Comparative repeatability of guide-pin axis positioning in computer-assisted and manual femoral head resurfacing arthroplasty

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Abstract: The orientation of the femoral component in hip resurfacing arthroplasty affects the likelihood of loosening and fracture. Computer-assisted surgery has been shown to improve significantly the surgeon's ability to achieve a desired position and orientation; nevertheless, both bias and variability in positioning remain and can potentially be improved. The authors recently developed a computer-assisted surgical (CAS) technique to guide the placement of the pin used in femoral head resurfacing arthroplasty and showed that it produced significantly less variation than a typical manual technique in varus/valgus placement relative to a pre-operatively determined surgical plan while taking a comparable amount of time. In the present study, the repeatability of both the CAS and manual techniques is evaluated in order to estimate the relative contributions to overall variability of surgical technique (CAS versus manual), surgeon experience (novice versus experienced), and other sources of variability (e.g. across specimens and across surgeons). This will enable further improvements in the accuracy of CAS techniques.

Three residents/fellows new to femoral head resurfacing and three experienced hip arthroplasty surgeons performed 20–30 repetitions of each of the CAS and manual techniques on at least one of four cadaveric femur specimens. The CAS system had markedly better repeatability (1.2°) in varus/valgus placement relative to the manual technique (2.8°), slightly worse repeatability in version (4.4° versus 3.2°), markedly better repeatability in mid-neck placement (0.7 mm versus 2.5 mm), no significant dependence on surgeon skill level (in contrast to the manual technique), and took significantly less time (50 s versus 123 s). Proposed improvements to the version measurement process showed potential for reducing the standard deviation by almost two thirds.

This study supports the use of CAS for femoral head resurfacing as it is quicker than the manual technique, independent of surgeon experience, and demonstrates improved repeatability.

Keywords: femoral head resurfacing, hip arthroplasty, computer-assisted surgery, repeatability, accuracy, hip, osteoarthritis, resurfacing, registration

1 INTRODUCTION

Femoral head resurfacing (FHR) arthroplasty has been re-emerging in recent years as a viable alternative to total hip arthroplasty (THA) for younger and more active patients [**1–3**] because proponents feel that the technique better preserves femoral head bone stock and allows the patient to return to higher levels of activity than THA [**4**]. Early clinical results appear to be good, with several of these authors reporting 2–5 year survival rates at or above 95 per cent.

In comparison with total hip arthroplasty, resurfacing is more challenging for the surgeon and currently requires a relatively wide exposure to

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visualize the femoral neck properly. The mechanical jigs used to place the guide pin can be time-consuming to use and can produce highly variable pin positions [**5**, **6**]. If the pin position places the implant in varus or produces notching of the femoral neck, there can be a significant increase in the risk of post-operative femoral neck fracture [**1**, **3**, **7**]. Conversely, a cadaveric study showed that 10° of valgus positioning increased the fracture strength following notching by a mean of 28 per cent for specimens with bone mineral density typical of hip resurfacing patients [**8**]. Similarly, a finite element analysis has shown increased stresses in varus and reduced stresses in valgus [**9**]. Incorrect orientation may also require the use of a larger head, which in turn requires more acetabular bone stock to be removed than would otherwise be necessary. There appears to be a link between accuracy of component placement and reductions in the rates of femoral neck notching, fracture, and revision [**10**, **11**].

Although various types of mechanical instrumentation have been developed to enable this procedure to be carried out more accurately, even surgeons experienced in femoral head resurfacing produce highly variable pin alignments [**6**]. A recent clinical study [**12**] showed that experienced hip surgeons ($>$1000 total hip replacements each) required 55–60 procedures using a manual jig before they were able to place the implant consistently within 5° of the intended position. In response to this problem, various researchers have proposed computer-assisted surgical techniques for femoral head resurfacing [**13–19**]. For example, Hess *et al.* [**13**] presented a navigated fluoroscopic technique and showed that varus/valgus control was excellent (within 2.6° of the surgical goal); the technique added less than 15 minutes to the duration of the surgical procedure. The other authors cited have used various localization techniques ranging from digitizing arms to computed tomography (CT) and several computer-assisted surgery companies are now offering computer-assisted surgical (CAS) modules for resurfacing; among these are ORTHOsoft, Praxim-Medivision, BrainLAB, MedTronic, and CAS Innovations, whose techniques are generally based on digitizing a set of points on the femoral neck. However, to date few reports of accuracy (e.g. see references [**13**] and [**20**]) and none of repeatability have been published, nor have any papers discussed accuracy or repeatability with regard to version or neck centre localization.

The authors recently presented an imageless CAS technique for positioning the guide pin and component and demonstrated in a cadaveric study that it allowed a novice surgeon to implement a pre-operative plan with significantly less variability in angulation (particularly in varus/valgus) than an expert working with a mechanical jig system, while taking a comparable amount of time to target the guide-pin axis [**5**]. This technique differs from the other imageless systems in its use of a registration tool instead of a digitizing probe. This tool, described in more detail in section 2 on methods, enables the surgeon to locate and determine the orientation of the femur in space rapidly, at which point the desired implant axis is immediately registered to the femoral reference frame based on pre-operative X-rays and the surgeon can begin drilling using computer guidance. While the previous study demonstrated improved accuracy relative to the pre-operative plan, the authors did not separate out the relative contributions to the overall variability of the CAS technique of (a) repeatability on a single specimen, (b) repeatability between surgeons, and (c) variability in translating the pre-operative plan to the patient. By understanding the sources of variation, researchers may be able to improve the accuracy of the computer-assisted technique further. In this study, the principal goal was to estimate the repeatability contributions to overall variability. The following primary hypothesis was therefore assessed:

(a) the repeatability of the computer-assisted procedure is significantly better than that of the manual procedure;

in addition, a pilot study was performed to estimate the extent to which:

(b) the repeatability of the manual technique depends on the experience level of the surgeon;
(c) the repeatability of the computer-assisted technique depends on the experience level of the surgeon;
(d) the repeatability of the two procedures is affected by variations between cadaveric specimens.

The time needed to perform each type of procedure was also investigated.

2 METHODS

Three residents/fellows new to femoral head resurfacing and three experienced hip arthroplasty surgeons performed 20–30 repetitions of each of the CAS and manual techniques on at least one specimen and the axis orientation and position were recorded, along with the time needed to perform the procedures.

2.1 CAS system description

The details of the authors' CAS system are described elsewhere [**5**]; a summary is presented below. This system was designed to transfer pre-operative plans specified on a pair of anteroposterior (AP) and mediolateral (ML) radiographs (the latter only if available) to the operating room. Intraoperatively, the surgeon attaches a reference frame to the femur, registers the patient's femoral geometry using a novel registration tool (patent pending), identifies the femoral neck axis using a novel tracked caliper, optionally uses a digitizing probe to identify potential notching points on the femoral neck, and drills the implant axis using a tracked drill or drill guide (see Fig. 1). These steps are presented in more detail below.

1. Pre-operative planning. The surgeon identifies the desired neck axis on an AP radiograph and draws a line across the superior aspects of the femoral head and the greater trochanter (GT). If an ML radiograph is available, the surgeon also indicates the desired angle of the femoral neck axis relative to a line drawn to fit as closely as possible the posterior aspects of the femoral head and the greater and lesser trochanter.
2. Registration tool. The registration tool has two rigid planar surfaces normal to each other; these are precalibrated relative to a marker array attached to the tool. Intraoperatively, the surgeon attaches a marker array to the femur, apposes the registration tool's surfaces to the superior and posterior aspects of the femur and the relative position is read. This enables the planned varus/valgus and version angulations to be identified relative to the femur.
3. Caliper tool. The caliper tool consists of two faces whose position and separation can be tracked by the localizer. By closing the caliper on the neck from an AP direction, the surgeon can identify the narrowest portion of the neck in the supero-inferior direction. The surgeon then applies the caliper several times along the anterior and posterior surfaces of the femoral neck. The midline between the caliper faces pierces the plane perpendicular to the posterior face of the registration tool at the desired varus/valgus angle at a point; a line fit to the points obtained from the caliper measurements defines the version angle and the position of the desired implant axis.
4. Digitizing probe. The surgeon may optionally use a conventional point digitizing probe to record points on the femoral neck near where it may be notched. The system can then compute a minimum reamer size to encircle these points when passed along the calculated implant axis. Adjustments to the translational position of the implant axis may be made to prevent notching.
5. Drill guide. The CAS system is then used to track a conventional drill guide to which a marker array has been attached. The surgeon manipulates the drill on to the desired implant axis guided by a computer-generated targeting display.

Since the current study focuses on repeatability rather than accuracy, only steps (2) and (3) were performed in this study.

2.2 Study design

2.2.1 Subjects

Two groups of three surgeons were recruited, all of whom provided informed consent. The surgeons in each group represented similar experience levels in femoral resurfacing – a Learning Group consisted of fellows or senior residents who had not performed any resurfacing procedures, while an Experienced Group consisted of attending surgeons with significant

Fig. 1 Femoral head as mounted for the experiment with registration tool apposed (left) and tracked caliper applied (right). A rigid body with an optical reference frame is attached to the femur. The contact point on the medial side of the femoral head is not required for the standard use of the registration plate and has no effect on the axis

experience in performing the procedure (the inclusion criterion was that they had performed at least 30 resurfacing procedures). The study was approved by the authors' institutional review board.

2.2.2 *Specimen preparation*

The UBC Anatomy Department specimen donation program provided four cadaveric specimens for this study – three male, one female, ages 61–93 – to represent variations in size and geometry, with an emphasis on male specimens since more males than females undergo hip resurfacing. A surgical fellow transected each specimen several inches below the lesser trochanter, stripped the soft tissues, planed off the proximal end of the femoral head in preparation for the alignment jig (described below), and froze the specimens until the day before the experiment when they were thawed. On the day of the experiment, the fellow fixed the specimens to a lab bench in a vice, with the femoral head positioned similar to the way it would present intraoperatively (see Fig. 1) and secured a marker array to the femur to establish a local reference frame. To ensure that the manual procedure was not inadvertently disadvantaged relative to the computer-assisted procedure, the femoral head and neck were not draped to simulate the surgical setting as described in the authors' earlier study [**5**]. While this does provide better exposure of the femoral head and neck than would be obtained intraoperatively and so will tend to improve the repeatability of the manual procedure, there will be little effect on the CAS procedure since the CAS alignment is determined solely by contacts with exposed portions of the femur. Any improvement in repeatability of the CAS procedure relative to the manual procedure will therefore tend to be underestimated. Following the conclusion of this study, the cadaveric specimens were disposed of according to the standard protocols followed by the Division of Orthopaedic Engineering Research at Vancouver Hospital.

2.2.3 *Procedure*

Two targeting procedures were used: the CAS technique described above and a manual positioning technique using a standard Durom alignment jig (Zimmer, Warsaw, Indiana). This is the standard system used by the attending surgeons recruited for this study. Each surgeon performed 20–30 registrations using each of the manual and CAS techniques in two sets of 10–15 registrations using one technique followed by 10–15 registrations using the other. The choice of which technique to perform first was randomized surgeon by surgeon. One surgeon in the learning group repeated the CAS and manual processes on three different specimens, performing 30 repetitions each time, to assess dependence of repeatability on specimen variation. While repeated application of the manual instrumentation in close succession may enable surgeons to use visual cues to improve their performance from repetition to repetition, this can only tend to improve the estimated repeatability of the manual procedure. This possible bias in favour of the manual technique is acceptable because the primary hypothesis is that the CAS technique improves on the manual one.

With the CAS technique, the surgeon performed the following three steps, starting from an exposed proximal femur (soft tissues removed): the surgeon (a) applied the registration tool, (b) recorded its location using an optical localizer (Flashpoint 5000, Image Guided Technologies, Boulder, Colorado), and (c) used the caliper tool to digitize the femoral neck from both the anterior and superior directions (five measurements for the latter). The procedure was timed from when the surgeon was provided with an audible signal to commence the procedure until they completed the fifth anteroposterior caliper measurement.

With the Durom technique, the surgeon mounted the base to the planed proximal head of the femur, mounted the adjustment elements of the jig, and positioned the guide axis according to the manufacturer's directions, using the ancillary tools (e.g. circular scribe) to identify an axis that would avoid notching. The time from beginning adjustments until the end of the final locking action was recorded. The surgeon completely loosened the jig again before repeating a trial.

2.2.4 *Measurements and data processing*

For the CAS technique, no additional measurements were made. The position of the registration tool relative to the femoral reference frame was recorded and the position of the resulting implant axis was computed as described in section 2.1. For the manual technique, the surgeon placed a tracked drill guide over the guide wire after it was locked in place, and pivoted the drill guide about the axis, allowing the system to calculate and record the axis position relative to the femur. In both cases, the orientations of each targeted axis in both the varus/valgus and ante/retroversion directions were computed, along with the resulting standard deviations. Similarly, the superoinferior and anteroposterior positions of the axes were computed in the plane perpendicular to the mean axis from each set at the level of the neck centre as determined by the caliper reading obtained from the AP approach. No comparison was made of differences in means because this was a study of repeatability, not accuracy (see reference [**5**] for accuracy results), and no pre-operative imaging was performed on the basis of which a surgical goal could be defined.

2.2.5 Statistical analysis

Differences between mean standard deviations were evaluated across the set of surgeons and between techniques using a two-tailed non-parametric Wilcoxon matched-pairs ranked-sign test. A Mann–Whitney U test was used to compare standard deviations between surgeon groups and an *F*-test to determine whether the standard deviations obtained by a single surgeon on different specimens or different surgeons on the same specimen were the same. All differences were evaluated for significance based on a p value of 0.05.

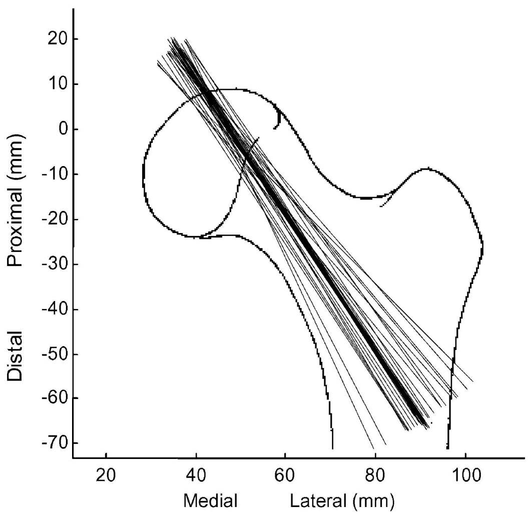
3 RESULTS

The CAS procedure resulted in significantly better varus/valgus repeatability compared to the manual procedure ($p = 0.008$). There was no significant difference in version repeatability ($p = 0.020$). Differences between the procedures are described first qualitatively and then quantitatively below.

Plotting the targeted axes for a representative surgeon from each group for each technique (Fig. 2) qualitatively demonstrates, based on the spread of the targeted axes, an improvement in varus/valgus repeatability with experience level for the manual technique but no apparent effect of surgeon experience for the CAS technique. This example furthermore demonstrates that the CAS technique is more repeatable in varus/valgus orientation than the manual technique regardless of surgeon experience.

3.1 Axis orientation

For the CAS technique, the repeatability in varus (defined as the average standard deviation across all surgeons) (Fig. 3(a)) is 1.2° (SD 1.2°), while for the manual technique the repeatability is 2.8° (SD 1.2°). For version, the comparable figures are 4.4° (SD 1.8°) for CAS and 3.2° (SD 0.6°) for manual (Fig. 3(b)). The p values for the Wilcoxon tests comparing the repeatabilities of CAS and the manual techniques are 0.008 for varus and 0.20 for version. There is considerable overlap in the ranges of repeatabilities for the two groups of surgeons (varus/valgus: 0.2–2.0° for learning (L) with CAS versus 0.7–3.6° for experienced (E) with CAS and 1.8–5.0° for learning with manual versus 1.6–4.2° for experienced with manual; version: 2.8–5.1° L versus 4.4–8.3° E for CAS; 2.6–3.5° L versus 2.3–4.0° E for manual). There is no influence of experience for either technique in either varus/valgus or version ($p > 0.05$ using the Mann–Whitney U statistic).



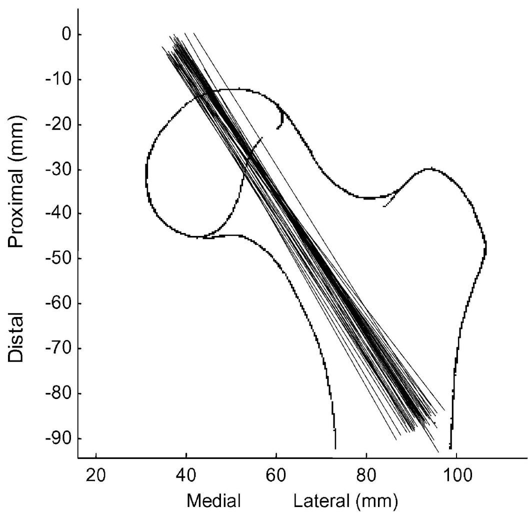


Fig. 2 Anteroposterior view of axes produced by a set of repetitions performed by a representative surgeon from the learning (left) and experienced (right) groups using the manual (dotted line) and computer-assisted (solid line) techniques. Note that the sketch of the femur's outline is solely for orientation purposes and does not represent the true outline of the specimen

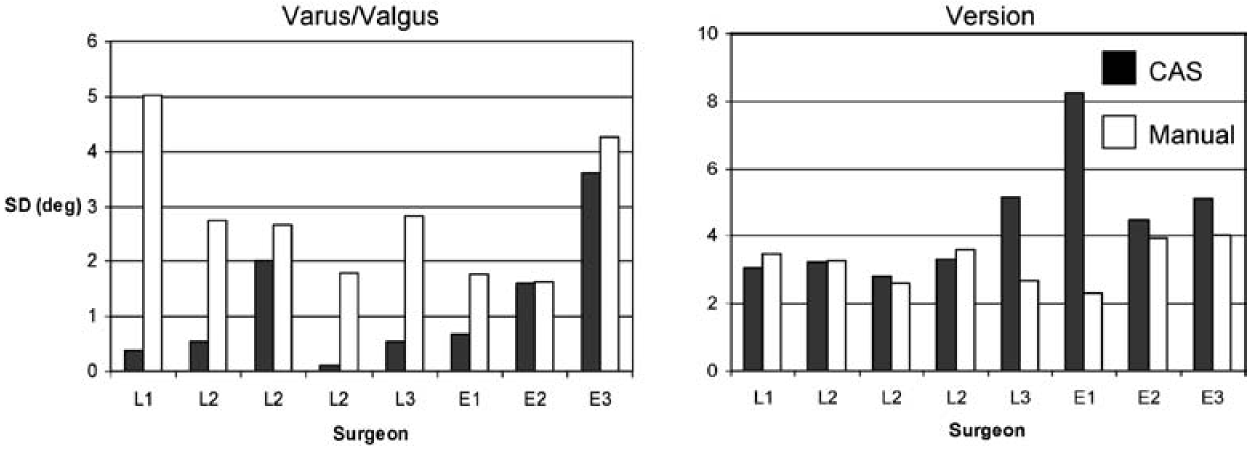


Fig. 3 Standard deviations in varus/valgus (left) and ante/retroversion (right) orientation associated with the CAS (■) and manual (□) procedures. 'L' refers to the learning group and 'E' to the experienced group

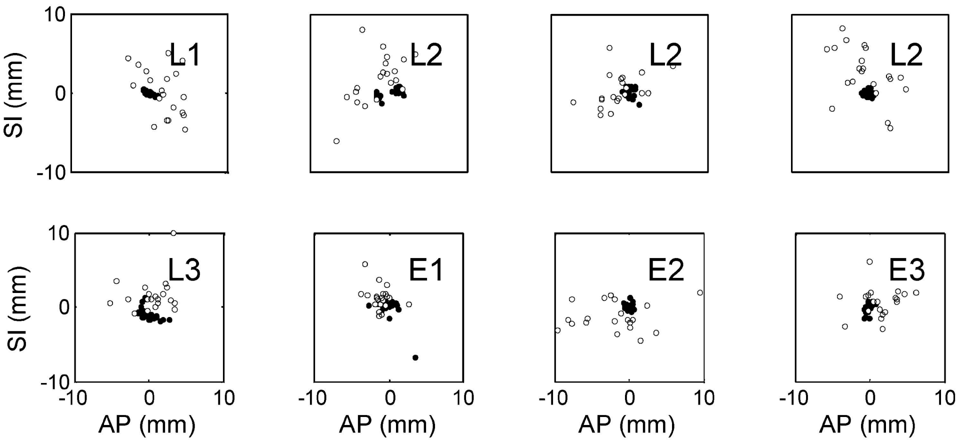


Fig. 4 Superoinferior and anteroposterior position of the targeted neck axis midway along the femoral neck associated with the CAS (●) and manual (○) procedures for the surgeons specified. Note that since no absolute standard was measured to define the neck centre unambiguously, only conclusions concerning repeatability may be drawn

3.2 Neck centre

The repeatability of the neck centre location in a plane perpendicular to the mean neck axis at the estimated midpoint of the femoral appears to be markedly better for the CAS technique than for the manual technique and to be independent of the experience level of the surgeon. Figure 5 shows the repeatability of the neck centre location on a surgeon-by-surgeon basis. For the CAS technique, the repeatability is excellent in both the superoinferior (0.6 mm, SD 0.4 mm) and the anteroposterior (0.7 mm, SD 0.4 mm). The manual technique is considerably less repeatable: superoinferior (2.4 mm, SD 0.7 mm) and anteroposterior (2.7 mm, SD 0.9 mm).

The Wilcoxon tests confirm the better repeatability of the CAS technique. The p value for CAS versus manual is 0.008 for both the superoinferior and anteroposterior directions. As with the axis orientation results, there is substantial overlap in the ranges of repeatabilities for the two groups of surgeons (superoinferior: 0.3–0.9° versus 0.4–1.4° for learning versus experienced with CAS and 2.2–3.6° versus 1.6–2.0° with manual; anteroposterior: 0.4–1.3° versus 0.4–1.1° for CAS and 2.2–2.9° versus 1.3–4.7° manual). The impression of a lack of dependence of positional repeatability on surgical experience is largely true. Although the influence of experience is significant for the manual technique for the superoinferior direction ($p < 0.05$), it is not significant in the anteroposterior direction for the manual technique nor for the CAS technique in either the superoinferior or the anteroposterior directions ($p > 0.05$ based on the Mann–Whitney U statistic).

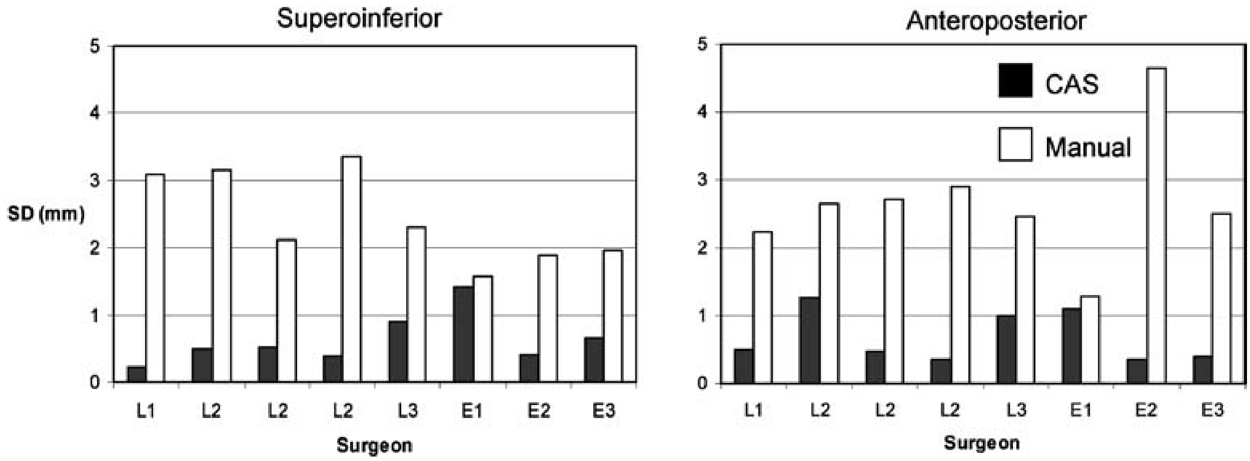


Fig. 5 Standard deviations in superoinferior (left) and anteroposterior (right) positioning at the neck centre associated with the CAS (■) and manual (□) procedures. 'L' refers to the learning group and 'E' to the experienced group

3.3 Time required

The time needed to locate the neck axis (Fig. 6) is significantly less using the CAS system (50 s, SD 9 s) than the manual technique (123 s, SD 72 s); $p = 0.008$ for the Wilcoxon test. With the CAS system, there was no significant difference in time needed for surgeons in the learning group (50 s) when compared with those in the experienced group (49 s); $p > 0.05$. With the manual system, although there was a large difference in the mean time (learning: 145 s; experienced: 86 s), there was high variability, so the difference was not significant ($p > 0.05$).

3.4 Dependence on the specimen

Surgeon L2 performed three repetitions of both the CAS and manual techniques on three separate specimens. Figures 3 and 5 show that results are generally consistent for both techniques, although the varus/valgus repeatability with the CAS system appears to be worse for the second specimen than for the first or third. The time needed to perform the manual procedure (Fig. 6) also decreases significantly each time ($p < 0.05$), although this may be a learning effect and not a function of the specimen itself.

In addition to this, one surgeon repeating both techniques on three specimens, surgeons L3, E2, and E3, all performed both techniques on the same specimen. Although it is impossible to separate out the relative effects of intra- and intersurgeon variability here, there are several significant differences between surgeons, most notably the significantly lower standard deviation that surgeon L3 achieved in varus/valgus relative to surgeons E2 and E3 ($p < 0.05$).

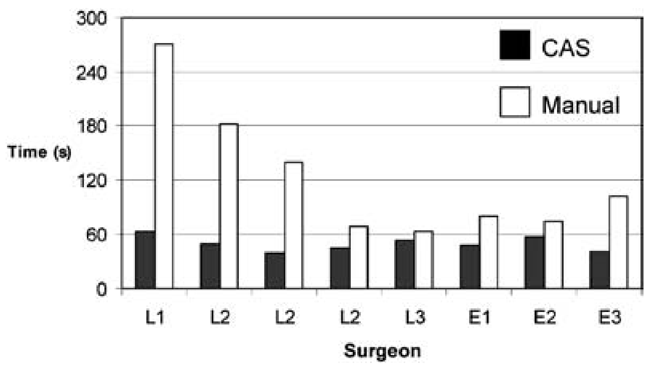


Fig. 6 Time to complete the axis aiming procedure for CAS (■) and manual (□) techniques

4 DISCUSSION

4.1 Response to research questions

In this study, the repeatability of a new computer-assisted surgical (CAS) procedure for femoral head resurfacing relative to a conventional manual procedure and the dependence of these repeatabilities on the experience level of the surgeon were assessed. There was evidence that the repeatability in determining the varus/valgus angle and neck centre location of the femoral neck axis was significantly better with CAS (1.2° versus 2.8° in varus/valgus, 0.7 mm versus 2.6 mm in the neck centre location). In contrast, the standard deviation for the current implementation of the CAS system was nominally worse than that of the manual procedure (4.4° versus 3.2°), though this difference was not significant.

Surgeon experience with hip resurfacing appeared to affect results when using the manual technique.

There was worse repeatability in superoinferior neck centre placement using the manual technique ($p < 0.05$) among novice surgeons. In addition, the surgeons in the learning group took, on average, twice as long as the experienced surgeons; although the p value was not significant, this was more likely due to the high variability between surgeons and the small number of subjects in each group than to a small difference in the mean time taken. There were no significant differences between the learning and experienced surgeons with the CAS technique, although the power of the test was low given the small number of subjects in each group.

Finally, the repeatability does seem to depend to some extent on the individual surgeon. Three different surgeons performing the techniques on the same specimen obtained significantly different repeatabilities on most measures using both the CAS and manual techniques.

4.2 Potential improvements

4.2.1 Varus/valgus alignment

Some of these results were unexpected. Given that the registration tool is based on a kinematic coupling principle commonly used in the design of precision machines, it had been expected that the repeatability of the CAS technique, particularly in varus/valgus angulation, would be excellent – on the order of a subdegree standard deviation. Indeed, this was typically the case, as evidenced in Fig. 3 by surgeons L1, L2 (first and third executions), L3, and E1. Similarly, there was excellent repeatability in neck centre targeting for all surgeons (Fig. 5). However, there was considerable variability between surgeons in some of these measures on a case-by-case basis.

Figure 7 shows an example of one of the most and least consistent distributions of varus angulations. The plot on the left demonstrates that the registration tool is able to be applied to the femur in a highly repeatable manner under some circumstances. The figure on the right shows a core set of ~ 20 highly repeatable applications of the registration tool, but it also shows that it is possible to misapply the tool a substantial portion of the time. Feedback from the surgeons suggests that the tedium of the multiple repetitions in the lab setting (the CAS portion of the experiment took approximately one hour) may have reduced the attention to detail that they would normally take in a live surgical situation. Occasional difficulties with line-of-sight issues between the camera and the marker arrays sometimes produced impatience, which again would be less of an issue if the procedure were being done only once. This particular specimen was used by three surgeons and two of these surgeons had two of the three largest varus variability measures (1.6° and 3.6°). Since one of the surgeons who used this specimen achieved excellent repeatability (0.5°), it is reasonable to conclude that the other two either did not or were not able to verify that the tool was properly applied to the bone.

To gain further insight into the source of variation, the cumulative distribution function for the varus/valgus angle for both the manual and CAS techniques was plotted (Fig. 8). The CAS results show that all

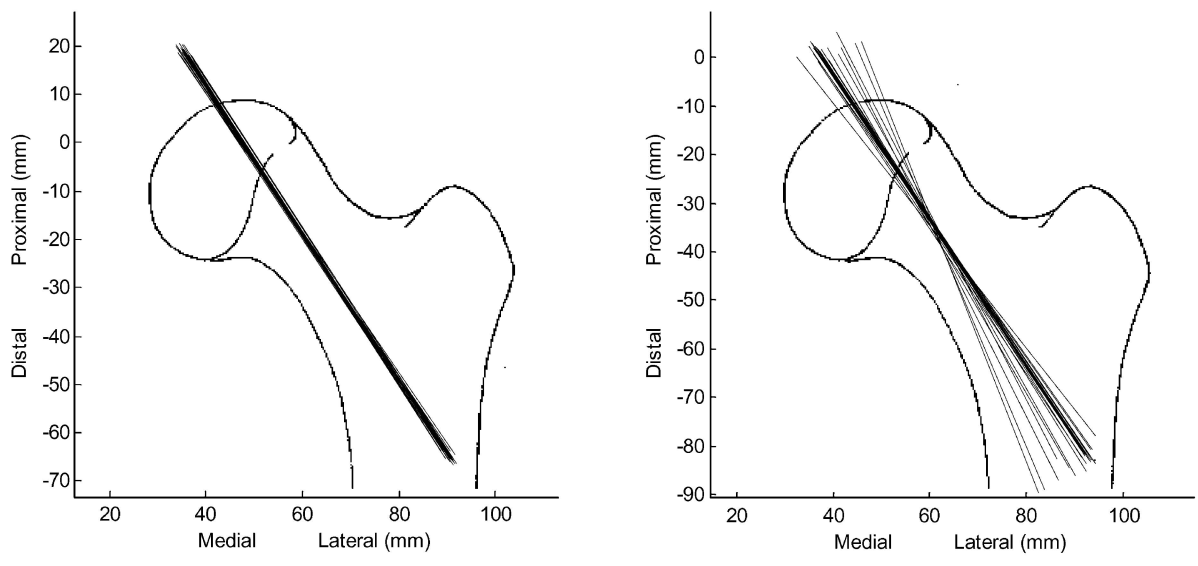


Fig. 7 Comparison of one of the most (L1, left) and least (E3, right) repeatable executions of the CAS protocol (different specimens)

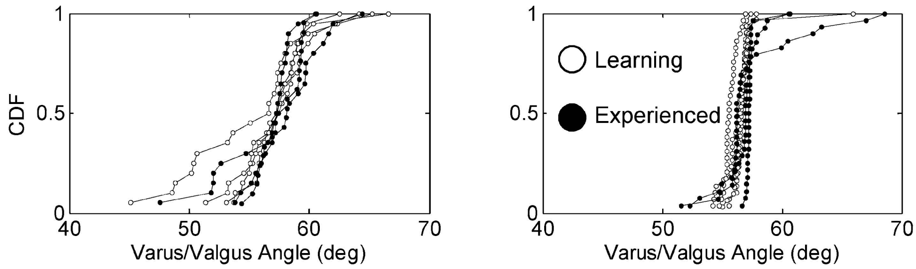


Fig. 8 Cumulative distribution functions for varus/valgus angle measured using manual (left) and CAS (right) systems for surgeons in the learning (○) and experienced (●) groups

surgeons, including the three with the largest overall standard deviations, had a substantial core of at least two thirds of their trials lying within a small fraction of a degree of the median varus/valgus angle; it appears that larger standard deviations result primarily from the presence of one or more outliers (up to about 10 outliers, or one third of the total, in the case of surgeon E3). The most plausible explanation for these outliers is that they are due to incorrect application of the registration tool to the femur, possibly due to tedium. Since several surgeons were able to use the registration tool successfully, two simple precautionary techniques could possibly largely solve this problem: (a) improved training in verifying correct application and (b) repeating the registration step (if two registrations were inconsistent, one of them would be likely to be in error, so the registration should be repeated until consistency is achieved; this is feasible because registration takes only a few seconds). This result emphasizes that CAS systems should have self-checks built in to the process as much as possible; an application confirmation indicator is recommended for incorporation in a future version of the registration tool.

4.2.2 *Version alignment*

The finding that the repeatability in version was worse than that in varus/valgus was not unexpected. The current implementation of the CAS technique calls for the surgeon to acquire five caliper readings along the length of the femoral neck. With about 30 trials in a set, this produces approximately 150 vertical lines through the neck centre of each specimen. Figure 9 shows the points where these 150 points pass through the transverse plane through the femoral neck, rotated up from the horizontal by the varus angle. This figure demonstrates that, although the points are generally close to being collinear, at any given position along the neck there can be several millimetres of anteroposterior variation in the estimated neck centre location. The results for surgeons L3, E2, and E3 show the importance of a consistent technique since all of these surgeons used the same specimen but obtained dramatically different results. If only five points are sampled, random sampling effects alone can introduce substantial variation in the resulting estimate. Furthermore, there was substantial variation in the mediolateral extent of the points sampled, ranging from a low of 5 mm in one trial to a high of over 30 mm in another.

This variation in version could potentially be reduced by refining the sampling technique using the caliper tool. In particular, if the surgeon ensures that they are taking points that are as widely separated as possible, rather than in the middle, and if they obtain multiple readings at both ends of the neck

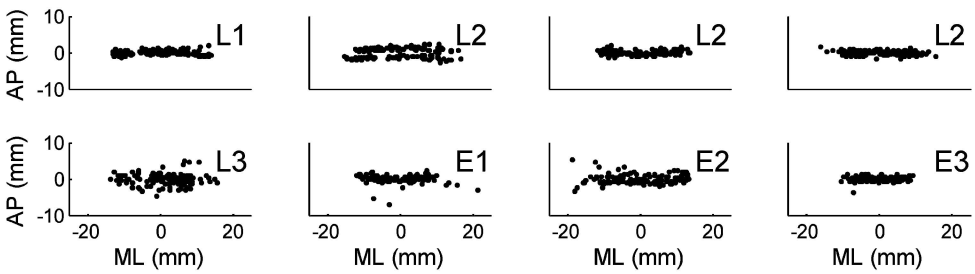


Fig. 9 In relation to the CAS technique, locations of points where the caliper midline intersects the plane through the mean target axis, which is normal to the frontal plane defined by the points of contact between the bone and the registration tool. Each subplot, labelled by the surgeon, shows approximately 150 points obtained from five femoral neck readings during each of the approximately 30 trials per specimen

and check them for consistency, they are likely to be able to reduce substantially the variation relative to the levels found in this study (although a central reading will still be needed to identify the AP position of the neck centre). Surgeon E1 had the highest standard deviation for version. Figure 9 shows that this may have been due primarily to a small number of outliers that could be easily identified intra-operatively if the acquisition were repeated and checked for consistency.

Since the general distribution of points is so linear, there is likely to be little benefit from sampling points midway along the neck because these will not contribute substantially to determining the neck's orientation. To evaluate this idea, a simulation was performed in which the 150 points from subject L1 were divided into quintiles based on the ML position; 1–10 points were randomly selected from the top and bottom quintiles, the positions averaged, and the version angle computed. This process was repeated one million times and the standard deviations of the resulting angle distributions computed. Despite the fact that the five-point sampling method produced a version standard deviation of 3.1°, simply sampling two points at either end produced a better repeatability of 2.4°, and this decreased with averaging multiple readings in the expected way; i.e. it decreased by the square root of the number of readings averaged. By obtaining four readings at each end, the repeatability improved to 1.2°. These results suggest that it would be prudent to build in repeated measurements and consistency checks into future versions of the CAS procedure.

The possibility that the natural anatomic variation in version angle relative to the line connecting the posterior aspects of the femoral head and greater trochanter is less than the variability found in this study was also considered. If true, it might be equally effective simply to select a fixed offset relative to the registration plate corresponding to the mean version angle across the patient population. CT scans of the four specimens were acquired and this angle measured. It ranged from 1.8° to 7.7°, with a mean of 5.1° and a standard deviation of 2.5°. This is more repeatable than either the CAS or the manual technique, so the idea warrants further exploration through a larger population-based study.

4.3 Implications

Overall, the results of the current study support the conclusions from the authors' earlier study [**5**] that a CAS system has the potential to improve implant alignment significantly in femoral head resurfacing procedures. As discussed above, the average repeatability of 1.2° in varus/valgus is consistent with this previous study, which showed a standard deviation of 2.2° relative to the pre-operatively defined plan. The difference between the two is likely to be due to variations introduced in measuring the desired alignment from the X-rays and during drilling of the guide wire.

The average repeatability of 3.0° in varus/valgus for the manual technique is likewise less than the 5.5° standard deviation found relative to the pre-operatively defined plan in that earlier study. Since this repeatability is equivalent to about 30 per cent of the total variance relative to the pre-operative plan, it is likely that the greatest contributor to overall variance in the manual technique is variation in intraoperatively matching the intended implant axis to the plan. This source of variance appears to be much smaller with the CAS procedure.

Despite the less than desirable repeatability results in version for the CAS system, the previous study [**5**] showed that the manual technique produced significantly retroverted results ($\sim 8^\circ$) relative to the CAS system. Since the CAS system produced a lower error relative to the pre-operative plan, this large difference suggests that the manual technique can inadvertently introduce large errors into the ante/retroversion placement of the implant. In the face of such large errors, the small difference in version repeatability is unlikely to be clinically important.

The timing results were also consistent with the previous study in which a resident using CAS took about as long as an expert using the manual system. In this study, the learning group took 50 s with CAS compared with 86 s for experienced surgeons with the manual technique, so the CAS system is, in a relative sense, even faster than was found previously, although the timings of the two studies are not directly comparable because more aspects of the mounting and targeting process were included in the earlier study. This finding of comparable or decreased time with CAS is important because CAS procedures are more likely to be accepted if they do not increase the time needed for a procedure. In the previous study, the targeting times for the manual procedure were much more variable and extended in the operating room than in the laboratory experiment, so the time benefits of using a CAS approach may in fact be understated by these results.

In the previous study, it had been concluded that the decrease in variance relative to the manual procedure when using CAS would be even more important for learning surgeons than for experienced ones, but in this study there was no significant difference found in varus/valgus repeatability between the two groups of surgeons. This may be due to the small sample size – two of the experienced surgeons had the smallest standard deviations for the manual procedure, but one had a considerably larger value. Fully addressing this point will require enrolling more surgeons in a future study. However, even if variability in the manual procedure is later found to be relatively independent of experience, the recent study mentioned in the introduction [**12**] showed that it takes even experienced surgeons many cases before they can accurately orient the implant axis, so a CAS system may well be of value to all surgeons.

4.4 Limitations

Although the number of surgeons and specimens used in this study was relatively small, several key hypotheses were falsifiable, so it was possible to show that some important differences in repeatability and targeting time do exist between the CAS and manual techniques. Despite the small surgeon sample size, there were strong hints that experienced surgeons do better with the manual technique than learning surgeons, but the experienced group has no apparent advantage over the learning surgeons with the CAS technique.

A further limitation of the current study is that it was conducted using cadaveric specimens with all soft tissues removed. Although the specimens were positioned so as to approximate operative orientations, the interactions with and constraints from soft tissue that a surgeon would normally have to deal with could not be replicated. Both surgical methods probably benefited somewhat from this. With the CAS system, it was potentially easier to appose the registration plate to the femur and to place one of the jaws of the caliper on the anterior side of the femoral neck than it would normally be intraoperatively, although the authors' surgeon consultants felt that this effect was small. With the manual jig, the participating surgeons felt that the variability could be considerably underestimated in the laboratory setting because, although they did loosen and realign the jig each time, they might be subconsciously using visual cues such as gap distances on the jig to verify that the position they chose on a given trial was similar to the previous position. In the live operating room, there is no previous reference available. In addition, in the operating room, overlying soft tissue often makes it very difficult to visualize the femoral neck axis, which is the key landmark surgeons use to align the manual jig, and the femoral shaft is invisible, so there can be no direct check of the neck-shaft angle. The participating surgeons further felt that it would be considerably easier to target neutral placement than 10° valgus; in contrast, the angle targeted is essentially irrelevant to the CAS system. For these reasons, the participating surgeons felt quite strongly that it might reasonably be expected that significantly greater variability in both repeatability and accuracy could be obtained when using a manual jig in the operating room than what was found here. The authors therefore believe that the experimental conditions used in this study tended to produce an understatement of the repeatability benefits of CAS relative to manual targeting.

In principle, it would have been interesting to have revisited the question of absolute accuracy relative to a 'gold standard' placement of the implant axis, but the question of how to define the optimal placement has not been fully resolved in the literature. For example, Muller *et al.* [**21**] proposed three automated methods for identifying the femoral neck axis, but found that manual adjustments were still required intraoperatively. The present experience has shown that pre-computing the optimal version angle on the basis of pre-operative X-rays alone remains problematic, particularly for version. It has been shown [**5**] that the CAS procedure is capable of accurately targeting a desired axis if it can be defined either pre- or intraoperatively, so this study focused instead on questions related to repeatability.

5 CONCLUSIONS

In conclusion, this study evaluated the repeatability of a novel CAS method for femoral head resurfacing and found that it offers highly repeatable varus/valgus alignment and neck centre targeting with no significant dependence on surgical skill level (in contrast to the manual technique), and the technique is likely to be performed in significantly less time than the conventional procedure. At the moment, the repeatability in achieving a desired version angle with this CAS system is sensitive to the surgeon's selection of points on the femoral neck, but promising remedies were proposed which will be evaluated more fully in future. The improved repeatability in varus/valgus alignment and neck centre targeting demonstrated here, coupled with a previous demonstration [**5**] of improved overall accuracy relative to a pre-operative plan, strongly supports the use of CAS techniques for femoral head resurfacing in the clinical setting.

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