Biomechanical comparison of two different locking plates for open wedge high tibial osteotomy

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Abstract

Background: The purpose of this study was to compare the mechanical stability of a relatively thin locking plate (FlexitSystem implant) with a relatively firm locking plate (TomoFix implant), both used for opening wedge high tibial osteotomy.

Methods: Seven fresh frozen paired human cadaveric tibiae were used. The opening wedge high tibial osteotomies in the left tibiae were fixated with the FlexitSystem implant and in the right tibiae with the TomoFix implant. The tibiae were CT-scanned to determine the bone mineral density. Axial loading was applied in a cyclic fashion for 50,000 cycles. We compared throughout the loading history the relative motions between the proximal and distal tibia using roentgen stereophotogrammetry analysis at set intervals. Also the strength of the reconstructions was compared using a displacement-controlled compressive test until failure.

Results: One pair (with the lowest bone mineral density) failed during the preparation of the osteotomy. The FlexitSystem implant displayed a similar stability compared to the TomoFix implant, with low translations (mean 2.16±1.02 mm vs. 4.29±5.66 mm) and rotations (mean 3.17±2.04° vs. 4.30±6.78°), which was not significant different. Although on average the FlexitSystem reconstructions were slightly stronger than the TomoFix reconstructions (mean 4867±944 N vs. 4628±1987 N), no significant (p = 0.71) differences between the two implants were found.

Conclusion: From a biomechanical point of view, the FlexitSystem implant is a suitable alternative to the TomoFix implant for a high tibial open wedge osteotomy.

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1. Introduction

Patients with knee osteoarthritis (OA) of the medial compartment often have a varus leg alignment which causes an overload of the medial compartment. Malalignment increases the risk for progression of knee OA and is associated with a decline in physical function and progression of pain [1–3]. In order to unload the medial compartment, a valgus high tibial osteotomy is the treatment of choice for the young and active patient [4].

The most commonly used techniques include closed-wedge osteotomy (CWO) and open-wedge osteotomy (OWO) [5,6]. The disadvantages of a lateral closed wedge osteotomy are the need for a fibular osteotomy, the high rate of tibial neuropathies, peroneal neuropathies, bone stock loss, and a more demanding subsequent total knee arthroplasty [6]. On the other hand, OWO has been associated with high non-union rates and loss of correction due to unstable fixation [6,7]. Therefore, fixation strength and maintenance of stability until osseous consolidation are a prerequisite of the implants used in OWO [8]. Several implants have been designed for OWO [8–11]. The TomoFix implant (Fig. 1) is widely used because of its well-reported clinical [5,12,13] and biomechanical [9,11,14] track record. The TomoFix implant is a long and rigid titanium plate with locking screws, which functions as an internal fixator [8]. Due to its size, the disadvantages of this implant have been reported to be local irritation and wound healing problems [15–18]. Therefore, implant removal after surgery is often needed [18]. The FlexitSystem implant (Fig. 1) is a novel implant to be used for OWO. The FlexitSystem implant is shorter and thinner...
compared to the TomoFix implant. To compensate for the smaller dimensions, a different grade of titanium alloy (stiffer and stronger) is used for the FlexitSystem. The characteristics of the implants used in this study are shown in Table 1. The potential benefit of the FlexitSystem implant is that, due to its smaller dimensions, patients may experience less discomfort from the plate, which may eliminate the necessity of implant removal after surgery. A potential concern is that the smaller dimensions of the implant may affect the primary stability of the reconstruction.

The purpose of this study was to compare the mechanical stability of the novel FlexitSystem implant to the well reported TomoFix implant based on mechanical tests (dynamically loading and compressive to failure) using fresh human cadaveric tibiae. Our hypothesis was that the mechanical stability of the FlexitSystem was not ‘inferior’ to that of the TomoFix.

2. Material and methods

2.1. Specimen preparation

Seven paired human cadaveric tibiae (mean age of 74 ± 6 years; three male, four female) were used for the study. Considering the relatively high age of the cadaveric specimens, the bone density was evaluated using quantified computed tomography (qCT). For this purpose, the bone mineral density (BMD) was measured in standardized regions of interest in the proximal tibia. These regions were defined as two spheres located in the medial and lateral compartment. The spheres had a radius of 7.8 mm (20 pixels), with the centers located at 11.7 mm (30 pixels) below the tibial plateau (Fig. 2). No significant differences (p = 0.45) were found in BMD between the tibiae used for the FlexitSystem and TomoFix reconstructions. The exact BMD values are given in Table 2. Specimen pair 1, in which a fracture occurred during implantation of the TomoFix implant, displayed the lowest BMD.

The cadavers were thawed over a time period of 24 h and all soft tissue was removed. The OWO were performed by one orthopaedic surgeon. A Kirschner wire was inserted parallel to the joint space, ending just above the head of the fibula. Along this wire, a single-cut supra-tuberosity osteotomy was performed, leaving 10 mm of the lateral cortex intact, which was used as a hinge during the opening of the osteotomy. The gap was standardized at 10 mm by using a custom-made spacer that was used in combination with both implants. The implants were fixed on the medial side of the tibia and aligned with the tibial diaphysis to avoid anterior and cortical overhang. The proximal part was parallel to the medial tibial slope. The proximal screws were placed in the proximal tibia just above the osteotomy gap. First the proximal screw holes were drilled bicortical holding the implant in the correct position. The screw length was measured using the depth gauge. The correct size self-tapping locking screws were inserted. After that the four distal correct size self-tapping locking screws were placed bicortical. The osteotomies in the left tibiae were fixated with the FlexitSystem implant (Neosteo, Nantes, France), while in the right tibiae the TomoFix...

Table 1

<table>
<thead>
<tr>
<th>Characteristics of the implants used in this study.</th>
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<td><strong>Table 1</strong></td>
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<td><strong>Characteristics implants</strong></td>
</tr>
<tr>
<td>Length</td>
</tr>
<tr>
<td>Width</td>
</tr>
<tr>
<td>Thickness</td>
</tr>
<tr>
<td>Screw holes</td>
</tr>
<tr>
<td>Material</td>
</tr>
<tr>
<td>Modulus of elasticity</td>
</tr>
<tr>
<td>Yield strength</td>
</tr>
<tr>
<td>Designed single cut osteotomy</td>
</tr>
<tr>
<td>Locking screws</td>
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</table>
implant (TomoFix Osteotomy system, DePuy Synthesis, West Chester, PA, USA) was used (Fig. 3).

After preparation of the osteotomy, the distal tibia was resected and potted using polymethylmethacrylate (PMMA), at a level of 30 mm distally to the lowest position of the TomoFix implant (the longest plate of the two systems). The contralateral tibiae with the FlexitSystem implants were resected at the same level (Fig. 3). Next, a custom load applicator was attached to the proximal tibia, which was aligned perpendicular to the long axis of the tibia using a goniometer. The load applicator was fixed using four screws, after which additional fixation was provided by potting the proximal tibiae using PMMA (Fig. 4). Care was taken that the osteotomy plates were not embedded in the cement. The custom load applicator was fixed perpendicularly to the tibial shaft.

2.2. Mechanical testing

The reconstructions were subjected to a loading regime representing the forces occurring during the toe-off phase of normal walking [19] (Table 3), which is the most frequent activity of daily living, and is therefore representative of one of the most frequent loading configurations that were applied to the reconstruction. During this phase, the axial force acting on the tibia is at its peak, but also substantial moments of force are acting, forcing abduction and external rotation of the tibia. The load applicator attached to the proximal tibia was specifically designed to apply this complex loading condition. It allowed loading at an offset of 8.7 mm. For this purpose, the proximal tibia was placed in the applicator with the intercondylar eminence aligned with the center of the load applicator. The compressive force was applied through the linear actuator of the mechanical testing system (MTS Systems, Eden Prairie, MN, USA). An abduction moment was accounted for by applying the force medially from the center of the tibia. External torque was applied through a separate air power driven actuator, attached to a lever arm of the load applicator (Fig. 3). This actuator was synchronized with the linear actuator of the mechanical testing system, and cyclically activated in an alternating fashion. To simulate partial weight bearing of a patient immediately after surgery, the applied forces were scaled down to 50% [9] of the values as reported by Bergmann et al. [19]. The resulting loading configuration applied to the constructs is given in Table 3.

The loading regime was applied for 50,000 cycles, at a frequency of 2 Hz (ca. 7 h of testing), representing approximately 2–3 weeks of normal functioning after surgery [20]. A frequency of 2 Hz was chosen to prevent the formation of fatigue damage in the bone tissue [9].

After completion of this loading history, a displacement-controlled crush test was performed, at a speed of 5.0 mm/min [21]. The maximum load measured during this test served as a measure for the strength of the reconstruction.

Table 2

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Sex</th>
<th>Age</th>
<th>BMD (mg/cm²) FlexitSystem</th>
<th>BMD (mg/cm²) TomoFix</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Female</td>
<td>83</td>
<td>51.07</td>
<td>18.25</td>
</tr>
<tr>
<td>2</td>
<td>Female</td>
<td>67</td>
<td>72.74</td>
<td>84.45</td>
</tr>
<tr>
<td>3</td>
<td>Female</td>
<td>78</td>
<td>85.52</td>
<td>115.04</td>
</tr>
<tr>
<td>4</td>
<td>Male</td>
<td>77</td>
<td>99.19</td>
<td>145.09</td>
</tr>
<tr>
<td>5</td>
<td>Male</td>
<td>70</td>
<td>152.83</td>
<td>129.04</td>
</tr>
<tr>
<td>6</td>
<td>Female</td>
<td>68</td>
<td>101.87</td>
<td>119.10</td>
</tr>
<tr>
<td>7</td>
<td>Male</td>
<td>70</td>
<td>126.59</td>
<td>139.28</td>
</tr>
</tbody>
</table>

BMD Bone mineral density.

* Fracture occurred during implantation, not included in experimental testing.

Fig. 3. Tibial osteotomies with the implants. Tibial osteotomies with the TomoFix (left) and FlexitSystem (right) implants. Notice the plastic tracers attached to the proximal tibia, containing tantalum roentgen stereophotogrammetry analysis (RSA) markers.
we focused on a comparison of the total translations and principal rotations between the two osteotomy implants. In order to condense the data, complicated a straightforward quantitative comparison based on Euler’s rotation theorem. In accordance with this theorem, a resulting axis of rotation was determined, representing the complex 3D rotation as a unit vector and a single angle, representing the total amount of rotation occurring in the system.

2.3. Statistical analysis

The aim of our analysis was to show that the FlexitSystem was ‘not unacceptably worse’ (i.e. non-inferior) than the TomoFix. The sample size calculation was based on a mean failure force of 2900 N with a standard deviation (SD) of 300 N, based on a study of Stoffel et al. [11]. We estimated the non-inferior limit to be 300 N. To show non-inferiority of the FlexitSystem versus the TomoFix with an α of 0.05 and a power of 80%, 6 cadaveric tibiae in each group were needed. To account for possible experimental failures, in each group 1 tibia was added to the sample size, resulting in 7 cadaveric tibiae per group.

Translations, rotations and compressive strength of the two systems were compared using paired t-tests. In cases the data were not normally distributed Wilcoxon Signed Rank tests were performed. P-values p < 0.05 were considered statistically significant.

3. Results

During preparation of the osteotomies, a fracture occurred in one tibia (female, 83 years) while preparing for the TomoFix implant. Although it was possible to implant the FlexitSystem plate to this marker (Fig. 4). The initial stability of the osteotomy was measured by calculating the difference in migration between the beginning of the experiment, and after 1,000, 10,000, 25,000 and 50,000 loading cycles. Considerable variation was seen in the results of the RSA measurements, expressing different modes of motions occurring in the reconstructions. These variations in motions complicated a straightforward quantitative comparison between the two osteotomy implants. In order to condense the data, we focused on a comparison of the total translations and principal rotations after 50,000 loading cycles, functioning as an indication of the final stability of the two systems. The total translation after 50,000 loading cycles was calculated as the root of the sum of the squared translations in the three orthogonal directions (Pythagorean theorem). Similarly, the resultant of the three rotations was based on Euler’s rotation theorem. In accordance with this theorem, a resulting axis of rotation was determined, representing the complex 3D rotation as a unit vector and a single angle, representing the total amount of rotation occurring in the system.

### Table 3

<table>
<thead>
<tr>
<th>Loading profile</th>
<th>Standard (Bergmann et al. [19])</th>
<th>Partial weight bearing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compressive force (−Fz)</td>
<td>1950 N</td>
<td>975 N</td>
</tr>
<tr>
<td>Abduction moment (−Mx)</td>
<td>17 Nm</td>
<td>8.5 Nm</td>
</tr>
<tr>
<td>External torque (−My)</td>
<td>6.2 Nm</td>
<td>3.1 Nm</td>
</tr>
</tbody>
</table>

a Achieved by applying the compressive force 8.7 mm medially from the center of the tibial plateau.
b Applied forces: 50% of the values as reported by Bergmann et al. [19].

to the proximal tibia using a tracer (left). (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

![Fig. 4. Schematic representation of the experimental set-up. A load applicator (top part) was fixed to the proximal tibia using screws and bone cement (in pink). The crossed circles indicate locations of RSA markers. The red circle, located at the tibial tuberosity, indicates the origin of the coordinate system, around which all rotations and translations were calculated. Markers were attached to the proximal tibia using a marker.](image)

Fig. 4. Schematic representation of the experimental set-up. A load applicator (top part) was fixed to the proximal tibia using screws and bone cement (in pink). The crossed circles indicate locations of RSA markers. The red circle, located at the tibial tuberosity, indicates the origin of the coordinate system, around which all rotations and translations were calculated. Markers were attached to the proximal tibia using a marker. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

The overall stability (e.g. the total translations and principal rotations) after 50,000 loading cycles, of the two systems are shown in Fig. 5. Statistical evaluation indicated that translations and rotations were not normally distributed. The FlexitSystem implant displayed a similar stability compared to the TomoFix implant, with median translations of 1.89 mm (range 1.10–3.53 mm) vs. 1.95 mm (range 1.07–15.65 mm) and rotations 2.77° (range 1.50–7.00°) vs. 1.69° (range 0.61–18.09°). A complete overview of the RSA measurements can be found in Online Resource 1 and 2. Wilcoxon Signed Rank tests demonstrated no significant differences between the total translations and principal rotations (p = 0.10 and p = 0.44, respectively).

3.2. Compressive test to failure

During the compressive test to failure, either a sharp change in the force was seen, or the force gradually reduced after reaching a maximum value (Fig. 6). All full force curves are given in Online Resource 3. The strength values had a normal distribution; no significant differences were found between the FlexitSystem and TomoFix reconstructions (mean 4867 ± 944 N vs. 4628 ± 1,987 N (p = 0.71)). The variation in strength was lower for the FlexitSystem reconstructions than for the TomoFix reconstructions (Fig. 7). No correlation (r = 0.53, p = 0.08) was found between compressive strength and BMD, with compressive strength increasing with increasing BMD.
3.3. Post-failure analyses

Radiographs of the reconstructions after the destructive test indicated that for both systems no damage occurred to the implants or screws. After removal of the plates, the screw holes in the proximal tibia appeared to be oval-shaped, suggesting a collapse of the proximal tibial bone, possibly due to fracturing of the lateral cortex, as the origin of failure of the reconstructions (Fig. 8).

4. Discussion

The results of the experiments showed that the FlexitSystem implant has a stability comparable to the TomoFix implant, which has a well-reported clinical and biomechanical track record. Open wedge high tibial osteotomy has been associated with high non-union rates and loss of correction due to unstable fixation [6,7]. Therefore sufficient strength of the implants is very important. The FlexitSystem implant displayed translations lower than 5 mm and rotations lower than 5°. The strength of the FlexitSystem reconstructions was slightly higher compared to the TomoFix reconstructions, although this difference was not statistically significant.

As this is a novel implant, no previous studies comparing the FlexitSystem to other implants have been performed. The strength of the reconstructions as found in the current study in general is slightly higher than published in the literature. Agneskirchner et al. [9] reported a strength of 3069 N for a reconstruction with a TomoFix implant in Sawbones. Stoffel et al. [11] compared the Puddu plate (modified Arthrex Osteotomy Plate) to the TomoFix plate, also in synthetic tibiae. Failure occurred after axial compression loading at a mean load of 2537 N (Puddu plate) and 2904 N (TomoFix plate). The TomoFix plate was also compared to the Aescular Plate and Puddu Plate by Kim et al. [10]. The maximal loads at failure were 6793.8 ± 499.8 N, 6055.1 ± 1184.7 N and 8798.2 ± 988.7 N, respectively. They used porcine bone and considered only axial loading, both could explain the higher maximal loads compared to our study. Evidently, there are differences between all these studies in terms of the type of bone used (synthetic or cadaveric, human or porcine), surgical approach (single- or bi-planar cuts), loading history and brand and type of implants.

We found no differences in the magnitude of the failure load and failure mechanism between the two implants. Post-failure analysis showed oval-shaped screw holes, due to a collapse of the proximal tibial bone. This suggests compressive failure of the lateral tibia and fracturing of the trabecular bone surrounding the screws as the origin of failure of the reconstructions. Fracturing of the lateral cortex as construct’s failure is also seen in the literature [9,11,22]. An intact lateral cortex is important for the stability of the osteotomy [23]. Our results suggest that with an intact lateral cortex, partial axial loading postoperative in both implants, could be tolerated.

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When evaluating the biomechanical functionality of implants for OWO, obviously, the choice of the base material affects the outcome of the investigation. The main advantage of using synthetic tibiae is that it minimizes the inter-specimen variability, making the results more reproducible [24,25]. Synthetic bones are designed such that they reproduce the structural biomechanical response of the bone, such as the global stiffness of the bone. A drawback of using such a material is that, although the global biomechanics are well-represented, the local interaction between the screw and the bone is not. Hence, testing with actual human cadaveric tissue therefore may provide additional insights into the actual failure mechanisms that otherwise would have been missed. Moreover it provides more information about the relation between strength of the reconstruction and bone quality. In the current experiments, the strength of the reconstructions with both implants decreased with BMD, suggesting that patient selection is important for the procedure, with a preference for younger, active patients with an adequate bone stock, in line with previous reports [4].

Some limitations of our study should be discussed. First, the use of cadaveric tissue over synthetic tibiae could reduce the reproducibility [24,25]. To minimize the effect of inter-specimen variation on the comparison between the implants, a paired study was performed comparing the left and right tibiae. Nonetheless, a significant amount of variation in translations and rotations was seen, of which the patterns could not be explained easily based on the local CT-based BMD measurements. Second, in the current study the fourth proximal screw for the TomoFix system was not used, as it lines up with the osteotomy gap. In the current study, supra-tuberosity osteotomies with a single cut were created using both systems. The biplanar cut technique allows for the use of the fourth screw. The biplanar cut and the additional screw for the TomoFix system may increase the initial stability of the osteotomy. From that point of view, one can consider the current experiments to represent a worst case scenario for the TomoFix implant. One could argue that, as the FlexitSystem implant does not facilitate a fourth proximal screw, the approach adopted in the current study provided a fairer comparison of the two systems. Moreover, as the post-failure analyses of the failure mechanisms indicated that the trabecular bone was crushed through the screws, rather than damage occurring to the screws or the connection between screws and implants, it is debatable whether the addition of the fourth screw would have provided a significant increase to the strength of the reconstruction. Third, the loading condition reported by Bergmann et al. [19], which evaluated the simulated loads during daily activities in patients with TKA, were used. Obviously, there still are substantial differences between an intact and a TKA reconstructed knee joint, but we tried to incorporate out-of-plane loads to apply a more rigorous loading regime, which may be more demanding on the osteotomy reconstruction compared with other experiments described in the literature [9–11]. Due to the pre-operative condition of the osteotomy patients the medial compartment will be off-loaded after the osteotomy, restoring a more natural alignment. We aimed at representing loads occurring during such an alignment by adopting loads of reconstructed patients. Moreover, by increasing the wedge in an OWO the loads may indeed be shifted further to the lateral compartment, which may be different from the loading configuration adopted here.

In conclusion, from a biomechanical point of view, the FlexitSystem implant behaves similarly to the TomoFix implant. Both systems can be used to fixate a high tibial open wedge osteotomy.

Conflict of interest

The authors declare that they have no competing interests.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.jos.2017.09.014.