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Use of the tarSys® for posterior lamellar grafting for lower eyelid malposition

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Abstract
Background Lower eyelid malposition is a common clinical finding encountered by the oculoplastic surgeon. We examine the short-term results with the use of the tarSys spacer graft for the correction of lower eyelid malposition.
Methods A retrospective chart review of one surgeon's outcomes with use of tarSys spacer graft for lower eyelid malposition was conducted.
Results Preoperative margin-to-reflex distance 2 (MRD2) ranged from 8 to 15 mm with a mean of 9.5 mm (±2.4 mm) and median 8.25 mm. Mean postoperative MRD2 was 6.2 (±3.4 mm) ranging from 4 to 17 mm with a median of 5.0 mm. Improvement in MRD2 averaged 3.33 (±2.07 mm), range −2 to 6 mm, and a median of 3.25 mm. Preoperative lagophthalmos ranged from 0 to 10 mm with mean 3.9 (±3.6 mm) and a median of 3.0 mm. Mean postoperative lagophthalmos was 1.3 (±1.5 mm) ranging from 0 to 4 mm with a median of 0.7 mm. Improvement in lagophthalmos averaged 2.5 (±2.7 mm).
Conclusions The tarSys spacer graft should be thought of as a dependable allogenic implant for posterior lamellar support when correcting lower eyelid malposition.
Level of Evidence: Level V, therapeutic study.

Keywords Eyelid · Oculoplastics · Posterior lamellar spacer graft · Ectropion · Eyelid retraction · tarSys

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Introduction

Often referred to as the skeleton of the eyelid, the tarsus is a hybrid collagenous tissue which provides structural support for the eyelids [1, 2]. The tarsus consists of mainly types I, II, and VI collagen arranged in a dense fibrous tissue rather than true cartilage. The unique structure of this tissue makes the selection of an appropriate graft material difficult. Contemporary grafts are often limited by tissue failure, difficult shape constraints, and the need to harvest tissue from other sites. Historically, both autogenous tissues and allogenic materials have been used for this purpose. These include upper tarsus grafts, oral and labial structures, conchal cartilage, nasal septum, and dermal fat grafts among others [3, 4]. These autogenous grafts are limited by their donor site morbidity, varying clinical success rates, and increased costs stemming from longer operative times and the need for extra surgical supplies [5, 6].

Allogenic materials such as acellular dermis and porcine dermal collagen have been used more recently with varying clinical results. The main difficulties encountered with these materials are graft resorption and loss of rigidity [7] secondary to graft encapsulation on a microscopic level.

Encapsulation creates a cellular framework on the surface of the graft that hinders fibroblast and capillary penetrance into the graft [8, 9].

A novel allogenic material, porcine small intestinal submucosa (SIS) (Cook Biotech, Inc., West Lafayette, IN, USA) has garnered much attention for its use as a biodegradable scaffold in numerous clinical scenarios [10]. The tarSys® graft (Innovative Ophthalmic Products, Inc., Costa Mesa, CA, USA), processed with SIS technology, is a complex organization of collagen that has both fibrous and porous characteristics. It is obtained by completely denuding the small intestine submucosal tissue of cellular material, leaving behind a dense connective tissue matrix consisting mostly of type I

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collagen, extracellular matrix proteins, and glycoproteins. The highly conserved nature of type I collagen and lack of residual porcine cellular material after preparation lend to the low antigenicity of this biomaterial [11]. In vivo, the graft acts as a three-dimensional scaffold, allowing for capillary and cellular ingrowth which is essential for balanced tissue remodeling without the loss of rigidity. The tarSys® undergoes no chemical cross-linking during preparation, as do most other graft materials in this class. Chemical cross-linking results in encapsulation that prevents cellular ingrowth and hinders tissue remodeling leading to less favorable clinical outcomes when using chemically cross-linked grafts [12].

The tarSys® graft is specifically engineered for posterior lamellar grafting and is biological similar to the tarsal plate. Prepared in either an 8 or 12 layer thickness, the graft provides vertical support while maintaining a low profile. The graft requires a 5-min soaking period before implantation and necessitates only a relatively small learning curve for surgeons. While the graft has monetary cost when compared to harvesting autogenous grafts, much of this cost is recuperated by shorter operative times, lower utilization of anesthesia and operating room staff, and less use of supplies.

Additionally, the reduced morbidity related to the lack of graft harvest sites has intrinsic value that offsets the cost of the graft.

Material and methods

Surgical records of one surgeon (A.J.C.) were reviewed for all patients who underwent placement of a Tarsys® spacer graft

Table 1 Patients preoperative examination results

Age	Diagnosis	Symptoms/ signs	Side	Patients						
				Preoperative	Preoperative	Postoperative	Postoperative	Mid-face lift	Graft	Follow-up (months)
				MRD2 (mm)	Lagophthalmos (mm)	MRD2 (mm)	Lagophthalmos (mm)		Thickness (mm)	
67	Bell's palsy	Exposure keratopathy/ tearing	Left	8	10	5	3	Yes	8	12
69	Acoustic neuroma	Exposure keratopathy/ tearing	Right	8	4	4	0.5	No	8	10
69	Cicatricial ectropion	Tearing	Right	7	8	5	4	No	8	9
77	Anophthalmia/ ectropion	Inability to retain prosthesis	Left	8	3	5.5	0	Yes	12	6
83	Cicatricial ectropion	Tearing	Right	13	7	7	2	Yes	12	5
53	Retraction after blepharoplasty	Lower eyelid asymmetry	Right	8	3	5	1	No	8	10.5
85	Cicatricial ectropion	Exposure keratopathy	Right	8.5	2	5	0	No	8	9
75	Cicatricial ectropion post-radiotherapy	Chronic conjunctivitis/ corneal erosions	Left	15	1	17	3	Yes	12	5
66	Cicatricial ectropion	Tearing	Right	10	0	5	0	No	12	4
66	Cicatricial ectropion	Exposure keratopathy	Left	10	0	5	0	N0	12	8
74	Cicatricial ectropion	Tearing	Left	8	0	5	0	No	12	7
38	Scarring/Bell's palsy	Exposure keratopathy/ corneal thinning	Right	11	9	6	3	Yes	12	3

MRD2 margin-to-reflex distance

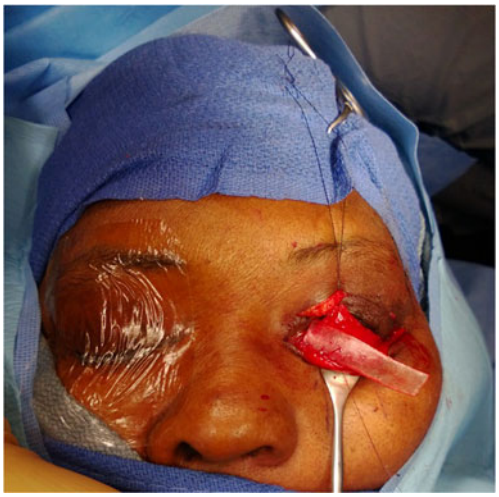

Fig. 1 Intraoperative view of graft prior to placement for correction of eyelid retraction

from 2010 to 2012 for lower eyelid malposition on an outpatient basis. Informed consent was obtained for each procedure and the retrospective review was Health Insurance Portability and Accounting Act of 1996 compliant and adhered to the Helsinki Declaration. The need for placement of a spacer graft was determined during the preoperative examination (see Table 1).

Surgical technique

After obtaining informed consent prior to the day of surgery, all patients underwent surgery in an ambulatory setting under monitored anesthesia care or a general anesthetic. Two percent lidocaine with 1:100,000 dilution was infiltrated into the surgical site. All patients underwent a lateral canthoplasty followed by an incision directly below the inferior tarsal border was created for the entire length of the eyelid freeing the conjunctiva and lower eyelid retractors. Any scar tissue found within the eyelid was excised. A 4-0 silk suture was used to retract the conjunctiva and lower eyelid retractors in a cephalad direction and was secured to the turban (Fig. 1). If an anterior lamellar deficiency was present, a myocutaneous cheek was elevated in a subperiosteal fashion and secured to the periosteum at the junction of the anterior maxillary face and inferior orbital rim using interrupted 4-0 silk sutures. One patient required a full thickness skin graft.

Either an 8 or 12 layer tarSys® 1×4 cm graft was soaked in normal saline for 20 min and plicated to the inferior tarsal in an interrupted buried fashion and secured with 5-0 polyglactin 910 sutures. The same technique was used to plicate the graft to the inferior tarsal border. Excess graft was trimmed at its lateral aspect. The graft was not vertically shortened in any patient nor were antibiotic and/or steroid drops used postoperatively.

Table 2 Comparison of preoperative and postoperative results

	Results					
	MRD2 (mm)			Lagophthalmos (mm)		
	Preoperative	Postoperative	Improvement	Preoperative	Postoperative	Improvement
	8	5	3	10	3	7
	8	4	4	4	0.5	2.5
	7	5	2	8	4	4
	8	5.5	2.5	3	0	3
	13	7	5	7	2	5
	8	5	3	3	1	2
	8.5	5	3.5	2	0	2
	15	17	−2	1	3	−2
	10	5	5	0	0	0
	10	5	5	0	0	0
	8	5	3	0	0	0
	11	6	5	9	3	6
Mean	9.5	6.2	3.33	3.9	1.3	2.5

MRD2 margin-to-reflex distance

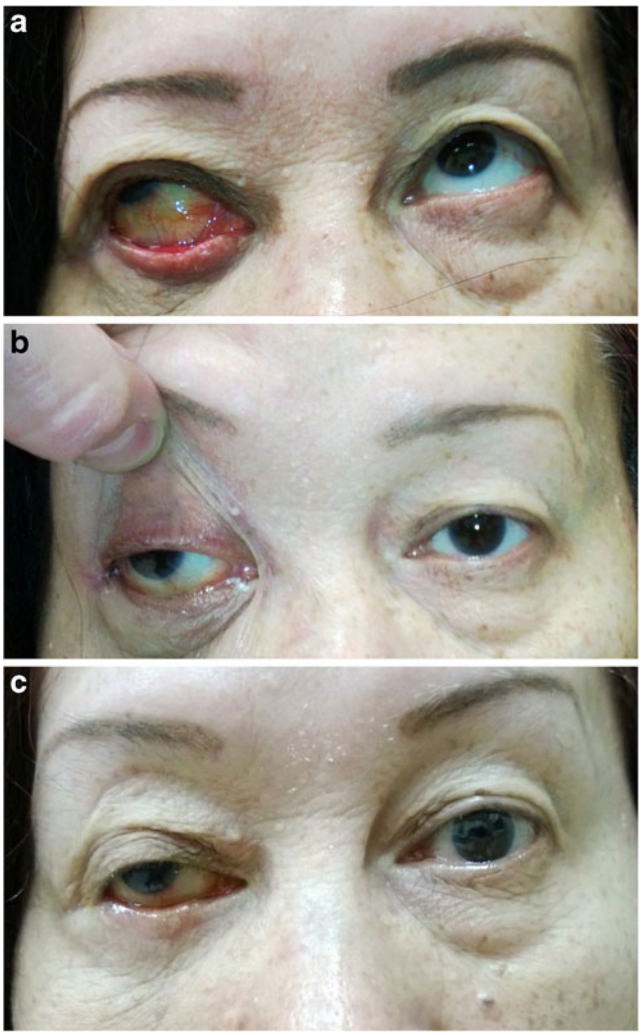

Fig. 2 Well positioned tarSys® graft 2 weeks following surgery after repair of cicatricial ectropion

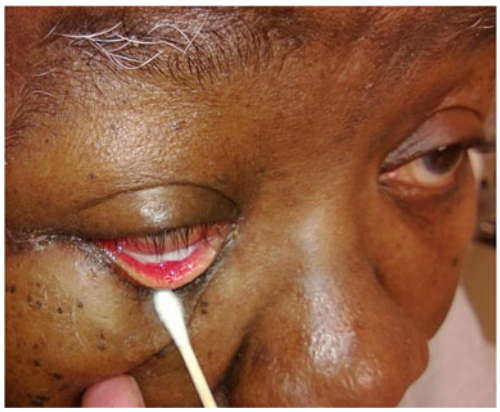

Fig. 3 **a** Preoperative view of patient with severe anterior lamellar deficiency and cicatricial ectropion and right upper blepharoptosis. **b** Postoperative view of patient at 10 days following right lateral canthoplasty, lysis of scar tissue, and mid-face advancement with placement of tarSys® via transconjunctival approach. **c** Postoperative view of patient at 8 weeks

Results

Surgery was performed on 12 patients, seven right eyelids and five left eyelids. The cohort included eight men and four women aged 38–85 with a median age of 69. Five patients in this series underwent concurrent mid-face lift procedure. Preoperative margin-to-reflex distance 2 (MRD2) ranged from 8 to 15 mm with a mean of 9.5 (±2.4 mm) and median 8.25 mm. Mean postoperative MRD2 was 6.2 (±3.4 mm) ranging from 4 to 17 mm with a median of 5.0 mm. Improvement in MRD2 averaged 3.33 (±2.07 mm), range −2 to 6 mm, and a median of 3.25 mm. Preoperative lagophthalmos ranged from 0 to 10 mm with mean 3.9 (±3.6 mm) and a median of 3.0 mm. Mean postoperative lagophthalmos was 1.3 (±1.5 mm) ranging from 0 to 4 mm with a median of 0.7 mm. Improvement in lagophthalmos averaged 2.5 (±2.7 mm) (see Table 2).

Improvement in eyelid position at median 9.5 month follow-up was achieved in 11 out of 12 patients (91 %) (Fig. 2). There were no major complications reported with any of the cases, albeit two patients developed mechanical keratoconjunctivitis secondary to suture exposure that was managed with topical antibiotics/steroid drops and removal of the exposed sutures. There were no graft extrusions or allergic reactions to the graft (Fig. 3).

Possible complications of lower eyelid reconstruction include bleeding, infection, dehiscence, graft failure and malposition, epiphora, lateral canthal dystopia, keratopathy, and reverse ptosis among others. There was failure to achieve improvement in postoperative eyelid position in one patient. This patient had a preoperative diagnosis of cicatricial ectropion, following local radiotherapy and chemotherapy for cutaneous lymphoma, chronic conjunctivitis and corneal erosions, MRD2 of 15 mm and 1 mm of lagophthalmos. Failure of a full thickness skin graft and complete breakdown of the tarSys® graft occurred. His MRD2 increased to 17 mm and lagophthalmos to 3 mm. Resolution or reduction of tearing and exposure keratopathy as well as surgeon satisfaction with postoperative eyelid position was achieved in 11 out of 12 cases.

Discussion

Lower eyelid malposition can arise from numerous etiologies and is a common diagnosis resulting in tearing, exposure keratopathy, corneal decompensation, keratoconjunctivitis, and keratinization with cicatricial changes of palpebral conjunctiva of the eyelid [13].

The effectiveness of lower eyelid reconstruction is well established; however, the optimal surgical technique and choice of graft material is still widely debated. The specific aims of surgical intervention are protection of the cornea, restoration of the lid and lamellar integrity, improved tear pump function, reduction of lagophthalmos, and improvement of facial symmetry. Historically, the choice of posterior lamellar graft material has varied. The first use of spacer grafts in eyelid reconstruction was reported in 1977 and was composed of preserved sclera [14]. Many autologous graft materials have remained popular since then. Mucosal hard palate has been one such graft material and has been used successfully as a lower eyelid spacer since its original description in 1985 [15]. As an autologous tissue, these grafts share excellent recipient tolerance; however, the surgeon is often limited by graft architecture, extrusion, difficulty with placement, donor site morbidity, and tissue availability.

More recently, several allogenic graft types have been incorporated by surgeons. One such material is porous polyethylene (Medpor, Fairburn, GA, USA). Tan et al. describe satisfactory outcome in 29/35 patients using porous polyethylene lower eyelid spacers at mean follow-up of 22 months. However, major complications occurred in 7/32 patients and minor complications in 8/32. The most frequent major complications were extrusion of the graft and localized pain, often requiring further surgery [16]. Human cadaveric acellular dermis is another widely used material [17]. Both of these allogenic materials have the advantage of no harvest site morbidity; however, complications such as graft extrusion and failure limit the effectiveness of these materials.

By design, the tarSys® graft was specifically engineered for posterior lamellar grafting while taking into account the limitations of most synthetic grafts in mind. In theory, the porous construct allows for tissue integration without premature resorption while limiting extrusion of the graft.

The purpose of our study was to describe the author's experience with the tarSys® porcine submucosal tissue graft for posterior lamellar grafting in lower eyelid repair via transconjunctival approach with concomitant lateral canthoplasty. Our results show favorable early outcomes at 9.5 months mean follow-up time comparable to other previously studied graft materials. All but one patient in our cohort achieved satisfactory outcome and required no further surgical intervention. There were no significant complications reported and patient and surgeon satisfaction with the surgical outcome were high. The outcomes of our study were comparable to those published for other graft materials rendering the tarSys® graft an adequate choice for posterior lamellar graft substrate with several distinct advantages over previously described graft materials.

Although our retrospective study was limited by the sample and follow-up period, the authors feel that short-term follow-up results often dictate long-term outcomes with regard to eyelid malposition. The authors support the use of this novel graft material for re-positioning of the lower eyelid and no longer use autogenous graft material. A prospective, randomized, longitudinal study would allow further characterization and comparison of the graft. In addition, further studies to assess the durability of the graft at longer postoperative periods are warranted.

Conflict of interest Dr. Cohen was a paid speaker in 2012 for the IOP Corporation.

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