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Delayed bone healing following high tibial osteotomy related to increased implant stiffness in locked plating

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ABSTRACT

Introduction: Asymmetrical callus formation and incomplete bone formation underneath stiff locking plates have been reported recently in clinical and experimental fracture healing studies. After similar effects were observed in the outcome of high tibial osteotomy (HTO) patients, a retrospective study was performed to quantify the frequency and level of such incomplete healing cases.
Material and methods: Twenty-three patients treated with medial open wedge HTO and locking plate (Tomofix^{TM}) for posttraumatic or congenital genu varum were investigated. No bone grafts were applied to fill the osteotomy gap. The median correction angle was 8° (5–18°). Elective hardware removal was performed after a median of 19.5 months (12–58 months) following an uneventful clinical course. The most recent postoperative X-ray available (median 21 months; 13–56 months) was evaluated for consolidation of the osteotomy. We performed an *in vitro* biomechanical experiment using the same HTO on a loaded cadaver knee joint to compare interfragmentary movements (IFMs) when using regular locking screws with the Tomofix^{TM} plate and screws that enabled dynamic stabilisation of this plate.
Results: Fifteen patients (65%) displayed incomplete consolidation of the osteotomy underneath the locking plate (10.9% of the osteotomy length) and cortical deficiency. The time to implant removal for these patients of 27 months was longer than the 21 months for the patients with a complete osteotomy gap healing. The biomechanical experiment demonstrated that very low IFMs and corresponding interfragmentary strain occur underneath the plate when using regular locking screws. Replacement with dynamic screws resulted in an increased IFM.
Discussion and conclusions: These results support the hypothesis that low bone formation underneath locking plates is induced by increased stiffness. This high stiffness situation could be altered by replacing the standard screws with dynamic screws which allow for a movement of 0.35 mm perpendicular to the screw axis. This resulted in an approximately threefold increase in the IFM and may be a potential concept to avoid incomplete bone healing under stiff plate fixations.

Introduction

The introduction of locking plates led to fundamental changes in fracture treatment through focusing on two aspects: mechanics and biology. While conventional compression plates gain stability through the frictional force between the plate and the bone, the angle stable screws in locking plates are loaded perpendicular to their axes in compression. Therefore, locking plates provide a much greater contact area between the screws and the bone, and a more even load distribution between the several screws in one fragment, ultimately leading to greater stability [1]. Numerous biomechanical investigations have confirmed this for different anatomical locations [2–5]. In addition, clinical results, particularly in osteoporotic fractures, have improved, accompanied by decreased rates of implant loosening and secondary dislocation [6,7]. The principles of biological osteosynthesis aim to preserve local blood flow, including in the periosteum, and to avoid unnecessary iatrogenic devascularisation of fragments [8]. In areas where no exact anatomical reduction is required and is frequently impossible (*i.e.*, metaphyseal comminution), locking plates are used as

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internal fixators to bridge the fracture zone [1]. This implies an indirect reduction technique, whereby the fracture zone is not or is minimally manipulated, resulting in larger gaps between the fragments. The lack of interfragmentary compression and the larger bridging length induce a more flexible fixation, which should stimulate a secondary fracture healing by callus formation [9]. The loads acting on a bridging plate must be supported exclusively by the plate and screws, thus requiring a rather thick locking-plate design to avoid fatigue fracture of the implant [10]. Because deformation of a thick plate under loading is small, this reduces the tissue strain underneath the plate together with the mechanical stimulus for callus formation [1,11]. However, to achieve an ideal fracture-healing scenario, sufficient interfragmentary tissue strain should occur under loading of the operated extremity, which should be ideally approximately the same underneath the implant and on the opposite side of the bone [1]. In current implants, this does not always appear to be the case because of low interfragmentary movement (IFM) and tissue strain underneath the plate [1,12]. This phenomenon is supported by clinical observations in which asymmetric and inconsistent callus formation was detected in distal femoral fractures treated with locked plating [13]. Consequently, this could impair fracture healing, resulting in complications, including delayed or non-union and secondary displacement requiring revision surgery.

We hypothesise that locking plates result in delayed bone healing in high tibial osteotomy (HTO) patients because of low IFM and tissue strain underneath a stiff plate, and that by using screws which enable greater motion, the IFM close to the plate can be increased.

Material and methods

Clinical study

We reviewed retrospectively the X-rays of 74 consecutive patients who underwent HTO for congenital or posttraumatic varus deformity between 2003 and 2012 after obtaining consent from the local ethics committee (12/13 Ethics Committee, Ulm University). Only patients who underwent elective hardware removal in our clinic without any complications and after an uneventful course were included because this allowed sufficient evaluation of X-rays with respect to cortical deficiency underneath the plate. In total, 23 patients (18 males, 5 females; median age 44 years, range 20–66 years) were included. The right leg was affected in 12 patients and the left in 11 patients. Prior to surgery, all patients underwent digital deformity analysis (mediCAD, Hectec, Landshut, Germany) to confirm the presence of a deformity and the indication for surgery based on the previously published criteria [14]. The median varus deformity was 6° (5–17°).

HTO was performed using the medial open wedge technique as described by Floerkemeier et al. [15]. The median correction angle was 8° (5–18°). No bone grafts were applied to fill the osteotomy gap. The osteotomy was stabilised using a locking plate designed for HTO in the medial open wedge technique (Tomofix^{TM}, Synthes, Oberdorf, Switzerland) (Fig. 1A). Elective hardware removal following an uneventful clinical course was performed after a median time of 19.5 months (12–58 months) following the osteotomy (Fig. 1B). Anterior to posterior X-rays of the affected knee were evaluated which were obtained after a median of 21 months (13–56 months) following the HTO, as shown in Fig. 2. The ratio (B/A, (%)) of the length of the osteotomy gap unfilled by bone (B, Fig. 2) to the overall length of the proximal tibia at the level of the osteotomy (A, Fig. 2) was determined at the most recent follow-up.

Biomechanical study

Whereas it is clear that the IFM close to the surface of a stiff plate is small, there were no quantitative data available previously for the HTO [1]. Therefore, we performed an *in vitro* biomechanical test to provide an orientation of the IFM that occurs under clinically relevant loading conditions (Fig. 3).

A human cadaver knee specimen (male, 57 years, left side) was used. An X-ray (Faxitron 43805N, Hewlett-Packard, Palo Alto, USA) was taken to ensure the absence of deformity, prior fracture, and cysts (45 kV, exposure time 5 min). The knee had angle of 11.5° between the femur and the tibia. The HTO was performed using the same technique as in the clinical study [15]. The height of the medial basis of the wedge was 10 mm. First, the Tomofix^{TM} plate was fixed with regular head locking screws as was performed in the clinical cases (Fig. 3C). For axial loading, the specimen was mounted in a cranial to caudal direction in a material testing

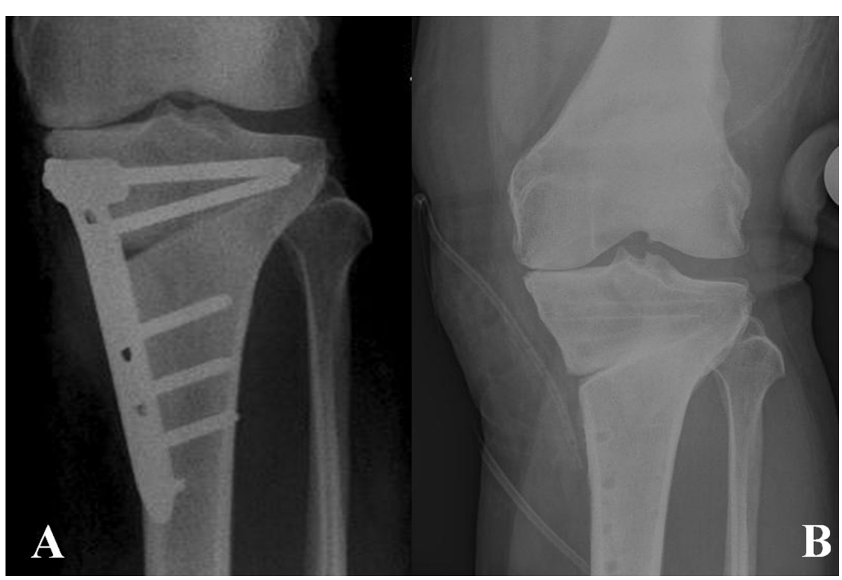

Fig. 1. High tibial osteotomy (HTO). (A) The HTO in the medial open wedge technique was stabilised using a standard locking plate (Tomofix^{TM}). (b) Consolidation of the osteotomy at implant removal 17 months following the operation (right). The osteotomy underneath the plate is not completely filled with bone and the cortical bone remains unrestored.