The Introduction of Augmented Reality

At the Oral & Maxillofacial
Department of the University
Medical Center Utrecht

Technical Medicine master thesis by

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THE INTRODUCTION OF AUGMENTED REALITY

- At the Oral and Maxillofacial Department of the University Medical Center Utrecht -

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Student number: 4551230

19 December 2023

Thesis in partial fulfilment of the requirements for the joint degree of Master of Science in

Technical Medicine

Leiden University; Delft University of Technology ; Erasmus University Rotterdam

Master thesis project (TM30004; 35 ECTS)

Dept. of Biomechanical Engineering, TUDELFT

15-02-2023 – 19-12-2023

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Summary

The complexity and interdependency of hospital activities make it challenging to seamlessly integrate new technologies into clinical routines, especially with various stakeholders involved. Considering contextual factors when implementing innovations has been recognized as critical to success. This highlights the significance of an approach that focuses on integrating technology with the existing healthcare culture and motivating the context to change, rather than focusing on technology alone. Therefore, the aim of this thesis is to provide a method to ensure the clinical context is considered when developing a new technology. This approach is put in practice by utilizing it to introduce augmented reality (AR) at the oral and maxillofacial surgery (OMFS) department of the University Medical Center (UMC) Utrecht, to provide new insights on how to better align the technology with clinical needs and to familiarize and motivate the medical team with the technology. This is done in close collaboration with the UMC Groningen. Currently, the UMC Groningen, UMC Utrecht, and the Center for Information Technology (CIT) of the University of Groningen are developing an AR surgical navigation system. The aim of the introduction is to provide valuable information for the further development of the system and to prepare and involve the clinical environment.

The approach used in this thesis is based on human-centered design and design-thinking. Furthermore, key factors for successful adoption found from previous research are considered. The approach consists of four main components. The first is to assign a med-tech innovation coordinator; someone with both a medical and technical background who will be responsible for driving adoption. Furthermore, it is an iterative three-step process: 1) Gain understanding; 2) Share understanding; 3) Actively engage stakeholders.

The application of this approach to introduce AR at the OMFS department of the UMC Utrecht has resulted in multiple positive effects. In clinical context it resulted in an understanding of the technology and its value, motivations to invest time in the system, and the establishment of a shared future perspective on the implementation of AR. Furthermore, valuable input from a clinical perspective is obtained, including confirmation of valuable system elements and new ideas/insights for the further development of the AR navigation system.

In conclusion, this thesis provides guidance for departments seeking to adopt new technologies based on a practical example. The methodology provides activities that facilitate the early introduction of technologies, ensuring the active involvement of the clinical context.

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Introduction

1.1. Challenges of introducing new technology in healthcare settings

In the recent years, Augmented Reality (AR) has shown to be a promising technology to aid surgeons during surgical procedures [1], [2]. AR is a technology which enhances the real world by overlaying virtual objects on top of it [3]–[5]. With AR, unlike virtual reality (VR), the real world remains visible while simultaneously superimposing computer-generated information upon it [4], [5]. Researchers of the Oral & Maxillofacial (OMF) department of the University Medical Center (UMC) Utrecht have shown interest in this technology and together with UMC Groningen, efforts are made to develop an AR system to guide surgical tasks (further elaborated on in **Chapter 3**).

The development and introduction of new technologies, such as AR, in clinical setting is a complex process that requires careful consideration of various aspects to ensure successful implementation. Concerns have arisen from past experiences, where AR devices were introduced, but subsequently rejected by the clinical context. They failed to seamlessly integrate into the surgical workflow, did not adequately meet the needs of the end-users, and/or were poorly adapted to the complex healthcare environment. One reason for this is that in many instances the AR system design approach is primarily technology driven [6]. Technology driven design refers to purposely using new and advanced technologies to develop healthcare products, services, or systems. However, focusing mainly on the technology and introducing too many devices and peripherals, without a clear understanding of the context, can lead to misalignment with clinical needs [7] and healthcare complexity [8]. Therefore, the implementation process and clinical setting should be intertwined with the development process [9], ensuring that the AR technology aligns with the needs of end-users and the complex healthcare environment. This requires a sophisticated and well-planned approach [8].

Issues of misalignment and failure to adopt is not only seen in AR systems. Many potentially valuable technologies fail to gain acceptance within healthcare settings, despite demonstrating their effectiveness and safety [10]. Misser [11] revealed that fifty to ninety percent of technological innovations in healthcare do not succeed to complete the development process and are not introduced into the market.

The complexity and interdependency in hospital activities make it challenging to seamlessly integrate new technologies into clinical routines, especially with various stakeholders involved. Considering contextual factors when implementing innovations has been recognized as critical to success [12]. This highlights the need of an approach that focuses

on integrating technology with the existing healthcare culture and motivating the context to change, rather than focusing on technology alone [8].

1.2. Purpose of this thesis

The aim of this thesis is to provide a method to ensure the clinical context is taken into account when developing a new technology. The focus is on bridging the gap between technological development and clinical requirements, thus enhancing the probability for success in implementing the innovation and better adherence rates for usage of the technology.

This leads to the central research question: *How can the development and introduction of technology-driven innovations be tailored to better suit the demands of clinical settings?*

The developed approach will be used to introduce AR at the OMF department of the UMC Utrecht and to provide new insights on how to better align the technology with clinical needs.

It is essential to emphasize that this method is not intended as a standalone framework but is designed to run in parallel with established development frameworks (e.g., internationally recognized ISO standards (ISO 14971, ISO 62304, and ISO 13485), and measurement systems, such as the Technology Readiness Levels (TRL)). These frameworks are crucial for ensuring the safety, quality, and effectiveness of medical devices across their lifecycle.

1.3. Thesis outline

Chapter 2 will elaborate on key factors to take into account when introducing new technologies in healthcare settings and will describe the approach which is utilized in the remainder of this research.

Chapters 3-7 will put the developed approach in practice. These chapters explain how AR for surgical guidance is introduced by a med-tech innovation coordinator at the OMF department of the UMC Utrecht following the developed approach.

Chapter 8 will discuss the proposed approach and critically evaluates the use of this approach in clinical practice. Furthermore, future improvements are recommended.

2

Approach

This chapter begins by assessing knowledge gained from past experiences. This is done by describing an illustrative example drawn from the clinical setting where this research was conducted. Additionally, key factors for introducing new technology in a healthcare setting are explored. Finally, an outline of a newly developed approach to introduce new technology and involve stakeholders from an early stage is presented. This approach takes into account the findings from this chapter and will be utilised during the introduction of AR at the department.

2.1. Lessons learned from previous experiences

In the OMFS department of the UMC Utrecht, a strong emphasis is placed on innovation to continually improve the provided care. Nevertheless, not all innovations meet with success. It has become evident that introducing an innovation is a time-consuming process that requires careful consideration of various factors.

An example is the introduction of the intra-oral scanner at different hospitals. In the UMC Utrecht a technician from the 3Dlab took responsibility for the introduction of this technology. This individual played a crucial role in consistently demonstrating the benefits of the technology over traditional (non-digital) methods and ensuring the clinical team became familiar with the technology. Moreover, this individual served as a point of contact for addressing any errors, ICT-issues, or questions related to the scanner. As a result, the intra-oral scanner has been successfully integrated into the workflow. There has been a near-complete transition from traditional methods due to the numerous advantages it offers, including increased speed, enhanced patient comfort, and improved accuracy and precision.

On the contrary, in hospitals where no one was specifically assigned to oversee the technology's introduction, the scanners remain unopened in their packaging. This example underscores the importance of a sophisticated approach, effort, and leadership to technology introduction and the realization that the adoption of a technology depends not only on its effectiveness and clinical relevance.

Inadequate communication, training, or resources can lead to users being unfamiliar with the technology, unclear benefits for stakeholders, and a lack of motivation for change in the clinical context. When introducing an innovation, the entire system should be taken into account and the someone should be present to drive the innovation.

2.2. Key factors

Previous research has identified some key factors to positively affect the uptake of a new technology in healthcare settings [11], [13], [14]. Shared conclusions can be summarised as follows:

1. *Leadership and support*: To drive the innovation someone needs to be responsible for guiding the introduction. Effective leadership is essential to convey the vision, inspire others, and secure support at all levels of the organization.
2. *Early clinical and stakeholder involvement*: Involve the clinical setting in an early stage of the development process. This is important to ensure the technology aligns with the real clinical needs and workflow.
3. *Awareness and effective communication*: The stakeholders should understand the technology's benefits and its impact on patient care. The necessity of the technology and benefits need to be known to get everyone on board. Furthermore, all stakeholders need to be well-informed about the innovation. Make sure there is clear and open communication across the organization.
4. *Integration with existing practices*: The new technology should be designed to seamlessly integrate with existing clinical practices, policies, and programs. Implementing a new technology can affect various aspects of the entire system. These need to be mapped and taken into account.
5. *Dedicated & ongoing resources*: The necessary support and infrastructure should be in place.
6. *Monitor and adaption*: Continuously monitor, adapt and evaluate the effectiveness of the technology (in clinical context). The end-users should have the opportunity to provide feedback and ideas on how to improve the technology (in terms of fitness/effectiveness).

2.3. Proposed approach

The previous observations and findings are taken into account in designing the approach for the early introduction of technology in healthcare setting. This approach is based on the key factors described in the previous section and a commonly used problem-solving and innovation methodologies: Human-Centered Design (HCD) and Design-Thinking (DT).

2.3.1. Human-Centered Design

HCD is a methodology that emphasizes an iterative, collaborative, people-centric approach and aims to create solutions tailored to human needs [15]. This is accomplished by adhering to four core principles [7], [16]:

1. **Problem-solving**: Solve the root of the problem. Investigate if the initial given problem is the actual problem.
2. **User empathy (People-centred)**: Focus on people and context. This includes gaining an understanding of the ones involved and involving all relevant stakeholders throughout the development process.

3. **System thinking**: Adopt a system thinking approach: consider the entire system which surrounds the product, service, or solution, with a focus on understanding how different components of the health system interact or what relationships exists between them.
4. **Small and simple interventions (iterative)**: Continually prototype, test, and refine the proposed designs to make sure it meets the user's needs. Often the "failing fast and often"- philosophy is used. This allows for rapid iterations and learning from mistakes.

2.3.2. Design-thinking

Design-thinking is a problem-solving process that starts with understanding and scoping a clear problem and then focusses on how to solve the problem [17]. This methodology can help designers to set aside their own assumptions and gain insight into users and their needs. It is an iterative approach which requires multiple cycles of ideation, prototyping, and testing [17], [18]. Design thinking fosters experiential learning and teamwork by involving staff and users in practical experiments [19]. This active engagement supports the development of a collective commitment and enhances confidence in the new product or strategy. The Design Council's Double Diamond [20] visualises the phases of the design thinking process (Figure 2.1). However, Design Thinking is a non-linear and iterative process. The findings from each phase are continuously used to improve the initial assumptions, understandings and solutions [20].

The design council describes four core principles [20]:

1. **Focus on people (people-centred)**: Gain an understanding of the users.
2. **Communicate (visually and inclusively)**: Ensure the people involved have a shared understanding of the problem and the solutions.
3. **Collaborate & co-create**: Multidisciplinary teamwork and get inspired by others.
4. **Iterate**: Iteratively improving the product and solving errors.

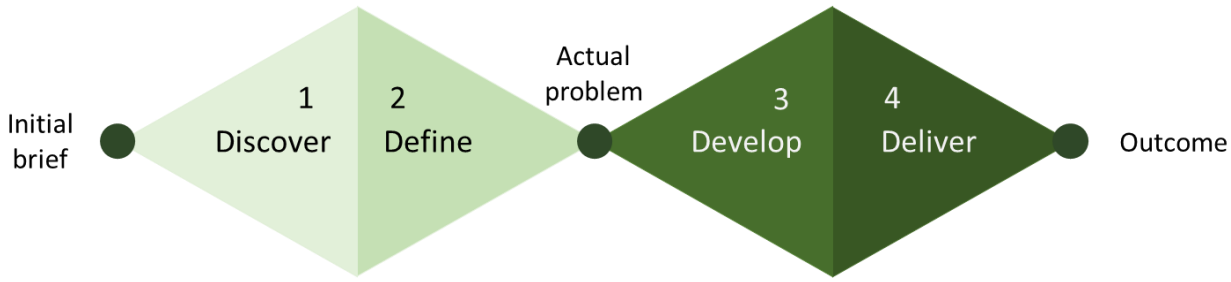


Figure 2.1: Design Council's Double Diamond [20]. *The fist diamond represents the 'Problem Space' and consists of the 'Discover' and 'Define' phase. The second diamond is the 'Solution Space' and consists of the 'Develop' and 'Deliver' phase.*

2.3.3. Description of approach

Figure 2.2. shows the developed approach which is based on the previous concepts. This approach was used to introduce AR at OMFS department of the UMC Utrecht.

Med-tech innovation coordinator The first step is to assign an innovation coordinator. Successfully introducing a complex technology into the clinic requires much effort and time. Therefore, having a dedicated individual in the hospital ('an innovation coordinator') to drive

the innovation is valuable. An innovation coordinator should have a technical and medical understanding and should be responsible for making sure the technology blends well within the clinical context (bridging the gap between the technical development and clinical implementation), inspiring early adaptors on the team, and ensuring everyone understands the technology. The responsibility goes beyond making sure the technology works in the environment, a culture of early adoption should be built within the clinical team, ensuring everyone is on board and the contextual factor are taken into account.

Iterative process. The innovation coordinator will be responsible for executing steps 1-3 in the iterative process. The principles of rapid prototyping and small and simple interventions are adhered to. The first cycle of the iterative process should be performed in an early stage of the development.

1. **Gain understanding**: Develop an in-depth understanding of the problem, the technology which aims to solve it, the context, and the stakeholders.
2. **Share understanding**: Share the understanding with the clinical context through small and simple interventions.
3. **Actively engage stakeholders**: As the stakeholders have an understanding of the problem and technology, they can provide valuable input for the development of the technology. This is assessed during this step.

The output of one cycle will be used as input for the development of the technology and will result in a new prototype which will also go through the cycle.

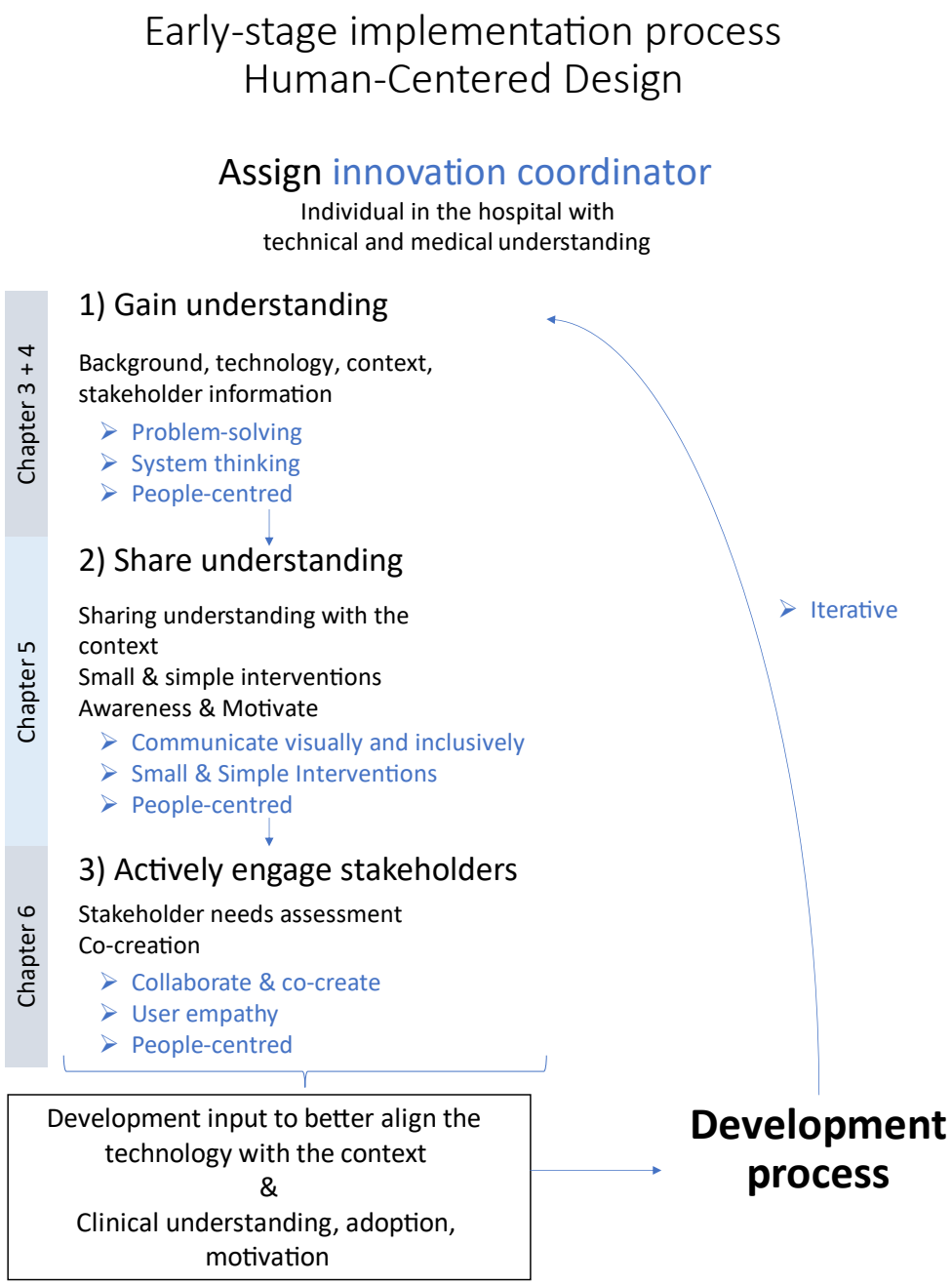


Figure 2.2.: Outline of the approach to technology introduction adopted in this thesis.

In the next chapters this approach will be applied to introduce AR within the OMFS department of the UMC Utrecht. Figure 2.2 illustrates the specific chapters in which each step of the approach will be executed.

3

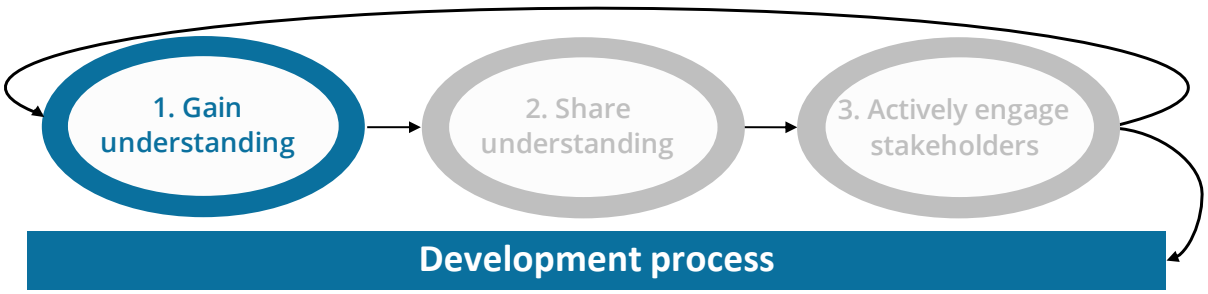
Gain understanding:

Understanding the technology

In this chapter, the background of the collaborative initiative to introduce AR for surgical guidance at the UMC Utrecht and UMC Groningen and an understanding of the technology is provided.

To provide a structured understanding of AR systems for surgical guidance, this chapter will explore their key components. The terminology used to describe AR systems is primarily drawn from the taxonomy from Gsaxner et al. [21] This taxonomy provides a systematic and structured approach for categorizing different aspects, topics, or subfields within medical AR research. This taxonomy encourages the use of shared terminology and categories.

In the final section of this chapter the AR navigation system, which is currently under development by the UMC Groningen, UMC Utrecht, and the Center for Information Technology (CIT) of the University of Groningen (Rijksuniversiteit Groningen, abbreviated as RUG), is described.



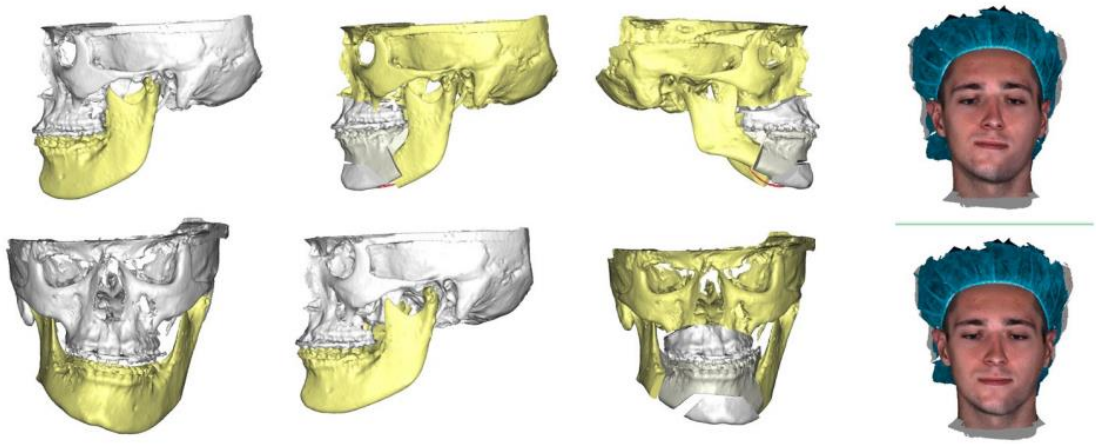


Figure 3.1: Example of a 3D Virtual Surgical Planning (VSP), Orthognathic surgery.

3.1. Background

Oral and maxillofacial (OMF) surgery comprises surgery of the face, mouth, and jaw, which have complex three dimensional (3D) shapes. OMF surgery requires enough expertise to understand these anatomical structures where postoperative aesthetics and functional outcomes are important [22], [23]. To assist the surgeon with complex surgeries, 3D virtual surgical planning (VSP) can be helpful and can result in a higher accuracy, predictability, and safety of the treatment [24]. 3D imaging technology and advanced software are utilized to create detailed models of the patient's anatomy and to develop a preoperative surgical plan. The preoperative plan can consist of tasks such as positioning screws, implants, or osteotomy planes, resecting bone or soft tissue, and reconstructing bony defects. Various treatment scenarios can be assessed in a virtual environment to select the best plan [24]. VSP has become standard of care for orthognathic and reconstructive maxillofacial surgery. Figures 3.1 and 3.2 show examples of 3D VSP in OMF surgery. In order to successfully transfer the preoperative plan to the operation room (OR), patient-specific surgical guides or surgical navigation systems can be used.

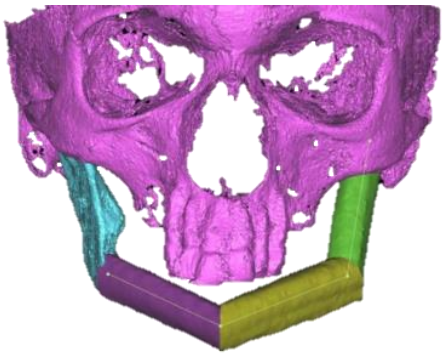


Figure 3.2: Example of a 3D Virtual Surgical Planning (VSP), fibula reconstruction.

3.1.1. Patient specific surgical guides

Patient specific surgical guides are 3D printed instruments based on preoperative planning aiming to improve the precision of surgical tasks to follow the preoperative plan (Figure 3.3). Surgical guides can improve the accuracy and can ensure correct angulation and depth. A disadvantage of these guides is that they require additional bony exposure in order to allow stable placement on the bone surface and, if used for flat bony structures, they might be misplaced due to the lack of good reference structures [25]. Moreover, they might not be applicable for soft-tissues or deep narrow surgical approaches [26]. Errors might go

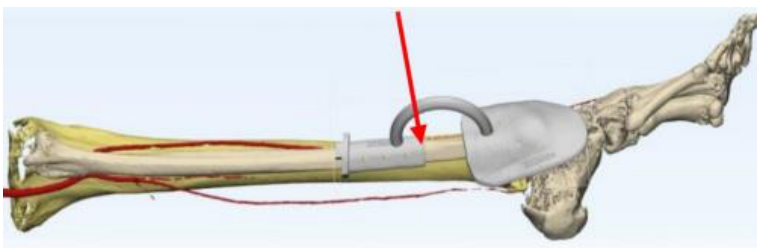


Figure 3.3: Example of patient specific surgical guide, fibula reconstruction.

unnoticed, as they do not provide intraoperative feedback or vision [27]. Lastly, the design and printing of surgical guides can be a time-consuming process.

3.1.2. Surgical navigation

Surgical navigation systems can precisely track the spatial location of both the instruments and the patient and correlated to the relative positions in the preoperative images. The instruments' position is projected onto the preoperative imaging data, containing the VSP. The locations are continuously updated, and resultantly real-time tracking of the instruments is possible (Figure 3.4). This way the surgeon can be guided throughout the procedure. Commonly, optical tracking systems are used to track the patient and instruments. Highly reflective spheres are connected to the surgical instruments and can then be tracked by an overhead camera. Surgical navigation has shown to improve surgical outcomes and can contribute to faster, safer and more effective surgical procedures [28].

Figure 3.4: Surgical navigation system (Brainlab AG, Munich, Germany). A drilling task is guided in this example.

Conventional surgical navigation systems can be challenging to use. The need to pay attention to both the patient and the monitor of the navigational system constitutes one drawback to their use. This attention shift negatively impacts the cognitive and motor capabilities of the surgeon, disrupts the continuity of the surgery, and decreases the situational awareness of the surgical field [5], [29]–[31]. Furthermore, the 3D VSP is shown on a 2D display and is not aligned with the viewpoint of the surgeon [26]. This can make it challenging to mentally translate the planning to the real surgical situation [26], [28]. This can lead to a loss in accuracy.

3.1.3. Augmented reality for surgical navigation

In the recent years, AR has shown to be a promising technology for surgical navigation [1], [2]. Using AR, 3D virtual models can be projected onto the real surgical field to guide the surgeon or give additional information, without the surgeon having to switch attention between the patient and the navigation monitor [3], [5], [28], [32]–[34]. AR has the potential to show anatomy in a recognizable, simplified way [35]. Furthermore, surgical guidance tool can be visualized in the surgical field and sterile interaction with the virtual content is possible through voice commands and hand gestures [36]. However, current limitations impact the application of AR in surgical domain, particularly concerning issues related to registration and tracking errors, as well as disparities in the perception of the projected virtual objects and the real world. As a result, AR has not yet been widely integrated into surgical practice [37]

3.1.4. Project background

A collaboration between the 3D Face Lab and the OMF department of the UMC Utrecht and 3D Lab and OMFS department of the UMC Groningen has been established in 2018 to collaboratively conduct research on AR for surgical guidance of OMF surgery. The research group developed an AR navigation system which links the Microsoft HoloLens 1 (HL1) to a surgical navigation system, Brainlab (Brainlab AG, Germany [38]). In this way, the AR system uses the registration and tracking information from the navigation system. Multiple studies [26], [31] have been conducted to evaluate the value, accuracy, and usability of the AR navigation system developed by this research group through testing the usability and accuracy of the system. These preclinical studies presented the added value of AR for

surgical navigation; however the results show that the accuracy is not yet sufficient enough for surgeries requiring high precision. This is due to technical limitations and challenges, such as errors in virtual to real world alignment, projection latency, depth perception, etc. A more detailed description of these challenges will be provided in the next sections. Efforts are made to address and improve these limitations. With the release of the Microsoft HoloLens 2 (HL2), the system is adapted to be compatible with the HL2. Using the HL2 the accuracy might be further improved due to the larger field of view (FoV) (43 × 29◦ vs 30 × 17.5◦) [39], improved depth detection with a new sensor, faster response speed and more detailed experience due to better processing power and RAM, and better eye tracking. A study from Pose-Díez-De-la-lastra et al. [40] compared the accuracy when using HoloLens versus the HL2 for surgical guidance. Results, show that the projection error is significantly reduced when using the HL2. Furthermore, the reduced weight and relocation of the battery pack to the backside of the HoloLens can result in improved comfort for the surgeon (566 g instead of 579 g) [39], [40]. Lastly, the HL2 greatly improves the hand gesture recognition providing a more intuitive interaction with the virtual content [40].

Furthermore, the following software updates are performed to improve the system:

1. Efforts are made to improving the user experience by updating the user interface.
2. The latency is decreased through more efficient coding and computation off-loading.
3. Improving the perceived alignment of the projections through new methods to perform the calibration of the virtual to real-world objects.

3.2. AR surgical navigation system

Within the context of AR surgical navigation systems, a general workflow can be identified, as shown in figure 3.5. Three components play a key role: registration, tracking and display [37], [41], [42].

3.3. Registration and Tracking

Registration is needed to align reality and virtuality in 3D. In a surgical guidance context, it is

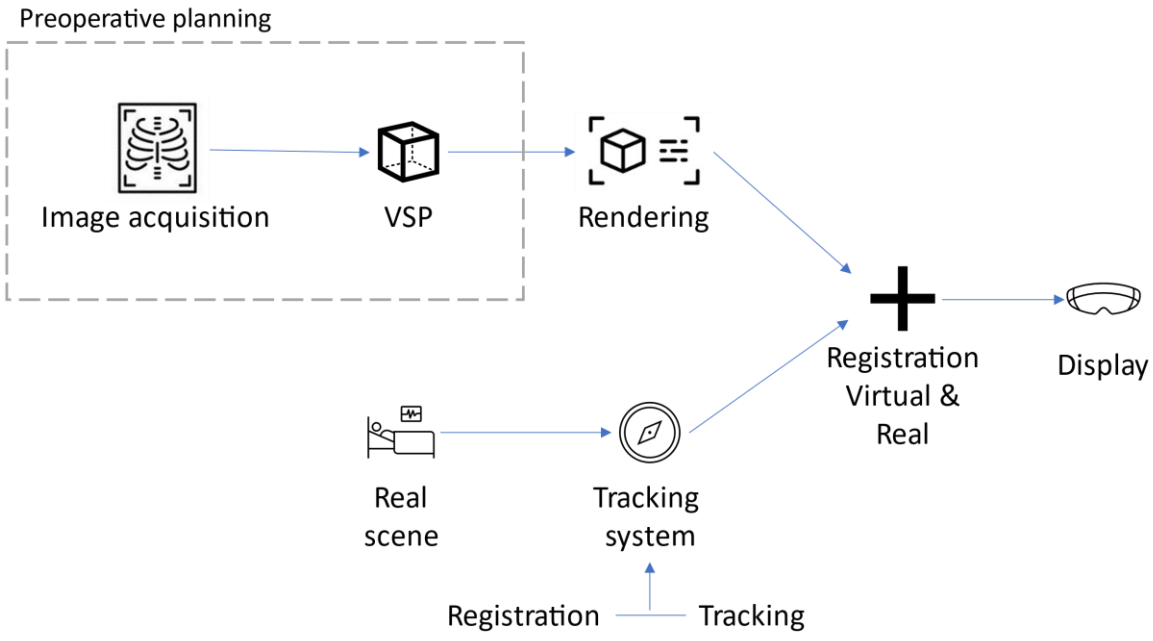


Figure 3.5: In general, the main steps of an AR surgical navigation system.

important that the virtual content appears in the correct position and orientation within the user's field of view. To register virtual content in the real environment, the viewer's position and orientation (pose) relative to the patient need to be determined [43].

By using tracking techniques, the registration is maintained and synchronized with the viewpoint of the user's perspective [21]. Tracking should ensure that virtual elements remain stable and accurately positioned as the user, the patient, and instruments move.

In short: the registration involves determining the viewer's position and orientation relative to the real-world anchor. Tracking is the process of refining the viewer's pose to match in real-time [43].

Paradigms

In the context of tracking and registration, we can identify two distinct paradigms: outside-in and inside-out (Figure 3.6).

- Outside-in: external sensors are used to monitor the device's, patient's, (and instrument's) movement from an external perspective.
- Inside-out: the sensors are incorporated within the AR device. The device can autonomously determine its position within an unprepared environment [21].

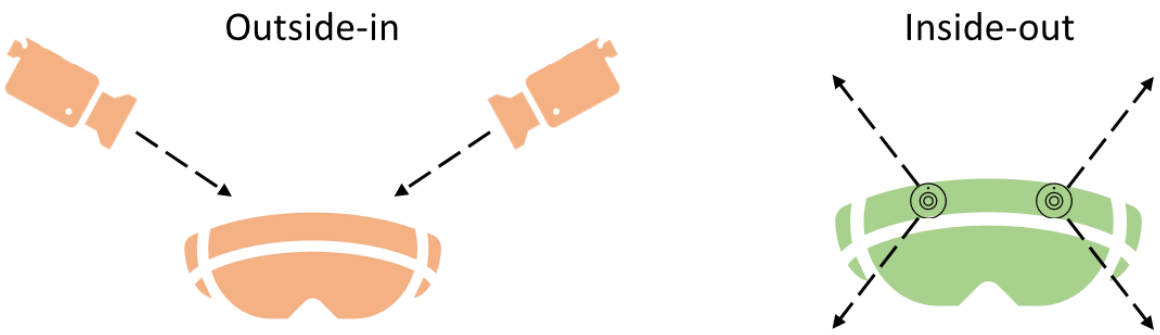


Figure 3.6: Tracking Paradigms: Outside-in (left) and Inside-out (right).

3.4. Tracking techniques

The tracking methods can be categorized by the presence or absence of markers: *Marker-based* or *Markerless.* Furthermore, the methods can be divided into *sensor-based* or *vision-based* techniques.

Marker-based vs markerless tracking

Marker-based tracking relies on indicators of pre-defined pattern and size, whose location in relation to the real world is precisely known (e.g., fiducial markers visible to visible light or infrared (IR) cameras). IR emitting markers are widely used in surgical navigation systems. A reference marker is anchored to rigid tissue to keep track of the relative position of the patient and camera. Furthermore, these can be attached to surgical instruments for tracking. [21]

Markerless tracking does not require predefined objects. It relies on naturally observable features. Computer vision or sensor data is used to detect and track natural features. [21]

Sensor- vs vision-based tracking

Sensor-based tracking relies on the data gathered from a sensor. Magnetic, inertia (gyroscope and accelerometer), or acoustic sensors can be used or a combination of multiple sensors (hybrid sensor) [43], [44].

The *vision-based tracking* techniques rely on observable features within the system's field of view. Computer vision techniques are used to identify and continuously track specific features, e.g., visual markers, patterns, images and objects with distinct characteristics.

3.5. Display

The display techniques of AR are generally categorized into the following:

- Video see-through (VST): the real world is recorded by a camera and before it is displayed to the viewer it is augmented with virtual objects [45]. Devices such as tablets, smartphones, and head-mounted displays (HMD) can employ VST to provide an AR-experience.
- Optical see-through (OST): the real world stays visible for the viewer, as transparent virtual content is projected in the FoV of the user. [45]. HMD or head-up devices can display virtual content using OST techniques.
- Projector-based (PB): virtual content is projected on top of a real physical surface using a video projector.

3.6. In-house developed AR surgical navigation system

Figure 3.7 is a visual representation of the system that is being developed by the UMC Groningen, UMC Utrecht, and CIT RUG. The developed system is an outside-in, marker-based AR navigation system. The hardware components used are the commercially available navigation system, Curve® Navigation from Brainlab (Brainlab AG, Munich [38]), the Microsoft HoloLens 2 (Microsoft, Redmond, Washington, United States [46]), a PC, and a router [26]. The Brainlab technology employs infrared tracking to continuously monitor the position of the patient and the surgical instruments. Reflective markers, placed on a star with unique distances apart, are affixed to the patient and the surgical instruments. Patient registration is done using point-based registration or surface matching to determine the patient position relative to the patient star. The instruments can be registered through a calibration block to determine the position of the tip of the instrument relative to the markers. These markers are tracked by a stereo IR camera which is connected to the system's computer. Additionally, to determine the users viewpoint relative to the patient and instruments, reflective markers are also placed on the HoloLens.

In short, the system works as follows: the PC receives the VSP and the tracking data (relative positions of the patient, instrument, and HoloLens) from the connected Brainlab. The data is rendered and wirelessly streamed to the HoloLens through the router. This enables the surgeon to view the 3D virtual content aligned with the surgical field [26].

The connection between the PC and Brainlab is based on the OpenIGTLink technology, which is an open-source network protocol for image-guided therapy (IGT) specifically developed for standardization of communication between medical equipment in the operating room.

A more detailed explanation of all the steps visualized in *Figure 3.7* is described below. The red arrows show the steps provided by Brainlab, the green arrows show the additional steps in the workflow provided by the in-house developed system.

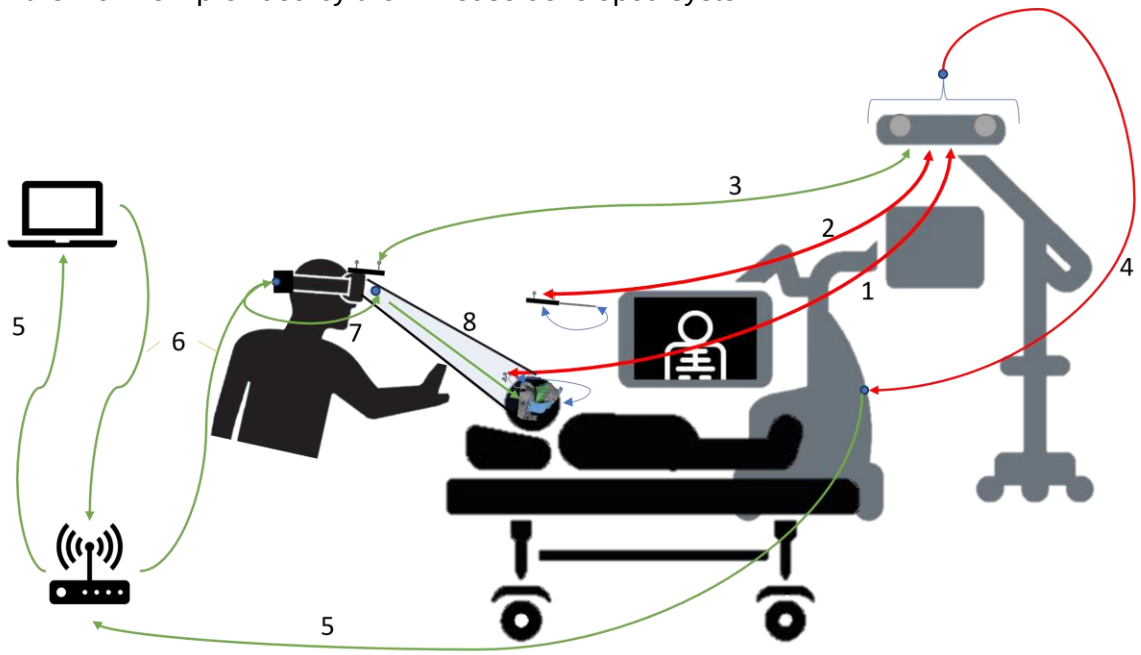


Figure 3.7: Visual presentation of the AR navigation system, which is currently under development by the UMC Groningen, UMC Utrecht, and the Center for Information Technology (CIT) of the University of Groningen. The red arrows show the steps from the conventional navigation system (Brainlab). The green arrows show the additional steps that are required for the AR navigation system.

1. The patient is tracked using Brainlab's tracking system. This is done by attaching a reference star with reflective markers at a unique distance apart to the patient (see figure 3.8). For OMFS it is usually fastened to the skull. A patient registration is performed to align the preoperative images and VSP to the patient during the surgery. Registration can be done though either point-based registration or surface-based registration.

Figure 3.8.: Brainlab's reference star to track the patient.

2. Similarly, Brainlab tracks surgical instruments by equipping them with distinctive stars with reflective markers spaced at known distances. The unique stars are detected by the Brainlab tracking system. Before tracking can be done, the instrument must be calibrated by identifying the position of the tip of the instrument, relative to the tracking star.

3. The HoloLens 2 also has a star with reflective markers at a unique distance apart attached to it. By tracking the star the position of the HoloLens relative to the patient and the instruments can be computed and in this way the view of the user is

determined. This is necessary for accurate alignment of the virtual objects in the surgical field.

4. The tracking information is sent to the Brainlab computer, where it is processed to display the preoperative planning correctly and enable accurate navigation.
5. Through the OpenIGTLink, the tracking information and VSP are transferred to the PC using the router. Using in-house developed software, the information given in the Brainlab coordinate system is converted to the HoloLens coordinate system. Additional virtual guidance tools are also added to assist the surgeon with surgical tasks.
6. The stereoscopic images are rendered on the PC and streamed to the HoloLens (through a wireless connection with the router).
7. The holograms must be projected in the correct position so that they align with the surgeon's perception. The HoloLens 2 includes eye-tracking to make the interaction more natural. Surgeons should perform an eye calibration before the surgery to enable accurate eye tracking. Furthermore, a manual registration has to be performed each time a user puts on the HMD. During this calibration the surgeon moves the perceived virtual content to align with real world objects (e.g., hologram of the pointer to the real pointer).
8. The virtual overlay is projected into the surgical field, visualizing patient anatomy, surgical guidance tools (e.g., planned trajectories), and real-time guidance to position surgical instruments.

System errors

It is essential to be aware of the different factors that contribute to the overall error. As shown in Figure 3.9, the total system error is an outcome of multiple individual components. Therefore, when validating the system, it is important not to only assess the total system accuracy but also to assess errors individually. This approach enables the identification of the sources of performance errors.

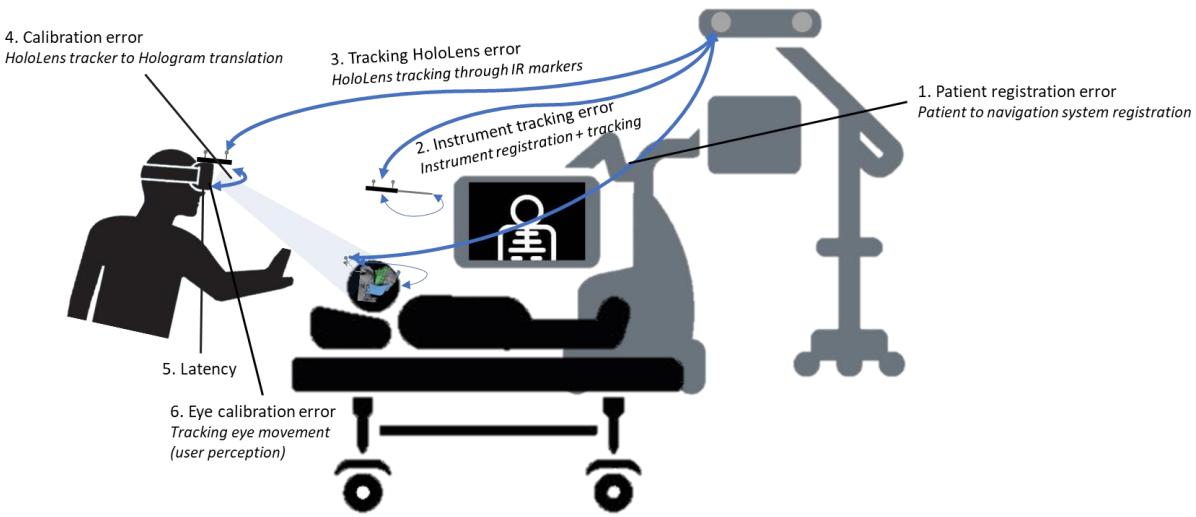
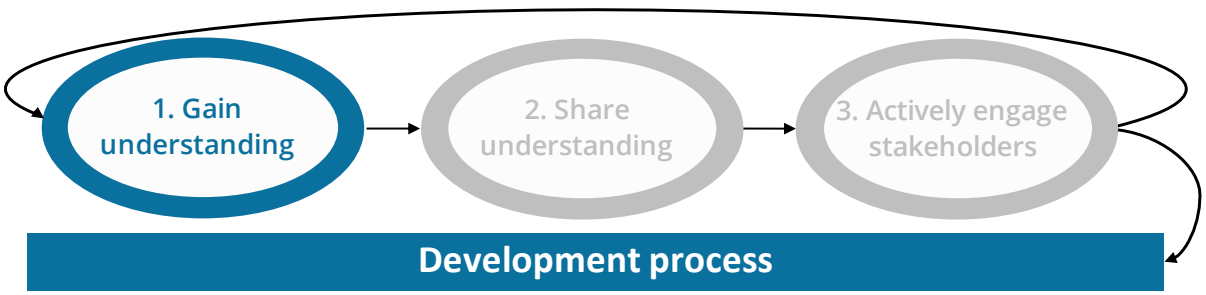


Figure 3.9: The factors of the AR system that contribute to the total error of the system.

4

Gain understanding:

Explore the field



4.1. Literature

To visualise the trend in the number of published papers on AR surgical navigation a quick search was performed in PubMed usings the following key words and their synonyms: “Augmented Reality” and “Surgical navigation”. The number of published articles by year are shown in Figure 4.1. This shows there is a steady increase in the number of publications and implying a growing interest in adopting such technology in surgical navigation.

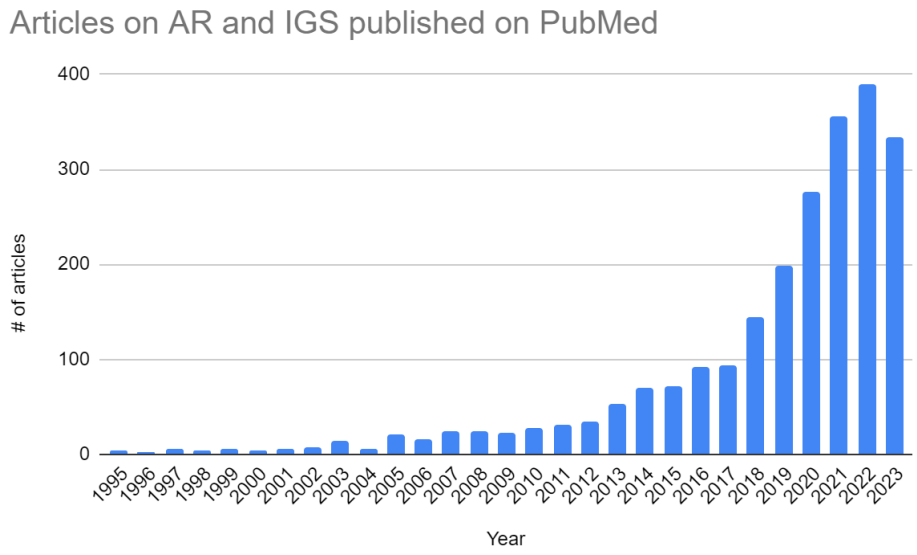


Figure 4.1: Graph showing the number of published articles on PubMed on Augmented or Mixed Reality and Surgery.

To provide an overview of recent research on the use of AR in surgical applications, different systematic reviews (SRs) published after 2020 were evaluated. Valuable information was extracted and summarized from the following systematic reviews: Chegini et al. [47], Birlo et al. [48], Bollen et al. [49], Doughty et al. [50], and Benmahdjoub et al. [51]. The SR of Benmahdjoub et al. [51] is specifically focussed on CMF surgery, all other SRs evaluate AR for surgery in general.

4.1.1. Characteristics research papers

All SRs evaluated in this research show the same trend in steady increase in number of publications. Doughty et al [50], Chegini et al [47], and Bollen et al [49]. show that most studies were performed in orthopaedic surgery, OMFS, and neurosurgery. This is shown in Figure 4.2 in the chart on the left, where Doughty et al. [50] present a pie chart illustrating the distribution of AR research across these specialties.

An important finding from the SRs is that, to date, published articles have reported findings from small-scale, non-randomized, and uncontrolled studies. Phantom experiments and experimental settings have been the primary focus of research. While there are a number of patient case studies, larger scale clinical studies remain minimal. This is shown in the graph reported by Birlo et al. [48] (Figure 4.2, right). These findings emphasize the need for further investigation in real clinical settings. Furthermore, the existing literature is characterized by substantial heterogeneity.

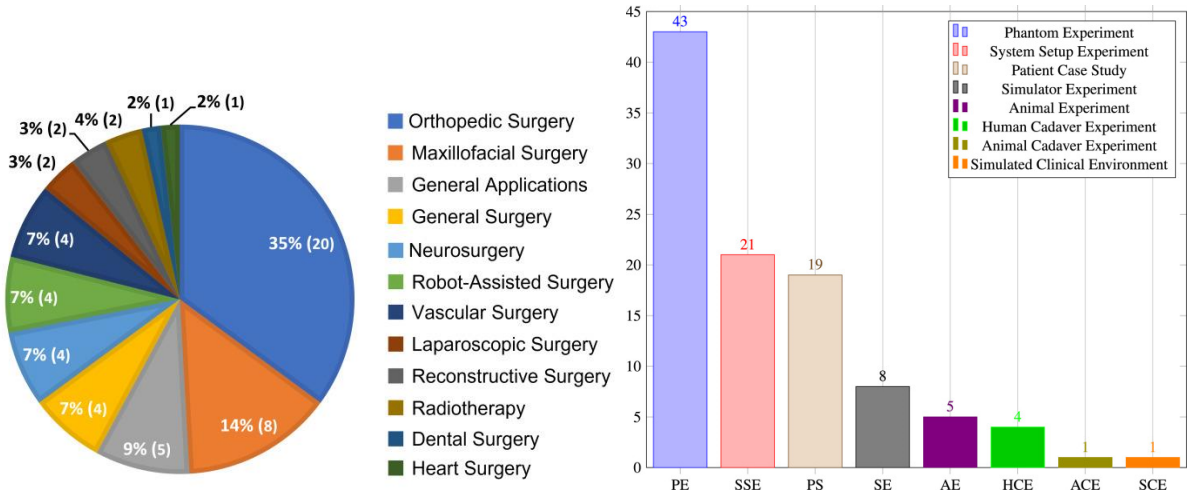


Figure 4.2: Overview of the medical specialty of the published papers in Doughty et al. [50] *(left). Study types of the articles found in the systematic review of Birlo et al.* [48] *(right)*

In the context of CMF, the same results are seen: phantom studies outnumber intraoperative ones. This observation underscores that AR is currently in research and development phase, both technically and clinically. However, the first steps towards clinical use are being taken [51].

4.1.2. Hardware & Software

The systematic reviews show that the Microsoft's HoloLens is by far the most often used display device. Birlo et al. [48] found that 66 out of 91 included studies used the HoloLens as HMD. Doughty et al. [50] used a similar methodology to Birlo et al. for an updated analysis of more recent articles (from 2021 and 2022) and found that 47 out of 57 studies utilized the HoloLens. This is mostly due to the relatively low costs of the device (€ 3500, -), wide availability [47], and its accessibility for research purposes through the research mode [52]. In contrast, there is no universally popular software, with the majority of studies developing their own in-house software [47].

4.1.3. Reported results

Chegini et al. [47] evaluated the reported registration errors in different types of studies, based on the registration method used. The overall mean registration error is reported to be 2.8 mm across all included studies. The results of the review are shown in figure 4.4.

Benmahdjoub et al. [51] reported on the accuracy in studies where CMF surgery is the focus. In this SR a distinction was made between intraoperative accuracy and accuracy obtained in phantom studies. Intraoperative accuracy ranged from 0.42 to 4.34 mm, while accuracy in phantom studies ranged from 0.02 to 2.97 mm. This discrepancy confirms the influence of intraoperative factors on accuracy.

Bollen et al. [49] elaborates on other surgical outcomes. This is visualised in figure 4.3 using the bar chart provided by Bollen et al. It shows the effects of AR on surgical outcomes compared to the control group of the included studies.

The validation methods used in published articles is characterized by substantial heterogeneity leading to incomparability [51]. Most included articles in the reviews reported on small-scale, non-randomised, and uncontrolled studies [49].

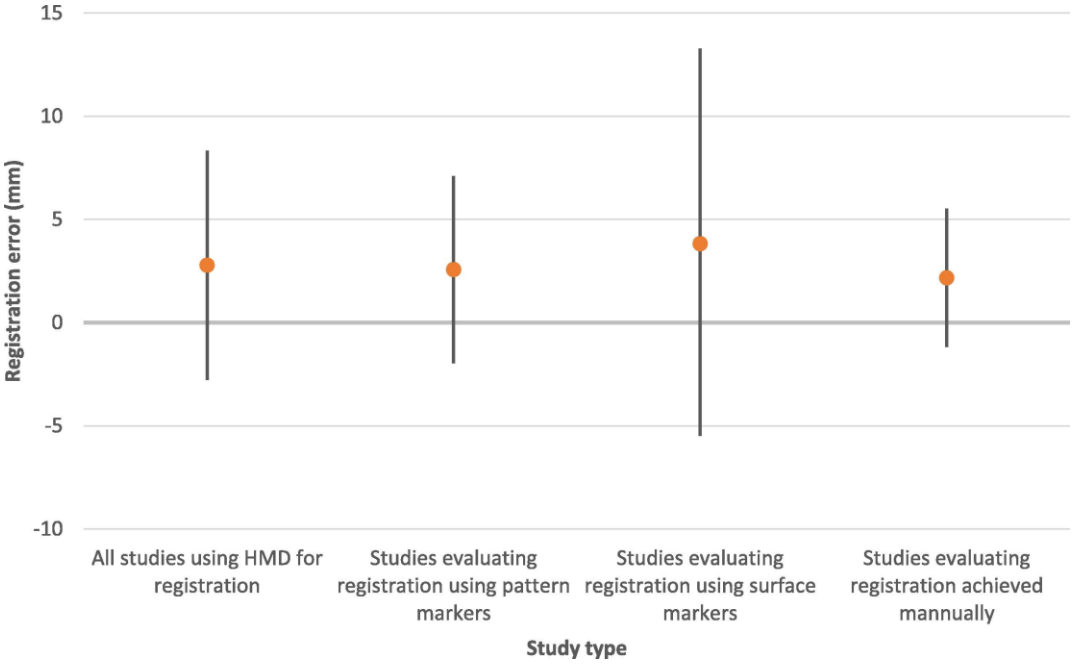


Figure 4.4: Results on the registration error found by Chegini et al. [47] *based on the different registration methods.*

Key findings

- There is a steady increase in the amount of published papers on AR and surgery.
- Phantom studies outnumber the intraoperative once, indicating that it is still in the research and development phase.
- Numerous studies suggest that AR has the potential to enhance surgical outcomes. However, there is a broad range in reported accuracies, incomparability between studies, and lack of large- scale, randomised control studies.

4.2. Market surveillance

4.2.1. MDR / FDA approved

As shown in the previous section, there is an increasing interest in research in the field of AR for surgical navigation. However, a significant number of research projects do not transition from being research prototypes to successful commercial products. Instead, they are mostly developed and validated in controlled settings on phantoms, human cadaveric specimens, or in case studies [36], [53], [54].

There are a few commercial systems who have received an FDA clearance [55].These are shown in Table 4.1. Knee+ by pixel medical received apart from an FDA clearance also a CE mark according to EU MDR 2017/745. The costs of FDA approved AR-HMD systems range from $60,000 to $300,000 USD [56].

Table 4.1: Overview of the FDA approved AR navigation systems.

System + Company Website	Clinical indication (FDA approved)	Tracking	Display device	Limitations
NEXTAR by Medacta (Castel San Pietro, Switzerland) https://nextar.medacta.com/	Total Knee Arthroplasty and Total disc arthroplasty	Single use infrared tracking device	Vuzix Blade Smart Glasses	Requires specific tools. Information displayed is based on pre-operative planning only.
SNAP – SyncAR by Surgical Theater (Beachwood, Ohio, USA) https://surgicaltheater.com/syncar-spine/	Pedicle screw placement	Infrared fiducial tracking	HoloLens 2	Unclear how AR is used.
Knee+ by Pixee Medical (Besançon, France) https://www.pixee-medical.com/en/knee/	Total Knee Arthroplasty	QR code tracking	Vuzix M400 Smart Glasses	Requires specific tools. Information displayed is based on pre-operative planning only.
VisAR by Novarad corporation (Provo, Utah, USA) https://www.novarad.net/visar	Pedicle screw placement	QR code tracking	HoloLens 2	2D overlay based on preoperative planning only.
HoloSurgical by Surgalign Spine Technologies (Deerfield, Illinois, USA) https://surgalign.com/	Stereotactic spine surgery	Infrared fiducial tracking	Projection display	No reactive anatomical animation
ARVIS by Insight Medical Systems (Austin, Texas, USA) ***Now acquired by EnovisTM (Lewisville, Texas, USA)*** https://www.djoglobal.com/Arvis	Hip and knee arthroplasty surgery	Infrared fiducial tracking	Own developed HMD	Restricted scalability due to and integrated hardware and software solution.
X-Vixion by Augmedics (Arlington Heights, IL, USA) https://augmedics.com/	Pedicle screw placement	QR code tracking	Own developed HMD	Restricted scalability due to and integrated hardware and software solution.

4.2.2. Under development

Widely known companies such as Brainlab AG (Munich, Germany) [38] and Materialise (Leuven, Belgium) [57] are currently in the process of introducing AR surgical navigation modules. Brainlab has revealed its plan to launch an AR module for spine navigation in early 2024. Meanwhile, companies like Augmedit (Naarden, the Netherlands) [58] and Holoma (Sofia, Bulgaria) [59] are also working on AR surgical navigation systems; however, they have not yet achieved full compliance with regulatory requirements.

Key findings

- There are a view AR surgical navigation systems on the market that are FDA approved.
- The intended use of all the FDA approved systems is orthopaedic surgery.
- Knee+ by Pixee Medical is currently the only AR surgical navigation system that has a CE-mark according to EU MDR 2017/745.
- There is no system intended for OMF surgery on the market that is in compliance with regulatory requirements.

4.3. Context

4.3.1. 'OMFS department of the UMC Utrecht

The context of this thesis is the OMFS department of the UMC Utrecht. The OMFS department works closely together with the Special Dental Care of the UMC Utrecht, due to many combined treatments. Annually, more than 9000 new patients with oral, jaw and face diseases or abnormalities are treated. These treatments are provided by a diverse team of professionals from various backgrounds. The multidisciplinary teams include medical staff, orthodontists, dentists, general practitioners, management personnel, residents, dental hygienists, nurses, dental technicians, operating room staff, departmental assistants, secretaries, and researchers.

The department routinely carries out a range of treatments, including orthognathic surgeries, (dental) implant placements, and treatment of malignant tumours occurring in the oral cavity, oral pharynx or salivary glands. OMF surgery can be categorized into: congenital conditions, reconstruction (pre-prosthetic surgery, transplantation, and implantology), traumatology, oncology, and general maxillofacial surgery. Many of these treatments require preoperative planning.

As it is a University Medical Center, there is much space for and a strong commitment to invest in education, training, research, and innovation.

4.3.2. 3D Facelab of the UMC Utrecht

In the MKA-BT department, where complex cases are a common occurrence, the role of 3D technology is of essential value. Therefore, the 3D Facelab plays an important role. The 3D Facelab performs dental technical tasks on behalf of the dentists and provides technical and digital work for OMF patients with complex care needs.

The 3D Face Lab is responsible for various tasks:

- Prosthetics: The 3D Face Lab patient-specific dental and facial prosthesis.
- 3D visualisation: The lab provides 3D image visualization techniques to help the surgeon with diagnostics and the treatment planning of complex cases.
- VSP: The 3D Face Lab makes digital preoperative plans of complex surgical procedures. It involves creating detailed surgical plans, optimizing approaches, and simulating the surgical outcome before the intervention.
- Intraoperative guidance: The 3D Face Lab plays a role in transferring digital surgical plans to the OR. This involves determining the most suitable method for this transfer, which may include surgical navigation systems or computer-aided design and computer-aided manufacturing (CAD/CAM) techniques. Commonly used techniques are the manufacturing of wafers and drilling guides.

Beyond clinical applications, the 3D Face Lab contributes to the advancement of new technologies and techniques in OMF surgery. Additionally, it plays a role in the residents' training program, as it educates residents to work in 3D digital environments and create VSP on their own. Lastly, the 3D Face Lab supervises (technical) medicine students and provides them with research projects, further promoting innovation in the field.

Key findings

- The context for the introduction of AR is the OMF department of the UMC Utrecht.
- The department comprises a diverse, multidisciplinary team of professionals from various backgrounds.
- Complex cases are treated within the department, and there is a significant emphasis on and dedication to investing in education, training, research, and innovation.
- The 3D Face Lab plays a crucial role in the treatment of complex cases that require 3D VSP. Additionally, it is a driving factor in innovations at the department.

4.4. Stakeholder analysis

The introduction of a new technology into a hospital is a complex process. The technology should not just work on its own, but it should fit into the entire healthcare environment around the use of the technology. To reach this goal, input from many different fields is required. This is where the concept of stakeholder involvement comes to play. Identifying and engaging stakeholders early in the development process is essential, as it helps to understand the healthcare environment and customize the technology to meet its demands [60], [61]. The MDR encourages the early involvement of healthcare professionals and experts in the development of medical devices [60].

To analyse and visualise the different stakeholders the following two steps are performed: 1. Stakeholder identification and 2. Stakeholder mapping. In stakeholder mapping the influence and interest of the stakeholders in the project is analysed. The aim is to provide an organized visualization which can help to develop a strategy for communication and engagement of stakeholders.t.

The results from these two steps are shown in the next sections using the knowledge obtained from literature and experts' opinion. This is an iterative process going back and forth between the two steps.

4.4.1. Identification

The first step is to list the stakeholders. It is important to identify everyone (including every group/organisation) who has an interest in, is impacted by, or has an influence on the implementation of the technology [61]. A list of the identified stakeholders is shown in figure 4.6 on the right of the graph.

4.4.2. Stakeholder mapping

A commonly used stakeholder mapping tool is Eden and Ackerman's power / interest grid [62]. After identifying the stakeholders, they can be mapped on the matrix, according to the interest (x-axis) and power (y-axis) of the stakeholders. The matrix is shown in Figure 4.5. In this way, stakeholders will be placed in one of the quadrants (*Key Players*, *Context Setters*,

Subjects, and *The Crowd*). Results from the placement can guide the way in which the stakeholders should be managed.

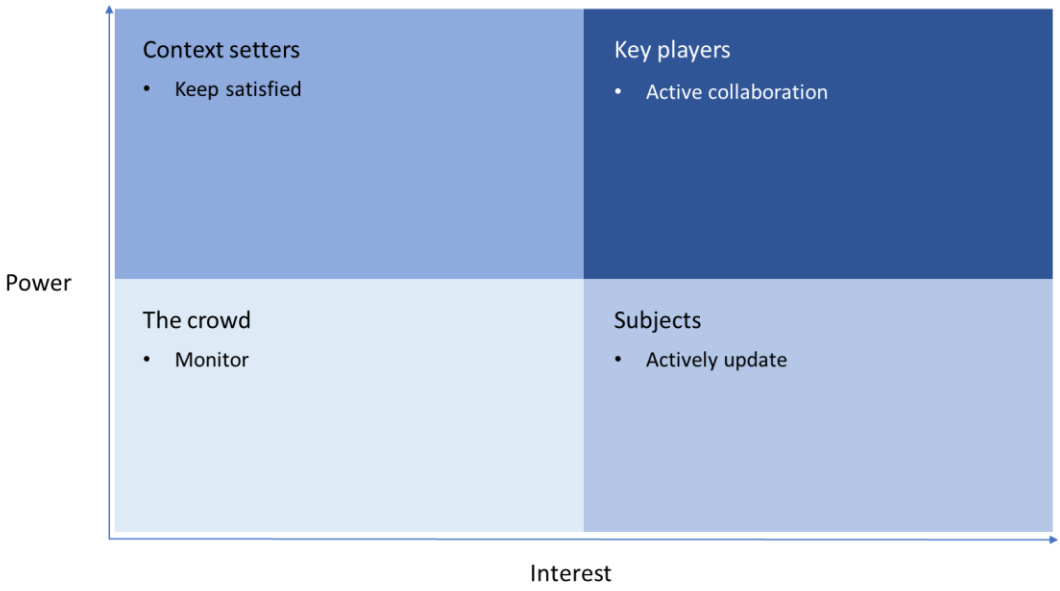


Figure 4.5: Power / interest grid with the different quadrants shown to identify how to manage and involve the stakeholders.

The position of the stakeholders cannot be objectively determined: different people (including the project team and stakeholders themselves) often have various ideas about where stakeholders should be positioned. These differences in perspectives can be interesting to explore and help to achieve a balanced assessment [63]. Therefore, the stakeholder analysis was conducted with input from field specialists (researchers from different hospitals, hospital division manager, surgeon, head of the department, hospital technician). They were asked to position the identified stakeholders on a Power-Interest Graph as shown in Figure 4.6. Any additional stakeholders suggested by the specialists were included in the analysis. The input from all the specialists was used to categorize the stakeholders into one of the quadrants (Table 4.2.). The stakeholders are put in one of the quadrants if more than half agreed on this quadrant (at least four out of seven times it was placed in that quadrant). If no clear mapping position was found, the stakeholder is place in 'Undefined'. More input from other experts should be included to verify their position.

Table 4.2: *The placement of stakeholders in one of the quadrants.*

The Crowd	Subjects	Context setters	Key players	Undefined
Patient & family	Research institutions/groups	MDR	Management team	Suppliers
		Financial stakeholders	Head of the department	Device maintenance & support teams
		Insurance	Surgeons	Medical technology team
		Ethics committees	Companies (medical device manufacturers)	OR staff
		IT	3D (Face)lab	Residents

Figure 4.6: Stakeholder graph used to gather input from experts in the field on their view.

Key findings

- The introduction of AR at the OMF department of the UMC Utrecht involves a multitude of stakeholders.
- Stakeholders who should be actively involved in the development process are: management team, head of the department, surgeons, companies (medical device manufactures), 3D (Face)lab.
- Stakeholders who should be kept satisfied are: MDR, financial stakeholders, insurance, ethics committees, IT.
- Stakeholders to actively update: research institutions/groups.
- Stakeholders to monitor: patient and family.
- No clear agreement was found for the mapping of the following stakeholders: suppliers, device maintenance & support teams, medical technology team, OR staff, residents

4.5. Compliance

When developing and implementing an AR surgical navigation system, it needs to be in compliance with the regulatory requirements which apply in the country of use. Regulatory considerations have to be included from the start of the implementation [36]. In this case, these requirements are outlined by the Medical Device Regulation (MDR). The MDR is a regulatory framework that applies to all medical devices in the European Economic Area (EEA) and regulates the required steps until a medical device for human use can be placed on the European market. The aim is to ensure a high level of protection for patients and

users while promoting effectiveness. The MDR includes an extended definition of software as a medical device and the requirements that come with this [64]–[66].

4.5.1. Medical Device Regulation

For a MDR approval, the following must be included: Classification of the medical device, technical documentation, Quality Management System (QMS), Notified Body involvement, clinical trials, and post-market surveillance. The medical device is classified into one of the four risk classes (Class I, Class IIa, Class IIb, and Class III) considering its intended use, duration of use, invasiveness, and potential harm to patients or users. The classification of the device determines what is required to obtain the Conformité Européenne (CE) certification of the MDR. The higher the risk class the stricter the MDR requirements. A technical dossier must be prepared to demonstrate compliance to the MDR and a QMS is implemented to ensure safety and quality throughout the medical device's lifecycle. A Notified Body reviews the technical documentation and audits the QMS to judge if it can be CE certified. Clinical studies must be conducted to demonstrate the safety of the medical device and effectiveness in clinical settings. Post-market clinical follow-up studies are required to gather additional data on the performance and safety of the medical device. This is required to monitor the performance and safety of the device in clinical use. [36], [65]

In the AR-IGS system, the HMD can be considered as a display device (like a computer screen), and it is therefore not classified as a medical device. The software used in the AR-IGS is classified as medical device software (MDSW), necessitating compliance with the Medical Device Regulation (MDR) [17]. The software is likely to be classified as Class IIa or Class IIb.

4.5.2. Standards and Regulations

Various regulatory standards must be met and it requires specific software development practices. To ensure compliance, the software must be coded following the guidelines set forth by the International Organization for Standardization (ISO) 62304. Additionally, ISO 14971 and ISO 13485 must be adhered to. ISO 14971 is a standard governing risk management for medical devices, ensuring that the software minimizes risks to patients and users. ISO 13485 specifies requirements for a quality management system of a medical device.

In terms of privacy, the General Data Protection Regulation (GDPR) must be met. A Data Protection Impact Assessment (DPIA) is conducted to ensure compliance with GDPR requirements.

4.5.3. Including the MDR in the project plan

It is advised to document, organise, and manage certain regulatory requirements right from the start of a development project. It is essential to document all the choices that have been made during the development process and the reasoning behind these choices. Completing the documentation at the end of a development project can be a huge task [64]. Furthermore, it is important to be aware of the costs, resources, and time needed to get an MDR approval. The *MDR Guide for Medical Device Software* by the FME [64] is a guide to help software developers with the steps needed to bring MDSW on the market which is in compliance with the MDR.

Key findings

- When developing an AR surgical navigation system it is essential to be aware of the regulatory requirements, which apply in the country of use.
- The software used in the AR navigation system is classified as a medical software (MDSW), necessitating compliance with the Medical Device Regulation (MDR).
- MDSW must adhere to the following standards: ISO 62304, ISO 14971 and ISO 13485. In terms of privacy, the GDPR must be met.
- To ensure the software is in compliance with the MDR, broadly, the following is important to include:
    1. Classification of MDSW
    2. Technical documentation
    3. Quality Management System
    4. Notified Body Involvement
    5. Clinical trails
    6. Post-market surveillance
- It is advised to document, organise, and manage certain regulatory requirements right from the start of a development project.
- It is important to be aware of the costs, resources and time that is needed to comply with the regulatory requirement. Suitable expertise should be available to implement the MDR.

5

Share Understanding

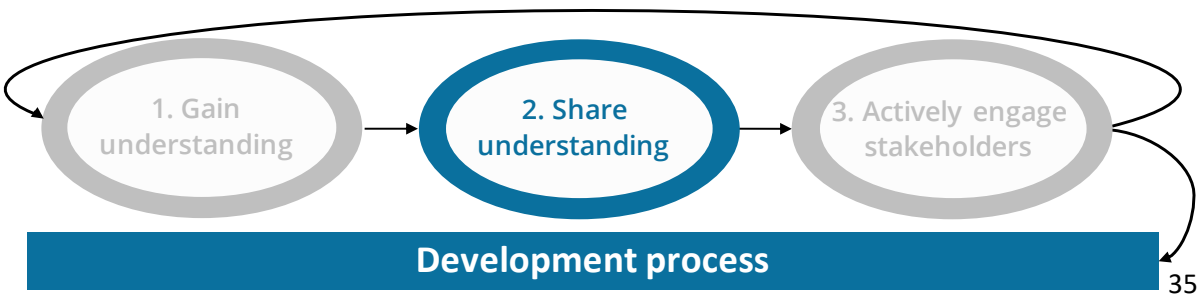
In chapters 3 and 4 an understanding of the problem, technology, context, and stakeholders has been acquired. The next step in the approach is to share the gained knowledge with the clinical context and the stakeholders. This is important to be able to get valuable feedback from the clinical context and stakeholders and to familiarize the context with the technology. With early evaluation in clinical content, hospitals can contribute to defining what makes the technology valuable and how it can benefit both patients and healthcare providers [67]. Furthermore, implementing a new technology in surgical setting demands the surgical team's commitment in terms of time and effort to learn it. Involving the team in the development process, sharing understanding, and presenting the value will enhance their motivation to invest time and effort in it [68].

In design thinking shared understanding is one of the core principles and can be achieved by offering experiences to users through very rough prototypes (pre-experiences of the solution). In this way, stakeholders can gain an understanding of potential value of the technology and provide feedback at low cost.

In this chapter an AR visualisation device is introduced in a controlled clinical environment. This is done through a randomized prospective clinical study: *Narrate – Augmented Reality for orthognathic surgery patient education*.

The purpose of this study is twofold:

First, it aims to evaluate whether the use of augmented reality (AR) for visualizing 3D models can be a valuable addition to patient information regarding orthognathic procedures compared to using only 2D visualization (on a computer screen). In this multi-centre study, it is evaluated whether AR visualization techniques could improve the patient satisfaction and the knowledge obtained during the explanation compared to using a 2D screen for visualizations.
Secondly, in line with design thinking, it is an essential step for introducing AR at the department. During this study an AR HMD is introduced at the department. This first, controlled introduction helps the medical team gain a better understanding of the technology's capabilities and its potential value. This is important to be able to collect valuable input from the surgeons about the development and future introduction of AR for surgical navigation. This will be explained in Chapter 6.



5.1. Small-scale trial in controlled environment

NARRATE – Augmented Reality for orthognathic surgery patient education

Embargo until 01-12-2025

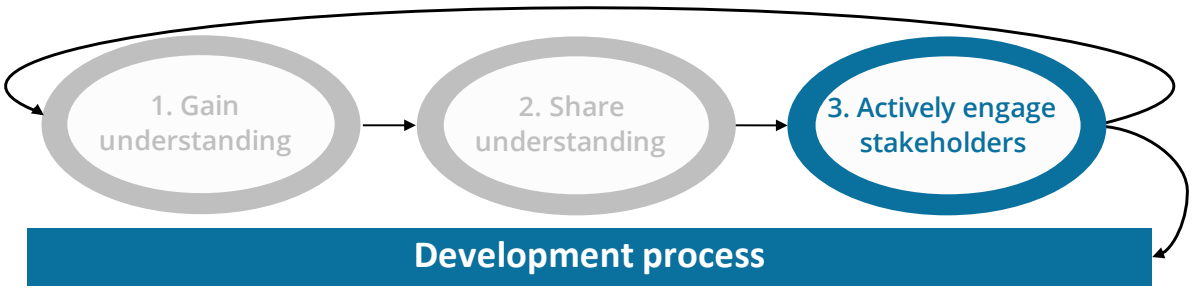
6

Actively engage stakeholders

The previous chapter focussed on familiarizing and sharing understanding of the technology with the end-users. This is important to be able to actively involve stakeholders in the development process. In this chapter, the stakeholders are actively engaged. The aim is to create a collaborative environment, where multidisciplinary expertise and perspective is shared.

In the first part of this chapter, perspective and expertise from the surgeons at the OMF department is collected through interviews.

Another useful step is reaching out to others who share the same goals. Therefore, the last part of this chapter is focused on establishing a research network where knowledge and individual strengths can be shared.



6.1 End-user interviews

6.1.1. Introduction

Surgeons are the end-users of the AR navigation system. Therefore, their needs and perspectives must be included in the development process of the system. This was done through an extensive interview of one and a half hour in total. The first half of the interview was about the development of an AR viewer app, which will be explained in Chapter 7 (*Section 7.6.*). The second half of the interview was about their vision on AR surgical navigation and what factors are important to take into consideration to make the system clinically applicable and useful.

6.1.2. Method

Surgeons of maxillofacial department of the UMCU were interviewed independently regarding their perspectives on AR for surgical navigation. The interview was conducted by two researchers: the interviewer (NN) and the note-taker (JK or MJK). A PowerPoint presentation, including visuals and videos, was used to facilitate discussion and gather feedback from the surgeons. The PowerPoint can be found in the Supplementary Material 1. Additionally, a structured questionnaire, filled in by the note-taker to systematically collect responses during the interviews, can be found in the Supplementary Material 2.

The total duration of each independent interview was one and a half hour and existed of two parts with different topics: AR viewer app development (further explained in Chapter 7) and AR for surgical navigation. In the first part the surgeons were able to use the Microsoft HoloLens, which gave them an idea of the technology's capabilities.

The second half of the interview was build-up of the following aspects:

1. **Demonstration**: A demonstration of systems found through market surveillance and literature research (*Section 4.1* and *Section 4.2*). This will give the surgeons an idea of what is possible.
2. **Application**: Questions aimed at clarifying the surgical tasks or procedures for which the surgeon sees the potential of AR surgical navigation systems.
3. **Virtual visualization**: Questions aimed at clarifying the type of virtual content that surgeons find valuable to project in AR.
4. **Surgical task guidance**: Questions aimed at clarifying how surgeons prefer to be guided.
5. **System options/functions**: Questions aimed at clarifying which at clarifying which options and functions surgeons find important to be included in the navigation system.

6.1.3. Results

Seven out of the eight surgeons of the maxillofacial department of the UMC Utrecht participated in the interview.

The following sections will summarise the results based on the aspects described in the method (with the exception of the '*Demonstration'*).

Application

The surgeons believe that AR has potential for guiding the following surgical procedures:

- Tumour resections
    - Bony tumours, malignant and benign
- Fibula reconstruction

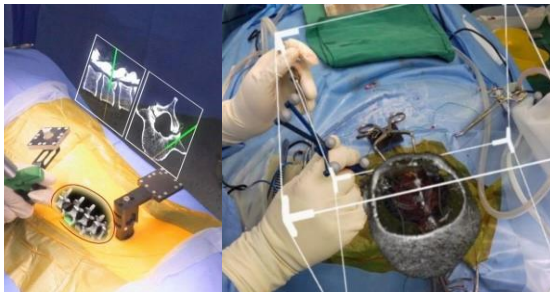


Figure 6.1: Methods to visualise the medical images. Left image presents the slices on a separate window (image from the XVision Spine System (Augmedics, United States) [72]). Right image the slice is overlayed on top of the patient (image from Jain et al. [73]).

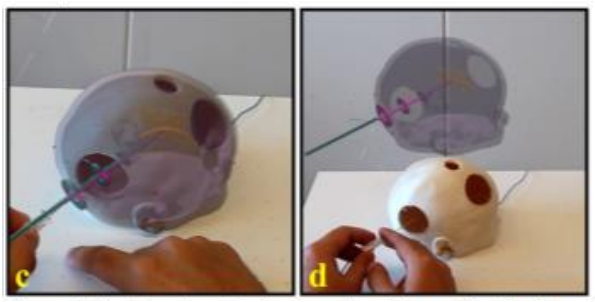


Figure 6.2: Visual content aligned on the patient in the correct real position (left) or above the patient but in the field of view of the surgeon and virtually and directionally aligned (right). Image from Benmahdjoub et al. [74]

- Zygomatic implant placement
- Orthognathic procedures (Sarme, BSSO, Le Fort 1)
- Zygoma osteotomy
- Cyst removal

To summarize, surgery in these categories: oncology, implantology, reconstruction, trauma, malformations, congenital abnormalities.

Furthermore, the following was mentioned by surgeons:

- *"AR can be helpful in all situations where the surgeon's visual access is limited during the surgical procedure*."
- *"AR can facilitate a more minimally invasive approach, as AR has the potential to make surgeries more minimally invasive*."

AR could be useful for performing the following surgical tasks:

- Checking for symmetry
- Navigated implant / screw placement
- Navigated drilling (indicating location, direction, and depth)
- Visualization of critical structures
- Tumour visualisation
- Soft tissue reconstruction
- Bone position verification
- Osteotomy at difficult locations.
- Biopsy

Furthermore, the following specific tasks were mentioned:

- Sawing between radix
- Extracting wisdom teeth (for surgeon in training)

Virtual visualization

The following was mentioned to be valuable to project during the surgery in the field of view of the surgeon:

- Tumour visualisation + margins (n=4)
- Tumour surroundings (n=3)
- Critical structures (n=4)
    - Blood vessels
    - Nerves
    - Dental roots
- Trajectories (n=3)
- Bone segments in the current and new position (n=2)
- Cutting planes

- STL objects aligned in the target position
    - Implants
    - Mesh
- Drill angle
- Mirroring contralateral side

Medical image visualization

Preoperative medical images can be projected onto the surgeon's FoV during the surgery to provide information about the spatial orientation of the instrument and its surroundings. When the instrument is tracked, the displayed image slice can dynamically correspond to the position of the instrument's tip. The two-dimensional image slices can be displayed on a separate window in the FoV of the surgeon showing the axial, sagittal, and/or coronal planes (anatomical planes). Another way is to overlay the dynamic slice on top of the patient and integrated in the real environment. Both options are visualized in Figure 6.1 (images from [72] and [73]). Figure 6.3. (Chart 1) shows the preferred way to visualize medical images.

Five surgeons preferred a separate window which is projected in the FoV of the surgeon, but not blocking the vision of the patient. Two surgeons explained that this preference was due to the opinion that transitioning to working with 3D visualizations requires a learning curve. Therefore, in the beginning, DICOMs should be displayed in the way surgeons were traditionally taught. The other surgeons indicated that they want the ability to choose from both options. The reason they gave for this was that the preferred display mode depends on the situation and preference of the surgeon, both have their advantages and disadvantages.

All surgeons indicated that they should have the ability to connect the slice visualisation to the tip of the surgical instrument.

Furthermore, there were differences of opinion on where the virtual content should be place: aligned on the patient aligned in the correct real position or above the patient but in the field of view of the surgeon (Figure 6.2, from Benmahdjoub et al. [74]). The second bar chart of Figure 6.3 (chart 2) visualises these results. A reason why above the patient is preferred is to not block the surgical field: "*The patient needs to stay clearly visible*".

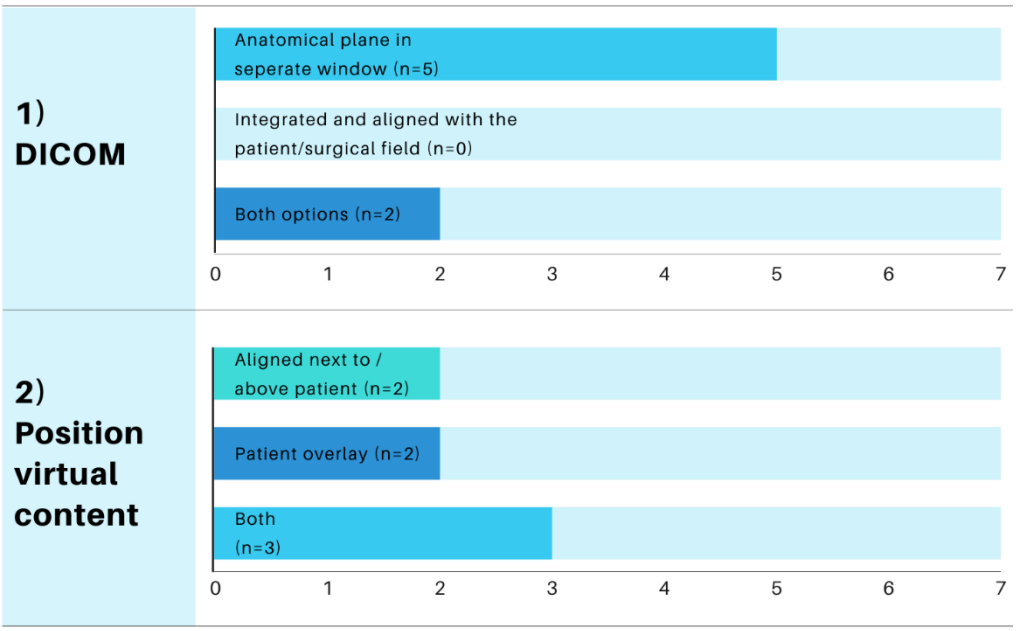


Figure 6.3.: Bar charts to visualise the preferences of the surgeons regarding DICOM visualisation and the position of the virtual content.

Others indicate that registered on the patient is the power of AR.

Surgical tasks

The surgeons indicated they would like the following navigation tools for surgical tasks guidance:

- Colour indicators
  - Change colour when surgical instrument / bone segment is in the correct position and direction.
  - Colour indicators based on a traffic light principle: warning colour when nearing the target.
  - *Important note*: colours should be chosen with care. It should be clear what is meant with the colours and should not lead to confusion (e.g., red for stop).
- Distance to target display in real-time (in millimetres)
- A surface model of the surgical instrument
- Saw/cutting route displayed as overlay
- Tracking of surgical instruments.

One important thing to take into account is that it should not block the view of the patient too much or distract the surgeon.

Figure 6.4. (chart 3) shows which surgical instruments were mentioned more than once when asked which surgical instruments the surgeons want to track. Furthermore, the following surgical instruments were mentioned by only one of the surgeons: piezotome, monopolar, needle, scissors, catheter, biopsy forceps, and tubes.

System options/functions

Figure 6.4, furthermore, shows the preferences to control the AR environment (chart 4). Voice commands, hand gestures and external system control were all mentioned by three surgeons as the preferred method. Furthermore, a foot pedal was mentioned by two surgeons.

All methods have their advantages and disadvantages, these are listed in Table 6.1 (based on the surgeons' opinions).

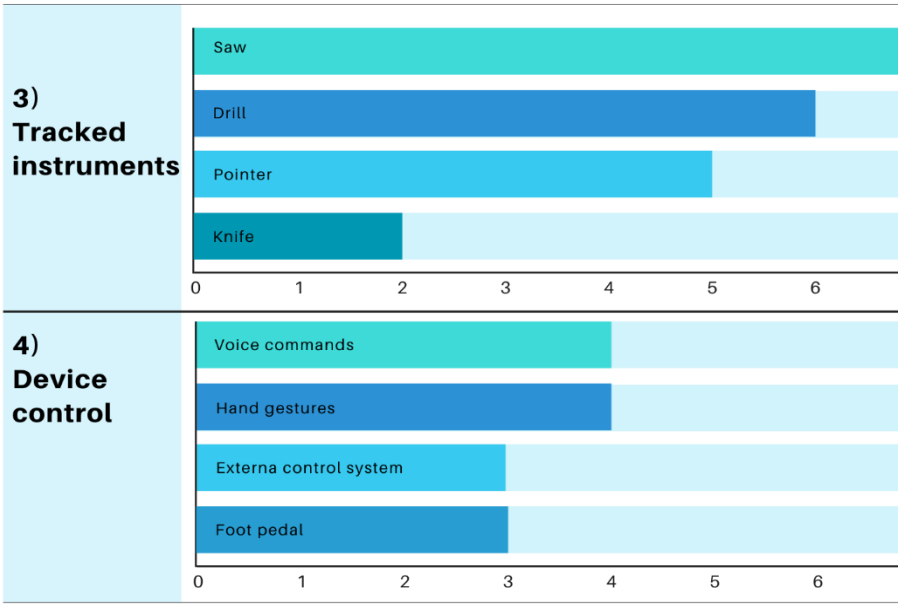


Figure 6.4.: Bar charts to visualise the preferences of the surgeons regarding control of the AR navigation system and displaying which surgical instruments they find useful to track.

Most of the surgeons indicated they want to be able to control the system using a combination of the methods (e.g., voice commands and hand gestures or hand gestures and an external control system).

Table 6.1:

Control method	Advantage	Disadvantage
Hand gestures	Sterile Surgeon has control (no in between person)	The surgeon needs to use both his hands during the surgery. Might be disrupted by using hands for the surgical procedure.
Voice commands	No need to use hands (sterile) Surgeon has control (no in between person)	Might be disturbed by the noise in the OR
External control system	The surgeon is relieved of the responsibility for adjusting settings and managing displayed information. Presence of someone knowledgeable about the system, which is increasingly essential in the increase of technology in healthcare. *Condition: Requires someone familiar with the system.*	Introduces an intermediary, potentially causing delays in the process.
Foot pedal	No need to use hands Familiar with foot pedals: many surgical devices/systems are controlled with foot pedals.	Limited amount of control buttons

Figure 6.5. shows the results regarding the importance of the inclusion of certain options and functionalities. A live stream displayed on the monitor of the OR (b) is rated the most important. This way the whole OR team can see what the surgeon sees through the HMD. Furthermore, the availability of multiple HMDs was said to be important (a). This allows multiple surgeons, the surgeon in training and the assistant be in the same environment. Also, the ability to make small changes in the preoperative plan during the surgery (f) and the option to document the surgery using video recordings (d) have an average rating higher than one on the importance scale.

Parameter monitoring is rated the least important. “Maxillofacial surgeons are not interested in these parameters, this is something that the anaesthesiologist has to keep track of.” Surgeons indicate that it would be distracting.

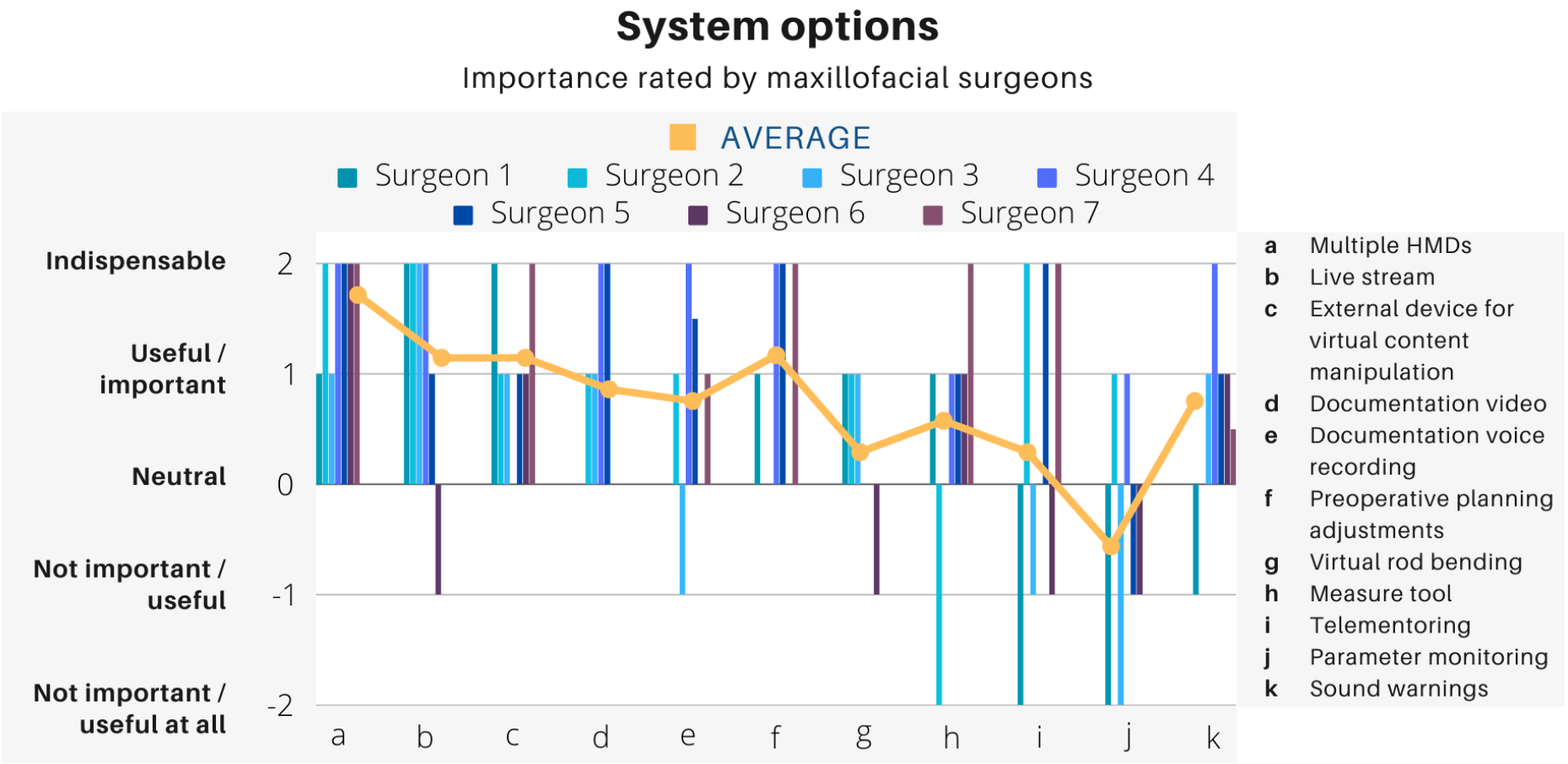


Figure 6.5.: The importance of the inclusion of certain options and functionalities. Scores are assessed using a likert-scale (not important at all to indispensable). The bars in the graph show the scores of each of the surgeons. The orange line show the average of the surgeons' score.

6.1.4. ***Discussion***

The interviews have identified the important factors from a maxillofacial surgeon's point of view which have to be taken into account when developing an AR surgical navigation system (see the next section, 6.1.5.). Furthermore, the interviews give an overview for which procedure AR can be valuable. Through these interviews the ideas and needs of surgeons are assessed.

Although the results already provide valuable information, only maxillofacial surgeons, from UMC Utrecht have been included. As identified in Section 4.4. there are many stakeholders involved. All important stakeholders within the department must be assessed. Furthermore, surgeons from other hospitals should be assessed as well and, in the future, also surgeons from other departments, to develop a system which is broadly applicable.

During the interview some example videos of developed systems were shown to give the surgeons an idea of what AR navigation systems are capable of. However, it was sometimes still challenging for the surgeons to fully envision how the AR system would function in a real surgical setting. Therefore, in the future, the surgeons' feedback should also be assessed, while they are using the AR system in a surgical environment.

6.1.5. ***Key findings / take aways***

- The surgeons of the maxillofacial department of the UMCU can imagine AR to be a valuable tool for various surgical procedures. In general, the following types of procedures: oncology, implantology, reconstruction, trauma, malformations, congenital abnormalities.
- The surgeons think AR can mainly be useful for guiding the following tasks:
    - Drilling: real-time instrument tracking and trajectory visualization
    - Cutting/sawing: real-time instrument tracking and displaying the planed route
    - Tumour resections: tumour volume visualization and critical structure visualization
    - Reconstruction: being able to control the bone placement, visualizing the 'health' contra-lateral side.
    - Implant / screw / mesh placement: model of the object on the target location, virtual tools to guide with the placement (e.g., distance to target).
- *"AR has the potential to assist in all situations where the surgeon's visual access is limited during the surgical procedure."* – Maxillofacial surgeon, UMC Utrecht
- *"AR has the potential to make surgeries more minimal invasive*." – Maxillofacial surgeon, UMC Utrecht
- Visualizing the virtual content aligned on the patient can be useful, but the surgeon should be able to easily switch to neutral view or move the content next to the patient.
- The surgeons found colour indications highly valuable.
    - Motivating colours
    - Traffic light-concept: go, warning, and stop colour.
    - However, it is important that it is clear what is meant by the colours.
- The pointer, drill, saw, and knife are the most important surgical instruments to track.
- A live stream, a connection between multiple HMDs, the ability to make small intraoperative changes in the treatment plan, and the option to document the surgery using video recordings are important to include in the system.
- The ability to control the device using multiple methods should be provided.

6.2. **Learning collaboratives: Expert workgroup session**

One key factor for innovation identified by Nolte [3] is the importance of interorganizational networks, such as learning collaboratives. The more complex innovations are, the more critical the interorganizational network becomes for the success of that implementation [6].

In alignment with this, a learning collaborative network between research groups from different UMCs of the Netherlands was established. This collaborative effort aims to create working groups that include researchers from various UMCs with a shared focus on AR for surgical navigation. The intention is to encourage collaboration among these research groups.

6.2.1. ***Purpose***

The objectives of this collaboration are as follows:

1) Sharing expertise and knowledge.
2) Clarifying the vision and objectives of each research group.
3) Encouraging researchers interested in the same field to collaborate and consider multi-centre studies. This can increase the scale of the research.
4) Identifying the different areas of expertise within each group and knowing where to find the necessary knowledge.
5) Recognizing and discussing the challenges faced.
    1. Collaboratively brainstorming and proposing solutions.
    2. Analysing how other research groups have tackled similar issues.
6) Aiming for consensus.
    1. Ensuring comparability in research approaches.
    2. Developing and implementing shared validation methods.

6.2.2. ***First workgroup session***

The first session was held online using Microsoft Teams in September 2023. This meeting involved a select group of researchers (n=10) from UMC Groningen, Erasmus MC, RadboudUMC, AMC, and UMC Utrecht. It was initiated and hosted by the UMC Utrecht (JK and NN).
The aim of the first meeting was to clarify the objectives of the workgroups and assess the commitment and determination to proceed with these sessions.
Furthermore, this session clarified some general thought about AR surgical navigation. This was done using a MentiMeter presentation, to promote the interactive nature of the meeting. The participants were able to share their ideas about AR through multiple choice, rating, and open questions. The key findings can be summarized as follows:

- None of the systems from the research groups are used in clinical practice.
- The following challenges and limitations of AR navigation systems were mentioned (open, three answer option per participant):
    - (Registration/tracking/alignment) accuracy
    - Processing power
    - (Depth) perception
    - Validation
    - Logistic and regulatory factors
    - User friendliness.
- Most of the participants voted on optical IR tracking to be the tracking technique with the most potential (multiple choice question). Three people chose “Other”, with the

explanation that it is dependent on the application and the requirements of the procedure (e.g., required accuracy, invasiveness, room available, size of incision).

- The following subjects were mentioned as key factors when implementing AR in the OR (open question, no answer limit):
    - Regulatory requirements (MDR) 4x
    - Simplicity 3x / user-friendly 3x
        - Simple user interface
        - Simple feedback
        - Simple to set-up + use
        - User-friendly 3x
    - Accuracy 2x
    - Added value/necessity 2x
    - Ethical approval 2x
    - Take into account the surgical workflow
    - Availability of surgeons
    - Prototype validation
    - Robustness of the system

See Supplementary Material 3 for a detailed overview of the results of the workgroup.

6.2.3. ***Discussion***

Different researchers with an interest on AR surgical navigation from UMCs in the Netherlands have been connected with each other to share knowledge and encourage collaboration. During the first workgroup session it was decided that these workgroups will be continued every two to three months. Every time it will be hosted in a different UMC and with the focus on a different topic within the field. Furthermore, it was decided to invite more research groups to join the sessions. The second workgroup will take place in January at the Erasmus MC.

During these sessions, researcher can demonstrate their AR systems and guest speakers (with different backgrounds, e.g., regulatory, management, medical background) can be invited to present new insights / perspectives / ideas. This could help to reach the shared goal more efficiently.

6.2.4. Key findings / take aways

- Learning collaboratives are important when introducing new complex technologies in clinical context.
- It was useful to connect and introduce research groups focusing on AR surgical navigation from various UMCs to share experiences.
- None of the current systems from the research groups are used in clinical practice.
- Similar challenges were identified, e.g., obtaining the required accuracy, depth perception limitations, challenges in validating the system, and processing power.
- Key factor to take into account when implementing AR in the OR from a research perspective have been identified.
- The continuation of these workgroup sessions is important for reaching the shared end goal, determining a widely accepted validation method, and ensuring comparability in research approaches.

7

Development in-house AR viewer app

This chapter is a follow-up to the study performed in Chapter 5 (the Narrate study). In line with the approach utilized in this thesis, feedback from the clinical environment (patients and medical specialists) will be used to improve the innovation. During the study, multiple times feedback was given that the use of AR for informing patients could become more effective if the medical specialist also has control over the virtual content seen by the patient. Therefore, it would be of much value to have an app available which is capable of this. This chapter contains the documentation of the process which was used to develop a conceptual design of an AR viewer application for medical use (AR viewer app). The AR viewer app will initially be designed to inform and educate patients on their diagnosis and/or treatment plan using 3D, interactive visualisations. The application of the app can be expanded in the future.

7.1. Introduction

One of the conclusions of the Narrate study is that, in the AR group, it would be highly desirable for the medical specialist to be able to control the AR environment shown to the patient. This makes it easier for medical specialist to explain the visualised environment and show the right visualisation with the desired settings. Moreover, the patient will not have to control the virtual environment on his/her (of patients) own, which could be a challenge for patients who are unfamiliar with AR technology. However, an AR viewer app with such functionality is not yet available at the UMC Utrecht. The in-house development of a collaborative AR app would therefore be of much value.

The main reasons for developing an AR viewer app are to:

1. Take command of the application's operations and maintain autonomy from external parties. This allows the department to have the ability and flexibility to add functionalities and features as desired. The app can be customised to the wishes of the end-users.
2. Gain knowledge about the development process of an AR app. When introducing a new technology for medical use it is important to know how the technology works. By going through the development process, the ins and outs of the system are known. The obtained knowledge can be used for further research in this field. Moreover, in the future the app might be expanded to other applications. Therefore, knowledge of the app is extremely useful.

7.1.1. Aim

The aim of this chapter is to create a conceptual software design for a collaborative AR viewer app. This app aims to enhance patient information by facilitating a better understanding of their diagnosis and treatment options through interactive visualizations. The app will initially be developed for the maxillofacial department of the UMCU and the initial focus is on patient education/information. Future development could expand the use of the app for other departments and/or other clinical applications (medical education, treatment plan discussion, surgical preparation, etc.).

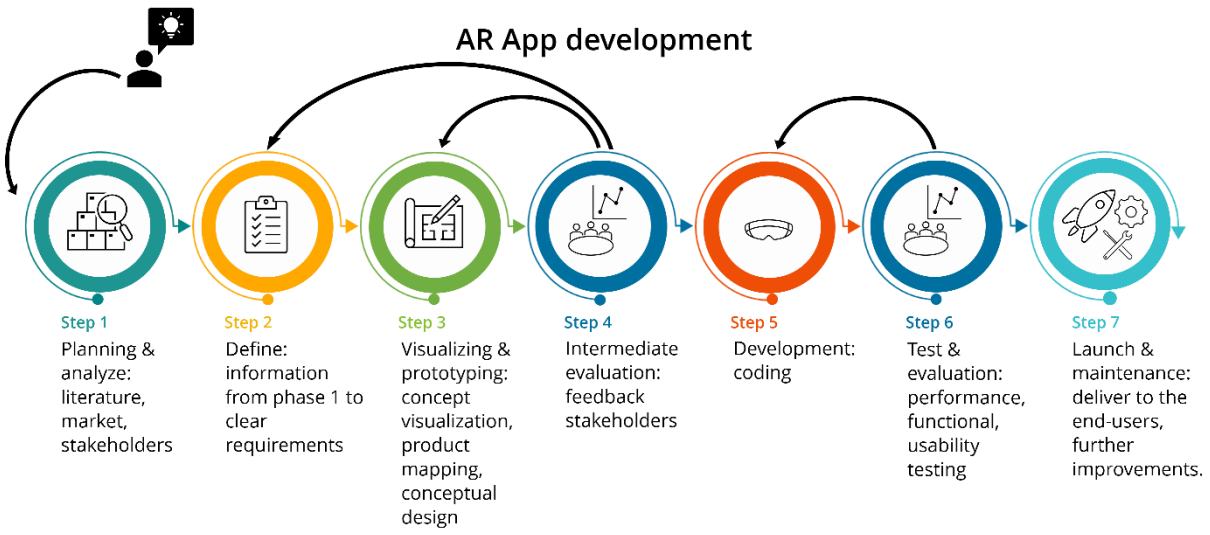


Figure 7.1: The AR app development workflow

7.2. Design workflow

The development process of the AR viewer app will follow the steps as shown in Figure 7.1. In this chapter, the first four steps of the development process of the app are conducted:

1. Planning & analysis step,
2. Define step,
3. Visualising & prototyping step,
4. Intermediate evaluation step.

Step 5 will be continued by someone with a background in software engineering / game development.

7.3. Step I: Planning & Analyse

7.3.1. Literature search & Market Research

A systematic review from Urlings et al. [75] gives an overview of the currently available AR applications for patient education. Three out of ten applications found in this study were used to show 3D models to explain the diagnosis / health status of the patient or the treatment plan: (1) an app developed by wake et al [76] to visualise AR models based on MRI or CT images; (2) the app Greymapp, developed by Sezer et al. [77] to visualise AR models based on MRI images; and (3) the app VSI PE, developed by House et al. [78] to visualise AR models based on MRI or CT images and the planned treatment plan. The app from Wake et al. and Greymapp are developed for the Microsoft HoloLens. VSI PE is developed for tablets. All these apps are commercially available.

A review from Helou et al. [79] gives an overview of the commercially available medical VR applications. This review found four AR viewer apps. Three of these apps (MEDICALHOLODECK, Medical-ImagingVR, and BrainVis) allow the user to import and view models based on MRI and CT imaging. The fourth app (syGlass View) is not specifically targeted at visualizing DICOM images, but also allows other large 3D data sets to be visualised.

In Table 7.1 a list of AR viewer apps is provided.

Table 7.1: AR viewer apps for patient education found through literature research and market surveillance.

App name & hyperlink	Description	Hardware device	Available on the market?	Collaborative app?
App Wake et al.	Viewer to provide patients with preoperative information using patient-specific 3D models. In this research patients treated for prostate cancer or renal masses were included.	Microsoft Hololens (© Microsoft, Redmond, U.S.A.)	Unclear	Not reported
Greymapp	Viewer mainly for teaching and studying neuroanatomy. Was used in the study of Sezer et al. [3] to inform patients about their brain tumor location and its relation to surrounding structures.	Tablet / Smartphone	Yes	No*
Apoqlar VSI PE	A multipurpose AR app for both clinical care (e.g. patient education, (multidisciplinary) discussion and collaboration, surgical training) and medical education	Microsoft Hololens (© Microsoft, Redmond, U.S.A.)	Yes (paid)	Yes
Medical HOLODECK	DICOM viewer used for case discussion, surgical training and medical education	Varius HMDs	Yes (paid)	Yes
Medical ImagingVR	A VR windows DICOM viewer app for medical teaching.	PC	Yes (free)	No
BrainVis	An educational viewer app for visualising and interacting with neuroimages. The app is a demo version / proof-of-concept and meant for medical education.	Meta Quest	Yes (free)	No
Syglass	A VR app for viewing and analysing medical data in 3D or 4D. Designed for (neuroscience) researchers.	Any VR headset that connects to the PC	Yes (free as well as paid licences)	Yes
Mimics Viewer	An AR view app for medical images. Mainly meant for (multidisciplinary) case discussion	Microsoft Hololens (© Microsoft, Redmond, U.S.A.) & PC	Yes (paid)	No

Feedback/input patients The feedback from patients who were assigned to the AR group in the Narrate study (Chapter 5) is used to assess their needs/wishes. The feedback and observations that are important for the define step and can be summarized as follows:

1. The medical specialist should be able to point out things in the AR environment to support the explanation.
2. The app should also display non-static images (animation of what happens with the jaw).
3. The surgeon should be able to control the AR environment to ensure continuity of the consultation.

Medical specialist The medical specialist will use the viewer app to inform patients about their diagnosis and/or treatment.

Feedback/input medical specialists During the Narrate study the medical specialists also gave the feedback that they wish to be able to control the AR environment well informing the patients. This would result in a better continuation of the workflow. Their needs are further assessed in 7.6.

7.4. Step II – Define

Important goal is to establish a connection between multiple devices (e.g., a HoloLens and a tablet). This will allow multiple users to view the same augmented environment and to manipulate and interact with the displayed content using both devices.

7.4.1. Design requirements and specifications

Non-functional requirements (these have to be extended and specified by someone with the right expertise):

1. Cross-device compatibility: it the app should at least be compatible with the Microsoft HoloLens 2 and a tablet.
2. Multi-user interaction: the app should allow multiple users to interact within the same AR environment, enabling them to manipulate the content collectively.
3. Secure data handling: security measures are required to be able to safely transfer and store patient information.
4. Network Stability: The application's connectivity should be robust and resilient to network fluctuations, ensuring uninterrupted collaboration and synchronization.

Functional requirements:

1. File support:
   i) Upload Compatibility: The software must support the upload of .stl or .obj files for conversion into AR models.
   ii) Organized Folders: Users should be able to create separate folders for each case, allowing multiple 3D objects to be grouped within these folders.
   iii) Presets: Presettings, including colour and size, should be configurable for each 3D object.
2. 3D model interaction:
   i) Manipulation: Users must be able to interact with 3D models by moving, rotating, and zooming them.
   ii) Object Control: The application should enable the toggling of individual objects, providing an option to turn them on or off.
   iii) Transparency Adjustments: Users should be able to change the transparency of objects, with a level adjustable to a fixed value (needs to be determined in practice through trial and error).
3. Content annotation and markup: Users should be able to annotate, mark up, and highlight specific areas of the visualized medical data.
4. Multi-Modal Interaction: Support for different interaction modes, such as voice commands and hand gestures.
5. Real-time synchronization: ensure that the users see the same information simultaneously.
6. Secure data handling: The patient specific cases should be protected with a password.

7.5. Step III – Visualizing

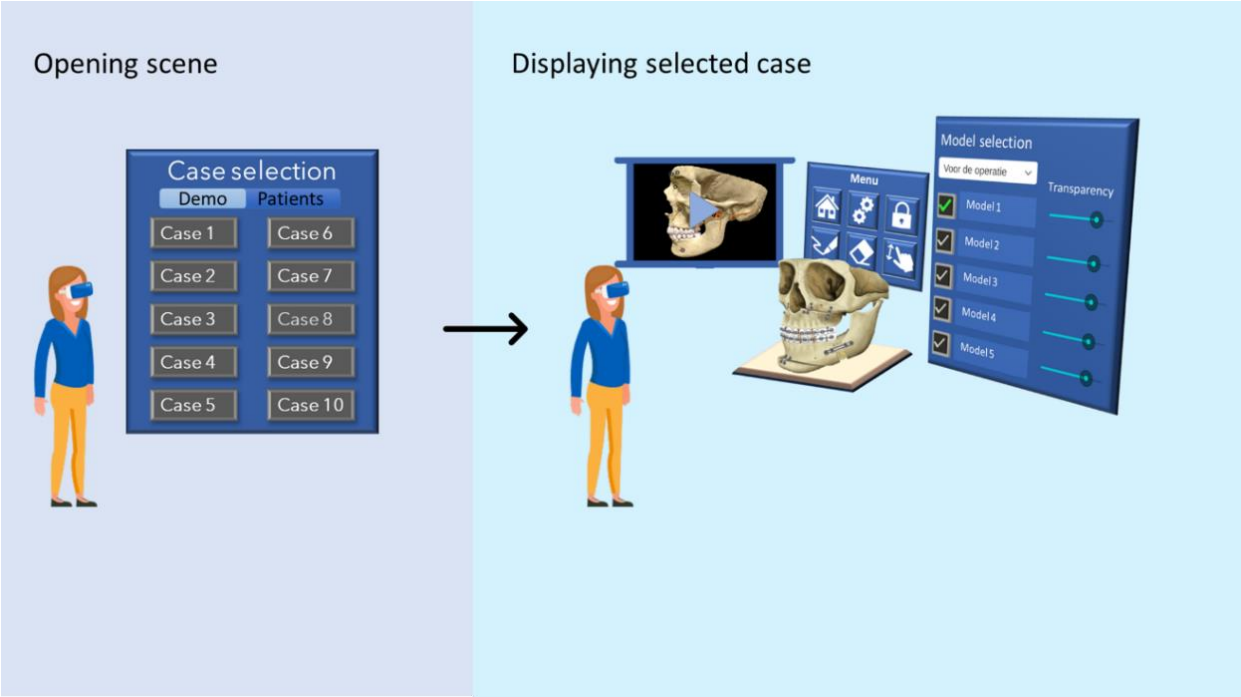


Figure 7.2: Concept visualization of the user-interface of the application on an HMD

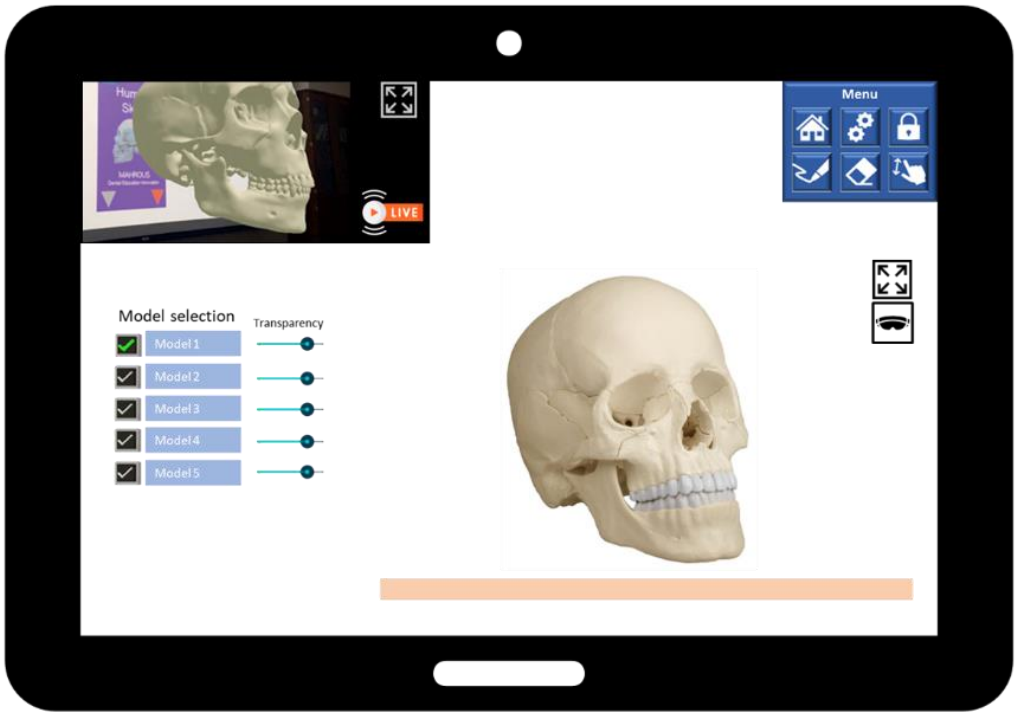


Figure 7.3: Concept visualization of the user-interface of the application on a tablet

7.5.1. Concept visualisation

A first visualization of the app user-interface has been made. Figure 7.2 shows the user interface of the client app using an HMD device (e.g. the HoloLens II). Figure 7.3 shows the user interface of the server app using a tablet.

7.6. Step IV - Intermediate evaluation

7.6.1. User feedback

Interviews with specialists

Medical specialists of maxillofacial department of the UMC Utrecht and of the UMC Groningen were interviewed with a depth interview between 45 and 75 minutes to obtain information on their needs and wishes and to assess their thoughts about the concept visualization. The interview was build-up of the following aspects:

1. Demo of the app which is currently used (Mimics viewer): the participants could experience the use of an AR viewer app, and questions were asked about their thoughts of the app (e.g., What are the important functionalities of the app? What is missing?).
2. Questions to assess the importance of functions that can be included in the app.
3. Questions to clarify practical factors: make sure it fits in the workflow of the patient consultation.
4. Demonstration of a conceptual design of the app (see Figure 7.2 and Figure 7.3). The feedback on the first conceptual design was discussed.

The full interview and the fill-in form for the asked questions can be found in the Supplementary Materials 4 & 5.

7.6.2. Results

Ten medical specialists participated in the interview (seven from the UMC Utrecht and three from the UMC Groningen). Eight of the specialists are maxillofacial surgeons, one a maxillofacial surgery resident and one a Technical Physician.

Demo

The main findings from the demo of the current viewer app are summarized as follows:

- Important factors for an AR viewer app:
  - The medical specialist should have control over the virtual content that the patient views.
  - The content displayed should be designed from a patient-centred perspective.
  - The workflow and user interface of the app should be intuitive.
- Strengths of the app:
  - Ability to toggle on/off separate objects.
  - Ability to change the transparency of objects.
  - Ability to view the objects from all sides.
- Limitations of the app:
  - The app requires a learning curve to smoothly move/manipulate the virtual objects.
  - Only static models.

Importance of functions

Figure 7.4 shows a visualization of how the importance of app functionalities are scored by the medical specialists. The scoring is based on a 5-likert scale as follows: -2 = not important / useful at all; -1 = not important / useful; 0 = neutral; 1 = important / useful; 2 = indispensable. Assessment was done for two applications separately: 1) informing patients and 2) (multi)disciplinary consultation.

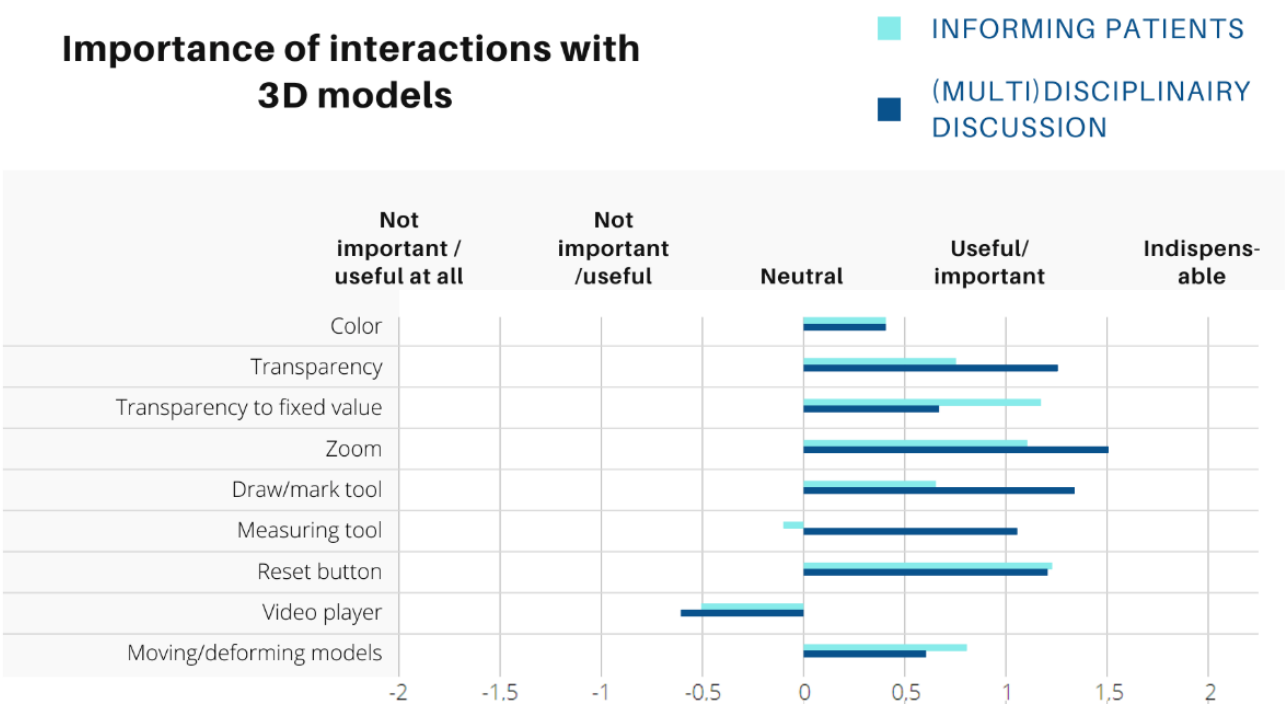


Figure 7.4: The importance of different interactions with the 3D models scored by the surgeons for -2 (not important/useful at all) to 2 (indispensable)

Furthermore, it was asked which functions are missing from this list. The following was answered:

- Export function:
  - To be able to share the information that is provided during the consultation.
  - To be able to export what has been discussed with colleagues in the viewer app.
- Ability to see a before and after visualization of the treatment plan in the same environment.
- Window level: ability to adjust the modelling threshold in the app.
- Cut planes: to be able to view what is in the inside of the models.
- For treatment planning and discussion: have the ability to make small adjustments of the preoperative planning (e.g., repositioning of the objects).

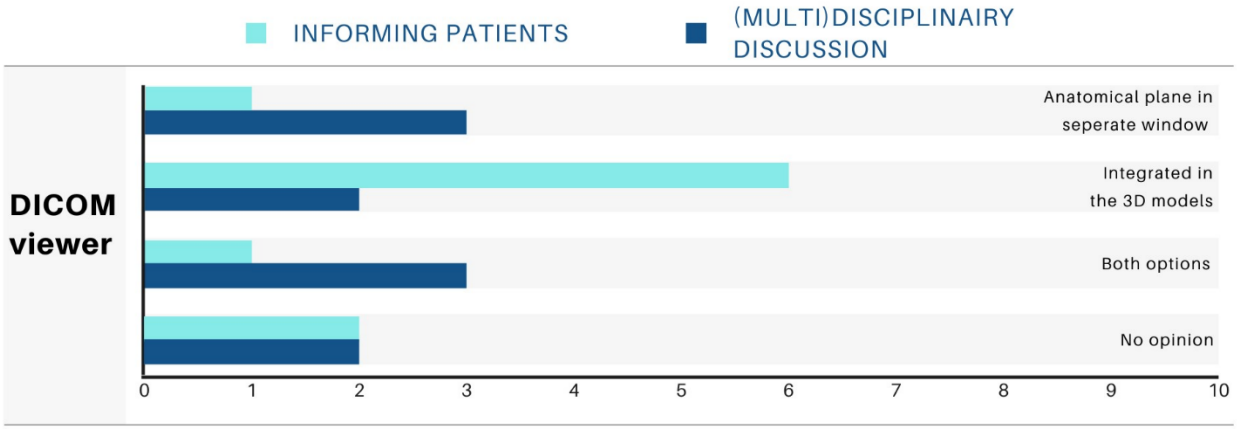


Figure 7.5: Preference for display technique of the DICOM images. '*Integrated in 3D model*' refers to being able to view the DICOM slices integrated in the 3D models in the real environment. '*Anatomical planes in separate window'* refers to showing the DICOM slices in anatomical planes (axial, coronal, and sagittal) in a floating window.

DICOM viewer

Questions were asked to evaluate if it is necessary to display DICOM images in the app and if so, how they should be displayed. For informing patients, the options differed: some thought it would be useful to have a DICOM viewer integrated in the AR viewer app, others had the opinion that 3D models are sufficient and if necessary, the medical images can be shown on a 2D screen. On average they scored the importance 0.375, using the same scale as in *Figure 7.4*. When the AR viewer app is used to discuss with colleagues, the medical specialist found the inclusion of DICOMs in the app more important (average importance score = 1.11).

The preferred techniques to show the medical images is shown in *Figure 7.5*. For informing patients, the most preferred method was to show medical images integrated in the 3D models. "*Patients are not used to the anatomical planes, therefore showing it in a 3D context can provide a better understanding to the patients*". When the app is used only between colleagues there was no technique that stood out to be the most preferred.

Display devices

The preferred display devices were the HMD for the patient and a tablet or the PC in the consultation room for the medical specialist.

Applicability

Surgeons expressed a desire to use AR for informing patients in various cases, including orthognathic surgery, oncology (to visualize reconstructive possibilities), paediatric oncology (to inform parents), implantology, and high-risk surgeries (to visualize the location of critical structures). One surgeon expressed that AR is applicable in all consultation where the VSP is discussed.

Furthermore, surgeons mentioned that the app could be used to prepare for complex surgeries, multi-disciplinary discussions, and (anatomy) education.

Conceptual visualization

Most medical specialists reacted positively to the conceptual visualization. They found the layout clear and the menu's practical. They furthermore found it useful that the demo cases and patient specific cases are separated.

Suggestions for improvement are summarized as follows:

- The patient environment needs to be simplified: less options and buttons.
- Include a wizard to simply walk through the steps.
- Include a cursor in the tablet version in order to point out things.
- Include non-static models.

7.7. New conceptual visualization based on the user feedback

The updated version of the conceptual visualization is shown in Figure 7.6 and Figure 7.7.

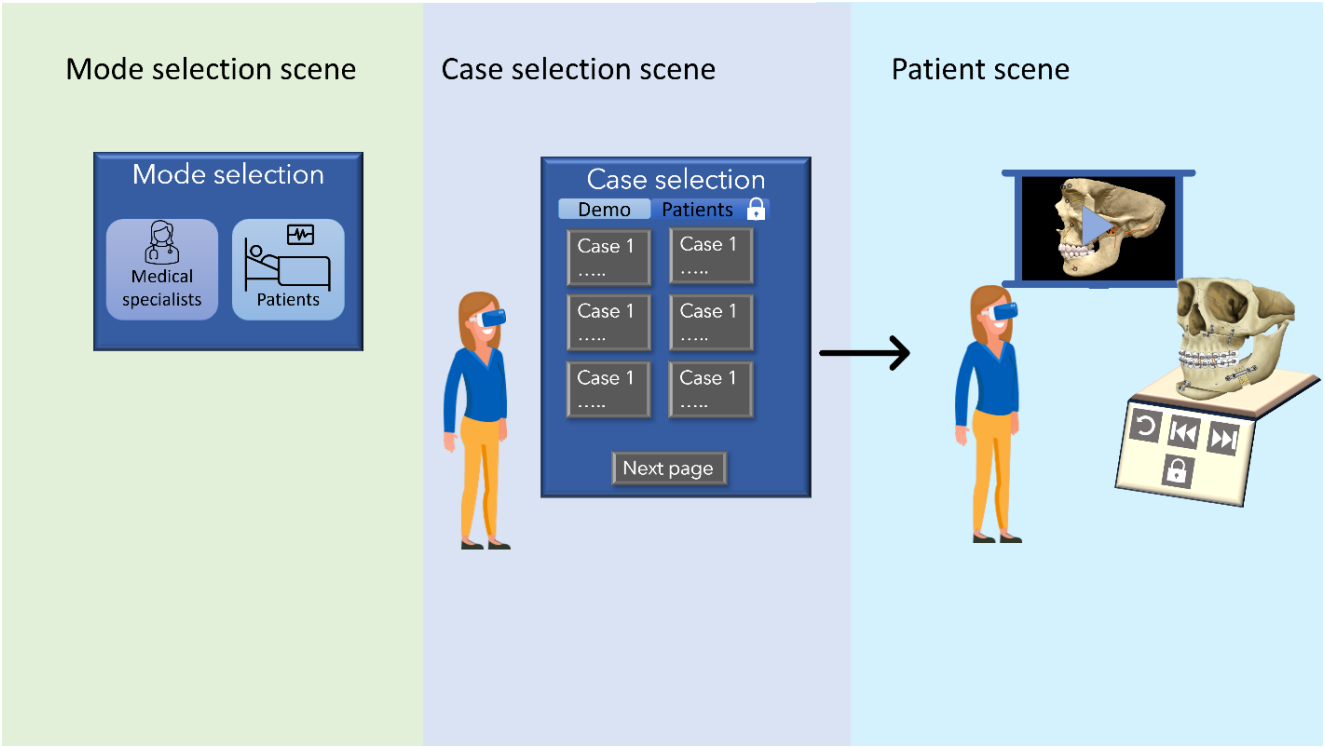


Figure 7.6: Version 2 concept visualization of the user-interface of the application visualised through an HMD. Changes based on feedback from medical specialists.

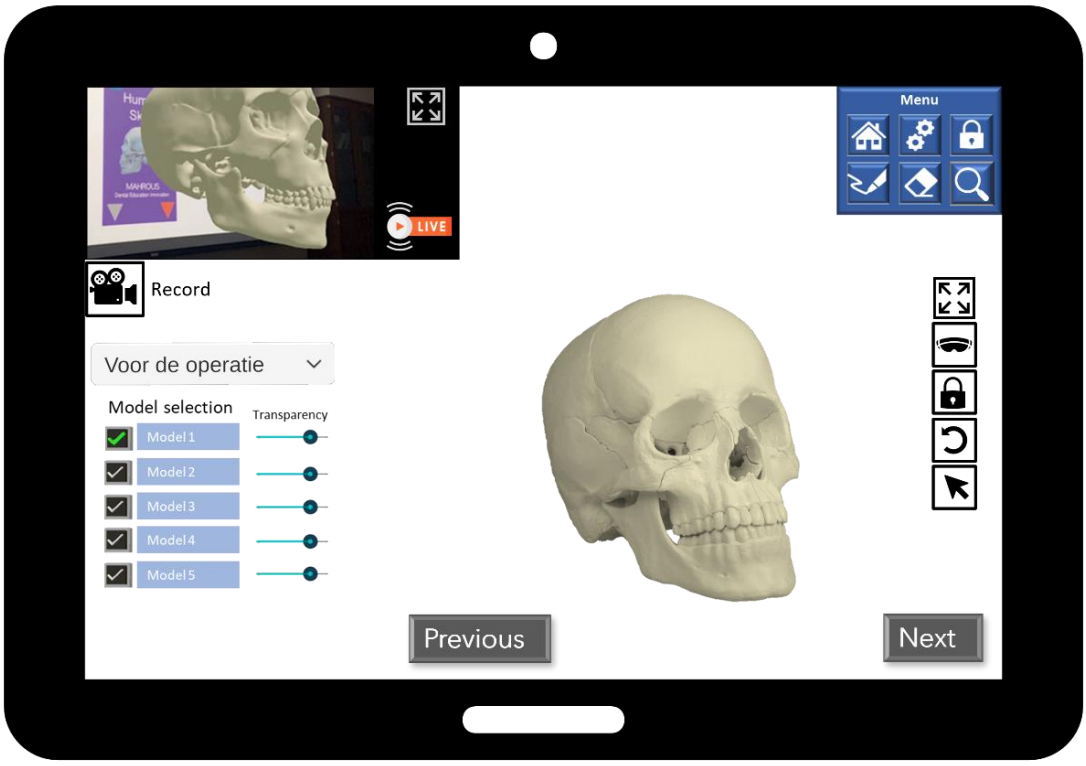


Figure 7.7: Version 2 concept visualization of the user-interface of the application on a tablet. Changes based on feedback from medical specialists.

7.7. Recommendations & Future

In this research step 1 to step 4 have been performed. A conceptual visualization of the app has been provided. The development workflow is an iterative process, therefore step 2 to step 4 can be repeated. The next step in the workflow is the development step. This should be done by someone with the right expertise (e.g., software engineering background, skills in Unity/C#). First the non-functional should be further extended and specified (e.g., requirements regarding performance, capacity, reliability, maintenance, security). Important factors to consider when the app is developed:

- Simplicity: The application should maintain a user-friendly and uncomplicated interface, particularly in the patient environment. For efficient patient consultations, medical specialists must have the capability to swiftly and effectively deliver information. To achieve this, the app should feature preset configurations that guide specialists through a structured presentation process during consultations, minimizing the need for extensive customization.
- Control: The medical specialist should be able to control the environment to keep the continuity in the consultation.
- Patient-centred: The focus of the app is to inform patients. Therefore, it is extremely important to take into account the patients perspective for the design of the visualizations. An example is to include non-static models to clarify the surgical process.
- Patient safety: Due to the sensitive nature of patient data, robust security measures should be implemented in the data workflow. Ensure that patient-specific cases are securely stored and accessible only with authorized permissions.

The initial release of the AR viewer app will be tailored to the maxillofacial departments of the UMCG and the UMCU. After the launch, an assessment of its performance and usability will be undertaken. Upon successful evaluation, the potential for expanding the application to other departments on medical centres will be explored.

8

Discussion

The primary aim of this thesis is to provide insight on how to effectively introduce a new technology in a clinical setting by early involvement of the clinical context in the development of a new technology. An approach to introduce technology in clinical setting has been tested during this thesis project by introducing AR in the clinic. The core principles from design-thinking and human-centered design and key factors which have been identified in previous studies were used. An important aspect is to assign a tech-med innovation coordinator; someone with both a medical and technical background who will be responsible for driving successful adoption. Furthermore, it is an iterative process, containing three steps per cycle: 1) Gain understanding; 2) Share understanding; 3) Actively engage stakeholders. Every cycle will lead to new inputs for the development of the technology to make it better aligned with the clinical context. Additionally, it leads to an increase in understanding, adoption, and motivation of the ones involved.

8.1. Main findings

8.1.1. Introduction of AR surgical navigation at the UMC Utrecht

During this research, AR has been introduced at the OMF department of the UMC Utrecht using the iterative approach as described above. This resulted in several positives effects which can be summarised as follows:

Understanding and value perspective: The approach provided an understanding of AR among surgeons and perspective on how it can be used as a tool in performing complex surgeries. The potential added value has been communicated to the surgeons.

Surgeon's motivation: Surgeons showed a willingness to invest time in the AR implementation. For instance, seven out of eight, made time to take part in the interview of at least one and a half hour. This can be challenging for surgeons with a full schedule, but they were all enthusiastic to share their perspectives and ideas. Furthermore, the surgeons indicated that they see the potential value of the technology and the potential of it to improve their work. This is very important for the continuation of the development.

- ***Confirmation of system elements***: The importance of elements which exist in the current prototype have been confirmed by the surgeons. The following highlights the key elements that surgeons find valuable: Real-time feedback for guiding surgical tasks in situations with limited vision;
- Guidance during drilling tasks;
- Visualisation of 3D models (e.g. critical structures, tumour margins, implants, and bones) aligned on the patient;
- The option to switch between a view where the virtual content is registered on top of the patient and a view where the virtual content is moved slightly above the patient;
- The ability to record the surgery (especially useful for educational and training purposes).

Insights for further system development: The study generated new insights and ideas for improving the AR system to better align with clinical usage. It can be concluded that simplicity and minimal distraction are key factors. Furthermore, the following elements could improve the current system:

- The inclusion of real-time guidance of cutting and sawing tasks;
- Colour indications using a traffic-light concept: go, warning and stop colours (green, orange, and red).
- The use of sound to warn the surgeon (e.g. when approaching a critical structure);
- The incorporation of a separate window for viewing 2D slices of the (preoperative) medical images, displaying multiple planes (axial, sagittal, and/or coronal views);
- A foot pedal in addition to the current control mechanisms to control the AR environment during the surgery.
- A connection between multiple HMD to allow multiple people from the surgical team to be in the same environment(rated indispensable by most surgeons);
- The capability to make small intraoperative changes of the preoperative plan.

Vision and future plan: A future plan and vision has been developed collaboratively. Surgical navigation has become a central developmental objective for the upcoming year. This plan will further be described in section *8.4. Future perspective*,

8.1.2. *Med-tech innovation coordinator*

The importance of having a med-tech innovation coordinator within the hospital to guide such innovations has been demonstrated. Consequently, the department has decided to expand the 3D Facelab with a med-tech innovation coordinator, providing more dedicated time for the implementation and evaluation of new technologies. The med-tech innovation coordinator assesses whether the technology adds value and effectively solves the real clinical problem. Following the demonstration of its relevance, the aim is to ensure the development aligns with clinical needs and that the introduction motivates clinicians to invest time in its proper utilization.

8.1.3. Augmented reality to inform patients

Additionally, the Narrate study (prospective clinical study where patients were informed with AR) has led to other useful outcomes, apart from familiarising the clinical context with AR. Surgeons have expressed interest in informing patients using AR. Surgeons expressed a desire to use AR for patient information in various cases, including orthognathic surgery, oncology (to visualize reconstructive possibilities), paediatric oncology (to inform parents), implantology, and high-risk surgeries (to visualize the location of critical structures).

The intermediate results reveal no significant differences between the AR group and the 2D group. The study will be extended to include more patients, possibly on an international scale.

Some limitations of the currently used AR viewer app are identified. This led to the design of a new app. Functional requirements for an AR patient education app have been identified and a conceptual visualisation of the design is provided. The final conceptual considers feedback from the end-users. These results will be used to guide the development of the app by a technician with a background in (AR) app development. The idea is to share the app with other departments and hospitals. If these other departments want to introduce AR following the steps provided in this thesis, they can use the app that aligns with the clinical needs.

8.1.4. Applicability to other situations

Throughout this thesis the focus was on the introduction of AR for surgical navigation. Nevertheless, a similar strategy can be applied to introduce other technologies in hospital settings. The main aim of this approach is to involve the clinical context early in the development process of new technologies. This enables the identification of misalignments with clinical needs in an early stage. Moreover, the clinical team can gain direct experience with the capabilities of the technology. Demonstrating the added value of the technology can motivate the team to put effort in its introduction. Additionally, this approach allows for early identification of technologies that may not add significant value or that may not be suitable in the clinical environment.

8.2. Similar approaches

The doctoral thesis of Sewberath Misser [11] focuses on the implementation of technological innovations within operating rooms. In this work an implementation framework is presented which consists of four categories: set up a project, organizational preparation, technological preparation, and training and evaluation. The framework includes similar steps as presented

in this thesis, e.g. ‘stakeholder identification’, ‘foster team familiarity’, ‘deploy activities to increase adoption with stakeholder’. Furthermore, the work emphasizes involving stakeholders, considering the clinical environment, and early-stage implementation. The focus of Sewberath Misser’s framework is focused on the implementation and provides an extensive guide for this. In this thesis, the focus is on including the clinical context in the development process.

Seyed Esfahani et al. [80] introduces a framework for successful adoption of surgical navigation, highlighting five key aspects. It draws attention to the role of an Innovation Facilitator, responsible for identifying needs, assigning clinician’s opinions, and introducing suitable innovations. This is comparable to the med-tech innovation coordinator described in this thesis. The framework also underscores the importance of explaining innovation relevance and early-stage knowledge acquisition. This is in line with the “*2) Sharing understanding*” step. A note-worthy concept described in Seyed Esfahani’s framework is ‘*ex-novating’*. This concept emphasizes the importance of not only innovating by introducing new technologies or practices, but also actively eliminating or replacing obsolete and unnecessary elements. This is important to prevent over-complexity.

The Royal College of Surgeons (RCS) [81] developed a six-step pathway to promote the adoption of new surgical innovations. This pathway also highlights the importance of early identification of the innovation’s value and the crucial role of leadership. Furthermore, it elaborates on defining what should be implemented and establishing a method to measure its impact. The expert workgroup session (*section 6.2*) aims to contributes to this.

8.3. Limitations

Although, there has been close collaboration with the UMC Groningen and Erasmus MC, the final evaluation of the approach was mainly conducted in one department in a single hospital. The idea is that this approach can be used in other departments and hospitals. The applicability in other hospitals needs to be evaluated.

During this thesis, the management of the division, the head of the department, surgeons, software engineers, and researchers have been involved in the introduction of the new technology. As has been shown in the stakeholder identification (section 4.4.), there are more stakeholders to consider. In different phases of the development and implementation process, different stakeholders are important to actively involve. As the potential and effectiveness of AR for surgical navigation is further shown the relevant stakeholders should be involved using the same approach.

The method primarily focuses on bridging the gap between technical development and clinical requirements, with acknowledgment that other crucial aspects, such as ongoing resources and infrastructure, must also be considered. Compliance with Medical Device Regulation (MDR) for effectiveness and safety is emphasized.

8.4. Future perspective

8.4.1. Development proces - AR surgical navigation system UMC Groningen & UMC Utrecht & CIT Groningen

To further guide the development of the AR navigation system the Technology Readiness Levels (TRL) can be used. This is a strategy developed by the National Aeronautics and

Space Administration (NASA) to measure the progress or maturity of a technology. The scale consists of nine levels, where TRL 1 is the lowest ("Basic principles observed and reported") and TRL 9 is the highest ("Actual system "flight proven" through successful mission operations"). Apart from being used in aerospace engineering, TRL has been used in various fields(e.g.) and is increasingly being used in the healthcare sector [82]–[85]. In 2014, it was incorporated as part of the European Union's Horizon 2020 research and innovation programme.

Based on the TRL and previous examples in the healthcare sector, the steps in *Table 8.1* can be identified and used for the remainder of the development process. Currently, the AR system is going back and forth between TRL 4 and TRL 5. Pre-clinical studies have been performed with the AR system connected to the first-generation HoloLens. However, as the desired results were not reached, continuous updates are being made and the updated system is undergoing more testing in laboratory setting.

Table 8.1: The Technology Readiness Levels (TRL) tailored to the development process of technology in medical setting.

TRL	**Short description**	**Requirements**
TRL 1	Early-stage concept	Basic principles observed: scientific and bioengineering knowledge obtained.
TRL 2	Early-stage concept	Technology concept formulated: hypothesis is generated. Research plan developed and approved.
TRL 3	Early-stage concept	Proof of concept is demonstrated in a limited number of laboratory models.
TRL 4	Design and development	Proof of concept confirmed and safety is demonstrated in laboratory setting (ex vivo / in vivo conditions). System is tested on efficiency and reliability.
TRL 5	Prototype fabrication	Pre-clinical studies: technology validated in in a simulated environment. Pre-clinical studies show the safety requirements are met. The device is compared to existing modalities and equivalency demonstrated. The device is classified by a Notified Body.
TRL 6	Pilot clinical trials	Clinical trials to demonstrate the safety in a small number of humans under carefully controlled and monitored conditions. Results support proceeding to clinical safety and effectiveness trials.
TRL 7	Demonstration system	Clinical safety and effectiveness in operational environment are demonstrated
TRL 8	System complete and qualified	Trials conducted to evaluate the overall risk-benefit. Device demonstrated in real life conditions, support structure in place for technical problems. Manufacturing process validated. Pre-market phase approved (CE certification).
TRL 9	Deployment	Medical device ready for clinical use. Post-marketing studies may be required. Surveillance should be continued.

In Q1 2024, a second cadaveric study will be conducted to evaluate the safety and effectiveness of the updated AR surgical navigation system compared to a conventional surgical navigation system. The study preparations are currently in progress.

8.4.2. Clinical involvement and introduction

The first cycle of the introduction approach has been completed in this thesis. The outcomes from this first introduction are being used to enhance the AR surgical navigation system of UMC Groningen and UMC Utrecht. In the continuation of the development process of the AR system, clinical setting involvement will be maintained. The approach will be used to assess other stakeholders which were assigned as key players (section 4.4.2.).

The system will be introduced in the clinical context in three phases to ensure the system is used in safely and effectively. It is important to familiarise the clinical team with the system and to ensure an infrastructure is established.

Phase one: Train the surgeons to work with the technology. Provide training in simulated environments.

Phase two: Controlled procedures in the outpatient clinic. To familiarise the clinical team with the technology first it will be used to guide small interventions in a controlled and monitored environment. This will furthermore help to create an optimized workflow.

Phase three: Integration into complex operating room environment. When the clinical team is highly trained and comfortable with the technology it will be brought to the operating room. Initially, qualified individuals will be present to guide the utilization of the device.

8.4.3. *Overview surgical guidance*

It is crucial to be aware that there is no universally optimal surgical guidance method for all procedures. An important step is to map out the suitability of each method (surgical guides, AR-based navigation, conventional navigation, freehanded) in specific situations and to clarify the advantages and disadvantages of each method. This ensures that well-informed decisions can be made, providing guidelines for the optimal surgical preparation for each case.

8.5. Conclusion

In conclusion, this thesis provides guidance for departments seeking to adopt new technologies. The methodology provides instructions and activities that facilitate the early introduction of technologies, ensuring the active involvement of the clinical context. This approach has been applied to introduce AR at the OMF department of the UMC Utrecht. It provided the researchers with valuable insights on further development of the AR surgical navigation system and resulted in understanding and motivation among the surgeons of the department. This approach, led by a med-tech innovation coordinator, provides an effective, iterative introduction of new technologies tailored to clinical needs.

Acknowledgement

With this thesis, I conclude the Master's in Technical Medicine. I look back on my master's program with joy. The internships in the second and third years, along with my graduation project have brought me numerous unique experiences. Notably, my second-year internship at the 3D Facelab of UMC Utrecht was particularly impactful. Not only was I enthusiastic about the project, but also felt right at home at the 3D Facelab. From that moment on I knew I wanted to come back to this team and be involved in a bigger project. Therefore, I was delighted the team was open to having me as a graduation student and could not have asked for a more fitting place to conduct my graduation project.

Throughout my graduation project, I was surrounded by much guidance and support and I want to thank each individual who played a role in it. First of all, I had a remarkable team of supervisors around me! I would like to extend a special thanks to my daily supervisors, Joël Kortes and Maartje Kienhuis. It is incredible how much you have contributed to my graduation project and how you managed to make it such a positive and enriching experience. Furthermore, I want to thank Mohamed Benmadjoub for supporting me with the technical aspects. You always had great advice for me, and I learned a lot from you. I enjoyed our Thursday meetings. Also, I want to thank my technical supervisor, Theo van Walsum, for his critical perspective and valuable knowledge of AR systems and surgical navigation. Finally, I extend my gratitude to my medical supervisor, Nard Janssen. Thank you for all your assistance in setting up the clinical study, sharing your valuable knowledge from the clinical field, and facilitating my involvement in clinical activities.

Apart from my supervisors, I want to thank the research team from Groningen: Sander Tabernée Heijtmeijer, Joep Kraeima, Peter Pijpker, and Max Witjes. I would especially like to thank Sander for the pleasant collaboration we shared.

A big thanks to the entire 3D Facelab (Joël, Maartje, Robbie and Robert (Harm)), whose warm inclusion made me feel as part of their team. Without this amazing team my graduation would definitely not have been as enjoyable. I feel extremely lucky to have had the opportunity to undertake my thesis in the 3D Facelab. Also, I want to express my appreciation to the neighbours (3D Lab). Thank you for your readiness to answer question and offer ideas and solutions from different perspectives.

I also extend my thanks to all OMFS staff members and colleagues from the OMF outpatient clinic. Thank you for the pleasant atmosphere in the department.

Lastly, I want to thank Thierry, my family, and friends who have supported me throughout the whole process. You are all really important to me and I could not have done it without you.

I look forward to applying all the knowledge and experience I have gained in my future work.

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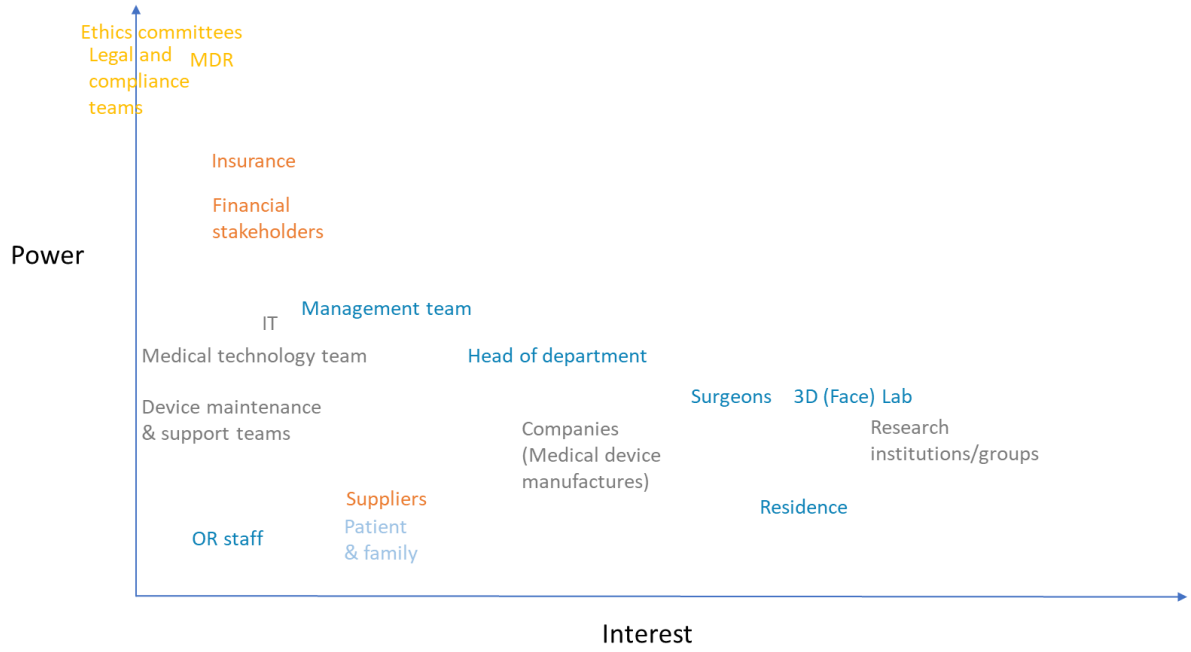
Appendix A

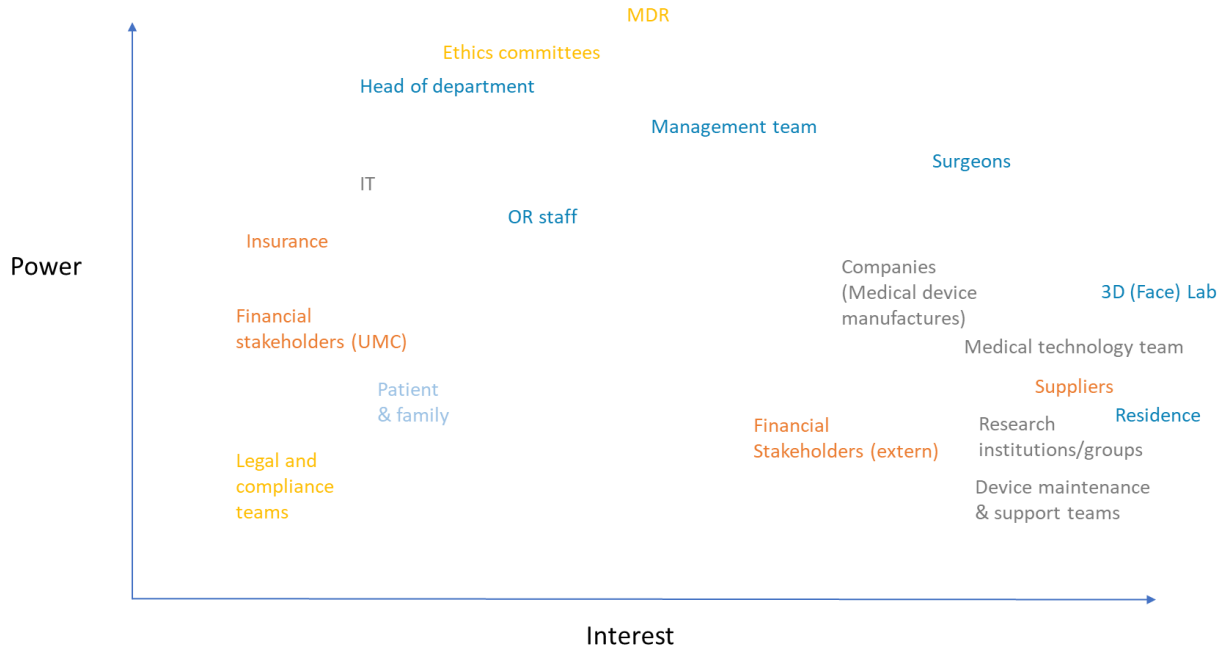
Stakeholder assessment by different experts in the field

Researcher 1:

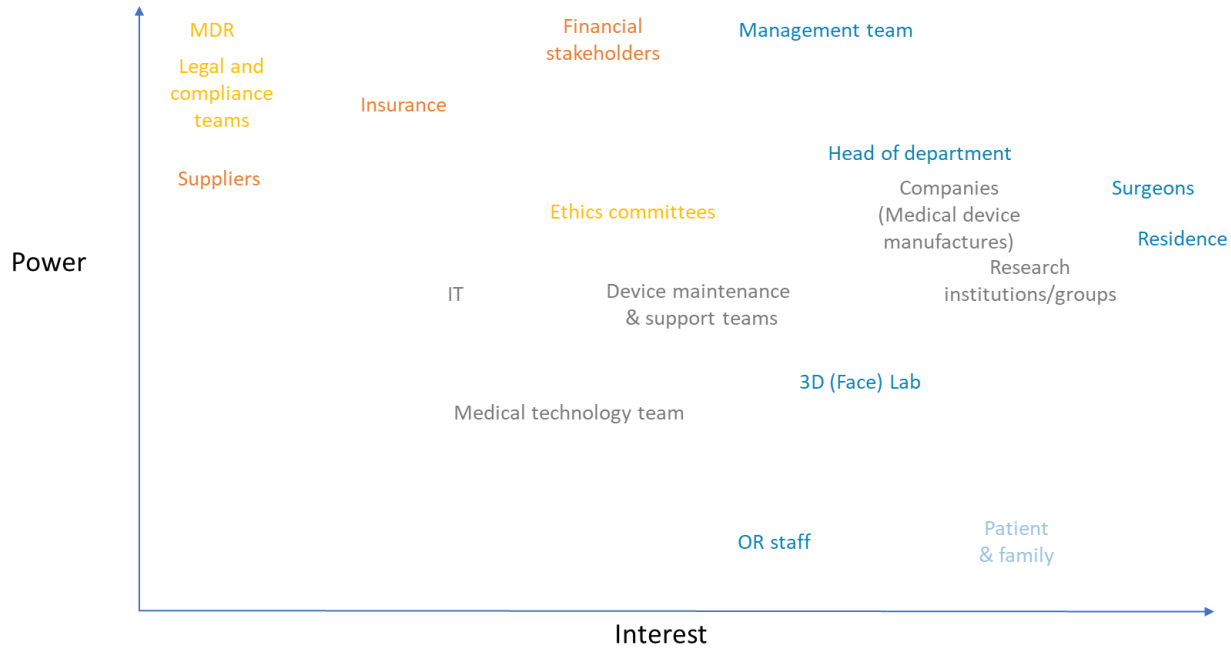


Researcher 2:

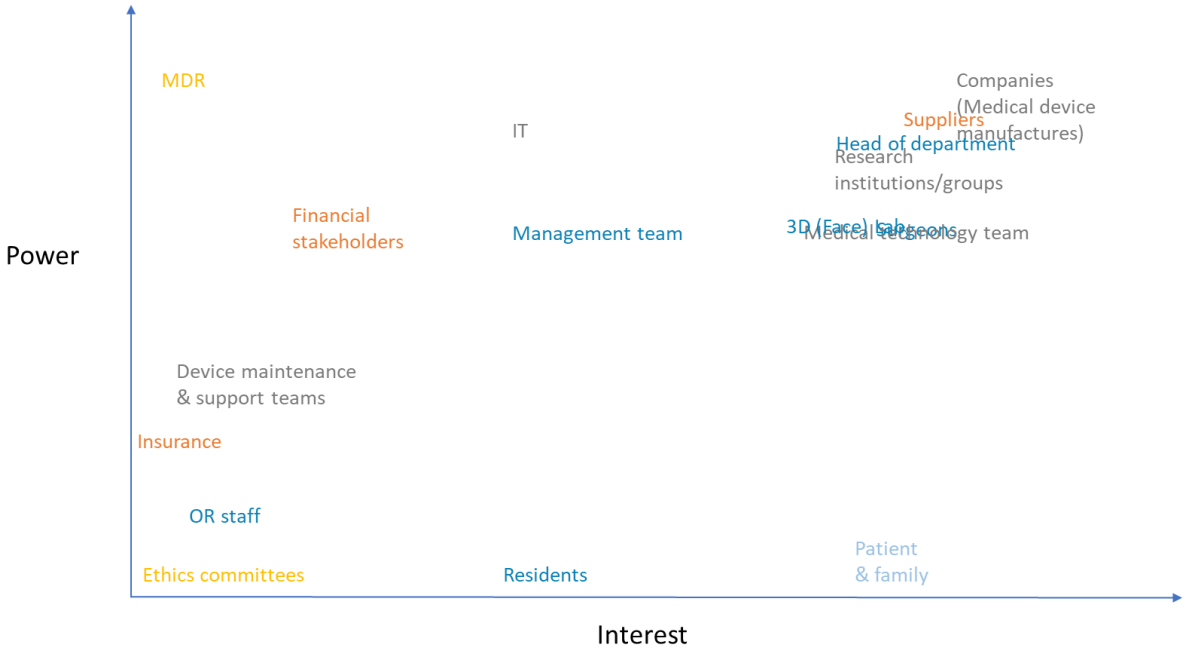
Maxillofacial technician



Clinical technologist



Surgeon


MDR
IT
Companies
(Medical device
manufactures)
Suppliers
Head of department
Research
institutions/groups
Financial
stakeholders
Management team
3D (Face) Lab
Medical technology team
Power
Device maintenance
& support teams
Insurance
OR staff
Ethics committees
Residents
Patient
& family
Interest

	Researcher 1 (UMC Groningen)	*Researcher 2/Software engineer (Erasmus MC)*	*Maxillofacial technician*	*Med-tech innovator of this project*	*Surgeon*	*Software engineer*	*QME in training*	*The crowd*	Subjects	Contex se	Key playe	**Majority location**
Management team	Context setters	Subjects	Key players	Key players	Context se	Key players	Key players	0	1	2	4	**Key Players**
MDR	Context setters	Context setters	Key players	Context setters	Context se	Context setters	Context setters	0	0	6	1	**Context setters**
Financial stakeholders	Context setters	Key players	Context setters / de crowd	Context setters	Context setters	Context setters	Key players	0.5	0	5.5	2	**Context setters**
Insurance	Context setters	Context setters	Context setters	Context setters	The crowc	The crowd	Key players	2	0	4	1	**Context setter**
Head of department	The crowd	Subjects	Context setters	Key players	Key playe	Key players	Key players	1	1	1	4	**Key players**
Suppliers	The crowd	Key players	Subjects	Context setters	Key playe	The crowd	Key players	2	1	1	3	**Undifined**
Surgeons	Subjects	Key players	Key players	Key players	Key playe	Subjects	Key players	0	2	0	5	**Key player**
Ethics committees	Context setters	Context setters	Context setters	Context setters	The crowc	The crowd	Context setters	2	0	5	0	**Context setter**
Companies (medical device manufactures)	the Crowd	Key players	Key players	Key players	Key playe	Subjects	Subjects	1	2	0	4	**Key player**
Research institutions/groups	Subjects	Key players	Subjects	Key players	Key playe	Subjects	Subjects	0	4	0	3	**Subjects**
IT	The crowd	Key players	Context setters	Context setters	Context se	Context setters	Context setters	1	0	5	1	**Context setters**
Device maintenance & support teams	The crowd	Context setters	Subjects	Key Players	The crowc	Context setters	Key Players	2	1	2	1	**Undifined**
3D (Face)lab	Subjects	Subjects	Key players	Subjects	Key playe	Key players	Key players	0	3	0	4	**Key players**
Medical technology team	The Crowd	Key players	Subjects	The Crowd	Key playe	Context setters	Key players	2	1	1	3	**Undifined**
Patient & family	The crowd	The crowd	The crowd	Subjects	Subjects	The crowd	Subjects	4	2	0	0	**The crowd**
OR staff	The crowd	Subjects	Context setters	Subjects	The crowc	Subjects	Key players	2	3	1	1	**Undifined**
Residents	Subjects		Subjects	Key players	The crowc	The crowd	Context setters	2	2	1	1	**Undifined**

Figure A.1: Graph showing the placement of each stakeholder in one of the four quadrants as determined by the different experts.

Appendix B

Embargo until 1-12-2025

Appendix C

Embargo until 1-12-2025

Appendix D: Intermediate results Narrate Study

Embargo until 1-12-2025