Surgery-first orthognathic approach: A “scoping review” for mapping outcomes and plausible recommendations to develop core outcome sets

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ABSTRACT

Aims and Objectives: The aim of this scoping review was to identify the type of outcomes measured in surgery-first orthognathic approach (SFOA). The objectives were to classify the outcomes into predetermined domains and explore the degree of representation of each domain. Furthermore, to identify which domains are over- or under-represented and determine whether the findings of this scoping review could be employed to provide a template for core outcome sets (COS). Five outcomes were identified, and all the research pertinent to SFOA were assigned to these outcomes.

Materials and Methods: Electronic databases and additional records were searched from January 2009 to March 2019 to source the data, and 525 records were identified.

Results: The initial database and additional search resulted in 525 records, of which 54 potentially relevant articles were retrieved in full. 35 studies met the selection criteria following screening and were included in the scoping review with the results of the search depicted in the preferred reporting items for systematic reviews and meta-analyses. Domains such as morphological features or changes in maxillofacial skeleton and occlusion (n = 25, 71.42%) and psychosocial well-being including quality of life outcome (n = 8, 22.85%) were well represented while functional status (n = 1, 2.85%), health resource utilization (n = 0), and adverse effects (n = 1, 2.85 %) were under-represented.

Conclusions: Limited research on SFOA precludes development of COS. However, future SFOA clinical trials should consider underrepresented outcome domains to address the SFOA treatment modality comprehensively.

Keywords: Surgery-first orthognathic approach, Core outcome sets, Scoping review

INTRODUCTION

A “scoping review” is a relatively new but increasingly becoming a popular research synthesizing approach. A scoping review plays an important role in mapping an existing literature on a subject or a topic or a field of interest that is not extensively reviewed or is of a complex in nature.[1-3] The basic premise of scoping review is to establish a groundwork on which an extensive research, such as full systematic review, could be carried out.[4] Furthermore, scoping review provides a robust and transparent method to identify research gaps in the existing literature pertaining to the specific topic and act as a preliminary step to a more comprehensive systematic review.[5,6] Surgery-first
orthognathic approach (SFOA) is an emerging sub-discipline of orthodontics-orthognathic jaw surgery domain whose roots can be traced back to 1960s, when Skaggs JE promulgated that, to achieve adequate interarch relationship, orthognathic jaw surgery should commence before orthodontic treatment.[9] Since then, a surfeit of SFOA treatment protocols is aimed at (1) reduction of total treatment time, (2) accelerating post-operative orthodontic tooth movement, (3) improving patient satisfaction rate, and (4) enhancing health-related quality of life (HRQoL).[8-14,15] Recent review on SFOA outcome shows that the researchers have placed emphasis on assessing morphological features of maxillofacial skeleton and occlusion, reduction in total treatment time, and patient or practitioners satisfaction level. However, there is no uniform consensus on which outcomes of SFOA needs to be analyzed to identify the potential benefits and pitfalls of SFOA or whether there is an impetus to develop an overall core outcome sets (COS) for clinical trials of SFOA to overcome or significantly reduce heterogeneity amongst SFOA studies and minimize outcome reporting bias. Development of COS is one such robust tool that can aid to standardize outcomes for clinical trials and systematic reviews to overcome the aforementioned limitations.[16] Outcome measures in rheumatology and harmonizing outcome measures for eczema are some of the initiatives that are undertaken, in medicine, to improve endpoint outcome measurement through a data-driven, iterative alignment process.[17-19]

**MATERIALS AND METHODS**

A scoping review of the literature was carried out with the analytic framework using the methodology described by Arksey and O’Malley.[5] The literature search, scope, and reporting of findings were focused with the following stages:

- **Framework Stage 1:** Identifying the research question.
- **Framework Stage 2:** Identifying relevant studies.
- **Framework Stage 3:** Study selection.
- **Framework Stage 4:** Charting the data.
- **Framework Stage 5:** Collating, summarizing, and reporting the results.

**Framework Stage 1: identifying the research question**

We formulated our primary research question: What are the types of outcomes measured in SFOA? This scoping review was undertaken with the following aims: (1) to identify the type of outcomes measured in SFOA; (2) to categorize the outcomes into predetermined domains; (3) to explore the extent of representation of each domain to identify which domains have been over- or under-represented; and (4) to determine whether the findings of this scoping review could be employed in providing a template for COS that should be measured in all future clinical trials involving SFOA.

**Framework Stage 2: identifying relevant studies, and framework Stage 3: study selection**

Reviews suitable for the central research question of this scoping review was carried out by adopting a comprehensive search strategy that involved searching different sources[5] such as, electronic databases, reference lists, manual searching of key journals, existing networks, relevant organizations, and conferences. The scoping reviews study selection criteria are enumerated in Table 1.

Electronic databases: The following electronic databases were searched from January 2009 to March 2019 without restrictions to language. The start date of 2009 was chosen because the case report by Nagasaka et al.[13] published in 2009 is often cited as the first clinical application of SFOA,[7] and subsequently, numerous research papers have been published with reference to surgery-first protocol.[8-11,20]

PubMed (www.ncbi.nlm.nih.gov/pubmed/), Cochrane Library Databases, MEDLINE via OVID, EMBASE via OVID, Literatura Latino Americana em Ciências da Saúde, ClinicalTrials.gov., Australian New Zealand clinical trials registry (http://www.anzctr.org.au/), Australian clinical trials (www.australianclinicaltrials.gov.au/search/node/), and Google Scholar were searched with following term sequence: (“surgery first OR surgery early”) AND (“orthognathic surgery”) OR (“surgery first”) AND (“orthodontics” [MeSH]). The term “modified surgery” was excluded from the search strategy and further during the full texts article assessment for eligibility, as it did not satisfy the true meaning of performing surgery-first without orthodontics or minimal orthodontics (i.e. placing only brackets and wires immediately or 1 month before orthognathic surgery).

**Framework Stage 4: charting the data**

The data extracted from the eligible studies were recorded with information of the first author, year of publication, and study characteristics. The specific information of the eligible studies was charted according to the PICO guidelines with enumeration of study design, participants, intervention, comparison, outcome (primary and secondary), method of measurement, and also outcome domain [Table 2]. Studies that were excluded from the review are shown in Table 3 with reasons for exclusion.

The outcomes were further categorized into the following domains using the method described by Sinha et al.[67] and Tsichlaki et al.[19]

1. Morphological features or changes in maxillofacial skeleton and occlusion.
2. Psychosocial well-being including quality of life outcome.
3. Functional status.
5. Adverse effects of SFOA.

RESULTS

Framework Stage 5: collating, summarizing and reporting the results

The initial database and additional search resulted in 525 records, of which 54 potentially relevant articles were retrieved in full. 35 studies met the selection criteria following screening and were included in the scoping review with the results of the search depicted in the preferred reporting items for systematic reviews and meta-analyses flow chart [Figure 1]. The studies included in the review are shown in Table 2, and excluded studies with reasons are enumerated in Table 3. Morphological features and oral HRQoL were evaluated in the majority of studies. Morphological features or changes in maxillofacial skeleton and occlusion ($n = 25, 71.42\%$) and psychosocial well-being including quality of life outcome ($n = 8, 22.85\%$) were well represented with under-representation of functional status ($n = 1, 2.85\%$), health resource utilization ($n = 0$), and adverse effects ($n = 1, 2.85\%$) [Figure 2]. No randomized control trials (RCTs) were identified with majority of the studies being retrospective in nature.

DISCUSSION

This is the first of its kind scoping review of studies that address selection of outcomes for use in SFOA clinical trials. Five outcome domains were identified, and the domains were examined for their degree of representation in the available literature. Also, to determine whether any recommendations could be made for the development of COS. Overall, the scoping review shows that SFOA evidence is in its formative stage with much emphasis placed on the assessment of morphological features and in determining the quality of life.

Clinical trials are only as credible as their outcomes. Core outcome set is an agreed, standardized group of outcomes to be reported by all the trials within the research field. COS provides a template for clinical trials such that the future clinical trials that follow the COS will have increased homogeneity, facilitate meta-analysis, reduce the risk of reporting bias, and involve a wide range of stakeholders (e.g., patients, caregivers, and health-care providers). Further, the tenets of COS state that, if no satisfactory core outcome set is found, and there is a need to develop one, then, a “scoping review” could be used as a conduit in establishing an informed base to conduct meaningful qualitative research (e.g., systematic research). Further, the scoping review assists in identifying the potential outcomes and ranks the outcomes to determine a “core” set. Although this scoping review might be unable to recommend standard COS, this scoping review has identified five outcome domains that are measured in the existing literature pertaining to SFOA. Among the 5 identified outcome domains, 2 are over-represented and 3 are under-represented [Figure 2].

![Figure 1: Preferred reporting items for systematic reviews and meta-analyses flow chart.](image-url)

<table>
<thead>
<tr>
<th>Table 1: Scoping reviews study selection criteria.</th>
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<tbody>
<tr>
<td><strong>Inclusion criteria</strong></td>
</tr>
<tr>
<td>All types of studies pertaining to SFOA</td>
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<tr>
<td>All age groups, non-syndromic individuals with skeletal maxillofacial deformity</td>
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<td>Individuals treated with minimum or no pre-surgical orthodontic interventions</td>
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<td>Any types of comparison with conventional orthognathic jaw surgery</td>
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<td>All types of reported outcomes</td>
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SFOA: surgery-first orthognathic approach
Table 2: Studies selected for the scoping review.

<table>
<thead>
<tr>
<th>Authors/Year</th>
<th>Study design</th>
<th>Participant</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Outcome primary/secondary</th>
<th>Method of measurement</th>
<th>Outcome domain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liao et al. 2010²¹</td>
<td>Retrospective study</td>
<td>33 pts, Conventional jaw surgery (n, 13; 21.0±4.0 years) and SFOA (n, 20; 23.0±4.0 years)</td>
<td>SFOA in skeletal class III open bite</td>
<td>Conventional surgery in skeletal class III open bite</td>
<td>Facial aesthetics, occlusion, stability, and efficiency</td>
<td>Lateral cephalograph, peer assessment rating</td>
<td>Morphological features</td>
</tr>
<tr>
<td>Back et al. 2010²⁹</td>
<td>Prospective study</td>
<td>11 pts, SFOA (n, 20; 22.95±2.54 years)</td>
<td>SFOA in skeletal class III</td>
<td>Surgical movement and postoperative orthodontic treatment</td>
<td></td>
<td>Lateral cephalographs</td>
<td>Morphological features</td>
</tr>
<tr>
<td>Wang et al. 2010²²</td>
<td>Case-control retrospective study</td>
<td>36 pts: 18 conventional jaw (23.3±4.2 years) and 18 surgery-first (22.3±3.8 years)</td>
<td>Patients with skeletal Class III undergoing SFOA</td>
<td>Conventional surgery, bimaxillary surgery</td>
<td>Changes of transverse dimension in both dental arches</td>
<td>Cephalometric measurements</td>
<td>Morphological features</td>
</tr>
<tr>
<td>Ko et al. 2011²³</td>
<td>Retrospective cohort study</td>
<td>53 pts, Conventional jaw surgery (n, 35; 22.0±4.1 years) and SFOA (n, 18; 24.6±4.9 years)</td>
<td>SFOA in skeletal class III dentofacial deformities</td>
<td>SFOA in skeletal class III dentofacial deformities</td>
<td>Changes of transverse dimension in both dental arches</td>
<td>Lateral cephalographs</td>
<td>Morphological features</td>
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<tr>
<td>Liou et al. 2011²⁰</td>
<td>Prospective</td>
<td>22 adult pts</td>
<td>SFOA in skeletal dentofacial deformities</td>
<td>Postoperative changes in bone metabolism, tooth mobility</td>
<td>Periotest method, immunoassay</td>
<td>Periotest method, immunoassay</td>
<td>Morphological features</td>
</tr>
<tr>
<td>Ko et al. 2013²⁴</td>
<td>Retrospective cohort study</td>
<td>45 pts, Conventional jaw surgery (n, 25; 25.1±6.8 years) and SFOA (n, 25; 25.4±6.4 years)</td>
<td>SFOA in skeletal class III dentofacial deformities</td>
<td>Groups based on the amount of horizontal relapse</td>
<td>Parameters identification related to skeletal stability after SFOA</td>
<td>Lateral cephalograph cephalometric measurements</td>
<td>Morphological features</td>
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<tr>
<td>Kim et al. 2014²⁵</td>
<td>Retrospective cohort study</td>
<td>61 pts, Conventional jaw surgery (n, 38; 21.6±3.5 years) and SFOA (n, 23; 23.0±6.3 years)</td>
<td>SFOA in skeletal class III dentofacial deformities</td>
<td>Conventional surgery</td>
<td>Stability of mandibular setback surgery</td>
<td>Lateral cephalograph cephalometric measurements</td>
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<td>Hernández-Alfaro et al. 2014²⁰</td>
<td>Prospective</td>
<td>45 pts: SFOA</td>
<td>SFOA in class II, III and asymmetry</td>
<td>Specific orthodontic and surgical protocol</td>
<td>VAS on patient satisfaction and orthodontists on selected treatment approach</td>
<td>Cephalograms generated from cone-beam computed tomography</td>
<td>Morphological features</td>
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<tr>
<td>Lee et al. 2014²⁶</td>
<td>Retrospective</td>
<td>40 pts (22.6±4.0 years)</td>
<td>SFOA in skeletal class III dentofacial deformities</td>
<td>Postsurgical skeletal changes</td>
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<td>Authors/Year</td>
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<td>Park et al./2014[27]</td>
<td>Retrospective</td>
<td>60 pts: 36 conventional jaw surgery (22.4±4.4 years) and 24 SFOA (22.4±4.6 years)</td>
<td>SFOA class III malocclusion Conventional surgery, bimaxillary surgery</td>
<td>Dental change</td>
<td>Lateral cephalograph</td>
<td>Morphological features</td>
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<tr>
<td>Choi et al./2015[20]</td>
<td>Retrospective</td>
<td>n, 35 pts; 24.7 years</td>
<td>SFOA clockwise MMC skeletal class III deformities</td>
<td>Posterior pharyngeal airway change</td>
<td>Lateral cephalograph cephalometric measurements</td>
<td>Morphological features</td>
<td></td>
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<tr>
<td>Choi et al./2015[29]</td>
<td>Case–control prospective</td>
<td>56 pts (average age, 22.4 years: conventional jaw surgery (n, 24) and SFOA (n, 32)</td>
<td>Surgery-first approaches for patients with skeletal class III dentofacial deformity Conventional surgery</td>
<td>Reliability of a surgery-first orthognathic approach without presurgical orthodontic treatment</td>
<td>Dental model, Cephalometric assessment</td>
<td>Morphological features</td>
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<tr>
<td>Park et al./2015[31]</td>
<td>Case-control retrospective</td>
<td>40 pts: 20 conventional jaw surgery (25.25±3.77 years) and 20 SFOA (22.60±5.39 years)</td>
<td>SFOA bimaxillary surgery Conventional surgery, bimaxillary surgery</td>
<td>Postoperative stability/relapse rate</td>
<td>Cephalometric radiographs</td>
<td>Morphological features</td>
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<td>Park et al./2015[32]</td>
<td>Retrospective</td>
<td>26 pts, Conventional jaw surgery (n, 15; 25.0±3.2 years) and SFOA (n, 11; 26.2±4.4 years)</td>
<td>SFOA in skeletal class III dentofacial deformities Conventional surgery</td>
<td>QoL</td>
<td>OQLQ</td>
<td>Oral health-related QoL</td>
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<tr>
<td>Rhee et al./2015[33]</td>
<td>Retrospective</td>
<td>34 patients (23 men, 11 women; mean age, 26.2±6.6 years)</td>
<td>SFOA in skeletal class III dentofacial deformities</td>
<td>Skeletal and dental changes</td>
<td>Cone-beam computed tomography</td>
<td>Morphological features</td>
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<td>Huang et al./2016</td>
<td>Prospective</td>
<td>50 pts: conventional jaw surgery (24.2±5.8 years) and SFOA (25.2±4.2 years)</td>
<td>SFOA class III malocclusion</td>
<td>Two questionnaires: OHRQoL related QoL, and satisfaction between surgery-first and orthodontic-first orthognathic surgery patients</td>
<td>Oral health-related QoL and satisfaction between surgery-first and orthodontic-first orthognathic surgery patients</td>
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<td>OHRQoL</td>
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<td>Choi et al./2016</td>
<td>Retrospective cohort</td>
<td>37 pts, Conventional jaw surgery (n, 17; 20.8±0.9 years) and SFOA (n, 20; 21.1±0.7 years)</td>
<td>SFOA in skeletal class III dentofacial deformities using IVRO</td>
<td>Conventional surgery using IVRO</td>
<td>Postoperative skeletal and dental changes</td>
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<td>Cephalometric measurements</td>
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<td>Wang et al./2016</td>
<td>Retrospective cohort</td>
<td>55 pts: conventional jaw surgery (n, 29; 22.1±3.8 years) and SFOA (n, 26; 21.6±3.3 years)</td>
<td>Bilateral sagittal split ramus osteotomy for mandibular prognathism using OFA</td>
<td>Conventional surgery</td>
<td>Compare the postoperative changes of the condylar position after mandibular setback surgery</td>
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<td>3D CT images</td>
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<td>Akamatsu et al./2016</td>
<td>Retrospective cohort</td>
<td>38 pts (14 SFOA and 24 conventional surgery)</td>
<td>SFOA in skeletal class III dentofacial deformities</td>
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<td>Postsurgical stability</td>
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<td>Jeong et al./2017</td>
<td>Prospective</td>
<td>52 conventional jaw surgery (29.7±2.2 years) and 45 pts in SFOA</td>
<td>SFOA bimaxillary</td>
<td>Conventional surgery, bimaxillary surgery</td>
<td>Postoperative skeletal and dental changes</td>
<td>Morphological features</td>
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<td>Feu et al./2017</td>
<td>Prospective</td>
<td>16 pts, Conventional jaw surgery (n, 8; 26.8±7.1 years) and SFOA (n, 8; 22.9±5.4 years)</td>
<td>SFOA in skeletal class III dentofacial deformities</td>
<td>Conventional surgery</td>
<td>OQLQ and the OHIP -short version (OHIP -14)</td>
<td>Oral health-related QoL</td>
<td>OHIP -14</td>
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<td>Wang et al./2017</td>
<td>Longitudinal prospective cohort</td>
<td>50 pts, Conventional jaw surgery (n, 25; 25.1±4.8 years) and SFOA (n, 25; 25.1±4.6 years)</td>
<td>SFOA in skeletal malocclusion</td>
<td>Conventional surgery</td>
<td>OHRQoL</td>
<td>Oral health-related QoL</td>
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<td>Pelo et al./2017</td>
<td>Retrospective cohort</td>
<td>39 pts (10.2±4.3 years)</td>
<td>SFOA in skeletal malocclusion</td>
<td>Conventional surgery</td>
<td>Level of satisfaction and QoL</td>
<td>Oral health-related QoL</td>
<td>OHIP, orthognathic QoL, OQLQ-22</td>
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<td>Zingler et al/2017</td>
<td>Prospective cohort</td>
<td>9 pts (26.7 years)</td>
<td>SFOA in skeletal class III and Class II dentofacial deformities</td>
<td>Psychological and biological changes in SFOA</td>
<td>OQLQ questionnaire, sense of coherence SO20 and longitudinal day-to-day, crevicular fluid by bead-based multiplex assays</td>
<td>Oral health-related QoL assessment</td>
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<td>Hernandez-Alfaro et al/2017</td>
<td>Prospective</td>
<td>8 pts (mean age 26.3 years)</td>
<td>Surgery-first class III patients</td>
<td>Surgery-early class III patients</td>
<td>Complications, final outcome</td>
<td>Plaque index, PPD, gingival recession, bleeding on probing, and CAL satisfaction with treatment (VAS)</td>
<td>Effects of Tx/Functional status/QoL</td>
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<tr>
<td>Jeong et al/2018</td>
<td>Retrospective</td>
<td>104 Patients (23.3 years, mean age)</td>
<td>SFOA in skeletal class III dentofacial deformities</td>
<td>Conventional surgery</td>
<td>Long-term outcomes of vertical skeletal stability</td>
<td>Lateral cephalograph cephalometric measurements</td>
<td>Morphological features</td>
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<tr>
<td>Holzinger et al/2018</td>
<td>Prospective</td>
<td>16 patients aged 18–37 years (8 female, 8 male, mean age 26 years)</td>
<td>SFOA in skeletal malocclusion</td>
<td></td>
<td>Quantitative accuracy assessment</td>
<td>CT scan</td>
<td>Morphological features</td>
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<tr>
<td>Guo et al/2018</td>
<td>Retrospective cohort</td>
<td>Symmetry group (n, 17; 22.9±4.4 years) and asymmetry group (n, 12; 20.0±52.2 years)</td>
<td>SFOA mandibular prognathism with asymmetry</td>
<td>SFOA mandibular prognathism without facial asymmetry</td>
<td>Corrective outcomes and transverse stability</td>
<td>CT scan</td>
<td>Morphological features</td>
</tr>
<tr>
<td>Lian et al/2018</td>
<td>Retrospective</td>
<td>n, 37, females 24.0±4.9 years</td>
<td>2-step group in SFOA</td>
<td>3-step group in SFOA</td>
<td>Stability, and treatment efficiency</td>
<td>Lateral cephalograph cephalometric measurements</td>
<td>Morphological features</td>
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<tr>
<td>Liao et al/2018</td>
<td>Retrospective cohort</td>
<td>n, 41, 24.0±4.9 years</td>
<td>SFOA in Skeletal Class III facial asymmetry</td>
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<td>Long-term outcomes of bimaxillary surgery</td>
<td>Photographs and study models</td>
<td>Morphological features</td>
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Table 2: Continued

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<th>Authors/Year</th>
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<th>Outcome primary/ Secondary</th>
<th>Method of measurement</th>
<th>Outcome domain</th>
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</thead>
<tbody>
<tr>
<td>Brucoli et al/2018</td>
<td>Prospective</td>
<td>33 pts, Conventional jaw surgery ($n$, 25; 25.0±5.5 years) and SFOA ($n$, 8; 35.6±13.4 years)</td>
<td>SFOA in skeletal class III dentofacial deformities</td>
<td>Conventional surgery</td>
<td>Oral health impact profile questionnaire, TCI, RSA, Italian validation of the PIDAQ, BDIII, the RSES</td>
<td>Psychosocial well-being, self-esteem, anxiety, and QoL</td>
<td>Oral health-related QoL</td>
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<tr>
<td>Liao and Lo/2018</td>
<td></td>
<td>$n$, 53 ($n$, 39 with genioplasty and $n$, 14 without genioplasty. Mean age, 25±6 years)</td>
<td>Skeletal Class III patients surgery-first approach</td>
<td>Study models and computer-aided surgical simulation</td>
<td>Guidelines, characteristics, and accuracy</td>
<td>Guideline features</td>
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<tr>
<td>Watanabe et al/2019</td>
<td>Retrospective study</td>
<td>5 patients (19–26 years) with facial asymmetry in hemifacial microsomia</td>
<td>Surgery-first approach combined with mandibular distraction</td>
<td>Photographs</td>
<td>Morphological features</td>
<td></td>
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</tbody>
</table>

Furthermore, this scoping review did not identify any RCT within the SFOA research, indicating that more pertinent research encompassing RCTs are required to arrive at formulating COS. However, the fact that many prospective studies are being carried out is itself promising in nature, and in the future, this will allow researchers and readers to make best use of the available reported trails to formulate the research question.

The shortcomings of this scoping review are predetermined outcomes and exclusion of studies having sample size <5. With outcomes being predetermined, this could have precluded from exploring other domains. Nonetheless, this is the first of its kind scoping review intended for mapping outcomes and provides plausible recommendations to develop COS for SFOA, and hence, it was essential to identify the more common outcomes and interventions. The decision to exclude case reports and studies involving less than five cases was deliberate to involve more meaningful data which could assist in identifying the more common outcome domains.
CONCLUSIONS

The scoping review shows that limited research has been carried out in SFOA. The outcome domains that are over-represented are morphological features or changes in maxillofacial skeleton and occlusion and psychosocial well-being including quality of life outcome. However, outcomes such as functional status, health resource utilization, and adverse effects of SOFA were under-represented. Future SFOA clinical trials should consider these aforementioned under-represented outcome domains to address the SFOA treatment modality in a comprehensive way to better understand the treatment approach and enhance the outcome consistency.

Declaration of patient consent

Patient's consent not required as there are no patients in the study.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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