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- **A Novel Approach for Intra-Operative Shape Acquisition of the Tibio-Femoral**
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#### Abstract

## 18 Background:

19Image registration (IR) is an important process of developing a spatial relationship20between pre-operative data and physical patient in the operation theatre. Current IR21techniques for Computer Assisted Orthopaedic Surgery (CAOS) are time consuming22and costly. There is a need to automate and accelerate this process.

# 23 Methods:

24 Bespoke quick, cost effective, contactless and automated 3D laser scanning 25 techniques based on the DAVID Laserscanner method were designed. 10 cadaveric 26 knee joints were intra-operatively laser scanned and were registered with the pre-27 operative MRI scans. The results are supported with a concurrent validity study.

### 28 **Results:**

The average absolute errors between scan models were systematically less than 1 mm. Errors on femoral surfaces were higher than tibial surfaces. Additionally, scans acquired through the large exposure produced higher errors than the smaller exposure.

### 33 Conclusion:

- This study has provided proof of concept for a novel automated shape acquisitionand registration technique for CAOS.
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- 37

### 39 Introduction

Osteoarthritis (OA) is one of the most common musculoskeletal diseases affecting around 8.75 million of the population in UK<sup>1</sup>. It is a chronic joint disorder characterised by degeneration of the articular cartilage which results in a severe pain while performing daily voluntary musculoskeletal activities. The knee joint is the most common site to be affected by OA and 4.7 million people in the UK had OA of knee in 2010. This is estimated to rise to 5.4 million by 2020<sup>1</sup>.

45 After non-surgical treatments have been exhausted, patients suffering from OA of the knee 46 are usually advised to undergo knee replacement surgery where the articulating surfaces of the 47 tibio-femoral joint are resected and are replaced with prosthetic implants. Recently, knee 48 replacement surgery has been increasingly supported using the computers (Computer Assisted 49 Orthopaedic Surgery (CAOS)) along with advanced robotic systems. CAOS robotic procedures such as MAKOplasty<sup>®</sup> typically comprise of three main phases: 1) Pre-operative planning; 2) 50 51 Intra-operative execution; and 3) Implant placement. Pre-operatively, high resolution DICOM 52 (Digital Imaging and Communications in Medicine) scans of the patient's knee joint are acquired 53 which are then used to plan the surgery. Based on this plan, intra-operatively the surgery is performed with the help of computer navigation and robotics. Finally, the implant prosthesis is 54 55 precisely placed and its position is monitored with the navigation system.

In most CAOS applications for knee surgery, pre-operative CT scans are acquired on the patient's leg and are segmented to create a patient specific 3D knee model. Image registration (IR) is one of the important intra-operative phases of CAOS in which a spatial relationship between the pre-operative imaging data and the physical patient present in the operation theatre is developed. IR in most CAOS knee surgery applications is achieved using a manual method comprising handheld navigated probes. Anatomical points are acquired by physically touching the probe over the articulating surfaces (tibial plateaux and femoral condyles) of the knee joint to form a point cloud 63 which can then be fitted to the pre-operative scan data using a best fit type minimisation. However,

64 this manual digitisation approach is laborious, time consuming and hence costly. In our recent

65 surgical trial of MAKOplasty<sup>®2</sup> this process consumed upwards of 14-20 minutes<sup>3</sup>.

## 66 Study Design

In this study, a bespoke automated and contactless 3D laser scanner was built and used to acquire the point clouds of the articulating surfaces of the cadaveric knee joints. In the first concurrent validity, the laser and MRI scanned data of the cadaveric knee joints was compared to establish the accuracy and reliability of the laser scanning technique.

In addition, a supplementary validity study was conducted for every cadaveric sample in
which the distance measurements acquired by the laser scanner were assessed against standard
digital vernier calliper measurements.

# 74 Materials and Methods

10 fresh frozen cadaver knee joints were used in the study. Eight out of the ten samples
were obtained from the Anatomy Gift Registry, 7522 Connelley Drive, Suite L, Hanover, MD
21076, USA. The remaining two samples were collected from the Clinical Anatomy Skills Centre
(CASC), Glasgow University, Glasgow, UK. All the samples were stored in the freezer at -19.5
°C and had their anatomical structure present from hemi-pelvis to toe.

Prior to these studies, all cadaver legs had been operated on post donation with a medial
UKA surgery. Lateral compartments of all the samples were intact with smooth articular cartilage
which were used in this investigation.

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86 Concurrent Validity Study 1:

87 The surface topology of the cartilage surfaces was experimentally acquired using 3D 88 FLASH (Fast Low Angle Shot) MR imaging technique. This technique is used clinically and 89 provides high signal to noise ratio (SNR) and contrast to noise ratio (CNR) to adequately set apart 90 cartilage and bone interfaces in healthy as well as arthritic knee joints<sup>4, 5</sup>. Although, 3D FLASH 91 MR imaging provides poor contrast between synovial fluid and cartilage and high sensitivity to 92 the artefacts; the technique still makes the segmentation of the articular cartilage and bone 93 relatively easier and is still therefore considered the standard MR imaging technique for depicting articular cartilage morphology <sup>4-8</sup>. 94 95 All the samples were thawed 48 hours prior to the MR imaging and were scanned on a Siemens MRI station at 1.5 T using 3D FLASH technique. A standard protocol presented in the 96 97 literature was followed<sup>4, 5, 9</sup>. The slice thickness was 1 mm with no gap width. With a field of view 98 (FOV) of 160 mm, flip angle of 12° was set at 0.3 mm X 0.3 mm in plane resolution and 512 X 99 512 acquisition matrix. The protocol was approved by a highly skilled clinical imaging research

100 team in the Western Infirmary, Glasgow where the scanning was performed. A sagittal MRI was 101 performed (figure 1) and the scan slices were converted into a 3D volume. Samples were placed 102 in the freezer post MRI scanning.

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### Figure 1: A sample MRI scan of the right knee joint

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DICOM MRI images were segmented using advanced clinical software Mimics
(Materialise's Interactive Medical Image Control System) designed for medical image processing.
3D point clouds of the articular cartilage surfaces were generated and were exported in binary.
STL (Stereolithography) format using the STL+ module.

111 For the laser scanning, a low cost range scanner was constructed using basic components such as a calibration mask, a camera and a laser source<sup>10</sup>. Winkelbach and co-authors<sup>11</sup> provided a real-time 112 113 self-calibrating hand-held 3D laser scanning system, which is now also known as DAVID 114 Laserscanner. This system is free from markers and uses sub-pixel analysis of greyscale difference 115 images. This method works with a fast surface registration and with an improved random surface matching process based on the RANSAC (Random Sample Consensus) algorithm<sup>12</sup>. This approach is 116 117 not only robust and efficient but also can match frames of objects without the need for an initial guess 118 of the position.

119 Using the typical DAVID Laserscanner software package, scanning can be achieved with 120 satisfactory accuracy and precision; but, the calibration planes need to be placed behind the object 121 at all times during scanning. Due to the complexity in the knee joint and its positioning in the 122 theatre, keeping the calibration curves behind the knee during scanning would be highly 123 impractical. Moreover, hand-held scanning could be further time consuming due to irregularities 124 in the manual movement by human arm. However, more recent versions of the software enable users 125 to perform the scanning without calibration planes; provided that the laser source is moved in a precise 126 constant motion and the relative distance between the receiving camera and the laser source remains 127 fixed at all times. Thus, the scanner developed using DAVID Laserscanner was automated to 128 eliminate the use of calibration planes during actual scanning.

After an extensive review of the relevant literature, possible laser emitters of suitable wavelength and power output were found which could generate a safe and undistorted output<sup>13-17</sup>. A low cost (£3) class 2 line laser module (1 mW, 650 nm) was interfaced with a standard Logitech 720p detector webcam costing £17. The laser source was attached to the shaft of a geared bipolar stepper motor using a bespoke machined T-joint slot. A2 sized calibrations planes were used for the calibration and were then removed for the actual scanning.

135 The laser emitter (attached to the geared stepper) and the detector camera were mounted 136 on a robust positioner assembly constructed using Aluminium extrusion plates (figure 2 (a)). In

137	addition, the scanning modules were mounted on the end-effector of the MAKO Surgical Corps's
138	RIO <sup>®</sup> arm shown in the figure 2(b). This mimics the setup which would be possible if this robotic
139	surgical system was in use during MAKOplasty <sup>®</sup> surgery.

Figure 2: 3D Laser scanner (a): Scanner mounted on the aluminium extrusion framework (b):
Laser scanner mounted on the joint six of the MAKO RIO<sup>®</sup> arm

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Each cadaveric leg sample was again thawed 48 hours prior to the experiments. The samples were attached to a surgical table in a typical knee flexed operating position using straps around the hemi-pelvis as shown in the figure 3. The foot was attached to a sliding foot holder to allow variable knee flexion. The scans for each leg were acquired using two setups (Aluminium extrusion and RIO) to investigate whether there is any difference between the bulky extrusion based scanner and a more portable RIO mounted scanner. In addition, two typical surgical exposures (UKA, TKA) were used as variables.

151

152 Figure 3: Sample cadaver set up on the bed with the attached arrays for MAKO registration153

154 The laser scans were post processed using a robust digital image software package, 155 Geomagic Qualify<sup>®</sup>12. This software is certified and has received very high accuracy certification 156 from widely accepted organisations such as Physikalisch-Technische Bundesanstalt (PTB) 157 institute and National Institute of Standards and Technology (NIST) in the area of least squared 158 surface and curve fitting (Accurate up to 0.1  $\mu$ m in length and 0.1" [1/36,000 of a degree] in 159 angle)<sup>18</sup>.

Each laser scan (test) was first visually aligned using manual registration with the segmented MRI (reference) (figure 4) by selecting 3 to 9 common points on each surface. This is a type of surface registration (point based registration or free-form surface matching) that works closely on the Iterative Closet Point (ICP) algorithm where the two surfaces are aligned with respect to the closest points leading to the segments and the triangles<sup>19-21</sup>. Thus, manual registration adjusts spatial position of the floating scan using position of the fixed scan based on the userdefined pairs of corresponding points from each scan.

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Figure 4: Manual registration by selecting random points over the left lateral tibial surface
(a): MRI generated 3D model (red) of the articular cartilage, set as a reference model. (b):
Corresponding 3D laser scan (green) of the same cartilage acquired intra-operatively, set as a test
model. (c): Rough manual registration between two surfaces

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173 After approximate manual registration, global registration was performed where the 174 alignment between the models is automatically fitted using ICP algorithm based on their spatial 175 position. Here, the fixed and floating scans are both moved around slightly to find the best 176 alignment possible. After this rough registration, reference and test models were aligned using ICP 177 based automatic best fit type of minimisation to produce a fine-tuned fit in order to evaluate 178 absolute errors between scans. In this alignment stage, test (laser) scan is sampled and the closest 179 points are computed to each point on the reference scan, based on the selected sample size. Using 180 the least-squares method, the sums of squares of distances between the sample pairs are evaluated 181 which are minimized over all the rigid motions that could realign the two objects. Having done 182 this, the closet points are re-computed on the reference to establish a new transformation matrix. 183 With the results of the fit, average absolute errors (AAE) between the models were calculated. 184 Each deviation is a Euclidean distance in a 3D space between the two closest points. 3D color-185 coded mappings of residual differences between the scans were then generated to visualise the 186 spatial distribution of the errors.

In the experimental design, three independent variables were used each with two levels viz., the exposure (UKA, TKA), the positioner setup (Aluminium assembly, MAKO RIO), and type of the surface (tibia, femur). A Repeated measures ANOVA test was performed using a standard statistical software package, SPSS (developed by IBM Corporation, NY, USA) to investigate the effects of the independent variables on the dependent variable (AAE).

192

193 Validity Study 2:

194 At the end of the scanning session for each sample, cadaver legs were employed in the 195 subsequent validity study where the Euclidean distance measurements acquired using 3D laser 196 scanner were compared with the standard digital vernier callipers measurements. Tibial and 197 femoral articulating condyles were treated as separate surfaces thereby providing 20 set of 198 surfaces. On each surface, 7 M2 screws were inserted in a random pattern but with a good spread 199 as shown in figure 5(a). The distances between the centres of each screw with the centres of every 200 other screw were measured thus providing 21 different distance measurements on each surface as 201 shown in figure 5(b). The 21 measurements for each of the 20 surfaces resulted in 21\*20 = 420202 different measurements. For every surface, 10 laser scans were acquired. Thus, in total 4200 203 distance measurements acquired from laser scans were compared with the corresponding digital 204 vernier calliper measurements.

205

Figure 5: Distance measurements between the screw markers on the tibial condyle (a): Placement of seven screws over the surface (b): Total number of measurements (21) computed between every pair of the points (c): Direct distance measurement acquired using digital vernier calliper (d): Distance measurement (in the white box) acquired on the corresponding digitised 3D laser scan and formulated using Geomagic Qualify<sup>®</sup>

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The laser scans were analysed in Geomagic Qualify<sup>®</sup> 12 in which the distances between the pairs of screws were evaluated using the distance calculation tool based on the Euclidean metric calculation in the 3D space (figure 5(d)).

For every set of measurements, an absolute error (AE) and absolute percent error (APE) were computed followed by average absolute error (AAE) and average absolute percentage error (AAPE, also known as MAPE, mean absolute percentage error). Significance in both studies was tested at  $\alpha$ =0.05 level.

### 219 **Results**

The key findings of the studies are reported in this paper. The in-depth investigation is available online<sup>10</sup>. The outcome of the data comparison for a single femoral scan example is explained in detail with its deviation distribution and spatial distribution of the deviations in a colour coded pattern. This is followed by a summary table of all the samples.

This particular example (figure 6 and 7) shows a comparison between MRI and the laser scan of the right femoral lateral cartilage. The AAE<sup>\*</sup> of 0.21 mm was reported with  $SD_{AE}^*$  of 0.32 mm. The +d<sub>max</sub><sup>\*</sup> and -d<sub>max</sub><sup>\*</sup> were 1.88 mm and -1.38 mm respectively.

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Figure 6: Deviation distribution between MRI and laser scan of an example right femoral lateral
 cartilage

230 Deviation in mm is plotted against the percentage of points within the range of deviations. Note: 231  $\pm d_{max}$  occurred at the periphery

233

<sup>\*</sup> AAE: Average absolute error, SD<sub>AE</sub>: Standard deviation of the absolute error, +d<sub>max</sub>: Maximum positive deviation, -d<sub>max</sub>: Maximum negative deviation

234	Figure 7: Top view of the colour deviation map showing spatial distribution of the deviations
235	between MRI and laser scan of right femoral lateral cartilage
236	The posterior and superior condylar region is clipped as the laser scan was acquired with a
237	minimal exposure (90 mm, mimicking UKA). Note: Large errors $(\pm d_{max})$ at the periphery of the
238	scan
239	
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242	
243	Table 1: Summary of the alignment statistics between MRI and laser scans of
244	femoral surfaces of all the samples
245 246	AAE; average absolute error between the models, $SD_{AE}$ ; standard deviation of the absolute error,
240 247	$+d_{max}$ and $-d_{max}$ maximum positive and negative deviations respectively. Average and standard
248	deviation of all the non-motors is shown at the bettern of the table. Note: d
249	deviation of an the parameters is shown at the bottom of the table. Note: d <sub>max</sub> values occurred at
250 251	the periphery of the scan zones
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253	Table 2: Summary of the effects of the independent variables on AAE between MPI and lessr scenes
254 255	Table 2: Summary of the effects of the independent variables on AAE between MRI and faser scans
255	The main and interaction effects of the independent variables indicating the P-value statistics, the
257	significance of the statistics and the interpretation of the results
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259 260	
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264 265	Effects of independent variables:
266	In the next stage, the effects of three independent variables i.e. type of setup (Aluminium
267	extrusion, RIO), type of exposure (UKA, TKA) and type of surface (Tibia, Femur) on the
268	dependent variable, AAE were studied. The main effects of the independent variables as well as
269	the interactions between the variables were studied. The summary of this analysis is reported in
270	table 2.
271	

272 Validity Study

A bar graph (figure 8(a) and 8(b)) along with error bars depicting variations in the measurements is shown for one of the 20 surfaces. In addition, a summary of all the 4200 measurement comparisons is reported in table 3. Both the methods (laser and vernier calliper) were responsive so changing the differences between the screws and inter measurement system differences were small with 95% of the scanned measurements within 1 mm of the vernier callipers.

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Figure 8: Bar graph comparison for the distance calculations between vernier calliper and 3D
 laser scans

(a): Bar graph for first 11 pairs of screws. (b): Bar graph for remaining 10 pairs of screws
Note: Blue bar is the measurement recorded by the vernier calliper, whereas red bar is the mean
value of the measurements on the laser scans. Error bars indicate the range of values (minimum
and maximum values). All the measurement differences between vernier calliper and laser were
statistically not significant; P>0.05

- 287
- 288Table 3: Summary of the assessment of the distance calculations performed using direct289measurements (vernier calliper) and the 3D laser scans290AAE; average absolute error between measurements, SDAE; standard deviation of the absolute291error, AAPE; average absolute percentage error, SDAPE; standard deviation of the absolute292percentage error. Average and standard deviation of all the parameters is shown at the bottom of293the table. Note: NS= Not significant. All the measurement differences between vernier calliper294and laser were statistically not significant; P>0.05295295

#### 296 **Discussion**

Over the last decade, CAOS has emerged particularly in the area of minimally invasive UKA surgery. With the more conservative approach of UKA (as compared to TKA), which have been reenergised with the development of the advanced robotic systems, only the affected 300 compartment (medial/lateral) is resected and an implant is placed to facilitate normal joint 301 function. One of the most important phases of the computer assisted surgical process in the 302 operating theatre is to develop a spatial relationship between the pre-operatively acquired patient 303 specific scan of the knee surface and the physical patient knee present in the operating theatre. It 304 is possible to visualise key anatomical points around the patient's knee joint in the CT/MRI scan 305 as well as to locate the same points on the actual patient during surgery using intra-operative 306 sensors or probes. However, their spatial correspondence remains unknown until IR is achieved. 307 IR is the process that generates the relationship between the scan and the patient and allows the 308 surgeon to visualise the 3D pre-operative scan data in-relation to the patient's anatomy in the 309 operating theatre. It is therefore a crucial aspect of the procedure. This study demonstrates a novel 310 laser scanning technique which is proposed as an alternative to the current time consuming IR 311 methods in knee CAOS. Laser based registration can be achieved in less than half the time used 312 in the manual technique which can save time in the theatre and thus  $cost^{41}$ .

313 An example showing detailed comparison between MRI and corresponding laser scan of 314 the cadaveric femoral condyle has been presented (figure 6 and 7). The average deviation (AAE) 315 between the laser and MRI scans was 0.32 mm with a standard deviation (SD<sub>AE</sub>) of 0.32 mm. The 316 maximum positive  $(+d_{max})$  and negative  $(-d_{max})$  deviations were +1.88 mm and -1.38 mm 317 respectively. The total number of point pairs used for the data comparison was 5266 out of which 318 98.48% were within ±0.94 mm of deviation. Moreover, in figure 7, it can be clearly seen that the 319 absolute errors tend to increase as the extreme edges of the scan area are approached. The tibial 320 surfaces and rest of the femoral surfaces showed a similar trend with maximum % of deviations 321 within ±1 mm and higher errors towards peripheries. Summary of the alignment statistics between 322 MRI and laser scans of femoral surfaces for all the samples is shown in table 1.

The effects of independent variables (setup, exposure and surface) were investigated using repeated measures ANOVA and are shown in table 2. There was no statistically significant 325 difference on AAE within two types of setups (Al and RIO), F(1,9) = 1.148; P=0.312 which 326 indicates that the bulky Aluminium extrusion setup can be replaced with the positioning RIO arm 327 which in our case would be already present in the theatre. Thus, it would be possible to make one 328 compact system consisting of the robot and the scanner and save plenty of space in the operating 329 theatre. The AAE with TKA exposure was significantly higher than UKA exposure, F(1,9) =330 40.808; P= 0.0001. It may seem that greater errors occurred with greater exposure but this was a 331 result of exposing more edges to the scan where the surface was at a greater angle to the incident 332 laser light and hence, the errors in depth perception possibly produced larger errors between the 333 laser scan and the MRI images. However, these errors remained sub-millimetric. The AAE on the 334 femoral surfaces was significantly higher than on the tibial surfaces, F(1,9) = 14.863; P = 0.004. 335 The ends of the femoral condyles contain more regions where the profile of the bone surface is at 336 a greater angle to the incident laser light and hence higher errors at the peripheries contribute to 337 overall higher AAE. However, these errors were again sub-millimetric. In other words, the higher 338 errors with TKA exposure (as compared with UKA exposure) and on femoral surfaces (as 339 compared to tibial surfaces) can be attributed to the 'edge effect' which affects most triangulation 340 systems. It can be seen in the colour coded deviation distribution map (figure 7) where the higher 341 % of the larger deviations appeared on the peripheries. 3D scanners and particularly laser based 342 scanners tend to produce errors at the spatial discontinuities or edges of the surfaces being scanned. 343 When the laser hits the surface edges, only a certain part is reflected from the actual point and 344 some reflection is always induced by the adjacent surfaces or the surface behind the object. Thus, 345 the final signal is a mixture of the signals from the foreground and the background. This 346 phenomenon is called a 'mixed-pixel effect' or 'edge effect'. Due to the higher slope on the edge of the surface and the viewing direction of the scanner, the laser plane falls almost tangentially on 347 348 the edge which leads to errors in location of these points in the cloud and thus causes inaccuracies and distortions in the scan<sup>22-28</sup>. 349

350 During the scanning, the scanner was always positioned such that the surface (tibial and 351 femoral condyle) being scanned was in the centre of the camera image. With the TKA incision, 352 additional surface exposure is provided which is usually towards the peripheral region of the 353 surface. Also, femoral condyles are more non-uniform and curved in their surface topography 354 when compared to the tibial plateau. So, while scanning the femoral condyles, there is a higher 355 slope of the target around the edges and the curved region which causes higher deviations in those 356 areas. As a result, the laser plane incidents more tangentially on the femoral condyles as compared 357 to the tibial plateau and thus the edge effect results in higher deviations.

Furthermore, a careful statistical investigation showed that there was no significant interaction (two-way and three-way) found between the variables. As the interactions were not significant, the main effects of the independent variables can be accepted<sup>29-32</sup>.

361 The second stage in the experimental design was to compare the automated distance 362 measurements acquired using the developed laser scanner with the manual measurements from 363 digital vernier calliper, an approach widely accepted in research and industry to evaluate the 364 technical performance of 3D imaging system for geometric accuracy<sup>33-40</sup>. A bar graph with error 365 bars for an example surface is presented in figures 8(a) and 8(b). The rest of the surfaces followed 366 a similar pattern. The error bars indicate the range (minimum and maximum) of the reported 367 values. The AAE values ranged from 0.3 mm to 0.62 mm with a mean of 0.46 mm and SD of 0.08 368 mm. The SD<sub>AE</sub> within each surface was 0.15 mm. Furthermore, for every set of data, AAPE was 369 reported which ranged from 1.19% to 2.45% with the mean of 1.66% and SD of 0.31%. The mean 370 standard deviation of AAPE within each surface (SD<sub>AAPE</sub>) was 0.82% with SD of 0.24% and 371 min/max values of 0.54% and 1.40%. The measurements between two systems were analysed using two sample independent t-test<sup>35</sup>. The P-values for each surface comparison are reported in 372 373 table 3. None of the differences were statistically significant, P>0.05 and in fact the P-values were 374 very close to 1. Hence, we conclude that there is no sufficient evidence to suggest that laser readings and vernier calliper distance measurements were different. The mean of the deviations (Mean AAE) for all the 20 surfaces was less than 0.5 mm (0.46 mm) with an average  $SD_{AE}$  of 0.15 implying that 95% of the deviations (4200 measurements) lay within 0.46±0.3 (2 SD) i.e. within 0.16-0.76 mm absolute deviation which is suitable for orthopaedic surgeries.

## 379 Limitations and future recommendations

380 3D laser scanners have obvious advantages such as high speed, accuracy, precision and 381 reproducibility. However, their strength can be affected by various factors. Stray light or an 382 unidentified light source can affect the quality of the scans. Thus, care must be taken to avoid such 383 sources and most importantly any proximal light source which might enter the triangulation plane 384 i.e. the plane formed by camera, laser source and object being scanned. Shadow of the surrounding 385 structures can produce gaps in the scans. Due to the awkward and complex structure of the tibio-386 femoral joint, femoral condyles may produce occultation on tibial plateaux. Further safely flexing 387 the knee joint can enable the user to acquire maximum exposed area. Also, to avoid possible 388 hindrance, the skin surrounding the incision needs to be retracted, especially in the smaller UKA 389 exposures to allow the detector camera to completely visualise the area (condyles) under scrutiny.

A simple way of controlling the edge effect would be by removing any regions where the slope of the scan is at an acute angle to the scanner as these are the areas that are most likely to add higher magnitude of errors to the fitting. An automated process is thus required as manually removing the edges would add additional time in the data post-processing phase in theatre. For the validity study, inter-operator variation was eliminated but intra-operator variation should be investigated by repeating the same measurement of the digital vernier calliper acquired by the same operator to check the variation.

This project focussed on acquiring accurate 3D surface geometry of tibio-femoral joints in the theatre. Optically navigating the scanner in real time was beyond the scope of this project. However, as the next stage of the project, the laser line could be navigated using geometrical

400 principles and with use of marker frame which are tracked by the IR cameras already utilised in 401 the surgery. Once this is achieved, it could be possible to plan and execute the surgery in theatre 402 there and then. This imageless navigation would be very effective in terms of reduced cost, time 403 and radiation dosage and would provide convenience to patients and clinicians. The proof of 404 concept in real surgery is still to be obtained and is the next step in the process towards a suitable 405 medical device which can be used in the general surgery.

406 Commercially available high precision laser lines and high-speed CMOS wireless cameras 407 could be used instead of the scanning components used in the study and would further improve 408 the accuracy of the scans and reduce the acquisition time. Further scanning of more cadaver legs 409 should be undertaken and more independent variables should be explored such as distance between 410 centre of the scanner and surface being scanned, sex of the patient, cross sectional area of the 411 surface, etc.

### 412 Conclusion

A series of experiments in this study demonstrated that average deviations between the MRI and the 3D laser scans were in general less than half a millimetre. This suggests that the system can repeatedly acquire accurate 3D scans of the tibio-femoral cartilage and bone and insitu in the operating theatre environment. The second validity study has proven that the developed laser scanner measurements were accurate, precise and repeatable as compared to the standard measurement system such as digital vernier calliper. The sample size of 10 surfaces should be born in mind with the sub-millimetric accuracy of the scans.

This study has addressed an important issue of replacing the current manual intra-operative surface acquisition and image registration process of CAOS with 3D laser scanning. In this study, the feasibility of using an automated 3D scanner based on the DAVID laser scanning technique was validated. The system is capable of acquiring scans of the tibio-femoral joints in theatre to

424 generate complete 3D models of the surface geometry and to an accuracy less than 1 degree across 425 the whole scan surface. The proposed technique is completely contactless and does not require 426 critical points in the hidden regions of the joint thereby allowing surgeons to control the overall 427 incision size limited to the surface being burred. The system was built using inexpensive 428 components and the total cost of the scanning hardware was less than £200. Using the MAKO 429 Surgical registration approach to register each bone surface required approximately 15 minutes 430 whereas the overall time for proposed laser based registration was less than 4 minutes for every 431 joint out of which majority of the time was spent in the post processing of scans which could 432 further be automated.

The system and method have much to offer to CAOS in terms of speed and accuracy of registration and also the potential for both imageless surgery as well as cartilage property assessments.

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443

# 444 **Competing interests**

445 The authors have no competing interests to disclose.

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4	50	

Table 1: Summary of the alignment statistics between MRI and laser scans of femoral surfaces of all the samples

maximum positive and negative deviations respectively. Average and standard deviation of all the parameters is shown AAE; average absolute error between the models, SD<sub>AE</sub>; standard deviation of the absolute error, +d<sub>max</sub> and -d<sub>max</sub>;

at the bottom of the table. Note: d<sub>max</sub> values occurred at the periphery of the scan zones.

			UK	A Ex	nsod	re					TK	A E	nsody	ıre		
	Ō	n Al Ey	ktrusic	uc		On F	OI		On	Al Ex	trusic	nc		On F	SIO	
Samples	AAE	SD <sub>AE</sub>	d <sub>1</sub>	max m)	AAE	SD <sub>AE</sub>	dn (m	ax m)	AAE	SD <sub>AE</sub>	d <sub>n</sub> (m	ax m)	AAE	SD <sub>AE</sub>	$d_n$ (m	ax m)
			+	I			+	I	Ĵ		+	·		(11111)	+	,
1	0.23	0.33	1.84	-1.50	0.26	0.42	1.51	-1.67	0.28	0.42	1.81	-1.82	0.27	0.44	1.85	-1.94
2	0.20	0.29	2.07	-1.37	0.18	0.28	1.30	-2.03	0.35	0.68	2.15	-2.47	0.33	0.61	2.30	-2.24
3	0.28	0.40	1.49	-1.60	0.28	0.44	1.51	-1.86	0.33	0.46	1.49	-1.69	0.32	0.47	1.87	-1.89
4	0.23	0.33	1.84	-1.50	0.26	0.42	1.51	-1.67	0.28	0.42	1.81	-1.82	0.27	0.44	1.85	-1.94
5	0.21	0.28	1.15	-0.99	0.24	0.33	1.34	-1.31	0.25	0.46	2.73	-2.20	0.27	0.37	2.72	-1.97
9	0.25	0.58	1.43	-1.91	0.25	0.53	1.79	-1.88	0.29	0.66	2.53	-2.20	0.30	0.60	2.46	-2.54
7	0.21	0.31	1.75	-1.39	0.23	0.33	1.72	-1.37	0.28	0.32	1.74	-1.25	0.29	0.38	2.52	-1.46
8	0.26	0.44	1.36	-1.97	0.26	0.46	1.32	-2.19	0.28	0.59	1.97	-3.03	0.30	0.64	2.56	-2.46
6	0.29	0.38	1.23	-1.57	0.28	0.40	1.43	-1.56	0.32	0.45	1.63	-1.73	0.33	0.54	1.93	-2.32
10	0.24	0.36	1.66	-1.65	0.23	0.31	1.31	-1.13	0.30	0.40	2.18	-1.63	0.27	0.40	2.61	-2.50
Average	0.24	0.37	1.58	-1.55	0.25	0.39	1.47	-1.67	0.29	0.48	2.00	-1.98	0.29	0.49	2.27	-2.12
SD	0.03	0.09	0.30	0.28	0.03	0.08	0.17	0.33	0.03	0.12	0.39	0.51	0.03	0.10	0.35	0.35

Table 2: Summary of the effects of the independent variables on AAE between MRI and laser scans

The main and interaction effects of the independent variables indicating the P-value statistics, the

significance of the statistics and the interpretation of the results.

Effects	Inde pendent variables	P-value statistics	Significance	Interpretation
	Type of Setup (Al, RIO)	F(1,9) = 1.148; P= 0.312	Not significant	No difference in two types of setup
Main Effects	Type of Exposure (UKA, TKA)	F(1,9) = 40.808; P= 0.0001	Significant	Errors slightly larger with TKA exposure
	Type of Surface (Tibia, Fenur)	F( 1,9) = 14.863; P = 0.004	Significant	Errors slightly larger on femoral surface
	Seup* <sup>±</sup> Xposure	F(1,9)=0.13; P=0.911	Not significant	No interaction between setup and exposure
	Setup*Surface	F(1,9) = 0.474; P = 0.509	Not significant	No interaction between setup and surface
Interaction Effects	Exposure*Surface	F(1,9)=1.097; P=0.322	Not significant	No interaction between exposure and surface
	Setup*Exposure*Surface	F(1,9) = 0.682; P = 0.430	Not significant	No interaction between setup, exposure and surface

- 454Table 3: Summary of the assessment of the distance calculations performed using direct455measurements (vernier calliper) and the 3D laser scans
- 456 AAE; average absolute error between measurements, SD<sub>AE</sub>; standard deviation of the absolute
- 457 error, AAPE; average absolute percentage error, SD<sub>APE</sub>; standard deviation of the absolute
- 458 percentage error. Average and standard deviation of all the parameters is shown at the bottom of
- 459 the table. Note: NS= Not significant. All the measurement differences between vernier calliper
- 460
- 461

and laser were statistically not significant; P>0.05

Surface	AAE (mm)	SDAE	AAPE (%)	SDAPE	P-value	Significance
1	0.49	0.17	1.66	0.65	0.930	NS
2	0.61	0.23	2.45	1.40	0.923	NS
3	0.44	0.12	1.66	0.91	0.972	NS
4	0.43	0.14	1.88	1.00	0.987	NS
5	0.48	0.13	1.72	0.63	0.993	NS
6	0.41	0.09	1.49	0.73	0.999	NS
7	0.38	0.13	1.47	0.76	0.992	NS
8	0.47	0.17	1.47	0.62	0.934	NS
9	0.50	0.12	1.55	0.67	0.996	NS
10	0.46	0.11	1.37	0.54	0.993	NS
11	0.49	0.12	1.88	0.80	0.967	NS
12	0.62	0.27	2.17	1.34	0.966	NS
13	0.59	0.23	2.18	0.97	0.986	NS
14	0.47	0.14	1.70	0.82	0.964	NS
15	0.43	0.20	1.50	0.65	0.976	NS
16	0.49	0.25	1.51	0.81	0.965	NS
17	0.39	0.14	1.49	1.10	0.978	NS
18	0.38	0.08	1.40	0.64	0.991	NS
19	0.30	0.09	1.19	0.70	0.974	NS
20	0.43	0.13	1.54	0.67	0.954	NS
Mean	0.46	0.15	1.66	0.82		
SD	0.08	0.05	0.31	0.24		

463	Figure legends:
464	Figure 1: A sample MRI scan of the right knee joint
465	
466	Figure 2: 3D Laser scanner (a): Scanner mounted on the aluminium extrusion framework (b):
467	Laser scanner mounted on the joint six of the MAKO RIO <sup>®</sup> arm
468	
469	Figure 3: Sample cadaver set up on the bed with the attached arrays for MAKO registration
470	
471	Figure 4: Manual registration by selecting random points over the left lateral tibial surface
472	(a): MRI generated 3D model (red) of the articular cartilage, set as a reference model. (b):
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474	model. (c): Rough manual registration between two surfaces
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476	Figure 5: Distance measurements between the screw markers on the tibial condyle
477	(a): Placement of seven screws over the surface (b): Total number of measurements (21)
478	computed between every pair of the points (c): Direct distance measurement acquired using
479	digital vernier calliper (d): Distance measurement (in the white box) acquired on the
480	corresponding digitised 3D laser scan and formulated using Geomagic Qualify <sup>®</sup>
481	
482	Figure 6: Deviation distribution between MRI and laser scan of an example right femoral lateral
483	cartilage
484	Deviation in mm is plotted against the percentage of points within the range of deviations. Note:
485	$\pm d_{max}$ occurred at the periphery
486	
487	Figure 7: Top view of the colour deviation map showing spatial distribution of the deviations
488	between MRI and laser scan of right femoral lateral cartilage
489	The posterior and superior condylar region is clipped as the laser scan was acquired with a
490	minimal exposure (90 mm, mimicking UKA). Note: Large errors ( $\pm d_{max}$ ) at the periphery
491	

492	
493	Figure 8: Bar graph for the comparison for the distance calculations between vernier calliper and
494	3D laser scans
495	(a): Bar graph for first 11 pairs of screws. (b): Bar graph for remaining 10 pairs of screws
496	Note: Blue bar is the measurement recorded by the vernier calliper, whereas red bar is the mean
497	value of the measurements on the laser scans. Error bars indicate the range of values (minimum
498	and maximum values). All the measurement differences between vernier calliper and laser were
499	statistically not significant; P>0.05
500	

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