

New interlocking intramedullary nail for treating acute midshaft clavicular fractures in adults: A retrospective study

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ABSTRACT

BACKGROUND: The aim of this study was to retrospectively examine the radiological and functional results of midshaft clavicle fractures that were treated with a new, interlocking intramedullary nail, and employing a different locking option.

METHODS: Between January 2018 and January 2020, 24 displaced midshaft clavicle fractures were operated with new, interlocking intramedullary nail. Fractures were classified according to the AO/orthopedic trauma association classification, according to which there were 22 15.2.B (wedge) and 2 15.2.C (comminuted) fractures. The mean patient age was 35.5±14.2 (range: 18–63) years. Eighteen (75%) of the patients were male and six (25%) were female.

RESULTS: Follow-up data were recorded at a minimum of 1 year (range 12–36 months), with an average of 21.5 months (SD±8). The mean interval between the injury and surgery was 4.1 (SD±2.3; range: 1–9) days. Full shoulder movements had been achieved by all patients, relative to the contralateral side. The mean constant score was 95.6 (SD±4.2; range 90–100), and the mean visual analog scale score was 0.8 (SD±0.8; range: 0–3). Union was achieved in all patients. The mean union time was 9.5 (SD±1.8; range 6–12) weeks as assessed by radiograph. Average shortening of the clavicle relative to the contralateral side was 3.4% (SD±1.1; range 1.1–6.3). One patient experienced implant irritation, implant removal was performed after 14 months. No implant migration, hardware loosening, implant breakage, or neurovascular damage occurred. One hypertrophic scarring developed. One wound detachment developed at the 3rd post-operative week.

CONCLUSION: We think that this new intramedullary nail is a good alternative for wedge type fractures in adult, acute, displaced, and midshaft clavicle fractures.

Keywords: Clavicle; fractures; interlocking; midshaft; nail.

INTRODUCTION

Clavicle fractures account for 2–10% of all adult fractures, and 80% of these occur in the middle third of the clavicle. Many clavicle midshaft fractures heal well with conservative treatment. However, it has been reported that a shortening of more than 2 cm and a displacement of more than 100% may cause decreased shoulder function, worse clinic results, and high non-union rates; therefore, surgical treatment is in-

creasingly utilized.^[1–4] There is no standard surgical treatment method for displaced fractures. Plates and different types of intramedullary nails are widely used. Intramedullary nails have advantages, such as smaller incisions and less soft-tissue dissections and may or may not be locked.^[5]

In our clinic, a high number of secondary surgeries have been performed after surgical treatment of midshaft clavicle fractures. Problems encountered included hardware prominence,

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implant irritation, skin breakdown, and infection in patients who underwent plate fixation for displaced midshaft clavicle fractures. Thus, it was decided to apply locked intramedullary nails for this type of fractures.

The aim of this study is to retrospectively examine the radiological and functional results of midshaft clavicle fractures that were treated with a new, interlocking intramedullary nail.

MATERIALS AND METHODS

Locked, intramedullary nails were used in the treatment of all midshaft clavicle fractures in our clinic between January 2018 and January 2020, and for which we were considering surgical treatment. The indication for surgical treatment was displaced midshaft clavicle fractures with no cortical contact between the fracture fragments. Fractures were classified according to the Association for Osteosynthesis-Orthopedic Trauma Association classification, according to which there were 22 type 15.2.B (wedge) and 2 type 15.2.C (comminuted) fractures. Inclusion criteria included patients with a follow-up of at least 1 year and have attended their most recent follow-up appointment. Exclusion criteria included open fractures, pathological fractures, medial or lateral third fractures, patients with a neurovascular injury, fractures with a delayed presentation (more than 10 days after an injury), intubated patients, immature bone, <1 year follow-up, and patients with an additional injury in the same extremity. Two patients were lost during the follow-up period. A total of 24 patients were included in the study.

Ethics committee approval was obtained for the study (2021–89), and written informed consent was obtained from all patients.

Surgical Technique

All patients were operated on by a single, fellowship-trained hand surgeon of experience level 3 based on the classification of Tang and Giddins.^[6] Each patient was placed on the operating table in the semi-beach chair position. The affected shoulder was elevated with a bolster to make the clavicle more prominent. A 5–7 cm long incision was made laterally from the fracture line. The fracture line was exposed after the platysma, deltoid, and pectoralis major attachments were divided. The intramedullary canal of the medial and lateral fragment was reamed to the greatest possible diameter with a soft reamer. The lateral fragment was drilled laterally by entering through the intramedullary canal with a 1 mm large drill from the last reamer and exited from the posterolateral cortex. The nail of the largest diameter fitting the canal and of appropriate length was inserted through the posterolateral hole with rotational movements using a T-handle. The fracture was reduced, and the nail was introduced into the medial fragment. A guide was attached to the lateral locking hole of the nail with a 2.5 mm drill; the clavicle was drilled

from the posterolateral to the anteromedial, opposite cortex, and locking which were accomplished with a 3.5 mm locking screw. The threads in the screw head locked into the threads in the nail. Butterfly fragments were cerclaged to the nail anatomically with absorbable sutures without disturbing the soft-tissue attachments to restore clavicle length. No graft was used in any patient. One type of nail was used: TST Rakor Medical Instruments Industry and Trade Limited Company, Istanbul, Turkey. The titanium alloy nails were solid, rounded, and J-shaped (Fig. 1a-c). There was a single locking hole in the proximal region of the nail. The nails came in 3.5 mm, 4 mm, and 4.5 mm diameter options, and length options ranged from 90 mm to 120 mm, in 5 mm intervals. Intraoperative fluoroscopy was not used. Nail removal surgery was performed under general anesthesia in the half-beach chair position. A small incision was made from the lateral part of the old incision; first, the locking screw was removed, the threads of the guide pin were inserted into the threads at the top of the nail, and the nail was extracted using rotational movements.

The patients used an arm sling for 1 week, and pendulum, elbow, and wrist exercises were allowed from day 1. After 1 week, the arm sling was removed, and free motion and daily activities (washing, writing, eating, etc.), above-shoulder arm movements, and active, assisted range of motion (ROM) in all planes were allowed. Patients who could not achieve a full ROM by week 4 were referred to the physical medicine and rehabilitation unit of our hospital and embarked on a rehabilitation program for 1 h/day and 5 days/week, which included neuromuscular electric stimulation and stretching exercises.

Using the healthy side as the control, clavicular shortening was calculated as a percentage of the difference between the two. Union was defined as the bridging callus formation be-



Figure 1. (a-c) Image of clavicle nail with its application guide and images of locking screw.

tween the fracture fragments on the radiographs. Follow-ups were conducted at 2 weeks and 4 weeks postoperatively and thence at intervals of 2 weeks until union was achieved, and the last follow-up was scheduled. Anterior–posterior shoulder X-rays showing both clavicles were taken at the final follow-up. A constant score was used to assess functional evaluation and a visual analog scale (VAS) was used to assess pain at the last control. Shoulder ROM was measured with a goniometer. Final examinations were performed (independently from the surgical team) by a blinded, physical therapy, and rehabilitation specialist in our hospital.

Statistics

Descriptive statistics were assessed: For continuous variables, mean and standard deviation are presented; for categorical data, numbers and percentages are presented.

RESULTS

The mean patient age was 35.5 years ($SD\pm 14.2$, range: 18–63). Eighteen (75%) of the patients were male and six (25%) were female. The right side was affected in 12 patients, and the left side in 12 patients. There were no bilateral fractures. The dominant side was affected in 15 patients (62.5%). The causes of the fractures were as follows: motorcycle accident $n=7$; falls $n=6$; traffic accidents $n=6$; electric scooter accident

$n=2$; skiing accident $n=1$; bicycle accident $n=1$; and physical assault $n=1$.

The follow-up data were recorded at a minimum of 1 year (range: 12–36 months), with an average of 21.5 months ($SD\pm 8$). The mean interval of time between the injury and the surgery was 4.1 days ($SD\pm 2.3$, range: 1–9). The mean initial operating time was 47.9 minutes ($SD\pm 11$, range: 35–75), and the nail removal surgery time was 20 min. At post-operative week 4, 17 patients achieved full shoulder ROM relative to the contralateral side. Patients who did not achieve full ROM received rehabilitation for an average of 3.7 weeks ($SD\pm 2.1$, range 2–8). At the last control, full ROM had been achieved by all patients relative to the contralateral side. The mean constant score was 95.6 ($SD\pm 4.2$, range 90–100), and the mean VAS score was 0.8 ($SD\pm 0.8$, range: 0–3).

Union was achieved in all patients (Figs. 2a–e and 3a–d). The mean union time was 9.5 weeks ($SD\pm 1.8$, range 6–12) as assessed by radiographic imaging. Average shortening of the clavicle relative to the contralateral side was 3.4% ($SD\pm 1.1$, range 1.1–6.3). All patients who were working returned to work, and non-working patients resumed their unlimited daily activities in both groups. One patient experienced implant irritation, resulting in implant removal after 14 months. No implant migration, hardware loosening, implant breakage, or

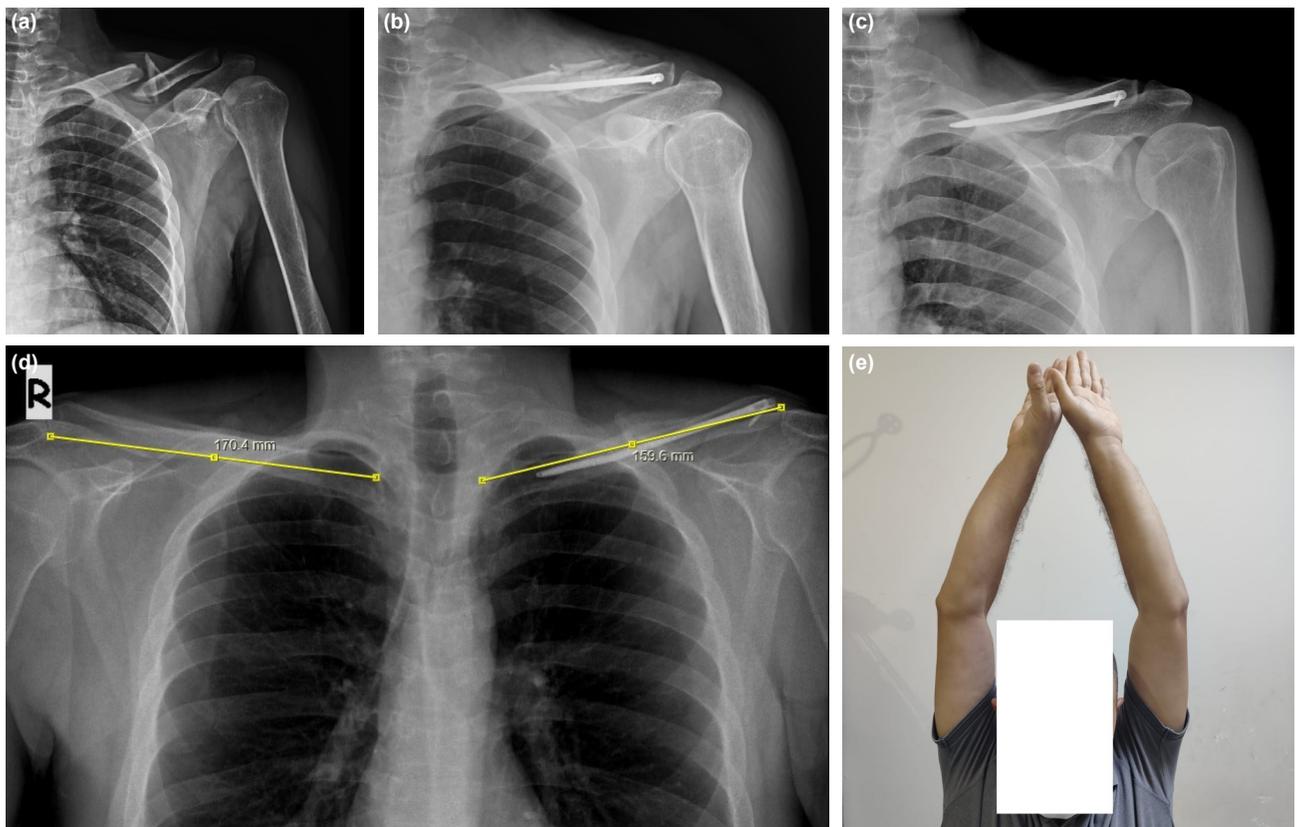


Figure 2. (a, b) Pre-operative and post-operative 8 week anteroposterior X-rays of a 38 year-old male, who sustained a comminuted fracture of the left clavicle, (c, d) 2 year post-operative anteroposterior X-ray after union with post-traumatic shortening of 6.3%, and (e) clinical image of same patient.

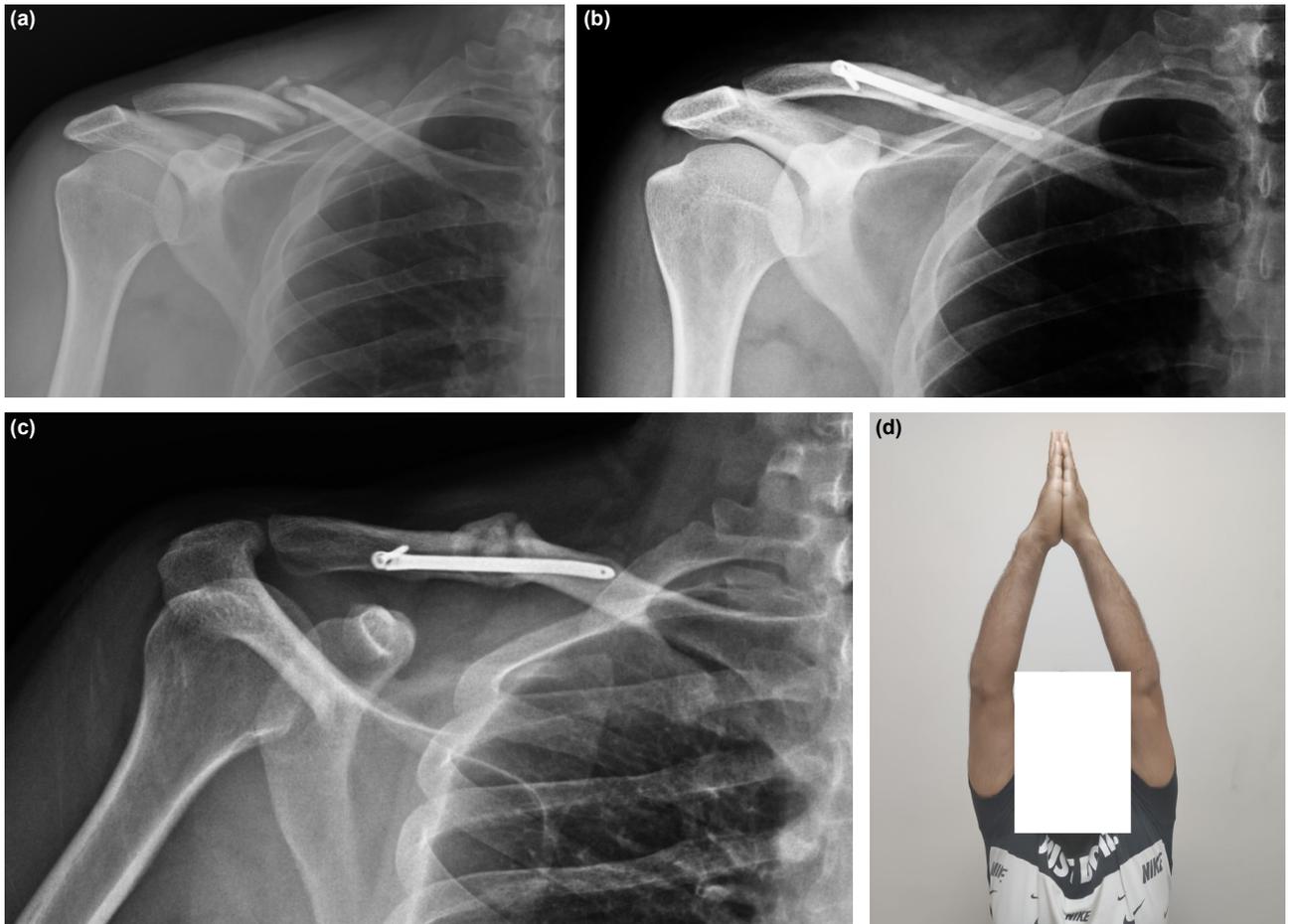


Figure 3. (a, b) Pre-operative and post-operative early anteroposterior X-rays of a 33 year-old male, who sustained a wedge fracture of right clavicle, (c) 1 year post-operative anteroposterior X-ray after union, and (d) clinical image of same patient.

neurovascular damage occurred. One patient developed hypertrophic scarring. One patient experienced wound detachment at the 3rd post-operative week; accordingly, wound debridement and primary suturing were performed, and healing was achieved.

DISCUSSION

This study has shown that the new intramedullary nail can be safely applied in acute midshaft wedge and comminuted clavicle fractures. The relative stability it provides allows for early movement, early return to daily activities, and abundant callus development during union. Successful union was achieved in all fractures and good functional results were seen in all patients, with a low complication rate. Additional advantages included less soft-tissue dissection and no requirement for fluoroscopic imaging.

Displaced clavicle fractures have a risk of symptomatic malunion (15.1%) after conservative treatment; therefore, there has been a trend toward surgical treatment in the last decade, with plate fixation becoming the standard treatment.^[3,7] Improved functional outcomes and lower rates of malunion and non-union were observed in displaced midshaft clavicle frac-

tures treated with plate fixation.^[8] There is debate with regard to which treatment – plate fixation or an intramedullary nail – is more effective. Many randomized clinical trials and meta-analyses have shown no difference between them in the long term, while some studies have shown plate fixation to be superior.^[9–11] The non-union rate was 11–12% in various studies utilizing non-operative treatment, while the results of this study showed a better rate of union (0%) compared with non-operative treatment.^[12,13] When comparing these constant scores and union rates with the literature, they are similar to those treated operatively and better than those treated conservatively.^[10,14,15]

The most significant complications associated with intramedullary nails are nail migration, implant irritation, and wound problems. Nordenstedt et al.^[16] treated 52 acutely displaced middle third diaphyseal fractures with a Rockwood clavicle pin. Wound problems occurred in 12 patients (18%), implant breakage developed in one patient (2%), and penetration of the lateral part of the pin was observed in five patients (8%). When Gadegone and Lokhande^[17] applied a screw elastic intramedullary nail to 36 midshaft clavicle fractures, a medial nail protrusion developed in three patients and a delayed

union occurred in five patients. In another study performed with titanium elastic nails, a medial migration developed in seven out of 31 (22.6%) fractures and a lateral cortex perforation occurred in one (3.2%).^[18] Millett et al.^[19] treated 58 clavicle fractures with a Rockwood clavicle nail, and adverse outcomes included two superficial wound infections, two post-union hardware failures, and five skin erosions with a pin exposure. Naimark^[20] reported a 15% rate of implant removal after treatment through plate fixation, and symptomatic implant-related implant removal was detected 4 times more frequently in female patients. The complication rate of the data in this study was low compared with other studies. Complications included one wound detachment and one hypertrophic scar development, and implant removal was performed per the patient's request due to their symptomatic pain. It was postulated that the overall rate of irritation was lower than previously published articles due to the fact that the nail was applied from the posterolateral side and there was sufficient soft-tissue coverage over the entry site of the nail. In addition, we did not see nail migration or nail dislocation as a result of the use of a locking screw and close fitting of the nail to the medulla.

The application of an intramedullary nail to treat comminuted fractures is controversial, with shortening, nail protrusion, and telescoping being the main complications. Post-operative clavicular shortening results in telescoping until the medial main fragment comes into contact with the lateral main fragment. In a series of 36 patients who underwent treatment using a screw elastic intramedullary nail, a shortening between 3 and 5 mm was observed in ten patients, but there was no functional impairment.^[17] In the study of Smekal et al.,^[21] a 2.2% shortening was found in simple fractures, 3.9% in wedge fractures, and 4.1% in comminuted fractures compared with the contralateral side. Treatment through plate osteosynthesis has been suggested to provide stability and clavicular length in comminuted fractures with severe shortening. In a study comparing plate and titanium elastic nails, clavicular shortening was found to be significantly higher in the titanium elastic nail group after union.^[15] In a randomized controlled study, in which 35 patients were treated with a plate and 37 patients with an intramedullary locked nail, a mean shortening of 14 mm in the plate group and 15 mm in the nail group was found, and no significant difference was found between the groups in terms of shortening.^[11] In this study, shortening was calculated by proportioning it according to the opposite side rather than the length, since there may be an error in the real measurement. In this study, the mean shortening of the clavicle was 3.4% compared with the contralateral side, but functional impairment did not develop in any of the patients. A 5.7% shortening in one of the two comminuted fractures was found and 6.3% in the other. These rates were the two highest values. Therefore, it can be concluded that this nail is not suitable for comminuted fractures. Furthermore, comparative studies with treatment through plate osteosynthesis for comminuted fractures are required for the evaluation of clavicular length.

The small size of the patient group, the absence of a control group, and retrospective design were the weaknesses of this study. J-shaped, rigid, tight fitting, and interlocking intramedullary nails in displaced midshaft clavicle fractures provided sufficient axial and rotational stability for union and early motion after surgery. An additional benefit of this technique was the lack of requirement for fluoroscopic imaging during the surgery.

Conclusion

This study concludes that a new intramedullary nail from TST Rakor Medical Instruments is a good alternative for the treatment of wedge-type fractures in adult, acute, displaced, and clavicle diaphysis fractures. Using this nail, excellent union rates with low complication rates were achieved. Patients had a faster return to their daily activities and reported satisfactory results on follow-ups, both subjectively and objectively.

Ethics Committee Approval: This study was approved by the Haydarpaşa Numune Training and Research Hospital Clinical Research Ethics Committee (Date: 15.03.2021, Decision No: 2021-89).

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ORJİNAL ÇALIŞMA - ÖZ

Erişkinlerde akut orta shaft klavikula kırıklarının tedavisinde yeni kilitli intramedüller çivi: Geriye dönük bir çalışma

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AMAÇ: Bu çalışmanın amacı, farklı bir kilitleme seçeneği kullanılarak yeni, kilitli intramedüller çivi ile tedavi edilen orta shaft klavikula kırıklarının radyolojik ve fonksiyonel sonuçlarını geriye dönük olarak incelemektir.

GEREÇ VE YÖNTEM: Ocak 2018 ile Ocak 2020 arasında, 24 deplase orta shaft klavikula kırığı yeni, farklı kilitleme seçeneği bulunan intramedüller çivi ile ameliyat edildi. Kırıklar AO/OTA sınıflamasına göre sınıflandırıldı, buna göre 22 adet 15.2.B (kama), iki adet 15.2.C (parçalı) kırık vardı. Ortalama hasta yaşı 35,5±14,2 (dağılım: 18–63) yılıdır. Hastaların 18'i (%75) erkek, altısı (%25) kadındır.

BULGULAR: Takip verileri en az bir yıl (12–36 ay), ortalama 21.5 aydır (SD±8). Yaralanma ile ameliyat arasındaki ortalama süre 4.1 (SS±2.3; aralık: 1–9) gündür. Tüm hastalarda karşı tarafa göre tam omuz hareketleri sağlanmıştır. Ortalama Constant skoru 95.6 (SD±4.2; aralık 90–100) ve ortalama VAS skoru 0.8 (SD±0.8; aralık: 0–3) idi. Tüm hastalarda kaynama sağlandı. Ortalama kaynama süresi, radyografi ile değerlendirildiği üzere 9.5 (SD±1.8; aralık 6–12) haftadır. Klavikulanın karşı tarafa göre ortalama kısalması %3.4 idi (SD±1.1; aralık 1.1–6.3). Bir hasta implant irritasyonu yaşadı, implantın çıkarılması 14 ay sonra gerçekleştirildi. Implant migrasyonu, donanım gevşemesi, implant kırılması veya nörovasküler hasar oluşmadı. Bir hipertrofik skar gelişti. Ameliyat sonrası üçüncü haftada bir yara dekolmanı gelişti.

TARTIŞMA: Bu yeni intramedüller çivinin erişkin, akut, deplase, orta shaft klavikula kırıklarında kama tipi kırıklar için iyi bir alternatif olduğunu düşünüyoruz.

Anahtar sözcükler: Çivi; kırıklar; kilitleme; klavikula; orta shaft.

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