Evidence gaps in orthognathic surgery, a Delphi study protocol.

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ABSTRACT

Aim: To assess the research gaps identified in a recent mapping review of orthognathic surgery through their evaluation by clinical experts, leading to a clinically relevant list of research gaps. This will guide future investigations of the topic, focusing on the outcomes of blood loss, infection, and relapse.

Methods: The Delphi technique will be used to appraise the identified research gaps. The expert panel will include maxillofacial surgeons who regularly perform orthognathic surgery. Potential participants will be identified through various methods, including contact information from articles in the mapping review, nominations from peers, and social media platforms. Two rounds of surveys will be undertaken with Likert-type and open-ended questions to assess the clinical relevance of research gaps. For the second round, participants will receive a report of the results of the first round. Questions will be modified depending on the answers obtained in the first round. A consensus of 60% will be considered valid.

Conclusions: Through this Delphi study, in a collaborative effort between researchers and clinical experts, a comprehensive understanding of the clinical relevance of research gaps in orthognathic surgery will be achieved. The outcomes will guide future investigations, ultimately improving the outcomes and practices in this field.

KEY WORDS:
Delphi study; Orthognathic surgery; Evidence gaps; Mapping review; Research gaps; Maxillofacial surgery.

INTRODUCTION

Orthognathic surgery (OS) is frequently used to treat dentofacial deformities that affect 20% of the population, such as skeletal discrepancies, asymmetries, airway dysfunctions, speech impairments, and temporomandibular disorders. There has been an increase in the frequency of OS performed each year, reaching a total of 8755 OSs performed in the United States in 2007, concomitantly leading to an increase in the production of scientific literature on the subject. Therefore, by complementing the available literature with clinical appraisal, a thorough, clinically relevant, and pertinent list of research gaps will be exposed to help guide future investigations in orthognathic surgery.

METHODS

Justification for study design

This study will use the Delphi technique. We have chosen this design as it is the most appropriate to appraise research gaps identified in a mapping review of orthognathic surgery, consequently establishing the most essential research gaps in the literature assessed by clinicians, and guiding future investigations.

Research steering group

A research steering group will be formed to undertake this research. They will be responsible for preparing and circulating the content of the Delphi rounds. It will comprise investigators with backgrounds in general dentistry, oral surgery, maxillofacial surgery, and research methodology. The research steering group will not participate in the surveys; rather, they will supervise and monitor the process.

Selection and identification of the expert panel

Potential participants must be maxillofacial surgeons who perform orthognathic surgery in their daily practice. They will be identified by the following methods:

1. Extraction of contact information of corresponding authors of articles related to the topic and their institutions.
2. Nomination from peers and colleagues within the field.
4. Contact information from articles in the mapping review.

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included in mapping review.
2. Nomination by identified peers.
3. Social media (LinkedIn).
Participants will be excluded if they have insufficient experience in the field (less than one year of experience or more than one year of not performing orthognathic surgery), or cannot commit to being available for the entire process. There will be no age, country, or gender restrictions.

**Recruitment**
Individuals identified will be sent a personalized letter of invitation via email (SM1), including a user-friendly information poster (Figure 1) and the study protocol. See figure 2 for details. Figure 1. Information poster

**Background**
A recent mapping review revealed a series of research gaps that should be addressed to improve the outcomes of blood loss, infection, and relapse in orthognathic surgery (10). Yet, a consensus on their clinical relevance is crucial to guide future pertinent research.

**Objectives**

1. To appraise the identified research gaps by clinical experts in OS.
2. To develop a thorough, clinically relevant, pertinent list of research gaps in OS.

**Steps**

1. **Round 1** Participants respond to survey on clinical relevance of research gaps
   Duration: 5 minutes
2. **Results analysis** Analytic team analyzes, summarizes, and shares results with participants
3. **Round 2** Participants respond to survey
   Duration: 5 minutes
4. **List of evidence gaps** A final list of clinically relevant research gaps in OS is developed

**Participants involvement**

What will be your requirements and benefits as participant?
- **Assignment** Review 2 rounds of quick questions to assess clinical relevance of research gaps
- **Time required** 3-5 minutes each round.

Benefits
Labeled in the acknowledgments of future publications of the results of this study.

Contribute to guide future research, thus, giving patients better healthcare.

Figure 1. Information poster

**Survey development**

Questions will be developed by the primary investigator (JB), based on the evidence gaps identified in a previous study (5,6). Subsequently, they will be piloted with the research steering group, then adapted according to their feedback.

**Definition of consensus**
We will opt for a 60% consensus for our results to be valid, following the suggestion of some authors (10-12).

**Enhancing response rate**
We will use several methods to enhance the response rate. Initially, participants will be invited to participate via personalized email, explaining the objectives and importance of the study. They will be presented with the survey in the same email, to decrease drop-out. Reminders will be sent via email to participants who have not answered the survey, with a frequency of 7 days. Participants will also be offered a participation certificate and their acknowledgment in future publications with Delphi results if they participate in both rounds.

**Rounds**

Recent evidence appears to show that the preferred number of rounds is either two or three (11,13,14). In our study, two rounds will be undertaken, allowing participants to have feedback and revise previous responses, reducing the number of attritions. If consensus is below 60% for a specific question, results will not be considered valid.

**First round**

Round one questionnaire will consist of 5-point Likert scale questions, where participants must select the clinical relevance of the identified evidence gaps in orthognathic surgery. These evidence gaps will be extracted from a previous mapping review and categorized depending on the outcome in question: blood loss, infection, and relapse. Also, a final open-ended question will ask participants to point out any evidence gap not mentioned in the previous questions.

**Second round**

For the second round, past questions will be modified depending on the answers obtained. Questions with low clinical relevance and high agreement (above 60%) between participants will be eliminated for the second round. Questions with low agreement (below 60%), will be repeated for the second round. Evidence gaps proposed by participants...
The category frequencies. Moreover, the media and standard deviation will be calculated for each question using the Jamovi software, by converting the Likert scale as a continuous variable. Weighted Kappa statistics will be calculated for the level of agreement within-subject and between participants. For a visually friendly analysis of the results, a graph separated into four quadrants comparing relevance (x-axis) and agreement (y-axis) will be developed. A post hoc Mann-Whitney U test will be performed to check for non-response bias. Finally, questions defined as relevant, including the categories “question is likely to be relevant” and “question is highly relevant”, with a consensus between participants of 60% or higher, will be listed as evidence gaps that should be addressed in future research.

**CONCLUSIONS**

Through this collaborative Delphi study, involving both researchers and clinical experts, we aim to gain a comprehensive understanding of the existing research gaps within the field of orthognathic surgery by assessing their clinical relevance with experts in the field. The outcomes of this study have the potential to drive positive change by informing and guiding the direction of future investigation, leading to improved surgical outcomes, enhanced surgical techniques, and more effective clinical decision-making.

**CONFLICT OF INTEREST AND SOURCE OF FUNDING**

This project does not receive external finance and authors declare no conflict of interest.

**AUTHOR INFORMATION**

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**References**