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# Finite element analysis of Puddu and Tomofix plate fixation for open wedge high tibial osteotomy

Q1,Raja Mohd Aizat Raja Izaham, <sup>a</sup>, Mohammed Rafiq Abdul Kadir, <sup>a,b,\*</sup>, Abdul Halim Abdul Rashid, <sup>c</sup>, Md. Golam Hossain, <sup>d</sup>, T. Kamarul, <sup>d</sup>

<sup>a</sup> Medical Implant Technology Group, Universiti Teknologi Malaysia, 81310 Johor Bahru, Johor, Malaysia

<sup>b</sup> Department of Biomechanics & Biomedical Materials, Faculty of Biomedical Engineering & Health Sciences, Universiti Teknologi Malaysia, 81310 Johor Bahru, Johor, Malaysia

<sup>c</sup> Department of Orthopaedics & Traumatology, Universiti Kebangsaan Malaysia Medical Centre, Bandar Tun Razak, 56000, Cheras, Kuala Lumpur, Malaysia

<sup>d</sup>National Orthopaedic Centre of Excellence for Research and Learning, Department of Orthopaedic Surgery, University of Malaya, Kuala Lumpur 50603, Malaysia

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#### ABSTRACT

The use of open wedge high tibial osteotomy (HTO) to correct varus deformity of the knee is well established. However, the stability of the various implants used in this procedure has not been previously demonstrated. In this study, the two most common types of plates were analysed (1) the Puddu plates that use the dynamic compression plate (DCP) concept, and (2) the Tomofix plate that uses the locking compression plate (LCP) concept. Three dimensional model of the tibia was reconstructed from computed tomography images obtained from the Medical Implant Technology Group datasets. Osteotomy and fixation models were simulated through computational processing. Simulated loading was applied at 60:40 ratios on the medial:lateral aspect during single limb stance. The model was fixed distally in all degrees of freedom. Simulated data generated from the micromotions, displacement and, implant stress were captured. At the prescribed loads, a higher displacement of 3.25 mm was observed for the Puddu plate model (p < 0.001). Coincidentally the amount of stresses subjected to this plate, 24.7 MPa, was also significantly lower (p < 0.001). There was significant negative correlation (p < 0.001) between implant stresses to that of the amount of fracture displacement which signifies a less stable fixation using Puddu plates. In conclusion, this study demonstrates that the Tomofix plate produces superior stability for bony fixation in HTO procedures.

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#### 1 Introduction

12 High tibial osteotomy (HTO) is a well established procedure 13 used to treat uni-compartmental osteoarthritis of the knee.<sup>1</sup> Due to 14 its success in treating this condition, the use of HTO has since been 15 extended to include many other indications such as, correction of 16 various angular knee deformities and ligamentous injury.<sup>2</sup> In addition, HTO have also been widely advocated for use in 17 paediatric patients which includes correction of congenital 18 19 malformation.<sup>1–3</sup> At present, there are two types of HTO which 20 are commonly described: the medial open wedge HTO (OWHTO) 21 and the closed-wedge HTO (CWHTO). It is apparent from most 22 studies that OWHTO is more widely preferred owing to the lesser 23 likelihood of developing complications; which may include 24

\* Corresponding author at: Medical Implant Technology Group, Faculty of Biomedical Engineering and Health Science, Universiti Teknologi Malaysia, Skudai, Johor, Malaysia. Tel.: <u>+60</u> 7 5535961; fax: <u>+60</u> 7 5536222.

E-mail address: rafiq@biomedical.utm.my (M.R. Abdul Kadir).

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peroneal nerve injury and disruption of the proximal tibiofibular 24 joint.<sup>4</sup> 25

To maintain the stability of the OWHTO, specialized implants 26 were introduced. The two most commonly described are the 27 Tomofix and Puddu plates.<sup>5</sup> Although the former provides stability 28 to the osteotomized tibia fixation using locking head screws (LHS), 29 the Tomofix plates maintains its fixation on the bone using the 30 fixed-angle plate concept.<sup>6</sup> However, the comparative biomechan-31 ics between these two different implants has not been demon-32 strated and analysed computationally. 33

One of the computational methods that has received wide 34 acceptance in orthopaedics research is the Finite Element Analysis 35 (FEA).<sup>7-9</sup> In this technique, three dimensional models of bone-36 implant construct are converted into finite elements with 37 simulated physiological loads applied to analyse and predict the 38 outcome of surgery. Various biomechanical studies via computer 39 simulation have provided further insight into the stability and 40 functionality of joints and bone construct.<sup>7,10–13</sup> Hence, the present 41 study was conducted to determine the stability of these implants 42 following OWHTO procedure through the use of finite element 43 analysis. 44

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#### Materials and methods 45

#### 46 Three dimensional model design

47 Three dimensional (3D) model of human tibia and fibula was 48 reconstructed from two dimensional computed tomography (CT) 49 image using 3D model reconstruction software (MIMIC 10.01, 50 Materialise, Belgium). The CT image dataset was obtained by 51 scanning the lower limb of a single male subject in one medical 52 centre. An opening of 10 mm gap was simulated by removing a 53 wedge-shaped bone piece from the proximal part of the tibia. The 54 three dimensional models of both implants were designed 55 according to the manufacturers' specifications using computer-56 aided design (CAD) software (SOLIDWORKS 2009 SP2.1, Dassault 57 Systems, Massachusetts, USA). Two components make up both the 58 Tomofix and Puddu plates, which is the plate and screws. The 59 Tomofix plate system has a total of 8 screw holes: 5 of these are 60 able to adapt either the LHS or conventional screws while the 61 remaining three can only allow the LHS screws to be inserted. In 62 the Puddu plate system, in addition to the plate and screw holes, a 63 block configuration was incorporated into the plate design to allow 64 additional support at the osteotomy. In this system, two conventional screws were used, which is commonly described 65 in several literatures.<sup>5,14,15</sup> 66

67 The implants were then carefully positioned across the gap. A 68 10 mm wedge size Puddu plate was selected, and placed across the 69 opening as shown in Fig. 1. The Tomofix was positioned as 70 recommended by the manufacturer as demonstrated in Fig. 2.

#### 71 Material properties

In this study, the properties of titanium alloy were adopted into 72 the simulated implant models. The Young's modulus (E) was set at 73 110,000 MPa with a Poisson's ratio ( $\upsilon$ ) of 0.3.<sup>16</sup> Both implants were 74 75 modelled to incorporate linear elastic, isotropic and homogeneous 76 properties. As for the tibia and fibula, the material properties were 77 also assumed as linear elastic, isotropic and homogeneous 78 material. Both tibia and fibula were modelled with an assumed 79 Young's modulus, E = 20,000 MPa and Poisson ratio, v = 0.3.<sup>10</sup> The 80 cortical bone and medullary canal was not modelled in this study.<sup>17</sup> These parameters are summarized in Table 1. 81

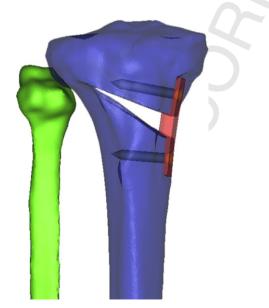


Fig. 1. Puddu plate positioning on 3D model of simulated open wedge high tibia osteotomy.

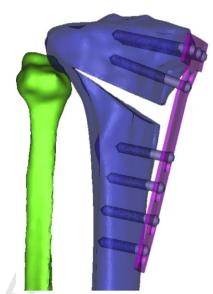


Fig. 2. Tomofix plate positioning on 3D model of simulated open wedge high tibia osteotomy bone.

#### Analysis

For finite element analysis, both the bones and implants were 83 meshed using 1.0 mm sized tetrahedral mesh.<sup>18</sup> The distal end of the tibia was fixed in all degrees of freedom to prevent rigid body motions during the analysis. An axial force of 2500 N with a distribution of 60% to the medial compartment was applied to simulate the axial compressive load on the knee of an adult during single limb stance.<sup>5,19</sup> The effect of axial load sharing between tibia and fibula was simulated by linking the two bones with virtual mechanical rigid links.<sup>20</sup>

For the Puddu plate system, it was assumed that this plate system had a direct contact with the bone. The same contact properties were also assigned between the LHS and the bone. The 94 contact between the plate and LHS was simulated to imitate strong contact attachment that mimics the locking screw mechanism. All friction coefficient values were set to 0.3.<sup>21</sup> The analysis was done using commercial finite element software (MARC, MSC.Software Corporation, California, USA) with the equivalent von Mises stress 99 (EVMS), displacement of the model relative to the distal tibia, and micromotion of the implant relative to the bone (as a measure of relative fixation strength) used as the output measures. Statistical 102 analysis was done using the IBM SPSS Statistics software using ttest.

#### Results

Higher amounts of displacement were observed in the Puddu plate system as compared to the Tomofix plate with a mean difference of 3.25 mm observed between the two (p < 0.001) (Table 2). The displacement appeared to be directed towards the anterior side of the tibia which was consistently observed in both systems (Fig. 3), decreasing as it approaches distally (Fig. 4).

| Fable 1  |            |    |               |    |        |
|----------|------------|----|---------------|----|--------|
| Material | properties | of | reconstructed | 3D | model. |

| Materials                 | Young's modulus, E (MPa) | Poisson ratio, $v$ |  |
|---------------------------|--------------------------|--------------------|--|
| Puddu plate/Tomofix plate | 110,000                  | 0.3                |  |
| Screws                    | 110,000                  | 0.3                |  |
| Tibia                     | 20,000                   | 0.3                |  |
| Fibula                    | 20,000                   | 0.3                |  |

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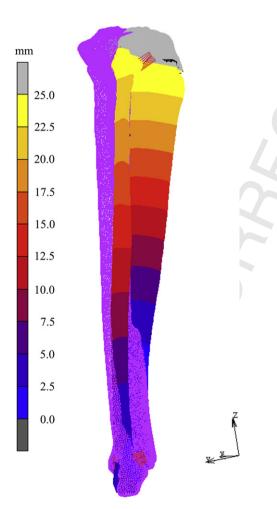
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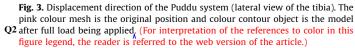
 Table 2

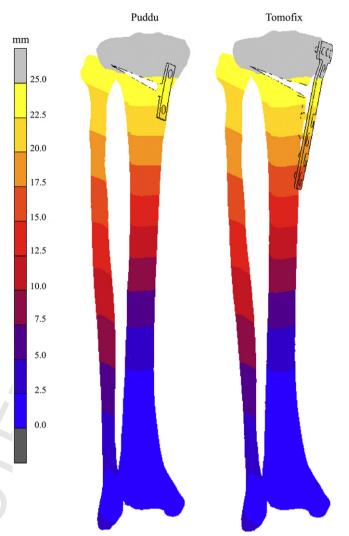
 Difference between Puddu and Tomofix for different biomechanical properties.

| Variable       | Group   | Number<br>of nodes ( <i>N</i> ) | Mean  | SD    | Mean<br>difference | p-value |
|----------------|---------|---------------------------------|-------|-------|--------------------|---------|
| Displacement   | Puddu   | 6872                            | 15.24 | 10.78 | 3.25               | 0.001   |
|                | Tomofix | 6872                            | 11.99 | 7.45  |                    |         |
| Implant stress | Puddu   | 3405                            | 24.74 | 22.46 | _20.75             | 0.001   |
| ^              | Tomofix | 6119                            | 45.49 | 39.71 | ▲20.75             |         |
| Model stress   | Puddu   | 6231                            | 1.11  | 1.73  | 0.53               | 0.001   |
| ^              | Tomofix | 6231                            | 0.58  | 0.31  |                    |         |

EVMS results demonstrated dissimilar stress pattern distribu-112 113 tions in both constructs (Fig. 5). The stress distribution in the Tomofix system was comparatively higher to that of the Puddu 114 115 plate. Stresses appear to be more concentrated at the corners of the 116 Tomofix plate and, between the connection of the LHS and the 117 plate itself. Stresses were also concentrated at the two distal screw 118 holes close to the opening for the screw insertions. In the Puddu 119 plate, stresses were mostly observed at the region around the 120 wedge. Analyses of the stresses on the whole bone model with the 121 implant showed that Tomofix plate had an average stress value of 45.5 MPa which was significantly (p < 0.001) higher to that of the 122 Puddu plate system which was 24.7 MPa (Table 2). The average 123 124 value was calculated from stress values of all nodes within the 125 plate. The Tomofix fixation produced high concentrated stress at 126 the lateral hinge of the osteotomy (Fig. 5g).







**Fig. 4.** Displacement result acquires from finite element for each model that being analysed.

The micromotion analysis demonstrates that the Puddu plate 127 underwent higher amounts of motion than that of the Tomofix 128 plates (Fig. 6). Higher micromotion was observed on the surface of 129 Puddu plate, which was in contact with the bone especially at the 130 distal part of the plate. For the Tomofix plate, micromotion was more evident between the LHS and the bone, most notably in those 132 that are placed near to the opening. 133

#### Discussion

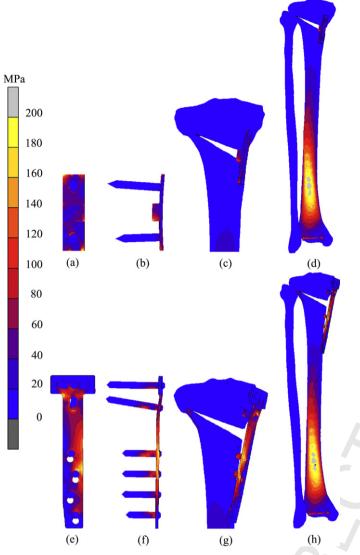
Although the CWHTO was established earlier than the OWHTO, 135 the disadvantages and complications arising from using the former 136 have prompted many surgeons to switch to the latter. The reasons 137 are many fold which include better stability and reduced incidence 138 of peroneal nerve palsy.<sup>22</sup> A variety of specialized plates have been 139 introduced for use in OWHTO however, two such implants remains 140 a-popular for many surgeons, i.e. the Tomofix system and the 141 Puddu system. In the present study comparison between the 142 Tomofix system which utilizes the locking compression plate (LCP) 143 design,23 and the Puddu plate which was designed with an 144 incorporated wedge to maintain the gap on the bone showed good 145 performance for maintaining stability due to their rigid con-146 struct.<sup>24</sup> 147

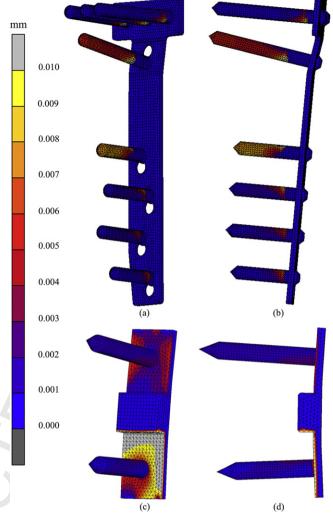
The characteristics of the load or stress distribution through the 148 Tomofix and Puddu plates were observed. Using the equivalent von 149

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**Fig. 5.** Equivalent von Mises stress (EVMS) distribution along the model. Bottom view of plates (a), (e). Plates side view (b), (f). Anterior view of fixation models (c), (d), (g), (h).

150 Mises stress (EVMS) analyses, Tomofix system underwent higher 151 amount of stress than the Puddu plate system. This can be 152 explained by the fact that the Tomofix which utilizes the LHS 153 provide a better anchorage than its Puddu plate, thereby displacing the stresses transmitted by the body weight.<sup>23</sup> In addition, the 154 angular stability of the LHS is more rigid than the conventional 155 screws used in Puddu plates.<sup>23</sup> Although it may show that loading 156 via the Tomofix will produce better stability with their rigid 157 fixation, in clinical applications this may be a disadvantage as the 158 159 stress shielding effect may cause severe osteoporosis in the long term as demonstrated in previous reports.<sup>10,16,25</sup> This however, has 160 yet to be determined in any known studies, as data for the 161 162 threshold that causes bone to undergo osteoporosis have not been 163 previously established.

164 It is interesting to note that in both systems, stresses are 165 generated within a region located namely on the anterior-distal 166 side of the tibia. Further analyses suggest that the stress appears to 167 be equally distributed to approximately within an area located at 1/3 of the anterior tibia surface. This may be attributed by the 168 169 slender appearance of the tibia itself, which is also observed in previous studies.<sup>18</sup> However, a contrasting effect is observed when 170 171 EVMS analysis was conducted. The micromotion appears to be

Fig. 6. Micromotion result for the Tomofix plate (a), (b) and Puddu plate (c), (d).

greater in the Puddu system with differences between the systems to be as high as 14 µm under the applied static condition. The value is expected to be higher during normal physiological cyclic loading. This is important as large amount of relative micromotion may result in implant loosening and lost of fracture stability.<sup>11,19,26</sup> However, small amounts of motion may be good for fracture healing.<sup>27</sup> Excessive displacement of the bone construct such as bending and torsion of the bone fragment relative to the distal bone may result in failure of the implant.<sup>28–30</sup> According to Aro and Chao, the change in the structural properties as well as the configuration by which an internal fixation device is designed may provide certain benefits but it may be the case that the loss of certain fundamental working principles may need to be accepted.<sup>31,32</sup> In this study, this principle appears to be applicable. The rigidity of the Tomofix implant in this study appears to be compensated with the loss of micromotion, which may lead to possibility of non-union and failure of fracture fixation when the micromotion becomes greater.

There are several limitations to the present study. Firstly,190although higher amounts of stresses are generated within the191Tomofix system, our study could not determine if these forces192would exceed the limits of the implant design. However, our static193analysis showed a maximum stress of 262.47 MPa which is less194than the strength of the material.<sup>33</sup> Data regarding these implants195are presently lacking and therefore will need to be established196using biomechanical testing models. While the present study197

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198 establishes the amount of micromotion which exist in both model 199 designs, the optimal physiological amount necessary to promote 200 tissue regeneration appears to be deluded. Again, this is attributed 201 to the lack of published data to allow a reasonable comparison to 202 be made. The bone model in this study was created using cortical 203 bone properties to preserve simulation time as suggested by Peleg 204 et al.<sup>17</sup> Only statics condition can be simulated as the idealistic dynamic motion of the joint was too prohibitive in terms of 205 206 computing resources and time. Rigid mechanical link was also used 207 in the study to simulate the tibiofibular joint which may not 208 represent the actual joint condition. Future studies can explore a 209 more suitable representation of the joint as well as analysing the 210 system under cyclic loading. Lastly, although the implant is 211 subjected to an assumed normal human weight of 70 kg, data 212 obtained from higher amounts of loads may be necessary to prove 213 the effectiveness of either implant during normal function. This is 214 important considering that the daily human activity requires the 215 knees to undergo stresses beyond that which is observed during 216 standing. For example, in climbing stairs, the load applied to these 217 implants may reach up to 3 times the normal body weight.<sup>34</sup> In 218 addition, while it has been generally assumed that the normal body 219 weight of a person is 70 kg, data appears to support the notion that 220 the present population is getting heavier and thus data of larger 221 loads would provide better representation of normal conditions.<sup>27</sup>

#### 222 Conclusion

223 While this study has demonstrated that the use of Tomofix 224 plates provides better rigidity and therefore stability than the 225 Puddu plate system, the stress experienced in the Tomofix plates 226 may be of concern especially in view that this implant may fail. In 227 addition, because of the smaller micromotion experienced in the 228 Tomofix plates, it may be the case that fixation using this implant 229 may lead to non-union of the osteotomized site. However, without 230 the normal data that determines the threshold to cause implant 231 failure or for fracture non-union to occur, these concerns may be 232 unwarranted. Further studies would therefore be needed to prove 233 that these concerns are valid before refuting that the Tomofix plate 234 is superior, as shown by its rigidity and stability to secure the 235 osteotomized site in HTO procedures.

236 **Conflict of interest** 

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None declared.

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