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Case Report

A RED system guiding stent to accurately mimic the pre-planned distraction vector; a case report study

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Abstract
Background: The RED system is one of the most effective midface distractors in maxillary deficiency of cleft patients. However, determining the correct vector and accurately transferring it to the patient is incompetent and time consuming. **Aims**: We designed a new guiding stent that allowed the precise replication of the virtual pre-planned vector prior to commencing the general anesthesia. Thus, improving the outcome, facilitating the procedure and dramatically reducing the operative time. The purpose of this study was determining the best vector via virtual surgery. **Methods**: Virtually mounting the haloframe of the red system and the oral device were put in place, accurately mimicking the preplanned red haloframe and oral device to the actual patient position via the guiding stent, and to facilitate preanesthetic mounting, disassembly to allow osteotomies then reassembly again in the same position. One patient with midface hypoplasia due to cleft lip and palate underwent maxillary distraction osteogenesis using a rigid external distraction device in combination with the proposed removable stent that was fixed onto the maxillary teeth and the face to provide accurate vectorial guidance to the proposed advancement. **Results**: Initial records showed severe maxillary hypoplasia and negative overjet. No complications inserting or removing the splint post-surgically, including pain or discomfort. **Conclusion**: were observed. The use of the removable stent has proved to be a highly effective guiding tool to manage the severely hypoplastic maxilla, eliminating unwanted advancement, reducing operative time and obtaining more accurate results.

Keywords: midface, stent, vector

Introduction

The rigid external distraction (RED) system in craniofacial surgery has been successfully used to correct severe maxillary hypoplasia in cleft lip and palate patients[(1)]. Traction forces to the maxillary bone are delivered through the dentition using an intraoral splint[(2)]. The main advantage of the RED system over internal devices is its versatility in controlling the maxillary position by simply adjusting the force vectors[(3,4)]. The design of the intraoral splint, with the external traction hooks located at the level of, or above, the palatal plane, assures control of distraction forces relative to the center of mass of the maxilla[(1)]. A disadvantage is that placement of the intraoral splint before surgery interferes with the osteotomy procedures[(5)]. The goal of midface distraction is uniform bodily advancement of the midface segment parallel to the cephalometric Frankfort horizontal plane defined by a line drawn from the porion to the suborbital; this goal will best address both the orbital retrusion and the class III malocclusion[(6)]. Although external distra-ctors are characterized by more vectorial control than internal distractors due to several points of fixation, providing mul-tiple levels of traction, the initial determi-nation of the direction of advancement is operator

dependent, which may lead to inaccurate advancement vector.

With the evolution of computer guided surgery it becomes feasible to predict the distraction vector and limit prior to surgery[7], so we will try to get the benefit of computer-guided surgery to help us in the initial determination of the distraction vector in cases of midface distraction, and to crown the study to be the first study discussing however the performed stent shall determine the distractor vector or not worldwide.

Patients and methods

A case of unilateral cleft lip and palate suffering from midface hypoplasia was operated, she was recruited from selected from the outpatient clinic department of oral and maxillofacial surgery MINIA university DENTAL Hospital, she was 16 years of age, with previously operated cleft lip and palate without previous orthognathic surgeries, non-syndromic, having gross midface hypoplasia and did not suffer from any disease that could render bone growth and metabolism after applying the following inclusion and exclusion criteria, she underwent a thorough history, clinical-radiological evaluation and presurgical orthodontic intervention and reviewed by cone beam computed tomography (CBCT). Impressions of the upper and lower dental arches were taken. A closed occlusal splint was fabricated with hooks and cemented to the maxillary arch to maintain continuity.

Fabrication of the guiding stent:

With the aid of the mimics software, we designed a stent that mimics the haloframe of red on the desired location on the skull, and also an intraoral part that fits on the maxillary teeth and ended by a bar that determined the proposed site of osteotomy, this stent was printed in resin, the stent was placed on the patient's head preoperatively to accurately determine the position of fixation screws and the direction of placement of midface advancement, the intraoral segment was used intraoperatively to determine the accurate position of osteotomy.

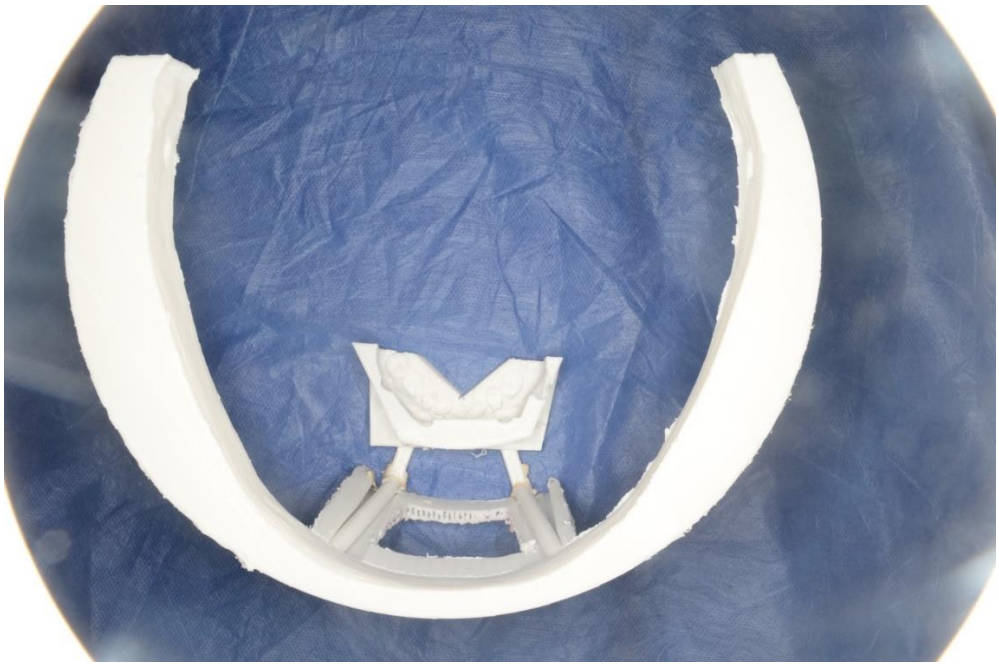

Fig. (1): the guiding stent made of resin with its haloframe and intraoral component

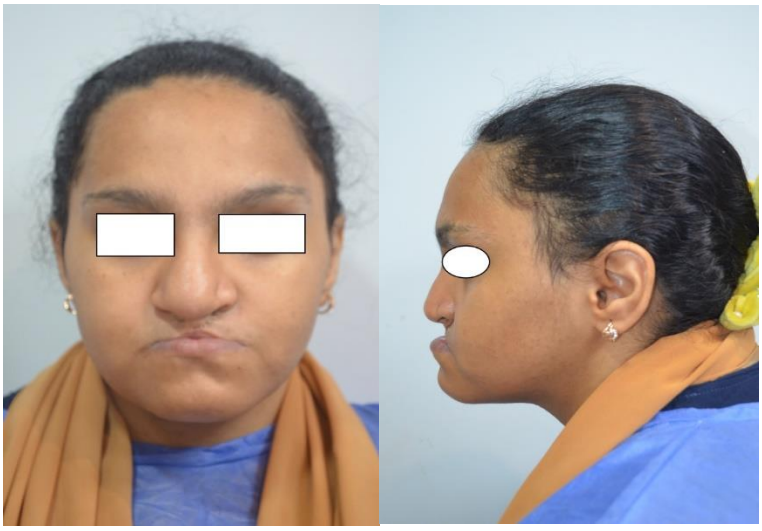

Fig. (2, 3): The preoperative PA and lateral profile photos of the patient

Ethical Consideration

Time was spent with the patient and his family, explaining the distraction process in detail utilizing photographs, video imaging, as well as discussions with other patients and their families who have undergone the procedure.

All Inquiries from the parent as regard: how to deal with RED device? How to take care by it? How the child can eat and drink? Is there is any obstacles during school activity with RED device? How long does the child wear the device? How much does it cost? Special clothes required?

Finally, the patient and parents were thoroughly familiarized with the distraction apparatus and its mechanics prior to the procedure. An explanation of the research project was given to the patients and/ or their parents. A consent form was signed by the patient's parents involved in the study

Operative procedures:

The surgical procedure done under general anesthesia with submental intubation. The tube secured with a 2.0 silk suture; External facial landmarks are important to establish prior to beginning the procedure so that the movement of the maxilla can be measured relative to the cranial skeleton. Injection of saline adrenalin (1/200000) into the gingivobuccal sulcus of the upper lip to help in hemostasis. The incision was made with electrocautery on a low setting as a tool to divide tissue and as a method of blood vessel coagulation to minimize tissue bleeding. The incision was made in the buccal mucosa above the reflection of the sulcus, sparing the frenulum and leaving a healthy cuff of sliding gingiva. This cuff range from will a ***7-10 mm*** aiming for easy watertight closure and avoiding the embarrassing complication of exposed hardware due to inadequate closure. It extends from ***first molar to first molar***, to expose both the lateral and medial buttresses of the maxilla. When the periosteum is identified, it is scored with electrocautery for the entire length of the incision. The margins of the superior flap are ***undermined subperiosteally*** to expose the ***infraorbital nerve,*** infraorbital rim, anterior and lateral maxillae, zygomatic crest, and root of the zygoma. Laterally, the dissection is carried around the lateral maxillary buttress, and then taken posteriorly beneath the mucoperiosteal tunnel to the pterygomaxillary space using a Cushing elevator. Care should be taken to stay in a subperiosteal plane laterally and not dissect into the soft tissue this will prevent exposure of the buccal fat pad, which can be a nuisance to retract. Also, exposure of the body and the root of the zygoma is mandatory and can easily implement the high-level Le Fort I osteotomy. The

intraoral part of the resin stent is then used to identify the location of osteotomy as it was planned on mimics, osteotomy was done, the intraoral Vitallium appliance was fixed to the first maxillary molars and the red system was mounted with fixation screws in its place and direction that was planned by the resin stent and fixed to the vitallium splint by circummaxillary wires.

The patient underwent a latency period of 4–5 days following the osteotomy and then began distraction. Distraction was performed at the rate of 1 mm/day. The patient was followed weekly to assess bone consolidation and to adjust in the vertical position of the horizontal traction bar and screws, to maintain control over the maxillary position. The first radio-graphic evidence of new bone formation is usually noted between 3 and 4 weeks after surgery. Once the appropriate amount of distraction was achieved, the distraction device was kept in place 8 weeks following completion of the distraction process for rigid retention ***(consolidation period).*** The consolidation period varies with the magnitude of movement and the patient's age. Following the period of rigid retention, the external distraction device was removed in an office setting. The distraction carried out was 16 mm, and the direction of distraction was compatible with the virtual advancement done on mimics preoperatively which support the use of the resin stent in such cases

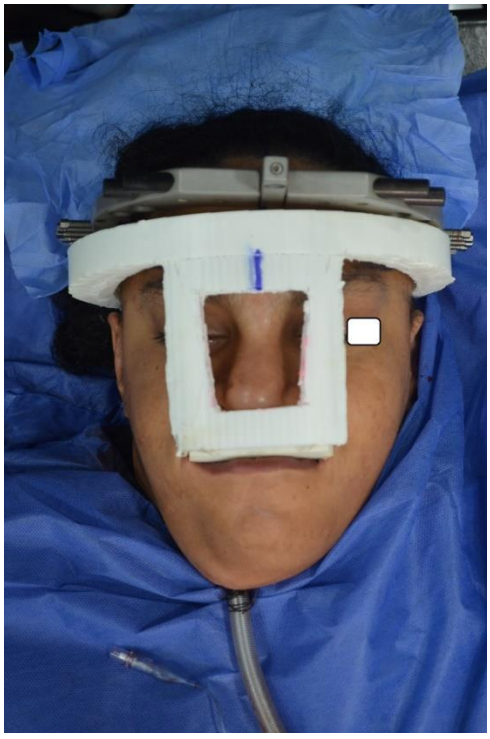

Fig. (4): the resin guiding stent applied to the patient to accurately determine the distraction vector

Discussion

Several protocols involving both internal and external distraction devices have been suggested to promote the distraction of the maxillary complex[8]. The RED system presents advantages over internal devices because of the versatility in controlling the maxillary position through external hooks by simply adjusting the force vectors[9]. The external traction hook may be incorporated into a dental intraoral splint [2,9] or fixed

directly to the maxillary bone by means of cortical screws and Plates [10].

Although external distraction devices offer more control over the distraction vector than internal devices with the 3d printed stent used in this article controlling the accurate distraction vector has become more feasible.

The Age of the case in our study was (16 years) which is compatible with Wen-Ching Ko. et al.,[11] studies. Whereas others chose early intervention during childhood which is much better because it occurs at a time when the deformity has not become fully expressed so we can minimize facial deformities, and also early intervention allows patients to better adapt**.**

Regarding major complication, which is null in our study, traumatic frame migrations occurred in this study as a result of falling down. Pin penetration to the outer and inner table of the skull without Dural tear or cerebrospinal fluid (CSF) leak. Early surgical intervention by repositioning of the frame and correction of the vector, aiming to avoid disturbance of the distraction process as much as possible and this had no effect on the final outcome, in comparable to van der Meulen et al.,[12] study, it has three traumatic frame migrations occurred from various causes, they have one case of intracranial penetration of one of the cranial fixation screws during removal of the halo frame is described, causing meningitis with Klebsiella pneumonia.

However this difference the virtual planning still has its benefit in distraction osteogenesis regarding to its accuracy in the diagnosis of the deformity, optimizing treatment planning (determined the level of osteotomy – predictive value about the mount and direction required for movement of the maxilla in both horizontal and vertical axis).

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