DEPARTMENT OF INFORMATICS

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Bachelor's Thesis

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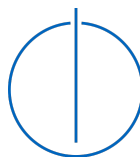
Alexander Koenig

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Visualization of Complex Bone Fractures in Augmented Reality during Reduction Surgery

Visualisierung komplexer Knochenfrakturen in Augmented Reality bei Repositionschirurgie

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I confirm that this bachelor's thesis is my own work and I have documented all sources and material used.

Munich, 23.10.2018   Alexander Koenig

Abstract

Purpose – The impressive advancements of imaging modalities throughout the past decades lead to significant progress in orthopedic research and clinical care. In the diagnosis and treatment of complex bone fractures, Computed Tomography (CT) scanning became an indispensable aid. However, surgeons still face a high cognitive load during the osteosynthesis of complex fractures as the intra-operative display of CT data proves to be cumbersome. Mentally transforming images from 2D monitors to 3D surgical space leads to poor orientation of surgeons during the fracture reconstruction process. This can result in worse treatment outcomes and increases healthcare expenses. Thus, a rethinking of intra-operative visualization to enhance spatial understanding of orthopedic surgeons is necessary.

Methods – This work follows an Augmented Reality (AR) based approach to the intra-operative visualization of CT data. A pre-operative workflow including the segmentation of the CT data using a medical imaging workstation (3D Slicer) and import into a custom application in a 3D game engine (Unity) is proposed. A commercially available optical see-through head-mounted display (Microsoft HoloLens) is used to display the segmented volumetric models. Through a Graphical User Interface or voice commands, surgeons can select various states with different functionalities to integrate the visualization better into their workflow.

Results – To evaluate the usability and clinical feasibility of the proposed method a statistical analysis of a user study was conducted. Four orthopedic surgeons were invited to take part in an experiment and rate the system using the System Usability Scale (SUS). While on average the SUS score was 81.9, three of four surgeons rated system usability with an average score of 90, which is a promising result. Qualitative data was gathered using comments boxes which yielded meaningful ideas for the extension of the project.

Conclusions – This work shows that the principle of AR can overcome current challenges involved with intra-operative visualization and has great potential in surgical applications. The study suggested that user training before the adoption into operating rooms may be necessary. The extension of the proposed software to incorporate information from a pre-operative planning tool may be sensible, and the further automation of the workflow should be investigated. Through the development of future AR devices with larger fields of view and more advanced technology a paradigm shift in surgical visualization is within reach.

Acknowledgments

Firstly, I would like to thank my supervisor Prof. Dr. Navab, head of the chair for "Computer Aided Medical Procedures and Augmented Reality" at the Department of Informatics, for providing me with the opportunity and the resources to conduct research in such a fascinating field. By giving valuable feedback and other advice, Prof. Navab enriched my work.

I also want to thank my advisors Dr. Ulrich Eck and Alexander Winkler for the continuous feedback they gave me throughout the development process of the custom HoloLens application. I am particularly grateful to Alexander Winkler for always being open to questions and for showing such great interest in the advancement of my work. Further, I would like to express my gratitude to the orthopedic surgeons that took part in the user study and provided valuable feedback.

Writing my Bachelor's thesis about medical Augmented Reality sparked my interest in this topic, and I am highly motivated to continue working in this sector. I developed a profound interest in computer science and am happy to refine my skills in industry settings and further academic endeavors.

Furthermore, I am grateful for the positive atmosphere and productive environment which the NARVIS Lab created. Through the many personal and work-related conversations with the other researches, I discovered the broad spectrum of medical Augmented Reality and received valuable suggestions for my life. I would like to thank my friends and family for supporting me throughout the process of writing this thesis.

Acronyms

AR Augmented Reality.

CBCT Cone Beam Computed Tomography.

CG computer-generated.

CT Computed Tomography.

CTA Computed Tomography Angiography.

FOV field of view.

GI Global Illumination.

GUI Graphical User Interface.

HMD Head-Mounted Display.

HU Hounsfield unit.

ICP Iterative Closest Point.

MRI Magnetic Resonance Imaging.

MRTK Mixed Reality Toolkit.

ORIF Open Reduction and Internal Fixation.

OST optical see-through.

RP Rapid Prototyping.

SUS System Usability Scale.

UI User Interface.

VR Virtual Reality.

VST video see-through.

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1. Introduction

This introduction will start with a brief discussion of the context of orthopedic surgery. In order to comprehend what complex bone fractures are some vital terminology is introduced. Furthermore, the process of fracture treatment will be explained. Later, the problem statement this thesis is concerned with will be formulated and the research goal will be clarified. Here, considerations on where and how to embed visualizations in the surgical workflow will be made based on the earlier explanations. Lastly, an overview of the scientific contribution of the proposed work is given.

1.1. Context

1.1.1. Medical Terminology

Bone is a biphasic tissue that consists of a hard outer layer called cortical bone and a less dense, spongy, internal tissue referred to as cancellous bone. Since bone is a lightweight yet very durable material it allows for several mechanical functions: "the protection of internal organs, the scaffold that provides points of attachment for other structural elements, and the levers needed to improve the efficiency of muscle action" [87, p. 1].

Bone fractures are among the most well-known medical conditions that a layman thinks about when hearing "orthopedics". Adler defines a bone fracture as "a complete or incomplete discontinuity of bone caused by a direct or indirect force" [2, p. 479]. Any person – young or old – is at risk for bone fractures. However, the probability and seriousness of such injuries are increased for older persons who suffer from osteoporotic and arthritic changes. Most often fractures heal successfully, but some may result in significant loss of function or permanent disability [41]. According to the National Ambulatory Medical Care Survey bone fractures annually account for 16% of all musculoskeletal injuries in the United States and an average citizen in a developed country can expect to suffer from two bone fractures in their lifetime [55].

Orthopedics is a branch of medicine that is "concerned with the diagnosis and management of disorders of the musculoskeletal system, that is the skeleton and the soft tissues associated with it" [22, p. 3]. In orthopedics, various terms and classification systems were introduced to more accurately describe the configuration and features of fractures. Some descriptors mentioned by Delahay et al. are as follows.

1. "**Open versus closed**: A closed fracture is one in which the skin is intact over the fracture site and an open fracture is one in which the skin is not intact.

2. **Simple versus comminuted**: A simple fracture is one in which there are only two major fragments and one fracture line. A comminuted fracture is one in which there are multiple fragments of bone and multiple fracture lines.

3. **Complete versus incomplete**: "Complete" essentially means that the fracture line goes completely across the bone. Incomplete fractures, most typically seen in children, have a fracture line that only crosses one cortex of the bone involved." [87, p. 40]

Furthermore, several typical fracture patterns can be identified. It is essential to accurately identify the fracture pattern from radiographs as they indicate the applied force at the fracture event. From that, an estimation of the soft tissue damage can be made [87]. The following presents a selection of the most prominent patterns.

1. **Transverse**: "This is usually caused by a force applied directly to the site at which the fracture occurs. This often represents a three-point force system" [22, p. 25] (see Figure 1.1a).

2. **Spiral**: "This is produced by a twisting force applied distant from the site of the fracture, usually at each end of a long bone" [22, p. 25] (see Figure 1.1b).

3. **Oblique**: This is a result of combined loading (e.g., bending and axial forces) [87]. "The break is at an angle of 30 degrees or more to the long axis of the bone" [35] (see Figure 1.1c).

4. **Greenstick**: "This occurs in children, whose bones are soft and yielding. The bone bends without fracturing across completely" [22, p. 25]. It is an incomplete fracture (see Figure 1.1d).

5. **Impacted**: This is a break "in which at least one bone (or fragment of bone) has been driven into another" [35] by axial loading [87] (see Figure 1.1e).

6. **Compressed**: "This occurs in cancellous bone as a result of a compression force" [22, p. 25] (see Figure 1.1f).

7. **Avulsion**: "This is caused by traction, a bony fragment usually being torn off by a tendon or ligament" [22, p. 25] (see Figure 1.1g).

(a) Transverse
Fracture [66]

(b) Spiral
Fracture [65]

(c) Oblique
Fracture [64]

(d) Greenstick
Fracture [63]

(e) Impacted
Fracture [67]

(f) Compressed
Fracture [62]

(g) Avulsion
Fracture [9]

Figure 1.1.: A selection of common fracture patterns

Finally, it needs to be clarified what *complex bone fractures* are. Delahay et al. describe complex fractures as a form of skeletal trauma with multiple of the above fracture patterns [87]. In general terms, they are more serious injuries than simple fractures [11] and are usually more difficult to treat. For example, Figure 1.2 shows a complex fracture of the distal tibia.

Figure 1.2.: Radiographs and volumetric rendering of a complex
tibial plafond fracture with severe comminution (approx. 15 fragments) [75]

According to Brinker the following features describe complex bone fractures.

1. "The fragments are comminuted. [...]

2. The soft tissues are severely damaged.

3. There is loss of bone due to severe trauma.

4. There is disruption of the articular surface (severe cartilage injury at a joint).

5. There are multiple fractures at several levels in a single bone.

6. There is an associated joint dislocation." [11]

According to Willis et al. complex bone fractures almost always occur as a result of high-energy trauma such as vehicular accidents or falls from a height [88]. Even at low speeds or heights, the sudden deceleration and high impact forces that are incident on the bone can leave the patient in the state of severe skeletal trauma with highly fragmented bones. The urgent treatment of complex fractures is imperative, especially since vasculature may be damaged and, in the case of open fractures, the risk of infection is very high.

Duckworth et al. reported that major trauma, which is a life-threatening condition, is appearing more often than in the past. In part, this is because of higher safety standards in modern vehicles,

which lead to greater survival rates in accidents that would have been fatal some decades ago, and in part, it is due to a rise in violent crime [22]. In a report on the assessment and management of complex fractures, the British National Clinical Guideline Centre gives more information on major trauma and complex fractures.

> "Trauma has a bimodal age distribution with the first peak in the under-20s and then the second peak in the over-65 age group. It is the most common cause of death for people below 45 years in the UK and in those people that survive a traumatic injury; a large number will have permanent disabilities. [...]
>
> Complex fractures are considered to make up the minority of the estimated 1.8 million fractures occurring in England each year, they are associated with considerable morbidity and are a large burden on healthcare resources. The treatment of complex fractures usually requires interaction between multiple healthcare professionals and specialists and the patient pathway is often complex." [56, p. 16, 17]

1.1.2. Fracture Treatment

In the process of diagnosing fractures radiological examination of a patient provides valuable information for the trauma surgeon. Reviewing X-ray images provides an important estimate of the severity of a fracture. Radiographs are typically taken in at least two plains at right angles to detect all fracture lines [22].

Computed Tomography (CT) scanning is a useful aid in diagnosing and planning surgery of complex bone fractures, particularly of the pelvis, spine and complex intra-articular fractures [22]. Whereas conventional radiographs certainly remain clinically relevant, it is widely acknowledged that CT scans are the superior imaging modality for assessing complex fractures [75]. However, as CT scans come along with a comparably high radiation dose to patients, it is usually only applied in difficult cases.

After having diagnosed the fracture accurately and carried out any necessary stabilization, the fracture itself must be treated [22]. First, the complex fracture needs to be reduced. Reduction is the surgical procedure to restore a fracture or dislocation to its correct alignment. The reduction must then be maintained such that the fracture will heal and the patient may be rehabilitated [22]. This process may be summarised as follows.
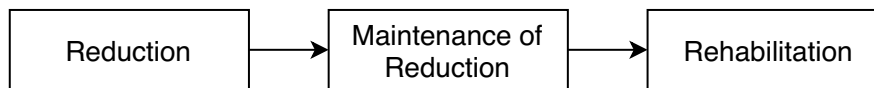
Figure 1.3.: Principles of Fracture Treatment

If a fracture needs reduction - this is not necessarily the case - different techniques may be used for achieving it. Duckworth et al. summarize them as follows.

1. "**Manipulation under anaesthesia**: This is the method adopted for most fractures [...].

2. **Traction**: Some fractures and dislocations may be reduced slowly by traction. This is usually used when manipulation is inappropriate, perhaps because an anesthetic would be dangerous [...].

3. **Open reduction**: This has the advantage of allowing very accurate reduction, but carries the risk of infection. Usually, open reduction is reserved for those cases where closed methods will not give the desired reduction, or where internal fixation is going to be needed for some other reason [...]. Open reduction does not necessarily imply internal fixation, although usually it does.

4. **Closed reduction and fixation**: For some fractures [...] the reduction is indirectly achieved, with traction and the fracture stabilized with a nail or a fixator." [22, p. 33]

After successful reduction the fracture needs to be fixated to keep it in the optimal healing position [87]. Common ways of maintaining fracture reduction and ensuring stability are the following.

1. **Intrinsic stability**: "Some fractures require no additional stabilization." [22, p. 33]

2. **External splintage**: "Many fractures can be adequately immobilized with a simple device, such as a splint made of wire, metal or polythene, bandaged in place, and a sling or crutches may be used to avoid load-bearing." [22, p. 33]

3. **Internal fixation**: "Soft tissues heal better with a stable and reduced fracture providing soft-tissue stability also. With this in mind, internal fixation has become more popular as techniques have improved. Fixation is necessary for those fractures where accurate reduction is necessary and when mobilization of the limb or the patient is particularly important [...]. Internal fixation can be used, but with more danger due to infection, in open fractures." [22, p. 38]

In the case of complex bone fractures mostly Open Reduction and Internal Fixation (ORIF) – also referred to as osteosynthesis – is contemplated. Whereas treating complex bone fractures still is a challenging task and there is no general, agreed upon treatment algorithm [30], most ORIF surgeries can be summarized as follows (also see Figure 1.4).
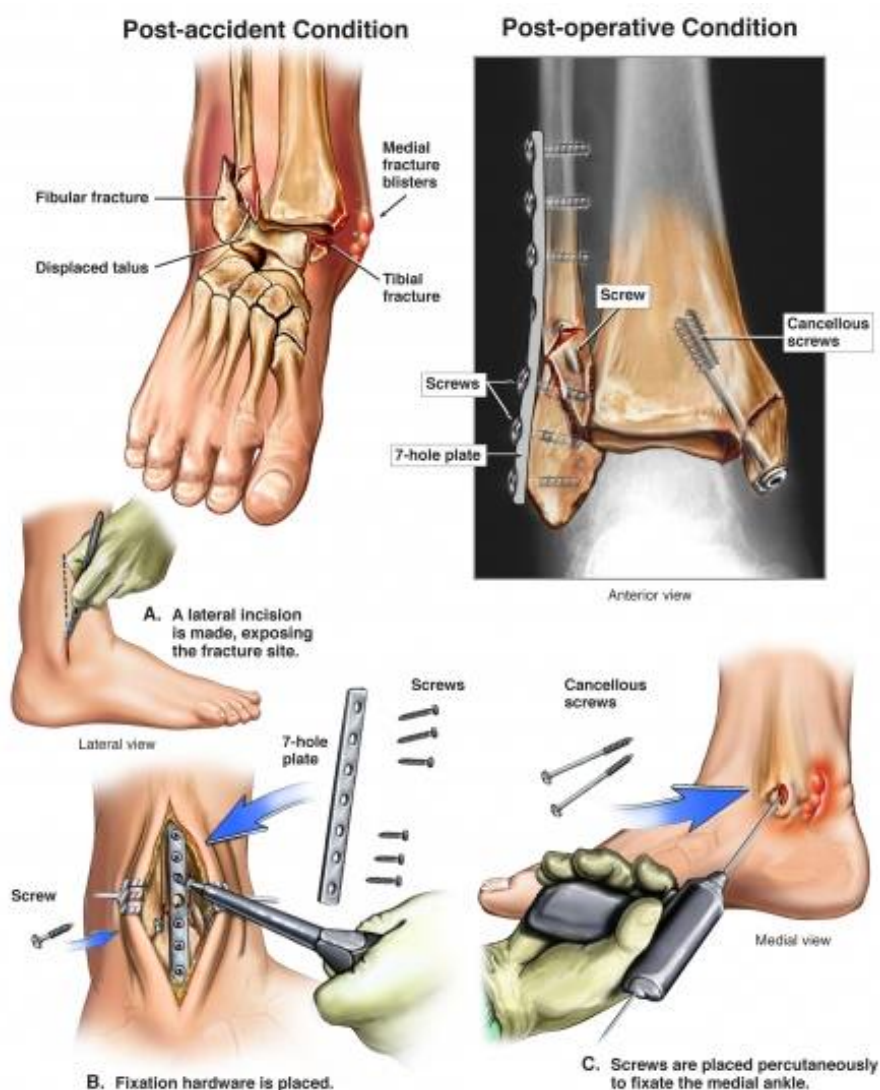
Figure 1.4.: Example of an ORIF ankle surgery [89]

Once the pre-operatively gathered radiological data was analyzed thoroughly the patient is anesthetized and the fracture site is cleaned with an antiseptic. The trauma surgeon starts the first part of the invention by making an incision and hereby exposing the area of the fracture [89]. By carefully moving ligaments, nerves and tendons aside the surgeon can reach for the bone fragments [57]. The "constant" fragment is identified and from there the reconstruction process of the other fragments starts [13]. The aim of the reduction process is to reconstruct the original geometry of the bone as accurately as possible. Surgeons may use preliminary fixation to hold the reduced bones in place during the intervention. Large voids which may be a result of the removal of bone may be filled with bioabsorbable bone substitute [13]. In the second major part of the operation, the surgeon uses internal fixation devices to secure the realigned bones in their final

position [89]. Examples of such devices are screws, plates, compression plates or intramedullary nails [22] which are usually made from stainless steel or titanium. Finally, the wound is closed with sutures and the injury will likely be protected and supported by a cast or a splint during the healing phase after surgery [89].

The process of rehabilitation and fracture healing starts immediately after the surgical treatment. Careful movement of the limb, as much as the fixation method allows, helps to prevent joint stiffness, stimulates union and accelerates convalescence. For example, it is beneficial for patients to return to their usual occupations during the healing process. Internal fixation has great advantages in this respect [22].

1.2. Problem Statement

When ORIF surgery is performed the procedure can be quite a "jigsaw puzzle" for the surgeon. Due to high comminution and the complex geometry of the fracture, the surgeon's spatial understanding of the fracture site might not be sufficient. Thus, it may be challenging to locate bone pieces or to find the correct final alignment of segments. This makes performing reduction surgery for complex bone fractures an extremely challenging task.

> *"It can be a very difficult procedure - especially as it gets more severe. Many times*
> *you open up, and all of a sudden [...] you see all these little pieces of bone and you*
> *are trying to figure out what to do. It can be pretty frustrating." [68]*

> – Dr. Richard Rogachefsky, Orthopaedic Surgeon

The complex nature of such a surgical task has negative influences on intervention durations and on the patient's rehabilitation [71]. Mistakes or inaccuracies during reduction can lead to complications after the surgery which dramatically affect the patient's recovery from a fracture.

For instance, when a fracture extends into an articular joint Post-Traumatic Osteo Arthritis (PTOA) is a common complication. According to Aurich et al. osteosynthesis for intra-articular fractures aims to minimize residual joint incongruity, and thereby decrease focal elevations of contact stress which are presumed to be responsible for PTOA. However, if the surgeon fails to restore the alignment and congruity of articular surfaces, this may lead to inappropriate mechanical load and axial deviations, which often result in degeneration of the joint and PTOA [4]. Willis et al. summarize the negative impact of PTOA on the patient in their work.

> "As a point of reference, for axial "pilon" fractures of the distal tibial articular surface
> (see Figure 1.2), the incidence of PTOA of the ankle is in the range of 60% to 80%.
> Post-traumatic OA is a serious health condition that often leads to substantial pain,
> disability, loss of work, and decreased general health status. Its overall adverse

impact on an individual's physical and psychological well-being is comparable to that of other major disorders such as stroke, heart disease, or diabetes. The societal cost of PTOA is high (estimated at $12 billion/year in the U.S.), since pain and loss of function frequently leads to loss of work capacity [...]. If PTOA develops, patients may require reconstructive surgery, including major procedures such as joint fusion or joint replacement. When these procedures are performed in a young patient, repeat surgeries throughout their lifetime may be necessary to maintain function, further raising the cost, and in some cases resulting in long term disability and unemployment." [88, p. 2]

Currently, surgeons often use average male and female morphologies as a reference when planning and performing interventions [33], or they rely on two-dimensional X-rays or CT scans [70]. However, this may not be sufficient for complex bone fractures (especially intra-articular fractures) where accurate reduction is essential. For these types of fractures it is desired that during an ORIF intervention orthopedic surgeons maintain a detailed overview of *their patient's* fracture. This is especially important because complex bone fractures differ largely from patient to patient. Furthermore, as a result of poor orientation surgeons often assess fragment inter-digitations visually and by touch, which may require considerable force and involves trial and error. Unfortunately, each "error" extends the intervention's duration and leads to iatrogenic trauma to the fragments and the surrounding tissues [75].

There is vast potential for a novel approach in the treatment of complex bone fractures that helps the orthopedic surgeon in addressing the difficulties presented above. This could aid in reducing intervention durations, avoiding complications during or after surgery and ultimately improving recovery rates from such fractures.

1.3. Research Goal

The goal of this thesis is to *provide trauma surgeons with Augmented Reality (AR) visualizations of the fracture site in order to support them during the geometric reconstruction of complex bone fractures*. In the treatment workflow, which was presented above, this visualization should be embedded at the moment of ORIF surgery.

These intra-operative visualizations should be three dimensional. Since in the case of complex fractures CT data is usually acquired preoperatively, it is sensible to generate a three dimensional model of the fracture site from this data and display it to the surgeon. There are three major challenges involved with this task.

1. Find a method for generating accurate segmentations of bone fractures with high comminution from CT data.

2. Develop a novel visualization technique for this three-dimensional model during reduction surgery.

3. Evaluate the usability of the system with orthopedic surgeons and propose future improvements and extensions based on the evaluation results.

Mastering the first challenge is very important since this ultimately defines the quality of the visualizations which are based on these segmentations. If the segmentation is inaccurate, this may lead to an incorrect understanding of the fracture site and might even result in worse recovery rates. However, if the segmentation provides a detailed representation of the geometry of the fracture site, this produces meaningful visualizations which can help surgeons in performing osteosynthesis.

The second task is the primary focus of this thesis. As mentioned before, the visualizations should be based on the principle of AR. A detailed explanation of why this makes sense is given later. Figure 1.5 gives a rough visual impression of what is desired. The orthopedic surgeon should work with a see-through Augmented Reality system in which the volumetric model of the segmentation is rendered. This system must allow for various manipulation methods to make the provided three-dimensional model interactive.
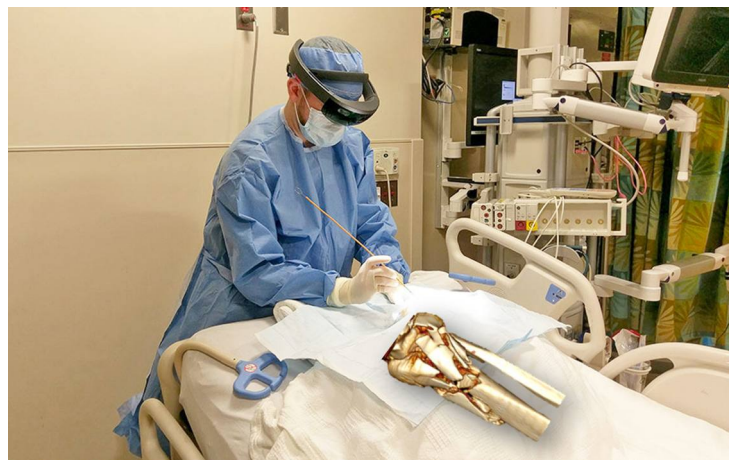
Figure 1.5.: Interpretation of operating room scenario:
surgeon with AR Head-Mounted Display sees rendering
of segmented CT data while operating [38, 88]

Since bulky and rather complex setups are needed to perform reliable image registration (i.e., bringing the virtual model of the bone into alignment with the patient's real anatomy) we decided to follow a non-registering approach in this project. Especially for complex fractures, accurate registration is a complicated task due to soft tissue movement. Thus, attempting registration may come along with substantial inaccuracies. If registration is attempted, the surgeon might rely on

the system's accuracy which may, in reality, be very low and unintentionally harm the patient. Therefore, the visualization technique should instead be an organizational tool, and for this a "hovering" model of the fracture is sufficient.

Good usability of this visualization technique during ORIF surgery is imperative since the system should help the surgeon and must not lead to further confusion. Therefore, in a third step, the system is evaluated in a user study to gather information about meaningful future improvements and extensions of the project.

1.4. Scientific Contribution

This section provides an overview of the scientific contribution of this work. The first contributions of this thesis are the identification of the problem statement and the research goal based on the presented medical background.

One major scientific contribution of this thesis is the literature review. As part of the methodology chapter, some explanatory information about the potential of Augmented Reality in medicine and surgery is given. Since Rapid Prototyping is a technology which has application areas that overlap with those generated by Augmented Reality a brief comparison between both techniques is made. Furthermore, a review of recent related works in the field of Augmented Reality supported surgery is given. By analyzing those related works, a research gap is defined.

A review of the most recent commercially available Augmented Reality devices is given, and it is evaluated which is most applicable for the task. Furthermore, the project workflow is elaborated thoroughly, and some issues (e.g., the leakage problem for segmentation of complex fractures) relating to it are pointed out.

The main contribution of this project is the development of a comprehensive visualization framework which can be employed during ORIF interventions for complex bone fractures. The current state of this self-contained system is functional and sophisticated but by no means fully mature. The application can be used for demonstrations in order to illustrate what the future of medical Augmented Reality could look like. Furthermore, this project constitutes an attractive opportunity to base further research upon.

In order to test the usability and clinical feasibility of such systems, a user study is conducted. This presents a significant scientific contribution as in this study various ideas to refine and advance the functionality of this tool in future work are generated. The last chapter summarizes some of these research opportunities and presents further thoughts on how to master challenges involved with the project.

2. Methodology

In this chapter, a brief review of the principle of Augmented Reality and its corresponding utilization methods is given. The potential of Augmented Reality in surgery is elaborated, and a short comparison to Rapid Prototyping technology is made. Furthermore, some related works are reviewed, and a research gap for this project is defined. It is then discussed which AR device is most applicable in this clinical scenario and the corresponding software for the task is presented. Finally, the proposed approach for this project is clarified.

2.1. Augmented Reality

2.1.1. Introduction to AR

Augmented Reality allows for the real-time fusion of computer-generated (CG) digital content with the real world. While Virtual Reality (VR) technology completely immerses users inside a digitally created environment, Augmented Reality allows them to observe three-dimensional virtual objects superimposed on the real world [31]. Through AR the users' life is simplified by enhancing their perception and interaction with the real world [14]. Milgram and Kishino (1994) defined a broader reality-virtuality continuum termed "Mixed Reality" that comprises both AR and VR [53].

Augmented Reality image registration usually consists of two stages: tracking and reconstruction. Firstly, points of interest are detected and tracked in camera images (e.g., fiducial markers) using computer vision methods such as feature detection, edge detection, or other image processing techniques. Tracking can usually be either feature based or model-based. The former reconstruct the connection between the 2D camera reference frame and the 3D world frame coordinates by identifying image features. Model-based techniques make use of virtual models of the tracked objects' features such as CAD models or 2D templates. Once the pose relationship between the 2D image and 3D world coordinates is established, virtual information of any kind can be brought into alignment with the real world and create the effect of Augmented Reality [14].

According to Carmigniani et al. most Augmented Reality display technology can be classified into the following three groups. Refer to Figure 2.1 to get a visual impression of the techniques.

1. **Head-Mounted Display (HMD)**: A HMD is a display device that is worn on the user's head and it can either follow a video see-through (VST) or an optical see-through (OST) approach. Video see-through systems (see Figure 2.1b) are equipped with two cameras that are mounted to the HMD. The images captured by the cameras are continuously streamed to the displays which are positioned in front of the user's eyes. Computer-generated content can be flexibly added with a great degree of control as the user's entire view is digitally created. For example, the virtual and real images can be synchronized before they are displayed to the user, which ensures good control over the timing of the scene. In optical see-through displays (see Figure 2.1a) the virtual information is typically overlayed by employing a half-silver mirror technology. Light from the real scene can pass through a lens and is augmented by reflecting digital information in the user's eyes. A great challenge in OST approaches is that any delay induced by image processing will be instantly noticed as the virtual images may be perceived as detached from the corresponding real objects [14].

2. **Handheld Display**: Handheld displays are display devices such as smart-phones and tablet PCs which users can hold in their hands. (see Figure 2.1c). They employ video see-through techniques to overlay virtual information on the real world. They are extremely portable and widespread, and their technology is advancing at a fast rate, which makes them a promising platform for Augmented Reality. Their small display size limits the degree of user immersion [14].

3. **Spatial Display**: Spatial AR techniques project virtual information directly onto real-world objects while the user is not required to wear or hold a display. As the technology is integrated into the environment spatial AR allows for multi-user collaboration. Spatial displays can be either video see-through, optical see-through or directly augmenting. Video see-though spatial displays (see Figure 2.1d) are screen based and are common for applications where the system does not need to be mobile. Since only standard hardware components are required this is a cost-effective approach. Spatial optical see-through approaches (see Figure 2.1e) attempt to align augmenting images with the real world. Similar to VST approaches, OST spatial AR technology is not suitable for mobile applications since the optics and displays (e.g., transparent screens) are spatially aligned. Directly augmenting systems (see Figure 2.1f) are projector based setups that directly project images onto real-world surfaces [14].
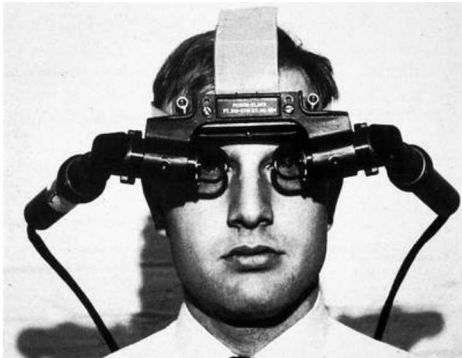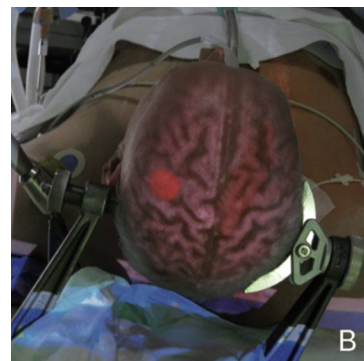
(a) First OST HMD by Sutherland [74]

(b) VST HMD [20]

(c) Handheld display [86]

(d) VST spatial display [10]

(e) OST spatial display [25]

(f) Direct augmentation [8]

Figure 2.1.: AR display technology

2.1.2. Potential in Surgical Applications

Augmented Reality has great potential in any field in which rapid information transfer is critical [92]. Medicine surely is one of those fields since fast and precise communication of medical data increases effectiveness and safety of treatments. AR has numerous promising areas of application in medicine such as education of medical students, surgical planning, incorporation of data visualization into diagnostic procedures, enhanced surgical training [83], minimally invasive surgery or integration of haptic devices to virtually explore the patient's condition via touch [92].

Douglas et al. (2017) introduced the term "*mixed procedure*" for any surgical intervention which is enhanced by AR. Mixed procedures allow for computer-generated content to be projected onto the patient's anatomy which helps in making surgery more efficient and arguably safer [21]. In the following, the main advantages of such mixed procedures over established approaches during surgical interventions are discussed.

The majority of modern operating rooms still rely on traditional ways of presenting information, like two-dimensional computer screens. However, as new types of procedures are being developed and surgical tasks get more complex novel means of visualizing data are needed. An accurate spatial understanding of the patient's unique anatomy is critical in surgery [21]. This may be an especially cumbersome task during ORIF procedures for highly comminuted bone fractures. Surgeons need to perform a mental transformation from data presented on 2D screens (e.g., CT image sequences) in order to form a three-dimensional map of the fracture. Augmented Reality has the potential to support the surgeon's spatial sense by providing 3D guidance and direct depth perception without any intermediate mental effort.

Some types of surgeries – especially orthopedic surgery – target structures which may change significantly during an operation due to removal (e.g., small fragments) or addition (e.g., internal fixation devices) of objects [83]. To get a clear view of the current state of the situs intra-operative imaging modalities such as Cone Beam Computed Tomography (CBCT) are commonly employed. However, such techniques may be associated with a significant radiation dose to both the patient and the surgeon. Mixed procedures employing an efficient 3D visualization of such data may reduce the need for further images an thus reduce radiation dose and lead to a more unobstructed surgical workflow.

Sielhorst et al. point out that each medical device in the operating room may introduce multiple screens and user interfaces [73]. Therefore surgeons spend valuable time finding the most ergonomic setup, and if they fail to do so, a natural workflow may be hindered. Augmented Reality could help in unifying the respective user interfaces and merge medical data of any kind in one device. One challenge involved with this task is to organize information meaningfully in order not to distract the surgeon with too much information. Many modern AR systems allow for direct interaction with computer-generated 3D content using gesture input or speech recognition. Freeing

the surgeons' hands from operating complex interfaces of conventional medical devices leads to a more sterile surgical environment and can enhance concentration on manual work.

Another advantage closely related to this issue is that by using AR technology, supplementary information can be displayed right into the surgeon's field of view. Currently, surgeons continuously need to redirect their view between the operating field and the diagnostic imaging monitors which may be positioned across the room [21]. While this applies to all types of surgery which are based on imaging data, a prominent example of this problem is minimally invasive surgery. Sielhorst et al. have demonstrated the problem of different positions and orientations of image acquisition and visualization by analyzing a minimally invasive spine surgery setup in Figure 2.2 [73]. Hanna et al. concluded in their paper that endoscopic task performance is optimal when the image display is located in front of the operator at a level close to the hands [32]. This suggests that projecting visualizations in the surgeon's direct and natural field of view is desirable. By using Augmented Reality systems, the offset between working space and visualization can be minimized so that no mental transformation of the visual information to the hand coordinates is necessary [73].
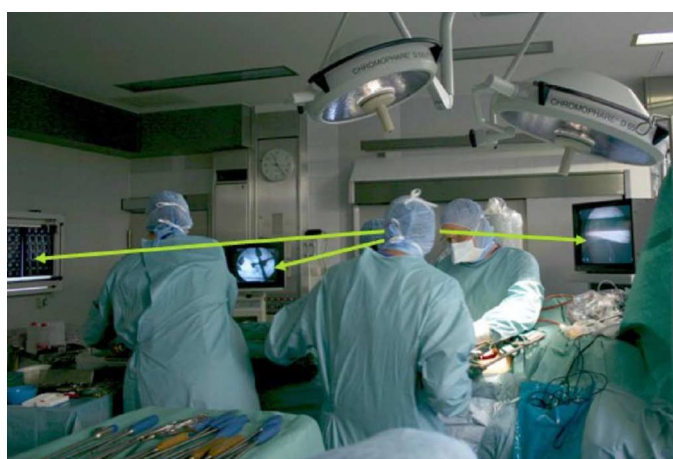
Figure 2.2.: Position and orientation of monitors
creates significant offset between operating
table and visualization [73]

Certainly, image registration can be of great advantage in medical Augmented Reality. Without having to make an incision surgeons can determine the location of anatomical structures such as bones, vessels or organs by projecting virtual models of them onto the patient's body [21]. While accurate registration of computer-generated content with real patient anatomy has great potential, there are several major difficulties involved with this task (e.g., non-rigid tissue registration, line of sight constraints for optical tracking systems or parallax error of projector-based spatial AR [8]) which are currently researched heavily.

Like all new technologies Augmented Reality faces some challenges that complicate a rapid adaption of AR systems into operating rooms. One of the central questions is how surgeons integrate the real and virtual environments [21]. To allow for thorough integration in the operative workflow training is necessary to get surgeons accustomed to this new technology. However, the familiarisation with AR systems is expected to be rather quick as they offer a somewhat more intuitive usage than current medical devices. The adoption of HMDs is likely to be seamless since most surgeons are required to wear sterile goggles or magnifying surgical loops and are thus accustomed to using eyewear during surgery [21]. Although some Augmented Reality devices may encompass poor depth perception, excessive latency, high prices or complicated setups, the ongoing research will develop more advanced hardware in the future.

None of the presented challenges is not surmountable. Augmented Reality has excellent potential to be used intra-operatively in symbiosis with surgeons. This may contribute to progress in shortening hospital stays and operation times, lowering healthcare expenditures and improving treatment outcomes [21].

2.1.3. Comparison to Rapid Prototyping in Orthopedics

Recently the technique of Rapid Prototyping (RP) was introduced to assist in the management of complex bone fractures. Since some areas of application of 3D printing may overlap with those covered by medical Augmented Reality, the former is briefly reviewed.

RP may be used as a pre-operative tool for surgical planning. Kelil et al. report that RP generates tangible models that aid in comprehending the geometry of complex fractures. This helps in determining the optimal positioning and size of hardware, such as screws and implants. Furthermore, they argue that working with a 3D printed model of the fracture can assist in pre-bending of reconstruction plates [40]. Although integrating haptic feedback in AR applications is possible, the impression of it may not be as realistic as assessing a real three-dimensional object. Another advantage is that other surgeons can also perceive the 3D printed model and base their discussions on it. A major pitfall of some AR techniques is that only one person can view them at a time. Battiato et al. have demonstrated that by using a 3D printed model of an acetabular fracture during ORIF surgery the intervention duration can be shortened by almost 20% and blood loss is reduced from 1000ml to 500ml [6].

One drawback is that 3D printed surgical guides need to be sterilized before intra-operative use. Fürnstahl et al. have shown that using steam pressure, which is a widely accepted way of sterilization, (130°C for 15 to 20 minutes) deformed the models slightly. Even though this effect is almost negligible (highest error of 0.5 mm), it introduces a further step before it can be used in surgery [27]. Probably the most notable disadvantage of RP in surgical use are the long printing times. Whereas AR guidance could be available shortly after performing a CT scan, printing 3D

models takes up to several hours (or even days). The cost of materials and the space needed to store models are further downsides [72].

The development of Rapid Prototyping techniques can be of great use for surgeons. Even though 3D printing offers great advantages for haptic pre-operative planning, intra-operatively Augmented Reality may offer a somewhat more flexible and broader approach to visualization. Any means of interaction and data visualization are imaginable in AR. Certainly, both AR and RP have potential in the medical field, and their simultaneous development is fascinating to watch.

2.2. Related Works

Given the rather large number of developments of pre-operative planning tools, the research body rethinking intra-operative data visualization is surprisingly small. A search for the keywords "intra-operative" and "Augmented Reality" on PubMed resulted in 46 entries which were filtered for their relevance. Additionally, more articles were found manually using references in these papers and Google Scholar to give a comprehensive overview of the current status of AR technology in surgery. Finally, eight papers were selected for this review. The date range lies between 2015 and 2018. The related works can be differentiated most clearly by the display type that is employed.

Head-Mounted Displays

Chen et al. (2015) proposed an AR-based surgical navigation system (AR-SNS) that facilitates preoperative surgical planning, registration, and intra-operative tracking. This advanced system features a high-performance graphical workstation, an OST HMD (nVisor ST60, NVIS) and an optical tracking device (Polaris Vicra, NDI Inc.). The system integrates virtual anatomical structures into the real-world operating scenario with remarkable accuracy: the mean distance and angular errors of registration were 0.809 ± 0.05 mm and $1.038° \pm 0.05°$ respectively. Besides this great accuracy Chen et al. also describe challenges involved with their setup. The small measurement volume of their optical tracking system and the slightly wet clinical environment may impact the tracking results. Further, they describe that time latency and heavy weight of the HMD may pose a burden on users [15].

Cutolo et al. (2017) presented an AR system based on a video see-through HMD (see Figure 2.1b) that can aid in complex neurological lesion targeting. The HMD consists of a 3D viewer (Sony HMZ-T2) and two external USB cameras (5 megapixels). Accuracy was tested on a patient-specific head mannequin. With a marker-based video registration method, employing three spherical markers which are rigidly constrained to the mannequin, they achieved sub-pixel registration accuracy. Cutolo et al. achieved improved depth-perception compared to similar systems and

circumvented the parallax problem [20].

Pratt et al. (2018) showed that using an OST HMD (Microsoft HoloLens) to identify the subsurface location of vascular perforators provides a more reliable and faster method of navigation than traditional techniques such as audible Doppler ultrasound. They introduced a pre-operative workflow that encompasses segmentation, model generation and mesh processing of the structures of interest (e.g., bones, vascularity, skin, soft tissues) from Computed Tomography Angiography (CTA) scans. Intra-operatively, their system was used to manually register these three-dimensional models and custom indicators to the patient's anatomy. Interestingly, Pratt et al. used hand gestures and voice commands to register the virtual models to the real body. Whereas their application incorporates a Graphical User Interface (GUI) which lets users switch between a translation and a rotation mode, scaling of the model is not intended. This is due to the preservation of spatial scale information throughout the pre-operative workflow [58].

Handheld Displays

Choi et al. (2015) developed a simple surgical navigation system using a tablet PC in order to circumvent the use of "expensive and uncomfortable" external optical tracking systems. The mono camera was used to track the multi-faced reference markers attached to the patient's body. Through the tablet PC, resection margins for bone tumors in the pelvic region are intuitively displayed as a contour shape. In an animal study with 36 pig pelvises Choi et al. verified that this simple setup helps to achieve a 10 mm resection margin (10.26 mm compared to 12.28 mm for conventional method) [17].

Wen et al. (2017) proposed an interactive guidance system featuring a Microsoft Kinect v2 sensor and a tablet on a gooseneck mount (see Figure 2.1c) for localization of anatomical structures and navigation of surgical tools. The Kinect sensor gathers spatial data of the patient's body, position of surgical tools and motion of the surgeon's hands. Their registration algorithm achieves efficient registration and is particularly robust to noise and missing data. They showed that the system helps surgeons in locating organs with errors between 1.74 and 2.96 mm. However, they reported problems with the GPU acceleration of the tablet PC which resulted in non-smooth visualizations of complex organs and vessels [86].

Cho et al. (2017) developed a system that supports tumor resection in long bones and employed a handheld tablet PC (Microsoft Surface Pro3) with an embedded mono camera. The camera is used to track reference markers with square graphic patterns to allow for registration. Their project is exciting as it does not visualize the bone's real geometry, but rather an abstracted view of it. The longitudinal relationship data of the long bone (e.g., femur) – including the position of a tumor – is rendered as a cylinder-shaped virtual template that is laid over the patient's anatomy. To test the system bone resection surgery was performed on 123 pig femurs. Their results show that using

this rather simple setup the probability of a surgeon obtaining the 10 mm margin with a 3 mm tolerance increased by almost 20% (70.7% in conventional resections and 90.2% in AR-assisted resections) [16].

Spatial Displays

Besharati et al. (2015) developed an AR system for the intra-operative use in neurosurgical procedures. In image-guided brain tumor surgery, this technique helps to plan skin incision and craniotomy. A commercially available projector (PicoPix 1020, Philips) was used to project regions of interest (segmented tumor, vessels, functional areas) generated from Magnetic Resonance Imaging (MRI)-based 3D models directly onto the patients head, skull and brain (see Figure 2.1f). Registration was manually performed using five fiducial markers in the region of the tumor. Although their method provides good clinical feasibility and high accuracy (projection error 1.2 ± 0.54 mm) Besharati's research shows several significant challenges involved with direct augmentation in surgery. The projection of the two-dimensional image onto the curved 3D surface of the head leads to image distortion, especially in the outer regions. Since the distortion grade decreases near the center of the projection axis, tumors need to be positioned along this axis to minimize the projection error. However, due to occlusion the surgeons viewing angle cannot coincide with the projection axis [8]. This might induce significant parallax errors which get more pronounced with the depth of the region of interest [21].

Befrui et al. (2018) introduced a novel screen based surgical navigation system which combines a CBCT capable C-arm with a combined color and depth (RGBD) camera. As the C-arm rotates around the region of interest the RGBD camera which is attached to the C-arm records the surface of the patient's body simultaneously. In a next step, the data sets of both systems are merged. Radiographs are digitally reconstructed from the CBCT and then virtually projected on the surface of the situs. This creates a 3D model of the body surface of the patient with the overlaid boney structures. This work presents an especially interesting approach as it allows for the processing of data which is acquired intra-operatively. Furthermore, Befrui et al. implemented object recognition based on the depth sensor of the camera, which allows for the real-time display of hands or surgical tools on screen. The great benefit of this approach is that no tracking markers are employed and that anatomical structures can be viewed from positions which may not be possible with a conventional setup due to spatial interference of the C-arm. The authors showed that imaging times and overall radiation dose can be greatly reduced with the system [7].

Research Gap

Analysing related works confirmed that a *non-registering* approach should be followed. A major downside of setups featuring optical tracking systems is that they can lead to a more error-prone surgical workflow [20]. Tracking difficulties caused by a small measurement volume, as reported by Chen et al., or line of sight constraints may be induced [20]. Although Pratt et al. reported that manual registration using gestures was sufficient for their application, this is most likely not be the case for complex fractures. This is because non-rigid soft tissue movement may be more pronounced for comminuted fractures than for subsurface vasculature.

Furthermore, the proposed system needs to be *specifically designed for complex fractures* and should feature *high ease of use*. Time latency which is described by Chen et al. and Wen et al. has negative influences on usability and needs to be avoided. The visualizations need to represent the actual geometry of the bones as complex fractures cannot be reduced to simpler shapes, which Cho et al. suggested for long bones. Unlike Pratt et al. proposed, it is meaningful to allow for scaling of the virtual models for complex bone fractures to view the fracture site in more detail.

HMDs are most applicable for displaying images to the user. Since these devices are worn on the head, as opposed to handheld displays, the surgeon is provided with free hand movement. This is an advantage in ORIF surgery as manual tasks need to be continuously performed. HMDs usually also allow for a great movement space of the user. Systems that feature a gooseneck mount for the tablet PC, like Wen et al. presented, do not provide enough adaptability for complex procedures and restrict movement space. New commercial developments of such devices offer continuously improved ergonomics through lighter and less bulky designs, which is an advantage over, for example, spatial displays. Furthermore, parallax errors arising with direct augmentation, for example in the project Besharati et al. presented, are avoided by displaying truly three-dimensional visualizations in the surgeon's field of view using an HMD.

Further, in the presented clinical scenario *optical see-through* HMDs provide clear advantages over video see-through systems. OST HMDs offer an essentially unobstructed, instantaneous view of the surgical site which ensures the synchronization of the visual and proprioception information [69]. The surgeon can still continue the intervention safely if the display malfunctions as the direct vision of reality is not affected. This is a great benefit in medical visualization in which safety is of top concern [59] and may be especially important in the early phase of adoption of AR technology by surgeons.

Summarizing, the identified research gap is the development of a non-registering AR approach that features an optical see-through HMD which provides trauma surgeons with user-friendly organizational support during the osteosynthesis of complex bone fractures.

2.3. Hardware

2.3.1. Review of HMDs

The current market for HMDs comprises a rather unsystematic yet broad spectrum of techniques and applications [60]. To provide an overview of commercially available OST HMDs a selection of devices, which have the potential to be used in the proposed context, are briefly reviewed. One HMD which was not released yet, but is an exciting project to watch, is also mentioned. See Figure 2.3 to get a graphical impression of the devices.

1. **Epson Moverio BT-350**: The Epson Moverio BT-350 smart glasses (see Figure 2.3a) are commercially available since 2017 and feature a bright 720p HD display. A powerful Intel Atom quad-core processor and 2GB of RAM ensure smooth visualization of 3D content. Its refresh rate is 30 Hz. These smart glasses offer improved ergonomics and six hours of battery life [23].

2. **ODG R-7**: The R-7 (see Figure 2.3b) is a standalone device and was released in 2015 [84]. The stereoscopic 720p displays are projector-based and allow for a refresh rate of 80 Hz. Due to its high processing power the R-7 is suitable for professional use [59].

3. **Microsoft HoloLens**: Since its appearance in 2016 HoloLens (see Figure 2.3c) attracted a lot of public attention. It features a custom holographic processing unit with waveguide optics and a resolution of 2.3M holographic light points [59]. The battery life is up to three hours during active use. HoloLens weighs 579g [48].

4. **Meta 2**: Meta 2 (see Figure 2.3d) was brought to market in 2016 and features a 60 Hz refresh rate, 2550×1440 resolution and sensors for hand interaction and positional tracking. It weighs 500g. At 90 degrees, the Meta 2 has the widest field of view (FOV) of all currently available OST HMDs. It comes at approximately half the price of Microsoft HoloLens, however - as opposed to HoloLens - it requires a cable for video, data and power transmission [47].

5. **Magic Leap One**: Magic Leap One (see Figure 2.3e), which was very recently released (August 2018), is a standalone device with a wearable computer and HMD. A one-handed wireless controller provides haptic vibrating feedback. Its field of view has a 4:3 aspect ratio (40 degrees horizontal, 30 degrees vertical and 50 degrees diagonal). So far, it is only available in the USA [18].

6. **Project North Star**: Project North Star (see Figure 2.3f) is an open-source experimental HMD platform which is currently being developed by Leap Motion. The company seeks to combine its advanced hand tracking technology with a novel AR platform. The headset features two 120 Hz, 1600×1440 displays with a combined field of view covering over a hundred degrees [44].

(a) Epson Moverio BT-350 [23]

(b) ODG R-7 [3]

(c) Microsoft HoloLens [49]

(d) Meta 2 [54]

(e) Magic Leap One [82]

(f) Project North Star [43]

Figure 2.3.: A selection of modern OST HMDs

2.3.2. Microsoft HoloLens

In this project the Microsoft HoloLens[1] is chosen. In a comparative multi-user study Qian et al. conclude that for clinical usability Microsoft HoloLens is more suitable than the ODG R-7. Results demonstrate that HoloLens outperforms R-7 in contrast perception, task load, and frame rate. Furthermore, they show that for surgical scenarios HoloLens is the optimal choice in terms of system lag [59]. Other studies similarly confirm that HoloLens is a suitable device for medical AR [29, 19].

One major drawback of the Meta 2 compared to HoloLens is that it employs a cable. In surgical procedures, this may be a problem since free movement of the surgeon is desired. HoloLens is a self-contained, wireless system which functions as a standalone computer. It features inside out tracking and thus no external optical tracking system is required. The Moverio BT-350 offers a significantly smaller FOV than the HoloLens (23 degrees [23] versus 35 degrees [36]) which makes it less applicable for surgical tasks. Magic Leap One was not released to the European market yet, and Project North Star is still in development. In summary, HoloLens provides a suitable all-in-one hardware solution for this project.

It is important to briefly explain the input methods provided by HoloLens in order to understand the following considerations made in chapter 3. As a means of input three systems are employed: Gaze, Gesture and Voice (see Figure 2.4).
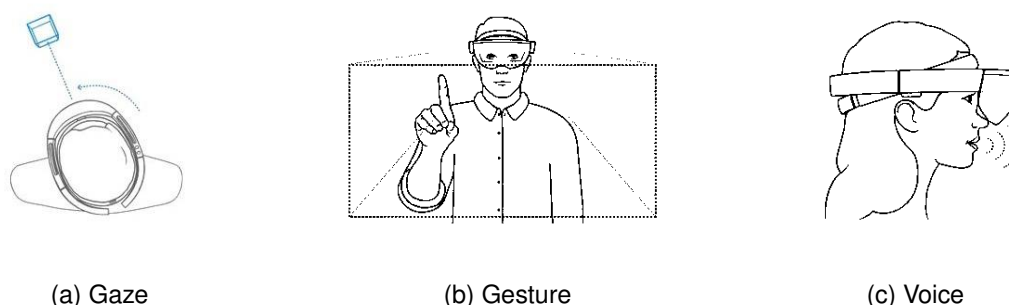

(a) Gaze   (b) Gesture   (c) Voice

Figure 2.4.: HoloLens input methods [45]

Gaze is a form of targeting within mixed reality and tells users where they are looking in the world. Just like in the real world, people first look at a point of interest before interacting with it in the augmented world. To determine the gaze vector, HoloLens uses the position and orientation of the users' head. This vector points straight ahead from between the user's eyes. The ray, which acts as a laser pointer, can intersect with virtual holograms or the spatial mapping mesh of the real world. To interact with an element, it should be targeted using gaze, followed by a gesture or a voice command [90].

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[1]For more information, please visit https://www.microsoft.com/en-us/hololens

Gestures are controlled by relative hand motions. Two core gestures are recognized: Air Tap and Bloom (see Figure 2.5). Both can be performed with either hand. Bloom brings users back to the start menu of the system. It is reserved for that alone and cannot be used by custom applications. Air Tap's functionality is similar to a mouse click. It is a tapping gesture with the hand held upright and is used to interact with targeted objects in any application.

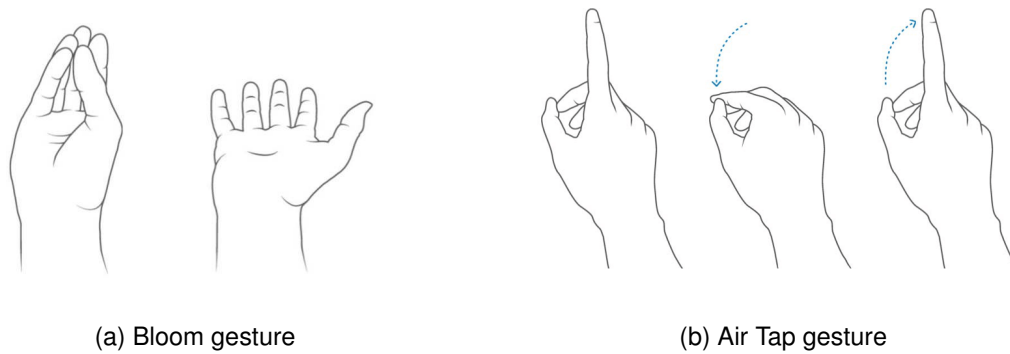(a) Bloom gesture   (b) Air Tap gesture

Figure 2.5.: The two core gestures of HoloLens [51]

For gestures to be successfully detected by HoloLens the hand must be within a range that is covered by the gesture-sensing cameras, referred to as the "gesture frame". It roughly ranges from nose to waist and from the left to the right shoulder. User training on the frame's boundaries needs to be considered both for success of action and for their own comfort [91].

HoloLens recognizes composite gestures by combining tap, hold and release hand movement.

- **Tap and Hold**: Hold gestures are activated by maintaining the finger in the downward position of an Air Tap. Drag interactions can be triggered when a hold gesture is combined with arm movement.

- **Manipulation**: Manipulation gestures are used to transform (translate, rotate, scale) holograms, responding with a one-to-one reaction to the user's hand movements.

- **Navigation**: Navigation gestures act like a virtual joystick. Users employ the tap and hold gesture and can then move their hand within a virtual normalized cube, centered around the initial tap position [91].

Voice is the third key form of input. Once an object is targeted using gaze, users can directly speak predefined commands to start an interaction. Voice offers a natural way of communicating which type of interaction is desired [91]. Furthermore, HoloLens offers dictation mode which can understand any form of speech.

2.4. Software

2.4.1. 3D Slicer

3D Slicer[2] is a software application for medical image computing. Besides various visualization methods which are also offered in usual radiology workstations, 3D Slicer features advanced analysis of medical images. Examples of such features include semi-automated segmentation and registration. Unlike other radiology workstations, 3D Slicer is free, open source, and is not tied to specific hardware. Its functionality can be readily expanded using custom extensions [24].
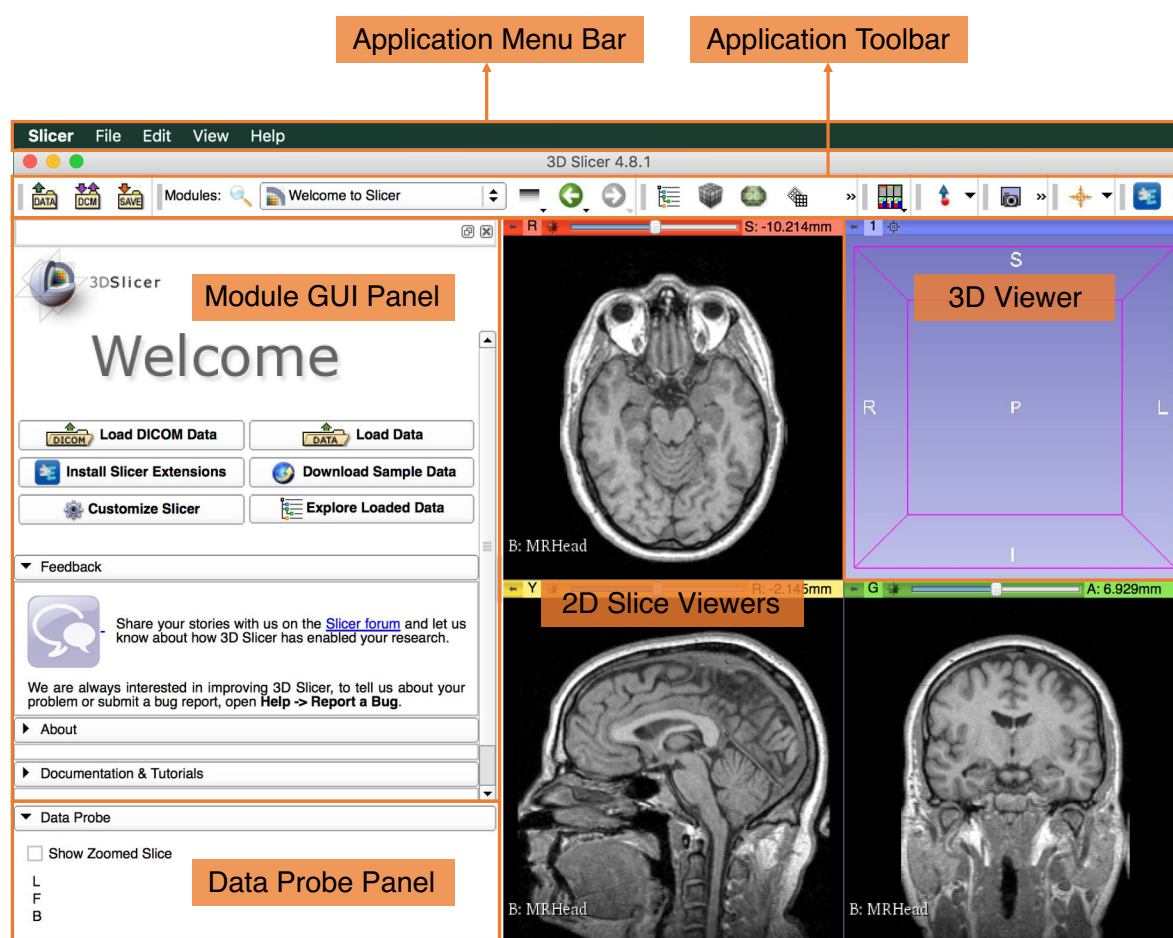

Figure 2.6.: GUI of 3D Slicer

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[2]For more information, please visit http://www.slicer.org/

3D Slicer's modular architecture is based on six components which are organized in a GUI: the Application Menu Bar, the Application Toolbar, the Module GUI Panel, the Data Probe Panel, the 2D Slice Viewers, and the 3D Viewer (see Figure 2.6) [1].

From the Application Toolbar, several built-in modules can be accessed. There are two modules which are extensively used in the proposed workflow: *Segment Editor* and *Segmentations*. What is precisely achieved with 3D Slicer and these modules, in particular, is explained in subsection 2.5.3.

2.4.2. Unity

In order for custom content to be displayed in HoloLens, a Windows Mixed Reality application has to be created. The most straightforward way of doing this is through Unity[3]. This is a 3D game engine developed by Unity Technologies. Game engines provide developers with a framework to build games quickly and efficiently.

Assets are any data that can be used in a Unity project (e.g., surface meshes from 3D Slicer) and can be assembled in scenes. In the scene users can add lighting, audio, effects, physics, interactivity, and gameplay logic. Furthermore, Unity is capable of debugging and optimizing content for desired target platforms [77]. The interface of Unity consists of six main components: the Project Window, the Scene View, the Game View, the Hierarchy Window, the Inspector Window and the Toolbar (see Figure 2.7).

The library of available assets is displayed in the Project Window, whereas the Scene View allows for visual navigation and editing of the scene in a 3D or 2D perspective. The Game View shows the final output which would be rendered on the target device (i.e., HoloLens) [78]. The Hierarchy Window shows every object contained in the scene in a hierarchical text representation. Users can view and edit properties of selected objects in the Scene View. The Inspector Window allows users to view and edit all properties of selected objects and Toolbar provides access to other essential features [79].

The fundamental objects in scenes are called GameObjects. Their behavior is controlled by the Components that are attached to them. Although Unity offers various built-in Components, users can implement their own gameplay features by creating Components using custom scripts. These enable developers to trigger game events, modify Component properties over time and respond to user input. Scripts are implemented in the C# programming language [76]. Listing 2.1 shows the most basic structure of a C# script in Unity.

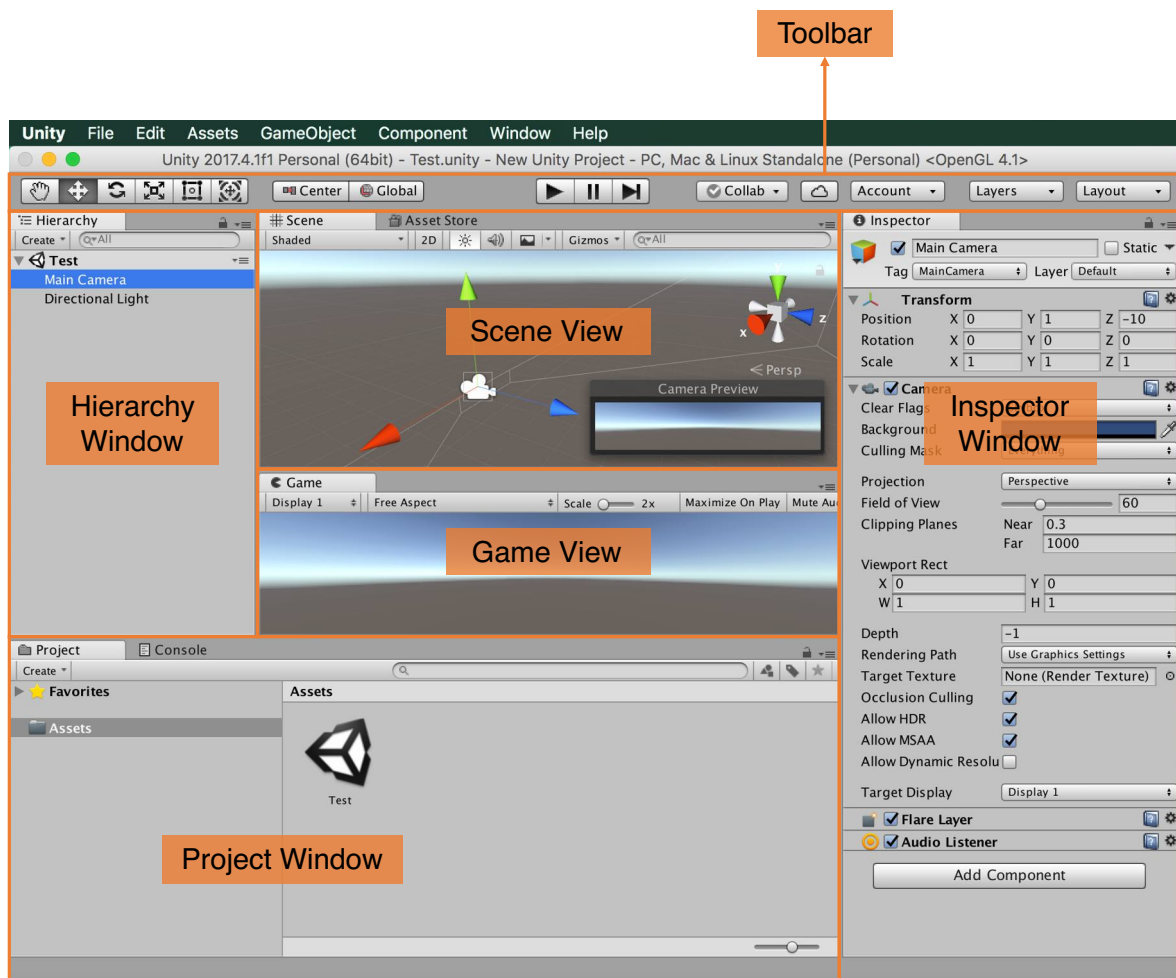[3]For more information, please visit https://unity3d.com

Figure 2.7.: GUI of Unity

```
1  using UnityEngine;
2  using System.Collections;
3
4  public class MyClass : MonoBehaviour {
5
6      // Use this for initialization
7      void Start () {
8      }
9      // Update is called once per frame
10     void Update () {
11     }
12 }
```

Listing 2.1: Basic structure of a script [76]

Unity scripts usually implement a class that derives from `MonoBehaviour`, which is a built-in class that functions as a blueprint for creating a new Component type. When a script is attached to a GameObject as a Component, it creates a new instance of the object defined by `MonoBehaviour`. Code that handles the frame update of the GameObject such as movement, triggering actions and responding to user input should be implemented inside the `Update` function. The `Start` function is called only once, prior to the start of gameplay. Since it is executed before the `Update` function is called for the first time it is often used to initialize variables [76]. Besides the `Start` and `Update` functions many more event functions can be implemented within `MonoBehaviour`[4].

A useful extension to the Unity environment for accelerating the development of Mixed Reality applications targeting Windows HMDs is the Mixed Reality Toolkit (MRTK)[5] by Microsoft. For this project, the resources provided in the Input feature area (e.g., scripts that power gaze, gesture and voice input) are especially handy.

2.5. Proposed Approach

2.5.1. Overview

So far, three different systems were introduced: an optical-see-through HMD (Microsoft HoloLens), a medical imaging software application (3D Slicer) and a 3D game engine (Unity). However, their connection and interaction still need to be clarified. Figure 2.8 provides an overview of the proposed clinical workflow from image acquisition to visualization during surgery. The pipeline can be divided into three different steps: data acquisition (red), pre-processing (green) and visualization (blue).

Immediate patient care, which may be provided in the hospital, is not part of the visualization workflow. The process which regards the visualization of patient data starts after the patient is stabilized and from X-ray radiographs, it is evident that the fracture is of complex nature. In this case, CT scans are frequently performed in order to plan surgery adequately.

Depending on the experience of the staff all steps until visualization should be completable within approximately two hours. CT scans are a routine task for medical staff, and their duration ranges from a few minutes to half an hour [85]. The process of accurate CT data segmentation roughly requires one hour for trained staff, depending largely on the complexity of the fracture. All pre-processing steps after segmentation can be executed rather quickly – they do not take more than 30 minutes.

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[4]For more information, please visit https://docs.unity3d.com/Manual/ExecutionOrder.html

[5]For more information, please visit https://github.com/Microsoft/MixedRealityToolkit-Unity
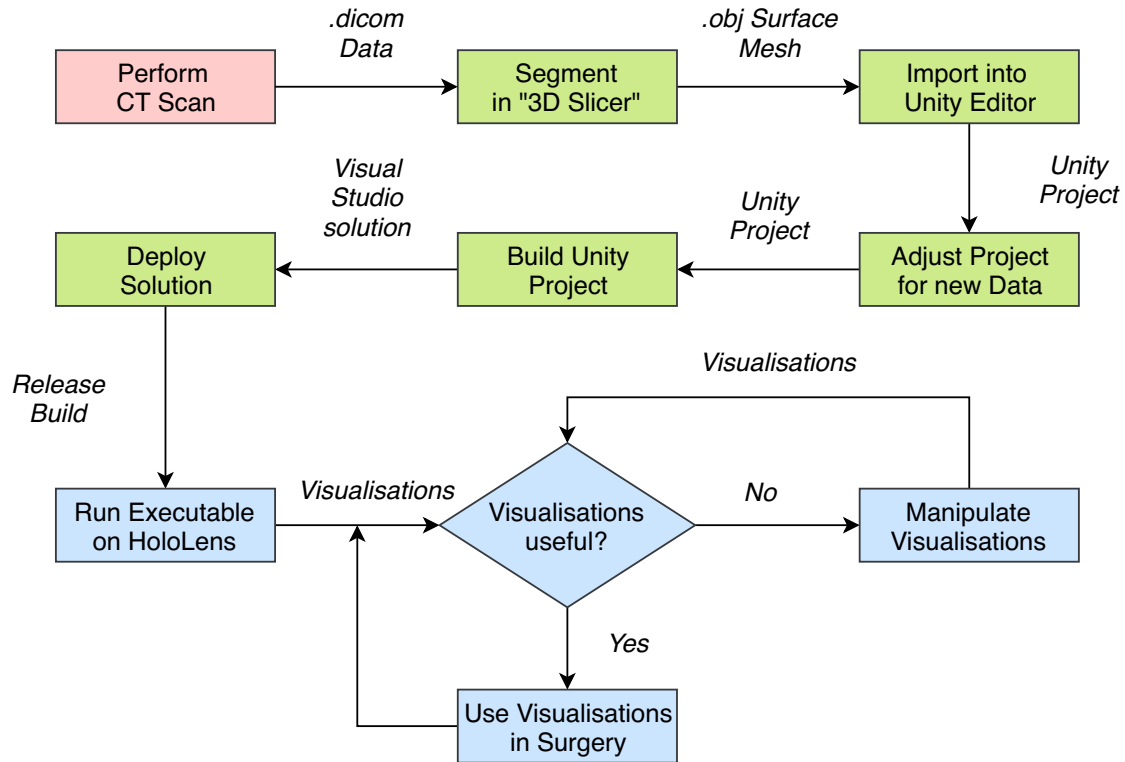
Figure 2.8.: Pipeline of proposed approach

2.5.2. Data Acquisition

Computed Tomography is a technology which is indispensable in today's orthopedic surgery. A CT scanner (see Figure 2.9) is a medical device that features an X-ray source which helically moves around the patient while a detector measures X-ray attenuation. From this, a three-dimensional radiodensity image is computed by the reconstruction of a sequence of two-dimensional CT slices (see Figure 2.10).

Each of the slices consists of a layer of voxels which in combination with all other slices yield the 3D CT scan. For each voxel, the corresponding attenuation coefficient in 3D space is stored. These coefficients result from the varying musculoskeletal tissue densities. In a next step, they are transformed into the Hounsfield unit (HU) which defines the attenuation of water to 0 HU and air to -1000. Tissues with high density (e.g., cortical bone) have values above 400 HU whereas low-density materials (e.g., fat) have negative HU values. To display this information on a computer screen, the values are mapped to greyscale intensities [26].

Figure 2.9.: Modern CT scanner [61]

Figure 2.10.: CT slice of pelvis fracture

After having generated data from a CT scan, this information needs to be encoded and distributed. For this, the Digital Imaging and Communications in Medicine (DICOM) format is the most widely used communications standard [39]. Besides transferring images, the aim of this file format includes the transmission of diagnostic and therapeutic information and associated data of any kind [52].

2.5.3. Pre-Processing

The pre-processing stage can be subdivided into the following three steps: segmentation and generation of a surface mesh from DICOM data, importing, adjusting and building the Unity project and deploying and running the solution on HoloLens.

The DICOM format introduced in subsection 2.5.2 can be opened by radiology workstations such as 3D Slicer. Loading the acquired DICOM data into this software allows for extensive processing of the images. The most relevant 3D Slicer modules for this workflow are the *Segment Editor*, which creates segmentations, and the *Segmentations* module, which manages Segmentations.

Firstly, using the "Add" button in the Segment Editor, multiple segments have to be created (see Figure 2.11). There should be one segment for the surrounding tissue and one for each incoherent boney structure (i.e., intact bones and fragments). For example, when segmenting an acetabulum fracture, both femora, the lumbar vertebrae, the intact part of the pelvis and the fragments should be separate segments. The number of segments can be edited at any time during the segmentation process. This process needs to be executed thoroughly in order to allow for full functionality of the visualization application on HoloLens.
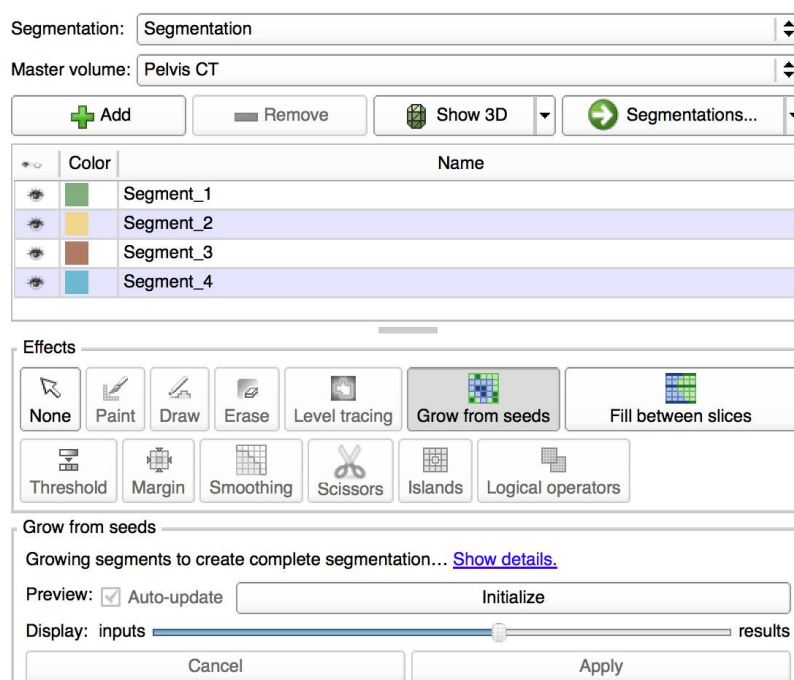
Figure 2.11.: GUI of Segment Editor module

For image segmentation, 3D Slicer offers a semi-automatic approach. The user sets seeds in the selected regions of interest (e.g., a fragment) in multiple slices in the 2D Slice Viewers by employing the drawing tools which can be accessed under "Effects" (see Figure 2.12b). After pressing "Initialize" under "Grow from seeds" a region growing algorithm computes a complete

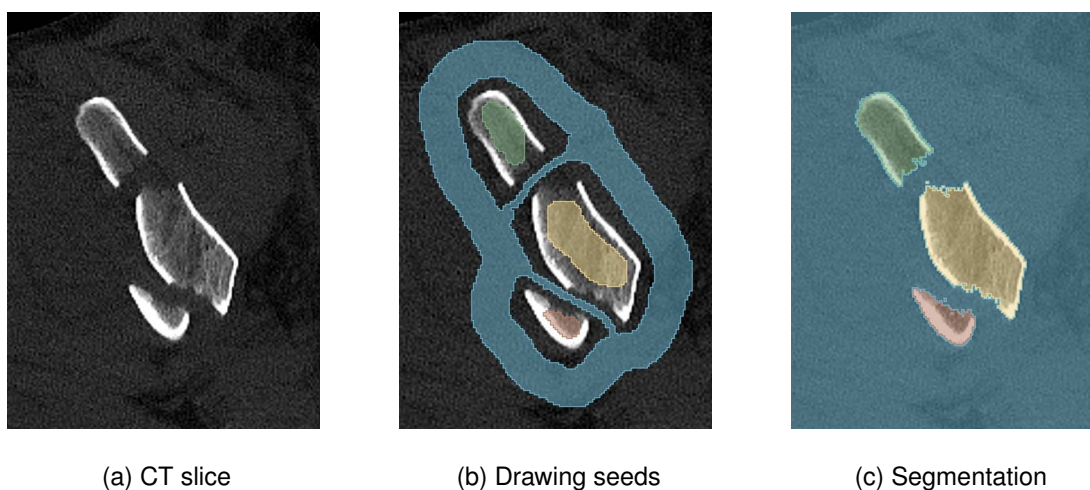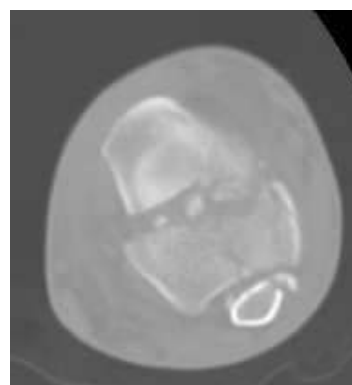(a) CT slice   (b) Drawing seeds   (c) Segmentation

Figure 2.12.: Segmentation process of part of a fractured pelvis
using the Segment Editor module

segmentation. The segment boundaries are placed where voxel intensity changes abruptly. A three-dimensional model can be shown in the 3D Viewer using the "Show 3D" button in the Segment Editor module.

One difficulty with using CT intensities to segment medical images is the leakage problem. This problem arises when the intensity values between two types of tissue are very similar. Intensity-based segmentation algorithms such as region growing are prone to leaking into the adjacent tissue. Figure 2.13 shows that in the more distal regions of the long bones the density of cortical and cancellous bone assimilates and therefore contrast to the surrounding soft tissues diminishes. Thus, segmenting fragment surfaces for comminuted fractures that extend into an articular joint (e.g., Figure 2.13b) may be especially cumbersome as the CT intensity difference between the revealed bone and the surrounding tissue is small and leakage may occur [88].
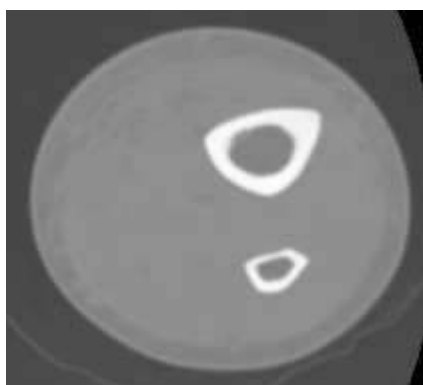
| (a) Dense cortical bone leads to high contrast in proximal midshaft of the tibia [88] | (b) Less overall contrast in more distal regions of the tibia [88] |

Figure 2.13.: Varying bone densities and contrast along a bone

In order to avoid the leakage problem presented a few things need to be taken into account. The initial seeds need to be accurately drawn in the region of interest without leaking into other regions in the first place. It proved to be useful to set seeds not only in one plane (e.g., the transverse plane) but in all anatomical planes (i.e., transverse, sagittal and coronal plane). When segmenting fragments explicitly specifying the intra-fragmentary space as non-osseous tissue by using the drawing tools helps to avoid between-fragment leaking (see Figure 2.12b). Generally, providing more seeds – especially in regions with low contrast – improves segmentation accuracy.

If by browsing through the CT slices or by viewing the 3D model it becomes evident that leakage occurred, the segmentation boundaries need to be edited. Users should add more seeds to the misclassified regions and update the segmentation. This process might need to be repeated until a satisfyingly accurate segmentation is computed. Employing methods to make segment boundaries smoother by removing extrusions or filling holes is often useful. Under "Smoothing" 3D Slicers

offers standard image processing methods such as opening, closing or Gaussian smoothing.

Other segmentation methods in the Segment Editor module are "Threshold" and "Fill between slices" which have both proven to be less accurate than region growing. Although segmenting fractures using a region growing approach may take longer, it is the most suitable method available in 3D Slicer as in this context high segmentation accuracy is proportionally more important than fast processing times.

After a sufficiently accurate segmentation of all structures of interest was created (see Figure 2.14) a closed surface representation of it needs to be computed in order to allow for further processing. This is done in the Segmentations module, which can be directly accessed through the "Segmentations" button in the Segment Editor module. It may be sensible to decimate the number of triangles in the surface mesh by using the built-in "Model Maker" module.
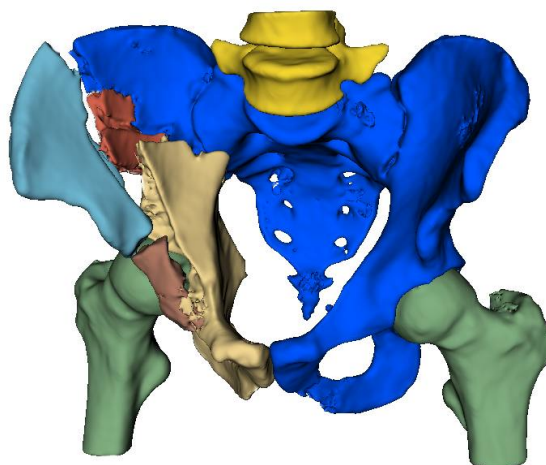

Figure 2.14.: Final segmentation of an acetabulum fracture

As the last step in 3D Slicer, by clicking "Save" in the Application Toolbar, the surface representation needs to be exported as an OBJ Wavefront file. OBJ is a geometry definition file format and is the only format that both 3D Slicer can export and Unity can import.

This surface mesh can then be imported into the Unity Project Window of the visualization application developed in chapter 3. Adjusting the application for new patient data is explained in section 3.4.

After these steps are completed the project needs to be built. Under "File" and "Build Settings" the Universal Windows Platform must be selected. The solution file (".sln") which was generated by Unity in the specified path needs to be opened with the integrated development environment Microsoft Visual Studio. In Visual Studio the application can be deployed remotely to the HoloLens

by entering its IP address. For this, a computer operating Windows 10 is required.

2.5.4. Visualisation

After a successful deploy of the application to the Microsoft HoloLens, the executable can be found under the "+" symbol in the main HoloLens GUI. Upon starting the application the "Made with Unity" logo will appear. After this banner disappeared the visualization software proposed in chapter 3 is ready to be used during ORIF surgery (see Figure 2.15).

Figure 2.15.: Visualisation of acetabulum fracture in HoloLens

3. Application Development

This chapter explains the development of the custom HoloLens application. Firstly, a requirements analysis is conducted to understand which features should be implemented in the proposed system. A use case is defined to illustrate the surgical application of the system. Further, it is explained how the main features are implemented. Lastly, an overview of which setup steps maintenance personnel need to take to use the app is given.

3.1. Requirements Analysis

3.1.1. Functional Requirements

The overarching goal of this thesis is to develop an Augmented Reality system that supports trauma surgeons during ORIF procedures. Therefore, the most important functional requirement of this software is to provide meaningful visualizations in the chosen HMD, the Microsoft HoloLens. An overview of all requirements for this software can be seen in Figure 3.1.

It is important to clarify what exactly needs to be visualized. The most important feature to display is the model of the fracture itself. However, when finding the correct alignment position of a fragment during ORIF interventions the surgeon might also want to visualize a healthy bone. Displaying a model of an intact reference bone, which has been acquired from a healthy person or an atlas, can help him precisely determine the correct geometry in which he can eventually fixate the fracture. Moreover, since users can – like in reality – only perceive the side of the object which is facing them, in some scenarios it may be useful to add a virtual mirror. Through this mirror trauma surgeons can see both models from another arbitrary viewpoint (e.g., the back side of the fractured bone) without changing their position or manipulating the visualizations. Furthermore, the users should be able to independently change which visualizations are active depending on their needs.

Providing "meaningful visualizations" implies that they need to be adaptable to the current use case. For example, when surgeons make the incision to start the operation, they might want to see different visualizations than compared to when he wants to examine a fracture surface of a specific fragment during surgery. Therefore, the surgeon needs to be able to manipulate the visualizations. This second functional requirement can be refined as follows:

Figure 3.1.: Requirements diagram for the proposed Augmented Reality System

1. **Transform all models**: The surgeon should be able to place the holograms (fracture, intact bone and mirror) wherever he needs them in the operating room. Besides translation, rotation of the models is an important feature since this might allow for a more meaningful view. This is especially important for the fracture model and the virtual mirror because their informative value depends highly on their rotation. Furthermore, scaling of the models can lead to a more detailed understanding of the geometry of specific areas.

2. **Transform fragments**: Individual fragment manipulation is an important feature of this software since in a complex fracture the pieces might occlude one another and might thus not be visible at first sight. Therefore it makes sense to enable the surgeon to grab individual fragments from the fracture site, where multiple fragments may lay on top of each other. Further, if the user can manipulate a fragment individually by translation, rotation and scaling this makes it much easier to grasp the characteristics of the fragment surfaces and determine what its correct alignment position is. Enlarging fragments by scaling is especially useful since in comminuted bone breaks the fractured pieces may be very small.

3. **Interact**: Due to surgical manipulation (e.g., changing position of fragments or removal of bone pieces) pre-operative images may rapidly lose accuracy during interventions [60]. Therefore the surgeon should be able to interact with the fragments. Interacting hereby refers to coloring the pieces, which also includes making them transparent if required. To avoid confusion, it makes sense to give the surgeon the opportunity to mark specific fragments as 'done' by color coding them. On top of that, the user might want to set a region of interest or mark removed pieces by hiding specific parts of the segmentation. For example, if an ORIF intervention for an acetabulum fracture is performed, the surgeon might not want to see the femur head which may also be part of the model. In this case, changing the appearance of the femur head to be transparent could help the surgeon keep a better overview of the situation and not be distracted by unnecessary visualizations.

4. **Expand**: When searching for more ways of displaying complex spatial information simply and intuitively, one quickly comes across exploded view drawings, which are typically used in mechanical engineering. These types of diagrams show the relationship of different components of an object by separating them by a distance often starting from a point origin. When observing and trying to understand the composition of the fracture making use of such an exploded view is very meaningful. The surgeon should be able to adjust the distance along which the fragments are translated using a variable slider. This allows for smooth movement of the fracture's pieces away from a calculated center and helps the user to grasp the spatial position and orientation of the fragments in the unexpanded state.

5. **Reset**: Since during the hologram manipulation the surgeon might take actions he did not intend, it is important to give him/her the opportunity to reset all models individually. Resetting the objects precisely requires changing their appearance back to default, removing any remaining expansion and fragment transformations, resetting their rotation to face the user, setting their scale back to 100% and moving them back into the user's field of view.

Besides allowing for hologram manipulation, the software should also increase the general organization of the surgeon. Accessing patient information is a vital part of this. As a point of reference, "over a period of 6.5 years, doctors in Colorado alone operated on the wrong patient at least 25 times and on the wrong part of the body in another 107 patients, according to a study, which appears in the "Archives of Surgery"" [28]. Wrong-patient or wrong-site surgery must be prevented and an information panel with the most important data to identify patients, and their diagnosis may aid in achieving this.

One disadvantage of Augmented Reality is that other persons who are not integrated in the augmented environment cannot see the computer-generated content which is projected into the user's world. Especially in the context of ORIF surgery this may become a major problem as frequently doctors are debating issues during an intervention and for this a common basis of discussion is needed. To give other people (e.g., students, assistants or other surgeons) in the operating room the opportunity to experience the virtual models the surgeon is seeing a collaboration mode is required. Thereby a network connection between multiple HoloLens devices should be established, and the holograms need to be displayed to each user in a common frame of reference.

To meet these functional requirements, various states have to be assigned to satisfy the functions presented so far. The user needs to be able to independently navigate through the software and decide which state is active (e.g., first translate, then expand fracture). To give the user direct visual feedback in which state he currently uses the software a meaningful and clear graphical user interface (GUI) should be provided.

Even though the GUI provides an intuitive structure, the surgeon might sometimes not want to see the menu. Especially when the surgeon operates all unnecessary information (e.g., GUI panels) needs to be hideable on demand. Furthermore, once the surgeon knows which states can be entered and got accustomed to the system another valuable feature is controlling the software via voice commands.

3.1.2. Non-Functional Requirements

To allow for a seamless integration of this technology in the surgical workflow, an essential non-functional requirement is good usability. In this project, the surgeon should be assisted and not confused.

The maintenance personnel, who process the surface meshes and deploy the software to the HoloLens, should also be provided with good usability since visualizations should be available as fast as possible and errors must be avoided. Using the GUI, voice commands and gestures to work with the application needs to be as intuitive as possible. If this is achieved training periods can be kept to a minimum and incorrect use can be avoided.

A big part of good usability of visualization software originates in its performance. It needs to be made sure that the application runs smoothly on the HoloLens, provides fast user interaction and avoids irritating lag. The user should be provided with sufficient feedback while using the software. If the system gets used in an operating room scenario, it needs to be highly reliable. It must not crash at any time and must deliver repeatable behavior.

Furthermore, the visualizations themselves need to have a meaningful appearance. A suitable material must be found, and the virtual lighting situation must be optimized. The segmentations need to represent the actual geometry of the fractured bones as accurately as possible, as they determine how useful the visualizations are to the surgeon.

3.2. Use Cases

Figure 3.2 provides an overview of the use cases of Augmented Reality supported ORIF surgery. Four main actors are part of the process: the surgeon, assistants and students, maintenance personnel and the patient. The use cases can be summarised as follows.

Before the surgery, the maintenance personnel deals with data generation and preprocessing as explained in subsection 2.5.2 and subsection 2.5.3. They make sure that the DICOM data, which has been acquired during the CT scan is accurately segmented in a medical image processing software like "3D Slicer". The maintenance personnel then imports the surface mesh of the fractured bone and a three-dimensional model of a corresponding generic reference bone into the Unity Editor, where the project needs to be adjusted for the new data. Specific functions and settings need to be updated, which is explained in detail in section 3.4. The personnel then deploys the software to the HoloLens and should check at all times if the software needs improvements or maintenance.
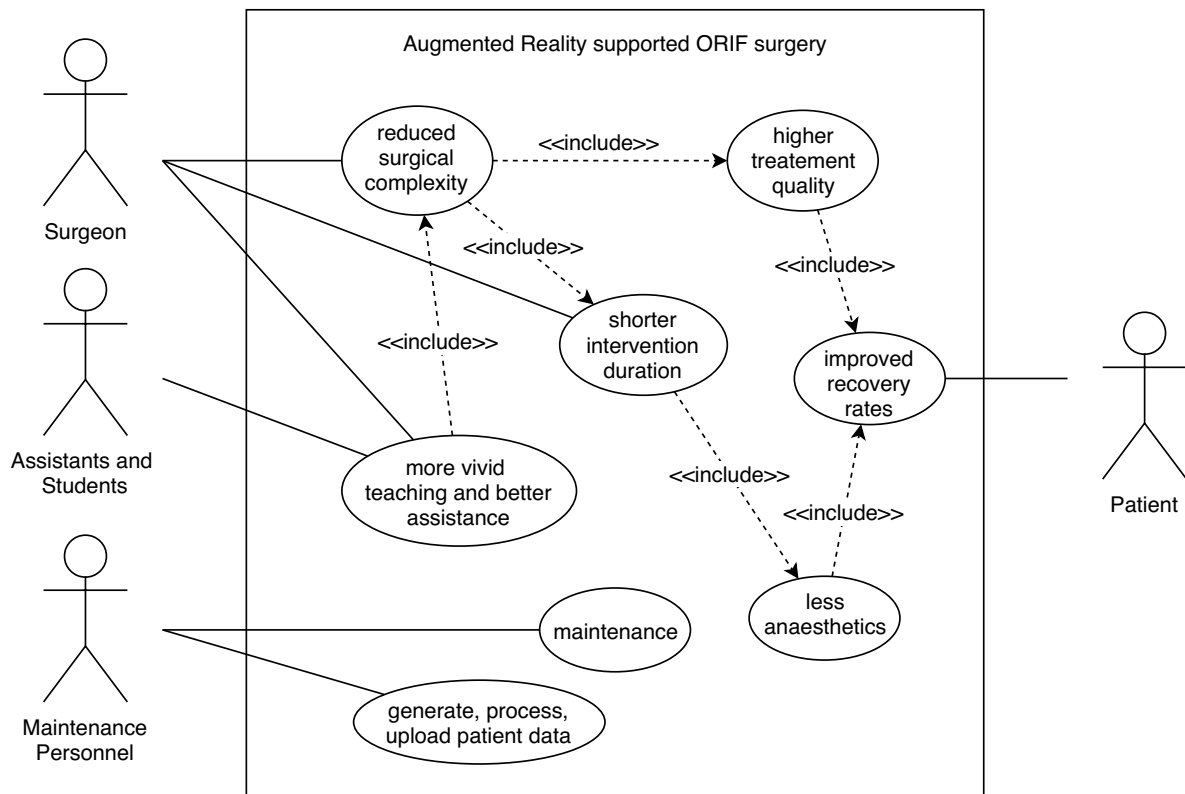
Figure 3.2.: Primary use cases of Augmented Reality supported ORIF surgery

Assistants and students are benefitting from more vivid teaching through the usage of an Augmented Reality system during surgery. By establishing a network connection between multiple HoloLenses, the surgeon can make more explicit demonstrations by not only referencing the patient's anatomy but by explaining the procedure using the three-dimensional models in the common frame of reference. Since assistants and students experience higher quality teaching their usefulness to the surgeon might increase as a result. Working with clear visualizations may reduce miscommunication between surgeons and assistants.

By using the AR system and by receiving improved assistance, the surgical complexity that the operating surgeon is experiencing is reduced. Since the surgeon's spatial understanding of the fracture is enhanced fewer mistakes are made, and reduction accuracy is improved. This results in higher treatment quality for the patient. Shorter intervention durations resulting from less complex procedures are also benefitting the surgeon and the hospital because higher numbers of patients can be treated.

The patient indirectly profits from AR supported ORIF surgery. Since higher treatment quality can be achieved with such a system the patient will find it easier to recover from the intervention and

complications are reduced. Because intervention times can be reduced fewer anesthetics may be administered which improves recovery rates even further. On a larger scale, this also means that the hospital is benefitting since they dismiss more content patients. The impact on society can be high if common diseases and complications after surgery like PTOA (see section 1.2) can be avoided.

3.3. Prototype Implementation

3.3.1. System Architecture

To satisfy the requirements analyzed in section 3.1 a Unity project was created. Here all relevant assets are grouped in the Hierarchy window, and all scripts are attached to the corresponding GameObjects as components in the Inspector panel.

The basic structure of the Hierarchy window is shown in Figure 3.3. The project is organised into six parent GameObjects: "Lighting", "MixedRealityCameraParent", "CustomCursorWithFeedback", "Managers", "Models" and "GUI". Each of these parent GameObjects contains multiple children.
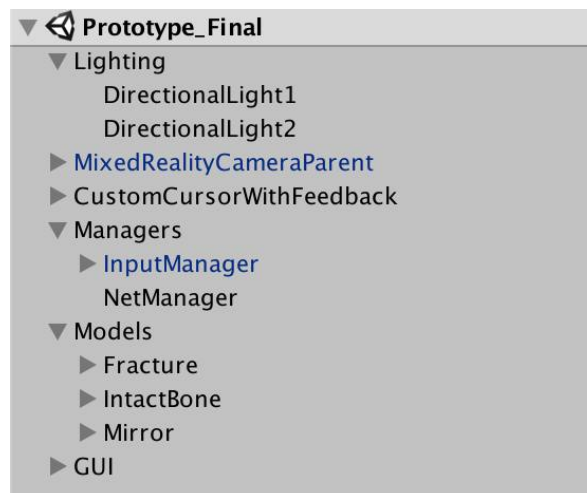

Figure 3.3.: Project structure in the Hierarchy window

3.3.2. Lighting

The Lighting parent object defines the virtual illumination of the scene. Unity can calculate complex, advanced lighting effects in various ways, each suited to different use cases. Lighting in Unity can be considered as either "real-time" or "precomputed" (see Figure 3.4), and both techniques can be used in combination to create immersive scene lighting.

- **Real-time lighting**: This means that the lighting is updated every frame. This makes real-time lighting especially useful for scenes with movable GameObjects. However, rays from Unity's real-time lights do not reflect when they are used by themselves, which leads to less realistic illumination [80].

- **Baked lightmaps**: Baking is a calculation process in which complex static lighting effects are precomputed using a technique called global illumination, or Global Illumination (GI). Those effects are stored in a lightmap, which can include direct and indirect light reflected from other surfaces. Baked lightmaps are static and cannot change during gameplay. This approach potentially increases performance [80].

- **Precomputed real-time global illumination**: This technique offers a solution for updating complex scene lighting and moves the calculation process to before the start of gameplay. An example of this is a time of day system, in which the position and color of the light source changes over time [80].
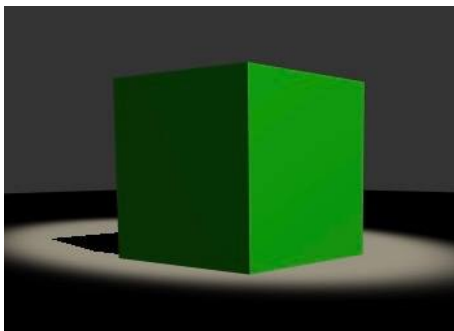
(a) Realtime lighting
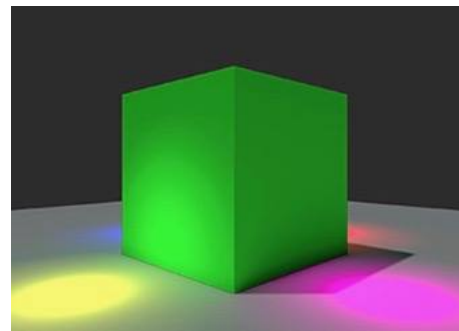
(b) Precomputed lighting

Figure 3.4.: Lighting techniques in Unity [80]

In this application real-time lighting needs to be employed. Baked lightmaps are not suitable for the task since they are unable to react to changes in illumination induced by relative transformation (e.g., rotation) of the models. Static lightmaps are likely to cause disillusion of the user as upon transformation model illumination starts to look unrealistic. Precomputed real-time global illumination is not applicable since the models' position, and orientation required for assessing global illumination is not known before deploying the software.

Besides different illumination concepts, Unity offers different types of light: point lights, spotlights, area lights and directional lights. Point and area lights are not suitable since their light intensity diminishes according to the inverse square law. Spotlights feature a cone-shaped illumination [81]. These behaviors create the effect of local light sources (e.g., lamps or headlights) and are not suitable as a global light source. Directional lights can be thought of as distant light sources which exist infinitely far away. Their light intensity does not diminish, which offers a uniform global illumination of the scene.

Two directional lights are therefore chosen for this project. They are pointing at each other – one illuminates the models from the top and one from the bottom. The lights are tilted slightly along the X and Y axis to achieve more pronounced shadows. The orientation of the lights to form optimal shadows can usually be determined using a trial and error approach. This is mostly dependant on the geometry of the fracture.

3.3.3. Camera, Cursors and Managers

As mentioned in subsection 2.4.2 the Microsoft Mixed Reality Toolkit proves to be a valuable extension for the development of HoloLens applications. Among other frameworks, it provides Prefabs – templates from which new object instances can be built – such as cameras, cursors and behavior managers.

The MixedRealityCameraParent object from the Input Module[1] of the MRTK in Figure 3.3 instantiates the Microsoft HoloLens as the project's camera and optimizes settings. The camera is used to display the scene to the surgeon.

To increase the usability of the application users are provided with cursors to receive feedback of where they are currently gazing. Cursors are directly coupled to the gaze vector and are always projected along the ray. Thus they can be moved by changing head orientation. The CursorWithFeedback.prefab from the MRTK is customized with two additional cursors. In total four cursors (Figure 3.5) are contained in the CustomCursorWithFeedback parent GameObject.

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[1] For more information, please visit https://github.com/Microsoft/MixedRealityToolkit-Unity/blob/ master/Assets/HoloToolkit/Input/README.md

- **Off Hologram**: When the users' gaze vector is not intersecting a hologram a faint red point light is shown approximately 1.5 meters along the vector. This is to indicate the direction of their gaze and to help them direct it at their point of interest.

- **On Hologram**: If a collision between the gaze vector and a hologram is detected and in the gesture frame there is no hand in the "ready" (left image in Figure 2.5b) or "pinched" position (middle image in Figure 2.5b) a cursor ring is shown.

- **Ready**: If a hand is held in the "ready" position inside the gesture frame the user is informed that the gesture was successfully detected by displaying a hand icon with the index finger raised.

- **Pinched**: Similarly, if the index finger is lowered in the "pinched" position the icon symbolizing this gesture is displayed upon successful recognition. A clicking sound is played when an AirTap is detected.
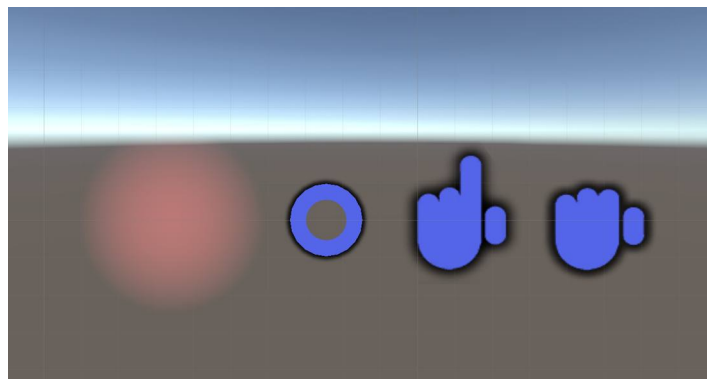

Figure 3.5.: Cursors (from left to right:
off hologram, on hologram, ready, pinched)

If the ray intersects a hologram the cursors ("On Hologram", "Ready" or "Pinched") are projected onto the surface of the model: they are tilted so that a right angle between the cursor icon and the surface normal of the intersection point develops. This gives the three-dimensional models a more tangible and realistic impression. The logic which cursor to display is handled by the MRTK `Object.cs` script and the custom `CursorManager.cs` script attached to the parent object as components.

There are two child GameObjects under "Managers" in the Hierarchy panel. The InputManager Prefab (also provided in the MRTK) manages gaze and various input sources currently supported by HoloLens, such as hands and gestures [50]. Furthermore, the NetManager is a GameObject to allow for sharing across multiple HoloLens devices. This object contains scripts which are offered by Unity to enable multiplayer gaming across a network.

3.3.4. Models

Under the "Models" parent object in the Hierarchy panel three surface meshes are loaded: a complex fracture, an intact reference bone and a virtual mirror.

As a complex fracture, the segmented acetabulum fracture in Figure 2.14 was loaded in the following example. Here the advantage of adding multiple segments in the Segment Editor module of 3D Slicer becomes evident. Note that all individual segments from 3D Slicer appear as child objects of the main model and can be individually selected (see "Fragment3" in Figure 3.6). This is a great benefit as it allows for individual manipulation of each child object (i.e., the fragments). The tissue segment was deleted as it is not relevant in this context.
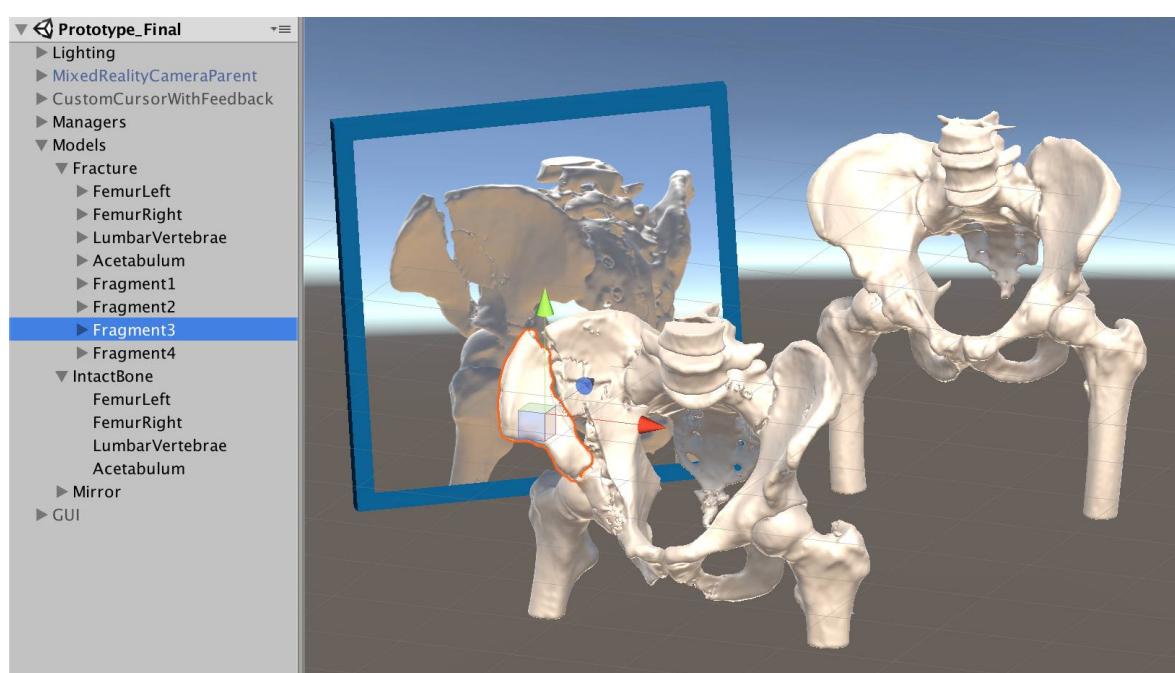

Figure 3.6.: Models in Unity Project

The intact bone was segmented from CT data of a healthy person. This is done analogously to the process explained in subsection 2.5.3. However, any model from a medical database of intact bones can be loaded.

The virtual mirror consists of a reflective plane and a blue rectangular box behind it to give the mirror a more realistic and graspable appearance. The mirror effect is achieved by adding a material with a custom shader and a script[2] to the plane.

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[2]For more information, please visit: http://wiki.unity3d.com/index.php/MirrorReflection4

3.3.5. States

State Logic

Users can enter states to control the application. In these states, custom scripts with a specific functionality are enabled to satisfy the requirements identified in section 3.1. Figure 3.7 provides a graphical overview of all states.

For the sake of clarity Figure 3.7 only provides an abstracted view of the states. Two collections of states are visualized as black boxes, and it does not become clear what the triggers are to enter each state. Table B.1 in Appendix B complements the state machine diagram. Here the triggers to enter the respective states are specified, and it is illustrated which scripts are enabled on which GameObjects. Note that a trigger most often is not equivalent to the precondition of state activation. Often GameObjects are activated to reach full functionality of a state (e.g., the Slider object in the "Expand" state).

Each state can be characterized by its functionality, its logic group and its activation time. These features are introduced to provide surgeons with an intuitive user experience with a systematic and reproducible response behavior. Table 3.1 provides an overview of the classification of all states.

State	Functionality	Group	Activation Time
Transform All Models	Manipulation	A	Permanent
Transform Fragments	Manipulation	A	Permanent
Interact	Manipulation	A	Permanent
Expand	Manipulation	A	Permanent
Reset Fracture	Manipulation	A	Temporary
Reset Intact Bone	Manipulation	A	Temporary
Reset Mirror	Manipulation	A	Temporary
Show Fracture	Options	B	Permanent
Show Intact Bone	Options	B	Permanent
Show Mirror	Options	B	Permanent
Show Information Panel	Options	B	Permanent
Share	Options	B	Permanent
Voice Input	Options	B	Permanent
Operate	Other	A	Permanent
Show Error Panel	Other	A	Temporary
Idle	Other	–	Permanent

Table 3.1.: Characterization of states

Manipulation states are all concerned with the manipulation of models and do this by enabling
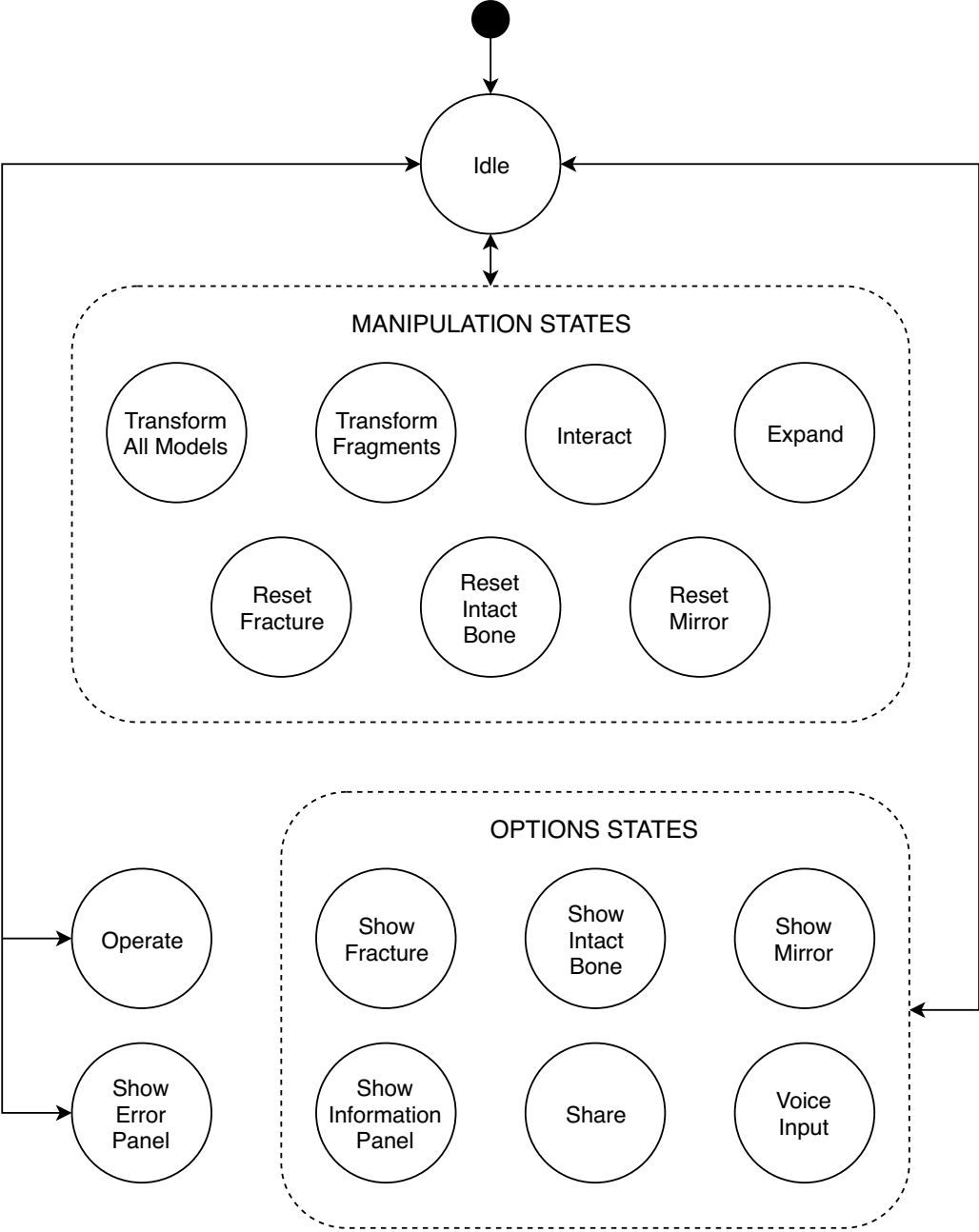
Figure 3.7.: Abstracted state machine of visualisation application

scripts on them. All manipulation states belong to logic group A. Options states manage options and extensions. And are mostly occupied with the activation of GameObjects. All Option states belong to logic group B. Other states are all states that do not fall into the above two groups. The "Operate" and "Show Error Panel" states belong to logic group A. The "Idle" state is only active if no other state is operating and does not affect the application's logic – therefore it does not belong to any group.

It is important to note, that at a time only a maximum of one state of group A can be active (i.e., running multiple A states simultaneously is not possible). The NAND logical operator models this behavior (see truth table for $V = A \uparrow A$ in Table 3.2a). Allowing only for a maximum of one active A state, which are mainly manipulation states, improves usability.

For example, if the "Transform Fragments" and "Interact" states would be active at the same time, the user would enable their corresponding functionality simultaneously. The fragments would move and change color at once which may result in confusion.

Although it is not possible to enter multiple A states simultaneously their respective manipulation is saved, so the user can continue to work with the manipulated model. An excellent example of this would be to "Transform Fragments" *after* expanding the fracture – the fragments are more easily reachable if separated by a distance.

Moreover, there are not logical constraints for the use of B states. B states can be entered at any time, and this will not switch off any other A or B state. The truth tables illustrate this tautological behaviour ($V = TRUE$ in Table 3.2b and Table 3.2c).

A	A	V
0	0	1
0	1	1
1	0	1
1	1	0

(a) A with A

A	B	V
0	0	1
0	1	1
1	0	1
1	1	1

(b) A with B

| B	B	V
0	0	1
0	1	1
1	0	1
1	1	1

(c) B with B

Table 3.2.: Truth tables of logic groups

A further characteristic of the states is their activation time. Most states are active as long as they are not switched off by the user or by their constraining logic – they are referred to as Permanent states. The remaining states are called Temporary states as they employ a method that deactivates them after a specified time without the user's interaction.

State Functionality

- **Transform All Models**: A bounding box is created around all activated models (see Figure 3.8a). Users can transform (translate, rotate, scale) the models using composite gestures (Tap and Hold and Manipulation).

- **Transform Fragments**: A bounding box is created around each child object of the fracture model (see Figure 3.8b). Users can transform (translate, rotate, scale) the fragments using composite gestures (Tap and Hold and Manipulation).

- **Interact**: Once the user's gaze intersects the fracture or the intact bone model the respective child is highlighted. When performing an Air Tap on a targeted child its color changes to green (see Figure 3.8c). The material changes to a transparent look (only specular reflections) if another Air Tap is detected (see Figure 3.8d). With a third Air Tap, users can change the material back to normal.

- **Expand**: A slider is shown and can be dragged using the Manipulation gesture or voice commands. According to the slider's position, the children of the fracture model are translated from a common center (see Figure 3.12).

- **Reset "Model"**: Moves the respective model back into the user's field of view (see Figure C.1b). It is coupled to the gaze vector at a custom distance for a specific hold time (default: 2 seconds). During this hold time, users can efficiently position the model by changing their head orientation.

- **Show "Model"**: The respective model is shown or hidden in the scene. If the model is shown the first time, it appears right in front of the user and the Reset "Model" state is activated. After that, the model is shown at the position where it was previously hidden.

- **Show Information Panel**: Shows panel with patient information (name, ID, date of birth and diagnosis) in GUI (see Figure C.1e).

- **Share**: Enables sharing between multiple devices. One user needs to host a session before others can join (see Figure C.1f).

- **Voice Input**: Enables voice recognition. Users can speak their commands to HoloLens.

- **Operate**: No cursors are shown in order not to distract the surgeon during operation (see Figure 3.8e).

- **Show Error Panel**: Panel with an error message is shown in the user's field of view for a specific hold time (default: 2 seconds) (see Figure C.1c).
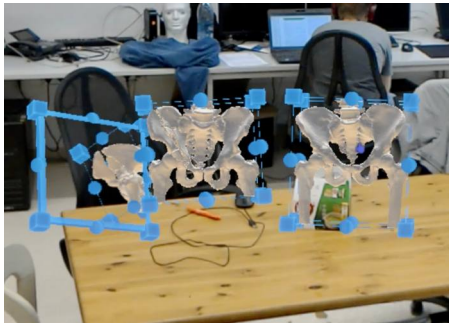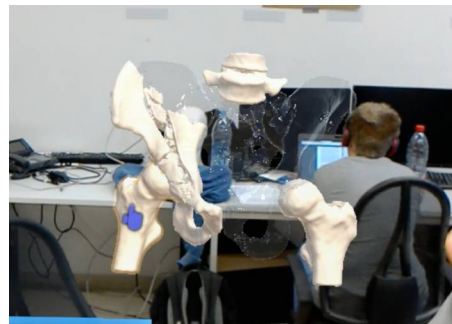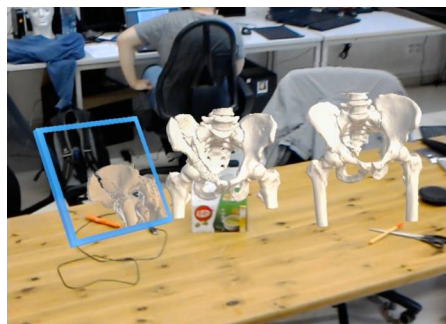
(a) Transform All Models
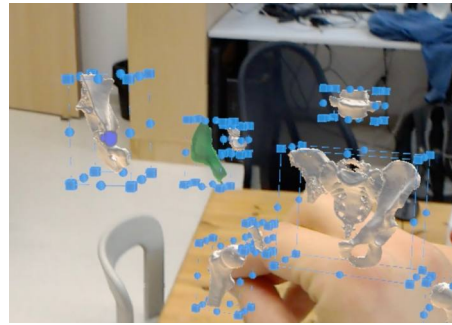
(b) Transform Fragments
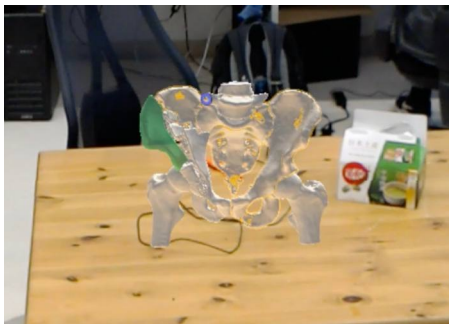
(c) Interact (one AirTap)

(d) Interact (two AirTaps)

(e) Operate

Figure 3.8.: Screenshots of states from HoloLens

3.3.6. Graphical User Interface

It is important to give users feedback about which states can be entered and which ones are currently activated. One solution to this problem is a Graphical User Interface.
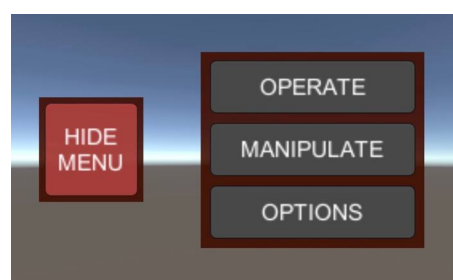
The system employs Unity's built-in solution to graphical interfaces: several toggles are organised in User Interface (UI) Panels on a Canvas. Toggles are derived from the `Selectable` class and feature an "on" and "off" state. They can stay in the respective states as opposed to Buttons which can only register `onClick` events. Thus, toggles are an optimal choice to base the logic which was introduced in subsection 3.3.5 upon.

The appearance of Unity's standard toggles was customized to be more intuitive. The text is displayed in capital letters and toggles change their color to red upon enabling them. Users can enable or disable toggles by moving the cursor on the desired toggle and performing an Air Tap. To provide feedback which toggle users are aiming for the targeted toggle changes its color to light grey before tapping.

To avoid distraction and occlusion of real-world objects by the GUI it can be hidden by clicking the "Hide Menu" toggle. Figure 3.9 shows this toggle in the activated and deactivated state. Note that the displayed message changes from "Show Menu" to "Hide Menu".
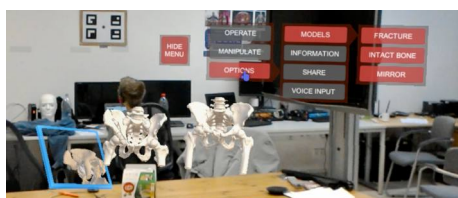
(a) Main menu panel hidden (b) Main menu panel shown

Figure 3.9.: Showing and hiding main menu panel

Toggles are organized in various UI panels. Once users press "Show Menu" the main menu panel (with "Operate", "Manipulate" and "Options" toggles) appears. From there they can navigate deeper into the menus. However, not all toggles lead to the expansion of a further panel. For example, activating "Operate" will directly result in entering the Operate state while pressing "Manipulate" leads to the expansion of further panels to enter all Manipulation States. Similarly, all Options states can be accessed by pressing "Options". To see all reachable panels of the GUI refer to Figure C.1 in Appendix C. If users press "Hide Menu" while multiple panels were expanded, selecting "Show Menu" brings them back to the panel they last worked on.

In this application, toggles are used to control states: evaluating the "isOn" property of toggles

through scripts is a simple way of determining which state the user wants to activate. In the `GUIManager.cs` script which is attached to the InputManager object all states are managed based on whether the respective toggles are on or off. Furthermore, for toggles belonging to logic group A states a Toggle Group is created. Toggle groups are Unity components which only allow for a maximum of one active toggle in the group, which is the desired behavior of group A states.

Considering the optimal positioning of the GUI is of critical importance to provide maximum usability. The GUI must continuously allow for good accessibility, but must at no times obstruct the real world view of the surgeon or other holograms. Therefore directly projecting the GUI into the user's field of view is not an option.

After extensive testing, it proved to be most meaningful to position the GUI Panels at head level and constant distance from the user. As users turn their head, the GUI should follow their gaze. A graphical interpretation of this behavior is given in Figure 3.10. Advantages of this technique are that as users move freely in the operating room, the GUI moves with them accordingly. They can never lose track of the GUI as it always stays oriented towards them. During ORIF surgery patients are lying down and surgeons are standing while operating. As surgeons look downwards to their patient most of the time and holograms are also likely to be placed near the patient, the GUI does not obstruct any important content if its position is fixed at head level (in the pink plane in Figure 3.10).
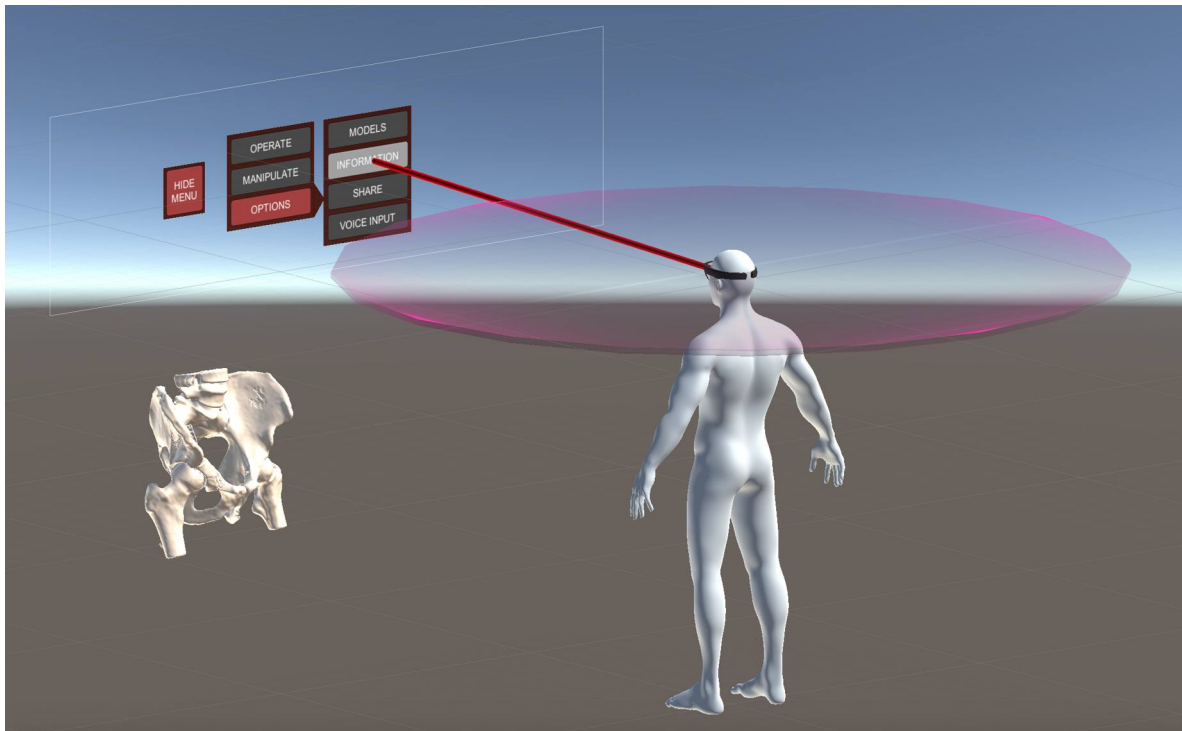

Figure 3.10.: Illustration of position of GUI

The MRTK offers extensive resources to model this behavior. The Billboard class ensures that the GameObject this component is attached to is always facing the user wearing the HoloLens. Furthermore, the Tagalong class keeps the GameObject at a fixed distance from the camera and moves it in all three spatial directions to keep it in the users' field of view. Both scripts are attached to the GUI object in the Hierarchy.

As by default, the Tagalong script moves the GUI in all three spatial directions a small modification needs to be implemented to keep it in the plane at head level. The code snippet in Listing 3.1 shows a script that uses the `LateUpdate` function derived from `MonoBehaviour` to achieve this modification. This function is executed after all `Update` functions were called (e.g. the `Update` function in the Tagalong script). Therefore it can be used to adjust the GUIs vertical position before rendering it to the user.

```
 1  public class GUIPosition : MonoBehaviour {
 2
 3      // Declare float variable for y-coordinate of head position
 4      public float LockY;
 5
 6      void LateUpdate () {
 7
 8          // Get y-coordinate of head position
 9          LockY = Camera.main.transform.position.y;
10
11          // Adjust y-coordinate of GUI position
12          transform.position = new Vector3(transform.position.x, LockY,
13              transform.position.z);
14      }
15  }
```

Listing 3.1: Script attached to GUI object

3.3.7. Voice Input

So far state management is based on tapping the toggles which are part of the GUI. Although the GUI was developed with usability in mind, it is sensible to provide surgeons with an additional input method. The third form of input that Microsoft HoloLens offers – voice – is implemented. The framework offered in the MRTK is attached to the InputManager object: `SpeechInputSource.cs` specifies the recognized keywords and `SpeechInputHandler.cs` defines the response when this word is detected.

The main advantage of voice commands is that surgeons can bypass the usage of nested menus and directly enter the desired state. This may require less time than traversing the GUI panels, especially as users get more accustomed to the system and understand which commands are recognized. A hands-free approach of controlling the application may be especially useful in surgical scenarios as surgeons need their hands to hold tools and operate.

To make use of the logic which is presented in Table B.1 the speech input directly triggers the GUI toggles. Employing speech recognition allows users for a more natural way of communicating their intents. However, for the sake of clarity, the number of voice commands needs to be strongly limited. Only the apparent and most used states can be entered via voice to avoid confusion. This also helps HoloLens to prevent ambiguities while recognizing keywords.

All manipulation toggles can be enabled by speaking the respective name of the state. Furthermore, each model can be shown or hidden by employing a voice command. Speaking "Exit" deactivates all Manipulation toggles and therefore exits the current Manipulation state. In the Expand state, a Slider GameObject is activated, and users can control its value by using their voice. This is a list of all voice commands users can speak.

- Operate
- Transform All Models
- Transform Fragments
- Interact
- Expand
- Reset Fracture
- Reset Intact Bone
- Reset Mirror
- Show Fracture

- Hide Fracture
- Show Intact Bone
- Hide Intact Bone
- Show Mirror
- Hide Mirror
- Exit
- Minimum (in Expand state)
- Center (in Expand state)
- Maximum (in Expand state)

3.3.8. Scripts

To explain the system architecture in more detail one central functionality of the application is reviewed more closely: the "Expand" state. This state is one of the core features of the software as it allows for the automated translation of all child objects of the fracture away from a common center. This improves the spatial sense of the user as the fragments are moved according to a clear rule, and the geometric composition of the fracture can be assessed playfully.

The activation process of any state starts with the triggering of the corresponding toggle. This is recognized by the `GUIManager.cs` script which manages the application's logic. Listing 3.2 shows an excerpt of its `Update` function: each frame it checks whether the Expand state should be entered. Note that the trigger (`ExpandToggle.isOn == true`) is not the only precondition for activating the state. The state is only entered if additionally the script is not yet enabled (i.e., the state is not already active) and the fracture is shown in the scene.

```
1  // Check if Expand state needs to be entered
2  if (ExpandToggle.isOn && !ExpandScript.enabled && Fracture.activeSelf) {
3
4      // Activate slider and script with state functionality
5      Slider.SetActive(true);
6      ExpandScript.enabled = true;
7  }
```

Listing 3.2: Excerpt of `Update` function of GUIManager script

Upon successful execution of lines 5 and 6, a slider UI element is displayed below the GUI (see Figure 3.11) and the Expand script is enabled. Users can drag the slider with a tap and hold high-level gesture or control it via voice input.
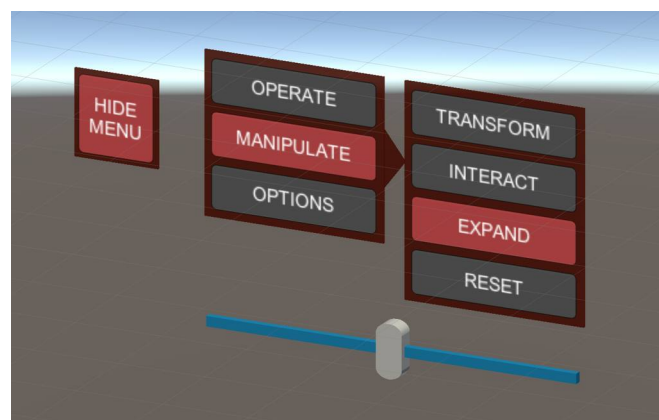

Figure 3.11.: Slider is displayed in Expand mode

The `Expand.cs` script in Listing 3.3 accesses the value of the slider every frame in line 2 and saves it to the `DesiredExpansion` variable. If the slider position changed compared to the previous frame (i.e. if the desired expansion differs from the current expansion) then the fragments are translated correspondingly by the `Move` function. The `ControlExpansion` variable can be either negative, zero or positive (see Equation 3.1).

$$\text{ControlExpansion} = \begin{cases} > 0 & \text{separate fragments} \\ 0 & \text{no action} \\ < 0 & \text{merge fragments} \end{cases} \qquad (3.1)$$

```
1   // Get desired expansion from value of slider
2   DesiredExpansion = Slider.GetComponent<SliderGestureControl>().SliderValue;
3
4   // Calculate control variable
5   ControlExpansion = DesiredExpansion - CurrentExpansion;
6
7   // Move fragments if current expansion differs from desired expansion
8   if (ControlExpansion != 0) {
9       Move(TranslationDirections);
10      CurrentExpansion = DesiredExpansion;
11  }
```

Listing 3.3: Excerpt of `Update` function of `Expand.cs`

The `GetTranslationDirections` function in Listing 3.4 calculates the directions in which each fragment is translated with basic linear algebra. This function is called before `Update` in `Expand.cs` is executed the first time. As input `GetTranslationDirections` takes the position of the previously calculated compound center and an array of positions for the centers of the individual children of the Fracture object. In a simple operation in line 9, it evaluates the translation direction for each fragment by subtracting both centers.

The individual centers are determined by assessing the center of the bounding boxes (structs in the UnityEngine which represent an axis aligned virtual box enclosing the GameObject) of each child. The compound center is the average of all individual centers and serves as the origin of expansion. As the number of GameObjects (i.e., fragments) is higher in the region of severe comminution the compound center is shifted towards a location with high fragment density. This has the advantage that primarily the region of high comminution, which is the surgeon's area of interest, is expanded.

```
1   private Vector3[] GetTranslationDirections(
2       Vector3 CompoundCenter, Vector3[] IndividualCenters) {
3
4       // Declare array of translation directions
```

```
5      Vector3[] TranslationDirections = new Vector3[transform.childCount];
6
7      // Calculate translation directions for each child
8      for (int i = 0; i < transform.childCount; i++) {
9          TranslationDirections[i] = IndividualCenters[i] - CompoundCenter;
10     }
11
12     // Return array of translation directions
13     return TranslationDirections;
14 }
```

Listing 3.4: `GetTranslationDirections` function

The `Move()` function in Listing 3.5 translates the fragments by the difference between the desired and the current expansion of the slider (i.e. `ControlExpansion`). In order to do that the direction vector of each fragment is multiplied with the desired `ControlExpansion` variable and is added to its current position. This achieves the desired expansion effect (see Figure 3.12). If the variable is negative (i.e., the slider value is decreased), the fracture's child objects move back towards their original positions.

```
1 private void Move(Vector3[] TranslationDirections) {
2
3      // Add expansion vector to position of each child
4      for (int i = 0; i < transform.childCount; i++) {
5          transform.GetChild(i).transform.position +=
6              TranslationDirections[i] * ControlExpansion;
7      }
8 }
```

Listing 3.5: `Move` function

Figure 3.12.: Fracture model in the expanded state

3.4. New Data Setup

This is a brief review on which steps the maintenance personnel needs to take to set the project up for new patient data. After successful segmentation which is described in subsection 2.5.3 the user is left with a surface mesh in OBJ format. Starting from this point, the instructions are as follows.

1. **Unity import**: After right clicking on the Resources folder in the Project window press "Import new Asset" in the panel. Navigate to the folder where 3D Slicer exports to, select the correct OBJ file and click "Import".

2. **Hierarchy import**: Select the new OBJ file in the Resources folder and add it to the Models GameObject in the Hierarchy by employing "drag and drop". All segments appear as children of the model. Delete the soft tissue segment if it is part of the parent object.

3. **Renaming**: For the sake of clarity give the parent object a meaningful name (e.g., "Fracture") by right-clicking it and selecting "Rename". The child objects can also be renamed.

4. **Fracture components**: With the parent object selected, add the following scripts by clicking "Add Component" in the Inspector panel and searching for the corresponding script names.

   - `ResetFracture.cs`
   - `Expand.cs`
   - `Billboard.cs`
   - `Tagalong.cs`

   - `HandDraggable.cs`
   - `BoundingBoxRig.cs`
   - `UpdateSpawnPosition.cs`

5. **Fragments components**: Similarly, to each child object of the Fracture model add the following components.

   - `HandDraggable.cs`
   - `BoundingBoxRig.cs`
   - `Interactible.cs`

   - `MeshCollider`
   - `Bone.mat`

6. **Intact Bone components**: Follow steps 1 to 5 for the Intact Bone model, too. Instead of `ResetFracture.cs` add `ResetIntactBone.cs` script to the parent GameObject. To the child objects add `Interactible.cs`, `MeshCollider` and `Bone.mat`.

7. **Referencing variables**: Some parameters (materials and other GameObjects) need to be referenced to the `ResetFracture.cs`, `Expand.cs` and `Interactible.cs` scripts. The correct GameObjects can be identified by their names and can be linked to the respective components directly from the Hierarchy panel via "drag and drop". The materials can be found in the "MyMaterials" folder in the Project window. Finally the new Fracture and Intact Bone parent objects needs to be connected to the `GUIManager.cs` script attached to the InputManager object.

8. **Adjust lighting**: Lastly, reorient the directional lights. For each project there are different ideal orientations to achieve optimal shadows. It may be useful to add even more light sources.

4. Evaluation

This chapter provides a detailed explanation of how a user study was conducted. Further, the quantitative results are statistically analyzed, and the participants' qualitative feedback is discussed.

4.1. Conducting a User Study

The Augmented Reality system was developed using a technology push approach. The technological innovation originated in research and development without the explicit request for it by orthopedic surgeons. As a result of this, no detailed study of the requirements of surgeons was conducted prior to the development process.

Since the overarching non-functional requirement of the AR system is good usability, its practical feasibility and clinical applicability need to be checked. It should be validated if the requirements identified in section 3.1 are sensible and if the functions which were implemented are useful to surgeons performing ORIF surgery.

A number of orthopedic surgeons were invited to use the HoloLens application and take part in an experiment to evaluate the system. Before the experiment, a survey (see Figure A.1) was conducted, which gathered information about their background and familiarity with computer systems. The questionnaire can be found in Appendix A. Following the pre-experiment survey, the principle of Augmented Reality was explained, and information regarding the Microsoft HoloLens was given (e.g., how gesture input works). Furthermore, the different functions of the software and the organization of the GUI were explained. The application visualizing the fractured acetabulum from chapter 3 was used.

During the experiment itself the subjects were instructed to enter the provided states (e.g., Transform or Interact) and to examine the functionality provided (e.g., rotate intact bone or color code a fragment). Figure 4.1 shows an orthopedic surgeon taking part in the experiment which lasted between 15 and 20 minutes. If questions arose while conducting the trial they were answered immediately.

Figure 4.1.: Orthopaedic surgeon evaluating the HoloLens application

After the experiment, the subjects were asked to take part in the post-experiment survey provided on the third page of the questionnaire (see Figure A.1c). This involved rating the usability of the application using a System Usability Scale (SUS), which is a ten-item questionnaire. Five response options are ranging from "Strongly disagree" to "Strongly agree". The SUS is a fast and reliable way of rating usability of a system; however, it is not diagnostic [12]. To not only provide a quantitative analysis of the usability and to collect diagnostic data, the subject were asked to provide further comments regarding the experiment or the system.

4.2. Study Results

In total four orthopedic surgeons took part in the experiment, which were all male and between 35 and 50 years of age. The subjects are surgeons that specialized in trauma surgery and orthopedics and have extensive experience in conducting complex surgical interventions. The subjects did not experience any of the listed conditions, two of them had limited AR and VR experience, two had none.

The overall feedback was very positive. Table 4.1 shows the results of the post-experiment SUS survey, where "1" means "Strongly disagree" and "5" means "Strongly agree". On average the experts rated the usability with a SUS score of 81.9, which is a favorable result. According to Bangor et al. who related mean SUS scores to adjectives a score between 70 to 85 means "good", one from 85 to 90 is "excellent", and a rating from 90 to 100 is "best imaginable" [5].

It is notable that on average three of the four users rated the system with a score of 90 (i.e., best

imaginable) and one gave a significantly lower usability rating (57.5). The fourth subject experienced problems with the input methods provided by HoloLens. Even though some complementary explanations during the experiment were given the user experienced difficulties performing the Air Tap gesture, which lead to an overall worse user experience. Note that his answers to questions 4, 8 and 10 are significantly less positive compared to the other three subjects. However, to questions which relate to the functions of the application (e.g., 2 and 5) he responded with a comparable score. Thus, it is likely that the difficulties the subject experienced were mainly due to the erroneous execution of the Air Tap gesture and not due to the implementation of the application itself.

Even though the system usability in total only evaluated to a "good" result, on average the majority of users rated the usability "best imaginable". Figure 4.2 shows a graphical interpretation of the individual SUS scores and Figure 4.3 represents the average results for each question.
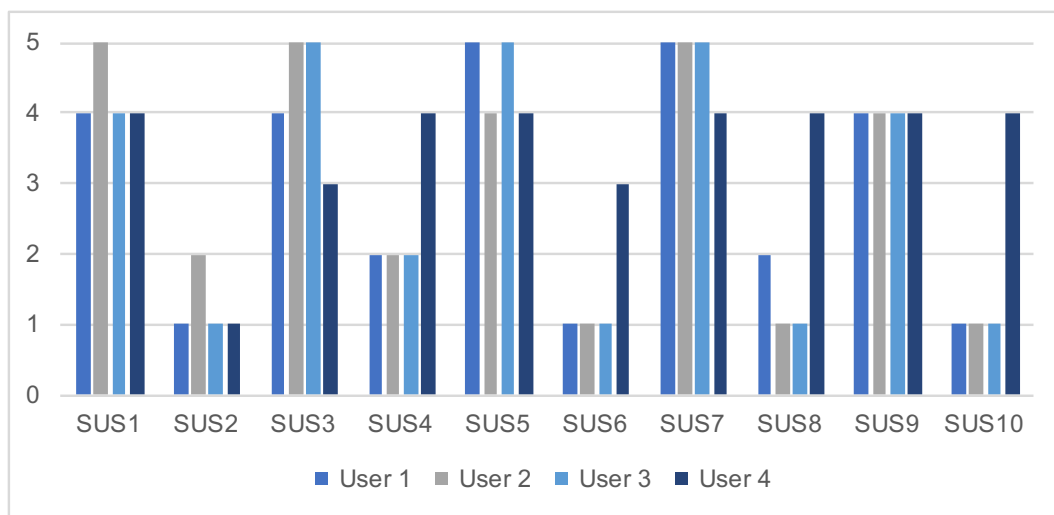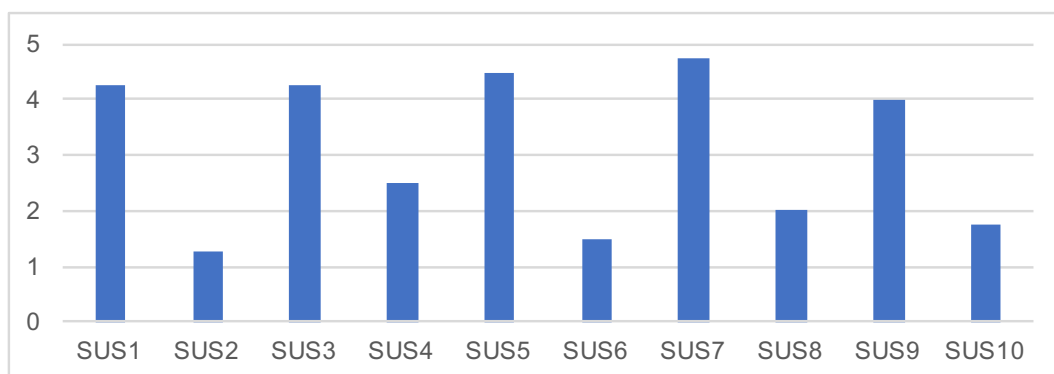

Figure 4.2.: Individual SUS response diagram

Figure 4.3.: Average SUS response diagram

No.	Question	User 1	User 2	User 3	User 4	Avg.
1	I think that I would like to use this system frequently.	4	5	4	4	4.25
2	I found the system unnecessarily complex.	1	2	1	1	1.25
3	I thought the system was easy to use.	4	5	5	3	4.25
4	I think that I would need the support of a technical person to be able to use this system.	2	2	2	4	2.5
5	I found the various functions in this system were well integrated.	5	4	5	4	4.5
6	I thought there was too much inconsistency in this system.	1	1	1	3	1.5
7	I would imagine that most people would learn to use this system very quickly.	5	5	5	4	4.75
8	I found the system very cumbersome to use.	2	1	1	4	2
9	I felt very confident using the system.	4	4	4	4	4
10	I needed to learn a lot of things before I could get going with this system.	1	1	1	4	1.75
	Average SUS	**87.5**	**90**	**92.5**	**57.5**	**81.9**

Table 4.1.: Results of SUS survey

Besides quantitative information, qualitative data was gathered using the comments boxes. The comments the experts provided are valuable to base further development of the system on. The answers can be roughly split into four different categories: responses regarding the underlying concept, feedback on the application, issues relating to the HoloLens and ideas for future work.

All participants are convinced that the idea behind the application makes sense as understanding the fracture configuration may pose a tremendous difficulty for complex fractures. Conventional methods of fracture visualization such as 3D printing or reviewing 2D CT images are somewhat troublesome as they may take a long time or are less intuitive. According to the surgeons especially exciting fields of application for such a system are complex fractures of the acetabulum, comminuted intra-articular fractures and oral and maxillofacial surgery. Overall, this novel system presents a more practical and economical solution to the proposed problem.

The comments regarding the application were very positive. The subjects especially liked the Expand and the Transform Fragments states as they allowed for playful and intuitive interaction with the virtual models. One surgeon found the system not yet applicable for intra-operative usage as in its current state it is not mature enough. However, as a pre-operative planning tool, he would definitely like to use it. The benefit of being able to walk around the models might not be apparent in an operating room as space may be more limited compared to the rooms where the experiment was conducted. All other surgeons pointed out that they could imagine using the system during reduction surgery.

The subjects made a few comments concerning the HoloLens. Whereas the lightly tinted glass does not pose a problem on the surgeon, the comparably small field of view was perceived to be somewhat disturbing. It disrupted the perfect illusion of augmentation by computer-generated content. Furthermore, it was pointed out that the battery life may be too short for surgeries that last several hours. The fact that the HoloLens is a self-contained system was perceived as very beneficial for surgical applications. All subjects were convinced that after a short training time they would be able to use the Air Tap gesture even more confidently. None of the participants criticised the wearing comfort of the HoloLens.

Lastly many ideas concerning future work were given. It was suggested that soft tissue simulation would be a very useful feature to estimate the least harming approach path (through e.g. muscles) to reach a fragment. Some subjects pointed out that automatic on-demand registration of the virtual fracture model with the patient's body would be desirable. Furthermore, the display of CTA data and the original 2D CT image sequences would be useful. Showing the 2D slices within the application could bridge the acceptance gap of such a system as it still incorporates a somewhat more traditional visualization approach. It was further desired to expand the system features to more types of surgeries. For example, to make this system applicable for tumor resection surgery, it would be useful to visualize safety distances around the segmented model of the tumor. Furthermore, wireless streaming of the footage captured by HoloLens including the virtual models to other devices (e.g., computers or smartphones) is a highly demanded function. This would

enhance the surgeon's ability to communicate problems to colleagues in conference calls which are already routinely done.

5. Conclusions

This last chapter provides a final discussion of the presented project. Here the main tasks and achievements which were involved with the application development are reconsidered and critically examined. Last but not least, to complement the discussion, an overview of open problems and possible future research matters is given.

5.1. Discussion

In this thesis, a system for the visualization of complex bone fractures using Microsoft HoloLens was successfully implemented. The reason for this research task was that surgeries involving open reduction and internal fixation of complex bone fractures are difficult procedures as it may be challenging for orthopedic surgeons to understand their three-dimensional fracture configuration. It was shown that a system that provides surgeons with Augmented Reality visualizations of the fracture site to support them during the geometric reconstruction of complex bone fractures is feasible.

The application was carefully developed with the requirements of trauma surgeons in mind. An extensive requirements analysis was conducted before realizing the system. While implementing the visualization framework a clear priority was to provide end users with good usability. To not confuse surgeons during operations the available states were thoroughly designed, and a Graphical User Interface with a clear menu structure was developed. Providing feedback to the users was achieved by showing graphical interfaces such as cursors, bounding boxes, a slider, highlighting of specific bone structures, changing toggle colors and sounds when Air Taps are successfully detected.

To be able to quantify the usability of the system an experiment with four surgeons was conducted. The usability was evaluated using the widely accepted System Usability Scale. The application scored a promising average result of 81.9, with three of the four subjects rating the system with an average of 90 points. The correct execution of the Air Tap gesture is critical for operating any HoloLens application. It proved to be the case that performing this gesture was somewhat troublesome for one user, which resulted in a worse usability score compared to the other subjects. This suggests that it is essential to offer training sessions to potential users before employing the

system during ORIF surgery.

It has to be noted that the group of subjects that took part in the experiment was rather small. The results suggested that such a study may result in a considerably large standard deviation as some participants may have difficulties with the hardware (i.e., HoloLens gesture input) which is mostly independent of the software (i.e., visualization application). As results were gathered for the entire system (i.e., hardware *and* software combined) the SUS score was drastically lower for the subject who had difficulties with gesture input. Therefore, it might make sense to evaluate hardware and software separately in future studies to get more accurate and diagnostic results for each part of the system. Furthermore, by working with higher numbers of subjects outliers should be averaged out, resulting in more accurate SUS scores.

Furthermore evaluating the software with multiple fracture models (i.e., not just the acetabulum fracture) may result in a more comprehensive impression of the software. To gather even more data, it would be useful to test the system during real ORIF surgeries. One could estimate the benefit of the AR-based visualization over traditional techniques by comparing intervention durations and patient recovery rates. Furthermore, the practicality of voice recognition and gesture input could be tested in an operating room.

If in a further study it turns out that the presented system can be nicely integrated into the intra-operative workflow there might nevertheless be some issues that may inhibit the acceptance of it in operating rooms. Whereas device and training costs may pose a small burden on the large scale adaption process of AR by hospitals, the certification of AR systems as medical devices may be a cumbersome and lengthy procedure. It is sensible to watch future developments of AR HMDs as they might provide even more economical and powerful hardware solutions.

One limitation of the current system is that the workflow is not fully automated yet. For the pre-processing steps (segmentation from CT and adjusting the Unity project for new data) a technical assistant is required. Dealing with the leakage problem – a common issue when segmenting complex bone fractures – by manual reworking of the segmentation may be very labor intensive. Therefore further work should focus on a higher degree of automation, for example by investigating autonomous image segmentation through more advanced algorithms. It needs to be noted that there already exists a large body of research working on fully automated image segmentation from CT which means that shortly the pre-processing steps could require significantly less time. Furthermore, a more intuitive integration of the surface mesh into the Unity editor would be desirable.

As mentioned previously a surgeon who took part in the user study suggested the pre-operative usage of the system. He is strongly convinced that the application can help surgeons precisely determine the number of fragments and classify the fracture. These are two routine tasks which need to be completed before ORIF interventions. In a study with 30 subjects (ten students, ten assistant physicians and ten senior physicians) both of these parameters should be assessed:

once in the HoloLens and once using the more traditional method of analyzing 2D CT sequences on a computer screen. By comparing the results of both approaches to ground truth, he would like to assess the impact of such an Augmented Reality system as a pre-operative tool. This study will take place in the near future.

Overall it can be concluded that this solution to intra-operative visualization overcomes many of the challenges of current approaches (e.g., difficulty to understand fracture composition or distance between operation site and displays) and offers a highly economic tool for surgeons. Ultimately, not only surgeons but patients can benefit from improved recovery rates induced by this novel system.

5.2. Future Work

The user study presented in chapter 4 constitutes an excellent source of inspiration for future work. The main ideas that were mentioned by the surgeons were the simulation of soft tissues, the display of more data (e.g., CTA or 2D CT sequences), extend the software to other types of surgery (e.g., tumor resection or oral and maxillofacial surgery) and wireless streaming of recordings by the HoloLens. More advanced HMDs with larger fields of view would be beneficial to make such software even more attractive for intra-operative use.

Soft tissue simulation might be realizable using the Unity platform as it features a physics engine. However, it would need to be evaluated if this simulation is accurate enough for intra-operative use. A further challenge involving this task is that patient-specific models of the soft tissues need to be segmented from CT data. This may be troublesome as intensity differences in soft tissues are comparably faint, and a lot of manual reworking of the automated segmentation may be required – unless no advanced algorithms are employed. Furthermore, accurate soft tissue simulation may be too CPU-intensive for a wearable computer with limited processing power such as HoloLens.

While the accurate simulation of soft tissue movement to reach points of interest within the patient may be too processing-intensive for a standalone device like Microsoft HoloLens the outsourcing of such a task to a pre-operative planning tool could be sensible. This tool could feature a desktop computer which provides the necessary processing power and a Virtual Reality HMD like Oculus Rift to fully immerse the surgeon in the planning environment.

Besides soft tissue simulation, another major feature for a pre-operative planning tool is imaginable. Once fragments were located during ORIF surgery, it is often challenging to find their correct alignment position and orientation. In a VR surgical planning tool, the surgeon could perform semi-automatic bone reconstruction: users could assess the model generated from CT data, pick individual fragments and maneuver them in their approximate correct locations using a haptic device. In a second step an automated surface registration algorithm such as the Iterative Closest Point (ICP) algorithm could reconstruct the original geometry of the intact bone. As mentioned previously there exist extensive research on such pre-operative planning tools (e.g. [26], [75], [46], [42], [34], [37]). Interestingly 3D Slicer offers an extension which allows for virtual fracture reconstruction[1].

There is a lot of room for further extensions of a VR surgery planning tool as compared to AR Virtual Reality offers a somewhat more flexible approach to visualization since all content the user perceives is computer generated. For example, the size of implants or the directions of screws could be determined in such an application. In future work, an extensive literature review of existing virtual surgery planning environments should be conducted. Further, it needs to be evaluated if the information generated in a pre-operative planning tool can be seamlessly integrated into the AR intra-operative system. The combination of both VR and AR in planning and conducting surgery constitutes a very promising body of future research.

While keeping clarity and usability of the application in mind, more features could be integrated into the existing AR system. It may be useful to display data from multiple pre-operative imaging modalities: CTA, MRI and X-ray images are interesting – especially if the area of application of the software is extended. Data generated by intra-operative imaging modalities such as C-arms should also be integrated. Allowing for efficient visualization of such images may reduce the demand for more scans during operations, resulting in a smaller radiation dose to both patients and surgeons. Furthermore, real-time updates on the patient's anesthetic data, blood pressure, heart rate, body temperature and breathing rates would be useful. Effectively, anything that is displayed on a computer screen in an operating room could be transferred to an AR HMD and be retrievable on demand (e.g., via voice commands). Additionally, if the software should be extended to other types of surgery then developing further modules (e.g., visualizing safety margins around a tumor similar to the work presented by Choi et al. [17]) needs to be considered.

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[1] For more information, please visit https://www.slicer.org/wiki/Documentation/Nightly/Extensions/ VirtualFractureReconstruction

Last but not least the input methods for such an Augmented Reality system need to be reconsidered. There are various ways of controlling AR systems. Optical hand tracking, voice recognition, haptic remote controls or gesture tracking based on Electromyography (e.g., the Myo armband[2]) are among them. So far only the optical hand tracking provided by HoloLens was tested. Further research needs to be conducted to decide which input technique is most applicable for ORIF surgery to provide surgeons with the most intuitive and efficient navigation of this intra-operative visualization framework.

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[2]For more information, please visit https://www.myo.com

A. Experiment Survey

Pre-Experiment Survey

By completing this survey you are consenting to be in this research study. Your participation is voluntary and you can stop at any time.

Thank you for participating in this experiment! In order for us to better understand the results of your use of the experimental system we would like to ask you a few questions about your background and familiarity with computer systems. After the experiment please rate the usability of the system with the System Usability Scale provided on page 3.

Please do not hesitate to ask the investigator any questions you may have about this form or the experiment in general.

Subject ID: _____

Age: _____

Gender: _____

Handedness: _____

Are you currently experiencing any of the following?

	Yes	*No*	*Prefer not to say*
Epilepsy	☐	☐	☐
Injuries to hands or arms	☐	☐	☐
Neurological disorders	☐	☐	☐
Uncorrected impaired vision	☐	☐	☐
Poor depth perception	☐	☐	☐
Color blindness	☐	☐	☐
Headache	☐	☐	☐
Fatigue	☐	☐	☐

If there are any other factors which you think might affect your performance in this experiment and wish to share them, please use the space below.

_____

_____

(a) First page of experiment survey

How experienced are you with Augmented Reality devices (such as Microsoft HoloLens)?

☐	*None*	This is my first time using such a device.
☐	*Limited*	I have used such a device once or twice.
☐	*Familiar*	I have used one or more devices many times.
☐	*Experienced*	I have developed Augmented Reality systems myself.

If you have used an Augmented Reality Device, did you suffer from any of the following?

	Major	*Minor*	*None*	*Prefer not to say*
Motion sickness	☐	☐	☐	☐
Eye discomfort	☐	☐	☐	☐

How familiar are you with Virtual Reality devices (such as Oculus Rift)?

☐	*None*	This is my first time using such a device.
☐	*Limited*	I have used such a device once or twice.
☐	*Familiar*	I have used one or more devices many times.
☐	*Experienced*	I have developed Virtual Reality systems myself.

If you have used a Virtual Reality Device, did you suffer from any of the following?

	Major	*Minor*	*None*	*Prefer not to say*
Motion sickness	☐	☐	☐	☐
Eye discomfort	☐	☐	☐	☐

(b) Second page of experiment survey

How familiar are you with Open Reduction Internal Fixation (ORIF) procedures for complex bone fractures?

☐	*None*	I have never seen or performed an ORIF surgery.
☐	*Observed*	I have seen an ORIF surgery.
☐	*Trained*	I have performed ORIF surgery on patients.
☐	*Intermediate*	I have frequently performed ORIF surgery or similar procedures.
☐	*Expert*	I routinely perform ORIF surgery or similar procedures.

Post-Experiment Survey

Please rate the usability of the system according to the following System Usability Scale. For each of the following statements, mark one box that best describes your reactions to the system.

		Strongly disagree				*Strongly agree*
1	I think that I would like to use this system frequently.	☐	☐	☐	☐	☐
2	I found the system unnecessarily complex.	☐	☐	☐	☐	☐
3	I thought the system was easy to use.	☐	☐	☐	☐	☐
4	I think that I would need the support of a technical person to be able to use this system.	☐	☐	☐	☐	☐
5	I found the various functions in this system were well integrated.	☐	☐	☐	☐	☐
6	I thought there was too much inconsistency in this system.	☐	☐	☐	☐	☐
7	I would imagine that most people would learn to use this system very quickly.	☐	☐	☐	☐	☐
8	I found the system very cumbersome to use.	☐	☐	☐	☐	☐
9	I felt very confident using the system.	☐	☐	☐	☐	☐
10	I needed to learn a lot of things before I could get going with this system.	☐	☐	☐	☐	☐

If you have any further comments regarding the experiment or the system please use the space provided below.

_____

(c) Third page of experiment survey

Figure A.1.: Experiment survey

B. States Overview

State	Trigger	GameObjects	Main Actions
Transform All Models	`TransformAllModelsToggle.isOn`	Fracture, Intact Bone, Mirror	`BoundingBoxRig.enabled = true;` `HandDraggable.enabled = true;`
Transform Fragments	`TransformFragmentsToggle.isOn`	All children of Fracture	`BoundingBoxRig.enabled = true;` `HandDraggable.enabled = true;`
Interact	`InteractToggle.isOn`	Fracture, Intact Bone	`InteractibleManager.enabled = true;` `GazeGestureManager.enabled = true;`
Expand	`ExpandToggle.isOn`	Fracture, Slider	`Slider.SetActive(true);` `Expand.enabled = true;`
Reset Fracture	`ResetFractureToggle.isOn ||` (first time `FractureToggle.isOn`)	Fracture	`ResetFracture.enabled = true;`
Reset Intact Bone	`ResetIntactBoneToggle.isOn ||` (first time `IntactBoneToggle.isOn`)	Intact Bone	`ResetIntactBone.enabled = true;`
Reset Mirror	`ResetMirrorToggle.isOn ||` (first time `MirrorToggle.isOn`)	Mirror	`ResetMirror.enabled = true;`
Show Fracture	`FractureToggle.isOn`	Fracture	`Fracture.SetActive(true);`
Show Intact Bone	`IntactBoneToggle.isOn`	Intact Bone	`IntactBone.SetActive(true);`
Show Mirror	`MirrorToggle.isOn`	Mirror	`Mirror.SetActive(true);`
Show Information Panel	`InformationToggle.isOn`	Information Panel	`InformationPanel.SetActive(true);`
Share	`HostToggle.isOn ||` `ClientToggle.isOn`	NetManager	`NetManager.SetActive(true);`
Voice Input	`VoiceInputToggle.isOn`	InputManager	`SpeechInputHandler.enabled = true;`
Operate	`OperateToggle.isOn`	Fracture, Intact Bone, Mirror	`MeshCollider.enabled = false;`
Show Error Panel	`ErrorDetected == true`	Error Panel	`ErrorPanel.SetActive(true);`

Table B.1.: Management of states
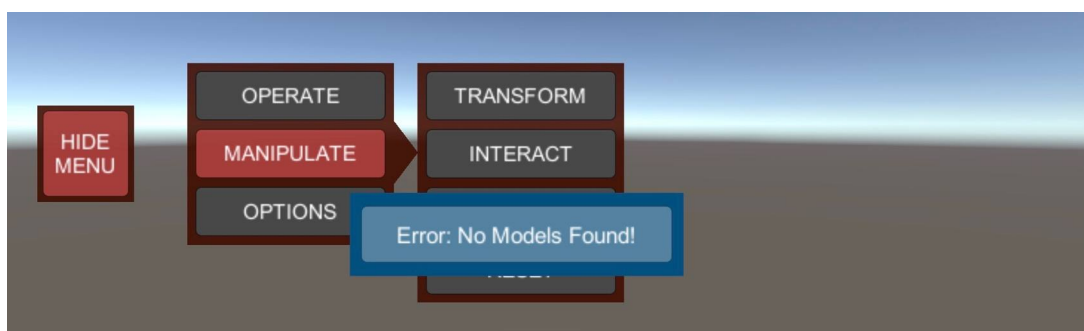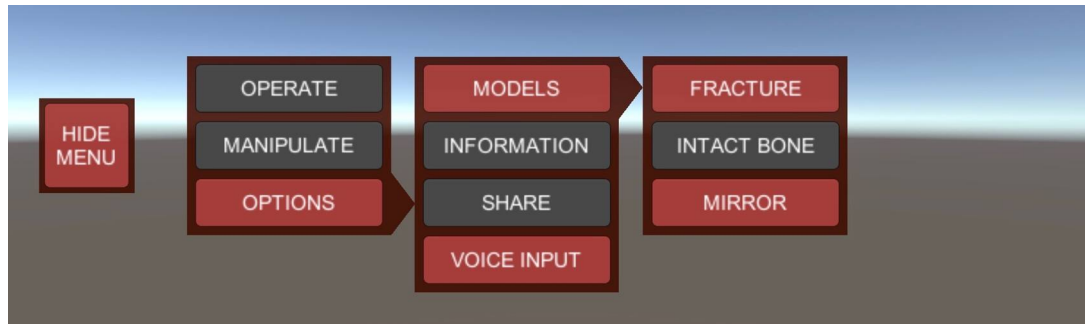
C. Graphical User Interface
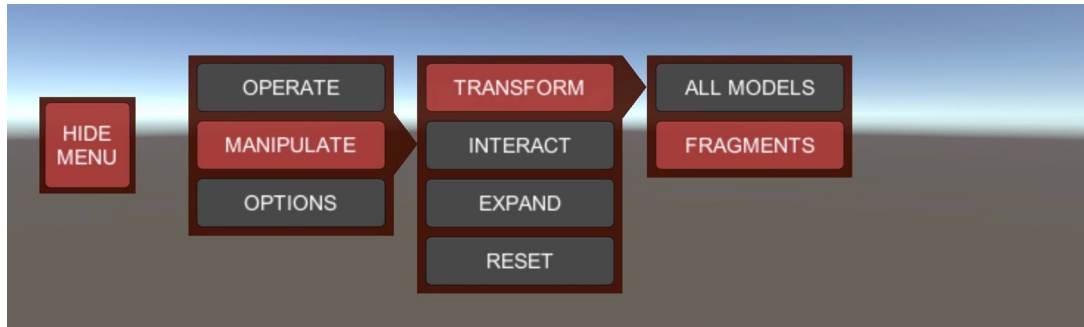
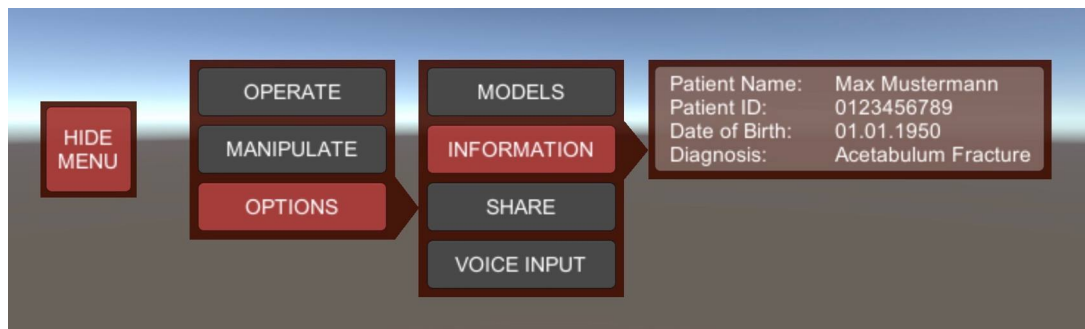(a) Activating `TransformFragmentsToggle`
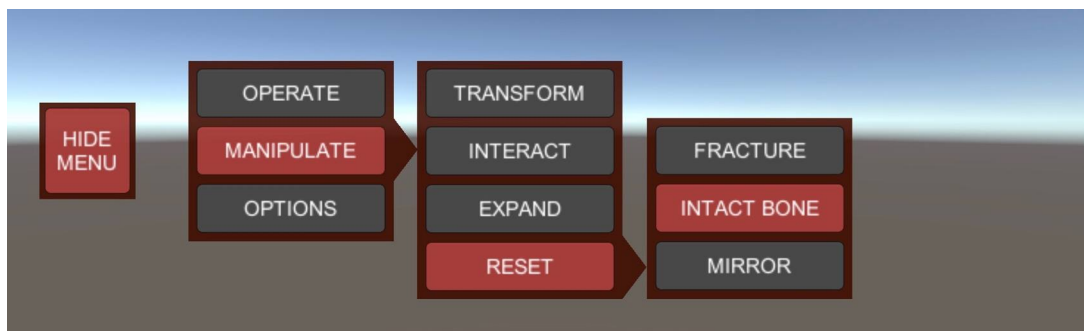
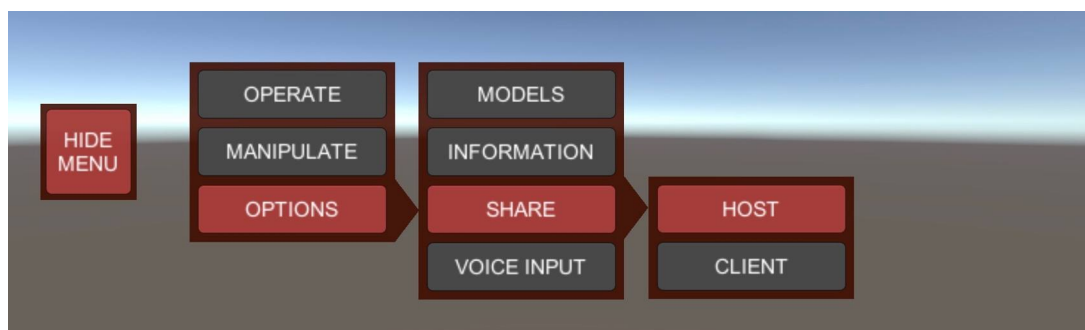(b) Activating `ResetIntactBoneToggle`

(c) Error message: attempting to activate a Manipulation state while no model is shown

(d) Multiple Options states can be activated at once

(e) Information panel is directly integrated into GUI

(f) Activating `HostToggle`

Figure C.1.: All reachable GUI panels

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