Biomechanical Evaluation of the Maxilla during Maxillary Distraction Osteogenessis with the New Hybrid Distraction Device: A Finite Element Analysis

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Background: *Patients with cleft lip and palate (CLP), who have malocclusion combined with severe skeletal Class III problems, usually have multidimensional maxillary hypoplasia. The present study invented a new hybrid distraction device to correct severe skeletal problems.*
Objective: *To evaluate biomechanical of a new hybrid distractor device during maxillary sagittal distraction osteogenesis.*
Material and Method: *Three-dimensional finite element skull models of a 20-year-old, non-syndromic male patient with bilateral complete cleft lip and palate was constructed. Stress distributions and displacement of the new hybrid distractor were analyzed using ANSYS v.10.0.*
Results: *The maximum stress levels were observed for both external and internal components of the new hybrid distractor device. The values of maximum stress were not exceeding yield stress and the range of safety factor was 2.36 to 3.76. The maxilla bone was in equilibrium balance between action force and reaction force and showed symmetrical displacement.*
Conclusion: *The new hybrid distractor device has enough strength during maxillary distraction osteogenesis and can provide controlled symmetrical displacement of the maxilla.*

Keywords: *Maxillary distraction osteogenesis, Maxillary distractor device, Cleft lip and palate patient*

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Patients with cleft lip and palate, who have malocclusion combined with severe skeletal Class III problems, usually have multidimensional maxillary hypoplasia. Many of these patients need orthodontic treatment combined with maxillary surgical procedure to obtain aesthetic, functional, and stable results(1). For correction of malocclusion combined with severe skeletal problems, orthognathic surgery is used to achieve normal skeletal pattern. The conventional approach that has been advocated to correct maxillary bone deficiency is Le Fort I osteotomy advancement(2). Nevertheless, literature review indicates that cleft patients who have had large maxillary advancement have high risk of relapse after treatment because of scar tissue resistance from previous surgical procedures resulting in postoperative anteroposterior skeletal relapse between 20 to 25%(1,3).

Distraction osteogenesis produces gradual bone displacement with bone regeneration accompanied by a simultaneous expansion of adjacent soft tissue(1). McCarthy recommended using distraction osteogenesis (DO) for correcting human craniofacial skeletal deficiencies that need gradual elongation of the mandible. Distraction osteogenesis technique has been advocated for craniofacial skeletal deficiencies such as craniofacial microsomia and patients with cleft lip and palate(4), especially for the patients with cleft lip and palate who need more than 6 mms of maxillary advancement and the non-cleft patients who need advancements in excess of 10 mms. Distraction osteogenesis provides more advantages than traditional orthognathic surgery, including no need for bone graft, more soft tissue adaptation, more long-term

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stability, and also can be performed in young patients(5). Maxillary distractor devices are classified into three systems: external distractor device, internal distractor device, and hybrid distractor device. Each system has advantages and disadvantages that affect a clinician's preference(1,6).

The finite element analysis has been used to evaluate biomechanical characteristics of the maxillofacial complex during maxillary distraction osteogenesis(7). Therefore, the purpose of this study was to make a biomechanical evaluation of a new hybrid distractor device that consisted of external and internal device components and to demonstrate the stability of the maxilla after distraction using three dimensional finite element analysis.

Material and Method

Construction of the finite element model

The subject was a 20-year-old, non-syndromic male patient with bilateral complete cleft lip and palate. He underwent primary repair closure of the cleft lip and palate and alveolar cleft bone graft. The patient had skeletal Class III deformity with maxillary hypoplasia and needed maxillary advancement. Maxillary distraction with the new device was planned to correct the maxillary defect.

The 3D image was obtained using computed tomography (CT) pre-operatively at 1mm intervals with spiral movements along the body axis to enable high geometric accuracy. The DICOM data were imported into Slicer 4.6 software. The geometry of the patient with bilateral complete cleft lip and palate anatomical model was imported using ANSYS v.10.0 (ANSYS Inc, Houston, Pa) to generate a tetrahedral finite element mesh. Then the finite element analysis was performed.

The patient with bilateral complete cleft lip and palate model consisted of approximately 5,443,371 tetrahedral elements and 9,928,301 nodes. Mechanical properties of cortical bone, cancellous bone and the callus tissue are shown in Table 1(7-10).

Boundary condition

Gautam et al recommended fixing and using the foramen magnum as the original point(11,12). In the reconstruction, a Le Fort I osteotomy and maxillary advancement procedure was simulated and the elements selected for the osteotomy line were defined as callus tissue. The magnitude of force for maxillary distraction osteogenesis was 26.8 N which was the maximum traction force as recommended by Sawada et al(13).

Design of the appliance

The new hybrid distraction device (pending patent) was designed and comprised external and internal device components (Fig. 1) that worked together using short term external component during distraction period to control the distance and vector of the maxillary distraction. Once the satisfactory displacement was gained with distraction, the external component will be removed and the internal component will be used to stabilize the distracted maxilla during the bone consolidation period. Then, the surgeon can avoid a second major operation for removal of the

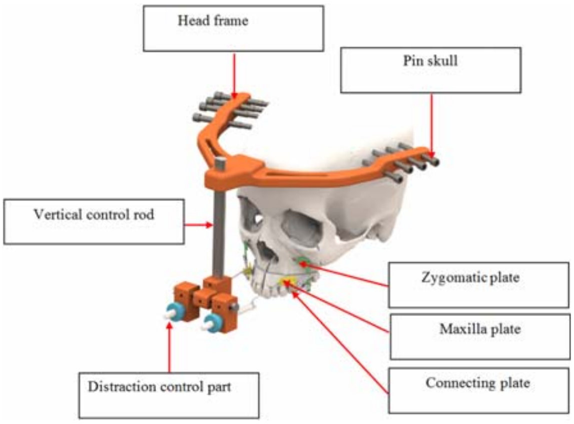

Fig. 1 The component of the new hybrid distractor device.

Table 1. Mechanical properties used in the finite element model

Material	Young's Modulus (MPa)	Poissons's ratio
Cortical bone	13,700	0.30
Trabecular bone	1,370	0.30
Callus	8	0.30
Aluminium 6061 T6	71,000	0.35
Titanium grade 4	105,000	0.34
Titanium grade 5	114,000	0.36

distraction device by operation under local anesthesia. The sequence of application of the new hybrid distractor device is illustrated in Fig. 2.

Three-dimensional finite element models of the new hybrid distractor device transmitting the force to the maxilla (Fig. 3) was made based on 3D data. This model was integrated with the skull model by the projection method.

Results

Fig. 3 and 4 and Table 3 show the 3D pattern of stress distributions of the new hybrid distractor

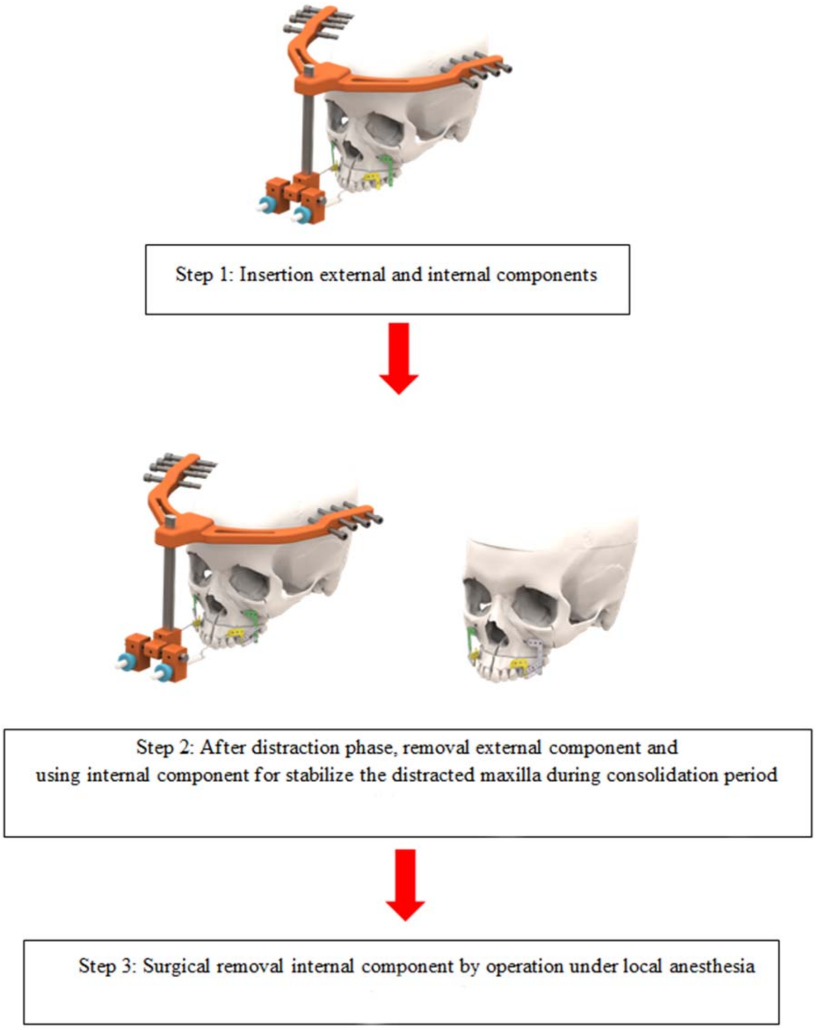

Fig. 2 The sequence of application of the new hybrid distractor device.

Table 2. Comparison between external distractor device, internal distractor device and the new hybrid distractor device

Type of appliance	Simplicity to control distance and vector	Avoidance of second major operation to remove device	Patient's comfort and acceptance
External distractor device	✓	✓	-
Internal distractor device	-	-	✓
The new hybrid distractor device	✓	✓	✓

device while Fig. 5 demonstrates displacement of the new hybrid distractor device.

Displacement of the maxillary bone was evaluated using reaction force of distraction force is made evident in Fig. 6 and Table 4.

Stress and displacement of the new hybrid distractor device

In order to establish the stress/strain capabilities of the new hybrid distractor device, the maximum stress levels were observed for both external

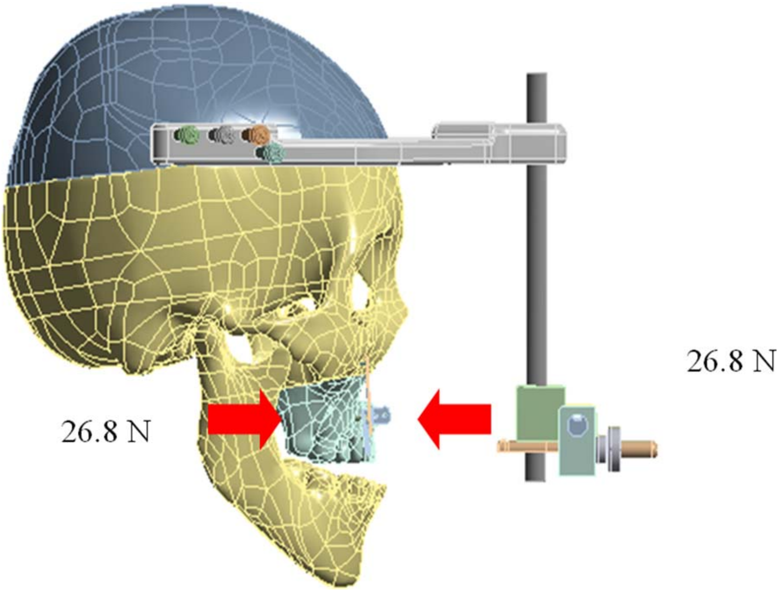

Fig. 3 Three-dimensional finite element models of the new hybrid distractor device transmitting the force to the maxilla.

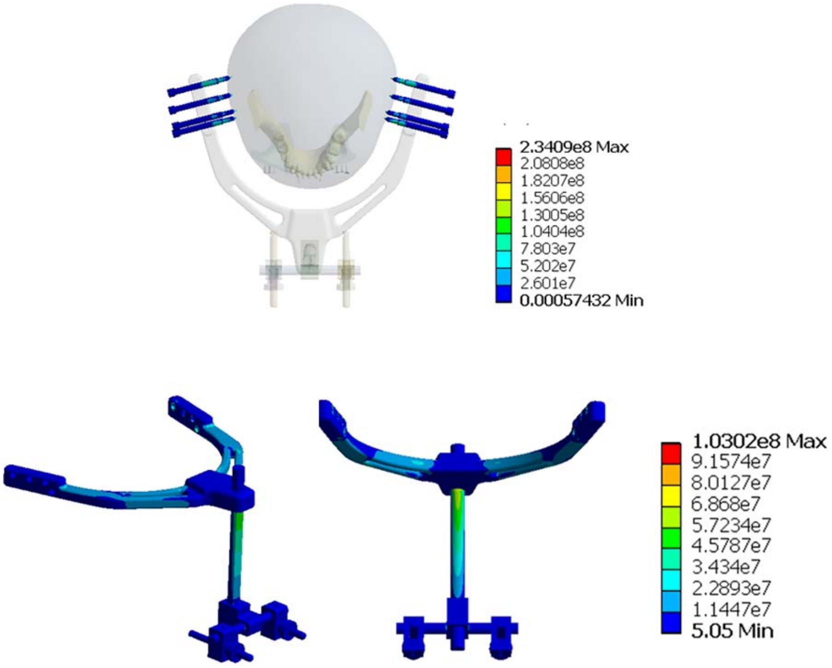

Fig. 4 Stress distribution of external distractor device component of the new hybrid distractor device.

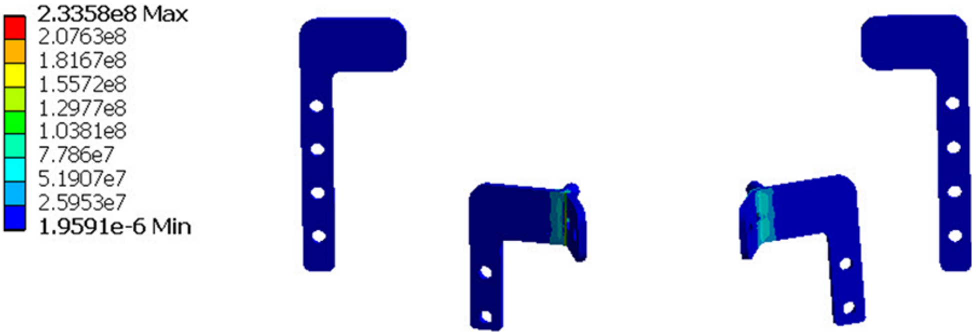

Fig. 5 Stress distribution of internal distractor device component of the new hybrid distractor device system

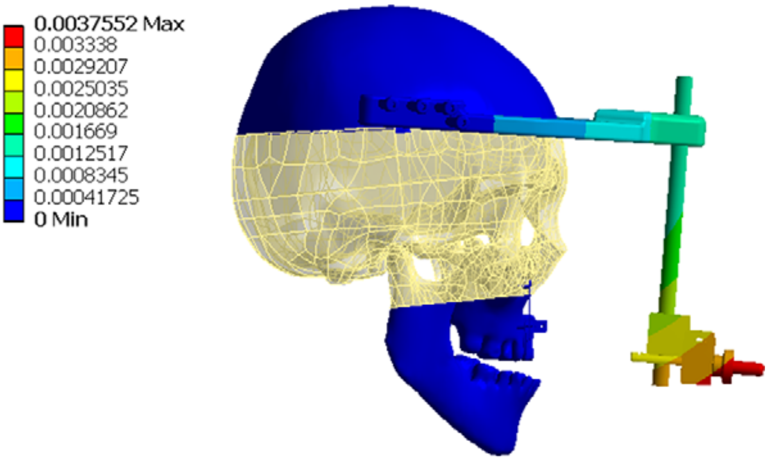

Fig. 6 Displacement of the new hybrid distractor device.

Table 3. Summary of maximum stress

Type of component of the new hybrid distractor device	Maximum stress (MPa)	Yield stress (MPa)	Safety factor
External part			
Head plate and distraction control part	103	280	2.72
Pin skull	234.1	880	3.76
Internal part	233.5	552	2.36

Table 4. Reaction force during maxillary distraction osteogenesis

Type of appliance	Area	Fx (n)	Fy (n)	Fz (n)
The new hybrid distractor device	A	8.23	-0.98	-26.61
	B	-8.23	0.98	-26.99

and internal components. The values of maximum stress were not exceeding yield stress and the range of safety factor was 2.36 to 3.76. The greatest displacement was around the adjustment knob of distractor part

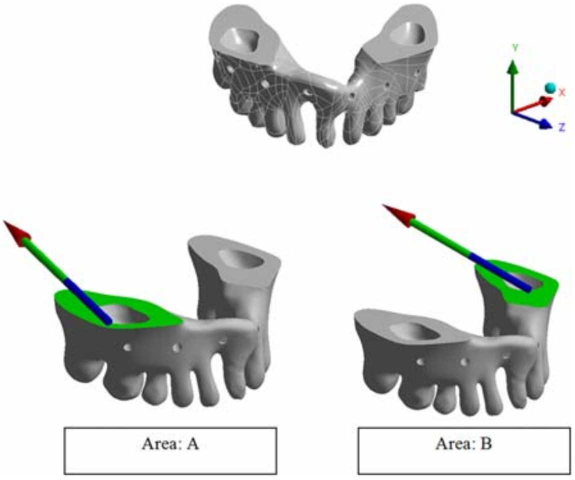

Fig. 7 Reaction force during maxillary distraction osteogenesis.

(3.76 mm).

Displacement of maxillary

Displacement of the maxillary bone was evaluated using comparing reaction force of distraction force indicating that the maxillary bone was in equilibrium balance between action force and reaction force and showed symmetrical displacement.

Discussion

Finite element analysis is a useful and accepted method to predict biomechanical behavior of the human maxillofacial complex(7,14). According to the results of the finite element analysis for stress and displacement, the new hybrid distractor device is capable of supporting maximum distractor force and can control maxillary bone in symmetrical displacement. However, the assumptions applied in finite element modeling are estimates(15). For maximum stress distribution, that found at Pin skull (234.1 MPa) and Zygomatic plate (233.5 MPa) were useful consideration when redesigned for new materials used in the future. Kim KY et al(12), evaluated maxilla displacement by indicating landmarks and compared difference between pre-treatment and post-treatment while in present study using reaction force that could be illustrated equilibrium and direction of maxilla which more easier method.

The advantages of the external distractor device are the ability to alter the distraction vector during distraction osteogenesis and need for only minor surgery for device removal after the consolidation period; but the disadvantages of the external device are that the patient has psychosocial problem during consolidation phase while continuing to use the appliance and slight residual external calvarial scar(6). On the other hand, the internal distractor device has advantages including not visible, better patient acceptance during treatment but, the disadvantages are difficulty in fixation and control of direction of distraction(16). Wong, recommended a hybrid technique so that the external distractor is worn only up to the end of the distraction phase followed by fixation of the maxillary segment to proper occlusion and stabilization with rigid fixation, but with this technique the patient had to receive a second major surgery to remove the intraoral appliance(17). With the new hybrid distraction device, the patient can avoid prolonged retention of the external component which will be much more comfortable and not disturb patient's daily activities and avoid prolong bulky internal distraction devices in the mouth so allowing improved patient's oral function and better control of oral hygiene. Moreover, the new hybrid distractor device in this study allows the surgeon to remove the distractor device under local anesthesia.

Conclusion

The results of the present study using the finite element analysis of patient with bilateral cleft lip and palate model indicate that the new hybrid distractor device has enough strength during maxillary distraction osteogenesis and can provide controlled symmetrical displacement of the maxilla.

What is already known on this topic?

Maxillary distractor devices are classified into three systems: external distractor device, internal distractor device, and hybrid distractor device.

What this study adds?

The new hybrid distractor device has enough strength during maxillary distraction osteogenesis and can provide controlled symmetrical displacement of the maxilla.

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Potential conflicts of interest

None.

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การประเมินชีวกลศาสตร์ของกระดูกขากรรไกรบนในขณะยืดถ่างขยายกระดูกด้วยเครื่องมือชนิดไฮบริดแบบใหม่วิเคราะห์โดยระเบียบวิธีไฟไนต์เอเลเมนต์

พูนศักดิ์ ภิเศก, สมชาย เศรษฐศิริสมบัติ, บรรยงค์ รุ่งเรืองด้วยบุญ

ภูมิหลัง: *ผู้ป่วยปากแหว่งเพดานโหว่ที่มีความผิดปกติของโครงสร้างกระดูกขากรรไกรประเภทที่ 3 ชนิดรุนแรง มักจะมีความผิดปกติของกระดูกขากรรไกรบนที่เล็กในหลายมิติ ในการศึกษานี้ได้ประดิษฐ์เครื่องมือยืดถ่างขยายกระดูกชนิดไฮบริดแบบใหม่เพื่อแก้ไขปัญหาโครงสร้างกระดูกขากรรไกรบนที่ผิดปกติชนิดรุนแรง*

วัตถุประสงค์: *เพื่อประเมินชีวกลศาสตร์ของกระดูกขากรรไกรบนในขณะยืดถ่างขยายกระดูกในแนวระนาบข้าง*

วัสดุและวิธีการ: *กะโหลกศีรษะจำลองสามมิติของผู้ป่วยชายที่มีภาวะปากแหว่งเพดานโหว่สองด้านซึ่งไม่มีกลุ่มอาการ ของโรคได้ถูกสร้างขึ้น แล้วใช้ระเบียบวิธีไฟไนต์เอเลเมนต์ด้วยโปรแกรมแอนซีสเวอร์ชั่น 10.0 ในการวิเคราะห์ การกระจายของความเค้นและการเคลื่อนตัวของเครื่องมือยืดถ่างขยายกระดูกชนิดไฮบริดแบบใหม่*

ผลการศึกษา: *ความเค้นสูงสุดที่เกิดขึ้นทั้งในส่วนของอุปกรณ์ชนิดนอกปากและอุปกรณ์ชนิดในปากของเครื่องมือ ยืดถ่างขยายกระดูกชนิดไฮบริดแบบใหม่พบว่ามีค่าไม่เกินจุดครากของวัสดุและมีค่าความปลอดภัยตั้งแต่ 2.36 ถึง 2.76 และกระดูกขากรรไกรบนจะอยู่ในลักษณะสมดุลระหว่างแรงกริยาและแรงปฏิกิริยาที่เกิดขึ้นทำให้มีการเคลื่อนที่ในลักษณะที่สมมาตร*

สรุป: *เครื่องมือยืดถ่างขยายกระดูกชนิดไฮบริดแบบใหม่มีความแข็งแรงเพียงพอในขณะยืดถ่างขยายกระดูกขากรรไกร บนและสามารถควบคุมให้กระดูกขากรรไกรบนมีการเคลื่อนที่ในลักษณะสมมาตร*