



# Large (9 mm) Deep Anterior Lamellar Keratoplasty with Clearance of a 6-mm Optical Zone Optimizes Outcomes of Keratoconus Surgery

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**Purpose:** To evaluate the outcomes of a 9-mm deep anterior lamellar keratoplasty (DALK) with removal of the deep stroma limited to the central 6-mm optical zone.

**Design:** Prospective, noncomparative, interventional case series.

**Participants:** A total of 80 consecutive keratoconic eyes without deep stromal scarring, with at least 1 postoperative examination 1 month after complete suture removal.

**Intervention:** A standardized DALK was performed, including (1) deep trephination of the recipient bed 450 to 550  $\mu\text{m}$  in depth and 9 mm in diameter; (2) pneumatic dissection; (3) debulking of approximately 80% of the anterior stroma; (4) removal of the deep stroma (bubble roof) from a central 6-mm optical zone; and (5) transplantation of a 9-mm anterior corneal lamella cut by microkeratome-assisted dissection (400- $\mu\text{m}$  head) and sutured with a double running 10-0 nylon suture.

**Main Outcome Measures:** Success rate and type of pneumatic dissection obtained; best spectacle-corrected visual acuity (BSCVA), refractive astigmatism (RA), and topographic astigmatism (TA), central corneal thickness (CCT) and endothelial cell density 12 months postoperatively; and intraoperative and postoperative complications.

**Results:** Pneumatic dissection created a “big bubble” in 67 of 80 eyes (83.7%), all of them but 1 (1.5%) being of type 1 according to the classification by Dua et al. After complete suture removal, BSCVA averaged  $0.09 \pm 0.72$  logarithm of the minimum angle of resolution (logMAR) and was  $\geq 20/20$  in 28 eyes (35%),  $\geq 20/25$  in 54 eyes (67.5%), and  $\geq 20/40$  in 76 eyes (95%); RA averaged  $3.10 \pm 1.30$  diopters (D), with 73 eyes (91%) within 4.5 D and none above 6 D; regular TA was detected in 72 eyes (90%); mean CCT was  $492 \pm 62.10$   $\mu\text{m}$ ; postoperative endothelial cell density averaged  $2026 \pm 397$  cells/ $\text{mm}^2$  with a mean cell loss of 11.2%. Intraoperative complications included loss of suction ( $n = 1$ ) and perforation ( $n = 4$ ). No conversion to penetrating keratoplasty was necessary. After surgery, double anterior chamber was observed in 2 cases (2.5%), both managed successfully by air filling of the anterior chamber. Stromal rejection was observed in 6 eyes (7.5%) and was reversed with topical steroids in all cases.

**Conclusions:** In keratoconic eyes without deep stromal scars, the combination of a graft larger than conventional ones with limited removal of deep stroma can improve visual and refractive outcomes of DALK, while minimizing the rate of complications. *Ophthalmology* 2017;■:1–9 © 2017 by the American Academy of Ophthalmology



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As shown by the 2015 annual report of the American Eye Bank Association, deep anterior lamellar keratoplasty (DALK) represents only 2.3% of the total number of corneal transplantations performed in the United States, increasing to 3% if tissues exported to other countries are included in the calculation.<sup>1–3</sup> These data show that surgeons weigh the undisputed advantage of preserving the recipient endothelium against other issues that make them prefer to perform a penetrating keratoplasty (PK) in the majority of eyes that could instead benefit from DALK, such as eyes with keratoconus (KC).

Three main arguments usually are put forward against performing DALK for KC, namely, the rarity of complications reported for PK, the lack of standardization in the surgical technique of DALK, and the lack of substantial advantages of DALK over PK in regard to visual and refractive outcomes.<sup>4,5</sup> Several studies contradict the first 2 arguments: A relevant percentage of short-term and long-term complications of PK has been reported, and several techniques have been presented over the years to simplify and standardize DALK.<sup>6,7</sup> Instead, all scientific articles published to date have shown values of post-DALK visual

acuity and residual refractive error matching at best those recorded after PK.<sup>8–10</sup>

With the purpose of profiting from the refractive advantages of large grafts, while trying to minimize the risks of complications, especially conversion to PK, we have modified DALK using lamellar grafts 9.0 mm in diameter in combination with stromal clearance of an optical zone limited to the central 6.0 mm. We report the outcomes of this procedure.

## Methods

All consecutive patients with KC without scars affecting the posterior third of the stroma, operated on by the same surgeon (M.B.) at “Villa Igea” Hospital (Forlì, Italy), according to the technique described in detail later, were included in a prospective clinical study undertaken at our institution, Villa Igea Hospital (Forlì, Italy), since September 2013 and still in progress. The study followed the tenets of the 2013 Declaration of Helsinki and was approved by the local ethics committee (Comitato Etico Ospedali Privati Villa Serena-Villa Igea); a detailed informed consent was provided to all patients undergoing surgery. Preoperatively, all patients did not gain useful visual acuity with spectacles and were contact lens intolerant.

Demographic data were recorded, and every patient underwent a complete preoperative ophthalmological evaluation including slit-lamp examination, best spectacle-corrected visual acuity (BSCVA), refraction, tonometry, funduscopy, endothelial specular microscopy (EM-3000; Tomey, Erlangen, Germany), and anterior segment optical coherence tomography (AS-OCT) (Casia; Tomey, Tokyo, Japan), from which both topographic and pachymetric maps were obtained. Intraoperatively, success or failure of pneumatic dissection, type and diameter of the bubble obtained, and complications were noted.

A thorough eye evaluation, including all preoperative examinations, was scheduled and performed in all patients between 6 and 9 months postoperatively, that is, after removal of 1 of the running sutures, as well as between 12 and 14 months postoperatively, that is, after complete suture removal. Postoperative complications occurring during the follow-up period were recorded. All data collected in the study were entered into an electronic database via Microsoft Excel 2007 (Microsoft Corp., Redmond, WA). Snellen visual acuity values were converted into the logarithm of the minimum angle of resolution (logMAR) scale for statistical purposes. Data were analyzed with the MedCalc Online Calculators (MedCalc Software, Mariakerke, Belgium). For the analysis of quantitative measures, we used the Student *t* test for normally distributed variables. Chi-square or Fisher exact test was used for the analysis of categorical variables. Differences were considered statistically significant when the *P* value was less than 0.05.

## Surgical Procedure

In all patients, anesthesia and akinesia were obtained by means of peribulbar injection of 10 ml of a 0.75% ropivacaine solution (Video 1, available at [www.aaojournal.org](http://www.aaojournal.org)). As described previously in detail,<sup>11</sup> in all cases pneumatic dissection was attempted advancing a dedicated probe and then a cannula up to 2 mm centripetally from the bottom of a deep trephination, 450 to 550  $\mu$ m in depth and 9 mm in diameter (Fig 1). To minimize the risk of perforation, because the measurable blade advancement can be regulated precisely only in 50- $\mu$ m steps, the trephine was set to a variable depth, always intended within 100  $\mu$ m from the thinnest AS-OCT measurement at the site of trephination (9 mm in diameter).

Regardless of the success of pneumatic dissection, in all cases the recipient cornea was debulked by performing an anterior keratectomy, which removed approximately 80% of the anterior stroma. Then a disposable handheld trephine was used to mark the central 6-mm optical zone. When pneumatic dissection succeeded, after measuring the diameter of the bubble, an adhesive viscoelastic substance (IAL-F, Fidia, Padova, Italy) was laid centrally onto the bubble roof and a 15° blade was used to enter the bubble. The inferior branch of a blunt Vannas scissor was inserted into the pre-descemetic space, and the slit was enlarged to allow corneal scissors to be used to complete the excision of the central deep stroma, following the 6-mm mark. Instead, if pneumatic dissection failed, layer-by-layer hand dissection was performed within the 6-mm mark, removing completely the emphysematous stroma, in an attempt at reaching the pre-descemetic layer. The donor cornea mounted on the artificial anterior chamber of the automated lamellar therapeutic keratoplasty system (Moria, Antony, France) was dissected by means of a 400- $\mu$ m microkeratome head. The anterior lamella obtained this way was punched to a diameter of 9 mm and sutured into the recipient bed using a double running 10-0 nylon suture. The final corneal architecture included a peripheral crown approximately 1.5 mm in width resulting from the overlap of the donor lamella on the residual deep stroma of the recipient, as well as a 6.0-mm central optical zone somewhat thinner than normal central cornea, where the donor tissue was laid directly onto the pre-descemetic bubble floor (Fig 2). At the end of the procedure, the anterior chamber was filled with balanced salt solution injected through the side entry created immediately before the pneumatic dissection was attempted, as per the technique previously described.<sup>11</sup>

Triamcinolone acetonide and gentamicin sulfate, 0.3%, were injected subconjunctivally at the end of the procedure, and the eye was patched. Beginning the following morning, dexamethasone phosphate, 0.1%, and tobramycin sulfate, 0.3%, antibiotic eye drops were administered every 2 hours, then tapered off to a single daily steroidal administration 1 month after partial suture removal, and finally discontinued at month 8 from surgery. In every patient, 1 of the 2 running sutures was removed 2 to 3 months postoperatively, whereas the second suture was removed within 10 months from surgery in patients aged less than 30 years and within 12 months from surgery in all other patients.

## Results

Since the introduction of this technique into our surgical routine, full evaluation after complete suture removal has been performed in 80 eyes of 80 patients. Twenty-eight of these were female patients and 52 were male patients; their age ranged from 12 to 71 years (average  $\pm$  standard deviation = 36.3 $\pm$ 13.1).

Pneumatic dissection succeeded in 67 eyes (83.7%), whereas hand dissection was performed in the remaining 13 eyes (16.3%). A purely Descemetic bubble (type 2 according to the classification reported by Dua et al<sup>12</sup>) was obtained in only 1 eye (1.5%), whereas in all other cases the bubble was of type 1. The average size of the bubbles obtained was 7.7 $\pm$ 0.8 mm (range, 6–9 mm).

Mean BSCVA improved significantly from 0.54 $\pm$ 0.85 logMAR preoperatively to 0.18 $\pm$ 0.74 logMAR after removal of 1 suture (*P* < 0.01) and further significantly to 0.009 $\pm$ 0.72 logMAR (*P* = 0.001) after complete suture removal. The BSCVA was  $\geq$ 20/20 in 7 eyes (8.7%),  $\geq$ 20/25 in 19 eyes (23.75%), and  $\geq$ 20/40 in 61 eyes (76.25%) after removal of 1 suture and  $\geq$ 20/20 in 28 eyes (35%),  $\geq$ 20/25 in 54 eyes (67.5%), and  $\geq$ 20/40 in 76 eyes (95%) after complete suture removal. Reasons for BSCVA below 20/40 (4 eyes) included amblyopia (*n* = 3) and cataract formation (*n* = 1). At the final examination time, BSCVA of eyes with

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