

Original Research

Augmented reality in robotic assisted orthopaedic surgery: A pilot study



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ABSTRACT

Background: The research and development of augmented-reality (AR) technologies in surgical applications has seen an evolution of the traditional user-interfaces (UI) utilised by clinicians when conducting robot-assisted orthopaedic surgeries. The typical UI for such systems relies on surgeons managing 3D medical imaging data in the 2D space of a touchscreen monitor, located away from the operating site. Conversely, AR can provide a composite view overlaying the real surgical scene with co-located virtual holographic representations of medical data, leading to a more immersive and intuitive operator experience.

Materials and Methods: This work explores the integration of AR within an orthopaedic setting by capturing and replicating the UI of an existing surgical robot within an AR head-mounted display worn by the clinician. The resulting mixed-reality workflow enabled users to simultaneously view the operating-site and real-time holographic operating informatics when carrying out a robot-assisted patellofemoral-arthroplasty (PFA). Ten surgeons were recruited to test the impact of the AR system on procedure completion time and operating surface roughness.

Results and Discussion: The integration of AR did not appear to require subjects to significantly alter their surgical techniques, which was demonstrated by non-significant changes to the study's clinical metrics, with a statistically insignificant mean increase in operating time (+0.778 s, p = 0.488) and a statistically insignificant change in mean surface roughness (p = 0.274). Additionally, a post-operative survey indicated a positive consensus on the usability of the AR system without incurring noticeable physical distress such as eyestrain or fatigue.

Conclusions: Overall, these study results demonstrated a successful integration of AR technologies within the framework of an existing robot-assisted surgical platform with no significant negative effects in two quantitative metrics of surgical performance, and a positive outcome relating to user-centric and ergonomic evaluation criteria.

1. Introduction

The traditional design of user-interfaces has undergone significant upheaval in a variety of fields with the emergence of novel visualisation techniques such as augmented-reality (AR) and virtual-reality (VR). As defined by Sielhorst et. al [1], AR refers to a mixture of VR and the real world, in which computer-generated imagery is superimposed onto the real-world; thus 'augmenting' the real-world with holograms.

Within the medical sphere, AR has seen increased use in research, with novel display modalities developed for a variety of surgical procedures such as neurosurgery [2], laparoscopies [3,4] and arthroscopies [5,6] in order to enhance pre-operative planning, intraoperative guidance, and even provide telepresence [7].

In the field of orthopaedics for example, researchers have recently

attempted to utilise this technology to enhance workflows for Computer and Robot Assisted Surgery (CRAS) by creating or supplementing surgical setups with AR tools that provide improved information management with immersive user-interfaces in a surgical environment. Recent examples include (but are not limited to) Liu et al. proposing holographic guidance for wire-insertion during phantom hip resurfacing [8], El-Hariri et al. describing an intraoperative overlay of an augmented anatomy model based on CT data [9], and Gibby et al. who proposed an AR system to guide pedicle screw implantation [10].

Traditionally, CRAS workflows are managed via touchscreen displays attached to a system, reducing a surgeon's interactions with any data to simple window, icon, menu, pointer (WIMP) based interactions. As a consequence, a surgeon is often required to manage data of a 3-dimensional nature (e.g. volumetric models of patient anatomy) in a

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2D orientation, leading to a repeated alternation of focus between the operating site and touchscreen display, which can impair concentration in the operating-room (OR). This repeated mental coordinate transformation can create unnecessary cognitive challenges and prove cumbersome in managing 3D data in the 2-dimensional space of a monitor or display. Conversely, visualising medical data in a 3D manner has been shown to have benefits in studies such as those conducted by Traub et. al, who reported savings in time during implant screw placement tasks as a result of utilising superimposed medical imagery when compared to standard navigation techniques [1,11].

Studies examining the integration of AR in a surgical context have cited advantages including faster detection of patient vital-signs, reduced rates of physical strain, and improved visual scanning within the operating-theatre. Within learning and assembly environments, the application of AR has also demonstrated a reduction in cognitive workload when training for new tasks [12] and the capability to improve learning retention [13].

These characteristics make AR a good match for the environment of CRAS, which typically requires the use of external monitors and screens. The use of such display technology can create challenges related to mobility and visibility due to their size and sterility requirements. Fig. 1 shows a typical OR setting for minimally invasive surgery, where a clinician's line of sight and focus is transferred away from the operating site, and instead is directed to external displays. The use of AR can help transfer the line of sight and focus back to the patient by rendering data in close proximity to patient anatomy or in-situ.

This paper presents a system where a mixed-reality surgical workflow is created by transmitting information from a traditional surgical robot LCD display, and rendering it onto a virtual heads-up display (HUD) visible to a clinical user wearing a HoloLens (Microsoft, WA) headset. It was envisioned that such a system could provide a superior performance to traditional workflow-interactions by allowing surgeons to reposition a virtual workflow window in a location such that in one direct line of sight, the surgeon was able to maintain continual focus on the surgical workflow information without impairing their view of the operating site.

A further contribution of this paper is a small-scale study aimed at providing an indication of how easily the developed AR system could be introduced into a surgical workflow. Indeed, while there are many potential benefits to using AR, it is important to note that the introduction of any novel technology in the operating theatre must be handled with care, as surgeons and OR staff may need time to familiarise with the technology, and may need to adapt their surgical procedures to accommodate the new system. Bearing these factors in mind, the study addressed two research questions:

- (1) Is the introduction of AR associated with a noticeable change in surgical performance?
- (2) What indications regarding usability can be drawn from participants' individual experiences with AR?

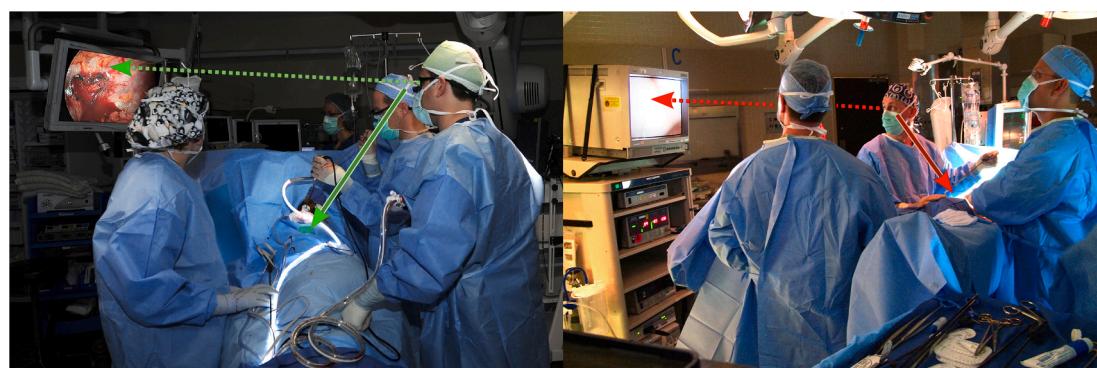


Fig. 1. A setup for minimally invasive spine surgery. A clinician's attention is spread across medical displays in addition to the operating site.

To address these questions, we recruited a group of clinicians unfamiliar with AR, who were asked to complete a simple orthopaedic procedure both with and without AR assistance. We then used two clinically relevant metrics (procedure completion time and operating surface roughness) to compare surgical performance in the two modalities and assess whether AR worsened surgical performance compared to the standard 2D touchscreen interaction. Additionally, we asked all participants to complete a post-operative survey to gather descriptive feedback on the ease or difficulty of adapting to the use of AR, which could motivate any differences in quantitative performance metrics.

2. Materials and methods

An AR system tasked with transmitting surgical instructions from a display unit on a surgical robot (NAVIO, Smith and Nephew plc.) to a virtual heads-up display (HUD) visible to a user wearing a HoloLens headset, was developed in this study. The system architecture consists of a client-HoloLens communicating wirelessly through WiFi protocol with a server PC. This setup has been tested against latency and real-time communication benchmarks in a prior study [14].

2.1. AR setup and user control

The previously constructed AR system architecture was developed further in order to replicate the surgical workflow and user-interface of a surgical robot in a mixed-reality environment. The expanded system (setup shown in Fig. 2) contained a capture card (AVerMedia GC553) attached to a DisplayPort output of the surgical robot which was utilised to capture compressed (jpeg) workflow screenshots. Captured frames were then transferred to a master server-PC via a wired USB 3.0 connection. A C# software running on the server-PC then transcoded and wirelessly transmitted image data via the universal datagram protocol (UDP, chosen to minimise latency) to a client HoloLens, where the data was decoded and processed in a C# application deployed on the HoloLens via Unity (Unity Technologies, San Francisco) resulting in a replica of the workflow onto a virtual heads-up display, as seen in Fig. 3. This system effectively untethered the surgical workflow from a fixed location (e.g. a touchscreen monitor) and enabled it to be projected onto a virtual display that could be placed anywhere in the operating space through voice-commands and gestures when utilising a HoloLens headset.

2.2. Subject information

To conduct the study, ten clinicians with varying degrees of surgical experience were recruited at the International Society for Technology in Arthroplasty (ISTA) Conference, with subject recruitment taking place between the 11th-12th October 2018 at the Queen Elizabeth II Centre in London.

Inclusion criteria for the subjects required participants to be above



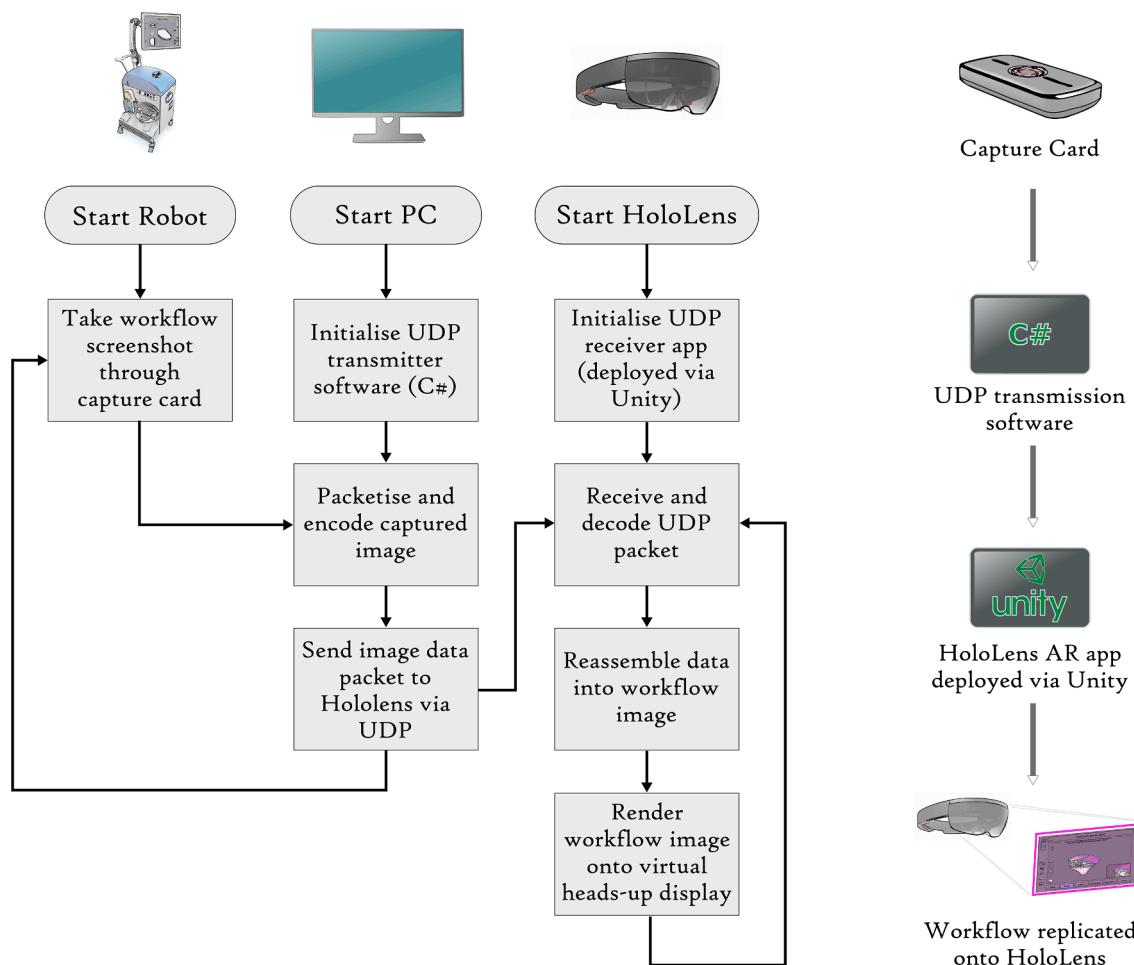


Fig. 2. AR system setup and process flowchart.

the age of 18 with an ability to provide their own consent in participating within the study. The study aimed to recruit clinicians who were at least surgical trainees, however there was no preference given to subjects of a certain level of seniority, specialisation, or with prior experience with CRAS systems. However, all subjects were recruited from a technology oriented medical conference, which should be considered when evaluating the results of this study.

Prior to the completion of trials, each subject completed an informed consent form to authorise the use of collected test data. This single-centre study received ethical approval from the Imperial College Research Ethics Committee following review from the Joint Research Compliance Office (ICREC ref: 18IC4769).

2.3. Experimental procedure

The AR-enhanced workflow was tested on an orthopaedic-centred application. Recruited subjects were requested to carry out the burring phase of a robot-assisted patellofemoral arthroplasty (PFA) on a synthetic plastic bone model of the knee joint. When compared to other orthopaedic procedures, such as unicompartmental or total knee arthroplasty (UKA and TKA respectively), the PFA procedure involved a reduced number of cuts (only burring on the femoral surface with no tibial cuts), and thus reduced operational time and the impact of a synthetic study setup on the user experience, both of which suited the time-constrained conference-based setting presented here.

Each subject carried out two robot-assisted PFA procedures; one with the standard robotic workflow, and one procedure supplemented by the AR-enhanced workflow described in Section 2.1. This approach allowed

the study to follow a 'within-subject' design model. The operating order (i.e. AR first, standard second or vice-versa) was randomly assigned a priori to trials in order to prevent biasing collected data due to training or learning-effects between trials.

As part of the setup prior to each trial, pre-operative workflow stages were carried out, including anatomical registration of the trial synthetic knee model, and implant location planning. In an effort to standardise the experimental protocol, this setup was carried out by a member of the research team, leaving the burring phase of the PFA procedure to be conducted by the trial subject. As part of the burring procedure, the femoral side of the patellofemoral surface was resurfaced to form a flat planar-surface with 3 post-holes to allow for implantation of a prosthetic insert. The operational accuracy of the robotic system employed in this study has been covered extensively within literature in both phantom and cadaveric procedures (with quoted RMS translational errors in implantation ranging from 0.61 to 1.27 mm, and mean rotational errors of implantation ranging from -0.1 to 2.43°) [15–18].

Following the completion of burring phases of the trial, subjects were left to complete a post-operative feedback form, which was utilised to qualitatively assess the usability of the AR system. Subjects were left at a separate station from the study team to complete the anonymised user-feedback forms that were subsequently collected for analysis. The following protocol was observed for each subject:

1. Test all equipment to ensure all apparatus is functioning correctly
2. Recruit participants who approach the stand and express interest and agree to taking part in the study

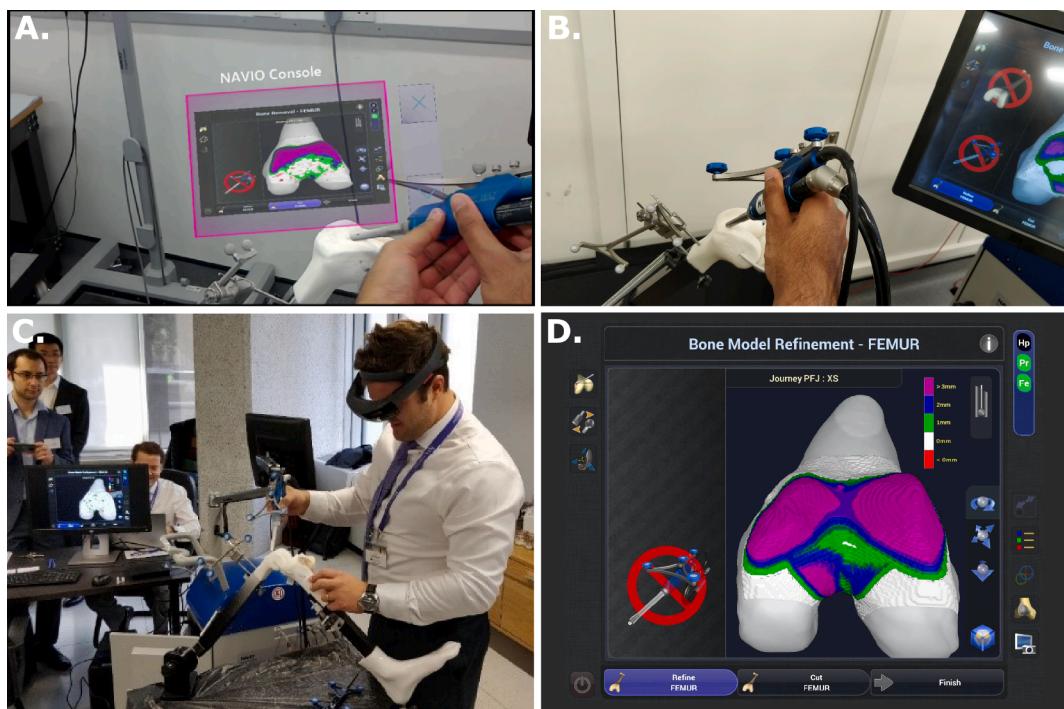


Fig. 3. (A) First-person view of AR-enhanced workflow (B) First-person view of standard workflow (C) Example of experimental setup for each subject carrying out a phantom PFA using AR-enhanced workflow (D) Screenshot of robotic navigation screen indicating regions requiring burring from one of the PFA procedures carried out during the study.

3. Use random-number generator to determine if user will use standard or AR-enhanced workflow first
4. Supply literature and answer queries regarding procedure to be carried out by participant
5. Researcher carries out surgical robot anatomical registration setup procedures on synthetic knee model
6. Participant carries out both standard and AR-enhanced procedure with the order of trials determined by Step 3
7. On completion of procedure, data-logs are downloaded from the robot to obtain data for post-processing
8. Participant is given user-feedback form to enable ergonomic evaluation of AR system
9. Next participant is brought in to repeat procedure

2.4. Outcome measures

In order to investigate the impact of the mixed-reality workflow on surgical performance, three key measures were examined. The primary quantitative measure investigated was the effect of the system on procedure-completion time as it was reasonable to assume that subjects who experienced difficulties or discomfort when using AR would require additional time to complete the procedure. Additionally, with theatre time costs representing a sizeable expenditure (between \$125-\$250 per minute [19]), any significant increases in operating time would represent a potential barrier to adoption.

In addition, it was hypothesised that the AR system could positively impact the continuity of any burring motions as a clinician could simultaneously focus on the surgical subject and virtual workflow HUD in the same field of view, potentially removing the need to pause cutting or change head position to review any workflow-related information. To characterise this phenomenon, the final surface roughness of the sculpted bone surface was chosen as a secondary quantitative measure, with more continuous resurfacing motions expected to result in a smoother operating surface.

The final measure was a post-operative survey designed to probe the usability and ergonomics of the AR workflow. The survey contained

questions on physical comfort and ease of use, whose aim was to provide subjective indications of the user experience that could motivate the presence or absence of quantitative differences between visualisation modalities. The full questionnaire is reported in [Table 1](#).

2.4.1. Outcome measure 1: Operating time

To examine the effect of AR on procedure completion time, each subject's operating time was recorded by a member of the research team. Each subject was timed between two key points; the time when bone removal began, and the time the subject verbally indicated they had completed the femoral cut based on the operating plan feedback from the surgical robot.

2.4.2. Outcome measure 2: Operating surface roughness

In order to characterise the continuity of the burring carried out, this study included a roughness metric analysing the deviation in the normal direction from the planar operating cut-surface. Consequently, the homogeneity of this achieved planar cut surface was investigated to characterise the roughness of each trial. Following completion of subject

Table 1

Statements included within the usability survey given to subjects.

	Label	Statement
Standard	A1	It is easy to understand how to interact with the workflow
	A2	It is inconvenient having the workflow screen fixed in one location
	A3	It is easy balancing my attention between the operating site and workflow
	A4	It is better to keep the workflow and operating site separate
AR	B1	It is easy to understand how to interact with the AR workflow
	B2	I experienced a distracting level of eye- and/or neck-strain when using the AR system
	B3	The ability to position the AR display anywhere was useful
	B4	I would like to use AR systems for future orthopaedic procedures
	B5	The availability of AR would encourage me to purchase/use CRAS systems in the future

trials, each trial synthetic knee model was scanned using a HDI C210 3D Scanner (Polyga, Inc., Vancouver, Canada) resulting in a surface model of each test specimen (with a scanning resolution of 0.06 mm). Each model was then imported into MATLAB (MathWorks Inc., MA). The operating surface/cut plane for each of the resurfaced specimen point clouds was then isolated by the use of the following algorithm (see Fig. 4 for illustration):

- Align the point clouds of the resurfaced specimen and an uncut synthetic bone model with an iterative-closest point (ICP) approach, utilising features that are common to both models (femoral shaft, any uncut condylar regions) to aid alignment
- Reduce size of resurfaced specimen point cloud and uncut bone point cloud by isolating a volume in a defined region of interest (ROI) corresponding to the distal femur where the operating surface is primarily located
- Boolean volumetric NAND operation with an uncut bone model to isolate regions not common to both models, i.e. those containing any resurfaced/cut bone
- Conduct distance-based segmentation to filter out cuts in trochlear groove and noise
- Conduct a rough linear least-squares plane fit to get first estimate of achieved cut-plane

- Redefine coordinate system utilising normal (z) of first cut-plane estimate
- Define new ROI and filter out points below (mean – 1.5 s.d.) in the normal direction
- Conduct least-squares plane fit on filtered point to get second, refined estimate of achieved cut plane
- Final noise-removal process to remove outliers in 3 coordinate directions using histogram analysis to remove frequency bins containing less than 1% of the total dataset.

The Computer Vision System and Curve Fitting MATLAB Toolboxes were used to obtain the estimated cut planes for each of the trials and served as a datum surface. The RMS of deviation in the normal direction from the planar datum surface was computed for each of the 20 trials to obtain measures of roughness.

2.4.3. Outcome measure 3: Post operative survey

After completing a pair of experimental trials, each of the ten subjects were taken to a separate location from where the burring occurred to individually complete a questionnaire designed to evaluate the ergonomics of the AR system. The questions evaluated the system's usability (physical comfort, ease-of-use etc.) on a five-point Likert scale (Strong Disagree, Disagree, Neutral, Agree, and Strongly Agree). In

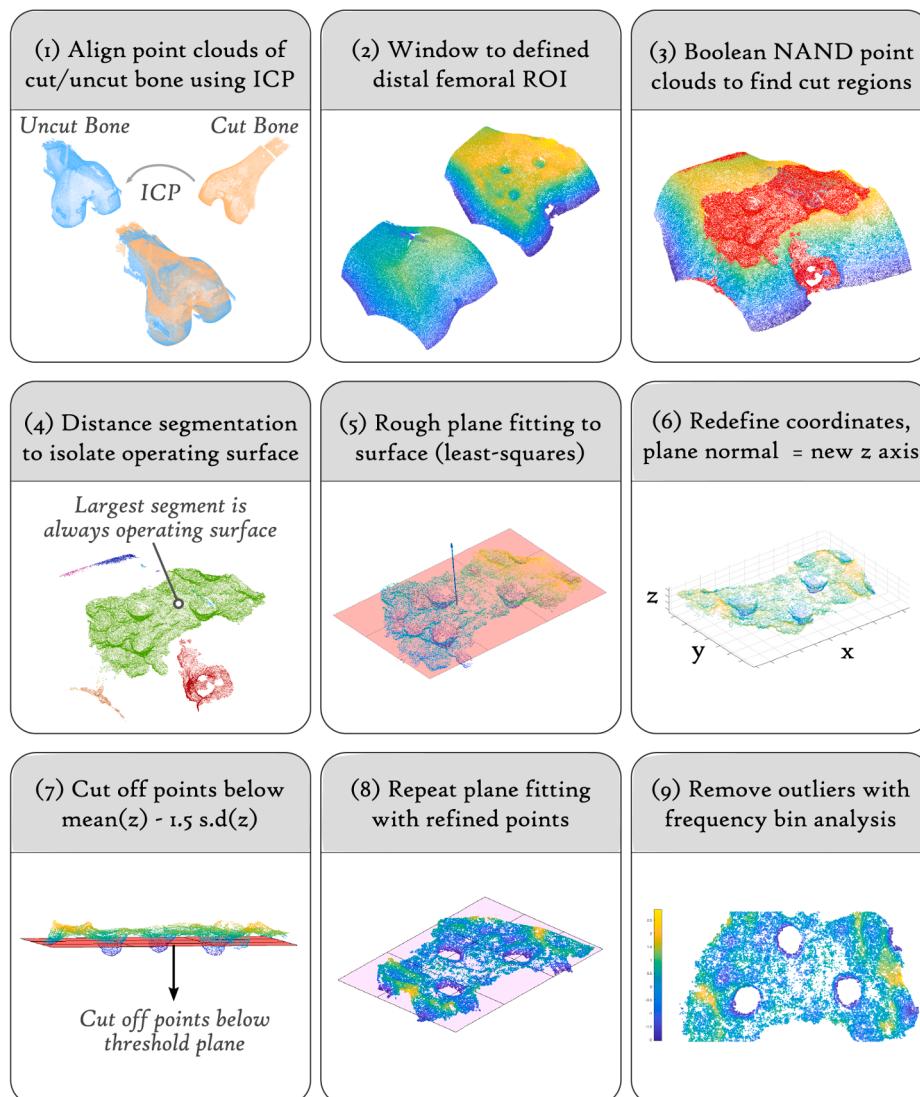


Fig. 4. Roughness cut plane estimation algorithm.

Table 2

Aggregated subject data from experimental trials.

Subject Metadata		
Age (Mean, S.D.)	41.4	12.7
Sex (Male, Female)	9	1
No. of knee arthroplasties per year (Mean, S.D.)	75	74.43
Prior experience in CAS/CRAS (Yes, No)	4	6
Current user of CAS/CRAS (Yes, No)	2	8
Total no. of CAS/CRAS procedures carried out (Mean, S.D.)	408.75	630.34

addition to the usability queries, the participants were asked to list 3 positive and negative aspects of utilising the standard and AR-enhanced procedures which served as open-ended qualitative feedback.

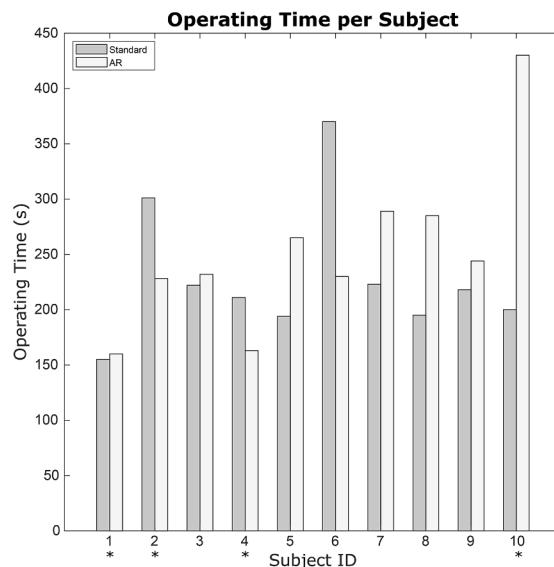
The questions from the survey were utilised to better gauge quality of user-experience when using the AR and standard systems. The survey was grouped into 2 broad categories; standard- and AR- robotic procedures. The following participant metadata was collected during each survey:

- Age and sex
- Years of experience in orthopaedic procedures
- Prior experience in navigated/computer-assisted surgery (Y/N)
- Number of navigated/computer-assisted procedures carried out
- Current user of computer/robot-assisted surgical system (Y/N)

The usability questions are included in Table 1, and the results of this survey are included within Fig. 7, Section 3.3.

3. Results

For each of the quantitative study measures, a comparative analysis was performed on each pair of trials corresponding to the 10 subjects (10 AR-enhanced, 10 standard trials). This allowed for a within-subject analysis, which could statistically investigate differences in operating time, and cut-plane roughness that were caused by introducing the AR system into a surgical workflow. Aggregated metadata regarding the subjects is included in Table 2. Within the 10 recruited subjects (9 M, 1F), 4 subjects reported prior experience of CRAS systems, and 6 had no prior experience, with the mean age of the population found to be 41.4 (s.d. 12.7).



3.1. Operating time

The operating times achieved by each test subject are included in Fig. 5, with the left- and right-hand bar series representing standard and AR-enhanced operating times, respectively, for each subject. The four subjects who had previous experience with CRAS systems are highlighted in Fig. 5. Summary statistics of the same data are reported in Table 3.

Interestingly, while five participants out of six who had no previous experience with CRAS required more time to complete the AR trials (median time cost 40.5 s), no pattern emerged among the four participants with previous CRAS experience, with two requiring more time in the AR trial, and two requiring more time in the standard trial (median time cost -11 s).

Examining the data indicated a possible anomalous data point, as subject 10 exhibited a noticeable training effect in their data. This subject demonstrated a noticeable improvement in performance; where their second attempt at using the surgical robot (standard procedure) took significantly less time than their first trial (AR-enhanced procedure). This subject's time cost (defined as $AR_{time} - Standard_{time}$) of + 230 s was found to be 3.56 median absolute deviations (MAD) outside the population median time cost (10 s), highlighting this as an outlier ($outlier(X) \geq median(X) + 3 \times MAD(X)$), and thus the data point was treated as an outlier and removed from further calculations.

The operating time data was then investigated to explore if utilising AR introduced a statistically significant time-cost. To achieve this, the time-cost was calculated for each subject and a one tailed paired *t*-test was conducted on the mean time-cost, which was calculated as + 0.778 s (Table 4). The time-cost data was verified to be normally distributed with a QQ plot.

The results of the *t*-test showed this mean time-cost had an associated p-value of 0.488, which was not significant when compared to the pre-set significance level of 5%. Thus, this data suggested that there was no statistically significant time-cost associated with integrating the AR system within the surgical workflow.

3.1.1. Assessing training effect on operating time

Following the detection of an outlying time-cost value within the dataset (when utilising the median absolute deviation), a statistical test was carried out to formally assess if there was a significant reduction in cutting time between each subject's first and second trials. The objective of this test was to verify if the training-effect and order of presentation

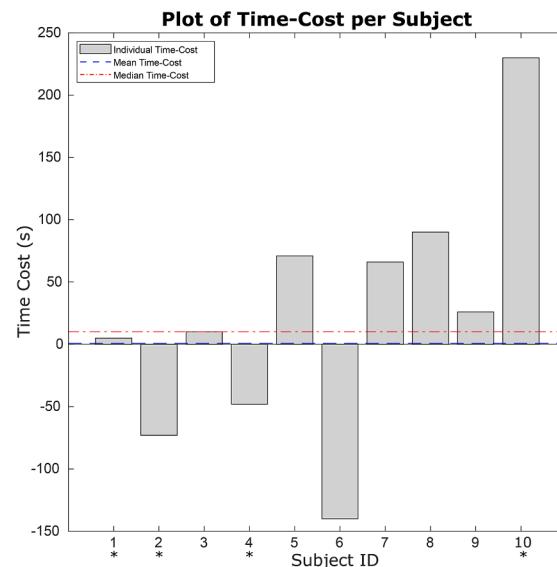


Fig. 5. (L) Operating times for standard and AR-enhanced procedures for each subject (R) 'Time-cost' per subject (anomalous data point of subject 10 has been left in for illustrative purposes). In both figures, subjects with prior experience in CRAS are highlighted with asterisks below their subject IDs.

Table 3Aggregated operating time data for subjects.²

	Standard Operating Time (s)	AR-Enhanced Operating Time (s)	Time Cost (s)
Mean (s)	232.11	232.89	0.778
S.D. (s)	64.58	46.43	75.44
Median (s)	218	232	10

² Aggregated data for subjects 1–9, with anomalous data point 10 excluded from mean, median and s.d. calculations

Table 4

Operating time–cost statistical test results.

Operating Time-Cost	
Mean Time-Cost (μ_{TC})	+0.778 s
Null/alternate hypothesis	$\mu_{TC} = 0, \mu_{TC} > 0$
P Value	0.488, ($\alpha = 0.05$)

Table 5

Results of statistical test of training effect.

Change in Cutting Time ($T_2 - T_1$)	
Mean Change in Cutting Time ($\mu_{\Delta T}$)	-6.111 s
S.D.	75.162
Null/alternate hypothesis	$\mu_{\Delta T} = 0, \mu_{\Delta T} < 0$
P Value	0.407, ($\alpha = 0.05$)

(standard vs AR-enhanced) was a statistically significant phenomenon associated with the entire study population. To achieve this, the difference in cutting time between each subject's first (T_1) and second (T_2) trial was calculated, and subjected to a one-tailed paired *t*-test. The details and result of this test are included within Table 5.

The results of this test indicated a mean decrease in cutting time of 6.111 s, with a p-value of 0.407. This was not significant in comparison to the pre-set significance level of 5%, which suggested there was no significant reduction in cutting time detected between trials in the study population.

3.2. Operating surface roughness

For each trial, a surface roughness metric was calculated by comparing a point cloud of the operating region with the estimated cut-plane (obtained via the algorithm illustrated in Fig. 4). The deviation in the normal direction from the cut plane was taken for each vertex within the operating surface point-cloud, following which an RMS value of deviation was taken in order to gauge an 'average roughness' metric for each trial. The results of this process are illustrated in Fig. 6 (with the figure highlighting subjects who declared previous experience in CRAS), which shows colour-maps corresponding to the deviation of each operating surface. The roughness data of the subject corresponding to the anomalous data point described in Section 3.1 was not included when characterising any descriptive statistics or carrying out statistical tests to maintain a consistent approach to data analysis between the roughness and time–cost datasets.

The difference in roughness between the standard and AR-enhanced cases for each subject was calculated, with the mean of this result included in Table 6. The mean difference in roughness was investigated to verify it was normally distributed, and then statistically tested utilising a paired *t*-test (two-tailed as directionality was not being investigated). This resulted in a p-value of 0.2742, which was not significant when compared to the pre-set significance level ($\alpha = 0.05$) which suggested that there was no statistically significant change in the

roughness of the operating surface when the AR workflow was employed instead of the standard workflow. When examining participants who had prior experience in CRAS, three of the four subjects had a small increase in the roughness metric corresponding to the AR procedure when comparing to the standard procedure (mean increase of roughness metric: +0.260 mm). Within the remaining six subjects who reported no prior experience in CRAS, there was an even split of 3 subjects with increases and 3 with decreases in the roughness metric when comparing the AR procedure to the standard (mean increase of roughness metric: +0.0568 mm). The small magnitude of these changes alongside the result of the statistical test overall appeared to indicate no significant changes of the roughness metric between the AR and standard workflows.

3.3. Post operative survey

Each of the subjects' survey responses to the questions contained in Table 1 were transcribed to map answers to a discrete number (1 – Strongly Disagree, 2 – Disagree, 3 – Neutral, 4 – Agree, 5 – Strongly Agree), which allowed each answer to have a Likert style 'score'. The survey data was collated to produce the plot in Fig. 7, which illustrates the distribution of answers and the average Likert score for each question.

Overall, subjects' responses indicate that both the standard and AR-enhanced workflows were found to be easy to use. Regarding the use of AR specifically, participants' answers to questions B1 and B2 indicate that they found the AR workflow easy to use and did not experience a distracting level of eye/neck strain. These answers suggest that while the AR system was unfamiliar to the subjects, they found it intuitive and easily adapted to its use, which may explain the lack of a significant difference in operating time and surface roughness (see Section 3.1–3.2) between the two visualisation modalities. Furthermore, subjects' answers to B3 and B4 indicate a preference and perceived benefit for the use of AR in orthopaedic surgery.

When characterising ease of use of the two systems (A1, B1), both experienced and novice users scored the usability of both the standard and AR-enhanced interfaces with an average Likert score of 4.3 and 4.4 respectively, indicating a strong and similar level of agreement that both systems were easy to use. Subjects presented a neutral opinion on keeping workflow information in a fixed space away from the operating site (A2), with no distinguishable preferences observed in the novice and experienced users. Subjected agreed with an average Likert score of 3.7 that it was easy to balance attention between the operating site and workflow monitor (A3). Despite this, most subjects disagreed that it was better to keep workflow information in a separate physical region from the operating site (A4).

The findings also indicate that the AR elements of the system add value to the process (B3, B4) without causing a noticeable level of neck and eye strain (B2). The responses obtained through this survey also indicated that participants found the AR system intuitive and easy to use (B1). These findings are summarised and linked with each survey question in Table 7.

4. Discussion

This paper presented a novel augmented reality surgical workflow for use in orthopaedic surgery, as well as the findings of a study designed to assess the impact of introducing AR visualisation within surgical workflows. The impact of AR was evaluated on the basis of two clinically relevant outcome measures (operating-time and surface roughness), which together with a post-operative survey examining usability, showed that the use of AR was highly intuitive and did not have any negative repercussions on surgical performance. This section reviews the results obtained and discusses their broader implications. This section also briefly highlights how AR tools can be utilised in a wider context; both within surgical applications and general medical

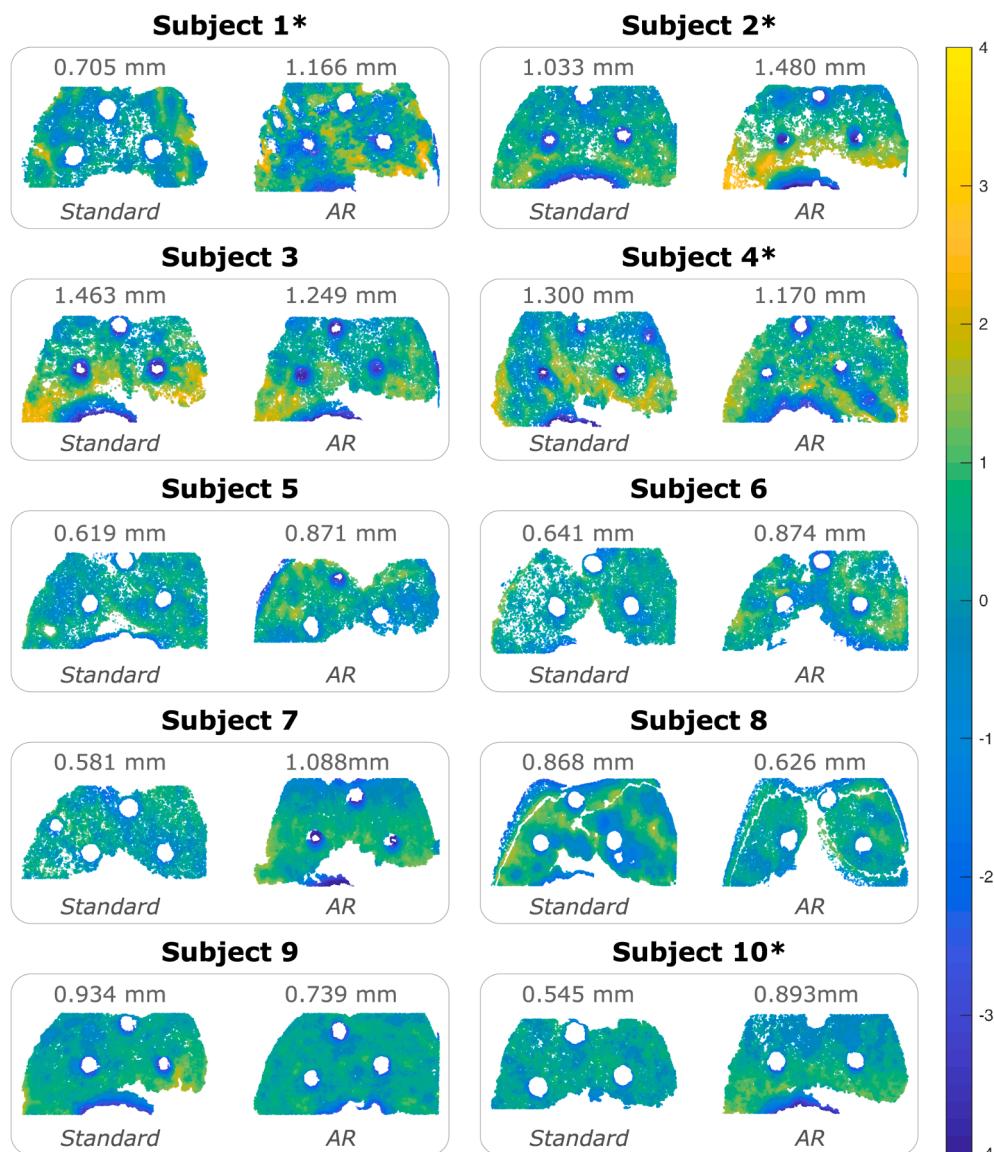


Fig. 6. Contour maps of cut-surface for each trial, colour indicates deviation (mm) in the normal direction from estimated cut plane per subject trial. Each contour map contains a data label of the mean deviation in mm. Subjects with prior experience in CRAS are highlighted with an asterisk symbol.

Table 6
RMS roughness metric aggregated data and statistical test results.

RMS Roughness Study Data		
Standard Procedures	Mean RMS roughness metric	0.869 mm
	S.D. of RMS roughness metric	0.316 mm
AR-Enhanced Procedures	Mean RMS roughness metric	1.016 mm
	S.D. of RMS roughness metric	0.259 mm
Statistical Test for Change in RMS Roughness Metric		
Mean change in roughness metric ($\Delta\mu_R$)	-0.124 mm (S.D. 0.476 mm)	
Null/alternate hypothesis	$\Delta\mu_R = 0$, $\Delta\mu_R \neq 0$	
P value	0.274, ($\alpha = 0.05$)	

applications. The section concludes with some lessons learned as a result of conducting this study.

4.1. Operating time

As highlighted in Table 4, the mean time-cost generated with the use of the AR system was + 23.7 s. This figure was likely to have been skewed by the large time-cost incurred by Subject 10. This subject exhibited a noticeable training effect; where their second attempt at using the surgical robot (standard procedure) took significantly less time than their first trial (AR-enhanced procedure). Despite this skewing effect, the mean time-cost represented a statistically insignificant result ($p = 0.24$). The mean-time cost can also be contextualised as a percentage of the mean and median operating times, 9.84% and 10.5% respectively. When comparing time costs of subjects with their prior experience in CRAS, there was no clear pattern that emerged indicating

Questionnaire Responses

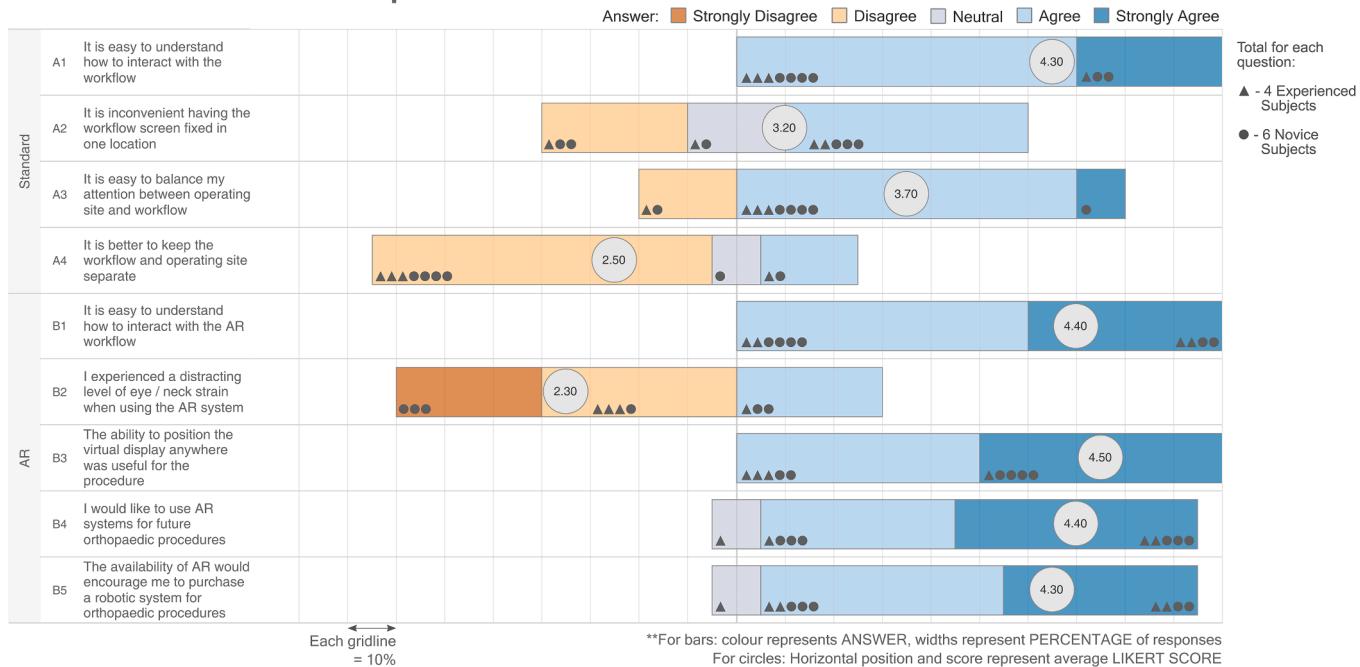


Fig. 7. Plot of questionnaire responses. Each stacked bar is coloured by response category, and sized by proportion of responses. Circular labels indicate average Likert score and are horizontally positioned based on average Likert score. Each stacked bar contains symbols showing a breakdown of the demographics for each answer. Every question contains a total of 10 symbols (corresponding to 4 users with prior experience in CRAS, and 6 novice users without prior experience in CRAS).

Table 7
Questionnaire responses and analysis.

Question	Mean Score	Findings
A1	4.3	Both novice and experienced subjects mostly agreed that the standard, robotic workflow is easy to use
A2	3.2	On average, subjects have a neutral opinion on having the workflow monitor fixed in one physical location, with a mixture of responses in both groups
A3	3.7	Subjects mostly agreed across both groups that it is easy for them to balance their attention between the standard workflow monitor and physical operating site
A4	2.5	The majority of subjects in both groups mostly disagree with the notion of keeping workflow information and the patient/operating site in separate physical paradigms
B1	4.4	Subjects had a unanimously positive response (split agree/strongly agree) indicating they found the AR workflow easy to interact with
B2	2.3	In both groups, subjects on average disagreed with the suggestion that they experienced a distracting level of eye/neck strain resulting from the AR system
B3	4.5	Subjects in both groups unanimously agreed that the functionality of an untethered virtual HUD was useful for the procedure
B4	4.4	On average, subjects agreed/strongly agreed that they would like to utilise AR system for future orthopaedic procedures. 1 experienced user out of the 4 was neutral on this question, with the remainder of the group agreeing or strongly agreeing.
B5	4.3	On average subjects agreed that they would be more likely to adopt or purchase robotic systems if bundled with AR technology. Besides one novice user providing a neutral response, the rest of the expert and novice users provided positive responses to this question.

significant differences in operating time between the standard and AR-enhanced procedures. A post-hoc power analysis indicated when comparing to a time cost of 60 s ($d = 0.78$), which corresponded to a 26.2% and 27.9% increase with respect to the mean and median standard operating times respectively, the statistical power of this measure was calculated to be 0.701.

These findings provide an encouraging result which appears to suggest the AR-enhanced system does not introduce a significant increase in operating time; an important factor when taking into account costings associated with theatre time and operative exposure time. Prior studies examining AR for task-learning have indicated the prevalence of shortened or parallel learning curves when training manual tasks [12,20], which provides an indication that the time-cost associated with AR in a surgical environment can potentially be further reduced.

4.2. Operating surface roughness

As shown in Table 6, operating surfaces of the study population had a mean deviation of -0.124 mm. This deviation result was not statistically significant ($p = 0.274$), indicating there was no significant change of the roughness metric as a result of using the AR system. As with operating time, there were no clear patterns in the roughness metric observed that corresponded to differences in experience with CRAS.

Part of this study examined roughness as an outcome, as it provided a unique method of characterising the surgical performance of each subject. As previously discussed, it was originally hypothesised that the mixed reality workflow would lead to a lowered roughness metric as the subject would be able to focus on virtual workflow information and the physical operating site in the same field of view without repeatedly altering head position and stopping bone-removal. A post-hoc power analysis of the surface roughness was carried out, and compared to a

mean surface roughness change of 0.5 mm ($d = 0.79$). The statistical power of the non-significant change in operating surface roughness was calculated to be 0.698.

Throughout the course of the investigation, it became apparent that this phenomenon may have carried over to the standard workflow, as some subjects chose to focus on the physical monitor for the duration of their procedure and neglected physically looking at the operating site while cutting bone. Future studies could investigate this behaviour further by tracking head rotation along the longitudinal axis of the neck for the duration of similar procedures in order to examine if this has influence over the final roughness of the operating surface.

Contextualising this result with prior literature proved challenging, as previous studies indicate surface roughness metrics are not traditionally utilised to characterise clinical performance in orthopaedics. A likely contributing factor to this is the expanding nature of bone cements during implant fixation where the mechanism of adhesion works to create a mechanical interlock between prostheses and cut bone [21] and as a result, voids left in the bony surface are filled, smoothing any rough surfaces. Alternatively, surface roughness characteristics of prosthetic implants have been investigated in a variety of studies to characterise their biomechanical performance and fixation based on the material properties of the implant [22].

4.3. Post operative survey

The findings of the post-operative survey (see Fig. 7) were used to characterise the ergonomic performance of the AR system. The results indicate that this study population had positive opinions on its functionality and usability, indicating an openness for adoption of AR technology in surgical robotics by a clinical audience.

Some of the key findings included in Section 3.3 indicated that experiences and novice users found both the AR and standard workflows were both easy to use during the procedure. Crucially, the survey results indicated participants found value in using AR (B3, B4) without experiencing physical distress through a noticeable level of neck and eye strain (B2). When coupling the insights gathered from the survey with the findings from the quantitative outcome measures, it appears that participants did not have to significantly change their surgical technique between the two procedures, and thus were not noticeably disrupted or impaired when using AR. When considering these factors alongside the fact the study participants were using this AR system for the first time, the overall positive consensus and performance of the subjects represents an encouraging indication that introducing AR did not negatively impact the study population's performance and experience.

Encouragingly, these findings suggest the participant group of surgical clinicians have an enthusiasm for adopting similar technology in the future of orthopaedic robotics, with all the experienced users agreeing or strongly agreeing with the idea of adopting AR technology for future procedures. These findings appear consistent with previous studies which have shown high levels of engagement and user-satisfaction by clinicians when utilising AR in both training and performing minimally invasive surgery tasks [23,24].

4.4. The role of AR within medicine and surgery

Overall, whilst the sample size of this study is not large enough to infer strong conclusions, the results obtained encouragingly suggest a minimal level of disruption caused when AR was introduced into the surgical workflow used in this study. When considering the general research questions outlined in Section 1, utilising the AR system in this setup did not appear to noticeably impair or impact the performance metrics with regards to operating times or surface roughness. Additionally, the post-operative survey provided a widely positive consensus regarding the usability of the AR system from a study population comprised of first-time users of the AR-system. The AR setup presented in this study; a tagalong virtual heads-up display, can be easily adapted

to other surgical platforms that use multiple displays to aid information management in the operating theatre, as it duplicates the output video stream of a surgical robot (see Fig. 1), which enables it to be a platform-agnostic tool. Given the benefits of AR technology within surgery are continually investigated without causing disruption to medical procedures, its use in mainstream orthopaedic procedures can be expected to continue increasing in the future, with systems beginning to transition from a laboratory setting and gaining approval for use in the operating theatre [25].

Whilst AR technologies can pose an advantage in offering localised and adaptive intraoperative guidance cues in surgery when compared to standard display techniques, there are challenges to consider with its use in surgical settings. The highly controlled environment of an operating theatre will require headsets to be used in a sterile manner, a constraint which can prove challenging if the surgeon is expected to wear protective equipment such as a surgical helmet or face-visor alongside a head-mounted display. Additionally, medical software and technology is highly regulated to ensure a high standard of reliability and robustness in use, so any AR systems will need to adequately address any performance issues that may be related to battery life, network dropouts, and general software stability. If AR systems utilise tracked holographic content which is overlaid on the operating site, the AR system utilised will need to ensure any tracking algorithms used to track patient anatomy and self-locate the headset are reliable and can precisely maintain rendering locations of holographic content. Additionally, further research is required to fully characterise the possible impact of perceptual conflicts in extended surgical use, such as focal rivalry and vergence-accommodation conflict which can lead to users struggling to optically focus on virtual content [26]. Perceptual conflicts such as these can lead to physical side effects associated with the use of AR/VR such as eyestrain and visual fatigue which may impair a surgeon's performance and focus. Beyond physical strain, AR systems can potentially negatively impact surgical performance and procedures through inattentional blindness [27] if users do not balance their attention between real and virtual content sufficiently. The impact of such potential drawbacks of using AR clinically warrant further investigation and represent potential topics for future researchers to focus on to determine the viability of the long-term use of AR tools in surgical settings.

Outside of a surgical context, AR technologies can provide benefits in various stages of practicing medicine before arriving at the operating theatre. Due to its immersive nature, educational applications of AR typically provide a more interactive method of visualising and studying human anatomy using medically accurate models of patient data [28] that students can directly interact with in mixed-reality environments. Robinson et al. tested the efficacy of an AR teaching tool and observed an improvement in assessment scores after the introduction of AR tools when teaching a medical cohort about respiratory anatomy at both a gross (3D holographic models of the lung) and micro scale (2D AR models of enlarged microscopic slides) [29]. Additionally, as AR can allow interaction with 3D models, it can offer an alternative to traditional learning experiences such as cadaveric specimen observation and dissection, which can be affected by sourcing issues and space limitations [30].

AR tools within medicine are suited to visualising patient specific data (e.g. CT/MRI scans etc.) in a 3D setting as opposed to a traditional use of monitors or screens. Research within this area has typically focused on tools that allow for AR-based visualization in pre-operative planning [2,3]. As AR does not obscure the natural environment unlike VR, it can allow for clinicians to view a patient as well as any holographic content in a merged surgical scene [31].

AR systems have also been developed for telemonitoring applications where a secondary user can remotely monitor a clinician or patient. An example of such a tool is detailed by Davis et. al [32] where an AR system enabled an expert to provide remote surgical assistance to an operating clinician. Outside of a surgical environment, Sutherland et. al have implemented a collaborative environment where healthcare

experts from different locations can inhabit a shared virtual workspace to interact with shared medical data[33]. The benefits of telemonitoring setups leveraging AR and mixed reality have gained additional relevance in settings where it is important to minimise the exposure of clinicians and patients to infectious diseases, with a study by Martin et al. showing a reduction in time exposed to harm for staff observing and caring for COVID-19 patients alongside a reduction in the use of PPE while maintaining a high level of collaborative work and quality of care across a medical team [34]. Finally, collaborative AR tools can also have a variety of possible use cases for non-technical skills training such as training situational awareness through attending virtual clinics and procedures.

4.5. Future work

With regards to the AR system presented in this paper, future work will explore fully exploiting AR technologies by moving from the application of screen replication towards custom designed holographic 3D objects that can provide localised, overlaid surgical guidance-cues on the operating site, allowing a clinician to visualise patient specific data (e.g. tissue scans, surgical plans etc.) while maintaining focus on the surgical site. Primary work has been conducted that can allow co-located holographic content to be generated in the surgical scene [35], with a view to target orthopaedic applications of AR in future work.

4.6. Lessons learned

Through conducting this study and evaluating its findings, it was possible to collate some key takeaways and the lessons learnt by the study team which may be useful to consider when conducting future research related to the use of AR in medical applications.

The AR module described in this study (see Fig. 2) predominantly carried over the 2D interface into a head-mounted display, and whilst it allowed test subjects to interact with the user-interface of a surgical robot in a mixed reality environment, it did not alter how the subjects interacted with the underlying patient data such as patient scans, as this was still displayed on a 2D monitor, albeit a holographic one. This created an AR experience that was analogous to existing display methods, and thus did not incur significant training or setup time when using the AR system. A helpful by-product and lesson learned here was that using an AR tool that replicated standard methods helped increase the efficiency of recruiting and conducting tests with 20 procedures (10 subjects, 2 procedures each) over a short period of two days.

In contrast, whilst there was no significant increase in operating time (as described in Section 2.4.1), recorded from using the AR tool in this paper, it is equally valid to interpret this result to say there were no gains or reductions made in operating time. As discussed in Section 4.4, there is value in using 3D display methods in AR in an educational setting, so a logical step for future research may be to explore if similar value can be obtained when using 3D holograms to display patient data in AR assisted procedures. The lesson learned here was that there were no significant performance gains observed from simply porting the standard surgical user-interface into an AR environment. Future iterations of this work could investigate combined surgical scenes which allow a clinician to view 3D holographic content registered onto a patient's anatomy to investigate if a more immersive AR experience can lead to any observable gains in performance.

The usability and ergonomics of the system were explored through the post-operative survey in Section 3.3. The AR system described in this study was presented through a head-mounted display, as opposed to alternative display methods such as screen-based displays or mobile devices. As discussed in Section 4.4, some key disadvantages associated with the use of AR include unwanted physical side effects such as nausea and eye strain. However, the findings of the post-operative survey which investigated this area (detailed in Table 7, entry B2) showed that subjects mostly disagreed when asked if they experienced distracting levels

of eye or neck strain when carrying out their test procedures. Additionally, all 10 test subjects were able to carry out their procedures to completion and without interruption without being impaired by such side effects. However, the duration of the procedures was on average 230 s (see Table 3), so extended usage of the AR system could further induce eye strain through longer periods of focus on the virtual content, or an increased risk of neck strain through longer time periods of wearing a head mounted display, as the form factor of modern displays is still relatively bulky¹. Therefore, a final lesson learned from this study's findings was that over short timeframes, investigating AR content rendered through head mounted displays did not appear to induce any neck or eye strain.

5. Conclusion

The findings of this study provide a promising indication that AR can prove a useful tool to augment CRAS procedures. Through a post-operative survey, the utilisation of an AR workflow was identified as useful in carrying out a simulated PFA by this study population, and did not cause a noticeable amount of physical distress or strain. However, with extended use, the bulky form-factor of the current generation of head-mounted displays can lead to neck strain, which may need consideration in future studies.

The perceived benefits of AR highlighted in the post-operative survey did not appear to come at a cost of lengthening the operating-time, with a reported average increase of + 0.778 s in procedure completion; a statistically insignificant result. As the entire study population were first-time users of the AR system, this is a promising finding which suggests that users were able to quickly adapt and learn to use the system during their PFA procedures. In terms of instrumentation costs, the current generation of AR head-mounted displays typically range in prices between \$800 – \$1500, with numbers likely to fall in future years due to economies of scale. This price range represents a small percentage of the investment required for a CRAS system (in the range of hundreds of thousands to millions of US dollars). Therefore, it is not envisioned that cost will represent a significant barrier for entry in equipping existing CRAS systems with AR or mixed reality setups.

The classification of operating-surface roughness did not provide significantly detectable changes in performance between standard and AR trials. However, the methodology proved successful in isolating operating surface for all 20 cases in this study and could prove useful in future studies as an alternate measure for characterising surgical performance and focus across procedures and sculpting technologies.

Within the constraints of this study design, the statistical power of the two measures obtained were 69.8% and 70.1% for the surface roughness and operating time respectively. This leaves room for improvement which could be addressed and improved in future studies with a larger sample size. Alongside this, there are further study limitations to consider which are listed below:

- The study was statistically underpowered due to a small sample size.
- The PFA procedure carried out is not as commonplace or complex as alternative orthopaedic procedures such as total or partial knee arthroplasties.
- The study was conducted and carried out in a controlled setting which is a less challenging environment to deploy AR to when compared to a standard operating theatre.
- The PFA procedure was carried out on plastic bone, which presents fewer challenges in burring than real tissue and bone.
- The study survey was a preliminary method for qualitatively evaluating the AR system which could be improved in future iterations

¹ HoloLens 1 (579 g), HoloLens 2 (566 g) <https://4experience.co/hololens-2-vs-hololens-1-whats-new/>

with standardised questionnaires, detailed interviews, and user walkthroughs.

Overall, these findings add to a growing body of literature which indicate AR has the potential to add value in various ways to medical robotics and minimally invasive surgery. This work represents an initial investigation to bring a commercial mixed-reality surgical experience to clinicians. Future work will consist of examining the impact of co-located, in-situ holograms in guiding and aiding the surgeon in assisted orthopaedic procedures.

6. Ethical Approval

This single-centre study received ethical approval for the design of its study protocol and informed consent forms from the Imperial College Research Ethics Committee following review from the Joint Research Compliance Office (ICREC ref: 18IC4769).

7. Consent for publication

Consent was obtained from subjects via informed consent forms for inclusion of anonymised data within any published manuscripts. Consent has been obtained from members present in the use of the photograph in Fig. 3C.

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CRediT authorship contribution statement

Hisham Iqbal: Software, Investigation, Writing - original draft. **Fabio Tatti:** Investigation, Writing - review & editing, Supervision. **Ferdinando Rodriguez y Baena:** Funding acquisition, Supervision, Writing - review & editing.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary material

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jbi.2021.103841>.

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