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Rapid prototyping assisted fabrication of customized surgical guides in mandibular distraction osteogenesis: a case report

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Abstract

Purpose – The purpose of this paper is to develop a workflow for design and fabrication of customized surgical guides (CSGs) for placement of the bidirectional extraoral distraction instruments (EDIs) in bilateral mandibular distraction osteogenesis (MDO) surgery to treat the bilateral temporomandibular joint ankylosis with zero mouth opening.

Design/methodology/approach – The comprehensive workflow consists of six steps: medical imaging; virtual surgical planning (VSP); computer aided design; rapid prototyping (RP); functional testing of CSGs and mock surgery; and clinical application. Fused deposition modeling, an RP process was used to fabricate CSGs in acrylonitrile butadiene styrene material. Finally, mandibular reconstruction with MDO was performed successfully using RP-assisted CSGs.

Findings – Design and development of CSGs prior to the actual MDO surgery improves accuracy, reduces operation time and decreases patient morbidity, hence improving the quality of surgery. Manufacturing of CSG is easy using RP to transfer VSP into the actual surgery.

Originality/value – This study describes an RP-assisted CSGs fabrication for exact finding of both; osteotomy site and drilling location to fix EDI's pins accurately in the mandible; for accurate osteotomy and placement of the bidirectional EDIs in MDO surgery to achieve accurate distraction.

Keywords Rapid prototyping, Computer aided design, Customized surgical guide, Mandibular distraction osteogenesis, Virtual surgical planning

Paper type Case study

1. Introduction

Zero mouth opening due to the temporomandibular joint (TMJ) ankylosis is a rare disorder. Only few such cases have been reported in the literature (Guruprasad and Hemavathy, 2012; El-Hadidy *et al.*, 2011; Amarnath *et al.*, 2011; Rajkumar *et al.*, 2011). The problem of reduced or zero mouth opening is caused by variety of reasons (Gupta *et al.*, 2010). In some patients zero mouth opening appears by birth. It may interfere with eating, speech and oral hygiene and could alter facial appearance (El-Hadidy *et al.*, 2011). There are various mandibular reconstruction principles and techniques available for the treatment, with their own advantages and disadvantages (Deshmukh *et al.*, 2011).

Mandibular distraction osteogenesis (MDO) is an alternative technique, which plays a vital role in the treatment of mandibular defects and deformities using various extraoral or intraoral distraction instruments (McCarthy, 2007; Zapata *et al.*, 2010; Sesenna *et al.*, 2012; Behnia *et al.*, 2013). Ilizarov in 1950s first described distraction osteogenesis (DO) technique for the reconstruction of long bones (Rajkumar *et al.*, 2011; Bukhari *et al.*, 2012). Then, McCarthy in 1992 first developed the technique of mandibular lengthening with extraoral distraction instrument (EDI) (Zapata *et al.*, 2010).

As per the requirement of "direction of lengthening", EDIs are available as unidirectional, bidirectional and multidirectional (Sethi *et al.*, 2006; Andrade *et al.*, 2011). The essential components of EDIs are middle joint (hinge joint for bidirectional EDI and multifunctional double ball joint for multidirectional EDI), distraction rods, fixation clamps and transcutaneous pins (Sethi *et al.*, 2006; Andrade *et al.*, 2011). Generally, EDIs are fixed to the bone by transcutaneous pins connected externally to the holes available on fixation clamps. The fixation clamps, in turn, are joined

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together by distraction rods. When these rods are activated, it effectively pushes the fixation clamps and fixed bone segments apart, generating growth of new bone in its path (Andrade *et al.*, 2011). Depending on the patient's anatomic situation and need, EDIs are selected and adopted in MDO surgery. This helps to move bony segments in almost any direction during distraction (Sethi *et al.*, 2006).

Although the technique of MDO with EDI is very effective, the procedure is very technique sensitive and time-consuming. Especially, achieving the proper alignment/parallelism of the transcutaneous pins, EDI placement and accurate osteotomy are very difficult (Guruprasad and Hemavathy, 2012). Inaccuracy in the procedure results malocclusion (Behnia *et al.*, 2013; Şençimen *et al.*, 2014). Imprecise placement of pins results: tooth injury, damage to adjacent vital structures, inappropriate distraction vector and pin loosening (Neelakandan and Bhargava, 2012; Rachmiel *et al.*, 2014). Conventional methods of the EDI placement are often not suitable for many patients, especially when technical difficulties like a thin ramus or relapse has occurred or the large advancement is needed (Rajkumar *et al.*, 2011). The orientation and growth of new bone depends upon vector of distraction by using EDIs (Zapata *et al.*, 2010; Rajkumar *et al.*, 2011). In MDO surgery, accurate placement of EDIs and finding accurate osteotomy sites are only possible by customized surgical guides (CSGs).

Nowadays, it is easy to design CSGs virtually using the computed tomography (CT) scan images (Ciocca *et al.*, 2012). However, due to intricate and complex shapes of CSGs, exact fabrication is very difficult using conventional processes. Alternatively, it is possible to create more accurate and effective CSGs, by implementing the integrated approach of rapid prototyping (RP). Basically, CSG is a jig, designed by an engineer with surgeon's input using medical imaging (MI), virtual surgical planning (VSP), computer-aided design (CAD) and manufactured by RP (Dérand *et al.*, 2012; Cansiz *et al.*, 2013; Parthasarathy, 2014; Ciocca *et al.*, 2014). These CSGs have capabilities to accurately transfer the VSP into actual surgery (Ciocca *et al.*, 2012; Fantini *et al.*, 2013; Barone *et al.*, 2014). RP not only allows the development of CSGs but also helps in pre-surgical planning and mock surgery (Singare *et al.*, 2009; Salmi *et al.*, 2012). In MDO surgery, CSG improves the accuracy of EDI placement and osteotomy. It also helps to reduce operative time and facilitates to achieve accuracy in distraction, when other conventional methods fail (Bibb *et al.*, 2009).

The present case report is a unique illustration of MDO surgery with RP-assisted CSGs which highlights CSGs' high accuracy in distraction technique.

2. Materials and methods

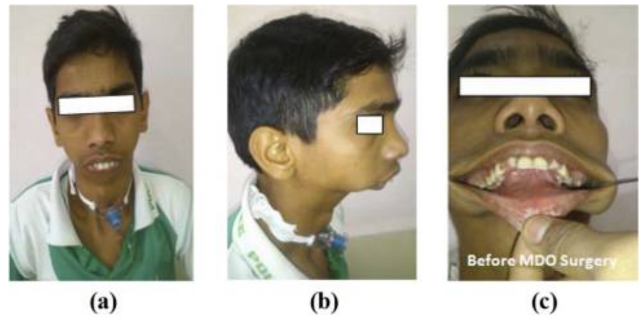
2.1 Patient history

A 20-years-old male patient had facial deformity with zero mouth opening since birth (Figure 1). He had undergone tracheostomy at six months of age. His parents delayed the evaluation and treatment because of economic circumstances.

On examination, there was no movement of TMJ on both sides (even on palpation). The CT scan confirmed bilateral TMJ ankylosis and severe retrognathia.

Following modality of treatment was planned:

Figure 1 Patient of TMJ ankylosis with zero mouth opening



Notes: (a) Front view; (b) right view; (c) zero mouth opening (only maxilla is visible, mandible is inside the maxilla)

- bilateral distraction of vertical ramus of mandible using bidirectional EDIs (20 mm);
- after three months, a second surgery for bilateral distraction of body of mandible using already placed bidirectional EDIs (20 mm); and
- bilateral gap arthroplasty.

A decision to use CSGs in bilateral MDO surgery was taken in view of patient's benefits and surgeon's convenience. CSGs were used for accurate placement of bidirectional EDIs and exact finding of osteotomy sites. In this paper, only the first step of treatment, i.e. bilateral distraction of vertical ramus of mandible using bidirectional EDIs was reported. The approach adopted for design and development of RP assisted CSGs is shown in Figure 2.

2.2 Design and development of rapid prototyping-assisted customized surgical guides

2.2.1 Data collection, segmentation and 3D region development

A 3D CT scan of patients skull in DICOM format prior to the actual surgery was adopted with 0° gantry tilt, slice thickness 0.8 mm, pixel size 0.3281 mm, number of slices 365, resolution 512 × 512, tube voltage 120 Peak Kilovoltage (KVP) and tube current 200 mA. The medical

Figure 2 Approach for design and development of RP-assisted CSGs

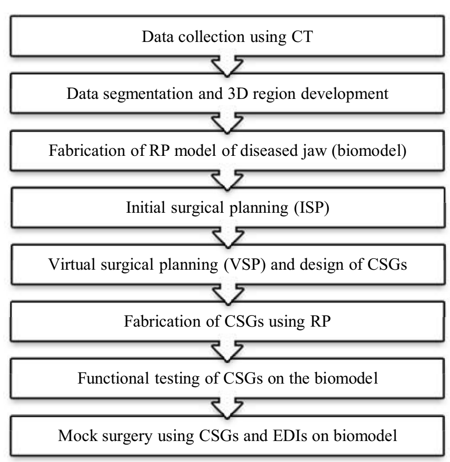


image processing software (Mimics 14.11, Materialise N.V.) processed 2D DICOM data by segmentation. In the software, appropriate threshold values were selected to divide the soft tissues and bone structures. Finally, desire area was separated and 3D diseased jaw model was generated by region growing in highest possible quality STL file. The segmentation and the editing tools enabled to manipulate the data to select bone, soft tissue, skin, etc.

2.2.2 Fabrication of the rapid prototyping model of diseased jaw (biomodel)

The STL file of biomodel was imported to the Catalyst EX, pre-processing software to link with RP machine. Then, this STL file was sent to the RP machine (uPrint SE, Stratasys Inc., Ontario, CA, USA) for fabrication. The fused deposition modeling (FDM), an RP technique was used to get biomodel in acrylonitrile butadiene styrene (ABS) material [Figure 7(a)].

2.2.3 Initial surgical planning

Initial surgical planning (ISP) was planned using bidirectional EDIs on the biomodel. In general to achieve precise symmetric bidirectional distraction, EDI should be placed such that:

- all pins are parallel to each other;
- two distraction rods are required to maintain proper angle between them;
- symmetric placement of EDIs and osteotomy sites; and
- both sides of lower distraction rods to be in line with mandibular plane.

The ISP was performed on biomodel following all above procedures. The surgeon had manually positioned all transcutaneous pins, selected osteotomy site and fixed the EDIs accordingly on biomodel. EDIs were placed on biomodel by checking the availability of the proper healthy bone for pin fixation and accurate osteotomy site. Osteotomy sites were selected on the biomodel as per the convenience of the space for osteotomies. After EDI fixation, the angle between two distraction rods of the EDI was measured. Also the positions of the pins were calculated by manual measurement of distances between the pin slots available on fixation clamps of EDI.

ISP can be avoided if advanced dedicated Cranio-Maxillo-Facial (CMF) simulation softwares (e.g. ProPlan CMF) are employed for VSP and simulation. These modern simulation softwares contains different type of intraoral & EDIs and tools (e.g. place distractor, reposition with distractor, align distractor) for distraction planning. Therefore it removes the distraction instrument designing phase. Hence, such softwares help to simplify VSP and design of CSGs.

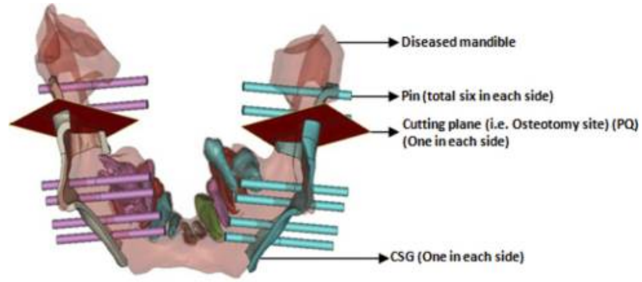
2.2.4 Virtual surgical planning and design of customized surgical guides

In VSP, the STL file of diseased mandible was imported into the medical CAD software (3Matics 8.0, Materialise N.V.) for reference to design CSGs accordingly. These CSGs were the combination of two guides, i.e. drilling guide and osteotomy guide. Drilling guides were designed to achieve exact drilling site and pins fixation for accurate placement of EDIs. However, osteotomy guides were designed to obtain exact osteotomy site.

As per the ISP, pins measurement and appropriate location were designed virtually and placed on the diseased mandible model in software. All pins were designed in such a way that all were parallel to each other. None of the pin damaged the teeth roots or neighboring tissues (Figure 3). Plane of lower distraction rod of EDI obtained in line with mandibular plane. Also, pins were placed where bone thickness was sufficient to avoid the loosening of the pins (Figure 3). Osteotomy site was confirmed by setting cutting plane on the ramus of mandible. Only bones were segmented, and no soft tissues were seen in the view, so the position and orientation of the pins as well as osteotomy site on the mandible finalized accurately. Mirror command then used to get pins and cutting plane on other side of mandible (Figure 3). Mirroring enables the ideal positioning of CSGs and helps in achieving the symmetric distraction. Furthermore, it helps to improve the accuracy in functional and aesthetic results.

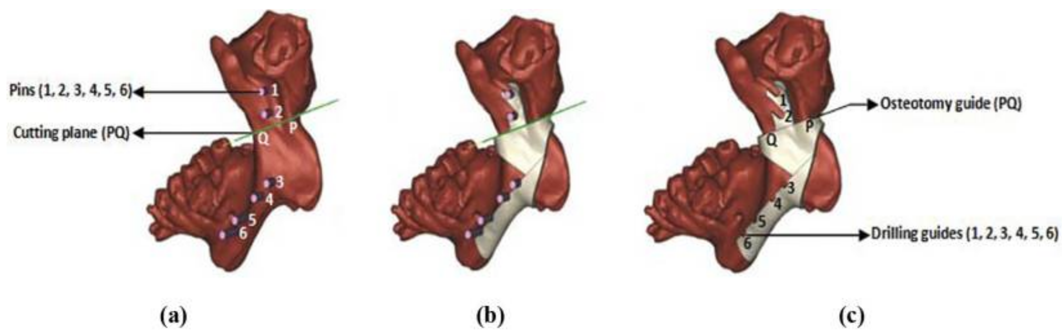
Two CSGs were shaped in such a way that they fit on the bone surface surrounding the immediate area of the pins. In the CSG, osteotomy guide was transferred just by projecting previously positioned cutting planes through the guide design. This was used to create a boundary of the osteotomy guide to enable access of the bur. The positions of the pins were transferred to the CSG design by Boolean operation. All six virtual pins were subtracted from the 3D model of CSG to leave holes indicating the necessary drilling locations (Figure 4). Same method was adopted on other side to obtain drilling locations and osteotomy site. The drilling guides were designed in semicircular shape for easy removal once EDI was fixed accurately. This plays dominant role in improving accuracy during surgery. Finally, after designing CSGs with surgeon's consent, the mandibles were subtracted from the CSGs using Boolean operation. Boolean subtraction left the CSGs with the exact fitting surface as a perfect fit with the mandibular reference surface. These CSGs covered area of anatomical shape which assisted positive location on the bone surface. Each CSG was designed with a thickness of 2 mm. The final designs of CSGs were approved by the surgeons and then exported in a high-quality STL format.

Figure 3 Back view of mandible showing mirror image of pins and cutting planes



Note: Middle shaded portion of the pins indicated the thickness of the bone. Two attached CSGs with the mandible also seen

Figure 4 CSG design



Notes: (a) Positioning pins (1, 2, 3, 4, 5, 6) and cutting plane (osteotomy site) (PQ); (b) Boolean subtraction of pins from CSG to design semicircular holes, i.e. drilling guides and cutting plane to design osteotomy guide; (c) combined CSG included drilling guide (1, 2, 3, 4, 5, 6) and osteotomy guide (PQ)

2.2.5 Fabrication of customized surgical guides using rapid prototyping

The Catalyst Ex software was used to link that STL model to RP machine (uPrint SE, Stratasys Inc., Ontario, CA, USA) for fabrication in ABS material. FDM technique was used for fabrication because of its minimum post-processing requirements and superior mechanical properties, like strength of the build material (Ng *et al.*, 2002; Deshmukh *et al.*, 2011). According to Xu *et al.* (1999), Bharath *et al.* (2000) and Raghatate *et al.* (2014), FDM process provided good accuracy, the surface quality as well as the economy. The final CSGs are shown in the Figure 5.

2.2.6 Functional testing of customized surgical guides and mock surgery

Figure 6 shows the bidirectional EDI, used in MDO surgery. Bidirectional EDI contains two distraction rods, i.e. upper rod (A) and lower rod (B), six holes (1, 2, 3, 4, 5, 6) for pins fixation on three fixation clamps (X, Y, Z), six transcutaneous pins and middle hinge joint (O).

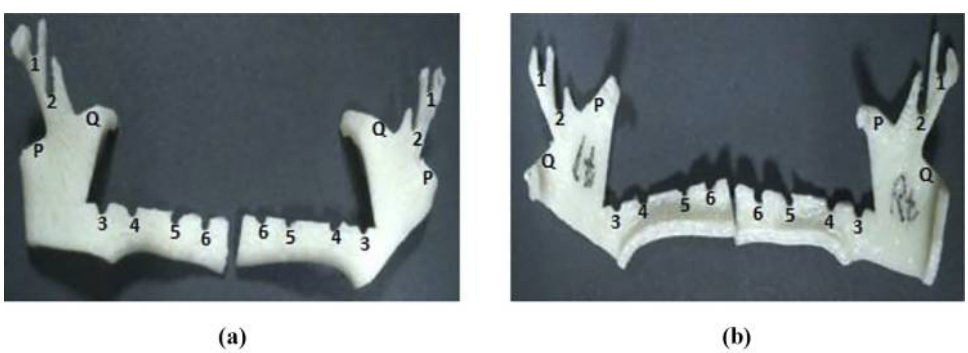
To test the utility of RP-assisted CSGs, a mock surgery was performed on the biomodel [Figure 7(a)]. Initially, the CSG was fixed on the biomodel and checked for fixation and accuracy [Figure 7(b)]. Then, holes were created using drilling guide (1, 2, 3, 4, 5, 6) [Figure 7(b)]. All six transcutaneous pins were exactly fixed on the drilled site on biomodel through drilling guide [Figure 7(c)]. Through the holes (1, 2, 3, 4, 5, 6), the fixation clamps (X, Y, Z) of EDI were fixed on already existing transcutaneous pins [Figure 7(d)]. Using osteotomy guide (PQ) of CSG, the osteotomy site was achieved accurately [Figure 7(d)].

Similar procedure was adopted on other side also. Figure 7(e) and (f) shows that lower distraction rod (B) of both the EDIs were obtained in the same plane, i.e. the mandibular plane. This step is important for symmetric distraction. The mock surgery was found to be effective in testing of CSGs for accurate fixation of the EDIs and obtaining accurate sites for osteotomy. Both the CSGs were then sent to the hospital for sterilization.

2.3 Surgical outcomes

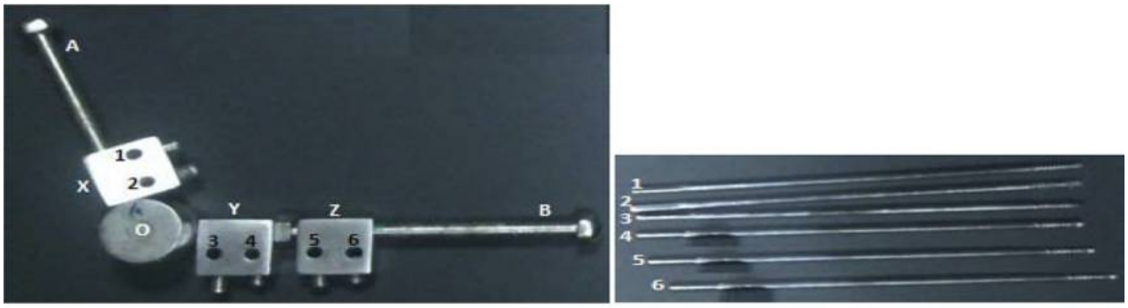
In surgery, the regular MDO approach was used. The ramus of the mandible was approached via a right submandibular incision. As per the testing and mock surgery accomplished on the biomodel, CSG was fixed by just pressing it on the patient's mandible by the same incision. This was used to find exact osteotomy site on ramus and fix transcutaneous pins for placement of EDI [Figure 8(a)]. Then, through the drilling guide, pins were

Figure 5 Final RP-assisted CSGs



Notes: (a) Top view of left and right CSG; (b) bottom view (base part) of the left and right CSG. Osteotomy guide (PQ) and drilling guides (1, 2, 3, 4, 5, 6)

Figure 6 Bidirectional EDIs containing parts



Notes: Two distraction rods: (A) upper rod and (B) lower rod; (O) hinge joint; (1, 2, 3, 4, 5, 6) six pin fixation holes on three fixation clamps (X, Y, Z), (1, 2, 3, 4, 5, 6) six transcutaneous pins

fixed in the mandible by stab incisions. Finally, EDI was fixed to the bone by pins connected externally to fixation clamps. Osteotomy was performed on the ramus of the mandible by osteotomy guide. The same procedure was applied on the left side also. Distraction was started after seven days of latent phase.

During the distraction, two segments of bone ends of the mandible were gradually moved apart, i.e. 1 mm per day for 20 days using EDIs by activating upper distraction rod of both sides. The distraction was along the vector distraction force, where the new bone formation takes place in MDO surgery (Rajkumar *et al.*, 2011; Mahajan *et al.*, 2013).

Three months time was given for consolidation of new bone growth within the gap. After three months, a second surgery was planned for distraction in the body of mandible by using already placed EDIs in first surgery. MDO benefitted for simultaneously increasing mandibular length and volume of surrounding soft tissues (Bukhari *et al.*, 2012; Bernal *et al.*, 2013). No bone grafts were used in this MDO surgery.

Surgeons have not used any extra guidance devices or instruments for measurement, to find exact location for osteotomy and fixation of pins. It was found that CSGs reduces the surgical time by direct and accurate selection of osteotomy site and pins locations. Otherwise in this type of surgery, surgeons have to depend on clinical guidance and experience, which enhances the chances of human error. The immediate outcome was successful. All pins were found parallel to each other and located at the right place as planned. Figure 8(b) shows that using CSG, EDI fixation and osteotomy obtained at planned location. Figure 9 shows the patient's photograph with pins and EDIs (a) just after surgery and (b) after four days.

3. Results and discussions

This paper describes the development and application of CSG using MI, VSP, CAD and RP in bilateral MDO surgery. The results and the observations have revealed that RP helped in surgical pre-planning, mock surgery and design and fabrication of the CSGs with high degree of accuracy. The application of RP-assisted CSGs in various complex surgeries for accurate drilling, osteotomy and positioning of resected bones have been proved satisfactory in many areas of medicine (Dahake *et al.*, 2015). It was observed that CSGs fabricated using RP were fixed well with bone during surgery.

The CSGs fabricated using FDM technique have proved to have an effective operational result in MDO surgery. These CSGs were found to be successful for the accurate placement of transcutaneous pins, fixation of bidirectional EDIs and exact obtaining of osteotomy sites. This has showed accurate distraction outcomes. Figure 10(a) and (b) shows photograph and radiograph of patient after 20 days of first surgery with accurate bilateral distraction of vertical ramus of mandible using bidirectional EDIs.

In previous practices, surgeons decided the final location and orientation of the EDIs, based on their clinical guidance and experiences (Meehan *et al.*, 2006). In Kaban *et al.* (2009), manually developed acrylic stents using biomodel. They manually marked sites for osteotomy and drilling location for pins fixation on the stents. The results of these conventional methods may be unpredictable and uncertain. That may enhance chances of bilateral asymmetric distraction. In Bibb *et al.* (2009), developed RP-assisted CSGs for accurate finding of osteotomy and drilling sites, required for placement of unidirectional EDIs on mandibular ramus. These unidirectional EDIs were screw type and contained only one distraction rod, so placement was easy using designed CSG.

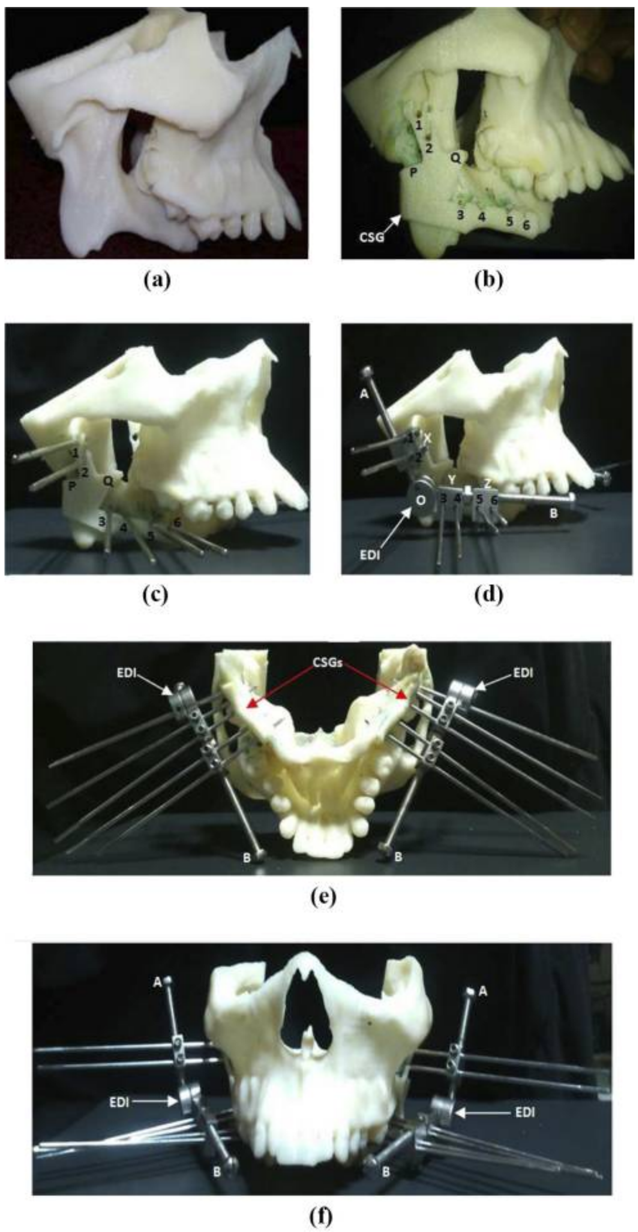
But in this case, accurate placement of EDIs and finding exact osteotomy sites were challenging due to:

1. patient had limited area on the mandible for fixation of transcutaneous pins and placement of EDIs because of very thin atrophic mandible with aberrant anatomy;
2. complex structure of bidirectional EDIs; and
3. complicated method of accurate EDI placement.

Because of these limitations, the available conventional EDI placement methods were not suitable for the surgery. Also locating exact clinical anatomic landmarks and EDI placement without using CSGs were less reliable. This directed the fabrication of RP-assisted CSGs to achieve accurate osteotomy, drilling and placement of bidirectional EDIs on the diseased mandible. These CSGs fabricated by considering the patient's specific needs possesses following features:

- it is a combination of two guides: an osteotomy and a drilling; so using same CSG both operations can be performed;

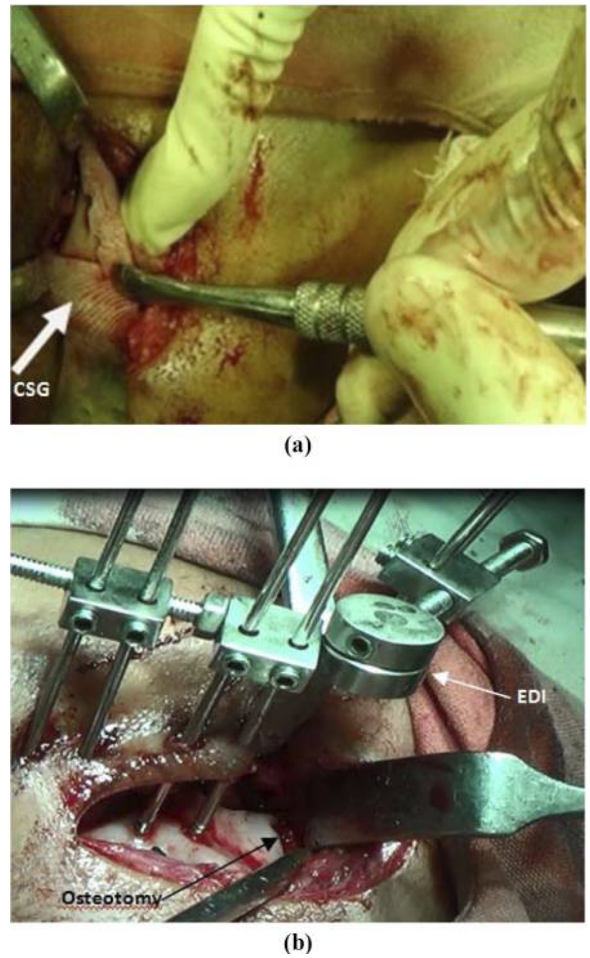
Figure 7 Functional testing of CSGs and mock surgery



Notes: (a) Biomodel; (b) CSGs placed on right side of biomodel and drilling performed using drilling guides (1, 2, 3, 4, 5, 6); (c) all six transcutaneous pins fixed in the drilled holes (1, 2, 3, 4, 5, 6); (d) bidirectional EDI fixed with pins through holes (1, 2, 3, 4, 5, 6) on three fixation clamps (X, Y, Z); (e and f) bidirectional EDIs fixed on both side and obtained lower distraction rod (B) of both EDIs in same mandibular plane

- it is simple and more concise than conventional stents;
- less fixation area is required hence accurate surgery can be performed through single and small incision in a much lesser time;
- it can fit exactly on the planned location, so it helps in direct transfer of VSP to operation theater accurately; and
- it helps in firm and accurate placement of EDI.

Figure 8 (a) RP-assisted CSG used in actual surgery and (b) obtained accurate pins fixation, EDI placement and osteotomy



The CSGs as described have several advantages, but certain care and long-term studies are required to put them into widespread commercial applications. The suggested approach allowed rectifying all possible errors in distraction prior to the MDO surgery which eliminates the need for repeat surgery in case of probable failures. The main drawback of CSG was the total cost of the MI, VSP, CAD and RP application in development.

4. Conclusions

An RP technology has shown to be a viable method for the pre-surgical planning, mock surgery and development of CSGs. Post-operatively, the CSGs proved successful and presented no major difficulties. This is being the first case of MDO surgery, where bidirectional EDIs with transcutaneous pins were fixed and osteotomy achieved accurately, on planned location using CSGs. The same methodology can be used to fabricate CSGs for accurate placement of multidirectional EDIs in MDO surgery. The patient is under regular follow-up. The post-operative results are positive; however, the long-term results are awaited.

The main conclusions regarding RP-assisted CSGs in MDO surgery can be summarized as follows:

Figure 9 Patient with EDIs

(a) (b)

Notes: (a) Just after surgery; (b) after four days

Figure 10 After 20 days (completion of first surgery)

(a) (b)

Notes: (a) Photograph; (b) radiograph (arrows showing distraction sites)

- it helps to achieve proper alignment/parallelism of the EDIs and vectors of distraction;
- it accurately describes locations of EDIs and osteotomy sites to achieve the proposed mandibular movements and thus accurately transfers the VSP into actual surgery;
- it reduces the operative time and increases the accuracy in surgery;
- it increases the self-confidence in placing the EDIs in the correct position and obtaining the accurate osteotomy site;
- it reduces the postoperative hospitalization period and increases the healing process;
- it avoids the future problem of pins loosening, by placing it on pre-planned location;
- it minimizes the complexity of the MDO procedure and risk of complications; and
- it attains good esthetic and functional outcomes.

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