Evidence-based craniofacial and surgical procedures: systematic review

Procedimentos cirúrgicos e craniofaciais baseados em evidências: revisão sistemática

Pedro Ribeiro Soares de Ladeira[1], Nivaldo Alonso[2]

ABSTRACT

Searches were made in PubMed, Embase and Cochrane Library on craniofacial surgery in general and on five central issues of the area: cleft lip and/or palate, orthognathic surgery, craniosynostosis, facial fractures, and hemifacial microsomia. From the 770 randomized controlled trials found, 18 were considered adequate to guide surgical procedures. Orthognathic surgery presented the highest proportion of RCTs in relation to the total number of papers. Hemifacial microsomia was the theme with lowest numbers in all searched categories. The comparisons made in the 18 articles were: locking miniplates *versus* non-locking, open reduction and rigid fixation *versus* intermaxillary fixation, osteogenesis distraction *versus* Le Fort I osteotomy, fixation with resorbable materials *versus* titanium materials, intraoperative awakening *versus* conventional surgery, rigid fixation *versus* wire, BMP-2 *versus* traditional iliac crest bone graft. We obtained evidences only with respect to: use of locking miniplates in management of mandibular fractures; intraoperative awakening in Le Fort I osteotomy and bilateral sagittal split osteotomy; application of rigid fixation in bilateral sagittal split osteotomy; and use of BMP -2 in alveoloplasties. There is still a great scarcity of high quality RCTs that could effectively guide clinical practice.

Keywords: Evidence-based medicine. Oral surgical procedures. Craniofacial abnormalities. Orthognathic surgery. Review.

RESUMO

Buscas foram feitas no PubMed, Embase e Cochrane Library em cirurgia craniofacial, em geral, e de cinco assuntos centrais da área: fissura labial e/ou palatina, cirurgia ortognática, craniossinostose, fraturas faciais, e microssomia hemifacial. Dos 770 ensaios clínicos randomizados encontrados, 18 foram considerados adequados para orientar procedimentos cirúrgicos. Cirurgia ortognática apresentou a maior proporção de ECRs em relação ao número total de artigos. Microssomia hemifacial foi o tema com números mais baixos em todas as categorias pesquisadas. As comparações feitas nos 18 artigos foram: bloqueio com miniplacas *versus* não-bloqueio, redução aberta e fixação rígida *versus* fixação intermaxilar, distração osteogênica *versus* osteotomia Le Fort I, fixação com materiais reabsorvíveis *versus* materiais de titânio, despertar intraoperatório *versus* cirurgia convencional, fixação rígida *versus* fio, BMP-2 *versus* enxerto ósseo tradicional da crista ilíaca. Obtivemos evidências somente com relação a: uso de bloqueio com miniplacas no tratamento de fraturas mandibulares; despertar intraoperatório em osteotomia Le Fort I e osteotomia sagital bilateral; aplicação de fixação rígida em osteotomia sagital bilateral e uso de BMP -2 em alveoloplastias. Ainda há grande escassez de ECRs de alta qualidade que possam efetivamente orientar a prática clínica.

Descritores: Medicina baseada em evidências. Procedimentos cirúrgicos bucais. Anormalidades craniofaciais. Cirurgia ortognática. Revisão.

1. Graduate student, School of Medicine, University of São Paulo, São Paulo, SP, Brazil.
2. Associate professor, Division of Burns and Plastic Surgery, Department of Surgery, School of Medicine, University of São Paulo, São Paulo, SP, Brazil.

Correspondence: Nivaldo Alonso
Rua Afonso Brás, 473 – cj. 65 – Vila Nova Conceição – São Paulo, SP, Brasil – CEP 04511-000
E-mail: nivalonso@gmail.com

INTRODUCTION

44 years ago, Paul Tessier marked the beginning of modern craniofacial surgery with his presentation at the "Fourth Annual Congress of the International Confederation of Plastic Surgeons" (1967, "Hotel Hilton Cavalieri of Rome")[1]. Since then, this area has been guided by the following principles: to approach the patient in a multidisciplinary manner, to provide continuous treatment between ages of 0-18 years, to have its own education and training centers, to possess financial resources and infrastructure in a organized way, to be connected to a research database and to be directed by protocols[2]. However, the latter principle, currently, is relatively more deficient than the others, given the great difficulty and uncertainty related to the surgical treatment of craniofacial anomalies. To reverse this situation, World Health Organization (WHO) has suggested that evidence-based medicine be applied to craniofacial surgery[3], which can be called: evidence-based craniofacial (EBC).

Sackett et al.[4] defined evidence-based medicine as the conscious, explicit and critical use of the best available evidence to make medical decisions about the care of individual patients. This set of ideas is considered the gold standard for medical treatment[5], and its practice is divided into four steps: the formulation of a clear clinical question regarding the patient's condition; the search on scientific literature for relevant articles; the assessment of the validity and usefulness of the found evidences; and the application of the information discovered in the health care[6]. Finally, if the clinical decision will be sustained by the best available evidence or will expose the patient to unnecessary risks, depends on the origin of the information[7].

In a WHO report, two electronic databases were considered necessary for a systematic review of the literature: Embase and MEDLINE[8]. The first has its origin associated with the Excerpta Medica, founded in Amsterdam (Netherlands), in 1946, aiming to increase the medical information flow after the Second World War. In 1972, Excerpta Medica joined to Elsevier group, and, after two years, arose EMBASE, the electronic database of this organization[9]. This scientific source contains approximately 7600 indexed peer-reviewed journals, and provides over 2000 abstracts published in proceedings of conferences[10]. An editorial committee is responsible for the review and assessment the quality of approximately 250 periodicals per year, which can be selected to compose the database[11]. On the other hand, the studies indexation with the Embase controlled vocabulary, the Emtree, is made by experienced indexers with biomedical knowledge[12].

In 1836, opened in Washington (United States) the "Library of the Office of the Surgeon General of the Army", the future "National Library of Medicine" (NLM), responsible for maintaining and updating the MEDLINE[13], often the first choice of health professionals as source of scientific data[14]. However, only in 1971 MEDLINE became available as a digital service on national scale of biomedical information searches, becoming worldwide in 1997, when it was accessible via World Wide Web[13]. PubMed is a database that searches, in addition to MEDLINE, the PREMEDLINE, which allows access to authors, titles and abstracts of articles before they are indexed in MEDLINE. For a PubMed search to include PREMEDLINE, it needs to be done through simple search by free-text. The controlled vocabulary used in MEDLINE is MeSH ("Medical Subject Headings"), and its descriptors are applied to scientific studies according to the concepts they address[15].

The relevance of MEDLINE and Embase are also accepted by "The Cochrane Collaboration", whose goals are to prepare, maintain, update and disseminate systematic reviews of randomized controlled trials (RCTs) and, when these are not available, of other reliable sources of information, always focusing on the improvement of health care. The dissemination of Cochrane reviews occurs through the "Cochrane Library"[16], the main database of evidence-based medicine[17].

Cochrane Library is a collection of six databases containing high-quality studies that have been analyzed individually by professionals with biomedical knowledge. They are: "Cochrane Database of Systematic Reviews" ("Cochrane Reviews" of the search results), "Cochrane Central Register of Controlled Trials" ("Trials"), "Cochrane Methodology Register" ("Methods Studies"), "Database of Abstracts of Reviews of Effects" ("Other Reviews"), "Health Technology Assessment Database" ("Technology Assessments") and "NHS Economic Evaluation Database" ("Economic Evaluations"). Additionally, in each search, there are data from a seventh database that contains information about possible sections of The Cochrane Collaboration related to the searched topic[18].

Aiming at the assessment of the current state of evidence-based craniofacial on the surgical treatment of deformities and which are the future goals to facilitate its practice, searches were made on craniofacial surgery in general and on five central themes of the area: cleft lip and/or palate, orthognathic surgery, facial fracture, hemifacial microsomia, and craniosynostosis. Therefore, we used three databases: Cohrane Library, Embase and PubMed. From the RCTs found approaching the surgical act on craniofacial surgery, we verified evidence-based procedures on the area.

METHODS

On March 3, 2012, searches were made in three databases (Cohrane Library, Embase and PubMed) on: cleft lip and / or palate, orthognathic surgery, facial fracture, hemifacial microsomia, craniosynostosis, and craniofacial surgery in general. When appropriate, we used search strategies involving: the MeSH descriptors and Emtree, Boolean logic operators and free-text truncated with an asterisk. We searched for: citations in general, RCTs, systematic reviews and clinical trials.

The main descriptors used were:

- MeSH: "cleft lip", "cleft palate", "orthognathic surgery", "orthognathic surgical procedures", "craniosynostoses";
- Emtree: "craniofacial surgery", "hemifacial microsomia", "cleft lip palate", "cleft lip", "cleft palate", "face fracture", "craniofacial synostosis", "orthognathic surgery".

1. Cochrane Library

The searches in this database were made in "Search History", and the search strategy was assembled in "Search For".

1.1. *Citations in General*

For these searches we used MeSH descriptors when available, and free-text truncated with an asterisk. The results were obtained by summing the results from the 7 databases.

1.2. RCTs

The following expression was added to the search strategy on item 1.1: "AND (randomized controlled trial*):ti,ab,kw". Only the results in "Cochrane Central Register of Controlled Trials" were considered.

1.3. Systematic Reviews

The following expression was added to the search strategy on item 1.1: "AND ((systematic review*):ti,ab,kw OR (meta-analysis*):ti,ab,kw)". Only the results in "Database of Abstracts of Reviews of Effects" were considered, and were added to those obtained in "Cochrane Database of Systematic Reviews" during the search for the item 1.1.

1.4. Clinical Trials

The results in "Cochrane Central Register of Controlled Trials" on item 1.1 were recorded.

2. Embase

The searches in this database were made in "Advanced Search", selecting the items: "Map to preferred terminology (with spell check)", "Also search as free text" and "Include sub-terms/derivatives". In "Records from", we selected only "Embase". The searches were performed by selecting or not selecting the item "Surgery" in "Advanced Limits", option "Areas of Focus."

2.1. Citations in General

To assemble the search strategies, we used Emtree descriptors.

2.2. RCTs

We selected the item "Randomized Controlled Trial" in "Advanced Limits", option "Evidence Based Medicine." The base of the search strategy was described on item 2.1.

2.3. Systematic Reviews

We selected the items "Meta Analysis" and "Systematic Review" in "Advanced Limits", option "Evidence Based Medicine." The base of the search strategy was described on item 2.1.

3. PubMed

The searches in this database were made in "Search details".

3.1. Citations in General

For these searches we used MeSH descriptors when available, and free-text truncated with an asterisk.

3.2. RCTs

Based on the search strategy of item 3.1, we selected "Randomized Controlled Trial" in "Limits", option "Type of Article".

3.3. Systematic Reviews

The following expression was added to the search strategy on item 3.1: "AND (Meta-Analysis[ptyp] OR "systematic review"[All Fields] OR systematic review/analysis[All Fields] OR systematic reviewers[All Fields] OR systematic reviewing[All Fields] OR systematic reviews[All Fields])".

3.4. Clinical Trials

The following expression was added to the search strategy on item 3.1: "AND (Clinical Trial[ptyp] OR Randomized Controlled Trial[ptyp] OR Clinical Trial, Phase I[ptyp] OR Clinical Trial, Phase II[ptyp] OR Clinical Trial, Phase III[ptyp] OR Clinical Trial, Phase IV[ptyp] OR Comparative Study[ptyp] OR Controlled Clinical Trial[ptyp])".

The results were recorded on graphics to determine which topics are the most and the least discussed in scientific literature, and if this approach corresponds to studies of high level evidence (i.d. RCTs and systematic reviews[19]).

In a second moment, all abstracts provided by the databases in the searches for RCTs were collected, resulting in a total of 770 different articles. From these abstracts, studies that addressed the surgery itself in some way were selected, resulting in 315 articles. From these 315 studies, still using the abstracts, we removed publications that were not related to craniofacial abnormalities, such as issues considered by us as: neurosurgical (e.g. decompression hemicraniectomy), purely aesthetic (e.g. rhytidectomy), dermatological (e.g. Mohs surgery), otorhinolaryngological (e.g. turbinectomy) and ophthalmological (eg dacryocystorhinostomy). After this last selection, 111 surgical articles approaching craniofacial abnormalities remained. In order to verify whether these studies were really RCTs, we searched by "Portal de Periódicos da CAPES" (http://www.capes.gov.br/) for the full-text articles. After meticulous reading of the studies, we found 55 RCTs approaching the surgical act on craniofacial abnormalities. Next, the procedures compared in each study were analyzed, in order to select articles in which the comparisons discussed appeared in two or more of the 55 studies. At the end of the selection, 18 articles were included for the analysis of the obtained conclusions. The flowchart below (Figure 1) outlines the process of articles selection.

Figure 1 – Flowchart outlining the selection process of the 18 articles.

RESULTS

The search results were recorded in the Figures 2 to 7, according to the topic that was searched.

The issues discussed by the 18 selected articles are:

- Management of mandible fractures: 6/19 (31.58%);
- Bilateral sagittal split osteotomy (BSSO) and Le Fort I Osteotomy: 4/19 (21.05%);
- Le Fort I osteotomy: 3/19 (25%);
- BSSO: 3/19 (21.05%);
- Alveoloplasty: 2/19 (10.53%).

The conclusions of the 18 papers will be presented by issue addressed in Tables 1 to 5, where the signs "<", ">" and "=" mean, respectively, that experimental procedure is "less recommended than," "more recommended than" and "equivalent to" traditional procedure.

Figure 2 – Results of searches on "cleft lip and/or palate" in the three databases.

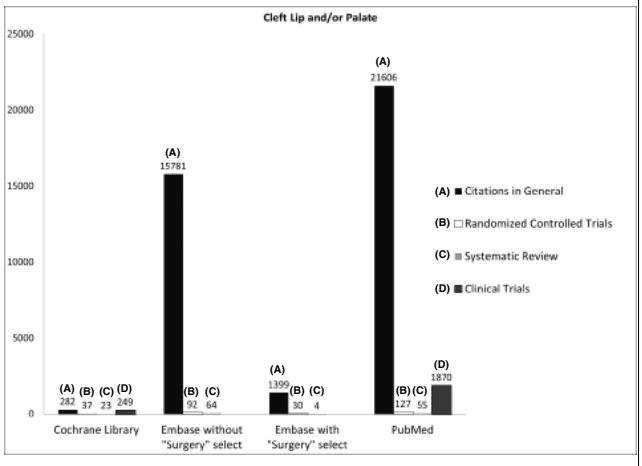

Figure 3 – Results of searches on "orthognathic surgery" in the three databases.

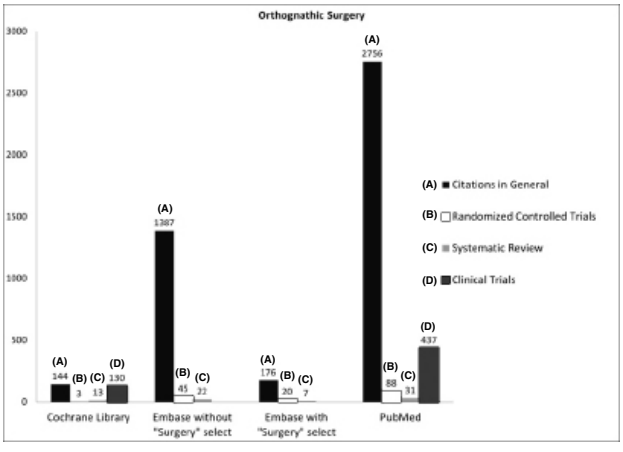

Figure 4 – Results of searches on "facial fracture" in the three databases.

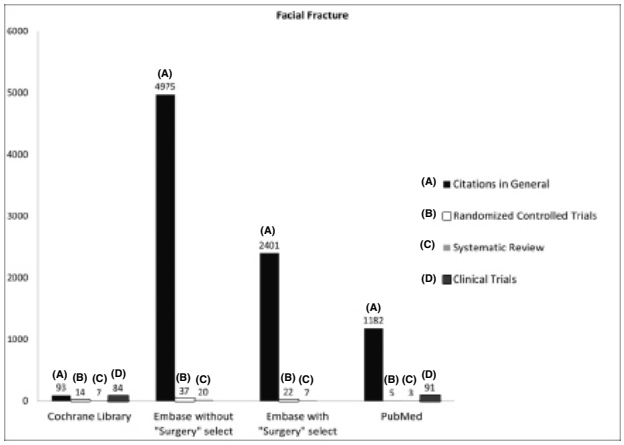

Figure 5 – Results of searches on "hemifacial microsomia" in the three databases.

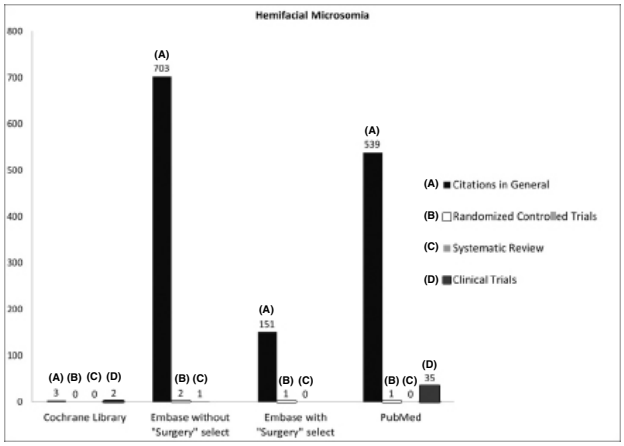

Figure 6 – Results of searches on "craniosynostosis" in the three databases.

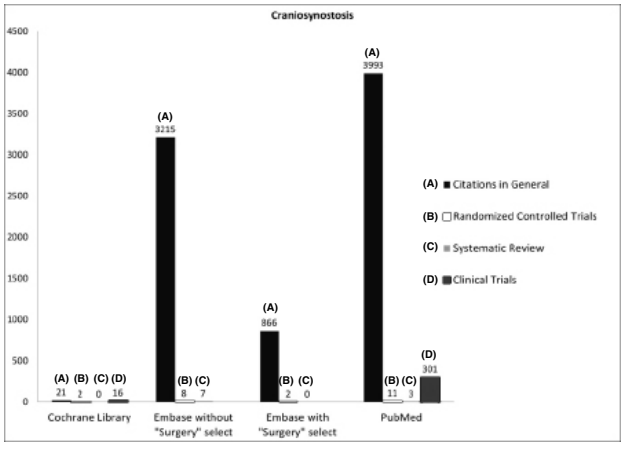

Figure 7 – Results of searches on "craniofacial surgery" in the three databases.

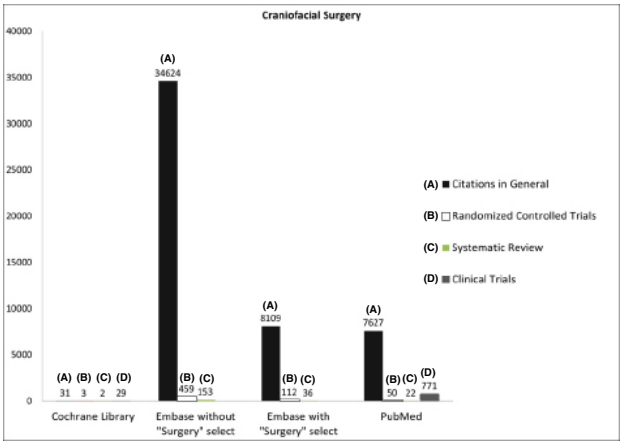

Table 1 – Conclusions of articles that addressed "management of mandible fractures".

Management of Mandible Fractures			
Experimental Procedure	**Conclusion**	**Traditional Procedure**	**Explanation for the Conclusion**
Locking miniplates	>	Non-locking miniplates	Restoration of mandibular function in lesser time[49,50] and greater bone stability[21].
Locking miniplates	=	Non-locking miniplates	Equivalent levels of morbidity, pain, swelling, infection, paresthesia, plate fracture, mobility of fracture fragments and bite force[20]; infection, occlusion disturbance, nerve injury, teeth injury and plate fracture[21]; infection and occlusion disturbance[51].
Open reduction and rigid fixation	>	Intermaxillary fixation	Shorter period for functional restoration[52,53] and lower complication rate[24].
Open reduction and rigid fixation	<	Intermaxillary fixation	High cost-benefit ratio of the technique analyzed, with the largest number of complaints and painful sensation expressed by patients[54].

Table 2 – Conclusions of articles that addressed "Le Fort I osteotomy".

Le Fort I Osteotomy*			
Experimental Procedure	**Conclusion**	**Traditional Procedure**	**Explanation for the Conclusion**
Osteogenesis distraction	=	Le Fort I Osteotomy	No significant differences in development of velopharyngeal insufficiency postoperatively[55] and patient morbidity (infection and occlusion disturbance)[56].
Osteogenesis distraction	>	Le Fort I Osteotomy	Better skeletal stability in maintaining the maxillary advancement in long-term[27,57].

*All studies addressed only patients with cleft lip and palate.

Table 3 – Conclusions of articles that addressed "BSSO and Le Fort I Osteotomy".

BSSO and Le Fort I Osteotomy			
Experimental Procedure	**Conclusion**	**Traditional Procedure**	**Explanation for the Conclusion**
Fixation with resorbable materials	>	Fixation with titanium materials	Decreased patient morbidity because there is no need to remove the material[58].
Fixation with resorbable materials	=	Fixation with titanium materials	Equivalents in regards to the function and morbidity postoperatively (pain, mobility of bone segment, palpability of plates and satisfaction with the results)[59].
Intraoperative awakening	>	Conventional surgery	Malocclusion prevention postoperatively[60,61].

Table 4 – Conclusions of articles that addressed "BSSO".

BSSO			
Experimental Procedure	**Conclusion**	**Traditional Procedure**	**Explanation for the Conclusion**
Rigid fixation	>	Wire fixation	Greater skeletal stability along 2 years[62].
Rigid fixation	=	Wire fixation	Equivalents in regards to the development of temporomandibular disorders[63]. No psychological differences between the patients[64].

Table 5 – Conclusions of articles that addressed "alveoloplasty".

Alveoloplasty			
Experimental Procedure	**Conclusion**	**Traditional Procedure**	**Explanation for the Conclusion**
Cleft repair with BMP-2 (Bone Morphogenetic Protein-2)	>	Traditional iliac crest bone graft	Increased bone regeneration and lower patient morbidity: oral wound quality, pain, infection, paresthesia and donor area wound healing[65]; infection, paresthesia, neuropathy and donor area wound healing[66].

DISCUSSION

In order to estimate the current state of evidence-based craniofacial on surgical treatment of deformities and which are the future goals to facilitate its practice, we performed a systematic review of available studies, with emphasis on high level of evidence articles (i.d. systematic review and RCT[19]), in the two main databases proposed by WHO (i.d. PubMed and Embase)[8], and in Cochrane Library, reference of studies for evidence-based medicine practice[17]). With this purpose, besides a general search, five central themes of craniofacial surgery were discussed: cleft lip and/or palate, orthognathic surgery, facial fracture, hemifacial microsomia and craniosynostosis. In a second moment, we aimed to find surgical procedures based on RCTs that could guide the surgical treatment of craniofacial deformities. Thus, from the 770 articles found in the searches for this study design, we reached 18 final studies that addressed the surgical act on craniofacial abnormalities. The issues of these 18 articles were collected together with its conclusions.

After a total of 96 searches performed, we perceived some characteristics of each database. The Embase was more intuitive and had more search tools than the other two, and also had a more specific controlled vocabulary, which is formed with words from the surgeon day-to-day, unlike the system used by PubMed and Cochrane Library, in which we need to use the search for MeSH terms to choose which is more suited to our goal. Bickley and Harrison[14] had already warned about this difficulty, emphasizing the difference between the terms typically sought in text-free and those who compose the MeSH vocabulary. However, regarding the use of the item "Surgery" in Embase, we noticed several indexing errors throughout our manual search for studies, even taking notice of articles specifically on surgical techniques[20,21] that were not included in searches with the item selected. We did not find any option in Embase that corresponds to the "Trials" of the Cochrane Library or the options available in "Type of Article" of the "Limits" tool from PubMed, which reflected in the absence of data on "Clinical Trials" from this database in the graphs. We consider Cochrane Library less intuitive than the other two, since does not have links to perform specific searches made with Boolean logical operators on homepage, which led us to select "Search History" to perform them.

Overall, in all databases there was a large difference between total results ("Citations in General") and the number of articles found in searches for high level of evidence studies. These findings are in agreement with data related to plastic surgery in general, that in an analysis of 2007 on 16 leading journals in the area presented the following distribution of the total number of articles: case report - 80%; RCTs - 2%; and meta-analysis - <1%[22]. In 2004, another study had highlighted the lack of RCTs on cranio-maxillofacial surgery, which represented 8.3% of articles with this design in "Plastic and Reconstructive Surgery", "British Journal of Plastic Surgery" and "Annals of Plastic Surgery. Subtracting the articles on cleft lip and/or palate from these 8.3%, we get the percentage of 2.3% for other issues in the area, fewer than RCTs about liposuction (3% of the total), a single surgical intervention[23].

Cleft lip and/or palate was the theme with more results on "Citations in General", RCTs and "Systematic Reviews", which is consistent with the interest given by scientific literature (41) and with the fact that it is the most prevalent craniofacial deformity[24]. However, proportionally the RCTs represent only 0.5% (127/21606) of the total published in PubMed. Concerning orthognathic surgery, the theme with the second highest number of RCTs and the second lowest number of "Citations in General" (only higher than hemifacial microsomia), there is a proportion of 3.2% (88/2756). This fact is also confirmed in the second part of the study, with 10 of the 18 final RCTs addressing procedures in orthognathic surgery (Le Fort I osteotomy and BSSO). Thus, we can conclude that researchers in this area probably are producing less and/or are fewer in number, but are more concerned with the methodology of their work, reflecting a clinical practice more driven by evidence.

Emphasis should be given to the lack of articles on hemifacial microsomia, the second most common congenital craniofacial anomaly (1 in 5600 live births) after cleft lip and / or palate[25].The largest numbers were 703 "Citations in General", 2 RCTs and one systematic review. This lack of articles may be due to the variety of phenotypes associated with the condition, which impairs the homogeneity of the sample and treatment standardization, necessary conditions to conduct a RCT[26].

In the search for RCTs that could lead the surgical treatment of craniofacial deformities, it was observed a low efficiency (defined

as ratio of included articles by found articles[8]) of the initial results, since 59.1% (455/770) of these studies did not address surgery and 26.5% (204/770) were not about craniofacial abnormalities. Moreover, when we carefully analyzed each of the remaining 111 articles, it was found that 50.45% (56/111) of this sample were not composed by RCTs, possibly reflecting imperfect search and/or indexation of the study. In order to not support a surgical procedure in a single article, we selected only studies in which comparisons were made on at least one more of the 56 articles. With a final sample of 18 studies, we verified the presence of five issues, arranged here in descending order by number of articles that addressed them: management of mandibular fractures; BSSO and Le Fort I osteotomy; Le Fort I osteotomy; BSSO; and alveoloplasty. Thus, it appears that there was no RCT in craniosynostosis or hemifacial microsomia.

The issues present at the end of selection were consistent with data from scientific literature, since: Le Fort I osteotomy and BSSO are among the three main procedures of orthognathic surgery[27] (there was a lack of papers about the third: osseous genioplasty); alveolar cleft is present in 75% of patients with cleft lip and/or palate and the surgery for its repair, alveoloplasty, is a intervention highly debated, especially with the advent of bone substitutes[28]; and the jaw is the most commonly fractured bone of the face[29].

Within the management of facial fractures, two comparisons were addressed: locking miniplates versus non-locking miniplates; open reduction and rigid fixation versus intermaxillary fixation. In the first comparison, the three RCTs defended the use of locking miniplates instead of the conventional. Chritah et al.[30] and Saikrishna et al.[31] used arguments similar to those found for the use of locking miniplates: higher stability than those without locks and treatment time reduction. Regarding the second comparison, two studies indicated the superiority of open reduction and rigid fixation[23,24] and one defended intermaxillary fixation[25]. However, there were no contradictions between them, but different approaches to treatment. In the systematic review of Andreasen et al.[32], there was a higher rate of complications, mainly nerve injury and infection, in open reduction and rigid fixation. But all ten studies analyzed were retrospective, what made him highlight the necessity for RCTs to clarify the issue.

On the theme "Le Fort I osteotomy and BSSO", there were also two comparisons: fixation with resorbable materials versus fixation with titanium materials; intraoperative awakening versus conventional surgery. There was a divergence between the two RCTs found on the first comparison, with one pointing a reduction of patient morbidity[29] and the other defending an equivalence between treatments[30]. This uncertainty is present in literature, with the two Cochrane reviews on the issue pointing to lack of high level of evidence studies, which could draw a definitive conclusion[33,34]. On the other hand, intraoperative awakening in order to avoid the displacement of mandibular condyle during surgery and, therefore, malocclusion postoperatively, is a practice defended by both RCTs found[31,32]. Costa et al.[35] also argues in favor of this practice after reviewing 79 articles, and concluded that it is a simple and inexpensive method for repositioning the condyle, and should be used in replacement of Condyle Positioning Devices ("Condylar Positioning Devices" or DPL), which have no evidence scientific efficacy.

In regard to the studies that addressed Le Fort I osteotomy, but not BSSO, there was only one comparison: distraction osteogenesis versus Le Fort I osteotomy for treatment of maxillary hypoplasia in patients with a history of cleft lip and palate. There were no differences in the studies conclusions, leading to a possible superiority of distraction osteogenesis over the conventional technique. On the other hand, scientific literature is divided regarding in relation to the choice between these methods of surgical correction. Some professionals question the use of distraction osteogenesis because multiple surgical procedures are required and it has longer treatment and cost compared to the conventional[36-38]. Moreover, Scolozzi[39], in a review of 80 scientific articles, believes that this choice is dependent on how much is the advancement of the maxilla, using distraction osteogenesis for displacements larger than 6 mm in patients with a history of cleft lip and/or palate or 10 mm in individuals with no history of this condition. He also found evidence of better velopharyngeal function with distraction osteogenesis, noting higher incidence of malocclusion with this procedure compared to Le Fort I osteotomy alone.

No divergences were found when RCTs that addressed BSSO were analyzed, which leads to an interpretation for the use of rigid fixation in replacement of wire fixation, since the first provides more osseous stability[33] and is equivalent to the second in regards to the development of temporomandibular disorders[34]. However, when lowest level of evidence studies are also analyzed, such as retrospective papers, there is presence of evidence considering the treatments equivalent regarding stability and relapse of the jaw[40-42] and of others in favor of using rigid fixation because of best results on these aspects[43-45]. The systematic review that analyzed these six articles (2009) concludes that there is a lack of rigorously designed RCTs, for example, with the performance of only one surgical procedure in patients included in the study[46].

The search for a way to avoid the morbidities associated with performance of autogenous bone graft in alveoloplasties was reflected in the results of this systematic review. The two found RCTs[36,37] concluded that BMP-2 is superior to the conventional technique, with an increase in bone regeneration and reduced patient morbidity. But, as the samples used were small (16[36] and 21[37]) evaluated patients), we still can not assure the safety of this bone substitute in relation to its theoretical risks: non-small-cell lung cancer; pancreatic and oral cancer; heterotopic ossification and undesirable bone growth, even in the malignant form[47].The lack of larger studies has been highlighted by a Cochrane review on the issue[46].

This systematic review indicated a lack of high level of evidence studies in craniofacial surgery, more specifically on hemifacial microsomia. On the other hand, it was found that, within the area, orthognathic surgery is the one that has more published RCTs and systematic reviews, in addition to contributing with more than half of the articles used in our search for evidence-based surgical procedures. In the second phase of the study, we discovered that few articles found in the search for RCTs had this study design, and a few addressed the surgical treatment of craniofacial deformities. We also had difficulty to choose which conduct was superior to the other, since in none of the studies there was a concern with the creation of surgical protocols. At the end, we obtained evidences only with respect to: use of locking miniplates in management of mandibular fractures; intraoperative awakening in Le Fort I osteotomy and BSSO; application of rigid fixation in BSSO; and use of BMP -2 in alveoloplasties. However, no studies analyzed more than 152 patients, a significant sample size, but not comparable to classic surgical multicenter RCTs, such as the one from Guillou et al.[48], which validated laparoscopic surgery for colorectal cancer

treatment with a sample of 794 patients. Thus, although the science is evolving in the craniofacial surgery field, there is still a great scarcity of high quality RCTs that could effectively guide clinical practice.

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