How useful is mixed reality in surgical treatment? - a Delphi Study

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Table of Contents

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Abstract

Background: Mixed reality (MR) is a tool that integrates elements from both the real and virtual worlds. Its potential applications are manifold, with promising developments observed in diverse fields, including healthcare, particularly in the context of surgical procedures. A number of studies have been conducted on mixed reality headsets, including the Microsoft HoloLens 2®, which may be employed in surgical training, planning, and navigation. It is imperative to ascertain whether medical professionals consider this technology indispensable in their professional lives. This study employs the Delphi method to assess the utility of MR in surgical settings and utilizes the Welphi online platform to facilitate this process. Furthermore, a PRISMA-like approach is employed to analyze the results of the initial round.

Objective: The objective of this study is to examine the feasibility and advantages of mixed reality technology in surgical contexts. The findings are intended to inform and direct healthcare professionals, researchers, and developers in the advancement of mixed reality integration in surgical environments, with the ultimate goal of optimizing the quality and safety of treatments.

Methods: A Delphi approach comprising of three rounds was implemented to ascertain consensus on the utility of MR surgical treatment. Participants were purposefully selected from experts with professional experience with technologies that provide a more immersive or interactive experience, such as virtual reality (VR), augmented reality (AR), 3D laparoscopy, robotics, and other similar technologies applied in the surgical field.
The initial round of the study was designed to allow surgeons to provide their insights into the potential applications of MR in surgical procedures. This phase employed a structured approach, with open-ended questions organized into five distinct sections. In the second round, the questions were derived from the analysis of the first round and organized according to main and sub-topics for hierarchical structuring. In the third round, the questions were identical to those posed in the second round, including the percentage results obtained in the previous round. This afforded the experts the opportunity to review their previous responses. A consensus round was subsequently conducted. In the analysis, Kendall's tau-b coefficient for correlation analysis was employed and significant correlations between distinct aspects were identified.

Results: Twenty-two of the invited experts provided responses in both the initial and subsequent rounds, representing a 100% response rate. In the third round and consensus round, 20 experts participated, representing 91% response rate. The consensus round was conducted to present the results that had achieved a level of majority consensus of 95% on the usefulness of MR in surgical treatment. The objective was to have experts validate the results. The primary benefits of MR in surgery were identified as surgical navigation (with 75% consensus), surgical planning (with 75% of consensus), and teaching and training (with 70% of consensus).

Conclusions: According to the Delphi study, the areas where MR technology is most beneficial in surgical contexts are surgical navigation, training, and planning. However, the costs and investments required for implementation may present a potential limitation for the integration of this technology in surgical procedures. Moreover, it is of crucial importance to comprehend the

ethical implications associated with this matter, which may have implications for the security of patients.

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How useful is mixed reality in surgical treatment? - a Delphi Study

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Keywords: Mixed Reality; Extended Reality, Augmented Reality; Operating Rooms; Surgery; Consensus; Delphi.

Introduction

Mixed reality (MR) is a technology that enables users to interact with and visualize both the physical and the virtual world. This technology is

increasingly being utilized in healthcare, with the global market projected to expand significantly over the next decade [1], [2].

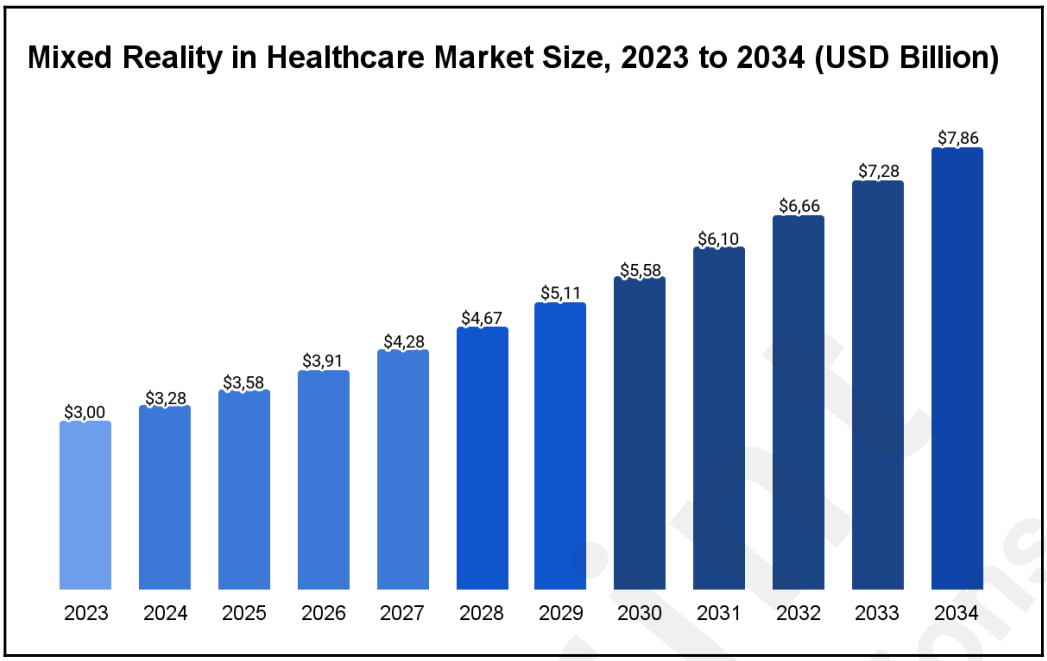

Figure 1. The global mixed reality in the healthcare market size during the forecast period 2023 to 2034. From: [2].

MR is distinct from augmented reality (AR), where the user can only see the virtual objects overlaid in the physical world but cannot interact with them. It also differs from virtual reality (VR), where the user can visualize a virtual environment, but is unable to perceive the real world[3].

A systematic review was conducted to allow for a comprehensive analysis, identification, evaluation, and synthesis of all available evidence on the use of MR in the operating room[4]. The conclusions drawn from the reviewed articles highlight the promising contribution of these innovations to surgical practice, highlighting notable benefits. Nevertheless, considerable obstacles were identified that must be surmounted for the more pervasive implementation of MR. The technical complexity, inflated costs and steep learning curves associated with MR present substantial obstacles to its broader integration in the surgical setting. This highlights the necessity for the development of solutions that can facilitate its adoption in this field.

There are numerous MR headsets currently available, including the Microsoft HoloLens 2®[5], the Magic Leap 2®[6] and the Meta Quest Pro®[7]. In particular, the Microsoft HoloLens 2® has a number of applications in the field of healthcare, including the VSI HoloMedicine® system[5], [8]. A review of the literature revealed that the Microsoft HoloLens 2® has a number of applications in surgery, including intraoperative use[9], surgical planning and training[8].

The operating room is a challenging environment for surgeons, with a number of difficulties being encountered. These include accurate documentation of surgical procedures, which may be solved through the intraoperative capture of multimedia content[10]. Another challenge is the potential for human error, where surgical simulation[11] may be beneficial to enhance surgeons' confidence[10]. Additionally, communication in real-time between operating rooms and different specialists is crucial[10].

Through the use of cutting-edge analytical techniques and review of pertinent literature, the main applications of MR in surgery consist in the surgical training[12], planning[13], simulation[14], and intraoperative applications, such as surgical navigation[15]. Three-dimensional models of the patient's structures can be obtained through the use of computed tomography data, which can then be viewed with an MR headset, such as the Microsoft HoloLens 2®[16]. Furthermore, MR enables surgeons to communicate remotely and in real-time[17], which is beneficial in situations where immediate communication is necessary. Surgical simulations[14] and training increase the surgeons and the students' confidence, by allowing them to make and correct mistakes in a more controlled environment.

MR also improves the safety and the accuracy[18] of the surgical procedures and may even reduce the amount of X-ray irradiation[9] in procedures that use a C-arm, a device used to obtain X-ray images during orthopedic surgery[19].

It should be noted that MR technology also has some limitations, but it is possible to mitigate these limitations by combining MR with other technologies. One potential limitation is the occurrence of eye fatigue[20], which can result from prolonged use. However, the 5G technology[21], [22], by providing a higher internet speed and lower latency levels[23], [24], is able to reduce this issue. Furthermore, some registration issues have been observed[25], whereby virtual objects fail to align with their physical counterparts[26]. This challenge could potentially be addressed by integrating MR with 3D printing technology[27].

There might be some issues with the sterility of the equipment, namely on Microsoft HoloLens 2®. However, the potential for voice commands eliminates the necessity of the surgeon interact with the headset physically[28].

With regard to intraoperative applications, it would be beneficial to conduct a more comprehensive study on the regulations and ethical[29] involved, as well as to undertake additional projects with control groups[16]. This would facilitate a comparison of MR use with more traditional approaches. Moreover, a larger study population[16] is typically required, as well as longitudinal data collection[9]. Although some references were made to the cost-effectiveness[12], [21] of MR, further research is required in this area. Furthermore, it would be beneficial to conduct a more in-depth investigation into the impact of eye fatigue and physical strain[30] when using these headsets, particularly when they are used for extended periods of time. Additionally, it would be advantageous to assess the comfort level of the headsets in terms of weight[18] and design.

There is considerable divergence among professionals in their understanding of the use of MR in surgical procedures. This discrepancy underscores the existence of significant gaps in comprehension and familiarity with this innovative technology. It is of the utmost importance to recognize and understand the diverse range of knowledge and expertise that exists among health professionals. This diversity of perspectives underscores the urgent need to identify and address specific gaps in the understanding regarding this technological tool. Conversely, in order to facilitate substantial advancements in this field, it is imperative to standardize the available information. The standardization of knowledge regarding the utilization of MR in surgical procedures can facilitate the establishment of a more consistent foundation for future investigations.

Accordingly, the objective of this Delphi study is twofold: firstly, to facilitate the homogenization of information, and secondly, to establish a robust foundation for the effective implementation of this innovative technology in the surgical environment. This will contribute to the continuous evolution of medical practice.

By analyzing past experiences, relevant research, and gathering insights from experts in the field, we aim to understand how MR can enhance surgical procedures. The study seeks to provide valuable insights into its effectiveness, acceptance, and potential challenges.

Methods

Study Design

In order to ascertain a consensus on the utility of MR in surgical treatment, a Delphi was employed for the evaluation of this technology in the surgical context. The Delphi method is a systematic technique for the collection and transformation of individual expert opinions into a group consensus through the administration of multiple rounds of surveys[31], [32]. This methodology has been widely employed in health-related research, including public health studies, the evaluation of health technologies, and the development of surgical education programs[33]. The Delphi method, by virtue of its anonymized application, feedback of each expert's opinions and contributions, serves to protect against the undue influence of any single expert in shaping the consensus. Furthermore, it reduces the likelihood of experts aligning with the group's opinion, regardless of the evidence supporting their individual perspectives[34].

The Delphi method was employed in this study to ensure a systematic approach to knowledge gathering, guarantee participant anonymity to mitigate individual influence, and protect against conformity bias. The Delphi process allows for a comprehensive assessment of perspectives from diverse surgical experts on the utility of MR in surgical procedures. Furthermore, this methodology minimizes the potential for bias, thereby promoting a robust and unbiased exploration of expert opinions.

The research team conducted the Delphi study online, managed through the Welphi platform[35], which is a platform designed specifically for Delphi studies.

Participant Selection for the Delphi Consensus

The diverse cohort of specialists from a range of medical specialties, including general, orthopedic, gynecological, pediatric, vascular surgery, anesthesiology, and interventional radiology, were invited to participate in this study. All invited participants were nationally renowned and currently employed in various regions of Portugal. The 22 participants were identified as professionals with experience in technologies that provide a more immersive or interactive experience, such as MR, AR, VR, 3D laparoscopy, robotics, or other similar technologies, with at least one year of experience, applied in the surgical area. All of the participants expressed interest in participating in the Delphi study. It is important to note that the aforementioned surgical areas were not the basis for inclusion in the sample; rather, surgeons working in Portugal, with at least one year of experience in immersive technologies were primary criterion for participation.

Questionnaire Development and Implementation

A Delphi process comprising three rounds was conducted between January and May 2024 with the objective of reaching a consensus among experts on related questions regarding the usefulness of MR in surgical treatment. The first author was designated as the facilitator, tasked with identifying and issuing the expert panel and sending the formal invitation and reminder.

The researchers were tasked with the organization of questionnaires and the conduction of the study. The Delphi framework for data collection and analysis is presented in Figure 2.

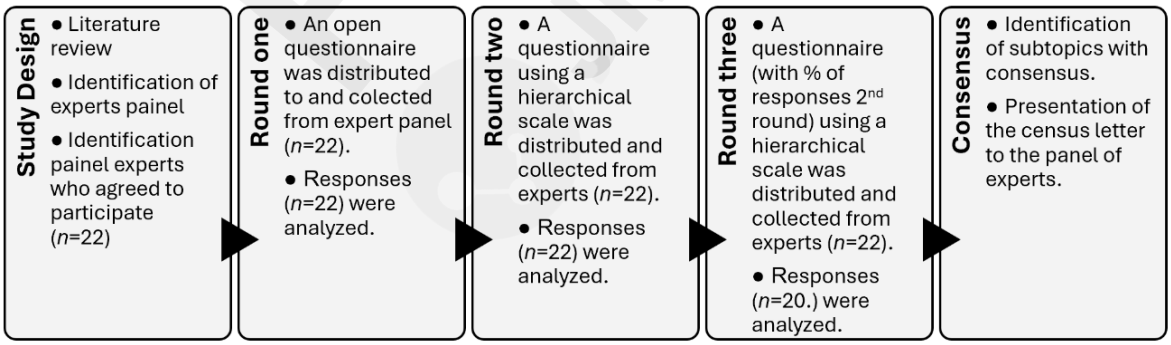

Figure 2 - The process of the Delphi study

The first round of the Delphi study was structured into five different sections, with thirteen questions. The first section focuses on the collation of data regarding the experts invited to take part in this study. The second section focuses on their perspectives on MR in surgery, exploring current practices and potential applications. The third section is dedicated to assessing the perceived potential of MR to improve surgical procedures. Ethical and safety considerations form the fourth section, addressing that is critical to integrate MR into surgical domain. Finally, in the fifth section, the experts are invited to provide any additional comments. The first 4 sections had 3 questions each; the last section had only one question. The questionnaire for the first round can be seen in Appendix 1.

In the second round of this Delphi study, the questions were derived from the analysis of the initial round of data. This round was divided into five

themes and experts were required to hierarchize the answers by sorting them from the most to least important. The initial section pertained to the utility of MR in surgical procedures. Experts were tasked with ranking three statements on this topic. The second section addressed the applications of MR in surgery, presenting four 4 sentences for consideration. With regard to Section 3, which was entitled “Benefits of MR in surgery”, experts were required to sort four statements. The subsequent section addressed the constraints associated with the implementation of MR in surgical settings, comprising five sentences. The last section delved into ethical considerations, presenting four statements for sorting.
In the third round, the exact same questions were posed as in the second round, but with one additional element: experts were permitted to view the group’s responses from the second round, with the aim of potentially influencing their own subsequent responses and thereby reaching a consensus.
Finally, the experts were presented with the results in a consensus letter.

Results

Round One

The following results, classified according to the different areas addressed in each question, were thus obtained through a substantial consensus among the evaluators involved in the study. To analyze the results of Round 1, a PRISMA-like approach was employed [36]. As the questions were only open-ended questions, two investigators divided all the answers to each question into areas of interest. These areas were then compared with each other by a third investigator, resulting in a consensus. The results of each question, along with the corresponding areas of interest, will be presented. It should be noted that the number of answers displayed on each table correlates with the total number of answers inserted in each area, considering the possibility of an answer being included in multiple areas. The other line of the table represents the number of participants whose answer (or answers) fall within that area of interest.
With regard to the initial question, pertaining to the applications of MR in surgical procedures, six areas of interest were identified by the investigators and are presented in Table 1.

Table 1. What, in your opinion, are the applications of Mixed Reality (MR) in medicine, especially in surgery? (Please identify up to three).

	Surgical planning	Teaching and Surgical Training	Navigation and Surgical Orientation	Data Integration and Visualization	Safety and Improvement of Results	Communication and Collaboration
Number of answers	12	14	17	13	12	7
Number of participants n (%)	10 (45%)	13 (59%)	15 (68%)	11 (50%)	9 (41%)	7 (32%)

In response to the second question, which pertains to the benefits of MR in surgical procedures, the experts proffered responses that can be classified into four distinct categories, as shown in Table 2.

Table 2. What are the main benefits that MR can offer to surgical procedures? (Please identify up to three).

	Accuracy and Improvement of Results	Communication and Collaboration	Efficiency and Optimization	Safety
Number of answers	24	9	13	13
Number of participants n (%)	15 (68%)	7 (32%)	10 (45%)	13 (59%)

The potential limitations and challenges of MR in surgical applications were similarly discussed, as can be seen in Table 3, which is divided into six areas of interest.

Table 3. What limitations or challenges do you identify in relation to the implementation of MR in surgical procedures? (Please identify up to three).

	Costs and Investment	Technological Challenges	Human and Technology Adoption Challenges	Logistics and Operational	Certification	Others
Number of answers	12	19	23	3	4	1
Number of participants n (%)	12 (55%)	14 (64%)	14 (64%)	3 (14%)	4 (18%)	1 (5%)

All experts agreed that MR has the potential to improve the precision and effectiveness of surgical procedures. Their responses were divided into two categories, as seen in Table 4.

Table 4. Do you believe that MR has the potential to improve the precision and effectiveness of surgical procedures? Yes/No. Please explain your answer.

	Accuracy and Results Improvement	Efficiency and Optimization
Number of answers	15	10
Number of participants n (%)	15 (68%)	10 (45%)

The experts were asked whether they were aware of any applications of MR in surgical procedures. A total of 73% of the respondents indicated familiarity with at least one case, with two experts reported awareness of one case, eight experts reported awareness of two cases, and six experts reported awareness of three cases (Table 5).

Table 5. Are you aware of specific examples or use cases where MR is already being successfully applied in surgery? Yes/No. If Yes, identify up to three.

	Surgical Planning	Visualization, Real-time Orientation and Intraoperative Navigation	Education and Surgical Training	Robotic Surgery	Others
Number of answers	17	11	3	4	4
Number of participants n (%)	11 (50%)	9 (41%)	3 (14%)	4 (18%)	4 (18%)

With regard to the particular surgical areas that may derive the greatest benefit from the application of MR technology, experts have identified 8 areas in total (see Table 6).

Table 6. What specific surgical areas might benefit the most from MR technology? (Please identify up to three).

	General Surgery	Neurosurgery	Orthopedics	Urology	Vascular	Thoracic	Interventional Radiology	Others
Number of answers	17	9	12	7	9	7	7	2
Number of participants n (%)	14 (64%)	9 (41%)	12 (55%)	6 (27%)	9 (41%)	5 (23%)	6 (27%)	2 (9%)

Six areas of interest were identified with regard to ethical concerns, as can be seen in Table 7.

Table 7. What ethical concerns should be considered in the usage of MR in surgical procedures? (Please identify up to three).

	Procedures' Safety and Patient Protection	Responsibility and Regulation	Privacy and Patient Confidentiality	Patient's Informed Consent	Cost/Benefit Relationship	Others
Number of answers	8	13	15	5	5	3
Number of participants n (%)	8 (36%)	10 (45%)	14 (64%)	5 (23%)	4 (18%)	3 (14%)

In regard to the inquiry concerning patient privacy, 50% of the experts indicated that it might be compromised (e.g., data privacy), while 50% believed that no issues existed in this regard.
In consideration of the potential impact on patient safety, 91% of the respondents indicated that they believed it could be affected. Among these experts, opinions were divided, with some proposing that the changes could be beneficial and others suggesting the possibility of adverse effects. Only 9% of the experts indicated that patient safety would remain unaltered.
The final question was not subjected to analysis, as the supplementary remarks were already addressed in the initial phase.

Round Two

Following the analysis of the responses provided by the experts in the initial round, a closed questionnaire was developed for the second round. The primary subjects under examination with regard to the potential applications of MR in surgical treatment were utility, areas of potential application, benefits, limitations and ethical considerations. The objective of this round is to assign a ranking (1^{st}, 2^{nd}, 3^{rd}...) to each items (a, b, c, etc.) based on the data obtained from the previous round. Items that are deemed the most relevant should be placed in the 1^{st} position, while those that are deemed the least relevant should be placed in the last position.
The experts' responses to the first section, which pertained to the utility of MR in surgical contexts, were as follows:

1. Surgical navigation is the main usefulness of MR in surgery;
2. Surgical planning is the main usefulness of MR in surgery;
3. Surgical teaching and training is the main usefulness of MR in surgery.

As for the section related to the applications of MR in surgery, the experts sorted the statements:

1. The main application of MR in surgery is surgical orientation and navigation;
2. The main application of MR in surgery is education and surgical training;
3. The main application of MR in surgery is surgical planning;
4. The main application of MR in surgery is integrating it with other surgical systems.

The main benefits of MR in surgery, the experts sorted the statements:

1. The main benefit of MR in surgery is accuracy and results improvement;
2. The main benefit of MR in surgery is safety;
3. The main benefit of MR in surgery is efficiency and optimization;
4. The main benefit of MR in surgery is communication and collaboration.

The experts sorted the limitations in the implementation of MR in surgery:

1. The main limitations in the implementation of MR in surgery are technology-related;
2. The main limitations in the implementation of MR in surgery are people-related;
3. The main limitations in the implementation of MR in surgery are the costs and investment;
4. The main limitation in the implementation of MR in surgery is the regulatory area;
5. The main limitation in the implementation of MR in surgery is data protection.

Lastly, the ethical considerations of MR in surgery, the experts sorted the statements:

1. The main ethical considerations of MR in surgery are the patients' privacy and confidentiality;
2. The main ethical considerations of MR in surgery are the responsibility and regulation;
3. The main ethical considerations of MR in surgery are safety in the procedures and patients' protection;
4. The main ethical consideration of MR in surgery is the patients' informed consent.

Round Three

In this round, the same questions as in the previous round were presented with visual representation, indicating the percentage of responses from the 22 participants in accordance with the Delphi methodology. This allowed each participant to review their position, knowing the answers of the group of experts, thereby reducing individual biases and reaching a collective understanding on the topic.

91% percent of the experts responded to this round. The results of Rounds 2 and 3 are presented in Table 8. A majority consensus was reached in all of the sections, with a consensus level of 70% or above. In all of the sections, the order of the answers remain consistent, however, a greater proportion of experts agreed with the initial statement in each section.

Table 8. Results from rounds 2 and 3, grouped by topic under discussion.

			Percentages obtained									
	Topic under discussion	Rounds	Two	Three	Two	Three	Two	Three	Two	Three	Two	Three
		Item hierarchy	1st		2nd		3rd		4th		5th	
		Number of participants per rounds (two=22; three=20)	*n* (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)	*n* (%)
Items to be Prioritized	Utility of Mixed Reality	Surgical navigation is the main usefulness of MR in surgery	14 (63,64%)	**15 (75,00%)**	4 (18,18%)	1 (5,00%)	4 (18,18%)	4 (20,00%)				
		Surgical planning is the main usefulness of MR in surgery	5 (22,73%)	2 (10,00%)	12 (54,55%)	**15 (75,00%)**	5 (22,73%)	3 (15,00%)				
		Surgical teaching and training is the main usefulness of MR in surgery	3 (13,64%)	2 (10,00%)	6 (27,27%)	4 (20,00%)	13 (59,09%)	**14 (70,00%)**				
	Areas of Wider Application of Mixed Reality	Surgical orientation and navigation	13 (59,09%)	**16 (80,00%)**	4 (18,18%)	2 (10,00%)	3 (13,64%)	1 (5,00%)	2 (9,09%)	1 (5,00%)		
		Surgical education and training	3 (13,64%)	2 (10,00%)	3 (13,64%)	3 (15,00%)	7 (31,82%)	8 (40,00%)	9 (40,91%)	7 (35,00%)		
		Surgical planning	5 (22,73%)	2 (10,00%)	8 (36,36%)	10 (50,00%)	4 (18,18%)	2 (10,00%)	5 (22,73%)	6 (30,00%)		
		Integration of Mixed Reality with other surgical systems (e.g. robotics)	1 (4,55%)	0 (0,00%)	7 (31,82%)	5 (25,00%)	9 (40,91%)	11 (55,00%)	5 (22,73%)	4 (20,00%)		
	Benefits of Mixed Reality in the surgical field	Accuracy and improvement of results	14 (63,64%)	**15 (75,00%)**	5 (22,73%)	3 (15,00%)	2 (9,09%)	2 (10,00%)	1 (4,55%)	0 (0,00%)		
		Security	4 (18,18%)	3 (15,00%)	11 (50,00%)	**14 (70,00%)**	5 (22,73%)	1 (5,00%)	2 (9,09%)	2 (10,00%)		
		Efficiency and optimization	3 (13,64%)	2 (10,00%)	5 (22,73%)	2 (10,00%)	8 (36,36%)	11 (55,00%)	6 (27,27%)	5 (25,00%)		
		Communication and collaboration	1 (4,55%)	0 (0,00%)	1 (4,55%)	1 (5,00%)	8 (36,36%)	7 (35,00%)	12 (54,55%)	12 (60,00%)		
	Limitations in the implementation of Mixed Reality in the surgical area	Technological	5 (22,73%)	4 (20,00%)	8 (36,36%)	10 (50,00%)	3 (13,64%)	3 (15,00%)	3 (13,64%)	2 (10,00%)	3 (13,64%)	1 (5,00%)
		Human rights and adoption	1 (4,55%)	0 (0,00%)	7 (31,82%)	5 (25,00%)	9 (40,91%)	13 (65,00%)	3 (13,64%)	2 (10,00%)	2 (9,09%)	0 (0,00%)
		Costs and investments	14 (63,64%)	**15 (75,00%)**	1 (4,55%)	2 (10,00%)	3 (13,64%)	2 (10,00%)	2 (9,09%)	0 (0,00%)	2 (9,09%)	1 (5,00%)
		Regulatory area	2 (9,09%)	1 (5,00%)	5 (22,73%)	3 (15,00%)	4 (18,18%)	1 (5,00%)	10 (45,45%)	**14 (70,00%)**	1 (4,55%)	1 (5,00%)
		Data protection	0 (0,00%)	0 (0,00%)	1 (4,55%)	0 (0,00%)	4 (18,18%)	2 (10,00%)	4 (18,18%)	3 (15,00%)	13 (59,09%)	**15 (75,00%)**
	Ethical considerations in the use of Mixed Reality in the surgical area	Patient privacy and confidentiality.	1 (4,55%)	1 (5,00%)	5 (22,73%)	4 (20,00%)	8 (36,36%)	8 (40,00%)	8 (36,36%)	7 (35,00%)		
		Liability and regulation	6 (27,27%)	4 (20,00%)	10 (45,45%)	11 (55,00%)	4 (18,18%)	4 (20,00%)	2 (9,09%)	1 (5,00%)		
		Safety of procedures and protection of the patient	12 (54,55%)	**14 (70,00%)**	4 (18,18%)	3 (15,00%)	3 (13,64%)	1 (5,00%)	3 (13,64%)	2 (10,00%)		
		Informed consent of the patient	3 (13,64%)	2 (10,00%)	3 (13,64%)	2 (10,00%)	7 (31,82%)	7 (35,00%)	9 (40,91%)	9 (45,00%)		

To facilitate the interpretation of the results, the Kendall's tau-b correlation (Tb) was chosen for this study due to its effectiveness in analyzing associations between ordinal variables. This test is particularly advantageous for evaluating the concordance between rankings, as it accurately accounts for tied ranks. Kendall's tau-b provides a precise measure of the association between variables, making it an ideal tool for ordinal data analysis. All results are presented in Appendix 2, where the coefficients indicate the strength and direction of the association between two ordinal variables. A negative value suggests that, in general, when one variable is rated higher, the other tends to be rated lower, and vice versa. Significant results were considered wherever the p-value was lower than 0.05. All calculations were done using IBM® SPSS Statistics, version 29.

In the initial section, 75% of the experts indicated that the primary utility of MR is surgical navigation. Additionally, 80% of the participants agreed that the predominant application of MR in surgery is surgical orientation and navigation. T_b between "Surgical teaching and training" and "Surgical planning" is weak, negative, but not significant (T_b = -0.313, *p*-value = 0.148). This implies that there is an insufficient evidence base to conclude that a relationship exists between the classification "Surgical teaching and training" and "Surgical planning" as perceived by the participants in question.

Consequently, it is not feasible to ascertain a meaningful relationship between these two variables, based on the available data. T_b between the variables "Surgical teaching and training" and “Surgical navigation” is moderate, negative, and significant (T_b = -0.457, *p*-value = 0.036). As participants rate "Surgical teaching and training" higher, they tend to rate “Surgical navigation” lower, and vice versa. The T_b between "Surgical planning" and “Surgical navigation” is moderate, negative, and significant (T_b = -0.450, *p*-value = 0.040). This indicates that participants who rate "Surgical planning" higher tend to rate “Surgical navigation” lower, and vice versa (see table 11).

The section on the applications of MR in surgery showed significant T_b between “integrating it with other surgical systems” and “surgical planning”, with a moderate, negative and significant correlation (T_b = -0.567, *p*-value = 0.006), and between “surgical planning” and “surgical orientation and navigation”, with a moderate, negative and significant correlation (T_b = -0.468, *p*-value = 0.025). It was thus concluded that participants who rated “integrating it with other surgical systems” higher tended to rate “surgical planning” lower, and vice versa. Similarly, participants who rated “surgical planning” higher tended to rate “surgical orientation and navigation” lower, and vice versa (see table 12).

In the section “Benefits of MR in surgery”, 75% of the experts indicated that accuracy and results improvement were the most significant benefits of MR in surgery. Significant T_b were identified between “communication and collaboration” and “efficiency and optimization”, with a moderate, negative and significant correlation (T_b = -0.435, p-value = 0.039), and between “efficiency and optimization” vs “Safety”, with a strong, negative and significant correlation (T_b = -0.740, *p*-value < 0.001). These results indicate a correlation between the ratings of “communication and collaboration” and “efficiency and optimization” with higher ratings of the former tending to correspond with lower ratings of the latter, and vice versa (see table 13).

A majority of experts (75%) identified cost and investment as the primary constraints on the implementation of MR in surgical settings. Significant T_b were identified between “data protection” and “costs and investment”, with a moderate, negative and significant correlation (T_b = -0.476, *p*-value = 0.027). Similarly, a moderate, negative and significant correlation was observed between “regulatory area” and “technology-related” (T_b = -0.457, *p*-value = 0.024). Additionally, a moderate, negative and significant correlation was noted between “costs and investment” and “technology-related” (T_b = -0.416, *p*-value = 0.041). These results indicate a correlation between the ratings of "data protection" and "costs and investment," with higher ratings of the former tending to correspond with lower ratings of the latter (see table 14).

The most important ethical considerations, as identified by 70% of the experts, pertain to the safety of the procedures and the protection of patients. It was possible to identify significant T_b between “safety in the procedures and patients’ protection” and “responsibility and regulation”. These correlations were moderate, negative and significant (T_b = -0.416, *p*-value = 0.044), indicating that participants who rate “safety in the procedures and patients’ protection” higher tended to rate “responsibility and regulation” lower, and vice versa (see table 15).

The following table identifies the primary topics and subtopics with a majority consensus 70% or greater, including their hierarchical importance (1st, 2nd, 3rd, ...), as determined by the panel of experts.

Table 9. Main topics and subtopics with majority consensus ≥ 70%, including hierarchical importance (1st, 2nd, 3rd, 4th, 5th).

Main topic	Sub-topic	Hierarchy	Agree n (%)
Utility of Mixed Reality	Surgical navigation is the main usefulness of MR in surgery	1st	15 (75%)
	Surgical planning is the main usefulness of MR in surgery	2nd	15 (75%)
	Surgical teaching and training is the main usefulness of MR in surgery	3rd	14 (70%)
Areas of Wider Application of Mixed Reality	Surgical orientation and navigation	1st	16 (80%)
Benefits of Mixed Reality in the surgical field	Accuracy and improvement of results	1st	15 (75%)
	Security	2nd	14 (70%)
Limitations in the implementation of Mixed Reality in the surgical area	Costs and investments	1st	15 (75%)
	Regulatory area	4th	14 (70%)
	Data protection	5th	15 (75%)
Ethical considerations in the use of Mixed Reality in the surgical area	Safety of procedures and protection of the patient	1st	14 (70%)

Consensus Round

In this phase of the study, the findings and conclusions were presented to 20 participants, who were then asked whether they wished to subscribe to them. An acceptance rate of 95% was obtained, as can be seen in Table 10.

Table 10. Results of acceptance of the consensus letter.

	Accept the consensus letter	Not accept the consensus letter
Number of participants n (%)	19 (95%)	1 (5%)

Principal Results

1. Usefulness of Mixed Reality in Surgical Treatment:

- "Surgical navigation is the main usefulness of MR in surgery" obtained a majority consensus of 75% of the experts, ranking it as the first use

of MR in surgical treatment. This use allows the surgeon to improve accuracy when identifying critical structures and an aid in decision making.
• "Surgical planning is the main usefulness of MR in surgery" was agreed upon by a majority of experts, ranking it as the second use of MR in surgical treatment. This use allows the surgeon a detailed visualization of the procedure before surgery, the simulation of different surgical approaches, allowing the definition of the most appropriate action plan and anticipating any complications and challenges before surgery.
• "Surgical teaching and training is the main usefulness of MR in surgery" was agreed upon by a majority of experts, ranking it as the third use of MR in surgical treatment. This use allows the practice of procedures in a holographic environment, without risk to patients, with real-time feedback of errors and access to teaching and training anywhere, reducing limitations on access to simulators in universities.

2. Application Areas:
• "Surgical orientation and navigation" obtained a majority consensus of 80% of the experts, ranking it as the first area of greatest application of MR in surgical treatment. This area assists the surgeon in real time to perform cuts and interventions with greater precision, minimizing damage to healthy tissues.
• For the other subtopics: "Surgical planning", "Integration of Mixed Reality with other surgical systems (e.g. robotics)" and "Education and surgical training" did not reach a significant majority consensus.

3. Benefits of Mixed Reality in the surgical field:
• "Accuracy and improvement of results" was agreed upon by a majority of 75% of experts, ranking it as the first benefit of MR in the surgical field. This benefit allows the visualization of three-dimensional holographic images superimposed on the field of surgical intervention, allowing for better precision and consequently may lead to a reduction in postoperative complications, such as infections, bleeding and accidental injuries.
• "Security" was agreed upon by a majority of 70% of experts, ranking it as the second benefit of MR in the surgical field. MR applied to surgery allows for continuous and accurate visual assistance, assisting surgeons in decision-making and visual notifications when the operator approaches critical areas.
• For the other subtopics: "Efficiency and optimization" and "Communication and collaboration" did not reach a significant majority consensus.

4. Limitations in the implementation of Mixed Reality in the surgical area:
• "Costs and investments" was agreed upon by a majority of 75% of the experts, ranking them as the first challenge for the implementation of MR in surgery. The need for an initial investment requires the acquisition of advanced headsets, specialized software, integration with clinical systems, and up-to-date wired and wireless network infrastructures.
• "Regulatory area" obtained a majority consensus of 70% of experts, ranking it as the fourth challenge in the implementation of MR in surgery, as the approval of new MR devices and software by regulators is a lengthy and complex process.
• "Data protection" obtained a majority consensus of 75% of experts, ranking it as the fifth-place challenge in the implementation of MR in surgery, indicating that systems must ensure the protection of sensitive patient data, complying with the General Data Protection Regulation.
• For the other subtopics: "Technological limitations" and "Human and adoption limitations", they did not reach a significant majority consensus, with divergence in the hierarchy, and these points can be explored in future research or discussions.

5. Ethical considerations in the use of Mixed Reality in the surgical field:
• "Safety of procedures and protection of the patient" was agreed upon by a majority of 70% of experts, ranking it as the first ethical consideration in the implementation of MR in surgery, and it is crucial to ensure that MR devices are highly reliable and that they function correctly during surgical procedures, as any technical failure can compromise patient safety.
• There was no majority consensus on the hierarchy of the subtopics "Patient privacy and confidentiality", "Accountability and regulation" and "Patient informed consent", despite a tendency to rank "Responsibility and regulation" as a second ethical consideration and "Patient informed consent" as a last position.

Discussion

The primary utility of MR in surgical settings was initially perceived to be its capacity for surgical orientation and navigation, which constituted the predominant application. The experts hypothesize that the accuracy and results of surgical procedures may be enhanced through the utilization of MR. One potential obstacle to the adoption of this technology is the cost of the equipment. In this article, the primary ethical concerns pertain to the safety of the procedures and the protection of the patients. This is consistent with the findings of Lam *et al.* [37], which identified the regulatory aspects and the welfare of patients as the most significant ethical considerations. All of the initial statements have been affirmed by the majority. The results of the Delphi study indicated that surgeons concur that the use of MR in surgery is warranted, despite the potential financial implications of the requisite equipment. The fact that the experts were able to view the group's responses following the conclusion of Round 2 facilitated the attainment of consensus, as it allowed them to rethink and reconsider their initial positions. To minimize the potential influence of authority figures[34], [37], the study was conducted anonymously.

Limitations

The conclusions derived from the Delphi exercise are the subjective opinion of a particular group, even though it was constituted by specialists from various surgical areas.
As future work, this study could be repeated using a Likert scale to verify whether the same conclusions are reached.
A larger number of experts considered in the sample would be recommended to achieve stronger results. The present study was conducted exclusively within the Portuguese context; it would be of interest to assess the impact of MR tools within an international panel. Regarding the results, it is notable that certain areas exhibited lower levels of consensus when compared to others. For instance, the ethical considerations reached an agreement of 70%. Further investigation into the discrepancies between surgical specialties may prove beneficial in future studies.
Cost-effectiveness and a cost-benefit analysis were not included in this study; it could be useful in the future to support managers' decisions on bet in these technologies. Also pertinent to future investigation are the economic aspects, including the return on investment and the costs associated with maintenance and updates.
Furthermore, additional investigation into potential technical barriers may have been beneficial. In future studies, it would be recommended to consider the technical specifications required for the implementation of these tools.
It also would be beneficial to evaluate the accuracy and complication rates associated with the procedures. Furthermore, it would be advantageous to

identify the learning curve associated with each of the surgical procedure.

Comparison with Prior Work

Despite this being an emergent topic with a lack of published work on the subject (Delphi surveys related to mixed and/or extended reality), some studies present similar objectives.

In K. Lam et al. [37], the objective of the four-round Delphi study was to ascertain a definition for the term “digital surgery”. This was an international Delphi study, involving 38 experts, a greater number than that included in the present article. The level of consensus was identical to that observed in the present study, reaching 70%. However, the experts participated in an online meeting, which was not present here. The main takeaways from this study that could be related to the one in this article were related to ethical issues that developers need to consider when developing digital applications for surgical use[37].

In J. R. Burke et al. [38], 43 surgeons participated in the 3-round Delphi study. This study had the same number of rounds as the one presented in the current article, and some of the questions in rounds 2 and 3 were added based on the answers from the previous rounds. The level of consensus was slightly higher, at 80%. The goal of this survey was to offer educational stakeholders a comprehensive overview of robotic surgery curriculum from the perspective of medical students[38].

As for B. K. Burian et al.[39], the Delphi study was related to training with augment reality, which could be a similar application to the one in this present article - MR for surgical training. There were 45 participants, and a modified Delphi method was used with online meetings took place. In this survey, a 7-point Likert scale was used, which could have also been used in the present article, as it could have provided additional information on the subject. The main conclusions of this survey are related to what extended reality functionalities should be present for medical training and navigation of astronauts during their missions. In the present article, the Delphi study has also provided some insights into the needs of surgeons in the operating room, such as the use of using MR for surgical navigation and training[39].

Conclusions

The results of the Delphi study provide a comprehensive overview of experts' perceptions of the usefulness of MR in surgery. Navigation, surgical planning, and surgical teaching and training are the areas of greatest utility, while accuracy and safety have been identified as the main benefits. However, excessive costs and regulatory barriers are the potential limitations in implementing this technology. Ethical considerations, especially in relation to patient safety, are crucial and should be included to ensure trust and acceptance of MR in surgical practice.
As future steps, it is intended to develop a tool for teaching and surgical training using the MR, which will allow us to obtain data on navigation, surgical planning and limitations of this process. Subsequently, proof of concept of an application area will be conducted in which metrics will be developed that evaluate feasibility, accuracy and usefulness.

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Abbreviations
3D: Three dimensions/dimensional
5G: Fifth Generation
AR: Augmented Reality
MR: Mixed Reality
VR: Virtual Reality

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Conceptualization and design, R.M.; analysis and interpretation of data, R.M., A.L., A.M., J.P., L.L.S.; writing original draft preparation, R.M. and A.L.; writing, review and editing, R.M., A.M., J.P., L.L.S. All authors contributed to the full Delphi consensus exercise and contributed to significant amendments to the final manuscript.

Statements and Declarations
Ethical approval: This article does not contain any studies with human participants or animals performed by any of the authors.
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Appendix 1

The questions from the first round of the Delphi study, as well as the areas of interest of each section, were presented as follows:

Section 1: Participant information

1. Position or title in the surgical field;
2. Years of professional experience in surgical treatment;
3. Years of professional experience in immersive or interactive technologies, such as virtual reality (VR), augmented reality (AR), 3D laparoscopy, robotics, or other similar technologies applied to surgery;

Section 2: MR and surgery

4. What, in your opinion, are the applications of Mixed Reality (MR) in medicine, especially in surgery? (Please identify up to three)
5. What are the main benefits that MR can offer to surgical procedures? (Please identify up to three)
6. What limitations or challenges do you identify in relation to the implementation of MR in surgical procedures? (Please identify up to three)

Section 3: Potential of MR in the improvement of surgical procedures

7. Do you believe that MR has the potential to improve the precision and effectiveness of surgical procedures? Yes/No. Please explain your answer.
8. Are you aware of specific examples or use cases where MR is already being successfully applied in surgery? Yes/No. If Yes, identify up to three.
9. What specific surgical areas might benefit the most from MR technology? (Please identify up to three)

Section 4: Ethical and safety concerns

10. What ethical concerns should be considered in the usage of MR in surgical procedures? (Please identify up to three)
11. Do you consider that patient privacy could be affected by the use of immersive technologies, such as VR, AR or other similar technologies, in surgery? Yes/No. Please explain your answer.
12. Do you consider that there may be changes to patient safety during the procedure when incorporating MR into surgical procedures? Yes/No. Please explain your answer.

Section 5: Additional comments

13. Which other aspects should be discussed?

Appendix 2 – SPSS Statistics

Table 11. Correlations of the 3 topic items of utility of Mixed Reality.

Correlations

			SUR_TRAIN	SUR_PLAN	SUR_NAV
Kendall's tau_b	SUR_TRAIN	Correlation Coefficient	--		
		Sig. (2-tailed)	.		
		N	20		
	SUR_PLAN	Correlation Coefficient	-,313	--	
		Sig. (2-tailed)	,148	.	
		N	20	20	
	SUR_NAV	Correlation Coefficient	-,457*	-,450*	--
		Sig. (2-tailed)	,036	,040	.
		N	20	20	20

*. Correlation is significant at the 0.05 level (2-tailed).

Table 12. Correlations of the 4 topic items of Areas of Wider Application of Mixed Reality.

Correlations

			INTEGRATION	PLANNING	EDUCATION	ORIENTATION
Kendall's tau_b	INTEGRATION	Correlation Coefficient	--			
		Sig. (2-tailed)	.			
		N	20			
	PLANNING	Correlation Coefficient	-,567**	--		
		Sig. (2-tailed)	,006	.		
		N	20	20		
	EDUCATION	Correlation Coefficient	-,258	-,264	--	
		Sig. (2-tailed)	,204	,187	.	
		N	20	20	20	
	ORIENTATION	Correlation Coefficient	,364	-,468*	-,298	--
		Sig. (2-tailed)	,086	,025	,150	.
		N	20	20	20	20

**. Correlation is significant at the 0.01 level (2-tailed).

*. Correlation is significant at the 0.05 level (2-tailed).

Table 13. Correlations of the 4 topic items of Benefits of Mixed Reality in the surgical field.

Correlations

			COMMUNICATION	EFFICIENCY	SECURITY	PRECISION
Kendall's tau_b	COMMUNICATION	Correlation Coefficient	--			
		Sig. (2-tailed)	.			
		N	20			
	EFFICIENCY	Correlation Coefficient	-,435*	--		
		Sig. (2-tailed)	,039	.		
		N	20	20		
	SECURITY	Correlation Coefficient	,202	-,740**	--	
		Sig. (2-tailed)	,347	<,001	.	
		N	20	20	20	
	PRECISION	Correlation Coefficient	-,285	,080	-,410	--
		Sig. (2-tailed)	,192	,702	,054	.
		N	20	20	20	20

*. Correlation is significant at the 0.05 level (2-tailed).

**. Correlation is significant at the 0.01 level (2-tailed).

Table 14. Correlations of the 5 topic items of Limitations in the implementation of Mixed Reality in the surgical area.

Correlations

			DATA_PROTECTION	REGULATORY	COSTS	HUMANS	TECHONOLOGICAL
Kendall's tau_b	DATA_PROTECTION	Correlation Coefficient	--				
		Sig. (2-tailed)	.				
		N	20				
	REGULATORY	Correlation Coefficient	,249	--			
		Sig. (2-tailed)	,240	.			
		N	20	20			
	COSTS	Correlation Coefficient	-,476*	-,246	--		
		Sig. (2-tailed)	,027	,241	.		
		N	20	20	20		
	HUMANS	Correlation Coefficient	-,166	,081	-,098	--	
		Sig. (2-tailed)	,442	,701	,645	.	
		N	20	20	20	20	
	TECHONOLOGICAL	Correlation Coefficient	,048	-,457*	-,416*	-,214	--
		Sig. (2-tailed)	,816	,024	,041	,296	.
		N	20	20	20	20	20

*. Correlation is significant at the 0.05 level (2-tailed).

Table 15. Correlations of the 5 topic items of Ethical considerations in the use of Mixed Reality in the surgical area.

Correlations

			CONSENT	SECURITY	RESPONSIBILITY	PRIVACY
Kendall's tau_b	CONSENT	Correlation Coefficient	--			
		Sig. (2-tailed)	.			
		N	20			
	SECURITY	Correlation Coefficient	-,260	--		
		Sig. (2-tailed)	,207	.		
		N	20	20		
	RESPONSIBILITY	Correlation Coefficient	-,228	-,416*	--	
		Sig. (2-tailed)	,260	,044	.	
		N	20	20	20	
	PRIVACY	Correlation Coefficient	-,188	-,132	-,279	--
		Sig. (2-tailed)	,350	,519	,167	.
		N	20	20	20	20

*. Correlation is significant at the 0.05 level (2-tailed).