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TECHNICAL NOTE

Midface distraction osteogenesis using a modified external device and 3D virtual simulation: technical note

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Abstract

Introduction/Background Distraction osteogenesis (DO) with an external distraction device such as the rigid external distraction frame has become an established method for treating midface hypoplasia in faciocraniosynostosis. It allows for greater advancement of the midface in comparison with traditional Le Fort III osteotomies, associated or not with fronto-orbital osteotomies (Le Fort IV). However, the forward movement of the bone segments may not always be performed obeying an ideal distraction vector, resulting in asymmetries, anterior open bite, and loosening of screws. In addition, the cost of the distraction devices is significant and may preclude their routine use in developing countries.

Method We present an alternative device and method for craniofacial advancement in a clinical case of Crouzon's syndrome.

Results A 3D virtual simulation of the distraction vector and a modified external device were used in the current case.

Conclusion The alternative external device in this case proved to be safe, effective, and reliable.

Keywords Crouzon's syndrome · Distraction osteogenesis · Le fort III osteotomy · Midface hypoplasia · Rigid external device · 3D surgery simulation

Introduction

Distraction osteogenesis (DO) is an effective treatment modality widely used for the correction of skeletal congenital defects. The goal is based on the concept of generating newly formed bone by progressive stretching of divided segments [1].

The utilization of DO in children is mainly for treating craniofacial deformities, especially in syndromic craniosynostoses such as Crouzon, Apert, and Pfeiffer syndromes, among others [2]. The establishment of a correct diagnosis and treatment plan is one of the most critical parts in the management of the craniofacial surgical patient. 3D imaging and computer simulation has certainly enhanced the ability of the clinician to deliver a more precise treatment outcome, reduce risk, and achieve better outcomes [3, 4].

The purpose of this report is to present the advantages and our experience with distraction osteogenesis, using 3D simulation and an alternative low-cost external device.

Illustrative case

An 11-year-old girl with typical features of Crouzon syndrome (exorbitism, midface hypoplasia, class III malocclusion, and severe obstructive sleep apnea) was referred for neurosurgical consultation. The initial 3D computed tomography

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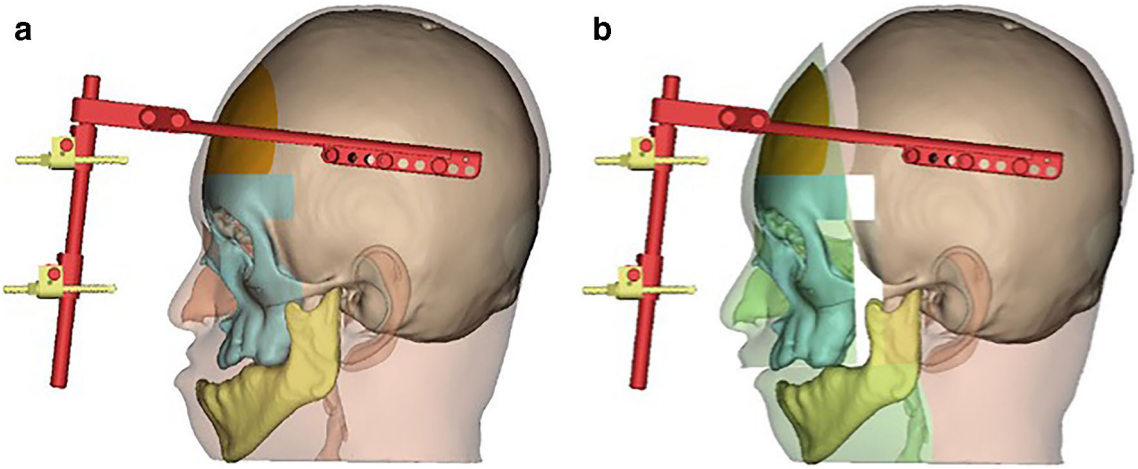

Fig. 1 Surgical planning using CT and 3D reconstruction. The suitable osteotomies were performed in the software Mimics-Materialize Medical 20.0®, allowing independent control of the middle and upper third advancement, as well as placement of the distraction device, according to an optimal vector for the distraction. **a** Before DO. **b** After DO

(CT) scans showed pansynostosis and signs of raised intracranial pressure (Fig. 1).

Afterwards, three-dimensional (3D) virtual planning and simulation were performed (Mimics-Materialize Medical 20.0® software), allowing control of the frontofacial advancement, as well as placement of the distraction device, using as reference 3D-printed cutting and marking guides.

After a multidisciplinary evaluation, a careful surgical strategy was planned. This study was approved by the local Ethics Committee (CAAE: 13798819.6.0000.5440). Surgical approach for the classic osteotomies (orbital floor, roof and walls, zygoma) was made with separation of the pterygomaxillary junction performed either from the coronal plane or through a gingivobuccal access. We have used a modified rigid external distraction device (Traumec® system, Rio Claro, Brazil) (Fig. 2), which was then fixed in the planned manner by screw fixation. A total of four distraction wires were attached transcutaneously to plates fixed laterally to the piriform aperture and infraorbital rims. The rate of distraction was 1 mm/day in two daily activations. A final midface advancement of 23 mm was obtained.

During the distraction period, only minor vector modifications took place. It was decided to stop the distraction at a point where the exorbitism, breath, and facial appearance were markedly improved, less than 2 mm than what was simulated in the computer. No major complications were observed in a 2-year follow-up period (Fig. 3).

Discussion

Distraction osteogenesis in syndromic patients has replaced conventional Le Fort III advancement in almost all cases. This is due to the fact that DO allows for greater advancement lengths, more stable long-term results, fewer and smaller bone gaps, and decreased risk of perioperative complications due to gradual soft tissue expansion. DO has been utilized for a multitude of indications and has opened up a whole new field of

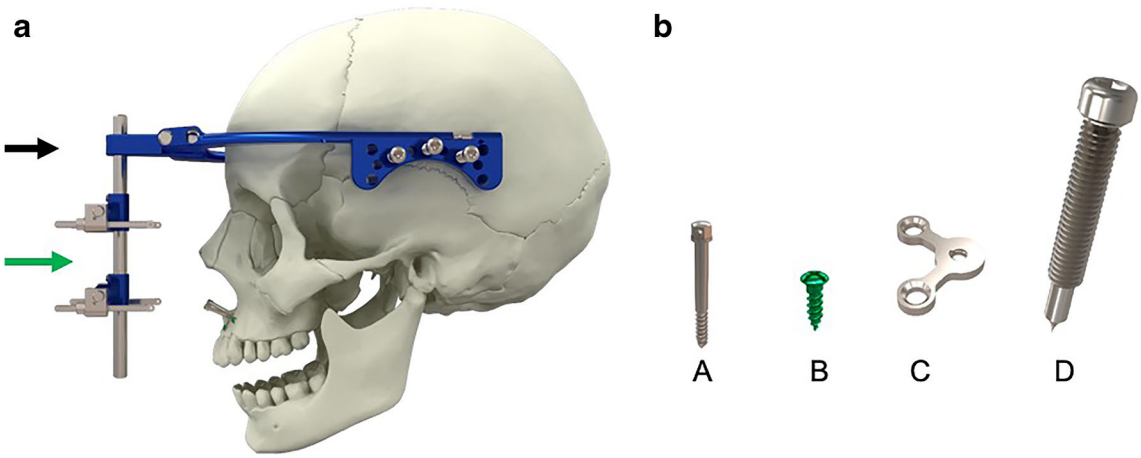

Fig. 2 The Traumec® system and its apparatus: cranial (black arrow) and facial (green arrow). **a** Wire fixation screw. **b** Titanium cortex screw. **c** Zygomatic/maxillary footplate. **d** Titanium cranial position pin

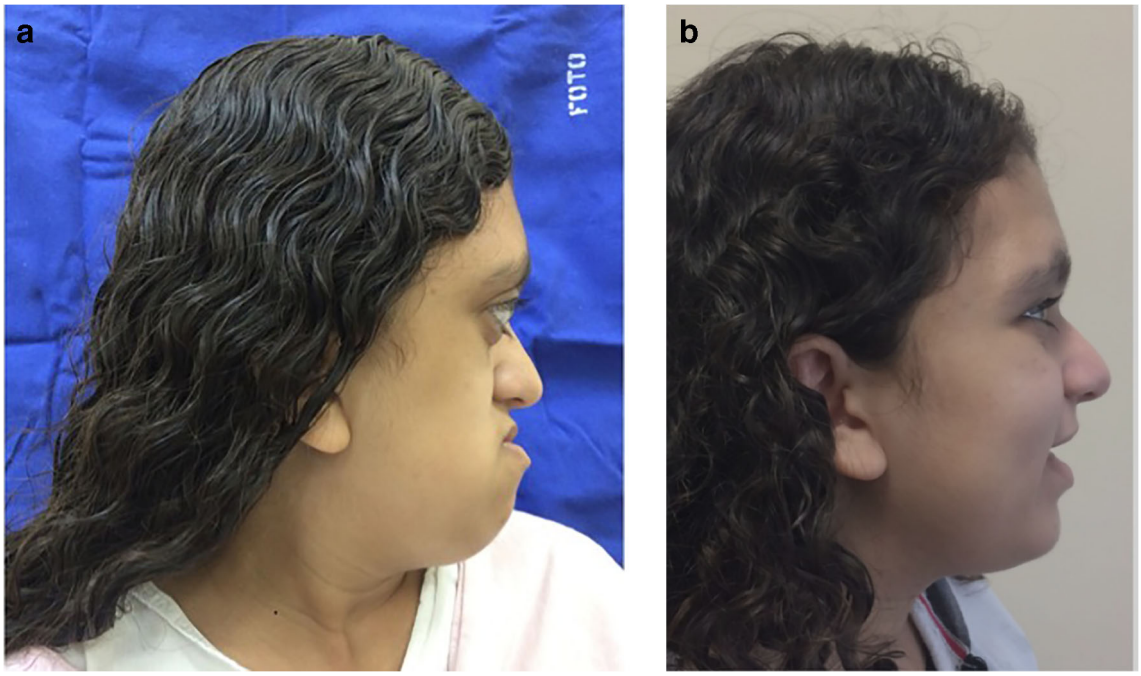

Fig. 3 Left lateral view of the 3D virtual simulation, before (**a**) and after (**b**) the craniofacial advancement. The osteotomies were performed digitally and the one segment advanced according to cephalometric landmarks, dental occlusion, and distraction device activation

therapeutic options. DO is a versatile and reliable way of bone generation, especially in younger patients. However, well-designed osteotomy lines, correct distractor placement, and vector selection are important for treatment success [5].

There is a variety of internal and external devices for DO. The costs of these devices range from 3100 to 5950 US dollars [6]. Although one to two devices can be used for each procedure, sometimes up to five devices might need to be implanted, according to the complexity of the skeletal deformity, as is the case, for example, raising the cost to more than 20,000 US dollars. While these devices are promptly available in North America, Europe, Australia, and parts of Asia, such costs preclude its routine use in Africa and Latin America and other developing countries. The hardware presented herein costs about 30% of the standard devices commercially available.

The external device features some advantages over the internal one: it is easier to place the fixation pins in various anatomic structures and permits longer distraction and broad changes of angle/vectors during its use. It is also simpler to remove and provides better 3D control during the distraction process [7–9]. Vector modifications might take place whenever necessary [10].

However, some concerns and restrictions apply for midface advancement devices in a developing and economically restrained country like ours. To overcome these issues, we developed a similar device to the ones previously reported in the literature, manufactured locally, with shape and measures that meet the patient's needs, and whose engineering project was imported into the planning software, allowing full simulation of the distraction together with the device activation. Albeit less expensive, the external device described herein is just as easy to install as its counterparts and provides multiple possibilities to set up the length and vectors of distraction. The frame can also be customized according to the shape of the patient's skull, avoiding complications during fixation of the pins. It has a light weight and has undergone a thorough biomechanical testing.

Three-dimensional virtual planning and simulation were used to maximize the results. Benefits of such technique are noticed from the engineering project of the distractor to the outcome evaluation. Techniques of computer-aided design and computer-aided manufacturing (CAD-CAM) allowed the creation of cutting and marking guides, with the goal of transferring the simulation to the patient at the time of the surgery. These guides were adapted to the skull contour, assisting the surgical team to reproduce the exact sites for the osteotomies and drillings over the bone surface, in the more appropriate regions. Once the holes of the distraction device and the markings over the bone were coincident with each other, then the distraction device could be fixed in the same position as the simulation, allowing the reproduction of the same distraction vector.

Superimpositions of the 3D virtual skulls created after the simulation and completion of the distraction were used to address the accuracy of the whole process. A gradient color map based on distance calculation revealed basically no discrepancy at the midface and a higher discrepancy in the frontal region. It was assumed that the discrepancy found in the upper third of the face was due to a counterclockwise rotation as a result of the traction vector, which originated from the wires anchorage in the middle third only, as well as to the decision of stopping the distraction as soon as the intended clinical outcome was achieved (Fig. 4).

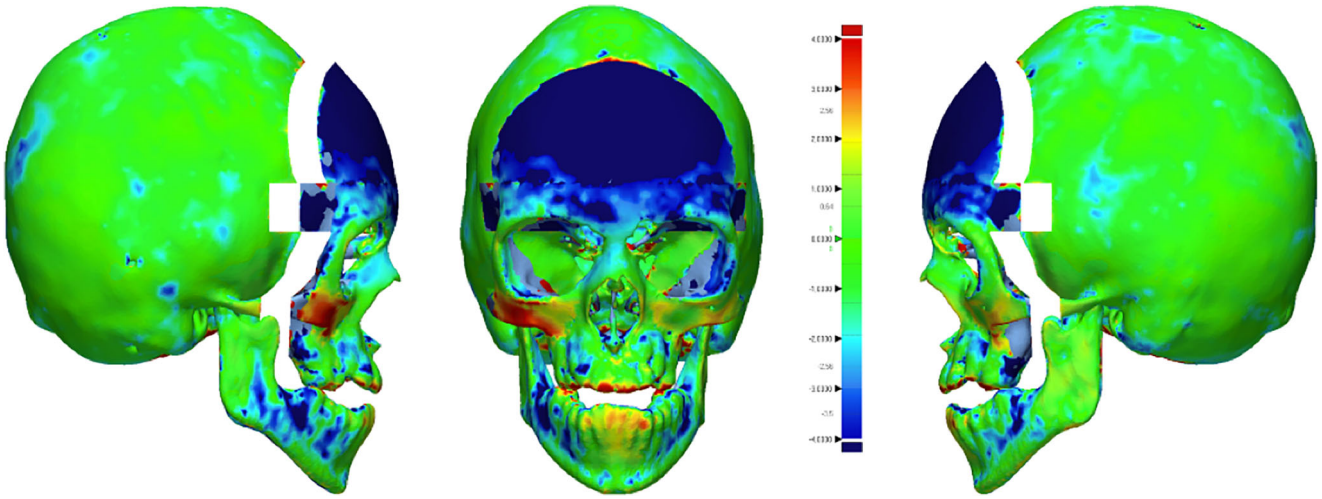

Fig. 4 Superimposition of the 3D virtual skulls from the 3D simulation and completion of the distraction. A gradient color map based on distance calculation reveals a small discrepancy at the midface and a higher in the frontal region (see graduation bar in millimeters), when considering what was planned and what was achieved. A less than planned advancement of the upper third is explained by the decision of stopping the distraction when full clinical improvement was achieved, as well as to a counterclockwise rotation caused by the traction vector

In order to further increase the reproducibility and accuracy of the 3D virtual simulation, once the amount of advancement is verified at each activation point in the planning software, the device must be activated following the same values, thus ensuring that the resulting distraction vector is the same as the planned one. In this way, common inconveniences of frontofacial distraction can be minimized, such as premature contacts of posterior teeth and development of anterior open bite. After 1 year postoperatively, the middle third of the face remained stable without any relapse, and there was no subsequent anterior growth. The patient effectively had clinical improvement of her sleep apnea and did not show any long-term deleterious effects on speech or mastication.

Conclusion

The Traumec® system has been proven to be an excellent device for craniofacial distraction osteogenesis with low and affordable costs. Although the possibility of modifying the distraction vectors and forces over the bone anchorage sites allow for optimal modulation of the distraction process, the 3D virtual simulation can drastically diminish such demand, delivering results that come very close to what was planned on the computer.

Compliance with ethical standards This study was approved by the local Ethics Committee (CAAE: 13798819.6.0000.5440).

Conflict of interest R.S.O received financial support to participate as a consultant during the scientific development of the Traumec® device.

F.M.E. received financial support as a consultant on 3D virtual simulation for Traumec®.

The other authors have no personal, financial, or institutional interest to disclose regarding any of the materials or devices described in this article.

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