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# High Degree of Accuracy of a Novel Image-free Handheld Robot for Unicondylar Knee Arthroplasty in a Cadaveric Study

Running title: Novel Image-free Handheld Robot for UKA

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The authors certify that the University of Strathclyde approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

This work was performed at the University of Strathclyde (Glasgow, Scotland, UK) (two users) and Blue Belt Technologies Inc (Plymouth, MN, USA) (two users).

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1 Abstract

2 Background Surgical robotics has been shown to improve the accuracy of bone preparation
3 and soft tissue balance in unicondylar knee arthroplasty (UKA). However, while extensive
4 data have emerged with regard to a CT scan-based haptically constrained robotic arm, little is
5 known about the accuracy of a newer alternative, an imageless robotic system.

6 Questions/purposes We assessed the accuracy of a novel imageless semiautonomous
7 freehand robotic sculpting system in performing bone resection and preparation in UKA
8 using cadaveric specimens.

9 Methods In this controlled study, we compared the planned and final implant placement in 25
10 cadaveric specimens undergoing UKA using the new tool. A quantitative analysis was
11 performed to determine the translational, angular, and rotational differences between the
12 planned and achieved positions of the implants.

13 Results The femoral implant rotational mean error was 1.04° to 1.88° and mean translational
14 error was 0.72 to 1.29 mm across the three planes. The tibial implant rotational mean error
15 was 1.48° to 1.98° and the mean translational error was 0.79 to 1.27 mm across the three
16 planes.

17 Conclusions The image-free robotic sculpting tool achieved accurate implementation of the
18 surgical plan with small errors in implant placement. The next step will be to determine
19 whether accurate implant placement translates into a clinical and functional benefit for the
20 patient.

21

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## Introduction

Unicondylar knee arthroplasty (UKA) was introduced as a surgical treatment option for degenerative arthritis of the knee in the 1970s and now accounts for approximately 8% of knee arthroplasties [22, 26]. When only one compartment of the knee is affected, there may be a clinical and functional benefit to the patient in preserving bone and ligaments with UKA rather than TKA [15, 25] as well as economic benefits [30, 34], including reduced duration of hospitalization and rehabilitation and rapid recovery and return to work [17]. Survivorship and clinical knee scores for UKA are similar at 10 to 15 years to those reported for TKA in the hands of high-volume UKA surgeons using sound implants [1, 3-4, 12, 21]. However, international registries and lower-volume institutions have shown higher rates of failure at early and mid-term follow up [2, 9, 22-24, 31-32]. Higher early revision rates of up to 30% [9-10, 16, 20, 31, 33] have tempered enthusiasm and limited broader utilization. Many failures have been shown to be related to improper patient selection, suboptimal implant or limb alignment, soft tissue imbalance, and poor designs [2, 6, 11-12, 22-24, 27, 32].

Computer navigation has improved accuracy in UKA, but outliers still occur in as many as 40% of navigated UKAs [14]. Semiautonomous robotic technologies have further improved the accuracy of bone preparation and component alignment with a reduction in outliers compared to conventional techniques [5, 7, 18, 28-29]. Robotic technologies are now utilized in approximately 15% of UKAs implanted in the United States. Currently FDA approved systems used for UKA are semiautonomous, which means that the surgeon moves the robotic instrument, but the device is preprogrammed with virtual boundaries that constrain a motorized burr from removing more bone than planned.

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Initial robotic systems for UKA in the United States combine a preoperative CT scan and intraoperative mapping to register anatomic landmarks with a haptically constrained surgeon-driven robotic arm that constrains a sculpting bur within the defined space of the knee [5, 7, 18]. A newer alternative robotic system is an image-free, surgeon-controlled handheld robotic sculpting tool that relies on intraoperative landmark mapping with safeguards achieved by controlling bur exposure and/or speed to enhance precision of bone preparation [28-29]. Since this image free approach is new then the accuracy of the final implant placement should be assessed for errors compared with the planned implant placement. Therefore, the purpose of this cadaveric study is to report on the accuracy of the imageless semiautonomous freehand robotic sculpting system in performing bone resection and preparation in UKA.

## Materials and Methods

### Robotic Description and Technique

The Navio$^{TM}$ Precision Freehand Sculpting system (Navio$^{TM}$; Blue Belt Technologies Inc, Plymouth, MN, USA) is an imageless handheld robotic tool (Fig. 1). Implant planning and development of the cutting zone take place entirely intraoperatively without the need for a preoperative CT scan. The system continuously tracks the position of the patients' lower limb and the handheld robotic device using an infrared navigation system.

The system is imageless in as much as it does not use a CT or MRI to map the femoral and tibial condylar surface. It therefore relies on accurate registration of intraoperative knee kinematic assessment, anatomic landmarks, and surface mapping of the knee using a calibrated optical probe designed for use with this robotic system

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After percutaneous insertion of bicortical partially threaded pins into the proximal tibia and distal femur and attachment of optical tracking arrays, mechanical and rotational axes of the limb are determined intraoperatively by establishing the hip, knee and ankle centers. Either the kinematic, anteroposterior (Whiteside) or transepicondylar axes of the knee are identified and selected to determine the rotational position of the femoral component. The condylar anatomy is mapped out by 'painting' the surfaces with the optical probe. In this way intraoperative mapping can be completed without a preoperative CT scan. This registration process takes about five minutes on average. The intraoperative data then are used by the system's software algorithms to determine the coronal, sagittal, and axial bone axes and morphology.

A virtual model of the knee is created. Implant planning for component sizing, alignment, and volume of bone removal takes place intraoperatively (Fig. 2A). The surgeon selects the implant size that best fits the patient's anatomy and closely matches the size of the condyle to be replaced, as well as its position in the coronal, sagittal, and rotational planes. Subsequent steps are directed at determining gap and ligament balance after virtual implant positioning, removal of osteophytes, and stressing of the ligaments and soft tissues. Osteophytes are excised and a dynamic soft tissue balancing algorithm is initiated. With an applied valgus stress to tension the medial collateral ligament (for medial UKA) or a varus stress to tension the lateral structures (for lateral UKA), the three dimensional positions of the femur and the tibia are captured throughout a passive range of knee motion. A graphical representation of gap spacing through the range of flexion is created and determination is made regarding whether the planned position of the femoral and tibial component is adequate or adjustments can be made to achieve the desired soft tissue balance. By adjusting the implant position,

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88 including tibial slope, depth or resection and anteriorization or distalization of the femoral
89 component the virtual dynamic soft tissue balance can be achieved. Adjustments in implant
90 position and size (Fig. 2A) can be made to optimize soft tissue balance (Fig. 2B) and
91 component tracking and position before beginning bone preparation.

92 Unlike predicate robotic technologies that provided haptic constraint via a robotic arm, this
93 system works with a combination of speed and exposure control safeguards applied through a
94 light-weight handheld surgeon-driven semiautonomous robotic sculpting tool. In "exposure"
95 mode the 5 or 6 mm burr is continuously moving and is switched on and off by the user by
96 pressing or releasing a foot pedal. A guard covers the burr, which only extends past the guard
97 when the burr is in the "expected" cutting zone. The cutting zone is pre-determined by the
98 surgeon during the implant planning stage of the operation and the system modulates the
99 exposure distance of the burr tip beyond the protective sheath. The position data is
100 continuously updated in real time, resulting in fluid adjustments in the position of the burr tip.
101 When the hand piece is moved out of the cutting zone the burr retracts within the guard. The
102 second control mode is "speed" mode where the burr only becomes active in the cutting zone.
103 The speed of rotating burr is at full power/full speed until the intended bone is removed or it
104 is moved beyond the desired preparation volume, at which point it linearly ramps down to
105 zero.
106 After planning for size, position, alignment, bone volume, and gap balancing, the arthritic
107 cartilage and bone are methodically removed using the handheld sculptor (Fig. 3).

108 Validation Study

109 The study was approved by the University of Strathclyde's ethics committee. In an
110 experimental study, UKA was performed using Navio$^{TM}$ in 25 fresh-frozen cadavers

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111 (hemipelvis, hip to toe) donated by the Anatomy Gift Registry (Hanover, MD, USA). For
112 consistency, all of the tests in this study used Tornier HLS UNI Evolution implants (Tornier,
113 Montbonnot, France). All procedures were medial UKAs. The sizes of the implants were
114 planned for the individual cadavers and therefore the implant sizes varied among cadavers.

115 The study was conducted by four individuals (JHL, JRS, FP, BH) trained to use the system
116 on synthetic bones (Sawbones®; Pacific Research Laboratories Inc, Vashon, WA, USA)
117 before the cadaveric validation study. The system was set up in a tissue laboratory in the
118 same configuration as a typical operating room. Arrays consisting of four reflective optical
119 markers in an asymmetric cluster were attached to partially threaded bicortical pins which
120 were drilled into the metaphyses of the femur and tibia. The robotic hand piece and the
121 probes had four reflective optical markers which were also tracked by the NDI Polaris
122 Optical Tracking System (NDI medical, Northern Digital Inc, Ontario, Canada) which has a
123 tracker error of 0.64mm in passive mode [8].

124 Bone preparation was performed per the manufacturer's recommended technique for robotic
125 UKA with the Tornier HLS UNI Evolution implants. The femoral component, with a central
126 lug and keel, was impacted rigidly onto the prepared bone surface and the slotted trough and
127 peg hole on the femoral condyle optimized positioning of the component. The tibial implant
128 in this particular design is a cemented unconstrained all polyethylene insert. This implant
129 design has reported good clinical and radiological results [19] where the aim is to permit
130 optimum positioning with the femoral component. It used no lugs or keel to indicate where
131 on the AP axis the implant should be positioned, therefore, the translational position of the
132 tibial component on the AP axis could only be estimated. At the time this study was

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conducted this was the only implant product that the system was programmed to be used with.

The main objective of the study was to assess the accuracy of the system by comparing the planned implant orientation with the actual implant orientation and report the errors calculated between the two orientations. Therefore, the positions of the implants were recorded after implantation using specially machined divots in the implants. A ball-point probe with optical markers was used to record the position of the divots and from this a three-dimensional image of the implant position was calculated and compared to the original plan. The planned and actual cut surfaces were also compared to determine any over- or undercutting of the bone surface. The mean error and root mean square (RMS) errors were determined for each measure. The difference between the 'plan' and 'actual' implant position was the calculated 'error'. The directionality of the error was not investigated therefore the error values were reported as a positive value. RMS was used as the errors were positive and negative values and an average would dilute the error reported. The surgeons were not involved in the data collection or analysis.

Results

The mean recorded variances in the cut surface compared to the preoperative plan was −0.30 mm (SD, 0.25 mm) for the femur and −0.26 mm (SD, 0.27 mm) for the tibia (negative values represent undercutting). The root mean square error was 0.67mm (SD 0.37mm) and 0.61mm (SD 0.29mm) for the femoral and tibial preparation respectively.

The femoral implant angular mean error was 1.04° to 1.88°, and the mean translational error was 0.72 to 1.29 mm across the three planes (Table 1). The femoral root mean square error

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ranged from 0.88 to 2.27. The tibial implant angular mean error was 1.48° to 1.98°, and the mean translational error was 0.79 to 1.27 mm across the three planes. The tibial root mean square error ranged from 0.95 to 2.43. There were no significant differences in alignment and implant position measures or variations between surgeons.

## Discussion

Semiautonomous robotic systems combine human expertise in surgical planning with the accuracy and reproducibility of a robotic device. They have been shown to be effective in reducing variance and improving precision in bone preparation [5, 7, 18, 28-29]. Unlike its predecessors [5, 7, 18], the handheld robotic sculptor analyzed in this study does not require a preoperative CT scan. In this study, we found the accuracy of this system to be in the range of 0.8-1.3 mm of translation and 1 to 2 degrees of alignment.

This study had a number of limitations. The user group consisted of three experienced orthopedic consultants and one research fellow. Each user completed a different number of cadaver tests (JHL n=10, JRS n=5, FP n=3, BH n=7) but there was no significant in the errors recorded between users. This study was completed in a laboratory using consultants and a researcher who were familiar with the system and instrumentation. Therefore the study was undertaken in ideal conditions which would be different to an operating theatre. Future work is required to determine whether similar results are recorded in a clinical setting with a broad range of surgeons with varying experience with the system, robotics and navigation for knee arthroplasty. In addition, future work will be required to determine the learning curve associated with this imageless system, as well as analysis of the economic argument of whether the clinical outcome for the patient justifies the additional equipment costs.

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In an initial feasibility study of this robotic system, Smith et al. [29] assessed the accuracy of bone preparation in 20 synthetic lower extremities and reported errors which were comparable with those calculated in this cadaveric study. Despite relying entirely on intraoperative surface registration and mapping, this study found that this system provides accuracy equivalent to that of earlier robotic devices (Table 2).

In the cadaveric tests performed in this study, the tibial components were screwed onto the prepared bone to rigidly secure the implant position. However, with no lugs for a corresponding post hole to indicate where the implant placement had been planned on the AP axis, translational position on the AP axis could not be considered completely accurate. Therefore, the translational error in the AP position of the tibial component could be considered a worst-case scenario. The data reported in our current study are consistent with earlier studies from other robotic systems on the market [5, 7] and support the hypothesis that variance of precision of bone preparation and implant placement is limited and accuracy may be improved with this robotic technology.

In conclusion, the results of this cadaveric study showed that bone preparation and implant position using this device were within a mean of 1.3mm and 2 degrees of the planned implant position. Our results are comparable with those published from clinical studies investigating other semiautonomous robotic orthopedic devices [5, 7]. Future studies will determine the accuracy in clinical use compared to conventional techniques, as well as functional outcomes and implant durability with this image-free robotic system, all of which are important elements of successful UKA. Certainly given the nature of this current study, these issues cannot be addressed at this time.

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Figures and Legends


Fig. 1 The Navio™ hand piece includes a blue clamshell central unit for the user to grip, an array to allow it to be tracked by the system, and a metal guard covering the bur. Calibration of the bur to the end of the guard means that the system registers when the bur is covered by the guard or cutting.

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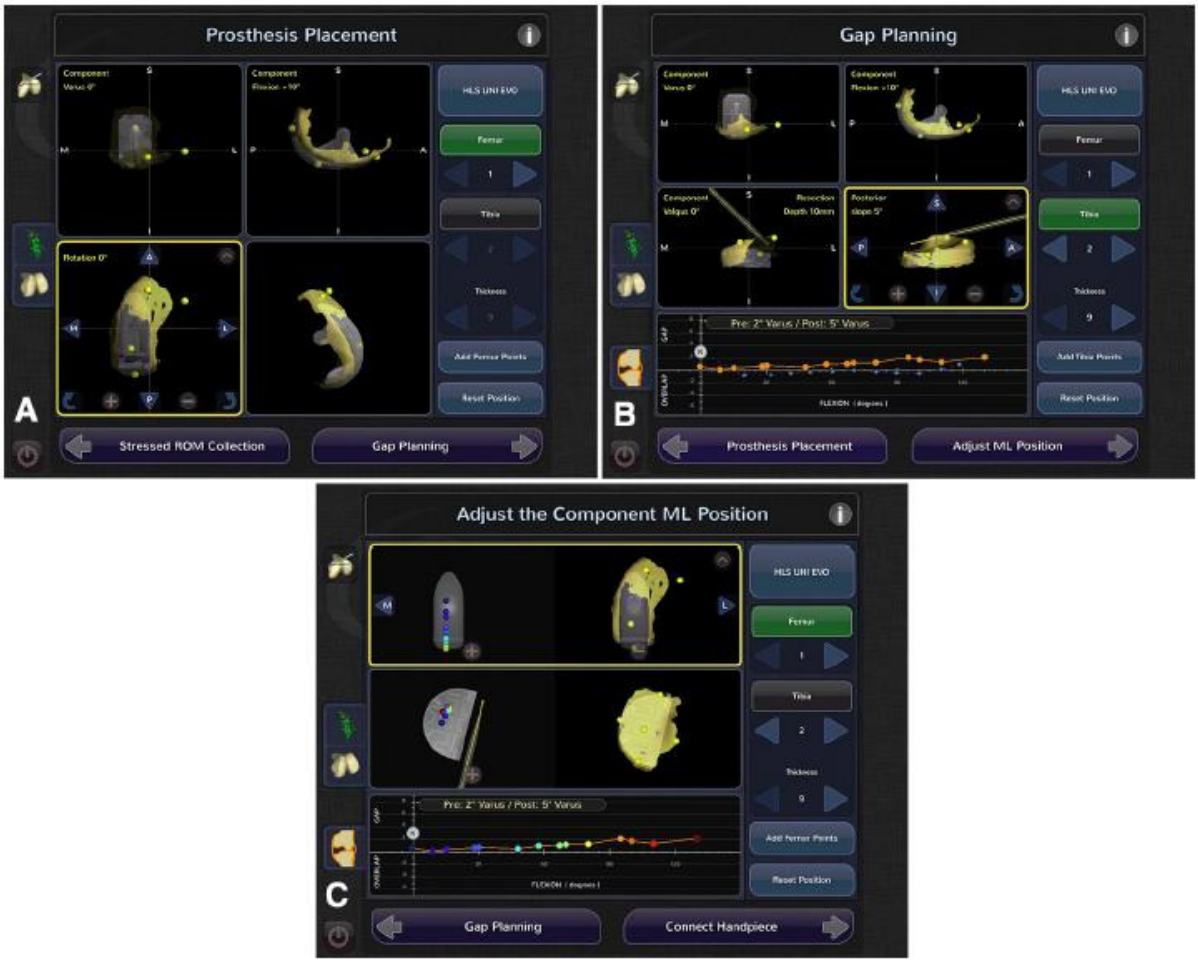


Fig. 2A–B (A) The planning stage screen where the user can adjust the implant size and move the position of the implant in all three planes to best match the patient's condyle. (B) The gap planning screen shows the position of the implant on the patients condylar surface (the green dots). The graph at the bottom of the screen illustrates the gap through a range of flexion predicted from implementing the planted implant position.

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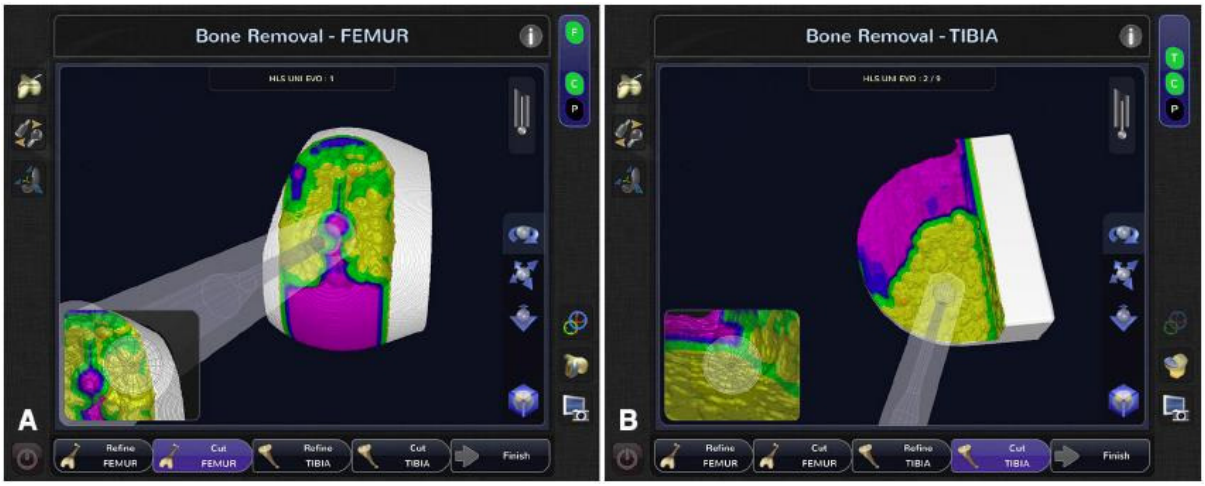


Fig. 3A–B (A) Femur and (B) tibia cutting screens show mid cutting. Yellow surface is the 'target' surface, green surface indicates 1mm of bone still to be removed, blue surface indicates 2mm of bone still to be removed and the purple surface indicates 3mm or more bone still to be removed.

Tables

**Table 1.** Angular and translational errors for each cadaver

| Femur | Angle | | | Translation | | |
|---|---|---|---|---|---|---|
| | Roll (flexion/extension) | Pitch (varus/valgus) | Yaw (internal rotation/external rotation) | Translation x-axis (medial/lateral) | Translation y-axis (anterior/posterior) | Translation z-axis (superior/inferior) |
| Mean (SD) | 1.04 (0.82) | 1.88 (1.31) | 1.17 (1.13) | 1.29 (0.99) | 0.81 (0.53) | 0.72 (0.51) |
| Maximum \|d\| | 2.18 | 4.27 | 3.84 | 2.64 | 1.51 | 2.43 |
| Minimum \|d\| | −2.87 | −5.21 | −1.24 | −3.99 | −2.21 | −1.33 |
| RMS error (SD) | 1.31 (1.30) | 2.27 (2.28) | 1.61 (1.54) | 1.61 (1.54) | 0.96 (0.98) | 0.88 (0.90) |
| **Tibia** | **Angle** | | | **Translation** | | |
| | Roll (flexion/extension) | Pitch (varus/valgus) | Yaw (internal rotation/external rotation) | Translation x-axis (medial/lateral) | Translation y-axis (anterior/posterior) | Translation z-axis (superior/inferior) |
| Mean (SD) | 1.51 (1.39) | 1.98 (1.52) | 1.48 (1.17) | 0.83 (0.48) | 1.27 (0.98) | 0.79 (0.64) |
| Maximum \|d\| | 4.99 | 5.03 | 3.46 | 1.43 | 3.68 | 2.11 |
| Minimum \|d\| | −4.11 | −3.85 | −4.12 | −1.73 | −1.80 | −2.37 |
| RMS error (SD) | 1.98 (1.95) | 2.43 (2.49) | 1.87 (1.92) | 0.95 (0.94) | 1.59 (1.50) | 1.01 (1.02) |

RMS = root mean square.

**AU: Please do not delete query boxes or remove line numbers; ensure you address each query in the query box. You may modify text within selected text or outside the selected text (as appropriate) without deleting the query.**

**Table 2.** Root mean square errors of robotic systems and conventional techniques in unicondylar knee arthroplasty

| Direction | Navio™ (Blue Belt Technologies Inc, Plymouth, MN, USA; current study) | MAKO Rio (MAKO Surgical Corp, Fort Lauderdale, FL, USA) [7] | Acrobot (MAKO Surgical Corp) [5] | Conventional techniques [5] |
|---|---|---|---|---|
| Flexion/extension (degrees) | 1.7 | 2.1 | 1.7 | 6.0 |
| Varus/valgus (degrees) | 2.4 | 2.1 | 2.1 | 4.1 |
| Internal/external rotation (degrees) | 1.7 | 3.0 | 3.4 | 6.3 |
| Medial/lateral (mm) | 1.3 | 1.2 | 1.0 | 2.6 |
| Anterior/posterior (mm) | 1.3 | 1.6 | 1.8 | 2.4 |
| Proximal/distal (mm) | 1.0 | 1.0 | 0.6 | 1.6 |

**AU: Please do not delete query boxes or remove line numbers; ensure you address each query in the query box. You may modify text within selected text or outside the selected text (as appropriate) without deleting the query.**