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Rapid prototyped patient specific implants for reconstruction of orbital wall defects

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ABSTRACT

Defects of orbital walls can be reconstructed using implants. The authors report a safe and accurate method to reconstruct bone defects in the orbital area using patient specific implants. A detailed process description of computer aided design (CAD) reconstructive surgery (CRS) is introduced in this prospective study.

The 3D volumetric virtual implant was design using MSCT data and PTCProEngineer™ 3D software. The intact orbital cavity of twelve patients was mirrored to the injured side. Specific ledges steered the implant into correct place. Postoperatively the position was assessed using image fusion.

One implant (8%) was rejected due to chemical impurities, two (16%) had a false shape due to incorrect CAD. Data of thin bone did not transfer correctly to CAD and resulted in error. One implant (8%) was placed incorrectly. Duration of the CRS was in average 1.17 h, correspondingly 1.57 h using intraoperative bending technique. The CRS process has several critical stages, which are related to converting data and to incompatibility between software.

The CRS process has several steps that need further studies. The data of thin bone may be lost and disturb an otherwise very precise technique. The risk of incorporating impurities into the implant must be carefully controlled.

1. Introduction

Defects of the orbital walls cannot be reduced, but instead, the injured area must be reconstructed using an implant. The aim of the reconstruction is to restore the shape and the original volume of orbit. Even a precise implant does not support the orbital soft tissue if it is not exactly placed.

Although computer aided design (CAD) is widely used in industry, its use in medicine is limited (Hassfeld and Mühling, 2001). The industrial CAD process starts from the designer's idea and is then visualized by creating a CAD model. This virtual model is then manufactured to a solid model with direct manufacturing (RP) or milling techniques (Ibrahim et al., 2009), which are very direct and reproducible processes. However, in medicine, the CAD process starts with the patient's computed tomography data (CT) (Rudman et al., 2011). This data cannot be visualized or processed by CAD software without additional measures taken. During the designing and manufacturing processes the data must be converted to certain formats (Schön et al., 2006; Fan et al., 2007; Lieger et al., 2010; Stoetzer et al., 2011; Mustafa et al., 2011). Rapid prototyping (RP) uses 3-dimensional (3D) CAD data and enables any 3D forms to be manufactured into solid models. There is good evidence that RP reproduces solid models with acceptable precision (Ibrahim et al., 2009).

The process in medicine has been described as a four steps flow (Winder and Bibb, 2005). But, only a few studies are available related to combination of 3D CAD and RP in medicine. Lopez-Heredia and co-workers have recently fabricated titanium alloy scaffolds using RP technique (Lopez-Heredia et al., 2008) and Klein and Glatzer (2006) fabricated CAD/computer aided manufacturing (CAM) glass-bioceramic implants to reconstruct orbital floor.

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The aim of the present follow up study was to assess if a precise patient specific orbital implant can be produced by CAD – RP technique and to analyse which the critical stages of such a process are. The third aim was to study if the implant can be placed similarly in clinical settings as planned in CAD. The fourth aim was to estimate if such an implant could reduce the time of surgery. The study was approved by the Ethical Committee of the Helsinki University Hospital Area with permission of research; Statement &156/2006 and Permission of Research &139/2007. The subjects enrolled in the study gave their informed consent to the work.

2. Material and methods

Twelve patients were included into this prospective study, 10 males and 2 females. The average age of the patients was 42 years (25.9–67.2). Patients had defects in two or more walls of the orbit. Diagnosis and site of reconstruction are shown in Table 1.

Preoperative multislice computed tomography (MSCT) imaging protocols are presented in Table 2, as well as the preoperative- and the postoperative delay of the CT examination in days.

Table 1
Diagnosis and corresponding site of surgery and type of incision.

	Diagnosis	Primary reconstruction	Secondary reconstruction	Site	Male	Female	Approach
Orbital wall fx	9	4	5	Orbit	7	2	Subciliary
SCC	1		1	Orbit	1		Midtarsal
OS	2	1	1	Combination of orbit and maxilla	2		Weber Ferguson
Total	12	5	7		10	2	

fx = fracture, SCC = squamous cell carcinoma, OS = osteosarcoma.

Table 2
Preoperative imaging protocols and timetable.

Patient no	CT device	kV	mA	Slice thickness	Kernel	Contrast	Preop	Postop
1.	GE LightSpeed Pro 32	120	80	1.25 mm	DETAIL		−13	
2.	Toshiba Aquilion 16	120	100	1.00 mm	BONE		−6	0
3.	GE BrightSpeed 16	120	120	0.625 mm	STD; BONE PLUS		−72	1
4.	GE LightSpeed Plus 4	120	100	1.25 mm	STD; BONE PLUS		−179	1
5.	GE LightSpeed VCT 64	120	40	1.25 mm	DETAIL		−8	1
6.	GE LightSpeed Plus 4	120	100	1.25 mm	STD; BONE PLUS		−14	1
7.	GE LightSpeed Plus 4	120	120	1.25 mm	STD; BONE PLUS	Yes	−162	1
8.	GE LightSpeed VCT	120	40	0.625 mm	EDGE		−247	16
9.	Toshiba Aquilion 16	120	100	1.00 mm	BONE		−10	1
10.	GE LightSpeed Plus 4	120	120	1.25 mm	STD; BONE PLUS	Yes	−85	5
11.	GE LightSpeed Plus 4	120	100	1.25 mm	STD; BONE PLUS		−84	3
12.	GE LightSpeed VCT	120	40	0.625 mm	BONE		−61	6

kV = kilovoltage, mA = tube current, kernel = kernel reconstruction algorithm, contrast = intravenous, iodine contrast enhancement, preop = number of days between preoperative CT and operation, postop = number of days between operation and postoperative CT.

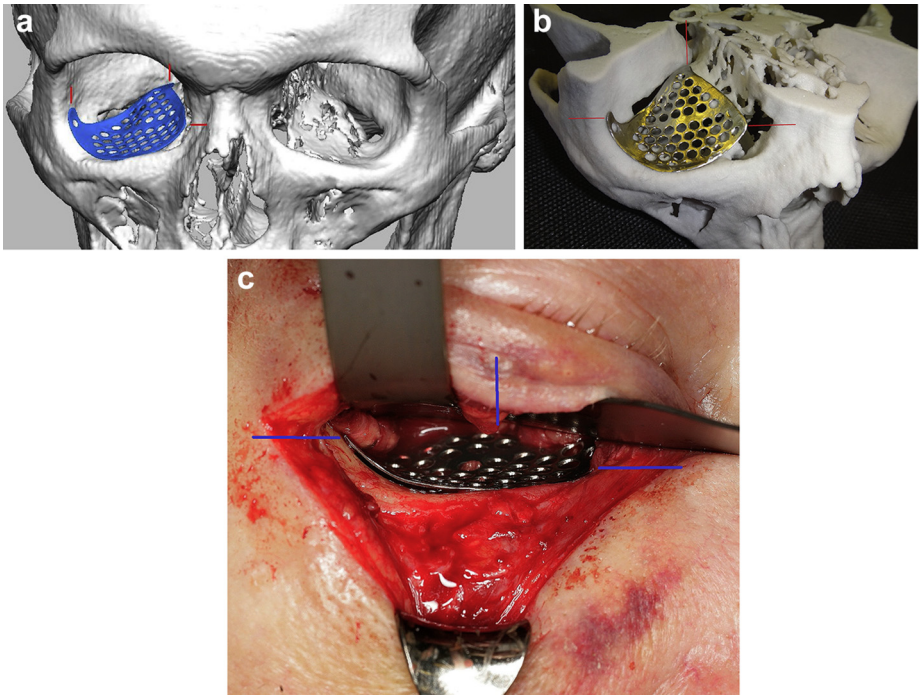

Fig. 1. Orbital wall implant. Specific ledges allow the implant to be placed only in to the designed position. Ledges are marked with coloured lines: a) CAD implant, b) solid implant manufactured using CAD data and EBM technology, c) intraoperative image.