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RESEARCH ARTICLE

DESIGN PROTOCOL AND MANUFACTURING WORKFLOW OF 3D PRINTED SURGICAL GUIDES IN MANDIBULAR RECONSTRUCTION WITH VASCULARIZED PERONEAL GRAFT AND MUSCULOCUTANEOUS FLAP

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ABSTRACT

Oro-maxillo-facial surgery in oncological patients is particularly challenging due to the complex nature of the disease and its treatment, which often involves extensive tissue resection and reconstruction. Traditional surgical techniques can result in functional and aesthetic deficits, and the risk of complications is high. The use of 3D printing (3DP) technology has revolutionized the field of Oro-maxillo-facial surgery, particularly in the area of mandibular reconstruction with vascularized peroneal graft and musculocutaneous flap. This complex procedure requires a multidisciplinary team, including an OMF surgeon, plastic surgery doctor, oncologist, medical imaging doctor, and technical team composed of graphics software expert and 3DP technician. 3DP is a revolutionary manufacturing technology, with immense potential impact on the medical field. In order to implement this technology into current medical practice requires the development of a workflow that enables efficient communication between members of the multidisciplinary team and the creation of accurate, patient-specific models that can be used for pre-surgical planning and for designing 3DP surgical guides. The design protocol of these surgical guides involves several steps, form correct image acquisition, DICOM segmentation of the region of interest, digital design of the surgical guide based on the patient's anatomy, selecting the appropriate 3DP technology and material, and validating the design. Combined, the use of 3DP technology and digital 3D workflows has greatly improved the accuracy and precision of mandibular reconstruction procedures, resulting in safer and shorter surgical procedures, with better outcomes for the patients.

Keywords: 3D printed surgical guides, oncological maxillofacial surgery, personalized treatment

INTRODUCTION

Definition, CAD-3DP Connection

3D printing, also known as additive manufacturing, is a manufacturing process that produces physical models by layering material in successive layers. By contrast, traditional manufacturing methods typically involve subtractive processes (such as cutting, drilling, or carving) or moulding and casting techniques. This innovative technology allows for complex physical 3D models to be made from digital 3D model sources, which can be either:

- Digital models obtained from physical models (3D scanning, imaging investigations, etc.) or
- Digital models developed entirely in software programs (Blender, Fusion 360, Inventor, MatLab, etc)

Thus, when we talk about 3D printing, we must also talk about CAD (Computer Added Design), the process of making graphic design, without which 3D printing would not be possible.

Combining two very versatile techniques: 1. CAD for graphic design and 2. 3D printing as an additive process result in an extremely complex, fast, robust and versatile manufacturing pipeline capable of creating complex models that cannot be manufactured with other current technology.

Due to the modern nature of the technology (the first 3D printing technology was invented in 1981) [1], and the individual manufacturing nature of the models, the technology initially found its application in research, prototyping and in domains requiring the manufacture of one-off models.

The following is a brief history of the development of 3D printing:

- The term "3D printing" was first used in Japan in 1981 by Hideo Kodama. Kodama published a paper titled "Automatic method for fabricating a three-dimensional plastic model with photo-hardening polymer," which described a method of fabricating 3D plastic models by using a photosensitive polymer and a laser to build up layers.
- 1984: Stereolithography (SLA) was invented by Charles W. Hull and later patented in 1986. The patent defines the use of a laser to solidify a liquid photopolymer resin layer by layer, creating a 3D object [2].
- 1990: Fused Deposition Modelling (FDM) was invented by Scott Crump. It uses a nozzle and heat to melt and extrude a thermoplastic material layer by layer, creating a 3D object.
- 1992: Selective Laser Sintering (SLS)[3] was invented by Carl Deckard and Joe Beaman. It uses a laser to sinter powdered material (mainly plastics) layer by layer, creating a 3D object.
- 1993: PolyJet Printing (PJP) was invented by Objet Geometries. It uses inkjet printing technology to deposit layers of photopolymer materials, which are cured by UV light to create a 3D object.
- 2002: Digital Light Processing (DLP) was invented by Larry Hornbeck at Texas Instruments as a variation of SLA. It uses a UV projector, instead of a LASER to project an image onto a vat of photopolymer resin, which is then cured to create a 3D object.[4]
- 2005: Electron Beam Melting (EBM) was invented by Arcam AB. It uses an electron beam inside a vacuum chamber to melt and fuse metal powder layer by layer, creating a 3D object.
- 2010: Binder Jetting was introduced by ExOne. It uses a printhead to deposit a liquid binder onto a bed of powder, which is then cured to create a 3D object.
- 2011: Direct Energy Deposition (DED) was introduced by Optomec. It uses a laser or electron beam to melt and deposit material onto a substrate, building up a 3D object.
- 2012: Carbon3D introduced Continuous Liquid Interface Production (CLIP). It uses a vat of liquid photopolymer resin and a combination of light and oxygen to create a 3D object continuously, without layer-by-layer printing [5].

With further development of the technique and the emergence of new 3D printing technologies, new 3D printing materials, the use and implementation of 3D printing is growing and its role in the age of 4.0 technologies is increasingly important.

3D printing in personalized medical treatment

3D printing is currently an important pillar for the development and implementation of personalized treatments in modern medicine [6].

In the medical field, 3D printing is currently being used mainly to create patient-specific, customized models. Whether we refer to devices used in preoperative or intraoperative 3D planning, or to surgical guides and definitive implants that assist surgeons in performing complex procedures, for each of these 3D printing offers a dedicated sub-technology and a complex range of 3D printing materials with increasingly performant properties (temperature resistance, chemical resistance, hardness, elasticity, biocompatible, implantable properties, etc.). The end result is a considerable reduction in the risk of complications during surgery, as well as improved post-surgical outcomes [7].

The steps necessary in order to obtain 3D medical models are presented in Figure no. 1.

1. DICOM

DICOM stands for Digital Imaging and Communications in Medicine, which is a standard format used for medical images such as CT scans, MRIs, and X-rays. DICOM is a highly specialized and structured format that is specifically designed for storing and transmitting medical image data. It was developed by the National Electrical Manufacturers Association (NEMA) and the American College of Radiology (ACR) in the 1980s, and has since become the de facto standard for medical image data. DICOM files contain both image data and metadata, such as patient information, imaging parameters, and study information.

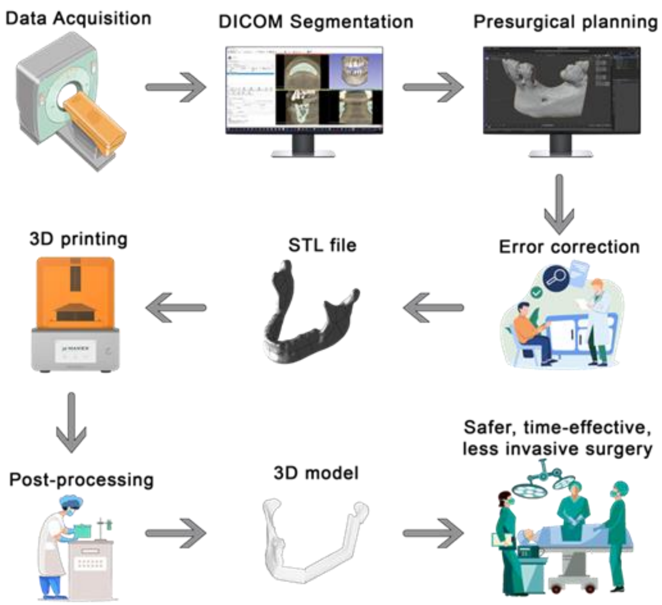

Figure 1 - Diagram showing the steps required to create usable medical 3D printed models for use in presurgical and surgical personalized treatment

The reason for developing this standard was the necessity to ensure interoperability between different medical imaging devices and software platforms, allowing healthcare providers to easily share and access medical image data across different systems. As such, all DICOM files and programs are compatible with one another. Furthermore, DICOM files are also highly secure and can be encrypted to protect patient privacy.

One of the key advantages of DICOM is its ability to store and manage large volumes of medical image data. This is particularly important in fields such as radiology and oncology, where high-resolution images are used to diagnose and treat complex medical conditions.

Overall, DICOM is a critical standard for the healthcare industry, providing a structured and interoperable format for storing and transmitting medical image data that is essential for providing high-quality patient care [8], [9].

2. Segmentation

Segmentation is the process of dividing an image or volume into separate regions based on their properties, such as color, intensity, or texture. In medical imaging, segmentation is used to isolate specific structures or regions of interest from surrounding tissues or structures. For this purpose, DICOM images are ideal as input data for segmentation algorithms, as they provide sequenced images with identical resolution, as well as metadata that defines distance between images (called spacing) as well as thickness of each image. Using this complex data, segmentation programs can be used to create 3D models of specific structures such as bones, organs, or tumors. These 3D models can then be used for a variety of purposes, such as surgical planning, medical education[10], or research. Using standard DICOM image data allows for a clear definition of parameters based on what anatomical structures are of interest in the segmentation process[11].

To ensure ideal segmentation results, the following parameters should be taken into consideration:

- Slice Thickness: The thickness of the slices in the DICOM data will affect the resolution of the 3D print. Thinner slices will result in a higher resolution but may require more processing time and storage space. For example, this research paper focuses on oncological Oral-Maxillofacial cases. As such, to obtain accurate 3D models of the complex anatomy in these cases, it is recommended to use high resolution CT imaging, with a slice spacing of 1mm and a maximum slice thickness of 1.25mm, with an ideal thickness of 0.625mm [12].
- Image Resolution: The image resolution of the DICOM data should be high enough to capture the details of the segmented anatomy. Higher resolution images will result in a higher quality 3D print but may require more processing time and storage space. Another important point to consider is the aspect ratio of the image. Data must not be distorted, via expansion or shrinkage, in order to keep anatomical proportions and dimensions accurate. The DICOM data we used in our research was provided at a resolution of 512x512px.
- Image Orientation: The orientation of the slices in the DICOM data should be consistent and accurately reflect the anatomy of the patient. Inconsistent

orientation can result in incorrect representations of the segmented anatomy in the resulting 3D printed model.

- Image Modality: Different imaging modalities, such as CT, MRI, and PET, can have different strengths and weaknesses, and may affect the final 3D print in different ways. For example, CT scans typically have higher resolution and contrast, but may not accurately represent soft tissue structures, while MRI scans typically have better representation of soft tissue structures, but lower resolution and contrast.
- Segmentation Algorithm: The segmentation algorithm used should be accurate and reliable, and should be tailored to the specific requirements of the 3D printing application.

Segmentation algorithms utilize different methods such as thresholding, region growing, edge detection, and machine learning. Each technique has its own strengths and limitations, and the choice of algorithm depends on the specific application and imaging modality.

For example, one of the challenges of segmentation in medical imaging is the presence of noise, artifacts, and variations in contrast and brightness. These can make it difficult to accurately segment specific structures. In addition, the anatomy of different patients can vary significantly, requiring customized segmentation algorithms or manual adjustments to achieve accurate results. Controlling this balance between image noise and sharp edge definition between different tissue types requires choosing the correct Kernel protocol. The following are examples of Kernel values, and what is their best use case [13]:

- B08s, B10s, B19s: very smooth settings, used for imaging very soft tissues, such as the brain or certain types of tumors. These low value kernels provide the least number of artefacts, but do not create a fine barrier between bone tissue and soft tissue.
- B20s, B29s: smooth settings, still optimized for soft tissues but with slightly more detail and contrast than the very smooth settings.
- B30s, B31s: medium smooth settings, useful for imaging both soft and harder tissues, with a balance of smoothness and detail.
- B35s, B39f: Heart View settings, optimized for imaging the heart or cardiovascular structures.
- B40s, B41s: medium settings, useful for imaging a range of tissues and structures with a moderate level of detail.
- B46s: another medium setting, optimized for specific applications or types of tissues.
- B50s, B60s, B565s: sharp settings, used for imaging harder tissues, such as bone or dense structures like the lungs.
- B70s, B75s: very sharp settings, used for imaging the edges of structures or other areas where very high resolution is needed.
- B80s, B90s: ultra-sharp settings, optimized for imaging very fine details or for certain specialized applications. Higher value kernels offer sharp, well-defined bone-tissue barriers, but come with heavier artefacting of soft tissue, resulting in larger 3D models that require extensive post-processing work.

Despite these challenges, segmentation is an important tool in medical imaging and has many applications in clinical practice and research. By accurately segmenting specific structures and regions of interest, healthcare providers can make more informed diagnoses, plan more effective treatments, and monitor patient outcomes over time [14].

3.Segmentation-CAD-STL

CAD (Computer Aided Design) is a software tool that enables the creation, modification, and optimization of digital design models.

In the context of 3D printing, CAD plays a crucial role in the design process. CAD software allows designers to create 3D models of their designs with high precision.

Using the digital anatomical models obtained via segmentation as a base, CAD software is used to create detailed 3D models of anatomical structures, medical devices, and implants. These models can then be converted into digital files that can be used by 3D printers to produce physical objects. In the medical field, this allows for the creation of highly customized and patient-specific implants, prosthetics, and other medical devices that fit the patient's unique anatomy and needs [15], [16].

4.STL

STL (abbreviation meaning Stereo Lithography, in the context of 3D Printing) is a file format that represents 3D models as a collection of connected triangles, called vertices, that describe the surface geometry of an object. The acronym "STL" may stand for different things, such as "Standard Tessellation Language" or "Standard Triangle Language".

The format is widely used in 3D printing mainly because its triangulated mesh structure allows for precise control over the print process and is easily sliced into layers. STL files are widely supported, simple and efficient, and compact in size. They are created using 3D modelling software and imported into 3D printer software to generate instructions for the printer. However, the STL file format has limitations. It only contains surface geometry information and does not include color, texture, or material information. It also only supports triangle shapes, which can be problematic for complex shapes or curved surfaces. STL files can become quite large for complex 3D models, making them difficult to store and transfer. Once an STL file has been created, it can be difficult to modify the 3D model without starting from scratch.

While newer file formats such as .3MF and .AMF have been developed to address some of the limitations of the STL format, they have not yet been widely adopted in the 3D printing industry, due to compatibility issues with existing tools and hardware, lack of standardization, complexity, and limited use cases. Many existing tools and hardware are designed to work with the STL format, as they do not need the complexity and metadata that .3MF and .AMF provide (mainly texture and colour metadata, that are irrelevant for most 3d printing technologies). Additionally, while .3MF and .AMF offer advantages over STL for certain use cases, they may not be necessary for many applications. However, as the technology continues to evolve, and new technologies emerge that can control material characteristics per individual layer and mesh triangle, it is possible that these file formats or others may become more widely adopted in the future.

5.3D Printing technologies

As we discussed previously, 3d printing has seen constant progress and evolution. As a result, a lot of 3d printing technologies have emerged, with important applications in medicine and personalized care:

- Fused Deposition Modelling (FDM) - FDM is a 3D printing technology that uses a heated extruder to melt and deposit plastic (mainly thermoplastic) filament layer by layer to create a 3D object. FDM is a popular and widely available technology with a wide range of materials and devices available. While FDM may not offer the same level of detail and precision as other 3D printing technologies, it is well-suited for creating large-scale models as well as rapid prototyping and iteration, because of its ease of use and low cost of production. In medicine, FDM is commonly used to create patient-specific anatomical models for surgical planning, creating prosthetics, personalized orthotics, as well as educational models. High-temperature thermoplastics (PEEK – poly-ether-ether-ketone, PEKK, ULTEM) can be printed using this technology to produce biocompatible medical implants.
- Stereolithography (SLA) - 3D printing technology that uses a liquid photopolymer resin that solidifies or "cures" when exposed to a UV laser beam. This process allows for the creation of highly accurate and intricate 3D objects with smooth surface finishes. SLA is particularly well-suited for medical applications that require high precision and detail, such as creating anatomical models for surgical planning, developing custom medical implants, and creating dental restorations. Its ability to produce highly accurate and intricate structures makes it a valuable tool for producing patient-specific medical devices and implants. Digital Light Processing (DLP) and MSLA (Masked Stereolithography) are similar 3D printing technologies, that use the same production process – photopolymerization. DLP uses a UV projector, instead of the UV LASER, while MSLA uses a UV lamp and an LCD screen, or "mask" to control light exposure.
- Selective Laser Sintering (SLS) - is a 3D printing technology that uses a high-powered laser to selectively melt, and subsequently fuse layers of powdered material, such as plastics, or ceramics, to create a solid 3D object. SLS has the advantage of being able to print with a wide range of materials and produce high-strength parts with no support structures needed, as the unsintered material that surrounds the model as it's being printed acts as the support. In medicine, SLS is commonly used to create medical surgical guides, and surgical devices, as it procures highly accurate and mechanically resistant models.
- Selective Laser Melting (SLM): SLM is a 3D printing technology that uses a high-powered laser to melt and fuse powdered metals and ceramics into layers of to create a solid 3D object. SLM is particularly well-suited for creating extremely complex, high-strength metal parts with intricate geometries that would be difficult or impossible to produce using traditional manufacturing methods. In medicine, using biocompatible materials such as Ti64 and zirconium, SLM is commonly used to create custom orthopaedic implants, dental restorations, and surgical instruments. The resulting models are currently unmatched in mechanical resistance.
- Binder Jetting - Binder Jetting has applications in the production of personalized medications.
- Direct Energy Deposition (DED) - DED technology is used in the manufacture of custom implants and prosthetics.
- Material Jetting - Material Jetting is used in the production of personalized medication and tissue engineering applications.

From this list, our laboratory has access to FDM, SLA and SLS technologies. As such, from this list, only these technologies were used for the purpose of this study. Each technology has advantages and disadvantages -Table 1 [17].

Based on these advantages and disadvantages, we chose SLA as the technology of choice for the 3D printing of surgical guides and models, as it offers a wide range of materials, including biocompatible materials, and the resulting models offer the highest level of detail – Figure 2 [1], [10], [18].

3D Printing Technology	Advantages	Disadvantages
Fused Deposition Modelling (FDM)	- Affordable and widely available technology - Can use a large variety of materials, including thermoplastics, for printing - Good for creating large-scale models or prototypes	- Can produce rough surface finishes - Limited resolution and accuracy - Layer adhesion can be a problem, affecting the mechanical strength of the printed parts
Stereolithography (SLA, DLP)	- High-resolution printing capabilities (70um smallest point of detail) - Can create intricate and detailed models with smooth surface finishes - Suitable for dental and medical applications that require high precision - Large array of materials available, including biocompatible materials suitable for medical use	- Material options are limited to photopolymers, which can be expensive - Requires post-processing to remove excess resin and curing to make parts rigid - Not as mechanically resistant as models produced using FDM or SLS
MSLA	- Fastest 3D printing technology - High precision and accuracy	- Lack of availability for biocompatible materials
Selective Laser Sintering (SLS)	- Can print with a wide range of materials, including ceramics, and polymers - High mechanical strength of printed parts - No support structures needed, as the unsintered material acts as the support	- Expensive technology, both in terms of equipment and materials - Surface finishes may not be as smooth as SLA, DLP or MSLA - Requires high temperatures, which may affect the quality of certain materials

Table 1 - Different 3d printing technologies with their advantages and disadvantages

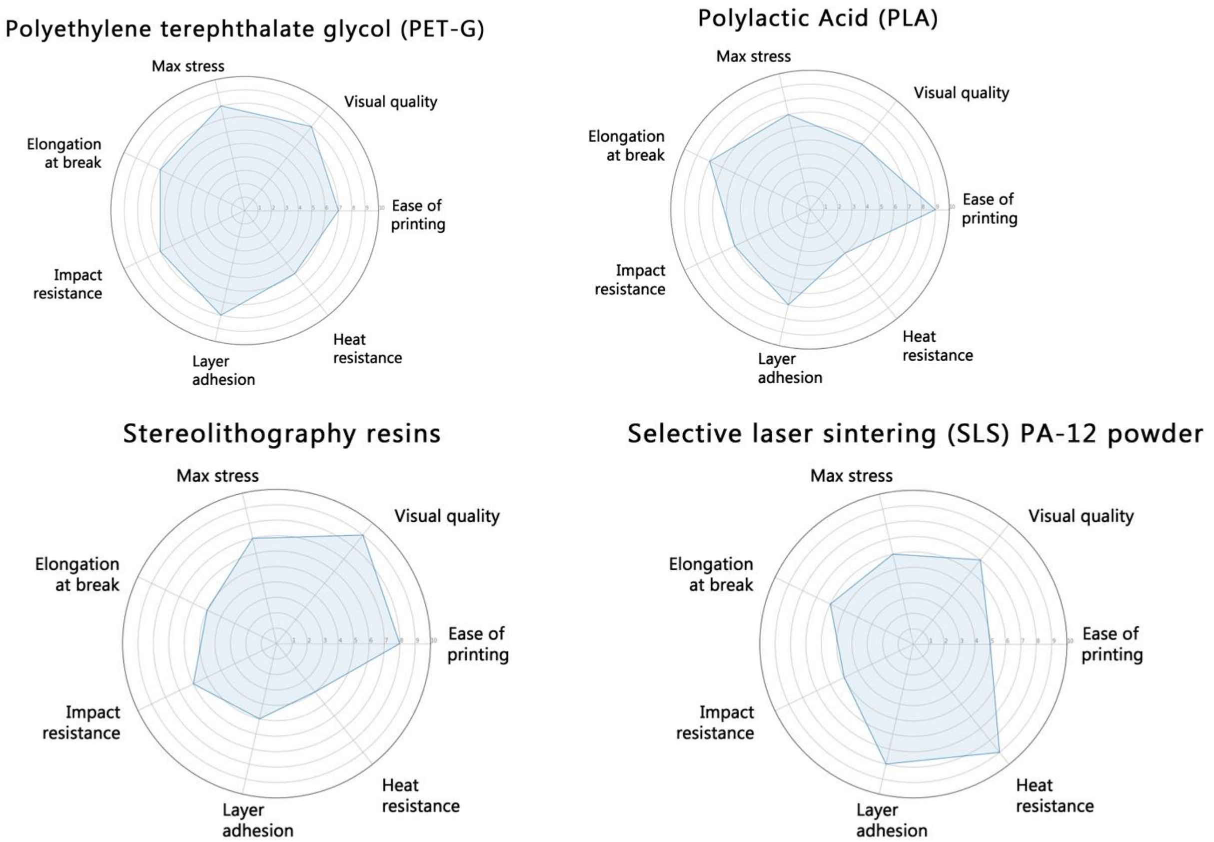

Figure 2 - Spider Diagrams comparing different 3D printer material properties

3D Printing materials

With the rapid evolution of 3d printing technologies, new materials are being developed that offer new and unique proprieties, such as temperature resistance, increased elasticity, and biocompatibility. Being one of the first 3D printing technologies to be developed, there are many SLA resins available, with new materials being developed all the time. Biocompatible resins, especially, are becoming increasingly important as 3D printing technology is adopted for medical and dental applications [1].

MATERIALS AND METHODS

Defining the team and working protocol

The main objective was to create a working protocol for the multidisciplinary team involved in mandibular reconstruction using the fibula free flap after segmental or total mandibular resections. The fibula free flap microsurgical transfer is currently considered to be the “gold standard” for large mandibular reconstructions.[19] A clearly defined working protocol facilitates efficient communication of information between the Medical Team and the Technical Team, consisting of Graphics Software Experts and a 3D Printing Technicians. For oncological cases, it is always necessary to form a multidisciplinary oncological commission, which will analyse and decide the optimal treatment of the patient. This complex treatment must be individualized for each case.

The multidisciplinary team consists of

- OMF Surgeon - The oral and maxillofacial surgeon plays a key role in mandibular reconstruction using 3D printing surgical guides, as they are responsible for planning and performing the oncological or post-traumatic surgical intervention and preparing the recipient area for reconstruction.
- Plastic Surgery Doctor - The plastic surgeon is mainly responsible for the reconstruction of the created defect, which can involve bone, bone and soft tissues, or bone, soft tissues, and skin. Thus, he is responsible for raising the fibular flap (only bone, osteo-cutaneous, or chimeric osteo-myo-cutaneous), for remodelling the fibula with the help of 3D surgical guides for maxillary or mandible reconstruction, for performing the anastomosis of the vascular pedicle to the recipient vessels in the area subject to reconstruction and for covering the remaining defect.
- Oncologist - The oncologist is also an important member of the team, as they provide valuable information on the patient's cancer diagnosis and treatment, as well as establishing the oncological resection limits, which can impact the reconstructive surgery plan.
- Radiotherapist - another important member of the team, because in head and neck tumour pathology postoperative adjuvant treatment is often needed.
- Medical imaging doctor - The medical imaging doctor is responsible for creating the CT scans that are used to generate the 3D models and surgical guides.
- Cardiovascular Physician - The cardiovascular physician can also be involved in the preoperative evaluation of the patient, helping to establish the correct indication for raising the vascularized fibular graft used in the reconstruction.
- Technical team composed of
- Graphics software expert
- 3D Printing Technician
- The technical team includes a graphics software expert and a 3D printing technician, who work together to generate the 3D models via the process of segmentation, using the DICOM images provided. They also are responsible for the design and production of the surgical guides. The use of computer aided design and computer aided manufacturing helps obtaining better functional and aesthetic outcomes for the patients. [20]
- Prosthetics technicians, Speech Therapist

Working Protocol

Working protocol - serves to bridge the gap between the doctors and engineers, providing a structured way for the surgical team to convey important information to the technical team. The working protocol was structured as a form, containing the following data points (Appendix 1):

- Personal data - This includes the patient's personal information, such as their name, age, and medical history.
- Oncological diagnosis - The type of cancer diagnosis is important in determining the appropriate treatment plan.
- Localization of pathological region at mandibular level - The location of the cancerous region in the mandible is important for planning the surgical reconstruction.
- Oncological limits
- Identification of fibula used for vascularized graft harvesting – Vascularization is the main criteria when choosing which limb will be used, as well as what part of the fibula will be harvested. It is essential to have a reliable blood supply from the peroneal artery and the peroneal vein, which supply blood to the transplanted bone and tissues [21]. As such, the surgical team will choose the section with the largest

calibre blood vessels, without plaques, areas of stenosis, or other defects. A well vascularized graft will heal properly and integrate with the surrounding tissues, which is important for long-term success. Lack of proper vascularization can even result in necrosis of the graft. This is another area where the presence of a multidisciplinary team shows its strength. Careful evaluation of by the Cardiologist, using Doppler echography is essential. In cases where the defect that needs to be covered involves soft parts and skin, is equally important the identification of the perforating branches from the peroneal artery - both by angio-CT and Doppler [22]. The location of these perforators determines where the osteotomies will be performed.

- Number of mandibular fragments - The number of mandibular fragments can impact the type of surgical approach and reconstruction plan.
- Orientation of the arrangement of the peroneal fragments- Depending on the orientation of the pedicle, which can be located anteriorly or posteriorly, and the need for chimeric flaps that include skin and/or muscle islands, based on perforators from the peroneal artery, the orientation of the peroneal segments and the location of the osteotomies at the level of the fibula will be decided.
- Dates - operation and CT scan - The operation date and CT scan date are important for tracking the patient's progress and ensuring that the appropriate information is being used. In oncological patients, the time between image acquisition and surgery must be as short as possible, to ensure that the tumour doesn't change significantly in morphology.

A clearly defined working protocol facilitates efficient communication of information between the medical team and the Technical Team, consisting of a Graphics Software Expert and a 3D Printing Technician. This overcomes language and terminology barriers and thus greatly reduces the error rate.

The information requested in the protocol proposed in this paper included:

- Patient's personal data - Name, age, gender
- Oncological diagnosis
- The localization of the tumour as far as the mandible is concerned.
- The mandibular resection limits. Image of the mandible obtained after segmentation – in order to clearly establish and accurately communicate the resection limits established by the surgical and oncology team. With the help of these images, the medical team can accurately draw the limits.
- Clear identification of the fibula to be used for vascularized graft harvesting. Indication is based on medical decision, influenced by possible complications or vascular variations in the fibula that may influence graft viability.
- Number of mandibular fragments to be used for reconstruction. The working protocol used and the method of fabrication of the surgical guides allow for mandibular reconstructions using between 1 and 4 vascularized peroneal fragments.
- Orientation of the arrangement of the peroneal fragments (a) and the orientation of the vascular pedicle (b). This information, at this stage of the guides, is used for guidance only. Throughout the process of producing the guides and models used for pre-surgical planning, constant communication is maintained between the technical team and the medical team. The role of this communication is to assess and approve, or reject, changes to the guidelines and models as they are made. Changes in orientation, fragment layout, fragment count are subject to change as new visual information is provided during the production process.
- Biopsy – was it performed and if it was, when?
- Timing of angio-CT acquisition date and
- Estimated scheduled date of operation.

Implementation of the working protocol

Obtaining DICOM images of the region of interest

- As explained in a previous chapter, medical 3D printed models are primarily created using DICOM imaging. The industry standard requires the use of CT or MRI images in the form of standardized DICOM files. These files are then processed using specialized CAD software and converted into 3D printable files. It is important to emphasize that the creation of 3D printed models in the medical field relies on the interdependence of Medical Imaging, CAD, and 3D Printing, unlike other fields where the CAD-3D Printing combination is enough[23], [24].
- At this step, a rough image acquisition is obtained, from which subsequent data will be extracted. The roughness of this initial data will determine how fine the resulting 3d model is.

DICOM image post processing (radiological software, 3D graphics software)

- At this point, intermediary images are interpolated with the initial ones, creating a finer slice thickness, and spacing. In our research, a spacing and thickness of at maximum 1.25mm was used.
- After the interpolation, a kernel protocol is applied, based on the region of interest. As discussed previously, a balance must be established between the allowed level of noise and the sharpness of the image. For our purposes, a medium kernel B40s was chosen,

which allowed for good separation between the mandibular and fibular bone wall and surrounding tissue, without introducing too much noise [23].

Segmentation of DICOM data – resulting in a digital 3D model of the region of interest – Figure 3

- The choice of the grafted area takes into account the viability of the circulatory system in the region of interest of the inferior limb, and the orientation of the vascular flap, depending on the surgical technique and the extent of the pathological process. This decision is made by the multidisciplinary medical team (plastic surgeon, OMF, imaging, cardiologist).
- Remove artifacts [25].
- Individualization of regions of interest: Separation of the Mandible from the rest of the skull, Defining the mandibular osteotomy plans, based on oncological limits, Individualization of the fibula from the tibia, Individualization of the fibular vascularization, Defining fibular osteotomy plans, Export model in .stl format – Figure 4.

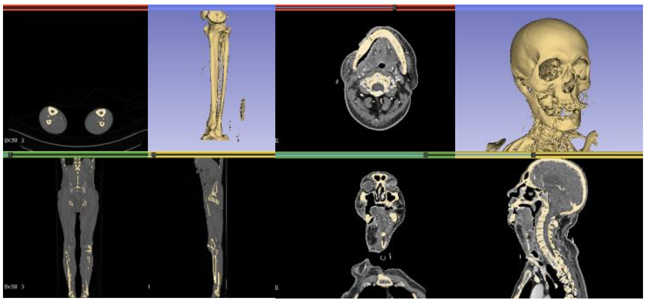

Figure 3 – Segmentation of CT scans and resulting models, before post-processing

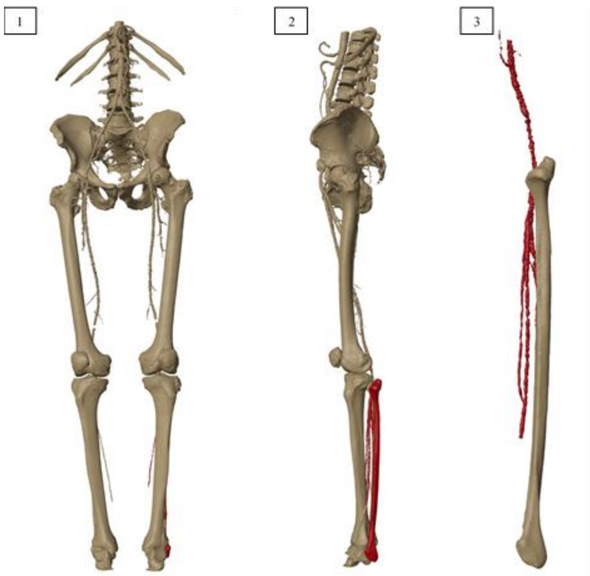

Figure 4 - Final 3D models obtained after segmentation. 1. Lower limbs and Pelvis, 2. Model after removal of opposing limb, fibular bone colored in red, 3. Fibula was individualized, and vascularization was colored in red

Design and construction of mandibular and fibular guides using open-source software (Blender 3D)

The purpose of these guides is to aid in the ideal cutting and fitting of the fibular fragments. Using digital planning, all factors of importance are taken into consideration:

Number of fragments, based on the completed form. A greater number of fragments are able to cover larger mandibular defects, but require longer recovery periods.

Size of each fragment. Although there are data that concluded that osteotomies performed at minimum 1,5 cm preserve the vascular supply [26], we considered that a fragment length of minimum 2,5 cm would be safe in terms of vascularisation. During the osteotomy manoeuvre, the heating caused by the blade can damage small blood vessel inside the bone. Smaller fragments may not recover blood flow afterwards and are at risk of long-term complications – necrosis of the bone graft.

Simple geometric elements are overlayed on the mandible and measured, to establish fragment dimensions, balancing ideal functional results and bone integration with minimum size requirements – Figure 5.

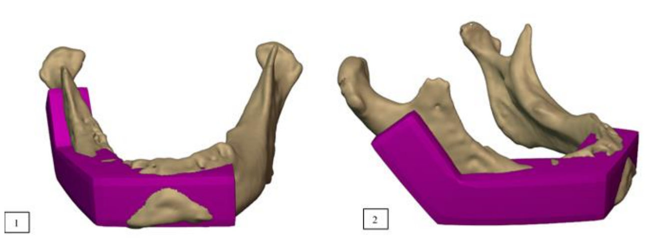

Figure 5 – Front view (1) and Side view (2) of the mandible (off-white) with Guide shapes overimpossed (magenta)

Once the fragment dimensions are established, the simple geometric elements are substituted with clones of the patient's fibular 3D model, which are then rotated and positioned based on the following criteria:

- Direction and position of the proximal and distal ends of the fibula
- Blood vessel positioning for ideal anastomosis (anterior or posterior)
- Rotation of fragments in relation to one another, as to ensure maximum surface contact between adjacent grafts. This guarantees maximal bone contact, with improved bone fusion and regeneration.
- The preservation of the mandible's anatomical contour is important to ensure an

improved aesthetic outcome and easier social integration, as it helps to maintain the natural jawline.[27]

Once ideal positioning is achieved, the fragments are cut from the fibular clones – Figure 6.

Figure 6 - Fibular bone (off-white) with fragment (blue) representing future mandibular graft fragments. The surgical guide will be designed based on these fragments

The mandible is cut, and the extracted mandibular bone is replaced with the fibular fragments, which were positioned before. This model is saved for 3D printing, as it will be used by the surgical team for the modelling of the anchoring metallic plates. These plates will hold the fibular fragments in place during the osteointegration period.

The fibular fragments are repositioned to their initial place on the fibula, preserving the cutting angles that were established during mandibular positioning – Figure 7.

Based on these cutting angles, a surgical guide is designed around the fibular bone and the mandible. The angles of the fragments offer the basis for the orientation of the surgical guide cutting slots – Figure 8.

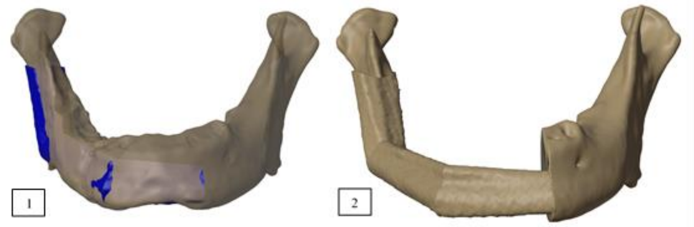

Figure 7 - Initial mandible, before digital osteotomy and fibular reconstruction (1), Final aspect of the reconstructed mandible (2)

During the design of the surgical guide, minimum model thickness is taken into consideration based on the 3D printing technology and material resistance. Based on our research, a minimum thickness of 1mm was sufficient to ensure mechanical resistance without compromising the intra-operatory visibility due to increased size.

Specific markers and lettering are applied to the model to ensure proper orientation and positioning of the guide during surgery.

The final 3d model is exported as .stl file

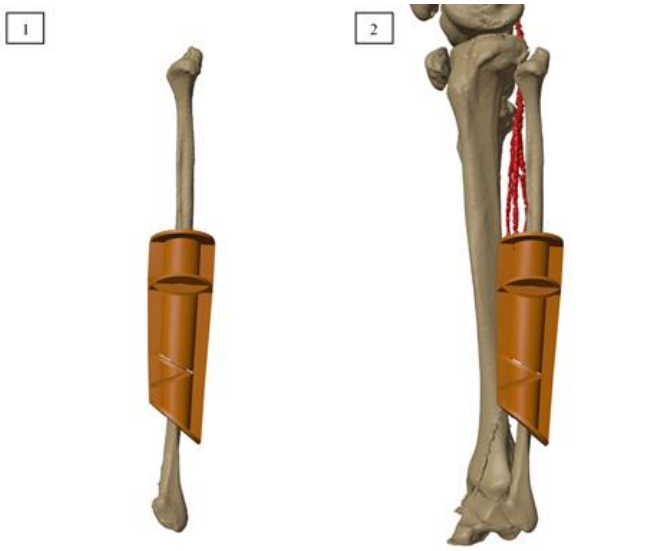

Figure 8 - Final surgical guide design, placed on the fibular bone (1). Surgical guide positioned on the entire lower limb (2)

Preparing .stl model for 3D printing (slicing process)

Our protocol provides a suite of 3D models, used both in presurgical planning and during surgery. These models are:

3D printed model of the pathological mandible, separated from the rest of the skull. This model is printed using normal, non-biocompatible resin, and has the purpose of offering visual guidance to the surgical team. The highly detailed, 1:1 scale model can be used by the surgeon to perform different surgical manoeuvres with the intent of finding the best approach for each case. These models effectively reduce time spent in the operating theatre by offering the knowledge and surgical information beforehand.

3D printed model of the mandible with resection of the pathological section and replacement with fibular graft. This model represents the ideal placement of the fibular graft fragments, as positioned during the digital planning phase. The main purpose of this model is to offer physical support during the process of warping and shaping the mandibular metallic plate that will be used to fix the fragments in place until complete osteointegration. Performing this step on this model, instead of during the surgery reduces both surgical times, and increases the chance of a perfect fit of the fragments, as intended during the digital planning phase.

3D printed surgical guides for the fibular bone, which will be used during surgery to section the bone into the fibular fragments used in the mandibular reconstruction. During surgery, the fragmentation of the fibula occurs after separation and extraction of the entire graft from the inferior limb. As such, the blood vessels that feed the now extracted bone are clamped, prepared for future anastomosis. This context limits the time allowed between extraction and anastomosis, and in turn limits the time necessary for the osteotomy. Because of this, the cutting manoeuvres must be done only once, with precision and minimal trauma on the bone. With the help of this guide the surgical team will be able to perform extremely precise cuts, resulting in a better fit between fragments, better recovery time and lower risk of complications. These models are printed using biocompatible resin certified for use in contact with human tissue, and that can withstand sterilization protocols.

3D printed surgical guides for the mandible, which will be used to establish the oncological limits of the resected part of the mandible. These models are also printed using the same biocompatible resin certified for use in contact with human tissue. These guides, together with the fibular guide, ensure correct positioning of the fibular graft, based on the digital planning models – Figure 10.

Based on these material needs, we analysed the 3DP technologies and materials available in our laboratory, in order to establish the ideal manufacturing methods for our 3D models. table with all the parameters that were taken into consideration (Table 2).

Technology	Precision	Printing Speed	Cost per part	Printing Volume	Biocompatible material availability
FDM	-	-	+++	+++	-
LFS	+++	0	0	0	+++
MSLA	++	+++	++	+++	-
SLS	+	-	0	0	-

Table 2 - Comparing the different strengths and weaknesses of 3D printing technologies

Based on these results, for our production we chose the following technologies and materials:

For the mandibular models, which require high levels of detail, without requiring biocompatibility, we chose MSLA 3D printers using standard resins.

- The 3D printer we chose was the ANYCUBIC Photon Mono X with UV LED with a wavelength 405nm, XY Res.: 0.050mm 3840*2400(4K), ZAxis Res.: 0.01mm, Layer Res.: 0.01-0.15mm, Printing Speed: MAX 60mm/h, Rated Power: 120W, Printer Size: 270mm(L)*290mm(W)*475mm(H), Build Volume: 192mm(L)*120mm(W)*245mm(H), compatible with 405nm UV Resins. Anycubic® Mono X Specification
- The material used for these models was Anycubic® Standard Resin with a Viscosity 150-200/mPa.s(25℃), Density 1.05-1.25 g/cm3, Wavelength 405nm , Hardness 82D/Shore D, Tensile strength36-45 MPa, Elongation 8-12%, Flexural strength 50-65 MPa, Flexural modulus 1200-1600 MPa, Volumetric shrinkage 4.5-5.5%, Notched impact strength 25 J/m, Heat deflection temperature 65-70 MPa/℃ (0.45MPa)Anycubic® Standard Resin Specification

For the Surgical guide models, which require high levels of detail and biocompatibility, we chose Low-Force SLA (LFS™) 3D printers using biocompatible resins:

- The 3D printer we chose was the Formlabs® Form 3B+ Low Force Stereolithography (LFS)™, with an XY Resolution of25 microns, a Laser Spot Size of 85 microns, Laser Power - One 250 mW laser, Build Volume (W x D x H) 14.5 × 14.5 × 18.5 cm, Layer Thickness 25 – 100 microns, which supports Biocompatible Materials. Formlabs® Form 3B+ Specification
- The biocompatible 3D resin used was the Formlabs® BioMed Clear Resin with the following specifications: Tensile Properties - Ultimate Tensile Strength 52 MPa 7.5 ksi ASTM D638-10 (Type IV) Elongation 12% ASTM D638-10 (Type IV), Flexural Properties - Flexural Strength 84 MPa 12.2 ksi ASTM D790-15 (Method B), Flexural Modulus 2300 MPa 332 ksi ASTM D790-15 (Method B), Hardness Properties - Hardness Shore D 78D 78D ASTM D2240-15 (Type D), Impact Properties - Notched Izod 35 J/m 0.658 ft-lbf/in ASTM D256-10 (Method A), Thermal Properties - Heat Deflection Temp. @ 1.8 MPa 54 °C ASTM D648-18 (Method B), Heat Deflection Temp. @ 0.45 MPa 67 °C ASTM D648-18 (Method B), Coefficient of Thermal Expansion 82 μm/m/°C 45 μin/in/°F ASTM E831-14, Sterilization Compatibility - Steam Sterilization Autoclave at 134°C for 20 minutes, Autoclave at 121°C for 30 minutes, Disinfection Compatibility, Chemical Disinfection 70% Isopropyl Alcohol for 5 minutes. Formlabs® BioMed Clear Resin Specification

Software used, 3D printing parameters

For the non-biocompatible models, printed on MSLA 3D printers, CHITUBOX® Software was used for slicing. The following 3D printing parameters were used: Layer height of 0.05mm, with a layer exposure time of 4s, at 60% UV intensity, Slow retraction speed of 60mm/min. A support density of 67%, with a contact diameter of 0.3mm was chosen to guarantee model stability, without major impact on surface quality. Even with these parameters, a small amount of surface deterioration is normal where supports structures contact the model. As such, model orientation was taken into account so that no supports were generated on the most important parts of the model: the surfaces where drilling occurs, and any other contact surfaces with the metallic anchoring plate.

For the 3D printed surgical guides, the software used was Formlabs® Preform, and the printing parameters were: Layer height of 0.05mm, with exposure and layer time based on the recommended parameters as provided by the manufacturer. Orientation of the model was, again, taken into consideration. Surfaces that come in contact with tissue had no support structure generated on them. Furthermore, the slits through which the osteotomy blade passes were left without supports as well – Figure 9.

Figure 9 - Fibular guide printed in SLA Biocompatible Resin, before post-processing

3D printing post-processing

Post processing required thorough washing of remaining uncured resin from the surface of the model using Isopropyl alcohol wash. Exposure time and concentration of the solvent were chosen as per the recommended settings provided by the resin manufacturer. Care was taken to ensure no contamination of the Isopropyl Alcohol solution with any other contaminants, to ensure maximum material biocompatibility.

- The models used in presurgical planning, which were printed on MSLA 3D printers using normal resin were washed in 99% pure isopropyl alcohol for 10 minutes.
- The biocompatible 3D models were washed as per the recommended manufacturing parameters, using a solution of 70% isopropyl alcohol for 20 minutes.
- Washed models were carefully and thoroughly dried to ensure no traces of solvent solution remain on the surface. For this purpose, the models were dried using compressed air.

Curing of the models was necessary to enable complete photopolymerization of the resin and to ensure that the final model respected the manufacturer specified mechanical and chemical properties of the material. The models were preheated beforehand

The presurgical models were cured for 20 minutes, preheated at 50˚

The surgical guides were cured at a temperature of 70˚, for 30 minutes.

After curing, the support structure was removed. During our testing, we found that, on occasion, some models without supports warped during the curing process. This warping must be avoided in order to ensure the models fit correctly on the patients' anatomy. As such, leaving the supports offers a supplementary structure that holds the model in place during heating and curing.

3D printed model analysis was performed to ensure quality control

We tested the following

- No traces of solvent present on the models, which would have shown in the form of white spots or discolorations on the surface of the model.
- No cracks, caused by improper removal of the support structure, or by mechanical damage to the model during handling.
- Correct dimensions, by comparing final model dimensions with the digital model, and testing fitness of the surgical guides on the 3d printed mandible.
-

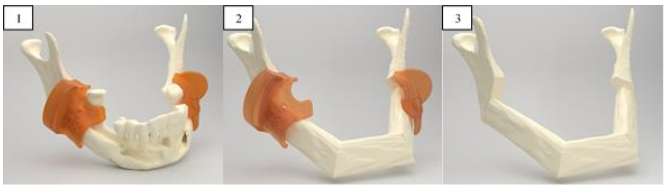

Figure 10 - Mandibular surgical guides placed on pathological bone (1), Surgical guides on mandible with peroneal graft (2), Final reconstructed mandible (3)

Implementation in current medical practice

Sterilization of the biocompatible models was done using steam sterilization using the following parameters:

- 30 minutes
- 130 degrees Celsius

Data was measured on post-cured samples.

Tumour resection - Radical resection of the tumour was performed, either from the mandible or from the maxilla. When necessary, unilateral or bilateral modified type III radical cervical dissection is performed. Bone surgical margins are located intraoperatively at regions without bone erosion or destruction present, at least 1 cm away from the most distant macroscopic lesion. The guides are fixed with the help of cortical screws and the osteotomies are performed distal to them, either with the help of the piezotome or with the help of the osteotome.

Elevation of the fibular flap. An "Italic S" incision is made on the lateral aspect of the calf, dissection with lifting of the peroneal muscles and identification of the fibula. The dissection continues in the anterior compartment with the detachment of the extensor digitorum longus and extensor hallucis muscles from the fibula. The interosseous membrane is identified, which is sectioned, entering the posterior compartment. Osteotomies are performed leaving distally at least 7 cm from the distal extremity of the fibula and proximally at least 6 cm from the fibular head. The peroneal bundle is identified and is distally ligated. The posterior tibial and flexor hallucis longus muscles are dissected and the perforators encountered are ligated or electrocauterized. If necessary, the posterior incision of the skin island is performed and/or a portion of the soleus muscle is harvested based on a perforator from the peroneal artery. Elevation of the bone/osteocutaneous/osteomyocutaneous flap is performed by detaching it from the soleus muscle. Dissection of the peroneal bundle proximally up to the level of the bifurcation with the posterior tibial bundle and visual check of its integrity. The periosteum is elevated off the fibula according to the preoperative surgical guide and the vascular pedicle is protected. [28][29]

The guide is fixed with cortical screws and fibula configuration osteotomies are performed. The resulting fragments are fixed with 2.4mm screws on a titanium osteosynthesis plate, configured preoperatively on the 3D printed mandibular model. All of this is done with the peroneal pedicle left in continuity, minimizing the flap ischemia time. In selected cases, dental implants are inserted at the level of the fibula during this operative time.

Reconstruction of the mandible- The entire reconstructed neo-mandible, fixed with the osteosynthesis plate is transferred to the mandibular level, where it is fixed to the remaining mandible with 2.4mm screws, so that the contour of the mandible is restored in the osteotomy area.[30] Vascular anastomoses are performed and, when necessary, skin, and soft tissue defects are covered with the skin and/or muscle islands of the freely transferred vascularized (chimeric) fibular flap. At the same time, the donor area is closed in anatomical planes.[28]

Dental prosthetic oral rehabilitation is especially important in cases where large resections are performed, being an essential step for restoring mastication, phonation, and swallowing. [31] For reasons of therapeutic efficiency and limitation of invasive procedures applied to the patient, we consider it opportune to insert the implants at the same time as the reconstruction is performed. The implant insertion is performed according to the preoperatory plan, using surgical guides to keep the insertion axes ideal for the desired prosthetic restoration. There are two main groups of patients in whom oral rehabilitation is performed differently: oncological patients who require postoperative radiotherapy (especially the cases with squamous cell carcinomas), and patients who do not require radiotherapy after the surgical intervention, either oncological or non-oncological. In the first group dental implants can be placed in the fibula at the time of reconstruction, but the prosthesis is placed later[32]. In the second category any scenario could be taken into account, including inserting the implants into the fibula 12 weeks before harvesting in order to get integrated, using the same surgical guide that will be used for the removal of the fibula, and the definitive prosthesis can be inserted right at the end of the intervention (having been carried out before operation through planning and design assisted by the computer in a manner similar to the surgical guide)[33].

DISCUSSIONS

As discussed in this article, current 3d printing technologies possess a great level of adaptability, offering the possibility of fast, personalized medical device production suitable for highly specific and unique surgical pathologies. However, there are still limits imposed by current biocompatible materials, especially when it comes to mechanical strength. Further testing using different, more resistant biocompatible materials will allow for the shrinkage of the surgical guide, limiting the amplitude of the incision and dissection required to fit the guide to the bone. One option comes in the form of biocompatible SLS PA12 powder. This 3d printing technology offers the same dimensional accuracy and level of detail as SLA, but presents a much higher physical resistance than SLA resin, allowing for smaller parts to be designed, without compromising on rigidity. Biocompatible titanium could be another such material, which, in a first step will allow for much smaller, more resistant guides, and, furthermore, might even replace the fibular bone graft as a viable implantable option for the mandibular reconstruction.

CONCLUSIONS

Computerized preoperative planning and 3D printing are innovative technologies which allow the reduction of operative time with a positive impact on lowering of intraoperative risks, obtaining much improved post-operative results, both from an aesthetic and functional point of view, with the possibility, in selected cases, to obtain the tumour resection and the restitution of the mandibular function even on the same day. The work protocol proposed by the multidisciplinary team allows to overcome some communication gaps, facilitating each member of the team to fulfil the therapeutic objectives, and allowing a more fluent transmission of information between departments. Considering the complexity of the team involved in solving a case of fibular reconstruction of defects in the oro-maxillo-facial sphere that requires computerized preoperative planning, the creation of this work protocol was a necessary consequence for the efficiency of communication.

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