Evaluation of a New System for Obtaining Donor Lamellar Grafts

Gustavo Victor, MD,† Sidney J. Sousa, MD,† Milton R. Alves, MD,‡ and Walton Nosé, MD*§||*

Purpose: To evaluate the performance of a new system for obtaining corneal lamellar grafts of preset sizes. The system consists of the combination of an artificial anterior chamber (MALKS) and an automated microkeratotome (MASYK).

Methods: A prospective study was performed. Lamellar tissue was obtained with the microkeratotome from 40 human corneoscleral buttons mounted in the artificial anterior chamber. The instrument was set to cut lamellae with a center thickness of 350 μm and a diameter of 10 mm. A new cutting blade for the microkeratotome was used for every 8 cases. Thickness was measured by ultrasound pachymetry. The lamellar diameter was assessed with a micrometric caliper.

Results: The center thickness of the corneal lamellae ranged from 230 to 430 μm (mean, 322 ± 48 μm; 95% confidence interval [CI], 307–337 μm). The diameter of the stromal ranged from 9.26 to 10.74 mm (mean, 10 ± 0.27 mm; 95% CI, 9.9–10 mm). There were no cases of perforation or incomplete/irregular lamellae. The interface between the residual stroma and the lamellae was macroscopically smooth. The repetitive use of the same blade up to 8 times did not significantly change these results.

Conclusion: The MALKS and MASYK system showed good accuracy in obtaining lamellae of specific thickness and size taken from human corneoscleral buttons. It is a promising instrument for use in deep lamellar keratoplasty. The technique may be useful in obtaining precut lamellar donor tissue for distribution by eye banks.

Key Words: artificial anterior chamber, automated microkeratotome, lamellar keratoplasty, lamellar keratectomy

(*Cornea* 2007;26:151–153)

Barraquer[1] first described the use of a microkeratotome in donor and recipient corneas for lamellar keratoplasty. Because of problems with accessibility and high cost, the procedure had little acceptance.[1,2] The development of automated microkeratotomes for refractive surgeries renewed the interest in lamellar grafting.[3–5] By virtue of their high quality of cut and easy operation, they offered an unprecedented possibility of obtaining corneal lamellae of excellent quality.[6–8]

Classically, corneal lamellae for lamellar keratoplasty were obtained from the whole donor eye. With the evolution of eye banking technology, the distribution of the corneal tissue was changed to corneoscleral buttons preserved in storage medium.[9] To obtain corneal lamellae from corneoscleral buttons, it is necessary to use a device that tightly holds the button, exposing its anterior surface without damaging the endothelial layer. This device was named the artificial anterior chamber. Systems that combine an artificial anterior chamber and a manual microkeratotome for lamellar keratoplasty are already available.[9–11] The purpose of this study was to evaluate a new system for corneal lamellar keratectomy that uses an automated microkeratotome connected to an artificial anterior chamber with digital control of its inner pressure.

MATERIALS AND METHODS

A prospective study was conducted in which 40 corneal lamellae were cut from 40 corneoscleral buttons. The tissues were taken from eyes that failed the screening tests of the Eye Bank. Buttons with a 17-mm diameter were taken from the whole globes in the surgical room 5 minutes before keratectomy. These larger-than-average buttons were a technical requirement of the artificial chamber.

The system used to obtain the lamellae consisted of an automated microkeratotome[13–15] (MASYK; Loktal, São Paulo, Brazil) for performing the cuts and an artificial anterior chamber[16] (MALKS; Loktal) for holding the corneoscleral button in the appropriate position (Figs. 1 and 2).

The MALKS system has 8 parts: (a) artificial chamber body; (b) corneal holder ring; (c) nut locker of the holder ring; (d) guide trail for the microkeratotome with a controller ring of the lamellar diameter; (e) corneal flattener to check the lamellar diameter; (f) trephine marker for corneoscleral buttons; (g) infusion system; and (h) digital manometer.[16]

After inserting the corneoscleral button into the MALKS, the balanced salt solution infusion system was activated to provide an inner pressure of 70 mm Hg in the artificial anterior chamber. The digital manometer attached to the system constantly monitored the pressure. The intended diameter of the lamellae was set to 10 mm. This was adjusted by rotating the controller ring of the lamellar diameter to the appropriate position. The selected value was checked with a transparent

Received for publication March 27, 2006; accepted for publication September 17, 2006.

From the *Eye Clinic Day Hospital and †Ribeirão Preto School of Medicine of São Paulo University, São Paulo, Brazil; ‡São Paulo University, São Paulo, Brazil; the §São Paulo Federal University, São Paulo, Brazil; and the ||Santos Metropolitan University, São Paulo, Brazil.

Reprints: Dr. Gustavo Victor, Av. Republica do Libano 1034, São Paulo—SP, Brazil, CEP: 04502-001 (e-mail: gustavo.victor@eyeclinic.com.br).

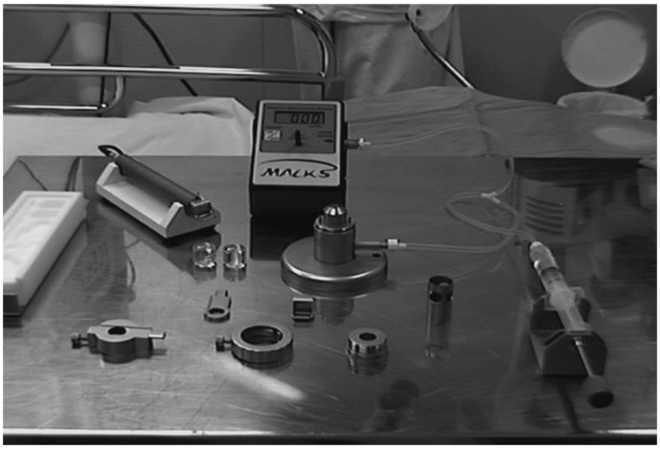

FIGURE 1. The MALKS and MASYK system. A: digital manometer. B and C: infusion system. D: artificial chamber body. E: corneal holder ring. F: nut locker of the holder ring. G: guide trail for the microkeratotome with a controller ring of the lamellar diameter. H: corneal flattener. I: MASYK microkeratotome. J: trephine marker. (Courtesy of Victor, G.).

corneal flattener displaying concentric rings of known diameters. Once pressed against the cornea, throughout the controller ring, it reproduces the diameter of the surface exposed to the cutting blade of the microkeratotome.

The intended thickness of the lamellae was set at 350 μm. This was achieved by choosing the appropriate size of the head of the microkeratotome. The instrument uses disposable blades (ALK; Bausch-Lomb) that cut the corneal lamellae at a rate of 17,200 oscillations/min at an angle of 25°.[13–15]

Before running the microkeratotome, the corneal epithelium was scraped with a spatula. Next, the center thickness of the cornea was measured 3 times by ultrasound pachymetry (P55; Paradigm). The same procedure was repeated after cutting the lamella. The difference between the means of the first and second measurements represented the thickness of the lamella.

Immediately after keratectomy, the vertical diameter of the stromal bed was measured with a micrometric caliper. This measurement was used to estimate the diameter of the lamella.

A new disposable blade was used for every 8 eyes. Therefore, the whole study group, comprising 40 corneoscleral buttons, could be divided into 5 subgroups of 8 eyes, each using a specific blade repeatedly.

FIGURE 2. Corneal lamellar grafts obtained with MALKS and MASYK system (Loktal, Brazil). (Courtesy of Victor, G).

RESULTS

The system was easy to use. The presence of air bubbles in the artificial chamber, observed in 10 cases, did not interfere with the procedure. There were no cases of perforation or incomplete lamella. All lamellae had round shape with no hinge. The entire corneoscleral residual button was macroscopically intact after disassembling the artificial anterior chamber.

The center thickness of the corneal lamellae ranged from 230 to 430 μm (mean, 322 ± 48 μm; 95% confidence interval [CI], 307–337 μm). The diameter of the stromal ranged from 9.26 to 10.74 mm (mean, 10 ± 0.27 mm; 95% CI, 9.9–10 mm). Table 1 presents the mean thickness and the mean diameter with the respective SDs for 5 groups of 8 lamellae each. The analysis of variance of these data did not show statistically significant differences among related means (P = 0.5739 and P = 0.8952, respectively). Also, the mean thickness and the mean diameter did not differ significantly among groups (P = 0.9358 and P = 0.3005) when the data were rearranged in terms of the number of times each blade was used[17] (Table 2).

DISCUSSION

The CI for the center thickness of the lamellae indicates that, for the heads of the microkeratotome with a nominal value of 350 μm, the real thickness tends to be 4% to 12% less than the intended value in 95% of the cases. This is an

TABLE 1. Characteristics of the Lamellae Obtained With 5 Separate Blades of the Same Make

		Thickness (μm)		Diameter (mm)	
Blade Label	N	Range (μm)	Mean ± SD	Range (mm)	Mean ± SD
1	8	340.00–430.00	338.75 ± 53.57	9.26–10.30	9.96 ± 0.25
2	8	250.00–400.00	308.75 ± 42.24	9.96–10.28	9.96 ± 0.29
3	8	330.00–340.00	312.50 ± 57.76	9.90–10.54	9.97 ± 0.48
4	8	230.00–370.00	337.50 ± 46.83	9.58–10.32	10.07 ± 0.93
5	8	280.00–350.00	312.50 ± 41.66	9.30–10.74	10.04 ± 0.27
Total	40	230.00–430.00	322.00 ± 48.16	9.26–10.74	10.00 ± 0.27

TABLE 2. Characteristics of the Lamellae Relative to the Times of Use of the Blades

		Thickness (μm)		Diameter (mm)	
Blade Use	**N**	**Range (μm)**	**Mean ± SD**	**Range (mm)**	**Mean ± SD**
1 time	5	270.00–430.00	328 ± 67.97	9.54–10.02	10.02 ± 0.11
2 times	5	290.00–350.00	340 ± 32.40	9.30–10.35	9.88 ± 0.11
3 times	5	250.00–390.00	312 ± 57.18	9.90–10.30	9.94 ± 0.26
4 times	5	230.00–340.00	312 ± 47.64	9.58–10.74	10.18 ± 0.37
5 times	5	310.00–400.00	312 ± 54.04	9.36–10.32	9.79 ± 0.37
6 times	5	260.00–340.00	308 ± 36.33	9.98–10.08	10.03 ± 0.09
7 times	5	300.00–400.00	322 ± 58.91	9.88–10.28	9.95 ± 0.25
8 times	5	250.00–390.00	342 ± 46.04	9.90–10.30	10.22 ± 0.14

acceptable error for lamellar transplantation purposes. Also, the underestimation of the intended thickness may function as a protection against accidental perforations of the cornea. However, to limit the error to this range, one should maintain the intracameral pressure at about 70 mm Hg. This value was determined by trial and error in an attempt to obtain consistent results in our experiment. In the present artificial chamber, this variable is easily controlled and monitored by the microinfuser and the digital manometer.

The CI for the diameter of the lamellae shows that, for an intended value of 10 mm, the real diameter tends to be 1% or less smaller than the programed value in 95% of the cases. This error is minimized by means of a tight fit of the corneoscleral button to the top of the artificial chamber, which is achieved only with corneoscleral buttons measuring 17 mm in diameter. Being larger than routine buttons delivered by eye banks, they involve the inconvenience of having to make special requests to these institutions.

Another important factor assuring good results is the quality of cut of the blades of the microkeratotome. The repetitive use of the same blade tends to increase the chances of undesirable events such as defects in the diameter or in the thickness of the lamellae and macroscopic irregularities in the interface between the stroma and the lamella. However, with the use of the same blade for up to 8 cuts, these events were rare and, when present, were minor. Obviously, one should not ignore the possibility of finding other optically important imperfections, under a more sophisticated scrutiny, like scanning microscopy analyses.[12] The 5 blades tested behaved similarly. The differences in mean thickness and mean diameter of the lamellae among blades were not statistically or clinically significant.

As far as we know, this is the first artificial chamber to use an automated microkeratotome. The MASYK microkeratotome[13–15] was first developed for refractive surgery. Its combination with the artificial chamber fulfills an old aspiration of corneal surgeons: to cut corneal lamellae that are similar in shape, diameter, and thickness either to the donor or to the host corneas. It also improves the chances of obtaining regular interfaces between the residual stroma and the lamellae, reducing the interface problems and favoring vision.[18,19]

The high cost of the systems for obtaining lamellar grafts is considered to be an important limiting factor of the procedure.[1,2,9] The maker of the MALKS system advertises it as being 2 to 3 times less expensive than the similar systems available. This new system for obtaining lamellae from human corneoscleral buttons seems to be a promising instrument for use in lamellar keratoplasty. The technique may be useful in obtaining precut lamellar donor tissue for distribution by eye banks.

REFERENCES

1. Barraquer JI. Lamellar keratoplasty (special techniques). *Ann Ophthalmol*. 1972;4:437–469.
2. Haimovici R, Culbertson WW. Optical lamellar keratoplasty using the Barraquer microkeratotome. *Refract Corneal Surg*. 1991;7:42–45.
3. Hanna K, David T, Besson J, et al. Lamellar keratoplasty with the Barraquer microkeratotome. *Refract Corneal Surg*. 1991;7:177–181.
4. Soong HK, Katz DG, Farjo AA, et al. Central lamellar keratoplasty for optical indications. *Cornea*. 1999;18:249–256.
5. Elkins B, Casebeer J, Kezirian G. Sutureless homoplastic lamellar keratoplasty. *J Refract Surg*. 1997;13:185–187.
6. Ruiz LA, Rowsey J. In situ keratomileusis. *Invest Ophthalmol Vis Sci*. 1988;29(Suppl):392.
7. Kim YH, Choi JS, Chun HJ, et al. Effect of resection velocity and suction ring on corneal flap formation in laser in situ keratomileusis. *J Cataract Refract Surg*. 1999;25:1448–1455.
8. Kwitko S. Microcerátomos. In: *Cirurgia Refrativa*. Rio de Janeiro, Brazil: Cultura Médica; 2003:77–85.
9. Springs CL, Joseph MA, Odom JV, et al. Predictability of donor lamellar graft diameter and thickness in an artificial anterior chamber system. *Cornea*. 2002;21:696–699.
10. Behrens A, Dolorico AMT, Kara DT, et al. Precision and accuracy of an artificial anterior chamber system in obtaining corneal lenticules for lamellar keratoplasty. *J Cataract Refract Surg*. 2001;27:1679–1687.
11. Li L, Ellis KR, Behrens A, et al. A laboratory model for microkeratotome-assisted posterior lamellar keratoplasty utilizing a running graft suture and a sutureless hinged flap. *Cornea*. 2002;21:192–195.
12. Soong HK, Mian S, Abbasi O, et al. Femtosecond laser assisted posterior lamellar keratoplasty: Initial studies of surgical technique in eye bank eyes. *Ophthalmology*. 2005;112:44–49.
13. Victor G, Alves MR, Nosé W. MASYK: specifications and development. *Arq Bras Oftalmol*. (in press).
14. Victor G, Alves MR, Nosé W. Evaluation of the cut quality of the Masyk® microkeratome in obtaining corneal flap from human eyes of an eye bank. *Arq Bras Oftalmol*. 2006;69:561–564.
15. Victor G, Alves MR, Nosé W. Evaluation of the cut quality of the Masyk® microkeratome in obtaining corneal flap from porcine eyes. *Arq Bras Oftalmol*. 2006;69:7–10.
16. Victor G, Sousa SJF, Alves MR, et al. MALKS: specifications and development. *Arq Bras Oftalmol*. 2006;69:151–155.
17. Gleason JR. Sg103 - Within subjects (repeated measures) ANOVA, including between subjects factors. *Stat Tech Bull*. 1999;47:40–45.
18. Maguen E, Azen SP, Pinhas S, et al. Evaluation of sources of variation in the accuracy and reproducibility of microkeratotome sections with the modified artificial anterior chamber. *Ophthalmic Surg*. 1982;13:217–220.
19. Azar DT, Jain S, Sambursky S, et al. Microkeratotome assisted posterior keratoplasty. *J Cataract Refract Surg*. 2001;27:353–356.

