Annals of Medicine and Surgery 61 (2021) 139–144

Contents lists available at ScienceDirect

Annals of Medicine and Surgery

journal homepage: www.elsevier.com/locate/amsu

Randomised Controlled Trial

A prospective study of resolution of post-traumatic orbital complications using PRECLUDE® MVP: A randomized controlled trial

Sylvio Luiz Costa De-Moraes [a,*], Rodrigo dos Santos Pereira [b], Alexandre Maurity de Paula Afonso [a], Ricardo Pereira Mattos [a], Jonathan Ribeiro da Silva [b], Roberto Gomes Santos [a], Monica Diuana Calasans-Maia [c]

[a] Clinic for Cranio-Maxillofacial & Reconstructive Surgery, Hospital São Francisco, Rio de Janeiro, Brazil
[b] Oral & Maxillofacial Surgery, UNIFESO, Rio de Janeiro, Brazil
[c] Oral & Maxillofacial Surgery, Federal Fluminense University, Rio de Janeiro, Brazil

ARTICLE INFO

Keywords:
Polytetrafluoroethylene
e-PTFE
Orbital fractures
Biomaterials
Reconstruction
Complications

ABSTRACT

Orbital fractures alone represent 10% up to 25% of all facial fractures, but when they are associated with other fractures of the middle-third of the face, their incidence can increase up to 55%. This study aimed to identify whether the size of the orbital defect based on the classification by Jaquiéry et al. influenced the resolution of post-traumatic complications after orbital wall reconstruction using PRECLUDE®MVP alone or in combination with a titanium mesh or autogenous bone graft. Thirty-five orbits were categorized into four groups on the basis of the size of the defect and the operative techniques: group 1 contained 16 Jaquiéry class I orbits treated only with PRECLUDE®MVP; group 2 included eight class II orbits treated with PRECLUDE®MVP along with autogenous bone graft harvested from the calvaria or a titanium mesh; group 3 included five class III orbits and group 4 included six class IV orbits that were treated the same way as those in group 2. Spearman correlation showed that the use PRECLUDE®MVP didn't improve the post traumatic complications for big orbital defects due to the three-dimensional anatomical changes that occurred by neurologic lesions and lipolysis of the orbital contents.

1. Introduction

Although orbital fractures alone represent 10%–25% of all facial fractures, their incidence can be as high as 55% when they are associated with fracture of the zygomatic bone and the naso-orbital-ethmoid complex [1–3]. The most frequent fractures are observed in the orbital floor and medial wall, which represents a challenge in facial traumatology due to the specific bone structure as well as the difficulty in reconstruction [2,4–6].

Jaquiéry et al. [7] classified orbital wall fractures into five categories: (1) orbital floor defects up to 20 mm^2 in size; (2) orbital floor defects larger than 20 mm^2; (3) orbital floor defects with lateral extension to the infraorbital fissure; (4) orbital floor defects extending to the medial wall and larger than 40 mm^2 in size; (5) orbital floor and medial wall defects extending to the orbital roof.

The materials used to repair the orbital wall include titanium meshes, autogenous bone grafts, and expanded polytetrafluoroethylene (e-PTFE) [8]. Titanium has been widely used to repair facial fractures and is considered the best option for large defects due to its relatively easy handling [9]. Autogenous bone grafts are considered the most predictable material in bone reconstruction because of their strength, vascular potential, ability to be osteointegrated, as well as a lack of immune reactivity [10].

The second generation of e-PTFE, which has been used for the treatment of dura mater lesions, has also shown suitable results in experimental studies on orbital wall repair without early inflammation reaction [11,12]. The PRECLUDE®MVP – Gore (WL Gore & Associates, Inc. Flagstaff Arizona - USA) is a type of e-PTFE membrane with 0.3-mm thickness and with two sides; a "smooth side" and a "textured side." It also shows other properties such as biological and chemical inertness; a non-antigenic nature; easy handling and adaptation; and the ability to allow the formation of fibrovascular tissue stabilizing the implant in the periorbital region, thereby reducing the risk of migration, extrusion, and infections [13].

* Corresponding author. Hospital São Francisco, Serviço de Cirurgia Crânio-Maxilo-Facial e Reparadora da Face, Rua Conde de Bonfim 1033, Prédio H, térreo sala 102-106, Tijuca, Rio de Janeiro, 20530-001, Brazil.
E-mail addresses: sdmoraes@yahoo.com.br, sylviodemoraes001@gmail.com (S.L.C. De-Moraes).

https://doi.org/10.1016/j.amsu.2020.12.021
Received 4 November 2020; Received in revised form 13 December 2020; Accepted 15 December 2020
Available online 29 December 2020

Therefore, the aim of this study was to identify if orbital wall reconstruction using PRECLUDE® MVP associated with an autogenous bone graft or a titanium mesh is correlated with the persistence of post-traumatic complications.

The hypotheses of this study were as follows:

- H_0 (null hypothesis): There is no correlation between the use of PRECLUDE® MVP in orbital wall reconstruction and the persistence of post-traumatic complications.

2. Materials and methods

2.1. Human subjects

The present research has been reported in line with Consolidated Standards of Reporting Trials (CONSORT) checklist [14] (Fig. 1). Besides, the procedures were in accordance with the Brazilian National Research Committee guidelines as well as with the tenets of the Helsinki Declaration of 1964 and the study was approved with the number 2.804.713 by Plataforma Brasil/CONEP. The present research was registered at www.researchregistry.com with the following unique identifying number (UIN): researchregistry5852 (www.researchregistry.com/browse-the-registry#home/?view_2_search=researchregistry5852&view_2_page=1).

2.2. Sample size

The number of samples for this study was determined using the simple size calculation at the website www.calculoamostral.bauru.usp.br using 0.99 as coefficient of correlation, a significance level of 5% (alpha error), and a power of 80% (beta error) resulting in a minimum of 5 orbits per group required to perform this study.

2.3. Inclusion & exclusion criteria

For this study, we included adult patients with trauma in the orbital region and orbital wall fractures according to the classification proposed by Jaquiéry et al. [7]; no history of allergies or drug use; and no history of sinusitis and orbital infection. Patients were excluded if had sequel fractures or a history of sinusitis and allergies; if they were smokers or had received radiation therapy in the head and neck region; if they were children, teenagers, or mentally ill; or if they had associated fractures of the roof or lateral wall of the orbit and showed a history of orbital surgery.

Computed tomography (CT) of the orbital region was performed to evaluate the patients and measure the orbital defects. To determine the size of the orbital defects, the CT images were reconstructed using OsiriX software version 4.1.2, 32-bits (OsiriX Foundation, Geneva, Switzerland), and the parameters to standardize the distance between

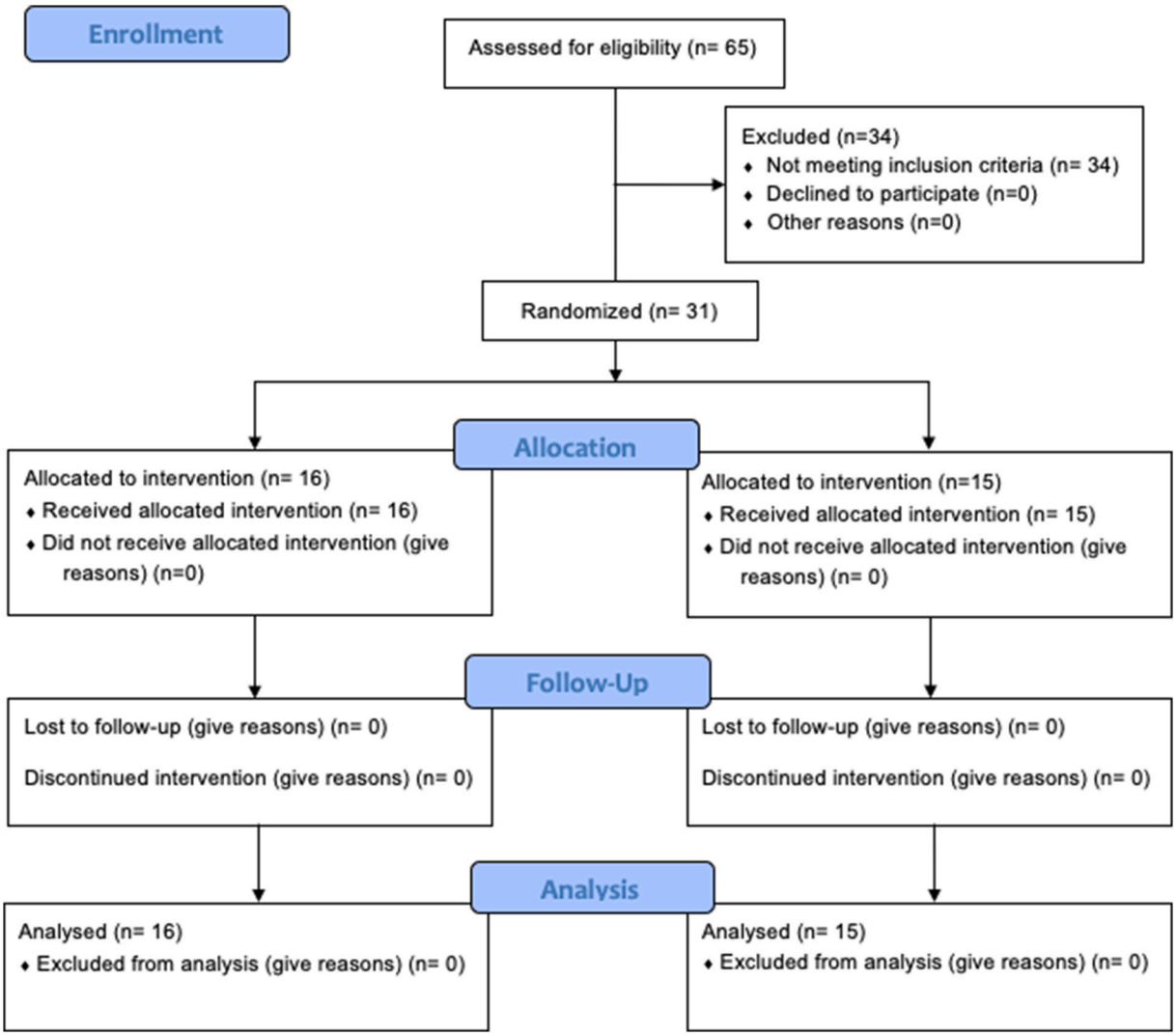

Fig. 1. CONSORT diagram of the patient allocation by randomization.

the slices and slice thickness were based on the study by Pereira et al. [15]. Next, using the scale tool, the measurements were obtained using the bigger distance in the coronal and sagittal views and expressed in mm^2. The patients' fractures were then classified into four categories, as reported by Jaquiéry et al. [7]: class 1, orbital floor fractures ranging from 10 to 20 mm^2; class 2, orbital floor fractures larger than 20 mm^2; class 3, orbital floor fractures larger than 20 mm^2 with lateral extension; and class 4, entire orbital floor fracture extending to the medial wall with fracture area greater than 40 mm^2.

2.4. Group determination

Based on these parameters, 35 orbits (31 patients) were selected for this study and divided into four groups:

Group 1: Sixteen class I orbits treated only with PRECLUDE®MVP.

Group 2: Eight class II orbits treated with PRECLUDE®MVP along with a titanium mesh or an autogenous bone graft harvested from the calvaria.

Group 3: Five class III orbits treated with PRECLUDE®MVP along with a titanium mesh or an autogenous bone graft harvested from the calvaria.

Group 4: Six class IV orbits treated with PRECLUDE®MVP along with a titanium mesh or an autogenous bone graft harvested from the calvaria.

Group 1 was considered the control group because the small defect presented as well as in order to identify antral packing due to the relationship of PRECLUDE® MVP with the sinus cavity. During the period of this study, none of the cases presenting class V were verified.

2.5. Randomization

A clinical assistant which not involved with this study, drew lots to make the choice between the titanium mesh or autogenous bone grafts along with PRECLUDE®MVP in orbital wall reconstruction for groups 2, 3, and 4.

2.6. Surgical procedure

The patients underwent surgery from December 2003 to March 2009, with the operations being performed 3–10 days after the trauma based on the modified Burnstine recommendations [16], with periods until 10 days being considered early treatment and periods over 14 days being considered late treatment. All the patients were treated under general anesthesia. The orbital floor procedures were performed by a subtarsal approach and the medial wall procedures were performed with a combination of subtarsal and coronal approaches.

Autogenous bone grafts were harvested from the calvaria and the PRECLUDE®MVP membranes were placed without any type of fixation, and with the textured side facing the maxillary sinus, or the autogenous bone graft or the titanium mesh (Fig. 2 and Fig. 3). The follow-up period ranged from 1 to 11 years to evaluate post-surgical complications as well as the evolution of the cases.

2.7. Statistical analysis

The Kolmogorov–Smirnov test was used to indicate the parametric or non-parametric distribution of the samples. Because of the non-parametric distribution, the correlation of persistent complications with defect size was determined by Spearman's test (SPSS, Statistics for Mac, IBM; Armonk, New York). An a priori p-value < 0.05 was used for all tests.

3. Results

Thirty-one patients with 35 orbital fractures were operated on in the present study, with the patients' ages ranging from 21 to 82 years (mean, 43.5 ± 19.0 years). In group 1 the median orbital defect size was 13.0 mm^2, and two cases presented with enophthalmos (5.4%) while one case showed persistent diplopia (3.7%) post-trauma, which were resolved with treatment using PRECLUDE®MVP alone. Group 2 included eight orbits with a median orbital defect size of 22.0 mm^2. Five orbits were treated using a combination of PRECLUDE®MVP and autogenous bone graft (13.5%), and three cases (8.1%) were operated on using the combination of PRECLUDE®MVP and a titanium mesh. The only case of post-traumatic enophthalmos (3.7%) was resolved after the surgery. In group 3, the median defect size was 23.0 mm^2, and four cases (10.8%) were operated on using PRECLUDE®MVP with the titanium mesh and one case (3.7%) was operated on using PRECLUDE®MVP with an autogenous bone graft. All patients presented with post-traumatic diplopia and enophthalmos; however, the treatment could resolve them. In group 4, the median defect size was 43.5 mm, and four orbits (10.8%) were treated with PRECLUDE®MVP with a titanium mesh while two were treated with PRECLUDE®MVP with a bone graft (5.4%). Post-traumatic complications were found in all cases, with one case (3.7%) showing enophthalmos and five cases (13.5%) showing enophthalmos and diplopia as well. Four patients presented with only post-surgical persistent enophthalmos; however, none of the patients complained of this complication, and it was diagnosed based on the clinical perception of the surgeon. Two patients reported post-surgical diplopia with persistent enophthalmos, but both showed traumatic brain injury (TBI), with the diplopia resulting from a neurogenic trauma.

None of patients who underwent post-surgical follow-up evaluations showed occurrence of infection as well as extrusion of the implanted membranes, even in group 1, in which the membranes were in contact with the maxillary sinuses. The Spearman's correlation test showed statistically significant differences between the orbital defects reconstructed using PRECLUDE® MVP and the persistence of post-traumatic complications ($p = 0.001$), with the coefficient indicating a moderate correlation ($r_s = 0.657$). The results indicate that the bigger the defects are, the post traumatic complications tend to persist thus, the use of PRECLUDE® MVP didn't improve the results for big orbital defects. With this, the null hypothesis was rejected (Tables 1–4).

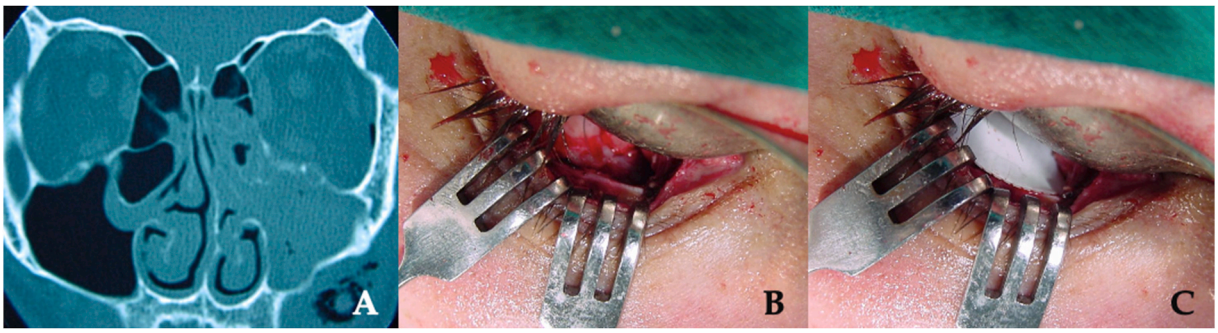

Fig. 2. PRECLUDE®MVP and bone graft. A- CT, coronal section; B- transconjunctival approach and grafting; C- PRECLUDE®MVP on the graft.

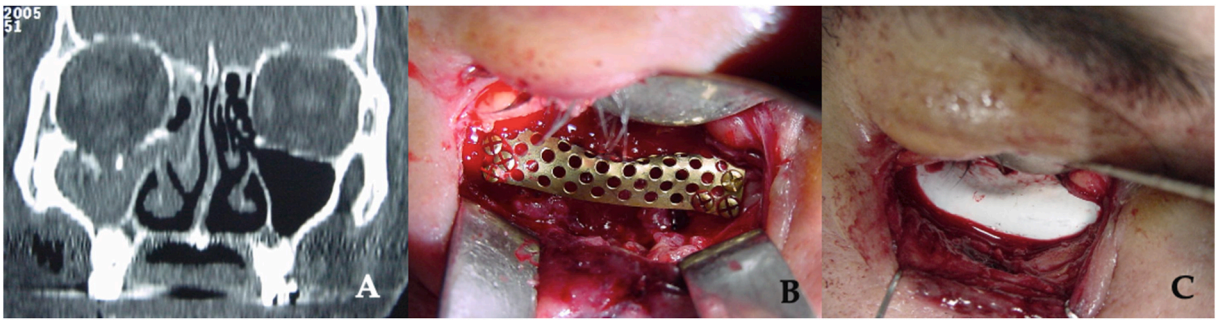

Fig. 3. PRECLUDE®MVP and titanium mesh. A- CT, coronal section; B- subtarsal approach and positioned titanium mesh, fixed on the infraorbital rim; C- PRECLUDE®MVP on the titanium mesh.

Table 1
Patients of group 1 treated with PRECLUDE® MVP alone.

Patient	Age	Gender	Associated fractures	Side	Defect size (mm^2)	Treatment	Post-traumatic complication	After surgery	Follow-up
1	22	Male	Zygomatic and maxilla	Left	11	Preclude	None	None	11 years
2	21	Male	Zygomatic and maxilla	Left	13	Preclude	None	None	1 year and 6 months
5	57	Female	Zygomatic and frontal	Left	11	Preclude	Enophthalmos	None	1 year and 2 months
6	70	Female	Zygomatic and maxilla	Right	13	Preclude	Diplopia	None	11 years
7	57	Female	Zygomatic and maxilla	Left	10	Preclude	Enophthalmos	None	1 year
9	36	Male	Zygomatic and maxilla	Left	10	Preclude	None	None	1 year and 6 months
10	65	Female	Zygomatic and maxilla	Left	14	Preclude	None	None	2 years
11	75	Female	Zygomatic and maxilla	Left	12	Preclude	None	None	1 year and 6 months
13	24	Male	Zygomatic and maxilla	Right	13	Preclude	None	None	1 year and 6 months
13	24	Male	Zygomatic and maxilla	Left	14	Preclude	None	None	1 year and 6 months
14	71	Female	Zygomatic and maxilla	Left	11	Preclude	None	None	1 year
15	22	Male	Zygomatic and maxilla	Left	13	Preclude	None	None	2 years
19	22	Female	Zygomatic and maxilla	Left	13	Preclude	None	None	10 years
23	45	Male	Zygomatic and maxilla	Left	13	Preclude	None	None	2 years
29	37	Male	Zygomatic and maxilla	Left	12	Preclude	None	None	1 year
31	70	Female	Zygomatic and maxilla	Left	13	Preclude	None	None	1 year
Median					13.0				

Table 2
Patients of group 2 treated with the association of PRECLUDE® MVP with autogenous bone graft or titanium meshes.

Patient	Age	Gender	Associated fracture	Side	Defect size (mm^2)	Treatment	Post-traumatic complication	After surgery	Follow-up
3	48	Female	Zygomatic and maxilla	Right	21	Preclude + Bone graft	None	None	2 years
8	39	Male	NOE	Right	22	Preclude + Bone graft	None	None	1 year and 4 months
18	48	Male	Zygomatic and maxilla	Right	21	Preclude + Bone graft	None	None	13 years
21	54	Male	Zygomatic	Right	22	Preclude + Bone graft	None	None	2 years
22	82	Female	Zygomatic and maxilla	Right	23	Preclude + mesh	None	None	1 year
24	32	Male	Zygomatic	Right	23	Preclude + mesh	None	None	1 year and 6 months
28	42	Female	Zygomatic and maxilla	Right	21	Preclude + Bone graft	None	None	1 year
30	33	Male	Zygomatic and maxilla	Right	22	Preclude + mesh	Enophthalmos	None	1 year and 6 months
Median					22.0				

NOE: naso-orbital-ethmoid fracture.

4. Discussion

PRECLUDE®MVP is primarily used to repair dura mater lesions, but it has been used in experimental models for orbital defects with remarkable outcomes [12]. Due to its easy handling and biological inertness, the use of this biomaterial can be recommended for orbital surgeries.

Although, the literature [17] recommends the fixation of the membrane in order to stabilize it, the biomaterial was not fixed in any sample of this study and was only accommodated on the orbital floor or on the titanium mesh/autogenous bone graft. In addition, the literature also reports complications associated with the use of e-PTFE with antral packing, In this study, no antral packing was performed, so this association was not evaluated [18,19]. Thus, the use of PRECLUDE® MVP alone in orbital floor defects presents suitable results for orbital floor defects up to 14 mm^2, avoiding extra costs and reducing the duration of

Table 3
Patients of group 3 treated with the association of PRECLUDE® MVP with autogenous bone graft or titanium meshes.

Patient	Age	Gender	Associated fracture	Side	Defect size (mm^2)	Treatment	Post-traumatic complication	After surgery	Follow-up
4	51	Male	Zygomatic and maxilla	Right	22	Preclude + mesh	Diplopia and Enophthalmos	None	1 year
16	22	Male	Zygomatic and maxilla	Left	22	Preclude + bone graft	Diplopia and Enophthalmos	None	2 years
25	20	Male	NOE	Left	23	Preclude + mesh	Diplopia and Enophthalmos	None	10 years
25	20	Male	NOE	Right	25	Preclude + mesh	Diplopia and Enophthalmos	None	10 years
27	31	Male	Zygomatic and maxilla	Left	24	Preclude + mesh	Diplopia and Enophthalmos	None	11 years
Median					23.0				

NOE: naso-orbital-ethmoid fracture.

Table 4
Patients of group 4 treated with the association of PRECLUDE® MVP with autogenous bone graft or titanium meshes.

Patient	Age	Gender	Associated fracture	Side	Defect size (mm^2)	Treatment	Post-traumatic complication	After surgery	Follow-up
6	70	Female	NOE and maxilla	Left	42	Preclude + mesh	Enophthalmos	Enophthalmos	11 years
12	27	Female	Panfacial	Right	43	Preclude + bone graft	Diplopia and Enophthalmos	Enophthalmos	1 year
12	27	Female	Panfacial	Left	45	Preclude + bone graft	Diplopia and Enophthalmos	Diplopia and Enophthalmos	1 year
17	70	Female	Zygomatic and frontal	Left	45	Preclude + mesh	Diplopia and Enophthalmos	Diplopia and Enophthalmos	2 years
20	45	Male	NOE and maxilla	Left	44	Preclude + mesh	Diplopia and Enophthalmos	Enophthalmos	2 years
26	46	Male	NOE and maxilla	Left	42	Preclude + mesh	Diplopia and Enophthalmos	Enophthalmos	10 years
Median					43.5				

NOE: naso-orbital-ethmoid fracture.

the surgical procedure.

Orbital reconstruction is one of the main challenges in facial traumatology [2,5,6,20,21]. The changes in orbital volume combined with the size of the defect are important factors in the choice of an appropriate biomaterial for the reconstruction [1]. The literature reports the use of different types of biomaterials as well as their combinations to treat orbital fractures [1,2,4]. However, fractures involving both the floor and medial wall promote severe sequelae and are the most difficult to resolve. These cases require a combination of at least two approaches and a surgical team with the knowledge to perform the reconstruction. In our study, all defects in groups 3 and 4 were treated by a combination of subtarsal and coronal approaches due to the extension of the defects. In both groups, a combination of biomaterials was used to reconstruct the orbit due to the seriousness of the fractures as well as the loss of anatomical dimensions.

According to Jaquiéry et al. [7], the differences in the orbital defects influence in the post-traumatic complications. In the present research, it was possible to demonstrate this mainly in group 4, in which the orbital floor fractures were combined with medial fractures. The authors believe that this can be explained by the severity of the fractures as well as TBI. The literature indicates that defects involving more than 50% of the orbital wall are associated with a higher risk of post-traumatic enophthalmos due to the three-dimensional changes, consistent with our study [1]. However, the persistent diplopia in the present study occurred due to neurogenic complications. Thus, the null hypothesis was rejected.

The post-surgical outcomes in orbital wall reconstruction are unpredictable mainly because of the size of the fracture as well as tissue fibrosis; loss of fat or its resorption; and injury of the periosteum or muscle [22]. The literature indicates that early treatment as well as overcorrection can decrease the post-surgical enophthalmos, but the clinical course is unpredictable even after following all of these recommendations [9,23,24]. Despite of the limitations of our study, it was possible to demonstrate that bigger the size of the orbital defect, higher the incidence of persistent complications such as enophthalmos, even after performing overcorrection in treatment. No patients complained about persistent enophthalmos, and the complication was diagnosed based on the clinical perception of the surgeon. Nevertheless, further studies need to be performed in order to identify the ideal orbital wall reconstruction biomaterial for major defects as the use of prototyped plates.

In conclusion, the present study demonstrated that the use PRECLUDE®MVP didn't improve the post traumatic complications for big orbital defects due to the three-dimensional anatomical changes that occurred by neurologic lesions and lipolysis of the orbital contents.

Ethical approval

This study received approval with ethics committee protocol number 2.804.713.

Sources of funding

The research had no source of funding

Author contribution

Sylvio Luiz Costa de Moraes: Conceptualization, Methodology, Validation, Software, Formal analysis, Investigation, Data curation, Writing – original draft, Writing – review & editing, Visualization, Resources, Supervision, Project administration. Rodrigo dos Santos Pereira: Conceptualization, Validation, Software, Formal analysis, Investigation, Data curation, Writing – review & editing, Alexandre Maurity de Paula Afonso: Validation, Investigation, Resources, Writing – original draft, Visualization, Ricardo Pereira Mattos: Validation, Investigation, Resources, Writing – original draft, Visualization, Jonathan Ribeiro da Silva: Conceptualization, Validation, Software, Formal analysis, Investigation, Writing – original draft, Writing – review & editing, Visualization. Roberto Gomes dos Santos: Validation, Investigation, Resources, Writing – original draft, Visualization, Monica Diuana Calasans-Maia: Conceptualization, Methodology, Validation, Formal analysis, Investigation, Data curation, Writing – original draft,

Visualization, Supervision, Project administration.

Research registration unique identifying number (UIN)

1. Name of the registry: "Prospective randomized study of resolution of post-traumatic orbital complications using PRECLUDE® MVP".
2. Unique Identifying number or registration ID: researchregistry5852
3. Hyperlink to your specific registration (must be publicly accessible and will be checked): https://www.researchregistry.com/register-now#home/

Guarantor

SYLVIO LUIZ COSTA DE MORAES MD, DDS, MSc.
Head-in-chief of Craniomaxillofacial & Reconstructive Surgery.
São Francisco Hospital – Rio de Janeiro – Brazil, Address: Clinic for Craniomaxillofacial & Reconstructive Surgery.
Hospital São Francisco.
Rua Conde de Bonfim, 1033, Prédio H, térreo sala 102–106, Tijuca, Rio de Janeiro, RJ, Brazil – CEP: 20530–001. cell phone: +5521-99986-4207. e-mail: sdmoraes@yahoo.com.br.

Data statement

Research data for this article.
Due to the reasons for surgical treatment, patients were assured raw data would remain confidential and would not be shared.
Data not available/The data that has been used is confidential.
The research protocols used in this study were approved by the ethics committee of the Federal Fluminense University, Niteroi RJ Brazil [UFF Protocol #2.804.713].

Provenance and peer review

Not commissioned, externally peer-reviewed.

Declaration of competing interest

The authors have no conflict of interest.

References

[1] L. Dubois, S.A. Steenen, P.J. Gooris, M.P. Mourits, A.G. Becking, Controversies in orbital reconstruction–I. Defect-driven orbital reconstruction: a systematic review, Int. J. Oral Maxillofac. Surg. 44 (2015) 308–315.
[2] C.F. Palmieri Jr., G.E. Ghali, Late correction of orbital deformities, Oral Maxillofac. Surg. Clin. 24 (2012), 694-693.
[3] M. Totir, R. Ciuluvica, I. Dinu, I. Careba, S. Gradinaru, Biomaterials for orbital fractures repair, J. Med. Life 8 (2015) 41–43.
[4] J. Liss, St Stefko, W.L. Chung, Orbital surgery: state of the art, Oral Maxillofac. Surg. Clin. 22 (2010) 59–71.
[5] S.L.C. Moraes, A.M.P. Afonso, B.G. Duarte, M.T.F. Oliveira, et al., Concepts in management of advanced craniomaxillofacial injuries, in: M.H.K. Motamedi (Ed.), A Textbook of Advanced Oral and Maxillofacial Surgery, first ed. vol. 3, InTech, Croatia, 2016, pp. 527–558, https://doi.org/10.5772/63738, 3.
[6] J.K. Potter, M. Malmquist, E. Ellis 3rd, Biomaterials for reconstruction of the internal orbit, Oral Maxillofac. Surg. Clin. 24 (2012) 609–627.
[7] C. Jaquiery, C. Aeppli, P. Cornelius, A. Palmowsky, C. Kunz, B. Hammer, Reconstruction of orbital wall defects: critical review of 72 patients, Int. J. Oral Maxillofac. Surg. 36 (2007) 193–199.
[8] L. Dubois, S.A. Steenen, P.J. Gooris, R.R. Bos, A.G. Becking, Controversies in orbital reconstruction-III. Biomaterials for orbital reconstruction: a review with clinical recommendations, Int. J. Oral Maxillofac. Surg. 45 (2016 Jan) 41–50.
[9] L. Dubois, S.A. Steenen, P.J. Gooris, M.P. Mourits, A.G. Becking, Controversies in orbital reconstruction–II. Timing of post-traumatic orbital reconstruction: a systematic review, Int. J. Oral Maxillofac. Surg. 44 (2015 Apr) 433–440.
[10] K. Chowdhury, G.E. Krause, Selection of materials for orbital floor reconstruction, Arch. Otolaryngol. Head Neck Surg. 124 (1998 Dec) 1398–1401.
[11] T.A. Barbolt, M. Odin, M. Leger, L. Kangas, J. Hoiste, S.H. Liu, Biocompatibility evaluation of dura mater substitutes in an animal model, Neurol. Res. 23 (2001) 813–820.
[12] L.J. Hanson, M.G. Donovan, J.W. Hellstein, N.C. H Dickerson, Experimental evaluation of expanded polytetrafluoroethylene for reconstruction of orbital floor defects, Neurol. Res. 23 (2001) 813–820.
[13] D.R. Meyer, Alloplastic materials for orbital surgery, Curr. Opin. Ophthalmol. 6 (1995) 43–52.
[14] K.F. Schulz, D.G. Altman, D. Moher, C. Group, CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials, J. Clin. Epidemiol. 63 (2010) 834–840.
[15] R.S. Pereira, J.D. Menezes, J.P. Bonardi, G.L. Griza, R. Okamoto, E. Hochuli-Vieira, Comparative study of volumetric changes and trabecular microarchitecture in human maxillary sinus bone augmentation with bioactive glass and autogenous bone graft: a prospective and randomized assessment, Int. J. Oral Maxillofac. Surg. 47 (2018 May) 665–671.
[16] M.A. Burnstine, Clinical recommendations for repair of isolated orbital floor fractures: an evidence-based analysis, Ophthalmology 109 (2002) 1207–1210, discussion 1210-1201; quiz 1212-1203.
[17] J.A. Aronowitz, B.S. Freeman, M. Spira, Long-term stability of Teflon orbital implants, Plast. Reconstr. Surg. 78 (1986) 166–173.
[18] J.K. Potter, M. Malmquist, E. Ellis 3rd, Biomaterials for reconstruction of the internal orbit, Oral Maxillofac. Surg. Clin. 24 (2012) 609–627.
[19] J.K. Potter, E. Ellis, Biomaterials for reconstruction of the internal orbit, J. Oral Maxillofac. Surg. 62 (2004) 1280–1297.
[20] E. Ellis 3rd, E. Messo, Use of nonresorbable alloplastic implants for internal orbital reconstruction, J. Oral Maxillofac. Surg. 68 (2004) 873–881.
[21] D.R. Gunarajah, N. Samman, Biomaterials for repair of orbital floor blowout fractures: a systematic review, J. Oral Maxillofac. Surg. 71 (2013) 550–570.
[22] H.M. Jellema, P. Saeed, Y. Everhard-Halm, L. Prick, M. Mourits, Bilateral inferior rectus muscle recession in patients with graves orbitopathy: is it effective? Ophthalmic Plast. Reconstr. Surg. 28 (2012) 268–272.
[23] J.E. Egbert, K. May, R.C. Kersten, D.R. Kulwin, Pediatric orbital floor fracture : direct extraocular muscle involvement, Ophthalmology 107 (2000 Oct) 1875–1879.
[24] G.J. Harris, Orbital blow-out fractures: surgical timing and technique, Eye 20 (2006) 1207–1212.