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Comparative Study of the Outcome of Reconstruction of the Defect in the Floor of the Orbit Resulting from Blowout Fracture Using Iliac Bone and Titanium Mesh

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Abstract | **Original Research Article**

This was an interventional study of quasi-experimental design. The study was distributed in the Department of Oral and Maxillofacial Surgery, Dhaka Dental College Hospital and Department of Oculoplastic surgery, National Institute of Ophthalmology, Dhaka, Bangladesh during the period from July 2008 to June 2010. Our aim was to determine the superiority of the corticocancellous iliac bone over alloplastic material in respect of outcome in the reconstruction of blowout orbital floor facture. A total of 21patients admitted into Dhaka Dental Collage Hospital and National Institute of Ophthalmology with blowout fracture. Of the 21 patients with orbital blowout fracture 9 were given with alloplastic material (titanium mesh) and 12 were given with autogenous material (corticocancellous iliac bone).A total of 4 assessments (Baseline, after operation, at 3 months and at 6 months) were done for the collection of data. Among the subject of alloplastic group 22.2%were aged below 20 years, 33.3% were aged between 20-39 years, 33.3% were aged between 40-59 years and 11.1% were aged above 60 years. In the autogenous group 16.7% were aged below 20 years, 41.7% were aged between 20-39 years, 25.0% were aged between 40-59 years and 16.7% were aged above 60 years. In the Alloplastic group 77.8% had operation in right side. At preoperative period 22.2% in Alloplastic group and 25% in Autogenous group had enophthalmos. No patient had extrusion of the graft. In Alloplastic group out of nine subject's signs of infection was found in one subject at post-operative. In Autogenous group out of 12 subject signs of infection was appeared in one subject in each of the assessment point. Muscle limitation score was assessed in three assessment point at post-operative period, after three months and after six months for comparison with preoperative score. Muscle limitation score is evident in both Alloplastic and Autogenous group. Diplopia was assessed in three assessment point at post-operative period, after three months and after six months for comparison with pre-operative score. Diplopia score is evident in both Alloplastic and Autogenous groups suggesting similar efficacy of two treatment arm. In general, autogenous material shows less complication and relatively better alleviation of symptoms of blowout fracture.

Keywords: Maxillofacial, Ophthalmology, Alloplastic, Autogenous, Corticocancellous.

INTRODUCTION

Blowout orbital flood facture means blowing out of some of the orbital contents through the orbital floor defect resulting from fracture of orbital floor. The orbit is particularly susceptible to fractures because of its exposed position and thin bones. External impact to this area can cause a pure blowout fracture (isolated orbital floor fracture) or impure blowout fractures (associated with an orbital rim fracture [1]). Both of which could be accompanied by orbital floor defects. Usual presentation of such fracture is diplopia, exophthalmos, reduced ocular motility. Diplopia is the most common manifestation caused by orbital floor defects. Others include limitation of ocular movement, infraorbital numbness, enophthalmos and reduced vision. Entrapment of the extraocular muscles or injury to the nerve supplying the muscles by blowout orbital floor fracture may cause diplopia [2]. The main treatment of orbital defects is surgical orbital reconstruction. At present, with the increase in traffic accidents, the incidence of orbital defects has risen substantially increased. At the same time, bone grafts and bone substitutes under barrier membranes have been increasingly utilized to optimize the treatment

outcome of bone reconstructive therapy for defects in the orbital floor [3]. If improperly diagnosed or treated, these fractures may lead serious complications, usually diplopia, enophthalmos and reduced globe motility. Goals of orbital floor fracture repair are to free the entrapped or prolapsed orbital tissue from the fracture defect and to span the defect with an implant to restore the correct anatomy of the orbital floor and the pre-trauma orbital volume. The main treatment of blowout orbital floor fracture is surgical reconstruction. Indication for repair of orbital blowout fractures include diplopia that persists beyond 7 to 10 days, obvious sings of entrapment, relative enophthalmos greater than 2mm, fracture that involves greater than 50% of the orbital floor. Most of these will lead to significant enophthalmos when the edema resolves [4]. The timing of repair is debated. Most agree that if operative intervention is not undertaken in the first 24 hours, it should be delayed 10 days to let the edema resolve. Fracture repair should be undertaken prior to 14 days. If surgery cannot be done in time, the prolapsed tissue becomes fibrotic and scarred [5] Multiple surgical approaches have been described to gain access to the surgical floor. The three most common are the sub ciliary, infraorbital and Trans conjunctival. The proper selection and use of materials usually ensure the success of orbital floor reconstruction. No consensus exists on the choice of implants for orbital floor reconstruction and several are available [6]. Alloplastic can be further subdivided into non-resorbable and resorbable materials. Nonresorbable materials include silicone [7]. Teflon, Medpor[8] and titanium mesh [9]. Examples of resorbable materials include poly, vicryl mesh and polyglycolic acid [10]. These may require late removal of the implant, sometimes many years postoperatively. These complications may be avoided by the use of resorbable implants. Recently, progress in biomaterial science has provided another option: bioabsorbable materials that consist of mainly Poly-L-lactic acid and polyglycolic acid, which are absorbed slowly and simultaneously replaced by tissues. Although these materials might be adequate for small defects of the orbital floor, they are not suitable for volume demanding defects [11]. Nonresorbable alloplastic implants are permanent foreign bodies, and late complications such as infection, extrution, implant migration, recurrent hemorrhage and residual diplopia can occur and are reported in the literature [12]. These may require late removal of the implant, sometimes many years postoperatively. Autogenous materials include iliac bone, nasoseptal cartilage, rib graft and mandibular bone [13]. All share the morbidity of a donor site and are associated with a variable degree of resorption [14]. Autogenous bone takes easily and may vascularize and has the advantage that there is no immunologic rejection [3]. The purpose of the present study was to evaluate the use of autogenous material in the reconstruction of orbital floor fractures and to compare the performances with alloplastic material (titanium mesh).

OBJECTIVES

a) General objective

- Comparative study of using iliac bone and titanium mesh for reconstruction of the defect resulting in the floor of the orbit from blowout orbital floor fracture.

b) Specific Objectives

- To assess safety and efficacy of the outcome of blowout orbital floor fracture reconstruction with autogenous material.
- To assess safety and efficacy of the outcome of blowout orbital floor fracture reconstruction with alloplastic material.
- To compare efficacy of the two material controlling for all baseline parameters.

METHODOLOGY AND MATERIALS

The study was conducted among the 21 patients admitted in to Dhaka Dental College Hospital and National Institute of Ophthalmology with blow out facture from July 2008 to June 2010. Although a total of 30 patients were targeted. Random allocation of treatment of the two options was not assigned. Approval from institutional ethical review board was taken prior to commencement of the study. The study adopted some criteria; Inclusion criteria: [a] Diagnosed cases of orbital floor fracture [b]. Developed diplopia, enophthalmos and extra ocular muscle limitation. Exclusion criteria: [a] Presence of others systemic co morbidity not fit for surgical management. [b] Concurrent fracture of vertebra and other cranial bone. [c] Patients with neurological deficit. [d] Patients didn't give consent. [e] Patient who didn't attend regular follow-up.

RESULTS

Prevalence of enophthalmos is similar in the both group throughout the treatment course. In alloplastic group 11.1% had extrusion of the graft and in Autogenous group none had extrusion of the graft. Although extrusion of the graft was more evident in Alloplastic group, the difference was not statistically significant (p>.05). Apparently alloplastic group had reported more infection however the difference was not statistically significant (p>0.05). Comparison of muscle limitation and diplopia score in the two groups through student t test was done. No significant difference in mean muscle limitation and diplopia score was found in two groups at post-operative period (p>0.05). Table I: Table shows distribution of the study subject by age and sex. Among the subject of alloplastic group 22.2%were aged below 20 years, 33.3% were aged between 20-39 years, 33.3% were aged between 40-59 years and 11.1% were aged above 60 years. In the autogenous group 16.7% were aged below 20 years, 41.7% were aged between 20-39 years, 25.0% were aged between 40-59 years and 16.7% were aged above 60 years. No

statistically significant difference was found in the subject of the two groups (p>0.05). Table II: Table shows the distribution of the study subject by side subjects by side if involvement. In the Alloplastic group 77.8% had operation in right side. No statistically significant exists in the groups (p>0.05). Table III: The table shows the distribution of the study subject by surgical approach. No statistical significant difference exists in two groups (p>0.05). Table IV: Following table shows the distribution of enophthalmos in two groups at different assessment point. At preoperative period 22.2% in Alloplastic group and 25% in Autogenous group had enophthalmos. At three months 11.1% in Alloplastic group and 8.3% in Autogenous group had enophthalmos. At 6-month follow up the distribution of prevalence of enophthalmos was similar as three months. In all assessment point the difference was statistically insignificant (p>.05). Figure I: Comparison of the trends in prevalence of enophthalmos in two treatment group is facilitated in the graph. In all four assessment point the distribution of enophthalmos was found to be similar in the two groups. A similar declining trend in prevalence of enophthalmos is evident in the two groups, suggestion a similar of the two procedures. Table V: Following table illustrates the distribution if the study participants by prevalence of extrusion of the graft and in Autogenous group 0% had extrusion of the graft. Although extrusion of the graft was evident in Alloplastic group, the difference was not statistically significant (p>.05). Table VI: Following table illustrates the distribution if the study participants by prevalence of signs of infection. The information was acquired in three assessment point at post-operative period, after three months and after six months. In Alloplastic group out of nine subjects' signs of infection was found in one subject at post-operative, one at three months and 2ta six months follow up. In Autogenous group out of 12 subject signs of infection was appeared in one subject in each of the assessment point. Apparently Alloplastic group had reported more infection however the difference was not statistically significant (p>.05). Table VII: Muscle limitation score was assessed in three assessment point at post-operative period, after three months and after six months for comparison with preoperative score. No significant difference in mean muscle limitation score was found in two groups at post-operative period (p>.05), at three months (p>.05) and after six months (p>.05). Figure II: Generally, a declining trend in the average muscle limitation score is evident in both Alloplastic and Autogenous group showed little more decline from the pretreatment baseline. Table VIII: Diplopia was assessed in three assessment point at post-operative period, after three months and after six months for comparison with pre-operative score. No significant difference in mean diplopia score was found in two groups at post-operative period (p>.05), at three months (p>.05) and after six months (p>.05). Figure III: Generally, a declining in the average diplopia score is evident in both Alloplastic and Autogenous groups suggestion similar efficacy of two treatment arm although in Autogenous group showed little more decline from the pretreatment baseline.

Table-I: Distribution of the study subject by age and sex. (n=21)

Variables		Group: Alloplastic (n=9)	Group: Autogenous (n=12)	Test statistics
Age	<20 years	2(22.2)	2(16.7)	X^2=.413 P=.938
	20-39 years	3(33.3)	5(41.7)	
	40-59 years	3.(33.3)	3(25.0)	
	>= 60 years	1(11.16)	2(16.7)	
Sex	Male	5(55.6)	7(58.3)	X^2=.016 P=.899
	Female	4(44.4)	5(41.7)	

Figure in parenthesis denotes percentage, P values are generated though fisher exact test

Table-II: Distribution of the study subject by side subjects by side if involvement. (n=21)

Side of involvement			Group: Alloplastic	Autogenous	Test Statistics
Right side	7(77.8)	5(41.7)	X^2=2.74 P=.098		
Left side	2(22.2)	7(58.3)			
Total	9(100)	12(100)			

Figure in parenthesis denotes percentage, P values are generated though fisher exact test.

Table-III: Distribution of the study subject by surgical approaches. (n=21)

Approaches	Group: Alloplastic	Autogenous	Test Statistics
Trans conjunctival	5(55.5)	7(58.3)	X^2=1.35 P=.623
Infra-orbital	3(33.3)	4(33.3)	
Sub ciliary	1(11.1)	1(8.3)	
Total	9(100)	12(100)	

Figure in parenthesis denotes percentage, P values are generated though fisher exact test.

Table-IV: Distribution of the study subjects by Enophthalmos. (n=21)

Enophthalmos	Group		Test Statistics
	Alloplastic (n=9)	Autogenous (n=12)	
Preoperative			
No	0(0)	0(0)	
Yes	9(100)	12(100)	
Post-Operative			
No	7(77.8)	9(75.0)	X^2=.022
Yes	2(22.2)	3(25.0)	P=.882
After 3 months			
No	8(88.9)	11(91.7)	X^2=.046
Yes	1(11.1)	1(8.3)	P=.830
After 6 months			
No	8(88.9)	11(91.7)	X^2=.046
Yes	1(11.1)	1(8.3)	P=.830

Figure in parenthesis denotes percentage, P values are generated though fisher exact test

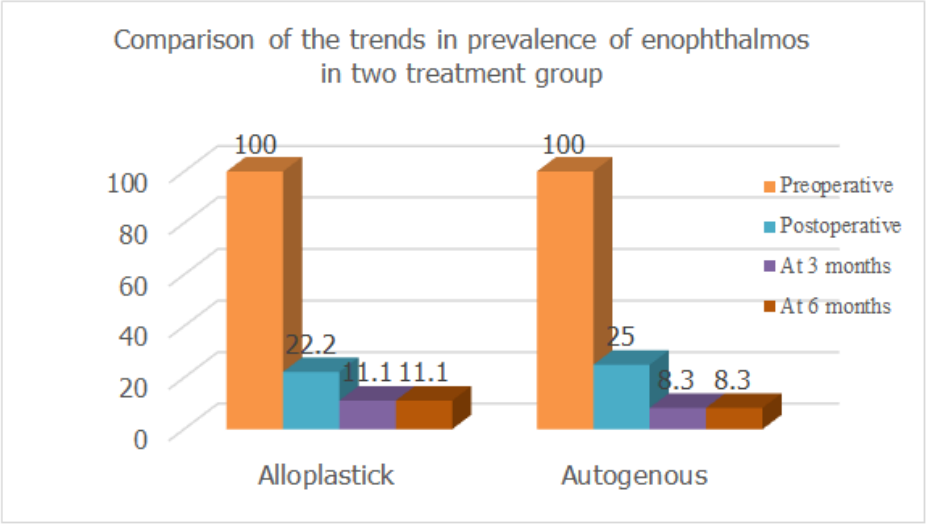

Fig-I: Comparison of the trends in prevalence of enophthalmos in two treatment group (n=21)

Table-V: distribution if the study participants by prevalence of extrusion of the graft. (n=21)

Extrusion of the graft	Group		Test Statistics
	Alloplastic (n=9)	Autogenous (n=12)	
No	8(88.8)	12(100.0)	X^2=.810
Yes	1(11.1)	0(0)	P=.368
Total	9(100)	12(100)	

Figure in parenthesis denotes percentage, P values are generated though fisher exact test

Table-VI: Distribution of the study participants by prevalence of signs of infection. (n=21)

Signs of infection	Group		Test Statistics
	Alloplastic (n=9)	Autogenous (n=12)	
Post-Operative			
No	8(88.9)	11(91.7)	X^2=.046
Yes	1(11.1)	1(8.3)	P=.830
After 3 months			
No	8(88.9)	11(91.7)	X^2=.046
Yes	1(11.1)	1(8.3)	P=.830
After 6 months			
No	7(77.8)	11(91.7)	X^2=.046
Yes	2(22.2)	1(8.3)	P=.830

Figure in parenthesis denotes percentage, P values are generated though fisher exact test

Table-VII: Comparison of muscle limitation score in two groups through student t test. (n=21)

Muscle limitation	Mean(SD)	Test Statistics
Pre-operative		
Alloplastic	3.44(.527)	t=.606
Autogenous	3.58(.515)	p=.552
Post-Operative		
Alloplastic	3.56(.527)	t=1.544
Autogenous	3.08(.793)	p=.139
After 3 months		
Alloplastic	2.11(.601)	t=.418
Autogenous	2.00(.603)	p=.680
After 6 months		
Alloplastic	1.22(.667)	t=.799
Autogenous	1.00(.603)	p=.434

Alloplastic (n=9) Autogenous (n=12)

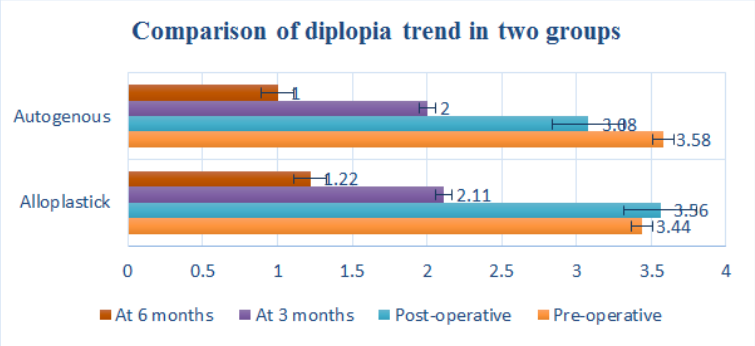

Fig-II: Comparison of muscle limitation trend in two groups. (n=21)

Table-VIII: Comparison of diplopia limitation score in two groups through student t test. (n=21)

Diplopia	Mean(SD)	Test Statistics
Pre-operative		
Alloplastic	3.00(.707)	t=.530
Autogenous	3.17(.718)	p=.602
Post-Operative		
Alloplastic	3.00(.707)	t=.860
Autogenous	2.75(.622)	p=.400
After 3 months		
Alloplastic	2.11(.782)	t=.072
Autogenous	1.83(.389)	p=.297
After 6 months		
Alloplastic	1.00(.500)	t=.860
Autogenous	0.83(.389)	p=.400

Alloplastic (n=9) Autogenous (n=12)

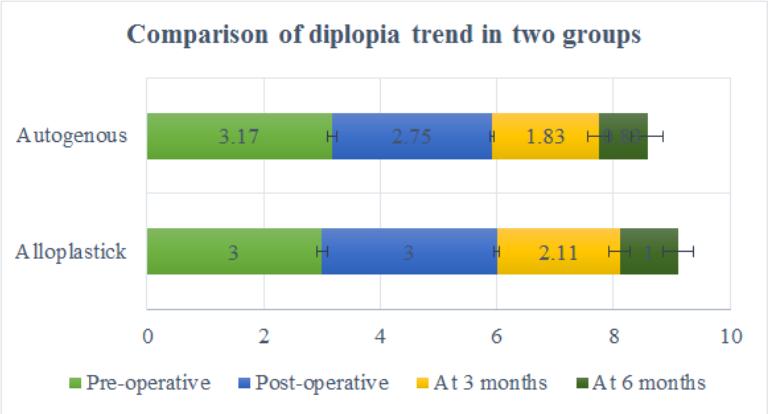

Fig-III: Comparison of diplopia trend in two groups (n=21)

DISCUSSION

In Alloplastic group 55.6% were male and in Autogenous group 58.3% were male. In the Alloplastic group 77.8% had operation in right side and Autogenous group 41.7% had operation in right side. At preoperative assessment all the patients in both the groups had enophthalmos. At preoperative period 22.2% in Alloplastic group and 25% in Autogenous group had enophthalmos. At three months 8.3% in Alloplastic group and 11.1% in Autogenous group had enophthalmos. In 1997[15] conducted a retrospective study on 16 patients who had isolated blowout fractures reconstructed with autogenous bone (mandibular symphysis bone grafts)[16]. Conducted a study in Wayne State University, Detroit, MI over 22 patients who underwent orbital reconstruction with bone for enophthalmos and diplopia after trauma to the orbit. There was a statistically significant change in enophthalmos of the patient when comparing pre and post-operative status, but statistically no significant difference between the result of the cranial and iliac bone [17]. Stated that titanium mesh has good biocompatibility and is easily adjustable. It can be reliably fixed with screws in areas such as the infraorbital border, but cannot be multi-filled to reduce the volume of the orbital cavity and can therefore only be used when there is no obvious enophthalmos, especially in fractures with large defects that are not easy to fix[9]. Conducted a study of 58 patients with unilateral pure orbital blowout fractures were included in the study. Demographic data and measurements of the pretreatment size of the defects were tabulated. The accuracy of reconstruction was assessed subjectively by 1 surgeon by scoring the position of the implant/graft, repositioning of orbital soft tissues, and assessment of orbital volume using the uninjured side for comparison [18]. Evaluated the effectiveness and complication related to the use of restorable alloplastic material (Ethisorb) in the reconstruction of orbital floor fractures. 87 patients were included in the study. 24.1% patients experienced complication (enophthalmos, diplopia). The authors concluded that restorable alloplastic material (Ethisorb) is suitable for small to moderate defect but not suitable for large defect [19]. Compared clinical findings on the use of autogenous bone graft and alloplastic material (bioresorbable Ply-L/DL-Lactide implants) to repair inferior orbital wall defects. 39 patients who suffered blowout orbital floor fracture with more than 2 square cm bony defects in the floor took part in the study. Alloplastic materials are subdivided in permanent and absorbable. Permanent implants like hydroxyapatite, porous polyethylene and metals like titanium, have been associated to complications related to foreign body reaction causing infection, extrusion, migration, eyeball movements restriction and consequent diplopia. Advantages are less surgery timing, limitless quantity and easy manipulation [20]. A comparative analysis was carried out. Clinical outcome was excellent in 19 out of 24 patients (79%) in Autogenous group and 13 out of 15 patients (87%) in Alloplastic group. Postoperatively, the most frequent type of symptoms found in both the group was enophthalmos with 5 cases (3 in Autogenous and 2 in Alloplastic group). Diplopia was the second most type of symptoms found postoperatively. A study conducted by [15] among 16 patients treated with autogenous bone showed no postoperative complaints, no instances of infection at the surgical sites and none of the grafts were extruded or lost during a mean follow up of 12 months (range 9 to 36 months). One of the important limitations of the study was the smaller sample size. And the study was not being designed as a classical trial setting which would have given much robust information about comparison. In current study, muscle limitation score and diplopia was assessed in three assessment point at post-operative period, after three months and after six months for comparison with pre-operative score. No significant difference in mean muscle limitation score and diplopia was found in two groups at post -operative period ($p>0.05$), at three months ($p>0.05$) and after six months ($p>0.05$). Generally similar distribution in the average muscle limitation and diplopia score is evident in both Alloplastic and Autogenous group suggesting similar efficacy of two treatment arm although, in Autogenous group showed little more decline from the pretreatment baseline. In Alloplastic group out of nine subject's signs of infection was found in one subject at postoperative, one at three months and 2 at six month's follow up. In Autogenous group out of 12 subject's signs of infection was appeared in one subject in each of the assessment point. Apparently Alloplastic group had reported more infection however; the difference was not statistically significant.

LIMITATIONS OF THE STUDY

It was an intervention study of quasi-experimental design study with small sample size, which doesn't reflect the scenario of the whole country.

CONCLUSION AND RECOMMENDATIONS

'Corticocancellous iliac bone' in the reconstruction of blow out orbital floor fracture doesn't show statistically significant superiority over alloplastic material in terms of enophthalmos, muscle limitation score and diplopia score. However, in general autogenous material shows less complication and relatively better alleviation of blow out fracture.

- Both the material can be used for the reconstruction of orbital floor fracture as no superiority of autogenous 'corticocancellous iliac bone' in the reconstruction of blow out orbital floor fracture have been achieved.
- Further study is recommended addressing the limitation of the current study.

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