

## RESEARCH ARTICLE

# The Effect of Iliotibial Band Tightness and Its Release on Postoperative Pain after Total Knee Arthroplasty in Patients with Varus Gonarthrosis: A Randomized Clinical Trial

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### Abstract

**Objectives:** This study aimed to evaluate the effect of iliotibial band (ITB) release on postoperative pain and functional outcomes following total knee arthroplasty (TKA) in patients with varus gonarthrosis.

**Methods:** This clinical trial included patients with varus gonarthrosis undergoing total knee arthroplasty (TKA). Participants were stratified into three groups: Group A, patients with a tight ITB who did not undergo ITB release; Group B, patients with a tight ITB who underwent ITB release; and Group C, patients with a loose ITB who did not undergo release. Outcome measures included the Knee Society Score (KSS) knee and function subscales and the Oxford Knee Score (OKS), which assesses pain and functional status. Evaluations were performed preoperatively and at three months and one year postoperatively.

**Results:** No significant differences were observed among the three groups regarding age or gender ( $P > 0.05$ ). At baseline, Group B demonstrated a significantly lower mean KSS compared with the other groups ( $P = 0.017$ ). Although Group B showed improvement in mean KSS at the final follow-up, no statistically significant differences in postoperative KSS ( $P = 0.468$ ) or OKS ( $P = 0.194$ ) were found among the groups at any follow-up time point. Furthermore, the incidence of subluxation and the severity of varus deformity were comparable across all groups.

**Conclusion:** In patients with a tight ITB undergoing TKA, ITB release is associated with improvement in functional scores compared with preoperative values; however, it does not lead to significant differences in clinical or radiographic outcomes when compared with patients who do not undergo ITB release. These findings suggest that ITB release may have a limited effect on overall postoperative outcomes, underscoring the need for further studies to more comprehensively evaluate the role and indications of surgical release techniques.

**Level of evidence:** I

**Keywords:** Iliotibial band, Pain, Total knee arthroplasty, Varus gonarthrosis

### Introduction

Total knee arthroplasty (TKA) is considered the definitive treatment for end-stage knee osteoarthritis. With the aging global population and increasing expectations for maintaining quality of life, the demand for knee arthroplasty continues to rise.<sup>1-4</sup> Varus deformity is one of the most common angular deformities encountered in primary knee arthroplasty procedures.<sup>5,6</sup> Anatomically, varus gonarthrosis is characterized by

progressive bone and cartilage loss predominantly affecting the medial compartment of the knee.<sup>7</sup> This pathological process leads to contracture of the medial soft tissues and ligaments, which often necessitates their release to restore proper limb alignment during arthroplasty.

Despite advances in surgical techniques, approximately 15–30% of patients report persistent knee pain following otherwise successful total knee arthroplasty (TKA).<sup>8,9</sup> A

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proportion of this pain is localized to the lateral aspect of the knee, where clinical suspicion frequently implicates the iliotibial band (ITB), particularly due to reproducible tenderness along its course.<sup>10,11</sup> However, robust prospective evidence directly linking intraoperative ITB tightness to the severity of postoperative pain remains limited.

The iliotibial band (ITB) is a longitudinal fibrous structure extending along the lateral aspect of the thigh from the iliac tubercle to the lateral tibial condyle, where it plays a critical role in lower limb biomechanics and knee stability.<sup>12</sup> Persistent pain lasting beyond three to six months postoperatively is widely recognized as a substantial contributor to impaired general health and reduced patient well-being. Moreover, chronic pain may lead to prolonged opioid use, sleep disturbances, mood disorders, and decreased work capacity.<sup>13,14</sup>

Previous studies have primarily focused on the role of iliotibial band (ITB) release in valgus knee deformities, in which ITB tightness is commonly addressed during total knee arthroplasty. However, clinical observations suggest that patients with varus deformity frequently exhibit a tight ITB at the conclusion of TKA.<sup>10,11,15,16</sup> Consequently, tenderness along the ITB is often reproducible in patients who report lateral knee pain postoperatively, supporting the hypothesis that ITB stiffness or contracture may represent an underrecognized contributor to chronic pain in this population.<sup>10,11,17</sup>

Iliotibial band (ITB) tightness is a relatively common musculoskeletal finding that may contribute to lateral knee pain and functional limitations. In the general population, the prevalence of ITB tightness has been reported to range from 12% to 25%, depending on age and activity level.<sup>18,19</sup> Among patients with knee osteoarthritis, ITB tightness appears to be more prevalent, with reported rates between 30% and 45%, particularly in individuals with varus deformity or lateral pain syndromes.<sup>17,20</sup> Following total knee arthroplasty (TKA), residual ITB tension may contribute to lateral-sided pain or restricted knee flexion, with previous studies estimating a prevalence of 10–15% among symptomatic patients.<sup>21,22,23</sup> Therefore, elucidating the role of ITB release in soft-tissue balancing during TKA is of considerable clinical importance.

Given that a substantial proportion of patients experience persistent pain following total knee arthroplasty (TKA) and considering the potential contribution of iliotibial band (ITB) pathology, this study aimed to investigate the effect of ITB release on postoperative pain outcomes in patients with varus gonarthrosis undergoing TKA.

## Materials and Methods

### Study design and patients' selection

This study included 114 patients aged 40 years or older scheduled to undergo total knee arthroplasty (TKA) at Valiasr Hospital in Arak. Eligible participants had clinically and radiographically confirmed knee osteoarthritis with varus deformity and were planned for primary TKA. Exclusion criteria included failure to attend follow-up visits, chronic use of analgesics or anti-inflammatory medications, the presence of significant comorbidities, or a documented history of mental illness. Patients who declined participation or died during the study period were also

excluded. Written informed consent was obtained from all participants before enrollment. A CONSORT flow diagram illustrating patient recruitment and allocation to study interventions is presented in [Figure 1].

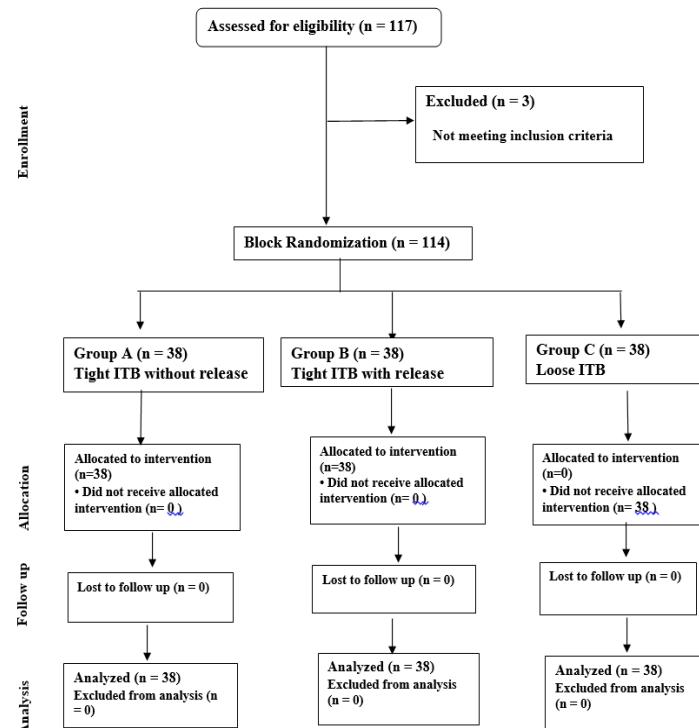


Figure 1. Consort flow diagram

All 114 eligible patients were randomly allocated into three groups using a computer-generated randomization sequence and sealed opaque envelopes. Patients with a tight iliotibial band (ITB) were assigned to two intervention groups: Group A (tight ITB without release, n = 38) and Group B (tight ITB with release, n = 38). Patients without ITB tightness were allocated to the control group, Group C (loose ITB, n = 38). Soft-tissue balancing was performed using a standardized, sequential medial release protocol for varus knees, aiming to achieve rectangular, balanced flexion and extension gaps. This protocol involved stepwise release of the deep medial collateral ligament (MCL), the posterior oblique ligament, and, when necessary, the superficial MCL until adequate coronal plane stability was achieved. Peripheral osteophytes were routinely excised to facilitate soft-tissue balancing. Following bone preparation, the symmetry of the flexion and extension gaps was assessed. Subperiosteal release of contracted soft tissues was performed based on the type of deformity, with medial releases applied for varus knees and lateral releases for valgus knees. In varus knees, the anterior fibers of the superficial medial collateral ligament predominantly influence the flexion gap. In contrast, the posterior fibers and the posterior oblique ligament primarily affect the extension gap.

Ethical considerations included the provision of clear and simplified informed consent forms and strict protection of patient confidentiality. The study protocol was approved by the Ethics Committee of Arak University of Medical Sciences (approval code: IR.ARANKMU.REC.1400.232). The trial was also registered in the Iranian Registry of Clinical Trials (IRCT20211207053320N1). All patient data were securely stored and were accessible only to the principal investigator.

The primary outcome measures were the Knee Society Score (KSS), including the knee and function subscales, and the Oxford Knee Score (OKS), which assesses pain and functional outcomes<sup>24</sup>. These measures were recorded preoperatively (baseline) and at 3 and 12 months postoperatively. Secondary outcome measures included radiographic evaluation of varus deformity and subluxation, which were assessed and compared across the study groups.

#### **Randomization and Blinding:**

Randomization was performed using a computer-generated random number sequence by an independent statistician who was not involved in patient recruitment or surgical procedures. Allocation was not stratified by variables such as age or sex, a limitation acknowledged by the study. Allocation concealment was ensured using sequentially numbered, sealed, opaque envelopes. Each envelope was opened only after patient enrollment and surgical incision, at which point the assigned study group was revealed.

Due to the nature of the surgical intervention (ITB release versus no release), blinding of the operating surgeons was not feasible. However, both patients and outcome assessors were blinded to group allocation throughout the study period to minimize performance and assessment bias.

#### **Definition and Intraoperative Assessment of ITB Tightness**

Iliotibial band (ITB) tightness was assessed intraoperatively after final component implantation and completion of medial soft-tissue balancing. The assessment was performed by the senior orthopedic surgeon using a standardized and consistent clinical protocol. The knee was taken through a full range of motion, and ITB tightness was defined as palpable firmness and resistance along the lateral structures, specifically the ITB cord, which is considered to contribute to residual lateral compartment tightness or suboptimal gap balancing. Although no formal quantitative measurement was used, this standardized clinical assessment ensured consistency across all patients, as the same experienced surgeon conducted evaluations.

#### **Radiographic Assessment**

Subluxation was defined as medial or lateral displacement of the tibia relative to the femur, measured in millimeters as the distance between the femoral and tibial mechanical axes at the level of the joint line. A displacement greater than 5mm was considered indicative of clinically significant subluxation.

The varus deformity angle was measured on standardized, full-length standing anteroposterior radiographs of the lower extremity obtained preoperatively. The mechanical femorotibial angle (FTA) was defined as the acute angle

formed between the mechanical axis of the femur, extending from the center of the femoral head to the midpoint of the femoral intercondylar notch, and the mechanical axis of the tibia, extending from the center of the tibial spines to the center of the talar dome. An angle of less than 180° was considered indicative of varus alignment. All measurements were performed by a single observer using digital measurement software to ensure consistency.

#### **Statistical analysis**

Statistical analyses were performed using SPSS software (version 26.0; IBM Corp., Armonk, NY, USA). The normality of continuous variables was assessed using the Shapiro-Wilk test. Continuous data are presented as mean  $\pm$  standard deviation (SD), and categorical variables are expressed as frequencies and percentages. Baseline characteristics among the three study groups were compared using one-way analysis of variance (ANOVA) for continuous variables (e.g., age and varus angle) and the chi-square test or Fisher's exact test, as appropriate, for categorical variables (e.g., sex and prosthesis type). For the primary outcome measures, including the Knee Society Score (KSS) knee and function subscales and the Oxford Knee Score (OKS), a mixed-effects repeated-measures ANOVA was conducted to evaluate the main effects of group and time, as well as the group-by-time interaction. A *P* value of less than 0.05 was considered statistically significant for all analyses.

#### **Results**

A total of 114 patients were enrolled and randomized equally into three groups ( $n = 38$  per group). The mean ages ( $\pm$  SD) of patients in Groups A, B, and C were  $65.29 \pm 2.49$ ,  $65.34 \pm 2.84$ , and  $64.84 \pm 2.79$  years, respectively, with no statistically significant difference among the groups ( $P = 0.727$ ). The proportion of female patients was also comparable across Groups A, B, and C, accounting for 92.1%, 94.7%, and 81.6% of participants, respectively ( $P = 0.229$ ). Similarly, the distribution of posterior-stabilized (PS) prostheses did not differ significantly among the groups, with usage rates of 73.7% in Group A and 81.6% in both Groups B and C ( $P = 0.622$ ) [Table 1]. These findings indicate that the three groups were comparable at baseline with respect to age, sex distribution, and prosthesis type.

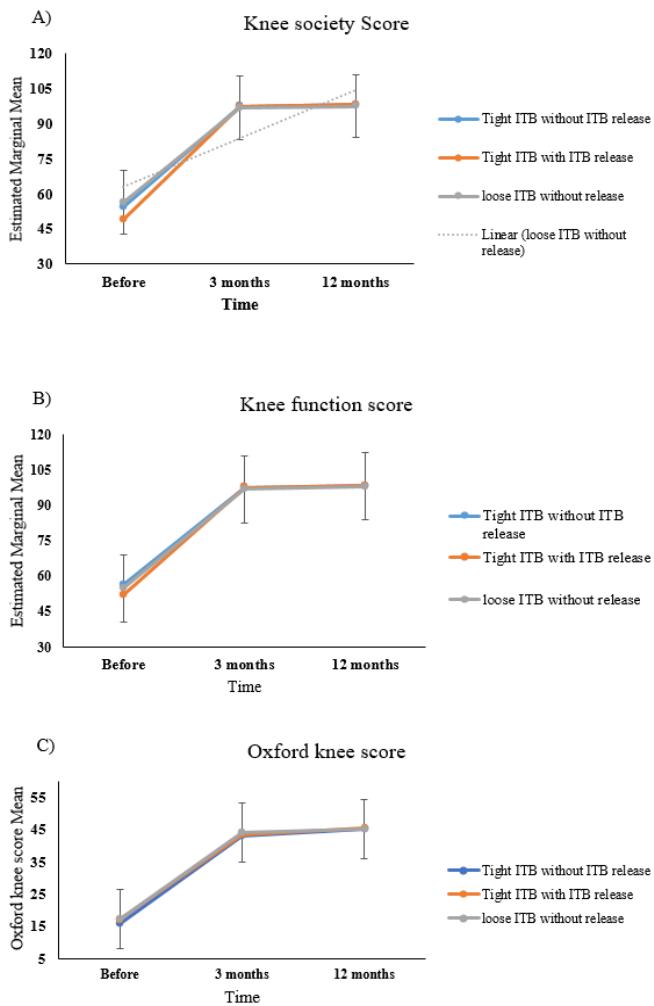
Longitudinal analysis of the Knee Society Score (KSS) demonstrated no significant overall differences among the three groups across the three assessment time points. However, a significant group-by-time interaction was observed for the KSS knee subscale ( $P = 0.015$ ), indicating that the trajectory of score changes over the follow-up period differed among the groups. In contrast, no significant group-by-time interaction or overall group differences were observed for the KSS function subscale across repeated measurements ( $P = 0.468$ ). Similarly, the Oxford Knee Score (OKS) did not differ significantly between groups throughout the follow-up period ( $P = 0.468$ ), reflecting comparable functional outcomes among all cohorts [Table 1 and Figure 2].

**Table 1- Baseline demographic and clinical characteristics**

Variables		Group A (n=38)	Group B (n=38)	Group C (n=38)	P-value	F
Age, Mean (SD)		65.29 (2.49)	65.34 (2.84)	64.84 (2.79)	0.727*	
Gender, n (%)	Male	3(7.9)	2(5.3)	7(18.4)	0.229**	
	Female	35(92.1)	36(94.7)	31(81.6)		
Type of prosthesis N (%)	PS	28(73.7)	31(81.6)	31(81.6)	0.622**	
	LCCK	10(26.3)	7(18.4)	7(18.4)		
Knee society score	Before	54.65 ±11.43	49.21±11.22	65.60±11.93		
	3 months	97.45±2.27	97.21±3.08	96.89±2.37		
	12months	98.42±2.05	98.21±2.26	97.45±2.28		
	Group				0.037	3.397
	Time				<0.001	1509.203
	Group*Time				0.015	4.215
Knee function score	Before	56.45±16.11	52.16±14.25	54.92±15.72		
	3months	97.63±4.15	97.66±3.80	96.84±3.91		
	12months	98.42±2.35	98.53±2.82	98.10±2.68		
	Group				0.536	0.627
	Time				<0.001	842.140
	Group*Time				0.468	0.787
Oxford knee score	Before	16.03±2.38	17.26±2.66	17.31±2.81		
	3months	43.24±2.12	43.53±1.78	44.21±2.23		
	12months	45.24±1.02	45.68±0.96	45.29±0.96		
	Group				0.013	4.494
	Time				<0.001	7624.165
	Group*Time				0.194	1.597
Degree of varus		15.39(6.26)	14.99(5.57)	17.05(2.79)	0.293*	
Presence of subluxation	Yes	7(18.4)	7(18.4)	9(23.7)		
N (%)	No	31(81.6)	31(81.6)	31(81.6)	0.750**	

The incidence of subluxation was 18.4% in both Groups A and B and 23.7% in Group C, with no statistically significant difference among the groups ( $P = 0.750$ ). The mean varus deformity angles were  $15.39^\circ \pm 6.26$  in Group A,  $14.99^\circ \pm 5.57$

in Group B, and  $17.05^\circ \pm 6.29$  in Group C. Although Group C exhibited a higher mean varus angle, the difference was not statistically significant ( $P = 0.293$ ) [Table 1].



**Figure 2:** A) Mean of the knee society score over time by the study group. B) Mean of the knee function score over time by the study group. C) Mean of Oxford knee score over time by the study group.

## Discussion

The primary finding of this randomized trial is that intraoperative iliotibial band (ITB) release did not result in superior postoperative pain relief or functional outcomes at one year compared with no ITB release in patients with varus gonarthrosis undergoing total knee arthroplasty (TKA). These findings suggest that the frequently observed intraoperative ITB tightness in varus knees may not, by itself, warrant routine release, thereby questioning a practice that has often been guided by surgical judgment rather than robust clinical evidence.<sup>16,25</sup>

In the present study, the mean age of participants was  $65.2 \pm 2.7$  years, with a marked predominance of female

patients (89.5%). This demographic profile is consistent with epidemiological evidence indicating that knee osteoarthritis disproportionately affects women over the age of 50 years.<sup>26,27,28,29</sup>

The main finding of this study was the absence of a statistically significant difference in overall functional improvement between patients undergoing total knee arthroplasty (TKA) with or without iliotibial band (ITB) release during follow-up. Although a significant group-by-time interaction was observed for the KSS knee subscale ( $P = 0.015$ ), post hoc analyses indicated that this interaction reflected a greater rate of improvement in Group B, which had a significantly lower baseline score, rather than a superior outcome. At both the 3- and 12-month follow-up assessments, mean KSS knee scores in Group B were not significantly different from those in Groups A and C. These findings suggest that while ITB release may facilitate early functional recovery in patients with a tight ITB, it does not appear to provide a clear long-term advantage in terms of final knee function or pain relief compared with not performing the release.

The literature on iliotibial band (ITB)-related pathology following total knee arthroplasty (TKA) is well established, with multiple studies identifying ITB friction syndrome as a recognized cause of lateral knee pain in the postoperative period.<sup>17,23,30</sup> However, high-level evidence to guide the use of prophylactic ITB release during the index arthroplasty remains limited. The existing literature largely consists of descriptions of surgical techniques and small case series rather than comparative trials. For instance, Takagi et al. advocated selective ITB release to address flexion contracture during TKA. In contrast, Amzallag et al. reported functional improvement following ITB release in patients with established postoperative friction syndrome.<sup>17,23</sup> In contrast, the present randomized controlled trial directly addresses this evidence gap by providing comparative data on the effectiveness of intraoperative ITB release when incorporated into soft-tissue balancing during varus TKA.

In contrast to the KSS knee subscale, the other patient-reported outcome measures—the Oxford Knee Score and the KSS function subscale—did not demonstrate a significant group-by-time interaction ( $P = 0.194$  and  $P = 0.468$ , respectively). This finding indicates that, from the patients' perspective, self-reported pain and functional status improved comparably over time, irrespective of whether an iliotibial band (ITB) release was performed.<sup>26</sup>

The existing literature on iliotibial band (ITB) release has predominantly focused on its role in correcting valgus deformity or treating ITB friction syndrome across heterogeneous patient populations. Case reports and small case series have described symptomatic improvement

following selective ITB release for lateral knee pain after total knee arthroplasty (TKA),<sup>17,20,23</sup> and several reviews have identified ITB pathology as an underrecognized contributor to postoperative discomfort.<sup>21,22,31</sup> However, much of this evidence is derived from studies involving valgus alignment or guided-motion TKA designs. Importantly, controlled data evaluating the efficacy of ITB release specifically in the setting of varus deformity remain limited. Although biomechanical considerations suggest that dynamic varus alignment may increase ITB loading, thereby providing a rationale for intervention, the present randomized controlled trial indicates that this theoretical advantage does not translate into a measurable clinical benefit in patients with varus gonarthrosis. These results contrast with the more established role of ITB release in valgus correction and highlight the importance of deformity-specific evaluation of soft-tissue release strategies.

A study by Amzallag et al. reported improved knee function following iliotibial band (ITB) release for ITB friction syndrome after total knee arthroplasty, highlighting the potential utility of this procedure in managing refractory lateral knee pain.<sup>23</sup> In the present study, the mean degree of Rohrs did not differ significantly among the study groups ( $P = 0.293$ ). In general, many patients with varus knee deformity exhibit a tight iliotibial band at the conclusion of arthroplasty surgery. This pattern of soft-tissue imbalance may play an important role in the development of postoperative pain following TKA. Consistent with this observation, Tian et al. reported that the degree of varus deformity, as well as severe valgus deformity of the knee, can increase lower-limb alignment deviation after TKA.<sup>32</sup>

Additionally, clinical and radiographic parameters, including the incidence of subluxation ( $P = 0.750$ ) and mean varus deformity angles ( $P = 0.293$ ), were comparable across all study groups. This finding supports the conclusion that iliotibial band (ITB) release does not result in significant differences in joint stability or coronal deformity correction following TKA. Although ITB tightness is frequently observed in patients with varus knee deformity after arthroplasty and may contribute to postoperative pain, the present study did not demonstrate a significant effect of ITB release on these structural outcomes.

This study has several limitations that should be acknowledged. First, because of the nature of the surgical intervention, blinding the operating surgeons to group allocation was not feasible, which represents an inherent source of potential performance bias in surgical trials. Second, although the sample size was determined a priori, the number of participants per group was relatively small, potentially limiting the ability to detect subtle clinical differences or subgroup effects and increasing the risk of a Type II error. Third, while the 12-month follow-up period

is sufficient for evaluating short- to mid-term functional outcomes, it is inadequate for assessing long-term endpoints such as implant survivorship, stability, or late-onset complications. Finally, randomization was not stratified by gender, resulting in a numerical imbalance—though not statistically significant—between groups. Although the groups were otherwise well balanced with respect to key prognostic factors, including age and baseline deformity, and no strong trends were observed in the primary analyses, the potential for residual confounding related to this demographic imbalance cannot be entirely excluded. Future studies should incorporate larger, gender-stratified cohorts with extended follow-up periods and, where feasible, enhanced blinding strategies to further validate these findings.

Nonetheless, findings from this cohort study suggest that although iliotibial band (ITB) release may lead to improvements in functional scores compared with preoperative status, it does not provide substantial advantages over non-release with respect to final knee function or patient-reported outcomes.

It is important to note that many previous studies have relied on pre- and postoperative comparisons without including control groups. In contrast, the controlled design of the present study allows for a more rigorous evaluation of the clinical impact of ITB release while simultaneously highlighting the need for further research to better define its role, along with that of other soft-tissue procedures, during total knee arthroplasty (TKA). Future investigations would benefit from stratified randomization to ensure balanced baseline characteristics, larger sample sizes, longer follow-up periods, and the incorporation of additional clinical, functional, and imaging outcomes to enable a more comprehensive assessment of the effectiveness of ITB release.

## Conclusion

This study found no significant differences in functional outcomes, radiographic alignment, or subluxation incidence between patients undergoing total knee arthroplasty (TKA) with or without iliotibial band (ITB) release for varus gonarthrosis. Although the ITB release was associated with improvements in functional scores compared with baseline values, it did not provide additional clinical or radiographic benefits compared with non-release. These findings suggest a limited role for routine ITB release in this patient population and underscore the need for further research to better define surgical indications for soft-tissue balancing in varus TKA.

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## Authors Contribution:

Authors who Conceived and designed the analysis: Hosseinali HADI, Mohammad H Ebrahimzadeh, Mohammad Zarei Dezkooh, Authors who Collected the data: Hosseinali HADI, Mohammad Zarei Dezkooh, Authors

who Contributed data or analysis tools: Hosseinali HADI, Mohammad Zarei Dezkooh, Authors who Performed the analysis: Hosseinali HADI, Mohammad H. Ebrahimzadeh, Mohammad Zarei Dezkooh, Authors who Wrote the paper: Hosseinali HADI, Mohammad H. Ebrahimzadeh, Mohammad Zarei Dezkooh.

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