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RESEARCH

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Impact of subtalar joint debridement on fusion rates and outcomes in tibiotalocalcaneal arthrodesis

Baris Ozkul[1*], Deniz Akbulut[2], Muhammed Bilal Kürk[1], Kutalmis Albayrak[1], Gökhan Pehlivanoglu[1] and Bilal Demir[3]

Abstract

Background Retrograde intramedullary nailing with tibiotalocalcaneal arthrodesis (TTCA) is a well-established procedure for management of hindfoot arthritis. This study aimed to evaluate the functional and radiological outcomes of TTCA with or without open debridement of the subtalar joint to determine whether formal subtalar joint is preparation necessary.

Methods A retrospective analysis of 48 patients who underwent TTCA with retrograde intramedullary nailing was conducted. Patients were divided into two groups: Group 1 ($n=20$) underwent open debridement of both the tibiotalar and subtalar joints, while Group 2 ($n=28$) underwent open debridement of the tibiotalar joint only, with closed intramedullary nail reaming of the subtalar joint. Outcomes were evaluated at mid-term and long term follow-up. Radiological findings, fusion rates, complications, and functional scores were compared between the groups.

Results Subtalar fusion rates were significantly higher in Group 1 compared to Group 2 (80% vs. 32%, $p=0.001$). Mid-term complication rates were significantly lower in Group 2 ($p=0.007$), though Group 1 had a higher rate of nerve complications ($p=0.004$). Tibiotalar fusion rates did not differ significantly between the groups ($p=0.936$). Functional improvement, based on the American Orthopaedic Foot and Ankle Society (AOFAS) and visual analog scale (VAS) scores, showed no significant differences between the groups at any follow-up time points ($p>0.05$). Subtalar nonunion was associated with significantly poorer long-term functional outcome scores.

Conclusions Open debridement of the subtalar joint during TTCA is essential for achieving optimal subtalar fusion. However, in cases where soft tissue conditions limit safe access to the subtalar joint, satisfactory functional outcomes and pain relief can still be achieved through tibiotalar fusion and subtalar joint immobilization, even without complete fusion. This approach may be particularly advantageous in post-traumatic or infectious cases with compromised soft tissue envelopes.

Level of evidence Level 3, Retrospective cohort study.

Trial registration Retrospectively registered.

*Correspondence:
Baris Ozkul
drbarisozkul@hotmail.com

Full list of author information is available at the end of the article

Highlights of the Study

- Open subtalar joint debridement improves fusion rates but does not significantly affect functional outcomes.
- Omitting subtalar debridement reduces surgery time and soft tissue complications while maintaining pain relief.
- Subtalar nonunion leads to worse long-term outcomes, though mid-term results remain comparable.

Keywords Ankle arthritis, Tibiotalocalaneal arthrodesis, Subtalar fusion, Retrograde nailing

Introduction

The tarsal joints are interconnected through ligamentous and capsular structures, resulting in biomechanical interdependence among them [1–3]. When the integrity of these joints is disrupted due to intra-articular fractures, adjacent fractures, avascular necrosis, septic arthritis, or neuropathic disorders [4–6]. Over time, such changes can significantly impair the alignment and function of the foot and ankle.

The tibiotalar and subtalar joints are particularly susceptible to degeneration after traumatic events, such as calcaneal fractures, pilon fractures, and trimalleolar fracture-dislocations, as well as in conditions like rheumatic diseases and deformities [7]. Degenerative changes may also occur following previously failed fusion attempts. In such complex cases, tibiotalocalcaneal arthrodesis (TTCA) with retrograde intramedullary nailing has became as a preferred surgical technique to restore hindfoot stability and alignment [7–9].

Both open and arthroscopic debridement of the tibiotalar and subtalar joints during TTCA are well supported in the literature [10, 11]. However, the necessity of open subtalar joint debridement remains a subject of debate. While some cadaveric and clinical studies have reported successful subtalar fusion through intramedullary reaming alone [12, 13], others emphasize that formal open debridement is essential to achieve optimal fusion rates and favorable clinical outcomes [14, 15]. This controversy underscores the need for a direct comparison these two surgical approaches.

Although various TTCA techniques have been explored in the literature, most studies have evaluated them independently, without direct comparison. To date, no study has systematically assessed the functional and radiological outcomes of TTCA performed with versus without formal subtalar joint debridement. Therefore, the aim of this study is to address this gap by determining whether open debridement of the subtalar joint is necessary to achieve satisfactory subtalar fusion and functional outcomes in patients undergoing TTCA with retrograde intramedullary nailing.

Materials and methods

A retrospective evaluation was made of patients treated with tibiotalocalcaneal arthrodesis (TTCA) with retrograde intramedullary nailing at our institution during the period form 2010 and 2015. Patients with concurrent degenerative changes in both the tibiotalar and subtalar joints were included. The following exclusion criteria were applied: neuromuscular or musculoskeletal disorders limiting objective functional assessment, neuropathic conditions (e.g., diabetes with baseline sensory impairment), arthrodesis involving other tarsal joints, use of additional internal fixation materials together with intramedullary nailing, talectomy during surgery, revision TTCA following previously failed fusion with plates or screws performed at other institutions, follow-up duration of less than 12 months, and morbid obesity (BMI > 45 kg/m²). After applying these criteria, 59 patients met the inclusion criteria, and 48 patients who completed the final follow-up examination were included in the study. All procedures were performed by experienced foot and ankle surgeons.

The patients were separated into two groups according to the surgical approach. Group 1 included patients who underwent open debridement of both the tibiotalar and subtalar joints, followed by intramedullary reaming. Group 2 consisted of patients who underwent open debridement of the tibiotalar joint only, without subtalar joint debridement, followed by intramedullary reaming. In all patients, autologous bone grafts (excised fibula or medial malleolus) were used to promote fusion. A summary of the demographic information of each group is provided in Table 1. Written informed consent was obtained from all patients prior to surgery.

Radiological and functional evaluation

Preoperative radiological assessment included the measurement of hindfoot alignment angles using the hindfoot alignment view (Fig. 1). In this technique, the X-ray beam was angled 20° downward, with the film cassette positioned perpendicular to the central beam of the radiation source [16]. Correction of hindfoot alignment—particularly the talocalcaneal angle-has been shown to be clinically relevant following arthrodesis procedures, as it correlates with improved functional scores and successful deformity correction [17]. Postoperative radiological

Table 1 Comparative analysis of patient characteristics between the two groups

	Group 1 ($n=20$) Mean±SD/n(%)	Group 2 ($n=28$) Mean±SD/n(%)	p
Age (Years)	51.0±11.0	52.1±15.3	0.426
Sex			
Female	10 (50.0%)	10 (35.7%)	0.322
Male	10 (50.0%)	18 (64.3%)	
BMI (kg/m^2)	27.6±4.2	27.5±3.5	0.969
Surgical Duration (Min)	98.6±16.2	71.4±16.9	**< 0.001**
Hospitalization time (Days)	9.25±6.0	8.36±4.4	0.557
Preoperative Surgical History			
Yes	12 (60.0%)	13 (46.4%)	0.238
No	8 (40.0%)	15 (53.6%)	
Follow-up period (Months)	119.0 ± 6.3	120.2 ± 19.9	0.970
Smoking			
Yes	8 (40.0%)	10 (35.7%)	0.762
No	12 (60.0%)	18 (64.3%)	
Tibiotalar Kellgren and Moore Grade			
1	4 (20.0%)	1 (3.6%)	0.195
2	0 (0.0%)	2 (7.1%)	
3	6 (30.0%)	8 (28.6%)	
4	10 (50.0%)	17 (60.7%)	
Subtalar Kellgren and Moore Grade			
0	0 (0.0%)	1 (3.6%)	0.595
1	4 (20.0%)	6 (21.4%)	
2	8 (40.0%)	7 (25.0%)	
3	4 (20.0%)	10 (35.7%)	
4	4 (20.0%)	4 (14.3%)	

Bold values indicate statistical significance

evaluations assessment of hindfoot angles and tibiotalocalcaneal fusion using **standard** radiographs. Computed tomography (CT) scans were performed between 6 and 9 months postoperatively in cases where bridging callus was not visible in at least three anatomical planes, in order to evaluate for potential fibrous callus formation.

Functional and pain outcomes were evaluated both preoperatively and at the final follow-up using the visual analog scale (VAS) for pain (range: 0–10), the American Orthopaedic Foot and Ankle Society (AOFAS) score [18], and the Roles–Maudsley scoring system [19]. Mean operative times and complication rates were compared between the groups.

Postoperative care

In the early postoperative period, patients were immobilized with a short leg splint. After suture removal, the splint was replaced with a short leg circular cast. Between the 2nd and 8th postoperative weeks, partial weight-bearing not exceeding 15 kg was allowed. At the end of the 8th week, if cast deterioration was observed, it was replaced with a walking cast; otherwise, full weight-bearing was initiated in the same cast. If no radiological signs of union were evident by the 12th postoperative week, cast treatment was extended for up to an additional month. The applied postoperative protocol reflects current literature recommendations for TTCA, considering the mechanical stress on the hindfoot, the need for dual-joint fusion, and the typically compromised patient profile [20–22]. Thromboprophylaxis with low-molecular-weight heparin was administered for a minimum duration of eight weeks.

Statistical analysis

Data were presented as mean ± standard deviation, minimum, maximum, frequency, and percentage, as appropriate. The Kolmogorov–Smirnov test was used to assess data normality. For independent quantitative data, the independent samples t-test or Mann–Whitney U-test was applied. For dependent quantitative data, paired samples t-test or Wilcoxon signed rank test was used. Independent qualitative data were analyzed using the Chi-squared test or Fisher's exact test. Statistical significance was set at $p < 0.05$. All analyses were performed using Jamovi software (version 2.5.4.0).

This clinical trial was registered before patient enrollment, but the registration number has been withheld for review.

Results

There were no significant differences between the two groups in terms of patient characteristics, except for surgical duration, which was longer in Group 1 (Table 1). Similarly, no statistically significant differences were observed between the groups regarding postoperative hindfoot alignment angles or tibiotalar fusion rates on radiographic evaluation. However, the subtalar fusion rate was significantly higher in group 1 compared to Group 2 (Table 2) (Fig. 2).

Both groups demonstrated statistically significant postoperative improvements in AOFAS, VAS, and Roles–Maudsley scores ($p < 0.05$, Table 2). Nevertheless, there were no statistically significant differences between the groups in terms of mean preoperative, postoperative mid-term, or long-term AOFAS, VAS, or median Roles–Maudsley scores ($p > 0.05$, Table 2). Group 1 demonstrated a significantly higher rate of mid-term postoperative complications compared to Group 2 (60.0% vs. 21.4%, $p = 0.007$). Group 1 patients received a more invasive intervention due to the addition of open subtalar joint debridement. This required an additional incision and a more extensive surgical dissection, resulting in longer operative times as shown in Table 1. Although

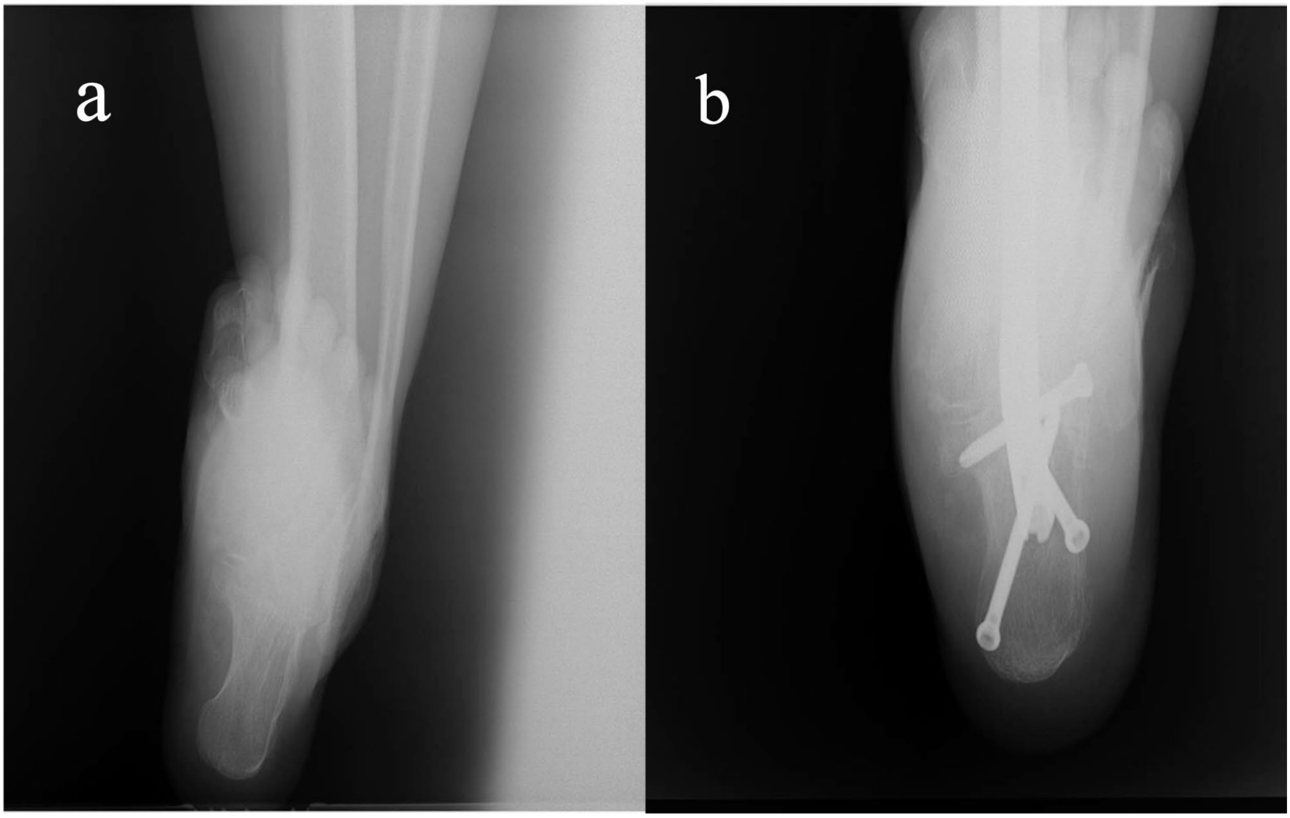

Fig. 1 The differences between the preoperative (a) and postoperative (b) hindfoot alignment X-rays are demonstrated

the difference in long-term complication rates between the groups did not reach statistical significance (25.0% vs. 42.9%, $p = 0.202$), the higher numerical rate observed in group 2 may still be clinically relevant. Patients without subtalar union demonstrated significantly lower long-term functional scores compared to those with successful fusion, whereas mid-term scores did not show significant differ between the two groups (Table 3).

Intraoperative fractures at the locking screw site in the tibial diaphysis were reported in two patients (10%) in Group 1; both were successfully managed with circular casts.

Mid-term outcomes

In Group 2, postoperative radiographs demonstrated tibial diaphyseal cortical fractures in two patients, both of whom achieved union following treatment with short leg casts. Subtalar fusion failure was observed in one patient, necessitating revision surgery with cannulated screw fixation after intramedullary nail removal. Superficial wound infections occurred in two patients (7%) in Group 2 and were effectively treated with oral antibiotics.

In Group 1, wound infections were identified in five patients (25%). Four of these cases responded well to oral antibiotic therapy. One patient required surgical debridement due to persistent wound drainage and subsequently developed osteomyelitis. Amputation was recommended; however, the patient declined further surgical intervention.

Additionally, deep vein thrombosis was reported in two patients from Group 1 and one patient from Group 2. No cases of pulmonary embolism were observed in either group.

Long-term outcomes

In Group 1, radiological assessments revealed signs of loosening around the nails and screws in three patients, accompanied by pain. Screw fractures were also detected in two patients. These complications led to secondary procedures: two patient with combined tibiotalar and subtalar nonunion underwent revision surgery with re-implantation of a new intramedullary nail. In two other patients, broken or loosened implants (nail and/or screws) were removed, but due to patient preference, revision fusion was not performed despite the presence of subtalar nonunion. In one other patient, hardware was removed due to implant-related irritation.

In Group 2, radiological evaluation identified nail fractures in three patients and screw fractures in seven patients (Fig. 3). Two patients underwent revision nailing procedures due to combined tibiotalar and subtalar nonunion. One patient underwent cannulated screw fixation

Table 2 Functional outcomes, radiological findings, fusion rates, complications, and secondary surgery rates in the two groups

	Group 1 ($n=20$) Mean±SD/n(%)	Group 2 ($n=28$) Mean±SD/n(%)	p
AOFAS			
Preoperative	29.3±9.9	29.3±8.9	0.998
Mid-term	76.4±15.5*	78.4±9.3*	0.574
Long-term	69.7±25.6**	63.0±20.1**	0.340
VAS			
Preoperative	7.7±1.9	7.5±1.9	0.822
Mid-term	2.7±1.9*	2.3±1.8*	0.402
Long-term	3.2±2.4**	4.0±2.2**	0.281
ROLES AND MAUDSLEY			
Preoperative	3.7±0.4	3.7±0.4	1.000
Mid-term	1.6±0.5*	1.4±0.5*	0.168
Long-term	2.0±1.0**	2.1±0.7**	0.838
Hindfoot Angle			
Preoperative	16.0±7.5	14.2±8.9	0.460
Postoperative	6.0±3.5	5.7±3.3	0.738
Sural Nerve Pathology			
Yes	7 (35.0%)	1 (3.6%)	**0.006**
No	13 (65.0%)	27 (96.4%)	
Tibiotalar Fusion			
Yes	18 (90.0%)	25 (89.3%)	0.936
No	2 (10.0%)	3 (10.7%)	
Subtalar Fusion			
Yes	16 (80.0%)	9 (32.1%)	**0.001**
No	4 (20.0%)	19 (67.9%)	
Mid-term Complications			
Yes	12 (60.0%)	6 (21.4%)	**0.007**
No	8 (40.0%)	22 (78.6%)	
Long-term Complications			
Yes	5 (25.0%)	12 (42.9%)	0.202
No	15 (75.0%)	16 (57.1%)	
Secondary Surgery			
Yes	6 (30.0%)	5 (17.9%)	0.324
No	14 (70.0%)	23 (82.1%)	

Bold values indicate statistical significance.

* indicates significant differences between preoperative and postoperative values.

** indicates significant differences between mid–term and long–term values

Table 3 Mid- and long-term functional outcomes in patients with and without subtalar joint union

	Subtalar union+ ($n=25$) Mean±SD	Subtalar union- ($n=23$) Mean±SD	p
AOFAS			
Mid-term	80.3±6.6	74.6±15.7	0.105
Long-term	81.5±5.5	49.7±22.5	**< 0.001**
VAS			
Mid-term	2.4±1.9	2.5±1.8	0.763
Long-term	2.1±1.3	5.3±2.0	**< 0.001**
ROLES AND MAUDSLEY			
Mid-term	1.5±0.5	1.5±0.5	0.991
Long-term	1.5±0.5	2.7±0.8	**< 0.001**

Bold values indicate statistical Significance

following nail removal due to symptomatic subtalar nonunion. Another patient, despite implant failure, declined re-fusion surgery after hardware removal. All these revision procedures were performed as management of complications **and** were monitored as part of the study's outcome data. Superficial wound infections also occurred in two patients. Sensory hypoesthesia in the sural nerve dermatome was significantly more prevalent in Group 1 (seven patients, 35%) compared to Group 2 (one patient, 3.6%) ($p=0.006$).

Discussion

This study evaluated the outcomes of retrograde intramedullary nailing in patients undergoing tibiotalocalcaneal arthrodesis (TTCA) for foot and ankle arthritis, with a comparison based on whether subtalar joint debridement was performed. Our findings demonstrated that, although mid-term functional outcomes were similar between the groups, long-term outcomes were significantly poorer in patients with subtalar nonunion. Nonetheless, improvements in hindfoot alignment were comparable across both groups.

Notably, subtalar joint nonunion was associated with poorer long-term functional outcomes, regardless of

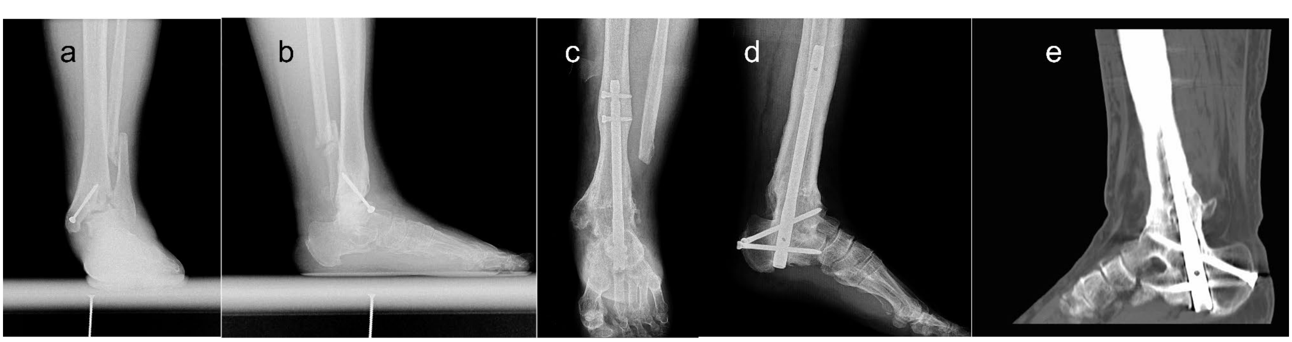

Fig. 2 Preoperative anteroposterior (**a**) and lateral (**b**) radiographs of a patient with posttraumatic arthritis. Final follow-up radiographs (**c**, **d**) demonstrate solid fusion and proper alignment of the subtalar and tibiotalar joints. Computed tomography (**e**) confirms the fusion

Fig. 3 A nail fracture that developed in a patient where the subtalar joint was not debrided

whether subtalar joint preparation was performed. These findings are consistent with the growing body of literature emphasizing the relationship between fusion rates, clinical outcomes, and the importance of advanced imaging in postoperative evaluation [23].

Tibiotalocalcaneal arthrodesis (TTCA) is a widely accepted surgical intervention for management of degenerative changes in the foot and ankle joints [10, 12]. A variety of fixation methods have been employed, including cannulated screws, arthrodesis plates, external fixation, proximal tibial anatomic locking plates, and intramedullary nails [10, 13, 24]. Among these, Retrograde intramedullary nailing is commonly used in the treatment of advanced hindfoot pathologies. Although Charcot arthropathy was excluded from the present study, this method has been extensively reported in the literature for managing such cases [13, 25]. The primary objective of retrograde intramedullary nailing is not only to restore joint stability, but also to achieve successful tibiotalocalcaneal arthrodesis and, ultimately, long-term pain relief and functional improvement [8, 9, 26]. Compared to external fixation, which is associated with lower fusion rates and reduced mechanical stability, intramedullary nailing has become the preferred option due to its superior biomechanical properties and reduced soft tissue distruption [10]. Although locking plates offer biomechanical advantages, particularly in osteoporotic bone, they are linked to higher rates of symptomatic nonunion [24, 27]. In contrast, intramedullary nailing allows for a minimally invasive approach, minimizing soft tissue trauma through smaller incisions [24, 26, 28]. In this study, retrograde intramedullary nailing was selected for patients with combined subtalar and tibiotalar arthritis due to its technical feasibility and high success rates in achieving fusion. Although neurologically based deformities were part of the exclusion criteria in our cohort, this technique has also been widely applied to such cases in the literature [29].

Long-term follow-up of patients with post-traumatic osteoarthritis has demonstrated the potential for varus or valgus malalignment in the hindfoot axis. Rammelt et al. [7] reported achieving anatomical hindfoot alignment in 92% of cases using hindfoot arthrodesis nails combined with debridement of both joints. Similarly, Gong et al. [10] emphasized the necessity of simultaneous debridement of the tibiotalar and subtalar joints to ensure hindfoot stability and alignment. In the present study, hindfoot alignment improved significantly in both groups, even though formal open debridement of the subtalar joint was performed only in Group 1. This suggests that careful preoperative planning and strict adherence to retrograde nailing principles can result satisfactory hindfoot alignment, even in the absence of subtalar joint debridement.

Hindfoot arthrodesis using intramedullary nails is associated with various complications, including infection, malunion, delayed union or nonunion, nail breakage, plantar foot pain, stress fractures, and cortical hypertrophy. Among these, nonunion remains the most frequently reported complication (Fig. 4) [30, 31]. Several

Fig. 4 Preoperative anteroposterior (**a**) and lateral (**b**) radiographs of a patient with bilateral talus avascular necrosis. Final follow-up anteroposterior radiograph (**c**) shows solid fusion in the tibiotalar joint. Sagittal CT scan (**d**) and lateral radiograph (**e**) reveal subtalar joint nonunion

studies have advocated for routine open debridement of the subtalar joint to improve fusion outcomes in TTCA [8, 32, 33]. Reported hindfoot fusion rates vary widely, ranging from 86 to 100% [9, 13, 25, 34]. Mader et al. [13] achieved complete fusion of both joints using retrograde intramedullary nailing without subtalar joint debridement. In contrast, Lowe et al. [12], in a cadaveric study, demonstrated that retrograde reaming of the hindfoot resulted in the destruction of approximately 5.8% of the talus posterior facet and 4.0% of the calcaneus posterior facet. Richter et al. [34] reported that while some patients with incomplete fusion were able to mobilize pain-free, others continued to experience symptoms. In the present study, Group 2 demonstrated significantly lower subtalar joint fusion rates, despite the application of intramedllary reaming during the procedure. Although mid-term pain and functional scores were similar between the groups, patients with subtalar nonunion exhibited significantly worse long-term outcomes, as reflected in AOFAS, VAS, and Roles–Maudsley scores (Table 3). These findings suggest that, even in the absence of complete subtalar fusion, effective tibiotalar fusion, proper hindfoot alignment, and joint immobilization may be sufficient to achieve meaningful improvements in pain and function.

Patients undergoing TTCA often present with compromised soft tissue conditions, frequently as a result of prior surgical interventions. In cases where the subtalar joint is not prepared, the absence of an additional incision may allow for more limited soft tissue dissection, potentially reducing the risk of neurovascular injury [12]. Mendicino et al. [8] reported soft tissue necrosis in only 5% of patients who underwent TTCA with intramedullary nailing. Similarly, Fang et al. [32] noted that although simultaneous debridement of both joints prolonged the operating time (mean: 128 min), it resulted in successful outcomes. In this study, omitting subtalar debridement resulted in shorter operating times, reduced sural nerve injury, and fewer superficial infections; however, patients without subtalar fusion had significantly worse long-term functional outcomes. These findings underscore the importance of individualized surgical planning and appropriate technique selection, suggesting that satisfactory outcomes may still be achieved without subtalar joint debridement in carefully selected cases.

Our study demonstrated a notable difference in complication patterns between the two surgical groups. Group 1, which underwent more extensive open debridement, exhibited higher mid-term complication rates—likely due to greater surgical exposure and increased risk of soft tissue-related issues. In contrast, Group 2 had fewer early complications but showed a higher rate of long-term issues, potentially related to subtalar nonunion. These findings suggest a clinical trade-off between short-term morbidity and long-term fusion success, depending on the surgical approach.

The relationship between bony fusion and clinical outcomes has been extensively studied, with nonunion consistently linked to poorer functional results [23, 35, 36]. Krause et al. [36] reported that nonunion was associated with lower AOFAS hindfoot and Foot Function Index (FFI) scores, as well as reduced quality of life. Additionally, factors such as smoking, obesity, and unemployment were identified as risk factors for nonunion. Glazebrook et al. [23] reported significantly better functional outcomes (SF-12, FFI, AOFAS) in patients with greater osseous bridging at the fusion site. In our study, subtalar joint nonunion was similarly associated with inferior long-term outcomes, although it did not significantly impact mid-term outcomes.

The retrograde intramedullary nailing technique has become a standard approach in TTCA, with multiple studies supporting its effectiveness. While formal open debridement of the subtalar joint is widely regarded as essential for achieving radiological fusion, our findings suggest that omitting subtalar debridement may reduce operative time and soft tissue complications without compromising mid-term pain relief or functional outcomes.

This study has several limitations. Its retrospective design introduces potential sources of bias, including incomplete data and selection bias. The relatively small sample size (48 patients) limits statistical power and generalizability. The heterogeneous patient population, which included both post-traumatic and rheumatologic cases, may have influced outcome comparisons. As a single-center study, external validity is limited. Furthermore, procedures were performed by multiple senior surgeons, potentially introducing variability in technique. The lack of routine advanced imaging, such as postoperative CT scans, may have led to under or overestimation of fusion rates. Variability in postoperative care and rehabilitation protocols may also have influenced outcomes. Lastly, the study focused on radiological and functional results without incorporating broader quality-of-life measures, which limits the comprehensiveness of outcome assessment.

Conclusion

Open debridement of the subtalar joint during TTCA remains important for achieving optimal subtalar fusion. However, in cases where soft tissue conditions preclude safe access to the subtalar joint, satisfactory pain relief and functional outcomes may still be obtained through tibiotalar fusion and subtalar joint immobilization, even in the absence of complete subtalar fusion. This approach may be particularly advantageous in post-traumatic or infectious cases with compromised soft tissue envelopes.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13018-025-05817-w.

Supplementary Material 1

Supplementary Material 2

Supplementary Material 3

Supplementary Material 4

Supplementary Material 5

Supplementary Material 6

Author contributions

• B.Ö and D.A designed the study and supervised data collection. • M.B.K and K.A. performed the data analysis and statistical evaluations. • B.Ö and G.P. contributed to the interpretation of the results and manuscript writing. • B.D. reviewed the final version of the manuscript and provided critical revisions. • All authors read and approved the final manuscript.

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Data availability
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
This study was conducted in accordance with the principles of the Declaration of Helsinki. Ethical approval was obtained from the relevant institutional review board on December 2, 2015, with approval number: 34.

Consent publication
Not applicable.

Informed consent
Written informed consent was obtained from all participants before their inclusion in the study.

Competing interests
The authors declare no competing interests.

Author details
[1]Metin Sabanci Baltalimani Bone Diseases Training and Research Hospital, Department of Orthopaedic Surgery and Traumatology, Hastaliklari Egitim ve Arastirma Hastanesi Ortopedi ve Travmatoloji Klinigi Rumeli Hisari Cad. No: 62, Baltalimani, Sariyer-Istanbul 34470, Turkey
[2]Özel Akdamar Hospital, Van, Turkey
[3]Medicana Zincirlikuyu Hospital, İstanbul, Turkey

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