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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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.

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22 Introduction

23 Unicondylar knee arthroplasty (UKA) was introduced as a surgical treatment option for

24 degenerative arthritis of the knee in the 1970s and now accounts for approximately 8% of

25 knee arthroplasties [22, 26]. When only one compartment of the knee is affected, there may

26 be a clinical and functional benefit to the patient in preserving bone and ligaments with UKA

27 rather than TKA [15, 25] as well as economic benefits [30, 34], including reduced duration of

28 hospitalization and rehabilitation and rapid recovery and return to work [17]. Survivorship

29 and clinical knee scores for UKA are similar at 10 to 15 years to those reported for TKA in

30 the hands of high-volume UKA surgeons using sound implants [1, 3-4, 12, 21]. However,

31 international registries and lower-volume institutions have shown higher rates of failure at

32 early and mid-term follow up [2, 9, 22-24, 31-32]. Higher early revision rates of up to 30%

33 [9-10, 16, 20, 31, 33] have tempered enthusiasm and limited broader utilization. Many

34 failures have been shown to be related to improper patient selection, suboptimal implant or

35 limb alignment, soft tissue imbalance, and poor designs [2, 6, 11-12, 22-24, 27, 32].

36 Computer navigation has improved accuracy in UKA, but outliers still occur in as many as

37 40% of navigated UKAs [14]. Semiautonomous robotic technologies have further improved

38 the accuracy of bone preparation and component alignment with a reduction in outliers

39 compared to conventional techniques [5, 7, 18, 28-29]. Robotic technologies are now utilized

40 in approximately 15% of UKAs implanted in the United States. Currently FDA approved

41 systems used for UKA are semiautonomous, which means that the surgeon moves the robotic

42 instrument, but the device is preprogrammed with virtual boundaries that constrain a

43 motorized burr from removing more bone than planned.

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44   Initial robotic systems for UKA in the United States combine a preoperative CT scan and

45   intraoperative mapping to register anatomic landmarks with a haptically constrained surgeon-

46   driven robotic arm that constrains a sculpting bur within the defined space of the knee [5, 7,

47   18]. A newer alternative robotic system is an image-free, surgeon-controlled handheld robotic

48   sculpting tool that relies on intraoperative landmark mapping with safeguards achieved by

49   controlling bur exposure and/or speed to enhance precision of bone preparation [28-29].

50   Since this image free approach is new then the accuracy of the final implant placement

51   should be assessed for errors compared with the planned implant placement. Therefore, the

52   purpose of this cadaveric study is to report on the accuracy of the imageless semiautonomous

53   freehand robotic sculpting system in performing bone resection and preparation in UKA.

54   Materials and Methods

55   Robotic Description and Technique

56   The Navio^{TM} Precision Freehand Sculpting system (Navio^{TM}; Blue Belt Technologies Inc,

57   Plymouth, MN, USA) is an imageless handheld robotic tool (Fig. 1). Implant planning and

58   development of the cutting zone take place entirely intraoperatively without the need for a

59   preoperative CT scan. The system continuously tracks the position of the patients' lower limb

60   and the handheld robotic device using an infrared navigation system.

61   The system is imageless in as much as it does not use a CT or MRI to map the femoral and

62   tibial condylar surface. It therefore relies on accurate registration of intraoperative knee

63   kinematic assessment, anatomic landmarks, and surface mapping of the knee using a

64   calibrated optical probe designed for use with this robotic system

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65   After percutaneous insertion of bicortical partially threaded pins into the proximal tibia and

66   distal femur and attachment of optical tracking arrays, mechanical and rotational axes of the

67   limb are determined intraoperatively by establishing the hip, knee and ankle centers. Either

68   the kinematic, anteroposterior (Whiteside) or transepicondylar axes of the knee are identified

69   and selected to determine the rotational position of the femoral component. The condylar

70   anatomy is mapped out by 'painting' the surfaces with the optical probe. In this way

71   intraoperative mapping can be completed without a preoperative CT scan. This registration

72   process takes about five minutes on average. The intraoperative data then are used by the

73   system's software algorithms to determine the coronal, sagittal, and axial bone axes and

74   morphology.

75   A virtual model of the knee is created. Implant planning for component sizing, alignment,

76   and volume of bone removal takes place intraoperatively (Fig. 2A). The surgeon selects the

77   implant size that best fits the patient's anatomy and closely matches the size of the condyle to

78   be replaced, as well as its position in the coronal, sagittal, and rotational planes. Subsequent

79   steps are directed at determining gap and ligament balance after virtual implant positioning,

80   removal of osteophytes, and stressing of the ligaments and soft tissues. Osteophytes are

81   excised and a dynamic soft tissue balancing algorithm is initiated. With an applied valgus

82   stress to tension the medial collateral ligament (for medial UKA) or a varus stress to tension

83   the lateral structures (for lateral UKA), the three dimensional positions of the femur and the

84   tibia are captured throughout a passive range of knee motion. A graphical representation of

85   gap spacing through the range of flexion is created and determination is made regarding

86   whether the planned position of the femoral and tibial component is adequate or adjustments

87   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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133   conducted this was the only implant product that the system was programmed to be used

134   with.

135   The main objective of the study was to assess the accuracy of the system by comparing the

136   planned implant orientation with the actual implant orientation and report the errors

137   calculated between the two orientations. Therefore, the positions of the implants were

138   recorded after implantation using specially machined divots in the implants. A ball-point

139   probe with optical markers was used to record the position of the divots and from this a three-

140   dimensional image of the implant position was calculated and compared to the original plan.

141   The planned and actual cut surfaces were also compared to determine any over- or

142   undercutting of the bone surface. The mean error and root mean square (RMS) errors were

143   determined for each measure. The difference between the 'plan' and 'actual' implant position

144   was the calculated 'error'. The directionality of the error was not investigated therefore the

145   error values were reported as a positive value. RMS was used as the errors were positive and

146   negative values and an average would dilute the error reported. The surgeons were not

147   involved in the data collection or analysis.

148   Results

149   The mean recorded variances in the cut surface compared to the preoperative plan was −0.30

150   mm (SD, 0.25 mm) for the femur and −0.26 mm (SD, 0.27 mm) for the tibia (negative values

151   represent undercutting). The root mean square error was 0.67mm (SD 0.37mm) and 0.61mm

152   (SD 0.29mm) for the femoral and tibial preparation respectively.

153   The femoral implant angular mean error was 1.04° to 1.88°, and the mean translational error

154   was 0.72 to 1.29 mm across the three planes (Table 1). The femoral root mean square error

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155 ranged from 0.88 to 2.27. The tibial implant angular mean error was 1.48° to 1.98°, and the

156 mean translational error was 0.79 to 1.27 mm across the three planes. The tibial root mean

157 square error ranged from 0.95 to 2.43. There were no significant differences in alignment and

158 implant position measures or variations between surgeons.

159 Discussion

160 Semiautonomous robotic systems combine human expertise in surgical planning with the

161 accuracy and reproducibility of a robotic device. They have been shown to be effective in

162 reducing variance and improving precision in bone preparation [5, 7, 18, 28-29]. Unlike its

163 predecessors [5, 7, 18], the handheld robotic sculptor analyzed in this study does not require a

164 preoperative CT scan. In this study, we found the accuracy of this system to be in the range of

165 0.8-1.3 mm of translation and 1 to 2 degrees of alignment.

166 This study had a number of limitations. The user group consisted of three experienced

167 orthopedic consultants and one research fellow. Each user completed a different number of

168 cadaver tests (JHL n=10, JRS n=5, FP n=3, BH n=7) but there was no significant in the errors

169 recorded between users. This study was completed in a laboratory using consultants and a

170 researcher who were familiar with the system and instrumentation. Therefore the study was

171 undertaken in ideal conditions which would be different to an operating theatre. Future work

172 is required to determine whether similar results are recorded in a clinical setting with a broad

173 range of surgeons with varying experience with the system, robotics and navigation for knee

174 arthroplasty. In addition, future work will be required to determine the learning curve

175 associated with this imageless system, as well as analysis of the economic argument of

176 whether the clinical outcome for the patient justifies the additional equipment costs.

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177   In an initial feasibility study of this robotic system, Smith et al. [29] assessed the accuracy of

178   bone preparation in 20 synthetic lower extremities and reported errors which were

179   comparable with those calculated in this cadaveric study. Despite relying entirely on

180   intraoperative surface registration and mapping, this study found that this system provides

181   accuracy equivalent to that of earlier robotic devices (Table 2).

182   In the cadaveric tests performed in this study, the tibial components were screwed onto the

183   prepared bone to rigidly secure the implant position. However, with no lugs for a

184   corresponding post hole to indicate where the implant placement had been planned on the AP

185   axis, translational position on the AP axis could not be considered completely accurate.

186   Therefore, the translational error in the AP position of the tibial component could be

187   considered a worst-case scenario. The data reported in our current study are consistent with

188   earlier studies from other robotic systems on the market [5, 7] and support the hypothesis that

189   variance of precision of bone preparation and implant placement is limited and accuracy may

190   be improved with this robotic technology.

191   In conclusion, the results of this cadaveric study showed that bone preparation and implant

192   position using this device were within a mean of 1.3mm and 2 degrees of the planned implant

193   position. Our results are comparable with those published from clinical studies investigating

194   other semiautonomous robotic orthopedic devices [5, 7]. Future studies will determine the

195   accuracy in clinical use compared to conventional techniques, as well as functional outcomes

196   and implant durability with this image-free robotic system, all of which are important

197   elements of successful UKA. Certainly given the nature of this current study, these issues

198   cannot be addressed at this time.

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Figures and Legends

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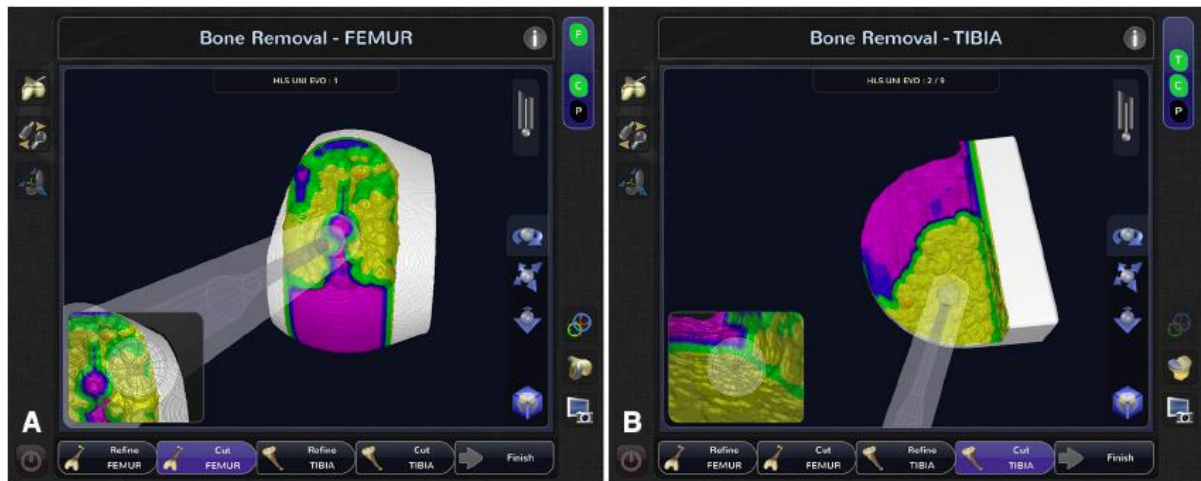
Fig. 3A–B (A) Femur and (B) tibia cutting screens show mid cutting. Yellow surface is the 'target' surface, green surface indicates 1mm of bone still to be removed, blue surface indicates 2mm of bone still to be removed and the purple surface indicates 3mm or more bone still to be removed.

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 ldl	2.18	4.27	3.84	2.64	1.51	2.43
Minimum ldl	−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 ldl	4.99	5.03	3.46	1.43	3.68	2.11
Minimum ldl	−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.

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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

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