

# Computer-Aided Design and Manufacturing of a Novel Maxillofacial Surgery Instrument: Application in the Sagittal Split Osteotomy

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*Mandibular sagittal split osteotomy (SSO) is an operation performed for the correction of mandibular deformities. In this operation, sharp rotary tools are used during osteotomies and this can induce some complications. For example, if the inferior alveolar nerve is damaged, paralysis of the teeth, the lateral side of the tongue, and the corner of the lip can occur. To decrease the occurrence of such possible complications, we designed and manufactured a novel computer-assisted, patient-specific SSO guide and soft tissue retractor in our previous study. And, we first tested this apparatus on a cadaveric bone in vitro. Now, in this study, a surgical application of the instrument, which was designed and manufactured according to the requirements of the mandibular sagittal split osteotomies, was performed. This paper gives and discusses the results obtained from in vivo application of the apparatus. [DOI: 10.1115/1.4034297]*

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## Introduction

Sagittal split osteotomy (SSO) is a common and useful operation performed for the correction of mandibular deformities [1]. During the SSO operation, uncontrolled use of sharp rotary tools, which are used for the osteotomies, and over-retraction of soft tissues can induce complications [2]. For example, if the inferior alveolar nerve is damaged, paralysis of the teeth, the lateral side of the tongue, and the corner of the lip can occur [3]. Furthermore, if the inferior alveolar artery is damaged, serious hemorrhagic complications can be encountered [4]. The inferior alveolar neurovascular sheet and its entrance to the mandible, the inferior alveolar foramen, must be properly identified for the protection of the neurovascular tissues. After the identification of the neurovascular sheet and the foramen, neurovascular tissues must be carefully retracted away from the osteotomy site for the protection. Since the retraction procedure is quite traumatic, hemorrhagic or neurological complications may occur [5]. In addition, uncontrolled use of rotary instruments during operation can lead to damage of the surrounding tissues or failure to achieve a proper osteotomy line. The unsuitable osteotomy line is one of the major factors of the bad split [6].

Thanks to the development of the technology about transformation of two-dimensional medical images to three-dimensional solid body models, it is possible to perform preoperative preparations for the complex surgical applications. Especially in the dental surgery, patient-specific surgical simulations or devices result in easy adaptations and fixations of the surgical instruments to the hard and soft tissues of the oral and maxillofacial regions, thereby enabling the surgeons to perform more accurate and successful operations.

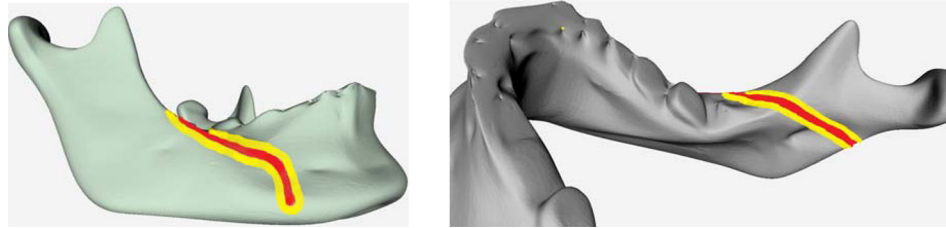
There are some surgical instruments designed for the soft tissue retraction which are the modifications of the original Obwegeser mandibular channel retractor [7]. Although these retractors are simple and useful, they are not suitable for all patients due to their nonspecific, standard geometry. Since their precise adaptation to the surgery region, custom-made maxillofacial surgery devices have gained importance over their generic counterparts [8].

To minimize the aforementioned complications occurred in the SSO, we designed and manufactured a novel apparatus, which can be considered as a subject-specific, computer-assisted SSO guide and a soft tissue retractor, in our previous study [9]. This instrument was successfully tested on a human cadaveric mandible in vitro [9]. Following the evaluation of the merits and shortcomings of this device in vitro, now, in the current study, the apparatus is implemented in a real SSO operation in vivo. This study aims to report the results of the performance of this surgical instrument.

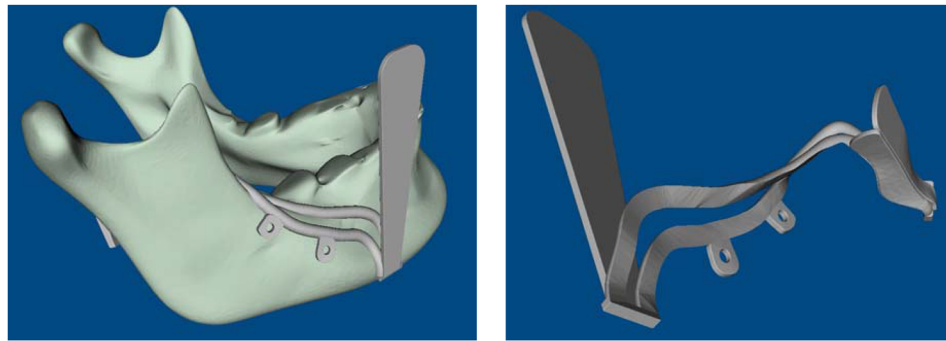
## Materials and Method

**Design of the Apparatus.** Written informed consent was obtained from the patient after a full explanation of the study. The first step in the preoperative stage of the SSO was to determine the osteotomy line which sharp rotary tool would follow for splitting the mandible. To be able to specify an exact osteotomy line, three-dimensional solid body model of the patient's mandible was required. Therefore, two-dimensional computed tomography (CT) images of the patient's mandible were converted into a three-dimensional solid body model using medical image processing software (3D Doctor, Able Software Corp., Lexington, MA). Then, SSO was designed such that it horizontally started on the medial surface of the mandibular ramus just above the mandibular foramen and reached to the posterior border of the ascending ramus from the anterior. Following the horizontal cut, a vertical osteotomy on the lateral surface of the mandibular corpus at the region of molar teeth including inferior border of the mandible was designed. Finally, the horizontal and the vertical osteotomies were joined by a diagonal osteotomy line between the anterior part of the horizontal osteotomy and the superior part of the vertical osteotomy [9]. The above-described osteotomy line was specified on the solid body model of the mandible (Fig. 1).

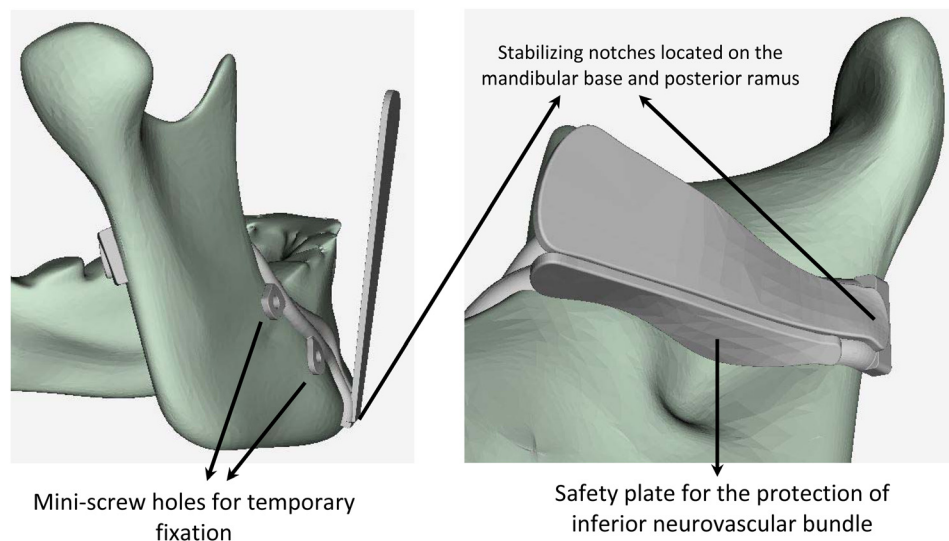
The patient-specific 3D model of the instrument was designed onto the surface of the mandible model according to the



**Fig. 1** Sagittal split osteotomy line specified onto the three-dimensional model of the patient's mandible



**Fig. 2** The designed sagittal split osteotomy guide and soft tissue retractor



**Fig. 3** Different views of the instrument placed on the mandible

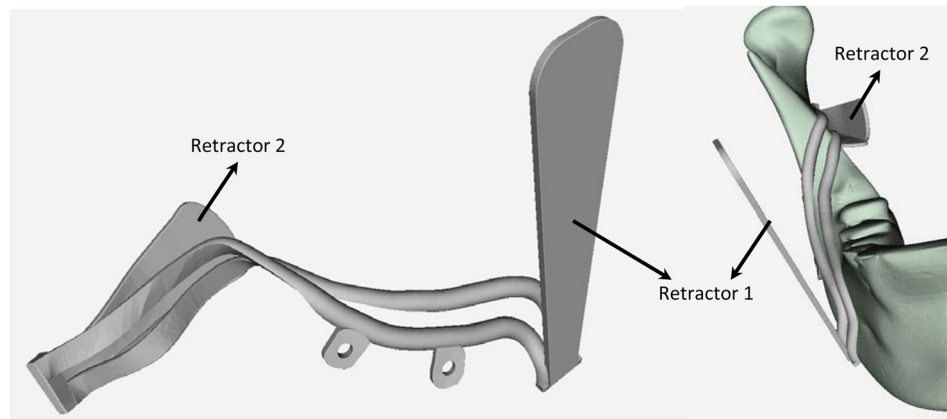
osteotomy line using the VR Mesh Studio software (VirtualGrid Company, Bellevue, WA) (Fig. 2).

Since the instrument was placed only in a single position on the mandible, positioning inaccuracy between the computer model and the real mandible would be restricted. Furthermore, mini-screws for temporary fixation and stabilizing notches located on the mandibular base and posterior ramus would provide a stable positioning of the apparatus (Fig. 3).

A safety plate (Fig. 3) and two soft tissue retractors (Fig. 4) were designed to protect the surrounding anatomic structures from the rotary osteotomy instruments.

**Manufacture of the Apparatus.** The instrument was fabricated based on its three-dimensional model using the metal laser sintering (MLS) method (Fig. 5). MLS is a technique preferred to fabricate metal prototypes and tools directly from computer-aided design data [10]. Since a suitable metal powder can be used to

produce the intended instruments with complex geometries, this process is widely employed in rapid tooling. In this production process, a high power laser was used to fuse small particles of stainless steel powders into a mass that has a desired three-dimensional shape. The manufacture of the device by the MLS lasted about 5 h which is quite an acceptable duration for such an apparatus with complex geometry. In our case, stainless steel was used as the material of the instrument since it shows ductile and biocompatible characteristics [11]. In addition, comparing with the titanium, which is widely used in medical device technology, stainless steel is a cheaper material. After the laser sintering of the stainless steel particles, instrument underwent heat treatment at 500 °C to improve the ductility and toughness, which specify the extent to which a solid material can be plastically deformed without fracture and the ability of a material to absorb energy, respectively. In dental surgery applications, surgeons may need to make small plastic deformations to tune the geometries of the instruments to match the dimensional requirements of the



**Fig. 4 Detailed views of the retractors designed to protect the inferior neurovascular bundle**



**Fig. 5 Manufactured instrument by laser sintering technology**

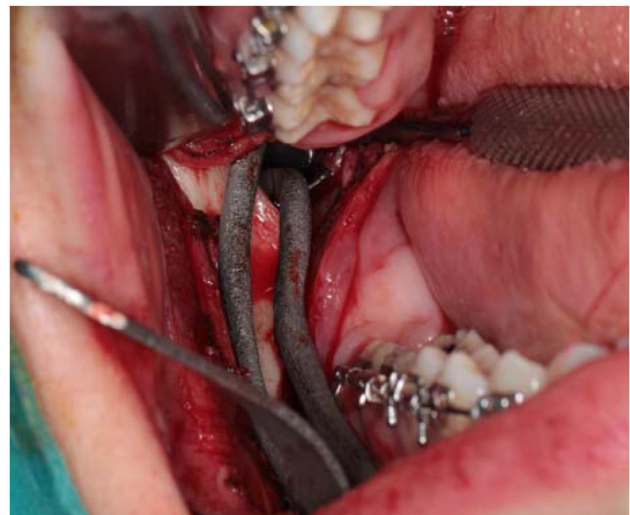
musculoskeletal tissues. Therefore, ductility and toughness are very important material properties in dental biomechanics.

## Results

In the operation, SSO was performed for mandibular advancement to correct mandibular retrognathism. The computer-assisted, patient-specific sagittal split osteotomy guide and soft tissue retractor was used at the right side of the mandible and the other side was performed by conventional instruments. On the anterior side of the ramus and the buccal side of the corpus, a diagonal full-thickness mucoperiosteal flap was elevated. Mandibular lingula and mental foramina were identified at the lingual side of the ramus and at the buccal side of the corpus, respectively. The medial retractor was cut and adapted to the lingual anatomic structures owing to its easily pliable characteristic. A periosteal elevator was used to retract the inferior alveolar bundle and the instrument's curved notch was inserted to the posterior border of the ramus. Then, periosteal elevator was removed and the inferior alveolar bundle stayed under the protection shield of the instrument. Finally, instrument was properly placed by attaching the other notch of the device to the mandibular basis (Fig. 6).

Two 5 mm mini-screws were used to fix the instrument to the mandible to prevent the disengagement during the operation. After the placement of the instrument, osteotomy was performed by using a Lindemann bur without using any other retraction instrument (Fig. 7). Following the completion of the osteotomy, the instrument was removed and splitting procedure was completed by using conventional SSO technique.

Although using the novel instrument for the first time in the surgery caused the prolongation of the total operation duration, it was clearly observed that the osteotomy step was remarkably



**Fig. 6 Application of the instrument during the sagittal split osteotomy**

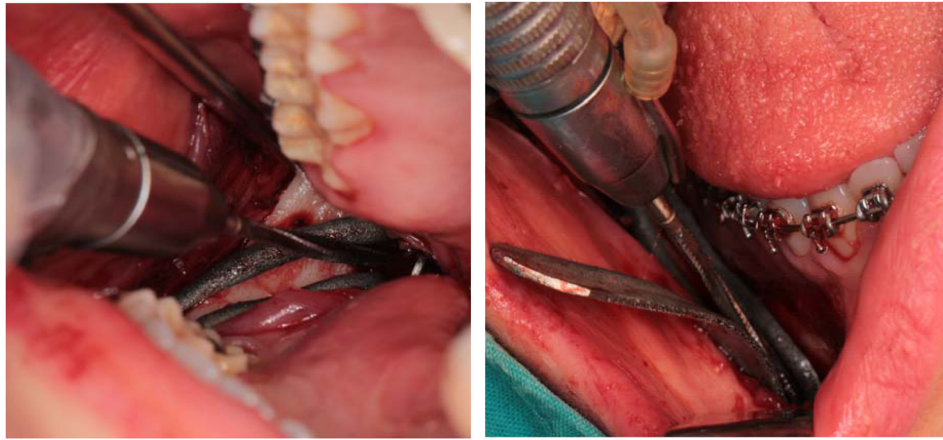
shorter and more accurate than the one applied to the other side operated by conventional method. Placement of the instrument onto the mandible, osteotomy procedure and the removal of the device were successfully performed without any assistance except aspiration of blood and irrigation solution.

This instrument is a combination of two soft tissue retractors and an osteotomy guide, which provided a generally accepted sagittal split osteotomy line starting from the posterior mandibular ramus and reaching the base of mandibular corpus. Although the main design purpose of the soft tissue retractors was to protect the surrounding anatomic structures from the rotary osteotomy instruments, they also provided good vision to the surgeon and eliminated the need for more tools during the operation. The flaps and surrounding soft tissues were kept stable during the operation owing to the fixed soft tissue retractors of the instrument and, it was evaluated that no soft tissue trauma occurred during the procedure. In addition, no hemorrhagic or neurologic complications occurred related with inferior alveolar neurovascular sheet.

## Discussion

SSO described by Trauner and Obwegeser [12] is a common operation technique used for the correction of mandibular deformities [12]. Although SSO is a well-known and widespread procedure, it requires careful planning and attentive operation technique to avoid complications.





**Fig. 7 Different views of the sagittal split osteotomy performed using the novel instrument. Rotary instrument follow the osteotomy line guided by the proposed device.**

Over-retraction of the soft tissues and using the sharp rotary tools for the osteotomy can induce complications especially during the approach on the medial side of mandibular ramus [13]. Careful identification and protection of inferior alveolar neurovascular bundle are required to prevent complications. Unsuitable oblique and vertical osteotomies are the major factors of bad splitting. Uncontrolled use of rotary instruments during operation can lead to damage of the surrounding soft tissues or failure to achieve a proper osteotomy line.

In this study, a computer-assisted, patient-specific sagittal split osteotomy guide and soft tissue retractor was designed and produced by using laser sintering method [9,14]. This instrument was developed to avoid complications such as soft tissue injuries, excessive edema, nerve and vessel damage caused by rotary instruments, and failures to perform correct osteotomy line. Also, the instrument provided more comfortable operation field by reducing the need for extra assistance.

The instrument has many advantages described above; however, challenging design and production processes of the device are limitations of the instrument. It requires a computer-aided design (CAD) operator to work on the design in cooperation with the surgeon who operates the patient. Also, it is still hard to fabricate this kind of custom-made, complex geometrical shaped objects with newly introduced laser sintering method. As a result of these factors, preoperative preparation period can increase. In addition, these processes bring extra costs.

During the placement of the instrument onto the mandible, the medial retractor slightly came into contact with the maxillary tuberosity. Therefore the length of the lingual soft tissue retractor was modified to be adapted to the internal dimensions of the mouth. Although it was not a serious complication and the retractor could be easily adapted to the lingual surface owing to its pliable character, this complication elongated the operation duration. For the computer-aided design procedure of the instrument, using not only the mandibular but also the maxillomandibular 3D model would eliminate such a complication.

Since the SSO is a specific operation, which requires a technical sensitivity, the use of the proposed instrument would be able to eliminate the most of the operator related complications. After elimination of the limitations of the instrument, it is expected to provide

- (i) shorter duration of operation,
- (ii) less time needed for the general anesthesia and accordingly less time for the exposure to the bacterial contamination,
- (iii) reduction of the complications and the operation costs due to shorter duration of operation,
- (iv) reduction of the corticosteroid need given for the edema control and,
- (v) reduction of the postoperative hospitalization period and the increase of the healing process.

Although it seems that using this novel instrument complicates the SSO procedure, it was clearly observed during the surgery that using this device provided a more accurate, sensitive, and controlled approach than the conventional method. Furthermore, it was confirmed that most of the operator-related complications can be eliminated by using this instrument.

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