Buttonholes in 315,259 LASIK procedures

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PURPOSE: We aimed to determine the incidence of buttonhole after laser in situ keratomileusis (LASIK). We also evaluated possible risk factors, treatment strategies and visual outcome.

SETTING: multicentric, including several international clinics.

METHODS: : In this comparative case series we reviewed the medical records of 164,603 patients (315,259 eyes) that underwent LASIK from January 2003 to December 2011 to identify cases of buttonhole. All surgeries were performed by means of a manual microkeratome. The main outcome measures were incidence of buttonhole after LASIK, response to treatment and visual outcome. Possible risk factors, clinical course, days to retreatment and surgical treatment were recorded.

RESULTS: Buttonhole was found in 137 eyes in 134 patients (105 myopes and 32 hyperopes). Age, preoperative refraction and keratometric power were not statistically significant independent risk factors. Buttonholes appeared in thinner corneas. Patients were retreated with a new flap or with surface ablation. Safety and efficacy were better with recutting than with surface ablation, although statistically significant differences were found for efficacy in the myopic group only.

CONCLUSIONS: The incidence of buttonhole after LASIK was 0.043%. Buttonhole is a potentially sight-threatening complication. Proper management can preserve useful vision in most cases.

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Laser in situ keratomileusis (LASIK) provides rapid recovery of visual acuity with a low incidence of complications; however, buttonhole may appear and can prove sight-threatening, as a result of induced irregular astigmatism[1].

As with other post-LASIK complications, the incidence of buttonhole remains difficult to estimate. Depending on the type of microkeratome used (ie, linear or rotational), incidence has been reported to vary between 0.03% and 2.6%[2-6]. The incidence of buttonholes and differences between microkeratomes and femtosecond lasers has yet to be determined in large series[7].

Because the frequency of buttonhole is low, analysis of a large series from a single center could provide more data on clinically relevant parameters and thus enable us to manage these complications more effectively. Single-center series can provide data on incidence in a setting in which most of the possible variables are controlled, because uniform protocols are followed by patients and surgeons before, during, and after surgery. However, given the low incidence of buttonhole, a large sample would be necessary to draw meaningful conclusions. Such a high number is difficult to recruit from a single center[8].

We report the largest series of buttonholes to date, with all procedures carried out in the same institution using the same microkeratome. Cases were retrospectively reviewed to provide information on clinical course, possible risk factors (age, preoperative refraction, and keratometric power), and treatment, with the aim of improving our understanding of this entity.

As treatment of buttonhole may require a different approach in hyperopic patients, we divided patients into two groups: group 1 comprised myopic patients and group 2 hyperopic patients[1].

PATIENTS AND METHODS

This retrospective case series review comprised 137 eyes with buttonhole from 134 consecutive patients who underwent LASIK at Clínica Baviera between 2003 and 2011. More than 30,000 refractive procedures are performed each year at the clinic, a private ophthalmologic institution with 19 centers and 84 surgeons throughout Spain. Patients with a diagnosis of buttonhole were identified by an electronic search of medical histories. Diagnosis of buttonhole was based on slit-lamp findings. The medical histories were reviewed to collect the following data: age, gender, eye affected, preoperative and postoperative distance corrected visual acuity (CDVA), postoperative uncorrected distance visual acuity (UDVA), possible risk factors, medical and surgical treatment, and complications. To obtain the average postoperative CDVA, we converted Snellen visual acuities to their logMAR equivalent to calculate mean final visual acuity. Data collection fulfilled Spanish legal requirements and institutional review board approval was obtained. Given the retrospective nature of the research design, no informed consent was needed.

Operative technique

Patients underwent a complete ophthalmologic examination before surgery following a standard protocol to determine whether they were suitable candidates for corneal refractive surgery. Written informed consent was obtained before surgery in each case. All procedures were performed according to standard protocols. The surgical suite met the criteria for ophthalmologic laser procedures, and all instruments were autoclaved before the procedure. Patients were instructed to perform appropriate lid hygiene during the 3 days before surgery. LASIK was performed using the Moria LSK-One manual linear microkeratome (Microtech Inc., Moria, France). The same microkeratome blade was used in both eyes when both eyes where operated on. Lamellar keratectomy was always performed first in the left eye and then in the right eye and was followed by laser ablation first in the right eye and then in the left eye using the Technolas 217C, 217-Z-100 excimer laser (Bausch & Lomb, Claremont, California, USA) or the Mel 80 excimer laser (Carl Zeiss Meditec Inc., Jena, Germany). After surgery, a topical combination of tobramycin 3 mg/ml and dexamethasone 1 mg/ml (Tobradex, Alcon Laboratories, Barcelona, Spain) was prescribed 4 times a day for 1 week together with preservative-free artificial tears. All patients were examined 12 hours, 7 days, 1 month, and 3 months after surgery, unless complications required more frequent visits.

When a procedure was canceled, the flap was replaced carefully. A new operation was performed after stabilization of both corneal topography and refraction. Management of the buttonhole involved 2 approaches: 1) creation of a new flap using the same microkeratome (trying to obtain a thicker flap with a different plate) followed by laser treatment, or 2) removal of the epithelium with alcohol or phototherapeutic keratectomy, followed by photorrefractive keratectomy, with or without mitomycin C 0.02% (MMC) applied to the central cornea for 20 seconds. The outcome measures of the study were the incidence of buttonhole, the response to treatment, and visual outcome, namely, UDVA and CDVA after the management of buttonhole (last available visit).

Visual results and predictability indicators

Efficacy. Percentage of eyes that showed equal or better postoperative UDVA than preoperative CDVA. The efficacy index was calculated as postoperative UDVA/preoperative CDVA.

Safety. Percentage of eyes that lost ≥ 2 lines of CDVA (Snellen) after the procedure. The safety index was calculated as postoperative CDVA/preoperative CDVA.

Predictability. Percentage of eyes within ± 1.00 D (spherical equivalent [SE]) of the intended correction after the procedure.

The last refraction recorded at last follow-up was used to calculate efficacy, safety, and predictability.

Statistical analysis

The homoscedasticity of quantitative variables was verified using the Kolmogorov-Smirnov test. Homoscedastic variables were assessed by testing independent group differences for continuous quantitative variables using the unpaired t-test; non-homoscedastic variables were analyzed using the Mann-Whitney test. Percentages were compared using the Pearson chi-square test. Statistical differences were considered significant when the P value was less than 0.05. Statistical analysis was performed using SPSS for Mac (version 20.0, SPSS, Inc.).

Table 1. Preoperative data and ring used

		Buttonhole	No buttonhole	p
Gender	**Male (N)**	57 pat. (1 bilateral)	78,356	0.24
	Female (N)	77 pat. (2 bilateral)	86,113	
Age (years)		34.84 ± 9.63	35.10 ± 9.56	
Myopic LASIK (N)		105	244,013	0.82
Hyperopic LASIK (N)		32	71,109	
Mean K (D)		43.92 ± 1.56	43.64 ± 2.26	0.15
N of eyes with MK <41 D		3	8,029	
N of eyes with MK 41 to 46 D		123	292,761	0.14
N of eyes with MK >46 D		11	14,332	
Cylinder (D)		–1.24 ± 0.92	–1.12 ± 0.86	0.10
Corneal central US pachymetry (microns)		546 ± 32	553 ± 30	
Eye	**N in 1st eye (LE)**	87	-	-
	N in 2nd eye (RE)	50	-	-
Plate	**80 µm**	10	23,777	
	100 µm	117	274,488	0.59
	130 µm	10	16,825	
Ring (N)	**–1**	67	164,982	
	–2	5	11,477	0.71
	H	65	138,529	

RESULTS

During the study period, 315,259 LASIK procedures were performed on 164,603 patients. We identified 137 eyes with buttonhole in 134 patients (77 women, 57 men; incidence, 0.043%). Mean age was 34.84 ± 9.63 years (range, 20–62). We found that 87 buttonholes (63.50%) involved the first eye (left eye) and 50 (36.50%) involved the second (right). Buttonhole was bilateral in 3 patients (see Table 1).

A total of 105 (76.64%) buttonholes presented in cases with myopic spherical equivalent (Group 1) and 32 (23.36%) in cases with hyperopic spherical equivalent (Group 2). Mean sphere and cylinder can be seen in Tables 2 and 3, and every attempted refraction in Figures 3 and 8.

No statistically significant differences in the incidence of buttonhole were found according to the preoperative mean keratometry or amount of the cylinder. No differences were found between the plate or the suction ring used when creating the flap. Corneas with buttonhole were thinner (p = 0.006).

In Group 1, 69 cases (65.71%) were managed with the microkeratome and 28 (26.67%) with surface ablation. In Group 2, 19 cases (59.38%) were managed with new usage of the microkeratome and 7 (21.88%) with surface ablation. The remaining patients were lost to follow-up and not retreated at our institution. Mean time from buttonhole to recut was 81 days in the myopic group and 132 days in the hyperopic group. Mean time to surface ablation was 77 days in both groups.

In both groups, efficacy and safety were better with recutting than with surface ablation, although statistically significant differences were only found for efficacy in Group 1 (see Tables 2 and 3 and Figures 1 and 2)[9].

DISCUSSION

We found an incidence of 0.043% (1 case in 2,325.58 procedures). To our knowledge, this is the largest series of post-LASIK buttonholes reported to date. Although lower, our incidence is consistent with that reported by Jacobs et al.[6], with an estimated rate of 0.070% from 84,711 eyes.

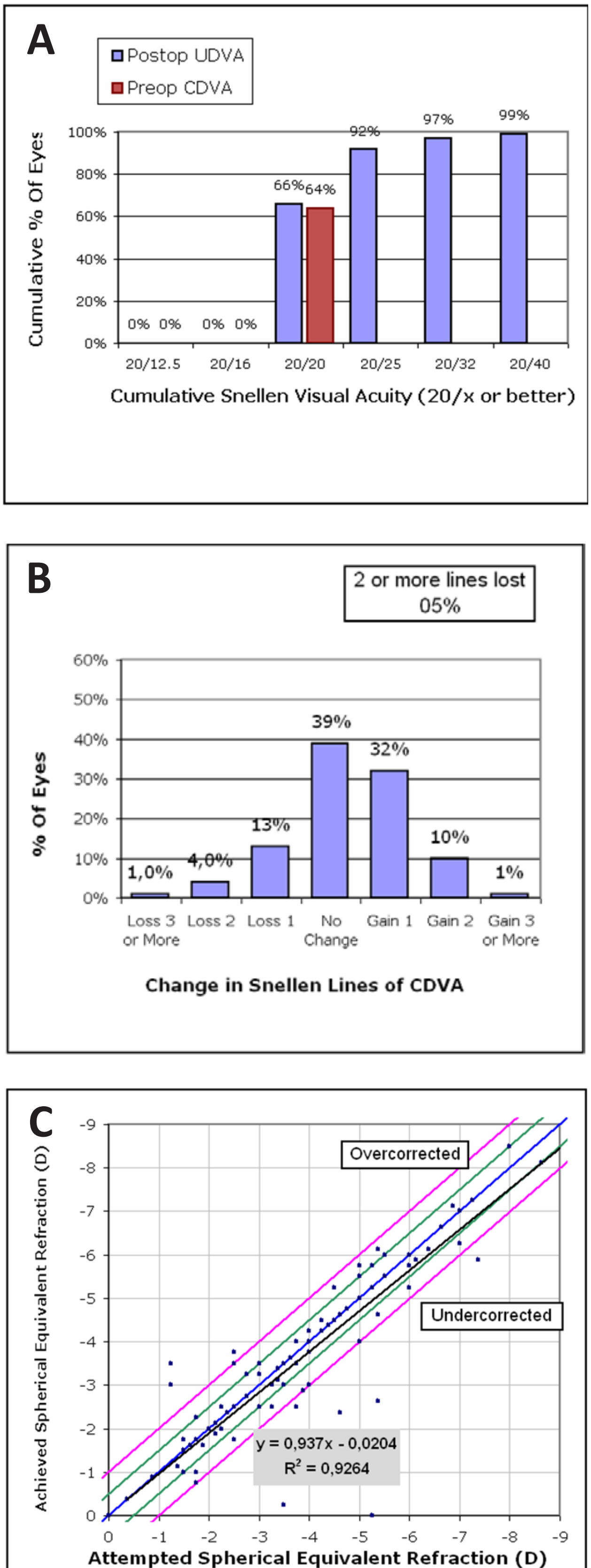
Buttonhole occurs when the microkeratome blade travels more superficially than intended and enters the epithelium–Bowman layer complex. Buttonholes can be of full or partial thickness depending on whether the

Table 2. Myopic group (105 eyes: 44 male patients/ 59 female patients)

	New flap	Surface ablation	p
N	69	28	
Time from buttonhole to new surgery (days)	81 ± 48	77 ± 36	
Preop CDVA (logMAR)	0.07 ± 0.09	0.04 ± 0.06	0.11
Preop mean K (D)	44.28 ± 1.44	44.19 ± 1.54	0.78
Preop Sphere (D)	–3.77 ± 2.65	–3.18 ± 1.67	0.28
Preop Cylinder (D)	–0.95 ± 0.78	–1.2 ± 1.08	0.20
Last postop UDVA (logMAR)	0.07 ± 0.11	0.13 ± 0.23	0.10
Last postop CDVA (logMAR)	0.03 ± 0.05	0.05 ± 0.09	0.17
Efficacy index	1.01 ± 0.14	0.89 ± 0.28	
Safety index	1.06 ± 0.11	1.00 ± 0.16	
Predictability ± 0.5 D	65%	71%	0.57
Predictability ± 1 D	82%	82%	1

Table 3. Hyperopic group (32 eyes: 13 male patients/ 18 female patients)

	New flap	Surface ablation	p
N	19	7	
Time from buttonhole to new surgery (days)	132 ± 228	77 ± 46	
Preop CDVA (logMAR)	0.18 ± 0.30	0.06 ± 0.06	0.39
Preop mean K (D)	42.93 ± 1.31	43.45 ± 2.17	0.46
Preop Sphere (D)	2.74 ± 1.09	2.50 ± 1.44	0.65
Preop Cylinder (D)	–2.01 ± 1.73	–2.36 ± 1.38	0.63
Last postop UDVA (logMAR)	0.15 ± 0.16	0.13 ± 0.08	0.85
Last postop CDVA (logMAR)	0.12 ± 0.15	0.06 ± 0.06	0.32
Efficacy index	1.03 ± 0.19	0.87 ± 0.18	0.06
Safety index	1.04 ± 0.22	1.01 ± 0.17	0.75
Predictability ± 0.5 D	58 %	57 %	0.81
Predictability ± 1 D	74 %	100 %	0.14



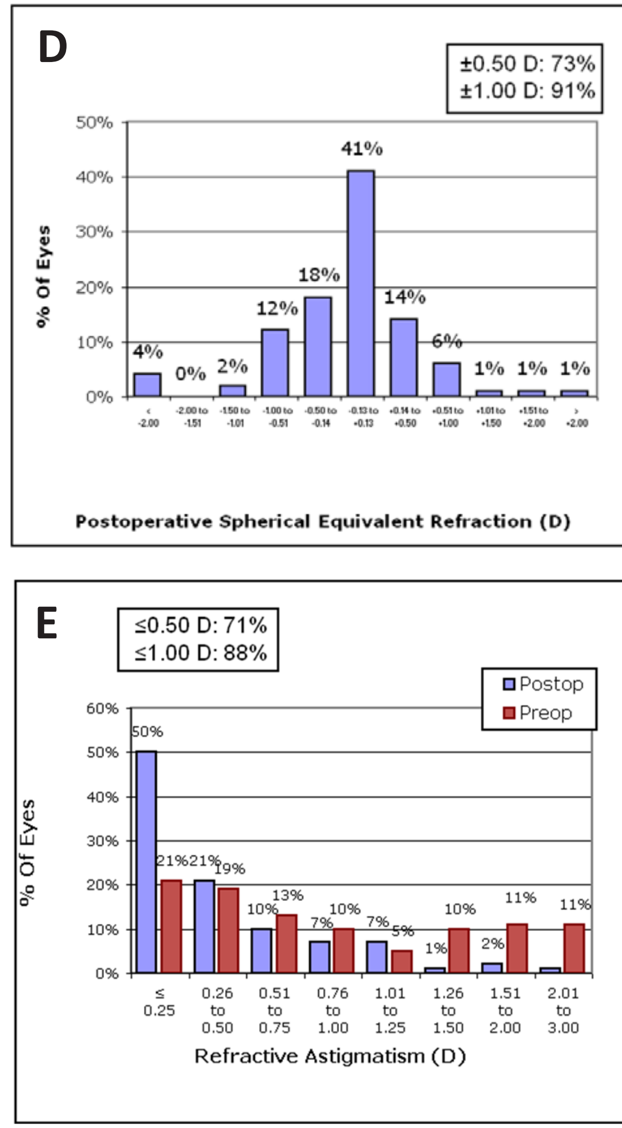
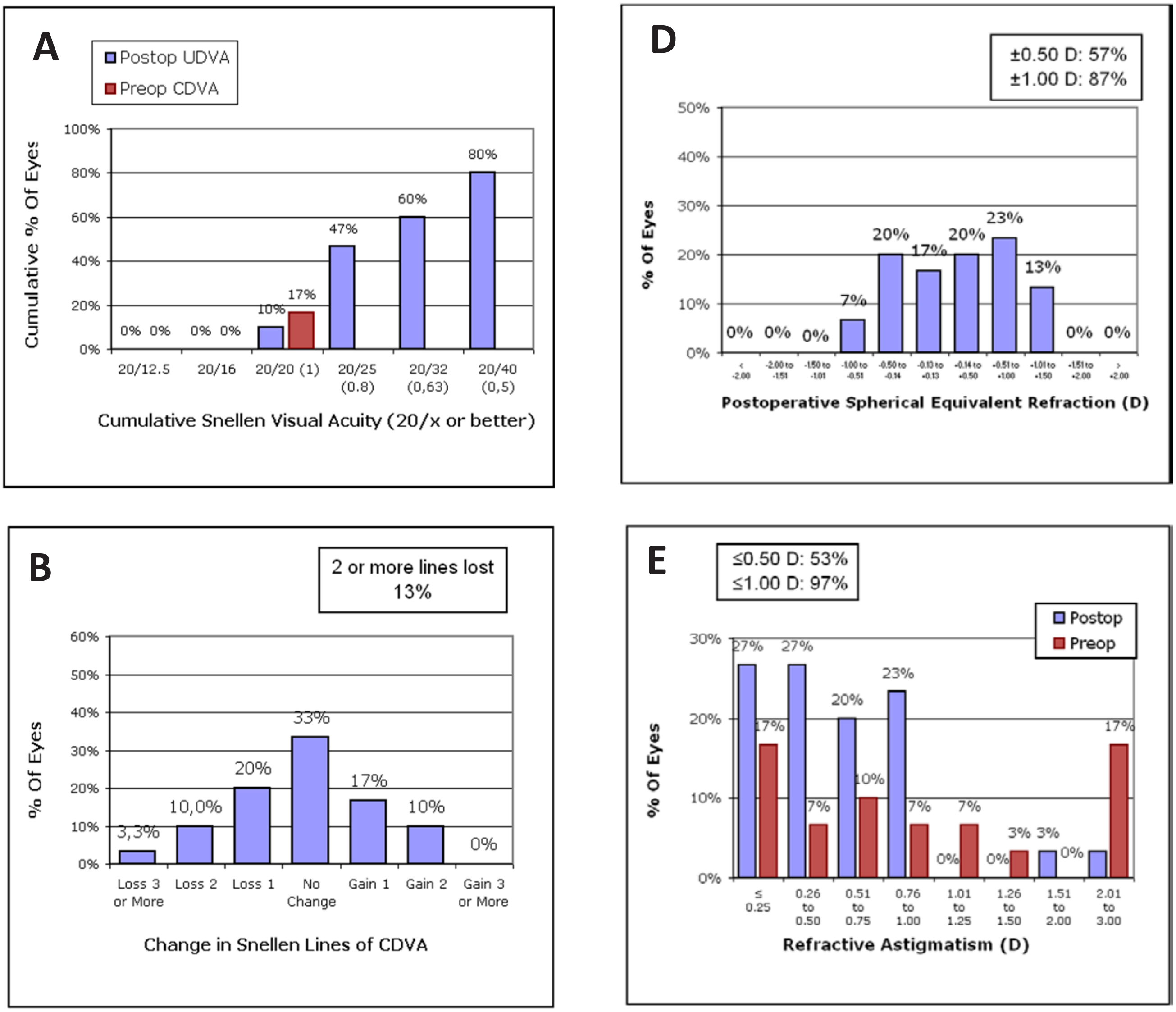


Figure 1. Results of Group 1
A. Uncorrected distance visual acuity.
B. Change in corrected distance visual acuity.
C. Spherical equivalent attempted vs achieved.
D. Spherical equivalent refractive accuracy.
E. Refractive astigmatism.

blade exits the overlying epithelium. In partial-thickness buttonholes, also called occult or near buttonholes, the flap defect does not extend above the Bowman layer[10].

Several causes have been proposed. Gimbel et al.[2] suggested that steep corneas are predisposed to buttonhole formation during LASIK. Steep corneas and lack of synchronization between the translational keratome movement and oscillatory blade movement have been suggested as causes[2,11]. In our case series, the mean keratometry reading was 43.92 ± 1.56 D. This is not consistent with steep curvature, although it is similar to that reported by Albelda-Vallés et al.[12], who also



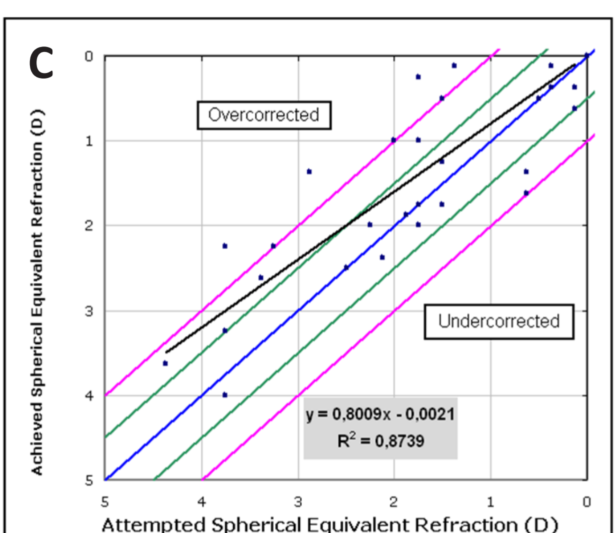


Figure 2. Results of Group 2

A. Uncorrected distance visual acuity.
B. Change in corrected distance visual acuity.
C. Spherical equivalent attempted vs achieved.
D. Spherical equivalent refractive accuracy.
E. Refractive astigmatism.

found no relationship between steep keratometry and buttonhole. As with Lichter et al.[13], we found that age, preoperative refraction, and keratometric power did not reach statistical significance as independent risk factors.

According to Harissi-Dagher[1], the most likely etiology of buttonhole seems to be microsuction loss. Pulaski[14] postulated that a partially opened eye can lead to dessication and thinning of the central cornea, which may result in a buttonhole during the keratome pass. Poor blade quality has also been suggested as a cause[4]. High astigmatism can sometimes compromise the adherence of the suction ring to the cornea[15].

Bilateral buttonholes were found in three patients. The blade is not routinely changed between eyes. Some clinicians recommend performing monocular surgery or using separate instruments when performing bilateral surgery[16], although this is not the practice of the members of the ASCRS Cornea Clinical Committee[17].

As observed by Albelda-Vallés et al.[11], we found more buttonholes in the first eye than in the second, although this finding is not consistent with those of other authors[12,18,19]. Consistent with the recommendations of other authors, all the surgeons canceled the procedure if a buttonhole was encountered, except in three cases[1,4,13]. We now recommend cancelling the procedure.

An interval of at least 3 months is usually recommended before re-attempting LASIK[11]. We waited until stabilization of both corneal topography and refraction was achieved. According to our data, we advise waiting at least two months before performing a surface ablation and three months before creating a new flap. The flap in the second treatment only works if the flap has had time to completely heal.

Our hyperopic patients achieved worse results than myopes; this fact was not confirmed in previous studies. In myopic cases, recutting seems to be a better approach than surface ablation. In cases of corneal scar, the surgeon usually prefers surface ablation. Consequently, cases in which surface ablation was applied may have been more difficult to treat. As no significant complications appeared in the cases in which MMC 0.02% was applied to the central cornea for 20 seconds, we recommend it be used to prevent corneal haze.

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