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

Massimo Busin, MD,1,2 Pia Leon, MD,1,2,3 Yoav Nahum, MD,1,2,4,5 Vincenzo Scorcia, MD1,2,6

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 µm 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-µm 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±0.72 logarithm of the minimum angle of resolution (logMAR) and was ≥20/20 in 28 eyes (35%), ≥20/25 in 54 eyes (67.5%), and ≥20/40 in 76 eyes (95%); RA averaged 3.10±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±62.10 µm; postoperative endothelial cell density averaged 2026±397 cells/mm² 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;124:1072-1080 © 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.1–3 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.4,5 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.6,7 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. 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, 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, fundoscopy, 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 categoric 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.aajournal.org). As described previously in detail, in all cases pneumatic dissection was attempted advancing a dedicated probe and then a cannula up to 2 mm 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-μm steps, the trephine was set to a variable depth, always intended within 100 μm 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 scissors 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-μm 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.

Triamcinolone acetoneide 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 ± standard deviation = 36.3 ±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.) 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 ±0.8 mm (range, 6–9 mm).

Mean BSCVA improved significantly from 0.54±0.85 logMAR preoperatively to 0.18±0.74 logMAR after removal of 1 suture (P < 0.01) and further significantly to 0.09±0.72 logMAR (P = 0.001) after complete suture removal. The BSCVA was ≥20/20 in 7 eyes (8.7%), ≥20/25 in 19 eyes (23.7%), and ≥20/40 in 61 eyes (76.2%) after removal of 1 suture and ≥20/20 in 28 eyes (35%), ≥20/25 in 54 eyes (67.5%), and ≥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
successful pneumatic dissection did not differ significantly from that of eyes with hand dissection ($P = 0.12$).

The mean absolute value of refractive astigmatism decreased significantly ($P = 0.002$) from 7.2 ± 2.5 diopters (D) (range, 3–10 D) preoperatively to 3.2 ± 1.50 D (range, 0–7 D) after removal of 1 suture and remained substantially stable at 3.10 ± 1.30 D (range, 0–6 D) after complete suture removal. At this last examination time, 73 eyes (91%) were within 4.5 D and none above 6 D; the mean spherical equivalent was −1.55 ± 3.3 D. Topographic astigmatism did not vary substantially from refractive astigmatism: At the last examination time it averaged 3.26 ± 1.16 D with a mean asymmetry value in the 3 mm central zone of 1.01 ± 0.15 D.

After complete suture removal, central corneal thickness (CCT) averaged 462.48 ± 62.10 μm (range, 401–519 μm). A discrete layer of residual stroma was not seen in any of the AS-OCT pictures regardless of the type of dissection performed. Morphologic examination of the posterior corneal contour could not detect a step at the edge of the 6-mm optical zone in any eye (Fig 3).

Postoperative endothelial cell density averaged 2026 ± 397 cells/mm² with a mean cell loss of 11.2% from the preoperative value. Surgery was complicated by perforation at the end of trephination in 1 case, which could be completed anyway by means of pneumatic dissection obtained by inserting the cannula at a site approximately 3 hours of the clock away from the perforation. In 3 additional cases that required hand dissection, microperforations occurred but did not necessitate conversion to PK. During the postoperative course, stromal immunologic rejection was seen in 6 eyes (7.5%) and was reverted completely with topical steroids in all cases. Inadvertent rupture and consequent removal of both running sutures occurred in 1 case as early as 3 months after surgery. No dehiscence of the surgical wound was seen at any time. Early postoperative Descemet’s membrane detachment occurred in 2 eyes (2.5%) and was managed successfully with single air filling of the anterior chamber both times. None of these eyes had had a microperforation, which was therefore not identified as a factor associated with increased risk for detachment ($P = 1$).

**Discussion**

Deep anterior lamellar keratoplasty has undisputed advantages over PK in terms of endothelial survival and complication rates. However, many surgeons are still reluctant to embrace this procedure, mainly because pneumatic dissection is difficult to master, but also because refractive and visual outcomes of DALK at best do not differ substantially from those of PK. The simplest way to attempt at improving postoperative refractive outcomes may be to use larger grafts, which have been reported to yield more regular astigmatism, but full-thickness grafts larger than 8 mm in diameter are associated with an increased risk of endothelial immunologic rejection and are not normally used for PK. Instead, lamellar grafts of larger diameter can be used for DALK, because no endothelial rejection is possible and eventual stromal or epithelial rejections can be
managed successfully with conservative treatment in most cases. As recently published in a relatively small study, lamellar grafts larger than 8 to 8.25 mm in diameter may provide better astigmatic outcomes than smaller ones. However, when conversion to PK is necessary, especially at the beginning of the surgeon’s learning curve, a full-thickness graft larger than 8 mm would be required to manage this complication and therefore increase the risk for immunologic rejection. In addition, with the current techniques, pneumatic dissection does not usually extend beyond 7.5 to 8.0 mm and would have to be completed by hand to reach beyond this size, thus posing an additional challenge to the surgeon and increasing the chances of requiring conversion to PK.

To address all these limitations while allowing the use of lamellar grafts 9 mm in diameter, we have modified DALK, introducing the concept that the diameter of the lamellar graft can be larger than that of the stromal clearance. In all the eyes included in this series, a 9-mm graft was transplanted, but the optical zone was cleared only in the central 6 mm.

A trephination larger than the conventional ones (8–8.25 mm in diameter) offers the advantage of...
comprising in most eyes the whole ectasia, especially when the KC is of the broad-base type (Fig 4), thus allowing a safer trephination into the deep stroma and suturing of donor tissue into a more regular recipient bed. As recently published,11 the deep trephination used for our technique optimizes the success rate of pneumatic dissection while being complicated by accidental perforation in a low percentage of cases (1 of 80 cases = 1.2%), without compromising the possibility of completing the procedure as initially planned. The block of the suction trephine with measurable blade advancement can be predetermined accurately on the base of the pachymetric map obtained by means of AS-OCT and is instrumental for the success of this technique.

Postoperative BSCVA of 9-mm DALK compares favorably with that recorded after conventional DALK with smaller grafts, averaging 0.18±0.74 logMAR after removal of 1 suture and 0.009±0.72 logMAR (P = 0.001) after

Figure 4. Pachymetric map of a keratoconic eye of the broad-base type. Only the 9-mm diameter includes the whole ectasia.

Figure 5. Schematic (A) and postoperative (6 months) anterior segment optical coherence tomography (AS-OCT) image (B) of the “lap-joint” type of wound configuration obtained with the modified deep anterior lamellar keratoplasty (DALK) technique. Dashed red lines and red arrows signify the donor-recipient interface.
<table>
<thead>
<tr>
<th>Authors</th>
<th>Bubble Success* (%)</th>
<th>Perforation (%)</th>
<th>Conversion to PK (%)</th>
<th>Trephination Size (mm)</th>
<th>Mean BSCVA (logMAR)</th>
<th>Mean RA or TA (D)</th>
<th>RA or T4A &lt; 4–4.5 D (%)</th>
<th>RA or TA Range (D)</th>
<th>SE (D)</th>
<th>ECL (%)</th>
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<td>Fontana et al, 2007</td>
<td>64</td>
<td>13</td>
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<td>0.14±0.74</td>
<td>2.94±1.45</td>
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<td>1–7.13±3.9</td>
<td>-1.81±3.2</td>
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<td>59</td>
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<td>8.00–8.50</td>
<td>0.09</td>
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<td>8.0±0.25</td>
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<td>77</td>
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<td>83.7</td>
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<td>0.09±0.72</td>
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<td>91±4</td>
<td>0–6±3.2</td>
<td>-1.55±3.3</td>
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</table>

BSCVA = best spectacle-corrected visual acuity; ECL = endothelial cell loss; NA = not available; PK = penetrating keratoplasty; RA = refractive astigmatism; SE = spherical equivalent; TA = topographic astigmatism.

*Success rate of pneumatic dissection.

1Outcomes at 2-year follow-up.

2Results in bared Descemet’s membrane cases.

3Results in manual dissection cases.

4Sutures still in place.

5Refractive astigmatism.

6Topographic astigmatism.

**Topographic astigmatism < 4 D.

7Refractive astigmatism < 4.5 D.

8Topographic astigmatism < 4.5 D.

9Excluding 1 perforation during trephination.
complete suture removal. Final BSCVA was \( \geq 20/20 \) in 28 eyes (35%), \( \geq 20/25 \) in 54 eyes (67.5%), and \( \geq 20/40 \) in 76 eyes (95%); thus always at the upper limit of or beyond the ranges of values published in previous articles (16.2%–23% for BSCVA \( \geq 20/20 \), 50%–73% for BSCVA \( \geq 20/25 \), and 80%–95% for BSCVA \( \geq 20/40 \)). In addition, the values considered in these reports were recorded at follow-up times from surgery considerably longer (2–8 years) than ours, thus allowing a longer time for visual recovery.

Although some authors have reported that BSCVA after hand dissection is significantly worse than after successful pneumatic dissection, similar to what has been reported by other authors, we could not see any significant difference in our population after complete suture removal. This is probably a consequence of the variable amount of residual stroma left in place by different surgeons. In the report by Borderie et al., the average thickness of the residual recipient stroma in the manual dissection group measured by AS-OCT was 87 \( \mu m \), reaching up to 150 \( \mu m \), whereas in our series after complete suture removal, the residual stroma could not be seen and was measured at the slit lamp or by AS-OCT.

The final mean absolute value of refractive astigmatism recorded in our series was 3.10±1.30 \( D \), thus supporting previous evidence that post-DALK astigmatism is lower if grafts larger than 8 \( mm \) in diameter are transplanted. In addition, only 7 eyes (8.75%) had more than 4.5 \( D \) of refractive astigmatism, and none had more than 6 \( D \). Fontana et al. reported that after complete suture removal, topographic cylinder greater than 4 \( D \) and 5 \( D \) was measured in 16.6% and 6.7% of eyes, respectively, in their series. In other articles, postoperative astigmatism was found to reach values greater than 8 \( D \) and 9 \( D \).

In our series, we also addressed the issue of regularity of postoperative astigmatism and recorded after complete suture removal a mean asymmetry value in the 3-mm central area 6 mm in diameter (28.26 \( mm^2 \)), which is approximately only 50% of the extension of an 8- to 8.25-mm area (50.24–53.42 \( mm^2 \)). Micro-perforation occurred in a small percentage of eyes of our series and always could be managed by hand dissection (3 of 80 cases = 3.7%), whereas conversion to PK was never necessary. However, as we previously reported, should macro-perforations occur, then rather than a 9-mm PK, we would perform a 2-piece mushroom keratoplasty, which replaces only the central 6 mm of deep stroma and endothelium. Alternatively, for those who are not familiar with this technique, a 1-piece mushroom-shaped graft can be transplanted after preparation by manual or femtosecond laser-assisted dissection. Only less-experienced cornea surgeons, who may not master any of these techniques, would have to convert to a 9.0-mm PK and should be aware of the risks related to large PKs before attempting to perform 9.0-mm DALK.

Clearing only a 6-mm central zone and leaving a peripheral crown of recipient stroma (~1.5 mm in width) creates a new corneal architecture under the donor lamella, which could offer both advantages and disadvantages.

However, postoperative CCT is lower than that obtained after transplantation of a whole donor cornea and the peripheral stroma is incised for 360°, but recurrence of ectasia was not seen in any case of our series. In addition, the final CCT values were higher than 250 \( \mu m \) (the thickness of deep stroma considered the limit for the risk of developing ectasia after LASIK), and the anterior lamella transplanted with our procedure included anterior stroma and a normal Bowman’s layer, which offers a higher resistance to ectasia than deep stroma does.

Another possible argument against our method could be the irregularity in the posterior corneal curvature created by the step at the edge of the 6-mm zone. However, no patient reported any specific symptom regarding the quality of their vision even at night, and in all cases the step itself disappeared within few months from surgery as demonstrated by the AS-OCT images (Fig 3). Refraction was not affected by this remodeling of the stroma, and the average spherical equivalent recorded in our series after suture removal does not show any substantial difference from the values recorded after conventional DALK in other series.

Finally, 9.0-mm lamellar grafts may be more susceptible to epithelial and stromal rejection episodes than lamellar graft of lower diameter. Especially in atopic patients, the latter ones can be accompanied by corneal neovascularization and lipid deposition, which can reduce vision to a great extent. In our series, slow tapering of steroids over an 8-month period limited the occurrence of stromal rejection to 6 cases (all treated successfully with topical steroids) and may have prevented further complications, such as the development of stromal neovessels and lipid deposition, which were not seen in any of our cases. However, the relatively short follow-up of our study does not allow to draw conclusions about the long-term safety of our technique in regard to possible immunologic complications.
On the positive side, unlike for conventional DALK, in our variant the 9-mm trephination need not be hand refined, thus creating a machine-cut perfectly circular incision, with optimal apposition to the punched graft, a feature that could contribute to optimize the regularity of the postoperative corneal profile. Furthermore, the “lap joint” type of wound configuration obtained with our DALK modification creates a large surface (Fig 5) of contact between donor and recipient stroma, possibly leading to faster wound healing and improved mechanical stability, as well as allowing earlier suture removal with earlier visual recovery.\cite{29,32,33}

In our series, no wound dehiscence was seen, although we completed suture removal within 10 months from surgery in all patients aged less than 30 years. In particular, a period of 3 months was sufficient to seal the wound in the patient who experienced inadvertent rupture and consequent removal of both sutures so early after surgery.

Finally, the crown of deep stroma surrounding the central debulked zone also protects the recipient bed from inadvertent perforations by the needle possibly occurring while suturing the donor tissue in place, a complication often reported anecdotaly by surgeons, but for which no statistics are available in the literature.

Also in regard to intraoperative and postoperative complications, the outcomes of our technique compare favorably with those of previous reports. As shown in Table 1, we observed the lowest rate of intraoperative perforation and conversion to PK. Double chamber formation was seen in 2 cases (2.5%) and managed successfully by a simple air fill of the anterior chamber. This complication was reported previously in a similar percentage of cases.\cite{22,24,35}

In addition, despite the larger diameter of our grafts, stromal rejection was observed in a percentage of cases (7.5%) comparable to that reported by authors using smaller grafts (up to 10%).\cite{7,24,35} Despite the larger size of the debulked area, the average ECL recorded 1 year after surgery in our series (11.2%) is within the range reported in the past.\cite{22,24}

In conclusion, as summarized in Table 1, the success rates of pneumatic dissection and visual and refractive results obtained with our DALK modification (transplantation of a 9-mm lamellar graft combined with stromal clearance of a 6-mm optical zone) compare extremely favorably with those obtained with other DALK techniques, whereas the rate of intraoperative and postoperative complications is minimized.

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Footnotes and Financial Disclosures

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1 Ospedale Privato “Villa Igea,” Department of Ophthalmology, Forlì, Italy.
2 Istituto Internazionale per la Ricerca e Formazione in Oftalmologia, Forlì, Italy.
3 Ospedale “SS. Giovanni e Paolo,” Department of Ophthalmology, Venezia, Italy.
4 Rabin Medical Center, Department of Ophthalmology, Petah Tikva, Israel.
5 Sackler Faculty of Medicine, Tel Aviv University, Tel Aviv, Israel.
6 University of “Magna Graecia,” Department of Ophthalmology, Catanzaro, Italy.


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Abbreviations and Acronyms:
AS-OCT = anterior segment optical coherence tomography; BSCVA = best spectacle-corrected visual acuity; CCT = central corneal thickness; D = diopters; DALK = deep anterior lamellar keratoplasty; KC = keratoconus; logMAR = logarithm of the minimum angle of resolution; PK = penetrating keratoplasty.

Correspondence:
Massimo Busin, MD, Ospedale Privato “Villa Igea,” Department of Ophthalmology, 47122 Forlì, Italy. E-mail: mbusin@yahoo.com.