-normally distributed data and mean±standard deviation for normally distributed data after testing normality using the Kolmogorov–Smirnov test. Significance of the obtained results was judged at the ( $\leq 0.05$ ) level.

Chi-square or Fisher's exact test was used to compare qualitative data between groups.

Mann–Whitney U test was used to compare between 2 studied groups for non-normally distributed data.

Student's t-test was used to compare 2 independent groups for normally distributed data.

A paired t-test was used to compare 2 paired readings for normally distributed data.

## RESULTS

In our study, the mean age was  $31.14 \pm 2.41$  in the HT group and  $31.10 \pm 2.53$  in the BTB group. The two groups were analyzed and showed no statistically significant difference ( $P = 0.8$ ). Similarly, there were no statistically significant differences in patient weight ( $P = 0.9$ ) or duration of symptoms until surgery ( $P = 0.07$ ). Both groups were comparable in these parameters [Table 1].

A CONSORT flow diagram of patient enrollment, randomization, and follow-up is provided [Figure 1].

### Primary outcomes

The primary outcomes were ATT using a rolimeter (measured in mm), Lachman and pivot shift tests (graded 0–2), and the single-leg hop distance test (in cm) [Figure 2].

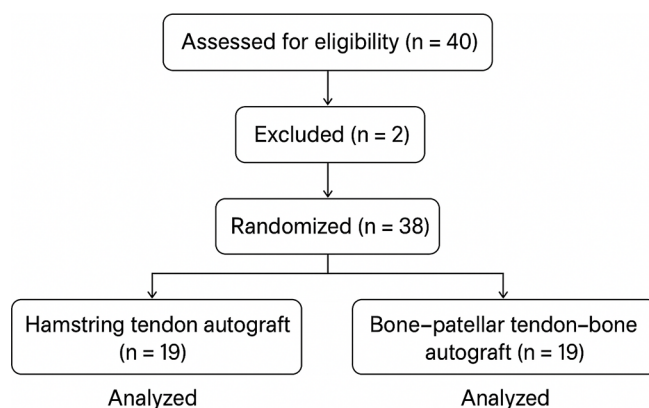
### Secondary outcomes

The secondary outcomes were Subjective International Knee Documentation Committee (IKDC) score (validated Arabic version), ROM measured with a goniometer, return to sport activity level, and post-operative complications (e.g., infection, graft failure, anterior knee pain). All clinical evaluations were performed by a trained orthopedic surgeon [Figure 2].

**Table 1:** Baseline demographic and clinical characteristics of patients undergoing ACL reconstruction with HT and BTB autografts.

Variable	HT group (mean±SD)	BTB group (mean±SD)	P-value
Age (years)	31.15±2.43	31.10±2.53	0.800
Body weight (kg)	74.42±5.08	74.47±4.73	0.900
Symptom duration (months)	12.42±10.34	7.94±4.09	0.070

ACL: Anterior cruciate ligament, HT: Hamstring tendon, BTB: Bone-patellar tendon-bone, SD: Standard deviation. Significance level:  $P < 0.05$ .



**Figure 1:** CONSORT flow diagram showing patient enrollment, randomization, allocation to treatment groups, follow-up, and final analysis.

## DETAILED RESULTS

### Patient demographics and baseline characteristics

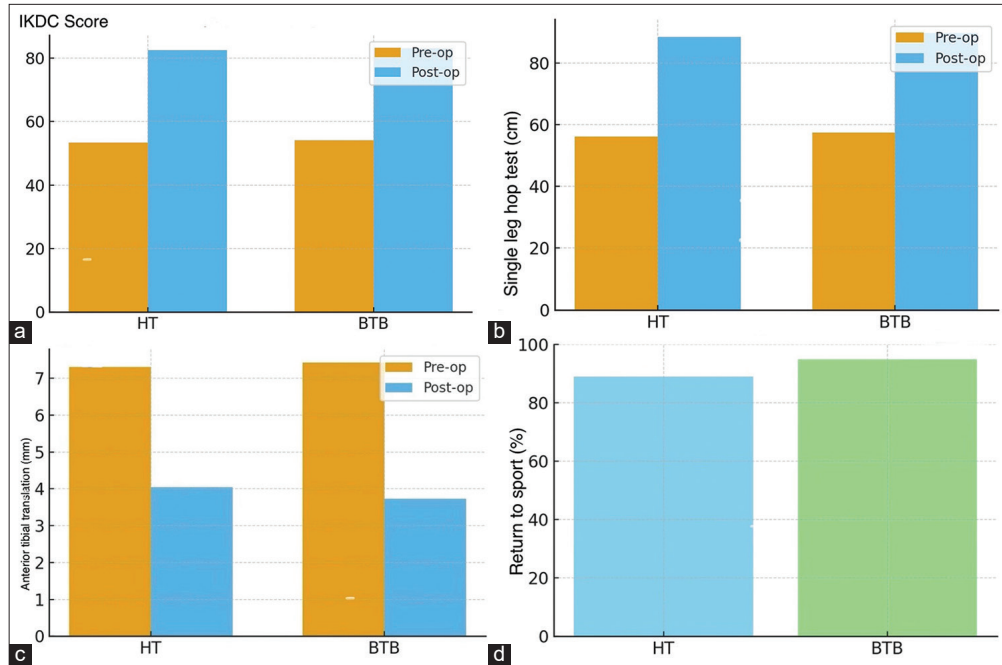
A total of 38 patients (19 in the HT group and 19 in the BTB group) were included in the final analysis. No statistically significant differences were observed between groups in terms of demographic data or symptom duration. These comparable baseline characteristics support the internal validity of the trial [Figure 1].

### Anterior knee laxity - rolimeter test

Both groups showed statistically significant improvements in ATT from pre-operative to post-operative evaluations:

- Pre-operative ATT (injured knee): HT group:  $7.31 \pm 1.94$  mm, BTB group:  $7.42 \pm 2.24$  mm,  $P = 0.8$ .
- Post-operative ATT at 12 months: HT group:  $4.05 \pm 1.08$  mm, BTB group:  $3.73 \pm 0.99$  mm,  $P = 0.3$ .
- Side-to-side difference (post-op): HT:  $2.58 \pm 0.77$  mm, BTB:  $2.42 \pm 0.69$  mm,  $P = 0.5$ .

Although the BTB group had slightly less residual laxity, the difference was not statistically or clinically significant. These values are within acceptable thresholds reported in comparative studies<sup>[17-19]</sup> [Table 2].



**Figure 2:** Clinical and functional outcomes at 12 months comparing hamstring tendon (HT) and bone-patellar tendon-bone (BTB) autografts: (a) International Knee Documentation Committee (IKDC) subjective score (pre- and post-operative). (b) Single-leg hop test distance (pre- and post-operative). (c) Anterior tibial translation measured with a rolimeter (pre- and post-operative). (d) Return-to-sport rates at final follow-up.

**Table 2:** Clinical and functional outcomes at 12 months in patients undergoing ACL reconstruction with HT and BTB autografts, including anterior tibial translation, clinical stability tests (Lachman and pivot shift), IKDC subjective score, range of motion, single-leg hop test, return-to-sport rates, and complications.

Outcome	HT group (n=19)	BTB group (n=19)	P-value
Anterior tibial translation (mm) - Preop	7.31±1.94	7.42±2.24	0.8
Anterior tibial translation (mm) - Postop	4.05±1.08	3.73±0.99	0.3
Side-to-side difference (mm) - Postop	2.58±0.77	2.42±0.69	0.5
Lachman test Grade 0/I/II (%)	26/58/16	26/53/21	0.6
Pivot shift negative/trace (%)	89	95	0.3
IKDC score – Pre-op	53.4±8.2	54.1±7.9	0.7
IKDC			

ACL: Anterior cruciate ligament, HT: Hamstring tendon, BTB: Bone-patellar tendon-bone, IKDC: International Knee Documentation Committee. Significance level:  $P < 0.05$ .

**Clinical stability - Lachman and pivot shift tests**

Lachman test (12 months): Grade 0 (firm endpoint): HT = 26%, BTB = 26%; Grade I: HT = 58%, BTB = 53%; Grade II: HT = 16%, BTB = 21%,  $P = 0.6$ .

Pivot Shift test (Grade 0/1): Negative/trace pivot shift: HT = 89%, BTB = 95%,  $P = 0.3$ .

These results demonstrate equivalent graft stability at 1-year follow-up [Table 2].

**Functional outcome - IKDC subjective score**

The IKDC subjective score improved significantly in both groups from baseline to final follow-up:

- Pre-operative IKDC: HT = 53.4 ± 8.2, BTB = 54.1 ± 7.9,  $P = 0.7$ .
- Post-operative IKDC (12 months): HT = 82.6 ± 6.3, BTB = 83.2 ± 5.9,  $P = 0.8$ .

The improvements were clinically significant and mirror those observed in high-volume registry-based trials<sup>[20,21]</sup> [Table 2].

**ROM**

Extension: Full extension (0°) was achieved by all patients except one in the HT group, who had a persistent 5° lag.

Flexion: Mean flexion  $>130^\circ$  in both groups at 12 months,  $P = 0.9$ .

ROM recovery was excellent overall and comparable to previous studies<sup>[22]</sup> [Table 2].

### Single-leg hop test

Pre-operative hop distance: HT =  $56.2 \pm 4.9$  cm, BTB =  $57.4 \pm 5.1$  cm,  $P = 0.6$ .

Post-operative hop distance (12 months): HT =  $88.4 \pm 6.2$  cm, BTB =  $89.7 \pm 5.7$  cm,  $P = 0.5$ .

This test reflects successful restoration of dynamic knee function in both groups [Table 2].

### Return to sport and complications

Return to previous sport level: HT = 89%, BTB = 95%,  $P = 0.3$ .

Complications: No graft failures, infections, deep venous thrombosis (DVTs), or neurovascular injuries were reported in either group. No donor site complications required reoperation.<sup>[22,23]</sup>

These results are consistent with reports from large ACL registries and confirm the safety and efficacy of both grafts when used with proper technique [Table 2].

## DISCUSSION

In this prospective RCT, we compared clinical and functional outcomes of ACL reconstruction using HT versus BTB autografts with 12-month follow-up. Our results demonstrated no statistically significant differences between groups in terms of anterior knee stability, functional outcomes measured by IKDC and hop tests, ROM, return to sport, or complication rates. These findings suggest that both graft options provide equivalent short-term outcomes when proper surgical technique and rehabilitation protocols are followed.

Our findings align with several large-scale registry studies and meta-analyses, which have consistently reported minimal differences between HT and BTB autografts in objective stability and patient-reported outcomes.<sup>[17-23]</sup> Connors *et al.*<sup>[7]</sup> conducted a meta-analysis including more than 8,000 patients and found no significant difference in return-to-sport or graft failure between HT and BTB autografts. Sollberger *et al.*<sup>[8]</sup> demonstrated that long-term outcomes at more than 10 years were largely equivalent, though donor site morbidity remained a differentiating factor. Samuelsen *et al.*<sup>[9]</sup> analyzed 47,613 patients and reported slightly higher revision rates with hamstring autografts, without a significant impact on overall function. Ciccotti *et al.*<sup>[10]</sup> confirmed that both graft types provided comparable stability in RCTs evaluating independent tunnel drilling techniques.

Donor site morbidity remains an important consideration in graft selection. BTB autografts are associated with higher rates of anterior knee pain, kneeling discomfort, and potential extensor mechanism issues.<sup>[21]</sup> In contrast, HT harvest can result in transient flexion weakness, though this rarely limits

athletic performance. Kunze *et al.*,<sup>[11]</sup> in a network meta-analysis, concluded that hamstring and quadriceps tendon autografts demonstrate lower donor site morbidity compared with BTB autografts. Our trial reinforces these findings, as no graft-related complications were recorded, though mild anterior knee pain was more common in the BTB group.

Raju *et al.*<sup>[24]</sup> emphasized that graft selection should be tailored according to patient-specific factors such as the sport and occupational demands, rather than assuming universal superiority of one graft. Connors *et al.*<sup>[25]</sup> reported that BTB autografts were associated with slightly reduced laxity but also increased anterior knee pain complaints. Sollberger *et al.*<sup>[26]</sup> highlighted the importance of strict rehabilitation adherence in determining post-operative functional outcomes irrespective of graft type. Samuelsen *et al.*<sup>[27]</sup> suggested that population-specific factors may influence outcomes, noting that Asian and Middle Eastern cohorts often report lower revision rates compared with Western registries. Ciccotti *et al.*<sup>[28]</sup> and Maheshwari *et al.*<sup>[29]</sup> demonstrated that quadriceps tendon autografts may provide an emerging alternative with reduced morbidity and comparable stability and functional outcomes.

Recent studies provide additional insights into the performance of HT autografts and their comparison with alternative grafts.<sup>[30-36]</sup> Dhariwal *et al.*<sup>[30]</sup> reported favorable functional outcomes for superficial quadriceps tendon versus HT autografts, suggesting that both graft types are reliable options with low complication rates. Charan Teja *et al.*<sup>[31]</sup> and Vijay *et al.*<sup>[35]</sup> demonstrated comparable knee stability and functional recovery between HT and peroneus longus grafts, supporting the versatility of HT grafts across different patient populations and graft alternatives. Radhik *et al.*<sup>[32]</sup> highlighted that variations in hamstring autograft thickness may influence post-operative functional outcomes, emphasizing the importance of individualized graft selection and surgical planning. Shah *et al.*<sup>[33]</sup> reported excellent results using six-strand HT autografts, noting minimal complications and favorable short-term functional recovery. Roy *et al.*<sup>[34]</sup> showed that remnant-preserving ACL reconstruction can enhance proprioceptive recovery and improve functional outcomes, underlining the value of surgical technique optimization in maximizing graft performance. Gupta *et al.*<sup>[36]</sup> found that quadrupled HT autografts reduce residual knee laxity while maintaining strong functional recovery, confirming that modern HT techniques provide both mechanical stability and excellent patient-reported outcomes. Collectively, these studies complement our trial's results, supporting HT autografts as a versatile, reliable, and safe graft choice for ACL reconstruction, particularly when careful attention is paid to graft characteristics, preservation techniques, and individualized rehabilitation strategies.

Our trial is particularly relevant in the Middle Eastern context, where data from high-quality randomized studies

remain limited. Most existing evidence is derived from Western or registry-based cohorts, which may not fully reflect the demographic, cultural, and sporting characteristics of our population. By providing prospective randomized data from an Egyptian cohort, this study addresses a regional evidence gap and contributes to a more globally representative understanding of ACL graft outcomes.

The strengths of our study include its randomized design, prospective data collection, and blinded outcome assessment. Unlike registry-based studies, our trial minimized selection bias and ensured uniform rehabilitation across groups. However, some limitations should be acknowledged. First, the follow-up period was limited to 12 months, which precludes conclusions regarding long-term graft survival or the development of osteoarthritis. Second, while the study was adequately powered for functional outcomes, the relatively small sample size may not detect rare complications or subtle differences in revision rates. Third, donor site morbidity was not assessed with a dedicated scoring system, which may underestimate clinically relevant but minor symptoms.

## CONCLUSION

These RCTs demonstrated that both HT and BTB autografts provide excellent and comparable outcomes in ACL reconstruction at 1-year follow-up. No significant differences were observed in stability, function, return to sport, or complications.

The findings highlight that graft choice should be individualized according to patient activity, occupation, and tolerance for donor site morbidity, rather than assuming superiority of one graft. Importantly, this trial adds prospective randomized evidence from the Middle East, addressing a regional gap in the literature where high-quality data remain limited.

**Authors' contributions:** AE: Conceived and designed the study, performed surgeries, and drafted the manuscript. WR: Contributed to patient management and surgical procedures. AMS: Participated in data interpretation and manuscript editing. AMG: Assisted in data collection, statistical analysis, and literature review. All authors read and approved the final version of the manuscript.

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**Ethical approval:** This research/study was approved by the Institutional Ethics Committee of faculty of medicine, Cairo university reference number CU-ORTHO-2020-043, Dated January 20, 2020.

**Declaration of patient consent:** The authors certify that they have obtained all appropriate patient consent forms. In the form, the patients have given their consent for their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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## Use of artificial intelligence (AI)-assisted technology for manuscript preparation:

The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

**Availability of data and materials:** The data supporting the findings of this study are available from the corresponding author upon reasonable request. The data are not publicly available due to institutional regulations and ethical considerations related to patients confidentiality

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