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Title: Novel Curved Surface Preparation Technique for Knee Resurfacing

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Cartilage repair instruments

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Abstract: Conventional tools are incapable of preparing the curved articular surface geometry required during cartilage repair procedures. A novel curved surface preparation technique was proposed and tested to provide a high-accuracy and low-cost solution. Three shapes of samples, with flat, 30 mm radius and 60 mm radius surfaces, were manufactured from foam bone substitute for testing. Registering guides and cutting guides were designed and 3-D printed to fit onto the foam samples. A rotational cutting tool with an adapter was used to prepare the surfaces following the guidance slots in the cutting guides. The accuracies of the positions and shapes of the prepared cavities were measured using a digital calliper, and the surface depth accuracy was measured using a 3-D scanner. The mean shape and position errors were both approximately ± 0.5 mm and the mean surface depth error ranged from 0 to 0.3 mm, range -0.3 to +0.45 mm 95% CI. This study showed that the technique was able to prepare a curved surface accurately; with some modification it can be used to prepare the knee surface for cartilage repair.

Dear Richard

We have been pleased to accommodate the final points raised by the reviewer, so hopefully good to be accepted now!

Thanks for your work on this,

Andrew Amis

Journal: MEDICAL ENGINEERING & PHYSICS

Title of Paper: Novel Curved Surface Preparation Technique for Knee Resurfacing

Declarations

The following additional information is required for submission. Please note that failure to respond to these questions/statements will mean your submission will be returned to you. If you have nothing to declare in any of these categories then this should be stated.

Conflict of 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.

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.

Competing Interests

none

Please state any sources of funding for your research

This study was funded by the National Institute for Health Research (NIHR) Biomedical Research Centre based at Imperial College Healthcare NHS Trust and Imperial College London.

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

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

This information must also be inserted into your manuscript under the acknowledgements section prior to the References.

Responses to Reviewer comments:

Thank you for taking the time to review our manuscript, we do appreciate your helpful and insightful comments. Our responses below are prefaced by AU:, and new text is highlighted by underlining in the marked-up version of the manuscript.

Reviewer #1: The authors have clearly taken my reservations on board, and I am happy with almost all their alterations. Only two points remain, which I am sure they can address.

Firstly (point 9), the authors seem reluctant to use standard "accuracy-terminology" - because their method is so accurate! But perhaps they have missed my point, what I tried to make them do is to use standard terminology in line with ISO 5725, which distinguishes accuracy, trueness and precision, and use the standard way of measuring these. This has nothing to do with the level of accuracy, it is simply a plea to use standard terminology. Since I reviewed the paper, a relevant article on this matter came out in the JBJS (Cartiaux O, Jenny JY, Joskowicz L. Accuracy of Computer-Aided Techniques in Orthopaedic Surgery: How Can It Be Defined, Measured Experimentally, and Analyzed from a Clinical Perspective?. JBJS. 2017 Apr 19;99(8):e39). To be clear, I am not one of the authors!

In line with the above, it is important that the authors make clear what the various $\pm$ in the results sections denote - are they SEM?

AU: Thank you for your guidance towards this very recent paper, and also to the ISO standard; we had been unaware of the introduction of use of the word trueness rather than accuracy, and have now brought the wording in line with the ISO recommendations, and have added a citation to the Cartiaux paper. We have also used this opportunity to clarify the definitions of precision. See lines 114-6, 134-5, for example, plus Ref 26.

Secondly (point 18) I am glad the authors have tried to find a fairer comparator. But even then I am not convinced, after all their comparator is now a robotic saw from a study of which the authors themselves mention that saws are not ideal for robotic cutting. Better comparators would be a freehand robot-assisted burr (e.g. Lonner JH, Smith JR, Picard F, Hamlin B, Rowe PJ, Riches PE. High degree of accuracy of a novel image-free handheld robot for unicondylar knee arthroplasty in a cadaveric study. Clinical Orthopaedics and Related Research. 2015 Jan 1;473(1):206-12) or a robotic mill (Martelli M, Marcacci M, Nofrini L, La Palombara F, Malvisi A, Iacono F, Vendruscolo P, Pierantoni M. Computer-and robot-assisted total knee replacement: analysis of a new surgical procedure. Annals of biomedical engineering. 2000 Sep 1;28(9):1146-53.), which all report accuracies below 1 mm. And this is not a problem per se, even if the templates give a comparable accuracy they may still be preferable, e.g. because they save costs. Interesting in this respect is also the comparison in Martelli of the (in)accuracies involved in each step (computer planning, registration and resection), of which this paper of course only addresses one accuracy.

AU: We deleted those references and substituted a paper by Smith et al (Ref 27), discussed at lines 192-7, which relates to preparation using a burr. We also added the step of deriving the templates via medical imaging in the discussion, at line 210.

Finally, in the introduction the authors should refer to some of the work on patient-specific templates (e.g. Radermacher K, Portheine F, Anton M, Zimolong A, Kaspers G, Rau G, Staudte HW. Computer assisted orthopaedic surgery with image based individual templates. Clinical orthopaedics and related research. 1998 Sep 1;354:28-38.), where this work clearly fits in. This should be done after line 70 of the paper. By the way, Rademacher et al. also mention an accuracy better than 1 mm.

AU: we added new text at lines 69-71, including a new reference [25] which makes the point that a template method reduces cost.

A novel system to prepare the curved geometry of articular surfaces is described

Custom designed cutting guides were made by rapid prototyping

Laser scanning showed depth accuracy within 0.3 mm

Title: Novel Curved Surface Preparation Technique for Knee Resurfacing

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23 **Abstract**

24 Conventional tools are incapable of preparing the curved articular surface geometry required during cartilage
25 repair procedures. A novel curved surface preparation technique was proposed and tested to provide an
26 accurate low-cost solution. Three shapes of samples, with flat, 30 mm radius and 60 mm radius surfaces,
27 were manufactured from foam bone substitute for testing. Registering guides and cutting guides were
28 designed and 3-D printed to fit onto the foam samples. A rotational cutting tool with an adapter was used to
29 prepare the surfaces following the guidance slots in the cutting guides. The accuracies of the positions and
30 shapes of the prepared cavities were measured using a digital calliper, and the surface depth accuracy was
31 measured using a 3-D scanner. The mean shape and position errors were both approximately ± 0.5 mm and
32 the mean surface depth error ranged from 0 to 0.3 mm, range -0.3 to +0.45 mm 95% CI. This study showed
33 that the technique was able to prepare a curved surface accurately; with some modification it can be used to
34 prepare the knee surface for cartilage repair.

35 *Keywords:* Curved bone resection, Joint resurfacing, 3-D printing, Cartilage repair instruments

36

37 **Introduction**

38 Articular cartilage damage is very common, affecting millions of people worldwide, especially the elderly [1,
39 2]. The disease does not only cause pain and disability to the individuals [3], but it also brings a heavy
40 burden to the medical insurance system [4, 5]. Non-surgical treatment may work for the mild to medium
41 conditions [6-8], but in severe cases patients are usually treated with knee replacement [9]. However, these
42 artificial components are not suitable for all cases [9], since they have limited life [10, 11], so are unsuitable
43 for younger, more active patients. In addition, total knee arthroplasty does not usually feel the same as the
44 human joint [12] and so a proportion of patients remain dissatisfied with their function. Therefore, instead of
45 replacing the knee after it has been badly damaged, earlier interventions such as biological methods to repair
46 damaged cartilage are being explored [13-18].

47 Researchers have already found several ways to repair damaged cartilage, but few of them have created an
48 effective way to prepare the damaged articular surface so that the natural articular geometry is accurately
49 recreated by the repair. One option is to 3-D print cartilage cells in vitro, or a scaffold for cartilage to grow
50 on with the aid of tissue engineering. Cui et al. reported an innovative bio-printing system with simultaneous
51 photo-polymerization suitable for 3-D cartilage tissue engineering [14]. Liu et al. demonstrated the
52 application of novel 3-D collagen scaffolds fabricated by an indirect printing technique in tissue engineering
53 [13]. Sampat et al. applied osmotic loading, so that the cultivated tissue-engineered cartilage would have
54 better mechanical properties [18]. Gel-type autologous chondrocyte implantation offers the patients another
55 option of cartilage repair, where the surgeon injects the mixture of collagen and bio-glue to the lesion to
56 stimulate the stem cells to grow into hyaline-like cartilage [16, 17, 19]. However, although all of these
57 techniques tackle the problem of creating new tissue for cartilage repair, none focussed on the recreation of
58 the curved articular surface geometry. In addition to accurate shape, a tissue-engineered cartilage construct
59 requires an accurate fit into the damaged area, particularly its level in relation to the surrounding articular
60 surface, to help restore the normal function of the joints [20-22].

61 Conventional orthopaedic jigs are incapable of preparing the curved articular surface geometry, while
62 computer-aided surgery (CAS) is usually too expensive. The typical cutting tools found in orthopaedic
63 surgery, such as oscillating saws or rotational cutters, are designed only for cutting flat or cylindrical
64 surfaces. In most cases, surgeons have to prepare articular surfaces either free hand or with the help of a

65 robot. Robotic systems have been developed [21-24] that provide a passive assistance to surgeons by
66 restricting the movement of the cutter in a pre-defined volume [23]. In such a way, the surgeon can feel the
67 virtual surface to be prepared and form a complex curved surface with a high accuracy following the surgical
68 planning. However, CAS is much more expensive than conventional surgery, so only large volume hospitals
69 can justify the big upfront investment [24]. In contrast, patient-specific cutting guides based on medical
70 imaging have been shown to offer a reduced-cost method for preparing bone surfaces with clinically
71 acceptable levels of accuracy, particularly for joint replacements [25]. Therefore, for cartilage repair
72 procedures, surgeons need an accurate, affordable and easy-to-use instrument to prepare curved surfaces.
73 In this research, a new curved surface preparation technique using 3-D printed guides was proposed and
74 tested. The aim of this work was to develop and evaluate the accuracy of a standard and easy-to-use device
75 and method, so even the less experienced operator can achieve highly repeatable results in cartilage repair
76 procedures.

77 **Materials and Methods**

78 *Testing samples*

79 The test samples were made of closed cell polyurethane foam (product serial number 1522-02, Sawbone,
80 WA, USA: Density 0.24 gm/cc; E_{comp} 123 MPa; Yield strength_{comp} 4.9 MPa). The foam was cut into blocks
81 40 mm × 30 mm × 180 mm, and one large face of each was machined to one of three shapes: flat (Figure 1
82 (a)), R60 where the surface had a radius of 60 mm about a longitudinal axis (Figure 1 (b)), and R30 with a 30
83 mm radius. Four of each type were made.

84 *Registering and cutting guides*

85 Guides were manufactured by 3-D printer (Objet Eden 250, Stratasys Ltd, MN, US) according to the surface
86 geometry of the samples. Each guide was 46 x 40 mm and 3 mm thick. Each set of guides consisted of one
87 registering guide (Figure 1 (a and b)) and two cutting guides (Figure 1 (c and d)). One set of guides was
88 made for each foam block geometry, with the deep surface fitting either flat, radius 30 mm or radius 60 mm
89 curvature. The registering guide provided a stable platform on which to attach the cutting guides. There were
90 fixing holes in the registering guides to allow them to be secured firmly to the sample by pins during the
91 operation. The cutting guides had slots to guide the cutting burr to remove a pre-defined area of 40 x 34 mm
92 and either 2, 3, or 4 mm depth. Two types of cutting guide were used, to remove central and edge areas.

93 Since the testing samples were symmetrical, the cutting guides were reversible during the operation to cover
94 the whole area to be removed.

95

96 *Cutting tools*

97 The cutting tool used in the experiment was a hand-held high-speed rotational burr (Dremel, Wisconsin,
98 USA) 3 mm diameter. An adapter was designed and 3-D printed, which could control the depth of the cutting
99 (Figure 2 (a)).

100 *Experiments*

101 The registering guides were placed on the samples with the help of a digital calliper (LUPO,
102 Northamptonshire, UK) with ± 0.01 mm resolution such that there would be three cavities prepared along the
103 foam block, with a space of 3 mm between each pair of cavities. The registering guides were fixed in place
104 by 3 mm pins, then the cutting guides were assembled to the registering guides (Figure (b)). With the burr
105 following the guidance of the cutting slots on the cutting guide, the operator could remove the material
106 underneath within a pre-defined area and depth (Figure (c)). The operator could feel the resistance force at
107 the beginning of the cutting, and once the material had been removed, the resisting force disappeared. Then,
108 the cutting guides were reversed (that is, rotated 180 degrees) and the remaining material was removed. The
109 same procedure was repeated three times on each foam block, giving 12 cavities prepared with each surface
110 curvature. Finally, the cutting guides were removed and the prepared surface was visually checked. If there
111 were any large chunk of material left, the cutting process was repeated. Each foam block received one cavity
112 at each of 2, 3 and 4 mm depth.

113 *Accuracy Evaluation*

114 The accuracy of the experimental cavities was evaluated by measuring their position, shape and depth. The
115 accuracy was determined in line with the ISO recommendations [26], where deviation from a desired value is
116 the *trueness* of the preparation, and the variability of the resulting values is the *precision* of the preparation.

117 For the position accuracy, two dimensions were measured, one from the Base Line 1 to the left side of each
118 cavity and the other one from the Base Line 2 to the bottom side of each cavity. (Figure) For the shape
119 accuracy, two dimensions were measured, one was the longitudinal length of each cavity and the other was

120 the transverse length of each cavity. (Figure) Each of these dimensions was measured three times at
121 positions spaced approximately equally across the width of the cavity to get the average using digital
122 callipers with ± 0.01 mm resolution. Then, the trueness was represented by calculating the deviations
123 between measured data and planned data. The precision (random error of the data) was represented by the
124 standard deviation of the mean of the data.

125 The depth accuracy was evaluated by comparing the prepared surface to the CAD planned surface. The
126 prepared surface was scanned using a 3-D laser scanner (NextEngine, CA, USA). The scanner had an
127 accuracy of ± 0.127 mm and scanned the whole cavity surface at a point density of 1.7 points/mm^2 , 2312
128 points per cavity.

129 **Results**

130 The results show the accuracy of the technique using the shape, position and the surface depth measurements.
131 Positive values in the figures mean that the planned values were less than the prepared values. The precision
132 of the dimensions, represented by the standard deviations of the means, was ± 0.02 mm for both shape and
133 position accuracy.

134 The accuracy of preparation of the shape of the cavities was defined by the trueness (mean deviations from
135 nominal dimensions) and precision (standard deviations about the mean); these were 0.52 ± 0.05 mm, $0.47 \pm$
136 0.05 mm and 0.48 ± 0.04 mm for the Flat, R60 and R30 geometries, respectively (Figure). The largest
137 variation was found on flat samples, with deviations from the nominal size ranging from 0.00 mm (minimum)
138 to 0.93 mm (maximum). The graph does not suggest that shape accuracy was affected by the underlying
139 curvature. The position accuracy values (trueness and precision, shown as mean $\pm$ standard deviation (SD))
140 were -0.39 ± 0.04 mm, $-0.47 \text{ mm} \pm 0.05$ mm and -0.42 ± 0.04 mm for the Flat, R60 and R30 geometries,
141 respectively (Figure). The maximum value was 0.04 mm, found on an R30 sample, while the minimum was
142 -0.97 mm, found on an R60 sample. To evaluate surface depth accuracy, the planned surfaces were
143 compared to the 3-D scanned surfaces; the mean 95% percentiles, the mean 5% percentiles and the mean
144 median of the deviations were calculated (Figure 6), with trueness and precision values (mean and SD of
145 errors) being 0.28 ± 0.08 mm for flat, 0.16 ± 0.11 for R60, and 0.04 ± 0.18 for R30 cavity depths, respectively.

147 **Discussion**

148 In this study, we developed and tested a curved surface preparation technique using simple 3-D printed
149 guides. The mean shape and position accuracies (trueness of preparation versus desired dimensions) were
150 each approximately ± 0.5 mm and the surface depth accuracy was better than ± 0.5 mm. This development
151 has provided surgeons with a sufficiently accurate, affordable, and user-friendly technique and set of
152 instruments to prepare a curved surface. This method has only been demonstrated with a one-directional
153 curvature (that is, a cylindrical geometry), but it may be used with advanced cartilage repair and regenerative
154 technology to create more accurate articular surface preparations which curve to match the anatomical shape.

155 In the study, we aimed to cut a curved surface, because natural subchondral bone surfaces and their
156 overlaying cartilage are curved. However, due to the limitation of the technique, systematic errors are
157 inevitable, because a limited number of flat surface facets were used to represent a continuous curved surface
158 (Figure). The systematic error is the radial distance between the curve and the chord, which might be
159 inwards (as in Figure 7), outwards, or both, but will remain almost the same magnitude for a given radius
160 and chord length. The chord length is no bigger than the diameter of the burr. Increasing the number of the
161 slots in the cutting guides can decrease the chord length and thus reduce the systematic errors, but meanwhile
162 it increases the complexity of the design and the time of the procedure. If the slots in the cutting guides do
163 not allow overlapping of the paths of the burr, then a larger diameter burr will also increase the error. The
164 flat samples had the smallest range of deviations (that is, the greatest precision), while the R30 sample had
165 the largest (least precise). The design of the cutting guides must ensure a balance between the systematic
166 errors (which are reduced by having smaller and more facets) and the efficiency of the device; the acceptable
167 error on form has not been defined. An obvious alternative, which avoids the geometrical error caused by
168 machining longitudinal facets to approximate the curvature, would be to have the guide slots running
169 circumferentially around the cylinder rather than along it. However, that was tried in a pilot study, when it
170 was found to be difficult to keep the cutter perpendicular to the curved surface of the guide, so the method
171 was changed to that described in this paper. Further evaluation of more realistic condylar geometry would be
172 appropriate.

173 The accuracy of the depths of the cavities increased as the radius of the surface decreased, while the
174 precision decreased. The thickness of all the guides was checked to eliminate the possibility of systematic
175 errors caused by the inaccurate manufacturing process. Inaccuracy might also have resulted from the
176 flexibility of the cutting guide. During the operation, the operator would push the cutter downward against
177 the guide, bending it. There is a trade-off between the low profile design and high mechanical strength,
178 which needs to be taken into consideration in the further development of the design of the cutting guides.

179 The shape errors were generally positive, meaning that the prepared shapes were larger than the planned
180 shapes. This was caused by the high-speed rotational cutter wearing the guides: a linear regression analysis
181 of the data showed that the wear caused a mean increase of the size of each cavity cut of 0.02 mm. In this
182 experiment, each cutting guide was used to prepare 12 cavities, whereas they would be single-use in live
183 surgery, and so the accuracy would be improved by a mean of approximately 0.12 mm in clinical use. The
184 positional errors were negative, which with the positive shape errors indicated that the guides were worn on
185 both sides. No attempt was made to try to discern the contributions to inaccuracy from separate mechanisms,
186 which might have included the manufacture of the guides and the handling of the cutter, for example, leading
187 to identification of systematic bias and random error effects (affecting trueness and precision). It was felt that
188 the errors were already below those normally attained in surgery, but that might be an objective for further
189 work.

190 The main advantages of this technique are high accuracy, affordability and that it is user friendly. The mean
191 shape, position, and surface depth accuracies were each approximately ± 0.5 mm. Smith et al. [27] reported
192 the errors of a computer-controlled freehand burring system, in terms of the attained versus planned positions
193 of unicondylar knee prosthesis components mounted onto Sawbones models. They had RMS errors in
194 translation of approximately 0.5 mm in all three directions, for both the femoral and tibial components. The
195 accuracy with the cutting guides presented in this paper was attained using simple devices which would be a
196 small fraction of the cost of a CAS system.

197 The cutting guide system is easy and straightforward to use. The operator only needs to follow the guidance
198 of the slots to remove tissue underneath. The technique is unaffected by the subjective adjustments in free
199 hand preparation, so less experienced operators can have similar results to experienced operators. This 3-D
200 printing based technique is affordable to hospitals because there is no upfront investment. The surgeons only

201 need to send the surgical plans to the manufacturers, and then their teams will design and manufacture the
202 patient-specific jigs. This flexibility will dramatically reduce the cost and increase the availability.

203 The main limitation of this study is the simplicity of the rectangular geometry of the testing samples
204 compared to the real shape of human joints, but the purpose of this study was to provide baseline data on the
205 accuracy of the curved surface preparation method, and the cylindrical geometry facilitated measurement. It
206 is clear that this technique is transferable to the more complex geometry of the articular surfaces of knees,
207 with curvatures varying across them. As long as the registering guide is assembled properly onto the bone,
208 this method should allow accurate surface machining, but a further study with more realistic geometry, and
209 with the cutting guides derived via medical imaging, should be performed.

210 **Conclusions**

211 The new curved surface preparation technique has demonstrated sufficient accuracy and potential for
212 application in cartilage repair surgeries, using a relatively low-cost technology. It is possible to prepare the
213 surface with sufficient accuracy to accept a tissue-engineered construct to restore the anatomical articular
214 geometry; the technique should be widely applicable in cartilage repair.

216 **Acknowledgement**

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219 those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health.

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291 **Captions for illustrations**

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313

314

Title: Novel Curved Surface Preparation Technique for Knee Resurfacing

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23 **Abstract**

24 Conventional tools are incapable of preparing the curved articular surface geometry required during cartilage
25 repair procedures. A novel curved surface preparation technique was proposed and tested to provide an
26 accurate low-cost solution. Three shapes of samples, with flat, 30 mm radius and 60 mm radius surfaces,
27 were manufactured from foam bone substitute for testing. Registering guides and cutting guides were
28 designed and 3-D printed to fit onto the foam samples. A rotational cutting tool with an adapter was used to
29 prepare the surfaces following the guidance slots in the cutting guides. The accuracies of the positions and
30 shapes of the prepared cavities were measured using a digital calliper, and the surface depth accuracy was
31 measured using a 3-D scanner. The mean shape and position errors were both approximately ± 0.5 mm and
32 the mean surface depth error ranged from 0 to 0.3 mm, range -0.3 to +0.45 mm 95% CI. This study showed
33 that the technique was able to prepare a curved surface accurately; with some modification it can be used to
34 prepare the knee surface for cartilage repair.

35 *Keywords:* Curved bone resection, Joint resurfacing, 3-D printing, Cartilage repair instruments

36

37 **Introduction**

38 Articular cartilage damage is very common, affecting millions of people worldwide, especially the elderly [1,
39 2]. The disease does not only cause pain and disability to the individuals [3], but it also brings a heavy
40 burden to the medical insurance system [4, 5]. Non-surgical treatment may work for the mild to medium
41 conditions [6-8], but in severe cases patients are usually treated with knee replacement [9]. However, these
42 artificial components are not suitable for all cases [9], since they have limited life [10, 11], so are unsuitable
43 for younger, more active patients. In addition, total knee arthroplasty does not usually feel the same as the
44 human joint [12] and so a proportion of patients remain dissatisfied with their function. Therefore, instead of
45 replacing the knee after it has been badly damaged, earlier interventions such as biological methods to repair
46 damaged cartilage are being explored [13-18].

47 Researchers have already found several ways to repair damaged cartilage, but few of them have created an
48 effective way to prepare the damaged articular surface so that the natural articular geometry is accurately
49 recreated by the repair. One option is to 3-D print cartilage cells in vitro, or a scaffold for cartilage to grow
50 on with the aid of tissue engineering. Cui et al. reported an innovative bio-printing system with simultaneous
51 photo-polymerization suitable for 3-D cartilage tissue engineering [14]. Liu et al. demonstrated the
52 application of novel 3-D collagen scaffolds fabricated by an indirect printing technique in tissue engineering
53 [13]. Sampat et al. applied osmotic loading, so that the cultivated tissue-engineered cartilage would have
54 better mechanical properties [18]. Gel-type autologous chondrocyte implantation offers the patients another
55 option of cartilage repair, where the surgeon injects the mixture of collagen and bio-glue to the lesion to
56 stimulate the stem cells to grow into hyaline-like cartilage [16, 17, 19]. However, although all of these
57 techniques tackle the problem of creating new tissue for cartilage repair, none focussed on the recreation of
58 the curved articular surface geometry. In addition to accurate shape, a tissue-engineered cartilage construct
59 requires an accurate fit into the damaged area, particularly its level in relation to the surrounding articular
60 surface, to help restore the normal function of the joints [20-22].

61 Conventional orthopaedic jigs are incapable of preparing the curved articular surface geometry, while
62 computer-aided surgery (CAS) is usually too expensive. The typical cutting tools found in orthopaedic
63 surgery, such as oscillating saws or rotational cutters, are designed only for cutting flat or cylindrical
64 surfaces. In most cases, surgeons have to prepare articular surfaces either free hand or with the help of a

65 robot. Robotic systems have been developed [21-24] that provide a passive assistance to surgeons by
66 restricting the movement of the cutter in a pre-defined volume [23]. In such a way, the surgeon can feel the
67 virtual surface to be prepared and form a complex curved surface with a high accuracy following the surgical
68 planning. However, CAS is much more expensive than conventional surgery, so only large volume hospitals
69 can justify the big upfront investment [24]. In contrast, patient-specific cutting guides based on medical
70 imaging have been shown to offer a reduced-cost method for preparing bone surfaces with clinically
71 acceptable levels of accuracy, particularly for joint replacements [25]. Therefore, for cartilage repair
72 procedures, surgeons need an accurate, affordable and easy-to-use instrument to prepare curved surfaces.
73 In this research, a new curved surface preparation technique using 3-D printed guides was proposed and
74 tested. The aim of this work was to develop and evaluate the accuracy of a standard and easy-to-use device
75 and method, so even the less experienced operator can achieve highly repeatable results in cartilage repair
76 procedures.

77 **Materials and Methods**

78 *Testing samples*

79 The test samples were made of closed cell polyurethane foam (product serial number 1522-02, Sawbone,
80 WA, USA: Density 0.24 gm/cc; E_{comp} 123 MPa; Yield strength_{comp} 4.9 MPa). The foam was cut into blocks
81 40 mm × 30 mm × 180 mm, and one large face of each was machined to one of three shapes: flat (Figure 1
82 (a)), R60 where the surface had a radius of 60 mm about a longitudinal axis (Figure 1 (b)), and R30 with a 30
83 mm radius. Four of each type were made.

84 *Registering and cutting guides*

85 Guides were manufactured by 3-D printer (Objet Eden 250, Stratasys Ltd, MN, US) according to the surface
86 geometry of the samples. Each guide was 46 x 40 mm and 3 mm thick. Each set of guides consisted of one
87 registering guide (Figure 1 (a and b)) and two cutting guides (Figure 1 (c and d)). One set of guides was
88 made for each foam block geometry, with the deep surface fitting either flat, radius 30 mm or radius 60 mm
89 curvature. The registering guide provided a stable platform on which to attach the cutting guides. There were
90 fixing holes in the registering guides to allow them to be secured firmly to the sample by pins during the
91 operation. The cutting guides had slots to guide the cutting burr to remove a pre-defined area of 40 x 34 mm
92 and either 2, 3, or 4 mm depth. Two types of cutting guide were used, to remove central and edge areas.

93 Since the testing samples were symmetrical, the cutting guides were reversible during the operation to cover
94 the whole area to be removed.

95

96 *Cutting tools*

97 The cutting tool used in the experiment was a hand-held high-speed rotational burr (Dremel, Wisconsin,
98 USA) 3 mm diameter. An adapter was designed and 3-D printed, which could control the depth of the cutting
99 (Figure 2 (a)).

100 *Experiments*

101 The registering guides were placed on the samples with the help of a digital calliper (LUPO,
102 Northamptonshire, UK) with ± 0.01 mm resolution such that there would be three cavities prepared along the
103 foam block, with a space of 3 mm between each pair of cavities. The registering guides were fixed in place
104 by 3 mm pins, then the cutting guides were assembled to the registering guides (Figure (b)). With the burr
105 following the guidance of the cutting slots on the cutting guide, the operator could remove the material
106 underneath within a pre-defined area and depth (Figure (c)). The operator could feel the resistance force at
107 the beginning of the cutting, and once the material had been removed, the resisting force disappeared. Then,
108 the cutting guides were reversed (that is, rotated 180 degrees) and the remaining material was removed. The
109 same procedure was repeated three times on each foam block, giving 12 cavities prepared with each surface
110 curvature. Finally, the cutting guides were removed and the prepared surface was visually checked. If there
111 were any large chunk of material left, the cutting process was repeated. Each foam block received one cavity
112 at each of 2, 3 and 4 mm depth.

113 *Accuracy Evaluation*

114 The accuracy of the experimental cavities was evaluated by measuring their position, shape and depth. The
115 accuracy was determined in line with the ISO recommendations [26], where deviation from a desired value is
116 the trueness of the preparation, and the variability of the resulting values is the precision of the preparation.

117 For the position accuracy, two dimensions were measured, one from the Base Line 1 to the left side of each
118 cavity and the other one from the Base Line 2 to the bottom side of each cavity. (Figure) For the shape
119 accuracy, two dimensions were measured, one was the longitudinal length of each cavity and the other was

120 the transverse length of each cavity. (Figure) Each of these dimensions was measured three times at
121 positions spaced approximately equally across the width of the cavity to get the average using digital
122 callipers with ± 0.01 mm resolution. Then, the trueness was represented by calculating the deviations
123 between measured data and planned data. The precision (random error of the data) was represented by the
124 standard deviation of the mean of the data.

125 The depth accuracy was evaluated by comparing the prepared surface to the CAD planned surface. The
126 prepared surface was scanned using a 3-D laser scanner (NextEngine, CA, USA). The scanner had an
127 accuracy of ± 0.127 mm and scanned the whole cavity surface at a point density of 1.7 points/mm^2 , 2312
128 points per cavity.

129 **Results**

130 The results show the accuracy of the technique using the shape, position and the surface depth measurements.
131 Positive values in the figures mean that the planned values were less than the prepared values. The precision
132 of the dimensions, represented by the standard deviations of the means, was ± 0.02 mm for both shape and
133 position accuracy.

134 The accuracy of preparation of the shape of the cavities was defined by the trueness (mean deviations from
135 nominal dimensions) and precision (standard deviations about the mean); these were 0.52 ± 0.05 mm, $0.47 \pm$
136 0.05 mm and 0.48 ± 0.04 mm for the Flat, R60 and R30 geometries, respectively (Figure). The largest
137 variation was found on flat samples, with deviations from the nominal size ranging from 0.00 mm (minimum)
138 to 0.93 mm (maximum). The graph does not suggest that shape accuracy was affected by the underlying
139 curvature. The position accuracy values (trueness and precision, shown as mean $\pm$ standard deviation (SD))
140 were -0.39 ± 0.04 mm, $-0.47 \text{ mm} \pm 0.05$ mm and -0.42 ± 0.04 mm for the Flat, R60 and R30 geometries,
141 respectively (Figure). The maximum value was 0.04 mm, found on an R30 sample, while the minimum was
142 -0.97 mm, found on an R60 sample. To evaluate surface depth accuracy, the planned surfaces were
143 compared to the 3-D scanned surfaces; the mean 95% percentiles, the mean 5% percentiles and the mean
144 median of the deviations were calculated (Figure 6), with trueness and precision values (mean and SD of
145 errors) being 0.28 ± 0.08 mm for flat, 0.16 ± 0.11 for R60, and 0.04 ± 0.18 for R30 cavity depths, respectively.

147 **Discussion**

148 In this study, we developed and tested a curved surface preparation technique using simple 3-D printed
149 guides. The mean shape and position accuracies (trueness of preparation versus desired dimensions) were
150 each approximately ± 0.5 mm and the surface depth accuracy was better than ± 0.5 mm. This development
151 has provided surgeons with a sufficiently accurate, affordable, and user-friendly technique and set of
152 instruments to prepare a curved surface. This method has only been demonstrated with a one-directional
153 curvature (that is, a cylindrical geometry), but it may be used with advanced cartilage repair and regenerative
154 technology to create more accurate articular surface preparations which curve to match the anatomical shape.

155 In the study, we aimed to cut a curved surface, because natural subchondral bone surfaces and their
156 overlaying cartilage are curved. However, due to the limitation of the technique, systematic errors are
157 inevitable, because a limited number of flat surface facets were used to represent a continuous curved surface
158 (Figure). The systematic error is the radial distance between the curve and the chord, which might be
159 inwards (as in Figure 7), outwards, or both, but will remain almost the same magnitude for a given radius
160 and chord length. The chord length is no bigger than the diameter of the burr. Increasing the number of the
161 slots in the cutting guides can decrease the chord length and thus reduce the systematic errors, but meanwhile
162 it increases the complexity of the design and the time of the procedure. If the slots in the cutting guides do
163 not allow overlapping of the paths of the burr, then a larger diameter burr will also increase the error. The
164 flat samples had the smallest range of deviations (that is, the greatest precision), while the R30 sample had
165 the largest (least precise). The design of the cutting guides must ensure a balance between the systematic
166 errors (which are reduced by having smaller and more facets) and the efficiency of the device; the acceptable
167 error on form has not been defined. An obvious alternative, which avoids the geometrical error caused by
168 machining longitudinal facets to approximate the curvature, would be to have the guide slots running
169 circumferentially around the cylinder rather than along it. However, that was tried in a pilot study, when it
170 was found to be difficult to keep the cutter perpendicular to the curved surface of the guide, so the method
171 was changed to that described in this paper. Further evaluation of more realistic condylar geometry would be
172 appropriate.

173 The accuracy of the depths of the cavities increased as the radius of the surface decreased, while the
174 precision decreased. The thickness of all the guides was checked to eliminate the possibility of systematic
175 errors caused by the inaccurate manufacturing process. Inaccuracy might also have resulted from the
176 flexibility of the cutting guide. During the operation, the operator would push the cutter downward against
177 the guide, bending it. There is a trade-off between the low profile design and high mechanical strength,
178 which needs to be taken into consideration in the further development of the design of the cutting guides.

179 The shape errors were generally positive, meaning that the prepared shapes were larger than the planned
180 shapes. This was caused by the high-speed rotational cutter wearing the guides: a linear regression analysis
181 of the data showed that the wear caused a mean increase of the size of each cavity cut of 0.02 mm. In this
182 experiment, each cutting guide was used to prepare 12 cavities, whereas they would be single-use in live
183 surgery, and so the accuracy would be improved by a mean of approximately 0.12 mm in clinical use. The
184 positional errors were negative, which with the positive shape errors indicated that the guides were worn on
185 both sides. No attempt was made to try to discern the contributions to inaccuracy from separate mechanisms,
186 which might have included the manufacture of the guides and the handling of the cutter, for example, leading
187 to identification of systematic bias and random error effects (affecting trueness and precision). It was felt that
188 the errors were already below those normally attained in surgery, but that might be an objective for further
189 work.

190 The main advantages of this technique are high accuracy, affordability and that it is user friendly. The mean
191 shape, position, and surface depth accuracies were each approximately ± 0.5 mm. Smith et al. [27] reported
192 the errors of a computer-controlled freehand burring system, in terms of the attained versus planned positions
193 of unicondylar knee prosthesis components mounted onto Sawbones models. They had RMS errors in
194 translation of approximately 0.5 mm in all three directions, for both the femoral and tibial components. The
195 accuracy with the cutting guides presented in this paper was attained using simple devices which would be a
196 small fraction of the cost of a CAS system.

197 The cutting guide system is easy and straightforward to use. The operator only needs to follow the guidance
198 of the slots to remove tissue underneath. The technique is unaffected by the subjective adjustments in free
199 hand preparation, so less experienced operators can have similar results to experienced operators. This 3-D
200 printing based technique is affordable to hospitals because there is no upfront investment. The surgeons only

201 need to send the surgical plans to the manufacturers, and then their teams will design and manufacture the
202 patient-specific jigs. This flexibility will dramatically reduce the cost and increase the availability.

203 The main limitation of this study is the simplicity of the rectangular geometry of the testing samples
204 compared to the real shape of human joints, but the purpose of this study was to provide baseline data on the
205 accuracy of the curved surface preparation method, and the cylindrical geometry facilitated measurement. It
206 is clear that this technique is transferable to the more complex geometry of the articular surfaces of knees,
207 with curvatures varying across them. As long as the registering guide is assembled properly onto the bone,
208 this method should allow accurate surface machining, but a further study with more realistic geometry, and
209 with the cutting guides derived via medical imaging, should be performed.

210 **Conclusions**

211 The new curved surface preparation technique has demonstrated sufficient accuracy and potential for
212 application in cartilage repair surgeries, using a relatively low-cost technology. It is possible to prepare the
213 surface with sufficient accuracy to accept a tissue-engineered construct to restore the anatomical articular
214 geometry; the technique should be widely applicable in cartilage repair.

216 **Acknowledgement**

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Figure 1
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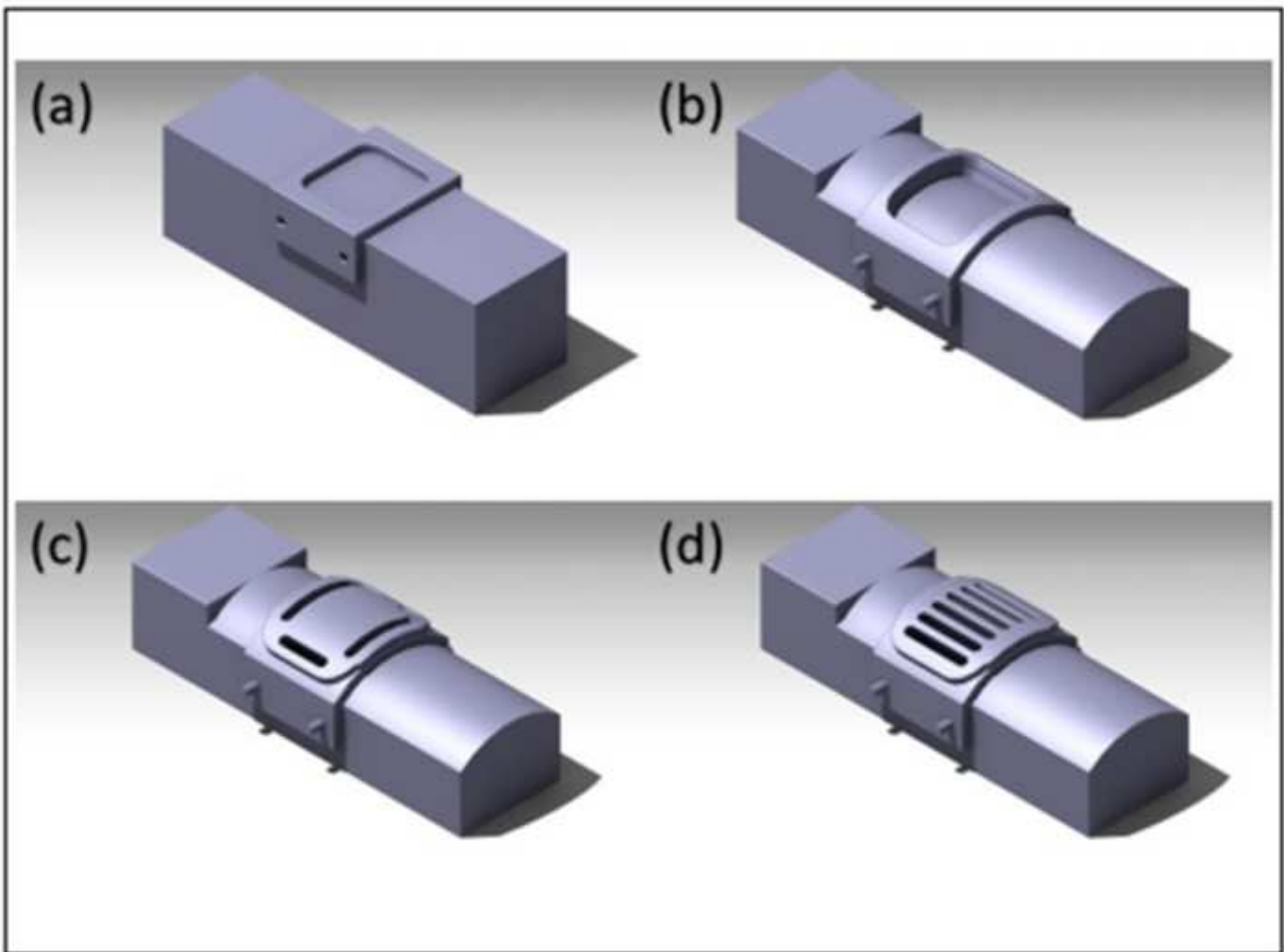


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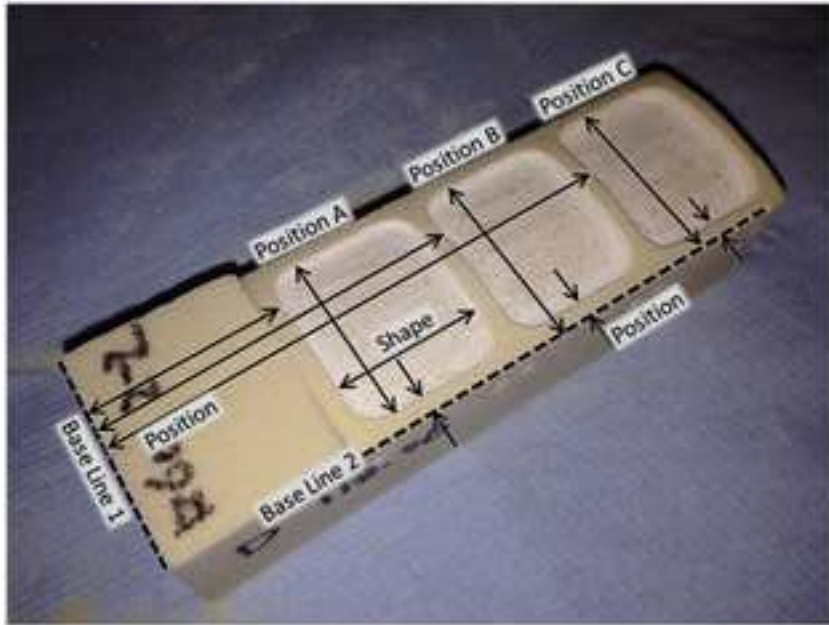


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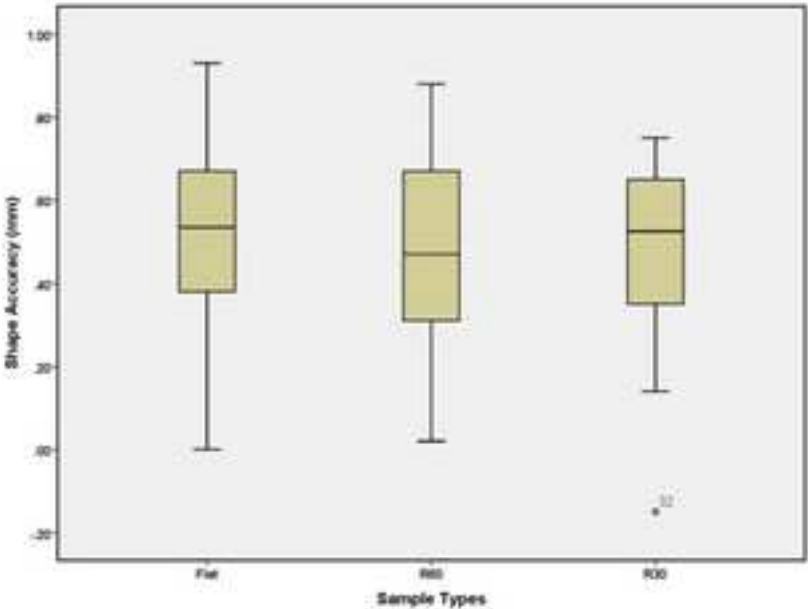


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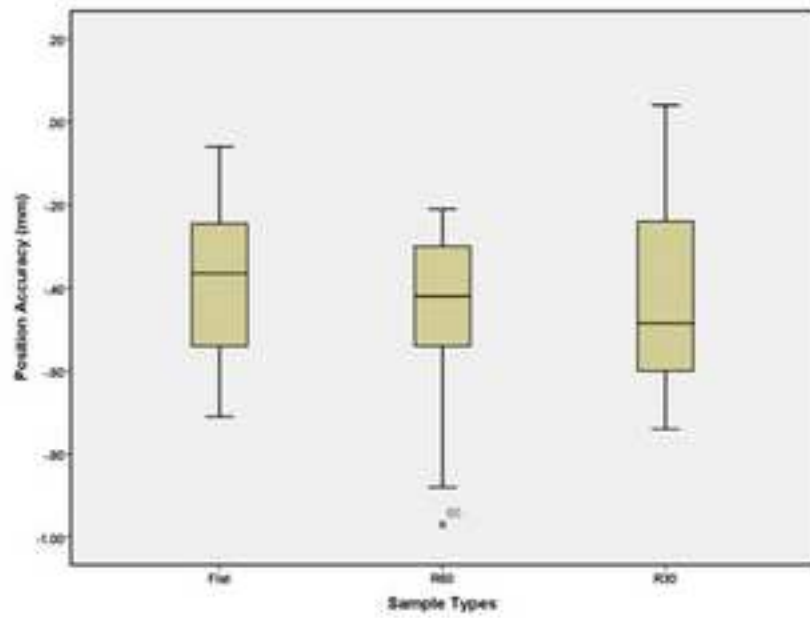


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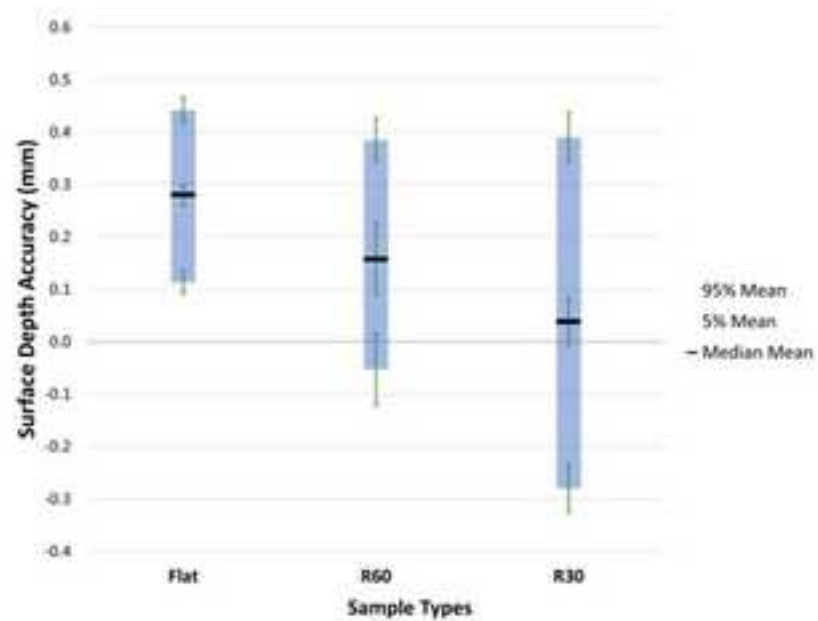


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