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Classical versus custom orbital wall reconstruction: Selected factors regarding surgery and hospitalization



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ABSTRACT

Purpose: Nowadays, in orbital wall reconstruction, maxillofacial surgeons have the possibility to treat patients in modern ways such as with individual implants. Nevertheless, conventional treatment including standard titanium mesh shaped during the surgical procedure is also widely used. The aim of this study was to compare the above methods of orbital wall reconstructions.

Materials and methods: In the first group (39 cases), patients were treated by means of computer-aided design/computer-aided manufacturing (CAD/CAM) milled individual implants made of ultra—high-molecular-weight polyethylene, dioxide zirconium and rapid prototyping titanium mesh pre-bent on an ABS model made by a three-dimensional (3D) printer. In the second group (54 cases), intraoperative bending of titanium mesh was implemented.

Results: Ophthalmologic outcomes were the same in both groups. In patients who had greater destruction of the orbit, surgical procedures were longer regardless of the material used for individual implants (p < 0.05). Time of surgery was shorter in patients in whom individual implants were used. Intraoperative bleeding was higher in patients who were treated using intraoperative bending titanium mesh (p < 0.01).

Conclusion: Application of CAD/CAM techniques do not give better ophthalmologic results in reference center but improve patient condition postoperatively. For this reason, CAD/CAM is a safer treatment method for patients.

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1. Introduction

For the past 15 years, even the most experienced practitioners and medical scientists have been faced with a dilemma: less expensive and standard treatment is better than expensive and custom computer-aided design/computer-aided manufacturing (CAD/CAM) for orbital wall reconstruction (Hoffmann et al., 1998; Manolidis et al., 2002; Yavuzer et al., 2004; Chang and Manolidis, 2005; Kozakiewicz and Szymor, 2013).

In maxillofacial surgery, reconstruction of the craniofacial region is a serious challenge. Nowadays, in the majority of maxillofacial departments, autological grafts are the gold standard in treatment. However, patients' discomfort, increased surgical time, resorption of graft, intraoperative bleeding, longer hospitalization time, greater chances of infection of recipient, and donor site of autografts lead practitioners to use other materials (Lane and Sandhu, 1987; Silber et al., 2003; St John et al., 2003; Shimko and Nauman, 2007; Schlickewei and Schlickewei, 2007; Parthasarathy and Parthiban, 2008; Kozakiewicz and Zieliński, 2015). Apart from autological grafts, many different alloplastic materials and techniques were developed in last decades as thin polyethylene sheets adjusted in blow-out fractures in pediatric populations (Theologie-Lygidakis et al., 2007).

Since 2006, individual implants have been widely used (Schön et al., 2006; Kozakiewicz et al., 2009). Individual implants as well as pre-bent titanium meshes will be used in many maxillofacial departments in the future because the method has reliable and predictable results (Kozakiewicz et al., 2011; Loba et al., 2011; He et al., 2012). Nowadays technical equipment and special software are more widely available to practitioners. Computed tomography saved in DICOM format can be easily transferred into a virtual three-dimensional (3D) model (Elgalal et al., 2010; Olszewski and Rychler, 2011).





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An undamaged orbit model is mirrored and exported as an .stl file to a 3D printer. On the printed model, the surgeon bends titanium mesh before the surgical procedure. Such a solution has some advantages, such as reduced operating time and improved safety (Rychler and Olszewski, 2010; Olszewski and Rychler, 2011) and allows one to achieve much greater accuracy in orbital reconstruction (Metzger et al., 2006; Kozakiewicz et al., 2011; Essig et al., 2013). The authors decided to use individual implants of any desired thickness to obtain volumetric support and more stable orbital wall reconstruction results (Kozakiewicz et al., 2013). In maxillofacial surgery, the most common are 3 types of material in individual implants: polyetheretherketone (PEEK), ultra-highmolecular-weight polyethylene (UHMW-PE), and titanium (Ti). High-density polyethylene (HDPE) and titanium mesh implants in the facial skeleton are used to restore anatomical harmony following accidental or iatrogenic trauma, to correct congenital deformities or unaesthetic surgery very widely, but in classical manual way (Frodel and Lee, 1998; Liu et al., 2004).

The aim of this study is to compare CAD/CAM methods of orbital wall reconstruction versus conventional intraoperative manual bending of titanium mesh.

2. Materials and methods

University Bioethics Committee approval was obtained for this study (RNN/266/11/KB, RNN/267/11/KB, RNN/141/12/KB). A total of 93 patients (64 males and 29 females, mean age 38.7 ± 16.7 years) affected by orbital wall fracture were treated from 2011 to 2014. The most common causes of patients' hospitalizations were injuries (68 patients); 16 patients were operated on due to upper jaw malignancy and 9 patients due to orbital decompression (Table 1). Unilateral side lesion was the inclusion criterion.

All the patients underwent head scanning with a multi-slice VCT GE Lightspeed 64-slice scanner (GE Healthcare, UK) (0.6 mm layers, gantry tilt 0° matrix) on admission to the hospital. Computed tomography, maxillofacial and ophthalmological examination allowed one to establish diagnosis.

Every patient was coded according to orbital destruction intensity (ODI) scale, which corresponded to reconstruction needs (Kozakiewicz et al., 2011). The scale is described as follows: 1) one site of destruction: floor, i.e., one wall (1 W); 2) floor + one wall medial or lateral (i.e., two walls 2 W); 3) floor + one margin, i.e., one wall and one orbital margin (1 W+1 M); 4) floor + one wall + one margin, i.e., 2 W + 1 M; 5) floor + one wall + two margins, i.e., 2 W + 2 M; 6) floor + two walls + one margin, i.e., 3 W + 1 M; 7) floor + two walls + two margins, i.e., 3 W+2 M; and 8) floor + two or three walls + more than two margin, i.e., 3-4 W + 3-4 M.

The first group included CAD/CAM milled individual implants made in ultra—high-molecular-weight polyethylene (UHMW-PE), dioxide zirconium (ZrO), and rapid prototyping (RP) titanium mesh pre-bent on an ABS model made by a 3D printer (Inspire S200). The

Table 1

Common causes (n, %) of hospitalization were injuries, neoplasms, and decompression of eye socket.

	Injury	Neoplasm	Other	Row total
CAD/CAM methods	29	3	7	39
	31.18%	3.23%	7.53%	41.94%
Intraoperatively bent titanium mesh	39	13	2	54
	41.94%	13.98%	2.15%	58.06%
Column total	68	16	9	93
	73.12%	17.20%	9.68%	100.00%

Chi-square test, p < 0.05.

second group consisted of arbitrary intraoperative bending of titanium mesh by the surgeon.

Medically certified UHMW-PE for surgical implants produced in accordance with ISO 5834-1 2007 type 1, 5834-2 2006 type 1 and ASTM F 648-07 type 1 standards (Ticona Engineering Polymers, 2011, Florence, USA; www.ticona.com) was chosen as the substrate material. All UHMW-PE implants were milled computer numerical controlled, 5-axis milling machine Speed Hawk 650 (OPS-Ingersoll Funkenerosion GmbH, Burbach, Germany) with 50 µm of accuracy. All the implants were sterilized using gas plasma (Kozakiewicz, 2014).

Implants made of zircon dioxide were manufactured in an AG Ceramill System. CAM Ceramill Match was used to set milling path and planning bur changes. Milling time depended on dimensions and shapes of implants and varied from 100 to 150 min. After milling in Ceramill Motion, implants were put into sinterized furnace with 22% shrinkage. All the implants were autoclaved.

Implants shaped on a 3D model were 400- μ m-thick titanium mesh. After model design, stl files were sent to the 3D printer. The Department has its own software (Mimics Z, PowerShape, Geo-Magic Qualify, GeoMagic Studio) and hardware (Inspire S200). The material from which models were printed had been ABS. ABS is quite an inexpensive and efficient material that allows the authors to print 3D models routinely. From 1 ABS pack (2000 cm³, 350 Euro), it is possible to print about 200 individual orbital models. The material cost of 1 individual implant is estimated at 1.75 Euros. Implants shaped on a 3D model were packed to surgical box and autoclaved.

The first step in designing implants was segmentation in Mimics Z (Materialise, Leuven, Belgium). DICOM files were imported to Mimics Z, and a 3D model of bone structure was built. The next step was to copy and mirror undamaged orbit by means of GeoMagic Studio 11 (GeoMagic Corp., Morrisville, NJ, USA) and superimposed on the model with the defect side. In every case, alignment analysis with symmetry checking was performed. The reference points were marked on undamaged upper walls and upper rims. The imposition allowed the authors to design the same shape of walls of damaged orbits as intact ones. The next step was transferring the 3D model to the CAD program PowerShape (Delcam, Autodesk Corp., USA) and finally preparing the file for manufacture. Every implant before manufacturing was scrutinized thoroughly by a maxillofacial surgeon (Kozakiewicz et al., 2009, 2011).

The first group consisted of 39 patients who underwent a surgical procedure in which individual implants milled in computerized numerical control machine of UHMW-PE (18 patients), ZrO₂ (5 patients), and in 16 cases pre-bent titanium mesh on a 3D model were implemented. In this group, binocular single vision loss preoperationally was 26% of the field of view. The second group comprised 54 patients in whom standard, intraoperatively bent titanium mesh was used; 21% was binocular single vision loss preoperationally in this group. Patients were operated on under general anesthesia with a transconjunctival approach by the same maxillofacial surgeon. All treatment methods were used to reconstruct the lower, the lower and medial, or the lower medial and lateral walls of orbit. The implant position was checked by means of reference areas that were a stable part of lower orbital rim anteriorly and orbital process of palatal bone posteriorly. Within 1 week, computed tomography was performed to evaluate the wall reconstruction and intra-orbital tissues. All patients underwent full ophthalmic and orthoptic assessment 1 and 6 months postoperatively.

All obtained data were statistically analyzed in Statgraphics Centurion XVI (Statpoint Technologies Inc., Warrenton, Virginia, USA) (summary statistics, analysis of variance, analysis of linear regression, t-test). Statistical significance was determined at p < 0.05.



Fig. 1. Clinical material for orbital wall reconstructions. Three columns in the left show group 1, in which treatment was based on CAD/CAM methods, i.e., custom implantation of ultra-high-molecular-weight polyethylene material (translucent in computed tomogram) – right side affected; zirconium dioxide implant (highly radiopaque) – left side affected; and use of ABS model for pre-bent titanium mesh – left side affected. The rightmost column presents group 2, in which titanium mesh was manually bent intraoperatively by a surgeon – left side affected. A typical issue is that titanium mesh was bent without a model, yielding a too-flat lower orbital wall profile.



CAD/CAM methods

Fig. 2. Patients who were treated by means of standard intraoperative bent titanium mesh were in a risk group of higher intraoperative bleeding in comparison to patients treated with CAD/CAM methods (p < 0.01).

3. Results

Clinical material is presented in Fig. 1. The loss of binocular single vision in the CAD/CAM group of 29% noted 1 month after operation decreased to 13% 6 months after the surgery. For classical intraoperative bending, titanium mesh these values were 21% at 1 month postoperatively and 16% observed 6 months after the surgery. Results were not statistically significant in this series. Patients with

Fig. 3. Analysis of variance (ANOVA) revealed (p < 0.001) that intraoperative liquid infusion was higher in cases with standard titanium mesh reconstruction.

higher ODI score were included in group 1 (p < 0.01). Despite this, patients who were treated by means of classical intraoperatively bent titanium mesh had higher intraoperative bleeding than patients treated with CAD/CAM technology (p < 0.01, Fig. 2). Analysis of variance (ANOVA) showed with p < 0.001 that liquid infusion was also higher in group 2 (Fig. 3). CAD/CAM support did not decrease time of surgical procedure (p = 0.1673, Fig. 4) or duration of hospitalization (p = 0.4667, Fig. 5). Patients with higher ODI score had insignificant intraoperative bleeding (p = 0.2189, Fig. 6), but



Fig. 4. Duration of surgical procedure (in minutes) was shorter when CAD/CAM implants were used, but without statistical significance.



Fig. 5. Hospitalization period is longer in group 2 but is without statistical significance.



Fig. 6. Patients with higher ODI score had more extensive intraoperative bleeding but without statistical significance.

increased duration of hospitalization (p < 0.01, Fig. 7) and duration of surgery (p < 0.001, Fig. 8). In younger patients, the modern ways of treatment (CAD/CAM methods) were used rather than traditional intraoperative titanium mesh bending (p < 0.01, Fig. 9). The most frequent were lower ODI scores (Table 2). Sex was not statistically significant. In all, 14 of female and 25 of male patients were operated on using CAD–CAM methods, whereas intraoperative bending titanium mesh was used in 14 female and 39 male patients. In CAD/ CAM methods of treatment, the most frequent was UHMW-PE individual implants applied (p < 0.001) (Table 3).



Fig. 7. Time of hospitalization was longer in patients with higher ODI score (p < 0.01).



Fig. 8. Surgery duration was longer in patients with higher ODI score (p < 0.001).



Fig. 9. In younger patients, CAD/CAM methods were used (p < 0.001).

4. Discussion

Innovative technologies such as CAD/CAM have become more widely available in medicine in the last few years (Hohlweg et al., 2005; Metzger et al., 2007; Kozakiewicz et al., 2009, 2011). Every year, new materials (Lane and Sandhu, 1987; Ciprandi et al., 2012; Gierloff et al., 2012; Schumann et al., 2013) and new methods of manufacture of patient-specific implants are introduced in the management of orbital fracture treatment (Schmelzeisen et al., 2004; Zizellmann et al., 2007; Elgalal et al., 2010; Mustafa et al., 2011; Essig et al., 2013). Each of these innovations has the aim to

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	0	1	2	3	5	8	Row total
CAD/CAM methods	5	26	0	5	1	1	38 ^a
	6.33%	32.91%	0.00%	6.33%	1.27%	1.27%	48.10%
Intraoperatively bent titanium mesh	28	7	1	5	0	0	41 ^a
	35.44%	8.86%	1.27%	6.33%	0.00%	0.00%	51.90%
Column total	33	33	1	10	1	1	79
	41.77%	41.77%	1.27%	12.66%	1.27%	1.27%	100.00%

Chi-square test, p < 0.001.

^a In one case in CAD/CAM group it was impossible to establish ODI, and in 13 cases in group with intraoperative bending of titanium mesh.

Table 3					
Methods	of	treatment a	nd	materials	used

	Ti mesh	UHMW-PE	ZrO ₂	Row total
CAD/CAM methods	16	18	5	39
	17.20%	19.35%	5.38%	41.94%
Intraoperatively bent titanium mesh	54	0	0	54
	58.06%	0.00%	0.00%	58.06%
Column total	70	18	5	93
	75.27%	19.35%	5.38%	100.00%

Chi-square test, p < 0.001.

In CAD/CAM methods of treatment, the most frequent were UHMW-PE custom implants in this series. In second place was pre-bent titanium mesh. Five patients had zirconia dioxide individual implants.

produce quicker, better, but seldom less expensive fitting of the implant (Kozakiewicz and Szymor, 2013). The most common materials in the world used for orbit rehabilitation are autologous bone grafts (Gellrich et al., 2002; Ellis and Tan, 2003; Schmelzeisen et al., 2004); however, polyethylenes have dominated autografts and other allografts in last years because of their advantages. Alloplastic materials have been shown to reduce the number of bacteria required to produce infection by a factor of 10^4-10^6 (Sclafani et al., 1997). Very slightly rough surface makes the UHMW-PE implant more resistant to late infections because superficial fibrovascularization encourages increased immune response mediators at this expanded surface of alloplast (Zimmerli et al., 1982). As far as the functional outcome of treatment (i.e., single vision) is considered, both methods of treatment are comparably effective.

The main advantage of CAD/CAM individual implants is significant reduction of surgery time (p < 0.05). In maxillofacial surgery, reduction of duration of surgery affects on reduction of intraoperational bleeding and short hospitalization time. Moreover, the shorter time of surgery, the less blood loss and the lower the costs of hospitalization.

Another outstanding feature of the CAD/CAM group is that the reconstruction shape was established before the beginning of the surgery and remained unchangeable during surgery. This is contrary to the fully arbitrary bending of implantation material during surgery without any anatomic guide in the group treated by classical method. In the first case, the eyeball position is designed by highly professional and precise CAD/CAM programs; in the second case, the eyeball position is fixed only by a human being. Surprisingly, functional results are similar in both groups.

Printing of 3D ABS model and preoperative bending titanium mesh are the least expensive means of individual implantations in the reconstruction of orbital walls. The necessary equipment is a personal computer (PC), segmentation software, 3D printer, and material for printing. Nowadays the cost of 3D printer and ABS material are quite low and affordable. In addition, the costs of longer hospitalization, higher liquid infusion, and eventually blood transfusion exceed the costs of the software and hardware necessary for preoperative bending titanium mesh. A model of the orbit is just helpful in intra-orbital handling and is a useful navigation tool.

As we demonstrated, surgical procedures in patients with higher ODI score lasted longer (p < 0.05) regardless of the material of individual implants used. To shorten the time of reconstruction of orbital walls, we suggest using individual implants rather than intraoperative bending titanium mesh. Despite the fact that patients with lower ODI score were in the second group, we have shown that intraoperative bleeding (p < 0.01) was higher in the second group. If an implant is prepared before an operation, milled UHMW-PE, zirconia or bent on a 3D-printed model, the time of operation is longer than when using intraoperatively bent titanium mesh. A longer time of operation means higher intraoperative blood loss, although bleeding intensity is quite low. Another aspect of the longer time of surgery in group 2 was a greater amount of liquid infusion (Kozakiewicz and Zieliński, 2015).

5. Conclusions

Application of CAD/CAM techniques did not give better ophthalmologic results in a reference center but improved patient condition postoperatively. The study shows that modern, expensive technologies do not necessarily lead to better functional results than classic treatment. Thus, treatment can be less expensive, as surgeons implement only manual titanium mesh bending, but simultaneously can be safer, as when using CAD/CAM technology.

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