

Research Paper
Orthognathic Surgery

Evidence gaps in orthognathic surgery: an international Delphi study

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Abstract. The aim of this study was to assess the evidence gaps identified in a recent mapping review of orthognathic surgery by evaluating them through consultation with maxillofacial surgeons. Using the Delphi technique, a panel of surgeons who regularly perform orthognathic surgery was engaged. Potential participants were identified through articles included in the mapping review, peer nominations, and social media platforms. Two rounds of surveys, incorporating Likert-type and open-ended questions, were conducted to gauge the clinical relevance of evidence gaps. Questions were refined based on responses from the initial round, with a consensus threshold set at 60%. Seventy-four surgeons participated in the first round and 55 in the second round (retention rate of 74%). The intra-class correlation analysis revealed 'almost perfect' agreement in each round. Participants in the first round proposed 11 new evidence gaps. A list of 15 potentially clinically relevant research questions was compiled to guide future investigations in orthognathic surgery. This collaborative Delphi study between researchers and clinicians has explored the existing understanding of the clinical relevance of potential evidence gaps in orthognathic surgery. The study findings offer others a pathway to address information gaps and guide future research endeavours.

Keywords: Delphi technique; Orthognathic surgery; Evidence gaps; Oral and maxillofacial surgeons; Surveys and questionnaires.

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Orthognathic surgery is frequently used to treat dentofacial deformities such as skeletal discrepancies, asymmetry, airway dysfunction, speech impairments, and temporomandibular joint disorders^{1,2}, which affect approximately 20% of the population, with the aim of restoring anatomical and functional relationships³. An increase in the frequency of

orthognathic surgery performed each year has been observed, with 8755 surgeries performed in the United States in 2007, over 2230 procedures performed in England in 2014⁴, and 1000 in Denmark in 2015⁵. This has concomitantly led to an increase in the scientific literature on the subject. However, a high flow of primary and secondary research continues to be

produced on certain resolved research questions and specific topics. Meanwhile, there is a need for researchers to address unresolved questions.

While orthognathic surgery is generally considered a safe procedure, a diverse array of complications exist, and their incidence varies depending on the specific surgical modalities employed and

perioperative co-interventions applied to optimize surgical outcomes^{1,3,6}. Common complications include issues such as blood loss, infection, and relapse⁶⁻⁸. The significant vascularity of the maxillofacial region contributes to blood loss during orthognathic surgery, which is exacerbated by challenges in cauterizing or ligating the vessels involved⁹. Post-operative infections, which are estimated to occur in approximately 7% of cases, manifest with symptoms such as localized pain, swelling, erythema, pus formation, and restricted movement¹⁰. The relapse of surgical corrections is associated with factors such as planning errors, intraoperative challenges, anatomical variations, or limitations in postoperative orthodontic management⁶. While the reported incidence of complications is relatively low, their occurrence poses potential risks of permanent deficiencies, necessitating reoperations and impacting the patient's overall quality of life.

A recent mapping review that identified, described, and analysed the available evidence on co-interventions and procedures in orthognathic surgery revealed evidence gaps that need to be addressed to improve the outcomes of blood loss, infection, and relapse^{11,12}. Yet, these knowledge gaps only portray what is available in the published literature; they do not consider the views of clinicians who perform the procedures daily.

The aim of this exploratory Delphi study was to assess and compare the results provided in the mapping review through their appraisal by maxillofacial surgeons. It was considered that complementing the available literature with a clinical appraisal would reveal a list of potential evidence gaps that could help guide future investigations in orthognathic surgery.

Materials and methods

All methods have been specified a priori in a protocol published in a peer-reviewed journal¹³.

This study used the Delphi technique. The study design was chosen to assess the results of a mapping review of orthognathic surgery through a collaborative approach by maxillofacial surgeons, consequently identifying potentially essential evidence gaps in the literature and guiding future investigations.

A research steering group was formed to undertake this research. This group was responsible for preparing and

circulating the content of the Delphi rounds. The group comprised investigators with backgrounds in general dentistry, oral surgery, maxillofacial surgery, and research methodology. The research steering group did not participate in the surveys; they only supervised and monitored the process.

Selection and identification of participants

Participants selected for this study were maxillofacial surgeons who regularly perform orthognathic surgery daily. They were recruited through the following methods: (1) extraction of contact information: the contact information of corresponding authors was obtained from articles included in the mapping review; (2) peer nomination: identified peers nominated other potential participants; and (3) social media: LinkedIn was used to reach out to suitable candidates.

Participants were excluded if they (1) had less than 1 year of experience in the field; (2) had not performed orthognathic surgery for more than 1 year; or (3) could not commit to being available for the entire study process. No restriction was placed on age, country, or gender for participation in this study.

Identified individuals were sent a personalized invitation letter via email. This email included a user-friendly information poster and the study protocol. The invitation provided detailed information on the study objectives, design, and required commitment. Participants were provided with a clear explanation of the anticipated process and were asked to commit to all rounds of the Delphi technique. The invitation also contained a link to the study survey, which included questions regarding the inclusion criteria and had a section to nominate peers. The same invitation email was sent to those nominated peers. After receiving all responses, only surveys from participants who met the inclusion criteria were considered for analysis. Fig. 1 shows details of the recruitment process.

A minimum requirement of 20 participants was established, with no upper limit, as larger panels increase the reliability of the outcomes^{14,15}. Following the iterative nature of the Delphi technique, this process was performed anonymously¹⁶.

Design, content, and development of the survey

The survey consisted of 5-point Likert scales and open-ended questions regarding evidence gaps identified in a previous study. The questionnaires were developed in Google Forms. Each round of the survey included an introductory paragraph that stated the intentions of the round. The second round provided details and feedback concerning the results of the first round.

Questions were developed by the principal investigator (J.B.) based on the evidence gaps identified in a previous study^{11,12}. Subsequently, they were piloted by the research steering group and adapted according to the feedback received. A 60% consensus was chosen for the results to be considered valid, following the suggestion of some authors¹⁷⁻¹⁹. Several methods were used to enhance the response rate. Initially, participants were invited to participate via personalized email, explaining the objectives and importance of the study. They were presented with the survey in the same email to decrease drop-outs. Reminders were emailed to participants who did not answer the survey, at a frequency of 7 days. Participants were also offered a participation certificate and their acknowledgment in future publications with Delphi results if they participated in both rounds.

Rounds

Recent evidence shows that the preferred number of rounds is either two or three^{18,20,21}. In this study, two rounds were undertaken, allowing participants to receive feedback and revise previous responses, reducing the number of attritions. Results were not considered valid if consensus was below 60% for a specific question.

The round 1 questionnaire consisted of 5-point Likert scale questions, where participants selected the clinical relevance of the identified evidence gaps in orthognathic surgery. These evidence gaps were extracted from a previous mapping review¹² and were categorized according to the outcome: blood loss, infection, or relapse. Also, a final open-ended question asked participants to point out any evidence gap not mentioned in the previous questions.

After the first round, to enhance transparency, feedback reports were distributed to the participants, which included (1) the

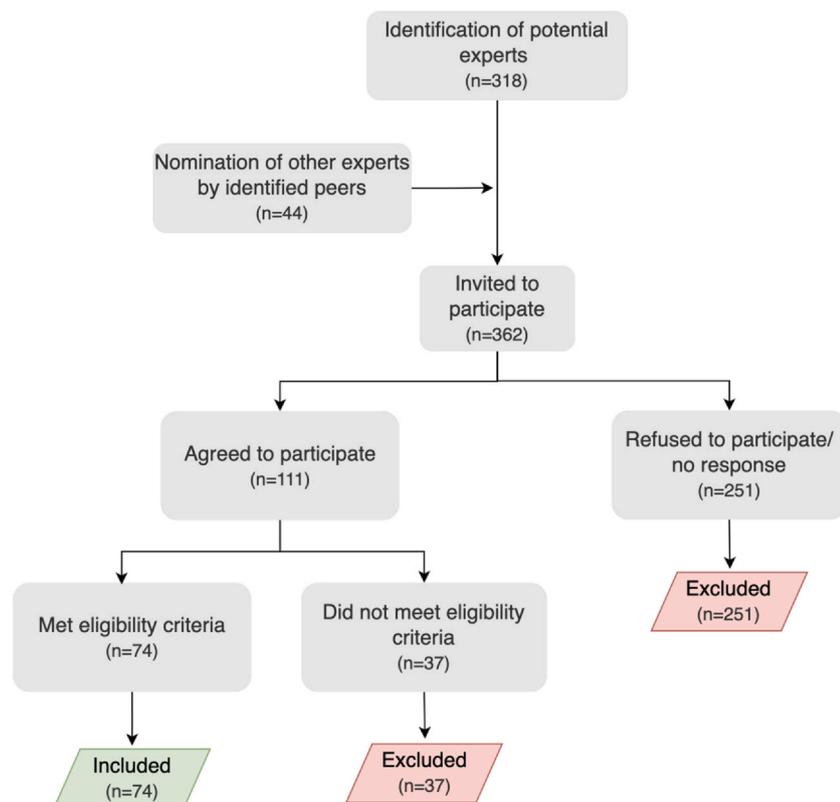


Fig. 1. Recruitment process.

mean and standard deviation (SD) score for each item, (2) the number of responses in the previous round, (3) the current level of consensus, and (4) a summary of the results from the previous round. These results were presented in a narrated and graphical manner.

For the second round, past questions were modified depending on the answers obtained. Questions with low clinical relevance and high agreement between participants (above 60%) were eliminated for the second round. Questions with low agreement (below 60%) were repeated for the second round. Evidence gaps proposed by participants in the previous rounds that fulfilled the inclusion criteria (Table 1) were added as new questions, or previous questions were modified.

Questions defined as relevant, which included the categories ‘question is likely to be relevant’ and ‘question is highly relevant’, with a consensus between participants of 60% or higher, were listed as evidence gaps that should be addressed in future research.

Statistical analysis

A descriptive statistical analysis was performed after each round. First, mean and SD values, the range, and numbers and

percentages were obtained for the following variables: years of experience in the field, work setting, and country. Histograms were developed for each question in each round, showing the category frequencies. Moreover, the mean and SD were calculated for each question using Jamovi software²², which converted the Likert scale as a continuous variable. Intra-class correlation coefficients were computed to assess the level of agreement within the subject and between participants.

Results

Participant characteristics

For the first round of the study, 74 participants from 17 countries and four continents agreed to be part of the Delphi process; 55 of these participants (74%) completed both rounds. The mean years of professional experience in orthognathic surgery of the participants was 13.4 years (range 1–43 years). Most worked in an academic setting (35/74, 47%), followed by a hospital (27/74, 36%), private clinic (10/74, 14%), and other (2/75, 3%). The participant characteristics are presented in Table 2.

First round

Seventy-four responses were collected in round 1. Six out of nine research questions were considered clinically relevant, as more than 60% of the participants marked them as ‘question is likely to be relevant’ or ‘question is highly relevant’. A consensus was not reached for three questions and these were repeated in the second round. For all questions, the minimum score recorded was 1 (‘question is highly irrelevant’), while the maximum score attained was 5 (‘question is highly relevant’). Results are detailed in Fig. 2.

Evidence gaps proposed by the participants

A total of 55 knowledge gaps were proposed by 41 participants in round 1; of these, 11 (20%) were included according to the inclusion and exclusion criteria, while 44 (80%) were excluded. Reasons for exclusion were as follows: no co-interventions or surgical modalities evaluated (12/44, 27%), regarding planning (7/44, 16%), repeated (7/44, 16%), only outcome presented (6/44, 14%), resolved gap (4/44, 9%), syndromic population (2/44, 5%), wrong outcome (2/44, 5%), wrong population (2/44, 5%), regarding orthodontic treatment (1/44, 2%), commentary (1/44, 2%) (Supplementary Material Table S1).

Second round

The retention rate was 74% (55/74 participants). A final consensus was not reached for any of the questions repeated from the first round. Nine of the 11 new evidence gaps presented by participants were considered clinically relevant (82%) (Fig. 3). In all questions in the second round, the minimum score recorded was 1 (‘question is highly irrelevant’) and the maximum score was 5 (‘question is highly relevant’). However, regarding the clinical relevance of the effect of tranexamic acid on blood loss, the minimum score obtained was 2 (‘question is likely to be irrelevant’).

A final list of 15 clinically relevant evidence gaps to address blood loss, infection, and relapse in orthognathic surgery was achieved (Table 3). The primary outcome addressed was relapse (47%, 7/15), followed by blood loss (40%, 6/15) and infection (13%, 2/15). Knowledge gaps achieving the highest scores for clinical relevance were (1) the

Table 1. Selection criteria for evidence gaps proposed by participants.

Inclusion criteria	Exclusion criteria
Evidence gap regarding co-interventions or surgical modalities used during the perioperative period in the adolescent or adult orthognathic surgery population	Evidence gap regarding surgical planning or quality of life Evidence gap regarding syndromic patients Evidence gap regarding economic outcomes

Table 2. Participant characteristics.

Variable		First round (n = 74)	All rounds (n = 55)
Work setting	Academic/university	35 (47%)	23 (42%)
	Hospital	27 (36%)	26 (47%)
	Private practice	10 (14%)	6 (11%)
	Other	2 (3%)	0 (0%)
Continent	Asia	6 (8%)	3 (5%)
	Europe	15 (20%)	9 (16%)
	South America	50 (68%)	41 (75%)
	North America	3 (4%)	2 (4%)
Years of professional practice	1–5	16 (22%)	12 (22%)
	6–10	20 (27%)	14 (25%)
	11–15	15 (20%)	11 (20%)
	16–20	8 (11%)	6 (11%)
	21–25	8 (11%)	7 (13%)
	26–30	5 (7%)	3 (5%)
	> 30	2 (3%)	2 (4%)

effect of the number of osteosynthesis plates on relapse (mean score 4.20, SD 0.96), (2) the efficacy of tranexamic acid in anaesthetic induction for blood loss (mean score 4.18, SD 0.81), and (3) the efficacy of induced hypotension in blood loss (mean score 4.05, SD 1.26). A flow diagram was developed to illustrate the results of the process (Supplementary Material Fig. S1).

Intra-class correlation

For the first round, the intra-class correlation coefficient was computed to assess agreement between the 74 maxillofacial surgeons in answering nine questions related to orthognathic surgery. According to the interpretation as described by Landis and Koch²³, there was ‘almost perfect’ agreement among the 74 surgeons using the two-way random-effects model and single rater unit: kappa = 0.77 (95% CI 0.66–0.83), $P < 0.05$. For the second round, 55 responses were analysed. There was also ‘almost perfect’ agreement between the 55 surgeons, using the two-way random-effects model and single rater unit: kappa = 0.86 (95% CI 0.81–0.91), $P < 0.05$.

The intra-class correlation was further analysed for the questions with low agreement in the first round that were

repeated in the second round. The results showed a moderate agreement on the clinical relevance of the efficacy of resorbable vs titanium fixation on infection (kappa = 0.43, $P = 0.023$), as well as for the use of rigid vs wire fixation on relapse (kappa = 0.50, $P = 0.012$). Additionally, there was a fair agreement on the clinical relevance of the efficacy of piezoelectric devices on infection, although this was not statistically significant (kappa = 0.30, $P = 0.10$) (Table 4).

Discussion

The aim of this exploratory study was to evaluate evidence gaps in orthognathic surgery identified in a recent mapping review^{5,6} through evaluation by maxillofacial surgeons, leading to a potentially clinically relevant list of evidence gaps. Using the Delphi technique, 74 surgeons identified 15 potentially clinically relevant evidence gaps to address blood loss, infection, and relapse in orthognathic surgery.

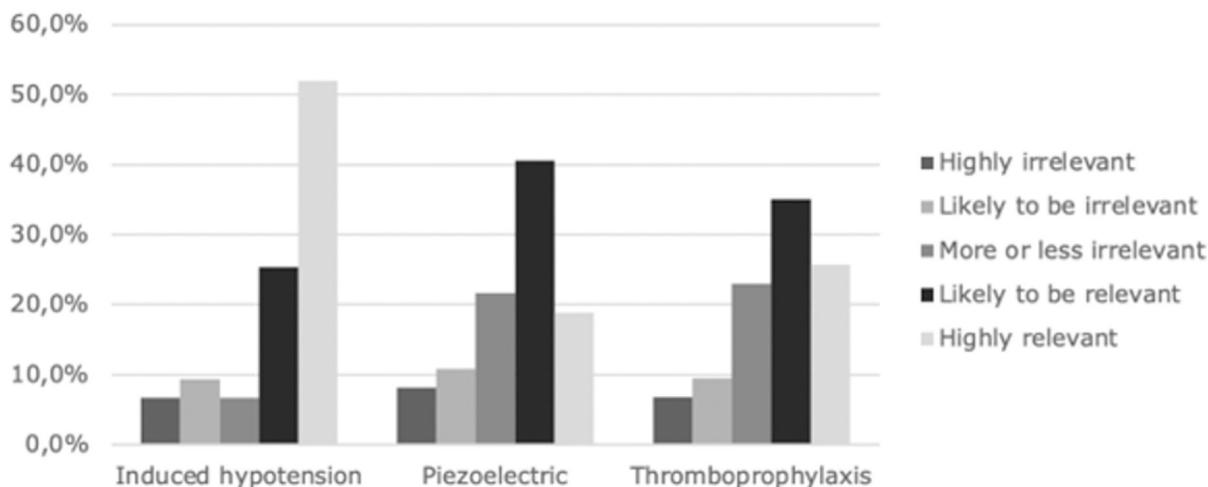
Intra-class correlation was evaluated throughout the study. An ‘almost perfect’ agreement was observed in each round, demonstrating consistency in results across all participants. Furthermore, three evidence gaps for which consensus on their clinical

relevance was not reached in the first round were included in the second round. The intra-class correlation for these questions, comparing both rounds, indicated moderate to fair agreement. Even though participants’ answers to these questions varied from round 1 to round 2, their mean clinical relevance was not ranked as high.

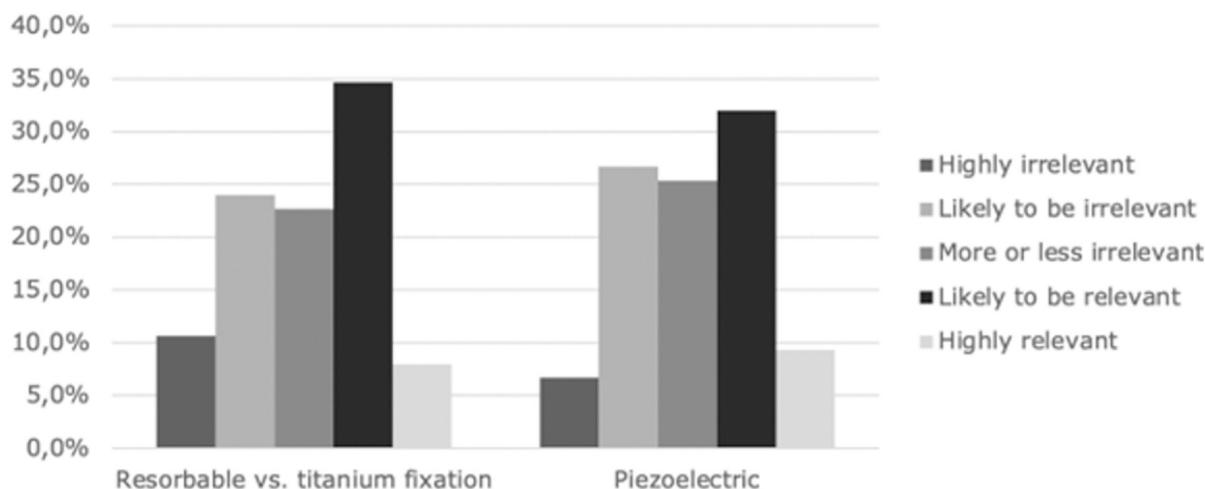
This study is novel in exploring the clinical relevance of identified evidence gaps in orthognathic surgery through examination by maxillofacial surgeons. This Delphi study suggests a potentially clinically relevant list of evidence gaps to be addressed in future research in the participating countries. Moreover, the results suggest future research directed mainly towards obtaining stable results over time (relapse 47%) and haemostatic control of the patients (blood loss 40%), given the degree of agreement among the participants. This reflects the importance that surgeons attribute to aspects directly related to the perioperative patient experience, constantly searching for alternatives that will improve results and reduce the need for new interventions to achieve the stated objectives.

The impact of new techniques on the outcome of infection, such as minimally invasive orthognathic surgery and the concomitant use of multilayer sutures,

a) Clinical relevance of co-interventions on blood loss, round one



b) Clinical relevance of co-interventions on infection, round one



c) Clinical relevance of co-interventions on relapse, round one

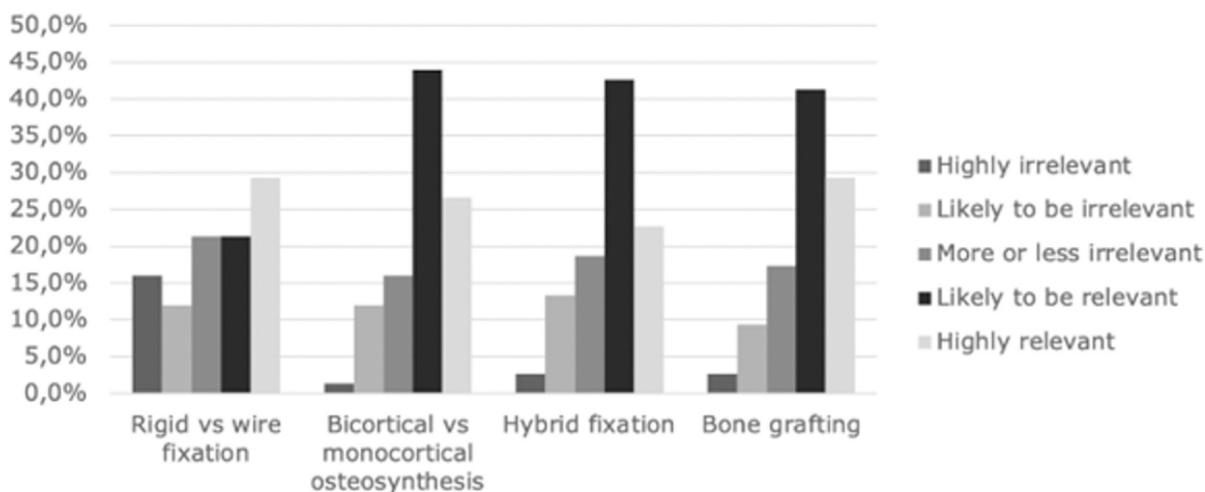


Fig. 2. (A) Clinical relevance of co-interventions on blood loss, round 1. (B) Clinical relevance of co-interventions on infection, round 1. (C) Clinical relevance of co-interventions on relapse, round 1.

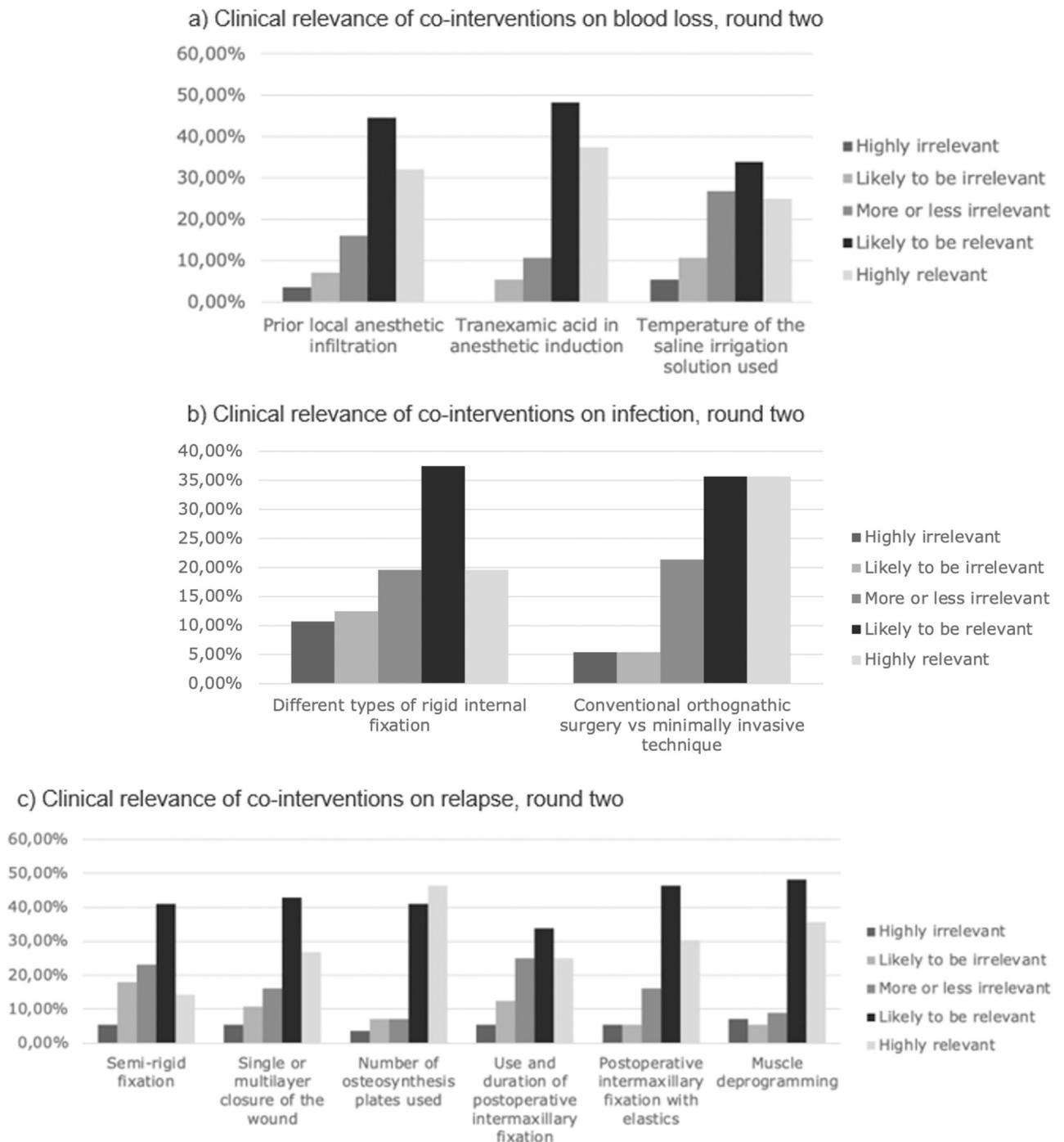


Fig. 3. (A) Clinical relevance of co-interventions on blood loss, round 2. (B) Clinical relevance of co-interventions on infection, round 2. (C) Clinical relevance of co-interventions on relapse, round 2.

also stands out as a concern for surgeons from the participating countries. Even though infection is a widely studied outcome in orthognathic surgery, research has mainly focused on pharmacological management²⁴, and it continues to be of constant interest to the consulted professionals, given the impact that infections have on the

perception of the results of the surgery and the patient's postoperative quality of life .

This study has several strengths. First, the Delphi technique was used, which is a reliable method for assessing evidence gaps and achieving consensus among a panel of clinicians. Second, the findings revealed a high level of

agreement among participants, and the retention rate was high (74%), suggesting that the responses were well-focused and grounded in the collective experience and knowledge of the maxillofacial surgery community, providing confidence in the results. Moreover, according to the methodological standards established in the Delphi

Table 3. Clinically relevant evidence gaps^a.

#	Evidence gap	Mean	SD
1	To compare the number of osteosynthesis plates used in relapse	4.20	0.96
2	To evaluate tranexamic acid in anaesthetic induction in blood loss	4.18	0.81
3	To assess the efficacy of induced hypotension in blood loss	4.05	1.26
4	To evaluate prior local anaesthetic infiltration in blood loss	3.95	0.96
5	To determine muscle deprogramming in relapse	3.95	1.13
6	To assess postoperative intermaxillary fixation with elastics in relapse	3.93	1.04
7	To compare conventional orthognathic surgery vs minimally invasive technique in infection	3.91	1.12
8	To assess the use of bone grafting on relapse	3.85	0.99
9	To compare the use of bicortical vs monocortical osteosynthesis on relapse	3.83	1.01
10	To compare single and multilayer closure of the wound in infection	3.75	1.13
11	To assess the efficacy of hybrid fixation on relapse	3.72	1.04
12	To evaluate the effect of thromboprophylaxis on blood loss	3.64	1.17
13	Temperature of the saline irrigation solution used in blood loss	3.63	1.14
14	To assess the use and duration of postoperative intermaxillary fixation in relapse	3.61	1.15
15	To determine the efficacy of piezoelectric devices on blood loss	3.51	1.16

SD, standard deviation.

^aA higher score represents higher clinical relevance; maximum score 5 .

Table 4. Intra-class correlation coefficient for repeated questions in both rounds.

Evidence gaps repeated in both rounds	Round 1 Mean (SD) score	Round 2 Mean (SD) score	Kappa value	P-value
Resorbable vs titanium fixation on infection	3.05 (1.16)	3.32 (1.27)	0.43	0.023
Efficacy of piezoelectric devices on infection	3.11 (1.51)	3.23 (1.21)	0.30	0.10
Rigid vs wire fixation on relapse	3.36 (1.43)	3.00 (1.66)	0.50	0.012

methods literature, the number of participants who completed both parts of the research is statistically robust¹⁵. Indeed, numerous previous Delphi studies with fewer participants have been published in well-rated, high impact factor journals, ensuring significant and reliable results^{15,25-30}. Finally, the study builds on a recent mapping review of orthognathic surgery, ensuring objective selection criteria encompassing all relevant literature.

However, this study also has some limitations. First, the nationality of the participants was not equally distributed, as most were from South America (68%). This may have implications for the generalizability of the results, as there may be cultural and regional variations in the practice of orthognathic surgery that were not fully captured by the participant panel. Additionally, the sample size of participants from other regions may have needed to be greater to provide a representative perspective. Therefore, the potential evidence gaps identified should be interpreted with caution, as they may reflect regional practices and concerns rather than universally applicable issues. It is important to note the predominance of younger, less experienced surgeons in hospital and academic settings within the dataset.

This demographic bias may influence the interpretation of the findings and warrants careful consideration in the broader context of this research. While the potential impact of a more diverse cohort of surgeons is recognized, the methodological approach and the systematic extraction of evidence gaps strengthen the validity and clinical relevance of the findings. Finally, the study may be limited by the use of the Delphi technique, as it is a subjective process that can be influenced by the opinions and biases of the participants.

The findings of this Delphi study may have meaningful implications for future research and clinical practice in orthognathic surgery. This study provides a valuable guide for future investigations by identifying and prioritizing potentially clinically relevant evidence gaps. The evidence gaps identified in this study, which focus on blood loss, infection, and relapse, may allow researchers and clinicians to direct future investigations towards critical areas of concern. By addressing these potential gaps in knowledge and developing more effective clinical decision-making tools, patient outcomes in orthognathic surgery will ultimately improve and this critical field will continue to progress.

Ethical approval

Not applicable.

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None.

Competing interests

None.

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Patient consent

Obtained.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at [doi:10.1016/j.ijom.2024.11.001](https://doi.org/10.1016/j.ijom.2024.11.001).

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