APS
Archives of Plastic Surgery

Original Article

Safety of Silastic Sheet for Orbital Wall Reconstruction

Seong June Moon, Hyun Suk Suh, Bo Young Park, So Ra Kang

Department of Plastic Surgery, Ewha Womans University Hospital, Ewha Womans University School of Medicine, Seoul, Korea

Background Many implants are being used for the reconstruction of orbital wall fractures. The effect of the choice of implant for the reconstruction of an orbital wall fracture on the surgical outcome is under debate. The purpose of this article is to compare the outcomes of orbital wall reconstruction of small orbital wall fractures on the basis of the implants used.

Methods The authors conducted a retrospective study using electronic databases. Between March 2001 and December 2012, 461 patients with orbital wall fractures were included in this study. Among them, 431 patients in whom the fracture size was less than 300 mm^2 were analyzed. The fracture size was calculated using computed tomography scans of the orbit in the sagittal and coronal images. Cases in which the fracture size was less than 300 mm^2 were included in this study.

Results One hundred and twenty-nine patients were treated with silastic sheets; 238 patients were treated with titanium meshes; and absorbable meshes were used in the case of 64 patients. Overall, 13 patients required revision, and the revision rate was 3.0%. The revision rate of the silastic sheet group was 5.4%. In the multivariable analysis, the revision rate of the group reconstructed with silastic sheets was highly statistically significant ($P=0.043$, odds ratio = 3.65). However, other factors such as age, sex, fracture type, and fracture size were not significant.

Conclusions Reconstruction of orbital wall fractures with silastic sheets may cause more complications than that with other materials such as titanium meshes and absorbable meshes.

Keywords Orbital fracture / Silicone

Correspondence: Hyun Suk Suh
Department of Plastic Surgery, Ewha Womans University Hospital, Ewha Womans University School of Medicine, 1071 Anyangcheon-ro, Yangcheon-gu, Seoul 158-710, Korea
Tel: +82-2-2560-5149
Fax: +82-2-2651-9821
E-mail: slimtj@hanmail.net

This article was presented at the Annual Meeting of Korean Society of Plastic and Reconstructive Surgeons on November 1, 2013 in Seoul, Korea.

No potential conflict of interest relevant to this article was reported.

Received: 5 Feb 2014 • Revised: 16 May 2014 • Accepted: 19 May 2014
pISSN: 2234-6163 • eISSN: 2234-6171 • http://dx.doi.org/10.5999/aps.2014.41.4.362 • Arch Plast Surg 2014;41:362-365

INTRODUCTION

An orbital blowout fracture is caused by a sudden increase in the intraorbital pressure in the orbit followed by a severe impact on the orbit. The purpose of orbital reconstruction is to restore the orbital volume and the shape of the orbital cavity with autogenous or alloplastic materials [1]. There can be many complications after orbital reconstruction, including infection, hematoma, nerve injury, diplopia, extraocular muscle limitation, enophthalmos, and sensory change [2,3].

Most surgeons think that the choice of implant material may contribute significantly to the long-term result of orbital reconstruction [4]. Recently, expensive materials, such as Medpor and absorbable meshes, have been used frequently for orbital wall reconstruction in order to minimize complications. In our department, silastic sheets are often used for the reconstruction of orbital fractures because they are extremely cheap and seem to cause relatively few complications. Some patients insist on the use of a silicone sheet because of its low cost. Therefore, until recently, we have used silastic sheets for orbital fractures.

The purpose of this study is to compare the complication rates of patients reconstructed with silastic sheets with those of patients reconstructed with other implant materials in the case of small orbital wall fractures.

METHODS

Four-hundred and sixty-one patients who presented with orbital wall fractures between March 2001 and December 2012 were included in this study. Among them, a statistical analysis was performed on the data of the 431 patients whose fracture size was less than 300 mm^2. All patients underwent primary surgical treatment. The patients were analyzed for age, sex, fracture type, preoperative symptoms, inserted material, and postoperative complications. Data from these 431 patients were analyzed retrospectively using electronic databases.

Diagnosis and treatment were based on physical examinations and computed tomography (CT) scans of the orbit in the axial and coronal images. The orbital fracture size was calculated by using the collected coronal and imaging data. For each slice, the length of the orbital floor was measured, and by applying the known slice thickness, the area of the orbital floor and medial wall could be calculated [5]. The calculated fracture size was the cross-sectional area of the fracture. Cases in which the fracture size was less than 300 mm^2 were included in this study.

Orbital reconstruction was performed in the acute phase (within 2 weeks). A subciliary approach was used in most of the cases of inferior orbital wall fractures. Further, medial orbital wall fractures were repaired through a medial eyebrow incision. By subperiosteal dissection, orbital implants were inserted below the periosteum. After orbital reconstruction, a forced duction test was conducted to confirm that the implant catches the orbital content. All patients received intravenous antibiotics preoperatively and postoperatively.

Postoperative facial bone CT was routinely performed 3 days after surgery. When ocular symptoms occurred after surgery, the postoperative CT scan was obtained as soon as possible. When there was hematoma with a volume effect or implant migration on the postoperative CT scan, revisional surgery was performed immediately. The follow-up period was 3–12 months; symptoms such as diplopia, limitation of eyeball movement, sensory change, and infection signs were checked, and exophthalmometry measurements were conducted. Revision surgery was performed in patients with prolonged diplopia, eye movement limitation, and prominent enophthalmos.

All statistical analyses were performed using PASW ver. 18.0 (SPSS Inc., Chicago, IL, USA). Fisher's exact test and logistic regression were used for the analyses. A multivariable analysis was performed along with the logistic regression analysis. $P < 0.05$ was considered to be statistically significant.

Table 1. Choice of materials

Material	Total	Inferior	Medial	Inferomedial
Silastic sheet	129 (29.9)	99 (35.6)	26 (23.9)	4 (9.1)
Titanium mesh	238 (55.2)	127 (45.7)	75 (68.8)	36 (81.8)
Absorbable mesh	64 (14.8)	52 (18.7)	8 (7.3)	4 (9.1)

Values are presented as number (%).

RESULTS

Four-hundred and thirty-one patients with orbital wall fractures were enrolled in this study during a 12-year period. The average patient age was 31 years; 337 of these patients were male, and 94 were female. Among the 431 cases, 355 cases were pure orbital wall fractures (82.4%), and 76 were combined with zygomatic fractures (17.6%).

Of the 431 patients, reconstruction with silastic sheets was conducted in 129 patients (29.9%). Titanium meshes were used in 238 patients (55.2%), and absorbable meshes were used in 64 patients (14.8%) (Table 1).

Thirteen patients required revision surgery because of postoperative diplopia, extraocular muscle limitation, enophthalmos, and hematoma. The overall revision rate was 3.0%. Seven patients with silastic sheet implants required revision surgery. The revision rate of the silastic sheet group was 5.4%, and that of the titanium mesh group was 1.7% (Table 2).

When the revision rate was classified by fracture size, the revision rate was higher when the fracture size was larger. However, there was no statistically significant difference among the three groups ($P = 0.693$, Fisher's exact test) (Table 2).

Table 2. Revision rate by materials and fracture size

Characteristic	Revision	No revision	P-value[a]
Material			0.124
Silastic sheet	7/129 (5.4)	122/129 (94.6)	
Titanium mesh	4/238 (1.7)	234/238 (98.3)	
Absorbable mesh	2/62 (3.1)	60/62 (96.9)	
Total	13/431 (3.0)	418/431 (97.0)	-
Fracture size (mm^2)			0.639
0–100	1/66 (1.5)	65/66 (98.5)	
101–200	6/218 (2.8)	212/218 (97.2)	
201–300	6/147 (4.1)	141/147 (95.9)	

Values are presented as number/total (%).
[a]Fisher's exact test.

Table 3. Materials used according to the fracture size

Fracture size (mm^2)	Silastic sheet	Titanium mesh	Absorbable mesh	P-value[a)]
0–100	23/66 (34.8)	29/66 (43.9)	14/66 (21.2)	0.022
101–200	67/218 (30.9)	115/218 (52.8)	36/218 (16.5)	
201–300	39/147 (26.5)	94/147 (55.2)	14/147 (9.5)	
300–	4/30 (13.3)	22/30 (73.3)	4/30 (13.3)	

Values are presented as number/total (%).
[a)]Fisher's exact test.

Table 4. Relationship between underlying condition of patient and revision rate

Characteristic	Odds ratio	95% Confidence interval		P-value[a)]
		Upper	Lower	
Material				
Titanium	1	-	-	-
Silastic sheet	3.65	1.039	12.827	0.043
Absorbable mesh	1.63	0.386	12.511	0.375
Fracture size (mm^2)				
<100	1	-	-	-
100–200	2.01	0.235	17.044	0.526
200–300	3.36	0.389	28.968	0.271

[a)]Logistic regression.

When the revision rate was classified by the type of orbital fracture, the revision rate did not differ statistically by fracture type ($P=0.573$, Fisher's exact test). Two hundreds and seventy-eight patients had an inferior orbital wall fracture, and the revision rate was 3.2% (9/278). One hundred nine patients had a medial orbital wall fracture, and the revision rate was 3.7% (4/109). Forty-four patients had inferior and medial orbital wall fractures simultaneously, and none underwent revision surgery.

Among the 431 patients analyzed, there were 355 pure orbital wall fracture cases, and the revision rate was 3.4% (12/355). Seventy-six cases combined with zygomatic fracture, and the revision rate was 1.3% (1/76). There was no statistically significant difference among these groups ($P=0.480$, Fisher's exact test).

There was a trend toward surgeons' selecting titanium as the orbital implant material when the fracture was relatively large. There was a statistically significant difference among the three groups in this case ($P=0.037$, Fisher's exact test; P for trend$=0.003$) (Table 3).

In the multivariable analysis, fracture size and implant material were included as variables. When the variables were adjusted, the odds of revision after silastic sheet insertion were 3.65 times higher compared with the titanium insertion ($P=0.043$, odds ratio$=3.65$; 95% confidence interval, 1.04–12.83) (Table 4). The larger the fracture size was, the higher was the odds ratio, but these findings were not statistically significant.

Table 5. Complications that needed re-operation

Characteristic	No./Total (%)	Silastic sheet	Titanium mesh	Absorbable mesh
Extraocular muscles limitation with diplopia	8/13 (61.5)	4	3	1
Hematoma	2/13 (15.3)	1	0	1
Enophthalmos	1/13 (7.7)	0	1	0
Infection	0 (0)	0	0	0
Implant malposition	2/13 (15.3)	2	0	0

Values are presented as number/total (%) or number.

The cases of complications that needed re-operation are listed in Table 5. The immediate postoperative complications were diplopia, extraocular muscleslimitation, hematoma, and implant malposition. These complications were resolved with re-operation. A delayed complication that needed revision in most cases was enophthalmos.

DISCUSSION

In the case of a large defect, calvarial bone grafts and titanium meshes have been successfully used as orbital implants [6]. In the case of relatively small defects, alloplastic implants have been used effectively. Each alloplastic material has its own advantages and disadvantages. The ideal implant should not increase the operative complication rate; it must be durable, pliable, biocompatible, and cost effective.

Silastic sheets are relatively inexpensive and easily available. However, past studies have pointed out that they have a high complication rate. Problems include infection, migration, and extrusion of the implant, along with intraorbital squamous epithelial cyst formation [7,8]. Titanium is very biocompatible and is easily molded and stabilized. However, titanium meshes firmly adhere to the periorbital tissue [9]. This interaction can result in extraocular motility restriction, eyelid retraction, and a difficulty in removing the implant when a second operation is required. Absorbable implants provide sufficient strength for supporting the orbital tissue until the implant resorbs in the body. After new orbital bone formation, an absorbable implant resorbs. Therefore, there are advantages of low risk of extrusion and low risk of late infection. However, exact data regarding the resorption rate and time are not available.

The result of orbital wall reconstruction using silastic sheets is controversial. Morrison et al. [7] conducted a review of 311 patients with silastic implants and found that 41 patients (13.2%) required implant removal. Their reasons for the removal of implants were infection, pain, extrusion, and diplopia. Yun et al.

[10] conducted a review of 115 patients reconstructed with silastic sheets. Six patients (4.3%) needed implant removal due to infection, hematoma, displacement, or extrusion, with a mean removal time of 23.3 months. These complications were associated with a delayed inflammation response; therefore, the authors insisted on using alternative materials. On the other hand, Prowse et al. [11] conducted a review of 58 patients with silastic sheets. Of these, 4 patients needed revision due to extrusion and infection, but compared with other groups reconstructed with other materials, there was no significant difference in the revision rate. Therefore, they concluded that reconstruction with silastic sheets can still be used for orbital fracture reconstructions.

Our study analyzed the difference in revision rate when the defect size was less than 300 mm^2 by orbital materials such as titanium meshes, silastic sheets, and absorbable meshes. We excluded the cases in which the fracture size was more than 300 mm^2. When the revision rate was analyzed in subgroups of fracture size 0–100 mm^2, 100–200 mm^2, 200–300 mm^2, and 300–400 mm^2, the revision rate was increased sharply when the fracture size was over 300 mm^2. When the fracture size was more than 300 mm^2, the revision rate increased to about 20%. There were 30 cases in which the fracture size was more than 300 mm^2. 22 out of these 30 cases were reconstructed with titanium meshes. Surgeons tend to select a titanium mesh as an orbital implant when the fracture size is large ($P=0.022$, Fisher's exact test). Because the selection of titanium mesh dramatically increased when the fracture size was more than 300 mm^2, the results of the statistical analysis could be confusing. The cause of the high revision rate could be misinterpreted as the use of titanium mesh, but in fact, the high revision rate was due to the severity of the fracture. This in turn increases the revision rate for the cases reconstructed with titanium meshes. The fracture size seems to be the greatest risk factor for revision irrespective of the materials used for reconstruction in the case of large fractures, as per the multivariable analysis. Therefore, we excluded the cases of large fractures (more than 300 mm^2).

A limitation of this study is that Medpor was not used in this study, although Medpor implants are among the most widely used implants in orbital reconstruction. Surgeons in our hospital did not selected Medpor because of their personal preferences. We found that the revision rate was higher when the orbital fracture was reconstructed with a silastic sheet than when with any other material even in the case of small defects. Silastic sheets have advantages of low price and cost-effectiveness but have a higher revision rate than that in the case of any other materials. Considering the cost, discomfort, and efforts of secondary revision surgeries, it is appropriate to use alternative materials such as absorbable meshes or titanium meshes instead of silastic sheets.

REFERENCES

1. Cole P, Boyd V, Banerji S, et al. Comprehensive management of orbital fractures. Plast Reconstr Surg 2007;120:57S-63S.
2. Brucoli M, Arcuri F, Cavenaghi R, et al. Analysis of complications after surgical repair of orbital fractures. J Craniofac Surg 2011;22:1387-90.
3. Park MS, Kim YJ, Kim H, et al. Prevalence of Diplopia and Extraocular Movement Limitation according to the Location of Isolated Pure Blowout Fractures. Arch Plast Surg 2012;39:204-8.
4. Bratton EM, Durairaj VD. Orbital implants for fracture repair. Curr Opin Ophthalmol 2011;22:400-6.
5. Ploder O, Klug C, Voracek M, et al. A computer-based method for calculation of orbital floor fractures from coronal computed tomography scans. J Oral Maxillofac Surg 2001;59:1437-42.
6. Jaquiery C, Aeppli C, Cornelius P, et al. Reconstruction of orbital wall defects: critical review of 72 patients. Int J Oral Maxillofac Surg 2007;36:193-9.
7. Morrison AD, Sanderson RC, Moos KF. The use of silastic as an orbital implant for reconstruction of orbital wall defects: review of 311 cases treated over 20 years. J Oral Maxillofac Surg 1995;53:412-7.
8. Schmidt BL, Lee C, Young DM, et al. Intraorbital squamous epithelial cyst: an unusual complication of Silastic implantation. J Craniofac Surg 1998;9:452-5.
9. Lee HB, Nunery WR. Orbital adherence syndrome secondary to titanium implant material. Ophthal Plast Reconstr Surg 2009;25:33-6.
10. Yun HK, Yi S, Joh SP, et al. Complications after open reduction of blow-out fracture using silicone sheet. J Korean Cleft Palate-Craniofac Assoc 2001;2:72-6.
11. Prowse SJ, Hold PM, Gilmour RF, et al. Orbital floor reconstruction: a case for silicone. A 12 year experience. J Plast Reconstr Aesthet Surg 2010;63:1105-9.