Computer-assisted Design of Patient-specific Sagittal Split Osteotomy Guide and Soft Tissue Retractor

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Abstract

Sagittal split osteotomy (SSO) is a maxillofacial surgery procedure that is used to correct mandibular prognathism, retrusion, or asymmetry. During an SSO, the use of sharp rotary tools for the osteotomy can induce complications, especially during the osteotomy of the medial side of the mandibular ramus. In this study, to decrease SSO complications, a computer-assisted, patient-specific sagittal split osteotomy guide and soft tissue retractor is developed. Computed tomography (CT) images of a human cadaveric mandible were digitally converted into a three-dimensional (3D) model. Then, a case-specific 3D model of the proposed device was designed for the surface of a cadaveric mandible, with the osteotomy line and geometric dimensions of the mandible both taken into consideration. The created 3D model was used to manufacture the device using the metal laser sintering method. Finally, an SSO with the device was performed on the cadaveric mandible used to acquire the CT data. The proposed device ensures that the osteotomy planned in computer-aided preoperative preparations is applied correctly in the operation. Its use during an SSO is expected to shorten the operation duration and time needed for general anesthesia, resulting in less exposure time to bacteria. The shorter operation time is expected to reduce complications, the postoperative hospitalization period, and required corticosteroid amount for edema control.

Keywords: Sagittal split osteotomy, Patient-specific sagittal split osteotomy guide, Soft tissue retractor, Three-dimensional modeling, Laser sintering

1. Introduction

Dentofacial deformities cause functional and aesthetic problems [1]. Such deformities may affect any cranial bone, but mostly affect the jaw bone. There is a variety of surgical methods and modifications for the correction of the jaw bone's malposition due to dentofacial deformities. Sagittal split osteotomy (SSO), first described by Obwegeser, is one of the most preferred methods for the correction of a malpositioned mandible [2].

SSO is a complex operation that combines three osteotomies in different directions [3]. SSO is started on the medial surface of the mandibular ramus, horizontally just above the mandibular foramen, and reaches to the posterior border of the ascending ramus from the anterior. Following a horizontal cut, a vertical osteotomy on the lateral surface of the mandibular corpus in the region of molar teeth, including the inferior border of the mandible, is performed. Finally, the horizontal and the vertical osteotomies are joined by a diagonal osteotomy between the anterior part of the former and the superior part of the latter [4].

Some special soft tissue retractors have been designed to protect neurovascular structures and surrounding soft tissues during splitting procedures [5,6]. Generally, these retractors are modifications of the original Obwegeser mandibular channel retractor [7,8]. These kinds of channel retractors are mostly used for the horizontal osteotomy on the medial surface of the ramus above the mandibular foramen to protect the mandibular neurovascular bundle and the surrounding soft tissues. However, they can also be used for the protection of soft tissue during the vertical osteotomy [4]. Although the Obwegeser mandibular channel retractor is simple and useful, it is not suitable for all patients due to its unadjustable geometry. Trauma, caused by over-retraction by this device, can be harmful, possibly causing postoperative complications such as severe edema or paralysis of the inferior alveolar nerve due to direct retractor trauma to the mandibular neurovascular bundle and surrounding soft tissues [9]. Patients have unique anatomic structures and thus custom-made surgical equipment, such as surgical guides, has received research attention [10-12].

In oral and maxillofacial surgery, no single device can be used both for retraction to protect the surrounding soft tissues and neurovascular structures (i.e., soft tissue retractor) and for

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isolating and locating the osteotomy line (i.e., operation guide). Therefore, the present study designed and fabricated a computer-assisted, patient-specific SSO guide and soft tissue retractor.

The fabrication of the proposed device was carried out using the metal laser sintering (MLS) method, which has been increasingly employed in rapid manufacturing applications [13-16] as it can be used to process many types of materials and composites [17]. Moreover, this technique allows for designs with highly complex geometries to be created directly from a three-dimensional (3D) computer-aided design model within hours [18] with a high level of accuracy [19].

In MLS, metal powder is fused into a solid using a focused laser beam, with parts built up additively layer by layer [17]. This technique enables the fabrication of parts with high accuracy and resolution, along with good mechanical properties and surface quality [20].

2. Materials and methods

A 3D surface model of a cadaveric mandible was created from a computed tomography (CT) dataset using a 3D modeling and image processing software tool (3D Doctor, Able Software, Lexington, MA, USA). CT image data were obtained from a cone-beam CT device (ILUMA, Ultra Cone Beam CT scanner, IMTEC, Monrovia, CA, USA) in the axial direction at 0.5 mm intervals to capture all the vital topological information with a high degree of precision.

The patient-specific 3D model of the proposed device was designed for the surface of the cadaveric mandible according to the osteotomy line using VR Mesh Studio software (VirtualGrid Company, WA, USA) (Fig. 1). In the design process, the osteotomy line was planned in such a way as to prevent the inferior alveolar nerve from being damaged during the SSO operation.

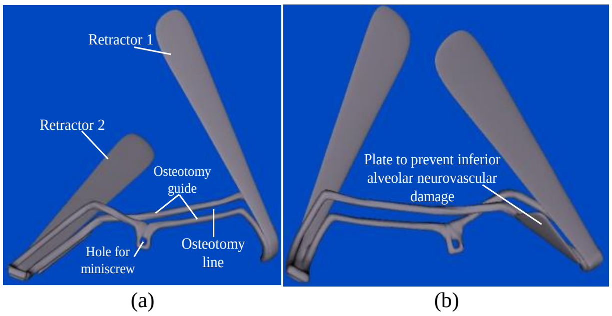

Figure 1. (a) Front and (b) back views of the proposed sagittal split osteotomy guide and soft tissue retractor.

The osteotomy line designed for the 3D computer model was set 0.5 mm wider than the planned osteotomy line to avoid excessive friction and abrasion, which can cause the production of residual metallic sawdust during osteotomy.

Since the device is placed at only a single position on the mandible, positioning inaccuracy between the computer model and the real mandible is restricted. The screw hole located on the device was designed for temporary fixation (Fig. 1(a)). Stable fixation of the device can be ensured using a single miniscrew. The device can be removed from the mouth after removal of the miniscrew at the end of the operation.

The proposed device is both a soft tissue retractor and an osteotomy guide that shows the generally accepted SSO line starting from the posterior mandibular ramus and reaching the base of the mandibular corpus (Fig. 1). There are two soft tissue retractors connected to the device. The first retractor originates from the posterior ramus region of the device and follows the horizontal osteotomy line to protect the inferior alveolar neurovascular bundle and surrounding soft tissues. The second retractor originates from the basis of the mandibular corpus region and follows the vertical osteotomy line to retract the buccal soft tissues during osteotomy (Fig. 1(b)). Although the main design purpose of these soft tissue retractors is to protect the surrounding anatomic structures from rotary osteotomy instruments, they also provide a good view of operation field, eliminating the need for more tools. The retractors are easily pliable and flexible, allowing the surgeon to change their shape and position if needed.

Figure 2 shows various views of the 3D model of the osteotomy guide and soft tissue retractor, along with the 3D model of the cadaveric mandible.

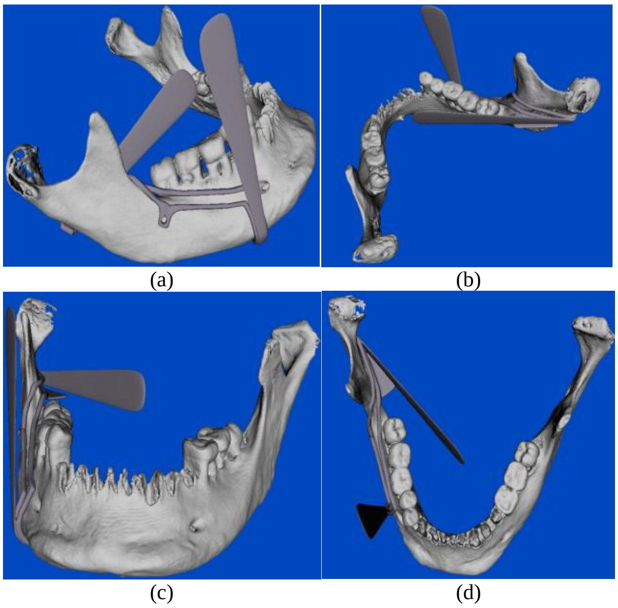

Figure 2. (a) Front, (b) back, (c) side, and (d) top views of the proposed device along with a 3D model of a cadaveric mandible.

The created 3D model was used to manufacture the device using MLS. In MLS, a high-power laser is used to fuse small particles of metal powders into a solid that has the desired 3D shape. Here, stainless steel, which is ductile and biocompatible [21], was chosen as the material for the device. After the laser sintering of the stainless steel particles, the device underwent heat treatment at 500 ℃ to improve ductility.

The design and manufacturing process of the device took approximately ten hours, with two hours for computer modeling, four hours for laser sintering, and four hours for heat treatment.

3. Results

An SSO operation with the manufactured device was conducted on the cadaveric mandible used to obtain the CT data (Fig. 3). The operation process for the cadaveric mandible is shown in Fig. 3.

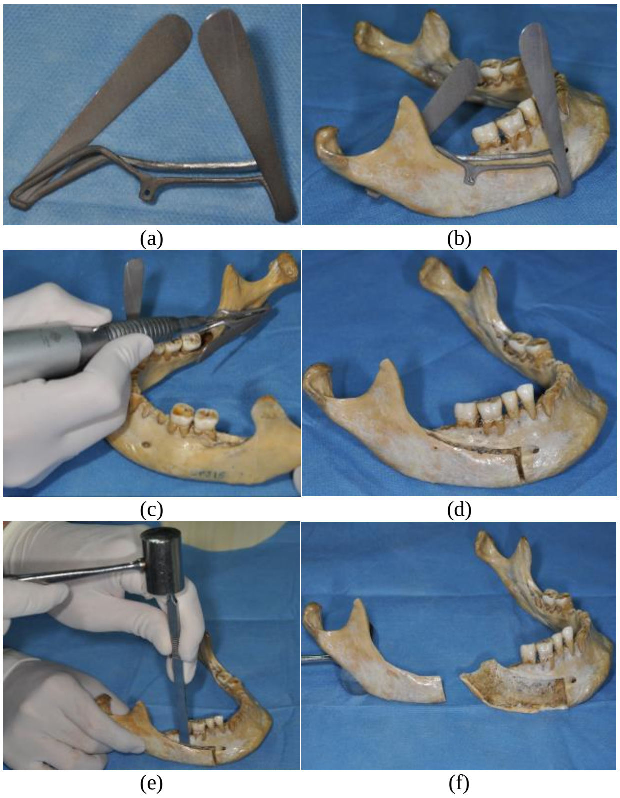

Figure 3. Sagittal split osteotomy test on a cadaveric mandible using proposed retractor and guide. (a) Osteotomy guide and soft tissue retractor, (b) positioning and fixation of the device, (c) horizontal osteotomy by rotary device, (d) completed vertical and diagonal osteotomies, (e) completion of SSO by separation of the corpus and ramus using chisel osteotome, and (f) sagittally split mandible.

In the first step of the osteotomy test, the device was firmly fixed to the cadaveric mandible. Since the design of the device is based on the 3D model of the mandible, the surfaces of the device and mandible match. A miniscrew was used to fully fix the device to the mandibula. After the placement and fixation of the device, the routine SSO described by Obwegeser was performed [2]. First, the horizontal osteotomy was performed at the medial surface of the ramus above the mandibular foramina in which the inferior alveolar neurovascular bundle passes through using a 5-cm-long Lindemann bur on a rotary instrument. Following the horizontal osteotomy, diagonal and vertical osteotomies, starting from the anterior border of the horizontal osteotomy site on the ramus and reaching to the base of the corpus at the level of the premolars, were performed using a reciprocating microsaw. The osteotomy step of the splitting procedure was completed in accordance with the osteotomy line planned in computer-aided preparations [22]. After this step, the fixation miniscrew was unscrewed and the proposed device was easily removed. Then, the osteotomy line was examined and it was confirmed that there was no deformation in the protected areas, such as the mental and mandibular foramens. Finally, the splitting procedure was performed using sharp chisel osteotoms [23] to complete the SSO.

In order to compare the dimensional discrepancies of the cadaveric mandible, guide, and osteotomy line with those of their computer models, six reference points were defined and marked on both the cadaveric mandible and its computer model. In addition to the accuracy of the osteotomy correction, positioning of the device on the mandible was also evaluated using these reference points. The reference points are miniscrew hole (A), superoposterior edge of vertical osteotomy line (B), superoanterior edge of vertical osteotomy line (C), mental foramen (D), superoanterior edge of horizontal osteotomy line (E), and inferoanterior edge of horizontal osteotomy line (F) (Fig. 4). The reference points were determined in such a way that they could be clearly identified on the mandible, guide, and their computer models. Moreover, five of these points are critical points close to the mental and mandibular foramina. The distances between these reference points were measured. The results are given in Table 1. The dimensional discrepancies between the actual objects and their computer models vary between 0.3 mm and 1.35 mm.

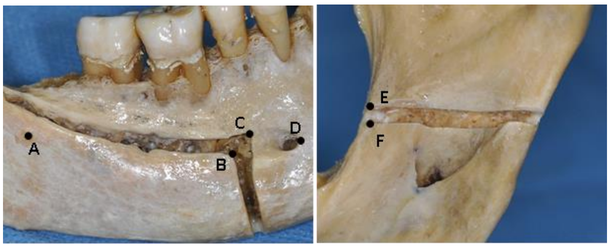

Figure 4. Reference points defined on (a) lateral surface of the mandibular corpus and (b) medial surface of the mandibular ramus. A: miniscrew hole; B: superoposterior edge of vertical osteotomy line; C: superoanterior edge of vertical osteotomy line; D: mental foramen; E: superoanterior edge of horizontal osteotomy line; F: inferoanterior edge of horizontal osteotomy line.

Table 1. Distances between reference points defined on the mandible and its computer model.

	Distances between points (mm)			
	A-D	B-C	C-D	E-F
Real mandible	46.35	3.80	9.83	3.30
Computer model	45.00	3.50	9.20	2.85

4. Discussion

During an SSO operation, the use of sharp rotary tools for the osteotomy and over-retraction can induce complications, especially during the osteotomy of the medial side of the mandibular ramus [3]. If the inferior alveolar nerve is damaged, paralysis of the teeth, the lateral side of the tongue, and the corner of the lip occurs. If the inferior alveolar artery is damaged, serious hemorrhagic complications can occur. The inferior alveolar neurovascular sheet and its entrance to the mandible, the inferior alveolar foramen, must be identified properly for the protection of the neurovascular tissues. After the identification of the neurovascular sheet and the foramen, neurovascular tissues must be retracted away from the osteotomy site carefully for protection. Since the retraction procedure is quite traumatic, hemorrhagic or neurological complications may occur. Also, the retraction procedure performed for the protection of the neurovascular tissues and surrounding soft tissues further narrows the operation field of view. This situation is also seen in the vertical and diagonal osteotomies. Uncontrolled use of rotary instruments during operation can lead to damage of the surrounding tissues or failure to achieve a proper osteotomy line. An unsuitable osteotomy line is one of the major factors of a bad split [4,24].

Damage to the inferior alveolar neurovascular sheet and surrounding soft tissues is mostly caused by failures in the osteotomy stage of the operation. If the rotating bur used for the osteotomy misses the planned osteotomy line, it can easily damage these tissues. At this point, creation of the correct osteotomy line depends on the capability and experience of the surgeon. Since SSO is performed by several doctors at the same time in the mouth, which provides a narrow and dark field of view, the operation is challenging. In addition, saliva, blood, and irrigation materials make the interior of the mouth difficult to see, further complicating the operation. Surgeons are thus more likely to make mistakes.

To avoid these SSO complications, this study designed a computer-assisted, patient-specific SSO guide and soft tissue retractor. It is observed from the osteotomy test on a cadaveric mandible that this device ensures that the osteotomy planned in the computer-aided preoperative preparations is applied correctly in the operation. Since this device has not been used in a real SSO yet, it is impossible to accurately evaluate it. However, it is likely that it will be useful for the prevention of neurovascular damage and the protection of the surrounding tissues by retraction.

It is expected that using the proposed device in SSO operations will reduce the duration of the operation. Therefore, the duration of general anesthesia is expected to decrease and patients will be less affected by possible bacterial contamination. Complications caused by the operation may also decrease. Smaller amounts of corticosteroids given due to edema can be used. Postoperative hospital stay and recovery time are expected to be shorter.

The team required for orthognathic surgery consists of two doctors for retraction and surgical assistance, one nurse, and one surgeon. In some cases, a third person may also be required for retraction and surgical assistance. In addition, connections of rotary devices and some instruments, such as electrocautery and suction equipment, make the operation area complicated. This complexity disrupts the ergonomics of the workspace. The proposed device may reduce the number of people required for retraction and surgical assistance and hence improve the workspace ergonomics. The number of the retractors needed for the operation can also be reduced. With these benefits, operation trauma may be reduced, resulting in less postoperative edema. Also, because the osteotomy line can be seen clearly by the surgeon, the osteotomy can be conducted more accurately, more precisely, and faster. In the future, more osteotomy guides and soft tissue retractors for different cadaveric mandibles and clinical testing are planned.

5. Conclusion

A patient-specific osteotomy guide and soft tissue retractor was developed. Since it has not been applied to a patient during a real SSO operation yet, it is not possible to give definitive conclusions. However, it is expected that the use of the proposed patient-specific osteotomy guide and soft tissue retractor during SSO will provide; i) shorter operation duration, ii) less time need for general anesthesia and thus less time for exposure to bacteria, iii) a reduction of complications, iv) a reduction of the amount of corticosteroid needed for edema control, and v) a reduction of the postoperative hospitalization period and increased healing. The use of the proposed device has the potential to eliminate most of operator-related complications.

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