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

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

Conventional orthopaedic jigs are incapable of preparing the curved articular surface geometry, while computer-aided surgery (CAS) is usually too expensive. The typical cutting tools found in orthopaedic surgery, such as oscillating saws or rotational cutters, are designed only for cutting flat or cylindrical surfaces. In most cases, surgeons have to prepare articular surfaces either free hand or with the help of a
Robotic systems have been developed [21-24] that provide a passive assistance to surgeons by restricting the movement of the cutter in a pre-defined volume [23]. In such a way, the surgeon can feel the virtual surface to be prepared and form a complex curved surface with a high accuracy following the surgical planning. However, CAS is much more expensive than conventional surgery, so only large volume hospitals can justify the big upfront investment [24]. In contrast, patient-specific cutting guides based on medical imaging have been shown to offer a reduced-cost method for preparing bone surfaces with clinically acceptable levels of accuracy, particularly for joint replacements [25]. Therefore, for cartilage repair procedures, surgeons need an accurate, affordable and easy-to-use instrument to prepare curved surfaces.

In this research, a new curved surface preparation technique using 3-D printed guides was proposed and tested. The aim of this work was to develop and evaluate the accuracy of a standard and easy-to-use device and method, so even the less experienced operator can achieve highly repeatable results in cartilage repair procedures.

Materials and Methods

Testing samples

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

Registering and cutting guides

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

Cutting tools

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

Experiments

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

Accuracy Evaluation

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

For the position accuracy, two dimensions were measured, one from the Base Line 1 to the left side of each cavity and the other one from the Base Line 2 to the bottom side of each cavity. (Figure ) For the shape accuracy, two dimensions were measured, one was the longitudinal length of each cavity and the other was
the transverse length of each cavity. (Figure ) Each of these dimensions was measured three times at
positions spaced approximately equally across the width of the cavity to get the average using digital
callipers with ±0.01 mm resolution. Then, the trueness was represented by calculating the deviations
between measured data and planned data. The precision (random error of the data) was represented by the
standard deviation of the mean of the data.

The depth accuracy was evaluated by comparing the prepared surface to the CAD planned surface. The
prepared surface was scanned using a 3-D laser scanner (NextEngine, CA, USA). The scanner had an
accuracy of ±0.127 mm and scanned the whole cavity surface at a point density of 1.7 points/ mm², 2312
points per cavity.

Results

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

The accuracy of preparation of the shape of the cavities was defined by the trueness (mean deviations from
nominal dimensions) and precision (standard deviations about the mean); these were 0.52 ± 0.05 mm, 0.47 ±
0.05 mm and 0.48 ± 0.04 mm for the Flat, R60 and R30 geometries, respectively (Figure ). The largest
variation was found on flat samples, with deviations from the nominal size ranging from 0.00 mm (minimum)
to 0.93 mm (maximum). The graph does not suggest that shape accuracy was affected by the underlying
curvature. The position accuracy values (trueness and precision, shown as mean ± standard deviation (SD))
were -0.39 ± 0.04 mm, -0.47 mm ± 0.05 mm and -0.42 ± 0.04 mm for the Flat, R60 and R30 geometries,
respectively (Figure ). The maximum value was 0.04 mm, found on an R30 sample, while the minimum was
-0.97 mm, found on an R60 sample. To evaluate surface depth accuracy, the planned surfaces were
compared to the 3-D scanned surfaces; the mean 95% percentiles, the mean 5% percentiles and the mean
median of the deviations were calculated (Figure 6), with trueness and precision values (mean and SD of
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.
Discussion

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

In the study, we aimed to cut a curved surface, because natural subchondral bone surfaces and their overlaying cartilage are curved. However, due to the limitation of the technique, systematic errors are inevitable, because a limited number of flat surface facets were used to represent a continuous curved surface (Figure ). The systematic error is the radial distance between the curve and the chord, which might be inwards (as in Figure 7), outwards, or both, but will remain almost the same magnitude for a given radius and chord length. The chord length is no bigger than the diameter of the burr. Increasing the number of the slots in the cutting guides can decrease the chord length and thus reduce the systematic errors, but meanwhile it increases the complexity of the design and the time of the procedure. If the slots in the cutting guides do not allow overlapping of the paths of the burr, then a larger diameter burr will also increase the error. The flat samples had the smallest range of deviations (that is, the greatest precision), while the R30 sample had the largest (least precise). The design of the cutting guides must ensure a balance between the systematic errors (which are reduced by having smaller and more facets) and the efficiency of the device; the acceptable error on form has not been defined. An obvious alternative, which avoids the geometrical error caused by machining longitudinal facets to approximate the curvature, would be to have the guide slots running circumferentially around the cylinder rather than along it. However, that was tried in a pilot study, when it was found to be difficult to keep the cutter perpendicular to the curved surface of the guide, so the method was changed to that described in this paper. Further evaluation of more realistic condylar geometry would be appropriate.
The accuracy of the depths of the cavities increased as the radius of the surface decreased, while the precision decreased. The thickness of all the guides was checked to eliminate the possibility of systematic errors caused by the inaccurate manufacturing process. Inaccuracy might also have resulted from the flexibility of the cutting guide. During the operation, the operator would push the cutter downward against the guide, bending it. There is a trade-off between the low profile design and high mechanical strength, which needs to be taken into consideration in the further development of the design of the cutting guides.

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

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

The cutting guide system is easy and straightforward to use. The operator only needs to follow the guidance of the slots to remove tissue underneath. The technique is unaffected by the subjective adjustments in free hand preparation, so less experienced operators can have similar results to experienced operators. This 3-D printing based technique is affordable to hospitals because there is no upfront investment. The surgeons only
need to send the surgical plans to the manufacturers, and then their teams will design and manufacture the patient-specific jigs. This flexibility will dramatically reduce the cost and increase the availability.

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

Conclusions

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

Acknowledgement

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. The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health.

References


Captions for illustrations

Figure 1: Testing samples with different shapes: (a) flat surface, (b-d) R60 radius surface. In (a) the locating guide is positioned onto the flat surface, and in (b) it is now pinned in place onto the curved surface. In (c) the edge cutting guide is located in place; in (d) the central area cutting guide is in place.

Figure 2: (a) The cutting tool with adapter attached; (b) the assembly of registering and cutting guides on the sample; (c) cutting in action.

Figure 3: Four measurements were taken on each of the three cavities including two for position accuracy (from each of the baselines at the side and end of the foam block) and two for shape accuracy (the two orthogonal arrows within the cavity at Position A). Twelve measurements were performed on each sample in total.

Figure 4: The boxplot shows the shape accuracy of three sample types. The shape accuracy was the deviations between the planned size and prepared size. A positive value means that the planned size was less than the prepared size. (Box shows second and third quartiles; bars show first and fourth quartiles.)

Figure 5: The boxplot shows the position accuracy of three sample types. The position accuracy was the deviations between the planned position and prepared position. A positive value means that the planned distance was less the prepared distance. (Box shows second and third quartiles; bars show first and fourth quartiles.)

Figure 6: The deviations between the planned surface depth and the measured surface depth. The values in the figure show the mean 5 and 95 percentiles, and mean median of each type of samples. Positive deviations mean that the cavity was deeper than planned.

Figure 7: Systematic errors were inevitable due to the flat end of the burr, which created facets to represent the desired curved surface.
Title: Novel Curved Surface Preparation Technique for Knee Resurfacing

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Materials and Methods

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

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**Experiments**

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

**Accuracy Evaluation**

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

For the position accuracy, two dimensions were measured, one from the Base Line 1 to the left side of each cavity and the other one from the Base Line 2 to the bottom side of each cavity. (Figure ) For the shape accuracy, two dimensions were measured, one was the longitudinal length of each cavity and the other was
the transverse length of each cavity. (Figure ) Each of these dimensions was measured three times at positions spaced approximately equally across the width of the cavity to get the average using digital calipers with ± 0.01 mm resolution. Then, the trueness was represented by calculating the deviations between measured data and planned data. The precision (random error of the data) was represented by the standard deviation of the mean of the data.

The depth accuracy was evaluated by comparing the prepared surface to the CAD planned surface. The prepared surface was scanned using a 3-D laser scanner (NextEngine, CA, USA). The scanner had an accuracy of ± 0.127 mm and scanned the whole cavity surface at a point density of 1.7 points/mm², 2,312 points per cavity.

Results

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

The accuracy of preparation of the shape of the cavities was defined by the trueness (mean deviations from nominal dimensions) and precision (standard deviations about the mean); these were 0.52 ± 0.05 mm, 0.47 ± 0.05 mm and 0.48 ± 0.04 mm for the Flat, R60 and R30 geometries, respectively (Figure ). The largest variation was found on flat samples, with deviations from the nominal size ranging from 0.00 mm (minimum) to 0.93 mm (maximum). The graph does not suggest that shape accuracy was affected by the underlying curvature. The position accuracy values (trueness and precision, shown as mean ± standard deviation (SD)) were -0.39 ± 0.04 mm, -0.47 mm ± 0.05 mm and -0.42 ± 0.04 mm for the Flat, R60 and R30 geometries, respectively (Figure ). The maximum value was 0.04 mm, found on an R30 sample, while the minimum was -0.97 mm, found on an R60 sample. To evaluate surface depth accuracy, the planned surfaces were compared to the 3-D scanned surfaces; the mean 95% percentiles, the mean 5% percentiles and the mean median of the deviations were calculated (Figure 6), with trueness and precision values (mean and SD of 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.
Discussion

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

In the study, we aimed to cut a curved surface, because natural subchondral bone surfaces and their overlaying cartilage are curved. However, due to the limitation of the technique, systematic errors are inevitable, because a limited number of flat surface facets were used to represent a continuous curved surface (Figure ). The systematic error is the radial distance between the curve and the chord, which might be inwards (as in Figure 7), outwards, or both, but will remain almost the same magnitude for a given radius and chord length. The chord length is no bigger than the diameter of the burr. Increasing the number of the slots in the cutting guides can decrease the chord length and thus reduce the systematic errors, but meanwhile it increases the complexity of the design and the time of the procedure. If the slots in the cutting guides do not allow overlapping of the paths of the burr, then a larger diameter burr will also increase the error. The flat samples had the smallest range of deviations (that is, the greatest precision), while the R30 sample had the largest (least precise). The design of the cutting guides must ensure a balance between the systematic errors (which are reduced by having smaller and more facets) and the efficiency of the device; the acceptable error on form has not been defined. An obvious alternative, which avoids the geometrical error caused by machining longitudinal facets to approximate the curvature, would be to have the guide slots running circumferentially around the cylinder rather than along it. However, that was tried in a pilot study, when it was found to be difficult to keep the cutter perpendicular to the curved surface of the guide, so the method was changed to that described in this paper. Further evaluation of more realistic condylar geometry would be appropriate.
The accuracy of the depths of the cavities increased as the radius of the surface decreased, while the precision decreased. The thickness of all the guides was checked to eliminate the possibility of systematic errors caused by the inaccurate manufacturing process. Inaccuracy might also have resulted from the flexibility of the cutting guide. During the operation, the operator would push the cutter downward against the guide, bending it. There is a trade-off between the low profile design and high mechanical strength, which needs to be taken into consideration in the further development of the design of the cutting guides.

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

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

The cutting guide system is easy and straightforward to use. The operator only needs to follow the guidance of the slots to remove tissue underneath. The technique is unaffected by the subjective adjustments in free hand preparation, so less experienced operators can have similar results to experienced operators. This 3-D printing based technique is affordable to hospitals because there is no upfront investment. The surgeons only
need to send the surgical plans to the manufacturers, and then their teams will design and manufacture the patient-specific jigs. This flexibility will dramatically reduce the cost and increase the availability.

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

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

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References


Captions for illustrations

Figure 1: Testing samples with different shapes: (a) flat surface, (b-d) R60 radius surface. In (a) the locating guide is positioned onto the flat surface, and in (b) it is now pinned in place onto the curved surface. In (c) the edge cutting guide is located in place; in (d) the central area cutting guide is in place.

Figure 2: (a) The cutting tool with adapter attached; (b) the assembly of registering and cutting guides on the sample; (c) cutting in action.

Figure 3: Four measurements were taken on each of the three cavities including two for position accuracy (from each of the baselines at the side and end of the foam block) and two for shape accuracy (the two orthogonal arrows within the cavity at Position A). Twelve measurements were performed on each sample in total.

Figure 4: The boxplot shows the shape accuracy of three sample types. The shape accuracy was the deviations between the planned size and prepared size. A positive value means that the planned size was less than the prepared size. (Box shows second and third quartiles; bars show first and fourth quartiles.)

Figure 5: The boxplot shows the position accuracy of three sample types. The position accuracy was the deviations between the planned position and prepared position. A positive value means that the planned distance was less the prepared distance. (Box shows second and third quartiles; bars show first and fourth quartiles.)

Figure 6: The deviations between the planned surface depth and the measured surface depth. The values in the figure show the mean 5 and 95 percentiles, and mean median of each type of samples. Positive deviations mean that the cavity was deeper than planned.

Figure 7: Systematic errors were inevitable due to the flat end of the burr, which created facets to represent the desired curved surface.
Figure 3
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Figure 7
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