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The effect of plate design and fixation type on primary stability after open wedge high tibial osteotomy

Stepanović Lj Željko[1,4], Živković M Miroslav[2], Vulović M Snežana[2], Aleksandrović R Srbislav[3], Ristić M Branko[1,4]
[1]Clinic for Orthopaedic and Trauma Surgery, Clinical Center Kragujevac,
[2]Laboratory for engineering software, Faculty of engineering, University of Kragujevac,
[3]Manufacturing engineering department, Faculty of engineering, University of Kragujevac,
[4]Faculty of Medical Science, University of Kragujevac

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Background: The stability of the open wedge high tibial osteotomy is dependent on an undamaged cortical hinge and design of the plate. Aims: We evaluated the primary stability of two internal fixation devices for open wedge high tibial osteotomy. Methods: Five pairs of cadaveric tibia with 10 valgus correction were stabilized with a newly designed plate with hybrid fixation and 10 mm spacer block and with conventional T plate with 10 mm spacer block. Static axial loads were applied until ultimate failure of the construct. Results: The average load at initial failure of the new plate construct was 4757.7 N compared to 3022.43 N obtained with the T plate, (p<0.01). The difference in initial stiffness of both constructs was not significant (p=0.27). The mean ultimate load at failure of the new plate construct was 5280.6 N compared to 3635.3N obtained with the T plate, (p=0.001). Conclusion: The new plate with hybrid fixation, provides substantial load resistance but similar stiffness when compared to standard T plate.

Key words: osteoarthritis, stability, high tibial osteotomy, fication methods, biomechanical evaluation

INTRODUCTION

High tibial osteotomy represents well accepted method for improving functional condition of the varus osteoarthritic knee in young individuals.[1] Open wedge high tibial osteotomy (OWHTO) is preferred over the lateral closing wedge osteotomy. With this osteotomy, numerous complications should be avoided, such as injury of the peroneal nerve, compartment syndrome, lateral muscle detachment, proximal fibula osteotomy and leg shortening.[2,3,5-7] Difficulties encountered when performing a subsequent total knee arthroplasty are also reduced.[8] The stability of the osteotomy is largely dependent on an undamaged cortical hinge and design of the plate.[9-11] Numerous fixation techniques have been described to prevent loss of correction and incomplete osseous consolidation for the OWHTO.[4,12] Short spacer plates (PudduTM plate, Arthrex, Naples, FL, USA) and long, rigid plates with locking head screw (LHS) concept are two common methods used to prevent failure of the procedure.[4-6,11,13] The first one is established as a medial pillar support. The long, angle stable plate (TomoFixTM plate, Synthes, Solothum, Switzerland) acts as an internal fixator and provides stability of both pillars. The locking plate technique has evolved from using all locked screws with a non-anatomically contoured plate to a newer concept of using a hybrid construct. It is a combination of locked and conventional, non locked screws, with a more anatomically contoured plate.[14] Various biomechanical studies related to all these issues have been published in recent years, but opinions are still divided when optimal fixation is considered.[4,10,13,15-17]

AIM

This study was biomechanical investigation of primary stability of two internal fixation devices for OWHTO in human cadaver model.

MATERIAL AND METHODS

Specimens

We used five pairs of fresh-frozen, human cadaveric tibia with the approval of the Institution Ethics Committee. The bones were kept at -20 °C until use. Specimens were measured in diameter, radiographed in both projections and bone density were determined by “DEXA” method (GE, Fairfield, Connecticut, USA). These measurements provided randomization for both experimental groups.

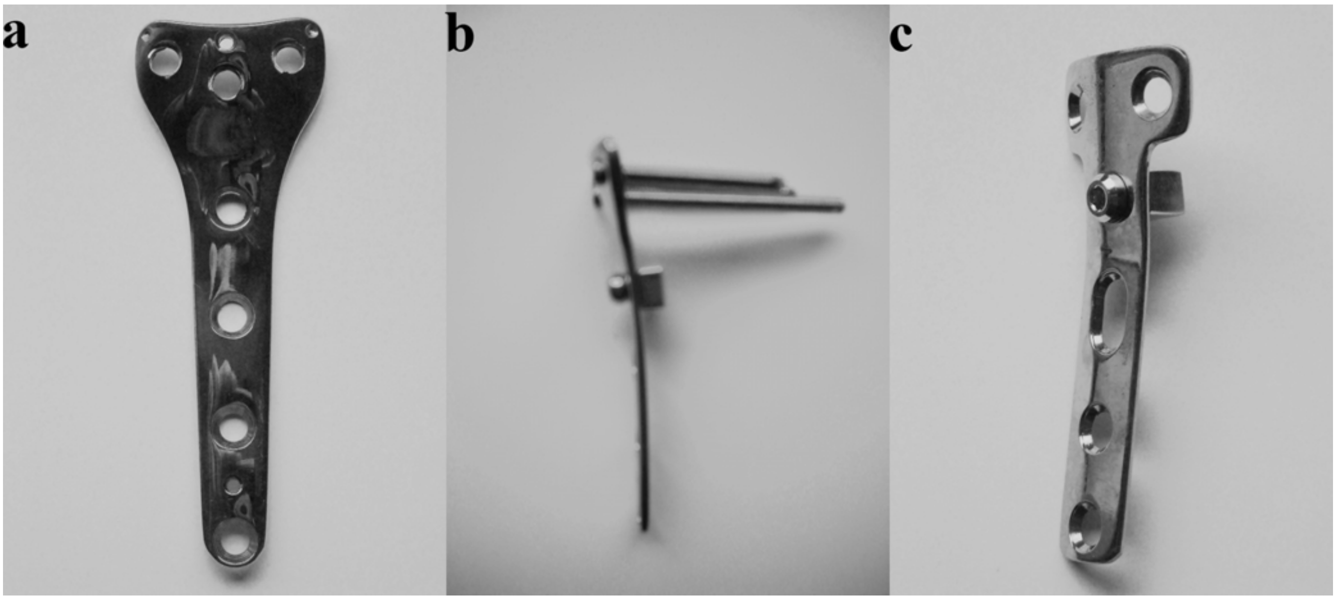

FIGURE 1.
THE NEW PLATE (A) WITH LOCKING BOLTS AND METAL BLOCK (B) AND SIX HOLE AO - T PLATE WITH SUPPORTIVE BLOCK (C).

Specimen preparation

The bones were thawed at room temperature for 24 hours. With the exception of periosteum, all soft tissues and fibula were entirely removed from the bone before osteotomies. Tibias were mounted in metal cylinders 10x2 cm proximally and 10x5 cm distally, and embedded with two component polyurethane resin (Tigrekol®, Tigar Pirot, Serbia) at their proximal and distal ends. Biplanar osteotomy of the tibia was performed by the same surgeon (ZS), according to the technique described by the AO knee expert group (KNEG, Switzerland).[5,6] The starting point of the medial osteotomy of the tibia was at 3.5 cm below the articular surface. The opening has carried out slowly, using a three-chisel technique for several minutes. The standardized valgus correction angle of 10 ° was created. No material was interposed in the osteotomy gap. In five samples, stabilization was carried out by conventional AO - T plate, with 10 mm spacer block. Two 6.5 mm cancellous screws were placed proximally, and three 4.5 mm cortical screws, below the osteotomy. The other five specimens were stabilized with a newly designed plate with three 5 mm locking head screws (LHS) placed into the tibial head, 10 mm spacer block and three 4.5 mm cortical screws below the osteotomy. We used the T plate as a starting point in designing a new one. Both plates had the same dimensions (93.5 mm in length and 3 mm in thickness) and made from stainless steel AISI 316L (Fig.1)

Mechanical testing system

All tests were performed on a mechanical testing machine (Zwick-Roell 100, Ulm, Germany) under standardized loading axis (Fig.2). Mechanical testing data were downloaded from the amplifier to the transducer, and linear variables were processed to original Zwick-Roell software package.

Static load

Axial load was directed at the 62% of the medio-lateral diameter of the articular surface of the tibia (Fujisawa's point), which corresponds to 3-6° of valgus hipercorrecton.[18] Samples were tested in two phases. In the first phase, a preload of 70 N was applied for 2 minutes at a rate of 2 mm/min. The second phase has consisted of controlled, continuous axial loading at a speed of 5 mm/min to complete fracture or structural deformation of the construct, when the test has stopped. The point of initial fracture of lateral tibial cortex was defined as the point of the first load reduction (point 1-P1). The point of ultimate failure of the structure corresponded with second load reduction (point 2-P2). Displacement of the each construct was recorded by the testing machine software.

Statistical analysis

The data were analyzed by using a commercially available statistics software package SPSS 16 (IBM SPSS Statistics). Distribution of the groups was analyzed with one sampled Kolmogrov–Smirnov test. All groups demonstrated the normal distribution so that the parametric statistical methods were used to analyze the data. In parametric statistics Student t - test, one and two-factor analysis of variance (ANOVA) were applied. Results were presented as means and standard deviation (SD). P values less than 0.05 were regarded as statistically significant.

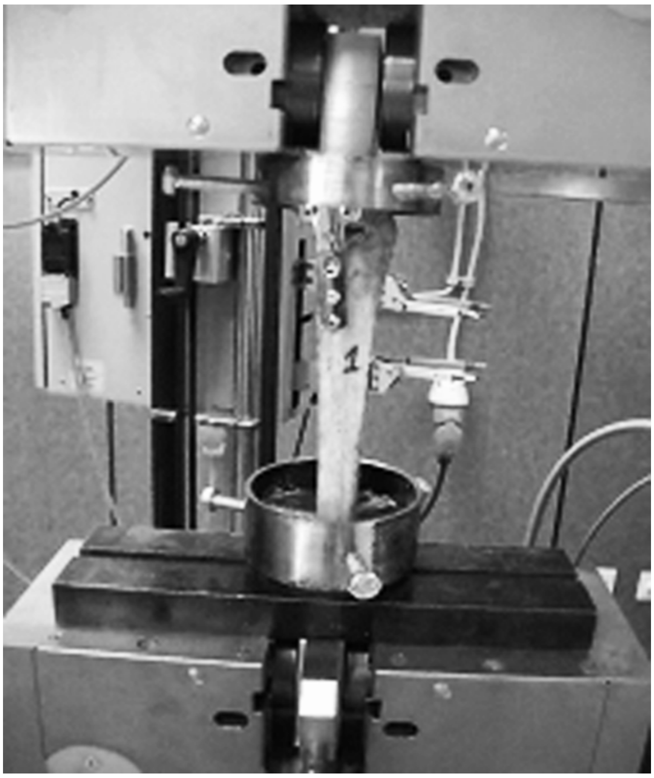

FIGURE 2.
THE MOUNTED SPECIMEN ON THE MATERIAL TESTING MACHINE ZWICK ROELL 100 BEFORE TESTING.

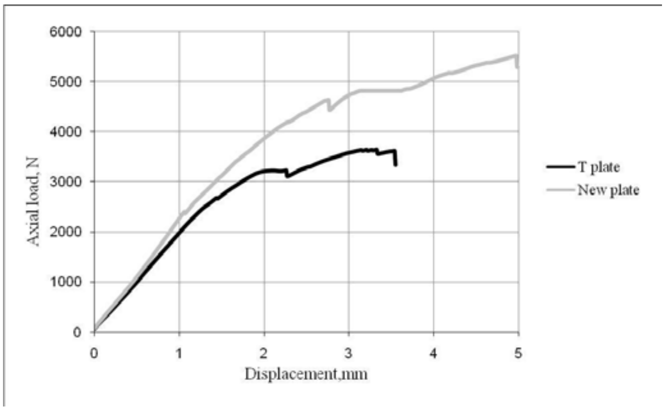

FIGURE 3.
THE AVERAGE LOAD - DISPLACEMENT CURVES OF THE NEW IMPLANT AND THE T PLATE. FAILURE OCCURRED IN TWO STEPS, MICROFRACTURE OF THE LATERAL WALL IN POINT 1 (P1) AND FRACTURE OF THE LATERAL CORTEX AND TOTAL FAILURE OF CONSTRUCT IN POINT 2 (P2).

RESULTS

3.1. Specimens

In the T plate group, the mean specimen age was 61.2 (SD 4.658) years, compared to 62.2 (SD 0.836) years in the new plate group (p=0.649). The mean BMD in the T plate group was 0.4616 (SD 0.09154) g/cm3 compared to 0.4198 (SD 0.15659) g/cm3 for the new plate specimens (p=0.427).

3.2. Static loading

The average compression load at initial failure (point 1 - P1) of the new plate construct was 4757.7 N (SD 1391.74) compared to 3022.43 N (SD 738.16) obtained with the T plate, (p<0.01). The average displacement of the new plate was 2.67 mm (SD 1.632) compared to 2.29 mm (SD 1.261) of the T plate construct (p = 0.12). The average stiffness before initial failure of the new plate was 2406.17 N/mm (SD 1009.67) compared to T plate 1851.62 N/mm (293.47), (p=0.27).

The mean load at ultimate failure of the new plate construct was 5280.6 N (SD 1741.85) compared to 3635.3 N (SD 1253.6) obtained with the T plate composite (p=0.001). According to displacement and stiffness of the construct, no significant differences between the plates were found. The mean displacement at failure of the T plate composite was 3.69 mm (SD 1.34), compared to 5.14 mm (SD 2.25) obtained at the new plate (p=0.161). The average stiffness before complete fracture of the new plate construct was 1347.26 N/mm (SD 866.7) compared to 1324.1 N/mm (SD 556.3) of the T plate (p=0.96).

3.3 Mode of failure and residual stability

The same mode of failure was manifested in all specimens regardless of plate construct. Initial cracks started at lateral cortex, in point 1 (P1), creating sudden drop in applied axial force. In point 2 (P2), we have observed sharp drop in loading force as total breakage of lateral bone bridge. In all cases, a closing of osteotomy gap occurred. Two shaft fractures below the new plate have been occurred. No macroscopic implant or screw breakage was recorded (Fig. 4 a-d).

DISCUSSION

Contrary to previous investigations, we have evaluated biomechanical properties of two similar devices. Thus, we put in scope the effect of plate design and fixation itself. In this study, both plates had medial pillar support. We have used two, 3 mm thick plates, where three locking bolts or two cancellous screws have been placed above the osteotomy. With three locking bolts above the osteotomy, the new plate model provided stability of both pillars. Two pillars support may provide favorable conditions for healing, as well as, maintain the desired level of angular correction in early weight bearing regime. It was found that the use of hybrid fixation concept allows a similar amount of reversible and irreversible deformation in response to an axial load, when compared to an all locked screw plate.[14] At single load to failure, a fracture of the lateral tibial cortex occurred in all specimens, indicating the weakest point of the construct. The plate with hybrid fixation achieved a greater load resistance and extended protection of lateral tibial wall before failure. Contrary to short spacer plates, the six hole T

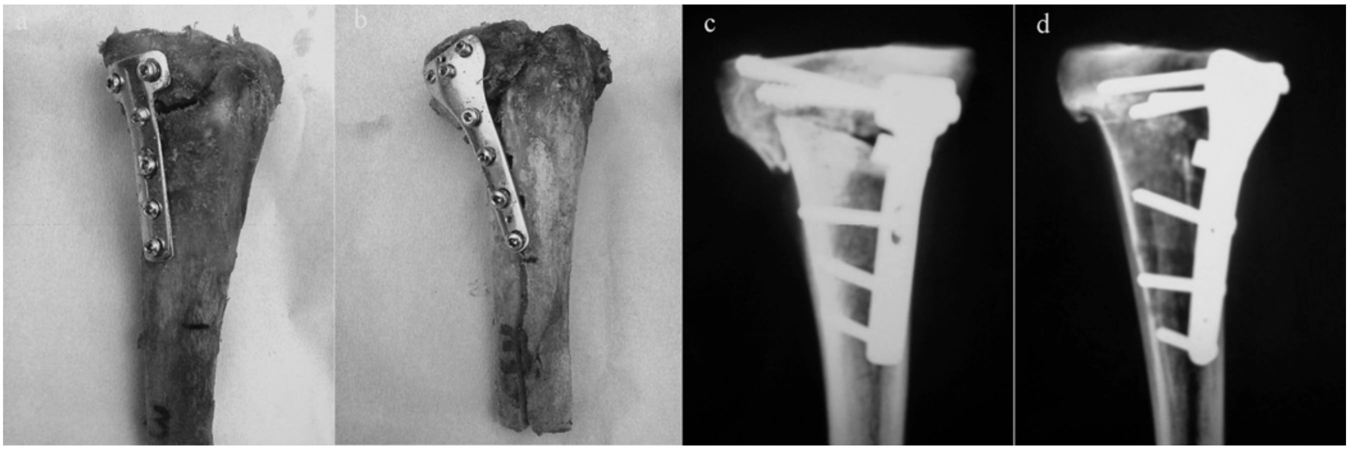

FIGURE 4.
FAILURE MODALITIES: LATERAL CORTEX FRACTURE WITH GAP COLLAPSE (A), GAP COLLAPSE WITH SHAFT FRACTURE (B), POST-TESTING THE T PLATE-SPECIMEN RADIOGRAPH (C), POST-TESTING THE NEW PLATE SPECIMEN RADIOGRAPH (D).

spacer plate acted as a more rigid, angle stable device. This can be attributed to supportive block and its length. The compressive loads responsible for the initial and final structural deterioration are considerably higher in both plates than the same parameters in the literature.[10,12,15,17] Both implants have sustained static compressive loads significantly above the expected, during stair climbing or walking.[19] Although the T spacer plate behaved as a more rigid structure (Fig.3), it seems that two cancellous screws above the osteotomy are not sufficient, when consider early postoperative weight bearing regime.

Different study designs and the plate specimens used previously, make a comparison of the obtained results difficult. The stability of the standard T plate, short Puddu plate and the plate with mobile spacer („C"- plate) on animal cadaveric models was investigated. The „C" plate construct behaved as an angle stable device with spacer block. The authors have found axial load resistance of Puddu plate at 1678N and 2042N for „C"-plate.[13] The stability of the „C"- plate was significantly higher than with Puddu and the T plate, respectively. They concluded that the best biomechanical properties are achieved with an angle stable plate with spacer block.[13] In this study, the new plate construct acted as same as a „C"- plate, by providing greater load resistance compared to T spacer plate.

The group of authors compared primary stability of four implants where two of them were long spacer plate with multi directional locking bolts and long tibial plate fixator (TomoFix). The other two were short spacer plates which provided better stability than the long spacer plate. This suggests that the length of the implant does not solely affects its stability regarding displacement.[14] They concluded that more than 4 screws should be placed in order to accomplish better stability. In this study, the new plate with six screw concept achieved greater load resistance and almost the same stiffness as standard T plate with five screws.

In vitro testing has its drawbacks, in particular due to the exclusion of the role of soft tissues and the use of different specimens. The use of human cadaveric bones has connected with difficulties in obtaining and storing, differences in size and quality of bone tissue and influence of gender and age on specimens.[13,16] The mean donors age of 61.7 years was more acceptable than the average 77 years reported previously.[16] The alternative use of animal or composite bone specimens includes some possible problems, as well.[10,13,17] A limitation of this study is the lack of data when the construct was in a dynamic mode and under torsion. Further tests in the future may validate the quality and performance of these implants.

CONCLUSION

This study has shown that the plate design and fixation type strongly influence the primary stability of the open wedge high tibial osteotomy (OWHTO). The plate model with hybrid fixation provided substantial load resistance but similar stiffness when compared to standard T plate. Such plate configuration should be considered as an option among well known devices for OWHTO, particularly in overweight individuals. Further comparative biomechanical studies of this and other implats may determine its place in clinical practice.

SUMMARY

EFEKAT DIZAJNA PLOČE I TIPA FIKSACIJE NA PRIMARNU STABILNOST NAKON OTVORENE KLINASTE OSTEOTOMIJE TIBIJE

Uvod: Stabilnost otvorene klinaste visoke osteotomije tibije je uslovljena neoštećenim kortikalnim mostom i dizajnom ploče. Cilj studije je evaluacija primarne stabilnosti dva implantata za unutrašnju fiksaciju kod otvorenih klinastih osteotomija tibije. Metode: Pet pari kadaveričnih tibija sa valgus korekcijom od 10° je stabilizovano novodizajniranom pločom sa hibridnom fiksacijom sa potpornim blokom od 10mm i konvencionalnom T pločom sa potpornim blokom od 10 mm. Na mašini za testiranje materijala su obavljena statika aksijalna opterećenja do potpunog loma konstrukcije. Rezultati: Prosečno opterećenje pri početnom popuštanju kod nove ploče je bilo 4757.7 N u odnosu na 3022.43 N ostvarenom kod T ploče sa blokom, (p<0.01). Razlika u početnoj krutosti obe konstrukcije nije bila značajna (p=0.27). Prosečno optere ćenje pri krajnjem lomu kod Narcissus ploče je bilo 5280.6 N i značajno veće u odnosu na 3635.3N ostvarenom kod T ploče sa umetkom, (p=0.001). Zaključak: Novodizajnirana ploča sa hibridnom fiksacijom obezbedjuje značajan otpor pri opterećenju ali je slične čvrstine kao i standardna T ploča.

Ključne reči: osteoartritis, stabilnost, visoka tibijalna osteotomija, metode fiksacije, biomehaničèka evaluacija

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Abbreviations:

(OWHTO) open wedge high tibial osteotomy, (SD) standard deviation,

(AISI) American Steel and Iron Institute, (ANOVA) analysis of variance

Conflict of interest statement

There is no potential conflict of interest regarding the work described in this paper.