Permanent Versus Bioresorbable Implants in Orbital Floor Blowout Fractures

Sophia Seen, M.B.B.S.*, Stephanie Ming Young, F.A.M.S., F.R.C.Ophth*†, Shao Jin Teo, M.B.B.S.*, Stephanie S. Lang, M.Sc.‡, Shantha Amrith, F.A.M.S., F.R.C.OPHTH*†, Thiam-Chye Lim, F.R.C.S., F.A.M.S.*§, and Gangadhara Sundar, F.R.C.S.ED, F.A.M.S.*†.

*Yong Loo Lin School of Medicine, National University of Singapore; †Orbit and Oculofacial Surgery, Department of Ophthalmology, National University Hospital Singapore; ‡Clinical Audit, Singapore National Eye Centre; and §Division of Plastic, Reconstructive and Aesthetic Surgery, National University Hospital, Singapore

Purpose: To compare the outcomes of bioresorbable and permanent implants in the reconstruction of isolated orbital floor blowout fractures.

Methods: Retrospective series of all patients who had orbital floor fracture repair in a single tertiary trauma center from January 2005 to December 2014. The authors reviewed the case notes and CT scans of patients with orbital floor fracture repair with either bioresorbable or permanent implants. Main outcome measures were enophthalmos, diplopia, and ocular motility restriction 1.5 years after fracture repair. Implant-related complications were collected for analysis.

Results: There were a total of 88 patients in our study. Bioresorbable implants were used in 48 patients (54.5%) while 40 patients had permanent implants (45.5%). The authors analyzed the implants used in various sizes of orbital fractures: small (<13.3 mm), medium (13.3–20 mm), and large (>20 mm). One and a half years after fracture repair, both groups had comparable clinical outcomes (n = 2 and n = 0 for diplopia for permanent and bioresorbable implant groups, respectively, n = 0 for enophthalmos for both groups and n = 1 for ocular motility limitation for both groups) overall and across all fracture sizes.

Conclusion: Bioresorbable implants degrade after fracture healing through hydrolysis and promote the gradual transfer of functional forces to healing bone during its disintegration. The clinical outcomes of diplopia, enophthalmos, and ocular motility restriction associated with the use of resorbable implants are comparable to that of permanent implants for all fracture sizes. Their study shows that bioresorbable and permanent implants are equally safe and effective for the treatment of patients with isolated orbital floor blowout fractures.

(Ophthal Plast Reconstr Surg XXX;XX:00-00)

Pure orbital blowout fractures are commonly encountered in the context of facial trauma and refer to fractures of the orbital walls with preservation of the orbital rim.¹ Of these, the orbital floor is commonly involved due to the thin bone medial to the infraorbital groove.^{1,2} Two theories for the mechanism of orbital blowout fractures have been proposed: an increase in

Accepted for publication January 2, 2018.

The authors have no financial or conflicts of interest to disclose.

Address correspondence and reprint requests to Gangadhara Sundar, F.R.C.S.Ed, F.A.M.S., Department of Ophthalmology, National University Health System, 1E Kent Ridge Road, NUHS Tower Block Level 7, Singapore 119228. E-mail: gsundar1@yahoo.com

DOI: 10.1097/IOP.0000000000001077

intraocular pressure as a result of posterior displacement of the globe (hydraulic theory) or a direct blow to the inferior orbital rim with force transmission from the more rigid infraorbital rim to the relatively weak orbital floor (buckling theory).² In addition, a recent study suggested that trauma directly to the globe predisposes a patient to a more posterior fracture while trauma to the rim demonstrates an anterior predilection.³ Fractures of the orbit can cause a multitude of problems, in particular diplopia,⁴ ocular muscle entrapment,¹ enophthalmos,⁴ and psychological trauma.⁵

Orbital floor blowout fractures can be repaired using different techniques and implant materials.^{6–9} Implant materials may be synthetic, and these synthetic implants can be either resorbable or permanent. The amount of empirical support for individual materials used for orbital floor fracture reconstruction differs, and no definite conclusion has been reached regarding the best material for orbital floor fracture repair.¹⁰ There is a lack of standardized guideline or consensus with different surgeons having different preferences and practices that are each supported by varying amounts of research.^{11,12}

Permanent implant materials such as titanium, porous polyethylene, silicone elastomers, or nylon foil provide good tensile strength, are readily available, and have a long track record in craniofacial reconstruction.^{7–9,13,14} Bioresorbable implants such as copolymers of poly-L-lactic acid, poly-D-lactide, polydioxanone, and polycaprolactone (PCL) offer a good readily available alternative to nonresorbable implants.^{15,16} As they become more available and widely used in craniofacial reconstruction, a comparison of these implants to standard permanent implants is timely.

There have been few studies comparing the different types of implants for orbital blowout fractures,^{14,16–19} and there have been only 2 studies looking at pure orbital floor blowout fractures. One study compared porous polyethylene and bioresorbable poly-L-lactic acid sheet¹⁴ and another compared autogenous bone grafts and bioresorbable poly-L/DL-lactide (P[L/DL]LA) implants.²⁰ These studies looked only at 1 type of bioresorbable implant (poly-L-lactic acid) and did not include titanium implant, which many craniomaxillofacial and oculofacial surgeons consider as a standard permanent implant. Hence, the authors conducted a study to compare the clinical outcomes of pure orbital floor blowout fractures repaired with either bioresorbable or nonresorbable implants (including titanium implants) in a single tertiary institution over a 10-year period.

PATIENTS AND METHODS

A retrospective review was performed on all patients who had orbital floor blowout fracture repair in a single tertiary trauma center

from January 2005 to December 2014. Main outcome measures included improvement in clinical findings of ocular motility, diplopia, and enophthalmos. Implant-related complications were collected from patients' case files for analysis. Written informed consent was obtained from all patients, and the study was conducted in accordance with the tenets of the Declaration of Helsinki as amended in 2008. Institutional Review Board approval was obtained (DSRB 2013/00751).

Preoperative CT scans of the orbit were conducted according to the image-guided surgery protocol (1 mm cuts with the gantry set at 0°) by Ang et al.²¹ The authors divided the fractures into 3 groups based on the preoperative CT scan results: small (<13.3 mm), medium (13.3– 20.0 mm), and large (>20 mm). The average length of the orbital floor is approximately 40 mm,²² and fractures that were less than 1/3 the size of the orbital floor were considered to be small while fractures between $\frac{1}{2}$ and 1/3 the size of the orbital floor were considered medium sized. Large fractures were fractures larger than $\frac{1}{2}$ the size of the orbital floor.

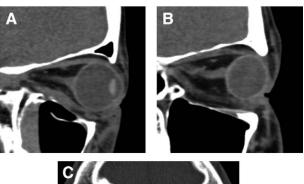
The choice of implant (bioresorbable or permanent) largely depended on patient, fracture, and surgeon factors. Small fractures in younger patients were more likely to be repaired with bioresorbable implants. Medium and large fractures were likely to be repaired with either bioresorbable or permanent implants. If the patient was likely to be involved in future trauma again, we would lean more toward using a permanent implant. For very large fractures (>25 mm), the authors were also more likely to use a permanent implant.

The size of the defect was confirmed using a Matrix Orbital (Synthes, Oberdorf, Switzerland) malleable retractor, and template implant measurement was also carried out (Fig. 1). Prolapse of orbital tissue was defined radiologically while entrapment required both radiologic evidence of prolapse and clinical evidence of ocular motility restriction and a positive forced duction test. During fracture repair, the authors assessed if there was prolapse of orbital tissue or extraocular muscle through the fracture defect. There were 4 surgeons in our study.

All patients underwent orbital fracture repair via a direct transconjunctival approach. The authors generally perform a canthotomy or cantholysis for very large or more posteriorly extending fractures for greater exposure and for maneuvering of larger implants in the orbital space. The fracture size and location were predicted based on preoperative CT. Sixteen patients (18.2%) had a lateral canthotomy and inferior cantholysis. For all cases of orbital floor fractures, the repair was done as follows. A preincision forced duction test was conducted in all patients, and restriction of motion was suggestive of inferior rectus entrapment. Dissection was either preseptal if a triplanar incision was used or postseptal if a direct forniceal transconjunctival incision was used, depending on surgeon preference. A periosteal incision was made along the anterior orbital rim and the periosteum was reflected to expose the orbital floor fracture. Entrapped tissue was freed from all edges of the



FIG. 1. Intraoperative sizing of implant.



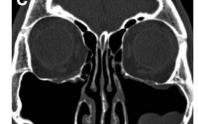


FIG. 2. Bioresorbable implants are radiologically visible especially in the early postoperative period. **A**, Early postoperative imaging was performed for this patient with a bioresorbable implant; the bioresorbable implant is clearly seen on the CT scan. This confirms the accurate placement of the implant. **B**, This patient experienced upgaze restriction at postoperative month 6. A CT scan was performed that showed a (poly-L/DL-lactide) 85/15 implant that was inappropriately small and not resting on the posterior ledge. The ability to visualize the implant on CT scan enables the surgeon to correlate the patient's symptoms with implant placement. **C**, Late postoperative imaging showing good reduction and neobone formation with complete resorption of bioresorbable implant (right eye).

fracture and elevated from the adjacent maxillary sinus cavity in the orbit. Care was taken to avoid damage to the infraorbital neurovascular bundle. The frequently encountered orbital branch of the infraorbital artery was identified, cauterized, and cut before posterior dissection to identify the posterior ledge. Likewise, in medium to large floor fractures, the structures of the inferior orbital fissure were identified, cauterized, and released to expose the entire orbital floor—lateral wall to medial wall, inferior rim to the posterior ledge. The authors ensured that the medial, lateral, and posterior edges of the fracture were clearly identified prior to insertion of the implant to ensure proper placement.

Forced duction test was performed postoperatively to confirm that the implant did not entrap any tissue. The periosteum and conjunctiva were closed with 6-0 vicryl (Ethicon, Johnson & Johnson, Somerville, NJ, U.S.A.) suture. Adjuvants used intraoperatively included the Brainlab system (Brainlab, Feldkirchen, Germany) or the Medtronic system (Medtronic, Minneapolis, MN, U.S.A.), which were used for intraoperative surgical guidance. Intraoperative image guidance was used mainly in more complex fractures (e.g., orbital fracture combined with other facial fractures) where the operation was performed in conjunction with the plastic surgery team. We monitored the optic nerve function of all patients. Patients were reviewed at the following intervals 1 day, 1 week, 1 month, 3 months, 6 months, 1 year, and 15–24 months.

Postoperative CT was done for all patients who underwent fracture repair to check on the implant postoperative. We performed late postoperative imaging as part of our protocol, mostly to confirm complete bone healing and complete resorption of the implant and to assure patients of the status of the implants after complete healing. Patients who had resorption of the implant on late postoperative imaging (Fig. 2C) and clinically stable were discharged from follow up.

The authors compared the type of implant used and clinical outcome measures such as diplopia, enophthalmos, and restriction of

Demographics (n = 88)	All Implants	Permanent Implants†	Resorbable Implants*	р
Eyes (%)	88 (100)	40 (45.5)	48 (54.5)	
Gender (%)				
Male	71 (80.7)	33 (82.5)	38 (79.2)	0.693
Female	17 (19.3)	7 (17.5)	10 (20.8)	
Age (years)				
Mean \pm SD	34.3 ± 15.6	35.7 ± 16.4	33.2 ± 15.1	0.399
Median	31	29	35	
Range	5-72	5-63	7–63	
Preoperative clinical outcome				
Present (%)				
Diplopia	54 (61.4)	23 (57.5)	31 (64.6)	0.497
Enophthalmos	12 (13.6)	8 (20.0)	4 (8.3)	0.121
Ocular motility limitation	62 (70.5)	25 (62.5)	37 (77.1)	0.135
Mechanism of injury (%)				
Assault	30 (34.1)	17 (42.5)	13 (27.1)	0.278
Motorcycle accident	8 (9.1)	3 (7.5)	5 (10.4)	
Other road traffic accident	6 (6.8)	2 (5.0)	4 (8.3)	
Sport-related trauma	20 (22.7)	7 (17.5)	13 (27.1)	
Fall on level ground	11 (12.5)	7 (17.5)	4 (8.3)	
Fall from height	4 (4.5)	0 (0)	4 (8.3)	
Other blunt trauma	9 (10.2)	4 (10.0)	5 (10.4)	

*Bioresorbable implants used in our institution included P(L/DL)LA implants 85/15 (Rapidsorb; Synthes, Oberdorf, Switzerland), P(L/DL)LA 70/30 (PolyMax; Synthes, Oberdorf, Switzerland), polycaprolactone mesh implant (Osteomesh; Osteopore International, Singapore), and P(L/DL)LA 70/30 implant (MacroPore; Biosurgery, Inc., San Diego, CA, U.S.A.).

[†]Permanent implants used included MatrixMIDFACE titanium preformed orbital plate (PFTi) (DePuy Synthes, Westchester, PA, U.S.A.), MatrixMIDFACE titanium orbital mesh plate (DePuy Synthes, Westchester, PA, U.S.A.), Titanium Orbital Anatomic Floor Plate (DePuy Synthes, West Chester, PA, U.S.A.), porous polyethylene Medpor (Stryker, Kalamazoo, MI, U.S.A.), titanium mesh with porous polyethylene SynPOR Titanium Orbital Floor Mesh Plate (Synthes, Oberdorf, Switzerland), and Medpor Titan (Stryker, Kalamazoo, MI, U.S.A.).

P(L/DL)LA, poly-L/DL-lactide.

ocular motility. Cochran Q test was used to determine if there were any differences between preoperative and postoperative clinical findings (ocular motility limitation, diplopia, and enophthalmos). A significance level of 0.05 was used, and statistical analysis was performed using SPSS Statistics 19.0 (IBM, New York, NY, U.S.A.).

RESULTS

Three hundred five orbits of 277 patients underwent an orbital fracture repair during the study period of 10 years. Of these, 176 (57.7%) were orbital blowout fractures, of which 88 were isolated orbital floor blowout fractures. Of the other orbital blowout fractures, 10 were isolated medial wall fractures and 78 were combined floor and medial wall fractures. Patient demographics and surgical data are listed in Table 1.

Bioresorbable implants were used in 48 patients (54.5%) while 40 patients had permanent implants (45.5%). Nineteen (47.5%) of the 40 patients with permanent implants had a prefabricated anatomical titanium implant. The medial wing of the titanium anatomical plate was trimmed completely, or a minimal wedge was left for medial support. Eighteen (45.0%) patients had a porous polyethylene implant, 2 (5%) patients had a porous titanium mesh with porous polyethylene, and 1 (2.5%) patient had a silastic implant.

Of the 48 patients with bioresorbable implants, the majority (n = 31, 64.6%) had a P(L/DL)LA 85/15 implant, 10 (20.8%) had a P(L/DL)LA 70/30 implant (PolyMax; Synthes, Oberdorf, Switzerland), 6 (12.5%) had a PCL implant, and 1 (2.1%) had a P(L/DL)LA 70/30 implant (MacroPore; Biosurgery, Inc., San Diego, CA, U.S.A.).

Preoperatively, fractures were classified as small (<13.3 mm), medium (13.3–20.0 mm), and large (>20.0 mm).²² The authors analyzed the fracture types and implant used for individual fracture types. Most of the small (66.6%) and large (63.0%) fractures were repaired with bioresorbable implants while 65.4% of the medium fractures were repaired with permanent implants (Table 3). Despite bioresorbable **TABLE 2.** Fracture characteristics for individual implant type

	All Implants	Permanent Implants	Bioresorbable Implants	р
Width (mm)				
Mean± SD	16.23 ± 4.72	17.75 ± 4.62	14.04 ± 4.19	< 0.001
Range	4.64-28.91	7.77-28.91	4.64-25.01	
Length (mm)				
Mean \pm SD	19.47 ± 5.01	19.96 ± 5.06	18.25 ± 4.71	0.117
Range	5.00-30.25	5-30.00	9.74-25.54	

fractures being used more frequently in large fractures, the average width (p < 0.001) and length (p = 0.117) of fractures repaired using permanent implants were still greater than that of fractures repaired using bioresorbable implants (Table 2). Patients were discharged from follow up after confirmation of complete healing and implant resorption for patients with bioresorbable implants.

The authors compared the clinical outcomes at postoperative year 1.5 (POY 1.5) for both bioresorbable and permanent implants based on different fracture types and illustrated them in Table 3. In both groups, few patients experienced residual diplopia, enophthalmos, or ocular motility limitation across fracture types. For the group with permanent implants, 2 patients experienced diplopia (within 30° of primary gaze) and 1 patient experienced ocular motility limitation at POY1.5. Conversely, 1 patient experienced ocular motility limitation at POY1.5 for the group with resorbable implants. All patients had a free forced duction at the conclusion of surgery. It should be noted that the ocular motility observed postoperatively may be due to other causes such as muscle ischemia, rather than an implant-related complication. There were no significant differences in clinical outcomes at POY1.5 between both groups for all fracture types.

		Permane reoperative													` `			
$ \begin{array}{ c c c c c c c c c c c c c c c c c c c$		reoperative	ant	Biores	orbable		Permai	nent		Bioresorb	able		Permanent		Bior	esorbabl	e	
Present (%) eithy imitation 2 (1000) 0 (00) 3 (133) 3 (143) 3 (133) 3 (143) 3 (133) <th col<="" th=""><th>- uılar motility limitation</th><th></th><th>POY1.5</th><th>Preoperativ</th><th></th><th></th><th>operative</th><th>POY1.5</th><th></th><th>erative</th><th>POY1.5</th><th>Preopei</th><th></th><th>0Y1.5</th><th>Preopera</th><th></th><th>POY1.5</th></th>	<th>- uılar motility limitation</th> <th></th> <th>POY1.5</th> <th>Preoperativ</th> <th></th> <th></th> <th>operative</th> <th>POY1.5</th> <th></th> <th>erative</th> <th>POY1.5</th> <th>Preopei</th> <th></th> <th>0Y1.5</th> <th>Preopera</th> <th></th> <th>POY1.5</th>	- uılar motility limitation		POY1.5	Preoperativ			operative	POY1.5		erative	POY1.5	Preopei		0Y1.5	Preopera		POY1.5
diffy limitation $2(100, 0, 00) = 4(100, 0, 00) = 8(77, 1) = 1(33, 3) = 5(55, 0, 00) = 1(14.3) = 25(57.3) = 26(77.3) = 0(00) = 1(14.3) = 25(67.3) = 0(00) = 1(14.3) = 25(67.3) = 0(00) = 1(14.3) = 25(67.3) = 0(00) = 1(14.3) = 25(67.3) = 0(00) = 1(14.3) = 25(67.3) = 0(00) = 1(14.3) = 25(67.3) = 0(00) = 1(14.3) = 25(67.3) = 0(00) = 1(14.3) = 25(67.3) = 0(00) = 1(14.3) = 25(67.3) = 0(00) = 1(14.3) = 25(67.3) = 0(00) = 1(14.3) = 25(67.3) = 0(00) = 1(14.3) = 25(67.3) = 0(00) = 1(14.3) = 25(67.3) = 0(00) = 1(14.3) = 25(67.3) = 0(00) = 1(14.3) = 25(67.3) = 0(00) = 1(14.3) = 25(67.3) = 0(00) = 1(14.3) = 25(67.3) = 0(00) = 1(14.3) = 25(67.3) = 0(00) = 1(14.3) = 25(67.3) = 0(00) =$	ular motility limitation							Presei	nt (%)									
brow over anothe to classify the fracture size of 2 patients (1 bioresorbable and 1 permanent implant) as they did not have preoperative CT scans. 5. possipperative comparisons A. Pre- and postoperative comparisons Bioresorbable Implants Prooperative POM1 POM5 AII Cases Bioresorbable Implants Prooperative POM1 POM5 AII Cases Bioresorbable Implants Permanent Implants POM1	plopia ophthalmos tal number	2 (100.0) 1 (50.0) 0 (0.0) 2	$\begin{array}{c} 0 \ (0.0) \\ 0 \ (0.0) \\ 0 \ (0.0) \\ 1 \end{array}$	$\begin{array}{c} 4 \ (100.0) \\ 3 \ (75.0) \\ 0 \ (0.0) \\ 4 \end{array}$	$\begin{array}{c} 0 \ (0.0) \\ 0 \ (0.0) \\ 0 \ (0.0) \\ 2 \end{array}$) (58.8) 3 (47.1) 5 (29.4) 17	$\begin{array}{c} 0 \ (0.0) \\ 1 \ (33.3) \\ 0 \ (0.0) \\ 3 \end{array}$		77.8) 55.6) 9.0) 9	$\begin{array}{c} 0 \ (0.0) \\ 0 \ (0.0) \\ 0 \ (0.0) \\ 4 \end{array}$	13 (6(14 (7(3 (15 20		(14.3) (14.3) (14.3) (0.0) 7	25 (73.5 22 (64.7 3 (8.8) 34		$\begin{array}{c} 1 \ (8.3) \\ 0 \ (8.3) \\ 0 \ (0.0) \\ 12 \end{array}$	
4. Pre- and postoperative comparisons Bioresorbalte Implants Preoperative comparisons All Cases Bioresorbalte Implants Preoperative PONI P	The authors were unable to cla POY 1.5, postoperative year 1.	ssify the fractun 5.	e size of 2 pa	tients (1 biores	sorbable and 1	1 permane	nt implant)	as they did	not have pr	eoperative	CT scans.							
4. Pre- and postoperative comparisons All Cases Bioresorbable Implants Permanent Implants All Cases Bioresorbable Implants Permanent Implants All Cases Bioresorbable Implants Permanent Implants Peroperative POMI	The authors were unable to cla POY 1.5, postoperative year 1.	ssify the fractur 5.	e size of 2 pa	ttients (1 biore:	sorbable and	l permane	nt implant)	as they did	not have pi	reoperative	CT scans.							
*. Tre- and posoperative Comparisons Bioresorbable Implants Permanent Implants Permanent Implants All Cases Bioresorbable Implants Prooperative POM1 POM6 POY1 POV1 <		co octivo co																
POM6 POY1 POV1:S p Preoperative POM1 POV1:S p Preoperative POM1 POV1:S p Preoperative POM1 POV1 p 1) 54 (83.1) 40 (87.0) 27 (93.1) <0.001 17 (35.4) 31 (64.6) 17 (35.4) 31 (64.6) 27 (77.1) 21 (84.0) 18 (100) <0.001 17 (42.5) 28 (70.0) 27 (90.0) 19 (90.5) 17 (35.4) 31 (64.6) 17 (35.4) 8 (22.9) 4 (16.0) 0 (0.0) 23 (57.5) 12 (30.0) 3 (10.0) 2 (95.5) 29 (56.7) 2 (30.0) 2 (90.5) 12 (30.0) 2 (90.5) 12 (30.0) 12 (90.5) 12 (30.0) 12 (90.5) 12 (30.0) 12 (90.5) 12 (30.0) 12	÷						Diamond	ml aldaha	nlante				Down	anont Im	alante			
$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	Drannara fiva DC						POMI I			2170		onorativa	POMI	DOM6		POV1 5	5	
$ \begin{array}{cccccccccccccccccccccccccccccccccccc$																	4	
$ \begin{array}{cccccccccccccccccccccccccccccccccccc$	34 (38.6) 54 (61.4)	67.0) 54 (83.1 33.0) 11 (16.9) 40 (87.0)				1 (64.6) 2 7 (35.4)	7 (77.1) 21 8 (22.9) 4	1 (84.0) 1: 1 (16.0) (28 (70.0) 12 (30.0)	27 (90.0) 3 (10.0)	19(90.5) 2(9.5)	9 (81.8) 0.010 2 (18.2)	0.01	
$ \begin{array}{cccccccccccccccccccccccccccccccccccc$		(0.0) 0 (0.0)								(21.0)	1			(crost) c	(?:.) 	(<u>1</u> 22)		
$ \begin{array}{cccccccccccccccccccccccccccccccccccc$								30 (1 20) 1					0 10 202 02			10,000,01	100	
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	/0 (00:4) 12 (13.6)	3.4) 2 (3.1)					1 (2.1)	$\frac{4}{1}$ (2.9) 2.					. (0.06) oc 2 (5.0)	29 (90.7) 1 (3.3)		(6.06) 01 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	10.0	
$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$	0(0.0)			1 (3.4)	~							_			` /	1(9.1)		
$ \begin{array}{cccccccccccccccccccccccccccccccccccc$	ular motility limitation, N	(%)																
$\begin{array}{cccccccccccccccccccccccccccccccccccc$	26 (29.5) 62 (70.5)	69.3) 54 (83.1 30.7) 11 (16.9) 41 (89.1) 5 (10.9)				6 (75.0) 3. 2 (25.0)	0 (85.7) 22 5 (14.3) 3	2 (88.0) 1	7 (94.4) < 1 (5.6)		5 (37.4) 5 (62.5)	25 (62.5) 15 (37.5)	24 (80.0) 6 (20.0)	19(90.5) 2(9.5)	10 (90.9) 1 (9.1)	0.00	
88 88 65 46 29 48 48 35 25 18 40 40 30 21	(0.0)	0.0) 0 (0.0)									1	() 	() 	(202)				
	88		46	29	4	8	48	35	25	18		40	40	30	21	11		

4

© 2018 The American Society of Ophthalmic Plastic and Reconstructive Surgery, Inc.

Copyright © 2018 The American Society of Ophthalmic Plastic and Reconstructive Surgery, Inc. Unauthorized reproduction of this article is prohibited.

Table 4 compares the preoperative and postoperative clinical outcomes at various follow-up times for all patients and for the subgroups of bioresorbable and permanent implants. There was significant improvement in diplopia, enophthalmos, and ocular motility limitation postoperatively in all implant types (p < 0.05). This improvement was sustained with postoperative follow up. The authors also compared the clinical outcomes of patients with PCL implants with patients with P(L/DL)LA implants and found the clinical outcomes to be comparable at POY1.5 (Table 5). Implant-related complications have been summarized in Table 6. One patient with a titanium mesh with porous polyethylene implant had orbital compartment syndrome with raised intraocular pressure secondary to orbital hemorrhage which subsequently resolved with medical therapy. While palpable plates and screws are a reported complication with permanent implants, none of the patients in this series had this complication. There were no complications of postoperative blindness in their study.

Structure may not always correlate with function in the reconstruction of orbital fracture. A well-positioned, suitably sized implant would likely result in good clinical outcomes. The converse does not always hold true. In their study, the authors found that while some patients had suboptimal implant positioning or sizing, they still had good clinical outcomes. For example, 1 patient who had an inappropriately large implant (Fig. 3A) had no functional impairments postoperatively and at subsequent follow ups. In addition, rarely and not in this study, some patients with well-positioned implants on CT imaging may have suboptimal clinical outcomes.

DISCUSSION

Precise reconstruction of the orbit is necessary to avoid functional deficits and for restoration of anatomical relations and cosmesis. The choice of implant material contributes significantly to the long-term success of orbital reconstruction.

Titanium is a commonly used manufactured nonresorbable material for the reconstruction of craniomaxillofacial fractures as it provides stiffness and strength to avert buckling at the injury site and reduces fracture-site movement allowing for tissue repair to occur correctly. The malleability of titanium allows for presurgical contouring, and it is used for larger orbital floor defects. These implants have evolved from thin titanium meshes of the past to the anodized anatomical 3-dimensional prefabricated implants small (purple colored) and large (gold colored). Titanium meshes have also been associated with orbital adherence syndrome.23 This has been overcome with the more recently available anodized thicker anatomical 3-dimensional prefabricated orbital titanium implants. Titanium implants are nonresorbable and remain as a permanent foreign body, with the persistent risk of complications.²⁴ In addition, they are not as easily positioned and the irregular edges of the mesh may catch prolapsed orbital fat. Thus, the advantages of the newer titanium plants include anatomical 3-dimensional reconstruction of orbits, relative customization of the implant to the deformity, and radiologic visibility.

Porous polyethylene implants have been the implant of choice of oculoplastic surgeons in western nations.²⁵ The open porous structure of the material allows for vascularization that creates the potential to transport cellular products and reduces the risk of implant migration.^{26,27} Due to its nonresorbable nature, there is a potential lifelong risk of infection and inflammation around the implant²⁸ although such cases are rare. Porous polyethylene is also easy to use as it does not require

	Preoperative		POY1		PO	OY1.5
	PCL	P(L/DL)LA	PCL	P(L/DL)LA	PCL	P(L/DL)LA
Diplopia (%)						
No	2 (33.3)	15 (36.6)	3 (100.0)	18 (81.8)	3 (100.0)	15 (100.0)
Yes	4 (66.7)	26 (63.4)	0 (0.0)	4 (18.2)	0 (0.0)	0 (0.0)
Enophthalmos (%)						
No	6 (100.0)	37 (90.2)	3 (100.0)	22 (100.0)	3 (100.0)	15 (100.0)
Yes	0 (0.0)	4 (9.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Ocular motility limitation (%)						
No	1 (16.7)	10 (24.4)	3 (100.0)	19 (86.4)	3 (100.0)	14 (93.3)
Yes	5 (83.3)	31 (75.6)	0 (0.0)	3 (13.6)	0 (0.0)	1 (6.7)
No. cases	6	41	3	22	3	15

TABLE 5. Comparison of clinical outcomes of patients with PCL implants and patients with P(L/DL)LA implants (Rapidsorb and PolyMax)

PCL, polycaprolactone; P(L/DL)LA, poly-L/DL-lactide; POY1, postoperative year 1; POY1.5, postoperative year 1.5.

No.	Type of Implant Used	Complications
1.	Titanium mesh with porous polyethylene	Secondary orbital hemorrhage resulting in raised IOP and orbital compartment syndrome. The impervious nature of porous polyethylene resulted in the formation of a collection of blood. The patient's IOP returned to normal following medical treatment with IV acetazolamide, topical brimonidine, and timolol.
2.	Titanium mesh orbital mesh plate	Reoperation due to malposition of titanium implant that was noted on the CT scan at postoperative day 1 (Fig. 3B). The medial aspect of the implant was inferior to the orbital wall.
3.	P(L/DL)LA 85/15	Patient reported upgaze restriction at postoperative month 6 follow-up review. CT scan revealed a malpositioned implant that was too small for the fracture (Fig. 2B). Patient was treated conservatively and upgaze restriction resolved by POY1.

© 2018 The American Society of Ophthalmic Plastic and Reconstructive Surgery, Inc.

Copyright © 2018 The American Society of Ophthalmic Plastic and Reconstructive Surgery, Inc. Unauthorized reproduction of this article is prohibited.

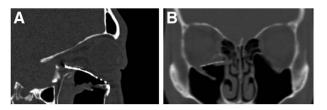


FIG. 3. Postoperative CT imaging of patients with titanium implants. **A**, Titanium implant used was inappropriately large. **B**, Medial aspect of the titanium implant was inferior to the orbital wall.

the fixation with screw and sutures although implant migration can occur until the device is fixed by the ingrowth of fibrous tissue. The silicone coating serves as a barrier sheet. The barrier sheet allows orbital contents to move and reduces incidences of orbital adherence. Disadvantages of the barrier sheet include the preclusion of the implant from integrating with the orbit. The impervious nature of the barrier sheet could also result in orbital compartment syndrome due to fluid accumulation postoperatively²⁹ and implant infection through the formation of a pseudocapsule allowing for abscess formation.³⁰

Bioresorbable implants degrade after the healing of the fracture through hydrolysis.¹⁵ The key advantages of bioresorbable implants are that they promote the gradual transfer of functional forces to healing bone during their disintegration and provide mechanical integrity while the polymer resorbs. Properties include thermolability (P[L/DL]LA), contourability (P[L/DL]LA), and porosity (PCL). Contourability is an important characteristic given the precise nature of orbital floor reconstruction.15 Biodegradable graft materials used in the internal orbit are mainly polymers comprising poly-L-lactic acid, poly-D-lactide, poly(L-lactide-co-glycolide), polydioxanone, and PCL in their pure form or in varying combinations with one another.11 Poly(L-lactide-co-glycolide) is more susceptible to hydrolysis when compared with PCL, with poly(Llactide-co-glycolide) having a shorter lifespan and expected to fully degrade by around 12 months, while PCL is expected to fully degrade by 24 months.¹⁴ Early scans showed the implant clearly (Fig. 2A). The implants were seen as isodense (PCL) to hyperdense (P[L/DL]LA) plates. In their study, bioresorbable implants were no longer seen on late postoperative CT scans after 15 to 24 months (Fig. 2C). Based on late postoperative CT scans, orbital volume and orbital symmetry could be satisfactorily restored with bioresorbable implants (Fig. 2C). In addition, not all bioresorbable implants are equally thermolabile. PCL has a melting point of 55°C and is typically not contoured by heating for orbital fractures, whereas that for P(L/DL)LA is higher and is usually contoured 3-dimensionally by heating to 65°C.14 Based on their experience, usage of a water bath with very high temperatures on PCL during surgery would not be appropriate for the same reason. A comparison of the various implants including their advantages and disadvantages is shown in Table 7.

Despite the rising popularity of bioresorbable implants since its first use in craniomaxillofacial surgery in the 1990s, there have been few studies published that directly compare bioresorbable implants to other types of implants. As such, it is difficult to draw formal and objective conclusions as to which material is best suited for orbital fracture repair.

Most importantly, the authors found that the clinical outcomes of diplopia, enophthalmos, and ocular motility restriction associated with the use of resorbable implants were comparable to that of nonresorbable implants. Han et al. compared the clinical outcomes of 331 patients with orbital blowout fractures repaired with either P(L/DL)LA 70/30 (MacroPore) or porous polypropylene and found that there was no difference in the degree of preoperative and postoperative diplopia, ocular motility limitation, and enophthalmos in the 2 groups.¹⁸ Another study by Baek et al. comparing the clinical outcomes of 78 patients with blowout fractures who were treated with either titanium or absorbable mesh plate had similar findings.¹⁷ The reservations that many surgeons have with the use of bioresorbable implant stem from studies that have associated resorbable implants with enophthalmos. These studies have reported that following the thorough resorption of the resorbable implants, the fibrosis and connective tissue that remain do not provide sufficient support resulting in enophthalmos.^{31,32} Their study found that enophthalmos improved in most patients, and at POY1.5, none of the patients who had bioresorbable implants had enophthalmos. The authors do acknowledge that with only 4 patients with preoperative enophthalmos in the bioabsorbable group, more evidence is needed before conclusions can be drawn in this regard. Nonetheless, most patients do not present with enophthalmos in the preoperative period due to periorbital edema, hence the number of patients is an underestimation of the patients who have enophthalmos. In addition, similar studies on bioresorbable implants had similar findings-that the prevalence of enophthalmos at long-term follow up in patients with bioresorbable implants for orbital floor fractures is similar to or even less than that of other nonresorbable implants.^{14,17,33,34} Their findings are similar to that of other studies which concluded that nonresorbable and resorbable implants were safe and reliable for the repair of orbital floor fractures.^{15,35,36} Nonetheless, there is always concern that the intrinsic mechanical properties of biodegradable osteofixation systems are less favorable than those of titanium. While the authors demonstrated that bioresorbable implants were successfully used in all fracture sizes including fractures that are greater than 20mm in their study, the average length and width of fractures were greater for permanent implants and might represent a preference for permanent implants in patients with extremely large orbital fractures. In addition, patients who are more prone to future trauma should consider having a permanent implant while younger patients would benefit more from a bioresorbable implant. Nonetheless, all patients should be given the option of bioresorbable or permanent implants and be counseled on the pros and cons of each. While surgeon preference also plays a role, the final choice should be made by the patient.

Limitations of our study include its retrospective nature. As a result, there were no defined criteria on implants to be used, and indications for each type of implant were not based on any fixed criteria of fracture size or type. Other factors such as the configuration and size of fracture or the surgeon's comfort level with a particular type of implant may have influenced the type of implant chosen. Finally, our patient numbers were also not as large as some other studies of orbital fractures as the authors were strict to include only pure orbital floor blowout fractures and excluded patients with combined fractures of other walls of the orbit or face.

In conclusion, their study has shown that the clinical outcomes achieved with the use of bioresorbable implants are comparable to that of traditional permanent implants for small, medium, and large orbital floor fractures. Therefore, both bioresorbable and permanent implants seem to be equally safe and effective for the treatment of patients with orbital floor blowout fractures. The advantages of bioresorbable implants include contourability and porosity, and patients with bioresorbable implants can be discharged when there is evidence of implant resorption

TABLE 7. Advantages and disadvantages of implants

Implant	Cost*	Advantages	Disadvantages	Radiologically Visible
Permanent				
Titanium	1.2x	 Good tensile strength and stiff Malleable allowing for anatomical 3-dimensional reconstruction of orbits 	 Case reports of orbital adherence syndrome with older titanium meshes²⁰ Nonresorbable; permanent foreign body with possibility of late-onset complications²¹ Not as easily positioned Irregular edges of mesh may catch prolapsed orbital fat 	Yes
Porous polyethylene	1.2x	 Open porous structure of the material allowing vascularization Does not require the fixation with screw and sutures Easily shaped 2 dimensionally 	 Silicone coating serves as a barrier sheet—possibility of orbital compartment syndrome²⁵ and abscess formation²⁶ Nonresorbable (see above) Inability to be contoured 3-dimensionally Late migration and exposure 	No
Composite (titanium- porous polyethylene)	x)	 Contourable and easy to shape Minimize soft tissue adhesion; globe is kept mobile Open porous structure of the material allowing vascularization 	 Silicone coating serves as a barrier sheet— possibility of orbital compartment syndrome and abscess formation Nonresorbable (see above) Inability to be contoured 3-dimensionally 	Yes
Bioresorbable				
P(L/DL)LA 70/30	1.8x	 Resorbable: avoids potential complications associated with permanent implants Thermolabile Contourable and easy to shape Not associated with higher incidence of enophthalmos³⁰ 	- Less favorable mechanical properties	Yes (hyperdense)
P(L/DL)LA 85/15	1.8x	 Resorbable (see above) Thermolabile Contourable and easy to shape 	- Less favorable mechanical properties	Yes (hyperdense)
PCL	1.2x	v 1	 Not thermolabile Less favorable mechanical properties 	Yes (isodense)

*Cost is based on the cost of implants to patients in a single tertiary center in Singapore. We quoted the cost for the various materials based on the cost for the following products: titanium, Titanium Orbital Anatomic Floor Plate (DePuy Synthes, West Chester, PA, U.S.A.); porous polyethylene, Medpor (Stryker, Kalamazoo, MI, U.S.A.); norous polyethylene, Medpor (Stryker, Kalamazoo, MI, U.S.A.); P(L/DL)LA 70/30, PolyMax (Synthes, Oberdorf, Switzerland); P(L/DL) LA 85/15, Rapidsorb (Synthes, Oberdorf, Switzerland); and PCL, Osteomesh (Osteopore International, Singapore). All costs are relative to the cost of Medpor Titan, where $x = \cot f$ Medpor Titan.

PCL, polycaprolactone; P(L/DL)LA, poly-L/DL-lactide.

and complete healing. With different implants having different advantages and disadvantages, the authors urge the surgeon to consider the various patient and implant factors before deciding and utilizing one of the many commercially available implants.

REFERENCES

- Cramer LM, Tooze FM, Lerman S. Blowout fractures of the orbit. Br J Plast Surg 1965;18:171–9.
- Ahmad F, Kirkpatrick NA, Lyne J, et al. Buckling and hydraulic mechanisms in orbital blowout fractures: fact or fiction? *J Craniofac Surg* 2006;17:438–41.
- Patel S, Andrecovich C, Silverman M, et al. Biomechanic factors associated with orbital floor fractures. *JAMA Facial Plast Surg* 2017;19:298–302.
- Converse JM, Smith B. Enophthalmos and diplopia in fractures of the orbital floor. Br J Plast Surg 1957;9:265–74.
- Sharma G, Kaur A. Quality of life after orbito-facial trauma. Orbit 2017;16:14.
- Mok D, Lessard L, Cordoba C, et al. A review of materials currently used in orbital floor reconstruction. *Can J Plast Surg* 2004;12:134–40.
- Bartoli D, Fadda MT, Battisti A, et al. Retrospective analysis of 301 patients with orbital floor fracture. *J Craniomaxillofac Surg* 2015;43:244–7.

- Holtmann H, Eren H, Sander K, et al. Orbital floor fractures–shortand intermediate-term complications depending on treatment procedures. *Head Face Med* 2016;12:1.
- Tong L, Bauer RJ, Buchman SR. A current 10-year retrospective survey of 199 surgically treated orbital floor fractures in a nonurban tertiary care center. *Plast Reconstr Surg* 2001;108:612–21.
- Enislidis G. Treatment of orbital fractures: the case for treatment with resorbable materials. J Oral Maxillofac Surg 2004;62:869–72.
- Gunarajah DR, Samman N. Biomaterials for repair of orbital floor blowout fractures: a systematic review. J Oral Maxillofac Surg 2013;71:550–70.
- Courtney DJ, Thomas S, Whitfield PH. Isolated orbital blowout fractures: survey and review. *Br J Oral Maxillofac Surg* 2000;38:496–504.
- Punja KG, Kikkawa DO, Morrison VL, et al. Reconstruction of complex orbitocranial deformities using bioresorbable mesh, sterilized orbital models, and in situ contouring. *Ophthal Plast Reconstr* Surg 2006;22:20–4.
- Hwang K, Kim DH. Comparison of the supporting strength of a poly-L-lactic acid sheet and porous polyethylene (Medpor) for the reconstruction of orbital floor fractures. *J Craniofac Surg* 2010;21:847–53.
- Young SM, Sundar G, Lim TC, et al. Use of bioresorbable implants for orbital fracture reconstruction. *Br J Ophthalmol* 2017;101:1080–5.

- Al-Sukhun J, Törnwall J, Lindqvist C, et al. Bioresorbable poly-L/DL-lactide (P[L/DL]LA 70/30) plates are reliable for repairing large inferior orbital wall bony defects: a pilot study. *J Oral Maxillofac Surg* 2006;64:47–55.
- Baek WI, Kim HK, Kim WS, et al. Comparison of absorbable mesh plate versus titanium-dynamic mesh plate in reconstruction of blow-out fracture: an analysis of long-term outcomes. *Arch Plast Surg* 2014;41:355–61.
- Han DH, Chi M. Comparison of the outcomes of blowout fracture repair according to the orbital implant. J Craniofac Surg 2011;22:1422–5.
- Ellis E 3rd, Tan Y. Assessment of internal orbital reconstructions for pure blowout fractures: cranial bone grafts versus titanium mesh. J Oral Maxillofac Surg 2003;61:442–53.
- Al-Sukhun J, Lindqvist C. A comparative study of 2 implants used to repair inferior orbital wall bony defects: autogenous bone graft versus bioresorbable poly-L/DL-Lactide [P(L/DL)LA 70/30] plate. *J Oral Maxillofac Surg* 2006;64:1038–48.
- Ang CH, Low JR, Shen JY, et al. A protocol to reduce interobserver variability in the computed tomography measurement of orbital floor fractures. *Craniomaxillofac Trauma Reconstr* 2015;8:289–98.
- Turvey TA, Golden BA. Orbital anatomy for the surgeon. Oral Maxillofac Surg Clin North Am 2012;24:525–36.
- Lee GH, Ho SY. Orbital adherence syndrome following the use of titanium precontoured orbital mesh for the reconstruction of posttraumatic orbital floor defects. *Craniomaxillofac Trauma Reconstr* 2017;10:77–83.
- Avashia YJ, Sastry A, Fan KL, et al. Materials used for reconstruction after orbital floor fracture. J Craniofac Surg 2012;23(7 suppl 1):1991–7.
- Christensen BJ, Zaid W. Inaugural survey on practice patterns of orbital floor fractures for American oral and maxillofacial surgeons. *J Oral Maxillofac Surg* 2016;74:105–22.

- Romano JJ, Iliff NT, Manson PN. Use of Medpor porous polyethylene implants in 140 patients with facial fractures. *J Craniofac Surg* 1993;4:142–7.
- Dougherty WR, Wellisz T. The natural history of alloplastic implants in orbital floor reconstruction: an animal model. *J Craniofac* Surg 1994;5:26–32; discussion 33.
- Ng SG, Madill SA, Inkster CF, et al. Medpor porous polyethylene implants in orbital blowout fracture repair. *Eye (Lond)* 2001;15(pt 5):578–82.
- Ryu YA, Park JB, Kyung HW, et al. Delayed orbital hemorrhage around alloplastic implants after blowout fracture reduction. *Arch Craniofac Surg* 2015;16:35–8.
- Kent SS, Kent JS, Allen LH. Porous polyethylene implant associated with orbital cellulitis and intraorbital abscess. *Can J Ophthalmol* 2012;47:e38–9.
- Merten HA, Luhr HG. [Resorbable synthetics (PDS foils) for bridging extensive orbital wall defects in an animal experiment comparison]. *Fortschr Kiefer Gesichtschir* 1994;39:186–90.
- Tuncer S, Yavuzer R, Kandal S, et al. Reconstruction of traumatic orbital floor fractures with resorbable mesh plate. *J Craniofac Surg* 2007;18:598–605.
- Teo L, Teoh SH, Liu Y, et al. A novel bioresorbable implant for repair of orbital floor fractures. *Orbit* 2015;34:192–200.
- Lieger O, Schaller B, Zix J, et al. Repair of orbital floor fractures using bioresorbable poly-L/DL-lactide plates. *Arch Facial Plast Surg* 2010;12:399–404.
- Blake F, Blessmann M, Smeets R, et al. Long-term follow-up of blowout fractures of the orbital floor reconstructed with a polyglactin 910/PDS implant. *Eur J Trauma Emerg Surg* 2011;37:609–13.
- Lin J, German M, Wong B. Use of copolymer polylactic and polyglycolic acid resorbable plates in repair of orbital floor fractures. *Facial Plast Surg* 2014;30:581–6.