A Novel Use of Biomaterial Implants For Reconstruction of Orbital Floor Fracture

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Abstract
Introduction: The progress in the field of biotechnology offers new materials for the reconstruction of orbital fractures. However, the choice of the best material for orbital floor repairs is still a controversial issue. In this paper the authors introduce the use of zirconium oxide implants for the first time in the reconstruction of orbital floor defects. Aim: Evaluate the clinical outcome of zirconium oxide implant material used for orbital floor repairs. Materials and Methods: From January 2008 to January 2015, six patients with orbital floor fractures referred to the Oral and Maxillofacial Surgery Department in Ramadi Teaching Hospital were surgically treated using zirconium oxide ceramic implants. The patients were examined after 7 days, 3 months and 2 years. Results: All cases achieved significant improvements in terms of diplopia and enophthalmos. No material related complications were reported in all treated cases. Post-operative radiograph and Computed Tomography Scans (CT) demonstrated that anatomical reduction of the orbital floor had been achieved. Conclusion: The study suggests that a zirconium oxide ceramic implant is a suitable implant biomaterial for the reconstruction of orbital floor fractures.

Key words: Orbit, blowout fractures, orbital floor reconstruction, biomaterials, implants, zirconium oxide ceramic implant

Introduction
The orbital floor is frequently involved in facial traumas (Blake, 2011). It has the potential to fracture in a similar manner to that of a safety valve, such as when there is a blow to the orbit and the energy dissipates (Banica et al., 2013). Orbital floor fractures could be isolated (pure orbital blow out fracture) or are associated with orbital rim fractures (impure blow out fractures) of the orbit (Charters et al., 1993 and Onofre, 2007). These fractures may cause the entrapment of orbital soft tissue structures with resulting vertical or horizontal ocular motility limitations and enophthalmos (Charters et al., 1993 and Onofre, 2007). There have been controversies regarding the surgical intervention of orbital floor fractures. However, it is generally agreed that indications for surgical intervention include severe hypoglobus, enophthalmos greater than 2mm, troublesome diplopia, periorbital tissue herniation in a fracture site, causing eyeball movement limitation (Sallam et al., 2010).
There are different available surgical techniques for bone contour reconstruction and the restoration of adequate orbital volume, ranging from osteotomies to inlay bone augmentation. These methods utilize a variety of biomaterials, which include bone grafts, alloplastic materials, cartilage, fat grafts and titanium meshes (Burnstine, 2002). However, to the best of the author’s knowledge there has been no previous attempt to restore orbital floor fractures with zirconium oxide implant material. The first paper on biomedical application of zirconia was published in 1969 by Helmer and Driskell. They examined the biocompatibility of zirconia with animal tissue. This study was followed by other studies on the use of balls, cylinders and bars of stabilized zirconia in animal bones. Another study carried out by Koch et al. on the effect of zirconia on soft tissue in animal models. They concluded that zirconia does not produce cytotoxic effects in soft tissues in any physical state (Koch et al., 2010). None of these studies found any local or systemic reactions in different material forms. The first use of ceramic biomaterials as a replacement for the entire hip bone in vivo was by Christel et al. (1988), followed by Kanchana and Sharmila (2013). Kamal used zirconium oxide in TMJ prosthesis and this has proven to be favourable, with study results demonstrating marked improvements in pain levels, the functioning of the jaw, and morphology (Kamal, 2013).

**Aim**

To evaluate the clinical outcome of zirconium oxide implant material used for orbital floor repairs.

**Materials and Methods**

This study was approved by the Human Ethics Committee at Ramadi Teaching Hospital, Al- Anbar, Iraq. From January 2008 to January 2015, six patients with orbital floor fractures were referred to the Oral and Maxillofacial Surgery Department in Ramadi Teaching Hospital with immaculate orbital floor fractures and diplopia, especially on extensive upward and downward gazes. Out of six patients, four of them were treated approximately 10 days after their initial admission to the hospital, due to the severe periorbital swelling present on admission. The other two patients were operated on a month after being referred from an ENT specialist. Extensive fractures were found in all patients with numerous bony fragments projected into the maxillary sinus cavity. These patients were treated with reshaped zirconium oxide inserts.

Zirconia is a white crystal-like zirconium oxide with a density of zirconium oxide is 5.85g/cm3, and melting point is higher than 2600 degrees celsius (Rita et al., 2008). A novel bearing surface modification has been made from zirconium alloy (Zrniobium [Nb] 2.5%) oxidised by thermal diffusion to create a 5-mm oxidised zirconium layer (Oxinium; Smith & Nephew, Memphis, Tennessee) (Kamal, 2013).

Computerized tomography scans and radiographic examination were used to evaluate all of the patients before operations. The assessment of the defect size was performed preoperatively with a CT scan of the sagittal view plus the coronal view. Otolaryngological, Maxillofacial, and Ophthalmology evaluations were carried out preoperatively and postoperatively. Forced duction tests were also performed perioperatively. The same surgeon performed all six operations. The zirconium oxide ceramic implant was constructed preoperatively by building cold cure acrylic patterns on a dried skull
model of different sizes as shown in Figure 1. Two various sizes were constructed (thickness of about 1-1.5 mm) and the size of the plate to be used was determined by the extent of the orbital floor imperfection and the hypoglobus severity. The pre-formed zirconium oxide plate was constructed to be thicker posteriorly and thinner anteriorly in order to push the eyeball anteriorly.

Surgical procedure
An infraorbital incision was made to approach the orbit. The periosteum was sharply incised using knife blade No. 15 and then bluntly dissected the periostium with a periosteal elevator. The orbital floor and the fracture site were exposed. The size of the zirconium oxide ceramic implant was reshaped according to the size of the defect. The herniated content in the maxillary sinus was reduced, and the implant material placed over the orbital floor covered the margins of the defect. The implants were not fixed. However, it was ensured that the implants were posterior to the infraorbital rim. Absorbable vicryl sutures 4/0 were used to close the periosteal incision and the subcutaneous incision. Vicryl sutures 5/0 were used to perform subcuticular suturing to achieve skin closure. A forced duction test was performed after the operation to assess the ocular motility. After the operation, radiographs and computed tomography scans were taken, which confirmed that anatomical reduction of the orbital floor had been achieved. Each patient was evaluated at week one, after three months, and follow-up after 2-4 years.

Results
Case No. 1
A twenty seven year old female patient was referred on 14th February 2008. The patient had diplopia, limitation of eyeball movement and enophthalmos with a his-
tory of blunt trauma to the left eye. A defect in the orbital floor was detected upon radiographic examination. Repair of the orbital floor was therefore indicated and the patient was admitted to hospital for surgical repair of the orbital floor under general anaesthesia. An infraorbital incision was made to explore the orbital defect and the entrapped rectus muscles were released. After this, a nasal decongestant and antibiotics were prescribed for three days. Sutures were removed on the sixth postoperative day. There was a complete resolution of diplopia. Radiographs taken after the operation showed a satisfactory implant position (Figure 2, A-F).

Figure 2 (A-C): A. Preoperative photograph showing slight enophthalmos in the right eye with limited upward movement. B. Computed tomography showing comminuted left orbital floor fracture C. Intraoperative photograph showing zirconium oxide ceramic implant in place. D. Occiptomental views postoperative. E. Postoperative computed tomography scan. F. Patient after four years.
Case No. 2
A 32 year old female patient was referred for persistant diplopia on June 15th 2008. The diplopia was the result of blunt trauma. Upon clinical examination, the left eye showed limited eyeball movement with diplopia on upward gaze. She was unable to open her right eye due to psychological trauma. A CT scan revealed a fracture in the orbital floor (Figure 3). The operation took place under general anaesthesia. An infraostral incision was made in order to explore the left orbital floor. After splitting the orbicularis oculi muscle, an incision in the inferior orbital rim periosteum was performed and care was taken to avoid perforation of the orbital septum. The orbital floor was gently explored subperiosteally. The incarcerated inferior rectus muscle was released. A suitably sized zirconium oxide ceramic implant was chosen and placed over the defect of the orbital floor. A clinical exam carried out two weeks postoperatively showed normal eyeball movement in upward gaze (Figure 3, A-D).

Figure. 3, A-D, A. Preoperative photograph. B. Preoperative MRI showing orbital floor fracture. C. Intraoperative photograph showing zirconium oxide ceramic implant in place. D. Patient three weeks after surgery

Case No. 3
A 56 year old male patient sustained a road traffic accident and was referred on March 17th 2010. The clinical examination showed enophthalmos and diplopia upward gaze with restriction of movement of the right eyeball. A CT scan confirmed the presence of the zygomatic fracture and orbital floor communication involving the orbital rim as shown in Figure 4 (A-D). Reduction of the depressed fractured zygoma, reduction and fixation of the fractured infraorbital rim, and right orbital floor reconstruction using a zirconium oxide ceramic implant were performed under general anaesthesia. An infraorbital incision was used as a surgical approach for the reduction and fixation of the fracture of the orbital rim and reconstruction of the orbital floor, whereas the Gillies approach was used for the reduction of the zygoma fracture as shown in Figure 4 (A-D).
Case No. 4
A six year old boy was referred for limitation of eyeball movement following a road traffic accident. Four weeks previously a clinical examination revealed diplopia on upward gaze and hypoglobus. A radiographic examination showed significant inferior displacement of the right orbital floor as well as the infraorbital rim. An infraorbital approach was used and the defect was reconstructed with the placement of a zirconium oxide ceramic implant after the reduction and fixation of displaced bones as shown in Figure 5 (A-C).

Figure 4 A-D: A. and B. preoperative CT scan showing destruction of the orbital floor, infraorbital rim fracture, and zygomatic bone fracture. C. Intraoperative photograph. D. Image showing the patient after six years.

Figure 5 (A-C). A. Preoperative photograph showing restriction of the eyeball on upward gaze. B. Preoperative computed tomography showing orbital floor communited. C. Patient six months postoperative.
Case No. 5

14th June 2009 a 23 year old male patient was suffering from diplopia in both upward and downward gazes, after trauma to the right zygomatico-orbital area two months previously. Clinical examination showed enophthalmos and right cheek flattening. A radiographic examination revealed an old comminuted zygomatic fracture. Under general anaesthesia an infraorbital incision was made in this area to prevent the development of an ugly scar. In addition to anticipating lymphedema, the orbital floor was comminuted with some pieces caught in the sinus. The inferior oblique muscle was liberated delicately from the scar tissue of the orbital floor. A reconstructed material implant of suitable size was reshaped and embedded subperiosteally. The patient was re-examined six months postoperatively. The results revealed no diplopia, and the radiograph demonstrated palatable recuperation of the orbital floor and rim.

Case No. 6

Twenty four year old female patient was referred on 23rd August 2010. She was injured in a traffic accident. The clinical examination revealed aggravation of vision in the right eye with diplopia on upward gaze and hypoglobus of the right eye globe. A radiographic examination showed acute descending of the right orbital floor and orbital rim. The right orbital floor was explored through an infraorbital approach and reconstructed by implant material after fracture reductions.

Discussion

An orbital floor fracture is formed as a result of a sudden ascension in intraorbital pressure, as described by Smith and Regan (Mordechai et al., 2002). Blow out fractures were classified by Converse and Smith into two categories: impure and pure blow out fractures. The characteristic of a pure blow out fracture is the rupture of one of the orbital walls with intact orbital rims. Impure blow out fractures, on the other hand, are characterised by a fracture of the orbital rim, in addition to the disruption and displacement of one or more of the orbital walls (Burnstine, 2002). Early detection of blowout fractures is of utmost importance, as this will prevent unfavourable atrophy of any entrapped rectus muscles. CT scans have been proven to play an important role in the confirmation of diagnosis. A thorough ophthalmologic evaluation before every intervention is necessary because of the significant accompanying ophthalmic damage (Totir et al., 2015). The orbital injury should undergo definitive repair as soon as the patient’s general condition allows.

Due to the extensive range of implant materials available, there is controversy regarding the choice of implants used in the reconstruction of the orbit. Different reconstructive constituents, such as alloplastic and autogenous materials, have been employed in the recreation of normal bony orbital dimensions, or to supplement an inadequate volume of orbit. Significant improvements were achieved with the use of reconstructive constituents and bone grafts for supporting and fixating the contents of the orbit in the accurate anatomical location. The advantages and disadvantages of the different implant types must be taken into consideration when selecting an implant to reconstruct the orbit (Thaigarajan and Ulaganathan, 2013).

There are three kinds of synthetic biocompatible reconstructive materials that are useful for the reconstruction of the orbit: non-porous, porous, and absorbable materi-
Non-porous implants include silicone, Teflon, and metallic grafts. In the case of a pure small orbital wall fracture, absorbable implants such as Gelfilm have been selected. The two most widely used porous implants are hydroxyapatite and porous polyethylene implants. Their biocompatible activity of alloplast material is the most advantageous, as this facilitates improved positional stabilisation and fixation to the orbital bone. Furthermore, the resistance against infection is also improved since it is vascularised. There are, however, downsides to alloplastic materials such as the movement of grafts and the infection of maxillary sinuses (Lerman, 1970).

The use of autogenous tissues dates back to the beginning of the century. While they avoid the complications of infection, which can be brought about with the usage of synthetic biocompatible materials, autogenous grafts have disadvantages including: being time consuming, an additional surgical site is needed for autogenous grafts, and the resorption of autogenous grafts. Regardless of this, the biocompatibility of autogenous grafts is still better in comparison to synthetic reconstructive grafts (Murdoch et al., 1996).

In this study, no complications were noted throughout the period of follow up. As far as we know, this was the first reported series of patients who underwent orbital floor fracture repair with the use of zirconium oxide ceramic implants. In all of the cases in our study, the infraorbital incision approach was used, and a reduced incidence of ectropion in addition to the Gillies approach was used for the reduction of zygoma fracture as shown in Figure 4 (A-D). No significant local foreign body or immunogenic reaction was produced by the zirconium oxide ceramic implants. The dynamic stresses created by large bony orbital defects cannot be withstood by more elastic materials. Foreign body reactions may be found with resorbable implants. Furthermore, the implant may undergo exposure, and, after resorption, only the fibrous connective tissue may remain.

The advantages of zirconium oxide ceramic implant plates are availability, rigidity, and high biocompatibility (Rita et al., 2008). Zirconium oxide ceramic implants are rigid and can therefore withstand the vigorous pressures of big orbital floor defects, as shown in the re-establishment of large floor defects of the orbit as represented in case 2. Furthermore, zirconia bioceramics have been recognized as an implant material because of their biological, mechanical, optical properties and good results in Osseointegration (Kanchana and Sharmila, 2013) which has been confirmed in numerous studies in Germany and the USA (Kamal, 2013).

One of the possible drawbacks is that contouring of the implant during an operation is difficult, and a turbine must be used during an operation to achieve this, even though fabricating the implant before an operation decreases the operative time (Bogdan, 2013). Furthermore, an artefact appears in the CT scans of patients who have a zirconium oxide ceramic implant (Figure 2, E). Time can be saved by using a zirconium oxide ceramic implant to reconstruct significant defects of pure blow out fractures. Nowadays, data from the virtual orbit reconstruction can be used to create an orbital model via computer-assisted methods. It allows for more precision in individual zirconium oxide ceramic implants.
Conclusion
The results from our study suggest that zirconium oxide ceramic implants are a suitable implant biomaterial for the reconstruction of orbital floor fractures.

Conflict of Interests: None declared regarding this work.

References


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