

Deep Anterior Lamellar Keratoplasty (DALK) with Lyophilised Tissue

Description

This lenticule is for use as a lamellar graft in the treatment of corneal scarring or keratoconus, and is made from human corneal tissue. It has been lyophilised (freeze-dried) and sealed under vacuum in a glass vial. The overall diameter and thickness of the lenticule is as stated on the vial.

Indications

Lamellar keratoplasty with lyophilised tissue may be indicated in a variety of corneal pathologies where resection of diseased tissue is required, and the lack of sensitisation of the recipient to donor antigens may be of benefit.

Contraindications

The following conditions may represent contraindications for lamellar keratoplasty with lyophilised tissue:

Corneal endothelial decompensation, or corneal epithelial stem cell failure.
Blepharitis or lagophthalmos.
Poor visual acuity based on retinal or other intraocular pathology.
Uncontrolled glaucoma, uveitis or rapidly progressing diabetic retinopathy.

Complications

Potential complications from surgery may include, but are not limited to, the following:
Corneal perforation leading to graft oedema and/or formation of a double anterior chamber.
Failure of corneal re-epithelialisation causing stromal melting of the lenticule.
Infection.
Post-operative iritis.
Ametropia or astigmatism.
Corneal vascularisation or scarring.

Warnings

Do not attempt to sterilise or repackage the lenticule. Do not autoclave. Do not soak in fluids other than balanced salt solution. Surgeons should be familiar with keratoplasty and the use of lyophilised tissue before attempting to carry out this operation.

Product Information

This product was processed under laboratory conditions, but as with any donor corneal tissue it cannot necessarily be regarded as sterile. However, all donor tissue is initially maintained in organ culture at 34°C for at least one week, and microbiological testing of the culture medium was negative. Tissue donors are all serologically negative for evidence of hepatitis B and C, HIV, HTLV I & II, and syphilis infection. Potential donors are also excluded on the basis of risk of other transmissible disease. We have exercised reasonable care in the manufacture of this lenticule. We exclude all guarantees, whether expressed, implied or by operation of law or otherwise, including, but not limited to any implied guarantees of merchantability or fitness. We shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from the use of this lenticule. We neither assume nor authorise any other person to assume, any other or additional liability or responsibility in connection with this lenticule.

Instructions for Use

A variety of surgical techniques may be employed and the surgeon is advised to use the method which his or her own practice and discretion dictates to be the best for the patient. The following technique is one that has been found to be satisfactory for use when deep anterior lamellar keratoplasty is proposed:

Pre-operative topical antibiotics are given and a single application of pilocarpine used to promote miosis. The eye is stabilised with inferior and superior rectus sutures. Air injection of the cornea can be used to facilitate the subsequent dissection. An air filled 1.0ml diabetic syringe with integral needle is inserted obliquely into mid-stroma. Air is injected until the whole cornea is insufflated, if necessary using multiple injection sites. A stab paracentesis is made in clear cornea at the limbus, and the intraocular pressure relieved if air has refluxed into the anterior chamber.

An unguarded trephine blade of the same diameter as the lenticule is used to mark the site of the graft, and the incision cut down gradually with a diamond knife until close to full-thickness. A lamellar knife is used to dissect in the plane of the cornea and remove the diseased tissue. If adequate resection has been achieved at this point, the graft can be applied. If full-thickness resection of the stroma is proposed, further injection of air or saline may help expand the remaining deep stromal fibres for resection. If the pre-Descemet's plane is defined, viscoelastic can be injected into this plane to hold Descemet's clear whilst the residual stroma is excised with scissors. The intra-ocular pressure must be kept low by repeated drainage of aqueous from the paracentesis site if rupture of Descemet's membrane is to be avoided. A small window of full thickness stromal resection on the visual axis will usually be sufficient, without having to take the resection right out to the full diameter of the graft.

The lenticule is rehydrated by injection of balanced salt solution through the rubber top of the glass vial. After five minutes the rubber stopper is removed and the lenticule and balanced salt solution poured rapidly into a sterile container on the operating theatre trolley.

The lenticule is stitched in place with interrupted or continuous mono-filament suture. Subconjunctival gentamicin and betamethasone are given and a topical mydriatic applied. A temporary tarsorrhaphy suture is placed using 6/0 Prolene passed through small segments of naso-gastric tube acting as a bolster. When the medial bite of the tarsorrhaphy suture is made in the mid-line of the lid and the other bite more laterally, it is possible to observe the graft post-operatively whilst still maintaining good graft protection. In patients with poor compliance where difficulty in removal of the temporary tarsorrhaphy suture is anticipated, alternative methods of protection such as botulinum toxin induced ptosis, bandage contact lens wear, or continuous pressure patching should be considered.

Topical mydriatic and antibiotic drops are applied four times daily from the first post-operative day. When re-epithelialisation is complete the tarsorrhaphy is opened, and a topical steroid / antibiotic ointment can be used until the eye is quiet. Topical lubricant ointment should be continued for a few months post-operatively. Any loose sutures should be removed as soon as they are detected; the remaining sutures may be removed selectively after a few months if there is significant astigmatism.

Post-operative complications

Further information on keratoplasty with lyophilised tissue can be found in:

*'Lamellar keratoplasty with Lyophilised Tissue for the Treatment of Corneal Scarring'.
Tayyib M, Sandford-Smith JH, Sheard CE, Rostron CK.
Refract & Corneal Surg 1993;9:140-142.*

*'Postoperative management of epikeratoplasty'. Steinert RF, Grene RB.
J Cataract Refract Surg 1988;14:255-264.*

Any untoward complications should be reported to the Keratec Eye Bank.

Storage

This tissue should be stored at or below room temperature. The tissue has a nominal shelf life of 3 months from the date of despatch. Unused tissue may be returned provided that the vial is unopened and that the tissue is received by Keratec Eye Bank within 30 days of the original date of despatch. Refund of tissue processing charges can only be made if these conditions are met.

Freeze-dried corneal lenticule for deep anterior lamellar keratoplasty (DALK).

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