The Surgeon's Experience with Head-Mounted Augmented Reality in Orthopedic Trauma Surgery

MSc Thesis

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- MSc Thesis -

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Preface and Acknowledgements

With this MSc Thesis, my seven years journey at the Technical University of Delft comes to an end. My enthusiasm for the medical world and clinical practice, as well as my interest in technological innovations were perfectly combined in the BSc 'Klinische Technologie' and MSc 'Technical Medicine'. I enjoyed the study and especially the internships during the last two years of the MSc made me realize how privileged I am to be part of the upcoming Technical Medical world. During my internship at the Department of Trauma Surgery in the Erasmus MC, I had the most amazing ten weeks. Every day, I came home with exciting stories and experiences, and I was very happy to return for my MSc Thesis. I entered the world of augmented reality in the Erasmus MC and discovered the high future potential of this new technology in medicine. I was able to attend extended reality events, demos, and research meetings on this topic. I have enjoyed working on the project and I am glad that I could set a small step toward the implementation of augmented reality in Trauma Surgery. I learned a lot in the field of 3D modeling, augmented reality, and trauma surgery, but I also developed myself personally. I am excited to combine my technical and medical knowledge as a Technical Physician in an innovative and multidisciplinary environment.

I would like to thank my supervisors Mark and Bart for their enthusiasm, time, and guidance during my MSc Thesis. The weekly meetings with Bart were always insightful and helped me to take my research to a higher level. The enthusiasm, resources, and motivation of Mark helped me to accomplish things that I did not think I could do. I would also like to thank Theo for using the Microsoft HoloLens of his research group, and Abdullah, who was flooded with my text messages about whether I could pick up or bring back the HoloLens. Also, many thanks to the trauma surgeons, fellows, and surgical residents for all the clinical lessons and experiences.
Last, I would like to thank all my friends and family for patiently listening to my stories about my research and the cool surgeries I attended. Thanks for all the support and believing in me and making my student time unforgettable.

Lucy Knöps
Rotterdam, November 2022

Abstract

Background

Head-mounted augmented reality (AR) can be beneficial in orthopedic trauma surgery by projecting 3-dimensional (3D) holograms of preoperative imaging data, drilling or cutting planes, and osteosynthesis material, directly onto the surgeon's field of view (FOV). For successful implementation of head-mounted AR in orthopedic trauma surgery, the surgeon's experience is of utmost importance. This prospective clinical study aimed to evaluate the surgeon's experience with head-mounted AR in orthopedic trauma surgery.

Methods

The Microsoft HoloLens 2 *(Microsoft, Redmond, WA, USA)* was used to project patient-specific 3D models of the patient's fracture site as 3D holograms in the surgeon's FOV during surgery of intra-articular fractures. The surgeon's experience was recorded using the Simulator Sickness Questionnaire, Borg CR10 Scale, National Aeronautics and Space Administration Task Load Index, System Usability Scale, and a custom-made questionnaire.

Results

A total of 14 ORIF surgeries were performed while using a head-mounted AR device. Overall, surgeons were satisfied with AR HMDs (67.9 ± 22.3 (mean ± SD)) and wanted to use it again (70.0 ± 22.54 (mean ± SD)). Good results were reported regarding the usability of the AR HMD (65.7 ± 16.6 (mean ± SD)) and the interaction with 3D holograms 72.1 ± 15.8 (mean ± SD). However, the mental demand, size, and weight of the AR HMD were rated less favorable.

Conclusion

The surgeon's experience with the intraoperative use of head-mounted AR in orthopedic trauma surgery is sufficient and head-mounted AR has great future potential in orthopedic trauma surgery. Future research has to focus on an ergonomic design of surgical AR HMDs, technological developments, a simple and fluent workflow, and proving clinical value of head-mounted AR.

Content

1. Background

1.1 Orthopedic Trauma Surgery

Orthopedic trauma comprises any severe injury to the elements of the musculoskeletal system, including muscles, joints, ligaments, bones, and soft tissue. These traumatic injuries are often the result of a sudden accident and require immediate medical attention. Among bony injuries, fractures are a global public health issue. The Global Burden of Disease Study estimated the global number of new fractures in 2019 to be 178 million; 102 million in males and 76.4 million in females [1]. The main anatomical sites for fractures were fractures of the patella, tibia, fibula, or ankle. The Global Burden of Disease Study reported a number of 25.8 million years lived with disability caused by fractures in 2019 [1]. Causes of fractures were (1) falls, (2) road injuries, (3) exposure to mechanical forces, (4) other unintentional injuries, and (5) conflict and terrorism [1].
The Müller AO classification of fractures is a common system for classifying fractures based on their localization, joint involvement, and morphology [2]. Intra-articular fractures are fractures that cross a joint surface and involve some degree of cartilage damage [3]. When not treated properly, permanent loss of joint motion is to be expected and posttraumatic osteoarthritis may occur as a result of the intra-articular fracture. Other posttraumatic conditions associated with insufficiently treated intra-articular fractures that could be encountered are bony prominences, deformity, stiffness, weakness, and reflex sympathetic dystrophy [4]. Therefore, restoring the congruity of the joint surface is the primary focus of treatment of intra-articular fractures, as restoring joint congruity will decrease the likelihood of these conditions significantly [4]. Intra-articular fractures, therefore, often require open reduction and internal fixation (ORIF) surgery to achieve anatomical reduction and stable fixation [5, 6]. Significant cartilage healing can be achieved in intra-articular fractures after anatomical reduction, interfragmentary compression, and stable fixation. By applying these principles to the treatment of intra-articular fractures, both the functional and radiological results could significantly be improved [3].

1.2 Imaging in Orthopedic Trauma Surgery

For preoperative planning and intraoperative decision-making in fracture surgery, a detailed understanding of the fracture is essential. In current clinical practice, two-dimensional (2D) X-ray images of the fracture are generated to preoperatively assess the fracture in 2D. When joint involvement or multi-fragmentation is suspected based on the X-ray, a computed tomography (CT) scan of the fracture is acquired to obtain additional three-dimensional (3D) information about the joint incongruity and complexity of the fracture [7]. The CT scan also offers support in preoperative planning and intraoperative guidance [7]. Intraoperatively, 2D fluoroscopy images are acquired; they assist the surgeon in precise positioning of fracture elements and osteosynthesis material [8, 9]. 3D rotational fluoroscopy is another imaging technique that can be used during ORIF surgery for intra-articular fractures; it generates conventional 2D fluoroscopic images, as well as 3D reconstructions of bony structures [10, 11]. 3D rotational fluoroscopy provides the surgeon with significantly more information with regard to fracture anatomy and fracture reduction when compared to 2D fluoroscopy [11].
However, for preoperative and intraoperative use in orthopedic trauma surgery, these imaging modalities have several drawbacks. First, the preoperative CT scan and intraoperative fluoroscopy images are displayed on a 2D monitor away from the operative field. Second, the 2D nature of these images precludes actual depth perception. In addition, translating these 2D images from the screen to the operative field (the actual situation) can be difficult and forces the surgeon to continuously shift his or her focus of attention from the operative field to the monitor [12-15]. At last, surgeons are unable to interact with the imaging information because of their sterile environment.

1.3 Augmented Reality (AR) in Orthopedic Trauma Surgery

Developments in medical applications of augmented reality (AR) and mixed reality (MR) have aimed to improve preoperative and intraoperative visualization and guidance [16]. Both AR and MR provide the user with an enhanced version of the real physical world by the projection of 3D holograms [17, 18]. MR differs from AR in offering the possibility to directly interact with the 3D holograms, whereas AR is limited to visualization of 3D holograms [19]. Despite the difference between AR and MR, many recent studies use the term AR to refer to the application of combining virtual and real worlds in the visualization [20]. Following their example, this study uses the term AR. AR can be delivered to the user through 2D or 3D visualization techniques using smartphones, computer screens, and wearable devices. Head-mounted devices (HMDs) such as the Magic Leap *(Magic Leap, Plantation, Florida, USA)* and the Microsoft HoloLens *(Microsoft, Redmond, Washington, USA)*, are frequently used for intraoperative 3D hologram projection [17, 21-23].

In orthopedic trauma surgery, head-mounted AR devices can be beneficial by projecting 3D holograms of preoperative CT data and computer-generated 3D models of the fracture site, surrounding anatomical structures, drilling or cutting planes, and osteosynthesis material, directly onto the surgeon's field of view (FOV). As a result, the trauma surgeon can access this information at the site of the procedure instead of on a 2D monitor. This will eliminate the need for external monitors, thereby reducing context switching and associated cognitive load and performance errors [24, 25]. Moreover, 3D holograms will enable independent real-time interaction by the surgeon and may improve ergonomics, because 3D holograms are projected in the surgeon's FOV and surgeons do not have to switch head and neck positions anymore [26].

Research into the intraoperative use of head-mounted AR is ongoing within various surgical specialisms [17, 21-23, 27, 28]. As investigated by Bhatt et al. [27], head-mounted AR-assisted spine surgery was safe and accurate for pedicle, cortical, and pelvic fixations. Besides, Liu et al. investigated whether intraoperative visualization of a 3D brain hologram could be helpful during brachytherapy for brain metastasis [28]. Neurosurgeons reported good visualization of the skull, tumor, and main vessels around the tumor and easy comparison between the patient's actual anatomy and hologram [28]. Other studies indicated that AR could improve safety, efficacy, and accuracy of surgical procedures [29, 30].

However, current literature describes mainly preclinical studies and lacks clinical, in-patient evaluation [20]. Moreover, current studies mainly focus on technological challenges regarding the required computational power, complex registration between the AR system and patient, smoothness of interaction, and precision and valid registration of movements [20, 31]. Little research has been conducted focusing on the intraoperative feasibility of AR in surgery. Furthermore, studies focusing on the use of AR in orthopedic trauma surgery are lacking [31].

For successful implementation of head-mounted AR in orthopedic trauma surgery, the surgeon's experience is of utmost importance. AR HMDs have to be sufficiently comfortable to be worn over long periods, must be easy to use, and additional workload of the AR HMD has to be limited. Surgical applications within orthopedic trauma surgery that could benefit from head-mounted AR have to be indicated and research on the surgeon's willingness to use an AR HMD during surgery has to be conducted.

1.4 Objectives

This study aims to evaluate the surgeon's experience with head-mounted AR in orthopedic trauma surgery. The surgeon's experience is assessed in terms of physical discomfort, physical exertion, mental demand, usability, and intraoperative feasibility of head-mounted AR devices.

As a primary outcome measure, the Simulator Sickness Questionnaire (SSQ) is used. As secondary outcome measures, the 1) Borg CR10 Scale, 2) National Aeronautics and Space

Administration Task Load Index (NTLX), 3) System Usability Scale (SUS), and 4) a custom-made 42-item questionnaire are used.

2. Design and Methods

In this study, patient-specific 3D models of intra-articular fractures were created and projected as 3D holograms in the surgeon's FOV during ORIF surgery of intra-articular fractures. During surgery, the surgeons could view and interact with the patient-specific 3D models of the patient's intra-articular fractures. After performing two ORIF surgeries with the AR HMD, the surgeons completed a questionnaire assessing their experience with surgical head-mounted AR.

2.1 Study Design and Regulations

This study was a prospective case series and has been conducted according to the principles of the Declaration of Helsinki [32]. This study has been exempted by the Medical Research Ethics Committee (MREC). Following review of the protocol, the MREC concluded this study was not subject to the Medical Research Involving Human Subjects Act (WMO). Surgeries were performed following the standard of care for intra-articular fractures and surgeons were instructed to not make any decisions based on the 3D holograms projected by the AR HMD.

2.2 Participants

Trauma surgeons, trauma surgery fellows, and fifth- or sixth-year residents specializing in trauma surgery that work at the Erasmus MC and regularly perform orthopedic trauma surgery were eligible for this study. Potential participants that were unable to wear the AR HMD during surgery were excluded. Informed consent was obtained from all participants.

2.3 Included Procedures

Head-mounted AR was tested during ORIF surgery of intra-articular fractures in adult patients with available preoperative CT imaging data. Intra-articular fractures of the foot and hand were excluded, because of the small size and complexity of these fractures.

2.4 Patient-Specific 3D Model Development

Patient-specific 3D models of the intra-articular fractures were created for each patient. The fractured bone and important surrounding bones were identified on the preoperative CT data by one researcher. If necessary, the researcher consulted the surgeon who would operate on the patient. Subsequently, raw DICOM data of the preoperative CT scan were exported and uploaded to the 3D medical image processing software Materialise Mimics (24.0) *(Materialise, Leuven, Belgium)* for segmentation of the bony structures. The first step of segmentation was to create an initial mask using '*thresholding'*. The predefined range of intensity values for bone, with a minimum value of 226 Houndsfield Units and a maximum value of 2723 Houndsfield Units, was used and the region of interest (ROI) was set to only include the fractured bone and important surrounding bones. Subsequently, the initial mask was split into separate masks for the different bones using the *'split mask'* feature. The resulting mask of the fractured bone was again split into separate masks for the different fracture fragments. The created masks suffered from segmentation errors, since *'thresholding'* may have incorrectly defined noise in the CT data as bone, resulting in protrusions in the masks, and may have missed cancellous or thin bone, resulting in holes in the masks. *'Hole filling'* and *'3D interpolation'* were applied to the masks to correct for those protrusions and holes. *'Hole filling'* with a voxel size ranging from one to four voxels was chosen, depending on the resolution of the CT data. *'3D interpolation'* was used to

remove remaining protrusions and holes, resulting in a solid mask for each bony structure. Initial 3D surface models were created from the solid masks by using the *'create part'* function. The initial 3D models were coarse and *'smoothing'* with a smoothing factor of 0.4 and eight iterations resulted in smooth 3D models of the bony structures. The 3D models were exported as STL files and imported to the 3D modeling software Materialise 3-Matic *(Materialise, Leuven, Belgium)* for the export of the models as OBJ files. The resulting patient-specific 3D models in OBJ files were used for 3D holographic visualization and interaction.

2.5 AR Application

2.5.1 AR Device

For 3D holographic visualization of the patient-specific 3D models, the Microsoft HoloLens 2 *(Microsoft, Redmond, WA, USA)* was used in this study [33]. The Microsoft HoloLens 2 is a commercially available holographic headset and the device has an electronic unity that calculates the visual real-world information and the AR objects. This electronic unity is stand-alone and fully integrated in the hardware of the HoloLens. Therefore, there is no need for additional computers or devices [34]. The use of the Microsoft HoloLens 2 in the operating rooms (OR) of the Erasmus Medical Center (Erasmus MC, Rotterdam), has been approved by the Quality Assurance & Regulatory Affairs (QA/RA) office of the Erasmus MC.

2.5.2 Software

To visualize the patient-specific 3D models of the intra-articular fractures with the Microsoft HoloLens 2 and to enable interaction with the models, an AR application was developed in the game engine software Unity (Editor 2020.3.33f1) *(Unity Technologies, San Francisco, California, USA)*. The open-source MRTK (version 2.8.2) *(Microsoft, Redmond, Washington, USA)* has been used to implement features based on MR functions. MRTK is a Microsoft-driven project that provides a set of components and features, used to accelerate cross-platform MR application development in Unity [35]. The toolkit provides the building blocks for Unity development on the Microsoft HoloLens. To correctly develop AR applications with MRTK, Visual Studio 2022 *(Microsoft, Redmond, Washington, USA)* has been used on Microsoft Windows 11 *(Microsoft, Redmond, Washington, USA)* with Windows SDK 10 *(Microsoft, Redmond, Washington, USA)*.

2.5.3 Required Functionalities

Required functionalities for the AR application were defined by the researcher (L.K.), a technical physician (B.C.), and a trauma surgeon (M.v.V.) (table 1).

2.5.4 AR Application Development and Configuration

An AR application was developed and configured to meet the required functionalities.
A scene in Unity was created and an empty object called *'Bone'* was added. The patient-specific 3D models in OBJ files were added to the *'Bone'* object and MRTK components '*object manipulator*', '*near interaction grabbable*', '*box collider',* and '*bounding box'* were attached to allow the surgeon to translate, rotate and resize 3D holograms of the bony structures with hand gestures. For multi-fragmentary intra-articular fractures, different colors were chosen for the bony structures to distinguish between the bony structures easily.
A menu was designed and MRTK's *'toggle buttons'* were added to allow toggling between solid and transparent visualization of bony structures. An MRTK *'pressable button'* was added to the menu and a script was attached to the button to be able to reset the 3D holographic view.
To build the application, the *'Universal Windows Platform'* was selected in the platform window and the build settings were set for configuration with the Microsoft HoloLens 2 (appendix 2). The build resulted in a Visual Studio solution (.sln) file, which was used to deploy the application to

the HoloLens. The application was tested by the researcher (L.K.), a surgeon with extensive experience in orthopedic trauma surgery (M.v.V.), and a technical physician (B.C.) before it was used for clinical evaluation. The developed AR application can be seen in figure 1.
During intraoperative use of the AR application, the surgeon's 3D holographic view was live-streamed to the monitors in the OR by connecting to the Windows Device Portal.

Table 1 - Set of requirements for AR application

Number	Requirement name	Description
1	*Bony structures*	Visualization of different bony structures
2	*Transparency*	Ability to change between solid and transparent visualization of bony structures
3	*Visualization*	Ability to toggle off visualization of bony structures
4	*Movements*	Translation, rotation, and resizing of the bony structures
5	*Interaction*	Hand gestures*
6	*Menu*	Menu with clear options and functionalities
7	*Reset*	Function to reset 3D holographic view
8	*Live stream*	Sharing 3D holographic view with other personnel present in OR

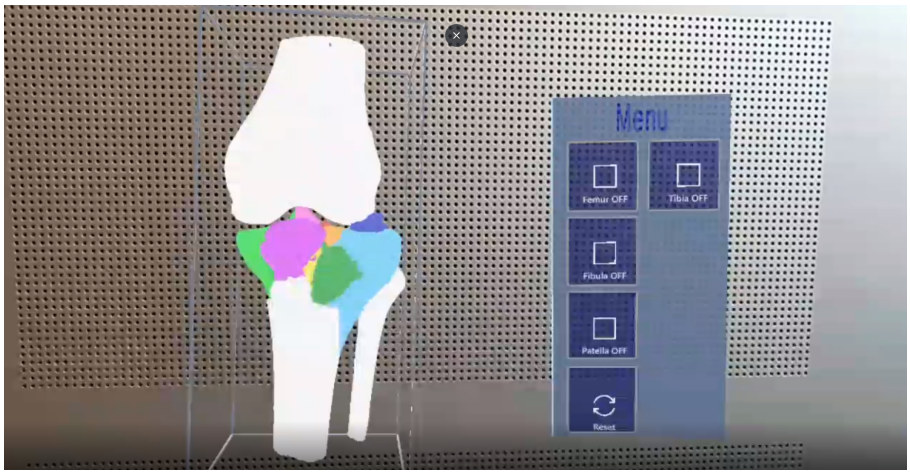

Figure 1 - AR application with a patient-specific 3D model and menu

2.6 User Experience Assessment

2.6.1 Preclinical Test

Prior to the intraoperative use of the AR HMD, each participating surgeon completed the preclinical test. First, a short training was given on using the AR HMD and interacting with the 3D holograms. Following the training, the surgeons performed an experiment in which three screws were screwed in a bone model of the tibia while assessing 3D holograms of the lower leg projected by the AR HMD. To simulate an intraoperative situation, the experiment took place in a real (empty) OR and the participant was fully dressed up for surgery.

2.6.1.1 User Experience Assessment after Preclinical Test

Following the preclinical test, each surgeon completed the Simulator Sickness Questionnaire (SSQ), to assess the physical discomfort associated with wearing the AR HMD. The SSQ is a widely used questionnaire to describe and assess simulator sickness, caused by 3D movies, 3D glasses, and 3D virtual reality games. In the SSQ, surgeons scored 16 symptoms on a four-point scale from 0 (none) to 3 (severe), with higher scores indicating worse motion sickness. Total scores can be associated with negligible (<5), minimal (5-10), significant (10-15), and severe (15-20) simulator sickness symptoms [36]. A simulator sickness score above 20 is considered as bad simulator sickness [36].

2.6.2 Intraoperative Test

After completing the preclinical test, the surgeons performed two surgeries on intra-articular fractures with the AR HMD to assess the surgeon's experience with the AR HMD under real clinical conditions (figure 2). Prior to the surgery, the participants started the AR application to allow assessment of the holograms at any moment during surgery. The surgeons could interact (translate, resize, rotate, and change visualization modes) with the holograms using contactless hand gestures.

The surgeons individually decided on the timing and duration of using the AR HMD during surgery. The total time of wearing the AR HMD during surgery was timed by the researcher. Conventional radiological imaging was displayed on monitors, to continue routine practice.

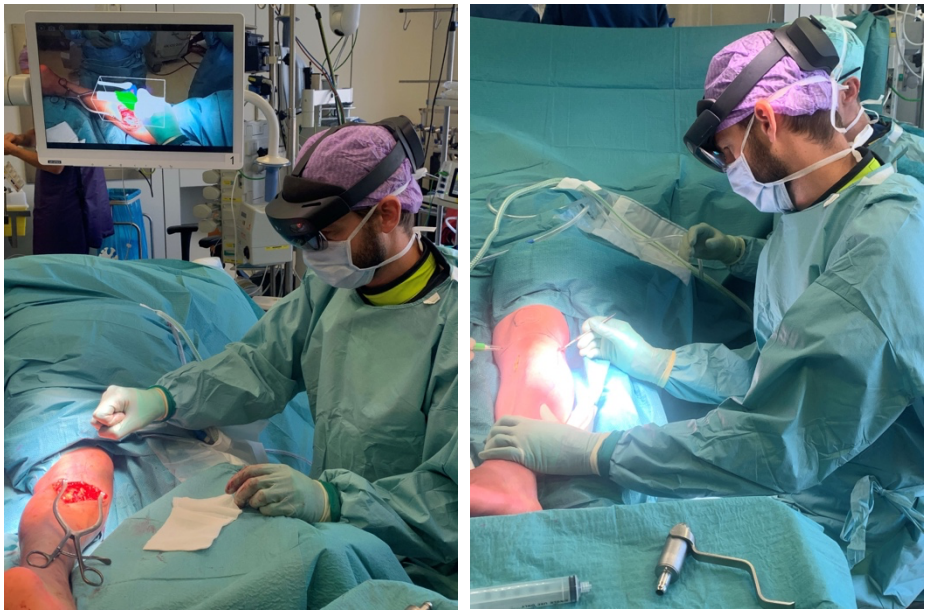

Figure 2 - Trauma surgeon wearing the Microsoft HoloLens 2 during surgery of a tibia plateau fracture

2.6.2.1 User Experience Assessment after Intraoperative Test

After the second surgery of the intraoperative test, the surgeon completed a questionnaire assessing the user experience with surgical head-mounted AR. This questionnaire consisted of:

- The SSQ to measure the physical discomfort related to the intraoperative use of an AR HMD [36].
- The Borg CR10 Scale to assess physical exertion related to the intraoperative use of an AR HMD. This scale rates physical exertion from 0 (no exertion at all) to 10 (maximal exertion) [37]. In this study, the Borg CR Scale was used to evaluate physical exertion of surgery with the AR HMD in eight body parts, consisting of 1) the head; 2) neck; 3) right

shoulder and arm; 4) left shoulder and arm; 5) right forearm and wrist; 6) left forearm and wrist; 7) legs; and 8) lower back [38].

- The NTLX to assess the mental demand of using head-mounted AR during surgery. The NTLX is a well-validated, multidimensional assessment tool for measuring subjective mental workload. It rates workload across six dimensions on an interval scale ranging from 1 (low) to 20 (high) [39, 40].
- The SUS to evaluate the usability of the AR HMD. This 10-item questionnaire measures the usability of products and services with five response options (strongly agree to strongly disagree) [41].
- A custom-made 42-item questionnaire based on the study of Dennler et al. to evaluate the intraoperative feasibility of head-mounted AR during surgery of intra-articular fractures [17]. This questionnaire assesses the intraoperative feasibility on eight different items; surgical steps, interaction, acceptance, wearing period, technology, future operations, future joints, and overall verdict. Each item was scored from 0 (not useful at all) to 100 (very useful).

2.7 Other Study Parameters

Surgeons completed an additional questionnaire to assess their demographic data, experience in surgery of intra-articular fractures, prior experience with extended reality, and type of intra-articular fractures operated on while wearing the AR HMD:

- Age in years
- Sex (male or female)
- Number of surgeries of intra-articular fractures performed in the past year (<20, 20-39; 40-59; 60-79; 80 or more)
- Prior experience with an extended (virtual, mixed, or augmented) reality device during surgery
- Performed procedure during which the AR HMD was used

All study data were assembled in a database platform (Castor Electronic Data Capture (EDC) that meets Good Clinical Practice (GCP) standards.

2.8 Statistical Analysis

Descriptive analysis was performed using the Statistical Package for the Social Sciences (SPSS) version 28 (SPSS, Chicago, III., USA). Normality of continuous data was tested with the Shapiro-Wilk test. Missing values were not imputed. Parametric variables were reported as mean ± standard deviation (SD) and non-parametric variables were reported as median (Mdn) with the interquartile range (Q3-Q1). For categorical variables, numbers and frequencies were reported.

3. Results

3.1 Participants

Seven participants with varying degrees of experience in trauma surgery (six male, one female, mean age 40.4 ± 6.7 (SD) years) participated in this study (table 2). Three participants were trauma surgeons, three were fellows in trauma surgery, and one sixth-year resident participated in this study. One participant performed more than 80 surgeries of intra-articular fractures per year, one participant 60-79, three participants 40-59, and two participants 20-39. Two participants reported having prior experience with extended reality.

Table 2 - Participant characteristics

Participant	Age in years	Sex	Experience in trauma surgery	Number of surgeries of intra-articular fractures per year	Prior experience with extended reality
1	53	Male	Trauma surgeon	40-59	No
2	46	Male	Trauma surgeon	40-59	Yes
3	38	Male	Trauma surgeon	20-39	No
4	38	Male	Fellow trauma surgery	40-59	No
5	34	Male	5th or 6th year resident	20-39	No
6	37	Female	Fellow trauma surgery	60-79	No
7	37	Male	Fellow trauma surgery	>80	Yes

3.2 User Experience Results

3.2.1 Results Preclinical Test

The physical discomfort after the preclinical test as measured with the SSQ was rated with a mean score of 12.5 ± 9.0 (SD) (figure 3).

3.2.2 Results Intraoperative Test

A total of 14 surgeries (four tibia plateau fractures, five distal radius fractures, one pelvic fracture, and four ankle fractures) were performed while using a head-mounted AR device.
The physical discomfort as measured with the SSQ was rated with a mean score of 17.6 ± 16.3 (SD) (figure 3).
Considering physical exertion, surgeons experienced *'slight exertion'* in the head (1.9 ± 1.5 (mean ± SD)) and a *'very, very slight exertion'* in the neck (0.5 (1.0-0.0) (Mdn (Q3-Q1)) (figure 4) [37]. The right shoulder and arm, left shoulder and arm, right forearm and wrist, left forearm and wrist, legs and lower back were rated with zero, indicating that none of the surgeons experienced any exertion in these body parts.
Mental demand related to head-mounted AR was rated with 31.3 ± 21.5 (mean ± SD) on a scale from 0 (no workload) to 100 (maximal workload) (figure 5). According to the interpretation score of the NTLX, this means that surgeons perceived a '*somewhat high*' mental demand [42]. Still, of the NTLX subcategories, surgeons rated their performance with a sufficient score of 58.6 ± 36.4 (mean ± SD), indicating that surgeons felt somewhat successful and were sufficiently satisfied with their performance. The effort of performing surgery with the AR HMD was rated with 47.9 ± 27.8 (mean ± SD), indicating that surgeons thought they had to work hard mentally and physically to accomplish their level of performance [39, 40].

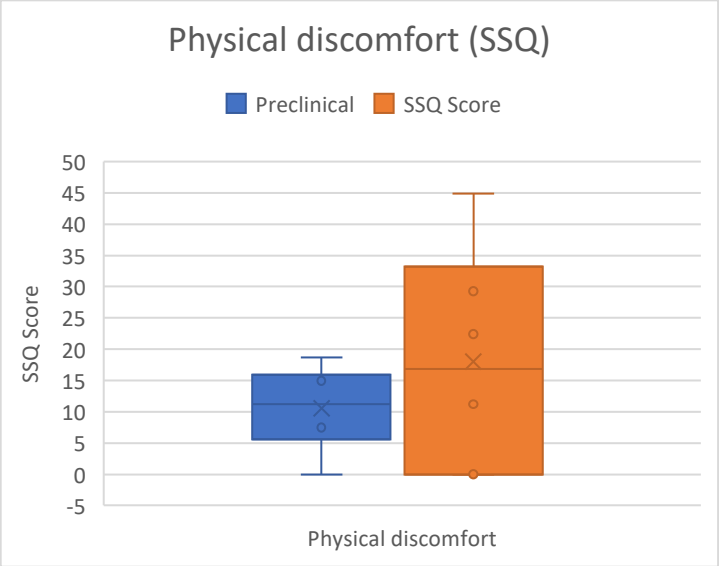

Figure 3 – Simulator Sickness Questionnaire results

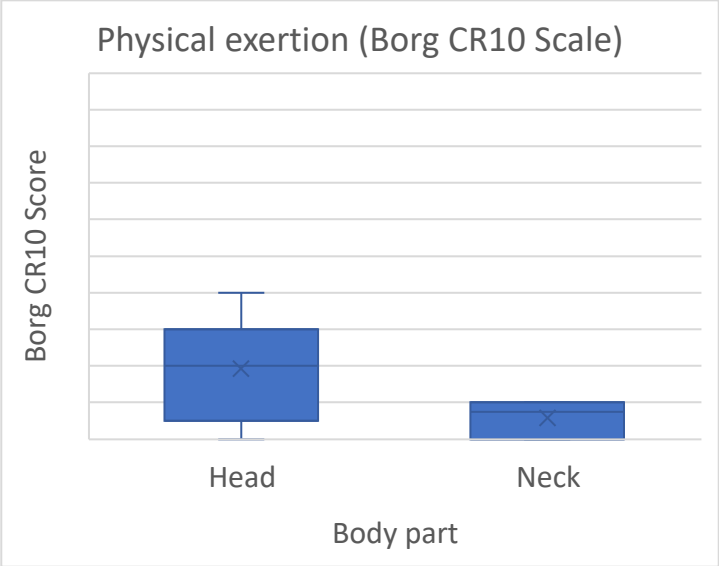

Figure 4 – Borg CR10 Scale results

The usability as measured with the SUS, received a score of 65.7 ± 16.6 (mean ± SD), which is just below the average usability score of 68, indicating '*okay'* usability [43].
All surgeons (n=7) reported to have used the 3D holographic view for orientation during surgery. In addition, one surgeon reported to have used the 3D holographic view for *'understanding of the fracture'* and one surgeon *'to see if one piece of bone was already broken before surgery'*.
Surgeons found the AR HMD to produce good image quality (80.0 (80.0-60.0) (Mdn (Q3-Q1)) and sufficient accuracy of 3D holograms (65.7 ± 18.1 (mean ± SD)). Learnability and functionality of gesture control were both rated with good scores of 72.1 ± 15.8 (mean ± SD). Surgeons were also generally satisfied with the quality of the surgical field when looking through the AR HMD (73.6 ± 12.1 (mean ± SD)). The total speed of control provided good results (75.0 (80.0-50.0) (Mdn (Q3-Q1)) (figure 6).
Considering the acceptance of the AR HMD, surgeons thought it looked good (75.7 ± 16.2 (mean ± SD)). The size was rated with a moderate score (63.6 ± 17.5 (mean ± SD)) and the weight (66.4 ± 14.4 (mean ± SD)) and comfort (66.4 ± 14.4 (mean ± SD)) of the AR HMD were rated with slightly higher scores (figure 7).
Most surgeons used the AR HMD for 30-59 minutes during surgery (4/7 surgeons). Two surgeons reported to have used the AR HMD for 60-89 minutes during surgery and one surgeon for 15-29 minutes. Five surgeons used the AR HMD during the entire surgery. The reasons for early termination of use were impaired visibility, discomfort, and disturbance by the AR HMD, and because surgeons had used the AR HMD for certain pre-determined surgical steps. Four surgeons expected to be able to wear the AR HMD continuously during surgery for 30-59 minutes and three surgeons reported an expected continuous use of >120 minutes.
Intraoperative head-mounted AR was expected to mainly improve the surgical result (70.0 (80.0-20.0) (Mdn (Q3-Q1)) and to increase precision (60.0 ± 20.8 (mean ± SD)) (figure 8). The greatest potential in orthopedic trauma surgery was found for tumor surgery (80.0 (80.0-10.0) (Mdn (Q3-Q1)), revision cases (75.0 ± 15.0 (mean ± SD)), reconstructive surgery (75.0 ± 13.8 (mean ± SD)), and osteotomies (73.6 ± 11.1 (mean ± SD)) (figure 9). Potential for future use was highest estimated for application in elbow (67.9 ± 25.8 (mean ± SD)), foot (64.3 ± 25.2 (mean ± SD)), and shoulder (62.9 ± 25.8 (mean ± SD)) surgery.
Overall, surgeons were satisfied with head-mounted AR in surgery (67.9 ± 22.3 (mean ± SD)), and they would like to use the proposed AR technology again (70.0 ± 22.4 (mean ± SD)).

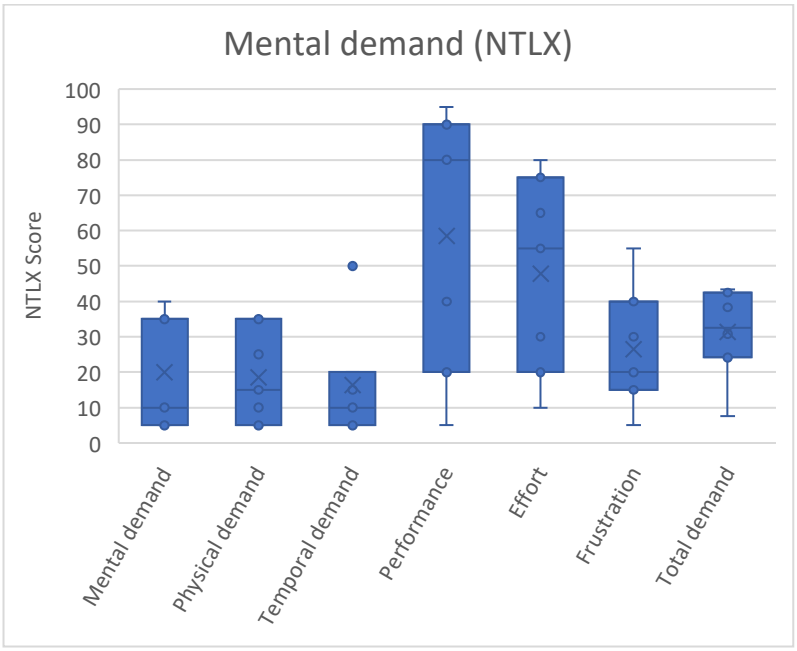

Figure 5 – NASA Task Load Index results

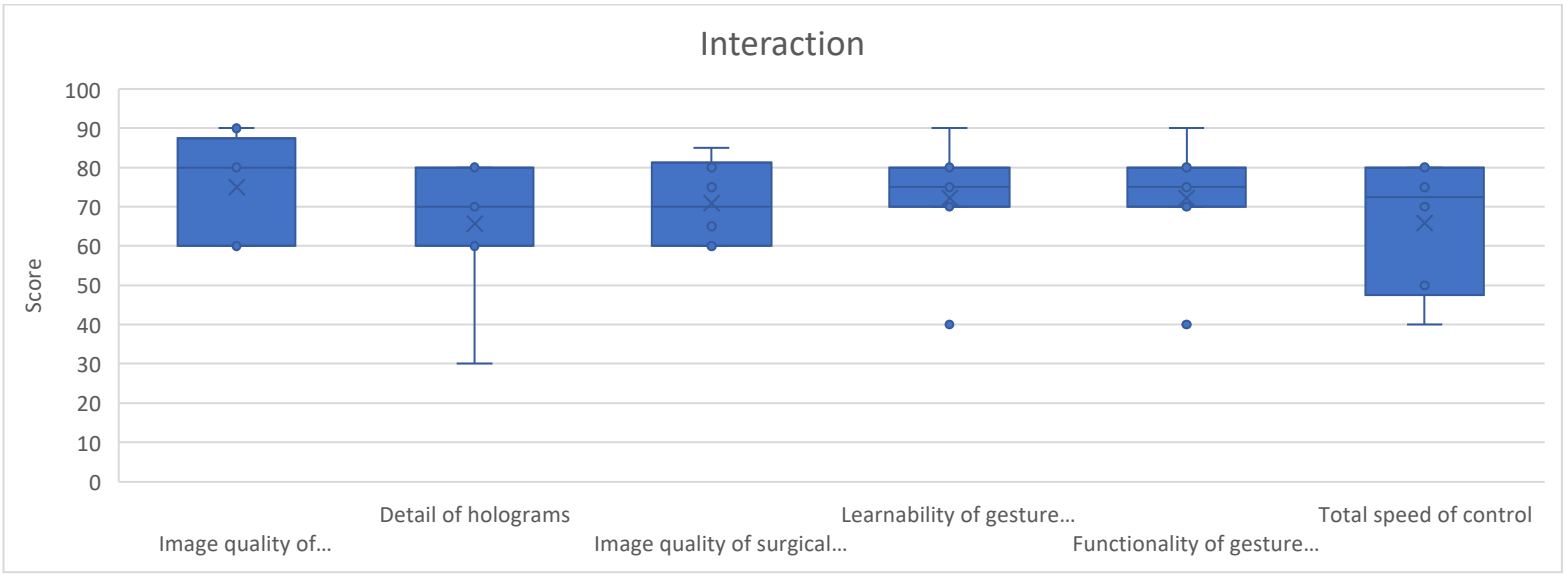

Figure 6 – Interaction of intraoperative use of head-mounted AR

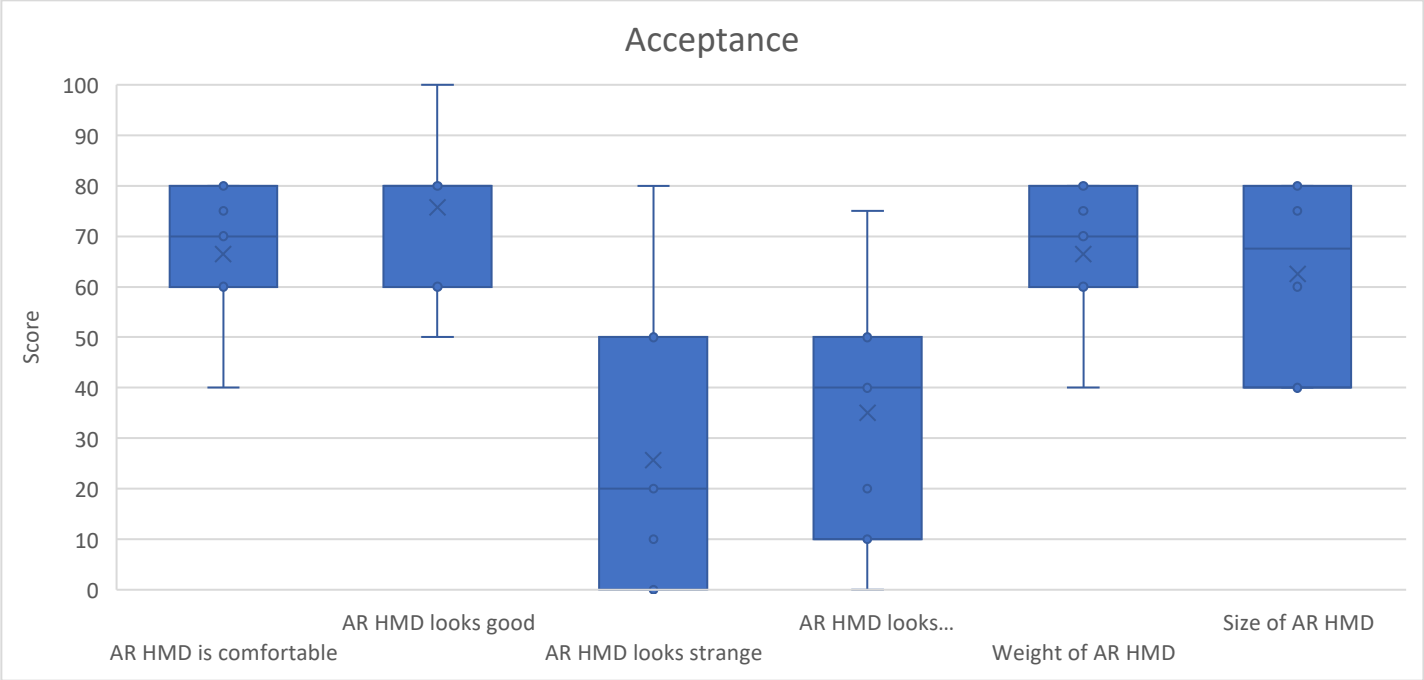

Figure 7 – Acceptance of intraoperative head-mounted AR

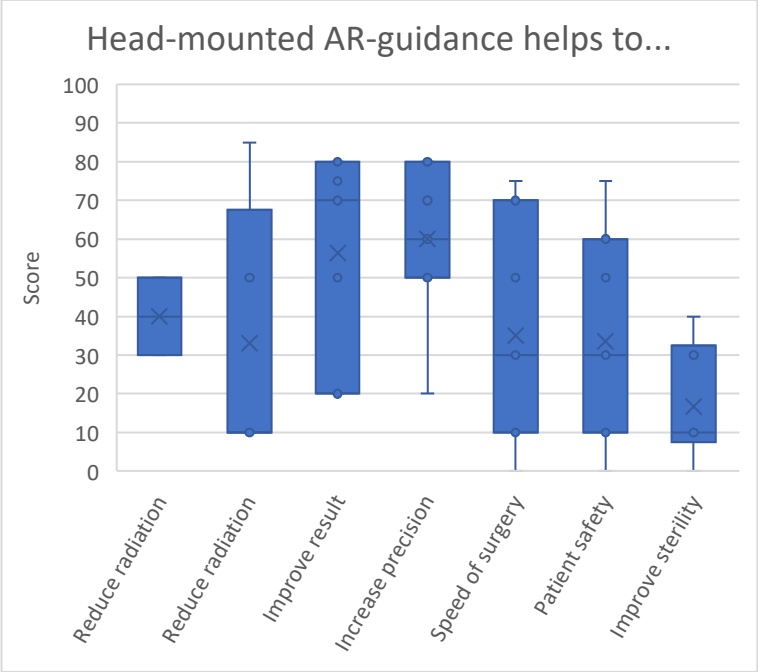

Figure 8 - Expected benefit of intraoperative AR

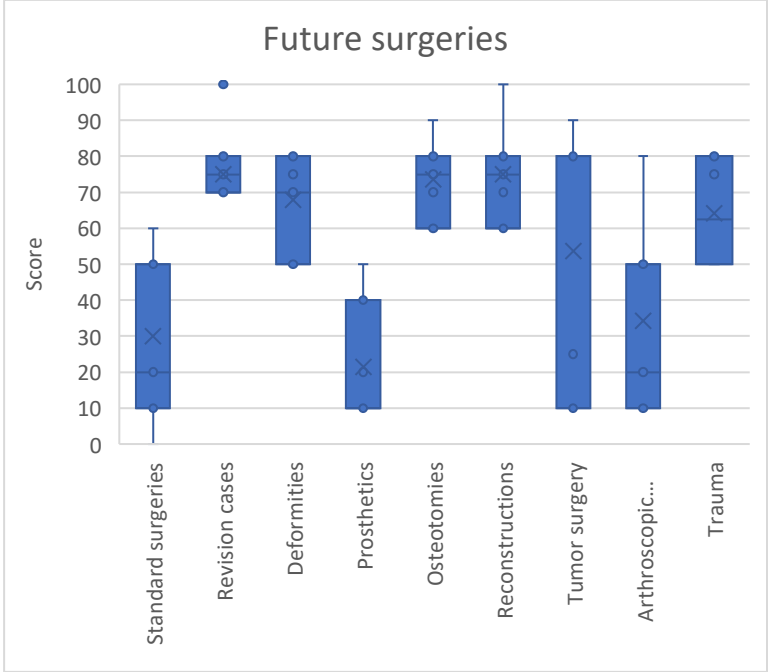

Figure 9 - Greatest potential of AR HMD in orthopedic trauma surgery

4. Discussion

4.1 Interpretation of Results

This prospective clinical study aimed to evaluate the surgeon's experience and intraoperative feasibility of orthopedic trauma surgery with head-mounted AR. Seven trauma surgeons used an AR HMD projecting holograms of patient-specific 3D models, during 14 surgeries of intra-articular fractures. It was found that surgeons were satisfied with AR HMDs and expected head-mounted AR to be beneficial in orthopedic trauma surgery, especially to enhance precision and improve the surgical result. Surgeons expected head-mounted AR to have high potential in tumor surgery, revision surgery, reconstructive surgery, and osteotomies. The usability of the AR HMD was satisfactory and the interaction with 3D holograms was good. However, a *'somewhat high'* mental demand was related to the intraoperative use of AR HMDs and the size and weight of the AR HMD were rated less favorable. These findings are important because the surgeon's experience and intraoperative feasibility are of utmost importance for successful implementation of AR in orthopedic trauma surgery.

The intraoperative physical discomfort was rated with 17.6 ± 16.3 (mean ± SD), indicating that surgeons experienced '*severe simulator sickness symptoms'*, according to the interpretation score of Kennedy et al. [36]. However, the study of Brown et al. demonstrated the interpretation of the SSQ to be inadequate, because the interpretation relies on the assumption that participants do not suffer from any of the symptoms assessed by the simulator sickness questionnaire at all at baseline [44]. Since no surgeons complained about severe simulator sickness after surgery with the AR HMD, the physical discomfort as being '*severe simulator sickness'*, seemed to be an overestimation.

The physical exertion related to the head-mounted AR device during ORIF surgery was minimal. To our knowledge, physical exertion is not previously evaluated in studies researching the intraoperative use of AR. However, there is one study that assessed the physical stress associated with head-mounted AR-guidance in surgical applications [45]. This study reported a physical stress of 5 on a scale from 1 (no symptoms) to 5 (severe symptoms), which is less favorable than our result.

The resulting mean mental demand score of 31.3 ± 21.5 (mean ± SD) on a scale from 0 (no workload) to 100 (maximal workload), indicated a '*somewhat high*' mental demand according to the interpretation score. This finding is in line with the results of other studies using the NTLX to assess the mental demand of surgical head-mounted AR [46]. The *'somewhat high'* mental demand of head-mounted AR may be explained by the limited experience of surgeons with the AR HMD. In our study, some surgeons struggled with performing hand gestures and positioning the holograms on the desired location. However, it can be expected that a steep learning curve is related to the control of holograms. Therefore, the control will less influence the mental demand when implementing AR technology in the future. The occurrence of performance errors in the AR HMD may also have influenced the rating of mental demand. Since the surgeons were constantly working with their hands in the FOV of the AR HMD, the AR HMD occasionally recognized unintended hand gestures. As a result, other functionalities of the AR HMD were accidentally enabled or disabled, which could have frustrated the surgeons and could have led to increased mental demand.

Our study shows a SUS score of 65.7 ± 16.6 (SD) for head-mounted AR in orthopedic trauma surgery. However, other studies investigating the usability of head-mounted AR found higher usability scores [47, 48]. Azimi et al. researched the intraoperative use of their head-mounted AR system in simulated ventriculostomy and found a *'good'* usability on the SUS [47]. In addition, the study of Gsaxner et al. found the usability of head-mounted AR in simulated head and neck oncological surgery to be *'good' [48]*. The discrepancy in usability ratings between the studies of Azimi et al. and Gsaxner et al. and our study, can be explained by the differences in evaluation set-ups. Azimi et al. and Gsaxner et al. tested their AR device in a phantom experiment, while our

study evaluated the usability of the AR HMD under real clinical conditions [47, 48]. Real clinical experiments are however not comparable to phantom experiments in terms of duration of usage of the AR HMD, environmental conditions, and practical issues, which may have resulted in a less favorable usability rating in our study.

With regard to the feasibility of head-mounted AR in orthopedic trauma surgery, surgeons were satisfied with the quality and interaction of the 3D holograms. These results are in line with the results presented by other studies researching the 3D hologram visualization and interaction for intraoperative use. However, functionality and learnability of gesture control were rated higher in our study than in two other studies assessing the participant's satisfaction with gesture control [17, 49]. The studies of Dennler et al. and Glas et al. both used the Microsoft HoloLens 1 as head-mounted AR device, which could declare the difference in rating of gesture control [17, 49]. The Microsoft HoloLens 2 has more advanced sensors that can recognize additional hand articulations, which makes the control more intuitive than the control of the Microsoft HoloLens 1 [50].

The comfort of the AR HMD was rated sufficiently with a score of 66.4 ± 14.4 (mean ± SD) on a scale from 0 (not useful) to 100 (very useful). However, other studies investigating the feasibility of AR in neurosurgery, graded the comfort of the AR HMD more favorably [23, 51]. This might be due to the fact that neurosurgeons are generally more accustomed to the use of optical aids such as magnifying glasses or headlights in their field of view. Therefore, neurosurgeons might be less disturbed by the AR HMD and rate the comfort of AR HMD higher.

Yet, the use of an AR HMD in orthopedic trauma surgery as investigated in this study, has some ergonomic limitations in terms of the size and weight of the device. Surgeons reported the AR HMD to be warm during surgery and some surgeons experienced mild headaches afterward. In our study, the Microsoft HoloLens 2 was used as AR HMD which weighs 566 g. Our findings are therefore specific to this AR device. The Magic Leap Two (Magic Leap, Plantation, Florida, USA) with its weight of 260 g, and the Meta 2 (Meta Platforms, Cambridge, MA, USA) with its weight of 420 g may provide more favorable results in terms of weight and size of the devices, however, these AR devices are not (yet) extensively evaluated for use during surgery [46, 52].

In this study, only two surgeons did not use the AR HMD during the entire surgery. Our outcomes in terms of duration of usage are favorable when comparing our findings with those of Dennler et al. [17]. Dennler et al. reported that no surgeons used the AR HMD during the whole surgery [17]. However, pre-terminally removing the AR HMD can be explained by the fact that holograms only contain information helpful in specific surgical steps, such as the orientation step. In the future, it is not expected that surgeons will wear the AR HMD during the entire orthopedic trauma surgery.

4.2 Strengths and Limitations

Current literature provides limited research on the user's experience, ergonomics, practicality, and feasibility of head-mounted AR. Therefore, this prospective clinical study aimed to evaluate the surgeon's experience and intraoperative feasibility of head-mounted AR in orthopedic trauma surgery. The surgeon's experience and intraoperative feasibility were assessed with five different questionnaires, whereof four questionnaires were standardized and validated questionnaires. This resulted in highly comparable outcomes of good quality. By projecting 3D holograms of the patient's anatomy in the surgeon's FOV, and not implementing multiple technological functionalities, we aimed to focus on fair user experience assessment and not focus on technological aspects.

The main limitation of this study is the small number of participants. Since the Department of Trauma Surgery in the Erasmus MC is a level one trauma centrum and tertiary referral centrum, intra-articular fractures are not treated on a daily basis. Moreover, intra-articular fractures are frequently treated in an emergency setting, disabling the inclusion in this study. These aspects could have limited the inclusion of participants. Furthermore, the SSQ, Borg CR10 Scale, NTLX,

and SUS were used in this study to evaluate the physical discomfort, physical exertion, mental demand, and usability of head-mounted AR in orthopedic trauma surgery. However, these validated questionnaires are not specifically designed for the evaluation of AR HMDs. Using these questionnaires might have affected the results of the studies. Validated user experience questionnaires for AR HMDs do however not (yet) exist. This study may also be affected by selection bias because surgeons participated voluntarily and only surgeons from the Department of Trauma Surgery were included. This could have led to the inclusion of participants enthusiastic about novel technology.

4.3 Future Perspectives

Further development on the ergonomic design of AR HMDs is necessary to overcome issues with wearability and acceptance among surgeons. D'Amato et al. conducted a study describing the key ergonomic requirements and possible mechanical solutions for AR HMDs in surgery [53]. This study is an important step toward the design of an authentically ergonomic AR HMD to support in surgical procedures [53].

Furthermore, future research focusing on technological developments is necessary. In this study, there was explicitly chosen to not include voice control in the AR application developed in this study. It was expected that voice control would not function properly during orthopedic trauma surgery since surgeons utilize all kinds of noise-emitting tools and instruments. Nevertheless, future technical advances will enable the implementation of voice control in AR applications for orthopedic trauma surgery, which is expected to result in improved usability. Moreover, the full potential of AR during surgery will rely on intraoperative navigation. Accurate registration of the 3D holograms with the real patient and surgical instruments is required to provide reliable navigation. The development and implementation of an accurate registration method that is feasible with intraoperative use is needed, providing the superimposition of 3D holograms on the patient. This will enable surgical AR navigation, resulting in even more future applications and higher future benefits. In addition, adequate, automatic segmentation algorithms need to be developed and validated that will reduce the work associated with the preparation of patient-specific 3D models. Besides, there is a need for a fluent and simple workflow, where the surgeon can select a patient and 3D holograms of this patient are automatically generated and ready to project in an AR HMD.

During the intraoperative tests, surgeons came up with suggestions for future use, which could be considered in the future design and development of an intraoperative AR system. First, surgeons suggested that it would be useful to be able to freeze the position of the 3D holograms. This may overcome issues as accidentally repositioning the holograms. Second, the ability to toggle the entire AR visualization off would be beneficial, because the holograms can limit the view on the surgical field during surgery. Surgeons also mentioned that the 3D holographic view during orthopedic trauma surgery was beneficial for the intraoperative education of residents. Moreover, projecting holograms of osteosynthesis material will enable virtual fitting of the osteosynthesis material. For this functionality, it is necessary that surgeons can virtually reposition the fracture fragments as they do in the real world.

At last, other surgical applications which may benefit from head-mounted surgical AR need to be explored and large clinical trials need to be conducted to prove the clinical benefit of head-mounted surgical AR in terms of improved patient outcomes, reduced operation time and surgical risk, decreased radiation exposure, and increased surgical accuracy.

5. Conclusion

There is a great future potential of surgical head-mounted AR in orthopedic trauma surgery. Surgeons are generally satisfied with head-mounted AR and expect it to be beneficial in orthopedic trauma surgery. Future research focusing on an ergonomic design of surgical AR HMDs, technological developments, a simple and fluent workflow, and proving clinical value is needed to benefit head-mounted AR visualization and navigation in orthopedic trauma surgery.

Appendices

Appendix 1 – List of Abbreviations

Abbreviation	***Meaning***
ORIF	Open reduction and internal fixation
2D	2-dimensional
CT	Computed tomography
3D	3-dimensional
AR	Augmented reality
MR	Mixed reality
HMDs	Head-mounted devices
FOV	Field of view
MREC	Medical research ethics committee
OR	Operating room
QA/RA	Quality assurance & regulatory affairs
PACS	Picture archiving and communication system
ROI	Region of interest
SSQ	Simulator sickness questionnaire
NTLX	National Aeronautics and Space Administration Task Load Index
SUS	System Usability Scale
EDC	Electronic Data Capture
GCP	Good clinical practice
SPSS	Statistical package for the social sciences
SD	Standard deviation
Mdn	Median

Appendix 2 – Build Settings Unity for Microsoft HoloLens 2

Target Device	*HoloLens*
Architecture	ARM64
Build Type	D3D Project
Target SDK Version	Latest installed
Minimum Platform Version	10.0.10240.0
Visual Studio Version	Latest installed
Build and Run On	Local machine
Build Configuration	Release

Appendix 3 – Intraoperative Feasibility Questionnaire

Please complete all of the following questions.

1. **Surgical steps the AR HMD was used for**
   - ☐ Orientation
   - ☐ Drilling
   - ☐ Screw placement
   - ☐ Osteotomy
   - ☐ Other

Interaction
Please rate every item on a scale from 0 (not useful at all) to 100 (very useful).

2. **Audio quality** _____
3. **Image quality of holograms** _____
4. **Detail of holograms** _____
5. **Image quality of surgical field when looking through the glasses** _____
6. **Learnability of gesture control** _____
7. **Functionality of gesture control** _____
8. **Total speed of control** _____

Acceptance
Please rate every item on a scale from 0 (not useful at all) to 100 (very useful).

9. **The glasses are comfortable to wear** _____
10. **The glasses look good** _____
11. **I think the glasses look strange and I therefore do not want to wear them** _____
12. **I think the glasses look aesthetic and I can therefore wear it well** _____
13. **Weight of the glasses** _____
14. **Size of the glasses** _____

Wearing period

15. **For how many minutes did you wear the device during the operation?**
    - ☐ 0-15 min
    - ☐ 15-30 min
    - ☐ 30-60 min
    - ☐ 60-90 min
    - ☐ 90-120 min
    - ☐ >120 min

16. **The device was used during the whole operation**
    - ☐ Yes
    - ☐ No

17. **I only wore the AR HMD for part of the surgery for the following reasons:**
    - ☐ My visibility was impaired
    - ☐ I think the AR HMD was too uncomfortable
    - ☐ I think the AR HMD was too heavy
    - ☐ I have worn the AR HMD for certain pre-determined surgical steps
    - ☐ I also had to use other devices that made it impossible to wear the AR HMD (e.g. microscope, magnifying glasses)
    - ☐ I felt disturbed and had to remove the AR HMD

18. **I think it is possible to wear the AR HMD continuously during an operation for the following period**
    - ☐ 0-30 min
    - ☐ 30-60 min
    - ☐ 60-90 min
    - ☐ 90-120 min
    - ☐ >120 min

Regarding the surgery, I think this technology…
Please rate every item on a scale from 0 (not useful at all) to 100 (very useful).

19. **Helps to reduce radiation exposure** _____
20. **Helps to improve the surgical result** _____
21. **Increases the precision** _____
22. **Increases the speed of the operation** _____
23. **Increases patient safety** _____
24. **Improves sterility** _____

Future – I see potential for this technology to support the following operations…
Please rate every item on a scale from 0 (not useful at all) to 100 (very useful).

25. **Standard operations** _____
26. **Revision cases** _____
27. **Deformities** _____
28. **Prosthetics** _____
29. **Osteotomies** _____
30. **Reconstructions** _____
31. **Tumor surgery** _____
32. **Arthroscopic operations** _____
33. **Trauma** _____

Future – I see potential of this technology in operations on the following joints…
Please rate every item on a scale from 0 (not useful at all) to 100 (very useful).

34. **Shoulder** _____
35. **Elbows** _____
36. **Hand** _____
37. **Basins** _____
38. **Hip** _____
39. **Knee** _____
40. **Foot** _____

Overall verdict
Please rate every item on a scale from 0 (not useful at all) to 100 (very useful).

41. **I am really satisfied with this new technology** _____
42. **I would like to use this technology again at any time** _____

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