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PRS GLOBAL OPEN

ORIGINAL ARTICLE
Cosmetic

Safety and Efficacy of Mucograft Porcine Collagen Bioengineered Acellular Dermal Matrix as a Spacer Graft in Lower Eyelid Elevation Surgery

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Background: Recent regulatory changes have limited the access to a widely used commercially available bioengineered acellular dermal matrix (BADM) product as a spacer graft in the surgical correction of lower eyelid retraction. We report our off-label usage of Mucograft, a porcine BADM, as an alternative BADM.
Methods: A retrospective review was conducted of patients undergoing bilateral lower lid surgery with Mucograft (12 eyes) at a single institution.
Results: For the six patients, there was a mean lower lid elevation of 1.93 mm, without any serious complications. There was greater elevation of the lower lid position for the Mucograft group compared with four septo-retractor control patients (1.93 versus 0.94mm, $P = 0.008$).
Conclusion: Mucograft performed satisfactorily, and further investigation is warranted regarding its longer-term safety and efficacy. *(Plast Reconstr Surg Glob Open 2024; 12:e5562; doi: 10.1097/GOX.0000000000005562; Published online 30 January 2024.)*

INTRODUCTION

Lower lid retraction is a common surgical problem that can be challenging to address, particularly in the aesthetic patients. Causes can include thyroid eye disease, iatrogenic (post lower lid blepharoplasty or orbital surgery via a lower lid approach), trauma, negative vector maxillary configuration, or congenital abnormalities. Conventional surgical repair involves inserting a spacer graft between the lower lid retractors and tarsal plate. Several materials are suitable for this purpose: autologous grafts such as free tarsoconjunctiva, hard palate mucosa, dermis fat, and aural cartilage; allogenic human grafts such as donor sclera; and manufactured human and nonhuman bioengineered acellular dermal matrix (BADM) grafts.[1] Our experience with BADM usage has mainly been with Alloderm (BioHorizons, Birmingham, Ala.), which is an acellular dermal matrix derived from human cadaveric tissue.

Regulatory restrictions limit the choice of BADMs available for use in particular locations. In the United Kingdom, Alloderm has recently become unavailable due to one such issue (personal correspondence). Other BADMs previously reported to be used in eyelids are similarly unavailable. Alternative products for lower eyelid graft materials, approved for use in the United Kingdom, are required for patients who require spacer grafts and in whom other graft options are unsatisfactory.

We therefore investigated a porcine collagen BADM Mucograft (Geistlich Pharma, Wolhusen, Switzerland), which is used as an alternative to free gingival grafts for dental procedures. In addition to orthodontics, its use has been reported in reconstructive dentistry after tumor excision around a native tooth.[2] A porcine BADM similar to Mucograft has also been described in lower lid reconstruction post Mohs surgery.[3]

With these similarities in mind, we undertook several procedures using Mucograft off-label as a spacer graft in the surgical correction of lower eyelid retraction. We hypothesized this material would perform satisfactorily in this context, similar to previously utilized BADM materials.

METHODS

We conducted a retrospective case-control study at a tertiary eye care center in central London, wherein six patients were recruited between November 2019 and July 2021. The study adhered to the tenets of the Declaration of Helsinki. The main indication for surgery in these patients

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Received for publication July 22, 2023; accepted October 24, 2023.

DOI: 10.1097/GOX.0000000000005562

Disclosure statements are at the end of this article, following the correspondence information.

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was aesthetic correction of inferior scleral show. For preoperative assessment, margin-reflex-distances (MRD1, center of pupil to the upper lid margin, and MRD2, center of pupil to the lower lid margin) were recorded in the clinic. However, for the purposes of this investigation, clinical photographs were used to determine these measurements. Post-operative MRD1 and 2 were measured in an identical fashion. Patients were followed up for a mean period of 9.16 months after surgery. Pre- and postoperative standardized clinical photographs were taken with a Canon 5D Mark II digital SLR camera without flash in a neutral expression. Informed consent was obtained for all patients. The horizontal corneal diameter was chosen as a reference standard of 11.68mm, and pixel measurements by a masked observer were taken from the center of the cornea to the upper and lower lid positions to measure MRD1 and MRD2, respectively, relative to the cornea size.[4] A control group of four patients were recruited between January 2020 and July 2021. These patients underwent bilateral septo-retractor recession without any spacer graft. They were followed up for a mean period of 11.25 months and the lid elevation following surgery was assessed in the same manner as above.

Takeaways

Question: Is Mucograft porcine collagen bioengineered acellular dermal matrix a safe and effective material to use as a spacer graft in aesthetic lower eyelid elevation surgery?

Findings: A retrospective case-control study was conducted with six Mucograft patients compared with four lower eyelid septo-retractor complex release patients (no spacer graft). The Mucograft patients achieved greater lower eyelid elevation (1.93 mm versus 0.94 mm) without any significant complications.

Meaning: Mucograft is safe and effective as a spacer graft in aesthetic lower eyelid elevation surgery.

Surgical Technique for Mucograft Spacer Group

Six patients underwent bilateral surgery as detailed below between November 2019 and July 2021. Informed consent was obtained for all patients and a second preoperative discussion was undertaken to answer any patient questions before proceeding to surgery. Operations were performed under general or local anesthetic with sedation according to patient preference. The surgical technique is outlined in Figure 1. After standard skin preparation and draping, a lateral canthotomy was performed to allow the Mucograft to extend into the lateral canthus. A transconjunctival incision was made with a scalpel blade. The dissection extended inferiorly to release the lower lid retractor band from the tarsal plate. The middle lamella of the lower eyelid was further released by dissection anterior to the orbital septum to the arcus marginalis. The septo-retractor complex was then recessed. A Mucograft sheet was trimmed to the length of the entire eyelid and to a height twice that of the required elevation (for example retraction of 3mm elevation was addressed with a 6mm high graft). The graft was placed with the spongy side facing into the wound, and the compacted side facing toward the conjunctiva to allow for conjunctival ingrowth. The graft was then sutured to the apex of the septoretractor complex with buried interrupted 6-0 absorbable polyglactin 910 (Vicryl, Johnson and Johnson) sutures and to the inferior border of the tarsal plate with buried interrupted 7-0 Vicryl sutures. A lateral

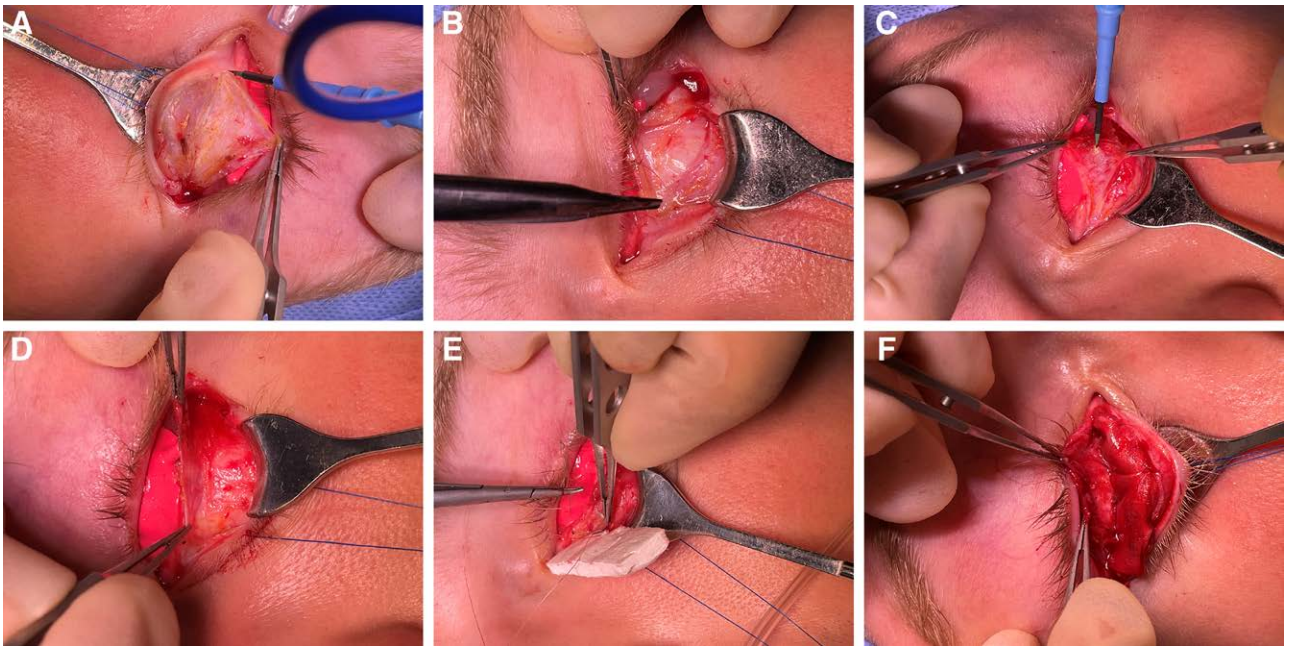

Fig. 1. Surgical procedure of lower lid Mucograft implant. A, Following lateral canthotomy, a transconjunctival incision inferior to the tarsus is extended. B, Pre-septal dissection to release anterior aspect of middle lamella. C, Release of septum and inferior retractor complex. D, Superior edge of septo-retractor complex displayed. E, Mucograft sutured to superior edge of middle lamella. F, Mucograft edges trimmed to fit and then sutured to inferior tarsus.

tarsal suspension was performed with 5-0 Vicryl to improve the canthal tilt, and the lateral canthal skin was closed with 7-0 Vicryl. A bandage contact lens was placed to prevent corneal irritation from the graft and sutures. A lower lid traction (Frost) suture was used for 6 hours postoperatively to keep the lower eyelid elevated. The contact lens was removed after 2 weeks. All patients were given postoperative prophylactic co-amoxiclav antibiotics and topical chloramphenicol drops.

Surgical Technique for Control Group

four patients underwent bilateral surgery as detailed below between January 2020 and July 2021. Informed consent was obtained for all patients before proceeding to surgery. Operations were performed under general or local anesthetic with sedation according to patient preference. After standard skin preparation and draping, a transconjunctival incision was made with a Colorado needle. The dissection extended inferiorly to release the lower lid retractor band from the tarsal plate. The middle lamella of the lower eyelid was further released by dissection anterior to the orbital septum to the arcus marginalis. The septo-retractor complex was then recessed. The conjunctiva was closed with 7-0 Vicryl. A lower lid traction (Frost) suture was used for 6 hours postoperatively to keep the lower eyelid elevated. None of the patients in the control group had lateral canthal laxity, and hence, canthoplasty was deferred in all patients.

RESULTS

A comparison of the demographics of the Mucograft and control group is presented in Supplemental Digital Content 1. [See Table 1 below and **Supplemental Digital Content 1**, which displays the case summary and results (all measurements in millimeters). **http://links.lww.com/PRSGO/D41**.]

Table 1. Demographic Comparison of Test and Control Groups

Group	Mean Age	Male	Female
Mucograft group	27 years	5	1
Control group	43 years	1	3

Case 1

A 27-year-old man presented complaining of a long-term "sleepy" look to his eyes and requested intervention to make himself look more alert. He had previously undergone an ear reduction and a rhinoplasty but no ocular or periocular procedures. Examination showed bilaterally low lateral canthi causing lateral upper eyelid ptosis with lash ptosis, in association with lateral brow ptosis. The remainder of the examination was normal. The patient underwent lower eyelid elevation septo-retractor recession with Mucograft implant, lateral canthoplasty, direct brow lifting, and upper eyelid ptosis correction with levator advancement.

Case 2

A 36-year-old-woman presented complaining of low-riding lower eyelids and requested intervention to elevate these. She had no significant medical or ocular history. Examination showed a bilateral negative-vector configuration to the eyes. Otherwise the examination was normal. The patient underwent bilateral lower eyelid septo-retractor recession with Mucograft implant and lateral canthoplasty.

Case 3

A 27-year-old-man presented complaining of aesthetic dissatisfaction with inferior scleral show and dry eye symptoms in windy conditions. He had a history of a left-sided orbital fracture which had left him with diplopia in lateral gaze. Examination showed physiological inferior scleral show and left lateral canthal dehiscence. The patient underwent bilateral lower eyelid septo-retractor recession with Mucograft implant and lateral canthoplasty.

Case 4

A 28-year-old man presented with aesthetic concerns of inferior scleral show on both eyes present since childhood and left upper eyelid skin crease asymmetry, and requested intervention to address these. There was no relevant ocular or medical history. Examination showed physiologically increased inferior scleral show on both eyes, and a larger skin crease measurement on the left eye, without ptosis (Fig. 2). The patient underwent bilateral lower eyelid septo-retractor recession with Mucograft

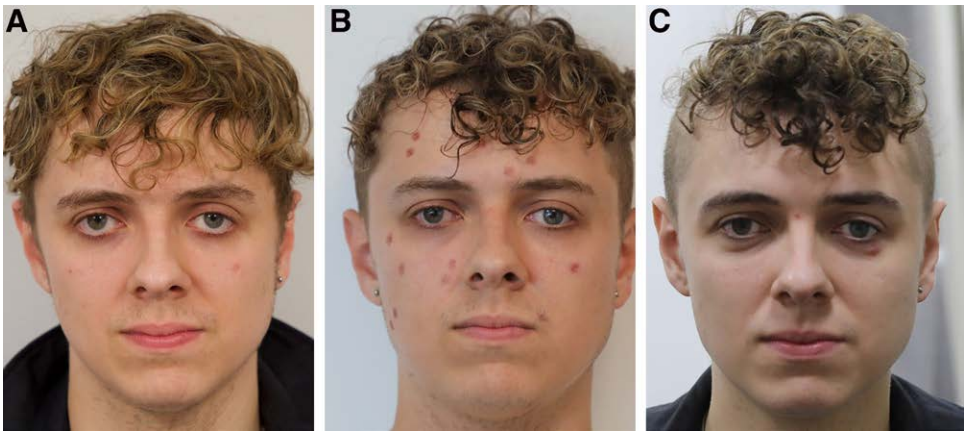

Fig. 2. Case 4 clinical photographs. Pre- (A), early post- (B), and late postoperative (C).

implant, lateral canthoplasty, and left upper eyelid skin crease reformation.

Case 5

A 27-year-old man presented with concern regarding the appearance of droopy and tired eyes which also interfered with his lateral peripheral visual field. On examination, he had bilateral upper lid ptosis, lash ptosis, negative lateral canthal tilt, bowing of the inferior lid contour and negative vector maxillary configuration. He had no diplopia, neurological signs, medical history, or ocular history. The patient underwent bilateral ptosis repair with anterior lamellar repositioning, lower eyelid septo-retractor recession with Mucograft implant, and lateral canthoplasty.

Case 6

A 19-year-old man presented with concern regarding the appearance of bilateral inferior scleral show, worse on the left, and dry eye symptoms. He had no medical or ocular history. On examination, he had bilateral asymmetrical inferior scleral show with a negative vector maxillary configuration. The patient underwent bilateral lower eyelid septo-retractor recession with Mucograft implant and lateral canthoplasty.

Summary of Results

The results of the Mucograft procedures detailed above are summarized in Supplemental Digital Content 1 (**See table 1, Supplemental Digital Content 1**, **http://links.lww.com/PRSGO/D41**). MRD2 was measured pre- and postoperatively, and mean elevation in both groups was compared using the Mann Whitney U test. The mean MRD2 measurement preoperatively in the test group was 6.7 mm and postoperatively was 4.6 mm, with a mean elevation of 1.9 mm for the right eyes and 2.0 mm for the left eyes at final follow-up. This showed that there was greater elevation for the Mucograft patients compared with the control group who underwent septo-retractor recession without spacer graft (1.93 versus 0.94mm, $P = 0.008$).

All patients had an unremarkable postoperative recovery and reported satisfaction with the outcome of the procedure with two patients reporting improvement in dry eye symptoms. The grafts all fully epithelialized after approximately 2 weeks and at the final review. Minor complications were observed in three eyes (symptomatic granulation tissue, conjunctivitis, and an eyelid cyst), which all resolved with minor medical management. There were no serious complications, including no episodes of infection or graft rejection.

DISCUSSION

Our previous experience with using a BADM as a lower lid spacer is with Alloderm (BioHorizons, Birmingham, Ala.). Due to a combination of UK Human Tissue Authority regulatory requirements, recent inspection results, and subsequent decisions by the manufacturer and importer (personal correspondence), Alloderm is no longer available for import into the United Kingdom. Accordingly, we sought an alternative BADM spacer to use as graft material. The use of BADMs for lower eyelid retraction correction has been recently reviewed with the results not indicating any one type of spacer graft material to be superior to others.[1]

Mucograft is one such BADM made of porcine collagen. It is approved for use in the United Kingdom by the Human Tissue Authority. The material comes packaged in various sizes ready for use in the operating theater. There are two sides to the material: a spongy side that facilitates blood clot formation and stabilization, vascular ingrowth and tissue incorporation, and a compact side that provides protection for the healing wound surface and is suitable for suturing. The first reported use in the literature of Mucograft was in 2009, as an alternative to free connective tissue keratinized gingival grafts to augment the keratinize gingiva at the base of a fixed dental prosthesis.[5] Free hard palate grafts have extensively been used in this setting, however this creates donor site morbidity and also suboptimal aesthetics at the graft site. Mucograft was developed as an alternative graft material to avoid donor site morbidity. These concerns are similar to those that arise with the use of hard palate grafts in lower eyelid retraction surgery. The use of a manufactured porcine product further avoid ethical, legal and biological concerns arising from the use of human cadaveric grafts. Mucograft has been shown to integrate well histologically in a dental setting.[6] The cost per patient of Mucograft used in the manner described is approximately £386 (US $496).

There are several alternatives to using a BADM for lower eyelid retraction repair, including autologous tissue grafts, or to not insert a spacer graft at all. As our patient cohort were all young patients seeking surgery for primarily aesthetic reasons, the only acceptable autologous graft material would have been hard palate, which in our experience can cause significant donor site morbidity. Retractor release surgery has been performed effectively without spacer grafts,[7] including in our control group. However, the amount of lower eyelid elevation achieved is greater when using a spacer. A commercially packaged spacer graft material is therefore ideal for these patients, removing donor site discomfort and morbidity, and simplifying postoperative management.

Our results are limited by short follow-up in some cases. Prospective comparison studies with longer follow-up periods are required to determine noninferiority, but our results seem encouraging. Case 5 demonstrates the limited benefit of lower eyelid elevation alone in patients with a negative vector eye, with the cornea protruding forward of the most anterior part of the maxilla. In these patients, the lower eyelid retraction is related to the relative retroplacement of the inferior orbital rim and the lower lid relative to the globe, rather than lower lid retraction due to posterior and middle lamellar cicatrix. To successfully address the lower eyelid retraction in these patients it may be necessary to perform orbital decompression surgery either in place of, or in conjunction with, lower eyelid elevation surgery as detailed above.

CONCLUSIONS

We have demonstrated successful off-label use of Mucograft as a spacer graft in lower eyelid retraction surgery, as an alternative to other reported commercially available BADMs, with comparable short-term results and safety profile. We showed a statistically significant benefit in the elevation provided by Mucograft compared with septo-retractor release controls.

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DISCLOSURE

The authors have no financial interest to declare in relation to the content of this article.

PATIENT CONSENT

The patient provided written consent for the use of his image.

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