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Personalised 3D Printed High Tibial Osteotomy Achieves a High Level of Accuracy: '*IDEAL*' Preclinical Stage Evaluation of a Novel Patient Specific System

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Highlight

- A 3D evaluation of pre- versus post-surgery anatomy was demonstrated using CT scans
- Custom surgical guides can improve accuracy and reliability for leg re-alignment
- This novel high tibial osteotomy surgery reliably achieves planned correction angle

Abstract

High tibial osteotomy (HTO) is an effective surgical treatment for isolated medial compartment knee osteoarthritis; however, widespread adoption is limited due to difficulty in achieving the planned correction, and patient dissatisfaction due to soft tissue irritation. The aim of this study was to assess the accuracy of a novel HTO system with 3D printed patient specific implants and surgical guides using cadaveric specimens.

Local ethics committee approval was obtained. The novel opening wedge HTO procedure was performed on eight cadaver leg specimens. Whole lower limb CT scans pre- and post-operatively provided geometrical assessment quantifying the discrepancy between pre-planned and post-operative measurements for key variables: the gap opening angle and the patient specific surgical instrumentation positioning.

The average discrepancy between the pre-operative plan and the post-operative osteotomy correction angle was: 0.0 ± 0.2°. The R^2 value for the regression correlation was 0.95.

The average error in implant positioning was -0.4 ± 4.3 mm, -2.6 ± 3.4 mm and 3.1 ± 1.7° vertically, horizontally, and rotationally respectively.

This novel HTO surgery has greater accuracy in correction angle achieved compared to that reported for conventional or other patient specific methods with published data available. This system could potentially improve the accuracy of osteotomy correction angles achieved surgically.

Key words: Patient-specific; PSI; custom; plate; accuracy

Introduction

Opening wedge high tibial osteotomy (HTO) aims to alter the hip-knee-ankle axis of the lower limb to decrease the forces within the medial compartment of the knee, reduce symptoms and thus delay the progression of osteoarthritis [1,2]. The procedure is a useful surgical option for medial tibiofemoral osteoarthritis in younger, more active patients as it can delay or even avoid the need for arthroplasty [3]. The aim is to preserve the native joint by creating an opening wedge to re-align the tibia, which is then stabilised using a plate; this reduces the pressure on the worn medial compartment. It is technically demanding and an accurate correction in multiple planes is essential for optimal effectiveness [4,5]. The evolution of locking plate techniques has helped address some of the challenges given the significant heterogeneity of patient biology and mechanics; however, some key barriers to widespread adoption remain. These include: (1) the inability to measure and achieve the planned correction intraoperatively; and (2) patient dissatisfaction due to soft tissue irritation, with up to 40% of hardware removed due to pain [6] resulting from a one size fits all plate.

Some have proposed that conventional operative methods could be superseded by computer assisted techniques, including patient specific instrumentation (PSI) addressing the need for surgical accuracy [3]. The creation of 3D printed patient specific guides (including pre-operative planning following a CT scan) has been shown to permit more accurate bone cuts [7]. Furthermore, previous work involving finite element analysis suggested that when compared with the current ‘gold standard’ osteosynthesis plates, use of custom implants could translate to improved interfragmentary movement without significantly affecting plate stress [8]. A new HTO system – Tailored Osteotomy Knee Alignment (TOKA®, 3D Metal Printing Ltd, Bath, UK) – is unique amongst patient-specific osteotomy systems having a custom titanium plate (Figure 1a) and titanium surgical guides (Figure 1b) featuring a proprietary mechanism for precise osteotomy opening as well as saw cutting and drilling guides (Figure 1c). This personalised procedure aims to improve accuracy whilst saving surgical time by minimising, or potentially removing, the need for intraoperative imaging.

The introduction of novel techniques and implants present particular challenges as outlined by the IDEAL collaboration, an international group of surgeons and academics who have developed an established framework for the stages of innovations [9,10]. (Table 1). The importance of adequate preclinical stage testing and reporting is emphasised. In combination with a computer simulated clinical trial (https://clinicaltrials.gov/ct2/show/NCT03419598), [11] this paper presents the results of an *IDEAL* preclinical stage study of TOKA ahead of first-in-human surgery. This cadaveric testing presents clinically relevant and rigorous assessment of the device involving high resolution CT scanning both pre-and post-procedure, which has not been performed widely in pre-clinical studies of other systems.

The aim of the study was to assess the accuracy of a novel system involving 3D printed patient-specific cutting guide and personalised plate for open wedge high tibial osteotomy using cadaveric specimens and highlight any potential areas for improvement for the system.

Materials & Methods

Local ethics committee approval was obtained (Bath University Research Ethics Approval Committee for Health: EP 17/18 135). Eight frozen cadaver lower limbs with surrounding soft tissues intact (four donors (3M; 1F), aged 81-96) were obtained from the Vesalius Clinical Training Unit (Centre for Comparative Clinical Anatomy, University of Bristol, Bristol, UK); no cartilage abnormalities were identified on CT scans. The TOKA procedure was performed by two consultant orthopaedic surgeons who were familiar with the surgical technique of HTO and had practical training using the new PSI surgical instrumentation on Sawbones surrogates. The cadaver tests were spread over three days.

Planning phase

All specimens underwent pre-operative whole lower limb CT scan (SIEMENS SOMATOM Definition Edge, Spire Hospital, The Glen Hospital, Bristol, UK). The acquisition parameters were: 120kV, 80 mA, 1.0 mm slices. DICOM images were imported into image processing software (ScanIP 2018, Synopsys, USA) and 3D reconstructions of the tibiae were generated using a 350 Hounsfield unit threshold and smoothing operations, and these were then exported in STL format. The same process steps were followed for both pre- and post-implantation scans. The bi-planar osteotomy planes were manually positioned using computer aided design (CAD) software (Rhinoceros 7, Robert McNeel & Associates). The post-operative geometry was simulated by splitting the tibia about the osteotomy planes and rotating the proximal tibia fragment about the hinge axis by the opening angle. The specimen specific cutting guide, and plate, were created using CAD software (Rhinoceros 7, Robert McNeel & Associates; Geomagic Freeform, 3DSystems, USA), taking into account to pre- and post-operative geometries for the opening-mechanism. The region where the cutting guide contacted the bone was based around the screw positions with a 1mm off-set from the bone surface to account for soft tissue. The cutting slots were positioned at the intersection between the osteotomy planes and the bone contacting surface. Gap opening angles for each specimen were selected such that 4 cases had the same opening angle and 4 cases had different opening angles (Table 2); the values were not related to any weight-bearing axes, and they were chosen to be representative of typical corrections applied in HTO surgery . Three-dimensional planning also allowed the screw lengths to be determined pre-operatively.

Cadaveric operation surgical technique

Specimens were fresh-frozen and thawed overnight ahead of the study procedures. On the operative day, limbs were positioned and draped as they would be during *in vivo* surgery to simulate operating conditions. No gross pathology was observed. All HTO operations were performed by a single surgeon, with the aid of a surgical assistant and a scrub nurse, using the custom 3D printed cutting guides and plates without using intraoperative radiology.

An antero-medial surgical approach was used in accordance with the manufacturer's User Manual (TOKA®, 3D Metal Printing Ltd). The custom surgical guide was used to drill the pilot holes in the bone to match the custom plate upon osteotomy gap opening. The guide was also used to perform the bi-planar osteotomy cuts, as well as open the osteotomy to the pre-planned correction angle. The custom plate was secured to the bone using 5.0 mm locking screws.

Evaluation phase

Following the operation all specimens underwent a second CT scan using the same protocol as the pre-operative scan. For each specimen, three-dimensional assessment was performed by comparing the virtually planned geometry against the geometry observed in the post-operative CT scan (Figure 2a and b). The post-operative segmented bone was aligned to the pre-operative geometry using the distal portion of the tibia using CAD software (Rhinoceros 7) (Figure 2c). The fibula position was ignored. For each case, upper and lower osteotomy planes were positioned, and the correction accuracy was assessed by measuring two distinct aspects of the surgical procedure:

1. **Gap Opening Angle** – the angular opening of the osteotomy gap by measuring the angle between the upper and lower osteotomy planes. This gives an indication of the ability of the instrumentation to achieve the planned opening angle (Figure 3a);
2. **Patient Specific Instrumentation (PSI) Positioning** - the positioning of the plate vertically and horizontally at two locations on the plate (A: proximal and B: distal, Figure 3b), and the rotation calculated by drawing a line between points A and B

(Figure 3c) on the planned and achieved plates and measuring the angle. This gives an indication of the accuracy of the positioning of the surgical guide against the bone during the surgery.

Note that the distance measurements were generated in 3D CAD software and the measured values are given to two decimal places, but subsequently calculated values are reported to a single decimal place as this level of precision is generally considered to be clinically relevant. The 3D gap opening estimation approach was first implemented on the pre-operative geometries with known values (Table 2), thereby providing validation and confidence in the post-operative measurements using the same approach.

Statistical methods

Regression and Bland-Altman plots were used to evaluate the relationship between the planned and achieved osteotomy opening angle and the influence of the rotational positioning error (as described in Figure 3c) on the achieved correction. The regression slope, R^2, mean, absolute mean, and standard deviation values were used to quantify accuracy Statistical analyses were performed using Microsoft Excel (Version 2111, Microsoft Corporation, USA).

Results

Osteotomy opening angle

The 3D estimation approach was found to accurately measure the known pre-operative values with a mean error of 0.0 ± 0.2°. The absolute mean error was 0.2°.

The PSI system accurately reproduced the planned osteotomy cut with an average difference between the pre-operative plan and the post-operative angular opening of the osteotomy gap of 0.0 ± 0.3° (Table 2). The absolute mean error was 0.3°. This represents 3.1 ± 3.6% of the total opening angle respectively. The absolute discrepancy in achieved opening angles was relatively small ranging between -0.5° and 0.4°; this represents between -4.5% to 5.0% of the corrections angles assessed (8 to12°).

Regression analysis of the planned versus achieved osteotomy opening angle determined that the regression slope was 0.93 and R^2 was 0.95 (Figure 4a). The Bland-Altman plot illustrates that the mean error was close to zero and there was no apparent bias in the data (Figure 4b).

PSI positioning

There was some variability in the placement of the PSI surgical guide with an average error (average of locations A and B) of -0.4 ± 4.3 mm and -2.6 ± 3.4 mm vertically and horizontally respectively. (Table 3). The absolute average error for all translational measurements was 3.8 ± 1.9 mm. The mean difference in rotational positioning was 3.1 ± 1.7°.

The achieved osteotomy opening angle accuracy had a weak relationship with the rotational error with a regression line slope of 0.13 and R^2 = 0.47 (Figure 5) indicating that small errors in PSI placement do not significantly influence the opening angle.

Discussion

This study evaluated the accuracy of a novel system (TOKA®) for opening wedge high tibial osteotomy (OW-HTO) in eight human cadaveric limbs. We found excellent agreement between the planned osteotomy and the surgical correction achieved using subject specific instrumentation, without the need for intraoperative radiology or measurements. The absolute mean error in correction angle achieved versus planned was 0.3°. This provides evidence that the combination of a 3D printed patient-specific cutting guide and custom plate enables a reliable method of correction.

Our accuracy results compare favourably to other PSI systems investigated in similar studies reporting pre- versus post-procedural accuracy using CT scans: for example: a custom-made system by Balgrist University Hospital using the Tomofix plate found average 3D rotational differences of $-0.1° \pm 2.3°$ in coronal plane [12]. Although not yet published in full, a different system using a standard skin incision (Embody PSI) report mean angular corrections to be within 3° of the 3D preoperative plan in all three planes [3].

In our study, observed errors in surgical guide / plate positioning – with an absolute average of 3.8 mm - did not significantly influence the accuracy of the osteotomy opening angle correction. We did not find this surprising as the surgical guide incorporates an opening mechanism which reproduces the correction regardless of the positioning. In comparison, conventional methods of determining the gap angle which use the gap opening height can be very sensitive to intraoperative measurement errors. For example, a rule of thumb presented in the Tomofix surgical technique guide is 1 mm opening equates to approximately 1 degree[1].

Accuracy can be defined as the ability to obtain the desired value with low systematic errors. In the case of osteotomy for alignment correction, this is influenced by both the pre-operative planning and the surgical implementation of that plan. Some studies have evaluated the accuracy of PSI systems clinically [7,13] and report Hip-Knee-Ankle in their assessments. While this metric is clinically relevant, it is a combined metric with potential sources of error including radiographic mal-alignment [14] and changes in joint space as a result of force re-distribution, as well as the performance of the device itself. This study used post-operative CT scans and analysis of the 3D geometry to evaluate both the accuracy (planned versus achieved) of PSI guides as used in surgery, without the confounding uncertainty in radiographic pre- and post-operative alignment assessments [14].

Pre-operative planning is essential, however the optimal axis correction can be challenging to achieve with standard operating techniques [15]. The accuracy of re-alignment is imperative as relatively minor changes in femorotibial alignment are associated with significant changes in load distribution [16–18]. While the precise amount of correction is still a highly debated topic, it is recognised that under- or over-correction during HTO can lead to early failure [18,19] and many researchers have explored ways to minimise this. Two-dimensional geometric methods were proposed by Miniaci et al, performed using long leg radiographs based on anatomical and mechanical axes [20], which have since been shown to be equally effective as using computer based planning software [20]. More recently, three-dimensional planning [7] and assessment [21] of corrections has been advocated using CT scanning. Accordingly, in this study we elected to plan and perform 3D assessment of our corrections using CT scans to compare pre-operative plans with post-operative measurements [4].

Prior work involving HTO in human cadavers randomised to either conventional or computer navigation methods revealed the latter to be more accurate [22]. These benefits have translated into improved accuracy in some clinical studies [5,23] but not in others [24,25]. One of the main limitations of navigation systems in HTO surgery is that data are acquired in the supine position and thus don't reflect the weight-bearing alignment [23]; this may explain the discrepancy between cadaveric lab studies [22] and clinical studies [24]. Additionally, other shortcomings of navigation have been highlighted including: surgical time (approx. 15-30 minutes extra) [24,26,27], cost-effectiveness and a long learning curve [23,28]. By comparison, two publications have reported average times of 30 minutes or under using PSI [29,30], which is substantially faster than conventional HTO with reported times of 66 ± 17 minutes [24].

There is evidence that patient specific cutting guides can improve OW-HTO accuracy when a conventional locking plate is used [7,31,32]. Some authors have also shown benefits in combining patient specific cutting guides with custom patient-specific plates in maxillofacial procedures [33], distal radius [21,34] and distal humerus osteotomies [21]. In addition, Kim *et al* found that a more accurate coronal angle correction was achieved for OWHTO when using a 3D printed model of the osteotomy section [35]. In line with these findings, the TOKA system uses a custom 3D-printed titanium plate and patient specific cutting guide. Unlike previous systems, it also incorporates a novel method of controlling the opening of the osteotomy during OW-HTO.

It has been reported that the majority of conventional HTO corrections deviate more than 1.5° from the planned correction, and achieving the hip-knee-ankle (HKA) angle within an accuracy of 3° is acceptable [24]. Lutzner *et al* however, suggest that good long-term results are more likely to require an accuracy of at least 1° [22]. While we did not evaluate the resulting change in HKA angle, the method used in our study was able to produce an opening angle with an accuracy well within this tolerance. It should be noted that some studies [22] reported their correction in terms of percentage M-L distance, making it difficult to compare against other studies as this relationship is dependent on a number of factors. In Table 4 we have reported results from studies that have expressed the deviation from planned correction in the coronal plane in degrees [7,24,30,32]; it is important to note that none of these studies performed post-operative CT scans, and so relied on long-leg x-ray assessment. In our relatively small sample of human cadaver limbs, the TOKA procedure has achieved a highly accurate correction (ABS mean error: 0.3 ± 0.3° between planned and actual correction). While clinical measurements of HKA correction could be expected to have larger errors than the bony correction alone, our system produced errors well within the reported values for standard gap measurement techniques or computer navigation [24], and is comparable to other patient specific procedures previously reported [7,30,32]. We attribute the accuracy of the TOKA system to two factors: (1) improved control the direction of the drills and saw cuts due to the surgical guide being manufactured from titanium rather which has higher print dimensional accuracy as well as increased resistance to change in orientation compared to plastic which is considerably softer than the surgical drills; and (2) the integrated screw-driven opening mechanism within the surgical guide which opens the osteotomy to the pre-planned angle without any additional instrumentation (i.e. laminar spreaders). These potential factors, however, must be examined further.

OW-HTO is recognised as an useful option for many with unicompartmental arthritis of the knee, although it is widely accepted that it is a demanding procedure with variable results and potentially significant complications [1] and this may account for its failure to gain widespread use and acceptance. Brinkman posited that OW-HTO procedures were once 'less popular, mainly because implants for internal fixation have, until recently, been unable to withstand the axial and torsion forces in the proximal tibia [1]. Developments in engineering allowed evolution from spacer plates to those based on locking plate technology which allowed the ability to perform OW-HTO without requirement for routine bone grafting [36]. Spacer plates were observed to have high rates of complications including plate breakage, screw failure or non-union [16,37]. Locking compression plates, such as the *Tomofix* (DePuy Synthes, Johnson & Johnson, New Brunswick, USA), allow more rigid fixation which have reduced such complications, but are more 'bulky' and associated with significant soft tissue irritation, with rates as high as 40.6% in one series [38]. The TOKA system includes a patient specific, lower profile titanium locking plate, which conforms precisely to the patient's anatomy – as confirmed visually during the surgery (Figure 6) and using the post-operative CT scans. The custom plate design has also been shown to produce higher interfragmentary movement, which is thought to beneficial for bone healing following osteotomy [39], when compared with the *Tomofix* design with similar levels of plate stress [8].

This novel system presents an alternative to time-consuming and expensive navigated surgery. While the system could potentially remove the requirement for intraoperative radiology once its safety has been demonstrated clinically, it does require a pre-operative CT-scan. This should be conducted using a low-dose protocol [40]. It is not uncommon to remove the plate due to soft tissue irritation following osteotomy healing, at around 12 to 18 months post-operation [41]. The low-profile custom plate (Figure 6) has the potential to significantly reduce soft-tissue complications following surgery and so should address this drawback.

As the drill holes are pre-drilled in the intact bone, prior to the osteotomy cuts, the custom plate system will only fit when the correct opening is achieved; we therefore believe that our measured errors and variability in opening angle can mainly be attributed to the 3D measurement method and slight deviations in the saw cuts allowed by the tolerance of the cutting slot. It should be noted that the vertical excursion of oscillating saw blades has been shown to be around 1.87 ± 0.35 mm [42]; our average measured errors in guide/implant positioning were similar in magnitude to this, indicating they are within a clinically acceptable range.

Limitations

The principal limitation is the relatively small number of specimens which was a practical issue. Nevertheless, even with eight specimens, the TOKA system was found to achieve the planned correction with a high degree of accuracy and precision. Small numbers have also been used in previous similar studies. Additionally, there were no control cases to permit comparison with conventional OW-HTO; however, the aim of the study was to assess the accuracy of the TOKA system in the preclinical setting, and this was demonstrated. The three-dimensional assessment for orientation and positioning showed good results but also highlighted potential targets for design improvement ahead of first in human studies to further improve accuracy.

Our leg specimens were all scanned in a non-weight bearing condition. The CT scan was conducted using 1 mm slice thickness; this value has been shown to be acceptable for volumetric segmentation - even for smaller bones such as the mandible [43]; it should be noted that the slice thickness of the CT scan does not represent the maximum accuracy. Additionally, as our pre- and post-operative measurements were performed in CAD software using the segmented geometries. The method of assessing translational and rotational positioning error used 2 locations (A and B) which is, by definition, not representative of the whole geometry; it was, however, adopted for simplicity and consistency as each plate was unique. Unlike 2D radiographic measures (long-leg x-rays), the CT-based method directly evaluates the geometry being altered; there are, however, several potential sources of error: the segmentation (including thresholding and smoothing), as well as the positioning of the planes used for the assessment. For this reason, we first evaluated the approach using the planned correction (with a known correction value), before assessing the achieved correction (unknown). Additionally, the plate geometry produced in CAD and the final implanted plate matched closely (see Figure 2) confirming the accuracy of the segmentation.

This study shows that the current PSI system achieved the planned osteotomy correction angle. Clinical cases are needed to evaluate whether accuracy in osteotomy opening translate into planned HKA axis correction; clinical trials of the device are now underway which will also reveal if the plate's personalised profile translates to less soft tissue irritation and greater patient satisfaction. It is known that significant errors can arise in 2D radiographic planning of osteotomy arising from the alignment of the limb [14], and other variables not routinely considered such as joint space, muscle activity and ligament laxity may also play a role.

Previous studies have stated that the saw thickness was not counted for thus reducing the amount of correction by the blade thickness [24]; we don't believe our study was influenced by this as the custom plate is designed to fit only when the correct opening has been achieved, therefore the saw blade thickness should not influence the final correction. Fitting the two osteotomy planes to the segmented post-operative geometry was not straightforward due to undulations in the surface and difficulty segmenting the bone near the plate due to metal artefact. Nevertheless, the variability in the measurements was not significantly larger than for the pre-operative geometries giving confidence in the results.

Conclusion

In conclusion, this method of performing HTO has greater accuracy in correction angle achieved compared to conventional HTO or to other PSI devices with published data available. These results indicate that TOKA could improve the accuracy of the osteotomy correction angle achieved surgically.

Author's Contributions

A MacLeod: Conceptualization, Methodology, Formal analysis, Investigation, Data Curation, Writing - Original Draft**; J Mathews**: Investigation, Writing - Review & Editing; **AD Toms**: Investigation, Writing - Review & Editing; **V Mandalia**: Investigation, Writing - Review & Editing; Implantation; **H Gill**: Conceptualization, Methodology, Writing - Review & Editing, Supervision, Project administration, Funding acquisition.

Ethical Approval

Local ethical approval was obtained for this cadaveric study (REACH EP 17/18 135).

Please state any sources of funding for your research

Research grants – Versus Arthritis grant number: 22262;

Ethical Approval

Work on human beings that is submitted to *Medical Engineering & Physics* should comply with the principles laid down in the Declaration of Helsinki; Recommendations guiding physicians in biomedical research involving human subjects. Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975, the 35th World Medical Assembly, Venice, Italy, October 1983, and the 41st World Medical Assembly, Hong Kong, September 1989. You should include information as to whether the work has been approved by the appropriate ethical committees related to the institution(s) in which it was performed and that subjects gave informed consent to the work.

DOES YOUR STUDY INVOLVE HUMAN SUBJECTS? Please cross out whichever is not applicable.

Yes

No

If your study involves human subjects you MUST have obtained ethical approval.

Please state whether Ethical Approval was given, by whom and the relevant Judgement's reference number

Local ethical approval was obtained for this cadaveric study (REACH EP 17/18 135).

DOES YOUR STUDY INVOLVE ANIMAL SUBJECTS? Please cross out whichever is not applicable.

Yes

No

If your study involves animals you must declare that the work was carried out in accordance with your institution guidelines and, as appropriate, in accordance with the EU Directive 2010/63/EU**.** http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32010L0063

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Declarations

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Declaration of Competing Interest

All authors must disclose any financial and personal relationships with other people or organisations that could inappropriately influence (bias) their work. Examples of potential conflicts of interest include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding.

Conflicts of Interest: AR MacLeod: Named inventor on related patent; Financial interest: Shares in 3D Metal Printing ltd

JA Mathews: None

AD Toms: Named inventor on related patent; Named clinical lead on the project

VI Mandalia: Involved with the development of the personalised surgical guides

HS Gill: Named inventor on related patent; editorial board member: Bone and Joint Journal + Medical Engineering and Physics; society executive board: president of the British orthopaedic research society.

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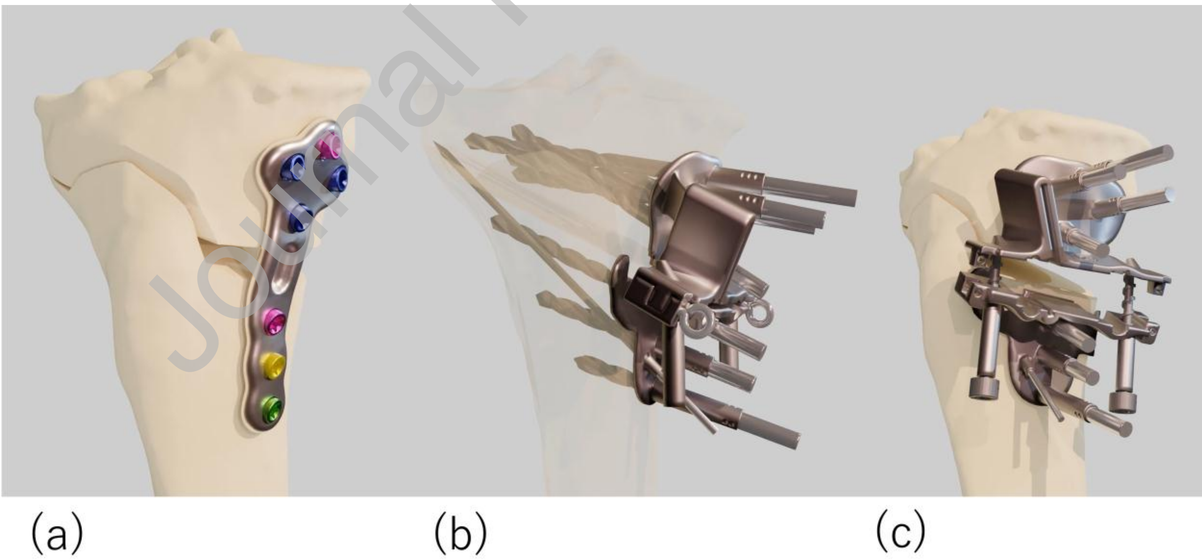

Figure 1. Illustration of the TOKA osteotomy system showing a) the custom-made titanium alloy plate; b) the custom-made titanium alloy surgical guide and c) the final post-operative geometry and the integrated opening mechanism. (COLOUR IMAGE REQUESTED)

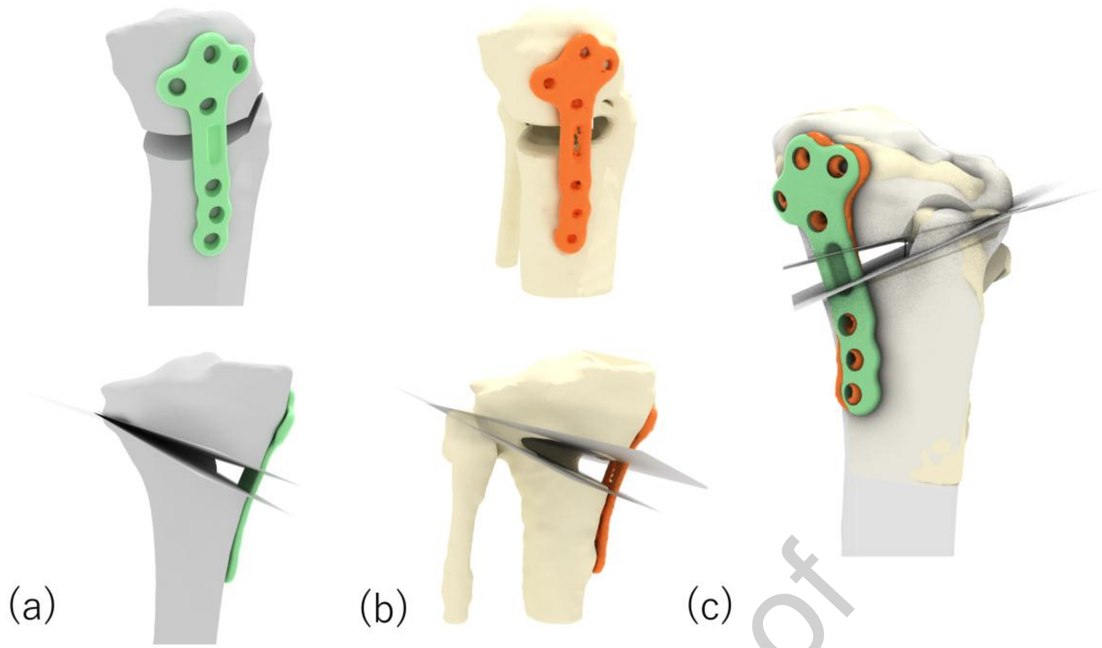

Figure 2. Three-dimensional assessment using CT scans showing: a) the virtually pre-planned geometry; b) the post-operative geometry and c) the aligned geometries. (COLOUR IMAGE REQUESTED)

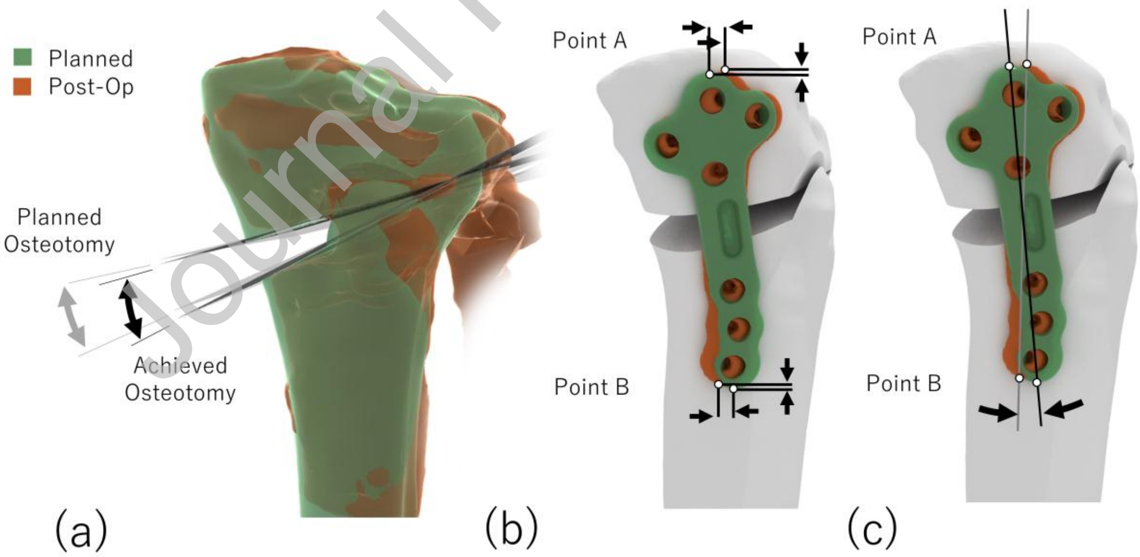

Figure 3. Evaluated parameters showing a) the osteotomy gap angle assessment; b) translational positioning error of the implant and c) rotational positioning error of the implant (COLOUR IMAGE REQUESTED).

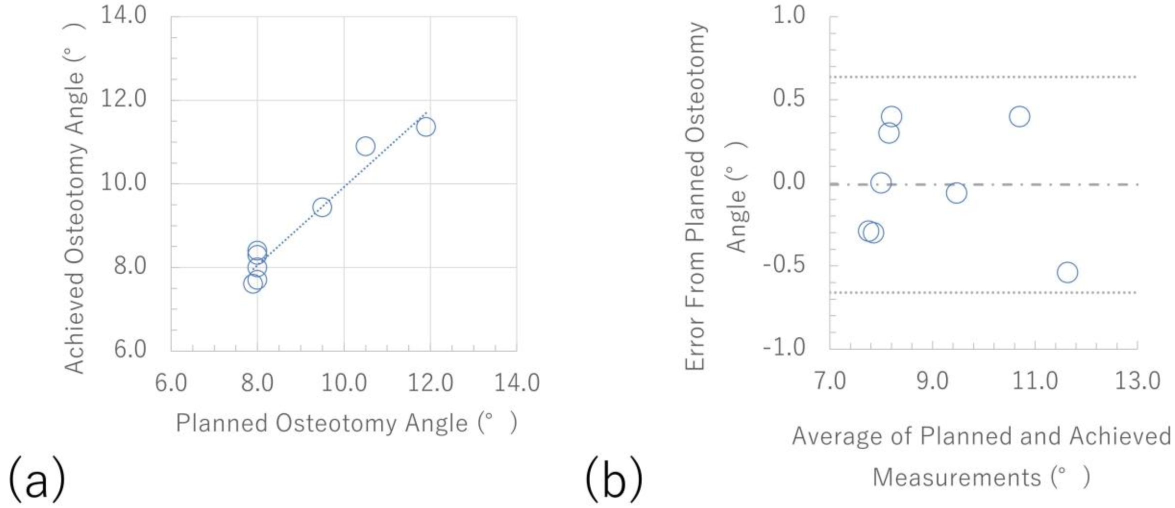

Figure 4. Evaluation of the achieved versus planned osteotomy angle showing (a) regression plot and (b) Bland Altmann plot of error from the planned osteotomy angle (degrees). The confidence limits are set to +/- 1.96 S.D.

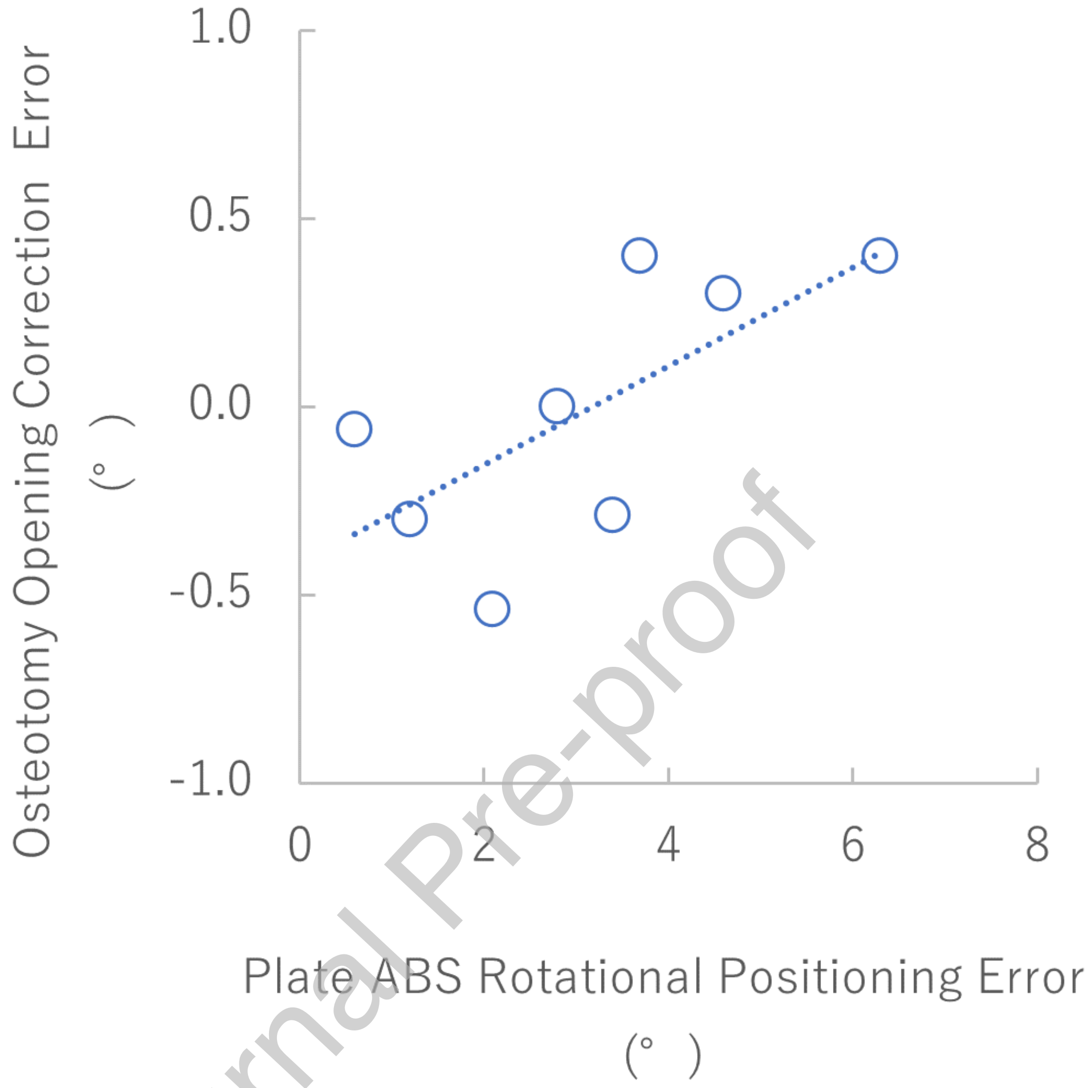

Figure 5. Correlation between the degree of rotational error and the achieved osteotomy opening angle.

Figure 6. Photo of the plate (unpolished) fitted to a cadaver specimen.

Table 1. Stages and features of innovation according to the IDEAL framework (adapted from Hirst et al. [9])

Stage of innovation	**Pre-IDEAL (Preclinical)**	**Stage 1 – Idea**	**Stage 2a – Development**	**Stage 2b – Exploration**	**Stage 3 – Assessment**	**Stage 4 - Long-term monitoring**
Purpose	Feasibility and definition of procedure	Proof of concept	Development of procedure	Achieving consensus between surgeons and centres	Comparative effectiveness testing	Surveillance
Number; types of patient	Preclinical	Single digit ; highly selective.	Few; selected	Many; broadening indication to include all potential beneficiaries	Many; expanded indications (well-defined)	All eligible
Number; types of surgeon	Very few; Innovators	Very few; Innovators	Few; innovators and some early adopters	Many; Innovators, early adopters, early majority	Many; early majority	All eligible
Output	Description addressing: 1) whether intended goal of procedure is accomplished 2)level of 3) Safety risks 4) Desirability of intervention	Description	Technical description of procedure and its development with reasons for changes	Effect estimate based on large sample; Analysis of learning curves; estimate of influence of prespecified technical variants and patient subgroups on outcome.	Comparison with current standard therapy	Description; audit; regional variation; quality assurance; risk adjustment
Intervention		Evolving; procedure	Evolving; procedure developm	Stable; acceptable variants	Stable	Stable

Method	Various, including simulator, cadaver, animal, modelling, and cost-effectiveness studies	Structured case reports	Prospective development studies	Prospective multicentre exploration cohort study; pilot/feasibility multicentre RCTs.	RCT with or without additions/modifications; alternative designs	Registry; routine database; rare case reports
Outcome		Proof of concept; technical achievement; dramatic success; adverse events, surgeon views of the procedure	Mainly safety; technical, and procedural success	Safety; clinical outcomes (specific/graded); short-term outcomes; patient centred/reported outcomes; feasibility outcome	Clinical outcomes (specific and graded); potentially Patient Reported outcomes, Health Economic outcomes	Rare events; long-term outcomes; quality assurance
Stage Endpoint	Any studies that could avoid predictable risks of failure or harm to the first human should have been conducted.	Outcomes will determine whether to proceed to stage 2a	Procedure should be refined enough to allow replication in Stage 2b and there should be no intent to make further major modifications	Fall into two main groups; Demonstrate that technique can be more widely adopted; and, Demonstrate that progression to RCTs desirable and feasible	Two main endpoints; Clear valid evidence on relative effectiveness of innovation; and, Identification of issues requiring long-term monitoring	

Table 2. Osteotomy Gap Opening Angle Assessment as shown in Figure 2a

Specimen ID	**Theoretical Planned Correction (°)**	**Planned correction using 3D estimation approach (°)**	**Theoretical Planned Correction vs 3D estimation (°)**	**Achieved correction using 3D estimation approach (°)**	**Error from theoretical plan (°)**	**Error from Theoretical Plan (%)**
1	8.0	7.8	-0.2	8.0	0.0	0.0
2	8.0	7.7	-0.3	8.4	0.4	5.0
3	8.0	8.3	0.3	8.3	0.3	3.8
4	8.0	7.8	-0.2	7.7	-0.3	-3.8
5	7.9	8.2	0.3	7.6	-0.3	-3.7
6	9.5	9.5	-0.1	9.4	-0.1	-0.6
7	10.5	10.6	0.1	10.9	0.4	3.8
8	11.9	12.0	0.1	11.4	-0.5	-4.5
		Mean	0.0	-	0.0	0.0
		ABS Mean	0.2	-	0.3	3.1
		Standard Deviation	0.2	-	0.3	3.6

Table 3. Patient Specific Instrumentation (PSI) Positioning at locations A and B as defined in Figure 2b and 2c.

	Positioning Error								
Specimen ID	**Location A Vertical off-set (mm)**	**Location B Vertical off-set (mm)**	**Average Vertical off-set (mm)**	**Location A Horizontal off-set (mm)**	**Location B Horizontal off-set (mm)**	**Average Horizontal off-set (mm)**	**Average Pos Error (mm)**	**ABS Average Pos Error (mm)**	**Measured rotational error (°)**
1	3.93	1.79	2.86	4.60	3.21	3.91	3.4	3.4	2.8
2	-2.68	-3.34	-3.01	-9.59	-1.26	-5.43	-4.2	4.2	6.3
3	2.86	11.12	6.99	1.64	-3.47	-0.92	3.0	4.8	4.6
4	1.57	2.77	2.17	-2.68	-0.82	-1.75	0.2	2.0	1.2
5	-1.60	-1.90	-1.75	-3.30	-7.43	-5.37	-3.6	3.6	3.4
6	-7.71	-8.26	-7.99	-6.58	-8.86	-7.72	-7.9	7.9	0.6
7	0.47	0.85	0.66	1.60	-2.30	-0.35	0.2	1.3	3.7
8	-4.06	-2.67	-3.37	-2.13	-4.89	-3.51	-3.4	3.4	2.1
Mean	-0.9	0.0	-0.4	-2.1	-3.2	-2.6	-1.5	3.8	3.1
ABS Mean	3.1	4.1	3.6	4.0	4.0	3.6	3.2	3.8	3.1
Standard	3.6	5.3	4.3	4.3	3.6	3.4	3.6	1.9	1.7

Deviation									

Table 4. Hip-Knee-Ankle (HKA) outcomes accuracy comparison of various studies in the literature.

	Gap Measurement, Schroter et al 2016 (n = 57)	Computer Navigation, Schroter et al 2016 (n = 56)	PSI, Chaouche et al, 2019 (n = 100)	PSI, Munier et al 2017 (n = 10)	PSI, Victor et al 2013 (n = 14)
Difference from Planned Correction (°)	1.7	2.1	1.0	0.84	0.56
Standard Deviation (°)	1.2	1.4	0.9	0.62	0.69