



Systematic Review

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

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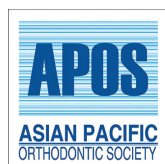
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ABSTRACT

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

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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.^[7] 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 Tsihaki *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.

4. Health resource utilization.
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

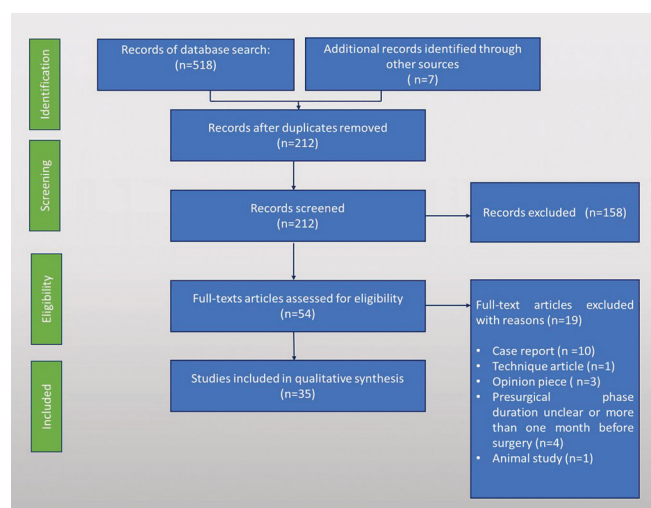


Figure 1: Preferred reporting items for systematic reviews and meta-analyses flow chart.

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.^[17] Core outcome set is an agreed, standardized group of outcomes to be reported by all the trials within the research field.^[68] 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.^[69] 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].

Table 1: Scoping reviews study selection criteria.

Inclusion criteria	Exclusion criteria
All types of studies pertaining to SFOA	Case reports and studies with less than five participants
All age groups, non-syndromic individuals with skeletal maxillofacial deformity	Personal opinions
Individuals treated with minimum or no pre-surgical orthodontic interventions	Non-human study
Any types of comparison with conventional orthognathic jaw surgery	Modified surgery with no surgery done immediately or within 1 month after orthodontic treatment
All types of reported outcomes	Technique article
SFOA: surgery-first orthognathic approach	

Table 2: Studies selected for the scoping review.

Authors/Year	Study design	Participant	Intervention	Comparison	Outcome primary/Secondary	Method of measurement	Outcome domain
Liao et al./2010 ^[21]	Retrospective study	33 pts, Conventional jaw surgery (n, 13; 21.0±4.0 years) and SFOA (n, 20; 23.0±4.0 years)	SFOA in skeletal class III open bite	Conventional surgery in skeletal class III open bite	Facial aesthetics, occlusion, stability, and efficiency	Lateral cephalograph, peer assessment rating	Morphological features
Baek et al./2010 ^[8]	Prospective study	11 pts, SFOA (n, 20; 22.95±2.54 years)	SFOA in skeletal class III		Surgical movement and postoperative orthodontic treatment	Lateral cephalographs	Morphological features
Wang et al./2010 ^[22]	Case-control retrospective	36 pts: 18 conventional jaw (23.3±4.2 years) and 18 surgery-first (22.3±3.8 years)	Patients with skeletal Class III undergoing SFOA	Conventional surgery, bimaxillary surgery	Changes of transverse dimension in both dental arches	Cephalometric measurements	Morphological features
Ko et al./2011 ^[23]	Retrospective cohort study	53 pts, Conventional jaw surgery (n, 35; 22.0±4.1 years) and SFOA (n, 18; 24.6±4.9 years)	SFOA in skeletal class III dentofacial deformities	MC approach	Dental and skeletal changes, postsurgical dental and skeletal stability, and treatment efficacy	Lateral cephalographs	Morphological features and treatment efficacy
Liou et al./2011 ^[20]	Prospective	22 adult pts	SFOA in skeletal dentofacial deformities		Postoperative changes in bone metabolism, tooth mobility	Periotest method, immunoassay	Morphological features, biomarkers
Ko et al./2013 ^[24]	Retrospective cohort study	45 pts, Conventional jaw surgery (n, 25; 25.1±6.8 years) and SFOA (n, 25; 25.4±6.4 years)	SFOA in skeletal class III dentofacial deformities	Groups based on the amount of horizontal relapse	Parameters related to skeletal stability after SFOA	Lateral cephalograph cephalometric measurements	Morphological features
Kim et al./2014 ^[25]	Retrospective cohort study	61 pts, Conventional jaw surgery (n, 38; 21.6±3.5 years) and SFOA (n, 23; 23.0±6.3 years)	SFOA in skeletal class III dentofacial deformities	Conventional surgery	Stability of mandibular setback surgery	Lateral cephalograph cephalometric measurements	Morphological features
Hernández-Alfaro et al./2014 ^[10]	Prospective	45 pts: SFOA	SFOA in class II, III and asymmetry		Specific orthodontic and surgical protocol	VAS on patient satisfaction and orthodontists on selected treatment approach	SFOA protocol development. Adverse effects of Tx physical consequence
Lee et al./2014 ^[26]	Retrospective	40 pts (22.6±4.0 years)	SFOA in skeletal class III dentofacial deformities		Postsurgical skeletal changes	Cephalograms generated from cone-beam computed tomography	Morphological features

(Contd...)

Authors/Year	Study design	Participant	Intervention	Comparison	Outcome primary/Secondary	Method of measurement	Outcome domain
Kim et al./2014 ^[11]	retrospective	37 pts (23±4 years)	SFO in skeletal class III dentofacial deformities		Postoperative stability using IVRO	Lateral cephalograph	Morphological features
Park et al./2014 ^[27]	Retrospective	60 pts: 36 conventional jaw surgery (22.4±4.4 years) and 24 SFOA (22.4±4.6 years)	SFOA class III malocclusion	Conventional surgery, bimaxillary surgery	Dental change	Lateral cephalograph	Morphological features
Choi et al./2015 ^[28]	Retrospective	n, 35 pts; 24.7 years	SFOA clockwise MMC skeletal class III deformities		Posterior pharyngeal airway change	Lateral cephalograph cephalometric measurements	Morphological features
Choi et al./2015 ^[29]	Case-control prospective	56 pts (average age, 22.4 years: conventional jaw surgery (n, 24) and SFOA (n, 32)	Surgery-first approaches for patients with skeletal class III dentofacial deformity	Conventional surgery	Reliability of a surgery-first orthognathic approach without presurgical orthodontic treatment	Dental model, Cephalometric assessment	Morphological features
Yu et al./2015 ^[30]	Retrospective cohort	50 pts (16–37 years)	Skeletal malocclusions		Report experience with the SFA for skeletal malocclusion		Morphological features
Park et al./2015 ^[31]	Case-control retrospective	40 pts: 20 conventional jaw surgery (25.25±3.77 years) and 20 SFOA (22.60±5.39 years)	SFOA bimaxillary surgery	Conventional surgery, bimaxillary surgery	Postoperative stability/relapse rate	Cephalometric radiographs	Morphological features
Park et al./2015 ^[32]	Retrospective	26 pts, Conventional jaw surgery (n, 15; 25.0±3.2 years) and SFOA (n, 11; 26.2±4.4 years)	SFOA in skeletal class III dentofacial deformities	Conventional surgery	QoL	OQLQ	Oral health-related QoL
Rhee et al./2015 ^[35]	Retrospective	34 patients (23 men, 11 women; mean age, 26.2±6.6 years)	SFOA in skeletal class III dentofacial deformities		Skeletal and dental changes	Cone-beam computed tomography	Morphological features

(Contd...)

Authors/Year	Study design	Participant	Intervention	Comparison	Outcome primary/Secondary	Method of measurement	Outcome domain
Huang et al./2016 ^[34]	Prospective	50 pts: conventional jaw surgery (24.2±5.8 years) and SFOA (25.2±4.2 years)	SFOA class III malocclusion	Conventional surgery, bimaxillary surgery	Oral health related QoL and satisfaction between surgery-first and orthodontic-first orthognathic surgery patients	Two questionnaires: the dental impact on daily living and 14-item oral health impact profile	OHRQoL
Choi et al./2016 ^[35]	Retrospective cohort	37 pts, Conventional jaw surgery (n, 17; 20.8±0.9 years) and SFOA (n, 20; 21.1±0.7 years)	SFOA in skeletal class III dentofacial deformities using IVRO	Conventional surgery using IVRO	Postoperative skeletal and dental changes	Lateral cephalograph cephalometric measurements	Morphological features
Wang et al./2016 ^[36]	Retrospective cohort	55 pts: conventional jaw surgery (n, 29; 22.2±3.8 years) and SFOA (n, 26; 21.6±3.3 years)	Bilateral sagittal split ramus osteotomy for mandibular prognathism using OFA	Conventional surgery	Compare the postoperative changes of the condylar position after mandibular setback surgery	3D CT images	Morphological features
Akamatsu et al./2016 ^[37]	Retrospective cohort	38 pts (14 SFOA and 24 conventional surgery)	SFOA in skeletal class III dentofacial deformities	Conventional surgery	Postsurgical stability	Lateral cephalograph cephalometric measurements	Morphological features
Jeong et al./2017 ^[38]	Prospective	52 conventional jaw surgery (29.7 Average age) and 45 pts in SFOA (23.7 average age)	SFOA in bimaxillary surgery	Conventional surgery, bimaxillary surgery	Postoperative skeletal and dental changes	Lateral cephalograph cephalometric measurements	Morphological features
Feu et al./2017 ^[39]	Prospective	16 pts, Conventional jaw surgery (n, 8; 26.8±7.1 years) and SFOA (n, 8; 22.9±5.4 years)	SFOA in skeletal class III dentofacial deformities	Conventional surgery	OQLQ and the OHIP-short version (OHIP-14)	OHIP-14	Oral health-related QoL
Wang et al./2017 ^[40]	Longitudinal prospective cohort	50 pts, Conventional jaw surgery (n, 25; 25.1±6.8 years) and SFOA (n, 25; 25.4±6.4 years)	SFOA in skeletal class III dentofacial deformities	Conventional surgery	OHRQoL	OHRQoL questionnaire	Oral health-related QoL
Pelo et al./2017 ^[41]	Retrospective cohort	30 pts (30.2±4.3 years)	SFOA in skeletal malocclusion	Conventional surgery	Level of satisfaction and QoL	OHIP, orthognathic QoL questionnaire OQLQ-22	Oral health-related QoL

(Contd...)

Table 2: Continued

Authors/Year	Study design	Participant	Intervention	Comparison	Outcome primary/Secondary	Method of measurement	Outcome domain
Zingler et al./2017 ^[42]	Prospective cohort	9 pts (26.7 years)	SFOA in skeletal class III and Class II dentofacial deformities		Psychological and biological changes in SFOA	OQLQ questionnaire, sense of coherence SOC-29 and longitudinal day-to-day, crevicular fluid by bead-based multiplex assays	Oral health-related QoL biomarkers assessment
Hernandez-Alfaro et al./2017 ^[43]	Prospective	8 pts (mean age 26.3 years)	Surgery-first class III patients	Surgery-early class III patients	Complications, final outcome	Plaque index, PPD, gingival recession, bleeding on probing, and CAL. satisfaction with treatment (VAS)	Effects of Tx/ Functional status/ QoL
Jeong et al./2018 ^[44]	Retrospective	104 Patients (23.3 years, mean age) with SFOA, and 51 with conventional surgery (23.1 years, mean age)	SFOA in skeletal class III dentofacial deformities	Conventional surgery	long-term outcomes of vertical skeletal stability	Lateral cephalograph cephalometric measurements	Morphological features
Holzinger et al./2018 ^[45]	Prospective	16 patients aged 18-37 years (8 female, 8 male, mean age 26 years)	SFOA in skeletal malocclusion		Quantitative accuracy assessment	CT scan	Morphological features
Guo et al./2018 ^[46]	Retrospective cohort	Symmetry group (n, 17; 22.9±4.4 years) and asymmetry group (n, 12; 20.0±52.2 years)	SFOA mandibular prognathism with asymmetry	SFOA mandibular prognathism without facial asymmetry	Corrective outcomes and transverse stability	CT scan	Morphological features
Lian et al./2018 ^[47]	Retrospective	n, 37, females 24.0±4.9 years	2-step group in SFOA	3-step group in SFOA	Stability, and treatment efficiency	Lateral cephalograph cephalometric measurements	Morphological features
Liao et al./2018 ^[48]	Retrospective cohort	n, 41, 24.0±4.9 years	SFOA in Skeletal Class III facial asymmetry		Long-term outcomes of bimaxillary surgery	Photographs and study models	Morphological features

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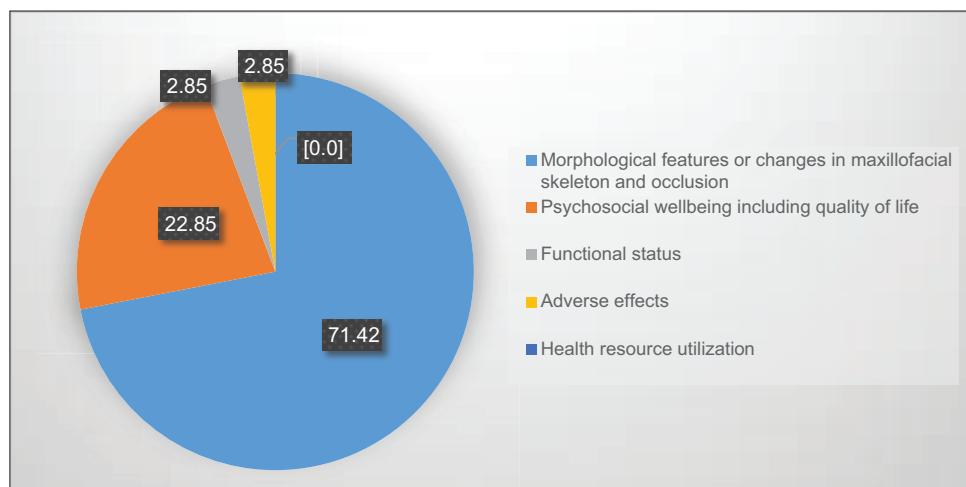
Table 2: Continued

Authors/Year	Study design	Participant	Intervention	Comparison	Outcome primary/Secondary	Method of measurement	Outcome domain
Brucoli <i>et al.</i> /2018 ^[49]	Prospective	33 pts, Conventional jaw surgery (<i>n</i> , 25; 25.0±5.5 years) and SFOA (<i>n</i> , 8; 35.6±13.4 years)	SFOA in skeletal class III dentofacial deformities	Conventional surgery	Oral health impact profile questionnaire, TCI, RSA, Italian validation of the PIDAQ, BDIII, the RSES	Psychosocial well-being, self-esteem, anxiety, and QoL	Oral health-related QoL
Liao and Lo/2018 ^[50]		<i>n</i> , 53 (<i>n</i> , 39 with genioplasty and <i>n</i> , 14 without genioplasty. Mean age, 25±6 years)	Skeletal Class III patients surgery-first approach		Establish guidelines for the surgical occlusion setup of SFOA, evaluate accuracy	Study models and computer-aided surgical simulation	Guidelines, characteristics, and accuracy
Watanabe <i>et al.</i> /2019 ^[51]	Retrospective study	5 patients (19–26 years) with facial asymmetry in hemifacial microsomia	Surgery-first approach combined with mandibular distraction		Soft tissue changes	Photographs	Morphological features

SFOA: Surgery-first orthognathic approach, IVRO: Intraoral vertical ramus osteotomy, MMC: Maxillomandibular complex, QoL: Quality of life, OQLQ: Orthognathic quality of life questionnaire, OHIP: Oral health impact profile, SOC-29: 29-Item scale, PPD: Probing pocket depth, CT: Computed tomography, CAL: Clinical attachment level, VAS: Visual analogue scale, OHRQoL: Oral health-related quality of life, 3D: 3-Dimensional, OQLQ: Orthognathic quality of life questionnaire, VAS: Visual analog scale, TCI: Temperament and character inventory, RSA: Resilience scale for adults, PIDAQ: Psychological impact of dental aesthetics questionnaire, BDIII: Beck depression inventory second edition, RSES: Rosenberg self-esteem scale, MC: Modified-conventional, Tx: Treatment

Table 3: Studies excluded from the scoping review (n=19).

Study author	Reason for exclusion
Nagasaka <i>et al.</i> 2009 ^[13]	Case report
Yu <i>et al.</i> 2010 ^[52]	Case report
Liou <i>et al.</i> 2011 ^[20]	Technique article
Villegas <i>et al.</i> 2012 ^[53]	Case report
Kim <i>et al.</i> 2013 ^[54]	Presurgical phase duration unclear or more than 1 month before surgery
Joh <i>et al.</i> 2013 ^[55]	Presurgical phase duration unclear or more than 1 month before surgery
Park <i>et al.</i> 2013 ^[27]	Case report
Uribe <i>et al.</i> 2013 ^[56]	Case report
Teng and Liou 2014 ^[57]	Animal study
Aristizábal <i>et al.</i> 2015 ^[58]	Case report
Huang <i>et al.</i> 2015 ^[59]	Opinion article
Uribe <i>et al.</i> 2015 ^[60]	Case report
Pelo <i>et al.</i> 2016 ^[61]	Opinion article
Zhou <i>et al.</i> 2016 ^[62]	Case report
Zhou <i>et al.</i> 2016 ^[63]	Pre surgical phase more than 1 month before surgery
Gandedkar <i>et al.</i> 2016 ^[15]	Case series
Larson <i>et al.</i> 2017 ^[64]	Presurgical phase duration unclear or more than 1 month before surgery
Choi and Bradley 2017 ^[65]	Opinion article
Aristizábal <i>et al.</i> 2018 ^[66]	Case report

**Figure 2:** Pie chart showing surgery-first orthognathic approach outcome domains.

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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Conflicts of interest

There are no conflicts of interest.

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