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## In vitro stability of open wedge high tibial osteotomy with synthetic bone graft

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#### ABSTRACT

It has been predicted that significant stress will be applied to the plate and lateral cortical hinge of an osteotomy site when early full weight bearing is commenced after an open wedge high tibial osteotomy. We hypothesized that the stress concentration on the plate or at the lateral cortical hinge would be reduced by inserting bone substitutes into the osteotomy gap. Two different types of tibia model were investigated: Group A, fixation with TomoFix with the osteotomy site left as an open space; and Group B, two  $\beta$ -TCP wedges are inserted into osteotomy site and fixed with TomoFix. Stress at five points was measured using strain gauges. Specimens were mounted onto a testing machine with an FTA (femoro-tibial angle) of 170°. Cyclic load tests and an ultimate load test were then performed. The mean stress on the plate was measured at  $15.5 \pm 1.8$  Mpa in Group A. On the other hand, this value in Group B was only  $9.52 \pm 2.1$  Mpa and this was a significant difference (P < 0.01). The mean stress on the lateral hinge in Groups A and B was  $3.31 \pm 0.5$  and  $2.49 \pm 0.2$ , respectively which was also a significant difference (P < 0.05). The mean maximum breaking load in Group A was  $2500 \pm 280$  N and in Group B  $4270 \pm 420$  N which was a significant difference (P < 0.01). Hence, for OWHTO procedures, the use of  $\beta$ -TCP wedges and TomoFix is thus likely to improve the initial axial and possibly rotational stability at the osteotomy site in comparison with methods that leave the osteotomy gap open.

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### 1. Introduction

HTO is a common surgical procedure for the treatment of medial compartmental osteoarthritis (OA) and osteonecrosis (ON) of the knee [1,2]. The long-term follow-up of HTO patients is well documented [3,4]. For the long-term treatment of medial OA, the outcome of HTO depends on the preservation of the appropriate correction angle after the procedure has healed. The traditional lateral closed-wedge technique is a procedure removing bone wedge at the proximal tibia. This procedure, previously advanced by Coventry et al., involves a wide dissection of the lateral soft tissue and a fibula osteotomy [5]. The main disadvantages of closed-wedge HTO are the long period of rehabilitation and complications associated with the surgery. It takes 2 or 3 months for a patient to be able to do full weight bearing walk.

Medial open wedge HTO (OWHTO) was reported by Debeyre and Artigou in 1951 [3]. In 1987, Hernigou et al. presented their findings on the long-term follow-up of OWHTO [6]. However, the procedure has not gained wide popularity despite the advantages of maintaining the bone stock, correction of the deformity close to its origin, and not

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necessary fibula osteotomy. OWHTO from a medial approach is minimum invasive technique and special internal fixation devices have been developed to prevent a possible loss-of-correction, non-union and to achieve more rigid fixation. The internal fixator TomoFix<sup>TM</sup> (Thyntes Inc., Bettlach, Switzerland) was developed by AO knee expert group to achieve optimal stability and hold the attained correction [7,8]. This implant is attached to the tibia with locking screws. Since the directions of screws are different to prevent from backing out of screws, rigid fixation is expected also with the case in osteoporosis.

Optimal postoperative rehabilitation following OWHTO enables the patient to walk with a full weight as soon as possible without any support which in turn prevents the aggravation of osteoporosis and dementia. However, patients are traditionally advised to use double crutches for six to twelve weeks after surgery. In our current study, we established that with an early and active rehabilitation program patients can walk bearing their full weight at two weeks after surgery. The procedure was performed utilizing TomoFix in combination with bone substitute grafts inserted into the osteotomy gap [9,10].

It is predicted that large stress will be applied on the plate and around the osteotomy site when early full weight bearing is started after OWHTO. It is thought that the stress concentration on the plate or at lateral cortical hinge becomes small by inserting bone substitutes into the osteotomy gap. In this study, the primary stability and fixation strength of two different fixation types were tested, one is



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fixed with TomoFix and osteotomy site left open and the other is two  $\beta$ -TCP wedges inserted into the osteotomy site and fixed with TomoFix using composite tibia sawbone model under axial loading.

#### 2. Materials and methods

Two different types of tibia model were produced which fixed with TomoFix and osteotomy site was left open space and two  $\beta$ -TCP wedges were inserted into osteotomy site, and fixed with TomoFix. Cyclic load test (the loading condition was from 0 to 1000 N, cycles at 1 Hz) and ultimate load test (cross head speed of 1 mm/s) were performed and stress on the 5 points around osteotomy site was measured using strain gauges.

#### 3. Bone models

The third generation composite tibiae (Sawbone Europe AB, Malmö, Sweden) were used in this experiment [11]. The mechanical properties of the tibiae have reported to reproduce healthy young adult. The distal end of tibiae was embedded into a component dental resin (Dental plaster, Maruishi Gypsum, Tokyo). They were applied to a special designed fixator that was attached to a materials testing machine. A third generation composite femur (Sawbone Europe AB, Malmö, Sweden) was used as an element which constitutes a knee joint too. Twenty cm length of distal part of femur was harvested and mounted in a special frame of the testing machine. The load was applied to the shaft of the distal femur through the knee joint and reached to the tibial plateau. Cork board was used as substitution of meniscus. Five mm thick cork board was cut into like medial and lateral shapes of meniscus and the thickness of the thin marriage of meniscus is 2 mm. The Young's modulus and the Poisson ratio of the cork are from 13 to 20 MPa, 0 from to 0.5, respectively [12]. These cork boards were attached on the tibial plateau with double-stick tape. During the mechanical testing, the meniscus attached to the tibial plateau firmly and was not dropped out. The mechanical property of the cork board is very close that of human meniscus [13,14].

All tibiae were performed open wedge high tibial osteotomy. The osteotomy was started from the medial side to the lateral using bone saw and the cut was incomplete, leaving 10 mm of lateral cortex intact, referred to as a bone-bridge, which served as a hinge-point during the opening of the osteotomy. The opening at the osteotomy site was carried out slowly and carefully using special open equipment in order to avoid fracture in the lateral cortex. The opening distance was 7.5 mm in all tested sawbones.

After the opening of the osteotomy site, the locking compression plate and screw system TomoFix were attached to the medial side of the tibia. The proximal fragment was fixed with four locking screws (proximal 3 screws were fixed bicortically) and distal fragment was fixed with four screws bicortically. Two different types of tibia model were produced, Group A (n=5); fixed with TomoFix and osteotomy site was left open space, and Group B (n=5); two  $\beta$ -TCP (Osferion 60; Olympus Terumo Biomaterials, Tokyo, Japan) wedges were inserted into osteotomy site and fixed with TomoFix. The porosity of the  $\beta$ -TCP wedges was 60% and the size of wedge measures 10 mm (width)×25 mm (length)×7.5 mm (height) (Fig. 1-A).



**Fig. 1.** Bone models. A: Open gap and inserted  $\beta$ -TCP wedges. Two  $\beta$ -TCP (Osferion 60; Olympus Terumo Biomaterials, Tokyo, Japan) wedges of 10 mm (width)  $\times$  25 mm (length)  $\times$  7.5 mm (height) were inserted into the osteotomy open gap (black arrow). B: Measurement points of strain. Uniaxial strain gauges were attached to five points. A; on the tuberosity just below osteotomy site, B; on the plate, C; on the posterior just below osteotomy site, D; on the medial site just below the osteotomy, E; on the lateral cortex hingepoint. C: Testing model. All specimens were mounted into the testing machine as the FTA was 170°. Cork board was used as substitution of meniscus and an axial load was applied to the femure.

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