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Orbital Floor Reconstruction with Xenogeneic Cartilaginous Graft: Preliminary Series of Cases

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Abstract

The management of orbital floor reconstruction has been a continuing challenge in the field of maxillofacial surgery. Although a large variety of materials and grafts have been used for orbital floor fracture repair, determining which can be the best remains a controversial topic. At the authors' department orbital fractures have been reconstructed using animal cartilaginous xenograft for several years. In this report a series of orbital reconstructions is retrospectively evaluated, with a special focus on clinical results and posing attention to xenogeneic cartilaginous grafts. None of the patients had complications such as rejection of the graft, infection, or zoonosis cartilaginous equine xenograft proves to be a good alternative in the reconstruction of orbital floor fractures.

Introduction

Orbital Floor Fractures (OFF) represent the most common fractures of the orbit and occur in almost 40% of craniofacial trauma [1]. Accidents, assaults, and falls are the principal causes [2].

In the case of OFF, the main symptoms are persistent diplopia and enophthalmos [3]. Moreover, OFF are sometimes associated with retina or optic nerve damage. Clinical ophthalmological evaluation is essential before surgery. Such an evaluation allows not only confirming diplopia or enophthalmos but also identifying possible concomitant globe-related traumatic pathologies (67% of orbital trauma) [4]. CT scan helps to diagnose and measure the size of the defect and possible muscle entrapment.

Surgery is performed taking into consideration the patient's symptoms such as persistent diplopia, gaze restriction caused by muscle entrapment, or in case of floor defect larger than 1 cm^2 to 2 cm^2. The goal is to restore orbital volume and eye function in the safest possible setting [5]. Initial diplopia is the most common complication after open reduction of orbital floor fractures with a reported incidence of up to 86% [6]. Sometimes diplopia is only caused by muscle dysfunction. Periorbital edema-related diplopia should show signs of resolution within 2 weeks after injury. On the contrary, when diplopia is related to muscle hemorrhage, ischemia, or entrapment, it can be permanent [7].

Different materials can be used to manage orbital wall reconstruction: Biological or alloplastic materials [7]. Autologous grafts have shown promise in terms of low resorption rate and low risk of infection. On the other hand, in the vast panorama of grafts, further types of materials with a low risk of complications can be found [7,8]. When a non-resorbable alloplastic material such as high-density porous polyethylene or silicone elastomer is used, graft migration and infectious reactions are the most common adverse events [9,10]. An adequate patient follow-up is essential to detect the onset of any complications. Sometimes post-operative imaging and ocular tests may be necessary [3].

The aim of this report is to retrospectively evaluate a series of patients whose orbital fractures were reconstructed by using a cartilaginous xenograft.

Materials and Methods

The study population consisted of 19 patients with OFF treated with equine cartilaginous grafts

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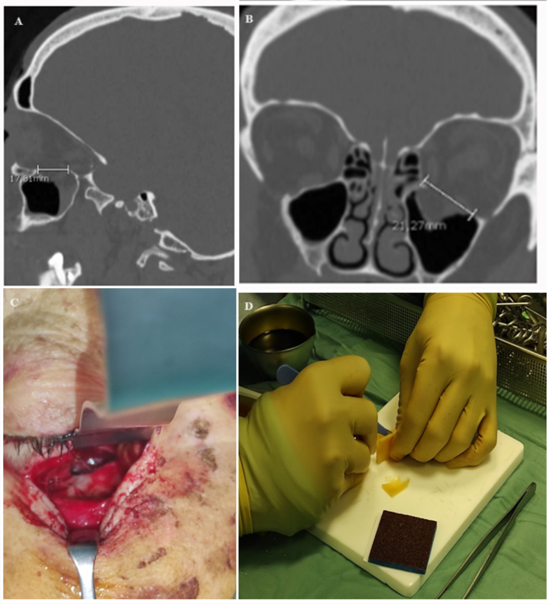

Figure 1 (A-D): (A-B): TC images in the saggital and coranal sections; C: Intraoperatory view of the fratcture; D: Modeling of the cartilage graft.

at the authors' University Hospital, between December 2017 and January 2020. The preoperative management was the same in all cases. Before the surgery, all patients underwent CT scan to assess the entity of the fracture and ophthalmologic examination to detect clinical diplopia and to exclude injuries to the eyeball structures. Long-term follow-up was conducted in collaboration with the ophthalmology and radiology departments, assessing each patient's condition with a multidisciplinary visit.

Radiographic study

The fracture was measured by CT scan, in the coronal and sagittal planes at the maximum extent of the defect (Figures 1).

Ophthalmologic follow-up

Two main parameters were analyzed: The presence of diplopia and enophthalmos. Diplopia and ocular motility were examined by performing the Hess screen test. Enophthalmos was measured by Hertel Exophthalmometry and documented to be present if the affected side showed 2 mm or more retro placement of the globe compared with the normal side, and absent if the difference was less than 2 mm.

Surgical technique

All patients received antibiotic prophylaxis and all surgical procedures were performed under general anesthesia. For each patient, the transcutaneous sub ciliary approach was used. In complex fractures, it has been associated with the frontozygomatic and transoral mucosal approaches. Subperiosteal skeletonization of the orbital floor and release of trapped soft tissue on the floor and bone fragment were performed. In all cases -chemically processed and E-Beam sterilized - equine perichondrium-free cartilage graft was used for the reconstruction of the orbital floor. It is a biocompatible graft that is non-toxic, non-mutagenic and does not cause allergy. The xenograft was cleaned 3 times in 10 min with saline, then sculpted and shaped according to the size of the defect, and finally placed on the orbital floor.

Results

A total of 19 patients were included, 11 males and 9 females, with a mean age of 46.2 years old (20 to 78 years old).

The cause of orbital fracture was assault in 7 patients (36%), fall in 5 patients (26.3%), road accident in 4 patients (21%), and sports trauma in 3 patients (15%).

Fourteen fractures were on the right side, and five were on the left side. Sixteen patients had isolated orbital floor fracture, while three had combined zygomaticomaxillary complex fractures.

The mean size of the orbital floor bony defect in the coronal and sagittal planes was respectively 20.7 mm and 30.1 mm (Table 1).

The CT scan detected entrapment of the extrinsic ocular muscles in five patients.

All the patients reported preoperative diplopia, further confirmed by ophthalmologic evaluation and orbital floor defect.

None of the patients had intraoperative or early postoperative complications such as retrobulbar hematoma, blindness, or graft migration.

No patient underwent CT and Hess screen immediately after surgery.

At the follow-up visits, all patients were free of primary gaze visually disturbing diplopia. Extreme gaze diplopia was detected in four subjects (21.05%). However, this did not seriously impair everyday life or work. Only two patients (10.52%) had significant enophthalmos (≥ 2 mm) (Table 2).

The mean follow-up duration was 18 months, during which time no severe permanent complications, nor clinical adverse events, such as wounds, orbital infection, or implant rejection, occurred.

All the xenogeneic cartilaginous grafts were well tolerated, and there was no evidence of foreign-body reactions.

Three patients reported persistent infraorbital numbness.

Discussion

Assessment and treatment of OFF have been debated in the last decade, and a multidisciplinary approach is necessary for an adequate evaluation [4,11].

Clinical assessment determines the need and type of surgery, attention must be paid to some important clinical signs such as the presence of diplopia or enophthalmos. Further, with the help of the ophthalmologist, the extent of the disturbance and the presence of any ocular lesion must be assessed [3].

CT scan and tridimensional reconstructions allow the evaluation of the orbital volume and the shape of the defect of the bone walls [3]. With a defect larger than 1 cm^2 to 2 cm^2 the fracture needs to be treated [12]. A CT scan can rule out inferior rectus entrapment, which can represent an emergency in pediatric patients since it can trigger oculocardiac reflex with consequent arrhythmia and in rare cases, death [6].

All the patients in this series reported diplopia, which was also confirmed by the ophthalmological assessment. Hence, they were referred for surgery. CT scan with 3D reconstruction confirmed the presence of the fracture and in five cases coexistent entrapment and

Table 1: Entrapment of the muscle.

	Age (Years)	Gender M/F	Cause	Entrapment of the muscle Y/N	Defect	Coronal mm	Sagittal mm	Complication
1	76	M	Road accident	N	Z.M.C. (inferior defect)	12.8	21.7	N
2	33	M	Sport	N	Isolate	18.7	20.5	N
3	32	M	Assault	N	Isolate	17.5	20.6	N
4	38	F	Assault	N	Isolate	17.7	24.7	N
5	20	F	Sport	N	Isolate	19.9	14.9	N
6	54	M	Assault	Y I.R.M.	Isolate	16.6	15.4	N
7	75	M	Falls	Y I.R.M.	Isolate	14.4	22.5	N
8	37	F	Road accident	Y I.R.M.	Isolate	13.3	23.2	N
9	78	F	Falls	N	Isolate	19.3	21.6	N
10	38	F	Assault	N	Isolate	21.7	17.2	N
11	59	M	Falls	Y I.R.M.	Isolate	19	29.8	N
12	42	M	Assault	N	Isolate	24.9	30.5	N
13	28	M	Assault	N	Isolate	17.3	20.3	N
14	29	M	Sport	N	Isolate	21.8	18.5	N
15	50	M	Falls	N	Isolate	19.4	23.4	N
16	27	F	Assault	Y I.R.M.	Z.M.C. (medial defect)	10.8	17.7	N
17	55	F	Road accident	N	Z.M.C. (lateral defect)	23.2	33.3	N
18	47	F	Road accident	N	Isolate	14.7	28.5	N
19	60	M	Falls	N	Isolate	24.1	28.6	N
	Mean: 46.2 Median: 42	11 M; 9 F		14 N; 5 Y	16 isolates; 3 ZMC	Mean: 20.7 Median: 23.2	Mean: 30.1 Median: 28.6	N:19; Y:0

M: Male; F: Female; N: No entrapment; Y: Yes entrapment; I.R.M.: Inferior Rectus Muscle; ZMC: Zygomatic Maxillary Complex; N: No complications; Y: Yes complications

Table 2: Orthoptics evaluation.

Patients	Eye: Right (R); Left (L)	Ex ophthalmometry value: R-L (mm)	Ex ophthalmometry Difference (mm)	Presence of diplopia: Yes (Y); No (N)	Diplopia description
1	L	16-16	0	N	
2	L	16-16	0	Y	in superolateral left gaze
3	R	20.5-20.5	0	N	
4	R	09-11	-2	N	
5	L	14-14	0	N	
6	L	14-14.5	0.5	N	
7	L	10-06	-4	N	
8	L	19-18	-1	N	
9	L	14-14	0	N	
10	L	18-18	0	N	
11	L	20-18.5	-1.5	N	
12	R	21.5-21	0.5	N	
13	L	16-17	1	Y	in extreme lateral left and right gaze
14	L	18-18	0	N	
15	L	14-15	1	N	
16	R	14-15	-1	Y	in extreme lateral and elevated right gaze
17	L	15-14	-1	N	
18	L	15-15	0	N	
19	R	14-15	-1	Y	in extreme lateral gaze

significant herniation of the inferior rectus muscle.

The surgical approach represents an important challenge for the surgeon. The transcutaneous subciliary and transconjunctival approaches are the most common way to reach the orbital floor. The risk of leaving an unsightly scar depends on the surgeon's experience [13], and is not discussed in this article. In the series of cases presented, all patients were treated with a transcutaneous surgical approach and none of them have reported scar discomfort.

More debated is the choice of materials for the defect reconstruction. It is possible to recognize three types of graft: Autograft, allogeneic graft, and xenograft [14-16].

It is possible to take autografts from the iliac crest, the anterior wall of the maxillary sinus, the calvaria, or the coast. Cartilaginous autografts can be taken from the auricular concha [2], cost, or nasal septum. Iliac crest bone and auricular concha are the most common donor sites. Maximal biocompatibility and low infection risk are autografts' principal advantages. However, the need for a second surgical site makes autografts increase patients' discomfort and expose them to a greater surgical risk [13].

Allogeneic grafts such as lyophilized dura and banked bone have been used successfully for orbital reconstruction. In particular, banked bone is available in large quantities, which reduces waiting time, and causes little to no donor-site morbidity. The potential risk of disease transmissions, such as HIV or other pathologies, and the high rate of resorption are the principal disadvantages [7,17].

Xenografts are taken from animals depending on the type of tissue (cartilaginous, bone xenograft), and depending on the animals (bovine, porcine, or equine) [7,15].

Since the last 1990s, following the discoveries regarding spongiform encephalopathy and given its high rate of transmission, the Food and Drug Administration has published a Guidance for Industry regarding the use of specific products in xenotransplantation. This guideline paves the way for safe use in human surgery in terms of low risk for zoonotic transmission, infection, and graft rejection [18].

At first, bovine xenografts for ear and nose reconstruction were used at the authors' institution [19], then they were also used for orbital floor reconstruction surgery. After the spread of mad cow disease, they were replaced by equine grafts. Equine tissue is unlikely to transmit animal infections such as spongiform encephalopathy disease or other zoonoses [5]. In addition, it is also easy to model material.

Diplopia is the main complication after orbit reconstruction. Different studies show an incidence from 20% to 50% after several months. Swelling and entrapment of the extraocular muscles are the main factors that cause permanent diplopia [20]. Postoperative diplopia generally persists from 7% to 33% [21]. If enophthalmos is present and it is not a cause of functional damage, this is not an absolute indication for surgery [20]. In this study, at 1-year of follow-up, three patients report persistent diplopia. In only four cases, EOM entrapments were recorded before surgery, and only in one of these, diplopia persists at 1-year follow-up. Enophthalmos or displacement of the globe was diagnosed in 10.5% of the patients, which conforms to other studies reporting incidences of enophthalmos following surgical repair near 13% [22,23].

Infection or implant migration are possible complications when using xenograft materials for reconstruction. In this series, evidence of biological incompatibility, inflammation, infection or cases of zoonosis were not recorded. The stability of the results was confirmed within 18 months mean follow-up.

After orbital floor reconstruction, post-operative CT can be useful to verify the correct position of the radiopaque prosthetic material and the correct repositioning of the end orbital tissue. The authors' opinion is that this test exposes patients to unnecessary radiation therefore it should not be performed routinely but only if the clinical conditions require it [24]. Furthermore, the graft described in this series of patients is radiolucent.

Conclusion

According to the collected data, the results lead to state that equine cartilage is a safe and valid reconstructive option and can be considered an effective alternative. The lack of direct comparison with other reconstructive materials and the small sample size were the main limitations of this study.

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