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# Development of customized implant and customized surgical osteotomy guide in ablative tumor surgery for accurate mandibular reconstruction

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## Abstract

**Objectives:** The objective of this study was to provide the generalized methodology for design and development of a customized implant and customized surgical osteotomy guide (CSOG) for precise mandibular tumor resection and placement of a customized implant in ablative tumor surgery for accurate mandibular reconstruction.

**Methods:** Medical imaging technique, image processing, virtual surgical planning (VSP), biomedical computer-aided design (CAD), and rapid prototyping (RP) were used to develop CSOG and customized implant. A mock surgical test and an experimental analysis were performed on the biomodel (RP assisted diseased model) to check the effectiveness of the CSOG.

**Results:** The paired t test showed the statistically significant result with the use of CSOG as compared to the without using CSOG in ablative mandibular tumor surgery.

**Conclusions:** A mock test and an experimental analysis proved that, the precise tumor resection and customized implant placement with minimal gap between bone-implant junctions in mandibular reconstruction using CSOG.

KEYWORDS

computer-aided design, customized implant, customized surgical osteotomy guide, rapid prototyping, virtual surgical planning

## 1 | INTRODUCTION

Ablative tumor therapy is one of the main important causes for mandibular continuity defects. Reconstruction surgery of continuity defects of the mandible is still challenging for craniomaxillofacial (CMF) surgeons. In the CMF rehabilitation field, the mandibular continuity resection is often recommended for the treatment of extensive oral cancer or malignant mandibular tumors requiring the surgical removal of the affected bone. This type of surgery becomes complex and unpredictable because of very limited visibility of closed internal structures, presence of teeth and their relationship with bone, influence of surgery on airway, and interference with occlusion.[1] Different extended mandibular malignant and benign lesions and inflammation are treated using ablative surgery, which can cause continuity defects in the mandible.[1,2] Furthermore, squamous cell carcinomas (SCCs) of the tongue, floor of mouth, and mandibular alveolar process are treated with ablative tumor therapy. The subsequent mandibular reconstruction can be performed either at the time of the resection (primary surgery) or in a second step after an oncological follow-up period (secondary surgery). In both cases, the stabilization of the resected stumps in the correct anatomical position during the surgical intervention is one of the key features to provide a

  

satisfactory aesthetic appearance and assure an accurate centric occlusion for the restitution of the correct masticatory function, thereby improving the quality of life.[3] Accurate mandibular reconstruction is needed for functional and aesthetic improvement. Loss of anatomical mandibular shape severely includes problems in speech, mastication, deglutition, and occlusion.[4]

In current practices, the most reliable therapy is instant reconstruction of defects using musculo-osseous flaps, harvested from the fibula, iliac crest, or scapula and are microvascularly anastomosed (a surgical technique used to make a new connection made between two body structures that carry fluid, such as blood vessels or bowel). However, the instant reconstruction of continuity defects of the mandible is not always possible. These techniques are sensitive, associated with donor site morbidity, and may have a limitation in shape and size of graft, which often precludes their use.[2] Commercially available titanium bridging plates are usually and extensively used for mandibular reconstruction purpose. These reconstruction plates are offered in standard shapes and therefore need to be manually bent and adapted intraoperatively to obtain the final required profile (preplating technique). Sometimes, according to the localization and the spread of the tumor, also the condylar process may be included in the full thickness resection of the mandible. In such cases, reconstruction plates with metallic condylar prosthesis made with a standard head are used. Manual operations for contouring and shaping the plate are intraoperatively required to position the condylar prosthesis in the glenoid fossa for a correct articulation of the temporomandibular joint (TMJ). In both cases, the result of this time-consuming phase is operator dependent since the surgeon needs to customize the bridging plate to the defect of the patient according to his or her own skill and experience. Alternatively, these reconstruction plates may be manually shaped preoperatively using the rapid prototyping (RP)–assisted diseased mandible biomodel of the patient.[3]

Although this method is being currently widely used to reduce the operative time during surgery, the shaping precision may be limited when large tumors producing other abnormalities such as bone deformities are present. It is well known that in the last decade RP has been more and more extensively used in many biomedical applications.[5-11] Combined with traditional computed tomography (CT) and computer-aided design (CAD) approaches, additive manufacturing (AM) technologies may be used nowadays as tools to directly produce customized surgical devices in different biocompatible materials.[12,13] These customized surgical devices may be designed according to the preoperative virtual surgical planning (VSP) of the surgical intervention to assure the correct transfer in the operating theatre when the surgery is carried out and therefore satisfy the functional and aesthetic requirements.[14]

Therefore, to avoid the above complications and to improve the results of the conventional method and techniques, there is a need to design and implement a customized instrument for accurate mandibular reconstruction. The present invention provides generalized methodology for design and development of a customized implant and customized surgical osteotomy guide (CSOG) in ablative tumor surgery for accurate mandibular reconstruction. The application of CAD/computer-aided manufacturing (CAM)– and RP-based technologies for the innovative development of customized surgical devices to assist in the mandibular rehabilitation is reported in this study.

The main objectives of the present invention are as follows:

1. To design and develop the customized implant that can avoid the bone grafts, metallic reconstruction plates, and trays in ablative tumor surgery for accurate mandibular reconstruction.
2. To design and develop the innovative patient-specific customized implant that exactly matches to the remaining mandibular bone after tumor resection to provide good aesthetics to a patient's face and fulfill the functional requirement.
3. To develop a new device (CSOG) for accurate resection of the mandibular tumor without damaging any neighboring healthy tissues.
4. To provide an innovative method for accurate placement of a customized implant at a planned location to improve the accuracy of the mandibular reconstruction.
5. To design and develop a device for tumor resection, which has a self-locking system to fix it exactly on the mandibular bone without using any external screws, which helps to avoid damage of the healthy bone.
6. To develop a device to obtain the accurate tumor resection with proper surgical margin to avoid the recurrence of cancer.
7. To develop a methodology that requires less time for designing and fabrication of devices (customized implant and CSOG) so that it can be used in emergency cases.
8. To develop the methodology to avoid the costly biomodels (RP assisted diseased model) generally used for mock surgery and required at the time of actual surgery.
9. To design and develop the instrument (CSOG) in such a way that, it should be simple and compact and easily fix to the patient's mandible without disturbing the neighboring healthy tissues.
10. To develop a handy, portable, cost-effective device for tumor resection, which can be used by any new surgeon.
11. To develop cost-effective instruments (customized implant and CSOG) used in ablative tumor surgery to improve the accuracy and simplicity of mandibular reconstruction.

## 2 | METHODOLOGY

In general, the computer-aided (or RP-assisted) mandibular reconstruction process involves two main phases before proceeding to the surgery:

1. virtual (data acquisition, image processing, VSP, CAD of customized implant, and CSOG) and
2. physical (fabrication of customized implant and CSOG using RP and postprocessing).

Generalized standard workflow of process for the development of a customized implant and CSOGs for mandibular reconstruction is

illustrated in Figure 1. In the first step, preoperative CT/cone beam CT (CBCT) scan data are used for the 3D reconstruction of the actual mandible and to allow the preoperative VSP of the surgical intervention. Then, innovative customized surgical devices are elaborated according to the shape of the mandible of the patient and to the planned surgery by the surgeon. In the case of mandibular reconstruction surgery, a CSOG is developed to assist the resection step while a customized implant is developed to assist the reconstruction step. As a customized implant is developed using a patient's mandible defect dimensions, design of the repositioning guide is not needed to bring back the resected mandibular stumps to the original position according to the original shape of the mandible. Examples of such devices are shown in Figures 3–7. Finally, the CSOG and customized implant are manufactured by RP technique in material suitable for biomedical applications.

## 2.1 | Data acquisition

Data acquisition of the CMF region is the first and most important step used for the development of a customized implant and CSOG in ablative mandibular tumor surgery. In this step, high-resolution CT or CBCT scan of the diseased mandible of a patient who needed ablative tumor surgery and mandibular reconstruction is adopted prior to the actual surgery, with setting of proper gantry tilt, slice thickness, pixel size, number of slices, resolution, tube voltage, and tube current. CT/CBCT scan data are used to visualize, diagnose, and examine the defect or tumor available in the mandibular bones, organs, and tissues. The accuracy and quality of fit between a customized implant/CSOG and the affected bone strongly depend on the quality of the preoperative CT or CBCT scan.

## 2.2 | Image processing and design of diseased mandibular CAD models

In image processing, previously obtained CT/CBCT images of a diseased mandible in DICOM format are processed using commercial available software (MIMICS 14.11, Materialise, Leuven, Belgium) to create a 3D CAD model of the diseased mandible. CT/CBCT data of a patient's diseased mandibles are processed using a proper threshold value in image processing software. Then segmentation and region growing tools allow to create the 3D virtual CAD model of the diseased mandible, so that the surgeon is able to simulate the mandibular osteotomies (Figure 2). Finally, the CAD model of the patient's diseased mandible is exported to STL format for VSP and design of the customized implant and CSOG. These STL files can also be used for the fabrication of biomodels (if needed) in acrylonitrile butadiene styrene (ABS) plastic material using fused deposition modeling (FDM) (RP) technique.

## 2.3 | Virtual surgical planning

The next important step is preoperative VSP. In VSP, first, previously prepared CAD models of a diseased mandible (STL format) are imported into the biomedical CAD software (3Matics 8.0, Materialise, Leuven, Belgium) for surgery planning. Then with biopsy report

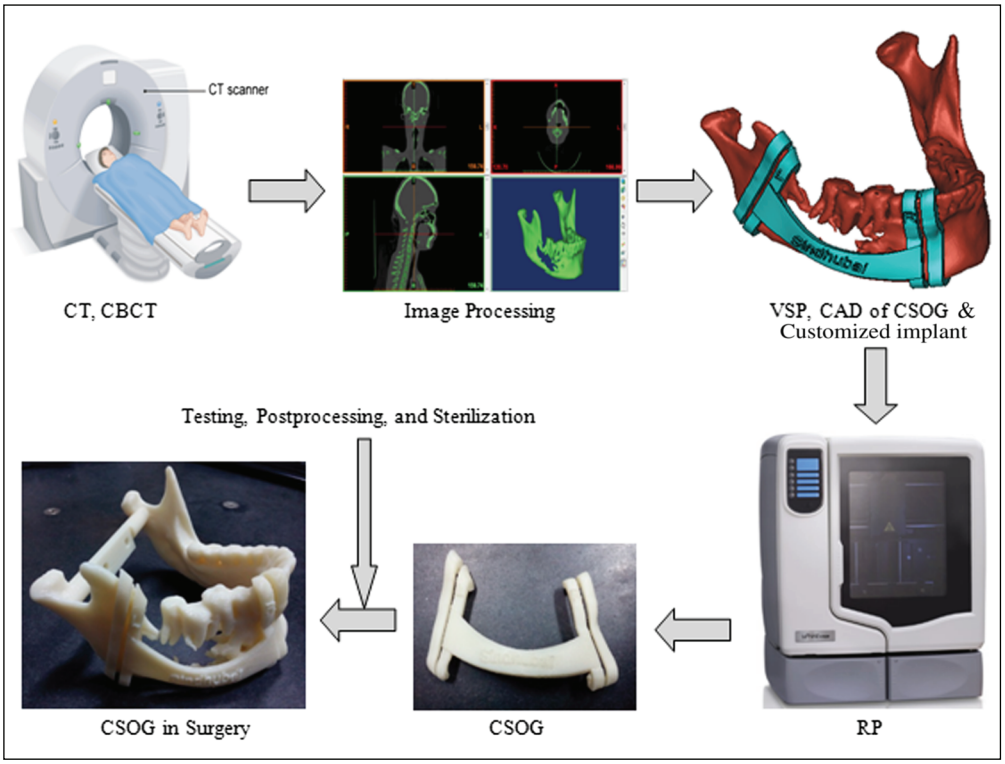


**FIGURE 1** Generalized standard methodology for development of customized implant and CSOGs

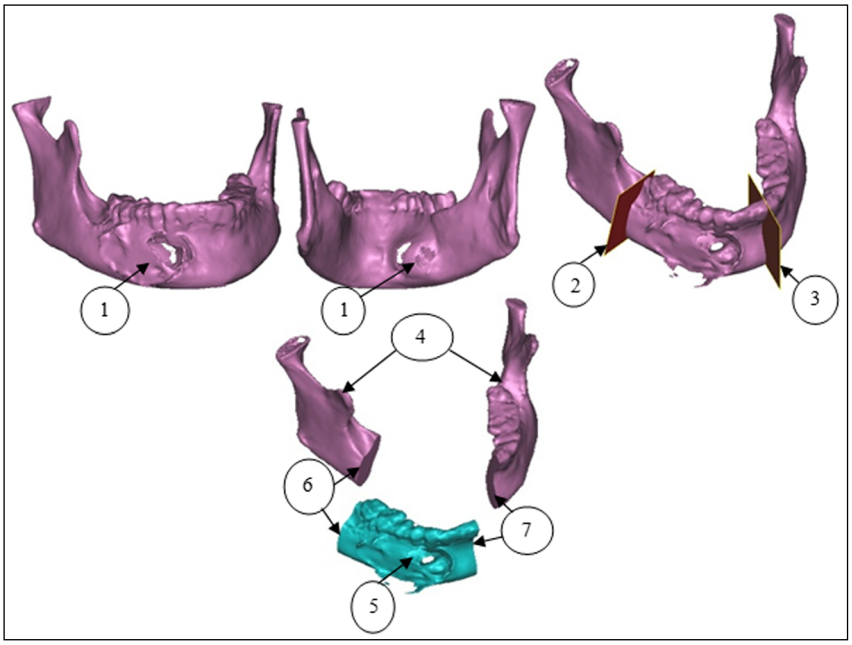


**FIGURE 2** CAD model of diseased mandible (front and back views) and preoperative virtual surgical planning (VSP)

| S.N. | Elements |
|---|---|
| 1 | Diseased mandible |
| 2 & 3 | Cutting planes showing the tumor length including surgical margin and cutting location |
| 4 | Remaining mandibular stumps |
| 5 | Resected tumor |
| 6 & 7 | Contact surfaces |

and surgeon's input, tumor/defect size, surgical margin (safety margin), cutting location, and cutting space as per the tool size, on both sides of the tumor, are finalized by fixing the cutting planes (2 and 3) on the CAD model of a diseased mandible (Figure 2). The cutting planes (2 and 3) indicating position and orientation of the osteotomies are planned considering surgical margins with respect to the region of the bone affected by the tumor. This VSP on the diseased mandibular CAD model of structure is further used for the design of the customized implant and CSOG in ablative tumor surgery.

## 2.4 | Design of a customized implant

The next step is design of the customized implant for mandibular reconstruction. Based on the previous preoperative VSP (Figure 2), the customized implant is designed using biomedical CAD software (3Matics 8.0, Materialise, Leuven, Belgium) in such a way that it can fit exactly into the mandibulectomized area (tumor-resected mandibular area) and match with the remaining mandibular contours. The main aim of designing the customized implant is to stabilize and support the remaining mandibular stumps after tumor resection. This customized implant is designed according to the previously resected part of the mandible dictated by the localization and the spread of the tumor. Also, this customized implant is developed according to the functional and aesthetic requirements of the surgical intervention. An example of a customized implant is shown in Figure 3.

As shown in Figure 3, the customized implant can be schematically decomposed into different functional elements. The table in Figure 3 lists the featuring elements of the customized implant with the function that they are expected to serve. This customized implant comprises a main body (8) exactly matches to the remaining mandibular contour and customized fixation plates (11 and 12) with screw holes (13 and 14) at the extremities on both sides of the customized implant with the main purpose of controlling the continuity of the anatomical mandibular reconstruction after tumor resection. The main body (8) maintains the connection and also carries out the function of supporting the remaining mandibular stumps after reconstruction process. These customized fixation plates (11 and 12) are designed in such a way that they perfectly fit and adhere to the surface of the remaining mandibular stumps. To achieve this, customized fixation plates (11 and 12) are designed by thickening the outer surface of the healthy contralateral side of the mandible mirrored with respect to the midsagittal plane. This approach allows obtaining an ideal patient-specific mandibular profile on the fixation plates (11 and 12), eliminating the presence of the bone deformities on the side affected by the tumor. The main body (8) is designed in such a way that it exactly matches with the contour of the remaining mandibular stumps to provide a better continuity of the profile and thereby enable a correct reconstruction from a functional and aesthetic point

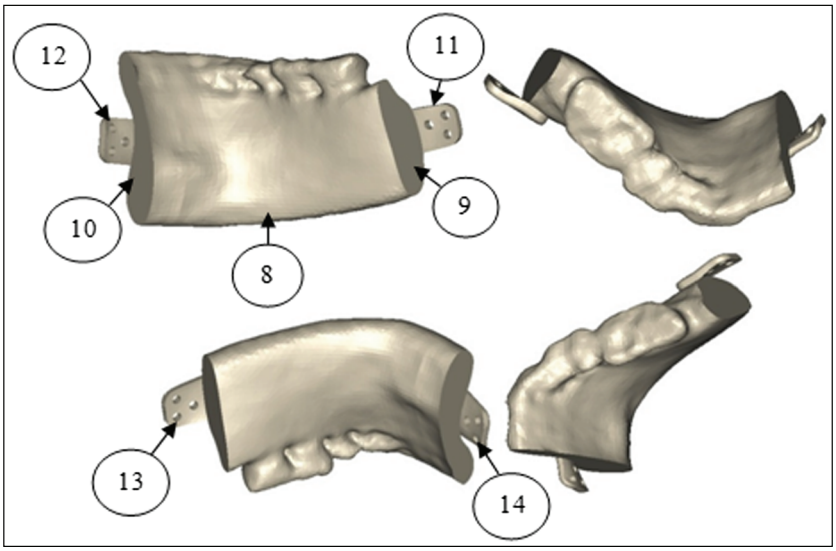


**FIGURE 3** Different views of the CAD model of the customized implant

| S.N. | Elements | Functions |
|---|---|---|
| 8 | Main body | To bridge the tumor resected gap and match the contour of the implant with the remaining mandibular stumps |
| 9 & 10 | Contact surfaces | To exact fixation of the customized implant in the resected mandibular area |
| 11 & 12 | Customized fixation plates | To exact fixation of customized implant on the remaining mandibular bone after tumor resection |
| 13 & 14 | Screw holes | To exact fixation of the customized implant |

of view. An array of holes (with diameter depending on the screws chosen by the surgeon) is arranged along the fixation plate to allow the customized implant to be fixed properly to the mandible of the patient. These fixation plates (11 and 12) should have at least two holes at each side to ensure a stable fixing. Each element of a customized implant has been designed separately. Finally, all the elements are assembled using Boolean union to form a customized implant. Figure 3 shows the different views of the CAD model of the customized implant.

## 2.5 | Design of the CSOG

The next step is the design of the CSOG. Based on the previous preoperative VSP (Figure 2), the CSOG is designed on the previously developed diseased mandibular CAD model in biomedical CAD software (3Matics 8.0, Materialise, Leuven, Belgium). A CSOG is designed for the resection of the mandibular portion affected by the tumor as intended by the surgeon during the preoperative VSP of the surgical intervention. An example of the CSOG for the removal of the mandibular tumor is illustrated in Figure 4. As shown in Figure 4, the CSOG can be schematically decomposed into different functional elements. The table in Figure 4 lists the featuring elements of this component and the function that they are expected to serve.

CSOG is designed in such a way that it can exactly fit into the diseased mandible for accurate resection of the tumor and exact placement of the customized implant in the mandibulectomized area (eradicated diseased mandibular area) to match accurately with the remaining mandibular contours. CSOG is designed by surgeon's input in considering tumor length, surgical margin, location and space required for cutting, size of cutting tool, and space required for the surgery. The main parts of the CSOG comprise the left guide and right guide (16 and 17) with cutting slots (one for anterior side cut and the other for posterior side cut) (18 and 19) for the surgical resection of the mandibular tumor in relation to the position and the orientation of the cuts identified by the surgeon during the preoperative VSP of the intervention. Two cutting guides (16 and 17) are connected with each other with a positioning plate (22). The positioning plate (22) helps to show the accurate tumor size with surgical margin. Furthermore, this positioning plate ensures the relative position between the guides (16 and 17) according to the preoperative VSP. The cutting slots (18 and 19) are designed as per the cutting tool thickness in such a way that the tool can easily move inside the slot intraoperatively, allowing the head of the cutting tool to be supported during the surgical cut. Retention plates (20 and 21) are provided between the cutting

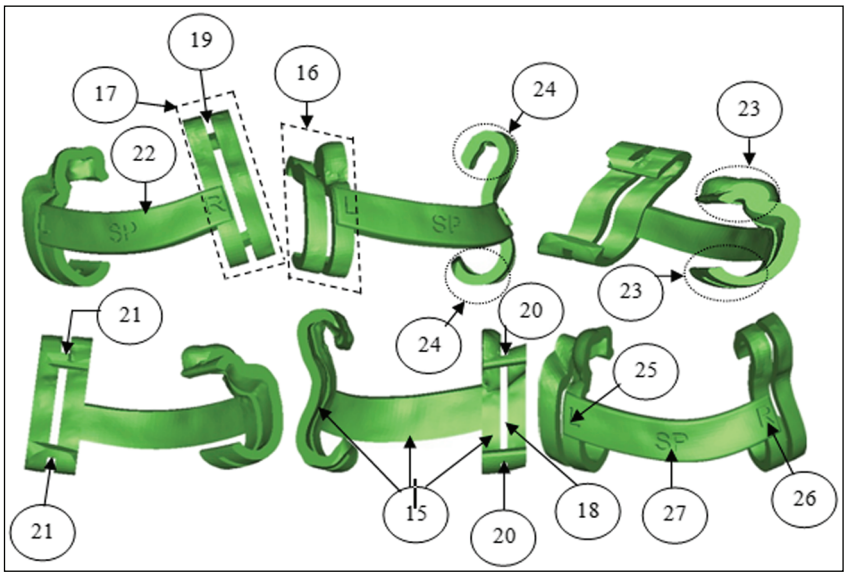


**FIGURE 4** Different views of CAD model of CSOG

| S.N. | Elements | Functions |
|---|---|---|
| 15 | Base surface | To fit CSOG exactly on the planned location |
| 16 & 17 | Left & Right CSOG | To accurate resection of tumor |
| 18 & 19 | Left & Right cutting slot | To accurate movement of cutting tool for resection |
| 20 & 21 | Left & Right retention plate | To maintain the gap between the cutting slot |
| 22 | Positioning plate | To fix the tumor size and osteotomy guide<br>To maintain the exact distance of tumor with surgical margin<br>To connect the left and right CSOG |
| 23 & 24 | Left & Right locking system | To fit CSOG properly on the diseased mandible and avoid dislocation while cutting |
| 25 & 26 | Left & Right indicator | To indicate orientation of the CSOG |
| 27 | Patient ID | To indentify the particular patient's CSOG |

slots (18 and 19) to maintain the exact distance for cutting tool movement. The base surface (15) of the CSOG allows the accurate fixation and placement of the CSOG on the planned location on the mandible. Base surface (15) represents the contact area between the CSOG and the mandible of the patient. Therefore, this element of the CSOG (15) is designed to perfectly fit and adhere to the surface of the bone by thickening the outer surface of the 3D reconstructed mandible. The locking systems (23 and 24) of the CSOG are designed on both sides of the cutting guide (16 and 17) for an exact snug fitting of the CSOG on the mandibular bone without using any screws externally. The left and right indicators (25 and 26) provided for the accurate orientation and placement of the CSOG. Patient ID (27) is designed on the CSOG to avoid the mismatching problem at the time of surgery. Finally, all parts, ie, left osteotomy guide, right osteotomy guide, positioning plate, left retention plates, and right retention plates, are assembled using Boolean union to form a complete CSOG. Figure 4 shows the different views of CAD model of the CSOG.

The cutting slots are designed so as to leave sufficient space for introducing the surgical cutting instrument and performing the cut, without exceedingly restricting the surgical space for the bone removal. This arrangement in the shape of the cutting guide also tries to provide a complete and correct view of the portion of the bone to be removed and reduces the risk of injury to any other anatomical structures needing to be preserved. While cutting the tumor from the cutting slot, the surgeon has to cut the retention plates at last and complete the cut, so that after complete resection from both sides,

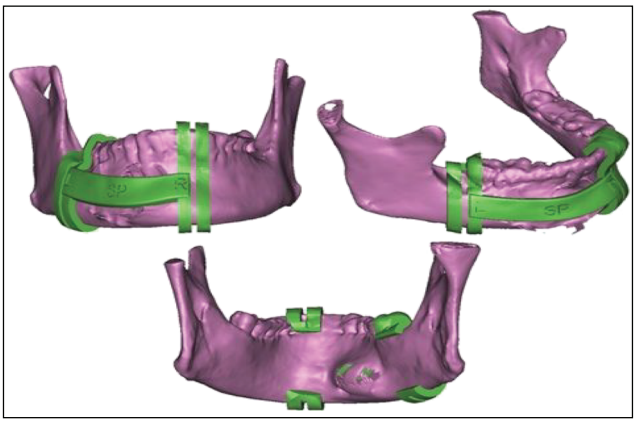

**FIGURE 5** Virtual testing of CSOG on the diseased mandible (different views)

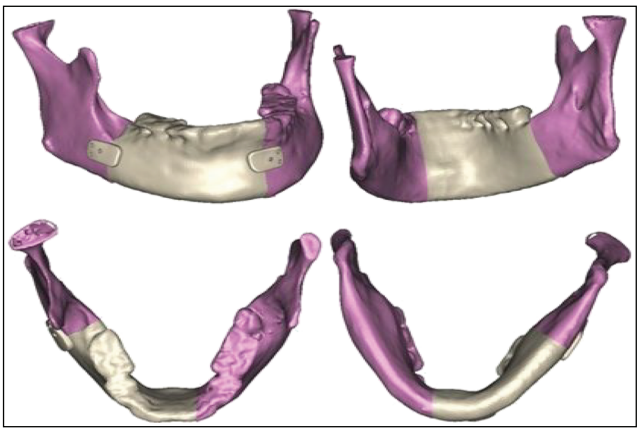

**FIGURE 6** Virtual testing of customized implant on the tumor-resected mandible (different views)

the tumor with a separated CSOG can be taken out easily without damaging the neighboring parts. The remaining parts of the separated CSOG then have to be separately taken out from the remaining mandibular stumps. Sometimes, according to the localization and the spread of the tumor, the condylar process may be included in the full thickness resection of the mandible. In such cases, the design of the CSOG may be simplified as a single-sided CSOG only. In this case, the positioning plate is not required.

## 2.6 | Virtual functional testing

The next step is the virtual functional testing of the CSOG on the diseased mandibular CAD model and customized implant on tumor-resected mandibular CAD model. In that, CSOG is fixed on the CAD model of the diseased mandible to check the CSOG fitting and positioning for accurate resection of the tumor and accurate placement of the customized implant. Also, a customized implant is fitted in the tumor-resected mandible, using a CAD models to check the implant positioning and fixation with ends of the remaining mandibular stumps. Also, accurate checking of location and positioning of implant fixation plates and screw holes have to be performed while testing the customized implant fixation. Once virtual testing of the CSOG and customized implant is finalized by the surgeon, then the STL files are exported for manufacturing using the RP technique in biocompatible material. Figure 5 shows the different views of virtual testing of the CSOG on the CAD model of a diseased mandible. Figure 6 shows the different views of virtual testing of the customized implant on the CAD model of the tumor-resected mandible.

## 2.7 | RP-assisted fabrication of customized implant and CSOG

The next step is the fabrication of the customized implant and CSOG using the RP technique. The CSOG and customized implant for mandibular reconstruction can directly manufactured using the RP technique using a high-quality STL file. For that, the STL file of the customized implant and CSOG is imported into an RP-compatible software and linked with the RP machine for fabrication in biocompatible material. Selection of the RP technique for fabrication depends on the availability, need, and cost of fabrication.

Generally, the customized implant is fabricated using a metal RP technique (like direct metal laser sintering [DMLS] technique) EOSINT M270 machine (EOS GmbH, Electro Optical Systems, Munich, Germany) in biocompatible materials (SS316L, cobalt chrome, or titanium alloy material). The working principle of this machine is based on the DMLS approach by fusing metal powder into a solid part and melting it locally by using a focused laser beam. As is usual for AM technologies, the components are built up additively layer by layer. Metallic materials like cobalt chrome and Ti6AlV4 alloy are in the form of a fine powder that is used to fabricate the customized implant and CSOG due to excellent mechanical properties and corrosion resistance combined with low specific weight and biocompatibility. These types of materials are particularly suitable for the production of biomedical implants. A polishing operation is also required on the titanium customized implant to reduce the surface roughness. Then postprocessing of the fabricated part is an important step for finishing the fabricated parts to remove the support structure. Postprocessing is an important step to obtain the exact base surface of the CSOG to place accurately on the diseased mandible. Finally, the surgeon finalizes the fabricated customized implant and CSOG by functional testing and checking and then can send these instruments to the hospital for sterilization and for further use in an actual surgery.

In this study, the fabrication of the CSOG, customized implant, and diseased mandible are directly manufactured using uPrint soluble support technology (SST) machine (Stratasys, Eden Prairie, Minnesota) to prove the concept of the CSOG and customized implant. The working principle of this machine is based on FDM of ABS and soluble support material to sustain the prototype under construction. By this RP process, models are built up layer by layer with two available filling

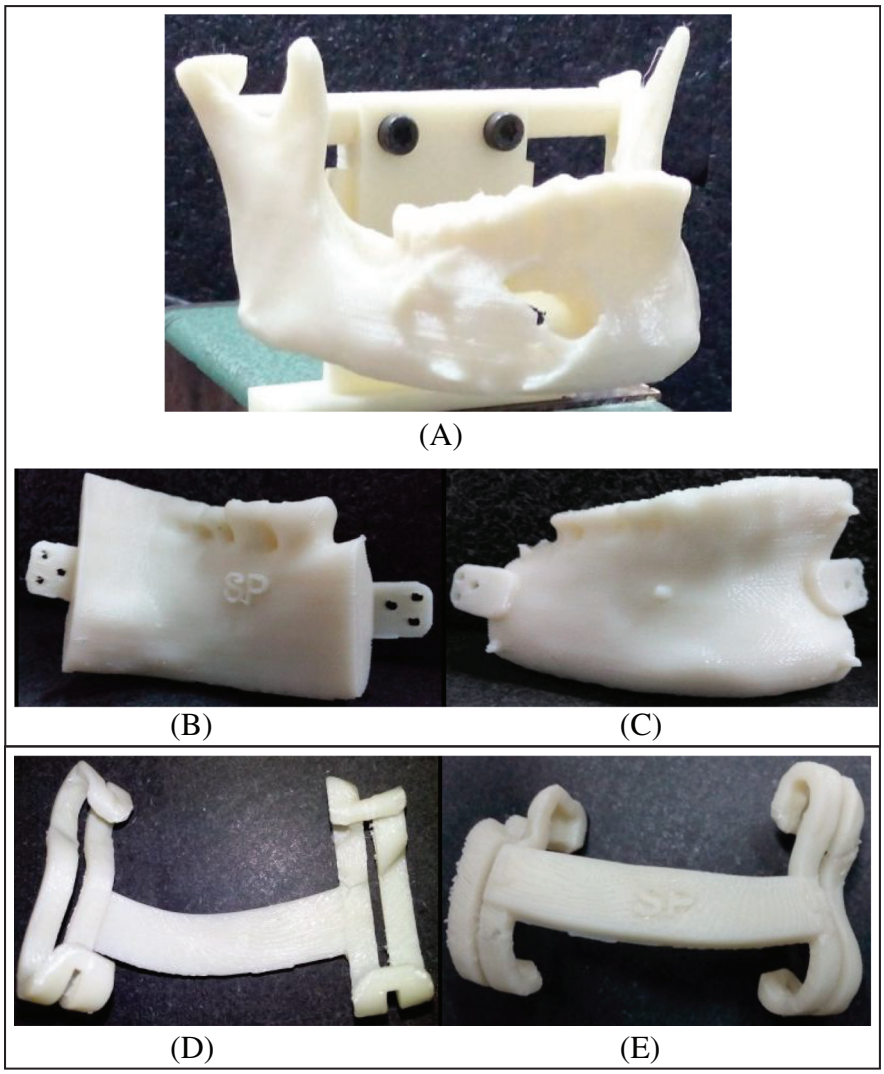


**FIGURE 7** RP-assisted fabrication. A, Diseased mandible (biomodel). B and C, Customized implant (back and front view). D and E, CSOG (back and front view)

options: solid and sparse. In the first case, each section of the model is completely filled with ABS material (solid fills are stronger and heavier). In the second one, the interior part of the model is replaced with a honeycomb structure (sparse fills are weaker and lighter). The mandibular biomodel is directly prototyped by choosing the sparse fill option to save material and speed up the build session. The process is finished by washing the model in an agitation system with a hot soapy water bath to remove all the support material for hands-free models completion. The ABS prototyped model of the mandible is then used by the surgeons to gain a better understanding of the surgical intervention and to test and validate the developed customized surgical devices before surgery (Figure 7).

## 2.8 | Use of the CSOG and customized implant in mandibular reconstruction

In mandibular reconstruction surgery, it is essential to use the CSOG and customized implant in proper sequence (first CSOG and then customized implant), to ensure the correct correspondence between the mandibular resection following accurate reconstruction at the same time of the intervention. The reconstructive customized implant is fixed after an accurate resection of the mandibular tumor using the CSOG in order to ensure the proper positioning. In particular, the fixation plates for fixing the customized implant are designed to fit perfectly with the remaining mandibular surface. Also, the contact surface available on the remaining mandible after tumor resection and on a customized implant should match exactly to each other to obtain exact fixation, which helps to improve the functionality and aesthetics of the mandible. Moreover, designing the CSOG and customized implant using the same virtual surgical plan allows the exact cutting of the mandibular tumor and placement of the customized implant on the planned location of cortical surface of the remaining mandibular stumps. The sequence of steps is as follows:

a. fixation of the CSOG using locking systems on the diseased mandibular surface (Figure 8A,B),
b. resection of the mandibular tumor from both sides using the CSOG (Figure 8C,D),
c. removal of the resected tumor with CSOG (Figure 8E,F),

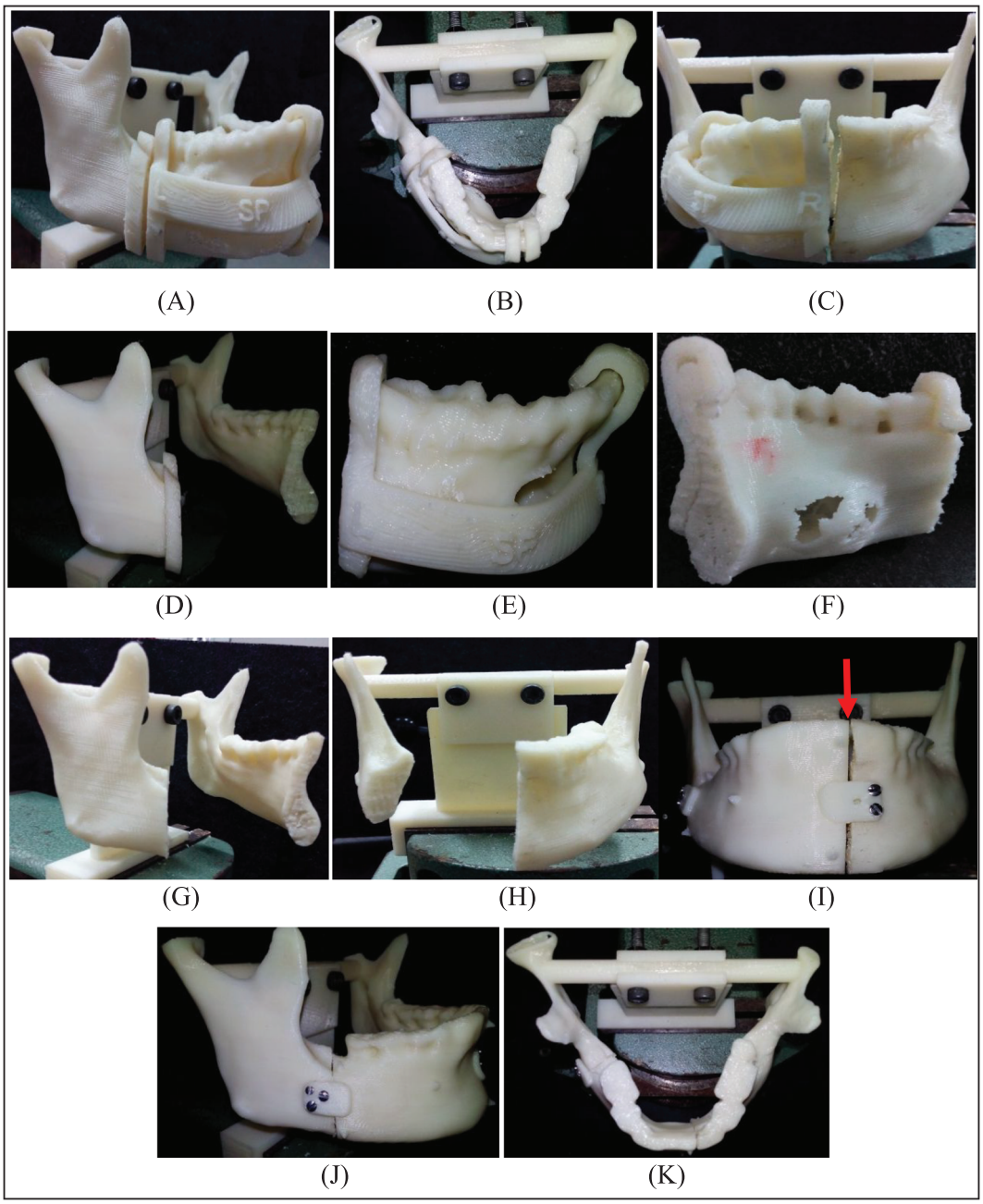


**FIGURE 8** A and B, Fixation of the CSOG on biomodel. C and D, Accurate tumor resection using CSOG. E and F, Resected tumor with CSOG. G and H, Remaining mandibular stumps after removing CSOG and shaping (for smoothening). I-K, Mandibular reconstruction with customized implant

d. shaping and smoothening of the remaining mandibular stumps (if needed) (Figure 8G,H), and
e. fixation of the customized implant on the remaining mandibular stumps (Figure 8I-K).

The aim of this approach is to assure a more precise relation between the two remaining mandibular stumps in view of the fact that a rigid connection is never missing. The mandibular tumor was resected through the cutting slot of CSOG, and the tumor with separated CSOG was removed, and then the customized implant is placed in the mandibulectomized area exactly on the planned location.

## 2.9 | Mock surgical test and experimental analysis

To check the effectiveness of the CSOG, a mock surgical test and an experimental analysis was conducted. Total 15 samples of diseased mandibles were collected from various CT scan centers, and biomodels were prepared using RP technique in ABS plastic. These 15 samples were registered for the control group (mandible reconstruction: tumor cutting and implant fixation without using CSOG) and the same 15 samples for the experimental group (mandible reconstruction: tumor cutting and implant fixation using CSOG). Figure 8 shows the complete procedure of resection and

reconstruction of the mandibles (mock surgical test) for both groups. The only difference in the control group was instead of using CSOG, manual measurement was taken on RP-assisted diseased mandible models for tumor resection and implant placement. Finally, after tumor resection and implant fixation on the bimodal, the maximum gap, minimum gap, and mean gap between implant and bone (Figure 8I, red arrow) (at the anterior and posterior sides) were measured by digital vernier caliper in both groups (with and without using the CSOG) to check the effectiveness of the CSOG in mandibular reconstruction surgery. Total 12 measurements on a fixed location (four on the front side, four on the back side, two on the top side, and two on the bottom side) were taken on each sample at each side (anterior and posterior); and maximum gap, minimum gap, and mean gap between implant and bone were calculated. Finally, statistical paired *t* test was conducted to check the significance of the CSOG. Significance level was set at .05.

## 3 | DISCUSSIONS

The present invention provides a generalized methodology for the design and development of the "customized implant" and "CSOG for the accurate resection of the mandibular tumor and the accurate placement of the customized implant" in ablative tumor surgery for accurate mandibular reconstruction. To place the customized implant exactly on the planned location, accurate resection of the tumor is very important. CSOG is a device that is designed for the accurate resection of the mandibular tumor and exact fixation of the customized implant. In a normal procedure, this CSOG can be easily placed at the planned location on the diseased mandible in a patient's mouth, and by moving the cutting tool through the cutting slot of CSOG, exact cutting of the tumor with proper surgical margin can be possible. This CSOG can be used easily by a snug fitting on the diseased mandible without using any external screws, which helps to avoid damage to the healthy bone. After accurate resection of the tumor, the customized implant can be placed accurately at the planned location with exact fitting in the mandibulectomized area. As compared to the other techniques, this procedure, helps to increase the functionality and the aesthetics of the patient's jaw and reduce the surgery time and cost of the surgery.

Experimental results showed that mean maximal gap (of 15 samples) at bone-implant junction with and without using CSOG at the anterior and posterior sides were statistically significant (Figure 9). Mean maximal gap at bone-implant junction at the anterior side was (2.04 ± 0.74 mm [mean ± SD] [95% CI, 0.64-3.11 mm]) and (5.04 ± 1.70 mm [mean ± SD] [95% CI, 2.56-7.12 mm]) ($P < .05$) for with and without CSOG technique, respectively (Figure 9A), and at the posterior side, it was (1.29 ± 0.46 mm [mean ± SD] [95% CI, 0.63-1.92 mm]) and (2.91 ± 0.96 mm [mean ± SD] [95% CI, 1.39-3.99 mm]) ($P < .05$), respectively (Figure 9B).

Also, mean gap (of 15 samples [of the mean of 12 points on each side of the]) with and without CSOG at the anterior and posterior sides was statistically significant. The mean gap at bone-implant junction at anterior side was 0.97 ± 0.43 mm (mean ± SD) (95% CI, 0.38-1.63 mm) and 2.73 ± 1.15 mm (mean ± SD) (95% CI, 1.09-4.56 mm) ($P < .05$) for with and without CSOG technique, respectively (Figure 9A), and at the posterior side, it was 0.66 ± 0.20 mm (mean ± SD) (95% CI, 0.38-0.91 mm) and 1.54 ± 0.52 mm (mean ± SD) (95% CI, 0.80-2.30 mm) ($P < .05$), respectively (Figure 9B).

The innovative design and the direct manufacturing of the CSOG and customized implant for mandibular resection and reconstruction based on a preoperative VSP may represent a novel approach in the treatment of oral tumors for patients undergoing mandibular rehabilitation. Some points can be focused:

1. During surgery, the mandible bone has to be cleaned (complete removal of soft tissue) to facilitate the placement of the CSOG. The CSOG is then fixed to the mandibular bone by using a locking system.
2. The use of the CSOG is only during the surgery for the removal of the affected bone, whereas the customized implant may be temporary only for rehabilitation period or permanent in a patient's body.
3. The time required for the placement of the CSOG in the correct position is not very long since this operation is aided by the presence of the base surface on the surface of the mandible.
4. Virtual planning helps to improve the self-confidence of the surgeon in placing the device in the correct position at the exact location.
5. The CSOG helps to simplify the surgery by obtaining accurate surgical margins and precisely transferring the virtual surgical plan into the operating site.[15-17]

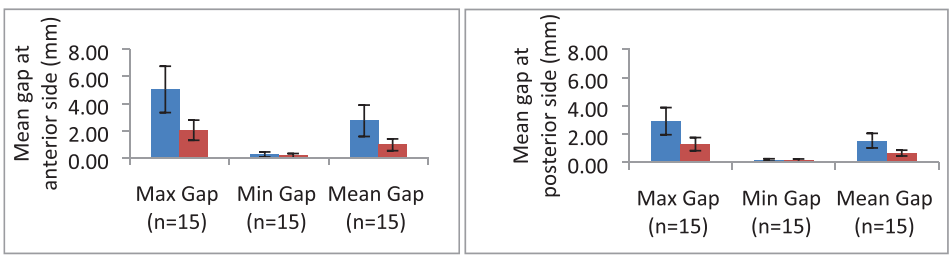


**FIGURE 9** Gap at bone-implant junction. A, At anterior side. B, At posterior side. (Blue: Without CSOG; Red: With CSOG)

6. By using the customized implant, the contour of native mandibular profile can be easily obtained, and resected stumps can be easily brought back to the original position.[18,19] So the need for extra positioning guide is not required in the surgery.
7. The customized implant also helps to improve the reconstruction step by exact restoration of original mandibular contour of the patient into the surgical environment.[18,19]
8. Cost of design and manufacturing of the customized implant should be as low as possible compared with that of the standard reconstruction plates commercially available, which need to be bended and adapted to the morphology of the patient.
9. Compared with traditional mandibular reconstruction, operating time is reduced since it is not spent on bending a commercial bone plate intraoperatively.
10. The time elapsing between the surgical planning and the delivery of the customized device ready to use for the surgery should be as short as possible, to avoid variations of the preoperative clinical conditions of the patient.
11. The design of the CSOG and customized implant may be different from patient to patient as per the need, shape, and size of bone, location of affected site, space available for surgery, neighboring tissues, patient and surgeon's comfort, RP technique availability, and material availability.

The design and development of customized surgical devices to assist surgery for mandibular rehabilitation have been presented in this study. The preoperative VSP of the surgery acquires an added value. The development of such CSOG and customized implant manufactured using RP technology permits the correct and precise transferring VSP into the operating theatre.[14-17] This approach allows the restoration of the patient's native mandibular contour, providing a satisfactory aesthetic appearance and assuring an accurate centric occlusion for the restitution of the correct masticatory function. Moreover, the surgeon has a better procedural control, and the operative time is reduced.

## 4 | CONCLUSIONS

This work builds a foundation for research in fabricating sufficiently strong and dimensionally accurate complex medical parts like customized implants and customized surgical guides (CSGs) by RP technology. For further development, research directions should be investigated.

A mock test and an experimental analysis proved that, CSOG gives significant result as compared to the without using CSOG, in tumor resection and fixation of customized implant with minimal gap between bone-implant junctions in ablative tumor surgery in mandibular reconstruction.

- ❖ RP-assisted CSGs can be used as an alternative to advanced computer navigation system and robotic surgery.
- ❖ RP technique can replace conventional fabrication methods for an accurate and precise manufacturing of CSGs and customized implants.
- ❖ Further research is required to reduce the overall cost and time (caused due to radiology, image processing, VSP, CAD, RP technique, postprocessing, and sterilization) to fabricate RP-assisted CSGs and customized implant so that it can be used in routine clinical practices.
- ❖ A more sophisticated way and an integrated approach are needed in the fabrication of the customized implants and CSGs using imaging, CAD, and RP technologies.
- ❖ Attempts are required to use cobalt chrome, titanium, ceramics, and special alloys as implant and CSG material, given their benefits/advantages from various recent studies.
- ❖ The evaluation of the mandibular reconstruction with a customized implant with and without using CSOGs by FEM under dynamic conditions should incorporate a more detailed model.
- ❖ Further development is needed to avoid the bias in the design, the fabrication process, or the positioning of the CSOG to develop the best CSOG, which will provide minimal errors.

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