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Complications during removal of stainless steel versus titanium nails used for intramedullary nailing of diaphyseal fractures of the tibia

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ABSTRACT

Objectives: Intramedullary nailing is the treatment of choice for fractures of the tibial shaft, which might necessitate the nail removal due to complications in the long-term. Although considered as a low-risk procedure, intramedullary nail removal is also associated with certain complications. Here, we compared the most commonly used stainless steel and titanium nails with respect to the complications during removal and clinical outcome for intramedullary nailing of diaphyseal fractures of the tibia.

Patients and methods: Sixty-two patients (26 females, 36 males) were included in this retrospective study. Of the removed nails, 24 were of stainless steel and 38 of titanium. Preoperative and intraoperative parameters, such as implant discomfort, anterior knee pain, operating time and amount of bleeding, and postoperative outcomes were evaluated for each patient.

Results: Titanium nail group had more, but not statistically significant, intraoperative complications than stainless steel group during the removal of nails ($p = .4498$). Operating time and amount of intraoperative bleeding were significantly higher in titanium group than stainless steel group ($p = .0306$ and $p < .001$, respectively). Preoperative SF-36 physical component and KSS scores were significantly lower in patients who had removal of titanium nails than those of stainless steel nails, whereas there was no difference in terms of postoperative SF-36 and KSS scores.

Conclusion: In conclusion, although greater bone contact with titanium increases implant stability, nail removal is more difficult, resulting in more longer surgical operation and more intraoperative bleeding. Therefore, we do not recommend titanium nail removal in asymptomatic patients.

1. Introduction

Intramedullary nailing is the treatment of choice for fractures of the tibial shaft [1–3]. In long-term follow-up of patients treated with intramedullary nailing, patients' function was comparable to healthy population, but objective and subjective evaluation shows considerable sequelae [4]. The most common complication of intramedullary nailing is anterior knee pain [5,6]; but other rare complications such as nonunion, malunion, joint stiffness, and infection were also reported [1–3,7–9]. Consequently, tibial nail removal is often needed in clinical practice [8].

Removal of an intramedullary nail is commonly regarded as a minor, low-risk procedure with little morbidity. Boerger et al. investigated the outcome of 100 nail removals, and reported that intramedullary nail removal is a safe procedure, but anterior knee pain may persist in a significant proportion of patients after nail removal [10]. There are few reports in the literature of the complications associated with the removal of intramedullary nails [9–12]. Depending on study design and composition and position of nails, nail removal may cause various problems and the operating time, amount of bleeding, and difficulty of removal can vary accordingly. The outcome of implant removal also depends on both the implant type and its anatomic location, and around 70% of patients had an improvement in their symptoms after implant removal [13,14].

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The most commonly used nails for intramedullary nailing are stainless steel and titanium nails. In vitro and animal studies have shown that titanium nails have less bacterial adhesion and biofilm formation than implants made of stainless steel [15–17], which translates into reduced infection rates with titanium nails in clinical application [18]. Furthermore, stainless steel is associated with accumulation of iron and heavy metals in the surrounding tissues leading to significant tissue corrosion and biomechanical instability [19,20]. Considering these obstacles of stainless steel nails, we believe that titanium intramedullary nails are convenient choices in tibial diaphysis fractures. Therefore, in this study, we aimed to compare the complications during removal and clinical outcome of titanium and stainless steel nails used for intramedullary nailing of diaphyseal fractures of the tibia.

2. Patients and methods

2.1. Study design and patients

This is a retrospective study in which patients with an age range of 16–70 years, who underwent reamed tibial intramedullary nailing and nail removal between August 2000 and August 2010, were included according to the following criteria; nonpathological diaphyseal fractures of the tibia, fracture union, unassisted mobilization, anterior knee pain and discomfort due to nail, patient's request for the removal of nail, and follow-up for at least 3 months after nail removal. Seventy-three patients who comply with given criteria were included in the study. Of these, 11 were excluded for the following reasons: none of the fractures extended to the distal or proximal metaphyses (five patients), bilateral fractures treated as separate fractures (one patient), and any disease or drug usage causing to bleeding diathesis (five patients). Consequently, 62 patients (26 females, 36 males) were enrolled into the study. The study was approved by the Institutional Ethics Committee.

The surgical procedures in all patients were performed by the same orthopedic surgeon (M.S.). All nails had been locked statically using two proximal and two distal locking screws. Of the removed nails, 24 were of stainless steel and 38 of titanium.

2.2. Evaluated parameters

Implant discomfort, anterior knee pain, and no complaint were the clinical parameters evaluated preoperatively. Implant discomfort was defined as irritation caused by a locking screw head or pain in the implant region both on proximal and distal locking screws; anterior knee pain was a feeling of pain in the anterior part of the knee despite the absence of a long nail proximally; and no complaint was the desire for implant removal due to concerns of future problems despite the absence of objective complaints.

Intraoperative parameters were operating time, amount of bleeding, and intra- and postoperative complications and difficulties. Operating time from initiation of anesthesia to end of surgery was obtained from the patients' charts. During nail removal, a tourniquet inflated to 250 mmHg were used on all patients. The amount of bleeding in milliliters was determined from the volume of blood aspirated during the operation, the sterile gauze stained with blood, and the postoperative drainage. Intraoperative complications and difficulties such as a stuck nail, screw breakage, or eroded screw heads were recorded, along with any procedures needed to solve the problem. Possible postoperative complications were refracture, incision site problems, infection, new-onset anterior knee pain, neurovascular injury, deformity, and limited or painful movement of knee and ankle joints.

Postoperative functional outcome was evaluated by the time from operation to assisted and unassisted mobilization in days. Additionally, health-related quality of life was assessed pre- and postoperatively by SF-36 short-form, a validated and well-recognized functional questionnaire to measure patients' overall function and well-being on physical and mental basis, and normalized to a population mean of 50 as described by the American Academy of Orthopedic Surgeons [21,22] Knee Society's Knee Scoring System (KSS) was also applied pre- and postoperatively.

2.3. Statistical analysis

Statistical analysis was performed using the MedCalc Statistical Software version 12.7.7 (MedCalc Software bvba, Ostend, Belgium; http://www.medcalc.org.2013). The normality of continuous variables was investigated by Shapiro-Wilk's test. Descriptive statistics were presented using mean and standard deviation for normally distributed variables and median (and minimum-maximum) for the non-normally distributed variables. For comparison of two normally distributed groups Student *t*-test was used. The χ^2 test was used for categorical variables and expressed as observation counts (and percentages). Statistical significance was accepted when two-sided p value was lower than .05.

3. Results

3.1. Demographics and preoperative clinical characteristics of patients

The mean age of patients in stainless steel and titanium type or removed nails were 34.5 ± 12.6 and 34.2 ± 12.8 years, respectively (p = .9282). Most of the patients were male in both groups (14/24 and 22/38 in stainless steel and titanium groups, respectively, p = .8180). Characteristics of intramedullary nails (e.g. length and diameter), patients' overall activity level, type of injury, AO/OTA fracture classification, duration of nailing did not show significant difference between stainless steel and titanium groups (p > .05 for all, Table 1). Follow-up duration, however, was significantly longer in stainless steel group compared to patients with titanium nail (21.5 ± 8.1 and 17.7 ± 5.2 months, respectively, p = .0279, Table 1). Of all 62 patients, preoperative implant discomfort was reported in 11 patients. Thirty-five patients reported preoperative anterior knee pain, seven of which continued postoperatively. Sixteen patients (seven in stainless steel and nine in titanium groups) had no complaint preoperatively, but requested implant removal due to concerns of future problems.

3.2. Intraoperative parameters

Although titanium nail group had more intraoperative complications than stainless steel group during the removal of nails, the difference between groups did not reach the level statistical significance (p = .4498, Table 2). While two screw head breakage and one nail compression were recorded during removal of 24 stainless steel nails; four screw head breakage, two nail compression, and three eroded screw heads were associated with the removal titanium nails used to treat diaphyseal fractures of the tibia (Table 2). Operating time and amount of intraoperative bleeding were significantly higher in titanium group than stainless steel group (p = .0306 and p < .001, respectively, Table 2).

3.3. Postoperative outcome

None of the patients reported any postoperative complications such as wound problem, infection, refracture or neurological deficit in either stainless steel or titanium groups. Patients in both groups were mobilized with assistance on postoperative day 1. Time to unassisted mobilization was around nine days without any significant difference between groups. While preoperative SF-36 physical component and KSS scores were significantly lower in patients who had removal of titanium nails than those of stainless steel nails, there was no difference between stainless steel and titanium groups in terms of SF-36 and KSS scores postoperatively (Table 3).

Table 1
Demographic and preoperative clinical characteristics of patients in stainless steel and titanium nail groups.

		Type of intramedullary nails		p value
		Stainless steel (n = 24)	Titanium (n = 38)	
Gender	Female	10 (41.7)	16 (42.1)	.8180
	Male	14 (58.3)	22 (57.9)	
Age	Total	34.5 ± 12.6 (20–66)	34.2 ± 12.8 (21–69)	.9282
	Female	36.8 ± 10.7 (20–48)	35.1 ± 10.5 (21–47)	.5399
	Male	33.2 ± 12.9 (21–66)	32.9 ± 13.4 (23–69)	.9309
Characteristics of intramedullary nails	Length (mm)	340 ± 72 (240–400)	350 ± 94 (250–450)	.6581
	Diameter (mm)	9 ± 1.7 (7–13)	10 ± 2.1 (7–13)	.0546
Patients' activity level	Sedanter/Light	2 (8.3)	5 (13.2)	.8370
	Medium	7 (29.2)	11 (28.9)	
	Heavy	15 (62.5)	22 (57.9)	
Type of injury	Sports trauma	13 (54.2)	19 (50.0)	.9834
	Falling	2 (8.3)	4 (10.5)	
	Traffic accident	8 (33.3)	13 (34.2)	
	Work accident	1 (4.2)	2 (5.3)	
	Others	–	–	
Fracture classification (AO/OTA)	A1	2 (8.3)	3 (7.9)	.8677
	A2	6 (35.0)	10 (26.3)	
	A3	3 (12.5)	3 (7.9)	
	B1	5 (20.8)	6 (15.8)	.6727
	B2	4 (16.7)	9 (23.7)	
	B3	1 (4.2)	3 (7.9)	
	C1	2 (8.3)	4 (10.5)	–
	C2	1 (4.2)	–	
	C3	–	–	
Duration of nailing (months)		32.4 ± 7.8 (24–60)	34.2 ± 8.7 (24–54)	.4126
Follow-up duration (months)		21.5 ± 8.1 (12–48)	17.7 ± 5.2 (12–48)	*.0279*
Implant discomfort	Preoperative	4 (16.7)	7 (18.4)	.8688
	Postoperative	0 (0.0)	0 (0.0)	–
Anterior knee pain	Preoperative	13 (54.2)	22 (57.9)	.9797
	Postoperative (cont.)	3 (12.5)	4 (10.5)	.8629
No complaint	7 (29.2)	9 (23.7)	0.9356	

Data are given as n (%) or mean ± standard deviation (min–max).

Table 2
Intraoperative parameters in stainless steel and titanium nail groups.

	Type of intramedullary nails		p value
	Stainless steel (n = 24)	Titanium (n = 38)	
Intraoperative complications	3 (12.5) *(2 screw head breakage and 1 nail compression)*	9 (23.7) *(4 screw head breakage, 2 nail compression, and 3 eroded screw heads)*	.4498
Operating time (min)	61.4 ± 24.8 (45–120)	77.3 ± 29.1 (55–130)	*.0306*
Intraoperative bleeding (mL)	64.4 ± 35.7 (10–305)	224.4 ± 74.6 (40–510)	*< .001*

Data are given as n (%) or mean ± standard deviation (min-max).
Italic signifies complications.

4. Discussion

Implant removal (hardware) is among the most common procedures in the bone and joint surgery. Indications for implant removal are pain, discomfort, infection, non-union, malunion, and patient request in asymptomatic patients [7,10]. Although the risk of toxicity, allergy and carcinogenity exist with tibial intramedullary nails, removal of nails in a routine fashion is not recommended [23]. Specific indications for intramedullary nail removal are anterior knee and/or leg pain, pain and infection over locking screws [14]. On the other hand nail removal may cause intra- or postoperative complications, such as neurovascular injury, wound problems, infection, recurrence of deformity, and refracture [13]. In the present study, we evaluated the differences in complications and outcome of implant removal between two nail systems. The confounding variables such as patient demographics, mechanism of injury, fracture classification, duration of implant

Table 3
Postoperative parameters in stainless steel and titanium nail groups.

		Type of intramedullary nails		p value
		Stainless steel (n = 24)	Titanium (n = 38)	
Postoperative complication		0 (0.0)	0 (0.0)	–
Time to unassisted mobilization (days)		9 ± 7.2 (3–30)	9.1 ± 6.8 (5–20)	.9562
SF-36 (physical component summary score)	Preoperative	49.5 ± 3.4 (37.4–51.8)	44.6 ± 4.8 (37.9–52.5)	*.0001*
	Postoperative	61.4 ± 5.7 (39.4–66.7)	60.1 ± 4.8 (40.5–65.6)	.3381
SF-36 (mental component summary score)	Preoperative	51.2 ± 5.4 (40.3–57.9)	50.6 ± 6.9 (39.2–59.3)	.7190
	Postoperative	60.7 ± 11.6 (41.8–67.4)	59.2 ± 9.8 (41.7–66.7)	.5867
Knee Scoring System (KSS)	Preoperative	79.7 ± 16.2 (63.5–90)	76.4 ± 14.7 (62.4–85.4)	*< .001*
	Postoperative	88.6 ± 17.54 (71.2–94.4)	87.8 ± 19.7 (74.5–95)	.8716

Data are given as mean ± standard deviation (min–max).
Italic signifies complications.

placement, physical activity of patient did not show significant difference between stainless steel and titanium types of nails. We primarily found that although outcome of nail removal was similar between two types of nails, removal of titanium nail was associated with longer operating time and more intraoperative bleeding than stainless steel nails.

Intramedullary nails are typically composed of stainless steel or titanium. The modulus of elasticity of titanium (ETi = 110 GPa) is almost half of that of 316L stainless steel (ESS = 200 GPa). The mean strength of titanium (UTi = 800 MPa) is ~1.6-fold that of stainless steel (USS = 500 MPa) [24]. Therefore, the use of titanium nails is increasing owing to its lower modulus of elasticity and higher strength in comparison to stainless steel nails. Studies showed that titanium implants are in direct contact with the surrounding bone tissue, but a soft tissue layer as thick as 2 mm can form around stainless steel nails [14]. Krischak et al. [19] used atomic emission spectrometry to measure the iron, chrome, molybdenum, nickel, and titanium accumulation in the tissues near stainless steel and titanium implants 12 months after implant placement, and found significantly higher concentrations of iron, chrome, molybdenum, and nickel in the tissues around stainless steel implants, but only titanium accumulation around titanium implants. In addition, electron microscopy revealed significant tissue corrosion with stainless steel implants compared to titanium implants [19,21]. Titanium and stainless steel implants also have different characteristics that can affect bacterial adhesion to their surface and tissue reaction [20]. Pieske et al. [25] reported that this facilitates bacterial growth in the area, leading to a higher rate of infection with stainless steel implants. Considering the toxic, allergic, and potential carcinogenic effects of stainless steel, titanium implants are recommended if the implant does not require removal; since animal experiments proved that bone contact area and required strength to remove nails are greater in titanium nails in comparison with stainless steel nails [19,26,27]. Similarly, in this study we found that titanium nail has longer removal time and more bleeding than stainless steel nails, which can be explained by the need for greater mechanical binding at the bone-screw interface in titanium nails. It is important to note that higher amount of bleeding associated with titanium nails did not put any patient at risk.

It is reported that anterior knee pain is diminished in up to 56%–97% of patients after nail removal [9,10,14]. Nevertheless, 12% complained of new onset anterior knee pain [7]. In series of 71 patients, Karladani et al. reported that nail removal has limited pain-decreasing effect [28]. In our study, patients with anterior knee pain were pain free postoperatively and no patient complained of new onset anterior knee pain. The removal of tibial nails in asymptomatic patients is still of concern [7,28]. In our series, in addition to the symptomatic patients, we removed the nails from 16 (25.8%) asymptomatic patients who concerned future problems with their implants. In the previous studies, 3% refracture, up to 20% infection, neural injury and wound scar rates have been reported during implant removal [29,30]. However, no complications were observed in any of the two groups postoperatively in our study. Our results also revealed no significant difference between the two groups in terms of time to postoperative unassisted mobilization and health-related quality of life.

Retrospective nature, small sample size and different follow-up duration in patients were the main limitations of our study. Additionally, lack of any clinical, radiographic, or functional outcome measures prevents us to reach a definitive conclusion. Furthermore, the shorter follow-up duration in stainless steel group precludes the assessment of long-term outcome of nail removal. Nevertheless, our findings indicate disadvantages of titanium nails during removal in clinical practice.

We recommend the use of titanium nails as they provide better stability owing to greater bone contact, lower modulus of elasticity, and greater strength, and has fewer toxic, allergic, and carcinogenic effects than steel. Considering the possible complications, we do not recommend nail removal in asymptomatic patients. In addition, if necessary precautions are taken while removing titanium nails, these disadvantages can be overcome.

In conclusion, although greater bone contact with titanium increases implant stability, nail removal is more difficult, resulting in more longer surgical operation and more intraoperative bleeding. Therefore, good planning is essential before a nail removal operation. Preoperatively, the patients should be informed about the operating time, possible complications, and postoperative recovery. In addition, tools for removing broken screws should be at hand during the operation. Thus, the nail removal should not be underestimated.

Ethical approval

There is ethical approval.

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Author contribution

MS: Surgeon.
OG: Writer and surgeon.
MM: Study design.
FD: Data collection.
AG: Statistical analyses.
SM: Data collection.

Declaration of conflicting interests

The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

Guarantor

Assoc.Prof. Guler, Olcay.

Institutional ethics committee

This study was approved by the Institutional Ethics Committee and conducted in accordance with the latest version of the Helsinki Declaration. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent

Informed consent was obtained from all individual participants included in the study.

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