Clin Oral Invest (2013) 17:511–516
DOI 10.1007/s00784-012-0716-2

ORIGINAL ARTICLE

Medial orbital wall reconstruction with flexible Ethisorb® patches

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Received: 10 May 2011 / Accepted: 5 March 2012 / Published online: 20 March 2012

Abstract
Objectives The aim of this study was to analyse the long-term result after reconstruction of the medial orbital wall with a flexible, biodegradable material (Ethisorb®).
Materials and methods During a period of almost 8 years, 31 patients with a medial orbital wall fracture were analysed retrospectively. Inclusion criteria were patients with a maximum size fracture of the orbital medial wall measuring 1.5–2 cm^2. Exophthalmos, enophthalmos, bulbus motility, diplopia and skin sensation were investigated over a period of 6 months. In all patients, the medial orbital wall was reconstructed with Ethisorb® patches.
Results No significant intraoperative complications were detected. No postoperative infection, abscess or seroma was found in any of the patients receiving an Ethisorb® patch.
Conclusions The advantage of the semiflexibility of the Ethisorb® patch is that it supplies an anatomically correct fit to the orbital medial wall but does not require fixation by screws or the use of sutures.
Clinical relevance The low rate of reported bulbus motility disturbance, diplopia, exophthalmos and enophthalmos demonstrates acceptable results after medial orbital wall reconstruction using the Ethisorb® patch.

Keywords Medial orbital wall · Reconstruction · Bulbus motility · Ethisorb®

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Introduction

Orbital fractures are frequently observed in maxillofacial traumas and can produce a wide range of functional disabilities and aesthetic deformities. The medial orbital wall is formed by the frontal bone, the lacrimal bone, the lamina papyracea of the ethmoid and the lesser wing of the sphenoid around the optic foramen; in addition, it is reinforced anteriorly by the frontal process of the maxilla. The lamina papyracea is the largest component and accounts for the structural weakness of the medial wall. The pneumatised portion is represented by the ethmoid, and this portion is likely to be fractured if a blow occurs [1].

Fractures of the medial orbital wall can be isolated or associated with other orbital defects arising from maxillofacial fracture. A medial wall defect results in a relative increase in orbital volume [1–3]. There are two theories which explain how an orbital fracture occurs: according to the first, increased fluid pressure in the eyeball and rising orbital pressure cause displacement of the posterior eyeball, while the second theory proposes that, it is caused by the inverted orbital floor resulting from direct impact to the lower orbital wall [4]. However, the number of patients with facial trauma tends to increase in traffic accidents and violence. De Visscher and coworkers [5] reported that medial orbital wall has the lowest incidence of injury among the orbital walls, but that this kind of injury occurs more often than suspected [6]. A similar observation was made by Jank

and coworkers. In his analysis, 1 patient (0.2 %) out of 424 was found to have an isolated medial wall fracture. A combined fracture with involvement of the medial orbital wall and the lateral wall was found in two patients (0.5 %). A combination of medial wall and orbital floor fracture was diagnosed in 29 patients (6.8 %). In contrast, 357 (84.2 %) patients were identified with blowout fractures [7].

The results of retrospective studies in patients who have not undergone medical treatment show that most patients experience late enophthalmos and perceive their facial asymmetry [8]. The clinical findings which arouse suspicion of orbital medial wall fractures are reduced bulbus motility caused by medial rectus muscle entrapment, enophthalmos, diplopia, orbital emphysema, epistaxis and periorbital oedema.

Thus, finding the correct method of diagnosing medial orbital wall represents a real challenge. Computed tomography (CT) is the gold standard used for imaging diagnosis in orbital traumatology [9].

Although the published data abound with description of surgical techniques and variations, no international consensus has yet been reached on the ideal method for medial wall fractures [10–15]. Various materials are used for the reconstruction of orbital wall fractures. These include autografts, allografts, xenograft and metallic or nonmetallic alloplastic bone substitutes and have yielded varying degrees of success [15].

In the present study, Ethisorb® patches were used to reconstruct fractures of the medial orbital wall. Ethisorb® (Ethicon, Norderstedt, Germany) is a synthetic absorbable implant that was designed for the bridging of dura mater encephali and spinalis defects [16]. The advantage of its semiflexibility is that it supplies an anatomically correct fit to the orbital medial wall without requiring fixation by screws or the use of sutures (Fig. 1). The aim of this study was to analyse the long-term result after reconstruction of the medial orbital wall with a flexible, biodegradable material (Ethisorb®).

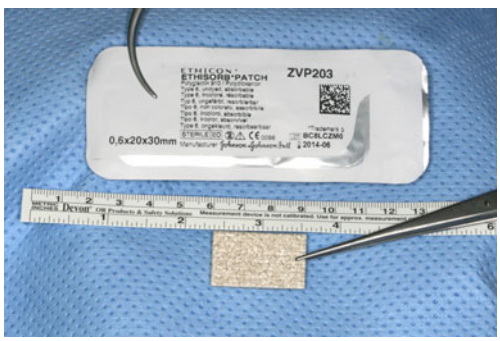

Fig. 1 Ethisorb® (Ethicon, Norderstedt, Germany) is a synthetic absorbable implant

Material and methods

Between January 2003 and October 2010, 31 patients (22 males and 9 females) with a medial orbital wall fracture were retrospectively analysed. Twenty-four had an isolated medial (77 %) and seven a combined medial wall/orbital floor fracture (23 %). Four combined fractures with involvement of the medial orbital wall and orbital floor have been reconstructed with Ethisorb patch. In the remaining three cases, individually adjusted titanium mesh was used for orbital reconstruction. The age range was 17 to 69 years (mean age, 32.5). The mechanism of injury was interpersonal violence (n=19), traffic accidents (n=7) and falls (n=5). Inclusion criteria were patients with a maximum size fracture of the medial orbital wall measuring 1.5–2 cm^2. The surgical procedure was performed from within 48 h up to 7 days (average, 36 h) after swelling from the injury was reduced. The indication for open reduction was based on coronal and axial CT and clinical and ophthalmological investigation. Every patient underwent a clinical (ophthalmologic) investigation within 24 h after trauma, which was performed by a highly experienced ophthalmologist. All patients were examined for their vision and any accompanying eye diseases. The indication for surgery, as well as surgical reconstruction strategy, was dependent on the results of preoperative analysis of the defects, which considered the size, localization and distinct anatomic landmarks, all of which determine clinical signs indicating the presence of reduced bulbus motility caused by medial rectus muscle entrapment, enophthalmos and diplopia. Bulbus motility was evaluated in terms of upward gaze, downward gaze, abduction and adduction. Diplopia was investigated according to the normal field of vision defined by 10° upward gaze movement, 30° downward gaze movement, 20° adduction and 20° abduction.

Exophthalmos and enophthalmos were investigated using the Hertel method. Imaging criteria include dislocated fractures of the orbital medial wall, incarceration of soft tissue between the bone fragments and herniation or dislocation of soft tissue into the ethmoid complex.

Surgery was performed under general anaesthesia. Surgical access to the medial orbital wall was by the transcutaneous approach through the upper eyelid, which involves placing the incision in the upper eyelid skin fold, the preferred route in blepharoplasty, with the aim of delineating clearly the fracture site from the herniated orbital tissue. Bony fragments that did not interfere with normal muscle action were preserved to obtain a more rigid medial wall postoperatively. Herniated orbital tissue was separated up to the ethmoid sinus mucosa, with the use of an elevator (Fig. 2). The standard inferior transconjunctival approach was additionally used in cases of large medial wall fracture involving the inferior portion of the medial orbital wall and combined fracture with the orbital floor (n=3). The fracture borders were exposed sufficiently to allow restoration of the

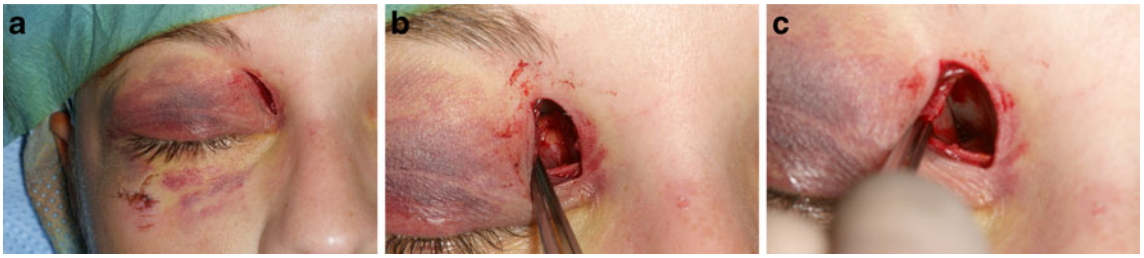

Fig. 2 **a** A 29-year-old woman with a fracture of the medial orbital wall on the right side following a traffic accident/surgical access to the medial orbital wall by the transcutaneous approach through the upper eyelid. **b** Separation of herniated orbital tissue. **c** Reconstruction of the orbital medial wall by Ethisorb® patch

orbital medial wall by Ethisorb® patch. In cases of severe mid-facial trauma with fractures of both medial orbital walls ($n=1$) and in three cases of unilateral fractures of the medial orbital wall, the surgical approach was performed on existing facial wounds (Fig. 3).

Ethisorb® is a synthetic, absorbable, semiflexible implant based on polyglactin (Vicryl) and polydioxanon (PDS). The different melting points of the two synthetic materials (approx. 200 °C for polyglactin and approx. 100 °C for polydioxanon) are exploited in the manufacturing process, which involves thermoplastic welding of the two synthetics. This results in a composite material with a three-dimensional filamentary structure which forms the framework for endogenous connective tissue. Ethisorb® was originally designed to bridge dura mater encephali and spinalis defects. Ethisorb® induces a medium-grade monocytic tissue reaction, which markedly decreases within 56 days after absorption of the Vicryl filaments and disappears completely on absorption of the PDS melt particles by the 180th day at the latest. The material is replaced by fibrous collagenous tissue, and only minimal inflammation has been observed during absorption.

Barbolt and coworkers evaluated the Ethisorb® patch in a 6-month dural tissue reaction study in rabbits. The absorbable material was generally characterized by low-grade granulomatous inflammation and initial adhesions to the brain surface. The three-dimensional structure of this implant acted as a scaffold to guide the development and integration of replacement dura mater. The absorption of the material was associated with the complete resolution of the inflammatory reaction, a lack of cerebral adhesions and restoration of the normal architecture of this region [17–21].

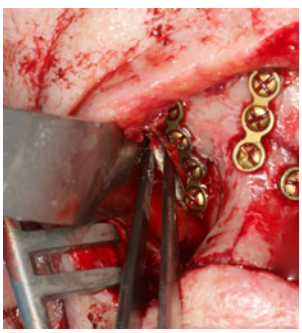

Fig. 3 A 69-year-old woman with a severe mid-facial trauma following open reduction, osteosynthesis and reconstruction of the orbital wall with Ethisorb patch

The semiflexible membrane allows the bridging of orbital wall defects that do not exceed 2 cm^2. Intraoperative cone beam computed tomography was performed to check the correction of orbital contour and the desired position of the graft. Ethisorb® is not radiopaque.

The postoperative investigation was performed within 1 to 3 days of surgery. Every patient underwent a subsequent assessment 3 and 6 months after surgery to evaluate the presence of diplopia, the degree of enophthalmos and the range of ocular movement and to determine the outcome. Only patients with pathologic findings were invited to further follow-up (maximum 12 months).

Cone beam computed tomography

The mobile C-arm Arcadis Orbic 3D features an isocentric design and 190° orbital movement. The basic system consists of an isocentric C-arm with integrated X-ray tube, opposite which is a 9-in. image intensifier. In our study, 50 and 100 2D images were taken between 30 and 60 s at a resolution of 1,024×1,024 pixels (1 K2). During scanning, a 3D image data set (a cube approx 12 cm^3 in volume, or 2,563 voxels) was simultaneously calculated and displayed on the monitor in real time. During imaging, the correct positioning of the reconstructed data is visible, and the 3D image data are immediately available after the scan is completed. These 3D data can be visualised in multi-plane reconstructions.

Results

In all patients, the medial orbital wall was reconstructed with an Ethisorb® patch. No significant intraoperative complications were detected. None of the patients experienced

ophthalmic complications related to the transcutaneous approach through the upper eyelid or the combined upper eyelid/transconjunctival approach or developed enophthalmos as determined by Hertel exophthalmometry. Preoperatively, 14 patients (45 %) had diplopia in the primary position of gaze and 18 patients (58 %) within 30° of gaze. Postoperatively, one patient developed a residual diplopia, which resolved completely after 12 months. This patient had no preoperative signs of diplopia. Nine patients (29 %) had various degrees of ocular motility deficits preoperatively. Postoperatively, the limitation of ocular motility was improved in all patients. Three patients experienced abnormal skin sensation in the medial epicanthal area which regressed within 2 months after surgery however (Fig. 4). No postoperative infection, abscess or seroma was found in any of the patients receiving an Ethisorb® patch.

Intraoperative 3D imaging was performed in all patients. Figure 5a shows a fluoroscopic image after treatment of a severe case of zygomaticomaxillary complex fracture in a 69-year-old patient following a car accident. The intraoperative cone beam computed tomography (CBCT) scan demonstrated the proper positioning of the reconstructed medial orbital wall on the right side. A follow-up computed tomography scan of this patient was performed 6 months postoperatively showing correct positioning of the orbital medial walls (Fig. 5b).

However, in three patients, a misplacement of the Ethisorb® patch was detected. Consequently, a revision was required to recontour and reposition the implant.

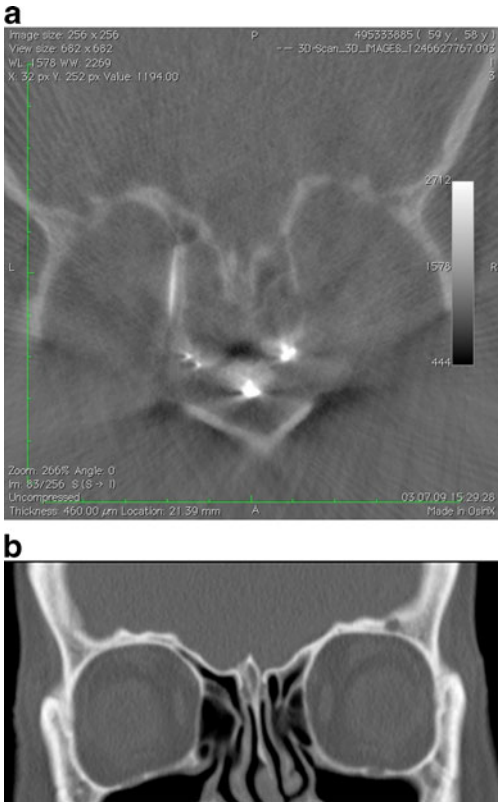

Fig. 5 **a** Fluoroscopic image after treatment of a severe case of zygomaticomaxillary complex fracture. The intraoperative CBCT scan demonstrated the proper positioning of the reconstructed medial orbital wall on the right side. **b** A follow-up computed tomography scan of this patient was performed 6 months postoperatively showing correct positioning of the orbital medial walls

Discussion

Orbital fractures are common facial injuries. The lamina papyracea is the largest component of the medial orbital wall and accounts for its structural weakness.

Medial orbital wall fractures are associated with a high possibility of enophthalmos and can lead to significant enophthalmos in spite of small volume changes [22]. Enophthalmos is one of the most undesirable complications, and the degree of the orbital fracture and potential for delayed enophthalmos are key factors in deciding on

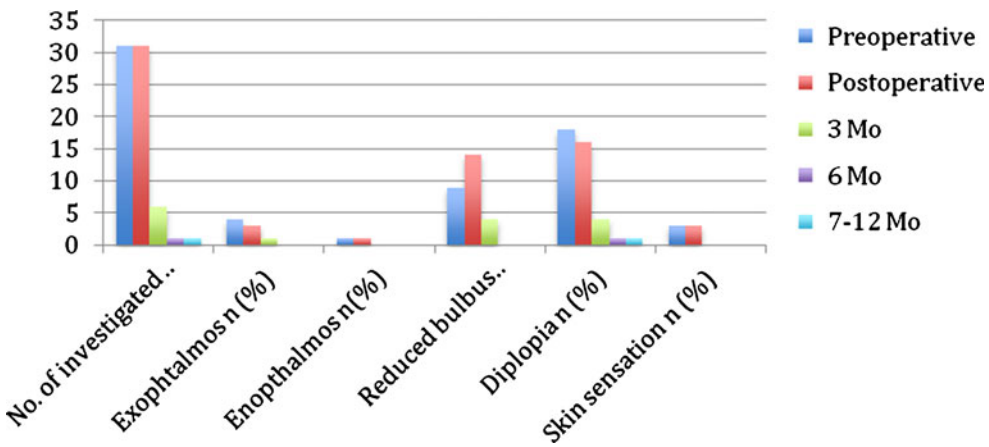

Fig. 4 Preoperative and postoperative findings of patients with medial orbital wall reconstruction with Ethisorb

surgical treatment when the motion of the eyeballs is not limited [15].

Therefore, surgical reconstruction of the internal orbit reliably prevents enophthalmos and ocular movement impairment. Anatomic reconstruction of the entire orbit is in fact necessary for the normal position and motility of the eye [23].

Medial orbital wall defects must be assessed with a CT scan in both coronal and axial projections. Scanning is also used to assess the precise localization of the thin bone fragments, size of defects, soft tissue prolapse, adjacent structure involvement and severity of the enophthalmos [1].

Not only is preoperative radiologic imaging very useful; intraoperative visualisation of the positioning of the reconstructed medial orbital wall also makes a significant contribution. Intraoperatively, the Arcadis Orbic 3D C-arm detected unsatisfactory reduction as well as unexpected complications, which could be immediately corrected in a surgical revision. This spared 3 out of 31 scanned patients from reoperation. Intraoperative CBCT may enable good reconstruction of the medial orbital wall despite the small operative access with a limited overview.

Different materials have been used to reconstruct the orbital walls [24], but none of them has been proven to be safe and as biocompatible as an autologous graft such as bone from rib, iliac crest or calvarium. Bone grafts have been considered advantageous because of their potentially lower risk for postoperative infections [25–27]. However, graft harvesting adds the problem of donor site morbidity and donor site complications. Furthermore, bone grafts may be difficult to mould to the desired shape for precise anatomic reconstructions. For primary reconstruction of medial wall defects, nonmetallic bone substitutes, such as polydioxamone, Medpor (Porex Surgical Products Group, Fairburn, GB) and Bioguide (Geistlich Parma AG, Wolhusen, Switzerland), have been the classic materials reported in published studies [15]. Rinna and coworkers [1] reported that deantigenated swine bone cortex is an excellent option to restore medial wall defects.

Metallic meshes, initially used to provide better stability for bone grafts, have also been demonstrated to be reliable and accurate in the reconstruction of internal orbital defects. Titanium meshes in particular possess flexibility, which allows conformation and moulding, even to a complex bone contour, with no donor site morbidity. However, as with all alloplastic materials, the main drawback of titanium implants is the risk of postoperative infection and/or extrusion [15, 28–30].

Ethisorb® is a well-known material used to close dural defects [16]. In earlier studies, no inflammatory reactions or low-grade granulomatous inflammation were found to be associated with the use of Ethisorb® [16]. A complete replacement by fibrous collagenous tissue was reported in combination with a low rate of postoperative inflammatory reactions and adhesions, which makes this an interesting material for use in the reconstruction of medial orbital wall defects.

Conclusion

The low rate of reported bulbus motility, diplopia, exophthalmos and enophthalmos demonstrates acceptable results in using Ethisorb patch for reconstruction of the medial orbital wall. The advantage of the semiflexibility of the Ethisorb® patch is that it supplies an anatomically correct fit to the orbital medial wall but does not require fixation by screws or the use of sutures.

Furthermore, Ethisorb® is a cost-effective material as it costs significantly less than PDS foils or titanium mesh. The cost-effectiveness of Ethisorb® could be a deciding factor in choosing which material is to be used for medial orbital wall reconstruction in the future [16].

Conflict of interest The authors declare that they have no conflict of interest.

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