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ORIGINAL STUDY

Biomechanical comparison of fracture site stabilities of femur nails after fracture site resorption

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Instability increases after fracture site resorption. This study aimed to compare the fracture site stabilities of different femoral nails after fracture site resorption. Thirty composite femurs were divided into three groups of 10 interlocking nails. Using axial compression–distraction machines and a custom-made torsion device, the fracture site rotational and axial stabilities after 1 mm fracture site resorption were determined. Between 6 Nm external and 6 Nm internal rotation torques, the means of the maximum fracture site rotation arc of motion were 5.94 mm for compression nails, 5.9 mm for interlocking nails and 3.5 mm for CAROT nails. Between 2300 N compression and 150 N distraction forces, the means of the fracture site axial motion were 3.15 mm for interlocking nails, 1.26 mm for compression nails and 1.26 mm for CAROT nails. CAROT nails are superior to compression and interlocking nails in fracture site rotational and axial stabilities after 1 mm fracture site resorption.

Keywords : femoral fractures ; fracture fixation ; intramedullary ; fracture healing ; bone resorption.

INTRODUCTION

Intramedullary nailing is the preferred treatment method for femoral shaft fractures and related complications such as non-unions. Bone healing with a disproportionate callus formation due to fracture site macro-motion is a common feature of interlocking nailing *(7)*.

Bone healing is negatively influenced by a completely restricted and excessive inter-fragmentary motion *(5,10)*. In an animal study, the continuous compression on fracture edges was shown to enhance the angiogenesis process at the fracture site *(19)*.

Interlocking nails have been reported to allow an overall 14.2° of inter-fragmentary motion between a 4 Nm internal rotation (IR) and a 4 Nm external rotation (ER) torque *(4)*. The narrowest circumference of femoral diaphysis has been reported to be around 91 mm *(6,17)*. A fracture site rotation of 14° causes a nearly 3.5 mm rotational movement at the fracture site *(6,17)*.

For locking screw insertion, an intramedullary nail should have at least a 0.5 mm wider screw hole diameter than the locking screws themselves *(4)*. It should also contain holes with an equivalent width with locking screws for a snug fit to prevent the toggling effect between the nail hole and

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the locking screw in order to prevent rotational instability. To avoid the toggling effect between the nail and the locking screw, we developed a novel compressive anti-rotational (CAROT) nail with proximal and distal keyhole-like screw holes.

Some studies demonstrated that a radiographically visible gap would appear at fracture sites later on because of fracture edge resorption even after a firm fixation with interlocking nails *(2,14)*. Searching the literature did not reveal any study on inter-fragmentary rotational stability after fracture site resorption.

The purpose of this study is to assess and compare the fracture site stability after a 1 mm fracture site desorption by measuring the fracture site arc of the rotational motion and the axial motion of compression nails, interlocking nails and the newly designed CAROT nails.

MATERIALS AND METHODS

Thirty medium, left and fourth-generation composite femurs (Model 3403; Sawbones Europe AB MALMOE, SWEDEN, cellular 20 pcf) were used. All femurs had a 455 mm length and a 13 mm intramedullary canal diameter. Before performing a transverse osteotomy (AO/OTA 32-A3) at the midpoint (21 cm distal to the trochanteric fossa), gradual reaming with 9– 14 mm-diameter reamers was conducted. To enable the free rotational movement of the nail, extra reaming of the most proximal and distal 7 cm portions of the femoral canals with 16 mm reamers was performed. To achieve a true transverse osteotomy, the roughened and irregular edges of the osteotomy margins were smoothened by a grinder to minimise friction between the fracture edges.

Composite femurs were divided into three groups of 10 conventional interlocking, 10 compression and 10 CAROT nails. All nails were stainless steel, 12 mm in diameter and 400 mm in length (Tıpsan Medical Device Company, İzmir, Turkey).

In interlocking nails, the diameter of the three screw holes was 5.5 mm. One proximal 5 mm non-threaded locking screw and two distal 5 mm low threaded locking screws were inserted.

In compression nails, the diameters of the screw holes were one proximal 5.5 mm × 20 mm oblong screw hole and two distal 5.5 mm screw holes. One 5 mm non-threaded proximal locking screw and two 5 mm low threaded distal locking screws were inserted. A constant inter-fragmentary compressive force was applied to compression nails with a proximal central compression screw by a 7 Nm torque wrench.

CAROT nails comprised one proximal 26 mm and two distal 14 mm long keyhole-like screw holes. The wide upper portion of the keyhole-like holes was 6.5 mm in width and the distal slot part was 5.5 mm in width (Figure 1). A 5.5 mm non-threaded proximal locking screw and two 5.5 mm low threaded distal locking screws were inserted to the wide upper region of the holes. The compression tube of CAROT nails is 59 mm in length and 13 mm in width (Figure 1).

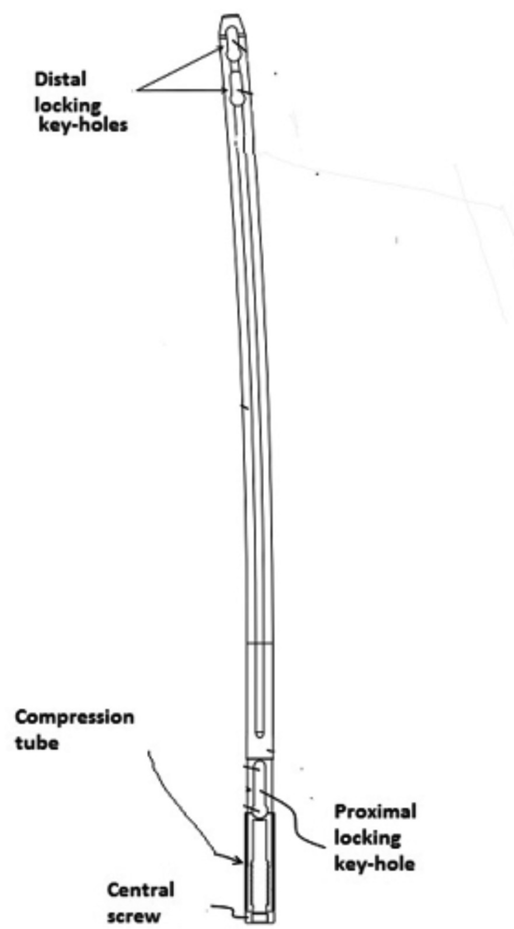

Fig. 1. — Illustration of keyhole-shaped one proximal and two distal locking screw holes of the CAROT nail

Compression was initiated when the distal locking screws touched the distal edge of the distal holes of the nail. The total length of the nail decreased by telescoping as the length between the proximal and the distal locking screws shortened, and a simultaneous fracture site compression occurred at the osteotomy site. A constant inter-fragmentary compressive force was applied to all CAROT nails by a 7 Nm torque wrench.

A 1 mm segmental composite bone was resected from the proximal fragment at the fracture site by a hacksaw to mimic minimal fracture site resorption.

The biomechanical experiment was conducted at the Biomechanics Laboratory of the Institute of Health Science at the University of Dokuz Eylül. A Shimadzu Autograph AG-5kNG universal test machine (Shimadzu Corp., Tokyo, Japan) was used for distraction–compression. The universal test machine was adjusted on an external torsion device with two height-adjustable arms and a base plate (Figure 3). Composite femurs were fixed within two 100 mm × 80 mm cylinders and stabilised with 6 mm × 8 mm pins. The proximal femoral segment in one cylinder was fixed to the apparatus, and the other cylinder attached to the distal femoral segment was anchored to a steering wheel device to enable unrestricted rotation in all directions (Figure 2) *(9)*.

On the lateral side of the composite femurs, optic markers were placed near the proximal and distal edges of the fracture site (osteotomy line). The rotational movement at the osteotomy site was measured by a video extensometer (DVE - 101 - 201, Shimadzu Corp., Tokyo, Japan). All samples were preloaded with a 0.5 Nm torque on both sides, and the rotational torque rate was adjusted to 0.30° per second in the displacement control mode *(11,18)*.

A 6 Nm IR torque and a 6 Nm ER torque were applied to the distal fragment of the composite femur–nail constructs similar to previous studies *(1,4,9,11,15,16,18)*. The values of the fracture site maximum arc of rotation were recorded in the femur–nail constructs between the 6 Nm IR and 6 Nm ER torques; these values represent the physiological loading of level walking. The values of the fracture site maximum arc of rotation between 10 Nm ER and 6 Nm IR torques in all the 30 constructs were also recorded; these values represent the physiological loading of descending stairs *(11,15,16,18)*.

To measure the fracture site axial compression and distraction movements in the universal test machine (without an external torsion device), optic markers were placed proximal and distal to the osteotomy site on the anterior–medial side of the composite femur–nail constructs (Figure 3). A 107 N distraction force was reported to occur in the femur in a 'hanging leg' position *(13)*. Thus, a 150 N distraction force after a 2300 N compression

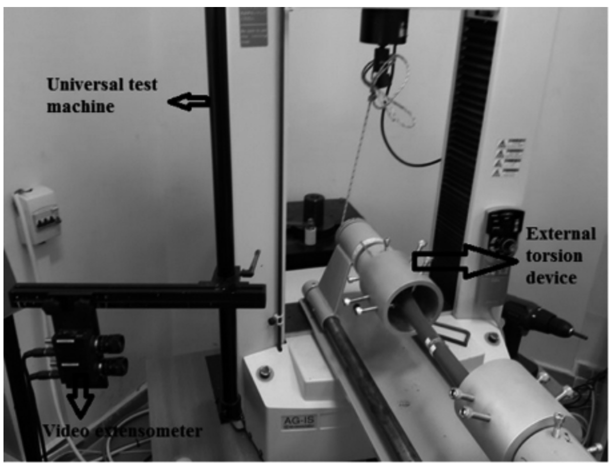

Fig. 2. — Video extensometer on the left side and optic markers on the composite femur in the external torsion device and the universal test machine to measure the fracture site rotational arc

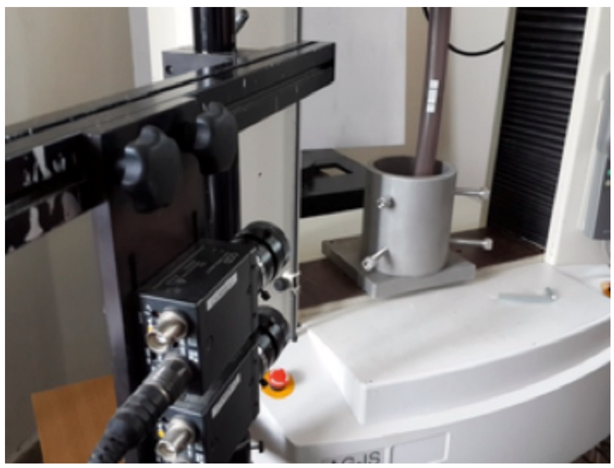

Fig. 3. — Video extensometer on the left side and optic markers on the composite femur in the universal test machine to measure the fracture site axial compression–distraction movement

load (peak axial load on the femur while going down the stairs for a 75 kg man) on all the 30 constructs was applied similar to previous studies *(9,11,13,15,16,18).* The loading rate was 20 mm/min in the displacement control mode *(11)*.

The data of the fracture site maximum arc of rotation and of the fracture site distraction gap of all three groups of femur–nail constructs after a 1 mm fracture site resection were compared using the Mann–Whitney U test. The level of significant difference was defined as P < 0.05.

RESULTS

Between 6 Nm ER and 6 Nm IR torques (the torques on the femur during a level walking activity for a 75 kg healthy man) after a 1 mm fracture site resection, the maximum arc of fracture site rotation motion of CAROT nails (mean 3.5 mm) was found to be 69% less than that of interlocking nails (mean 5.9 mm; p = 0.000) and 70% less than that of compression nails (mean 5.94 mm; p = 0.000) (Tables I and II).

Between 10 Nm ER and 6 Nm IR torques (stair descending activity for a 75 kg healthy man) after a 1 mm fracture site resection, the maximum arc of fracture site rotation motion of CAROT nails (mean 4.1 mm) was found to be 70% less than that of interlocking nails (mean 7 mm; p = 0.000) and 62% less than that of compression nails (mean 6.6 mm; p = 0.000) (Tables I and II).

Between 150 N distraction (loading on the femur in a 'hanging leg' position) and 2300 N compression forces (the forces on the femur while going down the stairs for a 75 kg healthy man) after a 1 mm fracture site resection, an average of 1.26 mm axial motion in compression and CAROT nails and an average of 3.15 mm axial motion in interlocking nails were recorded.

No permanent deformation was recorded in all three groups of nail bodies and locking screws during the biomechanical tests.

Table I. — Maximum arc of fracture site rotation of 30 composite femur–nail constructs after 1 mm fracture site resorption (mean±SD; 95%CI mm and angle) (n=30)

	Between 6 Nm RE and 6 Nm RI torques	Between 10 Nm RE and 6 Nm RI torques
Interlocking nail (mean±SD;95%CI mm and angle)	5.9±1 (5.24–6.49) 23.3°	7±1.22 (6.3–7.77) 27.7°
Compression nail (mean±SD;95%CI mm and angle)	5.94±1.36 (5.09–6.92) mm 23.5°	6.65±1 (5.86–7.65) mm 26.3°
CAROT nail (mean±SD;95%CI mm and angle)	3.5±0.51 (3.05–3.88) mm 13.8°	4.1±0.58 (3.62–4.63) mm 16.2°

Table II — Maximum arc of fracture site rotation of 30 composite femur–nail constructs after 1 mm fracture site bone resorption (Mann–Whitney U test) between CAROT nails and other nails and P values (mm, mean) (n=30)

Rotation torques	Nail fracture site arc of rotation (mm)	Nail fracture site of rotation (mm)	P value
max. rotation in 10 Nm Re-6 Nm RI	CAROT nail average 4.1 mm	Interlocking nail 7 mm	P=0.000 70% difference
		Compression nail average 6.65 mm	P=0.000 62% difference
Max. rotation in 6 Nm Re-6 Nm RI	CAROT nail average 3.5 mm	Interlocking nail 5.9 mm	P=0.000 69% difference

DISCUSSION

This study aimed to assess and compare the maximum fracture site arc of rotation and axial motions among three models of intramedullary nailing systems during daily activities after a 1 mm fracture site resection in a trial to imitate fracture site resorption.

Between 6 Nm ER and 6 Nm IR torques, CAROT nails demonstrated superior results to interlocking nails (69%) and compression nails (70%) in the maximum inter-fragmentary rotational stability in daily activities such as stair descending.

According to a previous study, between 6 Nm ER and 6 Nm IR torques without fracture site resorption, the maximum arc of fracture site rotational motion mean was 1.21 mm in compression nails (compressed 7 Nm torque wrench), 1.13 mm in CAROT nails (compressed 7 Nm torque wrench) and 5.61 mm in interlocking nails *(9)*. Consistent with the experimental design of the previously mentioned study, between 6 Nm ER and 6 Nm IR torques with 1 mm fracture site resorption, the mean maximum arc of fracture site rotational motion in the present study was 5.94 mm in compression nails, 3.5 mm in CAROT nails and 5.9 mm in interlocking nails. A significant difference was found in the fracture site maximum arc of rotation before and after 1 mm fracture site resorption among the three types of nails.

Under compression, the distal locking screws in compression nails are eccentrically and partially fitted in the distal portion of the distal round screw holes, and partial fitting reduces the toggling effect between locking screws and distal screw holes, which partially enhances the rotational stability. After 1 mm fracture site resorption, the partial fitting between hole and locking screw and the fracture site compression are lost. As the screw hole width is larger than the width of the locking screw, the toggling effect between locking screws and screw holes reduces the rotational stability of compression nails.

After fracture site resorption of 1 mm, the proximal and distal locking screws in CAROT nails remain in the narrow slot part of the keyhole-like screw holes, the width of which is equivalent to the diameter of the locking screw for a tight fit, which does not enable the toggling effect to take place. As the toggling effect is minimal, the rotational stability is substantially preserved in CAROT nails after fracture site resorption of 1 mm.

Fracture site resorption has been demonstrated to occur between even firmly fixed fractures fragments *(14)*. It leads to a radiographically visible gap at the fracture site *(14)*. Therefore, a slotted plate was designed to prevent this situation *(14)*. The bone ends at the fracture site are usually deprived of their blood supply. This deprivation leads to avascular necrosis and resorption later on, especially in severely comminuted and high-energy fractures. Moreover, fracture site resorption may create a radiographically apparent gap at the fracture site several weeks after trauma during a normal fracture healing process *(2)*. Searching the literature did not reveal any study determining the exact value of bone resorption occurring at fracture sites in low- and high-energy fractures. For that reason a one mm gap was created to simulate minimal fracture site resorption.

This biomechanical study revealed that the maximum fracture site arc of rotation and axial motions after 1 mm fracture site resorption in interlocking nails and compression nails were significantly greater than those of CAROT nails. Fracture site compression applied during surgery was demonstrated to reduce bone union time, even if resorption took place at the fracture site *(12)*. As the fracture site motion increases, the resorption of the fracture site increases *(8)*. Previous studies showed that the excessive mobility of the fracture ends prevents new vessel formation and traumatises the already present blood supply at the fracture site *(8,12)*. Bone healing can also be seriously affected if the fracture site motion is completely inhibited *(5,10)*. Therefore, a range of acceptable inter-fragmentary motion exists. However, no studies have been conducted to reveal the accurate inter-fragmentary arc of motion range allowed for an optimum bone healing to occur.

The ER torque on the femur was reported to reach its peak at 0.8 BWcm (6 Nm) rotational torque in the early stance phase, changing route (IR) in mid-stance at 0.8 BWcm (6 Nm) rotational torque on the femur in level walking for a 75 kg man *(15,16)*. The ER torque on the femur reaches its peak at 1.3 BWcm (about 10 Nm), followed by 0.73 BWcm (about 6 Nm) IR rotational torques in stair descending and quickstep for a 75 kg man *(15,16)*. In postoperative daily life activities, level walking may not be adequate for independent movement. Movements such as getting of a car, getting off a chair or wheelchair and getting up from the toilet resemble the loading of stair descending. The perfect femoral nail should resist rotational torques between 10 Nm ER and 6 Nm IR.

The results showed a peak axial load of 2060 N (2.8 BW) on the femur during level walking and a peak axial load of 2280 N (3.1 BW) on the femur while going down the stairs for a 75 kg man *(15,16)*. A 107 N distraction force was shown to affect the femur in a 'hanging leg' position *(13)*. The perfect femoral nail should also resist loading between 2300 N axial compression and 150 N axial distraction forces *(9,11,13,15,16,18)*. In the fracture site axial motion after 1 mm fracture site resorption, both CAROT (average 1.26 mm) and compression nails (average 1.26 mm) demonstrated superior results to interlocking nails (average 3.15 mm).

This work has some limitations. Working with composite femurs does not precisely resemble in vivo settings. Nevertheless, composite femurs produce more constant values than cadaveric femurs, which have different bone mineral densities and heterogeneous biomechanical properties. Composite femurs are commonly used in biomechanical research *(3)*. Composite bones are shown to be more practical than cadaveric bones in measuring the fracture site maximum arc of rotational motion in biomechanical studies *(1)*.

CONCLUSION

CAROT nails demonstrated superior results to interlocking and compression nails in fracture site rotational and axial stabilities after 1 mm fracture site resorption. Further clinical prospective studies should be conducted to evaluate their advantageous effect on the bone healing process.

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