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THE APPLICATION OF 3D PRINTING IN PLASTIC AND RECONSTRUCTIVE SURGERY: CASE-CONTROL STUDY IN FACIAL RECONSTRUCTION

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ABSTRACT

The aim of this study was to explore the efficiency and usefulness of tridimensional printing in plastic and reconstructive surgery for lesions of the maxillofacial region. This was comparison study between two groups of patients. Six patients underwent surgical reconstruction, using a three-dimensional model built on the basis of CT scans (group 1); and six patients underwent surgical reconstruction, without the use of a three-dimensional model (group 2). The following variables were evaluated: age, gender, histological diagnosis, cancer location, size of bone lesion, type of reconstruction, complications and surgical timing.
A statistically significant difference was found in microsurgical flap survival ($p = 0.019$), with a survival rate higher in group 1 than in the controls. This study provides preliminary evidence and partially confirms the validity of three-dimensional technology in plastic and reconstructive surgery. The results so far obtained, however, lead to hope for future uses of this ever-increasing technique.

1. Introduction

The aim of this study was to explore and verify the validity, efficiency and usefulness of tridimensional printing in plastic-reconstructive surgery and in particular in neoplastic and non-neoplastic lesions of the maxillofacial region.
The history of 3D-printing starts with Chuck Hull1, an American physicist and engineer who, between 1984 and 1985, obtained the first patent and founded one of the most important business in the field; 3D System. Hull's company was the first to use tridimensional rapid prototyping methodology to build solid object based on liquid synthetic resins.
Initially, this technique was mainly used in industry [2]; however, over a period of twenty years, more and more new ideas with regard to its possible uses were proposed, raising the profile of this technology and making it more accessible.
Since then, it has become possible through improving techniques to create various solid objects, with an impressive accuracy. Thus, fields of application for technology have increased, from mechanical industry to architectural models; from play objects, to medical and sanitary materials and in this case, the artificial recreation of bone structures, soft tissues and also complete organs, using entirely compatible biomaterials.[2]
Nowadays, this technique has garnered great attention due to its potential applications in various fields and in particular medicine.
The printing process is based on an assembled printer, based on the model "PRUSA I3", and uses a PLA wire (polylactic acid) with a diameter of 1,75 mm (ANYCUBIC-USA).
Tomographic scanned images of our patients were first analyzed by DICOM image elaboration software (OSIRIX LITE 8.0- Pixmeo Switzerland) in order to obtain an early virtual 3D reconstruction, which was then studied by the surgical team. The regions of anatomical interest were obtained from virtual reconstruction, while the remaining anatomical regions were discarded. Once the anatomical edges for tridimensional reconstruction had been established, DICOM images were sent to 3D SLICER software (3D slicer 4.4.0- slicer.org), for the next step in processing and preparation for tridimensional printing.
Through an automatic detection of specific thresholds for the selected tissue, this software allowed for the highlighting of only the tissues of interest (Figure 1): these values allow for the separation of the tissues of interest from the other tissues. The digital information about the tissue of

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that particular anatomical region was then converted in to a printing instruction, for the next step of reconstruction.

An “additive synthesis” system is used in 3D printers; the anatomic segment to be reproduced is created by using a thermoplastic PLA (polyactic acid) filament that is extruded by an metal heated extrusor called “hot end” with millimetric precision producing overlapping layers of PLA that attach to each other as they melt. The PLA filament, with a starting diameter of 1.75mm, is melted by the printer a temperature ranging between 180 °C and 250 °C and it is extruded with a final diameter of 0.3 mm, increasing the final resolution of the 3D object considerably. The printer moves the extruder, along the tridimensional coordinates x, y and z which allows for the right amount of polymer to be placed in that specific position.[3]

The final effect is a bottom-up layer by layer deposition, which reproduced the anatomic portion of interest with a maximum precision of 0.3mm (Figure 2).

In this way, 3D models of the bone defect and the donor site of the flap were created. Simulating the osteotomies allowed for the creation of cutting guides which model the donor site in order to make it perfectly suited for the surgical purpose. In previous studies, authors have demonstrated how the cutting guides thus created improved osteotomy [4], both in terms of positioning and orientation. [5]

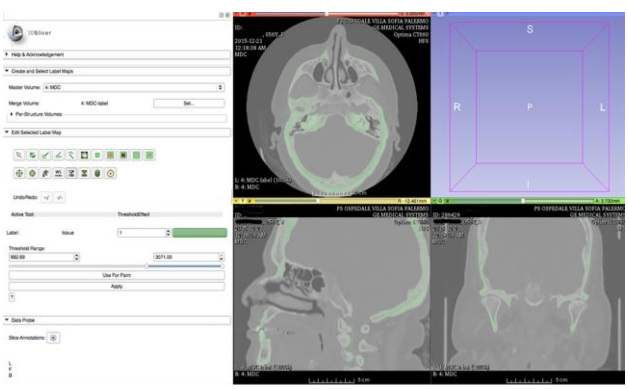

Figure 1 - CAM / CAD processing, creating instructions for the three-dimensional model using 3Dslicer software.

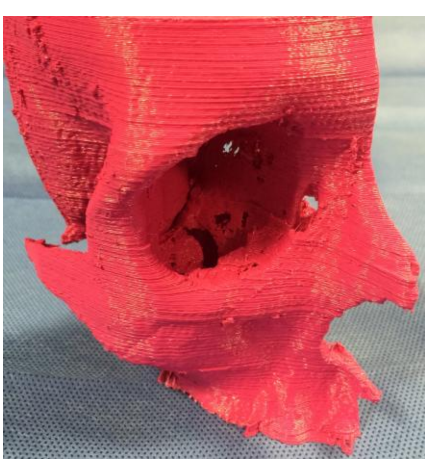

Figure 2 - Three-dimensional printed object using PLA filament. 1:1 reproduction of half human skull.

2. Material and Methods

The aim of this study was to compare two groups of patients, enrolled and treated between January 2010 and May 2017 at the Plastic and Reconstructive Surgery of the “Policlinico Paolo Giaccone” of Palermo.

Patients, 8 male (67%) and 4 female (33.3%) were divided into two groups: Six patients underwent surgical reconstruction using the three-dimensional model built on the basis of CT bone images (Table 1), and they were included in group 1 or case group; Six patients were subjected to surgical reconstruction, without three-dimensional model (Table 2), and they were included in group 2 or control group.

Inclusion criteria were patients with skull-facial neoplastic and non neoplastic bone lesions who underwent CT or MRI scans before surgery.

Exclusion criteria were patients younger than 18 years old, patients with previous surgery in the anatomic area of interest and patients without pre-surgical study by CT or MRI images.

All patients enrolled in the study were subjected to CT examination to obtain high-resolution stratigraphic images of sagittal and coronal tissue sections (DICOM files, digital imaging and communications in medicine). From these images, a three-dimensional thermoplastic polymer (PLA) model was rebuilt with the aim of evaluating the preoperative planning, maximizing the accuracy of the surgery, and allowing, in some patients, the preoperative modeling of the osteosynthesis plaque.

Patient	Age	Gender	Location	Histology	Reconstruction
1	71	M	Right Retromolar trigone. II CLASS [7]	SCC G3	Fibula homologous bone graft
2	69	M	Mandibular symphysis (2,5cm) , right ramus (2,3cm) and left ramus (3.4 cm). IV CLASS	SCC G3	Titanium plate for reconstructive ostheosyntesis and ALT flap.
3	56	F	Right half jaw (cm 6.5x3.5x4)distal body region and right ramus. II CLASS	SCC G2	Osteosynthesis plates and fibula bone graft
4	54	M	Medial alveolar arch, oral floor and ventral tongue region. Mandibular bone part (cm 6x2.8x1.3). II CLASS	SCC G2	Fibula flap
5	61	M	Left alveolar arch and oral floor. II CLASS	SCC G3	Fibula flap
6	76	F	Right maxilla region	Mucormycosis	Exenteratio orbitae

Table 1 - Summary table group 1 (cases). M = male; F = female; SCC = squamous cellular carcinoma; G = histological grading; ALT = anterolateral tight free flap.

Patient	Age	Gender	Location	Histology	Reconstruction
1	56	M	Hard palate	SCC G 1	Fibula flap
2	57	M	Left mandibular horizontal bar until 2 cm laterally mandibular symphysis on the right side. IV CLASS	SCC G2	Titanium plate and left pectoralis major mycutaneous flap
3	81	F	Mandibular symphysis and part of left mandibular ramus (IV e V sextants). II CLASS	SCC G2	Fibula flap
4	83	F	Mandibular paramedianahoryzontal ramus. II CLASS	SCC G2	Iliac crest bone graft and Alt flap
5	78	M	Right retromandibular trigone and lower alveolar crest. II CLASS	SCC G2	Fibula flap
6	62	M	II sextant maxilla	MRONJ	Maxilla sequestrectomy and local flap coverage per soft tissue defects

Table 2 - Summary table group 2 (controls). M = male; F = female; SCC= squamous cell carcinoma; G = hystologic grading; MRONJ = medication-related osteonecrosis of the jaw.

The ultimate goal was to compare the variables of the two groups and to determine whether the possibility of studying the patient with 3D technology during the preoperative period could improve surgical outcomes both in terms of the reduction of operating times and short-term and long-term complications.

For each patient, the following variables were evaluated: age, gender, histological diagnosis, cancer location/bone lesion, size of tumor/bone lesion, type of reconstruction, complications including fistula formation, infections, recurrent disease, microsurgical flap failure and surgical timing.

For numerical variables, average, standard deviation, minimum and maximum were calculated; for categorical variables frequency and percentage were calculated.

Statistical analysis

Given the sample size of our dataset, the non-parametric Mann-Whitney test was used to test for significant differences between patients in the two groups. The level of significance was set to P = 0.05.

3. Results

The average age was 67 ± 11 with a minimum of 54 and a maximum of 83 years. Tumor size varied from 1 cm to 10 cm (mean 4.56±2.77). Surgical time had a mean value of 417.92±292.96 minutes ranging from 35 minutes in the case of maxillary sequestrectomy for osteonecrosis MRONJ (Medication related osteonecrosys of the jaw)[6],[7] to 990 minutes for segmental mandibolectomy surgery and reconstruction with titanium osteosynthesis plaque and thigh muscular microsurgical muscle flap (ALT). Fifty percent of patients (6 patients) had a squamous cell type G2, another 25% (3 patients) had G3 squamous cell carcinoma, another 8.3% had G1 squamous cell carcinoma, the remaining 16.6% of patients had non neoplastic lesions, in particular 1 patient with mucormycosis and 1 patient with MRONJ. In 50% of the patients, cancer was found in the right hemimandibula, in 25% in the left hemimandibula, and in the remaining 25% in the maxillary region (16.5% (2 patients) in hard palate/maxilla region, 8.3% (1 patient) in the facial region). For patients requiring a mandibular surgical demolition, Brown classification was used[8]**.** Brown et coll. describe four main classes (I, II, II, IV) and three secondary classes (Ic, IIc, IVc), based on the type of mandibular defect (Table 3). 58.3 % of patients (7 patient) underwent a segmental mandibulectomy class II, that included ipsilateral canin or condyle but not the controlateral canin or condyle; 16.7 % of patients (2 patients) underwent a hemimandibulectomy class IV, that included both canines and one or both angles. 8.3 % of patients (1 patient) underwent a maxillary sequestrectomy and 16.7 % of patients (2 patient) underwent a maxillary lesion removal surgery. Surgical reconstruction was performed as follows: 58.3% of the patients (7 patients) underwent reconstruction by means of a fibula free flap, 2 patients (16.7%) underwent reconstruction by means of an anterior-lateral thigh flap (ALT) and the remaining 3 patients (25%) underwent other reconstructive procedures of the maxillofacial region with local flap and with titanium plaques. Regarding post-surgical complications**,** our sample was found to be free of disease recurrence in 91.7% of cases (11 patients). Fifty percent of cases were complicated by a cutaneous fistula (6 patients); post-operative infections occurred in 33.3% of cases (4 patients) and reconstruction with free flap was successful in 66.7% of cases. Data analysis showed no significant differences in sex, age, histological type, type of reconstruction, tumor location, size, surgical infections, or the presence of skin fistulas. On the contrary, a highly significant difference was found in the microsurgical flap survival (p = 0.019), with a survival rate higher in group 1"case group" than in controls. Results are summarized in table 4.

CLASS 1	ANGLE	LATERAL DEFECT NOT INCLUDING IPSILATERAL CANINE OR CONDYLE
CLASS IC	ANGLE AND CONDYLE	LATERAL DEFECT INCLUDING CONDYLE
CLASS 2	ANGLE AND CANINE	HEMIMANDIBULECTOMY INCLUDING IPSILATERAL BUT NOT CONTRALATERAL CANINE OR CONDYLE
CLASS 2C	ANGLE, CANINE, AND CONDYLE	HEMIMANDIBULECTOMY INCLUDING COINDYLE
CLASS 3	BOTH CANINES	ANTERIOR MANDIBULECTOMY INCLUDES BOTH CANINES BUT NEITHER ANGLE
CLASS 4	BOTH CANINES AND AT LEAST ONE ANGLE	EXTENSIVE ANTERIOR MANDIBULECTOMY INCLUDING INCLUDING BOTH CANINES AND ONE OR BOTH ANGLES
CLASS 4C	BOTH CANINES AND AT LEAST ONE CONDYLE	EXTENSIVE ANTERIOR MANDIBULECTOMY INCLUDING BOTH CANINES AND ONE OR BOTH CONDYLES

Table 3 - Classification of mandibular defects, based on mandibular angles by Brown et al.[7]

	U Mann-Whitney Exact significance P value (cases vs control group)
Age	0.31
Gender	1
Histology	0.24
Demolition	0.937
Reconstruction	0.699
Location	0.31
Tumor/lesion dimension	0.24
Flap failure	0.019
Infections	0.241
Fistula	0.055
Surgical time	1

Table 4 - Statistical associations.

4. Discussion

Surgical reconstruction of the face is a very delicate and complex task. It deals with anatomical regions involved in the most varied functions of the body, both sensory (sight, taste, hearing, smell) and motor, with a psycho-relational impact. For this reason, the main purpose in facial reconstruction is to restore the proper anatomy of the area, trying, whenever possible, to put in place the simplest and most effective method to obtain the best aesthetic and functional results.

Perforator and propeller flaps are novel techniques that have increased the possibility of achieving reconstruction with local flaps [9-10] , but in advanced oncological cases, major demolition surgery and more complex reconstructive techniques such as free microsurgical flaps[11], are required.

These techniques require an experienced surgical team, but also a multidisciplinary team of oncologists, radiologists and pathologists.

With the advent of three-dimensional technology, it became possible to adapt the three-dimensional creation of solid objects to the medical field in order to improve the skills of the physician and facilitate the treatment of several pathologies.

Three-dimensional reconstruction consists of converting data from bone CT images in DICOM format into three-dimensional stereo lithographic data: the three-dimensional bone defect model is then rebuilt. To allow this, different types of computer software and analysis software are used to read and re-elaborate the data.

Bibliographic research shows that in recent years, other authors have been exploring the application of three-dimensional technology in plastic and maxillo-facial surgery. Many of these studies, however, are of a descriptive and non-clinical nature, and theoretically explain the potential of this technique in the medical and surgical field.

The present study shows that 3D reconstruction can be considered an instrument of great potential that deserves to be further developed.

From the evaluation and comparison of variables in the two study groups, the most significant data relates to the survival of the free microsurgical flap, created on the basis of the three-dimensional model, which is statistically better in patients in Group 1 ($p = 0.019$). In our opinion, this indicates that 3d modeling in the pre-operative process can help surgeons to better understand surgical anatomy, to reduce length of surgery and to improve surgical outcome.

5. Conclusions

In conclusion, we can state that this study partially confirms the effectiveness and validity of three-dimensional technology in the field of plastic and reconstructive surgery. There are still many aspects of this technique that need to be explored and validated. The results so far obtained, however, lead to hope for future uses of this ever-increasing technique.[12,13]

In particular, the use of biocompatible printing materials is desirable for creating complex anatomical structures to be used directly in reconstructive surgery. Several studies have been conducted so far in this area. This further innovation could radically change the course of plastic reconstructive and transplantation surgery, by replacing human donors with three-dimensional custom-made tissues.

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