

## SURGEON'S CORNER

# Outcomes From a Modified Microkeratome-Assisted Lamellar Keratoplasty for Keratoconus

Massimo Busin, MD; Vincenzo Scorcia, MD; Luca Zambianchi, MD; Diego Ponzin, MD

To improve visual and refractive outcomes, microkeratome-assisted lamellar keratoplasty for the treatment of keratoconus (exchange of a 9.0-mm anterior recipient lamella with a 9.0-mm donor lamella, using a 200- $\mu$ m head for the former and a 300- $\mu$ m head for the latter) was modified by adding a 6.5-mm incomplete full-thickness incision in the recipient bed before suturing the donor graft in place. After complete suture removal, 1 year postoperatively, best spectacle-corrected visual acuity was 20/40 or better in 92 of 97 eyes and 20/25 or better in 67 of 97 eyes; regular astigmatism was 4.5 diopters or worse in 86 of 97 eyes; endothelial cell loss averaged 20.4%. The disruption of the recipient's architecture induced by the full-thickness circular incision makes the final corneal shape closely resemble the physiologic curvature of the donor cornea, thus optimizing postoperative refractive error and spectacle-corrected visual acuity.

*Arch Ophthalmol.* 2012;130(6):776-782

Lamellar keratoplasty (LK) for the surgical treatment of keratoconus involves either dissecting the deep stroma or barring the Descemet membrane.<sup>1-5</sup> With the nonbarring LK, the residual recipient stroma preserves a "keratoconus memory" that may cause excessive steepening and irregularity of the final corneal contour, up to recurrence of ectasia.<sup>5</sup>

To neutralize this adverse effect, we recently introduced a modification of the microkeratome-assisted LK (MALK) technique (selected as "Best of Show" video at the 2006 annual meeting of the American Academy of Ophthalmology),<sup>5</sup> including a full-thickness trephination of the recipient bed before suturing the donor graft in place. The resulting collapse of the residual bed eliminates its mechanical resistance, thus allowing the large (9.0-mm) anterior lamellar graft to determine, unaffected, the final corneal curvature. We report herein the results of the prospective evaluation of the first 100 patients in whom the new MALK technique was used.

## METHODS

All eyes of patients with keratoconus, intolerant to eyeglasses or contact lenses, that under-

went MALK at our institution between January 1, 2005, and June 30, 2008, were included in a nonmasked, noncontrolled prospective clinical trial. The study followed the tenets of the 1964 Declaration of Helsinki and was approved by the local ethics committee; detailed informed consent was provided by all patients undergoing modified MALK.

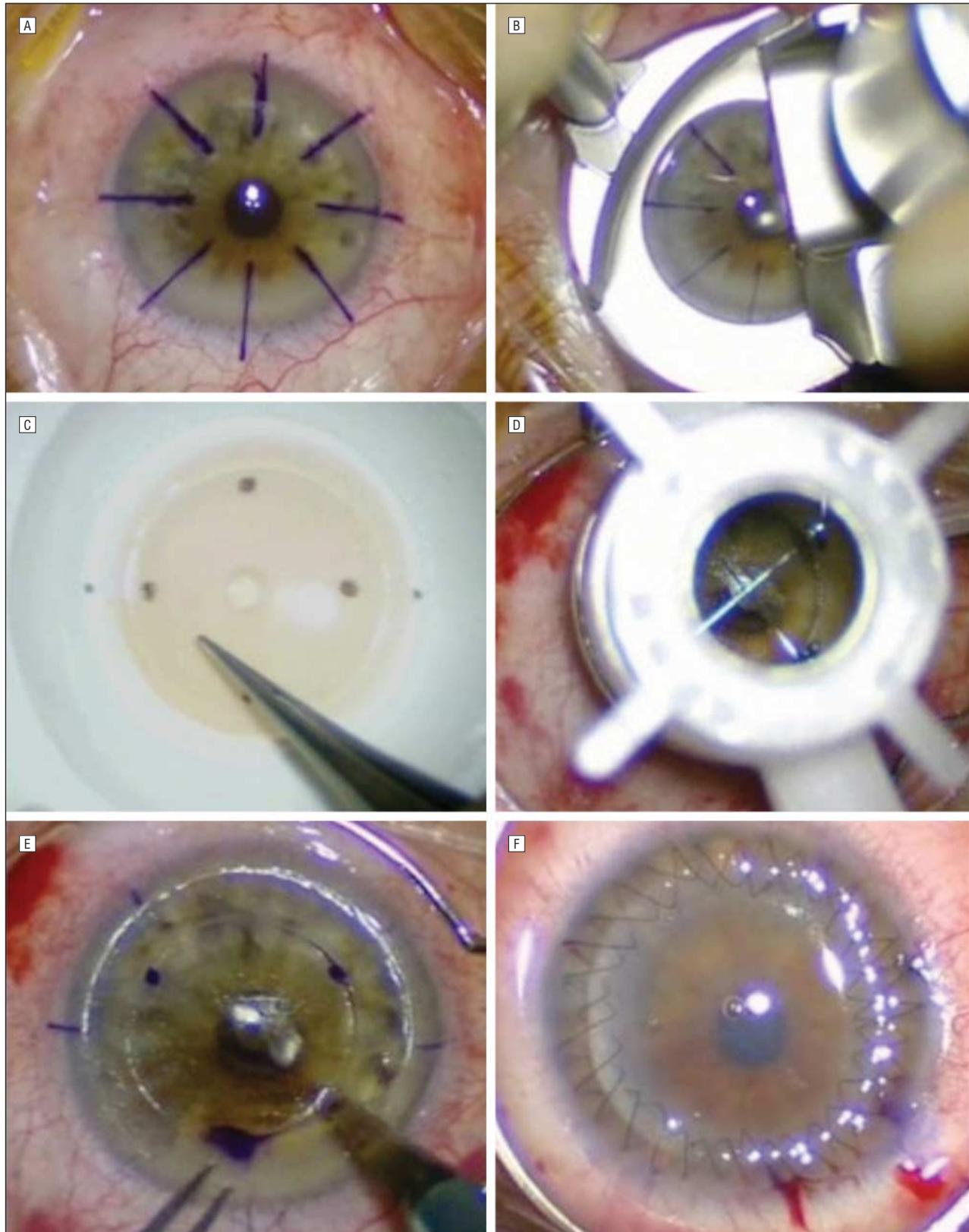
All procedures were performed by the same surgeon (M.B.) using the surgical technique described in detail herein. Regardless of cone steepness, the only exclusion criteria were the presence of preoperative pachymetric readings lower than 300  $\mu$ m at any of the locations tested (at the cone apex and at the 3-, 6-, 9-, and 12-o'clock positions, 1-2 mm from the cone apex, using an ultrasonic pachymeter (SP 3000, Tomey) and/or opacities extending beyond the anterior half of corneal thickness.

Preoperatively, as well as 6 months, 1 year (after complete suture removal), and 2, 3, 4, and 5 years after the operation, each patient underwent a complete eye examination, including uncorrected visual acuity and best spectacle-corrected visual acuity (BSCVA), refraction, slitlamp examination, computerized analysis of corneal topography (Eyesys) and endothelial microscopy (HRT-II, Heidelberg Technology). A paired 1-tailed *t* test was used for statistical evaluation. All complications and secondary interventions were recorded.

## SURGICAL TECHNIQUE

The modification of the standard procedure<sup>5</sup> is illustrated in **Figure 1**. After marking the recipient cornea with gentian violet (Figure 1A), microkeratome-assisted dissection was per-

**Author Affiliations:** Department of Ophthalmology, Magna Graecia University, Catanzaro, Italy (Drs Busin and Scorcia); Department of Ophthalmology, Villa Igea Hospital, Forlì, Italy (Drs Busin and Zambianchi); and Fondazione Banca degli Occhi del Veneto, Venezia, Italy (Dr Ponzin).



**Figure 1.** Surgical technique. A, Marking the recipient cornea. B, Microkeratome-assisted dissection of the recipient cornea. C, Punching the donor lamella. D, Trephination in the residual recipient bed. E, Full-thickness incision completed. F, Anterior donor lamella sutured in place.

formed both in the recipient cornea (using a 200-µm head, as in Figure 1B) and in the donor tissue (using a 300-µm head).

The donor lamella was punched to the required 9-mm size (Figure 1C). Then, a 6.5-mm Barron trephine (Katena Products Inc)

was centered on the pupil and the blade was advanced until the cornea was perforated (Figure 1D). The inci-



**Figure 2.** Clinical appearance of a microkeratome-assisted lamellar keratoplasty 1 year postoperatively.

sion was completed with a 15° blade, except for 2 or 3 small tissue bridges (Figure 1E), to prevent possible dislocation of the deep stromal disc obtained. Finally, the lamellar graft was sutured in place using a double 10-0 nylon running suture (Figure 1F). The knots were buried and the anterior chamber was deepened by injecting balanced salt solution (Alcon) with a syringe and a 30-gauge needle inserted obliquely through the limbus.

Two cases were complicated by buttonholing, which was managed with exchange of a 6-mm disc from the residual bed, thus converting the MALK into a “mushroom” penetrating keratoplasty (PK), as described previously.<sup>6</sup>

Postoperatively, tobramycin sulfate and dexamethasone phosphate eyedrops were given as in the previous series.<sup>5</sup> Of the 2 running sutures, one was removed 3 months after the operation and the other within 1 year. Earlier removal was feared to cause wound dehiscence in the presence of full-thickness incisions.

Surgical correction of high-degree astigmatism was always undertaken more than 3 months after removal of all sutures. Based on corneal topography, the peripheral annular scar was opened under control of intraoperative qualitative keratometry until a regular spherical corneal curvature was obtained. Patients who developed a cataract underwent uneventful phacoemulsification with in-the-bag implantation of an

intraocular lens performed through a scleral tunnel centered on the steeper meridian.

## RESULTS

One hundred eyes of 82 patients (44 males, 38 females) were included in the study; their ages ranged from 16 to 64 years (mean, 33.7 years). At the time of this review, all corneas were clear (**Figure 2**). **Figure 3**, **Figure 4**, and **Table 1** summarize the results that are reported in detail herein (excluding the 2 cases with buttonholing). Uncorrected visual acuity and BSCVA improved significantly ( $P < .001$ ) over preoperative values ( $\leq 20/200$  and  $< 20/40$  in all eyes, respectively) at each postoperative examination.

As early as 1 year after surgery, uncorrected visual acuity was better than 20/200 in 57 of 97 eyes (58.8%) while BSCVA was 20/25 or more in 67 of 97 eyes (69.1%). No substantial changes were recorded later. Only 6 patients had a BSCVA worse than 20/40, and this was associated with reasons unrelated to corneal conditions in 3 of them (2 with amblyopia, 2 with retinal disease, 1 with high-degree astigmatism, and central folds [all 3]).

The mean spherical equivalent increased significantly ( $P < .001$ ) 6 months after MALK. The 1-year values were significantly lower than those recorded at 6 months ( $P < .001$ ) but significantly higher than the preoperative values ( $P < .001$ ), and they did not change substantially at a later time. Similar changes (significant flattening, most pronounced with the sutures in place) were also measured for the mean value of average simulated keratometric readings.

Refractive cylinder within 4.5 diopters (D) was measured in only 4 of 100 eyes (4%) preoperatively but in 80 of 97 eyes (82%) and 86 of 97 eyes (90%) 1 year and 2 years postoperatively. Regular astigmatic patterns (symmetric or asymmetric bow-tie) were seen in only 16 of 98 eyes (16%) 6 months after MALK but in 86 of 97 eyes (89%) at 1 year and in a similar percentage of eyes at a later time. Mean (SD) endothelial cell density decreased from 2746 (322) cells/mm<sup>2</sup> preoperatively to 2186 (331) cells/mm<sup>2</sup> 1 year postoperatively (endothelial cell loss, 20.4%), with minor changes ( $P > .05$ ) thereafter.

The complications recorded are summarized in **Table 2**. In the 2 patients with conversion to mushroom PK, final BSCVA was 20/20 and 20/25 (refractive astigmatism, 3.5 and 2.5 D, respectively) 2 and 3 years after the operation, respectively. The 3 cases with double-chamber formation were managed successfully (**Figure 5**) with intracamerular injection of air through the limbus. All 6 eyes with postoperative epithelial defects persistent for longer than 2 weeks healed with the use of therapeutic contact lenses. Visually significant folds in the recipient cornea resolved spontaneously in 14 of 15 eyes after all sutures were removed (**Figure 6**).

Late complications included 2 cases of wound dehiscence resutured on the same day of onset (first day after suture removal); 2 cases of corticosteroid-induced cataract, uneventfully managed with phacoemulsification and posterior chamber intraocular lens implantation 2 to 3 years after MALK; and 7 cases of refractive astigmatism more than 4.5 D with BSCVA less than 20/40, all of which underwent relaxing in-

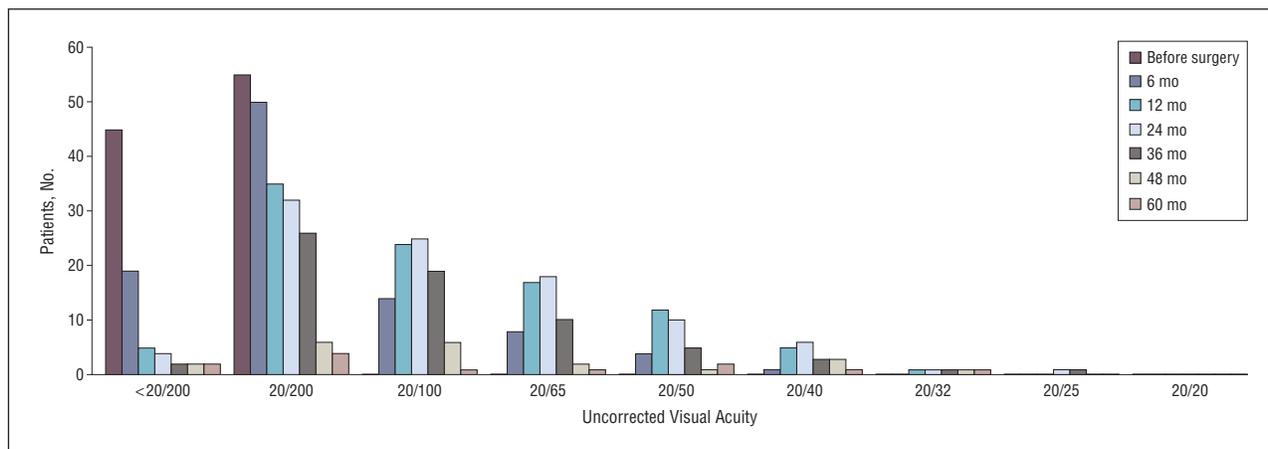


Figure 3. Distribution of uncorrected visual acuity over time.

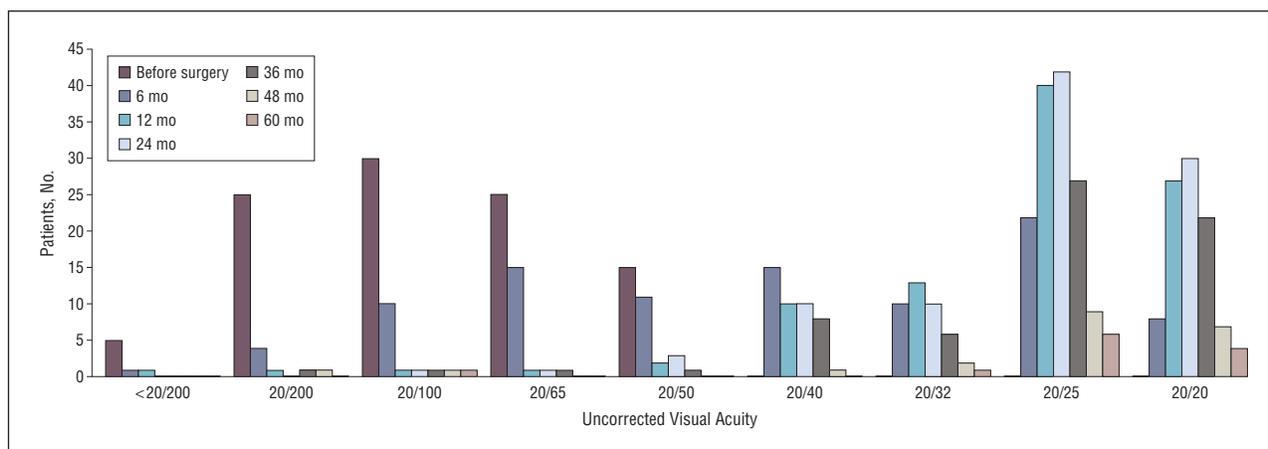


Figure 4. Distribution of best spectacle-corrected visual acuity over time.

Table 1. Main Outcomes of Modified Microkeratome-Assisted Lamellar Keratoplasty for Keratoconus

Follow-up	Eyes, No.	Mean (SD)					
		Spherical Equivalent, D	Absolute Value of Astigmatism, D	K Readings, D	Regular Topographic Pattern, %	Endothelial Cell Density, Cells/mm <sup>2</sup>	Endothelial Cell Loss, %
6 mo	98	+1.93 (4.51)	4.02 (2.51)	40.1 (5.6)	16	2423 (324)	12.7
1 y	97	-1.83 (4.42)	3.11 (1.91)	42.5 (3.2)	88	2186 (331)	20.4
2 y	96	-1.97 (4.31)	3.34 (1.84)	42.7 (3.3)	91	2142 (328)	22.0
3 y	67	-2.13 (4.65)	3.85 (1.75)	42.8 (3.5)	80	2124 (307)	22.7
4 y	21	-1.84 (3.45)	4.25 (1.81)	42.6 (3.2)	86	2102 (301)	23.5
5 y	12	-2.07 (3.64)	3.27 (1.72)	42.8 (3.4)	83	2085 (287)	24.1

Abbreviations: D, diopters; K, keratometric.

cisions performed as described in the "Methods" section.

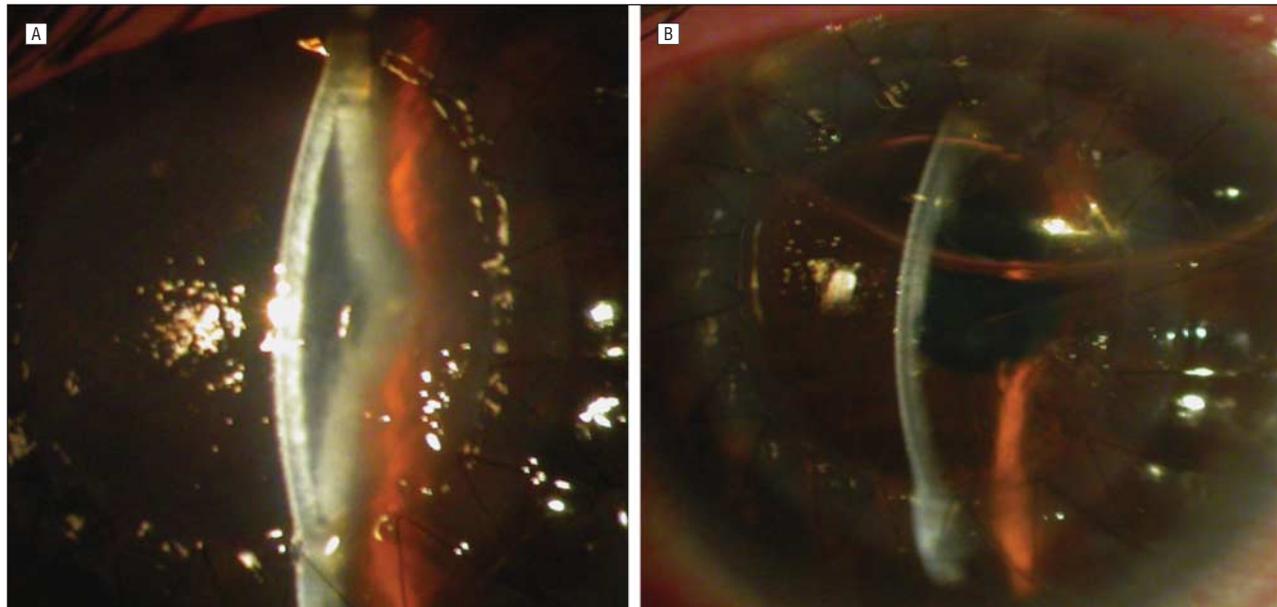
### COMMENT

Lamellar keratoplasty for keratoconus has not yet been fully accepted among corneal surgeons, as most of them still consider manual and pneumatic ("big bubble") dissection of deep stroma a painstaking procedure with a steep learning

curve. Many believe that PK (a technique easily performed by anyone with average surgical skills) offers a better visual outcome with a shorter surgical time.<sup>7-11</sup> Recently, deep dissection of the recipient cornea, possibly up to the Descemet membrane (ie, deep anterior LK), has been introduced with the purpose of minimizing, if not eliminating, the optically negative effects of a stromal interface and therefore achiev-

ing visual results comparable to those of PK.<sup>1,3,4</sup> Several attempts have been made to simplify and standardize LK by using either excimer or femtosecond lasers, but concerns remain about the safety and feasibility for the former and the optical quality of the dissection for the latter.<sup>12-15</sup>

The experience with laser-assisted in situ keratomileusis and, more recently, with Descemet strip-



**Figure 5.** Slitlamp appearance of microkeratome-assisted lamellar keratoplasty 1 day postoperatively. A, Corneal edema and double-chamber formation are evident. B, A few hours after filling the anterior chamber with air, the cornea is transparent with no double chamber.

**Table 2. Complications Recorded During the Study**

Complication	No. (%)
Buttonholing, conversion into mushroom penetrating keratoplasty	2 (2)
Double-chamber formation	3 (3)
Persistent epithelial defects	6 (6)
Folds in the recipient central cornea	15 (15)
Wound dehiscence after suture removal	2 (2)
Corticosteroid-induced posterior subcapsular cataract	2 (2)
Refractive astigmatism >4.5 D	7 (7)

Abbreviation: D, diopters.

ping automated endothelial keratoplasty has shown that microkeratome-assisted dissection of corneal stroma is easy to perform and compatible with excellent vision.<sup>16-18</sup> The microkeratome also has been used for the surgical treatment of keratoconus, with excellent reproducibility.<sup>5,19</sup> Despite the variability of the preoperative corneal curvature, we routinely obtain a host bed with a regular 9.0-mm diameter, probably as a consequence of the standardized use of a 0 ring for all eyes.<sup>5</sup> However, because of the limited precision in depth of dissection, we aim to leave a layer of residual stroma of approximately 100  $\mu$ m to avoid perforation.<sup>5,20</sup> In the previous series,<sup>5</sup> the residual ectatic tissue nega-

tively affected final vision by causing excessive corneal steepening and a high incidence of postoperative irregular astigmatism (9 of 50 patients [18%]).

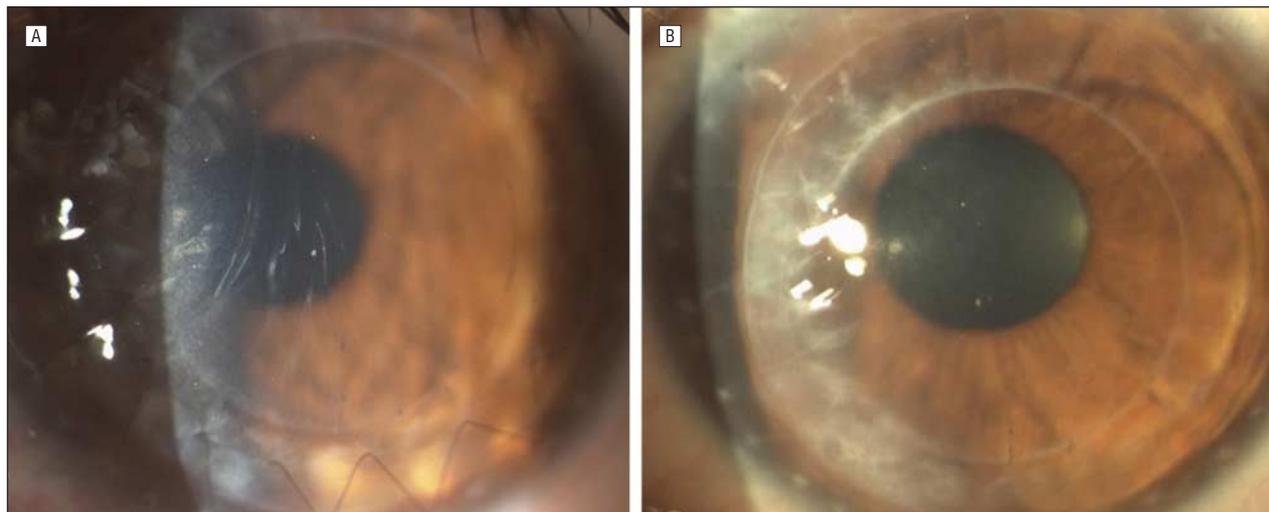
To maintain the ease and standardization of microkeratome dissection but, at the same time, eliminate the mechanical resistance of the residual bed, we modified MALK by adding a central, 6.5-mm, incomplete full-thickness trephination of the residual bed. As a result, the structure of the recipient cornea collapses after its central part is disconnected from the periphery, while the attachments prevent dislocation of the button. The recipient endothelium and deep stroma are maintained in place and simply adapt onto the posterior surface of the graft after it is sutured in place. The corneal shape as a whole resembles that of the large anterior lamella, and its steepness does not change substantially even after sutures are removed, as the keratoconus memory in the recipient cornea has been cancelled by the perforating incision.

The effect of this modification was such that average postoperative simulated keratometric readings were substantially lower than those of the patients in the previous series,<sup>5</sup> with a mean spherical equivalent closer to emmetropia by

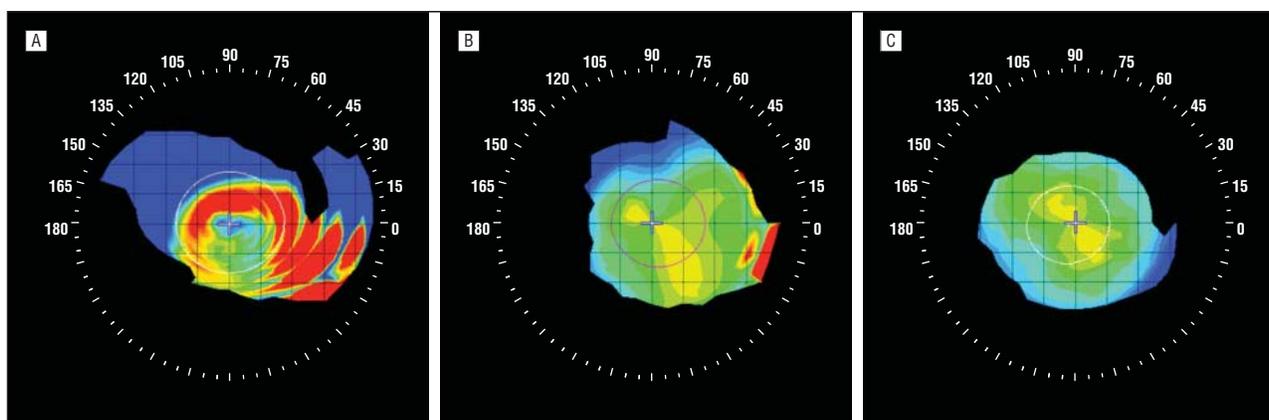
about 2 D (**Figure 7**), similar to that found after PK and less myopic than that observed after deep anterior LK of other types.<sup>21,22</sup>

Despite absolute values of astigmatism similar to those recorded after PK or LK,<sup>23,24</sup> the 9-mm graft of MALK produced mostly regular topographic patterns and BSCVA of 20/40 or better in all but 5 eyes. One year after the operation, BSCVA was 20/25 or better in 67 of 97 eyes (69%) and remained substantially unchanged thereafter, improving over previous MALK results (44% of eyes seeing  $\geq$ 20/25).<sup>5</sup> Overall, visual results after MALK are similar to those of PK or big-bubble LK but better than those of deep anterior LK without Descemet membrane baring.<sup>5,7-11</sup>

The "step" wound of MALK adds to the refractive advantages of the 9-mm graft the possibility of performing full-thickness relaxing incisions to correct high-degree astigmatism. This is not possible with any conventional LK, which all use grafts, often 8 mm in diameter, with a straight vertical wound. As in the previous study,<sup>5</sup> we could not identify any effect of the minor peripheral discrepancy resulting between the slanted contour of the surgical wound in the recipient cornea and the vertical edge of the donor tissue.



**Figure 6.** Postoperative slitlamp appearance of microkeratome-assisted lamellar keratoplasty 1 month postoperatively. A, Folds in the recipient cornea involve the pupil area. B, One year postoperatively, after all sutures have been removed, the folds have disappeared.



**Figure 7.** Corneal topography of a cornea with central keratoconus. A, Before surgery. B, One month postoperatively. C, One year after microkeratome-assisted lamellar keratoplasty.

In our experience, the very slow motion of the microkeratome has proven instrumental in avoiding buttonholing keratoconic corneas. If the instrument is forced at high speed against the ectatic cornea, it can dislocate the tissue, causing loss of suction and consequent buttonholing. In our series, this complication occurred in 2 eyes with rather low average keratometric readings (54.50 and 58.75 D), thus, independent of cone steepness.

MALK is not an extraocular procedure because of the full-thickness incision; therefore, it exposes the eye to the dangers of intraocular procedures (ie, infection), the same as with other LK techniques, such as the big bubble, which use stab wounds. The endothelial cell loss we measured is somewhat higher than that recorded after other LKs.<sup>24-26</sup> However, the endothelial

cell density remained far above the limits endangering corneal function and stabilized by 1 year postoperatively.

Vision-threatening complications were not seen after MALK. Surgery other than that required to correct astigmatism was necessary only in 2 eyes (uneventful phacoemulsification), thus comparing favorably, especially with the results of PK.<sup>11,22</sup>

In conclusion, the modification of MALK that we propose maintains all the advantages of other LK techniques over conventional PK. However, in contrast to other types of LK, MALK requires no particular surgical skills, can be fairly standardized, and allows excellent BSCVA in most cases. Complications are rare and can be easily managed by corneal specialists, who may therefore consider adding MALK to their surgical armamentarium.

**Submitted for Publication:** April 5, 2011; final revision received September 6, 2011; accepted September 7, 2011.

**Correspondence:** Massimo Busin, MD, Department of Ophthalmology, Villa Igea Hospital, Viale Gramsci 42-44, 47122 Forlì, Italy (mbusin@yahoo.com).

**Author Contributions:** Dr Scorcia had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

**Financial Disclosure:** Travel expenses of Dr Busin were reimbursed in part by Moria from 2005 to 2010; he received royalties from Moria in 2008, 2009, and 2010.

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