

## Review of Evaluation of the Accuracy of Rapid Prototyped Stents in Maxillary Le Fort I Osteotomy Procedures

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**Abstract: Purpose:** To evaluate the accuracy of the computer-generated stents in producing the virtually simulated surgical movements in Le Fort I osteotomies. **Material and methods:** A literature survey in the PubMed, Embase, Cochrane Central Register of Controlled Trials and Cochrane Database of Systematic Reviews was performed and covered the periods to June 2014, June 2014, Jan 2014 and March 2014 respectively. The inclusion criteria were controlled or prospective studies where patients underwent Le Fort I osteotomies using virtual computer assisted technique and CAD-CAM fabricated stents. Three reviewers selected and extracted the data independently. The quality of the retrieved articles was evaluated by four reviewers. **Results:** The search strategy resulted in 718 articles, in which 5 met the inclusion criteria. All articles supported the use of computer planning and the CAD/CAM fabricated stent. **Conclusion:** The CAD/CAM stents can provide accurate production and transfer of the virtual surgical plan to operating room, but more controlled studies are needed to compare results obtained from the computer guided planning and the CAD/CAM stents to that obtained from the conventional method.

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### 1. Introduction

Computer-assisted orthognathic surgery using 3-dimensional imaging and computer-aided design and manufacturing (CAD/CAM) techniques provides innovative treatment modalities in the field of orthognathic surgery<sup>1</sup> specially for the independent positioning of the maxilla after Le Fort I osteotomies.

Traditionally, the planning required mock surgery of model casts and fabrication of an intermediate wafer. This process necessitated many laboratory steps that contain potential errors and consumed a lot of time.<sup>2,3</sup> Moreover, the instability of the mandible on which the intermediate wafer is placed may directly interfere with the placement of the maxilla in the desired position.<sup>4</sup> It is also very difficult for the surgical splint to guide the vertical maxillary movement accurately without additional instruments.<sup>5</sup>

As an alternative, computer planning was introduced to orthognathic surgery for a more precise control over the maxillary position. The planned osteotomies and movements of cut bony segments relative to fixed structures are stored structurally in CAD/CAM templates. Virtual three-dimensional planning could be accurately transferred to the operating room without additional equipment.<sup>6</sup>

The aim of this review is to evaluate the accuracy of computer planning and CAD/CAM wafers in Le Fort I osteotomy.

### 2. Material and Methods

#### Data sources and key words

To identify all studies that examined the accuracy of CAD/CAM splints in le fort I osteotomy procedures a literature survey was performed using the databases: PubMed, Cochrane library, Cochrane database of systematic reviews and EMBASE. PubMed articles were systematically searched till 1 June 2014, Cochrane Central Register of Controlled Trials till January 2014, Cochrane Database of Systematic Reviews from 2005 to March 2014, EMBASE Dastabase articles were searched till 5 June 2014.

The search terms included “Le Fort I osteotomy, Maxillary orthognathic surgery, Fort I osteotomy, maxillary lefort I osteotomy, Computer assisted or computer planning, rapid prototyped stent, stereolithography, 3-D planning, CAD/CAM splint or template, virtual planning and accuracy”.

#### Selected criteria

Titles and abstracts were screened for eligibility according to the following inclusion and exclusion criteria.

Inclusion criteria included

- Controlled and prospective studies
- Patients who underwent Le Fort I osteotomies.



Fig 1: shows the study screening process.

Computer-assisted virtual planning and the use of CAD/CAM stents.

Exclusion criteria included:

- Case reports.
- Studies that uses virtual articulators.
- *In vitro* studies.
- Studies were dynamic intraoperative navigation was used to reproduce the virtual plan.
  - Studies on cleft lip/palate patients.
  - Skeletal disharmonies resulting from trauma or degenerative conditions such as rheumatoid arthritis, severe facial dysmorphology and reconstruction or correction of a congenital birth defect.

#### Selection of relevant studies

The data extraction and quality scoring from each article were assessed independently by three evaluators. Discussion was done to resolve any conflicts till a consensus was reached. Data were extracted on the following items: author, year of publication, patients' age, sample size, pre-operative radiological assessment, timing of post operative radiological assessment, software program used and the author's conclusion.

#### Quality assessment

To document the methodological quality of each article, a quality evaluation by the methods described by Antczak *et al.*<sup>7</sup> and Jadad *et al.*<sup>8</sup> was performed with respect to pre established criteria. The following five variables were evaluated: study design (RCT = 3 points, prospective study = 2 points, retrospective study = 1 point), adequate sample size = 1 point, defined selection criteria = 1 point, valid measurement methods = 1 point, adequate statistics provided = 1 point. By summing the five variables, a study could score a maximum of 7 points in quality. A study's quality was categorized as low (0 to 2 points), medium (3 to 5 points), or high (6 or 7 points).

### 3. Results

#### Literature search

The search strategy resulted in 718 articles. After excluding duplicated articles they were reduced to 569 articles and after initial screening by titles and abstracts 547 articles were excluded. Following retrieval of full papers, 17 articles were excluded and the reasons for their exclusion are listed in Table 1. Thus five articles were included in this review. The study screening process is summarized in fig 1.

### Description of studies included

Summarized data of the included five articles are shown in Table 2. In total, 44 patients were enrolled in this review and all the studies were prospective. Patients' age ranged from 18-35 in 4 studies<sup>6,9,10,11</sup> and the remaining study<sup>12</sup> did not mention the age range. The preoperative radiographical assessment depended on CT scanning in 2 studies<sup>6,9</sup> and in 3 studies<sup>10-12</sup> both CT and CBCT were used. The post operative radiological assessment varied from 3 days to 6 months.<sup>6,9-12</sup> Four studies used tooth –bone supported stents<sup>6,9-11</sup> and only one study used an occlusal wafer splint.<sup>12</sup>

### Accuracy evaluation in Le Fort I osteotomy

All articles<sup>6,9-12</sup> supported the use of computer planning and rapid prototyped stents despite the use of different software programs and different designs for the stents, evaluated the accuracy by comparing postoperative linear and angular measurements to the preoperative virtual plan.

### Quality assessment

Each trail was assessed for risk of bias, the scores are summarized in table 3.

No study was judged to possess a high risk of bias, two studies were considered moderate whereas three were considered of low bias.

**Table 1: shows list of excluded articles and their reasons**

Exclusion criteria	No. of Excluded Articles
Case report	4
<i>In vitro</i> study	1
Studies not concerning the objectives of this review	12

**Table 2: Summarized Data of the five Studies Included in This Review**

Author	No of pts	Age	published	Pre operative x-ray	Follow up time	Design of the stent	Program used	Conclusion
Aboul-Hosn Centenero	16		2012	CT/CBCT	3months	Occlusal wafer	Simplant OMS 10.1 (Materialise, Leuven, Belgium)	it is possible to manufacture CAD/CAM surgical splints that can precisely reproduce our treatment planning in the operating room
Zinser <i>et al.</i>	8	19-35	2012	CT:CBCT 4:4	6months	Tooth-bone supported stent	SimPlant pro crystal, Materialize Dental, Leuven, Belgium)	The precision of a computer assisted orthognathic surgical protocol incorporating virtual planning and transfer to the surgical environment using CAD/CAM fabricated surgical splints.'
B.Li <i>et al.</i>	6	19-30	2013	CT	3 days	Tooth-bone supported stent	SurgiCase CMF 5.0 (Materialise, NV Leuven, Belgium)	CAD/CAM templates provide a reliable method for transfer of maxillary surgical planning, which may be a useful alternative to the intermediate splint technique
Zinser <i>et al.</i>	8	19-35	2012	CT:CBCT 4:4	6months	Tooth-bone supported stent	SimPlant pro crystal, Materialize Dental, Leuven, Belgium)	The precision of a computer assisted orthognathic surgical protocol incorporating virtual planning and transfer to the surgical environment using CAD/CAM fabricated surgical splints.'
Shehab <i>et al.</i>	6	18-30	2013	CT	1 week	Tooth-bone supported stent	Voxim (IVS Solutions, Chemnitz, Germany)	The surgical stent showed accurate control on the osteotomized maxilla and succeeded its repositioning to the preplanned positions.

**Table 3**

Author	Published	Study design	Adequate sample size	Selection criteria	Valid measurement methods	Adequate statistics provided	Quality assessment
Aboul-Hosn Centenero <i>et al.</i>	2012	2	1	1	1	1	High
Zinser, Max <i>et al.</i>	2012	2	1	1	1	1	High
B. Li <i>et al.</i>	2013	2	0	1	1	1	Medium
M Shehab F <i>et al.</i>	2013	2	0	1	1	1	Medium
Zinser, Max <i>et al.</i>	2013	2	1	1	1	1	High

### 4. Discussion

This review aimed at answering the question whether rapid prototyped stents in maxillary Le Fort I osteotomies allowed for accurate final outcomes as

compared to the virtual plan. We reviewed 5 articles with 44 patients. All articles<sup>6,9-12</sup> supported the use of CAD/CAM templates after computer planning. However, the included studies showed some

limitations, the sample sizes in Li and Shehab studies was insufficient.<sup>6,9</sup> Two studies did not use standard radiological assessment for all the patients; Aboul-Hosn<sup>12</sup> used C.T. for ten patients and in the remaining six patients he used CBCT, Zinser<sup>10,11</sup> in four patients used C.T. and in the other four, he used CBCT. Aboul-Hosn<sup>12</sup> used occlusal wafer stent, not like the other four studies<sup>6,9-11</sup> where they used tooth – bone supported stent with the advantage of repositioning of the osteotomized maxilla in three dimensions especially the vertical independent on condylar positioning and eliminating the use of a bone caliper intraoperatively, this should not have caused a discrepancy in the results because the same modality has been used pre- and post-operatively. Measuring the postoperative results as early as possible is essential since the main concern is the accuracy of the treatment plan before relapse occurs that might alter the results. This was not fulfilled in the studies of Aboul-Hosn<sup>12</sup> and Zinser<sup>10,11</sup> as they measured the accuracy of the results three and six months postoperatively.

It is well known that case reports had low scientific evidence, and this was the reason why such studies were excluded. Although it is also well known that uncontrolled studies had low scientific evidence but we were obligated to include them as in our search. there was not any randomized controlled trial or even controlled one that is why we recommend upcoming studies in this field to be randomized controlled trial to allow authors to find evidence of using computer planning rather than traditional planning or vice versa, instead of only concluding the viability and reliability of computer planning and CAD/CAM splint fabrication

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