Flap Loss in More Than 1 Million LASIK Procedures: Incidence, Management, and Visual Outcomes

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ABSTRACT

PURPOSE: To analyze the incidence of flap loss in laser in situ keratomileusis (LASIK), management of this complication, and visual outcomes.

METHODS: This multicenter, multisurgeon, single-protocol, retrospective case series study enrolled patients who had undergone LASIK and experienced flap loss. Patients were operated on using a Moria LSKONE or a Moria One-Use-Plus-SBK microkeratome (Microtech Inc, Moria Ophthalmic Instruments). The study assessed uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), predictability (accuracy to the intended target), safety (change in Snellen lines of CDVA), and efficacy (difference between UDVA and CDVA). A control group was created to compare refractive outcomes, predictability, safety, and efficacy for eyes with flap loss and patients whose LASIK procedure was free of complications.

RESULTS: The analysis included 1,008,849 eyes. Flap loss occurred in 16 eyes from 16 patients. Patients received topical mitomycin C (MMC) after flap loss in 9 cases (7 did not receive MMC). A bandage contact lens was applied in all 9 cases. Mean UDVA was significantly worse in the group of patients with a flap loss (P = .013), although the difference in CDVA was not (P = .077). Both the mean efficacy index and the mean safety index were significantly worse in patients with flap loss (P = .004 and .02, respectively).

CONCLUSIONS: Flap loss is an extremely rare complication after LASIK. It can be managed with MMC and a bandage contact lens, with a reasonable safety index and visual outcomes.

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Laser in situ keratomileusis (LASIK) is one of the most commonly performed refractive surgeries worldwide. Although rare, flap-related complications can occur during or after surgery and sometimes lead to significant visual loss. LASIK involves the creation of a hinged corneal flap, which is then lifted, enabling the excimer laser to be applied over the corneal stromal bed. When the hinge of the flap detaches from the cornea, the flap is called a free flap or free cap. This is a rare intraoperative complication, mostly associated with the microkeratome. Corneas with flat keratometry, deep orbits, or decentered suction rings may predispose to a low lenticule diameter and a free flap.

The incidence of flap loss varies from 0.004% to 5.9% depending on the study and the method used to create the flap.[1-5] If adequately managed, free caps do not lead to significant or permanent vision loss. However, free flaps can also be lost after surgery, and hinged flaps can be lost as a result of eye trauma months or years after the surgical procedure, especially when the LASIK flap is created with a microkeratome and not a

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TABLE 1

Demographic Data

Characteristic	Control (n = 16)	Study (n = 16)	Total (n = 32)	*P*
OD / OS (%)	7 / 9 (43.8 / 56.2)	9 / 7 (56.2 / 43.8)	16 / 16 (50.0 / 50.0)	.724[a]
Male / Female (%)f	6 / 10 (37.5 / 62.5)	6 / 10 (37.5 / 62.5)	12 / 20 (37.5 / 62.5)	1.000[a]
Age (years), mean ± SD (range)	35.1 ± 9.6 (20.2, 53.6)	35.1 ± 8.5 (20.0, 50.5)	35.1 ± 8.9 (20.0, 53.6)	.985[b]

OD = right eye; OS = left eye; SD = standard deviation
[a]*Fisher's exact test.*
[b]*t-test.*

femtosecond laser.[6] Flap loss can induce corneal haze and irregular astigmatism, which could lead to significant visual impairment.

To our knowledge, the incidence of flap loss has only been addressed in case reports, but not in large series. The objectives of this study were to analyze the demographic, visual, and refractive data of a large series of patients who experienced flap loss after LASIK surgery and to compare them with a control group in which this complication did not occur.

PATIENTS AND METHODS

We performed a retrospective study based on data from our institution for the period January 2012 to January 2024. The data collected included age, sex, visual acuity, preoperative refractive data, and postoperative visual and refractive data at the last available visit. The procedure that was performed to manage the complication was also collected; it included the use of mitomycin C (MMC) and a contact lens bandage. This multicenter, multisurgeon, single-protocol, retrospective case series study enrolled patients who had undergone LASIK and experienced flap loss.

The research is based on data recorded from the central computerized clinical records system at Clinica Baviera, Spain. The data were recorded anonymously using identifiers linked to the patients. Given its retrospective nature, the study was approved by our institutional legal and ethics committee as an exempt review (Ethics Committee of Clinica Baviera, Spain). The study adhered to the tenets of the Declaration of Helsinki. All patients received detailed information and gave their written informed consent before undergoing LASIK surgery and for the use of their anonymous and aggregated medical data for clinical research.

LASIK was performed using two microkeratomes with nasal hinges: the Moria LSK ONE and the Moria One-Use-Plus-SBK (Microtech Inc, Moria Ophthalmic Instruments). The excimer laser models used for laser vision correction with surface ablation were the Technolas 217C and 217-Z-100 (Bausch & Lomb, Inc), Teneo (Bausch & Lomb, Inc), MEL 80 and MEL 90 (Carl Zeiss Meditec AG), Schwind Amaris 500 (SCHWIND eye-tech-solutions GmbH), and WaveLight-Allegretto Wave-Eye-Q (Alcon Laboratories, Inc).

Snellen visual acuity was converted to logarithm of the minimum angle of resolution (logMAR) visual acuity. Efficacy was defined as preoperative logMAR corrected distance visual acuity (CDVA) – postoperative logMAR uncorrected distance visual acuity (UDVA). Safety was defined as preoperative logMAR CDVA – postoperative logMAR CDVA. Predictability was defined as the postoperative accuracy of spherical equivalent to intended target. The occurrence of flap loss, the time between occurrence of the complication and final visual acuity, and loss of efficacy and safety were also recorded.

A control group was created to compare the results of the eyes of patients who experienced flap loss with those of patients whose LASIK procedure was free of complications. Eyes were matched by age, sex, and preoperative sphere, cylinder, and CDVA with nearest neighbor matching and distance defined by propensity scores from the generalized linear model. Five eyes were selected from the database for every eye with a lost flap (80 eyes); then one eye, from those five, with a follow-up visit close to each study eye was selected to create the control group (16 eyes).

STATISTICAL ANALYSIS

The differences between the matched groups were assessed using either the Mann-Whitney test or an independent *t*-test, depending on whether the assumptions of the parametric *t*-test were satisfied. Normality was assessed using the Shapiro-Wilk test, and the presence of outliers was determined using the box-plot method. The inferential results are reported as value, effect size, and *P* value. Fisher's exact test was applied to assess differences in factor variables.

RESULTS

A total of 1,008,849 consecutive eyes underwent LASIK during the study period. A free flap occurred in 10,520 eyes (1.04%). The flap was lost in 16 eyes, 12 of them with a free flap and 4 with a narrow hinge (after

TABLE 2

Preoperative Data

Parameter	Control (n = 16)	Study (n = 16)	Total (N = 32)	*P*
Sphere (D)				
Median (Q1, Q3)	-1.62 (-3.06 to 0.00)	-1.50 (-3.12 to +0.06)	-1.50 (-3.06 to 0.00)	.986[a]
Mean ± SD (range)	-1.50 ± 2.51 (-6.00 to +3.00)	-1.48 ± 2.56 (-6.00 to +3.00)	-1.49 ± 2.49 (-6.00 to +3.00)	
Cylinder (D)				
Median (Q1, Q3)	-2.12 (-2.50 to -0.75)	-1.88 (-2.50 to -0.69)	-2.00 (-2.50 to -0.75)	.939[a]
Mean ± SD (range)	-1.77 ± 1.13 (-3.50 to 0.00)	-1.73 ± 1.15 (-3.50 to 0.00)	-1.75 ± 1.12 (-3.50 to 0.00)	
Spherical equivalent (D)				
Median (Q1, Q3)	-2.25 (-3.62 to -1.22)	-2.12 (-3.66 to -1.22)	-2.12 (-3.62 to -1.22)	0.971[b]
Mean ± SD (range)	-2.38 ± 2.38 (-7.25 to 1.75)	-2.35 ± 2.44 (-7.25 to 2.12)	-2.37 ± 2.37 (-7.25 to 2.12)	
UDVA (logMAR)				
Median (Q1, Q3)	0.73 (0.70 to 1.39)	1.00 (0.52 to 1.52)	0.78 (0.54 to 1.52)	1.000[b]
Mean ± SD (range)	0.96 ± 0.54 (0.40 to 2.00)	1.02 ± 0.54 (0.32 to 2.00)	0.99 ± 0.53) (0.32 to 2.00)	
CDVA (logMAR)				
Median (Q1, Q3)	0.01 (-0.00 to 0.05)	0.02 (-0.00 to 0.04)	0.02 (-0.00 to 0.05)	0.938[b]
Mean ± SD (range)	0.08 ± 0.15 (-0.00 to 0.52)	0.08 ± 0.15 (-0.02 to 0.40)	0.08 ± 0.15 (-0.02 to 0.52)	

CDVA = corrected distance visual acuity; D = diopters; logMAR = logarithm of the minimum angle of resolution; SD = standard deviation; UDVA = uncorrected distance visual acuity
[a]*t-test.*
[b]*Mann-Whitney test.*

TABLE 3

Postoperative Refractive Data

Parameter	Control (n = 16)	Study (n = 16)	Total (N = 32)	*P*
Follow-up (days)				
Median (Q1, Q3)	205.0 (133.8 to 254.0)	225.5 (206.0 to 289.8)	215.0 (161.5 to 284.8)	.169[a]
Sphere (D)				
Median (Q1, Q3)	0.00 (-0.25 to 0.00)	0.12 (-0.88 to +0.62)	0.00 (-0.50 to +0.50)	.490[a]
Mean ± SD (range)	-0.17 ± 0.58 (-1.75 to +0.50)	-0.11 ± 2.34 (-5.25 to +5.00)	-0.14 ± 1.68 (-5.25 to +5.00)	
Cylinder (D)				
Median (Q1, Q3)	-0.38 (-0.56 to 0.00)	-1.12 (-1.81 to -0.69)	-0.62 (-1.06 to -0.19)	< .001[a]
Mean ± SD (range)	-0.34 ± 0.35 (-1.00 to 0.00)	-1.56 ± 1.30 (-4.50 to 0.00)	-0.95 ± 1.12 (-4.50 to 0.00)	
Spherical equivalent (D)				
Median (Q1, Q3)	0.00 (-0.50 to 0.00)	0.00 (-2.25 to +0.25)	0.00 (-0.91 to 0.00)	.923[a]
Mean ± SD (range)	-0.34 ± 0.63 (-2.12 to +0.25)	-0.89 ± 2.15 (-5.88 to +3.12)	-0.62 ± 1.59 (-5.88 to +3.12)	
UDVA (logMAR)				
Median (Q1, Q3)	0.02 (-0.00 to 0.05)	0.35 (0.03 to 0.64)	0.05 (0.01 to 0.45)	.013[a]
Mean ± SD (range)	0.12 ± 0.28) (-0.08 to 1.00)	0.44 ± 0.52 (-0.00 to 2.00)	0.28 ± 0.44 (-0.08 to 2.00)	
CDVA (logMAR)				
Median (Q1, Q3)	0.02 (-0.00 to 0.05)	0.06 (0.02 to 0.22)	0.04 (-0.00 to 0.14)	.077[a]
Mean ± SD (range)	0.06 ± 0.14 (-0.08 to 0.52)	0.13 ± 0.15 (-0.00 to 0.46)	0.10 ± 0.15 (-0.08 to 0.52)	

CDVA = corrected distance visual acuity; D = diopters; logMAR = logarithm of the minimum angle of resolution; SD = standard deviation; UDVA = uncorrected distance visual acuity
[a]*Mann-Whitney test.*

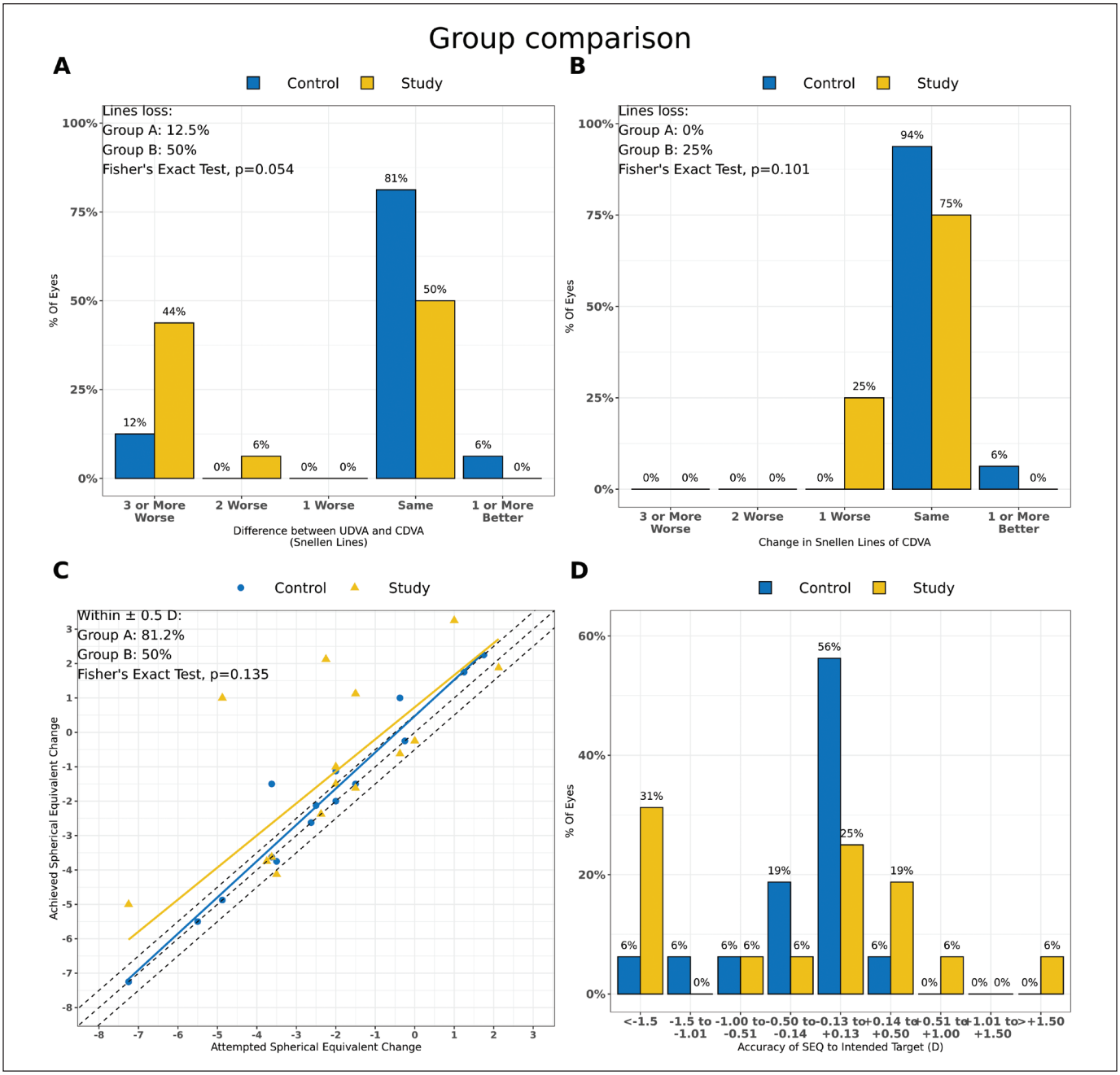

Figure 1. (A) Efficacy, (B) safety, (C) attempted vs achieved spherical equivalent, and (D) predictability in the control (group A) and study (group B) groups. D = diopters

surgery, presumably due to rubbing or trauma). In 8 eyes, the free flap was lost during surgery; the other 8 eyes, including those with a narrow hinge, lost the flap after surgery. No patient experienced flap loss in both eyes. The incidence of flap loss in patients with a free flap was 0.1141% (overall incidence of flap loss, 0.0016%).

Demographic data of the eyes with flap loss (study group) and the control group are shown in **Table 1**. Preoperative data are shown in **Table 2**.

Postoperative mean follow-up time was 225.5 days (interquartile range: 206.0 to 289.8). There were no statistically significant differences in sphere and spherical equivalent between the study and control groups; however, mean cylinder was higher in the study group ($P < .001$). Mean UDVA was significantly worse in the study group (0.35 vs 0.02 logMAR; $P = .013$), but the difference in CDVA was not (0.06 vs 0.02 logMAR; $P = .077$) (**Table 3**).

TABLE 4

Predictability, Efficacy, and Safety

Parameter	Control (n = 16)	Study (n = 16)	Total (N = 32)	*P*
Predictability ±0.50 D				
No	3 (18.8%)	8 (50.0%)	11 (34.4%)	.135[a]
Yes	13 (81.2%)	8 (50.0%)	21 (65.6%)	
Predictability ±1.00 D				
No	2 (12.5%)	6 (37.5%)	8 (25.0%)	.220[a]
Yes	14 (87.5%)	10 (62.5%)	24 (75.0%)	
Efficacy index				
Median (Q1, Q3)	1.00 (0.94, 1.07)	0.67 (0.36, 0.95)	0.94 (0.40, 1.00)	.004[b]
Mean ± SD (range)	0.97 ± 0.29 (0.30, 1.50)	0.62 ± 0.36 (0.01, 1.09)	0.80 ± 0.37 (0.01, 1.50)	
Efficacy (no change or gain)				
No	2 (12.5%)	8 (50.0%)	10 (31.2%)	.054[a]
Yes	14 (87.5%)	8 (50.0%)	22 (68.8%)	
Safety index				
Median (Q1, Q3)	1.00 (0.99, 1.11)	0.95 (0.84, 0.99)	0.99 (0.90, 1.00)	.002[b]
Mean ± SD (range)	1.06 ± 0.15 (0.90, 1.50)	0.89 ± 0.14 (0.65, 1.09)	0.97 ± 0.17 (0.65, 1.50)	
Safety (no change or gain)				
No	0 (0.0%)	4 (25.0%)	4 (12.5%)	.101[a]
Yes	16 (100.0%)	12 (75.0%)	28 (87.5%)	

D = diopters; SD = standard deviation
[a]*Fisher's exact test.*
[b]*Mann-Whitney test.*

TABLE 5

Description of Flap Loss of Every Patient

Case	Eye	Flap Loss	MMC (Time)	Free Flap	Other Data
1	OD	Intraoperative	60″	Yes	
2	OD	Intraoperative	N/A	Yes	PRK 1 month later
3	OS	Intraoperative	30″	Yes	No ablation treatment
4	OS	Intraoperative	25″	Yes	
5	OS	1 day	N/A	No	
6	OS	1 day	30″	Yes	WFG PRK 2 months later
7	OD	Intraoperative	15″	Yes	
8	OD	< 24 hours	30″	Yes	
9	OD	Intraoperative	N/A	Yes	No ablation treatment
10	OD	1 day	40″	Yes	PRK 10 months later
11	OS	< 24 hours	60″	No	
12	OD	< 24 hours	40″	No	
13	OS	Intraoperative	N/A	Yes	
14	OS	4 days	N/A	No	
15	OD	6 days	N/A	Yes	
16	OD	Intraoperative	N/A	Yes	

MMC = mitomycin C; OD = right eye; OS = left eye; N/A = not available; PRK = photorefractive keratectomy; WFG = wavefront-guided

Both the mean efficacy index and the mean safety index were significantly worse in the flap loss cases (0.67 vs 1.00 [P = .004] and 0.95 vs 1.00 [P = .02], respectively) (**Figures 1A-1B**), and although predictability was better in the control group, there were no statistically significant differences with the study group (**Table 4** and **Figures 1C-1D**).

Nine of the patients received topical MMC (0.02%). A bandage contact lens was applied in all cases. Two patients in whom the flap was lost during surgery did not receive ablation treatment afterward. Three of the patients needed enhancement treatment with photorefractive keratectomy (**Table 5**).

DISCUSSION

Flap dislocation is the most frequently described complication of LASIK after ocular trauma,[7] even with minor incidents, especially within the first postoperative week. We previously reported that late dislocation of the corneal flap due to trauma has a prevalence of 0.0122%.[8]

The presence of a free cap may facilitate loss in the event of ocular trauma, thus complicating the posttraumatic visual recovery process. However, flap loss usually occurs within the first week after surgery, mostly because of minor trauma after eyelid squeezing and eye rubbing.[6,9-12] In our series, 8 of the 16 patients lost a flap during the first days after surgery.

Free flaps have been associated with flat corneas, deep orbits, decentered suction rings, and inadequate suction.[1] The incidence of free flaps depends on the microkeratome used, and comparisons between different devices have been published. Some authors describe a significantly lower incidence of free flaps with the Bausch & Lomb Hansatome than with the Chiron Automated Corneal Sharper and the Nidek MK-2000.[5,13] Al-Mezaine et al[14] did not find significant differences in the incidence of free flap between the Hansatome and the Carriazo-Barraquer Moria LSK2.

Free flaps may occur—albeit less frequently—after femtosecond laser–assisted LASIK (FS-LASIK). Schallhorn et al[2] reported an incidence of 0.005% using a Johnson & Johnson Vision Care IntraLase iFS or FS-60 device. The incidence of free flaps is therefore clearly greater in flaps created with a microkeratome than in those created using FS-LASIK. Moreover, flap adhesion has been shown to be significantly superior in FS-LASIK. Thus, the occurrence of lost flaps, although extremely rare, seems more likely after microkeratome LASIK, as in our series, than after FS-LASIK.

Visual outcomes after flap loss have received little attention in the literature. Outcomes are generally good, irrespective of whether MMC, photorefractive keratectomy, or contact lenses are used, with overall CDVA ranging from 20/20 to 20/15.[6,11,12] In our study, we found no difference in CDVA between the groups (study and control), with a mean of 0.06 versus 0.02 logMAR, respectively (P = .077), consistent with previously published results.[11,12] However, visual outcomes resulted in 4 of the eyes having loss of lines of CDVA. Two of the eyes did not undergo excimer laser ablation, leading to a lower, but not statistically significant, predictability in the study group. As other authors have reported, some of our cases subsequently required photorefractive keratectomy.[12]

CONCLUSION

Considering the potential severity of this complication, our study reinforces and supports the conclusion that proper management of a lost flap can restore good visual acuity to the affected eye. We found that the management of flap loss with the use of MMC and a bandage contact lens is reasonable, as previously proposed in a case report where the authors reported a favorable outcome.[6]

AUTHOR CONTRIBUTIONS

Study concept and design (JO-U, FM-C, KL, Julio Baviera-Sabater, FL-O); data collection (Jaime Beltrán-Sanz); analysis and interpretation of data (RB-C, AL-R, KL, Julio Baviera-Sabater); writing the manuscript (JO-U, RB-C); critical revision of the manuscript (FM-C, AL-R, Jaime Beltrán-San, KL, Julio Baviera-Sabater, FL-O); statistical expertise (Jaime Beltrán-Sanz); administrative, technical, or material support (Jaime Beltrán-Sanz, FL-O); supervision (Julio Baviera-Sabater)

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