Correction of Enophthalmos by Titanium Mesh Versus Iliac Bone Graft in Case of Orbital Floor Fracture

This Thesis is submitted in partial fulfillment of the Degree of Doctor of Philosophy (Ph.D.) under the Faculty of Postgraduate Medical Science & Research of the University of Dhaka

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July 2023

DECLARATION

I hereby declare that the Thesis entitled '**Correction of Enophthalmos by Titanium Mesh Versus Iliac Bone Graft in Case of Orbital Floor Fracture'** is my original research work carried out in the Department of Oral and Maxillofacial Surgery, Dhaka Dental College, Dhaka and in the Department of Oculoplasty, National Institute of Ophthalmology and Ispahani Islamia Eye Institute and Hospital, Dhaka.

I also declare that I did not submit this Thesis either in part or full or in any other form to any other University or Institution for any Degree or any other purpose.

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SUPERVISOR'S CERTIFICATE

This is to certify that the research work described in this Thesis entitled '**Correction of Enophthalmos by Titanium Mesh Versus Iliac Bone Graft in Case of Orbital Floor Fracture'** by **Kazi Lutfor Rahman,** is an original work and has been carried out under my supervision in the Department of Oral and Maxillofacial Surgery, Dhaka Dental College, Dhaka and Department of Oculoplasty of National Institute of Ophthalmology & Hospital and Ispahani Islamia Eye Institute & Hospital for the degree of Doctor of Philosophy (Ph.D.) under the Faculty of Postgraduate Medical Science & Research, University of Dhaka.

No part of this thesis has previously been submitted to any Institute for any Degree.

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Dedicated to
My Beloved wife, son and daughter
And to my esteemed
Teachers with respect

ACKNOWLEDGEMENTS

Surely All Praise is for Allah; We Praise Him and seek His help.

It is the greatest pleasure to acknowledge my deepest regards and profound gratitude to Prof. Dr. Ismat Ara Haider, MS, DDS, BDS, Professor and Head of the Department of Oral and Maxillofacial Surgery, Dhaka Dental College & Hospital, supervisor of this study, for her continuous guidance, suggestions and close supervision in clinical training and preparing this thesis work. Without her vigilance and care, this study would have been difficult.

I am greatly indebted to Professor Dr. Mohammad Ghulum Rasul, MS, MPH, MBBS, Professor, Department of General Ophthalmology, National Institute of Ophthalmology and Hospital and my Joint Supervisor who underwent the painful task of going through my thesis and correcting my work patiently and encouraging me through. I give my special thanks and gratitude for his enormous support.

It is of great pleasure to express my deepest regards and sincerest gratitude to my respected teacher and joint supervisor, Dr.AKM Nazmus Saquib, Ph.D., DO, MBBS, Senior consultant, Department of Oculoplasty, National Institute of Ophthalmology, Dhaka. I am indebted forever to him whose interest, able guidance, constant supervision, made this study a success.

I am highly obliged to express my deepest regards to the principal of Dhaka Dental College, Prof. Dr. Md. Humayun Kabir, for providing me an opportunity to carry out my work in this hospital.

I have a great pleasure and heartfelt gratitude that, I acknowledge their constant supervision, patronage and excellent working and learning environment provided by Dr. Sadia Sultana , Associate Professor, Department of Oculoplasty, Ispahani Islamia Eye Institute and hospital, and Dr. Riffat Rashid , Assistant Professor , Department of Oculoplasty , Ispahani Islamia Eye Institute and Hospital.

I want to express my sincere gratitude to Associate Prof. Dr. Tarin Rahman, Associate Prof. Dr. Md Harun-Ur-Rashid, and Associate Prof. Dr. Md. Morshed Alam Talukder for their inspiration, affectionate encouragement and giving moral support during my thesis.

My special thanks to Mr. Ian Holland, Chief Consultant, Department.of Oral and Maxillofacial Surgery, Queen Elizabeth Hospital, University of Glasgow, for inspiring me greatly during my training in United Kingdom.

They say a friend in need is a friend indeed. I have such an amiable friend who helps me a lot. I am glad to mention my friend, Mr. Sunil Kumar Shah, Consultant Oral and Maxillofacial Surgery, Leeds Teaching Hospitals, Yorkshire, England.

It is a great pleasure to acknowledge my gratitude to Dr. Shamim Al Mamun, Professor and Chairman, Mawlana Bhashani Science and Technology University; Dr. Md. Abdullah Yusuf, Associate Professor, National Institute of Neuroscience and Hospital; Dr. Mezbahul Alam, Associate Professor, Vitreo-Retina, National Institute of Ophthalmology and Hospital, Dhaka.

My special gratitude and thanks to Prof. Golam Haider, MBBS, FCPS, MS, Professor, Department of Oculoplasty, National Institute Of Ophthalmology, for his whole-hearted co-operation and guidance throughout the time.

I am grateful to Assistant Prof. Dr. Nesar Ahmed; Assistant Prof. Dr.Md. Farhad Hossain and Assistant Prof. Dr. Mehbub Kadir for their valuable advice and support, from ophthalmological aspect, during the study period.

I am also grateful to Prof. Anamul Haque, Department of Chemistry, Jahangirnagar University and Md. Tuhinoor Rahman for their support during the preparation of thesis.

I must give my thanks to Md. Sayeem Noor, Data Analyst; Md. Helalul Mozadded, Radiographer; and Imtiaj Rasul, Research Assistant; for their kind support.

I want to extend my sincere gratitude to all my teachers and colleagues and all supporting staff of the Department of Oral and Maxillofacial Surgery, Dhaka Dental College Hospital, Department of Oculoplasy, National Institute of Ophthalmology and Hospital and Ispahani Islamia Eye Institute and Hospital, Dhaka.

I want to thank the patients of my study for their active cooperation and participation to make this study successful.

Finally, I would like to thank my family members for their continuous support and inspiration. I am highly grateful to my parents and brothers for supporting me every now and then. And special thanks to my beloved wife and my four children for their sincere sacrifice during this period of research work.

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Achievements

Published article (Appendix-VII)

Rahman, K.L., Haider, I.A., Rasul, M.G., Saquib, A.N., Shakoor, S.A. and Sultana, S., 2019. Titanium Mesh Versus Iliac Bone Graft For Reconstruction of Orbital Floor Fracture: Our Experience. *Journal of Bangladesh Academy of Ophthalmology*, 22(1), pp.37-46.

Rahman, K.L., Haider, I.A., Rasul, A.N. and Rashid, R., 2020. Surgical Correction Of Sequels Involving Orbitozygomatic Fractures: A Case Report. *Journal of Monno Medical College,* 6(2), pp.52-55.

Rahman, K.L., Hayder, I.A., Rasul, M.G., Ghosh, A.L. and Basak, S., 2014. Management of Traumatic Orbital Wall Fracture with Titanium Mesh. *The Journal of Bangladesh Orthopaedic Society,* 29(2), pp.126-131.

Conference paper (Appendix-VIII)

- ✓ 11st Asian congress on Oral and Maxillofacial surgery, Xi'an, China, 2014.
- ✓ 13th Asian congress on Oral and Maxillofacial surgery, Taiwan, 218.
- ✓ 1st Regional Conference on Oral and Maxillofacial Surgery and Allied Dentistry, 2020.

Training (Appendix-IX)

- ✓ Workshop on develops manpower in health research by using, learing by doing, methods.
- ✓ 7th AOCMF Advanced Course on Orbital Reconstruction, Birmingham, UK.

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ABBREVIATIONS

BMRC	Bangladesh Medical Research Council
CT	Computed Tomography
DDCH	Dhaka Dental College Hospital
IBG	Iliac Bone graft
IIEH	Ispahani Islamia Eye Institute and Hospital
mm	Millimeter
MRI	Magnetic Resonance Imaging
NIO	National Institute of Ophthalmology
OMS	Oral and Maxillofacial Surgery
TiM	Titanium Mesh

ABSTRACT

Background: Management of orbital fractures are one of the most interesting and difficult areas in maxillofacial surgery. Improper reconstruction of the orbit frequently results in ophthalmic complications. Keeping all these views in mind, a study had been proposed to determine the best materials in order to repair orbital floor fracture with consideration of cost, patients, benefits, time and surgical outcome.

Objective: To determine the surgical outcome of orbital floor fracture reconstruction by using titanium mesh and iliac bone graft for correction of enophthalmos.

Study Design: Multicenter, parallel-group, single-blind, randomized controlled trial.

Study setting and period: The study was carried out in three hospitals located at Dhaka city as in the Department of Oral and Maxillofacial Surgery, Dhaka Dental College and Hospital (DDCH) Dhaka; in the Department of Oculoplasty, National Institute of Ophthalmology and Hospital (NIOH), Dhaka and Ispahani Islamia Eye Institute and Hospital (IIEIH), Dhaka. This study was conducted from 1st May, 2016 to 30th April 2021.

Method: Total 60 patients with orbital floor fractures with enophthalmos were taken for reconstruction. The patients were divided into two groups. 30 patients were taken in an intervention group where titanium mesh was used for reconstruction of orbital floor fracture. And other 30 patients were grouped into control group where iliac bone graft was used for the reconstruction of orbital floor fracture. The efficacy of titanium mesh over iliac bone graft was evaluated in terms of demographical data, facial asymmetry, enophthalmos, diplopia, ocular motility, extra ocular muscle limitation, inferior rectus muscle action, step deformity, radiological evaluation; implant migrated, bone resorption as well as post-operative complications.

Results: Results of the study showed that the highest 21 – 30 years aged people (72%) usually were affected due to orbital floor fracture. More than 90% (91.67%) of orbital floor fracture patients were male. The main cause of orbital floor fracture was Road traffic accident (72%). Enophthalmos corrected 93.3% in intervention group, which was higher than control group (86.7%) at 24th postoperative week. The mean time of correction of enophthalmos was less for intervention group (8.43 weeks) than control group (14.93 weeks); and it was statistically significant. According to Kaplan Meier Curve, between intervention and control group, enophthalmos was corrected 4 weeks earlier in intervention group. The cost-benefit analysis was conducted between the intervention group, which received titanium mesh, and the control group, which received iliac bone graft. The results showed that the intervention group had a significantly shorter recovery time of 7.45±2.30 days compared to the control group's 12.61±3.47 days ($p<0.001$). The operation time for the intervention group was significantly lower at 2.12±0.74 hours compared to the control group's 3.45±0.97 hours ($p<0.001$).

Conclusion: The titanium mesh is similar and, in some cases, better than the iliac bone graft for the correction of enophthalmos in case of orbital floor fracture. It takes less operative time, less time stayed in the hospital, recovers quickly than iliac bone graft patients. Besides, unlike iliac bone graft, titanium mesh does not require a second operation. And titanium mesh is also precisely adaptable to the bone as compared to iliac bone graft. Considering all these aspects, titanium mesh is a good alternative option in comparison to iliac bone graft with more benefits for the correction of enophthalmos in orbital floor fracture.

Chapter I

Introduction

1.1 Background

Orbital floor fracture is a traumatic deformity of the orbit, usually resulting from the impact of a blunt object larger than the eye and hitting the orbit. Orbital floor fractures are one of the most common occurring facial bone injuries (Kwon et al., 2005). They are frequently faced (21.4% of all facial fractures) and managed by oral and maxillofacial surgeons, ophthalmologists, and ear, nose and throat specialists (Kwon et al., 2005).

Two theories have been postulated-hydraulic and buckling. According to Smith and Regan (1957), who described the hydraulic approach, explained that when an object greater than the orbit which pushes the globe backward and transmits the energy to the periorbital tissue, and to relieve this increased pressure, the force goes inferiorly (which is the weaken part). The floor blows out to the maxillary sinus (Emery et al., 1971).

Lefort first described the buckling theory, explains that the force of trauma transmits from the orbital rim to bones of the floor of the orbit, which buckles and distracts the floor bones, and eventually, fractures occur (Ethunandan et al., 2011).

There are two types of orbital floor fracture, one is pure blowout fracture and the other one is impure blowout fracture. The impure blowout fracture is associated with orbital rim fracture only. It involves contiguous bones where as Pure orbital fracture is the isolated orbital floor fracture.

Pure blowout fractures occur on the floor of the orbit. The number of pure orbital floor fractures (blowout) has been increased for the last ten years. The accidents are usually taking place due to blunt force trauma in the periorbital area, including road traffic accidents, assault, fall from height, sports injuries, industrial accidents, and others (Shin et al., 2013).

The orbital trauma causality depends not only on the size of the defect and the number of orbital walls involved but also on the location of the defect and the technical difficulties that may arise in surgical repair (Jaquiery et al., 2007). An orbital floor defect with an intact medial border of the orbital rim can be easily repaired by surgery while maintaining the angle between the orbital floor and the lateral wall.

Maxillofacial injuries, especially the early diagnosis and management protocol, must avoid cosmetic and functional problems such as enophthalmos, diplopia, restricted ocular motility, orbital, and facial paresthesia. The defect that depends on the increase the orbital volume together with the shrinkage of the orbital tissue related to the trauma. It leads to a return to the eyeball within the orbit and a visible enophthalmos (posterior dislodgement of the orbital contents) following a renewed alteration of the motility of the affected eye (Meyer et al., 1988).

According to Jayamanne and Igillie (1995), enophthalmos is a common complication that appears after a mid-facial injury, the range of reported incidence is from 30% to 62%.

The well-accepted concept that suggests enophthalmos is the enlargement of the orbital cavity after displacement due to orbital fractures. Generally, 0.8 mm of enophthalmos is caused by the increment of 1 cm^3 in orbital volume. Hence, 2 or 3 mm of enophthalmos is clinically detectable, and more than 5 mm is disfiguring.

Enophthalmos can be assessed only when oedema, hematoma, and inflammatory reaction following fracture subsides. There is a wide range of causes of Enophthalmos.

Early literature suggests that one cause of enophthalmos is atrophy of orbital muscles, seen in the floor of orbit due to injury to the sympathetic nerves causing Horner's syndrome and third nerve paralysis. Enophthalmos is caused by trauma to the orbit and its changes done by the configuration of the orbital floor, and there is no change in the orbital soft tissue.

Repairing the orbital floor is a challenging problem due to its unique shape and size. The 3-dimensional reconstruction of the orbital floor is the key procedure in the case of a primary or secondary orbital deformity. Enophthalmos, diplopia, and impaired visual acuity caused by increased orbital volume are severe complications of posttraumatic orbital deformities. This is best accomplished by determining the location and extent of the injury preoperatively with computed tomography (CT), exposing a large area of the injured area, removing orbital soft tissues and replacing invariably broken fractures with autogenous or alloplastic material.

Indication and timing of repair of orbital floor fractures are debatable. Some studies show early intervention makes aesthetic, anatomical, functional, and clinical improvements (Jaquery et al., 2007). Other group offers a quick treatment without intervention is more beneficial (Putterman, 1991).

During the first two weeks and every 2 to 3 days, the patient needs to be re-evaluated. All fractures need not be repaired. Orbital hemorrhage and oedema usually are resolved over the first week. The objective of treatment is to reduce the fracture fragments to restore the orbital anatomy and restore the physiologic functions and the aesthetic appearance of the injured area.

Currently, the indication for the repair of orbital floor factures has been divided into immediate repair within two weeks and observation. A thorough assessment is needed to find out the severity of the fracture to start the treatment at the appropriate time. This is very important for the proper treatment of orbital floor fracture.

With ongoing studies of the outcome of repaired orbital floor fractures with a different material is still controversial. It largely depends on the surgeon's choice, chosen technique, co-morbidities of the donor site, availability of synthetic material, and the prices of the implants. Depending on the place and size of the defect, titanium mesh, lyophilized dura, silastic sheet, polyethylene or polydioxanone sheet, hydroxyapatite blocks, ceramic inlays, and autogenous iliac bone grafts are suggested in treating off patients.

Usually, autogenous bone grafts are used. Moreover, some newer alloplastic materials have shown better results. When looking for a perfect material, some materials to consider here include volume regains, anatomical shape, minimal absorption, ease of placement, minimal or no inflammatory response, reproducibility and no morbidity. Unfortunately, the perfect material has yet to be found but some materials are close to perfect. Of these, titanium mesh and autogenous iliac bone (graft) are the closest.

Titanium mesh consists of pure titanium and varying amounts of oxygen or titanium alloys. Titanium is not as rigid as iliac bone. Therefore, it is complaint to maintain the necessary strength. Besides, a protective oxide is formed in titanium mesh that resists corrosion and achieves good tissue biocompatibility (Champy et al., 1978), whereas iliac bone graft has shown resorption after a period of time.

Titanium mesh was first used in the 1940s. It showed excellent ductility and tensile strength and was completely non-toxic, as well as the unique ability to join between the bones (osseointegration) (Mirko et al., 2009).

On the other hand, an autogenous iliac bone graft works like a scaffold that forms another bone. Also, ironically, the loosening torque of titanium screws exceeds the insertion torque. Thus, the fixation process is relatively easy, but it is quite difficult for the iliac bone graft. However, titanium mesh is expensive and is a significant drawback to titanium usage in the cost-sensitive economics of developing countries (Deepak et al., 2014). So, an Autogenous Iliac bone graft is considered another option for repairing the orbital floor in these developing countries. Nevertheless, in orbital floor reconstruction alloplastic materials are getting popular day by day due to their requiring just one operation, whereas iliac bone grafting needs double.

In the present study, the difference between the outcome of orbital floor fracture reconstruction (especially correction of enophthalmos) by titanium mesh and Autogenous iliac bone graft were showed. We randomly chose the patients for titanium mesh or bone grafting. About 60 patients of different age groups have been selected for this study. Among them, all met up the criteria repair within two weeks.

Differences between pre and post-operative improvement of diplopia, enophthalmos, ocular motility are evaluated among both groups and analyzed to see the better possible option to apply in the future for the betterment of the injured. Keeping all these views in mind, a study has been proposed to determine the best materials for repairing fracture of orbital floor with consideration of cost, patient benefits, time and surgical outcome.

1.2 Rational of the study

Among the oral and maxillofacial conditions, maxillofacial injuries are common in Bangladesh (Islam et al., 2015). But unfortunately, there is no proper guideline for managing these injuries. Here the injured are seen confused and roaming in a circle in this flawed system. So, the patients may not be properly and appropriately referred. As a result, there is a great chance to miss critical clinical findings that may threaten visual systems.

The orbital floor fracture patients are generally in a condition where they don't understand where to go to get the proper treatment whether to a maxillofacial surgeon or an ophthalmologist. Moreover, as it is a complex surgery of both Maxillofacial and Oculoplastic surgeons for the poor patients it is really hard to arrange two specialists at a time. By this study, better treatment and mental relief can be given to the poor patients in Bangladesh.

So, early identification of orbital floor fracture is important. Because its management may take precedence over the treatment of orbital fracture, on the other hand, early and appropriate diagnosis of such injuries is a medico-legal issue. The principal objective of treating the fracture of the orbital floor is to prevent long-term sequels, for example: enophthalmos, persistent diplopia, and reduced globe mobility. Here the selection of materials is very important. If the proper material is not used, then the patient will be deprived of appropriate treatment.

Here, autogenous bone grafts have some benefits. The surrounding tissues can tolerate the bone graft easily as they are from the same body. Autogenous grafts have the advantages of biocompatibility and lower infection rate, and less foreign body reaction.

Cortical iliac bones are widely used for reconstructing the orbital floor. Particularly, this bone is rigid enough for applications without any special fixing. Nevertheless, the drawback of bone grafts is unexpected resorption (Sakakibara et al., 2009).

The disadvantage of autogenous bone graft mentioned in the literature is the unpredictability of the reabsorption level of the graft (Ellis and Tan, 2003). Therefore, one crucial aspect of diminishing the reabsorption level of the bone graft is its binding to the receptive area since micro movements made by the ocular muscles conduct more significant resorption of the graft. Besides, autogenous bone graft requires another surgery to harvest and thus increasing the chance of morbidity.

Several merits of titanium mesh have made it a choice for reconstructing orbital floor fracture with enophthalmos. Titanium mesh is biocompatible. It has the property of malleability, making it adaptable to the orbital contour. Titanium mesh though strong, its thin binding attachment facilitates the reconstruction of significant orbital defects. Surrounding soft tissues grow quickly through their light mesh giving integrity and stability to the orbit in the desired place. In a CT scan or conventional radiograph, titanium mesh does not give any artifacts. Considering the advantages of titanium mesh for the reconstruction of orbital defects, it can be regarded as the ideal option for the reconstruction of orbital floor fracture.

Early management of orbital floor fracture is very important; otherwise it may cause enophthalmos, permanent diplopia or blindness of the eye. There are many ways to manage the orbital fracture, like conservative or surgical management. So many studies have already happened in developed country regarding the treatment modalities of orbital floor fracture. In a developing country like Bangladesh, this type of study was not conducted ever. In this study, the outcomes of titanium mesh and iliac bone graft for the treatment of orbital floor fracture with correction of enophthalmos and the complications regarding these treatment modalities are evaluated.

The data generated from the study will be helpful for the oral and maxillofacial surgeons to choose a better treatment option to achieve less complication and better functional outcomes in the repair of orbital floor fracture associated with enophthalmos.

1.3 Hypothesis

The efficiency of titanium mesh is as good as iliac bone graft for the reconstruction of orbital floor fracture with correction of enophthalmos in Bangladeshi people.

1.4 Objectives of the study

General objective:

To determine the surgical outcomes of orbital floor fracture reconstruction by using titanium mesh and iliac bone graft for correction of enophthalmos.

Specific Objectives:

The specific objectives of the study are:

1. To determine the surgical outcomes for orbital floor fracture reconstruction by titanium mesh and iliac bone graft.
2. To compare the post-operative correction of enophthalmos by titanium mesh and iliac bone graft.
3. To assess post-operative complications between two groups (titanium mesh and iliac bone graft).
4. To identify the socio-economic status of the enophthalmos patients affected by orbital floor fracture.

Chapter II

Review of Literature

2.1 Mechanism of orbital floor fracture

Orbital floor fracture was described at first in 1844 by MacKenzie (Ng et al., 1996). Two principal theories have been proposed-

1. The hydraulic theory
2. The bone buckling theory

The hydraulic theory was first proposed by Pfeiffer in 1943 as a challenge to Le Fort's hypothesis. He concluded: "It is evident that the force of the blow received by the eyeball was transmitted from it to the walls of the orbit with the sensitive parts.". In 1944, King stated that "The simplest clarification for orbital floor fractures is trauma transmitted from the eye to the orbital floor" (He et al., 2007). Smith and Regan (1957) showed an investigational mechanism for the hydraulic theory of orbital floor fracture. They defined an entrapment of the lower rectus muscle with reduced ocular motility in the context of an orbital floor fracture, called 'Blowout fracture' (Strong et al., 2004).

In 1967, Jones and Evans introduced the subdivision of the orbital floor into six zones and produced experimental fractures, 79% of which are situated in the posterior medial floor.. These results support the hypothesis previously proposed by Le Fort, who also thought that the orbital floor fracture was caused by the direct trauma force through the orbital rim to the orbital floor (Brown et al., 1999).

Fujino and Makino (1980) reported that they favored the buckling mechanism using high-speed photography that indicated the occurrence of a straight line fracture of the orbital floor by buckling by the infraorbital edge replaced later when a rapid force was exerted on the infraorbital edge of an orbit fixative model .Bullock et al. (1999) carried out a clinical trial to find the two approved mechanisms (hydraulic and buckling) for orbital floor fracture.

Chen et al. (2016) showed that an orbital floor fracture could involve both theories. The researcher described that the pyramidal structure and the contents of the orbit could create a temporary and pronounced increase in intraocular pressure when an external force is produced, then the orbital floor break to prevent damage to the globe.

2.2 Classification of orbital floor fracture

Harris et al. (1998) classified orbital floor fractures according to the relationship between fractured bone fragments and soft tissue using CT images:

- Type I. Trapdoor fractures in which bone fragments realign.
- Type IA. There is no visible orbital soft tissue within the maxillary sinus. Type IB. Orbital soft tissue is visible within the maxillary sinus.
- Type II. Through the spaces between these fragments, the bone fragments are distracted, and the soft tissues are displaced into the maxillary sinus.
- Type IIA. There is no soft tissue prolapse, or the soft tissue displacement is less than that of the distracted bone fragment.
- Type IIB. The soft tissue herniation is larger than the distracted bone fragment.
- Type III. Displaced bone fragments surround the displaced soft tissue.
- Type IIIA. Soft tissues and bones are moderately displaced towards the maxillary sinus.
- Type IIIB. The soft tissues and bones are clearly displaced towards the maxillary sinus.

Yano et al. (2010) divided the floor into linear type, punched-out type, and burst type. Linear fractures were slightly dislocated bone fragments. Punched-out fractures involved less than a third of the floor. In burst-type fractures, more than two-thirds of the orbital floor is affected.

2.3 Incidence of orbital floor fracture

Orbital floor fractures are not that common types of facial fractures. Ioannides et al. (1988) reported 59 fractures in a series of 509fracturedpatients, out of orbital, zygomatic, nasoethmoid, Le Fort II, Le Fort III, and floor fractures. Injuries to the middle third of the face usually destroy the integrity of the orbital skeleton and are often complicated by injuries to the eye (Jamal et al., 2009).

AI-Ourainy et al. (1991) conducted a prospective study of 363 patients who suffered midface trauma with 438 midface fractures. They found that serious eye diseases were more common after road traffic accidents. They have shown that a third of all patients with a comminuted fracture had severe eye disease, while blowout fractures ranked second. They also found that 15.4% of the patients experienced temporary or permanent vision loss. Ashar et al. (1998) found 49 fractured patients with midface, 20% of the patients were blind in one eye. Amrith et al. (2000) demonstrated in 104 patients with craniofacial fractures that the orbital floor was the most common fracture type (36% of cases). Malara et al. (2006) found 5 cases out of orbital floor fractures in 198 patients with facial trauma as a result of a road traffic accident. Gosau et al. (2011) report only 19.6% (n = 37) of orbital floor fractures in 189 patients with facial injuries.

Baek et al. (2003) reported that 29-floor fractures happened, most commonly in the age range of 20 to 29 years, more common in men than in women. The most common cause was violence, and orbital floor fracture was the most common fractured site.

2.4 Orbital floor fracture diagnosis

Patients report a history of blunt trauma to the orbit with enophthalmos, diplopia, orbital bleeding or oedema, extraocular muscle injuries, and floor fractures (Brady et al., 2001). An intact orbital rim may indicate an orbital floor fracture (pure blowout), and clinicians think of an orbital floor fracture (Rowe and Williams, 1994; Brady et al., 2001).

Rowe and Williams (1994) suggested orbital floor fracture findings including history and type of injury, immediate eye elevation restriction, especially the restriction of other directions. Lerman (1970), due to the motility defect, it was found the fracture site in relation to the equator of the globe.

As the inferior rectus muscle gets injured, the eye is fixed in a low position, resulting in hypotropia on the side of the injury when the opposite eye is in the primary position.

2.4.1 Enophthalmos

Enophthalmos as described by Rowe and Williams (1994) is an imbalance among the periorbital fats and the orbital floor. Enophthalmos, which is a posterior recession of the eyeball in the orbit, is an anteroposterior plane (Cline and Rootman, 1984).

Enophthalmos is not unusual to place trouble of orbital floor fractures with a mentioned prevalence variety from 30% to 62% (Jayamanne and Igillie, 1995; Hossal and Beatty, 2002; Barry, 2005; Wang et al., 2008). Rowe and Williams (1994) defined the motive for enophthalmos with the aid of using the boom of the orbital quantity with the aid of using outward motion of orbital floor or a lower in the number of orbital fats with the aid of using herniation into the maxillary sinus. Hammerschlag et al. (1982) said that, in the intense section of the trauma, enophthalmos could simplest end result from prolapse of orbital contents into the maxillary sinus.

Gilbard et al. (1985) believed that CT evidence of a fracture extending more than half the floor would increase developing enophthalmos but include an increased likelihood of developing diplopia.

Detecting the main cause of enophthalmos, in 1944, Whitehouse et al. (1994) conducted research on 25 patients with orbital floor fractures using Computed Tomography. The research concluded that if the orbital volume is increased by about 1 cm^3, it causes enophthalmos of 0.8 mm. This implies the fact that after orbital floor fracture, the intraocular pressure of the orbit is increased, causing the herniation of the orbital content into the maxillary sinus. As a result, the orbital volume is increased, whereas the fat content is being shrunk, called fat atrophy. That experiment also showed that about 20 days after surgery, the retrobulbar soft tissue swelling could conceal about 3 mm of enophthalmos, and this phenomenon is exposed after that period.

In 1996, another experiment was conducted by Dolynchuk using software analysis for coronal and axial Computed Tomography, stating that enophthalmos becomes clinically visible when there is about a 4% increase in orbital volume. Yab et al. (1997) found in a computed tomography assessment of thirty-two patients with orbital floor fractures that up to 2 ml of orbital expansion, enophthalmos remained approximately 1 mm, then increased corresponds to a total orbital expansion of 4 ml, which then stabilized.

The establishment of the relationship between enophthalmos, linear displacement, and volume change for different models of experimentally created orbital fractures was described by Cunningham et al. (2005).

The measurement of orbital volume before initial reconstructive surgery in major fractures to predict a possible enophthalmos was also recommended Ye et al. (2006). Kokemueller et al. (2008) analyzed the degree of persistent enophthalmos and its course using a spiral computed tomography data measurement protocol in combination with image fusion techniques. They said their measurement protocol was particularly suitable for monitoring changes in the bone pathway and its contents in trauma patients.

Kolk et al. (2008) found that 3D orbital volume size is important for the identification of postoperative and post-traumatic changes in orbital volume and the resulting extension of the enophthalmos. Their 3D MRI data 3-4 months after surgical fracture reconstruction showed that all enophthalmos orbits showed a significant increase in bone volume and a reduced sagittal projection of the eye compared to the contralateral side. Mean increases lead to an enophthalmos of 0.93 mm, a value parallel to that of Whitehouse et al. (1994) in the orbital volume of 1.0 cm^3 and Fan et al. (2003).

2.4.2 Diplopia

Diplopia is a general complexity of orbital floor fractures. In the publication, double vision ranges from 58% to 84% (Hammerschlag et al. 1982; Biesman et al., 1996; Amrith et al., 2000; Brady et al., 2001; Hossal and Beatty, 2002). Diplopia is once and again raised to reduced vertical mobility in orbital fractures, the most common ocular motility disorder in orbital floor fractures (Bansagi and Meyer, 2000).

The study conducted by Harris et al. (1998) on the predictive value of preoperative computed tomography found poor results for ocular mortality due to damage of the muscle fibro-fatty complex in varying degrees since it is driven between bone fragment with subsequent intrinsic fibrosis and the movement of the balloon from union to contraction.

In summary, this review of the literature suggests that the etiology of diplopia is likely to be multifactorial. However, it appears that the most likely causes of diplopia in orbital floor fractures are a combination of orbital soft tissue injury and varying degrees of tissue involvement in the fractured defect.

2.4.3 Subconjunctival haemorrhage:

Subconjunctival hemorrhage can happen with trauma limited to the periorbital tissue. In case of an orbital fracture, the blood begins to store the tool for diagnosis in the extraconal space and then continues; this will show up as an indeterminate posterior subconjunctival hemorrhage, a useful diagnostic sign. However, the initial absence of subconjunctival bleeding does not rule out the presence of a fracture because, in some cases, the periorbital tear is not broken, and blood from the fracture accumulates slowly below the orbital plane. It persists several days for conjunctiva to appear (Rowe and Williams, 1994). Circumorbital bruising is a common sign of preseptal soft tissue trauma. The loosening of the tissue allows blood to flow freely to the loose subcutaneous orbital tissue. The filtered blood can persist for many weeks. While the treatment itself is not necessary, other investigations should be done to rule out more serious injuries.

2.5 Radiographic examination

In the determination of the fracture of the orbital floor, the usage of CT is now common practice. The nature of the study includes not only its convenience in diagnosing orbital fractures but also its value in classifying orbital floor fractures. Iliff et al. (1999) listed a principle for a correct assessment of an orbital fracture as an axial scan, starting at the upper surface of the frontal sinus and progressing through the entire orbit of the eye up to the maxilla and orbit. Coronal cuts should begin forward in the nasal pyramid and continue back to the point of the orbit. CT scans can show the area of the orbital floor and its relationship to soft tissue in the axial and crown planes (Hartstein and Roper- Hall, 2000).

Charteris et al. (1993) noted the potential importance of computed tomography measurement in patients with orbital floor fractures. Baek and Lee (2003) also found that estimating fracture size on CT better predicted late postoperative enophthalmos. Hamedani et al. (2007) found for prognosticating diagnosis of late enophthalmos and surgical reforming, we can use volumetric CT measurement with digital reconstruction.

We can come to a consensus that CT is a valuable diagnostic tool in the treatment of floor fractures of the orbit. CT scan can also provide the information and the location, size of the orbital fracture and the degree of muscle involvement in the fractured site.

2.6 Ocular motility assessment

The assessment of diplopia with cautious follow-up is important in making decisions about the treatment of orbital floor fracture. A primary clinical evaluation can be made using light. The patient is asked to concentrate and follow the light in the 9 main gaze directions and reported the existence of double vision (Stassen and Kerawala, 2007). If diplopia is found, a referral for an ophthalmic examination is indicated.

2.6.1 Forced duction test

A forced duction test perfumed initially by placing a drop of local anaesthetic in the cul-de-sac of lower lid, using a pair of small toothed forceps, grasping the tendon of rectus muscle in question and rotating the globe passively away from the restriction and is invariably indicated for restricted eye movement (Alhamdani, 2012).

2.6.2 Extra ocular muscle limitation

The Hess chart test is generally recommended to evaluate extraocular motility faults. It provides reproducible data of ocular motility. It is determined for both eyes, and normally the unaffected eye muscles show hyperactivity alternatively to the affected muscle contra laterally of the eye which is affected (Stassen and Kerawala, 2007). In 1992 Aylward offered a different classification method for Hess diagrams because they realized that the explanation of Hess diagrams was subjective. Unilocular fixation field dimension of ocular motility is also suggested for objective actions of eye movements, despite Hess diagrams, that give a statistical score for the six extraocular muscles of both globes (Haggerty et al, 2005). However, it's being used in patients with orbital injury has not been reported yet. Turnbull et al. (2007) analyzed the measurement of intraocular pressure to restrict the movement of the globe, and the pressure in the affected eye increased when looking up. He contemplated the same measurements between each eye (injured and normal) as a sign of recompensate from the weakness of the ocular muscles.

2.7 Orbital floor fracture management

2.7.1 Surgical management

According to Dulley and Fells (1974), 4,444 surgeries were held. They observed the following findings, e.g., slow-resolving diplopia on the first day after the injury, large invasive fracture, tissue entrapment in the fracture leading to retraction of the eyeball, and enophthalmos not less than 3 mm. Straker and Hill (1989) suggested the criteria described by Dulley and Fells (1974) along with a positive compulsive test. Research has shown that (Putterman 1991) lists the subsequent indications for initial surgery (within one to three weeks after trauma): Severe diplopia, visually impaired patients that are not resolved by a positive forced duction test that does not allow the eye to move up, and with CT detection of lower rectus muscle trap or in patients with cosmetically unacceptable severe enophthalmos.

Muscle entrapment was considered by Bansagi and Meyer (2000), which leads to impaired ocular motility with diplopia, early enophthalmos (more than 2 mm), and orbital defects with more than 50% of the floor orbital as generally established suggestions for repair in the orbital floor fracture. Shantha et al. (2000) also considered an enophthalmos greater than 2 mm in their surgical indications.

Turnbull et al. (2007) recommend 12 weeks as the optimal time needed for the surgery, as it allows resorption of orbital edema and bleeding. They also revealed that most surgeons approve that large fractures, enophthalmos, and trap signs are indications for surgery. Farwell et al. (2007) suggested the following criteria as indications for surgical intervention:

a) When ocular motility is restricted and diplopia
b) Enophthalmos present clinically
c) Computed tomography (axial section)

These are the indications for surgery of fracture more than 2 cm floor fracture and increased orbital volume.

The clinical indications for surgery into groups of adults and children were divided by Parbhu et al. (2008). The numbers which are showed for the entrapment accounted for the highest number of surgical indications for pediatric blowout fractures compared to enophthalmos among the adults.

Also, they said that when the edema goes away, and fibrosis begins, early enophthalmos will worsen. Courtney et al. (2000) sent a questionnaire to 256 practicing Fellows of the British Association for Oral and Maxillofacial Surgery.

They found that more than half of the respondents preferred to operate between 6 and 10 days after injury.

2.7.2 Surgical approach

Orbital approaches are the best common approaches used to treat orbital fractures. They are considered safe and effective access routes to fractures and allow a smooth reconstruction of the orbital floor with expected results (Humphrey and Kriet, 2008).

A. Subciliary and B. Subtarsal approach

Originally Converse et al. (1967) described the subciliary and subtarsal approach with a preference for the subtarsal technique. Most of the orbital floor (Baumann and Ewers, 2001) allow access to both transcutaneous approaches. The cutaneous approach provides excellent visualization of the entire orbital floor and the lower part of the medial and lateral walls. Almost all areas can be reached safely and easily, even better in the case of large-area changes or if the exact extent of the injury is unknown combination with other approaches from the outside or inside of the brow, could be estimated accurately in advance (Rowe and Williams, 1994). Subciliary and subtarsal approaches for the extensive surgical exposure mandatory for extensive orbital reconstruction were recommended by Smith et al. (1998).Both the surgical exposures are easy to learn and provide ample access to the orbital floor. Weaknesses are greater postoperative misalignment of the lower eyelid and visible scars contrasted to the transconjunctival approach. Therefore, the transcutaneous access technique of the lower eyelid must be flawless to minimize the risk of sclera and ectropion.

Rohrich et al. (2003) claimed that the subtarsal variant of this approach caused a lower risk of vertical eyelid shortening, sclera exposure, and ectropion, but a slightly higher risk of visible scarring. Innervation of the pretarsal orbicularis and most of the preseptal is better preserved in the subtarsal variant, which may help to maintain the preoperative position of the lower eyelid (Baumann and Ewers, 2001). Baqain et al. (2008) described the security and easiness of the lower eyelid. Subtarsal approach used for orbital floor fractures with good functional and aesthetic surgical results.

C. Trans-conjunctival approach:

Bourguet (1928) originally used the transconjunctival technique for the treatment of fatty prolapse of the lower eyelids and by Converse et al. (1967) and Tessier (1973) on the surgery of orbital floor fractures. The drawback of limited access and size of Trans-conjunctival approach is described below:

It has the evident benefit of an invisible scar but also requires a higher level of operational skills. It is obviously useful for procedures that do not require extensive exposure of the orbit and fractures, limited to the inferior margin and anterior side of the floor (Rowe and Williams, 1994). Another benefit of this approach is the lower risk of ectropion compared to the subciliary approach (2000).

2.7.3 Reconstruction of the orbital floor by Autogenous and Alloplastic materials

The reconstruction of the orbital floor material should fulfill the following functions: closure of the antrum provides a physiological and physical surface to prevent sticking, to restore the orbital contour and measurement, and indirectly support the orbit (Rowe and Williams, 1994). These goals can be achieved by inserting an autogenous graft or biomaterial between the remaining orbital floor and the prolapsed soft tissues of the maxillary sinus and repositioning it accordingly in the orbit (Morax 1998). In this sense, several alternative opinions in the literature have alternated over the years. The choice of particular substances depends on several factors. These include the surgical approach, the size of the defect to be repaired, the morbidity at the extraction site, the quality and quantity of bone available.

Titanium mesh is widely used to reconstruct orbital floor fractures. It is highly biocompatible, has osseointegration and mechanical properties, and is a suitable bone substitute (Baino, 2011). Ellis and Tan (2003) found that both bone and titanium meshes can be used effectively to reconstruct the orbital floor. In addition, they cautioned that a titanium mesh would be more suitable for reconstructing orbital floor fractures.

Büchel et al. (2005) assessed the effectiveness and advocated the use of absorbable alloplastic material (Ethisorb) in the reconstruction of orbital floor fractures. Eighty-seven patients were included in the study. 24.1% of the patients presented with complications of enophthalmos, diplopia. The researchers concluded that absorbable alloplastic material (Ethisorb) is appropriate for small to medium defects but not for big defects. Transmission et al. (2002) found that titanium mesh has suitable biocompatibility and is easy to adapt. It can reliably be fixed with screws in the infraorbital margin (Kelley et al. 2005) Especially in large herniation. Schon et al. (2006) described repairable defects that are not easy. Preoperatively preformed titanium mesh implants based on 3D CT models are more accurate, less invasive, and less time- consuming. The authors found that this method accurately anticipated the reconstruction required for complicated orbital defects with more than one orbital wall.

The suggestion for the use of bone grafts as implant material is based on the fact that it has the advantages of biocompatibility and the lowest potential for infection, exposure, and foreign body reaction. Therefore, the cortical and endochondral bones are often used to reconstruct the orbital floor. Cortical bone is sufficiently rigid, especially for only applications without special fixation. However, the disadvantage of bone grafts is unexpected resorption (Harsha et al., 1986; Krishnan and Johnson, 1997). Enneking (1957) advocated autogenous bone grafts of the iliac, ribs, and mandible to reconstruct orbital floor defects. Bagatin (1887) reconstructed six orbital floor defects with mandibular symphysis bone grafts. The lower jaw is considered a desirable donor site. For the reconstruction of the orbital floor, grafts from the lingual plate of the mandible and the lateral side of the mandible were used. In addition, the contour of the bone graft conforms to the floor of the orbit quite easily. A 2 x 4 cm grafts can be removed from the symphysis. Grafts of this size would be helpful in repairing most orbital floor defects. When maxillary sinus and maxillary bone grafts were used to repair orbital floor defects, there were no cases of loss due to infection.

The symphysis of the lower jaw was used as a source of bone grafts for alveolar cleft repair, alveolar ridge augmentation and orbital floor reconstruction (Iannetti and D'Arco, 1977). It is relatively easy to remove with little morbidity, and the quality and contour of the bone graft are highly adaptable for orbital floor reconstruction.

Krishnan and Jhonson (1997) showed the usefulness of the mandibular symphysis as a source of bone grafts for the reconstruction of the orbital floor. A previous study was conducted in 16 patients with isolated floor fractures (n = 10) or orbital floor defects (n = 6) who were reconstructed with bone grafts from the symphysis of the mandible. Physiological bone grafts were used when the defects were less than 2 cm in diameter. Patients were examined at follow-up visits for signs of failed reconstruction by checking for extraocular movements and signs of diplopia or enophthalmos. During a mean follow-up period of 12 months (9 to 36 months), the patients had no postoperative symptoms.

Good restoration of the orbital floor without clinical signs of enophthalmos or diplopia. Extraocular muscle actions were intact in all patients. Sindet-Pedersen and Enemark (1988) described that there should be no complaint in removing a bone graft. on the orbital floor.

In autografts, the cartilage of the ear is indicated at the extraction site for the reconstruction of relatively small spaces in the orbital floor due to its shape very similar to the orbital floor, its easy and fast extraction, its malleability, its good support and its limited morbidity (Stark and Frileck, 1969; Constantian, 1982). Zins and Whitaker (1983) state that membranous bone grafts, when used in the cranial skeleton and face, are significantly less resorbed than endochondral bone grafts and that membranous bone grafts should be preferred. Siddique and Mathog (2002) found that there was no difference in the ability of the skull (membranous) and the iliac bone (enchondral) to correct post-traumatic enophthalmos. They conducted a study at Wayne State University, Detroit, MI, in 22 patients undergoing orbital floor reconstruction for enophthalmos and diplopia after orbital trauma. A comparison of the pre and postoperative status showed a statistically significant change in the patient's enophthalmos, but no statistically significant difference between the results of the cranial and iliac bone graft. Synthetic materials have shown less morbidity at the extraction site and easier handling: polyethylene plates (Hossal and Beatty, 2002), hydroxyapatite, and silicone were adapted for the reconstruction of the orbital floor. However, these non-resorbable materials have a higher potential for infection and foreign body reaction (Seiff and Good, 1989, Tan CS et al. 2006, Ono I et al. 1994).

The outstanding width of the grafts matches to the thickness of the intact orbital floor reconstruction of the orbital area, the loss of up to 30% of the thickness of these grafts. The researchers found that there is no indication that one biomaterial is superior to another in terms of orbital tissue response. As well as calvarial bone grafts, iliac bone grafts are presently considered appropriate material for bone grafts (Baino, 2011). Furthermore, the morbidity at the donor site builds such bone graft inappropriate for small isolated orbital floor fractures with a minimal likelihood of enophthalmos (Fries, 1994).

A consensus on reconstruction materials has not yet been reached. Sakakibara et al. (2009) stated that ilium bones were used for orbital floor reconstruction with good results. The patients included in this study (n=101) received an orbital floor reconstruction of a pure blowout fracture with a thinned and trimmed bone of approximately 1mm without graft fixation. The results were evaluated by CT scan. Postoperatively, diplopia occurred in 15 patients and resolved in 86 patients. After six months of follow-up, CT scan showed that the morphology of the orbit was well preserved, and no desquamation or incorrect placement of the transplanted bone was observed in any of the patients. Furthermore, the CT scan images showed ossification of the transplanted bone graft. The procedure that uses the iliac bone has several advantages. First, the grafted bone is sufficiently malleable and flexible, adapting to the gently curved orbital floor. Secondly, it is easy to cut since it is smooth. Furthermore, due to its fragility, complications are not observed in the short and long-term follow-up the 1 mm thick iliac bone graft.

Kontio et al. (2006) reported resorption of almost 80% of iliac bone grafts with accompanying bone formation of 75%, probably due to the presence of osteoblasts in the cortex. Some researchers have recently used autogenous cartilage grafts. The advantages of autogenous cartilage grafts are that they are simpler to remove and operate. They offer long-term support since cartilage is not reabsorbed for a long time (Baino, 2011).

In spite of the choice of material for the reconstruction of orbital floor defects, there seems to use titanium mesh for the reconstruction of the orbital floor.

2.8 Surgical anatomy of the orbit

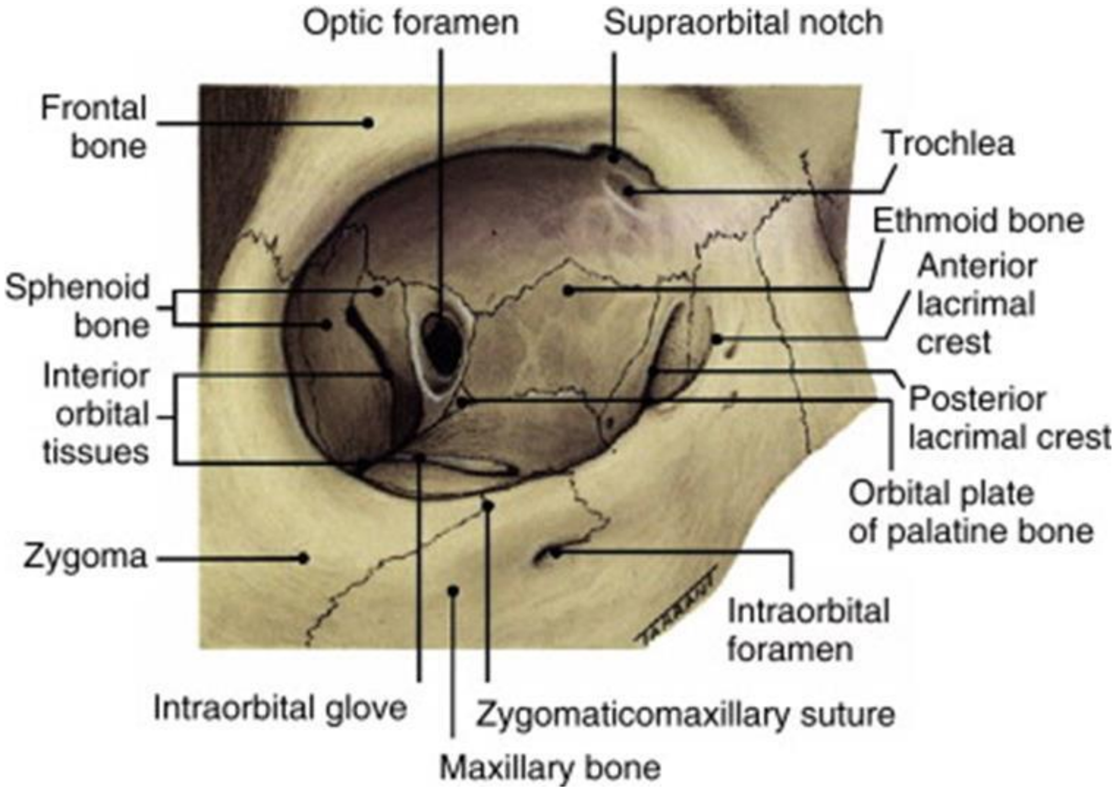


Figure 2.1: The bony orbit (Courtesy: AAO, 2018)

The bony orbit is being formed by the paired bony socket in the facial part of the skull, which is situated on both sides of the nasal root. The shape of the orbit is quadrilateral, pyramidal shaped. Its base is facing forward and lateral. There is a three-dimensional reconstruction of the orbit, which is more likely to be shaped like a pear than like a quadrilateral pyramid, losing one of its facets in the orbital apex area. The orbit consists of extra ocular muscles, globes, fat, blood vessels, and nerves.

Adult orbital dimensions:

- Volume.. 30 cm^3
- Entrance height .... 35 mm
- Entrance width… .... 40 mm
- Medial wall-length… 45mm

The bony orbit consists of seven bones, including the maxilla, zygomatic, frontal, ethmoid, sphenoid, lacrimal, palatine bones, and also has four orbital walls (superior, inferior, medial, and lateral).

The orbital roof:

- It consists of a frontal bone and a small wing of the sphenoid bone.
- It is located behind the anterior cranial fossa in the posterior part and the anterior frontal sinus with the lacrimal fossa to receive the orbital part of the lacrimal gland.
- It is thin and frequently may have spontaneous cracked.

Lateral wall of the orbit:

- It consists of the zygomatic bone and the greater wing of the sphenoid, separated from the lesser wing part of the orbital roof by a superior orbital fissure. It is made at an angle of 45 degrees with the anteroposterior axis.
- It is the thickest and most potent of the orbital walls.
- Situated adjacent to the middle cranial fossa and the temporal fossa.
- It extends anteriorly to the equator of the globe.

Medial wall of the orbit:

- It consists of ethmoid, maxilla, lacrimal, and sphenoid bones.
- Located next to the ethmoid sinuses and the nasal cavity.
- The medial wall of the optic canal forms the lateral wall of the sphenoid sinus.
- The thinnest wall of the orbit is the lamina papyracea, which lines the ethmoid sinuses along the medial wall and the maxilla, especially in the posteromedial part. These are the bones that are most often broken as a result of orbital floor fractures.

The floor of the orbit:

- They are composed of maxillary, palatine, and zygomatic bones.
- Forms the roof of the maxillary sinus, it does not extend to the orbital apex but ends at the pterygopalatine fossa. Hence it is the shortest of all orbital wall
- The orbit floor is the commonest site involved with pure blowout (orbital floor) fractures.
- The infraorbital groove begins at the inferior orbital fissure and runs forward in the maxillary sinus.
- Orbital floor slopes medial and upward till it turns out to be horizontal as it approaches the anterior margin of the inferior orbital fissure. Then the floor curves into the infratemporal fossa from the posterior border of the maxillary antrum. Rebuilding of this area during surgery requires attention to maintain the sigmoid structure. (Orbit, Eyelid and Lacrimal system, American Academy Ophthalmology, Chapter-1, Page: 15-17).

2.9 Soft tissue of the orbit

The rapidly moving eyelids are rich in blood supply having levator palpebrae superioris, muller, and orbicularis oculi muscle innervated by the oculomotor, sympathetic, and facial nerve, respectively. The former two lift the lids, and later one closes.

Orbital septum is a fibrous structure of the orbit that extends from orbital bones to tarsal plates. The septum acts as a barrier of the orbit that prevents blood, fluid, or pus from escaping. The septum is incomplete or lacks at the medial and inferior aspect of the orbit; that’s why a nasoethmoidal fracture may cause surgical emphysema of the lids. Tarsal plates are the fibrous structure of the lids semilunar in shape and act as a skeleton of the lids.

Conjunctiva is the transparent structure of the eye which has three parts bulbar, palpebral, and forniceal. It is firmly attached at the junction of the cornea and conjunctiva, so the subconjunctival hemorrhage does not cross the limbus to the cornea.

The lacrimal apparatus produces and transports tears which are essential for making tear film and hence takes part in vision and nutrition, and protection. Periorbital fat is seen in extra conal and intraconal space and acts as a cushion for the eyeball to rotate.

2.9.1 Muscles of the orbit:

The movement of the eyeball is occurred by six extrinsic or intrinsic ocular muscles. The four recti (superior, inferior, medial, and lateral) muscles arise from a ring-formed fibrous band called the annulus of zinn posteriorly in the orbit. The muscles run forward and insert anterior to the equator of the globe. The medial and lateral muscles adduct and abduct the eyeball respectively. The main function of the superior and inferior rectus is to elevate and depress the eye. There are some torsional and horizontal movements due to the angle between the muscles plane and visual axis. The superior oblique arises superior to the annulus of zinn. It goes forward along the medial wall of the orbit where its tendon slides through the trochlea and turns laterally, and inserts posterior to the equator, postero-superior side of the eye. Intrusion, depression, and abduction are the movements of the superior oblique. The inferior oblique originates from the maxilla anteriorly and goes laterally and posteriorly to insert in the infero-posterior side of the globe, producing extrusion, elevation, and abduction of the eye.

Lateral rectus is innervated by the abducent nerve, superior oblique by trochlear nerve, and the rest of the extraocular muscles by the oculomotor nerve.

The extraocular muscles are easy to see on CT scans when orbital floor fracture is happened due to herniation of muscles into the maxillary sinus. (Orbit, Eyelid, and Lacrimal System, American Academy of Ophthalmology, reprint from latest larger edition 2014-2015).

2.9.2 Nerves of the orbit:

Sensory supply of the orbital and surrounding area is carried out by the ophthalmological and maxillary division of the trigeminal nerve. In the ophthalmic section, the trigeminal nerve advances from the ganglion on the lateral wall of the cavernous sinus and is divided into three branches; lacrimal, frontal, and nasociliary. The frontal part and the tears go in the eye socket via the superior orbital fissure above the tin ring that supplies the medial angle of the eye through the supratrochlear ramus, the upper eyelid through the tear and ramus supratrochlear, and the forehead through the supraorbital branch. The nasociliary branch enters the eye socket through the superior orbital fissure and supplies the eye through the ciliary branches. The facial muscles, which include the orbicularis oculi, procerus, corrugating supercili, and frontalis, get their motor supply from the branches of the facial nerve.

The parasympathetic supply, which controls the accommodation, papillary constriction, and lacrimal gland section, are innervated by the short posterior ciliary nerves Sympathetic care through the long ciliary nerves. The optic nerve is the extension of the brain, which is being covered by the arachnoid, dura, and pia mater. The orbital portion is long and less likely to be traumatized by orbital trauma.

The ocular common motor nerve is abducent nerve located in the common tendon ring and is less prone to injury. The trochlear nerve is more prone to injury because it runs along the top of the medial wall. A nerve that supplies the inferior oblique muscle is more prone to trauma because it leaves the shield of the lateral rectus and the inferior rectus along its path.

2.9.3 Vessels of the orbit:

Primarily by the ophthalmic artery provides the blood supply to the orbit, which is a branch of the internal carotid artery. The smallest contributions come from the external carotid artery through the internal maxillary artery and the face. The ocular artery enters the eye through the visual canal within the dural sheath of the optic nerve. The core fields of the ocular artery are:

- The eye muscles.
- Central artery of the retina (to the retina and optic nerve).
- Posterior ciliary arteries (long to the anterior segment and short to the choroid)

The external carotid artery supplies blood through the ophthalmic artery in the face and in the periorbital area.

The superior ophthalmic vein creates the major venous drainage from the orbit. Venous drainage arises in the upper nasal quadrant of the orbit and extends posteriorly across the superior orbital fissure to the cavernous sinus. The superior ophthalmic vein is the only diagonal intersection of the structure in axial CT slices.

2.9.4 Eyeball of the orbit:

The eyeball is globular shaped with three coats; Outermost Fibrous is lsclera, inner vascular choroid, and innermost nervous layer retina. The anterior one-fifth of the sclera is the transparent cornea. Behind the cornea, there is aqueous humor which gives nutrition to the cornea and other structures. Behind fluid aqupus there is the iris that divides anterior and posterior chambers. The human crystalline lens is suspended into the eye by a suspensory ligament, and it divides the eye into anterior and posterior segments. (American Academy of Ophthalmology, Orbit,Eyelid and Lacrimal system, Section VII, Page-17).

Chapter III

Materials and Methods

Materials and Methods

3.1 Study type: This study was designed as multicenter, parallel-group, single-blind, randomized controlled trial.

3.2 Study period: This study was conducted from 1^{st} May, 2016 to 30th April 2021.

3.3 Study place: This study was carried out in three hospitals located at Dhaka city as in the Department of Oral and Maxillofacial Surgery, Dhaka Dental College and Hospital (DDCH) Dhaka, in the Department of Oculoplasty, National Institute of Ophthalmology and Hospital (NIOH), Dhaka and Ispahani Islamia Eye Institute and Hospital (IIEIH), Dhaka.

3.4 Study population: Patients with enophthalmos and orbital floor fracture, age ranges from 15 to 70 years conserving male and female who actively participated from the outpatient department, in the Department of the Oral and Maxillofacial Surgery at DDCH, NIOH and IIEIH were selected as study population.

3.5 Sampling method: Random sampling. The selected patients were informed about the surgery. Those who have fulfilled and gave consent for the study and agreed to return for follow-up were enrolled for the study. Simple random sampling method was applied to generate the random number for performing the randomized control trial. Then Microsoft Excel was used to generate the random number.(Appendix, page-xxxiii)

3.6 Sample Size: In the conducted study 60 patients with enophthalmos with orbital floor fracture were divided into two groups. In which 30 patients were included under

Intervention (Titanium mesh) and 30 patients were under Control (Iliac bone graft). Each group contained 30 patients. Age range of the study population was from 15 to 70 years for each group.

3.7 Sample size calculation

Sample size was determined using the formula of hypothesis testing for a single proportion as follows:

$$n = \frac{\{Z_\beta\sqrt{P}(1-P)+Z_\alpha\sqrt{P_0}(1-P_0)\}^2}{(P-P_0)^2}$$ (Haque, 2021)

Here,

P= Expected proportion of patients to be corrected for enophthalmos after reconstruction = 75% = 0.75.

P_0 = Proportion when Null hypothesis is true = 50% = 0.50

Z_α = Z-value (two-tail) at 5% level of significance = 1.96

Z_β = Z-value (one-tail) at 80% power (when $\beta = 0.2$) = 0.85

$$n = \frac{\{0.85\sqrt{0.75}\,(1-0.75)^2 + 1.96\sqrt{0.5}\,(1-0.5)\}^2}{(0.75-0.50)^2}$$

$$n = \frac{(0.368+0.98)^2}{0.25^2}$$

$$n = \frac{1.817}{0.0625}$$

n=29.07 ≈ 30

n = 30

Therefore, the required number of patients needed to produce the expected outcome was 30 for Intervention group (Titanium Mesh) and another 30 for control group (Iliac bone grafting)

3.8 Sample size: A total number of 60 Patients with enophthalmos were operated in this study, of which 30 patients were in the Intervention group (Titanium Mesh) and the rest 30 patients in the Control group (Iliac Bone Graft).

3.9 Study Design

It was a randomized controlled study of patients attending in the Dept. of Oral and Maxillofacial Surgery in Dhaka Dental college Hospital, Dhaka, as well as Department of Oculoplasty, National Institute of Ophthalmology and Hospital (NIOH), Dhaka and Ispahani Islamia Eye Institute and Hospital (IIEIH), Dhaka. All the parameters for functional outcome were evaluated separately for each patient and put in tabulated form for detailed qualitative analysis. All the patients were followed up to 24 weeks and one each follow-up enophthalmos and all other post-operative parameters were evaluated.

3.10 Selection of the cases

Patients who attended in the Department of Oral and Maxillofacial Surgery, in Dhaka Dental College Hospital, Dhaka and Department of Oculoplasty, National Institute of Ophthalmology and Hospital (NIOH), Dhaka and Ispahani Islamia Eye Institute and Hospital (IIEIH), Dhaka for orbital floor fracture with enophthalmos. The selections were based on certain inclusion and exclusion criteria.

3.11 Selection criteria

Inclusion criteria:

1. Patients with enophthalmos due to orbital floor fracture need surgical correction
2. Age group: 15- 70 years.
3. Both male and female.
4. Orbital floor fracture not older than 14 days
5. Enophthalmos more than 2 mm

Exclusion criteria:

1. A fracture involving the roof of the orbit
2. Orbital floor fractures in both sides
3. In such cases, where orbital floor reconstruction is failed
4. Patients suffering from uncontrolled diabetic Mellitus, thyroid abnormalities
5. Patients with a history of previous neurological deficit
6. Orbital floor fracture due to other pathology such as multiple myeloma, other carcinomas
7. Debilitated patient with orbital floor fracture unfit for surgical management.
8. Multiple craniofacial fracture

3.12 Ethical consideration:

a) A research protocol was approved by the ethical review committee of Bangladesh Medical Research Council (BMRC) and ethical clearance committee of Dhaka Dental College (DDC) before starting this study (Appendix-I & II).
b) Informed written consent (English/Bengali version) was taken from each patient (Appendix-IV).
c) The purpose and procedure were briefly explained to all participants.
d) The final database and report do not contain the names of participants.
e) There was less chance of major physical risk.
f) There was hardly any possibility of mental or social harm in the participation of the study.
g) All the participants were treated if they desired.
h) All sorts of confidentiality were ensured.
i) No money was given to the participants of the study.

Informed consent: For this study, a well-informed, voluntarily signed written consent was taken in an understandable local language from the study subjects after convincing them that their privacy & confidentiality would be safeguarded. If there was any injury or complication as a result of the study, proper treatment was available. However, no monetary compensation was provided for the loss of work time.

Confidentiality: To maintain Confidentiality, each of the study subjects was given a special ID number which will be followed during each and every step of the study Procedure. All the research data was coded and stored in a locked cabinet. Only research personnel would be allowed to access the data.

Use of hospital records: Hospital records, especially the investigation reports were needed to fill up the data collection sheet. The data collection sheet was filled up after taking a brief interview of 20-30 minutes from the participants.

Procedure of maintaining confidentiality:

1. A signed informed consent was taken after convincing all the study subjects that their confidentiality would be safeguarded & privacy maintained.
2. To maintain Confidentiality, each of the study subjects was given a special ID number which was followed during each and every step of the study procedure.
3. All the research data were coded and stored in a locked cabinet. Only research personnel would be allowed to access the data.
4. Privacy was maintained during physical examination & interview and also at the time of procedure.

3.13 Key Variables to be studied:

Demographic variables

- Age
- Gender
- socio-economic condition
- Incidence of aetiology

Outcome variables:

- Facial symmetry
- Degree of Diplopia
- Extraocular muscle limitation
- Enophthalmos measured by Hertel Exophthalmometer
- Ocular motility (up gaze, down gaze, medial gaze, lateral gaze)
- Visual acuity
- Implant migrated
- Signs of infection

3.14 Socio-economic condition (salaryexplorer.com)

Economic condition of the participants was ascertained by interviewing the parents or guardians regarding their monthly income from all possible sources. For the purpose of simplicity the subjects were classified into different income groups.

1. Lower income group :The person who had monthly income less than Taka 15,000/-
2. Middle income group :The person who had monthly income between Taka 15,000-30,000/-
3. Upper income group :The person who had monthly income above Taka 30,000/-

Source: salaryexplorer.com

3.15 Operational Definitions:

Orbital floor fracture

It is defined as a traumatic deformity of the orbital floor typically result from impact of blunt object larger that hits orbital aperture or eye socket (Bowling, 2016).

Enophthalmos: Posterior displacement of eye-ball, including orbital contents. It describes the position of the eye moving more posterior than its normal position compared to other eye (Bowling, 2016).

Diplopia: Double vision as complained by patients (Bowling, 2016).

Infection: Infection is the multiplication of an infectious agent within the body causing disease (Penman et al., 2022).

Single blind: This treatment was applied where the surgeon knew the treatment but the patient was unaware, it means that the patient was informed about titanium mesh and bone graft. Moreover, the patient was also informed about titanium mesh and the bone graft, either of the treatment would be used. The patients were previously informed about the study before the operation and they happily gave their positive consent (Haque, 2021).

Parallel group: Orbital floor is reconstructed by two groups of materials- the Intervention group (Titanium mesh) and Control group (Iliac bone graft). These two groups ran side by side which indicates this study was parallel. Furthermore, these two groups would be separately treated by different groups for the correction of enophthalmos (Haque, 2021).

Allocation: Patients were divided into two groups named as Intervention group and Control group. The intervention group was treated with titanium mesh, and the Control group was treated with iliac bone graft (Haque, 2021).

A. Type of Fracture based on C T images: (Harris et al, 1998)

Type IA. No orbital soft tissue is visible within the maxillary sinus.

Type IB. Orbital soft tissue is visible within the maxillary sinus.

Type IIA. There is no herniation of soft tissue or the displacement of the soft tissue is less than the distracted bone fragment.

Type IIB. The herniation of soft tissue is greater than the distracted bone fragment.

Type IIIA. Soft tissue and bone are moderately displaced towards the maxillary sinus.

Type IIIB. Soft tissue and bone are markedly displaced towards the maxillary sinus

Ophthalmological evaluation done by Ophthalmologist by the Oculoplasty Department of National Institute of Ophthalmology, Dhaka and Ispahani Islamia Eye Institute and Hospital, Dhaka.

B. In case of Degree of Diplopia: (Grant et al., 2002)

- 0 = If the patient does not complain of diplopia.
- 1 = If the patient complains of diplopia when looking up or down at an angle greater than 45° from the horizon
- 2 = If the angle is between 30° and 45°
- 3= If the angle is within 15th and
- 4= When looking straight ahead.

In case of Extra Ocular muscle (Inferior rectus) limitation: (Grant et al., 2002)

- 0 = If eye movement is the same as that of a normal eye
- 1 = If the distance measured from the bottom boundary of the cornea of the healthy side to the bottom boundary of the cornea of the affected side with the eye looking up as high as possible is no longer than 1 mm
- 2 = If the distance is between 1 and 2 mm
- 3= If the distance is between 2 and 3 mm
- 4= If the distance is longer than 3mm

Visual Acuity (Basak, 2016)

1= 6/6-6/9 = No impairment

2= 6/12-6/18 = Visual impairment
3= 6/24-6/60 = Severe impairment
4= <6/60 = Very severe impairment
1= 6/6-6/9 = No impairment

Diplopia charts

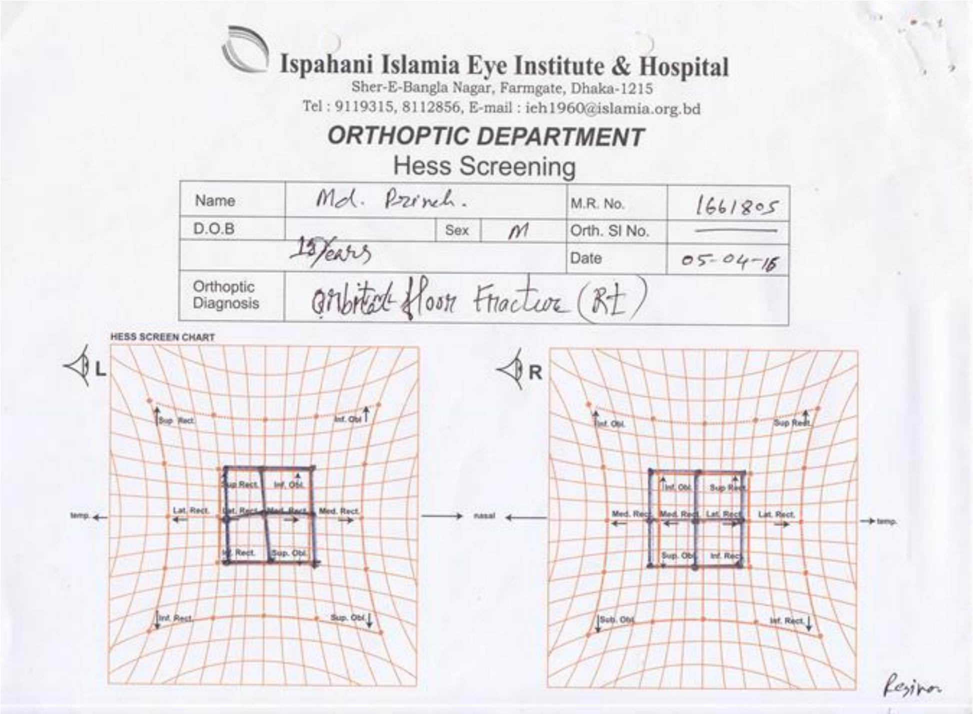
This can be a useful tool for differential diagnosis of incomitancy without a Hess chart. It works by the patient vi8ewign a vertical bar of light though red and green goggles at a set distance (50cm). The goggles are made to have the red lens over the right eye and the green lens over the left eye. The bar of light is then moved into the nine positions of gaze and the patient is asked to describe the appearance and separation. The symbol $ is used to describe superimposition of the lines. When interpreting diplopia it should be remembered that the most distal image belongs to the underacting eye. The position of the image is the reverse of the position of the eye (Zubair and Touseef, 2005).

Hertelexophthalmometer: This instrument measures the tip of the cornea with a reference cone on the device to record corneal alignment on a millimeter scale. Hertelexophthalmometry is the most suitable measurement technique for enophthalmos measurement O'Donnell et al. (1999).

Figure 3.1: Hertel Exophthalmometer for measurement of enophthalmos (mm)

Hess chart/Less screen

This method of analysis is a major advantage in providing the differential diagnosis in diplopia. The patient is seated squarely facing the screen being plotted. The head is cantered to the fixation spot being used. The central positions are plotted firs. The fixation point is then moved around in 15° intervals. This should be done ensuring that the head does not move. Interpretation of a Hess chart can be difficult. However, a number of basic principles are applied: - the smaller field belongs to the eye with the defect, neurogenic paresis will show the muscle sequele to a greater or lesser extent and mechanical defects show a compressed field. The last rule is one of more importance in blow-out fractures. The compressed field is not normally and obvious over action of the direct antagonist, nor under action of the contra lateral antagonist, so the effects of the defect are limited to the direction of action of the mechanical restriction. The other obvious feature of a mechanical defect is the marked over activity of the contra lateral synergist. However, the drawback of this technique is that t6he plotting o diplopia largely depends on the degree of ocular motility (Zubair and Touseef, 2005).



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ORTHOPTIC DEPARTMENT
Hess Screening

Name	Md. Rzineh.			M.R. No.	1661805
D.O.B		Sex	M	Orth. Sl No.	———
	15 Years			Date	05-04-16
Orthoptic Diagnosis	Orbital floor Fracture (Rt)				

Rezina

Figure 3.2: Hess chart for measurement of diplopia

Titanium Mesh: Titanium mesh is thin, stiff and easy to contour. They are easily stabilized, maintain their shape, and have the unique ability to compensate for volume without the potential for resorption. It is highly biocompatible material.

Figure 3.3: Titanium mesh (Pure) by Medicon made in Germany

Osteoinduction: It is the formation of bone by connective tissue cells transformed into osteocompetent cells by inductive agent, usually proteins such as bone morphogenetic protein.

Osteoconduction: It is describes bone formation by the process of ingrowth of capillaries and osteoprogenitor cells from the recipient bed into, around and through a graft or implant which acts as a scaffold for new bone formation.

Osteogenesis: It is the process of new bone formation. Osteoblasts of the transplanted bone graft and of fractured bone are responsible for this process.

Subcilliary: This incision is made 2mm below the edge of the eyelid.

Subtarsal: It is a mid-tarsal incision and made between the edge and the orbital rim

Transconjunctival: This approach involves no disruption of the outer surface of the eye lid. The lower lid is pulled forward. To help increase the laxity of the lid a lateral canthotomy cab be performed.

Armamentarium:

- Bard Parker Blade No. 15 and No. 10.
- Moltz no. 9 Periosteal Elevator
- Howarth’s periosteal Elevator
- Tongue Depressor
- Langenback’s Retractor
- Micromotor and NSK Straight Handpiece
- Titanium Drill Bits -1.5 mm
- Titanium mesh made in Germany
- Titanium Screws 5 mm length and 1.5 mm width and 1mm diameter Drill Bits made by Titanium (1mm)
- Bone Holding Forceps
- Wire twister , Wire Cutter and 26 Gauge Wire
- Titanium Screw driver and screw holder

3.16 Study procedure

Patient preparation: A standard history sheet containing all the variables of interest was prepared for collecting relevant information from each patient. Demographic information to be collected is age, sex, and socioeconomic condition. Relevant baseline clinical information was needed to select or to exclude patient's history of known systemic comorbidity and not fit for surgical management.

Furthermore, the patient was examined for facial asymmetry, step deformity, periorbital swelling, or oedema, movement of the eye, backward displacement of the eye, and visual acuity. On admission, all patients were undergone routine blood tests, including blood grouping and cross-matching, Biochemical investigations like random blood sugar, serum urea, and serum creatinine. ECG was done to detect any abnormality in aged (more than 40 years) patients. X-ray chest (postero-anterior view) was performed to check for any abnormality in the heart and lungs. Preoperatively CT scan of orbit with 3D images was conducted in every case.

For reconstruction of orbital floor fractures, the materials and instruments to be used were pure Titanium mesh (rectangular, multiple-hole with a gap) made in Germany, pure titanium bone screws (Length 5mm and Width 1.5 mm), round-nosed pliers, straight and angled wire-cutting scissors, twist drills with stops, self-tapping titanium screwdriver with a screw holding device.

Randomization was done in all cases before surgery.

Surgical procedure for titanium mesh and iliac bone graft:

- General Anesthesia: Proper patient assessment and anesthesia
- Tarsorraphy: Tarsorraphy was performed on the affected eye before giving incision.
- Incision: The orbit was explored by approach through subcilliary/subtersal, transconjunctival/infraorbital incision. The periosteum was sharply incised at the infraorbital rim, and the fractured area was exposed.
- Implant fixation: The prolapsed orbital content was repositioned. The orbital

floor was reconstructed using titanium mesh with titanium screws.

- Iliac bone grafting procedure:
  - Ipsilateral iliac crest was selected for graft.
  - Perineal region was shaved and was prepared with an antiseptic solution.
  - A roll is placed under the supine positioned patient to elevate the iliac crest by lateral rotation of the hip.
  - Incision was then mapped out with marking ink at a distance 2 cm lateral to the iliac crest avoiding the lateral femoral cutaneous nerve. It started from 1 cm posterior to the anterior superior iliac spine upto 2cm anterior to the posterior iliac tubercle.
  - Incision line was infiltrated with 2% adrenaline.
  - Incision was then started by keeping the abdominal musculature taut after incising the skin and subcutaneous tissue. Electrocautery was used for hemostatic control. The incision is then manipulated to be centered on the crest. A sharp dissection was completed through the external and internal oblique musculature and periosteal layers to gain access to the bony crest. A subperiosteal reflection of the iliac crest in the medial direction was done to avoid dissection of the tensor fascia lata muscles laterally, to overcome gate disturbances. Osteotomy was done with conventional chisel and mallet in" hollowed crest" approach (Tschop approach) by decapping the crest and reflecting the crest cap laterally. The desired inner cortical bone was harvested from the central portion.
  - The harvested iliac graft was shaped, contoured, and stabilized at the orbital floor defect to reconstruct the orbital floor fracture.

    - Hemostasis was achieved with electrocautery of small perforating vessels or placement of bone wax.
    - A suction drain was kept at low intermittent level.
- Stitches: Periosteam and subcutaneous tissues were stitched by 3/0 vicryl, layer by layer. Skin was closed by 4/0 prolene.

Post- operative management and follow-up

1. Antibiotics in per-enteral form were given for five days-3rd generation cephalosporin and clindamycin.
2. Adequate analgesia was ensured by Ketorolac tromethamine or Diclofenac sodium or Ibuprofen in oral, suppository, and intramuscular injection form.
3. Steroids and H_2 receptor blocker like Ranitidine was given in some patients to reduce post-operative oedema and stress ulcer.
4. Wound dressing of both donor and recipient site was given after 3rd POD.
5. Skin sutures were removed after seven days post operatively.
6. Remove the drain after 48-72 hours after surgery.

Follow-up and outcome measure:

The patients were followed-up after the operation till 24 weeks. The patients were examined on 1st week, 4th week, 12th week, and 24th postoperative week. Postoperative computed tomogram was obtained to verify implant position and correction of enophthalmos (12 & 24th week). The facial asymmetry, ocular motility, sign of infection, and extrusion of the graft was examined in the follow-up period to see the post- operative outcomes. Furthermore, visual acuity was measured by Snellen,s test. Enophthalmos measured by Hertel Exophthalmometer.

3.17 Data collection:

Data were collected using a structured questionnaire (research instrument) containing all the variables of interest. The data was collected by the researcher himself.

3.18 Data processing and analyses:

Data were processed and analyzed using SPSS (Statistical Package for Social Sciences) version 23. Test statistics to be used to analyze the data were descriptive statistics, Chi- square or Fisher's Exact Probability Test, and Student's t-Test. Categorical data are compared between the groups using Chi-square (or Fisher's Exact), while continuous variables were compared between groups with the help of Student's t-Test. Comparison of data before and after reconstruction was being done using Chi-square if the data are categorical one and with the help of paired-sample t-test if the data were continuous one. Level of significance was set at 0.05 and $p < 0.05$ considered significant.

Chapter IV

Results

RESULTS

A study was conducted to compare the efficacy of titanium mesh and iliac bone graft. 30 patients were in the titanium group and other 30 patients in the iliac bone graft were conducted in this study.

4.1 Demography of the patients:

Table 4.1: Age distribution of the participants by Intervention (Titanium mesh) and Control (Iliac bone graft) groups in orbital floor fracture (N=60)

Demographic variables	Group		P value
	Intervention (Titanium mesh) N=30	Control (Iliac bone graft) N=30	
Age (years)			
○ ≤20	5 (16.7%)	9 (30.0%)	
○ 21-30	13 (43.3%)	8 (26.7%)	
○ 31-40	8 (26.7%)	8 (26.7%)	
○ 41-50	3 (10.0%)	3 (10.0%)	
○ 51-60	1 (3.3%)	1 (3.3%)	
○ >60	0 (0.0%)	1 (3.3%)	
Mean ± SD	33.70 ± 4.8	30.7 ± 7.88	0.991[c]

[c] Unpaired t-test was done to measure the level of significance.

From table 4.1, it is observed that there is no significant difference in the age group of patients affected due to orbital floor fracture. About the choice of titanium mesh and iliac bone graft, the patients are treated by both treatment similarities. Out of the 60 orbital floor fracture patients, the highest patients were 21 (35%) were observed in the age group of 21-30 years.

4.2 Reasons of the orbital floor fractures

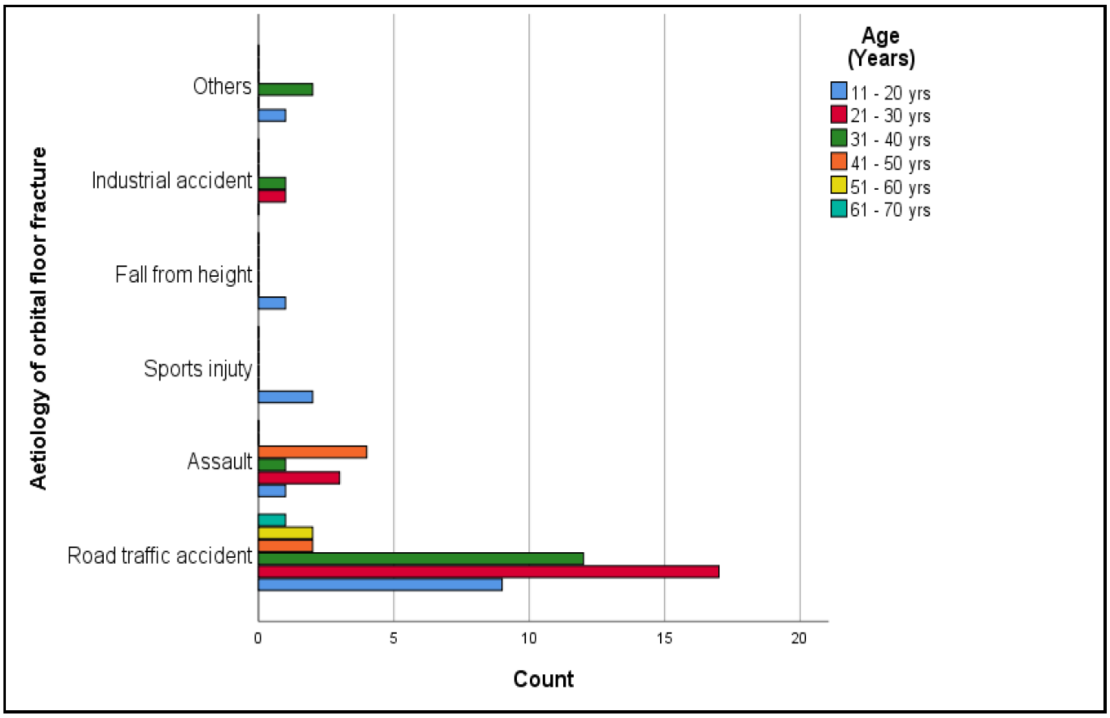

Figure 4.1: Aetiology of orbital floor fracture related with different age groups

In orbital floor fracture patients, road traffic accident was the most common cause of injury where most common incident age range was 21-30 years and 31-40 respectively.

4.3 Gender distribution of the orbital floor fracture

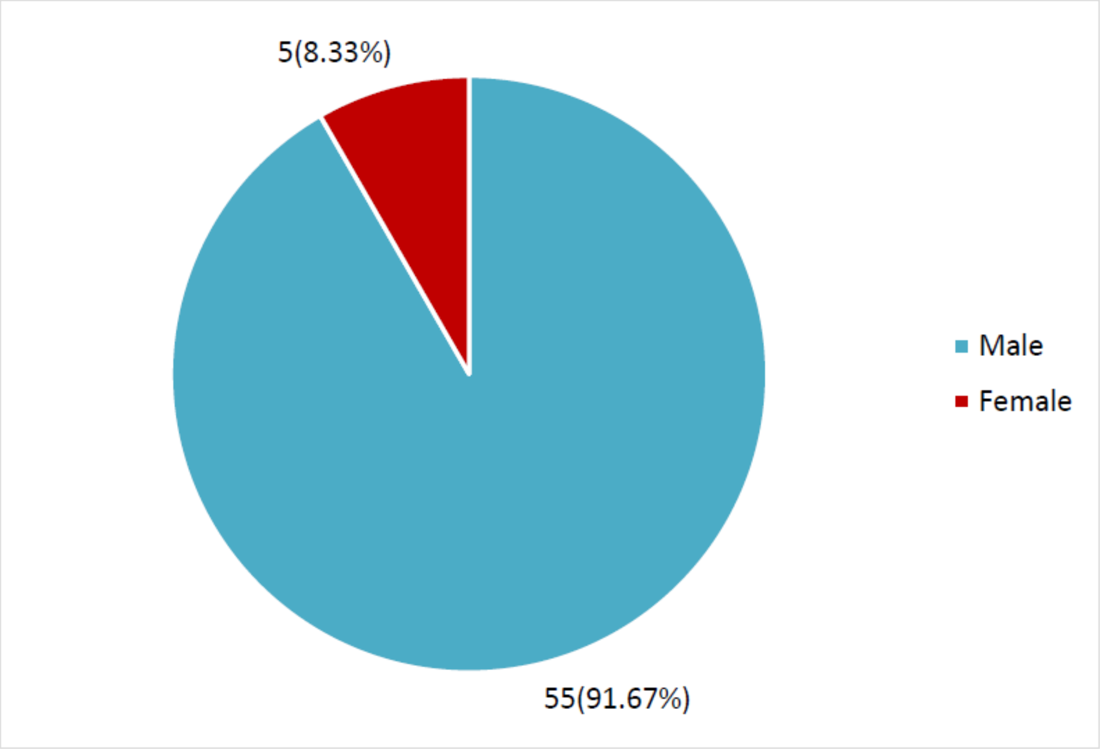

Figure 4.2: Gender distribution of the study participants

Among the orbital floor fracture patients, male was predominant. Male female ratio was 11:1.

4.4 Relationship between gender and causes of orbital floor fracture

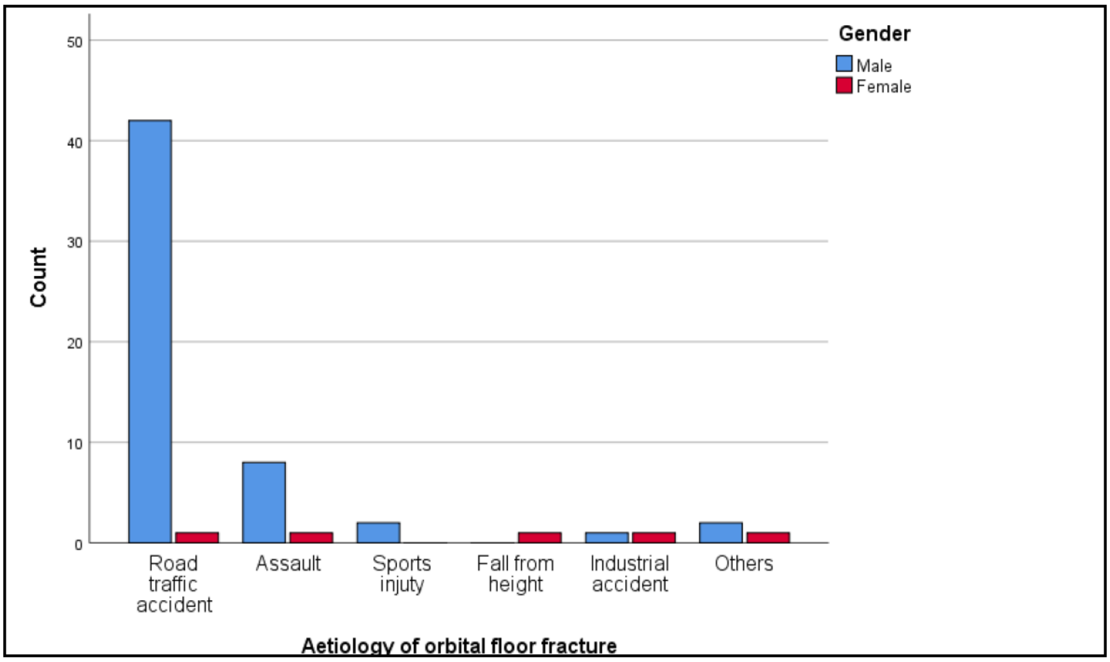

Figure 4.3: Aetiology of Orbital Floor Fracture related to Gender Distribution.

4.5 Relationship between income group and orbital floor fracture of intervention and control groups

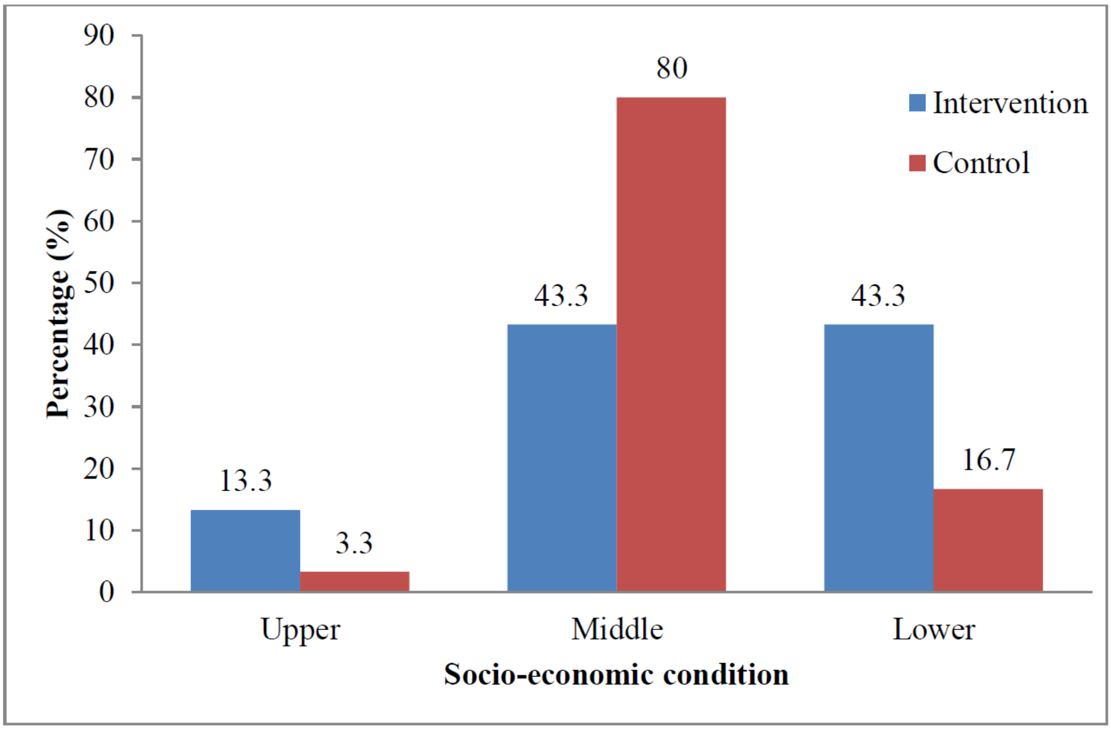

Figure 4.4: Patients according to socio-economic condition by Intervention (Titanium mesh) and Control (Iliac bone graft) groups

4.6 Gender distribution between intervention and control groups

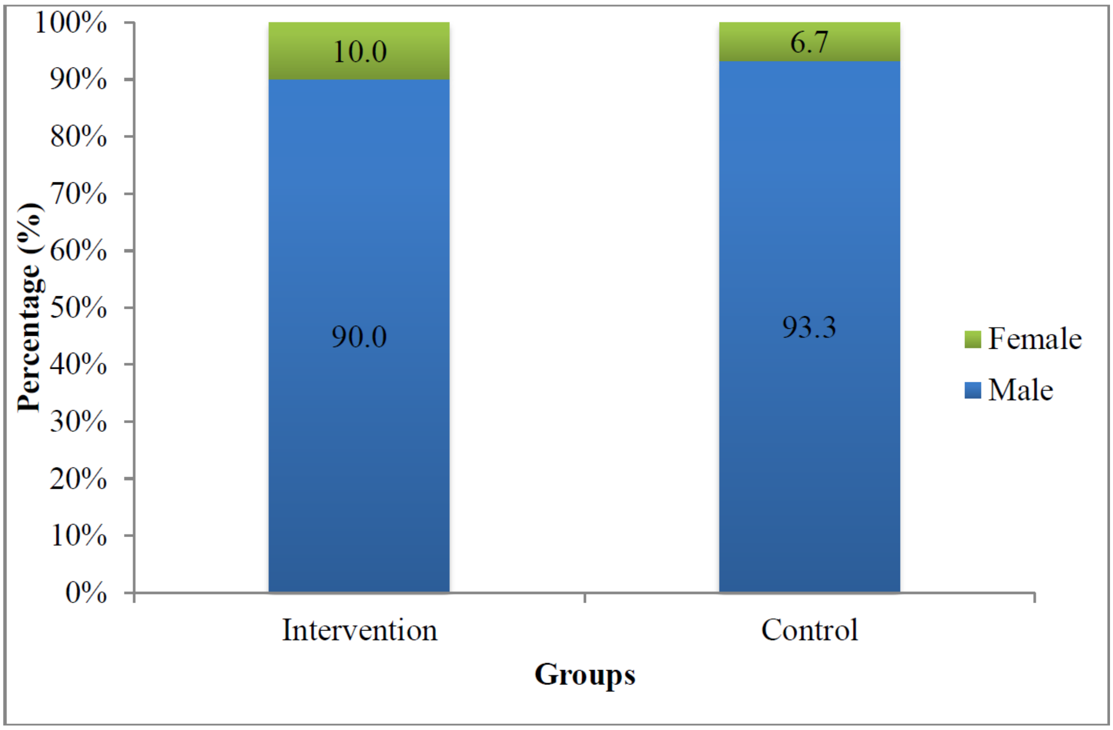

Figure 4.5: Gender distribution between Intervention (Titanium mesh) and Control (Iliac bone graft) groups

4.7 Involved orbit of orbital floor fracture patients

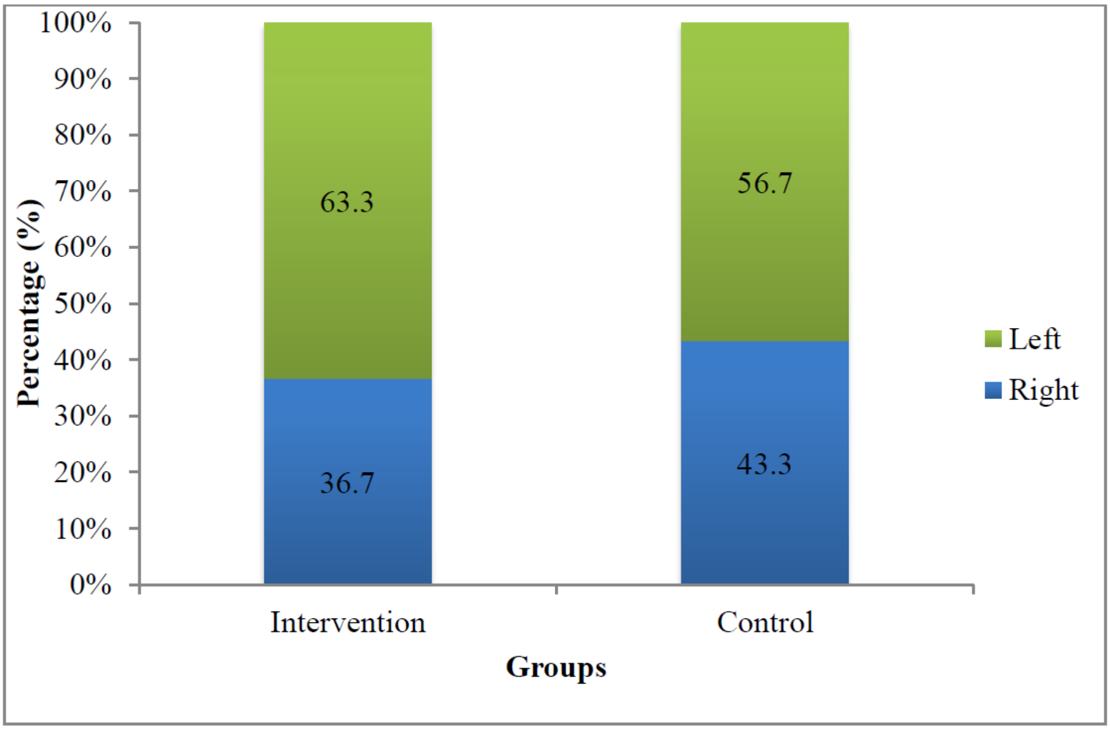

Figure 4.6: Involved orbit by Intervention (Titanium mesh) and Control (Iliac bone graft) groups

4.8 Aetiology of orbital floor fracture

Table 4.2: Comparison of the patients according to Aetiology by groups (N=60)

Aetiology of orbital floor fracture	Intervention (Titanium mesh) N=30	Control (Iliac bone graft) N=30	P value
○ Road traffic accident	27 (90.0%)	16 (53.3%)	0.002[a]
○ Assault	1 (3.3%)	8 (26.7%)	0.026[b]
○ Sports injury	0 (0.0%)	2 (6.7%)	0.492[b]
○ Fall from height	1 (3.3%)	0 (0.0%)	0.999[b]
○ Industrial accident	1 (3.3%)	1 (3.3%)	0.999[b]
○ Others	0 (0.0%)	3 (10.0%)	0.237[b]

[a]Chi-square test was done to measure the level of significance.
[b]Fisher's Exact test was done to measure the level of significance.

From table 4.2 it is observed that the causes of orbital floor fracture is due to road traffic accident. Among the 60 patients 43 patients were injured due to road traffic accident (table 4.2) which is 72% of the total incoming orbital fractured patients. The p value of the road traffic accident is 0.002, which is highly statistically significant. It implies that main cause of orbital floor fracture is road traffic accident. There is no statistically significant difference among the other causes of orbital floor fracture ($p>0.05$).

4.9 Classification of orbital floor patients by CT scan

Table 4.3: Comparison of the patients according to Type of fracture by groups (N=60)

Type of fracture based on CT images	Intervention (Titanium mesh) N=30	Control (Iliac bone graft) N=30	P value
○ IIA	0 (0.0%)	1 (3.3%)	0.999[b]
○ IIB	2 (6.7%)	4 (13.3%)	0.671[b]
○ IIIA	20 (66.7%)	13 (43.3%)	0.069[a]
○ IIIB	8 (26.7%)	12 (40.0%)	0.273[a]

[a] Chi-square test was done to measure the level of significance.
[b] Fisher's Exact test was done to measure the level of significance.

Table 4.3 shows orbital floor fracture occurs mostly in the type IIIA, 20 (66.7%) in intervention group and 13 (43.3%) in control group. There was no statistically significant difference among the other causes of orbital floor fracture (p>0.05).

4.10 Surgical approach of orbital floor reconstruction

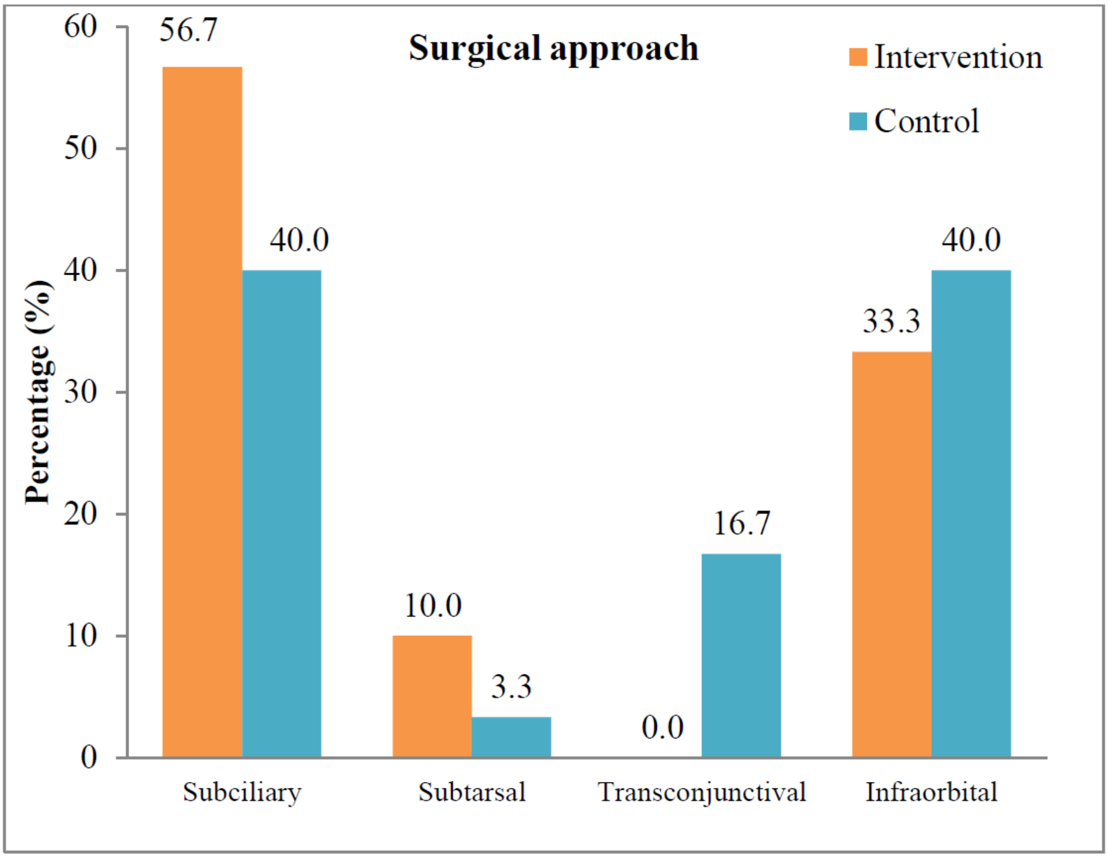

Figure 4.7: Patients according to surgical approach by Intervention (Titanium mesh) and Control (Iliac bone graft) groups in floor fracture

4.11 Preoperative and postoperative visual acuity evaluation

Table 4.4: Comparison of the patients according to Visual acuity (N=60)

Visual Acuity	Group		P value*
	Intervention (Titanium mesh) N=30	**Control (Iliac bone graft) N=30**	
Preoperative evaluation			
o 6/6-6/9	8 (26.7%)	3 (10.0%)	0.385
o 6/12-6/18	12 (40.0%)	16 (53.3%)	
o 6/24-6/60	8 (26.7%)	8 (26.7%)	
o <6/60	2 (6. %7)	3 (10.0%)	
Post-op At 1st week			
o 6/6-6/9	8 (26.7%)	2 (6.7%)	0.226
o 6/12-6/18	12 (40.0%)	15 (50.0%)	
o 6/24-6/60	8 (26.7%)	10 (33.3%)	
o <6/60	2 (6.7%)	3 (10.0%)	
At 4th week			
o 6/6-6/9	16 (53.3%)	4 (13.3%)	0.011
o 6/12-6/18	10 (33.3%)	16 (53.3%)	
o 6/24-6/60	3 (10.0%)	7 (23.3%)	
o <6/60	1 (3.3%)	3 (10.0%)	
At 12th week			
o 6/6-6/9	18 (60.0%)	12 (40.0%)	0.173
o 6/12-6/18	10 (33.3%)	10 (33.3%)	
o 6/24-6/60	2 (6.7%)	7 (23.3%)	
o <6/60	0 (0.0%)	1 (3.3%)	
At 24th week			
o 6/6-6/9	21 (70.0%)	19 (63.3%)	0.605
o 6/12-6/18	7 (23.3%)	6 (20.0%)	
o 6/24-6/60	2 (6.7%)	4 (13.3%)	
o <6/60	0 (0.0%)	1 (3.3%)	

*Chi-square test was done to measure the level of significance.

4.12 Preoperative and postoperative evaluation of facial asymmetry

Table 4.5: Comparison of the patients according to Facial asymmetry by groups (N=60)

Facial asymmetry	Group		P value
	Intervention (Titanium mesh) N=30	Control (Iliac bone graft) N=30	
Preoperative evaluation			
○ Present	30 (100.0%)	30 (100.0%)	
Post-op at 1st week			
○ Corrected	25 (83.3%)	22 (73.3%)	0.347[a]
○ Not corrected	5 (16.7%)	8 (26.7%)	
At 4th week			
○ Corrected	30 (100.0%)	30 (100.0%)	
At 12th week			
○ Corrected	30 (100.0%)	30 (100.0%)	
At 24th week			
○ Corrected	30 (100.0%)	30 (100.0%)	

[a]Chi-square test was done to measure the level of significance.

Table-4.5 shows preoperative and postoperative evaluation of both intervention and control group by facial asymmetry. In intervention group 25 (83.3%) patients had facial asymmetry corrected in the 1st postoperative week whereas in control group 22 (73.3%) corrected in control group. In 4th, 12th and 24th postoperative weeks all patients in both groups were corrected in facial asymmetry.

4.13 Correction of enophthalmos of orbital floor fracture patients by titanium mesh and iliac bone graft

Table 4.6: Comparison of the patients according to Correction of Enophthalmos by groups (N=60)

Enophthalmos correcttion	Groups		p value*
	Intervention (Titanium mesh) N=30	**Control (Iliac bone graft) N=30**	
Corrected	28 (93.3)	26 (86.7)	0.671
Not corrected	2 (6.7)	4 (13.3)	
Total	**30 (100.0)**	**30 (100.0)**	

*Fisher's Exact test was done to measure the level of significance.

Table 4.6 shows that enophthalmos correction was 28(93.3%) patients in the intervention group and 26(86.7%) in the control group. On the other hand, 2(6.7%) patients are not corrected in the intervention group and 4(13.3%) patients in the control group.

4.14 Preoperative and postoperative enophthalmos correction between two groups

Table 4.7: Comparison of pre and post-operative enophthalmos correction by Intervention (Titanium mesh) and Control (Iliac bone graft) groups in floor fracture (N=60)

Enophthalmos measured by Hertel Exophthalmometer (mm)	Group		P value
	Intervention (Titanium mesh) N=30	Control (Iliac bone graft) N=30	
Preoperative evaluation	16.30 ± 1.70	16.23 ± 2.50	0.904
Normal eye (Uninjured eye)	19.37 ± 1.59	19.17 ± 2.45	0.709
Post- op At 1st week	17.80 ± 1.52	17.77 ± 2.60	0.952
At 4th week	19.03 ± 1.65	18.27 ± 2.64	0.183
At 12th week	19.23 ± 1.55	18.60 ± 2.47	0.239
At 24th week	19.30 ± 1.56	19.00 ± 2.49	0.578

Post-op= post-operative, SD= Standard deviation, n= number of patients. Data were expressed as Mean ± SD.

From table 4.7, it is seen that Enophthalmos patients normal eye (uninjured eye) had Hertel Exophthalmometer (HE) (mm) reading of 19.37±1.59 and 19.17±2.45 in Titanium mesh (TiM) and Iliac bone graft (IBG) respectively. Hertel Exophthalmometer (mm) of injured eyes of titanium mesh and iliac bone graft patients are 16.30±1.70 and 16.23±2.50 respectively. In next few weeks of operation, the patients HE (mm) started to increase at 24th week the HE measurement of injured eyes of Titanium mesh and Iliac bone graft became almost same, because there is no statistical significance between the two groups at 4th weeks, 12th weeks and 24th weeks of after operation. So, it is clear that the iliac bone graft is not superior to titanium mesh.

Table 4.8: Statistical analysis

	Intervention (Titanium mesh)		Control (Iliac bone graft)	
Preoperative vs.	**Mean difference**	**P value[a]**	**Mean difference**	**P value[a]**
Post-operative				
At 1st week	-1.50	<0.001	-1.53	<0.001
At 4th week	-2.73	<0.001	-2.03	<0.001
At 12th week	-2.93	<0.001	-2.37	<0.001
At 24th week	-3.00	<0.001	-2.77	<0.001

[a] Paired t test was done to measure the level of significance.

From Table 4.8, it is evident that - correction of enophthalmos between preoperative and postoperative, at 1st, 4th, 12th and 24th week, between intervention and control group, is showing statistically significant (p<0.001).

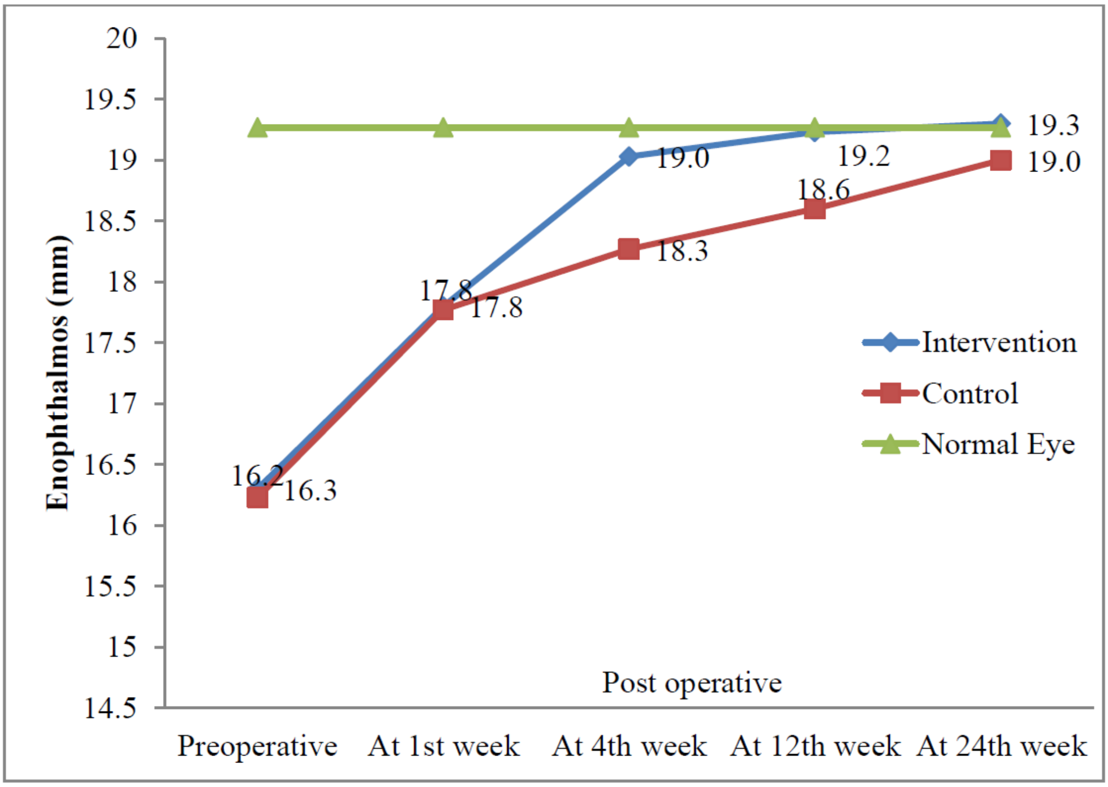

Figure 4.8: Line diagram showing the change of mean Enophthalmos between Intervention (Titanium mesh) and Control (Iliac bone graft) groups in different postoperative follow-up

Gradually increase correction of enophthalmos in both intervention and control group in 1st postoperative week. At 4th postoperative week, intervention group correction of enophthalmos is more than control group.

4.15 Correction of enophthalmos by different groups

Table 4.9: Means and Medians for time of correction of enophthalmos in different groups (N=60)

Enophthalmos correction	Groups		p value*
	Intervention (Titanium mesh) N=30	**Control (Iliac bone graft) N=30**	
Mean (95% CI)	8.43 weeks (5.50-11.37)	14.93 weeks (11.67-18.20)	0.020
Median (95% CI)	4 (3.32-4.69)weeks	12 (5.30-18.70)weeks	

Statistical analysis was done by Log Rank test and P value was considered as significant (<0.05) at 95% Confidence Interval.

Table-4.9 shows that, there is a statistically significant difference between the Means and Medians for time of correction of enophthalmos in different groups (p<0.02). It means that titanium mesh treated patients took significantly lesser time than the patients treated by iliac bone graft to correct enophthalmos. The mean time of correction of enophthalmos was 8.43 weeks. Whereas iliac bone graft is it was 14.93. For titanium mesh, median correction of enophthalmos is 4 weeks whereas iliac bone graft is 12 weeks.

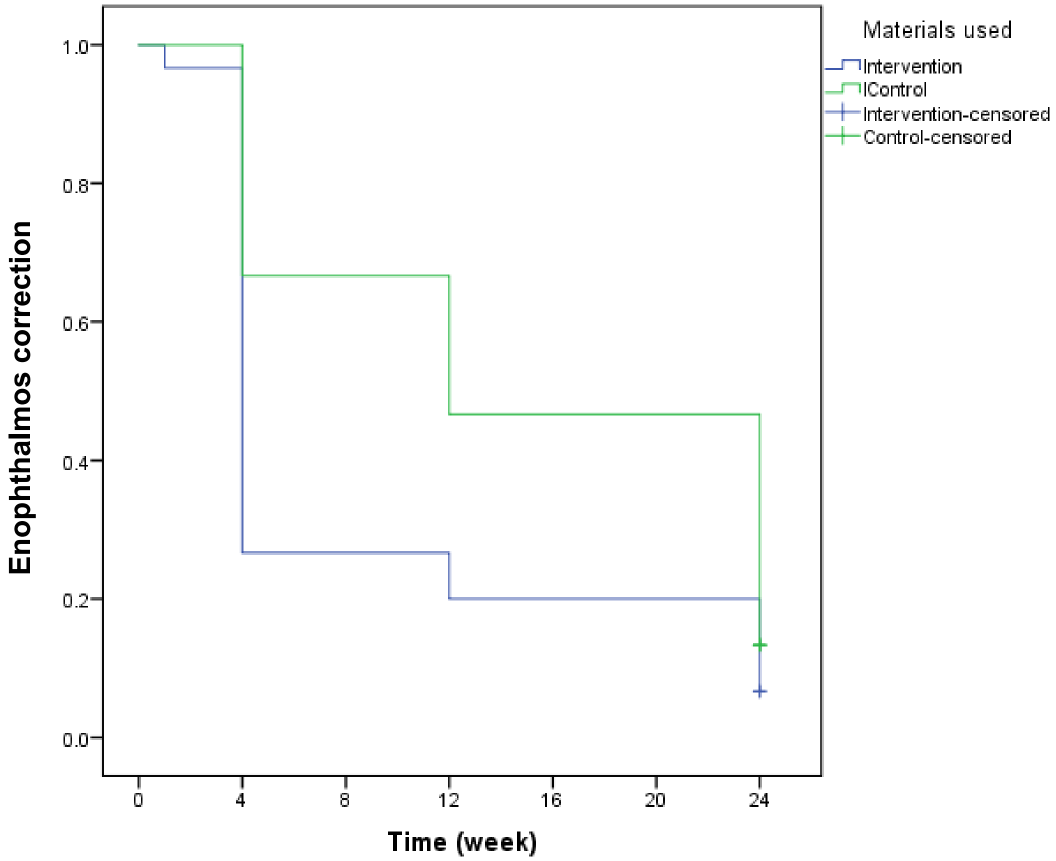

Figure 4.9: Kaplan Meier curve was plotted to observe the difference in time (week) to cure like normal eye between intervention and control groups based on different follow- up data using the log-rank test.

According to Kaplan Meier curve, between Intervention (Titanium mesh) and Control (Iliac bone graft) groups, Enophthalmos was corrected at 4 weeks earlier than Iliac bone graft.

4.16 Preoperative and postoperative orbital swelling with different follow-ups

Table 4.10: Comparison of the patients according to Periorbital swelling by Intervention (Titanium mesh) and Control (Iliac bone graft) groups in floor fracture (N=60)

Periorbital Swelling	**Group**		**p value**
	Intervention (Titanium mesh) N=30	**Control (Iliac bone graft) N=30**	
Preoperative Evaluation	30 (100.0%)	30 (100.0%)	
Post- op At 1st week	3 (10.0%)	8 (26.7%)	0.095[a]
At 4th week	0 (0.0%)	0 (0.0%)	
At 12th week	0 (0.0%)	0 (0.0%)	
At 24th week	0 (0.0%)	0 (0.0%)	

[a] Chi-square test was done to measure the level of significance.

Table shows at 1st postoperative week 3 (10.0%) had periorbital swelling in the intervention group but 8 (26.7%) had periorbital swelling in the control group. The difference was not statistically significant.

4.17 Ocular motility evaluation by different groups

Table 4.11: Comparison of the patients according to Ocular motility by Intervention (Titanium mesh) and Control (Iliac bone graft) groups in floor fracture (N=60)

Ocular motility	Group		p value
	Intervention (Titanium mesh) N=30	**Control (Iliac bone graft) N=30**	
Preoperative evaluation			
Up gaze			
○ Restricted	30 (100.0%)	30 (100.0%)	
Down gaze			
○ Not restricted	25 (83.3%)	27 (90.0%)	0.706[b]
○ Restricted	5 (16.7%)	3 (10.0%)	
Medial gaze			
○ Not restricted	21 (70.0%)	21 (70.0%)	0.999[a]
○ Restricted	9 (30.0%)	9 (30.0%)	
Lateral gaze			
○ Not restricted	19 (63.3%)	26 (86.7%)	0.037[a]
○ Restricted	11 (36.7%)	4 (13.3%)	

[a]Chi-square test was done to measure the level of significance.
[b]Fisher's Exact test was done to measure the level of significance.

Table 4.11 shows Ocular motility score was assessed in preoperative and at 1st, 4th, 12th, 24th post-operative weeks in both groups. On 1st postoperative week 25(83.3%) patients recovered in intervention group and 23(76.7%) patients in control group in up gaze. Ocular motility was normal after 4th postoperative week in both groups in all gazes. It was not statistically significant.

Table 4.12: Comparison of the patients according to Ocular motility by groups (N=60)

Ocular motility	Group		p value
	Intervention (Titanium mesh) N=30	Control (Iliac bone graft) N=30	
Post-op 1st week			
Up gaze			
○ Not restricted	25 (83.3%)	23 (76.7%)	0.508[a]
○ Restricted	5 (16.7%)	7 (23.3%)	
Down gaze			
○ Not restricted	29 (96.7%)	30 (100.0%)	0.999[b]
○ Restricted	1 (3.3%)	0 (0.0%)	
Medial gaze			
○ Not restricted	25 (83.3%)	26 (86.7%)	0.999[b]
○ Restricted	5 (16.7%)	4 (13.3%)	
Lateral gaze			
○ Not restricted	25 (83.3%)	28 (93.3%)	0.424[b]
○ Restricted	5 (16.7%)	2 (6.7%)	
4th week			
Up gaze			
○ Not restricted	29 (96.7%)	29 (96.7%)	0.999[b]
○ Restricted	1 (3.3%)	1 (3.3%)	
Down gaze			
○ Not restricted	30 (100.0%)	30 (100.0%)	
Medial gaze			
○ Not restricted	30 (100.0%)	30 (100.0%)	
Lateral gaze			
○ Not restricted	30 (100.0%)	30 (100.0%)	

[a] Chi-square test was done to measure the level of significance.
[b] Fisher's Exact test was done to measure the level of significance.

Table 4.13: Comparison of the patients according to Ocular motility by groups (N=60)

Ocular motility	Group Intervention (Titanium mesh) N=30	 Control (Iliac bone graft) N=30	P value
Post-op At 12th week			
Up gaze			
○ Not restricted	30 (100.0%)	30 (100.0%)	
Down gaze			
○ Not restricted	30 (100.0%)	30 (100.0%)	
Medial gaze			
○ Not restricted	30 (100.0%)	30 (100.0%)	
Lateral gaze			
○ Not restricted	30 (100.0%)	30 (100.0%)	
At 24th week			
Up gaze			
○ Not restricted	30 (100.0%)	30 (100.0%)	
Down gaze			
○ Not restricted	30 (100.0%)	30 (100.0%)	
Medial gaze			
○ Not restricted	30 (100.0%)	30 (100.0%)	
Lateral gaze			
○ Not restricted	30 (100.0%)	30 (100.0%)	

At 12th and 24th postoperative weeks all patients were improved of ocular motility. No restriction in any gazes.

4.18 Degree of Diplopia measured by Hess Chart in different groups with postoperative follow-up

Table 4.14: Comparison of the patients according to Degree of Diplopia in primary gaze by groups (N=60):

Degree of diplopia	Group		P value
	Intervention (Titanium mesh) N=30	Control (Iliac bone graft) N=30	
Preoperative evaluation			
○ 1	26 (86.7%)	25 (83.3%)	0.468[a]
○ 2	3 (10.0%)	5 (16.7%)	
○ 3	1 (3.3%)	0 (0.0%)	
Post- op At 1st week			
○ 0	14 (46.7%)	15 (50.0%)	0.585[a]
○ 1	13 (43.3%)	14 (46.7%)	
○ 2	3 (10.0%)	1 (3.3%)	
At 4th week			
○ 0	27 (90.0%)	25 (83.3%)	0.448[a]
○ 1	3 (10.0%)	5 (16.7%)	
At 12th week			
○ 0	30 (100.0%)	30 (100.0%)	-
At 24th week			
○ 0	30 (100.0%)	30 (100.0%)	-

[a]Chi-square test was done to measure the level of significance.
[b]Fisher's Exact test was done to measure the level of significance.

Table 4.14 shows degree of diplopia was assessed at 1st, 4th, 12th, and 24th postoperative weeks in both groups. No significant difference in the mean diplopia score was found in two groups ($p>0.05$).

4.19 Inferior rectus muscle limitation by different groups and follow-ups

Table 4.15: Comparison of the patients according to Extraocular muscle (Inferior rectus) limitation (N=60)

Extraocular muscle (Inferior rectus) limitation	Group		P value
	Intervention (Titanium mesh) N=30	Control (Iliac bone graft) N=30	
Preoperative evaluation			
○ 1	25 (83.3%)	25 (83.3%)	0.574^a
○ 2	4 (13.3%)	5 (16.7%)	
○ 3	1 (3.3%)	0 (0.0%)	
Post- op At 1st week			
○ 1	25 (83.3%)	22 (73.3%)	0.137^a
○ 2	2 (6.7%)	7 (23.3%)	
○ 3	3 (10.0%)	1 (3.3%)	
At 4th week			
○ 0	29 (96.7%)	29 (96.7%)	0.999^b
○ 1	1 (3.3%)	1 (3.3%)	
At 12th week			
○ 0	30 (100.0%)	30 (100.0%)	
At 24th week			
○ 0	30 (100.0%)	30 (100.0%)	

[a]Chi-square test was done to measure the level of significance.
[b]Fisher's Exact test was done to measure the level of significance.

Table 4.15 shows extraocular muscle limitation score was assessed in three assessment point at 1st, 4th, 12th and 24th postoperative weeks comparison with preoperative score no significant different in extraocular muscle score was found in tow groups at postoperative follow-up at 4th weeks ($p>0.05$). At 12th weeks inferior rectus muscle was normal in both titanium mesh and iliac bone graft group.

Table 4.16: Comparison of the patients according to Inferior rectus muscle action by groups (N=60)

Inferior Rectus muscle action	Group		P value
	Intervention (Titanium mesh) N=30	Control (Iliac bone graft) N=30	
Preoperative evaluation			
○ Restricted	30 (100.0%)	30 (100.0%)	
Post-op At 1st week			
○ Restricted	9 (30.0%)	11 (36.7%)	0.584[a]
○ Normal	21 (70.0%)	19 (63.3%)	
At 4th week			
○ Restricted	2 (6.7%)	5 (16.7%)	0.424[b]
○ Normal	28 (93.3%)	25 (83.3%)	
At 12th week			
○ Normal	30 (100.0%)	30 (100.0%)	
At 24th week			
○ Normal	30 (100.0%)	30 (100.0%)	

[a] Chi-square test was done to measure the level of significance.
[b] Fisher's Exact test was done to measure the level of significance.

Table 4.16 shows inferior rectus muscle action in 1st postoperative week was normal 21(70.0%) in Titanium mesh but 19(63.3%) in Iliac bone graft. But improved inferior rectus muscle action in 12th and 24th postoperative weeks was normal.

4.20 Step deformity evaluation by pre and post- operative follow-up by Titanium mesh and Iliac bone graft

Table 4.17: Comparison of the patients according to the presence of step deformity of infraorbital margin by groups (N=60)

Step deformity of infraorbital margin	Group		P value
	Intervention (Titanium mesh) N=30	**Control (Iliac bone graft) N=30**	
Preoperative evaluation	30 (100.0%)	30 (100.0%)	
Post- op At 1st week	2 (6.7%)	18 (60.0%)	<0.001$_a$
At 4th week	2 (6.7%)	7 (23.3%)	0.145^b
At 12th week	0 (.0%)	0 (.0%)	
At 24th week	0 (0.0%)	0 (.0%)	

^{a}Chi-square test was done to measure the level of significance.
^{b}Fisher's Exact test was done to measure the level of significance.

Table 4.17 showed that the step deformity of orbital floor fracture patients improved in 1 week in almost all the patients of Titanium mesh, whereas the Iliac bone graft patients step deformity improvement is much lower than the Titanium mesh. This result is highly statistically significant (p<0.001). This result implies that 93.3% patients step deformity recovered in 1st week. Whereas in the same time only 40% of Iliac bone graft patients step deformity was corrected.

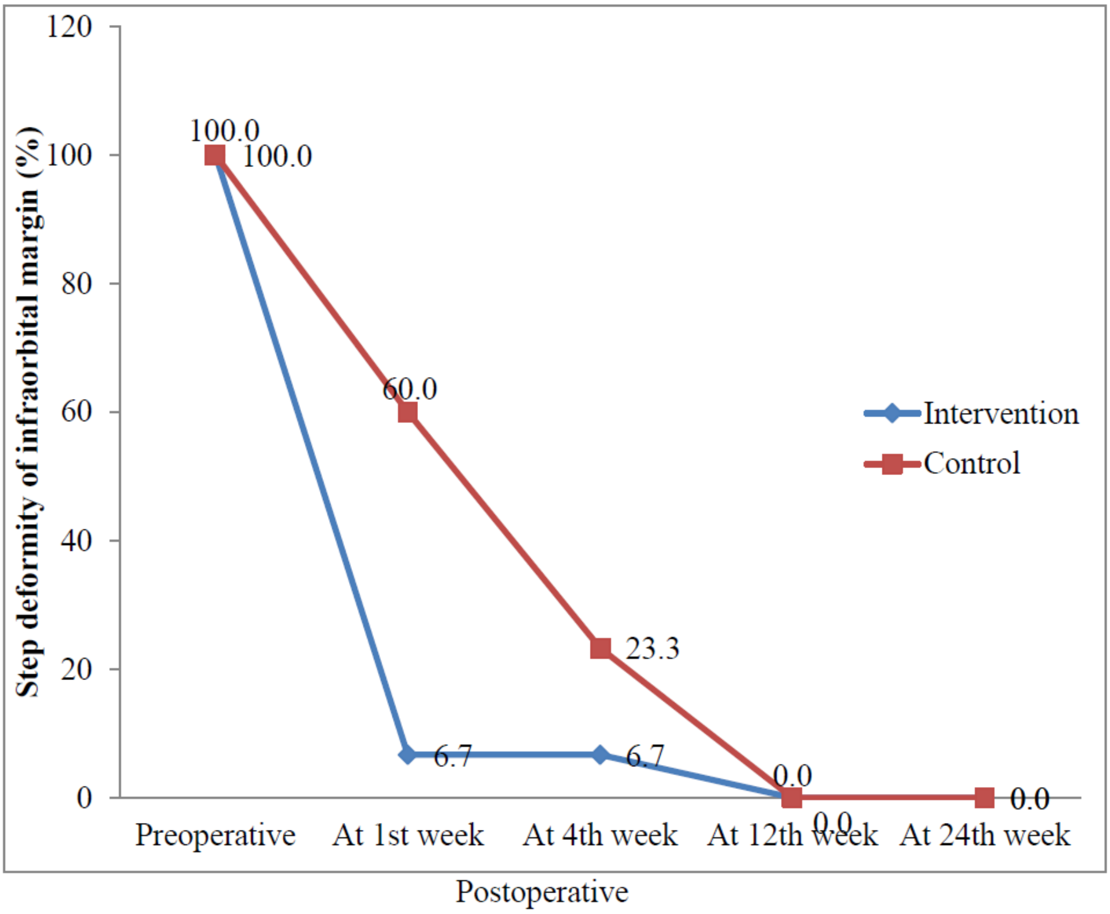

Figure 4.10: Line chart of the patients according to the presence of step deformity of infraorbital margin by Intervention (Titanium mesh) and Control (Iliac bone graft) groups

Line chart shows significant improvement in intervention group in 1^{st} postoperative week than control group at different postoperative follow-up periods.

4.21 CT scan evaluation by Titanium mesh and Iliac bone graft at different follow-ups

Table 4.18: Comparing of the patients according to Bone resorption, Implant migrated and Signs of infection by group (N=60)

CT scan	Group		P value*
	Intervention (Titanium mesh) N=30	Control (Iliac bone graft) N=30	
Bone resorption			
○ At 1st week			
○ At 4th week			
○ At 12th week	0 (0.0%)	4 (13.3%)	0.112
○ At 24th week	0 (0.0%)	4 (13.3%)	0.112
Implant migrated			
○ At 1st week			
○ At 4th week			
○ At 12th week	1 (3.3%)	0 (0.0%)	0.999
○ At 24th week	1 (3.3%)	0 (0.0%)	0.999

*Fisher's Exact test was done to measure the level of significance.

Table 4.18 shows the distribution of the study patients by bone resorption in 12th and 24th postoperative week, intervention group had no bone resorption where as in control group 4(13.3%) had bone resorption. The difference was not statistically significant (p>0.05). On the other hand Implant migrated in both 12th and 24th postoperative week, intervention group had 1(3.3%) but there was no patient in the control group. The difference was not statistically significant (p>0.05)

4.22 Signs of infection by Titanium mesh and Iliac bone graft at follow-up periods

Table 4.19: Comparing of the patients according to Signs of infection by group

Signs of infection	Intervention (Titanium mesh) N=30	Control (Iliac bone graft) N=30	p value
o At 1st week			
o At 4th week			
o At 12th week	1 (3.3%)	1 (3.3%)	0.999
o At 24th week	2 (6.7%)	0 (0.0%)	0.492

*Fisher's Exact test was done to measure the level of significance

Table 4.19 illustrates the distribution of the study participants by prevalence of signs of infection. The information was acquired in 4 assessment point at 1st, 4th, 12th and 24th postoperative weeks in Titanium mesh group, out of 30 patients signs of infection was found in 1(3.3%) patient and Iliac bone graft 1(3.3%). At 24th weeks Titanium mesh has 2(6.7%), but there is no infection in the Iliac bone graft. There is no statistically significance between two groups (p>0.05).

4.23 Inferior rectus muscle evaluation by forced duction test

Table 4.20: Comparison of the patients according to positive Forced duction test (N=60)

Forced Duction test	Group		P value*
	Intervention (Titanium mesh) N=30	Control (Iliac bone graft) N=30	
Preoperative evaluation	30 (100.0%)	30 (100.0%)	
Post- op At 1st week	1 (3.3%)	0 (.0%)	0.612
At 4th week			
At 12th week			
At 24th week			

*Fisher's Exact test was done to measure the level of significance.

Table shows all patients in both groups preoperatively tested by forced duction test to see the entrapment of inferior rectus muscle. Only 1(3.3%) patient in the intervention group positive of forced duction test which is not statistically significant.

Table 4.21: Comparing of the patients according to the presence of Ectropion by group (N=60)

Ectropion	Group		P value*
	Intervention (Titanium mesh) N=30	Control (Iliac bone graft) N=30	
Post- operative At 1st week	3 (10.0%)	5 (16.7%)	0.706
At 4th week	2 (6.7%)	3 (10.0%)	0.999
At 12th week	0 (.0%)	0 (0.0%)	
At 24th week	0 (.0%)	0 (0.0%)	

*Fisher's Exact test was done to measure the level of significance.

This table shows that 3 (10%) had ectropion in intervention group but 5 (16.7%) in control group in 1st Post-operative weak. At 4th Post-operative week intervention group, 2 (6.7%) patients whereas 3 (10%) in control group which was not statistically significant.

Table 4.22: Cost benefit analysis between Intervention (Titanium mesh) and Control (Iliac bone graft) group patients

Variable	Group (For one person) Intervention (Titanium mesh) (N=30)	Group (For one person) Control (Iliac bone graft) (N=30)	p-value
Recovery time (days)	7.45±2.30	12.61±3.47	<0.001[a]
Cost (Tk.)	15212.4±321.2	10120.7±214.3	<0.001[a]
Surgeons' team required.			
Single team	27(90.0%)	10(33.3)	<0.001[b]
Double team	3(10.0%)	20(66.7)	
Operation time (hours)	2.12±0.74	3.45±0.97	<0.001[a]

[a] Unpaired t-test Exact test was done to measure the level of significance.
[b] Chi-square test was done to measure the level of significance.

The cost-benefit analysis was conducted between the intervention group, which received titanium mesh, and the control group, which received iliac bone graft. The results showed that the intervention group had a significantly shorter recovery time of 7.45±2.30 days compared to the control group's 12.61±3.47 days (p<0.001). Additionally, the cost for the intervention group was higher at Tk. 15212.4±321.2 compared to the control group's Tk. 10120.7±214.3 (p<0.001). The intervention group required a single team of surgeons in 90% of cases, while the control group required a double team in 66.7% of cases (p<0.001). Finally, the operation time for the intervention group was significantly lower at 2.12±0.74 hours compared to the control group's 3.45±0.97 hours (p<0.001). Overall, these results suggest that the use of titanium mesh is more effective and efficient than iliac bone graft in terms of recovery time, operation time, and surgeon team requirements, despite being more expensive.

Chapter V

Discussion

Discussion

The present study was designed as a randomized controlled trial carried out at the Department of Oral and Maxillofacial Surgery, Dhaka Dental College Hospital; Department of Oculoplasty, National Institute of Ophthalmology and Ispahani Islamia Eye Institute and Hospital, Dhaka. Among 60 patients admitted with orbital floor fracture with enophthalmos, 30 patients were treated by titanium mesh named as intervention group and remaining 30 patients were treated by iliac bone graft named as Control group.

The orbit, which is made up of seven facial bones, provides eye support and protection. The orbit is 50 mm depth in anterior posterior, 40 mm in height, 35 mm in width, and has an average volume of 30 ml .Subtle loss or increase in volume can lead to aesthetic or functional problems. It is challenging to restore orbital architecture and volume. Here, it is to be noted that 60 patients of this current study were treated surgically.

Traumatic fractures of the face are common in Bangladesh, and this type of patient is managed by oral and maxillofacial surgeons.

In the present study, the majority of the patients were in the age group of 20 to-30 years, which was 13 (43.0%) patients in the Intervention group and up to 20 years which was about 9 (30%) in the Control group, followed by 8 (26.7%) patients in 30-40 years in both groups.

Young people, especially men between 30 and 40 years, are mainly affected due to reckless driving and other types of outdoor activities. Many pieces of evidence are published in several studies (Runci et al., 2017; Fama et al., 2017; Piombino et al., 2013).

Out of 60 orbital floor fracture patients, the highest patients is 21 (35%) were observed in the age group of 21-30 years.

The minimum age was 20 years in both the intervention and Control group. Maximum age was 60 years in the Intervention group and more than 65 years in the Control group. The mean age of patients was 33.7±4.8 years for the Intervention group and 30.7±7.88 for the Control group. Therefore, it was showed that there was no significant difference in the age group of patients affected due to orbital floor fracture.

In this study, 27(90 %) patients were male and 3(10%) were female in the Intervention group and 28(93.3%) patients were male and 2(6.7%) were female in the Control group. Gender distribution in this study was 55 males and 5 females (ratio 11:1).

In the study of Chen et al. (2016), reported of the eligible patients, 218 (71.7%) were males and 86 (28.3%) were females which is similar to the current study as well. It is to be noted that the age of the patients ranged from 7 years to 74 years. The mean age was 27.6 years. Hartwig et al. (2019) reported in a study the patients' median age was 36 years (ranging from 6 to 90 years).

Sensese et al. (2018) revealed that 79 patients had orbital floor fracture, in where 18 (22.8%) were women and 61 (77.2%) were men (male to female ratio, 2:9) with a mean age of 37 years (range, 13 to 72 years).

Folkestad et al. (2006) conducted a study to assess experiences of the result and outcome of orbital floor fracture. Desensitization, ability to open the mouth, appearance, and eye function all improved significantly, primarily in the first month after surgery ($p < 0.05$ at the group level). The sclera was common (41%), and 14% had valgus on a one-month examination. A year later, 29% and 4% had these diseases, respectively. Enophthalmos (N=6) occurred postoperatively and was diagnosed only at the 6-month appointment, which was overlooked by half of the affected patients.

The etiology, type, and area affected by the fracture are related to a variety of factors. Nevertheless, studies show how jaw fractures are most commonly caused by trauma such as road traffic accidents, suspected assaults, and falls (Senese et al., 2018; Rhim et al., 2010; Christensen and Zaid, 2016).

In the present study, the majority of the patients suffer from road accidents. Among them, 27(90.0%) patients were in the intervention group and 16(53.3%) in the Control group, followed by assault in which is 1(3.30%) in Intervention and 8(26.7%) in the Control group.

Among the 60 patients 43 patients were injured due to road traffic accident (table 2) which is 72% of the total incoming orbital fractured patients. The p value of the road traffic accident is 0.002, which is highly statistically significant. It implies that main cause of orbital floor fracture is road traffic accident. There is no statistically significant difference among the other causes of orbital floor fracture (p>0.05).

From Runci et al. (2017), a study was conducted to retrospectively assess and record the frequency of central facial trauma and orbital floor fractures observed in northeastern Sicily. Most of the fractures were isolated mandibular fractures. The most common cause of fractures appears to road traffic accidents, followed by assaults, jobs, and falls. The average age of the patients was 35 years, but the average age was 37 years for men and 33 years for women.30 patients suffering from various types of eye and extraocular injuries or complications.

Previous studies from Europe and the United States have shown that road accidents are the leading cause of facial fractures (Consoli et al., 2013; Van Hoof et al., 1977). Runci et al. (2017), reported in a study conducted at Messina University Hospital, confirms that road accidents are the most common cause of jaw and facial fractures. This observation is consistent with the study by Yang and Liao (2019), Christensen et al. (2016), and Chang et al. (2005).

In the Intervention group, 11(36.7%) patients had an operation in the right and 19(63.3%) on the left side, and in the Control group, 13(43.3%) patients had an operation in the right and 17(56.7%) in the left side.

In the current study orbital floor fracture occurs mostly in the type IIIA, 20 (66.7%) in intervention group and 13 (43.3%) in control group. There was no statistically significant difference among the other causes of orbital floor fracture (p>0.05).

Present study showed at 1st post-operative week 3 (10.0%) had periorbital swelling in the intervention group but 8 (26.7%) had periorbital swelling in the control group. The difference was not statistically significant.

In this study, on pre-operative evaluation, all patients in both groups had enophthalmos. Enophthalmos correction was 28(93.3%) patients in the intervention group and 26(86.7%) in the control group. On the other hand, 2(6.7%) patients are not corrected in the intervention group and 4 (13.3%) patients in the control group. After 12 weeks, enophthalmos was present in 2(6.7%) patients in the intervention group, and 4 (13.3%) patients in the control group. After 24 weeks of follow-up, the enophthalmos was to that after 12 weeks was statistically significant ($P > 0.02$). We compared the enophthalmos in the two treatment groups and it was found to be similar in the two groups, suggesting that the performance of the two outcomes was identical.

Current study showed that enophthalmos patients' had normal eye (uninjured eye) Hertel Exophthalmometer (HE) (mm) measurement were 19.37±1.59 and 19.17±2.45 in Titanium mesh (TiM) and Iliac bone graft (IBG) respectively. Hertel Exophthalmometer (mm) of injured eyes of titanium mesh and iliac bone graft patients were 16.30±1.70 and 16.23±2.50 respectively. In next few weeks of operation, the patients HE (mm) started to increase at 24th week the Hertel Exophthalmometer measurement of injured eyes of titanium mesh and iliac bone graft became almost same, because there is no statistical significance between the two groups at 4th weeks, 12th weeks and 24th weeks after operation. So, it is clear that the iliiac bone graft is not superior to titanium mesh.

Correction of enophthalmos, between preoperative and postoperative, at 1st, 4th, 12th, and 24th week between intervention and control group is showing statistically significant ($p<0.001$). This result indicates the benefits of titanium mesh and iliac bone graft similarly.

In this study, the treatment modalities of orbital floor fracture showed all the patients 60(100.0%) operated at the open reduction method. Out of 30 patients, 17(56.7%) patients underwent subciliary incision approach in the intervention group, and 13(43.33%) in the control group, 3(10.0%) patients underwent the subtarsal incision in the intervention group, and 1(3.3%) in control group, 1(3.3%). Patients were given transconjunctival incision for exposure of the orbital floor in the intervention group and 4 (13.33) in the control group. Infraorbital incision was given in 9(30%) patients in the intervention group and 12(40%) patient were reconstructed s in the control group.

Orbital floor fractures of 30(50.0%) patients were reconstructed by titanium mesh (intervention group), and the remaining 30(50.0%) patients were treated by iliac bone graft (control group).

This study showed there is a statistically significant difference between the Means and Medians for time of correction of enophthalmos in different groups. It means that patients treated by titanium mesh took significantly lesser time than the patients treated by iliac bone graft to correct enophthalmos. The mean time of correction of enophthalmos was 8.43 weeks.

Kaplan Meier curve was plotted to observe the difference in time (week) to correct enophthalmos like normal eye between intervention and control groups based on different follow-up data using the log-rank test.

According to Kaplan Meier curve, between intervention (titanium mesh) and control (iliac bone graft) groups, enophthalmos was corrected at 4 weeks earlier than iliac bone graft.

Consistent with this study, Rhim et al. (2010) 40 of the 43 patients reported undergoing an anterior septal conjunctival incision to expose the periorbital area. Senese et al. (2018) said the subciliary approach was initially more applied, as observed in the literature (Gosau et al., 2011; Liss et al., 2010). A transconjunctival incision replaced these surgical approaches to expose the orbital floor fracture.

Villar real et al. (2002) revealed a 20% valgus incidence associated with the accessory ciliary approach compared to 0% for the transconjunctival approach. Villar real et al. (2002) also found a 22% increase in the incidence of epiphora with the conjunctival approach, compared to 13% with the subciliary approach. Predisposing factors for eyelid contraction and valgus after correction of an orbital fracture include hematoma, eyelid edema, orbital septal adhesions, and scar contraction.

Unlike many other studies, although subciliary incision had been uesd in most 17(89.5%) of our cases and ectropion occurred in 3(10%) of cases, Barbon et al. (2002) found a 20% incidence of ectropion in subciliary incision. It can be said that proper incision, reduction, and closure of all respect layers, including the periosteum, could reduce the chance of ectropion. Our study had the transconjunctival approach in

5(16.7%) cases. There are two different transconjunctival approaches: (1) the pre-septal interconjunctival approach requires more time to expose the orbital floor, and (2) the post-septal interconjunctival approach. This method is fast, but handling a herniated disc is cumbersome.

In the year, 1997 Krishnan and Jhonson conducted a retrospective study on 16 patients who had orbital floor fractures reconstructed with autogenous bone (mandibular symphyseal bone grafts). These autologous bone grafts were used when the diameter of the defect was less than 2 cm. Patients were examined during callback visits for signs of failure to reconstruct by checking the movement of the extraocular muscles and for signs of diplopia or enophthalmos.

Present study shows preoperative and postoperative evaluation of both intervention and control group by facial asymmetry. In intervention group 25 (83.3%) patients had facial asymmetry corrected in the 1st postoperative week whereas in control group 22 (73.3%) corrected in control group. In 4th, 12th and 24th postoperative weeks all patients in both groups were corrected in facial asymmetry.

Post-operatively, at recall visit of mean follow-up of 12 months, there was a good restoration of the orbital floor, with no clinical evidence of enophthalmos or diplopia. Extraocular muscle movement was intact in all patients.

In our study, 30 (50.0%) patients benefited from iliac bone grafts, and 30 (50.0%) patients benefited from titanium mesh.

The clinical situation determined the choice of bone graft and, if possible, tailored to each patient, taking into account patient preferences. Some bald patients prefer iliac bone grafts to avoid visible scarring on the scalp.

According to Rhim et al. (2010), of the 43 orbital floor fractures, 17 (39.5%) patients reported reconstructed with porous polyethylene and 26 (60.5%) patients reconstructed with titanium mesh. These results were confirmed in a retrospective study of 337 adult patients comparing patients reconstructed with bone grafts with patients reconstructed with titanium mesh or polyethylene (Kirby et al. 2011).

Ellis and Tan (2003) conducted a study to assess the adequacy of internal orbital reconstruction in orbital floor fractures using calvarial bone grafts or titanium mesh Fifty-eight patients with unilateral orbital floor fractures were included in the study.

Demographics and measurements of pretreatment defect size are tabulated. The surgeon subjectively assessed the accuracy of the reconstruction by determining the location of the implant or graft, the rearrangement of the orbital soft tissue, and the assessment of the orbital volume with the undamaged side for comparison.

Finally, they came to the conclusion that individual differences are large, and both materials can be used successfully. The orbits, which are reconstructed with titanium mesh, showed an overall better reconstruction than the orbits reconstructed with iliac bone grafts.

Folkestad and Granstrom (2003) showed a study to investigate the circumstances surrounding the considerable increase in the number of orbital floor fracture repairs. The male: female ratio changed to 2.2:1, and the implied age was forty-three years (varied between 16-90 years). High falls by younger guys contributed to growing the frequency of falls from height is a cause of orbital floor fracture, so that the prevalence of orbital fracture because of falls (35%) have become better than that of fractures because of assault (33%). 39-9 orbital floor operations had been carried out for the duration of the 12 months of the investigation.

Forced duction test trying out changed into carried out at termination of surgical treatment in 45% of the orbital floor operations. An excessive incidence of sequelae (78%; reaction fee 86%) changed into found out 12 months after surgical treatment.

Büchel et al. (2005) investigated the efficacy and complications associated with the use of absorbable alloplastic material (Ethisorb) in the reconstruction of orbital floor fracture. The study included eighty-seven patients. Complications (enophthalmos, diplopia) occurred in 24.1% of patients. The authors conclude that absorbent aromatic materials (Ethisorb) are suitable for small to medium defects but not for large defects.

Current study shows inferior rectus muscle action in 1st postoperative week was normal 21(70.0%) in titanium mesh but 19(63.3%) in iliac bone graft. But improved inferior rectus muscle action in 12th and 24th postoperative weeks was normal.

Folk High School (2006) whether the recorded curve changes and patterns can correlate with simulated confinement with or without simultaneous coverage of injured eye and whether it is a normal eye as control after surgery. We conducted a study to investigate—orbital floor fracture. The male-female ratio was 1: 1 for healthy volunteers and 2.5: 1 for patients. The average age was 31 and 36, respectively. Simultaneous recording of ocular motility allowed the use of intact eyes as a reference for each individual. Since eye motility is usually synchronized, differences in the recording were expected, causing diplopia. The results showed that vEOG can be used to measure vertical eye motility even when the restricted eye is covered. This tool can be used to (i) differentiate between patients with vertical diplopia and healthy subjects ($p < 0.05$). (ii) Detect and verify one-sided mechanical limits ($p < 0.001$).

This study showed inferior rectus muscle action in 1st postoperative week was normal 21(70.0%) in titanium mesh but 19(63.3%) in iliac bone graft. But improved inferior rectus muscle action in 12th and 24th postoperative weeks was normal.

A study by Rhim et al. (2010) was conducted at the Level 1 Trauma Center in Southern California to investigate treatment options for orbital floor fracture. A review of 45 isolated orbital floor fractures treated in between February 2004 and April 2007 was conducted at the University of California, Irvine; patients were previously analyzed for gender and age. Injury mechanism associated facial injuries, symptoms, treatments, and postoperative complications. 36 male patients and 9 female patients were treated. Road accidents were the most common cause of injury, with an average patient age of 35.5 years. Ecchymosis covering the orbital tissue was the most common symptom.

Diplopia was seen in 8 of 45 patients, and 1 patient required urgent decompression due to post bulbar hematoma. Forty-three patients were surgically repaired. Forty people underwent a transconjunctival approach with lateral canthotomy. 17 was reconstructed with porous polyethylene medpor, and 26 was reconstructed with titanium mesh plate. Immediate postoperative difficulties included 12 patients with infraorbital deafness, 3 with diplopia, 1 with encephalitis, and 1 with valgus with subcapillary access.

Present study showed that the step deformity of orbital floor fracture patients improved in 1st postoperative week in almost all the patients of titanium mesh, whereas the iliac bone graft patients step deformity improvement is much lower than the titanium mesh. This result is highly statistically significant ($p<0.001$). This result implies that 93.3% patients step deformity recovered in 1st week whereas time only 40% of iliac bone patients step deformity was corrected.

According to Gosau et al. (2011), a retrospective study was conducted to investigate indications, surgical approaches, materials used for orbital floor reconstruction, and clinical follow- up care, especially for postoperative difficulties. The study included 189 patients who had surgery for a fracture of the orbital floor between 2003 and 2007. Diagnosis and treatment were based on both physical examination and CT scan examination of the orbit. Patients were previously analyzed for data such as injury mechanism, fracture classification, and difficulties. The most common cause of injury was physical assault, followed by a traffic accident. Surgery has performed an average of 2.9 days after the accident. An incision in the middle of the Subcilliary approach was the most common surgical approach to the orbital floor. Polydioxanone plates (70.5%) were mainly used for orbital floor reconstruction, followed by Ethisorb Dura (23.3%) and titanium mesh (6.2%). 19.0% of patients showed postoperative complications: 5.8% with persistent movement disorder,3.7% with enophthalmos, 3.2% with consistent diplopia, 2.6% with valgus, 0.5% with orbital infection bottom. Infraorbital hematoma (3.2%) was the most serious complication, with one patient suffering from permanent visual impairment and another suffering from complete blindness of the affected eye.

A study was conducted by Senese et al. (2018) to assess the management of isolated orbital floor fracture, taking into consideration clinical, functional, and aesthetic outcomes, depending on the surgical approach and the type of material used.

Patients accepted to fill out a questionnaire that evaluated functional and aesthetic results with high satisfaction in this study. Patients treated with the subciliary approach were at increased risk of contractile scarring compared to other surgical approaches.

This study shows degree of diplopia was assessed at 1st, 4th, 12th, and 24th week postoperatively in both groups. No significant difference in the mean diplopia score was found in two groups ($p>0.05$).

Muscle restriction scores and diplopia were evaluated at four endpoints after surgery, 1st week, 4th week, 12th week, and 24th week postoperatively to compare with preoperative scores in the current study. There was no ocular muscle limitation was found.

Diplopia is much more problematic in the primary field or when looking down and can affect walking. Diplopia in the postoperative setting may be due to a defect in the extraocular muscles. The usually forced test at the end of the operation should efficiently rule out this. In many cases, periorbital swelling, bruising, or edema of the muscles can be the root cause.

In the treatment of orbital floor fractures, postoperative enophthalmos is painful and problematic. The majority of cases result from sustained enlargement of orbital volume as a result of non-anatomical repair of the orbital cone. Initial assessment of postoperative enophthalmos should include computed tomography to locate the implant and characterize the intraorbital volume (Hollier et al., 2003).

In general, similar distributions of mean muscle limitation and diplopia scores were evident in both the intervention and control groups. The intervention group showed a slight significant decrease from the previous, but 2 treatment arms similar efficacy suggests treatment baseline.

Sakakibara et al. (2009) et al. used iliac bone grafts for this reconstruction and obtained good results. 101 patients underwent orbital floor reconstruction of a floor fracture with a thinly trimmed iliac bone of approximately 1 mm without graft fixation. Postoperatively, diplopia occurred in 15 patients and resolved in 86 patients. At 6 months of follow-up, CT scan showed that orbital morphology was well preserved, and no detachment or misplacement of the transplanted bone was observed in any patient.

The most common subjective complaint in our study was ectropion. It shows that 3 (10%) had ectropion in intervention group but 5 (16.7%) in control group in 1st Post - operative weak. At 4th Postoperative week intervention group, 2 (6.7%) patients; whereas 3 (10%) in control group which was not statistically significant.

Rhim et al. (2010) reported infraorbital numbness 12(27.9%), diplopia 3(7.0%), ectropion 1(2.3%), and cellulitis 1(2.3%), which is consistent with the present study.

No major complications took place during follow-up, and all patients were pleased with the final appearance and function.

In the current study, the information about complications was acquired in three assessment points at 1st post-operative week, at 12thweek, and after 24thweek. In the intervention group, out of thirty patients, signs of infection were found in two patients at post-operative, one at 12th week, and one at 24th week follow-up. In the study group, out of 30 subjects, bone resorption appeared in 4 patients on the CT scan assessment. The intervention group had reported 1 implant migrated on CT scan. However, the difference was not statistically significant.

This study shows the distribution of the study patients by bone resorption in 12th and 24th postoperative week, intervention group had no bone resorption where as in control group 4(13.3%) had bone resorption. The difference was not statistically significant ($p>0.05$). On the other hand implant migrated in both 12th and 24th postoperative week, intervention group had 1(3.3%) but there was no patient in the control group. The difference was not statistically significant ($p>0.05$)

Villarreal et al. (2002) conducted a study of 32 patients with orbital floor fractures treated with an aromatic plastic material (porous polyethylene). Postoperative facial infections were 4 cases (12.5%), 2 of which were cutaneous fistulas. These appeared to be associated with maxillary sinusitis, osteosynthesis (loose screws) . In their opinion, the infection was secondary in all patients. Two were treated with systemic antibiotics, one was treated with systemic antibiotics and bone isolation, and one removed alloplastic implants (porous polyethylene). All patients were treated with amoxicillin-clavulanate and corticosteroids before and after surgery.

Comparing patients who received antibiotics postoperatively with those who did not, there was no statistical difference in the presence of infection or in patients treated with amoxicillin-clavulanate and clindamycin. (Fisher's exact test, P = 1.0).

In the present study, participants by prevalence of signs of infection enrolled. The information was acquired in 4 assessment point, at 1st, 4th, 12th and 24th postoperative weeks in Titanium mesh group, out of 30 patients signs of infection was found in 1(3.3%) patient and iliac bone graft 1(3.3%). At 24th weeks titanium mesh has 2(6.7%), but there is no infection in the iliac bone graft. There is no statistically significance between the two groups ($p>0.05$).

Autogenous grafts have the advantages of biocompatibility and lower potential for infection, exposure, and foreign body reaction (Harsha et al., 1986).

However, a 1997 study by Krishnan and Jhonson in 16 patients treated with autologous bone showed no postoperative discomfort or infection at the surgical site, with an average follow-up of 12 months. The graft was not extruded or lost (area 9-36 months).

Titanium mesh is available in a variety of shapes and can be easily contoured for orbital defects of any size. The main drawback of these implants is the difficulty that is occasionally encountered during transplantation. Another popular option is porous high-density polyethylene. These implants are relatively easy to use, in contrast to the titanium mesh, which often gets caught in the periorbita. They can be cut to the exact size, Kelly et al. (2005).

Although titanium mesh is expensive than iliac bone graft, but patients have other benefits those offset the cost of the titanium mesh over iliac bone graft. Titanium mesh required less operation time, early recovery time, single surgeons’ team, single operation and no donor site morbidity. Moreover, in iliac bone graft 30% bone resorption occurred whereas in titanium mesh there is no chance of bone resorption.

The cost-benefit analysis was conducted between the intervention group, which received titanium mesh, and the control group, which received iliac bone graft. The results showed that the intervention group had a significantly shorter recovery time of 7.45±2.30 days compared to the control group's 12.61±3.47 days ($p<0.001$). Additionally, the cost for the intervention group was higher at Tk. 15212.4±321.2 compared to the control group's Tk. 10120.7±214.3 ($p<0.001$). The intervention group required a single team of surgeons in 90% of cases, while the control group required a double team in 66.7% of cases ($p<0.001$). Finally, the operation time for the intervention group was significantly lower at 2.12±0.74 hours compared to the control group's 3.45±0.97 hours ($p<0.001$). Overall, these results suggest that the use of titanium mesh is more effective and efficient than iliac bone graft in terms of recovery time, operation time, and surgeon team requirements, despite being more expensive.

The orbital floor fractured patients are generally in a condition where they do not understand where to go to get the treatment, whether to an oral and maxillofacial surgeon or an eye specialist. Moreover as it is a complex surgery of both maxillofacial and ophthalmology for the poor patients, it is really hard to arrange two specialist at a time. By this study, we can give better treatment and mental relief to the poor patients in Bangladesh.

Chapter VI

Conclusion, Limitations and Recommendations

6.1 Conclusion

In conclusion the use of titanium mesh for the correction of enophthalmos is better than the use of iliac bone graft, in case of orbital floor fracture. However, in some cases, similar result has been achieved. Application of titanium mesh has also showed some advantages over iliac bone graft including less operation time, shorter stay in the hospital, quick recovery of the patient. Unlike iliac bone graft; titanium mesh does not require second operation for doner site. It can be adapted precisely to the bone. Considering all these aspects, titanium mesh is a good alternative option in comparison to iliac bone graft with more benefits for the correction of enophthalmos in case of orbital floor fracture.

6.2 Limitations

The author admits some limitations in this study:

This type of study required specialized operation theatre involving multidisciplinary teams which was not very easy for us to arrange. The operation and follow- up of the patients required a significant expenditure which was tough to arrange due to unavailability of sufficient fund and facilities. During COVID-19 pandemic situation, library facilities were indefinitely not available in Bangladesh and it was difficult to arrange required books, journals, articles for long time. This is why we had to take 60 patients, 30 for Titanium mesh and 30 for iliac bone graft. We would be able to take more patients if we would have enough supply/availability of above mentioned facilities.

6.3 Recommendation

Further study is suggested to determine the effect of 3D reconstruction with computerized virtual planning of Titanium mesh over iliac bone graft. Before starting this kind of study, the researcher should ensure the facilities required for the operation and he should also arrange sufficient funds. Otherwise it is extremely hard to conduct this kind of research specially in developing countries like Bangladesh.

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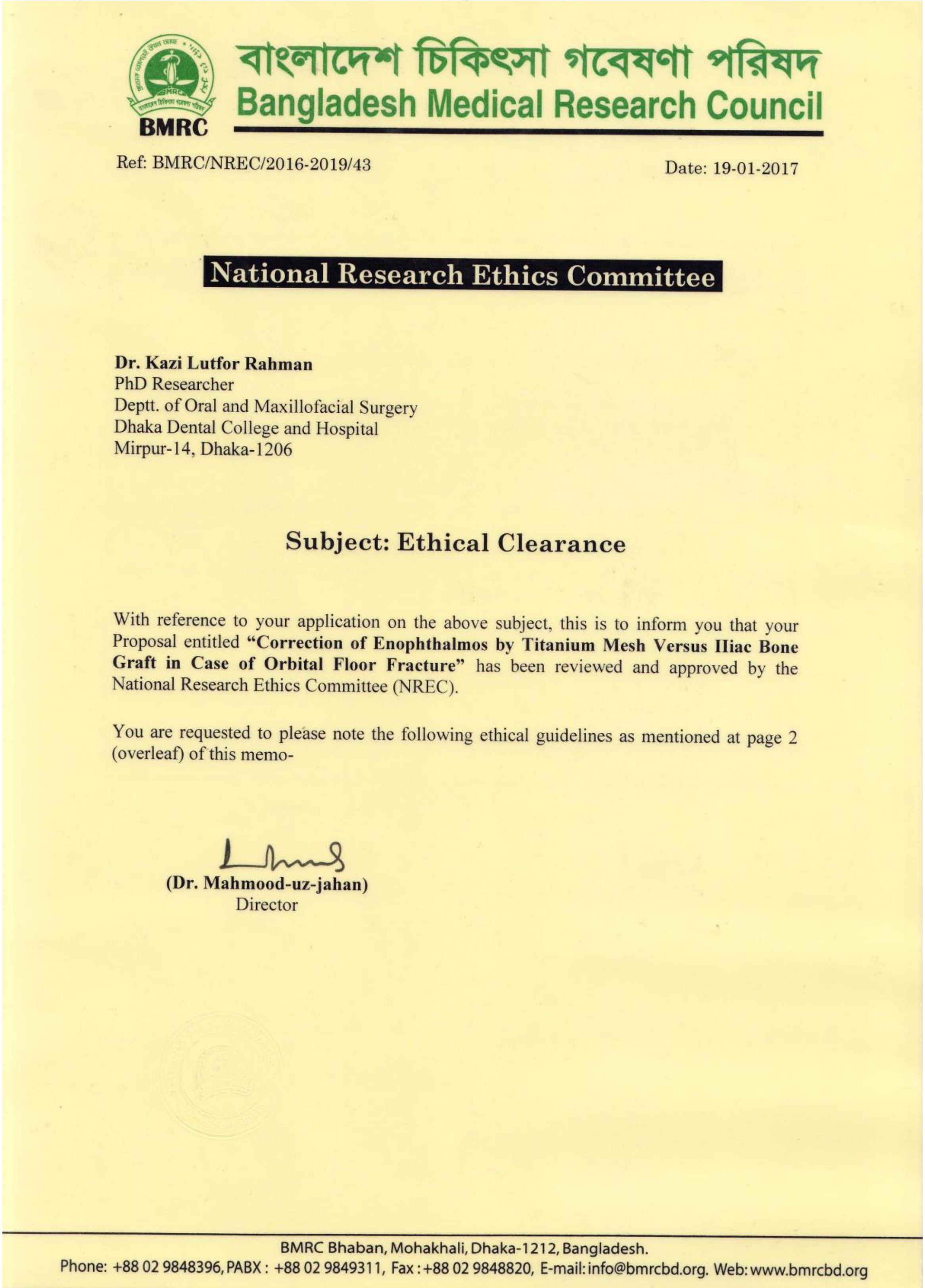
APPENDICES

Appendix-I

Ethical clearance certificate (BMRC)



BMRC

বাংলাদেশ চিকিৎসা গবেষণা পরিষদ
Bangladesh Medical Research Council

Ref: BMRC/NREC/2016-2019/43

Date: 19-01-2017

National Research Ethics Committee

Dr. Kazi Lutfor Rahman
PhD Researcher
Deptt. of Oral and Maxillofacial Surgery
Dhaka Dental College and Hospital
Mirpur-14, Dhaka-1206

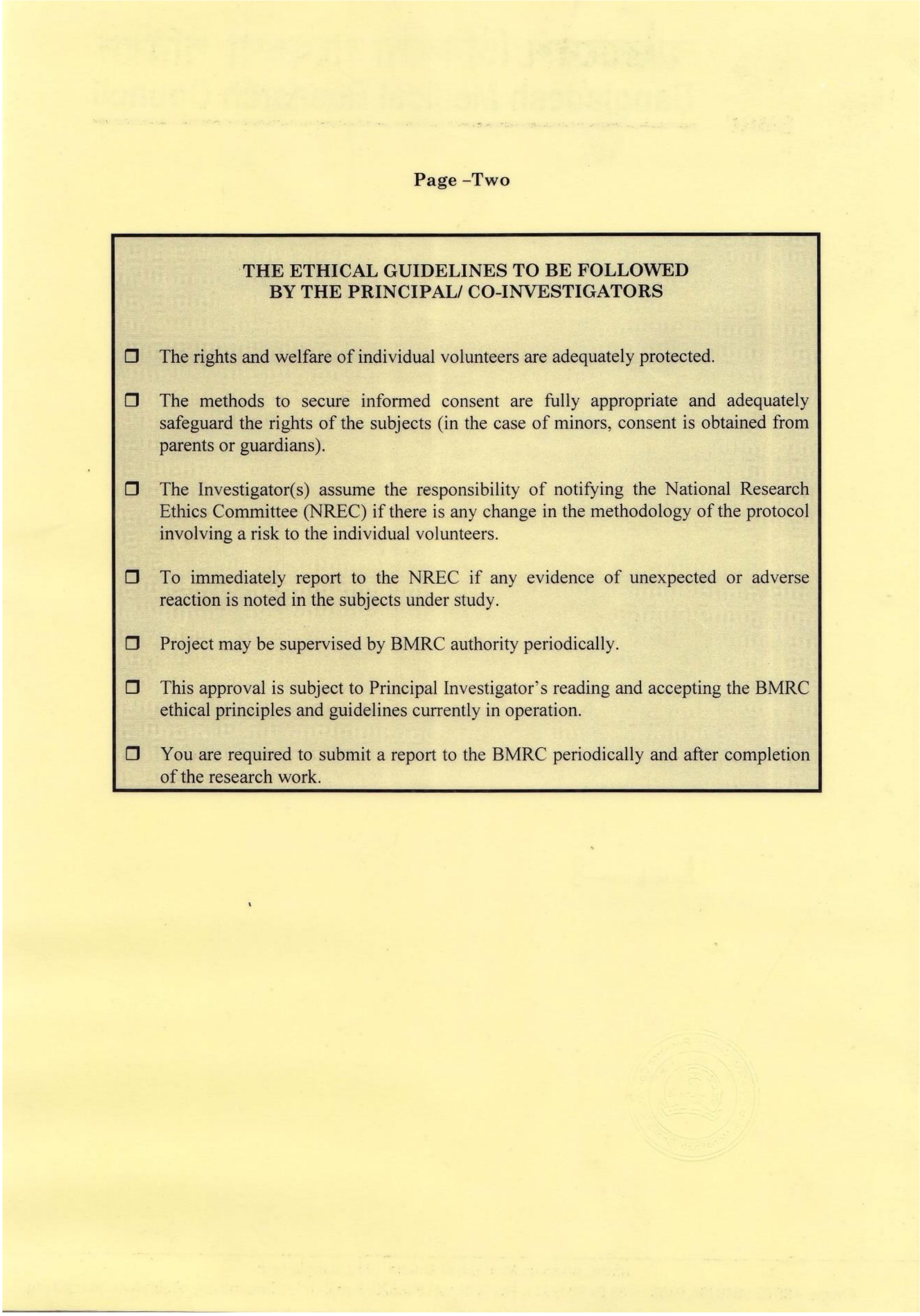
Subject: Ethical Clearance

With reference to your application on the above subject, this is to inform you that your Proposal entitled **"Correction of Enophthalmos by Titanium Mesh Versus Iliac Bone Graft in Case of Orbital Floor Fracture"** has been reviewed and approved by the National Research Ethics Committee (NREC).

You are requested to please note the following ethical guidelines as mentioned at page 2 (overleaf) of this memo-

(Dr. Mahmood-uz-jahan)
Director

BMRC Bhaban, Mohakhali, Dhaka-1212, Bangladesh.
Phone: +88 02 9848396, PABX : +88 02 9849311, Fax : +88 02 9848820, E-mail: info@bmrcbd.org. Web: www.bmrcbd.org



Page –Two

THE ETHICAL GUIDELINES TO BE FOLLOWED BY THE PRINCIPAL/ CO-INVESTIGATORS

☐ The rights and welfare of individual volunteers are adequately protected.

☐ The methods to secure informed consent are fully appropriate and adequately safeguard the rights of the subjects (in the case of minors, consent is obtained from parents or guardians).

☐ The Investigator(s) assume the responsibility of notifying the National Research Ethics Committee (NREC) if there is any change in the methodology of the protocol involving a risk to the individual volunteers.

☐ To immediately report to the NREC if any evidence of unexpected or adverse reaction is noted in the subjects under study.

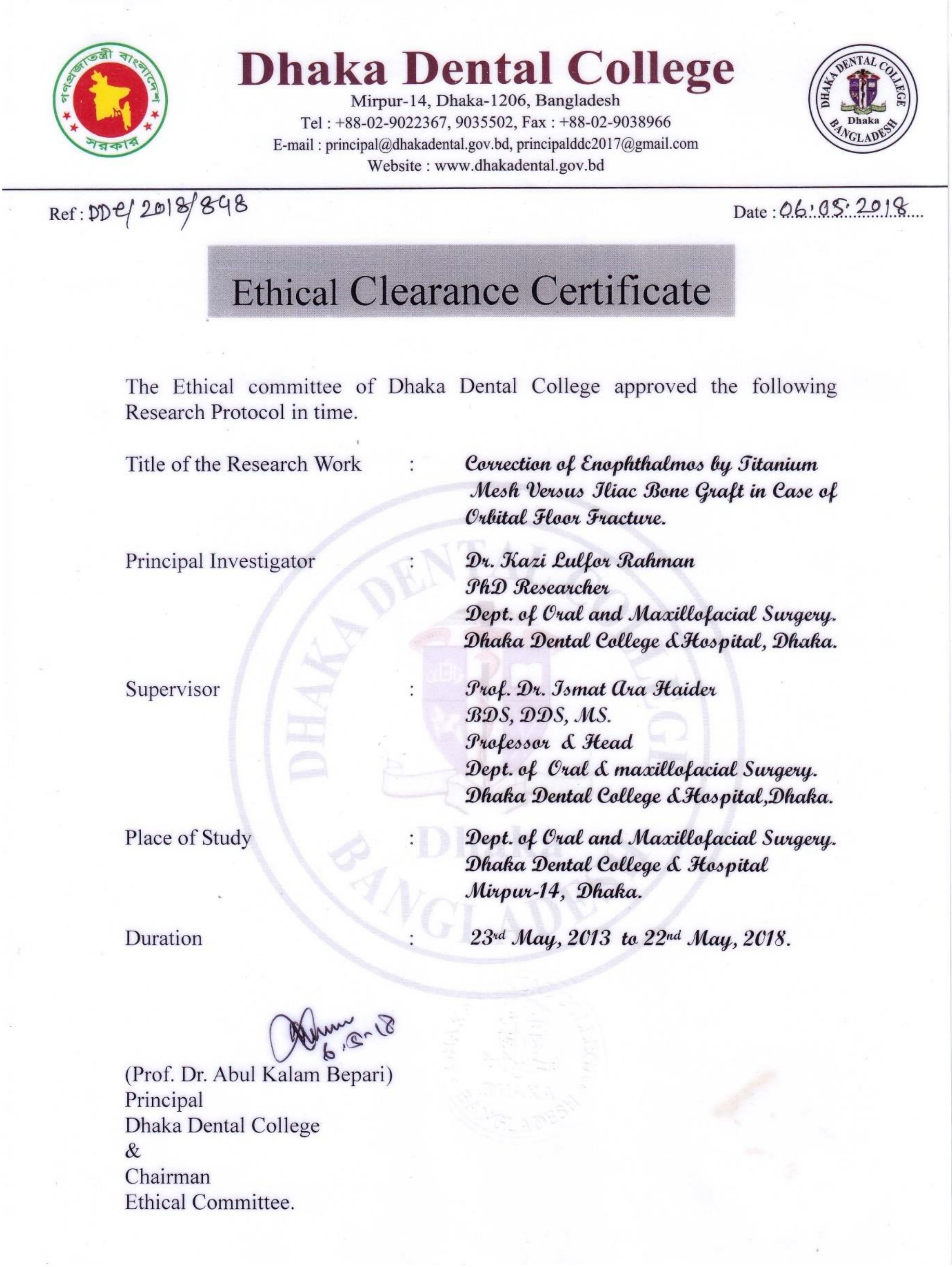
☐ Project may be supervised by BMRC authority periodically.

☐ This approval is subject to Principal Investigator's reading and accepting the BMRC ethical principles and guidelines currently in operation.

☐ You are required to submit a report to the BMRC periodically and after completion of the research work.

Appendix-II

Ethical clearance certificate (DDC)



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Website : www.dhakadental.gov.bd

Ref : DDC/ 2018/848

Date : 06.05.2018

Ethical Clearance Certificate

The Ethical committee of Dhaka Dental College approved the following Research Protocol in time.

Title of the Research Work : *Correction of Enophthalmos by Titanium Mesh Versus Iliac Bone Graft in Case of Orbital Floor Fracture.*

Principal Investigator : *Dr. Kazi Lutfor Rahman*
PhD Researcher
Dept. of Oral and Maxillofacial Surgery.
Dhaka Dental College &Hospital, Dhaka.

Supervisor : *Prof. Dr. Ismat Ara Haider*
BDS, DDS, MS.
Professor & Head
Dept. of Oral & maxillofacial Surgery.
Dhaka Dental College &Hospital,Dhaka.

Place of Study : *Dept. of Oral and Maxillofacial Surgery.*
Dhaka Dental College & Hospital
Mirpur-14, Dhaka.

Duration : *23rd May, 2013 to 22nd May, 2018.*

6.৫.18

(Prof. Dr. Abul Kalam Bepari)
Principal
Dhaka Dental College
&
Chairman
Ethical Committee.

APPENDIX-III

Patient’s Data Sheet

Title: Correction of Enophthalmos by Titanium Mesh Versus Iliac Bone Graft in Case of Orbital Floor Fracture

Investigator: Dr. Kazi Lutfor Rahman
Assistant Professor and Ph.D. Researcher
Department of Oral and Maxillofacial Surgery
Dhaka Dental College& Hospital, Dhaka, Bangladesh

A. Particulars of the patient:

Sl. No :……........… Date of admission : ...…...……..……Reg. no ....…..
Name :……………..
Permanent Address :……………….....…………………………Phone: ………………
Present Address:…………..

B. Demographic variables:

1. Age: ....yrs
2. Gender: 1 = Male 2 = Female /______/
3. Socio-economic condition : 1= Lower income group
   2 = Middle income group
   3= Upper income group /______/
4. Aetiology of Orbital Floor Fracture: 1=Road traffic accident
   2=Assault
   3=Sports injury
   4= Fall from height
   5=Industrial accident
   6=Others /______/

5.Type of Fracture based on CT images:

IA	IB	IIA	IIB	IIIA	IIIB

/______/

C. Preoperative evaluation:

1.Visual acuity : 1 = 6/6 – 6/9 2 = 6/12 – 6/18
3 = 6/24 - 6/60 4= < 6 /60 /______/

2.Facial asymmetry: 1= Present 0 = Absent /______/

3.Involved orbit : 1= Right 2 = Left /______/

4. Enophthalmos: 1 = Present 0 = Absent /______/

5. Periorbital swelling: 1 = Present 0 = Absent /______/

6.Ocular motility: 1 = Present 0 = Absent /______/

i. Up gaze: 1 = Restricted 0 = Not restricted /______/

ii. Down gaze: 1 = Restricted 0 = Not restricted /______/

iii. Medial gaze: 1 = Restricted 0 = Not restricted /______/

iv. Lateral gaze: 1 = Restricted 0 = Not restricted /______/

7. Degree of Diplopia: | 0 | 1 | 2 | 3 | 4 | /______/

8. Extraocular muscle (Inferior rectus) limitation : | 0 | 1 | 2 | 3 | 4 |

9.Step deformity of infraorbital margin :1 = Present 0 = Absent /______/

10.Enophthalmos measured by Hertel Exophthalmometer: ……. mm

11. Forced Duction test : 1 = Positive 0 =Negative /______/

12. Hess Chart (Lees screen) :Inferior rectus muscle action:

1= Restricted 2= Normal /______/

D. Perioperative variables:

1. Surgical approach : 1=Subciliary 2= Subtarsal

3 = Transconjunctival 4 = Infraorbital /______/

2.Materials used: 1=Titanium mesh (Intervention Group)

2 = Iliac bone (Control Group) /______/

E. Postoperative assessment:

(a) Outcome assessment on the 1stweek :

1.Visual acuity : 1 = 6 / 6 – 6 /9 2 = 6 / 12 - 6 /18

3 = 6 / 24 - 6 / 60 4 = < 6 / 60 /______/

2. Facial asymmetry: 1 = Corrected 0 = Not corrected /______/

3.Enophthalmos measured by Hertel Exophthalmometer:……… m m

4. Periorbital swelling: 1 = Present 0 = Absent /______/

5. Ocular motility :

i. Up gaze: 1 = Restricted 0 = Not restricted /______/

ii. Down gaze: 1 = Restricted 0 = Not restricted /______/

iii. Medial gaze: 1 = Restricted 0 = Not restricted /______/

iv. Lateral gaze: 1 = Restricted 0 = Not restricted /______/

6.Degree of Diplopia: /______/

0	1	2	3	4

7.Extraocular muscle (Inferior rectus) limitation: /______/

0	1	2	3	4

8.Step deformity of infraorbital margin: 1 = Present 0 = Absent /______/

9. Bone resorption (CT Scan) : 1= Yes 0 = No /______/

10.Implant migrated(CT Scan) : 1= Yes 0= No /______/

11. Signs of infection : 1 = Yes 0 = No /______/

12. Forced Duction test : 1 = Positive 0 =Negative /______/

13. Hess Chart (Lees screen): Inferior rectus muscle action :

1= Restricted2 = Normal /______/

14. Ectropion : 1= Present 0 = Absent /______/

(b) Outcome assessment on the 4th week :

1.Visual acuity : 1 = 6 / 6 – 6 /9 2 = 6 / 12 - 6 /18

3 = 6 / 24 - 6 / 60 4 = < 6 / 60 /______/

2. Facial asymmetry: 1 = Corrected 0 = Not corrected /______/

3. Enophthalmos measured by Hertel Exophthalmometer:……… m m

4. Periorbital swelling: 1 = Present 0 = Absent /______/

5. Ocular motility :

i. Up gaze: 1 = Restricted 0 = Not restricted /______/

ii. Down gaze: 1 = Restricted 0 = Not restricted /______/

iii. Medial gaze: 1 = Restricted 0 = Not restricted /______/

iv. Lateral gaze: 1 = Restricted 0 = Not restricted /______/

6. Degree of Diplopia: /______/

0	1	2	3	4

7.Extraocular muscle (Inferior rectus) limitation: /______/

0	1	2	3	4

8. Step deformity of infraorbital margin: 1 = Present 0 = Absent /______/

9. Bone resorption (CT Scan) : 1= Yes 0 = No /______/

10.Implant migrated(CT Scan) : 1= Yes 0= No /______/

11. Signs of infection : 1 = Yes 0 = No /______/

12. Forced Duction test : 1 = Positive 0 =Negative /______/

13. Hess Chart (Lees screen): Inferior rectus muscle action:

1= Restricted 2 =Normal /______/

14. Ectropion : 1= Present 0= Absent /______/

(c) Outcome assessment on the12th week :

1.Visual acuity : 1 = 6 / 6 – 6 /9 2 = 6 / 12 - 6 /18

3 = 6 / 24 - 6 / 60 4 = < 6 / 60 /______/

2. Facial asymmetry: 1 = Corrected 0 = Not corrected /______/

3. Enophthalmos measured by Hertel Exophthalmometer:……… m m

4. Periorbital swelling: 1 =Present 0 = Absent /______/

5. Ocular motility :

i. Up gaze: 1 = Restricted 0 = Not restricted /______/

ii. Down gaze: 1 = Restricted 0 = Not restricted /______/

iii. Medial gaze: 1 = Restricted 0 = Not restricted /______/

iv. Lateral gaze: 1 = Restricted 0 = Not restricted /______/

6.Degree of Diplopia: /______/

0	1	2	3	4

7.Extraocular muscle (Inferior rectus) limitation: /______/

0	1	2	3	4

8. Step deformity of infraorbital margin: 1 = Present 0 = Absent /______/

9. Bone resorption (CT Scan) : 1= Yes 0 = No /______/

10.Implant migrated(CT Scan) : 1= Yes 0= No /______/

11. Signs of infection : 1 = Yes 0 = No /______/

12. Forced Duction test : 1 = Positive 0 =Negative /______/

13. Hess Chart (Lees screen): Inferior rectus muscle action:

1=Restricted 2 = Normal /______/

14. Ectropion : 1= Present 0= Absent /______/

(d) Outcome assessment on the 24th week :

1. Visual acuity: 1 = 6 / 6 – 6 /9 2 = 6 / 12 - 6 /18

3 = 6 / 24 - 6 / 60 4 = < 6 / 60 /______/

2. Facial asymmetry: 1 = Corrected 0 = Not corrected /______/

3.Enophthalmos measured by Hertel Exophthalmometer:……… m m

4. Periorbital swelling: 1 = Present 0 = Absent /______/

5. Ocular motility:

i. Up gaze: 1 = Restricted 0 = Not restricted /______/

ii. Down gaze: 1 = Restricted 0 = Not restricted /______/

iii. Medial gaze: 1 = Restricted 0 = Not restricted /______/

iv. Lateral gaze: 1 = Restricted 0 = Not restricted /______/

6. Degree of Diplopia: | 0 | 1 | 2 | 3 | 4 | /______/

7.Extraocular muscle (Inferior rectus) limitation: | 0 | 1 | 2 | 3 | 4 | /______/

8. Step deformity of infraorbital margin: 1 = Present 0 = Absent /______/

9. Bone resorption (CT Scan) : 1= Yes 0 = No /______/

10.Implant migrated(CT Scan) : 1= Yes 0= No /______/

11. Signs of infection : 1 = Yes 0 = No /______/

12. Forced Duction test : 1 = Positive 0 =Negative /______/

13. Hess Chart (Lees screen): Inferior rectus muscle action:

1=Restricted 2 = Normal /______/

14.Ectropion : 1= Present 0= Absent /______/

A. Type of Fracture based on C T images :

Type IA. No orbital soft tissue is visible within the maxillary sinus.

Type IB. Orbital soft tissue is visible within the maxillary sinus.

Type IIA. There is no herniation of soft tissue or the displacement of the soft tissue is less than the distracted bone fragment.

Type IIB. The herniation of soft tissue is greater than the distracted bone fragment.

Type IIIA. Soft tissue and bone are moderately displaced towards the maxillary sinus.

Type IIIB. Soft tissue and bone are markedly displaced towards the maxillary sinus

B. In case of Degree of Diplopia :

- 0 = If the patient does not complain of diplopia.
- 1 = If the patient complains of diplopia when looking up or down at an angle greater than 45° from the horizon
- 2 = If the angle is between 30° and 45°
- 3 = If the angle is within 15th and
- 4 = When looking straight ahead.

C. In case of Extra Ocular muscle (Inferior rectus) limitation:

- 0 = If eye movement is the same as that of a normal eye.
- 1 = If the distance measured from the bottom boundary of the cornea of the healthy side to the bottom boundary of the cornea of the affected side with the eye looking up as high as possible is no longer than 1 mm
- 2 = If the distance is between 1 and 2 mm
- 3 = If the distance is between 2 and 3 mm
- 4 = If the distance is longer than 3mm.

Signature of the Researcher

APPENDIX-IV

Consent Form

I am ………………………………aged………years……duly informed about the objectives, the possible interventions, outcome and complications of the study **“Correction of Enophthalmos by Titanium Mesh Versus Iliac Bone Graft in Case of Orbital Floor Fracture”** conducted by **Dr. Kazi Lutfor Rahman**

I fully recognize that my participation in this study will generate valuable medical information that might be used for the interest of oral and maxillofacial surgical patients in the future. I am fully aware that the information given by me will remain confidential and if I withdraw myself from the study at any time during the course of the study, my treatment will not be hampered. I will be given due compensation if the selected procedure does any harm to my health.

I am also fully informed that this study required clinical intervention in my orbit and surrounding structures which may cause temporary discomfort to the eye.

I spontaneously agree to be included in the said study.

I have given permission to publish my photographs for publication in any form that is needed for the public interest.

	……………………………….
Name of the patient	Signature / Thumb impression of the patient

Date…………………………………….

ওরাল এন্ড ম্যাক্সিলোফেসিয়াল সার্জারী বিভাগ

ঢাকা ডেন্টাল কলেজ হাসপাতাল, মিরপুর-১৪, ঢাকা।

অংশগ্রহনকারীর/রোগী আইডি নংঃ-

অংশগ্রহনকারীর/রোগীর সম্মতিপত্র

গবেষণার বিষয়ঃ Correction of Enophthalmos by Titanium Mesh Versus Iliac Bone Graft in Case of Orbital Floor Fracture

এই সম্মতিপত্রে স্বাক্ষর প্রদানের মাধ্যমে আমি নিম্নলিখিত বিষয়গুলোর ব্যাপাওে সম্মতি দিচ্ছি:-

১. আমি সম্মতিপত্র বিস্তারিতভাবে পড়েছি এবং গবেষাণার সাথে জড়িত ঝুঁকি সম্পর্কে অবগত আছি।
২. গবেষণা সম্পর্কিত আমার প্রশ্নের উত্তর আমি পেয়েছি।
৩. যে কোন সময় এই গবেষণা কর্ম হতে নিজেকে বিরত রাখতে পারব।
৪. রোগীর তথ্যাবলী এবং সম্মতিপত্রের এক কপি আমি গ্রহন করেছি।

রোগীর নামঃ..

ব্যাখ্যা প্রদানকারীর নামঃ..

....
রোগীর স্বাক্ষর /টিপ সহি ও তারিখঃ

....
অভিভাবকের স্বাক্ষর/টিপ সহি ও তারিখঃ

....
ব্যাখ্যা প্রদানকারীর স্বাক্ষর ও তারিখঃ

APPENDIX-V

Study work Plan

Months → Work schedule ↓	1 – 6 months	7 – 12 months	13 – 24 months	25 – 30 months	31 – 36 months
I. Preparatory phase a) Development of protocol b) Preparation of the questionnaire	🟦				
II. Literature review	🟧	🟧			
III. Implementation phase		🟦	🟦		
IV. Data analysis & Report writing				🟦	
V. a) Dissemination study findings and b) Final presentation and submission of the report to the University.					🟩

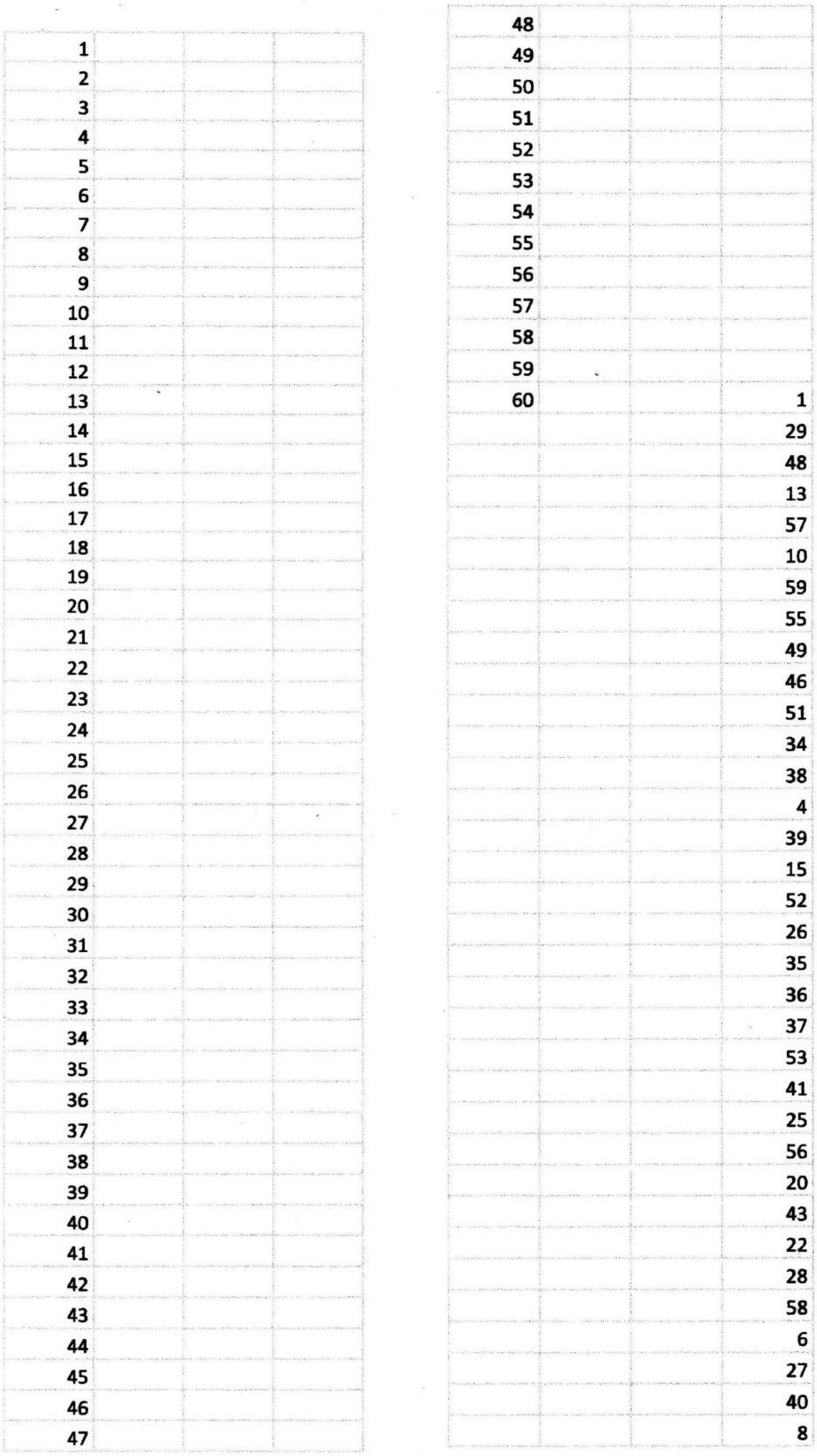
Random numbers for randomized control trial study

Please find the random numbers attached herewith.

In the excel sheet 60 random numbers is generated. From Column D you have to take the first 30 to Intervention Group (Titanium Mesh) and the rest second 30 will be Control Group (Iliac Bone Graft).

Link for generating random numbers:

https://www.excel-easy.com/examples/random-numbers.html



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Intervention group
(Titanium Mesh)

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			32
			54
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			14
			2
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			50
			44
			7
			11
			30
			9
			16
			47
			21
			3
			17
			18
			45
			42
			24
			23

Control group
(iliac bone graft)

APPENDIX-VI

Illustrations

Case-1

Photograph of a patient having enophthalmos and ocular motility in the left eye

Three dimensional computed tomographic scan of the left orbit

Per operative photograph showing demonstration of titanium mesh placement

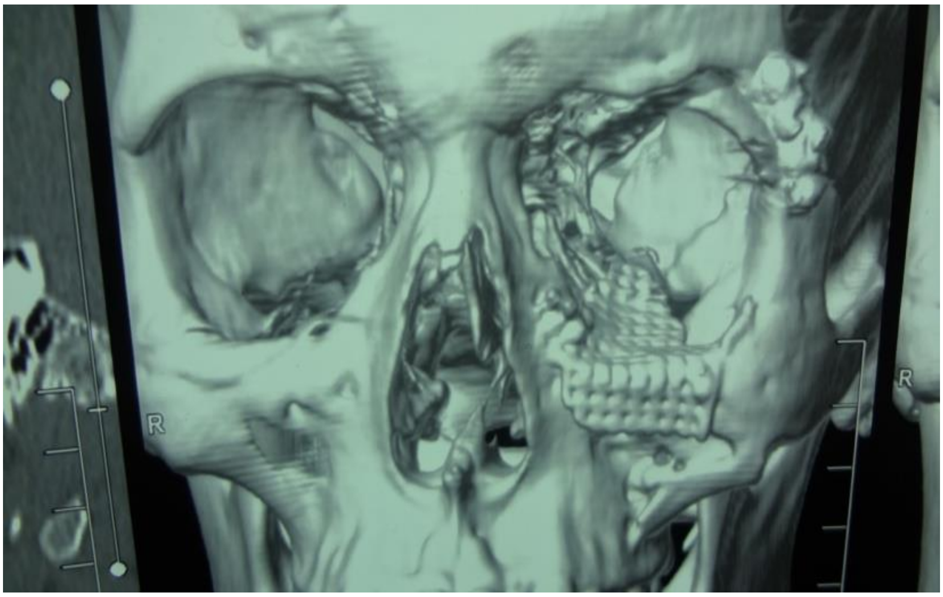
Post operative clinical photograph demonstrates correction of enophthalmos at 4th, 12th and 24th weeks.

Case -2

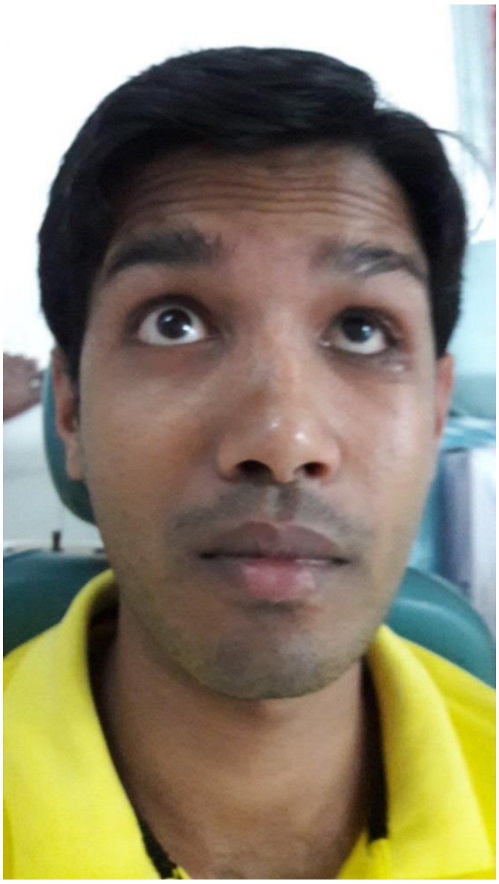
Preoperative clinical photograph

Enophthalmos measured by Hertel Exophthalmometer

Preoperative and Postoperative coronal CT scan showing radiodensity of titanium mesh



Post operative CT scan showing good reduction of left orbital fracture and adaptation of the titanium mesh to the left orbital floor



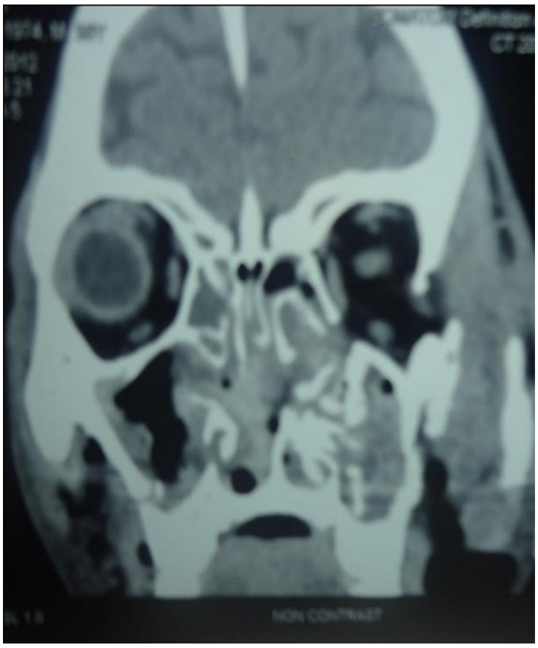
Postoperative photograph showing correction of enophthalmos following titanium mesh placement

Case-3

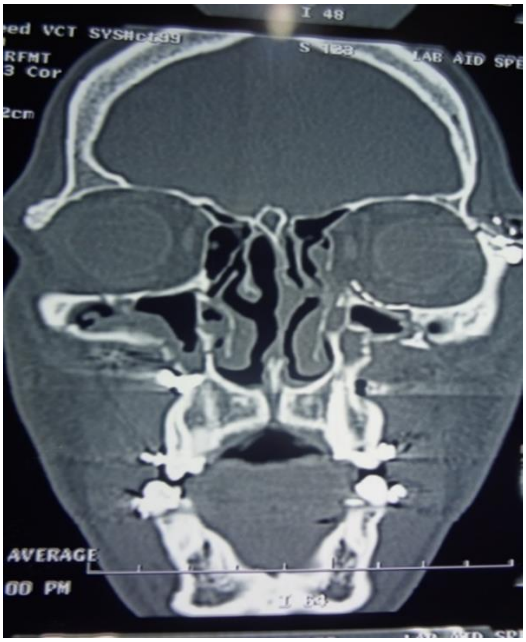
Preoperative frontal view showing left hypoglobus and ptosis

Postoperative frontal view at 24th weeks following orbital floor reconstruction and correction of enophthalmos

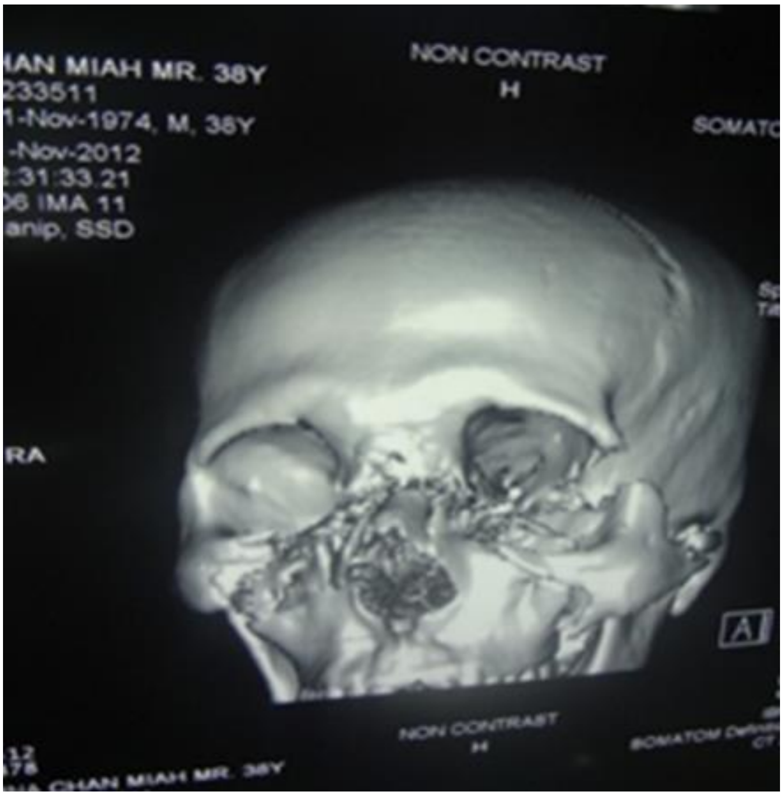
Placement of titanium mesh in the left orbital floor



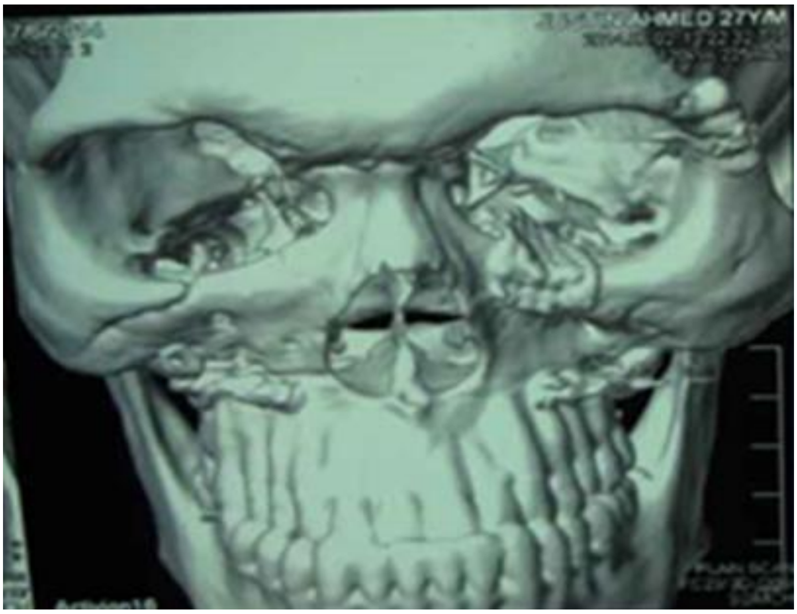
Coronal view of preoperative CT scan showing fracture in the left orbital floor



Coronal view of postoperative CT scan after reconstruction of left orbital floor by titanium mesh



Preoperative computed tomography showing fracture in the left orbital floor and frontozygomatic suture



Postoperative CT scan with 3D image showing reconstruction of left orbital floor by titanium mesh

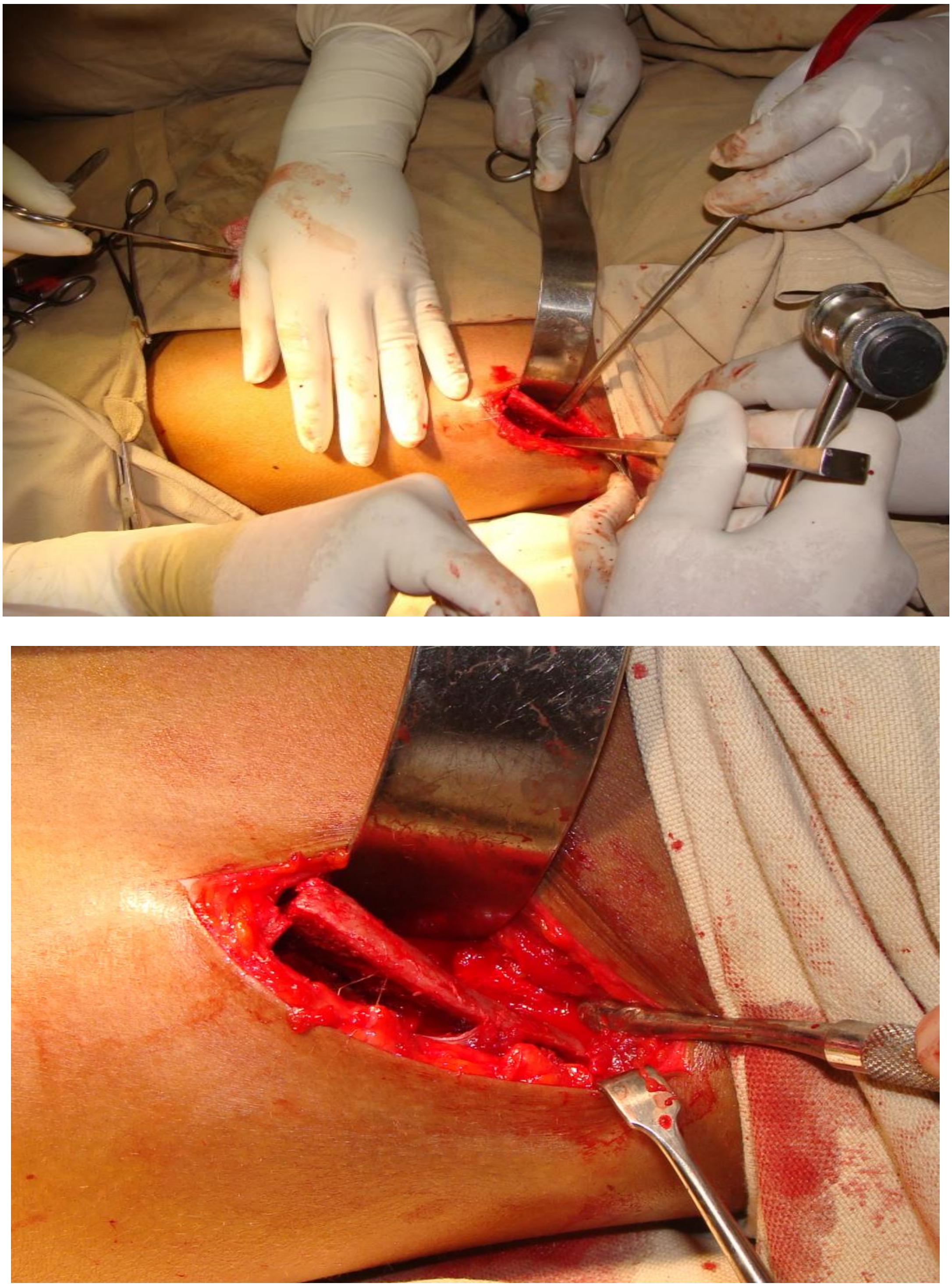
Case-4

Preoperative view showing enophthalmos

Postoperative frontal view showing correction of enophthalmos by iliac bone graft

Harvesting of the Iliac Bone

Incision and exposure of left iliac crest

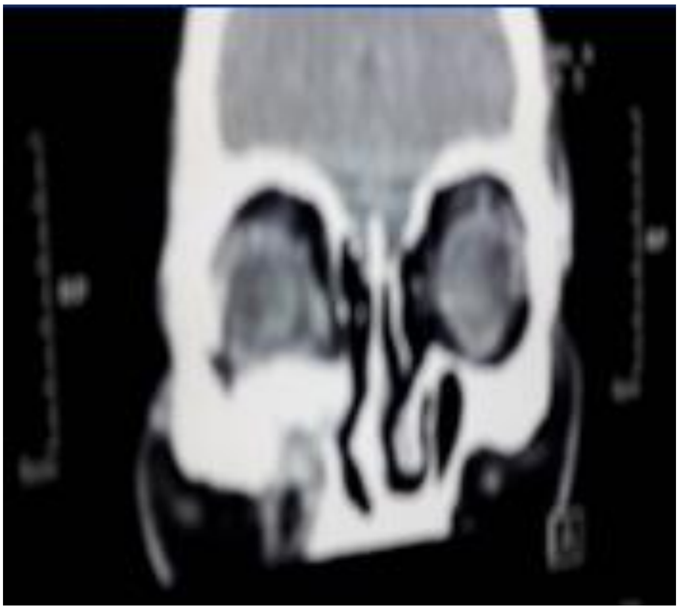


Harvested of iliac bone for the reconstruction of orbital floor

Per operative closing layer by layer after harvesting of iliac bone

Peroperative photograph showing implantation of Iliac bone graft in the right orbital floor

Preoperative CT scan showing fracture in the right orbital floor



Postoperative CT scan showing the defect of right orbital floor with replaced by Iliac bone graft

Appendix-VII

Publications

Original Article

Management of Traumatic Orbital Wall Fracture with Titanium Mesh

Kazi Lutfor Rahman[1], Ismat Ara Hayder[2], Mohammad Ghulam Rasul[3], Anjal Lal Ghosh[4], Shibasis Basak[5]

ABSTRACT

The management of orbital injuries is one of the most interesting and difficult areas in maxillofacial surgery. The improper reconstruction of the orbit frequently results in ophthalmic complications. Though a number of materials are available for the use in orbital wall reconstruction, at present titanium mesh could be considered to be the ideal orbital floor repair material. Ten cases of internal orbital wall defects were reconstructed by titanium mesh at the Dept. of Oral and Maxillofacial Surgery, Dhaka Dental College and Hospital, Dhaka from January, 2013 to December, 2014 were considered for this study. The study involved patients with symptomatic zygomatico-orbital fractures requiring orbital wall reconstruction. Under general anaesthesia the floor of orbit was explored and reconstructed with contoured titanium mesh after repositioning of the entrapped orbital contents.The patients were on periodic follow- up for 3 months where clinical and radiographic data were recorded. Ten male patients age ranging from 18 to 50 years (mean 30.50 years) received titanium mesh for impure orbital fractures (eight patients) and pure orbital floor fractures (two patients). The main cause of fractures was road traffic accidents. They also complained of enophthalmos (n = 9), diplopia (n = 8), infraorbital nerve paresthesia (n = 4), dystopia (n = 1) and epiphora (n= 2). No implant extrusion or infection was seen. The symptoms were corrected in eight patients with enophthalmos, seven with diplopia, three with infraorbital nerve paresthesia and all patients with epiphora. Dystopia persisted post-surgically in one patient. Titanium orbital implants were used to confirm titanium as a useful repair material for orbital floor fractures. Their use leads to less morbidity as no donor site operation is needed. Titanium mesh provides favourable healing as it is biocompatible.

Keywords: Orbital floor fractures · Titanium mesh · Enophthalmos · Reconstruction of floor.

INTRODUCTION

The management of orbital injuries is one of the most interesting and difficult areas in maxillofacial surgery. The consequences of an orbital injury are dramatic. They vary from loss of vision, enophthalmos, diplopia,loss of an eye, epiphora, a disturbing loss of facial sensation to an unsightly and unacceptable appearance of the eye and the hard and soft tissues around it.These injuries demand careful attention to detail but they are often underestimated and undertreated[1].

Damage to the orbital walls themselves can cause disorders such as enophthalmos, diplopia and much less frequently vertical dystopia. It is therefore mandatory to reconstruct the orbital floor and also repair of orbital rims in the same time[2].

Numerous materials - both naturally occurring and synthetic substances - are available for reconstructing damaged internal orbital walls to restore orbital volume. This is a prospective study for the management of post-traumatic orbital internal wall defect reconstruction by titanium mesh implants to provide long term chemically inert, biocompatible material which can replace autogenous bone grafts. The demerits include the need for a donor site and its complications.

MATERIALS AND METHODS

Ten patients (ten male patients between 18 to 50 years of age) with internal orbital wall fractures were randomly selected and treated at the Department of Oral and Maxillofacial Surgery, Dhaka Dental College and Hospital,

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2. Professor & Head, Department of Orthopaedic Surgery, Dhaka Dental College Hospital
3. Associatge Professor, Department of Orthopaedic Surgery, NITOR, Dhaka
4. Assistant Professor, Department of Orthopaedic Surgery, ZH Sikder Medical College
5. Registrar, Department of Orthopaedic Surgery, Dhaka Medical College, Dhaka

Correspondence to : Dr.Kazi Lutfor Rahman, M.S (Oral and Maxillofacial Surgery), PhD Researcher, Fellow IAOMS (USA),Department of Oral and Maxillofacial Surgery, Dhaka Dental College and Hospital, Dhaka, Bangladesh, Cell: +8801711235845, E-mail: dr.lutfor123@yahoo.com

Dhaka after obtaining ethical clearance between January, 2013 to December, 2014. The study involved patients with symptomatic zygomatico-orbital fractures requiring orbital wall reconstruction.

Patients presented with orthoptic symptoms including enophthalmos, diplopia,and dystopia or other associated symptoms like nerve paresthesia or epiphora.

All patients were operated under general anaesthesia through nasoendotracheal tube.

All patients were evaluated by the ophthalmologist for errors in vision, presence of enophthalmos, diplopia or dystopia and a through clinical history was recorded. Routine presurgical blood investigations and radiographs or computed tomography (CT) scans were obtained.

Diplopia charting was done clinically in all nine cardinal positions of gaze pre- operatively and post- operatively.

Following thorough skin preparation with betadine and sprit, tarsorrhaphy was done. Infraorbital incision was given in eight patients and subcilliary incision was given in two patients. Dissection layer by layer done and fracture site was exposed. The entrapped orbital tissues were repositioned and walls were reconstructed using cut and contoured 0.2 mm titanium mesh [Medicon Mesh Plate,contourable, Pure Titanium]. The mesh was fixed to the infraorbital rim using 2 mm screws to ensure graft stability.

The surgical skin defect was closed primarily in layers taking care to prevent any tension across suture line.

All patients were evaluated for the correction of their preoperative complaints through clinical and radiological examinations for a period of 3 months. Coronal CT scans with 3D reconstruction was done in all cases postoperatively following reconstruction (Figs. 1,2, 3, 4, 5, 6, 7, 8, 9,10).

Fig.-1: *Case 1 pre-operative and post-operative profile view*

Fig.-2: *Case1 preoperative and postoperative coronal CT scan*

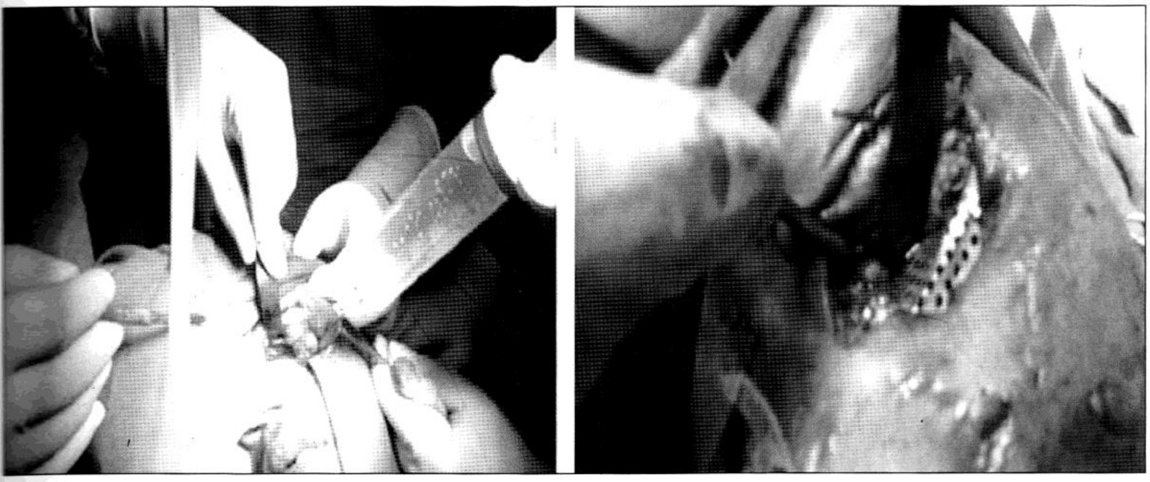
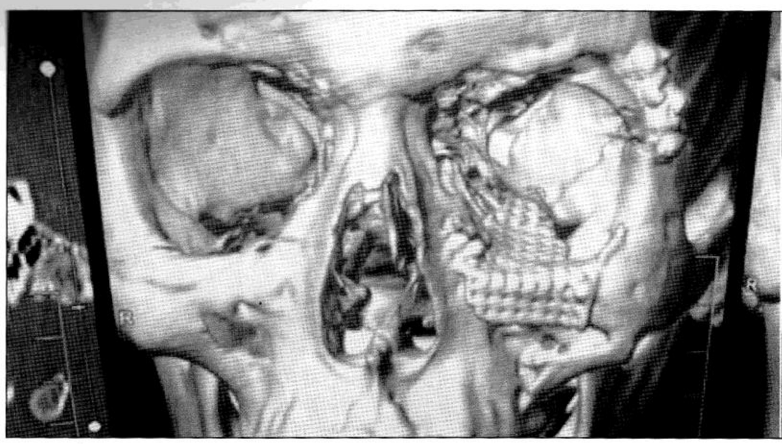


Fig.-3: *Case 1 before and after intra operative reconstru-ction*



Fig,-4: *Case 1 post operative 3D reconstruction scan*

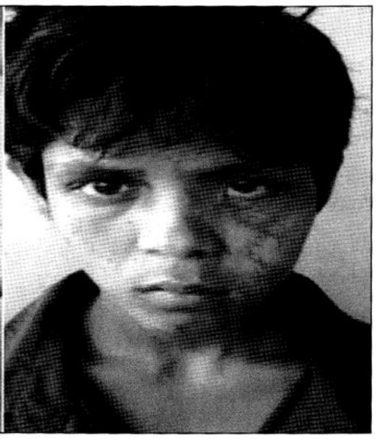


Fig.-5: *Case 1 post-operative 3 months follow up*

RESULTS

The main aim of the investigation was to evaluate clinically the efficiency of use of titanium mesh for the reconstruction of orbital floor post traumatically.

In this study, the most common mode of injury causing orbital wall fractures were associated with road traffic accidents (80%), followed by assault (20%).

Majority of fractures involving orbit were caused by indirect forces associated with fractures of zygomatico - maxillary complex with 80% of the study sample being orbital fracture of impure type and two patients with pure orbital blow out fractures. Minimum time lapse between trauma and surgery was 7 days and maximum period was 27 days.

This study showed no cases with infection of the surgical site.None of cases showed any other complications associated with the use of alloplastic materials like implant migration, extrusion of implant or hypersensitivity. Epiphora was noted in two patients (20%) preoperatively on fractured side which resolved considerably over the period of 3 weeks. None of the patients complained of epiphora upto 8 weeks following surgery.

Enophthalmos was seen in 90% of patients included in the study preoperatively. Correction of enophthalmos was seen in 88.9% of our patients, on the 8th week following surgery only one patient showed signs of enophthalmos.

Though the possibility of late post- operative enophthalmos is a possible sequale, all our patients were reviewed after 1 year and did not show any signs of enophthalmos to date.

This study showed correction of diplopia in 87.5% of patients. Persistance of double vision was only noted in one patient in extreme upward gaze, this error in the vision did not affect the patient's day to day activities.

Dystopia was present in one patient preoperatively which corrected after surgery. In this study 40% of the patients reported numbness over the infraorbital and lateral part of the nose following trauma. Patients showed considerable improvement over time and 80% of patients involved in the study had no complaints of paresthesia over 8 weeks of surgery.

None of cases showed any obvious entrapment of the orbital muscles on surgical exposure. Though orbital connective tissue and fat were noticed to be entrapped in the fracture site none of the cases showed any obvious restriction of globe movement.

Fig.-6: *Case 2 preoperative and post-operative profile view*

Fig.-7: *Case 2 preoperative and post –operative coronal CT scans*

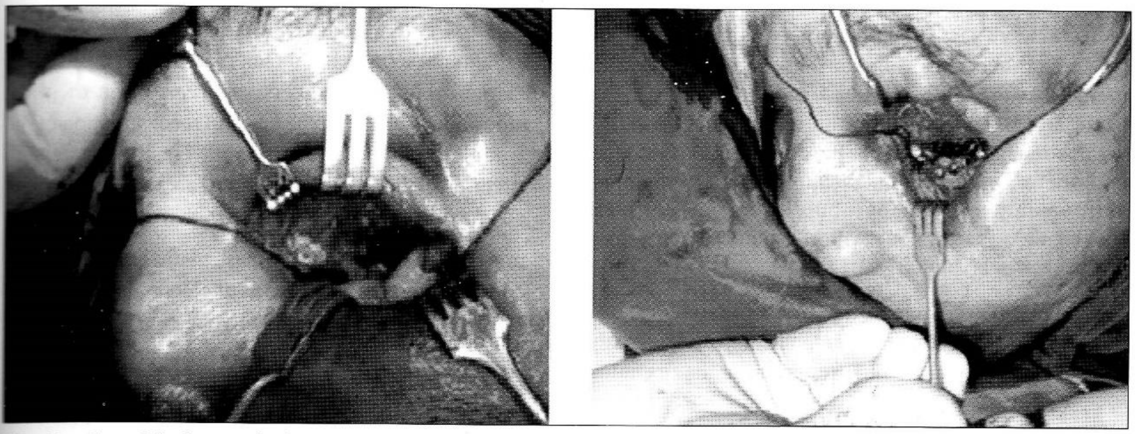


Fig.-8: *Case 2 before and after intra operative reconstruction*

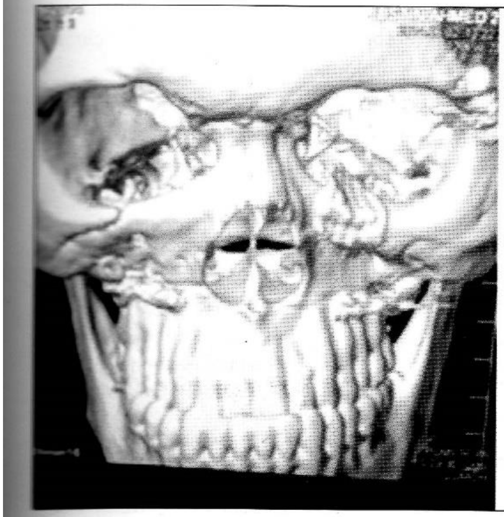


Fig.-9 *Case 2 post-operative 3D reconstruction scans.*

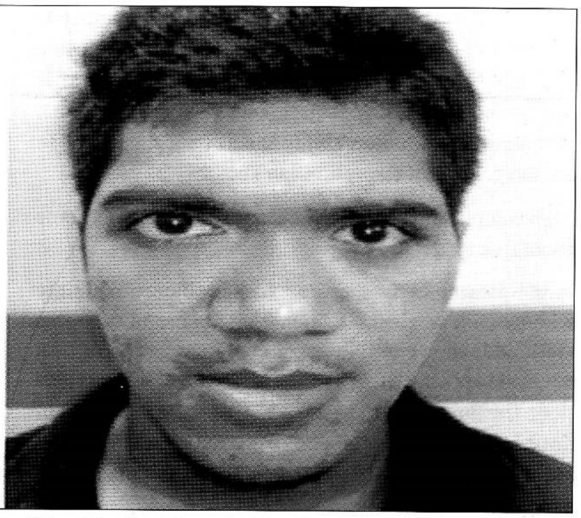


Fig.-10: *Case 2 post-operative 3 months follow up.*

DISCUSSION

The orbital floor is most vulnerable to fracture because of thinness of the maxillary roof, existence of the infraorbital canal and curvature of the floor. Immediately behind the orbital rim, the floor is concave, whereas further back , it becomes convex and is called posterior ledge or bulge, where the bony structure becomes thicker and less deformed in the orbital floor fracture[3].

Reconstruction of this posterior bulge or retrobulbar bulge by proper contouring of this titanium mesh before insertion into the defect has to be strictly followed to ensure that the antero – posterior globe position is maintained after reconstruction (Fig. 5). Failure to achieve this step during surgery could result in late post- operative enophthalmos.

There has been extensive debate over the standard of care of orbital floor and wall fractures. Recommendations of treatment range from exploration to observation. Clinical indicators such as enophthalmos, persistent diplopia, infraorbital nerve paresthesia, muscular entrapment or incarceration, hypoglobus, potentiation of the oculocardiac reflex, severe orbital emphysema, as well as various radiographic criteria have all been proposed as indications for surgical intervention. Of these, diplopia, entrapment and hypoglobus, with or without enophthalmos, seem to be the most common clinical signs for surgical intervention[4].

The ideal material for orbital reconstruction remains controversial. It should be cheap, biocompatible, readily available, easy to manipulate and insert in the operating room and it should allow fixation to the host bone by screws, wire or sutures.

The more elastic materials are unable to withstand the dynamic stresses of large defects. Resorbable implants may be prone to foreign- body reaction, implant exposure and having only fibrinous connective tissue remains after resorption. The disadvantages of autogenous bone grafts include minimal contourability and a donor site defect. In addition, implant resorption can occur.

High complication rates have been reported in use of some alloplastic materials[5-8].

In the present study showed excellent biocompatibility with no post surgical infection with the use of titanium mesh and shows excellent results in correction of post traumatic orthoptic problems with titanium mesh for orbital floor fractures. Only one patient showed persistence of double vision at the end of 8 weeks following reconstruction in only extreme upward gaze. Some alloplastic materials like porous polyethylene implants have shown persistence of diplopia in 25- 30% of patients[5-9].

Correction of enophthalmos yielded excellent results with titanium mesh with 88.9% of the test sample showing resolution of the symptoms. One patient who showed persistent enophthalmos presented with extensive injury (panfacial trauma) to surrounding bony structures with loss of bony architecture. At the 8 week following surgery there was significant improvement in globe position and volume with mild persistent enophthalmos compared to the uninjured eye. Extensive injury could be postulated to be the reason for difficulty to correct the globe volume satisfactorily.

Numbness over the skin in the infraorbital region was noticed in 40% of the patients which was seen to persist over a period of 3 weeks following surgery and slowly resolved over 8 weeks with 80% of patients showing no symptoms of paresthesia.

CONCLUSION

Titanium mesh has a long track record of reconstruction of large orbital floor defects and correction of globe malposition. Care has to be taken in reconstruction of the retrobulbar bulge with titanium mesh by adequate contouring of the mesh in this critical area to ensure proper globe position.

Some advantages of titanium mesh plates are availability, biocompatibility, easy intraoperative contouring and rigid fixation. Disadvantages are difficulties with ease of insertion.Any rough edges on the mesh tend to catch on prolapsed orbital fat. Removal of the titanium mesh after the healing period is challenging due to scar tissue that grows through the mesh perforations.

This study highlights the ability of the alloplastic mesh to satisfactorily correct post traumatic orbital sequel including enophthalmos and diplopia.

Titanium mesh can be considered to be the ideal orbital floor repair material.

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Case Report

Journal of Monno Medical College,
December 2020, Vol. 6, No. 2, pp. 56-60

ISSN (Print) 2412-3277

Surgical Correction of Sequels Involving Orbito-Zygomatic Fractures: A Case Report

Rahman KL[1], Haider IA[2], Rasul MG[3], Saquib AKMN[4], Rashid R[5]

Abstract

The treatment of the sequels involving the orbito-zygomatic complex is a challenging problem in the oral and maxillofacial surgery. The surgical correction involves the reestablishment of the zygomatic contour with the adjacent bones and the normal functional, restoration of ocular globe. With this purpose several techniques and materials can be used, among them one biomaterial-titanium mesh and plate was used here. The aim of the present paper is to present a surgical treatment of zygomatico-orbital fracture sequel using titanium mesh and plate, to improve the repositioning of ocular globe and bone edges. Moreover, discussions on the handling of fractures sequels involving zygomatico-orbital complex will be argued under the form of literature revision. *[Journal of Monno Medical College, December 2020;6(2): 56-60]*

Keywords: Zygomatico-orbital fractures; surgical correction; biomaterial

Received: : 7 June 2020; **Accepted:** 20 October 2020; **Published:** 1 December 2020

Introduction

The fractures involving the orbito-zygomatic complex are sufficiently common and the literature reports a high occurrence of it[1]. Significant complications can occur as consequence of an absence or inadequate therapy, including facial asymmetry, enophthalmos, persistent diplopia, vertical dystopia,restriction of ocular movements and sensorial deficit involving infra-orbital nerve[2]. The main causes of these complications happen due to an inadequate reduction of fracture fragments and to a loss of ocular globe support, which cause alterations in the relation content-container of the ocular globe and its bony compartment. The treatment of zygomatico-maxillary complex sequels aims to repair the bone continuity in the orbital floor, the contour of zygomatico-frontal suture and the zygomatic arch, the alignment of the zygomatico-maxillary pillar and the internal portion of orbital bone walls.

The present paper aims to report a surgical treatment of zygomatico-orbital fracture sequel using titanium mesh and plate to obtain a correct repositioning of ocular globe and infraorbital margin in addition to proportion an adequate bone contour in the region of fronto-zygomaticand zygoamtico-maxillary suture, resetting the morpho-functional integrity of involved facial structures.

Case Presentation

Having suffered a car accident three days before, a thirty eight-old male patient came to our Department of Oral and Maxillofacial Surgery of Dhaka Dental College Hospital, November, 2017 with a history of trauma in the zygomatico-orbital area. Immediately after the accident, the patient received first-aid treatment only.

Through the clinical examination, we identified facial asymmetry and mild enophthalmos on the left side, as well as vertical dystopia and injuries both in the fronto-zygomatic suture and in the infraorbital rim. The outcome of the palpation was an irregularity in the fronto-zygomatic suture

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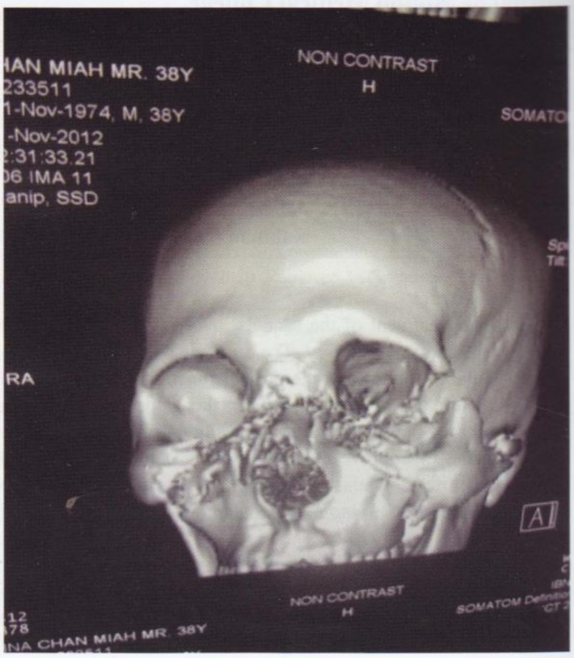
Conflict of interest: We do not have any conflict of interest (financial or others).

How to cite this article: Rahman KL, Haider IA, Rasul MG, Saquib AKMN, Rashid R. Surgical Correction of Sequels Involving Orbito-Zygomatic Fractures: A Case Report. J Monno Med Coll 2020;6(2): 56-60

Picture-I: The computed tomography shows medial rotation in the left fronto- zygomatic, zygomatico-maxillary and zygomatico- temporal sutures.



Picture-II: The computed tomography with three dimensional reconstruction shows medial rotation in the zygomatico-orbital area

Figure III: Titanium mesh fixed with screws in the left infra orbital rim

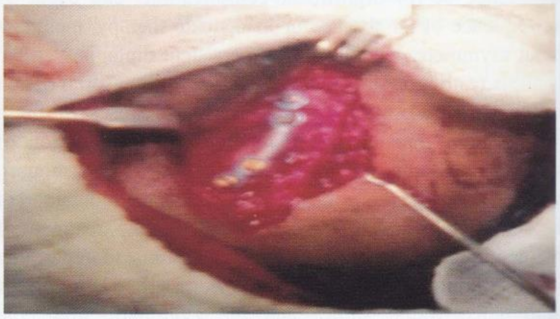


Figure IV: Titanium Plate fixed in the left fronto-zygomatic suture

and in the left infra-orbital margin. In addition, the intraoral examination confirmed the unevenness in the zygomatico-maxillary area. Although the patient reported feeling paresthesia in the left infraorbital margin, he did not complain about diplopia. The computed tomography showed in the zygomatic bone is separated with medial rotation in the left fronto-zygomatic, zygomatico-maxillary and zygomatico-temporal sutures. Furthermore, a dislocation of the lateral wall in relation to the medial wall was found in the maxillary area, with volume decrease. As for the eyeball, its diameter had increasedvertically. Finally, by means of axial sections themedial dislocation in the spheno-zygomatic suture was observed (Figure I, II). Based upon these findings, we reached a diagnosis of complete dislocation of the zygomatic bone (medial direction) associated with increase in the eyeball volume.

The suggested surgical technique consisted of titanium mesh and plate in the orbital floor and margin. As for the fronto-zygomatic suture, we decided to use the titanium plate. The orbital floor was reconstructed by titanium mesh and fixed by three titanium screws. The new contour of the infraorbital margin was reestablished by adjusting the titanium plate to the zygomatico-maxillary body, in order to simulate the infraorbital border. The titanium plate was affixed with three 5 mm long screws (Figure III). Aiming at fixing the other bone defect, located in the fronto-zygomatic suture, we inserted another four screws, and juxtaposed to the site wherethe bone had been fractured, in order to reestablish the orbital lateral projection (Figure IV).

Figure V: Follow up by PNS imaging exams (OM view)

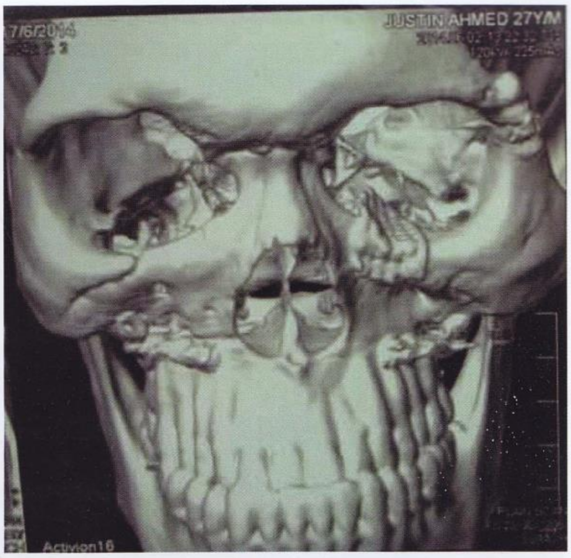


Figure VI: Post-operative 9 months follow-up by CT scan with 3D image showing reconstruction of the orbital floor and margin

The patient is undergoing follow-up sessions which consist of clinical and imaging examinations, in which we can clearly see the improvement in the projection of the eye ball, the decrease of the enophthalmos, the better infraorbital margin as well as the excellent recontour of the fronto-zygomatic suture (Figure V & VI).

Figure VII: Pre-operative facial profile

Figure VIII: 9 months post-operative photograph

Figure IX: 18 months post-operative facial profile

Discussion

Zygomatico-orbital fracture sequels may derive directly from the absence or inadequate reduction of the fractures, as well as from bone instability due to the inappropriate choice of the site and number of screws for stabilizing the bone. In order to deal with the traumatic sequels of the zygomatico-orbital complex, it is mandatory that a complete assessment of the patient be made. For establishing an objective plan of treatment,various factors must be determined and analyzed,such as the level of bone dislocation, the integrity of the orbital walls, the position of the eyeball, thevolume of the orbital content, the changes in the insertions of the canthal ligament, the periorbital soft tissues, the radiographic examination and the ophthalmologic evaluation[3]. In the present case, the combination of all these data has provided the precise information about the level and extension of the dislocation of the zygomatic bone, the volume of the orbital cavity and the conditions of the orbital floor.

The treatment of the zygomatico- orbital sequels involves surgical modalities repositioning of the bone and employment of titanium mesh and plate. The time period between the injury and the treatment plays an essential role in the selection of the best surgical procedure to be adopted. From 21 days to 4 months, Carr and Mathog[4] recommend performing osteotomies on the lines of the fracture in order to reposition of the zygomatic bone. Cohenand Kawamoto Jr.[5] describe a technique for correcting late enophthalmos and facial asymmetry by using an oscillating saw to recreate fracture lines,and then reposition the zygomatic bone in an overcorrected way.

The use of bone grafts is frequently required in late traumatic reconstructions[6]. Due to the longtime period between fracture and surgery, a process of remodeling and reabsorption of the juxtaposed, fractured bone margins and of the smashed fragments takes place. As a result, the identification of the exact site of the fracture lines, the anatomic repositioning of the segments and the bone stabilization may be difficult to be achieved[3]. After 4 months of untreated fracture, the most adequate therapeutic conduct for surgical correction, according to Carr and Mathog[4], excluding the processes of osteotomy and bone repositioning, aiming at reestablishing adequate bone contours and eyeball leveling.

In the present case, we chose titanium plate to reestablish the contour in the fronto-zygomatic and maxillary-zygomatic areas. For a better stabilization and support of the eyeball in the orbital floor area, the association of titanium mesh was employed. In the infraorbital margin area, due to the absence of projection, the plaque was modeled in such a way to simulate that anatomic area. Craniofacial bone defects may be repaired by using different techniques and implant materials. The choice of the implant material will depend upon the size and shape of the defect to be repaired, in addition to the conditions of the area that will receive it.

Disadvantage of autogenous bone graft mentioned in the literature, is the unpredictability of the reabsorption level of the graft[7]. Therefore, one important aspect to diminish the reabsorption level of the bone graft is its binding to the receptive area, since micromovements made by the ocular muscles conduct to a greater resorption of the graft.

For this reason, we use titanium mesh on the orbital floor. Studying the long term outcomes of craniofacial reconstruction using titanium mesh, Kuttenberger and Hardt[9] have demonstrated that the tridimensional reconstruction capacity produced by such procedure guarantees long term, functional and aesthetic stability, making it an alternative to bone and cartilaginous graft.

The excellent biocompatibility and easy handling of the titanium mesh have allowed us to reestablish, in a rather faithful way, the infraorbital and orbital floor areas of the patient whose case is described here, which matched perfectly with the titanium mesh. Moreover, the titanium mesh worked as a support structure for the orbital floor, which takes us back to what Hammer and Prein[10], Kuttenberger and Hardt9 and Oliveiera[6] have stated.

Conclusion

By carefully analyzing the treatment of the sequels produced by fractures in the zygomatico-orbitalcomplex, we may conclude that Detailed clinical and imaging examination must be carried out in order to establish the level of dislocation of the fracture and the extension of the orbital floor fragmentation, aiming at determining the necessary correction for the reestablishment, adequate bone recontour and at the enophthalmos correction. Fractures are better corrected through titanium plate and mesh in the fronto-zygomatic sutureand zygomatico-maxillary areas, as well as in the infraorbital margin and orbital floor. The association of titanium mesh adds the strength, adaptation and support of the orbital floor.

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Titanium Mesh versus Iliac Bone Graft for Reconstruction of Orbital Floor Fracture: Our Experience

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Abstract

Objective: The purpose of this studywas to assess the aesthetic and functional outcome of orbital floor fracture reconstruction performed bytitanium mesh or iliacbone graft.**Methodology:**Ten cases of orbital blowout fractures treated at Dept. of Oral and Maxillofacial Surgery, Dhaka Dental College and Hospital,Dhaka, in the Dept. of Oculoplasty, National Institute of Ophthalmology and Hospital, Dhaka &IspahaniIslamia Eye Institute and Hospital, Dhaka fromJanuary, 2018 to March, 2019 were considered for this study. All patients were evaluated by the Ophthalmologist and Oculoplastic surgeon for errors in vision, presence of enophthalmos, diplopia and infraorbital nerve anaesthesia both preoperative and upto six months of postoperatively. Clinical examination, patient satisfaction and radiographic investigations were used to assess repaired orbital floorfracture.**Results**:Titaniummesh was used in six cases and iliacbone graft used in four cases. Nine patients had significant improvement in their aesthetic appearance. Symmetry was restored in all cases. All ten cases had a noticeable improvement in the function. Of total ten cases six had diplopia, three recovered completely during the six months after the surgery. Three cases showed improvement later. All ten cases with enophthalmos recovered completely. Of the nine patients with infraorbital numbness, all recovered completely during the six months following surgery. One patient where the reconstruction was done byiliac bone graft showed mild discrepancy in the ocular level.**Conclusion:**For small tomedium defects measuring more than 2cm with enophthalmos and restricted ocular movements, iliac bone graft (four cases) was used. For larger defects and impure blowout fractures involving the infraorbital rim, titanium mesh (six cases) was used. The outcome of surgery with two materials was satisfactory. No postoperative complications were seen except for mild hypoglobus in a case reconstructed byiliac bone graft. These two materials, iliac bone graft and titanium mesh has the potential to be useful reconstructive materials in orbital floor fracture.

Keywords: Titanium Mesh –Iliac Bone Graft, Reconstruction of Orbital floor

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Introduction

The orbit's close proximity to the nose, paranasal sinuses, nervous system along with its important role in support and function of the eye as well as facial aesthetics makes it a vital anatomical structure. A variety of injuries ranging from subtle orbital floor blowout to gross communication may result in disruption of this anatomically complex region of the middle third of the face. With inadequate treatment, permanent orbital deformity, incapacitating visual dysfunction and unsatisfactory aesthetics may handicap an individual functionally, aesthetically and socially.[1] Orbital floor fracture results in a disruption of bony continuity permitting bone fragments, which is well visualizedin CT scan with 3D image (Fig. 1) beyond the original bony orbit[2,3] leading to enophthalmos, dystopia,infraorbitalparesthesia and hypoglobus. Soft tissue incarceration or entrapment may also occur, causing restricted ocular movements.[4] Of these, entrapment, diplopia and hypoglobus with or without enophthalmos have traditionally been considered to be indications for surgical intervention.[4] With Computed Tomography (CT) scanning permitting better visualization of location and extent of orbital floor defects and associated soft tissue prolapsed[3,5] surgical techniques to free entrapped tissue, reposition herniated orbital tissues and restore original orbital volume have become increasingly more aggressive as it is recognized that a failure to do so will predispose to atrophy and cicatricial contracture of herniated and incarcerated intraorbital soft tissues.

Numerous materials - both naturally occurring and synthetic substances – are available for reconstructing damagedorbital walls to restore orbital volume. The ideal material is that whose biomechanical properties most closely replicate those of the tissue it replaces. There is little consensus as regards the choice of material which has been, and remains, controversial with many workers enumerating the relative advantages and disadvantages of each class of material. Autogenous materials remain the gold standard to which other materials are compared yet alloplastic materialshave gained popularity for orbital floor fracture reconstruction for their easy of use and elimination of the need for a second operation and its associated morbidity [5]. In our study, the functional and aesthetic outcomes of ten patients were evaluated topresent our experience with autogenous bonegrafts (iliact bone graft) and alloplastic material (titanium mesh) for orbital floor reconstruction. We have also attempted to compare autogenous and alloplasticmaterials for orbital floor reconstruction.

Materials and Methods

This study was conducted at the Department of Oral and MaxillofacialSurgery, Dhaka Dental College and Hospital, Dhaka.in the Department of Oculoplasty, National Institute of Ophthalmology and Hospital, Dhaka &IspahaniIslamia Eye Institute and Hospital . Patients who reported to abovecentre from January, 2018 to March,2019 with orbital floorfractures were consideredfor inclusion in this study.

Inclusion criteria

- A clinical diagnosis of orbital floor fracture.
- CT with 3D image and radiograph imaging showing orbital floor defects, specifically, a loss of bony integrity of the orbital floor and displacement of soft tissue into the maxillary sinus resulting in 'tear drop' appearance (seen in a Water's view of the skull).

Exclusion criteria

Patients suffering from uncontrolled diabetes, rheumatoid arthritis, metabolic bone disease, immune compromised status and previous facial trauma were excluded from this study.

History was recorded and nature and severity of injury assessed with a thorough search made for:

- Restricted ocular movement
- Alteration of ocular level (dystopia)
- Enophthalmos – after seven to ten days
- Deepening of supratarsal fold
- Narrowing of palpebral fissure
- Development of diplopia – especially upward gauze
- On palpation, step deformity at infraorbital margin
- Paresthesia in the distribution of infraorbital nerve

Ten patients who fulfilled the inclusion criteria were selected for this study. After routine work – up, all patients underwent imaging examination which included radiographs (paranasal sinus view) and CT scan with 3D image and coronal cuts to detect and measure defects of the orbital floor.

All the patients were operated under general anesthesia and were given antibiotics and 8 mg of dexamethasone intravenously one hour prior to surgery. Open reduction and orbital floor reconstruction was performed in all cases. Infraorbital approach was used to obtain surgical access to the orbital floor.

Two materials were considered for the reconstruction of defects in the orbital floor: iliac bone graft in four cases and titanium mesh in six cases .Iliac crest was identified. A 5 cm long incision was made along with the skin lines. Inner table of the ilium immediately below the crest was exposed and the graft was harvested. This was shaped, contoured and stabilized at the orbital floor defect. Titanium mesh were fixed at the defect with titanium screws.

Pupillary reflexes were monitored postoperatively and the fundus was examined periodically. Patients were discharged after suture removal and recalled for review after one, three, and six month intervals.

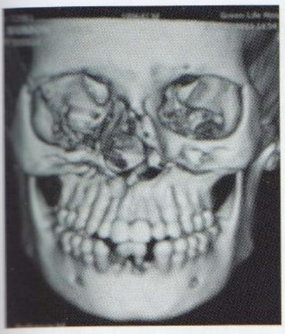

Fig1: 3D image of right orbital floor

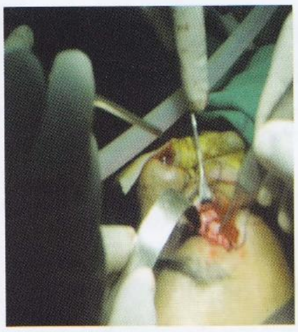

Fig 2: Iliac bone graft positioned fracture at right orbital floor

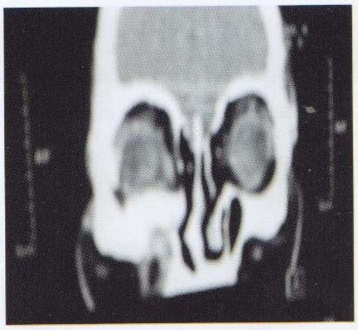

Fig 3: Post- operative CT Scan in Coronal view of Iliac bone graft in right orbital floor

Fig 4: Titanium mesh fixed with screws in the left orbital floor preoperatively

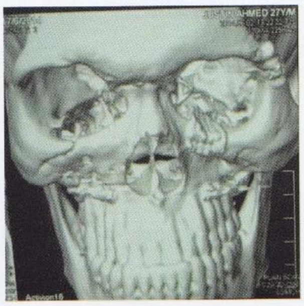

Fig 5: Post- operative 6 months showing reconstruction of the left orbital floor Titanium Mesh

Fig 6: Enophthalmos and hypoglobus present follow-up by CT scan with 3D image

Fig 7: Pre-operative facial profile of right orbital floor fracture with EnophthalmosIliac bone graft

Fig 8: Post treatment correction of right orbital floor fracture by

Fig 9: Post treatment correction of left orbital floor with Titanium Mesh

Results

Ten patients (8 males, 2 females) of ages ranging from 18 to 50 years were included in this study. The fractures were recent (less than 4-weeks-old) in 9 cases and old (more than 4 weeks) in one case. In addition to orbital floor fracture, in 5 cases there was associated zygomatico-maxillary complex fracture and in 2 other patients. Diplopia was noted in six cases, limitation of ocular movements as well as enophthalmos in all ten cases and infraorbital numbness in nine cases.

All 10 patients enrolled in the study consented to participate; there were no dropouts. After orbital floor reconstruction to restore volume of the orbital cavity and continuity of the orbital floor, CT scans and clinical examination were used to evaluate patients on follow-up visits. Nine patients had significant improvement in aesthetic appearance. Injured and uninjured sides had acceptable symmetry. One case of iliac crest bone graft reconstruction had mild discrepancy in ocular level possibly since graft size was not enough ascompared to extent of the defect. However ocular movements and vision were normal and no noticeable enophthalmos was present.

All ten cases had a noticeable improvement in function. Three of six cases with diplopia recovered completely within six months of surgery. The other three improved later. All ten cases with enophthalmos recovered completely and normal ocular movements were restored. All nine patients with infraorbital numbness recovered completely during the six months following surgery.

Four patients underwent orbital floorreconstruction with iliac crest bone graft where inner cortex was harvested from the iliac bone without intraoperativecomplications or postoperative complications.Although none of the patients revealed any abnormality or relevant findings radiologically, clinically one case with iliac crest graft had mild, residual hypoglobus. Complications such as infection,extrusion of graft, implant migration, haemorrhage and residual diplopia did not occur in our study cases and all patients were satisfied with the results of their surgery.

Discussion

In the reconstruction of orbital floor, timing is vital to restore lost globe support and to normalize orbital volume to prevent afunctional and cosmetic defect. Delayedsurgery permits cicatricial contracture of herniated or incarcerated intraorbitalcontents.[5]If diplopia is caused by the inferior rectus or the inferior oblique muscles being caught in the fracture, urgent surgery is required to free them within threeweeks or these delicate muscles willatrophy since timely reduction of orbital soft tissue limits the degree of ischemia caused by entrapment.

Of ten patients, nine were operatedupon for reconstruction of the orbital floor within two weeks from the day of the trauma. Only one patient was operated upon after three weeks because of panfacialfracture and surgery was attempted only after neurosurgical clearance.

The indications for surgical exploration of the fractured orbital floor include (1) enophthalmos, (2) limitation of extraocularmuscle function, (3) a large orbital floor defect with herniation of soft tissue into the maxillary sinus on CT (4) step deformity along the infraorbital margin with parasthesia of the infraorbital nerve causing numbness (6). Our selection of choice material for orbital floor reconstruction was based on the above mentioned indications.Patients were randomized either of two groups: iliac crest bone graft or Titanium mesh inconsideration of the size of defect.

Jason K. Potter reviewed the biomaterials that were available for orbital floor reconstruction to provide insight into their selection and application.[5] Because of the diversity of problems that maypresent in orbital reconstruction and limitations of each material, currently no single material is ideal. Rigid materials are best suited for reconstruction of large defects to prevent sagging and displacement into the maxillary antrum.

Konito et al have reported almost 80% resorption of iliac bone grafts, with 75% concurrent new bone formation, probably because of the presence of osteoblasts in cortial bone.[7]In our experience, cortical bone from the ilium (Fig.2) satisfies the requirement of rigidity. Its curvature is useful for floor reconstruction but rigidity makes contouringnearly impossible. Verification by a postoperative C T scan , coronal view (Fig. 3).

Titanium mesh has good biocompatibility and is easily adjustable. It is easy to trim and mould exactly to the orbital contour. Because of the mesh structure, connective tissue can grow around and through the implant, preventingits migration. It can be reliably fixed with screws (Fig. 4) in areas such as the infraorbital border. Titanium mesh has good physical strength in thin sections and it produces less artifacts on CT scans than other metals. It can be sterilized in conventional autoclaves. However, the mesh structure makes removal difficult. Ingrowth of fibrous connective tissue through mesh pores has been documented in at least one recent study.[8]

Literature is aplenty with several studies where titanium has been compared with various other materials. Edward Ellis III performed a study to assess the adequacy of internal orbital reconstruction in pure blowout fractures using either cranial bone grafts or titanium mesh implants and concluded that orbits reconstructed with titanium mesh showed better overall reconstructions than those reconstructed with bone grafts.[9] However, subsequent orbital trauma may displace titanium mesh toward the orbital apex endangering the optic nerve.[5] Hence, the resorbability of iliac crest bonegraft may be considered to be a potential advantage.[10]

In our study six patients underwent orbital floor reconstruction with titanium mesh. Preoperatively all the six patients showed signs of enop thalmos andrestriction of eye movements. Postoperatively, the orbital volume of all the six patients was restored with resolution ofexophthalmos. Normal eye movements were restored. None of the patient showed signs of infection nor extrusion of the implant. The mesh was stable on CT evaluation without any dislodgement.

The advantages of alloplastic materials like polyethylene, polypropylene include good biocompatibility, mild rejection reactions, and easy contouring.Autogenous tissue can grow into the porous material, biologically integrating the material with thesoft tissues and orbital floor. Advantages include decreased operative time, reduced pain, avoidance of donor site complications, and the ability to adjust the volume of filling as needed, particularly in cases of enophthalmos Non-resorbable alloplastic implants are permanent foreign bodies and reports of late complications such as infection, extrusion, implant migration and residual diplopia are plentiful in the literature.[11] However, it is salutary to note that such complications are not predictable as a recent study of 26 orbital floor fractures reconstructed with porous polyethylene demonstrated no extrusion even though mesh was not fixed to bone with screws.[12]

Goals of orbital floor fracture repair are to free incarcerated 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 pretrauma orbital volume. These goals may be achieved by interposing an autologous graft or alloplastic material between the residual orbital floor and the soft tissues prolapsed into the maxillary sinus, suitably repositioned inside the orbit. Our experience with ten patients in orbital floor reconstruction with two types of reconstruction materials (iliac crest bone graft and titanium mesh) has been encouraging and the results obtained were equal across the 2 groups.

Several other studies conducted on different parts of the world shows the different results of repair of orbital floor fracture by different materials depending on the size of the defects. For small to medium defects measuring more than 2cm with enophthalmos (Fig. 6, 7) and limitation in ocular movements due to entrapment of the extraocular muscles, iliac bone graft (four cases) was used. For larger defects and impure blowout fractures involving theinfraorbital rim, with gross communication of the orbital floor and herniation of the orbital contents into the maxillary antrum, titanium mesh (six cases) was used. Indeed, biological tissue appears to be well-accepted by the body as a graft.[13] When the results were assessed postoperatively, two materials were found to be satisfactory (Fig. 8, 9). No postoperative complications were seen except for mild hypoglobus in a case reconstructed with iliac crest bone graft.We conclude with the opinion that iliac bone graft and titanium mesh appear to have equal potential to offer stable reconstruction of the fractured orbital floor. However, the criteria for choice of implant material for reconstructive material is empirical in even recent literature.[14]

Conclusion

No consensus exists on the choice of implants for orbital floor reconstruction and several materials are available.The ideal material for the reconstruction of the orbital skeleton is influenced by many factors including specific characteristics of the injury and experience and opinion of the surgeon.There is now a real need for multicentric, randomized controlled trials using a large sample size as well as meta-analysis of such trials to derive definite opinions regarding the most appropriate materials for reconstruction of orbital floor fracture which would pave the way for definitive protocols to guide both the Maxillofacial and Oculoplastic surgeon in decision-making.

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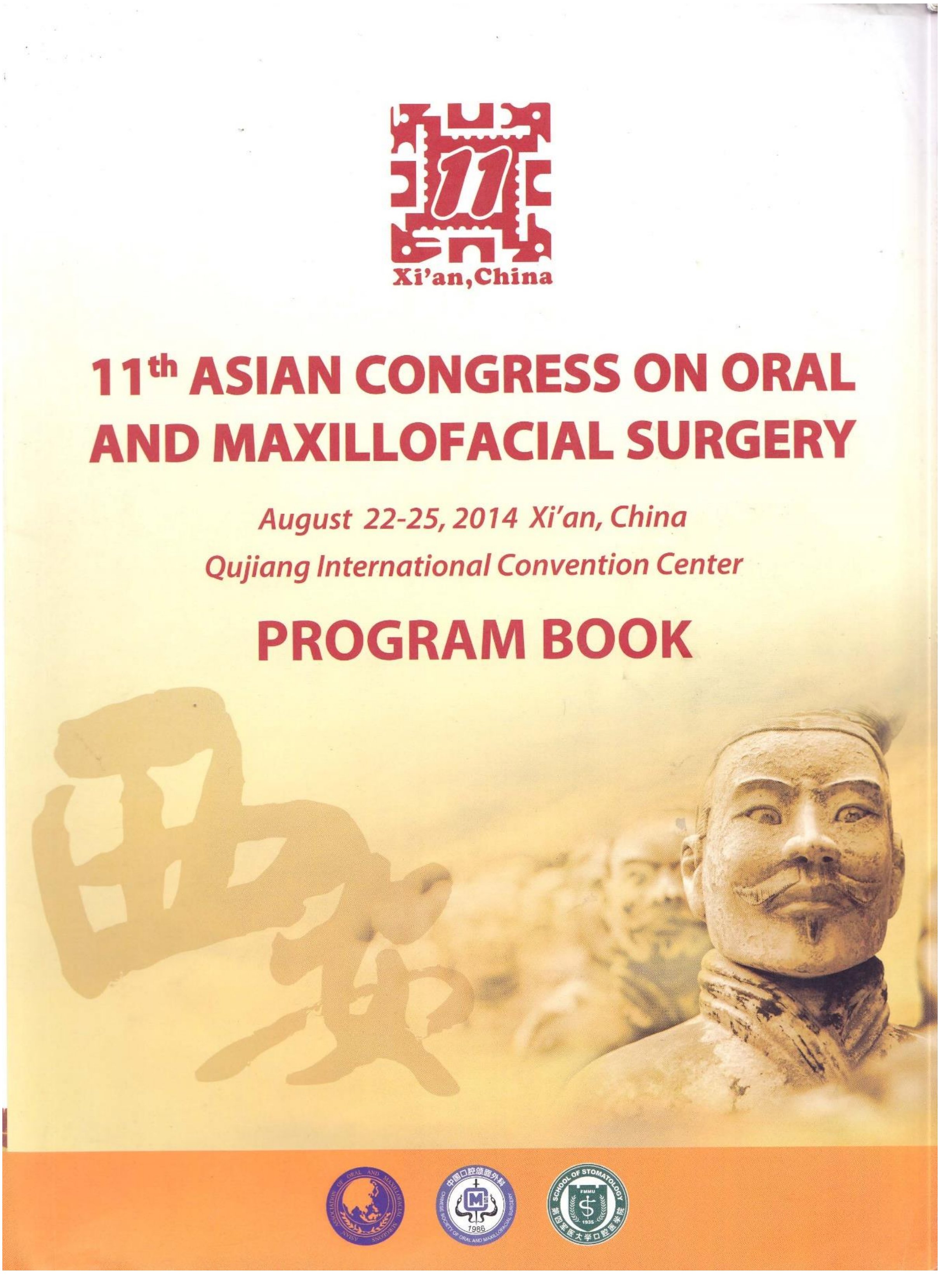
Appendix-VIII

Conference paper



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PROGRAM BOOK

Correction of Posttraumatic Enophthalmos by Titanium Mesh in case of Orbital Floor Fracture

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Posttraumatic enophthalmos is one of the common sequelae that appears after facial injury and remains a challenge to treat for Maxillofacial Surgeons. Several theories have been advocated regarding enophthalmos; however, the most well accepted concept is the enlargement of the orbital cavity after displacement due to orbital floor fractures. Generally, a 1cm3 increase in orbital volume causes 0.8 mm of enophthalmos. Thorough knowledge of the orbital anatomy is fundamental and critical for the successful surgical correction of enophthalmos because most treatment failures are due to inadequate orbital dissection from fear of injuring the optic nerve and globe. A complete preoperative plan should be built on a comprehensive clinical examination of the periorbital soft tissue and bony components, detailed ophthalmic examination and high resolution computed tomography scans in the axial, coronal and reformatted sagittal planes with 3-dimensional image. Based on the anatomic deformities, there are two major fractures on the types including orbital blowout fractures and zygomatico-orbital fractures, resulting in posttraumatic enophthalmos. Treatment modalities and methods of approach are adapted according to severity of the orbital deformities. The success of the procedures depend on adequate dissection and mobilization of the displaced soft tissue, correct repositioning of the dislocated of malunited bony orbit. The aim of this article is to describe one of the orbital floor reconstruction techniques conducted with the placement of titanium mesh, to correct enophthalmos and post operative evaluation of patients attending in the Department of Oral and Maxillofacial Surgery, Dhaka Dental College and Hospital, Dhaka, Bangladesh and Oculoplastic, Orbit and Eye Plastic Surgery Unit, National Institute of Ophthalmology and Hospital, Sher-e-Bangla Nagar, Dhaka, Bangladesh.

Complications after surgical treatment of sagittal fracture of the mandibular condyle

Chang-kui Liu, DDS, MD, PhD; Xin-ying Tan, DDS, MD; Min Hu, DDS, MD, PhD; Huawei Liu, DDS, MD; Hai-tao Huang, DDS, MD; San-xia Liu, DDS, MD; Juan Xu, DDS, MD, PhD
Chinese PLA Medical School
28 Fu Xing Road, Beijing 100853 China

Objective: This study was conducted to investigate the complications that occur after surgical treatment of sagittal fracture of the mandibular condyle (SFMC).

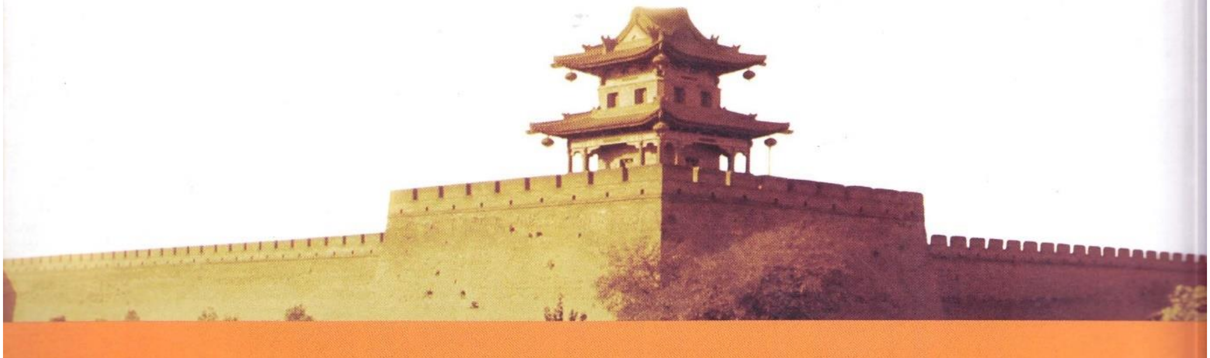
Methods: A retrospective study was conducted on cases in which SFMC was treated using surgical methods (87 cases, 105 sides) between January 1995 and December 2011. The longest follow-up was 17 years, and the shortest was 2 years. Follow-ups were conducted to assess mandibular activity, mouth opening and CT scans of condylar morphological alterations. The postoperative complications were evaluated and the causes were analyzed.

Results: We observed three cases of joint ankylosis; eight, mouth opening less than 30 mm; 23, deviation on mouth opening at 6 months. At 4 weeks, 19 patients had facial nerve weakness, which was resolved within 6 months. The radiological investigation showed complete remodelling in 56.2% of the condyles; partial remodelling, 27.6% condyles; poor remodelling, 16.2% condyles.

Conclusions: Considering that adult condyles have poor ability for healing and reconstruction, condylar sagittal fractures should be treated with surgical reduction and fixation.

11

Xi'an,China



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Correction of Posttraumatic Enophthalmos by Titanium Mesh in case of Orbital Floor Fracture

K.L..Rahman[a] ,I.A.Haider[a], A.K.M.N.Saquib[b] ,M.G.Rasul[b]

[a] Department of Oral and Maxillofacial Surgery, Dhaka Dental College and Hospital, Dhaka, Bangladesh
[b] Oculoplastic, Orbit and Eye Plastic Surgery Unit, National Institute of Ophthalmology and Hospital
Sher-e-Bangla Nagar, Dhaka Bangladesh.

Background:

Posttraumatic enophthalmos is one of the common sequelae that appears after facial injury and remains a challenge to treat for Maxillofacial Surgeons in Bangladesh. Several theories have been advocated regarding enophthalmos; however, the most well accepted concept is the enlargement of the orbital cavity after displacement due to orbital floor fractures. Generally, a $1cm^3$ increase in orbital volume causes 0.8 mm of enophthalmos. Thorough knowledge of the orbital anatomy is fundamental and critical for the successful surgical correction of enophthalmos because most treatment failures are due to inadequate orbital dissection from fear of injuring the optic nerve and globe. A complete preoperative plan should be built on a comprehensive clinical examination of the periorbital soft tissue and bony components, detailed ophthalmic examination and high resolution computed tomography scans in the axial, coronal and reformatted sagittal planes with 3-dimensional image. Based on the anatomic deformities, there are two major fractures on the types including orbital blowout fractures and zygomatico-orbital fractures, resulting in posttraumatic enophthalmos. Treatment modalities and methods of approach are adapted according to severity of the orbital deformities. The success of the procedures depend on adequate dissection and mobilization of the displaced soft tissue, correct repositioning of the dislocated of malunited bony orbit.

Methods:

The aim of this article is to describe two orbital floor reconstruction techniques conducted with the placement of titanium mesh and corticocancellous iliac bone graft in the orbital floor fracture to correct enophthalmos and post operative evaluation of patients attending in the Department of Oral and Maxillofacial Surgery, Dhaka Dental College and Hospital, Dhaka, Bangladesh and Oculoplastic, Orbit and Eye Plastic Surgery Unit, National Institute of Ophthalmology and Hospital, Sher-e-Bangla Nagar, Dhaka, Bangladesh.

Ten cases of orbital floor fractures with enophthalmos treated at our center from October 2012 to July 2014 were conducted for this study. Clinical examination, patient satisfaction and radiographic investigations were used to assess repaired fractures and correction of enophthalmos.

Results:

Titanium mesh was used in six cases and corticocancellous iliac bone graft used in four cases. All ten cases with enophthalmos recovered completely. Nine patients had significant improvement in their aesthetic appearance. Symmetry was restored in all cases. All ten cases had a noticeable improvement in their function.

Conclusion :

The outcome of surgery with two materials (titanium mesh and corticocancellous iliac bone graft) was satisfactory. No postoperative complications were seen except for mild hypoglobus in a case reconstructed with corticocancellous iliac bone graft. These two materials have the potential to be useful reconstructive materials in the orbital floor fractures with enophthalmos.

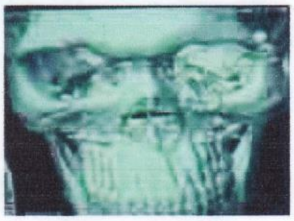
Fig1 . Pre operative photograph of a Patient showing severe enophthalmos

Fig2. Exposure of the Left Orbital floor

Fig 3. Fixation of Titanium Mesh in the left Orbital floor

Fg4. 1 Month post operative photograph with correction of diplopia

Fi9g5. 3 months post operative photograph with correction of enophthalmos



Fi9g6. 3 Dimensional Computed Tomography showing Titanium Mesh in the left orbital floor

Xi'an,China

Speaker Certificate

This is to certify that

Kazi Lutfor Rahman

had an excellent performance in the E-Poster Presentation at the 11th Asian Congress on Oral and Maxillofacial Surgery held in Xi'an, China on August 22 -25, 2014

Prof. Guang-yan Yu
Congress Chairman of 11th ACOMS
President of Asian Association of Oral and Maxillofacial Surgeons

Asian Association of Oral
and Maxillofacial Surgeons

Chinese Society of Oral and
Maxillofacial Surgery

School of Stomatology
Fourth Military Medical University

13th ACOMS TAIPEI 2018
Asian Congress on Oral & Maxillofacial Surgery

Title: Use of Titanium Mesh in Orbital Blow-Out Fractures and Enophthalmos Correction: Four Years' Experience in Tertiary Level Hospitals in Bangladesh

E-Poster Number: ACOMS-EP421

Original Research Article

Authors name: Kazi Lutfor Rahman[1], Ismat Ara Haider[2], Mohammad Ghulam Rasul[3], A.K.M Nazmus Saquib[4]

[1]Assistant Professor & PhD Research Fellow, Department of Oral and Maxillofacial Surgery, Dhaka Dental College and Hospital, Dhaka, Bangladesh; [2]Professor, Department of Oral and Maxillofacial Surgery, Dhaka Dental College and Hospital, Dhaka, Bangladesh; [3] Associate Professor, Department of Ophthalmology, National Institute of Ophthalmology, Dhaka, Bangladesh; [4]Senior Consultant, Department of Oculoplasty, National Institute of Ophthalmology, Dhaka, Bangladesh.

Purpose: To evaluate the efficacy of Titanium Mesh in reconstruction of orbital blow-out fractures and correction of enophthalmos.

Results: Patients stayed in the hospital between 14 and 20 days. The enophthalmos and hypoglobus of all 28 patients was corrected except for one. The patient needs another surgery 6 months after operation to remove a piece of Titanium Mesh because the hypoglobus was over corrected. Diplopia was resolved in 26 of 28 patients postoperatively. Visual acuity was improved in 24 of 28 patients where no change was observed in 4 cases. Infraorbital nerve hyposthesia was resolved in 25 of 28 cases 6 months after operation. Only one patient developed post-operative ectropion. No infections were seen after operation.

Materials & Methods: Twenty-eight patients with orbital blow-out fractures were treated at Department of Oral and Maxillofacial Surgery, Dhaka Dental College and Hospital, Dhaka, in the Department of Oculoplasty, National Institute of Ophthalmology and Hospital, Dhaka & Ispahani Islamia Eye Institute and Hospital, Dhaka from December, 2013 to November, 2017 were considered for this study. All patients were evaluated by the Ophthalmologist for errors in vision, presence of enophthalmos, diplopia or dystopia, visual acuity and infraorbital nerve anaesthesia both preoperative and postoperatively. Titanium Mesh were used to repair the defects of orbital floor and to correct the enophthalmos.

Conclusion: Titanium Mesh is a very reliable material for reconstruction of the orbital blow-out fractures and enophthalmos correction. Use of Titanium Mesh leads to less morbidity as no donor site operation is needed. They provide favourable healing as it is biocompatible.

Figure : 1,2 Exposure and Fixation of Titanium Mesh In the left orbital floor.

Figure : 3, 4 Pre and Post operative Photograph

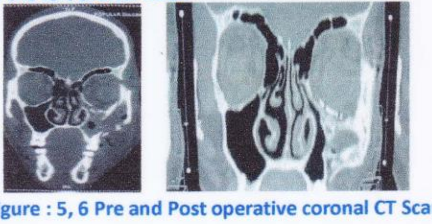
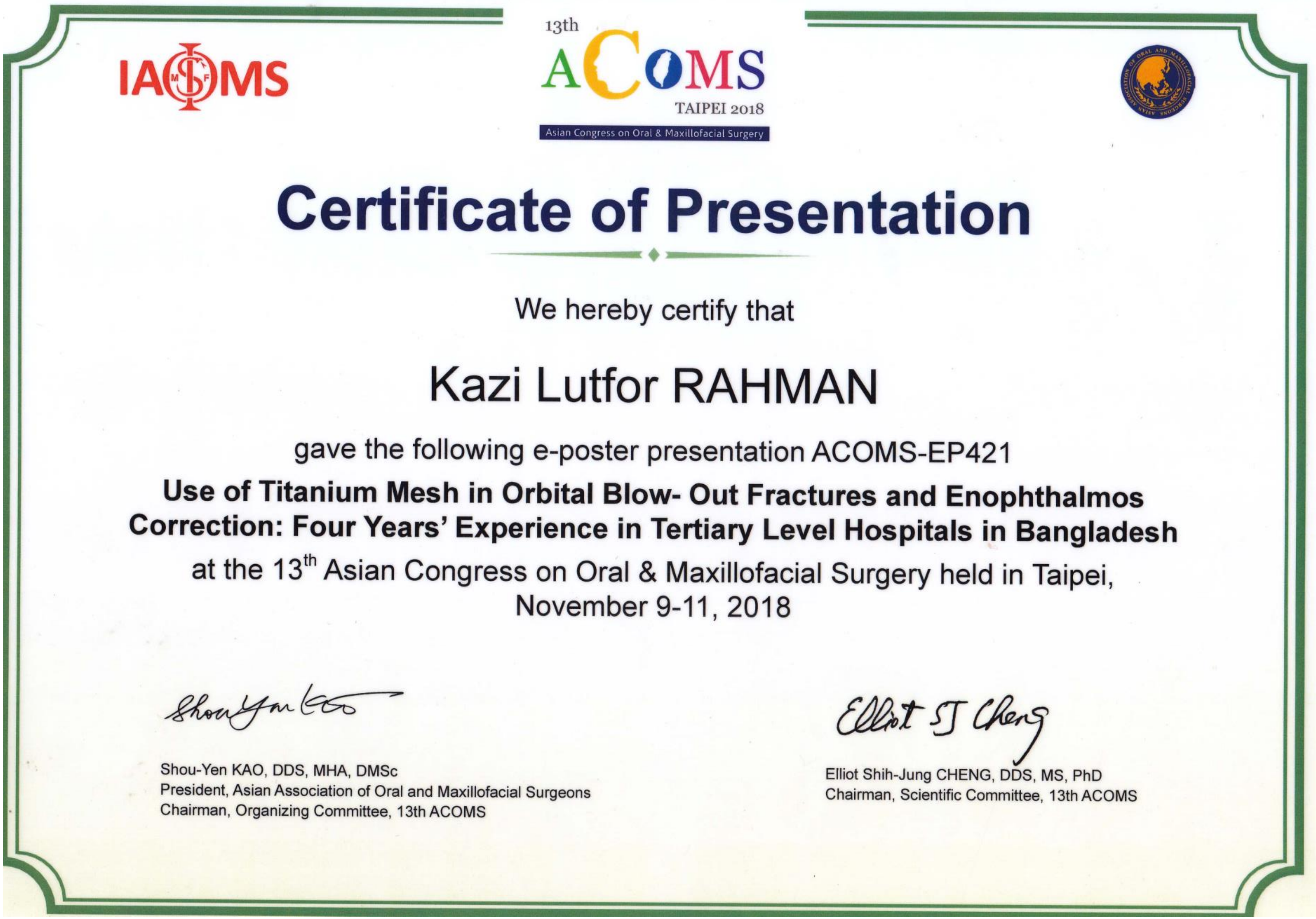


Figure : 5, 6 Pre and Post operative coronal CT Scan

Figure : 7, 8 Six months Follow up by CT scans and Facial Profile

Correspondence: Dr. Kazi Lutfor Rahman, Assistant Professor & PhD Research Fellow, Department of Oral and Maxillofacial Surgery, Dhaka Dental College and Hospital, Dhaka, Bangladesh; E-mail : dr.lutfor123@gmail.com



IAOMS

13th ACOMS
TAIPEI 2018
Asian Congress on Oral & Maxillofacial Surgery

Certificate of Presentation

We hereby certify that

Kazi Lutfor RAHMAN

gave the following e-poster presentation ACOMS-EP421

Use of Titanium Mesh in Orbital Blow- Out Fractures and Enophthalmos Correction: Four Years' Experience in Tertiary Level Hospitals in Bangladesh

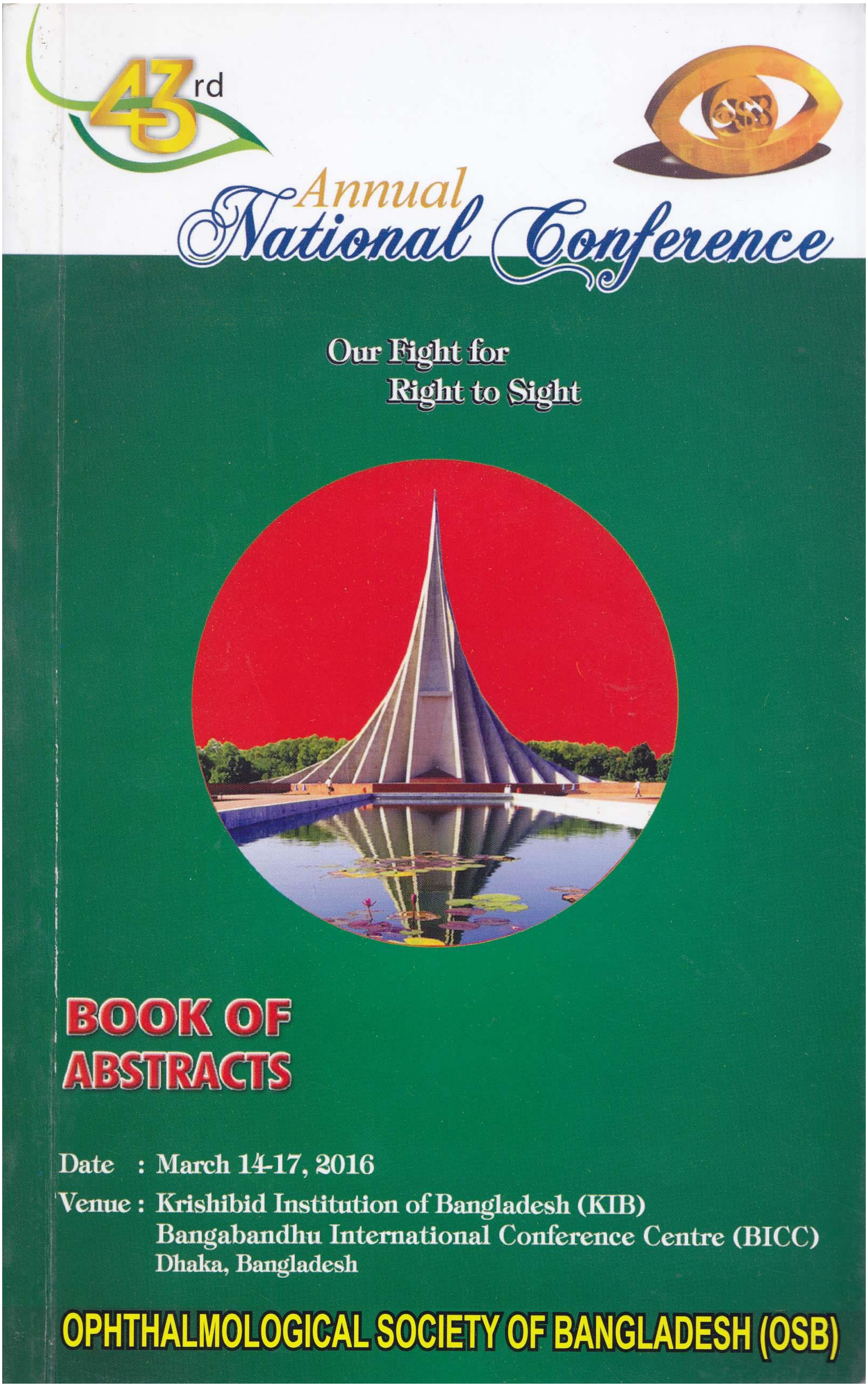
at the 13th Asian Congress on Oral & Maxillofacial Surgery held in Taipei,
November 9-11, 2018

ShouYen Kao

Shou-Yen KAO, DDS, MHA, DMSc
President, Asian Association of Oral and Maxillofacial Surgeons
Chairman, Organizing Committee, 13th ACOMS

Elliot SJ Cheng

Elliot Shih-Jung CHENG, DDS, MS, PhD
Chairman, Scientific Committee, 13th ACOMS



43rd Annual National Conference

Our Fight for
Right to Sight

BOOK OF ABSTRACTS

Date : March 14-17, 2016
Venue : Krishibid Institution of Bangladesh (KIB)
Bangabandhu International Conference Centre (BICC)
Dhaka, Bangladesh

OPHTHALMOLOGICAL SOCIETY OF BANGLADESH (OSB)

Options in Orbital Floor Recenstruction in Blowout Fractures

Kazi Lutfor Rahman[1], Ismat Ara Haider[2], Mohammad Ghulam Rasul[3]
A.K.M. Nazmus Saquib[4], Riffat Rashid[5], Sadia Sultana[6]

ABSTRACT

Objective:
The purpose of this study was assesss the aesthetic and functional outcome of orbital floor reconstruction performed with titanium mesh or iliac bone graft.

Methods:
Ten cases of orbital blowout fractures treated at Dept. of Oral and Maxillofacial Surgery, Dhaka Dental College and Hospital, Dhaka from October, 2014 to December, 2015 were considered for this study. Clinical examination, paitent satisfaction and radiographic investigations were used to assess repaired fractures.

Results:
Titanium mesh was used in six cases and liliac bone graft used in four cases. Nine patients had significant improvement in their aesthetic aesthetic appearance. Summetry was restored in all cases. All ten cases had a noticeable improvement in the function. Of total ten cases six had diplopia, there recovered completely during the six months after the surgery. Three cases showed improvement later. All ten cases with enophthalmos recovered completely. Of the nine patients with infraorbital numbness, all recovered completely during the six months following surgery. One patient were the reconstruction was done with liliac bone graft showed mild discrepancy in the ocular level.

Conclusion:

For small to medium defects measuring more than 2 cm with enophthalmos and restricted ocular movememts, iliac bone graft (four cases) was used. For larger defects and impure blowout fractures involving the infraorbital rim, titanium mesh (six cases) was used. The outcome of surgery with two materials was satisfactory. No postoperative complications were seen except for mild hypoglobus in a case reconstructed with iliac bone graft. These two materials, titanium mesh and liliac bone graft has the potential to be useful reconstructive materials in orbital floor blowout fractures.

Keywords:

Orbital blowout farctures liliac bone graft titanium mesh reconstruction of floor.

---

1. PhD Researcher, University of Dhaka & 2 Professor and Head, Department of Oral and Maxillofacial Surgery, Dhaka Dental College and Hospital, Dhaka.

2. Ex-Assistant Professor & 4. Ex-Senior Consultant, Department of Oculoplasty, National Institute of Ophthalmology and Hospital, Dhaka.

3. Junior Consultant & 6. Associate Professor, Department of Oculoplasty, Islamia Eye Institute and Hospital, Dhaka.

Ophthalmological Society of Bangladesh

10th Biennial conference of SAARC Academy of Ophthalmology
And
38th Annual National Conference of Ophthalmological Society of Bangladesh
Dhaka, Bangladesh

This is to certify that

Dr. Kazi Lutfor Rahman

Participated in the scientific deliberations on

Orbital floor reconstruction with Titanium Mesh Implant

&

contributed to the advancement
in
the field of Ophthalmology

Prof. Ava Hossain
President, OSB

Prof. Md. Shafiqul Islam
Chairman, Scientific Sub-committee

Prof. Ashraf Sayeed
Secretary, Scientific Sub-committee

Prof. Md. Sharfuddin Ahmed
Secretary General, OSB

SIGHT SAVES FUTURE

47th Annual National Conference
4-7 February, 2020
Ophthalmological Society of Bangladesh (OSB)

Ophthalmological Society of Bangladesh (OSB) at Krishibid Institution of Bangladesh (KIB), Dhaka

Certificate of Participation

This is to certify that

Dr. Kazi Lutfor Rahman

attended the 47th Annual National Conference 2020

Presented on tropic: *Correction of Enophthalmos by Titanium Mesh in case of orbit floor fracture:four years experience in tertiary Level Hospital in Bangladesh*

Prof. Md. Sharfuddin Ahmed
President
OSB

Prof. Dipak Kumar Nag
Chairman
Scientific Sub-Committee, OSB

Dr. Md. Mostak Ahmed
Member Secretary
Scientific Sub-Committee, OSB

Prof. Md. Abdul Quader
Secretary General
OSB

Ophthalmological Society of Bangladesh

45th Annual National Conference of Ophthalmological Society of Bangladesh
Dhaka, Bangladesh

This is to Certify that

Dr. Kazi Lutfor Rahman

Participated in the scientific deliberations on

Titanium mesh versus iliac bone graft for reconstruction of orbital floor fracture.

&

contributed to the advancement in the field of Ophthalmology

Prof. Sharfuddin Ahmed
President, OSB

Prof. Ashraf Sayeed
Chairman, Scientific Sub-committee

Dr. M. Shish Rahman
Member Secretary, Scientific Sub-committee

Prof. Dr. Anisur Rahman Anjum
Secretary General

1st Regional Conference on Oral and Maxillofacial Surgery and Allied Dentistry, 2020, 26th-28th February, Shaheed A.H.M Kamaruzzaman Auditorium, Rajshahi, Bangladesh

Dear Dr. Kazi Lutfor Rahman,

We are contacting you with regards to the abstract submitted for the 1st Regional Conference on Oral and Maxillofacial Surgery and Allied Dentistry, 27th February, 2020 in Rajshahi, Shaheed AHM Kamaruzzaman Auditorium.

On behalf of the Scientific Committee we would like to inform you the status of the following abstract:

Conference Paper

Paper Details	
Title	Correction of Enophthalmos by Titanium Mesh in Orbital Floor Fracture: Our Experience. ***Dr. Kazi Lutfor Rahman***
Paper Status:	**Accepted**
Presentation Type:	**Oral Presentation**
Presentation time:	**4:20 PM -4:30 PM, 27th February,2020**
Session Name:	**Session - 5**

*** We will strictly maintain the time, you are requested to complete your presentation timely. Your cooperation will help other speaker to present properly and run the session smoothly.

We would also like to remind you that the abstract will be published in the souvenir of the conference.

Thank you very much for sending your paper and taking part in this special event and do not hesitate to contact us for any further information and assistance you may need.

We look forward to meeting you 27th February, 2020.

Kind regards,

Dr. Shaheen Ahamed
Conference Secretary
Chairman, Seminar Sub-Committee
1st Regional Conference on Oral and Maxillofacial Surgery
rcoms2020@gmail.com

Dr. Md. Ariful Islam
Secretary Seminar Sub-Committee
1st Regional Conference on Oral and Maxillofacial Surgery

BANGLADESH ASSOCIATION OF ORAL AND MAXILLOFACIAL SURGEONS (BAMOS)

5th National & 2nd International
BCOMS
Bangladesh Conference on Oral & Maxillofacial Surgery 2018

Bangladesh Conference on Oral & Maxillofacial Surgery 2018

20th January 2018
Bangabandhu International Conference Center, Dhaka, Bangladesh

Certificate of Appreciation

This certificate is proudly presented to

Dr. Kazi Lutfor Rahman

SPEAKER

Prof. Dr. Mohiuddin Ahmed
Chairman
BCOMS 2018

Prof. Dr. Ismat Ara Haider Lita
Secretary
BCOMS 2018

Dr. Md. Masudur Rahman Iqbal
Chairman
Scientific Committee, BCOMS 2018

Prof. Dr. Md. Ruhul Amin
President
BAMOS

Prof. Dr. Quazi Billur Rahman
Secretary General
BAMOS

29th Annual Scientific Congress

01 - 03 February, 2016
Pan Pacific Sonargaon Hotel
& NITOR, Dhaka.

Certificate

The Organizing Committee has the pleasure to award this certificate to

Dr. Kazi Lutfor Rahman

for his valuable contribution to BOSCON 2016 *by paper presentation.*

Prof. M. Amjad Hossain
President
Bangladesh Orthopaedic Society

Prof. Ramdew Ram Kairy
Chairman
Scientific Committee, BOSCON 2016

Certificate
of Participation

PlastiCon 2017

28 February 2017
Dhaka, Bangladesh

Society of Plastic Surgeons of Bangladesh

This Certificate of Participation is hereby granted to

Dr. Kazi Lutfor Rahman

for participation in the 5th International Conference on Plastic Surgery

Dr. Samanta Lal Sen
President
Conference Committee

Kalam
Prof. Md. Abul Kalam
Secretary
Conference Committee

SOCIETY OF PLASTIC SURGEONS OF BANGLADESH

PlastiCon 2015

CERTIFICATE

Paper Presentation

26 FEBRUARY 2015
NATIONAL INSTITUTE OF BURN & PLASTIC SURGERY
&
PAN PACIFIC SONARGAON HOTEL, DHAKA, BANGLADESH

This Certificate of Participation is presented to

Dr. Kazi Lutfor Rahman

for his / her participation in the Paper Presentation.

Dr. Samanta Lal Sen
President
Conference Committee

Kalam
Prof. Md. Abul Kalam
Secretary
Conference Committee

Prof. Dr. Md. Sazzad Khondoker
Chairman
Scientific Committee

PlastiCon 2017

SOCIETY OF PLASTIC SURGEONS OF BANGLADESH

Certificate
Paper Presentation

28 FEBRUARY 2017
DHAKA, BANGLADESH

This Certificate of Participation is presented to

Dr. Kazi Lutfor Rahman

for his / her participation in the Paper Presentation

on Options in orbital Floor Reconstruction in Blowout Fracture.

Kalam

Prof. Md. Abul Kalam
Secretary
Conference Committee

Dr. Samanta Lal Sen
President
Conference Committee

Rayhana Awwal.

Prof. Rayhana Awwal
Chairman
Scientific Committee

Appendix-IX

Training

BANGLADESH MEDICAL RESEARCH COUNCIL (BMRC)

BMRC Bhaban, Mohakhali, Dhaka-1212

WORKSHOP ON DEVELOPS MANPOWER IN HEALTH RESEARCH BY USING 'LEARNING BY DOING' METHODS

Certificate of Participation

Serial No. 793

Date: 19-03-2015

Dr. Kazi Lutfor Rahman participated in the Workshop on Develops Manpower in Health Research by using 'Learning by Doing' Methods *conducted by Bangladesh Medial Research Council from 25-01-2015 to 19-3-2015.*

His performance as a participant was satisfactory.

Director

Chairman

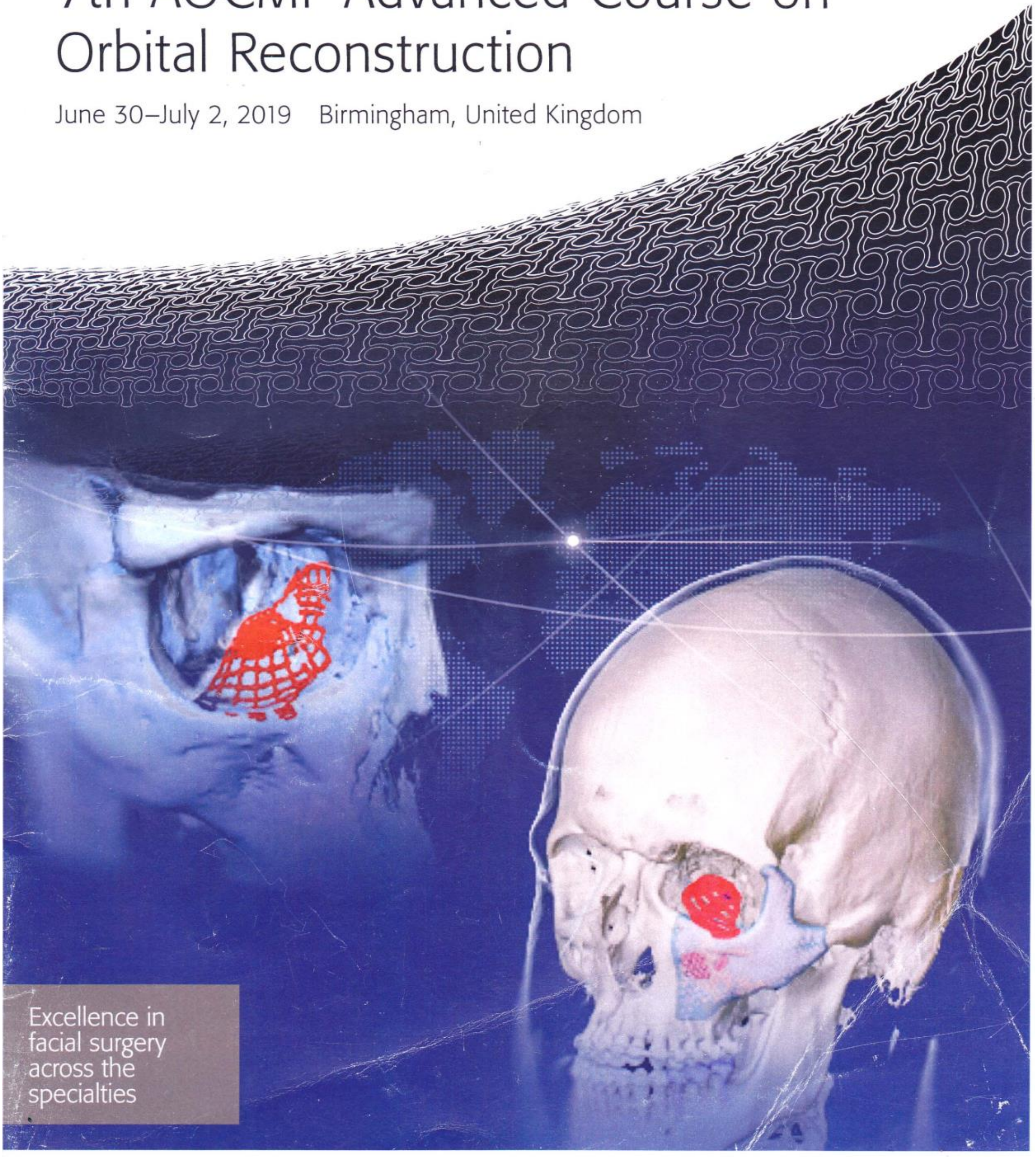
AOCMF

Event program

European Forum

7th AOCMF Advanced Course on Orbital Reconstruction

June 30–July 2, 2019 Birmingham, United Kingdom



FACEAHEAD

26–28 March, 2020

CMF SUMMIT

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AOCMF

Certificate

Course Participant Certificate

This is to certify that

Kazi Lutfor Rahman

Attended and completed

7th AOCMF Advanced Course on Orbital Reconstruction (pre BAOMS)

Date/location

30 June-02 July 2019, Birmingham, United Kingdom

Course chairperson(s)

Nils-Claudius Gellrich   Beat Hammer   Alexander Schramm   Ian Sharp
Frank Wilde   Rüdiger M. Zimmerer

This certificate pertains only to the participant's completion of the educational activity and does not in any way attest to the proficiency of the participant's clinical or surgical expertise.

Daniel Danielsson
Chair AOCMF Europe and Southern Africa

Gregorio Sánchez-Aniceto
Chair AOCMF International

Robert A. McGuire

Robert A. McGuire
President AO Foundation

EACCME
European Accreditation Council for Continuing Medical Education

Certificate

7th AOCMF Advanced Course on Orbital Reconstruction

Birmingham, United Kingdom, 30/06/2019-02/07/2019

has been accredited by the European Accreditation Council for Continuing Medical Education (EACCME®) for a maximum of **18** European CME credits (ECMEC®s).

Each medical specialist should claim only those credits that he/she actually spent in the educational activity.

The EACCME® is an institution of the European Union of Medical Specialists (UEMS), www.uems.eu. Through an agreement between the European Union of Medical Specialists and the American Medical Association, physicians may convert EACCME® credits to an equivalent number of AMA PRA Category 1 Credits™. Information on the process to convert EACCME® credits to AMA credits can be found at www.ama-assn.org/education/earn-credit-participation-international-activities.

Live educational activities occurring outside of Canada, recognised by the UEMS-EACCME® for ECMEC® credits are deemed to be Accredited Group Learning Activities (Section 1) as defined by the Maintenance of Certification Program of the Royal College of Physicians and Surgeons of Canada.

Kazi Rahman
Bangladesh

has been awarded **18** European CME Credits (ECMEC®s)
for his/her attendance at this event