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Journal of Cranio-Maxillo-Facial Surgery 39 (2011) 30–36

Contents lists available at ScienceDirect

Journal of Cranio-Maxillo-Facial Surgery

journal homepage: www.jcmfs.com

Treatment with individual orbital wall implants in humans – 1-Year ophthalmologic evaluation☆

Marcin Kozakiewicz [a,*], Marcin Elgalal [b], Loba Piotr [c], Anna Broniarczyk-Loba [c], Ludomir Stefanczyk [b]

[a] Clinical Department of Maxillofacial Surgery (Chair: Dr. hab. M. Kozakiewicz), Medical University of Lodz, Lodz, Poland
[b] Department of Radiology and Diagnostic Imaging (Chair: Prof. L. Stefanczyk), Medical University of Lodz, Lodz, Poland
[c] Department of Ophthalmology (Chair: Prof. W. Omulecki), Medical University of Lodz, Lodz, Poland

ARTICLE INFO

Article history:
Paper received 28 May 2009
Accepted 10 March 2010

Keywords:
Orbital injury
Titanium mesh
Rapid prototyping

ABSTRACT

Background: In 2009 a method of creating individual, patient specific orbital wall implants using rapid prototyping (RP) was shown in a preliminary human study. That study showed that it is financially viable to produce anatomical models and that this technology could be used in the repair of orbital floor fractures.
Materials and methods: In this study, 24 consecutive subjects who had sustained orbital fractures (14 males, 6 females) without any coexisting central nervous system or globe injury were assessed post-operatively. The first series of 12 patients, recruited during the period 2005–2006, were treated with classical method (CM) of forming titanium mesh by manual manipulation, based on individual subjective assessment of the extent and shape of damaged orbital walls. The following 12 cases, recruited between 2007 and 2008, were treated with patient specific titanium mesh implants designed with an RP method. Early (2 weeks) and late (12 months) follow-up was performed. Patients were evaluated by binocular single vision (BSV) test and an assessment of eye globe motility.
Results: The superiority of the RP treatment method over CM was shown on the basis of early results when BSV loss area and reduction of vertical visual disparity (VVD) in upgaze were considered. Better outcomes for the RP group were confirmed in the late follow-up results which showed a reduction of BSV loss area, correction of primary globe position and a very significant improvement in upgaze.
Conclusions: One-year post-operatively, functional assessment of pre-bent individual implants of the orbital wall has shown the technique to be a predictable reconstruction method. Nevertheless longer follow-up and an increase in the number of cases treated are required for the full evaluation of the technique.
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1. Introduction

Orbital fractures and the accompanying functional and aesthetic defects (e.g. double vision, enophthalmos, infraorbital nerve dysfunction) are fairly common. Patients (predominantly males) in the third decade of life (34%) show the highest incidence rate and over 40% of all craniofacial trauma is associated with an orbital injury. As a result these complications, which may be severe, affect a relatively young population (Manolidis et al., 2002; Hoffmann et al., 2004; Bouguila et al., 2008).

Open reduction, internal microplate fixation and exact reconstruction of inferior and medial orbital walls are indicated for unstable, markedly displaced or comminuted fractures (Nolasco and Mathog, 1995; Burm et al., 1999; Bouguila et al., 2008). Such treatment restores the structure of the orbit and prevents late complications (Hammer and Prein, 1995; Nagasao et al., 2007). A series of methods and different materials have been described in the literature (Parsons and Mathog, 1988; Hammer and Prein, 1995; Eufinger et al., 1998; Burnstine, 2003; Hoffmann et al., 2004; Potter and Ellis, 2004; Buchel et al., 2005; Burm, 2005; Metzger et al., 2006; Schön et al., 2006). It must be emphasized that establishing the correct shape and position of the orbital wall are essential to restore correct orbital volume, obtain accurate globe position and achieve the desired long-term outcomes. The complex anatomy of

☆ Study was supported by grant no. 3627/B/T02/2008/34 from Ministry of Science and High Education.
* Corresponding author. Department of Maxillofacial Surgery, Zeromskiego 113, Lodz 90-549, Poland. Tel.: +48 42 6393781; fax: +48 42 6566547.
E-mail address: marcin.kozakiewicz@umed.lodz.pl (M. Kozakiewicz).

1010-5182/$ – see front matter © 2010 European Association for Cranio-Maxillo-Facial Surgery.
doi:10.1016/j.jcms.2010.03.007

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the orbit makes the process of shaping and cutting the reconstruction material intraoperatively very difficult, and it is almost impossible to achieve a 'true-to-original' three-dimensional (3-D) shape. The use of rapid prototyping (RP), anatomical models and pre-surgical planning can provide the necessary information to achieve this task (Kozakiewicz et al., 2009).

The aim of this study was to assess the functional results of orbital wall repair 1 year after treatment using a novel a reconstruction method with pre-shaped titanium mesh implants in human subjects.

2. Material and methods

In this study 24 consecutive subjects were included (14 males, 6 females) who had sustained orbital fractures without any coexisting central nervous system or globe injury. The first series of 12 patients recruited during the period 2005–2006 were treated using the classical method (CM) of forming titanium mesh by manual formation based on individual subjective assessment of the extent and shape of damaged orbital wall. The subsequent 12 cases, recruited in 2007–2008, were treated using titanium mesh implants designed using an RP method. All patients were operated on by the same maxillofacial surgeon. The mean age, sex and treatment delay were comparable for both groups (Tables 1 and 2).

The RP group consists of a previously published series of six cases (now supplemented with 12-month follow-up), and six additional new patients. An example of treatment with an individual implant of the inferior orbital wall is presented in the Figs. 1–4.

Diagnosis was established in all cases on the basis of maxillofacial and ophthalmological examination, including computerized tomography (CT). CTs were obtained with a Multi-slice VCT, GE Lightspeed 64-slice scanner using 0.6 mm cuts, a gantry tilt of 0° and with a matrix of 512 × 512. Scans were obtained for all patients on the day of admission to hospital.

The types of injury were classified (Tables 1 and 2) by an orbital destruction intensity (ODI) scale to compare the distribution of injury intensity in both groups. The scale is described as follows:

1. site of destruction: floor i.e. one wall (1W);
2. floor + one wall (medial or lateral) i.e. two walls (2W);
3. floor + one margin i.e. one wall and one orbital margin (1W + 1M);
4. floor + one wall + one margin i.e. 2W + 1M;
5. floor + one wall + two margins i.e. 2W + 2M;
6. floor + two walls + one margin i.e. 3W + 1M;
7. floor + one or two walls + two margins i.e. 3W + 2M;
8. floor + two or three walls + more than one margin i.e. 3–4W + 2–4M.

In the RP group, CT studies were used to create both virtual and physical models of the orbit of the uninjured side. DICOM data were exported to specialist software [MIMICS, Materialise, Belgium] and 3-D virtual models were created. The unaffected orbit was mirrored onto the contralateral side, i.e. the injured orbit. After modifying the inner walls of the virtual orbit, solid physical models were created from acrylic resin using a 3-D RP system [Objet Geometries, Israel]. These models were used as templates to shape and form 0.4 mm thick titanium mesh and prepare reconstructive plates for either inferior or medial orbital wall repair. These custom implants were then sterilized in an autoclave. Models were available in the operating theatre during surgery in order to compare a previously established virtual plan with actual intraorbital status. Transconjunctival or transcaruncular approaches were used for all patients and revision of the inferior or medial orbital walls was performed. Herniated orbital tissue was reduced and bone fragments, if possible,

Table 1
Results of treatment by CM of shaping titanium mesh implants (manual shaping during surgery).

n	Age	Gender	Side	Time to surgery (months)	ODI scale	Number of affected orbital walls	Pre-operational				ER (2 weeks)				LR (12 months)			
				Delay			PRE BSV loss	PRE upgaze	PRE primary position	PRE downgaze	ER BSV loss	ER upgaze	ER primary position	ER downgaze	LR BSV loss	LR upgaze	LR primary position	LR downgaze
1	20	M	R	2.5	5	2	0.42	20	1	8	0.43	27	2	2.5	0.18	11	1	1
2	22	M	L	0.43	3	1	0.83	32	10	1	0.22	10	1	2	0.05	6	0	0
3	56	M	L	24	5	2	0.26	12	0	1	0.28	11	0.5	3	0.08	9	1	0
4	14	M	L	0.17	1	1	0.51	23	7	4	0.25	11	3	1	0.04	3.5	1	1.5
5	56	M	L	0.17	1	1	0.22	13	0	1	0.09	8	0	4	0.06	6	0	1
6	30	M	R	2	4	2	0.28	6	2	4	0.53	8	2	8	0.23	8	1	3
7	73	F	L	3	1	1	0.76	4	15	34	0.48	0	10	26	0.18	0	1	16
8	37	F	L	0.33	1	1	0.22	6	1	1	0.08	6	2	0	0.02	3	0	0
9	23	M	L	0.3	1	1	0.62	19	7	1	0.34	12	2	0	0.04	3	0	0
10	64	F	L	0.07	7	3	0.58	23	5	2	0.4	15	0	1	0.17	9	1	3
11	29	M	R	0.17	5	2	0.36	7	2	7	0.15	8	2	3	0.07	5	1	2
12	58	M	R	0.67	4	2	0.84	34	21	1	0.28	3	0.5	19	0.15	4	2	6
$\bar{x}$	40 ± 20			2.82 ± 6.75	3 ± 2		0.49 ± 0.23	16.58 ± 10.22	5.92 ± 6.6	5.42 ± 9.34	0.29 ± 0.15	9.92 ± 6.72	2.08 ± 2.67	5.79 ± 8.23	0.11 ± 0.07	5.63 ± 3.17	0.75 ± 0.62	2.79 ± 4.52

Abbreviations: M, male; F, female; R, right; L, left; BSV loss, loss of BSV (0 = best; 1 = worst).

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Table 2
Results of treatment by RP method of shaping the titanium mesh implants (pre-operational, patient specific implants).

n	Age	Gender	Side	Time to surgery (months)	ODI scale	Number of affected orbital walls	Pre-operational			ER (2 weeks)					LR (12 months)			
				Delay			PRE BSV loss	PRE upgaze	PRE primary position	ER downgaze	ER BSV loss	ER upgaze	ER primary position	ER downgaze	LR BSV loss	LR upgaze	LR primary position	LR downgaze
13	28	M	R	0.2	3	1	0.84	19	8	39	0.15	2	2	8	0.1	2	0	8
14	53	F	L	0.17	3	1	0.2	8	0	2	0	0	0	0	0	0	0	0
15	22	F	R	22	5	2	0.43	15	1	5	0	2	0	3	0	2	0	3
16	40	M	L	12	1	1	0.07	8	1	1	0	2	0	0	0	0.5	0	0
17	34	F	R	0.2	4	2	0.27	8	2	12	0.12	2	0	8	0.07	0	0	8
18	33	M	R	0.27	2	2	0.3	14	2	8	0.06	5	0	1	0.06	5	0	0
19	49	M	L	0.23	1	1	0.43	1	9	19	0.25	7	1	13	0.07	1.5	0	5
20	27	M	R	0.1	1	1	0.07	4,5	1	0	0	0	0	0	0	0	0	0
21	50	M	L	0.13	3	1	0.67	16	12	2	0.45	8	4	16	0.04	1	1	3
22	31	M	L	0.1	1	3	0.12	8	0	4	0.04	2	0	4	0	0	0	2
23	35	M	L	0.1	5	2	0.37	12	3	6	0.15	2	1	4	0.05	0	0	0.5
24	25	M	L	3	7	2	0.48	21	6	4	0.43	10	2	8	0.12	8	1	1
$\bar{x}$	36 ± 10			3.20 ± 6.83	3 ± 2		0.35 ± 0.24	11.21 ± 5.98	3.75 ± 4.00	8.5 ± 10.98	0.14 ± 0.16	3.50 ± 3.23	0.83 ± 1.27	5.42 ± 5.28	0.04 ± 0.04	1.67 ± 2.47	0.17 ± 0.39	2.54 ± 3.00

Abbreviations: M, male; F, female; R, right; L, left; BSV loss, loss of binocular single vision (0 = best; 1 = worst).

were also reduced. The pre-shaped titanium mesh was positioned to support the globe. Passive movements of the globe were evaluated at the end of surgery. Post-surgery functional orthoptic examination and CT scans to confirm the position of the implants were performed.

For both groups the treatment was similar except for implant shaping. In the CM group the surgeon formed titanium mesh manually on the basis of personal assessment of the orbital concavity and the extent of damaged tissue. During the procedure it was necessary to check the shape and size of the implant several times by placing and aligning it within the orbital cavity. This allowed the surgeon to perform any necessary modifications. Such manoeuvres were required to check proper alignment of the implant to the residual orbital wall.

All 24 patients underwent full ophthalmic and orthoptic assessment 2 weeks (early result – ER) and 12 months after surgery (late result – LR). None of the patients had a history of binocular vision impairment prior to injury. In our analysis we have included the vertical visual disparity (VVD) measurement, which is the difference in relative globe position in degrees assessed using a major amblyoscope (Clement–Clarke 2001). The VVD results from 30° upgaze, primary position and 30° downgaze were compared in both groups. The extent of diplopia was assessed on the binocular single vision (BSV) screen (Medmont M700) with the examination field extending 30° superiorly and 40° inferiorly. The results of this method (BSV loss) are presented as a percentage of the examined field in which the patient reports double images (Fig. 5). For statistical reasons the range 0–100% was changed into 0–1. The improvement was graded on a 3° scale based on BSV loss. The result was considered as “good” when the BSV loss was less than 0.05. A “moderate” result corresponds to BSV loss of 0.06–0.25. Any results above these values were considered as “poor”.

2.1. Statistics

Statistical analysis was performed in Statgraphics Plus for Windows ver. 5.1 (Summary Statistics, ANOVA, analysis of linear regression, *t*-test). Statistical significance was determined as $p < 0.05$.

3. Results

Both groups (CM and RP) were similar when pre-treatment ophthalmological data (PRE BSV loss, PRE upgaze, PRE primary position, PRE downgaze) were compared.

The average age in the two groups (CM and RP) was similar (confidence level of 95.0%, using the Kolmogorov–Smirnov (K–S) test = 1.021). The new method of treatment (RP) did not delay the timing of surgery (delay $t = -0.141$; $p = 0.89$). Both groups of patients had a similar degree of injury (ODI $t = 0.20$; $p = 0.84$) and number of affected orbital walls ($t = 0.0$; $p = 1.0$). Neither ERs nor LRs of treatment (ER BSV loss, LR BSV loss, ER upgaze, LR upgaze, ER primary position, LR primary position, ER downgaze, LR downgaze) showed any relationship to the degree of orbital damage (factor ODI in ANOVA). In two-wall orbital defects the LRs were significantly worse than in one-wall defects using the CM of treatment (LR primary position $F = 4.46$; $p = 0.045$ in group CM), but the RP group had similar outcomes for both groups of injury irrespective of the number of orbital walls affected.

Patient sex and side of injury did not influence the results of therapy. Delay in commencing surgical treatment had no significant correlation with any of the outcome parameters considered. In general, better results were achieved for younger patients (ER downgaze $R2 = 27.79$; $p = 0.008$; cc = 0.53. LR downgaze

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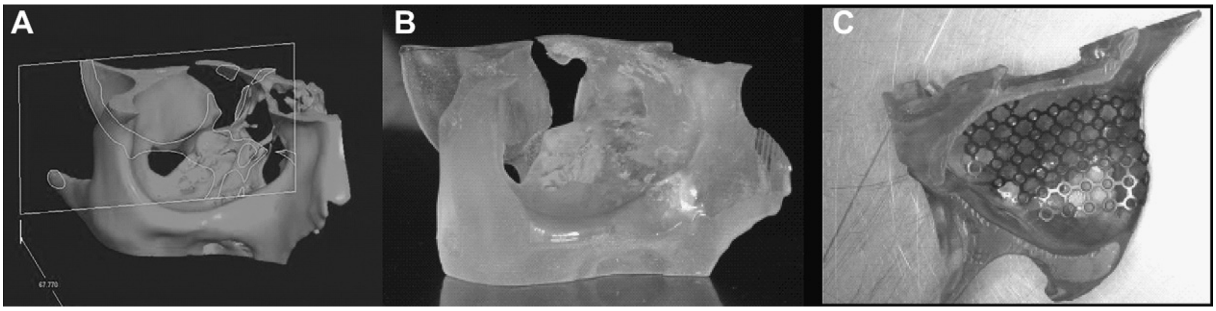

Fig. 1. Patient (#13) after improper treatment of blow-out fracture of the right orbit. Inappropriate alloplastic reconstruction with hypercorrection was previously made. Upward dislocation of right globe is the effect of a decrease in orbital volume. A – mirrored intact (left) orbit-virtual model (3-D CT). B – solid RP model, and C – titanium mesh fitted to the shape of inferior orbital wall in the model.

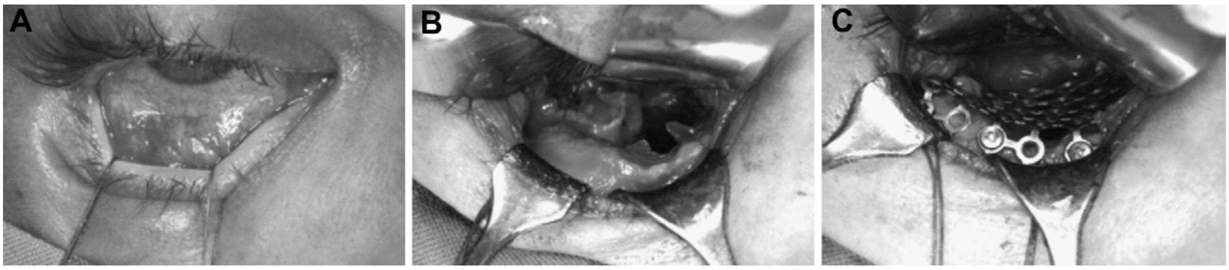

Fig. 2. Surgical procedure: A – transconjunctival approach, B – orbital floor bone defect, and C – positioned individual implant.

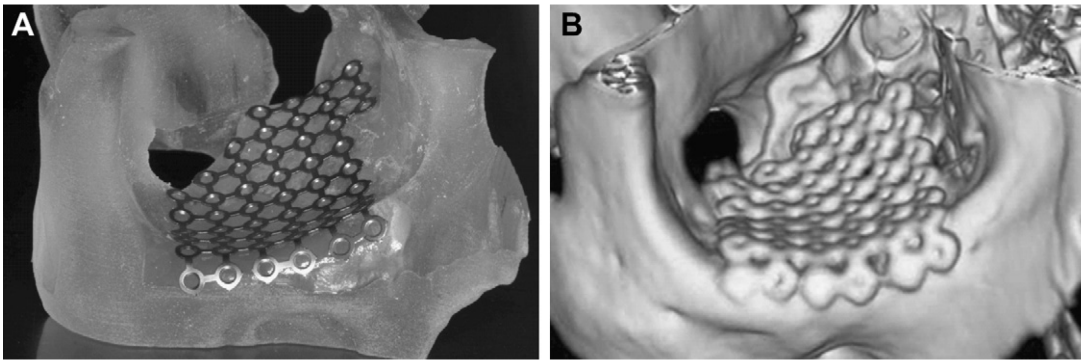

Fig. 3. Comparison of implant position on the model (A) and in patients – 3-D CT reconstruction post-operationally (B). Shape of the deepest border of the implant was modified during surgery. Three microscrews in implant holes fixed to inferior margin of the orbit.

$R2 = 18.84$; $p = 0.034$; $cc = 0.43$), but not when diplopia was considered (BSV loss). The statistical analysis indicated a relatively weak correlation between final outcomes and patient age. Regression analysis performed to evaluate correlation of injury intensity with ophthalmopathy (ODI and number of affected orbital walls; Tables 1 and 2) revealed a positive, significant, and a moderately strong association between the degree of orbital injury (ODI) and long-term ophthalmological disturbances (LR upgaze $R2 = 30.1\%$; $p = 0.006$; $cc = 0.54$). A similar, but weak, relationship was found between the ODI and long-lasting diplopia, or the VVD in primary position (LR BSV loss $R2 = 19.6\%$; $p = 0.030$; $cc = 0.44$. LR primary position $R2 = 20.0\%$; $p = 0.029$; $cc = 0.45$).

When comparing the CM and RP groups, in the CM group the long-term results were found to be poorer the lower the ODI (LR upgaze $R2 = 56.6\%$; $p = 0.005$; $cc = 0.75$), unlike in the RP group, where there was no statistical difference in long-term outcomes.

Because the *p*-value for the *F*-test was less than 0.05, there is a statistically significant superiority for the RP treatment method over the CM method when the area of diplopia (ER BSV loss $F = 6.16$; $p = 0.021$ i.e. ER of BSV loss, Fig. 6) and upgaze VVD reduction (ER upgaze $F = 8.88$; $p = 0.007$ i.e. ER of upgaze) are considered at the 95.0% confidence level.

The ERs are the same for both methods of treatment for correction of VVD in downgaze and primary position.

In the long-term the outcomes for the RP method were superior, with a reduction of double vision area ($F = 6.97$; $p = 0.015$ LR BSV loss i.e. LR of BSV loss), improved primary globe position correction ($F = 7.59$; $p = 0.012$ LR primary position i.e. LR of primary position), and for upgaze ($F = 11.64$; $p = 0.003$ LR upgaze i.e. LR of upgaze). The LRs for correction of VVD in downgaze were the same for both methods of treatment.

The ERs for both RP and CM groups were similar (BSV loss $t = -0.62$; $p = 0.54$. Upgaze $t = 1.63$; $p = 0.12$; primary position $t = -0.20$; $p = 0.84$; downgaze $t = -1.31$; $p = 0.20$).

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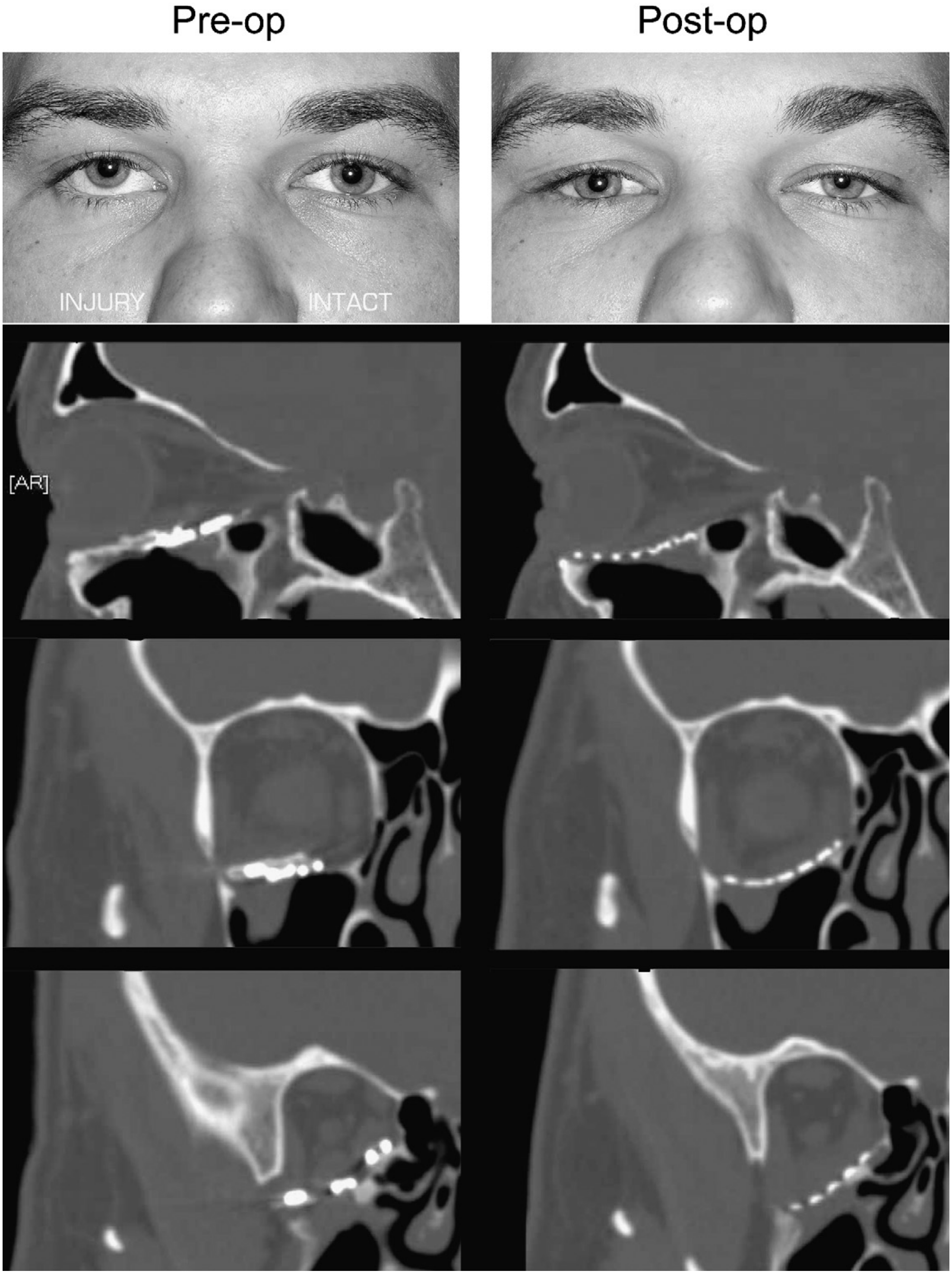

Fig. 4. Pre-RP surgery and post-operational comparison of clinical status and shape of inferior orbital wall in MPR CT reconstructions. Hypercorrection of vertical globe position is presented pre-operationally, when surgery was made with subjective shaping the titanium mesh by operator – improper shape of inferior orbital wall. Normalization of globe position was achieved after application of pre-bent titanium mesh implant.

4. Discussion

This paper demonstrates the results of an uncomplicated method of creating orbital wall implants, which can be successfully used in daily maxillofacial practice to reduce complications developing due to changes in orbital dimensions.

A review of the advantages and disadvantages should be the starting point of a discussion regarding this treatment method.

The disadvantages are the length of time required to build models, the need for cooperation between a number of people in different locations and the difficulty of using this method in panfacial fractures, problems associated with indentifying stable

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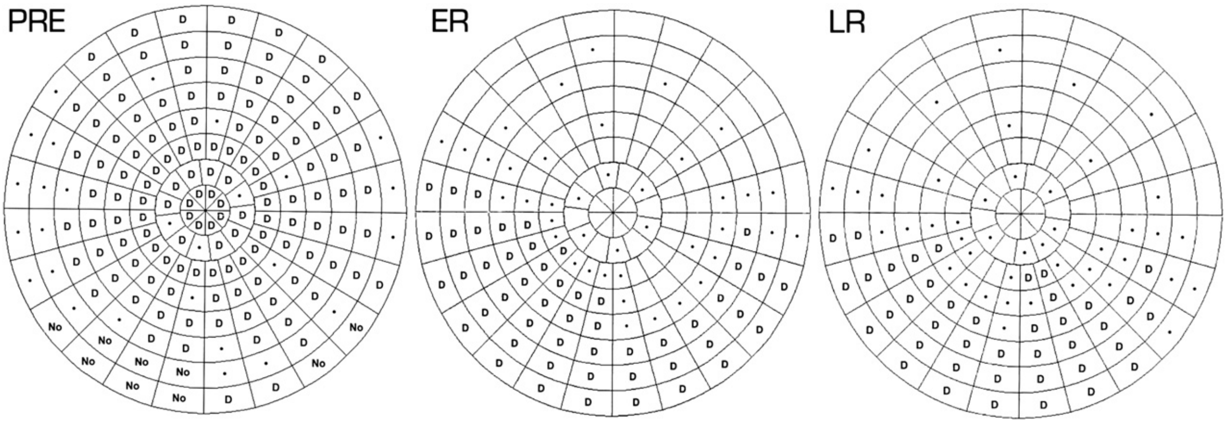

Fig. 5. BSV test. BSV loss chart of patient #13 (D – double response, no – no response). PRE – before the surgery (0.84); ER – early post-operational result i.e. 2 weeks after application of individual implant (0.15); LR – late post-operational result i.e. 12-month follow-up (0.1).

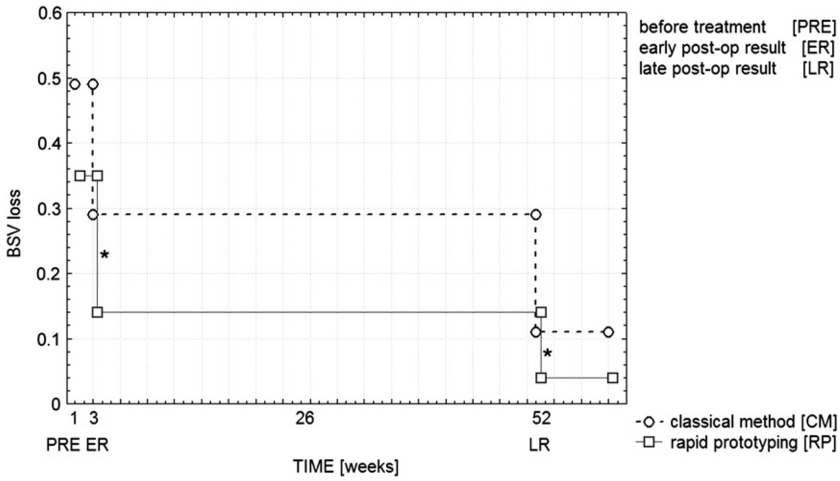

Fig. 6. Plot of loss of BSV (BSV loss) in investigated cases for both methods of treatment. *Significant statistical difference for $p < 0.05$.

orbital margins [before surgery] for virtual planning of the model and establishing accurate positions for pre-bent plates.

Advantages include greater accuracy, straightforward planning and model construction, better understanding of the morphology of the orbital injury, shortened operating times, a decrease in the number of attempts at positioning the implant in the orbital cavity including assessing the shape and fit, excellent adaptation of implants in large defects, the availability of a model for the surgeon during the operation, low costs and ease of access for revision or re-operation (Kozakiewicz et al., 2009).

Until recently appropriate computer software and hardware, as well as telemedicine, were not available. Before they became available it was only possible to perform relatively simple tissue reconstruction (Scholz et al., 2006). As a result of developments in diagnostic imaging (Nagasao et al., 2007), materials science (Kuttenberger and Hardt, 2001) and of registration methods (Luebbers et al., 2008) it is now possible to produce individual, inexpensive, implants and improve orbital wall reconstruction. Computer-assisted surgery can improve the clinical outcome of reconstructive bone surgery and reduce the number of additional hard tissue procedures (Lauer et al., 2006). Intraoperational navigation is the one of the most useful tools available at the moment (Luebbers et al., 2008).

There are numerous studies in the literature in which titanium has been compared with other materials. Edward Ellis III performed a study to assess the adequacy of internal orbital reconstruction in pure blow-out fractures using either cranial bone grafts or titanium mesh implants and concluded that orbits reconstructed with titanium mesh showed better overall reconstruction than those repaired using bone grafts (Ellis and Tan, 2003). For small, linear defects measuring less than 2 cm with enophthalmos and restricted ocular movements, a flexible material can be used (for example prolene mesh). For larger defects and impure blow-out fractures involving the infraorbital rim, calvarial graft or titanium mesh are a typical choices. The outcome of surgery with all these materials is satisfactory (Shetty et al., 2009). We believe that titanium mesh is a versatile and predictable reconstructive material for orbital surgery.

There is considerable interest in digitally designed titanium mesh implants at the current time. There are several scientific centres that routinely use individual titanium implants for orbital wall fractures (Metzger et al., 2006; Schön et al., 2006; An et al., 2008; Andrades et al., 2009; Guo et al., 2009). A Chinese team confirmed that the difference in orbital volume between unaffected and affected sides post-operatively was not significant in the group that received individually designed titanium mesh implants, but

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was significant in the group that received conventional treatment. Furthermore, they concluded that individual pre-bent titanium mesh is the correct choice of implant material to regain precise volume of the orbit in both recent and older fractures (Guo et al., 2009). One of the most important aspects that should be considered in the discussion is the problem of predicting treatment outcome (Andrades et al., 2009). Clinical evaluation significantly correlated with CT mesh placement, but there was no correlation between clinical evaluation and any of the variables measured on CT. The most important factors influencing post-operative orbital volume correction were type of fracture, affected walls, and use of prefabricated mesh (Andrades et al., 2009). We attempted to evaluate these factors and included comparable data in this paper. The RP method was equally effective regardless of the number of affected orbital walls. LRs using the CM of treatment were significantly worse for two-wall orbital defects when compared to one-wall defects. Late outcomes for the CM treatment were associated with an increase in ODI ($p = 0.005$). The RP method was equally effective and independent of the ODI value.

Several cases of re-treatment or old, untreated, fractures are included in this series together with less complex pathology. The authors assess the results of treatment in these cases as satisfactory; however the best outcomes were seen in cases of immediate treatment and total reconstruction.

The degree of orbital damage is associated with worse long-term outcomes for the classic method of repair. Greater intensity of orbital damage and an increase in the number of walls involved resulted in deterioration of eye globe motility. This leads to permanent diplopia in some areas of the visual field. This correlation was not seen in cases treated using custom designed orbital wall implants.

VVD in patients after orbital wall fractures occurs as a result of various mechanisms that limit ocular movements. The most affected are vertical ductions on the side of the injury. In such circumstances the patient is troubled by diplopia in upgaze, downgaze and sometimes in primary globe position. Reconstructive surgery significantly reduces the amount of VVD and the area of diplopia. Despite this surgery could not entirely eliminate the double vision, especially in upgaze. Such patients should have careful orthoptical follow-up for a period of at least 1 year (Hoşal and Beatty, 2002). After this time it is likely that VVD may spontaneously reduce to the level of approximately 4–6Δ, which makes image fusion possible.

With the RP method an improvement in VVD for upgaze was observed much earlier, and after 12 months was better, when compared to the CM group. As a result more patients reached the level necessary for image fusion in the RP group. This result suggests that RP is a more effective tool for elimination of restriction factors due to injured extraocular muscle.

Persistent diplopia and significant VVD in downgaze after reconstructive surgery suggest the existence of an additional factor – muscle paresis. The lack of any significant reduction of VVD in downgaze within both groups is probably due to the minor effect of reconstructive surgery on this condition. In most cases paresis resolves within 1 year (Kerr, 2004). Nevertheless, if it persists after this time surgery on the extraocular muscles should be performed. A better understanding of the mechanics of the extraocular muscles after orbital trauma is the subject of further research on our department.

By choosing this new method of titanium mesh shaping it is possible to achieve better results when compared to the classical treatment method (see Fig. 6) using a less invasive procedure. This study provides evidence for the value of RP in surgery (Tables 1 and 2) and shows good ERs and LRs in comparison to the CM.

5. Conclusions

One-year functional result assessment of pre-bent individual implants of the orbital wall has shown it to be a predictable reconstruction method. Longer follow-up and a larger series will give further evidence of the effectiveness of the technique.

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