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Application of the three-dimensionally printed biodegradable polycaprolactone (PCL) mesh in repair of orbital wall fractures

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ABSTRACT

Purpose: The present study aims to investigate the surface characteristics and biomechanical properties of 3D-printed polycaprolactone (PCL) mesh and present the clinical outcomes of this implant in the treatment of orbital wall fractures.

Patients and method: A retrospective review of patients who underwent surgery for medial, inferior and inferomedial orbital wall fractures using PCL mesh was performed between April 2017 and June 2018. Two clinical outcomes were investigated: functional recovery and anatomical accuracy of reduction detected in image. Furthermore, scanning electron microscopy was used to evaluate the microscopic morphology, surface characteristics, and porosity of the PCL mesh.

Results: Among a total of 22 patients with a mean age of 41.3 years, the most common cause of injury was assault (54.5%). Fourteen patients (63.6%) had isolated orbital floor fractures. At postoperative 1-week follow-up, three patients (13.6%) exhibited diplopia and a further three patients (13.6%) showed restriction in ocular motility, but these patients had completely recovered by their 6-month post-operative follow-up. Ideal repair of orbital fracture was almost achieved in 21 patients (95.4%) and there were no cases of implant infection, inflammatory response, migration of implant, or hemorrhage. Microscopic imaging of PCL mesh surface revealed fully interconnected micropores with 50% porosity.

Conclusions: The repair of orbital wall fracture using PCL mesh offers reliable stabilization of orbital wall defects with a low complication rate, leading to outstanding functional and aesthetic outcomes. Therefore, PCL mesh is a good alternative for bioresorbable implants in the treatment of orbital wall fractures.

1. Introduction

The aim of surgical repair of orbital fractures includes the release of tissue entrapment or compression, the reduction of prolapsed tissue, and anatomic replacement of the bony defect (Lee and Baek, 2012). During these procedures, orbital implants are essential for the reconstruction of orbital wall fractures. To avoid donor morbidity of autologous bone grafts, artificial implants have been frequently used. Early artificial implants included titanium and porous high-density polyethylene and these non-absorbable synthetic materials provided tensile strength without resorption (Young et al., 2017). However, currently used non-absorbable materials are associated with serious complications, such as infection, delayed inflammation, hemorrhage, migration and exposure over time. These factors must be carefully considered by reconstructive surgeons (Gilhotra et al., 2002; Totir et al., 2015).

With the shift of the basic paradigm towards biodegradable and biocompatible synthetic materials in alloplastic implant, new alternatives (polymers or their copolymers) have been added to the surgeon's armamentarium in orbital fracture repair (Asamura et al., 2010; Morotomi et al., 2014; Young et al., 2017). Currently, specific representative bioresorbable materials include: poly (L-lactide-co-glycolide) (PLGA), poly (lactide), poly (glycolide), polydioxanone, and their copolymers with varying compositions (Al-Sukhun et al., 2006; Totir et al., 2015; Young et al., 2017). However, there remain several concerns regarding the use of these materials in orbital wall fractures, including rapid degradation with possible contour loss; difficulty handling the materials at room temperature due to

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thermoplastic characteristics with high glass transition temperature; reaction to sterile foreign bodies and inflammatory response of the surrounding tissue caused by acidic metabolites following degradation (Kulkarni et al., 1966; Bergsma et al., 1993; Shikinami and Okuno, 1999, Shikinami and Okuno, 2001; Al-Sukhun et al., 2006; Totir et al., 2015).

All alloplastic materials possess their own disadvantages, but polycaprolactone (PCL), a hydrophobic and biodegradable polymer, has several beneficial characteristics for use in the repair of orbital fracture, including a slower degradation rate, a reduced reaction to foreign bodies, adequate mechanical strength, and greater flexibility for manipulation, when compared to other resorbable-polymer counterparts (Dash and Konkimalla, 2012; Teo et al., 2015). 3D-printing recently has been applied to the production of alloplastic synthetic materials. 3D-printed PCL mesh has been developed with a three-dimensional and microporous structure, which can provide the additional benefit of biocompatibility, allowing for cell ingrowth and even regeneration of the surrounding host tissue (Schantz et al., 2003; Shim et al., 2017). To the best of our knowledge, there have been no published reports describing the use of 3D-printed PCL implants with optimal porosity in orbital fracture repair. The aim of the present study was to investigate the surface characteristics and biomechanical properties of 3D-printed PCL mesh implants and present the clinical outcomes of this implant in the treatment of orbital wall fractures.

2. Patients and methods

2.1. Study subjects

After approval from the institutional review board of our school of medicine [No. 2019-01-011], this retrospective study was conducted in patients who underwent surgery for orbital wall fractures using 3D-printed PCL mesh between July 2017 and June 2018 in the Department of Plastic and Reconstructive Surgery of my institute. Patients who were younger than 16 years of age or had a previous history of exposure to orbital trauma or injury and ophthalmologic surgery were excluded. The determination of surgery was based on the clinical evidence for 1) orbital tissue entrapment, 2) poor ocular motility and diplopia that interferes with daily activities beyond the fifth day after the accident, 3) an estimated orbital wall defect size larger than 2 cm^2 in the CT image, and 4) enophthalmos with a difference of more than 2 mm, by exophthalmometry. Finally, a total of 22 patients were included in the present study and their medical records were reviewed for general demographics and surgery related data. All patients included in the present study had no economical gain and had received surgery of their own free will under written informed consent.

2.2. PCL mesh fabricated by a 3D printing system

The customized PCL mesh (T&R mesh, Biofab Co., Ltd, Siheung, Korea, Korean Food and Drug Administration registration number 2016-147, C7851440) was manufactured using an in-house 3D printing system, applying a solid-free form fabrication technology known as the multi-head deposition system, along with 100% PCL. The PCL mesh was sterilized via gamma irradiation with a maximum absorbed dose of kiloGray (kGy) and minimal absorbed dose of 15 kGy before use. The final 3D-printed PCL scaffold had a mesh size of 40 mm by 40 mm and thickness of 0.8 mm (Shim et al., 2017). Scanning electron microscopy (FE-SEM) (S-4700; HITACHI Co., Tokyo, Japan) was used to evaluate the microscopic morphology, surface characteristics, and porosity of the PCL mesh. To identify the biomechanical properties of the PCL mesh, bending and molding simulation was carried out.

2.3. Implantation of 3D-fabricated PCL mesh

The surgery was performed by a single surgeon using PCL mesh. The surgical approaches of fracture repair were sub-ciliary for inferior or inferomedial fracture and transcaruncular for medial fracture. After dissection of the soft issue and elevation of periosteum periorbital wall, the herniated orbital contents were reduced by gently depressing bone edges with the elevator and separating adhesions from the sinus mucoperiosteum with complete, atraumatic release and anatomic reduction out of the fracture site (Harris, 2014). In the cases where it was necessary to cover the defect or protect a mobile orbital bone fragment from falling out of reduction into the sinus, the 3D-printed PCL mesh was implanted. The mesh was manipulated by the traditional method, using scissors, based on individual subjective assessment of the extent and shape of the damaged orbital wall. The segmented PCL mesh was curved mechanically by hand, to represent the curvature of the internal orbital wall (Fig. 1). The fabricated mesh was inserted above the fracture site under the periosteum without rigid fixation to the skeleton using plates or screws (Fig. 2). Combined floor and medial wall fractures were repaired using the “wraparound” technique by curving the mesh implant to fit into the inferomedial orbit (Nunery et al., 2008). Finally, the eyeball forced duction test was performed to confirm the impingement of the implant to the orbital contents.

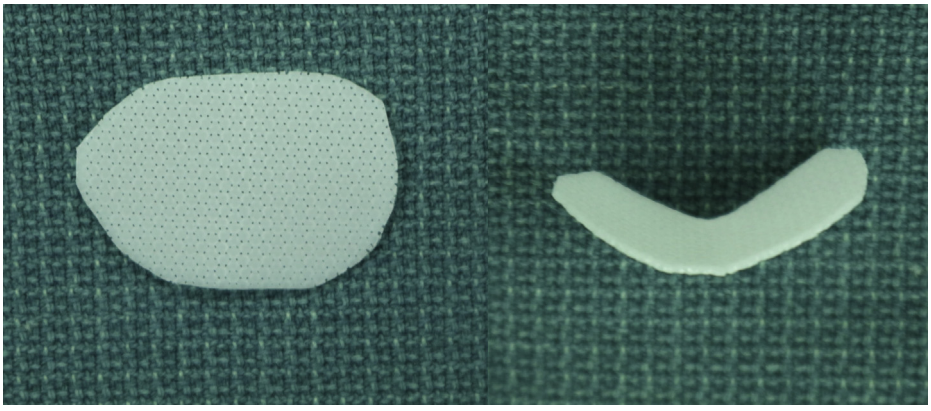

Fig. 1. (Right) A segment of mesh based on individual subjective assessment of the extent and shape of damaged orbital wall. (Left) Bent PCL mesh segment with hands representing curvature of internal orbital wall.

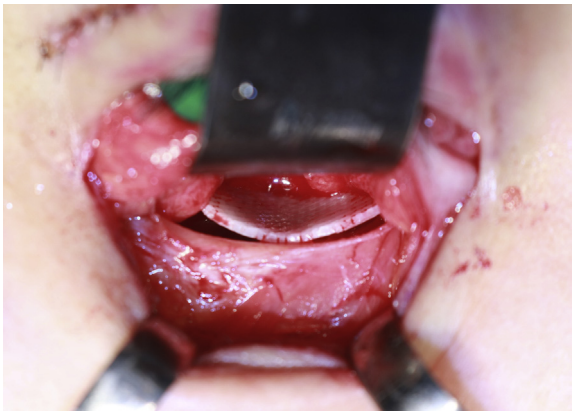

Fig. 2. Intraoperative photos of the implantation of polycaprolactone (PCL) mesh. Insertion of molded PCL mesh overlying the bony defect in the subperiosteal space of orbital floor.

2.4. Outcome measurement

The outcomes measured were: 1) the anatomical accuracy of reduction detected by CT scan; 2) the functional ocular motility and enophthalmos. Ocular symptoms were evaluated before surgery, and at postoperative 1 and 6 months. Evaluations at each visit included: visual acuity, enophthalmos, the assessment of diplopia, and ocular motility. All patients underwent computed tomography (CT) using a GE LightSpeed VCT (GE Medical System, Milwaukee, WI), via continuous 3 mm thick axial and coronal slices before surgery and immediately post-surgery, to confirm the reduction of the fractured bone and the position of the PCL mesh implant. The curved linear line of margin of the inferomedial orbital wall was measured in all coronal sections of the CT scan, and the results were summed and multiplied by the section thickness to obtain the total defect size. According to the orbital wall defect classification proposed by Jaquiery et al., a model which demonstrates the extent and localization of the defect (Jaquiery et al., 2007), all included cases were classified into three categories (Table 1). For assessing postoperative reduction accuracy, the quality of reconstruction was scored as follows: 3 for ideal, 2 for satisfactory, and 1 for poor at three distinct localizations: directly dorsal to the orbital rim; in the middle of the reconstructed area; and slightly anterior to the end of the reconstruction using coronal postoperative CT images.

3. Results

A total of 22 patients were included. The average age was 41.3 years (range: 18–75). Twenty patients (90.9%) were male. The most common cause of injury was assault (54.5%), followed by traffic accidents, sports accidents and fall (Table 2). In terms of extent of fracture, more than 50% of the patients were allocated to the category 'large defect'. Among them, 4 patients were categorized as 'extremely large defect'. Fourteen of 22 patients (63.6%) had isolated orbital floor, 5 patients (22.7%) had isolated medial wall fractures, and 3 patients (13.6%) had inferomedial fracture. Preoperatively, three patients (13.6%) exhibited diplopia and 7 patients (31.8%) showed restriction of ocular motility. The timing of surgery was between 3 and 13 days, with a median of 10.5 days. The follow-up period ranged from 6 to 13 months, with a mean follow-up time of 7.2 months.

Table 1
Classification of orbital wall defect size.

Class		Description
Class I	Small	Isolated defect of the orbital floor or medial wall, <2 cm^2
Class II	Large	Defect of orbital floor and/or of the medial wall >2 cm^2 within anterior two thirds
Class III	Extremely large	Defect of the entire orbital floor and the medial wall, extending into the posterior third

Table 2
Demographics and fracture related data of study patients.

Variable	
Age, years	41.3 (18–75)
Sex, n (%)	
F	2 (9.0%)
M	20 (90.9%)
Cause of Injuries, n (%)	
Assault	12 (54.5%)
Traffic accident	4 (18.1%)
Sports accident	3 (13.6%)
Fall	3 (13.6%)
Extent of orbital wall defect, n (%)	
Small	10 (45.4%)
Large	8 (36.3%)
Extremely Large	4 (18.1%)
Location of orbital wall defect, n (%)	
Medial	5 (22.7%)
Inferomedial	3 (13.6%)
Floor	14 (63.6%)
Related preoperative clinical features	
Diplopia	3 (13.6%)
Enophthalmos	3 (13.6%)
Restriction of ocular motor	7 (31.8%)

3.1. Morphological characteristics and biomechanical properties of 3D-printed PCL mesh

Scanning electron microscopy of PCL mesh revealed fully interconnected micropores formed by lattice-type and lay-down pattern of 0/60/120 °C. The triangular pore size was 500 μm and the porosity of mesh was classified as medium (approximately 50%, see Fig. 3). Simulation of PCL mesh handling for implantation revealed that, as the mesh was very flexible, it could be easily customized by the manual method and well-molded at room temperature (Fig. 4).

3.2. Clinical outcomes of PCL mesh

At the immediate post-operative status (within 1 week following surgery), the presence of diplopia and the restriction of ocular motility was observed in 3 and 3 patients, respectively, but these symptoms improved spontaneously in most patients during the observation period (3–6 months after surgery). Enophthalmos was observed in only 1 out of 22 patients. In this patient, enophthalmos had resolved by the 6-month postoperative visit (Table 3). Postoperative CT imaging revealed that ideal repair of orbital fracture was achieved in 21 patients (95.4%): specifically, 'excellent' in 13 patients (59.0%) and 'good' in 8 patients (36.3%). The one patient in whom repair of orbital fracture was not ideal had a small-sized medial wall fracture in the posterior third of the orbit, where the meticulous insertion of implant is technically difficult. During the follow-up period, there were no cases of implant infection, inflammatory response, migration of implant, hemorrhage, or visual loss (Fig. 5–7).

4. Discussion

Orbital wall repair remains a controversial topic in terms of the most suitable material for the repair of fractured bone. As such, the

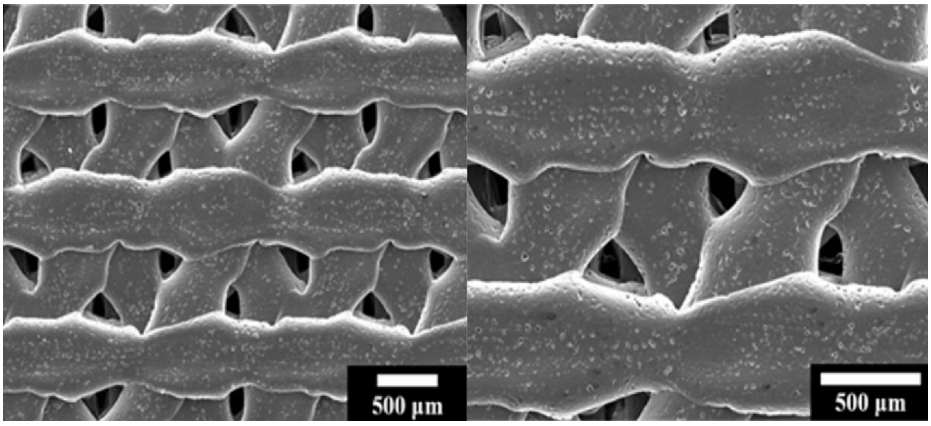

Fig. 3. (Right) Scanning electron microscopy image of the polycaprolactone (PCL) mesh reveals fully interconnected and regular pores with triangular shapes. (Left) The image shows a further magnified view, with 50% discernible porosity.

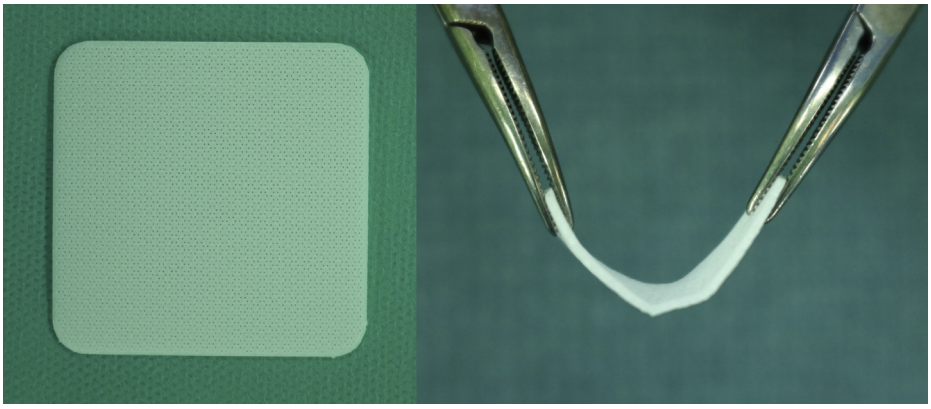

Fig. 4. (Right) Gross view of polycaprolactone mesh (4 cm × 4 cm) and the image showing (Center) the flexibility of implant and (Left) malleability of molded implant after being manually carved.

search is ongoing for a material meeting the requirements of the ideal implant. There are several characteristics for an ideal implant for the reconstruction of orbital wall fractures. The first is flexibility, to allow easy contouring for the simulation of 3D anatomical inferomedial orbital wall contours. Another one is sufficient mechanical strength that makes it capable to support the orbital tissue and maintenance of implant structure over time. This property is a more important consideration in larger sized fractures. Non-absorbable alloplastic implants such as titanium mesh and porous polyethylene (Medpore) have excellent benefits in terms of mechanical stability and maintenance. Titanium mesh has strong stability and durability, so is suitable for large-sized three wall fractures. However, its major drawback is low biocompatibility. Therefore, there is still a lack of potential for new bone growth, and poor remodeling adjacent to the reconstructed area. Alternatively, Medpore has a pore structure which induces fibrovascular ingrowth from surrounding tissue into the implant pores. In turn, this permits biological anchoring of the implant, thus reducing the incidence of migration or extrusion. It also allows vascular access within the implant, thereby maintaining its long-term structural stability (Lee and Baek, 2012). However, the utility of this non-absorbable material is accompanied by concerns such as infection, corrosion and inflammatory response (Totir et al., 2015).

Table 3
Functional outcome of study patients at 1 week and 6 months postoperative follow up.

	Postoperative 1 week	Postoperative 6 months
Diplopia	3 (13.6%)	0 (0.0%)
Enophthalmos	1 (4.5%)	0 (0.0%)
Restriction of ocular motor	3 (13.6%)	0 (0.0%)

Thus, biocompatibility has emerged as one of the ideal characteristics for alloplastic implants. Various biodegradable implants aim to restore fractured bony defects and provide temporary support, leaving fibrous granulation tissue during their degradation. Examples of biodegradable materials that have been recently introduced are: polydioxanone (PDS), poly lactic acid (PLA), poly glycolic acid (PGA), and their copolymers, poly (L-lactide-co-glycolide) (PLGA), poly- L or D, and L-lactide (PLLA), with varying compositions such as poly-L/DL-lactide implants (P [L/DL]LA) 85/15 (Rapidsorb) or poly-L/DL-lactide implants (P [L/DL]LA) 70/30 (PolyMax, Macropore) (Al-Sukhun et al., 2006; Totir et al., 2015; Young et al., 2017). Known typically as an absorbable suture material, PDS mesh has also been used in orbital fractures, but this implant is not recommended for the treatment of large orbital defects. This is due to the rapid degradation of this material (in approximately 6 months) and the resulting scar following absorption. This material is not stable enough to provide adequate support to the globe, resulting in 50% of patients developing enophthalmos or hypophthalmos in one prospective case study (Baumann et al., 2002). Polylactide- or polyglycolide-derived implants have excellent mechanical properties with relatively slow resorption (expected to fully degrade by around 1–2 years). However, due to their

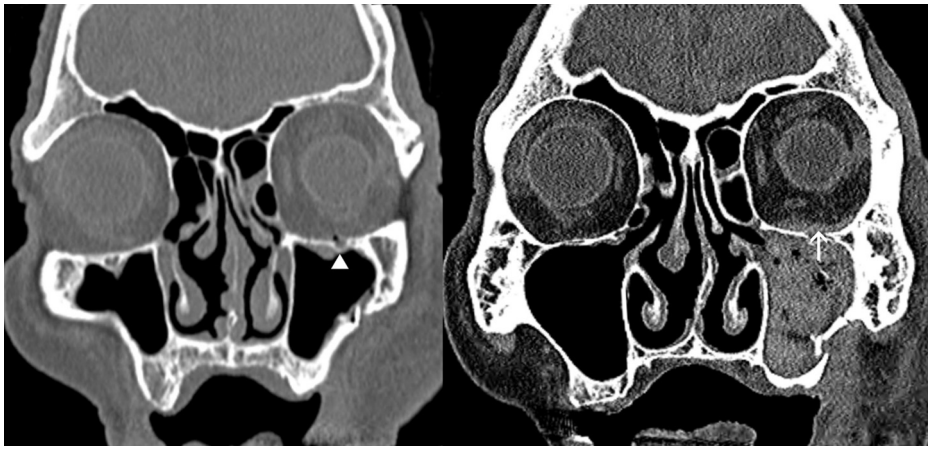

Fig. 5. A 75-year-old man with left orbital floor fracture underwent orbital repair using polycaprolactone mesh. (Right) Preoperative computer tomographic scan showing bony defect in left orbital floor (white arrow head) and (Left) immediate postoperative image showing good reduction status using polycaprolactone mesh (white arrow).

thermoplastic characteristics with a high glass transition temperature (57 °C), this material is too hard and stiff to be manipulated at room temperature, so a cumbersome additional step is required that involves dipping and molding of the material in a warm bath. During the PLLA and PLGA degradation processes, the acidic metabolites (pH ~3.5) following hydrolysis can cause a prolonged inflammatory and foreign body response in the surrounding tissue, which may lead to an unfavorable healing process (Kulkarni et al., 1966; Al-Sukhun et al., 2006; Park et al., 2015). According to a long-term follow up study in patients with displaced zygomatic

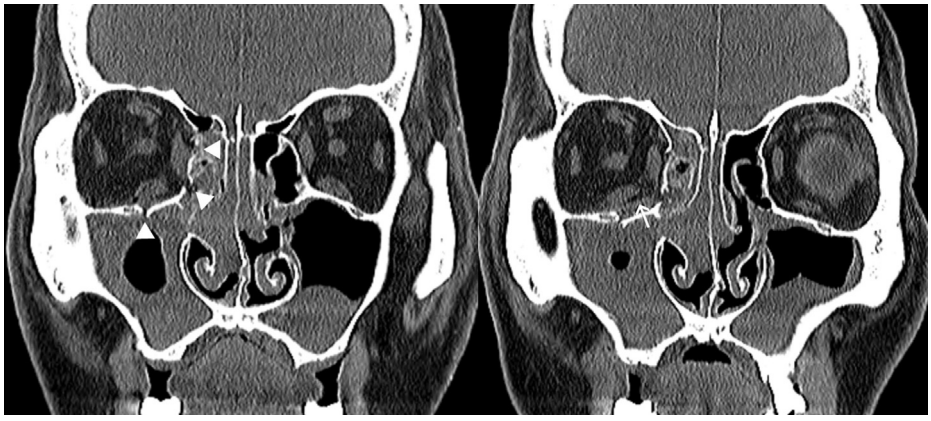

Fig. 6. A 54-year-old man with right inferomedial wall fracture underwent the orbital repair using a wrapping around technique with curved polycaprolactone mesh. (Right) Preoperative computed tomographic scan showing bony defect in right inferomedial wall (white arrow head) and (Left) immediate postoperative image showing good reduction status using polycaprolactone mesh (white arrow).

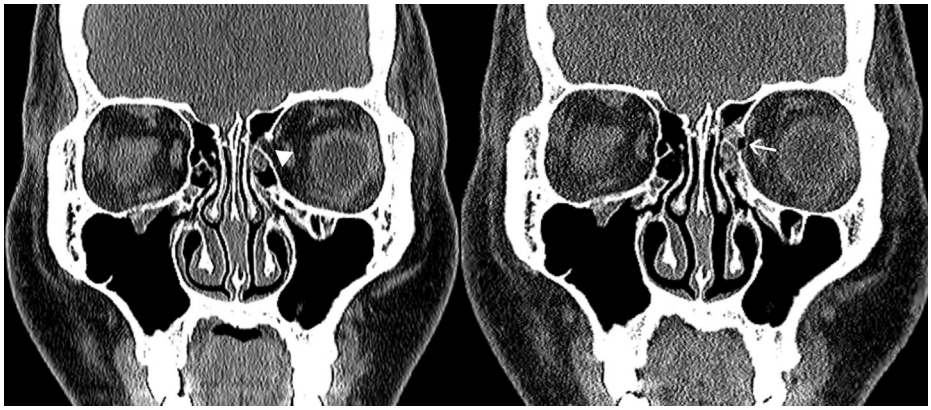

Fig. 7. A 19-year-old man with right medial wall fracture underwent the orbital repair using polycaprolactone mesh. (Right) Preoperative computed tomographic scan showing bony defect in right medial wall (white arrow head) and (Left) immediate postoperative image showing good reduction status using polycaprolactone mesh (white arrow).

fracture treated using resorbable poly (L-lactide) (PLLA) plates and screws, intermittent swelling and pain at the site of implantation was observed in 40% of the patients. In revisional surgery for explantation of an implant, a dense fibrous capsule surrounded the remnants of the degraded PLLA, suggesting a nonspecific foreign body reaction to the degraded PLLA (Bergsma et al., 1993).

Developed in the early 1930s, polycaprolactone (PCL), has been approved for use in craniofacial procedures. Some animal studies have reported successful application of PCL mesh implants in orbital wall fractures (Jacono and Moskowitz, 2000). Our study demonstrates that the use of this 3D-printed biodegradable PCL implants has excellent safety and good functional and aesthetic outcomes in the repair of orbital fracture. As mentioned above, PCL mesh has several beneficial characteristics for use as implants in orbital wall reconstruction. Firstly, its semi-rigid property is sufficient to maintain structural stability to support the orbital tissue, and its malleability allows surgeons to contour easily, for a close anatomical fit of the bony defect that is superior to other biodegradable thermoplastic implants. Secondly, caproic acid, a monomer of PCL, is dissociated constantly through hydrolysis into weak acidic metabolites of ~ pH 5 (comparatively weaker acids than metabolites of PLGA or PLLA-based implants). The safety of PCL metabolites has been investigated in an animal study. Biopsied PCL scaffolds were grafted for 3 months in orbital floor defects, and no signs of an inflammatory reaction were observed (Rohner et al., 2003). In our study, no signs of delayed infection or inflammatory response were observed during a long follow-up period (6 months). We suggest that the degradation metabolites of PCL mesh are safe, and thus the inflammatory response around the implant is minimal.

The fundamental concern regarding the use of an absorbable implant is the complete resorption of this biodegradable material. It has been established that PCL mesh degradation takes, on an average, 24 months (and can be up to 3–4 years), which is much slower than that of other absorbable alloplastic materials (Woodruff and Hutmacher, 2010). The results of our study confirmed this. The use of PCL mesh for orbital reconstruction provides maintenance of functional ocular motility and absence of enophthalmos during the follow-up period of our study. We propose that PCL mesh has controllable degradation and resorption rates, allowing for surrounding living tissue ingrowth owing to its high biocompatibility characteristics.

Scanning electron microscopy of the PCL mesh showed that the implant has regular and fully interconnected microporous structures on the surface, as expected (Fig. 1). This microporous structure was formed by a fused deposition modeling (FDM) process based on a 3D printing technique. This allowed highly reproducible design fabrication of scaffolds and the production of a completely interconnected honeycomb structure. The structure of this fully interconnected micropore network might enhance fibrovascular ingrowth into the mesh implant and invasion of fibrovascular tissue into the interior of the implant. This not only fills a tissue void and dead space but also provides an avenue for cellular response. Following PCL mesh degradation *in vivo*, 2–3 years after implantation, we hypothesize that this structure is sufficient to stabilize the reconstructed orbital wall in its corrected position.

When compared to other absorbable implants, the most remarkable benefit of PCL mesh is that it provides an osteoconductive environment that is desirable for guiding cellular growth, bone-directed differentiation and tissue formation within the interconnected honeycomb architecture of the mesh implant. Thus, it can act as a scaffold, inducing host tissue integration into the alloplastic implant (Schantz et al., 2003; Lee and Baek, 2012; Morotomi et al., 2014). This fact has been established in an animal study, in which histological results revealed new woven bone trabecula formation at the host construct interface and PCL scaffold in the orbital floor fractured site (Rohner et al., 2003). Clinically, in 20 patients with orbital floor reconstruction, a PCL mesh implant, Osteomesh (Osteopore International, Singapore), has been shown to induce definite features of neobone formation (detected by CT scan, performed 1.5 years after implantation) (Teo et al., 2015). The Osteomesh was fabricated through a similar 3D printing technology. However, an important difference between Osteomesh and the mesh used in the present study is the porosity of the implant, which has been regarded as a determining factor for vascular tissue infiltration (Chvapil et al., 1969). According to Shim et al., a PCL implant with a small pore size (less than 100 μm) and decreased porosity is inadequate for capillary penetration, and is likely to be filled with avascular tissues. Meanwhile, a large pore size (more than 500 μm) and high porosity prohibit the cellular component from migrating into the mesh scaffold, resulting in a variable extent of tissue proliferation and reduced stability of the grafted implant (Shim et al., 2017). The pore size and porosity of the mesh used in the present study are 500 μm and 50%, respectively, which is within the ranges of the most effective pore size for cellular integration and proliferation, as suggested by previous studies (Shim et al., 2017). In contrast, the porosity of Osteomesh used in the aforementioned clinical study was as high as 70%. Furthermore, our PCL mesh has a beneficial membranous structure on the surface of the mesh implant because it is manufactured using an advanced type of fused deposition modeling (the multi-head deposition system), which is able to mass-produce membranes. Furthermore, these membranes tend to elongate without early fracture under a tensile load, and they are flexible enough to cover irregular defect sites.

Concerns have been expressed regarding the possibility that fibrovascular integration into the porous implant may increase the risk of cicatrization between the porous implant and the orbital soft tissue, potentially causing diplopia, restricted eye movement, and lid retraction (Lee and Nunery, 2009). Tissue adhesion around porous titanium or Medpor mesh is attributable to thick and dense fibrous capsule formation, resulting from a general foreign body reaction to non-absorbable materials. However, in the integration process of biodegradable PCL mesh, fibrous capsule formation around the mesh is minimal, and the replacement of PCL mesh into viable host tissue occurred simultaneously with fibrovascular tissue ingrowth, thereby constructing the combined structure of implant degradation scar with integrated host tissue. In the present study, there was no case of persistent diplopia and functionally restricted ocular motor symptom during the follow-up period.

The limitation of the present study is a lack of the number of cases treated, and a lack of consistent and longer-term data (when considering that the degradation period of PCL mesh *in vivo* is more than 2 years). Fundamentally, various materials have their own benefits. Varying results are published in different studies. However, an increasing body of evidence for implant choice is pointing toward reducing the incidence of complications and increasing biocompatibility in complexity-based treatment models for general trauma surgery. Nevertheless, to the best of our knowledge, this is the first study to report the clinical outcomes of 3D-printed PCL mesh implants with the most optimal porosity for tissue integration.

5. Conclusion

Based on our experience, the use of PCL mesh in the repair of orbital wall fractures is a safe and effective method to recover both

ocular motor function and aesthetic outcome with high biocompatibility. Therefore, PCL mesh may be an effective, bioresorbable alternative to traditional implants for orbital wall reconstruction.

Financial disclosure statement

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jcms.2019.03.009.

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