Comparative Study of Evaluation of Results of Orbital Floor Reconstruction with Calvarial Bone Graft Vs Sialastic Implant

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Introduction: Orbital floor fractures can result in considerable facial deformity. A vast array of autogenous and alloplastic materials are being used to reconstruct Orbital floor defects. Amongst the alloplastic materials sialastic implants are most commonly being used for orbital floor reconstruction whilst among the autogenous bone grafts calvarial bone graft are commonly used. Unfortunately no study has been conducted in Pakistan to compare the post operative results of these two commonly used materials for orbital floor reconstruction. The aim of this study is to compare the results of orbital floor reconstruction using sialastic implants and calvarial bone graft in order to find out which of the two materials shows better post operative results**.**

Methods: A Quasi experimental randomized trial was conducted from November 2006 to November 2007 in the department of Oral and Maxillofacial surgery, King Edward Medical University/Mayo Hospital, Lahore. A total of 60 patients were recruited over a period of 12 months. All patients were followed up at regular intervals i.e. 1 week, 2 weeks, 2 months and 6 months. The six month evaluation of Orbital floor reconstruction was done by noting the improvement in diplopia, enophthalmous and presence or absence of infection, extrusion, dislodgement in 30 cases with calvarial bone graft (group A) and in 30 cases with sialastic implants (group B).

Results: Approximately 44% patients presented with one of the post operative complaints of diplopia, enophthalmous and both (diplopia and enophthalmous) at the 6 months follow up in group B as compared to only 17% patients with post operative complaints in group A ($p = 0.05$). Post operative complications i.e. infection, extrusion and dislodgement occurred in 43.4% patients from group B as compared to 20% patients from group A ($p = 0.02$).

Conclusion: Reconstruction of orbital floor fracture with autogenous bone (calvarial bone) should be preferred as compared to reconstruction with the sialastic implants because of lesser post operative complications.

Key Words: Orbital floor defect, Orbital rim, Para Nasal Sinus, Computerized tomogram, Magnetic Resonance Imaging, intraocular pressure.

Introduction

The face should have the harmonious symmetrical relationship between the paired and unpaired facial structures that forms our first impression of what person is like. The eyes, their color, three dimension position and synchronous movement are a major contribute to this overall picture. Eye position and movement should be symmetrical and are important from an esthetic point of view.[1] The anatomy of paper thin orbital floor is complex and important surgically and is the most important site for orbital blow out.[2] Fracture in and around the orbit are common. They vary from simple zygomatic fractures to complex craniofacial injury involving the orbital rim and several orbital walls. Blow out fracture of the orbit most commonly involve the floor and the medial wall.[3] Trauma to the orbit can result in considerable facial deformity and at the same time affect both vision and the nervous system of the face. Orbital floor fracture is in most cases open defect fracture, and this distinguishes it from other facial bone fractures.

Orbital floor fractures are one of the most common complications in patients with mid – face trauma. Orbital floor is a common injury accompanying midface traumas.[4-8] The etiology is traffic related 77.7%, violence related 10%, work related13.3% and from other reasons.[9]

Rehabilitation of the patient requires an understanding both of the factors that cause changes in the form and function of the orbit, intraocular and intraorbital tissue and of the methods and materials available for their repair. There is a general consensus that the ideal material for repairing the orbital floor defect (OFD) should be rigid enough to support the orbital contents. It should restore the original orbital form and volume, be easy to size and shape, inexpensive, readily available and most importantly, biocompatible. A vast array of autogenous and alloplastic materials are being used to reconstruct OFD.

Until recently the treatment of choice for repairing orbital floor fractures has been autogenous bone grafting.[10] The calvarial bone is a membranous bone which has been shown to undergo less resorption, greater graft volume survival and is an ideal bone graft for orbital floor reconstruction.[11] However the density of the bone makes it very difficult to mould.[12]

Alloplastic materials have been gaining popularity for reconstruction of the OFD because they do not require

second operation becoming fibrotically encapsulated.[13] They are non resorbable and easily shaped accordingly.[14] Among alloplastic materials are Sialastic implants, gilastic, Teflon, polyethylene, methylemethacrylate, polyrnyle sponge, Marlex mesh, gel film and hydroxyapatite. Sialastic implants can be placed at the time of immediate reconstruction. However, alloplastic materials have been used with caution, because of infection, extrusion and unpredictable foreign body reaction.[15,16] Amongst the alloplastic materials sialastic implants are most commonly being used for orbital floor reconstruction whilst among the autogenous bone grafts calvarial bone graft are commonly used. Unfortunately no study has been conducted in Pakistan to compare the post operative results of these two commonly used materials for orbital floor reconstruction.

The aim of this study is to compare the results of orbital floor reconstruction using sialastic implants and calvarial bone graft in order to find out which of the two materials shows better post operative results.

Methods

This study followed a quasi experimental randomized trial design. Sixty patients with orbital floor fracture with or without other facial bone fractures were selected from the out patient and emergency department mayo hospital Lahore, Pakistan. The patients were then admitted to department of oral and maxillofacial surgery mayo hospital Lahore. Inclusion criteria was medically fit patients having defect in the floor of orbit (assessed radiographically) with the complaints of diplopia and enophthalmous. Exclusion criteria were patients who were medically unfit for surgery, ipsilateral or contralateral loss of vision. All the cases were diagnosed, treated and followed up from November 2006 to November 2007. Selected sixty subjects were divided into two equal groups A and B consisting of 30 patients each. Each patient was assigned a study number and then allocated a group using a simple random sampling method. Group A consisted of patients who were treated with calvarial bone graft and group B comprised of patients who were treated with sialastic implant. The allocation of treatment was random, irrespective of the gender and age.

A standard history and examination chart was completed for each patient. CT scan with 3_D reconstruction was the standard radiograph for each patient however PNS at 45degree of the face was used as supplementary radiograph. The pre-operative initial details collected from the patients included age, gender, side of orbital floor fracture and its etiology. All cases were carried out under general anesthesia using nasal endotracheal intubations. Different types of approaches were used for treatment including infraorbital incision, subcilliary and subconjuctival incision. Depending upon the type of fracture and size of orbital floor defect Group A patients were either treated with calvarial bone graft alone or with calvarial bone grafts secured with miniplates and screws to the intact adjacent bone. All patients in Group B were treated using sialastic implants secured with screws.

In group B patients were discharged after 2 days but in group A patients were discharged after 7 days. The purpose for late discharge in group A was to see the donor site morbidity. Post operative CT scan and PNS at 45 degree was done where felt necessary. After discharging the patients the post operative follow ups were performed at intervals of 1 week, 2 weeks, 2 months and 6 months (final follow up). All patients were followed up equally and given equal importance and time at recall visits. At each follow up visit the post operative improvement in diplopia was checked clinically by questioning the patients about double vision. The improvement in enophthalmous was checked per operatively and postoperatively by comparing with the normal orbit. Post operative infection, extrusion and dislodgement was also noted at the final follow up visit. The collected data was entered and analyzed using SPSS version 15.0.

Results

A total of 60 patients who started the trial completed it till the last follow up (6 months post operative). Thus the total response rate was 100%.

The demographic details collected in this study included age, gender, side of orbital floor fracture and etiology of the orbital floor fracture. Histogram below shows the distribution of sample according to age.

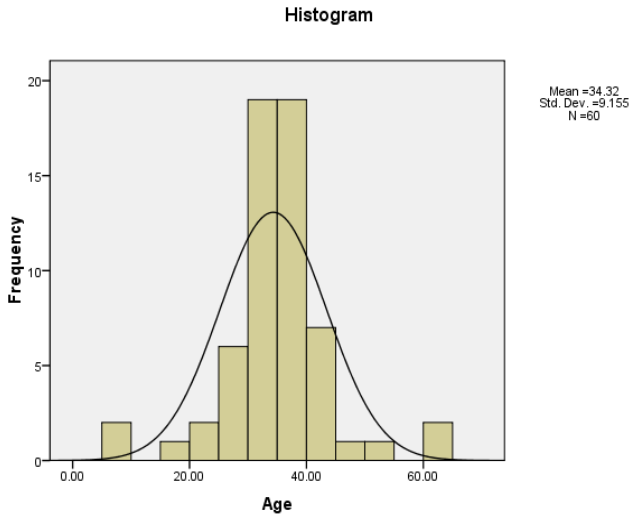

Fig. 1: *Distribution of sample according to age.*

Histogram shows that the mean average age of the sample regardless of gender was 34.32 years (95% CI, 28.92 to 37.38) with a range from 6 to 60 years.

Table 1 shows the distribution of sample according to gender, side and etiology of orbital floor fracture.

The table shows that the sample consisted of 81.7% male and 18.3% female participants. It also shows that 75% of the sample reported with right sided orbital floor fracture.

Similarly 85% of the sample reported traffic accident as the cause of orbital floor fracture.

Table 1: *Distribution of sample according to gender, side and etiology of orbital floor fracture.*

Variable	n (%)
Gender	
Male	49 (81.7%)
Female	11 (18.3%)
Side of Orbital Floor Fracture	
Right sided orbital floor fracture	45 (75.0%)
Left sided orbital floor fracture	15 (25.0%)
Etiology of Fracture	
Traffic accident	51 (85.0%)
Falls	07 (11.7%)
Other	02 (3.3%)

Table 2 reports the frequencies of complaints of diplopia, enophthalmous and both (diplopia and enophthalmous) at the Base line amongst participants of groups A and B.

The Table shows that both groups A and B had patients with all three complaints. The groups were comparable at the baseline. Diplopia was present in 33% patients of group A as compared to 30% of group B. Enophthalmous was present in 43.3% patients of both groups A and B.

Table 3 shows the association between age and gender. It shows that there was a difference in age of female and male participants of the sample.

The table shows that the mean age of male participants was 34.57 years (95% CI 32.10 – 37.03) as compared to this the mean age for female participants was 33.18 years (95% CI 25.27 – 41.08). The table also reports that the range of age for both male and female categories was 06 – 60 and 08 – 60 years respectively. It demonstrates the statistically significant difference between the ages of male and female participants. Female participants were younger in age as compared to the male participants of the study.

Table 2: *Frequencies of complaints of diplopia, enophthalmous and both (diplopia and enophthalmous) at Baseline.*

Complaints at Baseline	Group A n (%)	Group B n (%)
DIPLOPIA	10 (33.3%)	9 (30.0%)
ENOPHTHALMOUS	13 (43.3%)	13 (43.3%)
BOTH (Diplopia and Enophthalmous)	7 (23.3%)	8 (26.7%)

Table 3: *Association between age and gender Age of respondents in (years).*

Gender	Mean	95 % CI	Range
Male	34.57	32.10 – 37.03	06 – 60
Female	33.18	25.27 – 41.08	08 – 60

Table 4 reports the association between type of orbital floor reconstruction material and postoperative results noted at 1st week follow up.

The key finding of the table is that 70% of patients from group A were satisfied with results at the 1st week follow up as compared to 60% of satisfied group B patients. The postoperative complaint of diplopia was reported by only 10% patients of group A as compared to 16.7% patients of group B. Similarly 6.7% patients of group A reported postoperative complaint of both diplopia and enophthalmous as compared to 10% patients of group B. However this difference was found to be statistically insignificant at p = 0.52.

Table 5 reports the association between type of orbital floor reconstruction material and postoperative results noted at 2nd week follow up.

The key finding of the table is that 73.3% of patients from group A were satisfied with results at the 2nd week follow up as compared to 56.7% of satisfied group B patients. The postoperative complaint of diplopia and both (diplopia and enophthalmous) remained the same as reported at 1st week follow up by group A and B patients. However the postoperative complaint of enophthalmous alone was reported by 10% of patients from group A as

Table 4: *Association between type of orbital floor reconstruction material and first week postoperative results.*

Type of Orbital Floor Reconstruction Material	First Week Postoperative Results				Significance
	Satisfied n (%)	Diplopia n (%)	Enophthalmous n (%)	Diplopia and Enophthalmous n (%)	
Calvarial bone graft (group A)	21 (70.0%)	03 (10.0%)	04 (13.3%)	02 (6.7%)	0.52
Sialastic implant (group B)	18 (60.0%)	05 (16.7%)	04 (13.3%)	03 (10.0%)	

Table 5: *Association between type of orbital floor reconstruction material and second week postoperative results.*

Type of Orbital Floor Reconstruction Material	Second Week Postoperative Results				Significance
	Satisfied n (%)	Diplopia n (%)	Enophthalmous n (%)	Diplopia and Enophthalmous n (%)	
Calvarial bone graft (group A)	22 (73.3%)	3 (10.0%)	3 (10.0%)	2 (6.7%)	0.24
Sialastic implant (group B)	17 (56.7%)	5 (16.7%)	5 (16.7%)	3 (10.0%)	

Table 6: *Association between type of orbital floor reconstruction material and two months postoperative results.*

Type of Orbital Floor Reconstruction Material	Two Months Postoperative Results				Significance
	Satisfied n (%)	Diplopia n (%)	Enophthalmous n (%)	Diplopia and Enophthalmous n (%)	
Calvarial bone graft (group A)	24 (80.0%)	2 (6.7%)	3 (10.0%)	1 (3.3%)	0.05
Sialastic implant (group B)	17 (56.7%)	4 (13.3%)	5 (16.7%)	4 (13.3%)	

Table 7: *Association between type of orbital floor reconstruction material and six months postoperative results.*

Type of Orbital Floor Reconstruction Material	Six Months Postoperative Results				Significance
	Satisfied n (%)	Diplopia n (%)	Enophthalmous n (%)	Diplopia and Enophthalmous n (%)	
Calvarial bone graft (group A)	24 (80.0%)	2 (6.7%)	3 10.0%	1 3.3%	0.05
Sialastic implant (group B)	17 (56.7%)	4 (13.3%)	5 (16.7%)	4 (13.3%)	

Table 8: *Association between type of orbital floor reconstruction material and six months postoperative complications*

Type of Orbital Floor Reconstruction Material	Six Months Postoperative Complications				Significance
	Satisfied n (%)	Infection n (%)	Extrusion n (%)	Dislodgement n (%)	
Calvarial bone graft (group A)	24 (80.0%)	4 (13.3%)	2 (6.7%)	0 (0.0%)	0.02
Sialastic implant (group B)	17 (56.7%)	5 (16.7%)	5 (16.7%)	3 (10.0%)	

compared to 16.7% patients of group B at the 2nd week follow up. This difference was found to be statistically insignificant at p = 0.24.

Table 6 reports the association between type of orbital floor reconstruction material and postoperative results noted at two months follow up.

The key finding of the table is that 80% of patients from group A were satisfied with results at the 2 months follow up as compared to only 56.7% of satisfied group B patients. The postoperative complaint of diplopia was noted in 6.7% patients of group A as compared to 13.3% patients of group B. Enophthalmous remained the same as reported at 2nd week follow up by group A and B patients. However the postoperative complaint of both (diplopia and enophthalmous) was reported by 3.3% of patients from group A as compared to 13.3% patients of group B at the 2 months follow up. This difference was found to be statistically significant at p = 0.05.

Table 7 reports the association between type of orbital floor reconstruction material and postoperative results noted at six months follow up.

The table shows that the postoperative results remained the same as noted at the 2 months follow up. The difference of postoperative results between groups A and B remained

statistically significant at p = 0.05 at the final 6 months post-operative follow up visit.

Table 8 reports the association between type of orbital floor reconstruction material and postoperative complications noted at six months follow up.

The table reports the postoperative complications amongst groups A and B at the six months final follow up visit. According to the table infection was noted by 13.3% patients of group A as compared to 16.7% patients of group B. Extrusion was present in only 6.7% patients of group A as compared to 16.7% patients of group B. No complaint of dislodgement was present in group A patients while 10% group B patients showed dislodgement. This difference was found statistically significant at p = 0.02.

Discussion

The aim of this study was to compare the results of orbital floor reconstruction using sialastic implants and calvarial bone graft in order to find out which of the two material shows better post operative results. The results show that reconstruction with calvarial bone grafts has a higher success percentage (80%) in terms of correction of diplopia, enophthalmous and both (diplopia and enophthalmous) as compared to reconstruction with sialastic implants (56%). This finding is similar to results of other studies conducted in United States, Germany and Poland where 80 – 85% success in correction of diplopia enophthalmous and dystopia was achieved by reconstruction with calvarial bone grafts as compared to only 40-46% success with sialastic implants.[17-20]

The results also show that extrusion of Sialastic implant occurred in 16.7% patients at the 6 months follow, indicating a rapid loss of strength. This finding is similar to other studies conducted by Merten and Luhr[21] who reported that sialastic implant looses 50% of its strength during the first postoperative month. The fact that sialastic implant causes extrusion and loses much of its strength during the first few months is probable reasons for this. Autogenous bone grafting has been the gold standard providing framework for the facial skeleton and orbital walls. Dempf et al[20] used calvarial bone and iliac crest graft in repairing osseous orbital defects. Of 42 patients 34 were followed up for at least four months. They concluded that with autogenous bone transplants, good aesthetic and functional results can be achieved and that autogenous bone graft can be broadly recommended. Calvarial bone split grafts were particularly suitable for this purpose. Both Barthowski and Kyzystkowa[18] and de Vissscher and van der Wal[22] used calvarial bone graft for orbital floor and medial wall reconstruction. Both study groups concluded that autogenous corticoconcellous bone, like calvarial bone, is extremely well tolerated and is suitable for orbital floor reconstruction which is outcome of our present study as well that calvarial bone has given much better results as compared to sialastic implant.

In the present study using calvarial bone graft reconstruction only one patient had enophthalmous after the follow- up. These results are satisfactory and well correlated to other studies (Greenwald et al., Barthowski and Kyzystkowa, de Visscher and van der Wal, Friesenecher et al.).[17,18,22,23] Patients treated with calvarial bone graft retained its shape up to 06 months after assessing radiographically. At the end of follow up the outcome of the bony reconstruction was graded excellent suggesting that resorption and remodeling of the cortical bone graft is anatomically beneficial as compare to the sialastic implant. The disadvantage of the autogenous calvarial bone graft includes donor site morbidity. Despite the large volume of calvarial bone graft used, donor site morbidity seems to be low. A study by Banwart et al[24] revealed that none of the 261 patients studied had a severe per operative complication and none of the 225 patients in a long-term follow up had a severe late complication. The author concluded that severe complications from calvarial bone grafts harvesting can be avoided by proper surgical methods. In our study we did not face any complication as far as the donor area is concerned which is close to the above mentioned literature as well.

Based of the results of the study the following recommendations for future research and policy are made:

1) Future research should be focused on the effect of material properties and boundary conditions on stress / strain readings and their role in successful treatment of fractures.
2) Alternative and new techniques of orbital floor fracture management should be evolved.
3) During treatment planning one should consider all other factors such as defect size, surgical morbidity, duration of hospitalization and cost of treatment.
4) Government should provide the best available modality of treatment with less complication to all the patients free of cost.

From this study we can conclude that:

- Orbital floor reconstruction with calvarial bone graft is better choice than sialastic implant because of fewer post operative complaints of diplopia, enophthalmous, more biocompatibility and fewer post operative complications i.e. infection, extrusion and dislodgement.
- However no material has yet been reported to be successful without any complication in clinical work. The ideal material should have biological and physical properties that replicate those of the tissue it replaces.

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