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The safety and efficacy of leaving Titanium Elastic Nail tips outside the skin in pediatric femoral diaphyseal fractures

Çocuk femur diafiz kırıklarında Titanyum Elastik Nail uçlarının cilt dışında bırakılması güvenli ve etkin midir?

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ABSTRACT

Aim: The aim of this study was to assess the efficacy of two different techniques involving titanium elastic nails (TEN) in pediatric femur diaphyseal fractures: leaving the nail tips outside the skin and placing them under the skin.

Patients and methods: We conducted a retrospective analysis of forty-six patients (comprising forty-seven fractures) who underwent TEN procedures for femoral diaphyseal fractures between January 2016 and July 2019. Patients were divided into two groups: Group 1 (nail tips left outside the skin) and Group 2 (nail tips left under the skin). We recorded patient age, gender, fracture side, and follow-up periods. Clinical assessments included hip and knee range of motion, presence of rotational or angular deformities, pin-site serous drainage, incision scars, and signs of infection. Radiological evaluations examined angulation, deformity, and length differences using anteroposterior (AP) and lateral radiographs. Implant removal times and complications were also documented.

Results: Group 1 consisted of twenty-one fractures, while Group 2 comprised twenty-six fractures. Age, gender, and fracture sides were similar between the two groups (p>0.05). However, the follow-up period was significantly longer in Group 2 (p<0.05), with a minimum follow-up period of nine months in both groups. Significant differences were observed in coronal and sagittal angulation measurements between the groups (p<0.05), although all measurements were within acceptable ranges for their respective age groups. Pin-site drainage was comparable between the two groups (p>0.05). Group 1 demonstrated a shorter implant removal time compared to Group 2 (p<0.05). Union was successfully achieved in all fractures in both groups, with no notable angulation defects, rotation defects, or shortening observed. No patients developed deep tissue infections.

Conclusions: In pediatric femur diaphyseal fractures, outpatient removal of implants without anesthesia by leaving the TEN tips outside the skin is feasible. This approach offers advantages similar to those of leaving the nail tips inside the skin in terms of union and angulation. However, pin-site infection remains a concern, which can be addressed through vigilant monitoring and parental education.

Keywords: Pediatric femur diaphyseal fracture, Titanium elastic nail (TEN), Elastic nail tip, Pin-site infection

ÖΖ

Amaç: Bu çalışmanın amacı, çocuk femur diyafiz kırıklarında Titanyum Elastik Çivi (TEN) uygulamasında çivi uçlarının cilt dışında ve cilt altında bırakılmasının geriye dönük olarak değerlendirilmesidir.

Hastalar ve yöntem: Ocak 2016 ile Temmuz 2019 tarihleri arasında femur diyafiz kırığı nedeniyle TEN uygulanan 46 hasta (47 kırık) geriye dönük olarak incelendi. Hastalar, çivi uçları cilt dışında bırakılanlar için Grup 1 ve çivi uçları cilt altında bırakılanlar için Grup 2 olarak adlandırıldı. Yaş, cinsiyet, kırık tarafı ve takip süreleri kaydedildi. Klinik değerlendirme; kalça ve diz hareket açıklığı (ROM), rotasyonel veya açısal deformiteler, pin dibi akıntısı, insizyon izleri ve enfeksiyon belirtileri; radyolojik değerlendirme ise anteroposterior ve lateral radyografilerde angulasyon, deformite ve uzunluk farkları üzerine yapıldı. İmplant çıkarılma süreleri ve gelişen tüm komplikasyonlar değerlendirildi.

Bulgular: Grup 1'de 21 kırıkta (TEN uçları cilt dışında bırakıldı), Grup 2'de ise 26 kırıkta (TEN uçları cilt altında bırakıldı). Her iki grup da yaş, cinsiyet ve kırık tarafları açısından benzer dağılıma sahipti. Grup 2'nin takip süresi anlamlı derecede daha fazlaydı (p<0,05), ancak her iki grupta da minimum takip süresi 9 aydı. Her iki grupta da koronal ve sagittal angulasyon dağılımları arasında anlamlı farklılıklar ortaya çıktı (p< 0,05), ancak angulasyon değerleri her iki yaş grubunda kabul edilebilir sınırlardaydı. Pin dibi akıntısı her iki grupta da benzer dağılıma sahipti (p > 0,05). Grup 1, implant çıkarma süresi açısından Grup 2'ye kıyasla daha kısa bir sürede başarı sağladı (p < 0,05). Her iki gruptaki tüm kırıklarda sorunsuz kaynama sağlandı. Hastalarda dikkate değer angulasyon kusuru, rotasyon kusuru veya kısalık gözlenmedi. Hiçbir hastada derin doku enfeksiyonu gelişmedi.

Sonuç: Pediatrik femur diyafiz kırıklarında TEN uçlarının cilt dışında bırakılması, poliklinik şartlarında ve anestezi gerektirmeden implantların kısa sürede çıkarılmasını sağlamanın yanı sıra, çivi uçlarının içeride bırakılmasıyla benzer güvenlikte olduğu için oldukça avantajlıdır. Ancak, çivi dibi enfeksiyonu hala ciddi bir endişe kaynağıdır. Bu nedenle, bu sorunun sıkı takip ve ebeveyn eğitimi ile çözülebileceği kanaatindeyiz.

Anahtar Kelimeler: Çocuk femur diyafiz kırığı, Titanyum elastik çivi (TEN), Elastik çivi uçları, Pin dibi enfeksiyon

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Introduction

Femoral diaphyseal fractures are the second most common fractures affecting the lower extremity in children, occurring at a rate of 20-26 per 100,000 children annually and accounting for 1-2% of all fractures in children. [1] The patient's age plays a crucial role in determining the appropriate treatment approach. While nonsurgical methods such as Pavlik bandage, skeletal or skin traction, and pelvic-pedal casting are preferred for young children, surgical intervention has gained prominence in the last decade to mitigate the adverse effects of prolonged immobilization, enhance patient compliance, and promote early mobilization in older children.

Surgical treatment options for femoral diaphyseal fractures include plate-screw fixation and the use of rigid or elastic nails. These procedures can be performed using closed, minimally invasive, or open techniques. [2] The ability to frequently perform these procedures using a closed or minimally invasive approach has led to the popularity of elastic intramedullary nails. In pediatric femoral diaphyseal fractures, titanium elastic nails (TEN) are considered the standard of care for children aged 5-11. [3-4] However, a common issue associated with the use of TEN is the formation of excessive callus around the implant tips left under the skin, leading to difficulties during removal. Additionally, if left in place for an extended period, these tips can become palpable and cause skin irritation, most commonly. [5-6] Nonetheless, leaving the ends of TEN outside the skin, similar to the technique used for excluding K-wires in pediatric supracondylar humeral fractures, may be considered as an alternative. Similarly, studies have reported low rates of pin-site infection in pediatric humeral supracondylar fracture cases. [7-8]

Although the outside-the-skin technique has been reported in the performance of titanium elastic nails (TEN) for pediatric forearm double fractures, studies on its application in femoral fractures are lacking. [9-10] Therefore, our study aimed to retrospectively evaluate the use of nail tips outside and under the skin during TEN procedures performed in pediatric femoral diaphyseal fractures.

Patients and methods

Forty-six patients (47 fractures) who underwent titanium elastic nail (TEN) procedures for pediatric femoral diaphyseal fractures between January 2016 and July 2019 were retrospectively examined. Local ethics committee approval was obtained (KAEK/2018.12.79).

All pediatric patients who underwent TEN for femoral diaphyseal fractures were included in the study. Exclusion criteria comprised delayed fractures, pathological fractures, and patients with syndromes or comorbidities.

Patients whose TEN ends were left outside the skin constituted Group 1, while those with TEN ends left under the skin formed Group 2. Although closed reduction and casting were initially attempted for all patients, surgical intervention was recommended when radiological acceptance criteria were not met. All surgeries were performed by qualified surgeons. While some surgeons routinely left the TEN tips under the skin, others left them outside. The same implant material and system were utilized for all patients.

Surgical Technique

Group 1 (Outside the skin)

After the patient is sterilely draped in the supine position, medial and lateral entry points are marked under fluoroscopic guidance, slightly above the distal femur physis line. Mini-incisions are made to pass through the skin layers, reaching the distal femur. Medial and lateral nails of appropriate diameter are selected and inserted through the guide holes. The fracture line is typically reduced closed, but in cases of unsuccessful reduction, a mini-open approach may be employed, and reduction is achieved manually. Once the fracture line is stabilized with nails, the tips of the titanium elastic nails (TEN) are trimmed to protrude outside the skin, and the skin is sutured to cover the nail tips. (Figure 1) No splint is routinely applied postoperatively to any patient. During outpatient clinic follow-ups, passive hip and knee flexion exercises are encouraged, while weight-bearing is restricted until fracture healing is evident. Families are instructed to perform daily passive hip and knee flexion exercises. Immediate weight-bearing

is recommended for both groups once radiographs confirm bridging callus formation across the fracture site. In cases of pin-site infection, daily dressing changes and close monitoring are advised. If pin-site infection persists despite dressing changes, early removal of the affected implant and continued monitoring with a single TEN nail in a splint may be considered. If both implant tips are infected and pin-site discharge does not improve with serial dressings, early removal of both implants and continued follow-up in a splint are planned.



Figure 1: Appearance of TEN tips left outside the skin on the patient

After radiological union is confirmed, the titanium elastic nail (TEN) tips are removed in the outpatient clinic setting. Prior to the procedure, all patients and their relatives are informed, and their consent is obtained. If the implant cannot be removed or if the patient's tolerance is low, the procedure will be deferred and performed under operating room conditions. The implant is grasped with pliers and removed using gentle hammer taps. Following removal, the patient is advised to bear partial weight and is scheduled for follow-up appointments.

Group 2 (Under the skin)

The surgical procedure is completed in a manner

similar to Group 1. The titanium elastic nail (TEN) tips are trimmed very close to the bone, left beneath the skin, and the incision is closed with sutures. During outpatient clinic follow-ups, knee and hip movement is permitted, but weight bearing is restricted until the fracture has healed. Once radiological union is confirmed, the TEN is removed under anesthesia, and the patient is readmitted to the hospital for an average duration of 6 months to 1 year.

Evaluation criteria

Age, gender, fracture side, and follow-up periods were recorded. Clinical evaluation included assessment of hip and knee range of motion (ROM), presence of rotational or angular deformities, pinsite serous drainage, incision scars, and signs of infection. Radiological evaluation involved examination of angulation, deformity, and length differences using anteroposterior (AP) and lateral radiographs. Implant removal times and all complications were assessed.

Statistical analysis

The statistical analysis was performed using IBM SPSS Statistics 26 (IBM, Chicago, IL, USA). Descriptive statistics, including mean, standard deviation, median, frequency, ratio, and range, were calculated, and data distribution was assessed using the Shapiro-Wilk test. Student's t-tests were utilized to compare data between the two groups. A significance level of p < 0.05 was considered statistically significant for all analyses.

Results

The study included a total of 46 patients, comprising 15 boys and 31 girls, all of whom had unstable closed fractures. One patient in Group 1 presented with bilateral femoral diaphyseal fractures. In Group 1, TEN tips were left outside the skin for 21 fractures, whereas in Group 2, TEN tips were left under the skin for 26 fractures. The average age in Group 1 was 7.19 years, whereas in Group 2, it was 7.58 years. The male-to-female ratio was 0.42 in Group 1 and 0.52 in Group 2. Both groups demonstrated similar distributions in terms of age, gender, and fracture sides. (p>0.05) (Table I)

		Outside the skin (Group 1) n= 20	Under the skin (Group 2) n = 26	p value
Age	Avg±Sd	7,19±1,5	7,58±2,14	0,471
	Min-Max	3-9	4-13	
Gender	Male	6	9	0,484
	Female	14	17	
Fracture side	Right	10	18	0,251
	Left	9	8	
	Bilateral	1	0	
Follow-up time (months)	Avg±Sd	12,47±4,3	24,38±8,86	0,001*
	Min-Max	9-23	9-42	
Coronal angulation	Avg±Sd	6,67±3,37	4,62±3,05	0,018*
	Min-Max	3,5-13,4	0,5-9,8	
Sagittal angulation	Avg±Sd	3,99±2,15	6,8±3,14	0,001*
	Min-Max	1,2-7,14	1,3-10,9	
Pin-site serous drainage	Yes	5	2	0,149
	No	16	24	
Implant	Avg±Sd	9,78±2,06	24,92±14,52	0,001*
removal times (weeks)	Min-Max	7-12	12-56	

ʻp< 0,05

When comparing the follow-up periods, the average follow-up period in Group 1 was 12.47 months, whereas in Group 2, it was 24.38 months. The follow-up period in Group 2 was significantly longer (p<0.05), although the minimum follow-up period in both groups was nine months. In terms of radiological evaluation, the average coronal angulation was 6.67 degrees in Group 1 and 4.62 degrees in Group 2, while the sagittal angulation was 3.99 degrees in Group 1 and 6.8 degrees in Group 2. There was a significant difference in the distribution of both coronal and sagittal angulation between the two groups (p<0.05), but all angulations were within acceptable limits for their respective age groups. (Table I)

In Group 1, superficial pin-site serous drainage occurred in 5 patients but resolved smoothly following implant removal. In Group 2, superficial pin-site serous drainage developed in 2 patients due to the migration of the implant tip from the skin. However, it regressed without any complications after implant removal. The distribution of pinsite drainage was similar between both groups. (p>0.05)

In Group 1, the implants were readily removed

under outpatient clinic conditions after callus bridging was observed, with an average duration of 9.7 weeks (range: 7-12 weeks). Conversely, in Group 2, implant removal was performed at an average of 24 weeks (range: 12-56 weeks) by reopening the incision under general anesthesia to locate the implant tip. Group 1 achieved a significantly shorter implant removal time compared to Group 2. (p<0.05)

In Group 1, all cases were successfully removed under outpatient clinic conditions, obviating the need for an operating room. However, in 5 patients in Group 2, removal necessitated creating a window with an osteotomy in the bone due to excessive burying and closure of the tip with callus. Consequently, these patients were monitored with a splint for a period.

Union was successfully attained without complications in all fractures in both groups. No significant angulation defects, rotational abnormalities, or shortening were noted in any of the patients. Furthermore, complications such as malunion, pseudoarthrosis, and refracture did not occur. Additionally, there were no instances of deep tissue infection among the patients.

Discussion

In this study, we demonstrated that leaving titanium elastic nail (TEN) tips outside the skin does not yield clinically or radiologically different outcomes compared to those left under the skin. Moreover, both approaches exhibited similar infection rates. However, leaving the TEN tips outside the skin offers the advantage of easier and earlier removal without anesthesia in outpatient clinic settings, thereby reducing implant removal time.

Percutaneous pinning treatment using Kirshner wires is commonly employed and considered safe for various fractures. Additionally, percutaneous implants placed outside the skin, such as external fixators or Ilizarov devices, are utilized in clinical practice. Although pin site infections associated with Kirshner wires or fixator pins have been reported, the incidence of severe infections is generally low. [11] For instance, in a multicenter study by Combs et al. [7], which included 369 supracondylar fracture patients treated with chrome-cobalt or titanium implants, only three

cases of pin site infection (0.81%) were identified. The authors recommended preoperative antibiotic prophylaxis, minimizing the duration of pin fixation, and early cast changes to mitigate infection risk. Another study suggested that leaving Kirshner wires outside the skin reduced the need for hospital admissions compared to burying them under the skin and did not result in significant clinical or radiological differences. [12] However, in our study, we observed a higher incidence of pin site infections than expected. Specifically, five patients with TEN tips left outside the skin developed pin site infections, while two patients with TEN tips left inside experienced pin migration during follow-up, resulting in pin site infections. Although these infections were superficial, the occurrence rates appear elevated relative to the study population size.

The studies by Kelly et al. [8] and Dincer et al. [9] closely resemble our study in terms of methodology and focus. Kelly et al. retrospectively analyzed 339 patients with forearm diaphyseal fractures treated with titanium elastic nails (TEN). They compared outcomes between patients with buried versus exposed TEN tips and found no significant differences in infection rates, refracture incidence, or other complications. Similarly, Dincer et al. conducted a current and prospective study involving 192 patients with forearm diaphyseal fractures treated with TEN. They observed that leaving the pin tips exposed was associated with shorter implant removal times and a lower incidence of skin irritation and embedded pins compared to burying the pins. Although superficial infections were detected in a small percentage of cases with exposed pin tips, the overall complication profile was comparable between the two groups, suggesting that leaving the ends of the implant exposed is safe. While our study did not directly compare fracture union times, we found that leaving the implant tips outside the skin facilitated earlier removal of the implant without anesthesia in outpatient clinic settings. Conversely, cases where the implant tips remained inside necessitated postponing the removal procedure due to the inability to remove the implant in outpatient settings. This was often due to concerns about repeat anesthesia procedures, lack of infection concerns at the nail site, and the availability of appropriate surgical conditions for the removal procedure.

The findings from our study align with those of Kelly et al. [8] and Dincer et al. [9], particularly regarding the challenges associated with leaving the implant tip under the skin. In our study, we also encountered difficulties related to the length of the implanted tip, where leaving it too short could lead to removal problems, while leaving it too long could cause skin irritation and discomfort. While forearm TENs have shown low infection rates when the implant tip is excluded, our study revealed a superficial infection rate of approximately 25%. Several factors may contribute to this higher infection rate in femoral TENs. Firstly, the femur is a weight-bearing bone subjected to significant stress and load compared to the forearm, which may increase the likelihood of infection. Additionally, the care and maintenance of lower extremities are inherently more complex than that of upper extremities, potentially contributing to the higher infection rates observed. The proximity of the femur to the urogenital area may also increase the risk of infection. Furthermore, the union time following femoral TEN procedures is longer compared to forearm TENs, resulting in the implant tip remaining exposed for a prolonged period. This prolonged exposure may increase the likelihood of infection, especially considering that the femur takes longer to fuse compared to forearm bones. However, it's worth noting that the superficial infections observed in our study resolved promptly following implant removal.

In adults, internal implants are typically left in place after osteosynthesis unless there are specific reasons for removal. However, in pediatric patients, implants are often designed to accommodate growth, or they may need to be removed post-osteosynthesis to prevent interference with skeletal development. Unlike external implants, which can be safely removed in outpatient clinic settings, internal implants usually require removal in the operating room. In a retrospective study by Simanovsky et al. [10], 143 children who underwent femur and forearm TEN implant removal were assessed. The study found that in 16 patients, implant removal was necessary due to bone embedding and skin irritation. Moreover, the implant could not be removed in 3 children, and refracture occurred

in 2 children after implant removal. This study prompted discussions regarding the necessity of implant removal in pediatric patients. In our study, conducted on the group where the TEN tips were left under the skin, we encountered challenges such as excessive burial and bone coverage of implants in 5 patients, leading to difficulties during implant removal.

Our studv demonstrates that radiological evaluation shows angulations within acceptable ranges, indicating that leaving the ends of the implant inside or outside does not biomechanically disrupt the effectiveness of the implant on reduction. Both coronal and sagittal angulations are equally affected by this approach. Clinically, successful outcomes regarding joint range of motion, rotation, and leg length differences in both groups indicate the efficacy of TEN treatment, unaffected by whether the TEN tips are left under or outside the skin.

However, it's essential to acknowledge the limitations of our study. Being retrospective and having a minimum follow-up period of nine months, along with the limited number of cases, are notable weaknesses. Therefore, prospective, randomized, and more extensive studies are warranted to provide more robust evidence for making decisions on this matter.

Conclusion

In pediatric femur diaphyseal fractures, leaving the TEN tips outside the skin enables quick removal of implants under outpatient clinic conditions without anesthesia. This approach offers advantages, as union or angulation issues are comparable to when nail tips are left inside. Nevertheless, the risk of pin-site infection remains a significant concern, which can be addressed through vigilant monitoring and parental education.

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