# Intraocular Lens Power Calculation After Double Keratorefractive Procedures: A Case Series

# Cálculo do Poder da Lente Intraocular Após Duplo Procedimento Queratorrefrativo: Uma Série de Casos



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# ABSTRACT

**INTRODUCTION:** Our purpose was to report the results of intraocular lens (IOL) power calculation in patients who received two sequential keratorefractive procedures.

**METHODS:** Biometry data were collected using IOL Master 500 and 700. Formulas available at the American Society of Cataract and Refractive Surgery (ASCRS) online calculator, PEARL-DGS and Emmetropia Verifying Optical (EVO) formulas were used.

**RESULTS:** Seven eyes of 6 myopic patients were enrolled. Six eyes have been submitted to radial keratotomy (RK) and laser-assisted *in situ* keratomileusis (LASIK) and one eye had a history of RK followed by a photorefractive keratectomy (PRK). The ASCRS formulas and PEARL-DGS for prior RK conditions were found to have the greater predictability for patients with 8 or more RK. For those with only 4 RK, the most predictable formulas were those from ASCRS for prior myopic LASIK/PRK condition and EVO and PEARL-DGS formulas.

**CONCLUSION:** The IOL power calculation for patients with history of keratorefractive surgery remains a challenging and there is still lack of evidence and consensus for these scenarios.

**KEYWORDS**: Biometry; Keratomileusis, Laser In Situ; Keratotomy, Radial; Lenses, Intraocular; Photorefractive Keratectomy.

#### RESUMO

**INTRODUÇÃO:** O nosso objetivo foi relatar os resultados do cálculo da potência de lente intraocular (LIO) em pacientes submetidos a dois procedimentos queratorrefrativos sequenciais.

**MÉTODOS:** Os dados de biometria foram obtidos com os IOL Master 500 e 700. Foram usadas as fórmulas disponíveis no calculador *online* da Sociedade Americana de Catarata e Cirurgia Refrativa (ASCRS) e as fórmulas *Emmetropia Verifying Optical* (EVO) e PEARL-DGS.

**RESULTADOS:** Foram incluídos sete olhos de 6 pacientes míopes. Seis olhos foram submetidos a queratotomia radiárias (RK) e queratomileuse local assistida por laser (LASIK) e

um olho a RK seguida de queratectomia fotorrefrativa (PRK). As fórmulas da ASCRS e a PEARL-DGS para olhos com RK prévias têm maior previsibilidade para casos com 8 ou mais RK. Para os olhos com apenas 4 RK, as fórmulas mais previsíveis foram as da ASCRS para olhos previamente submetidos a LASIK/PRK e as fórmulas EVO e PEARL-DGS.

**CONCLUSÃO:** O cálculo do poder da LIO para pacientes com histórico de cirurgia queratorrefrativa permanece um desafio e ainda faltam evidências e consenso para esses cenários.

PALAVRAS-CHAVE: Biometria; Lentes Intraoculares; Queratomileuse por Laser In Situ; Queratectomia Fotorrefractiva; Queratotomia Radiária.

## **INTRODUCTION**

Cataract surgery is the most commonly performed refractive procedure worldwide. Corneal refractive surgery has been used for nearly three decades and many treated patients are now developing senile cataracts.<sup>1</sup> Thus, patients with past history of keratorefractive surgery will represent a significant proportion of the patients with cataracts in the near future.<sup>2</sup> While corneal refractive surgery achieves excellent results of uncorrected distance visual acuity, it increases the complexity of accurate intraocular lens (IOL) power calculation.<sup>3</sup> This complexity increases in patients who have been submitted to a second keratorefractive surgery for enhancement of the first procedure.

The development of the American Society of Cataract and Refractive Surgery (ASCRS) IOL power calculator (https://iolcalc.ascrs.org) has allowed IOL calculation for prior keratorefractive surgery to be more efficient and precise. For the IOL Master biometer and using only postoperative data, Haigis-L,4 Shammas5 and Barrett True K no history<sup>6</sup> are the formulas available for prior laser-assisted in situ keratomileusis (LASIK) and photorefractive keratectomy (PRK), whereas only Barrett True-K (BTrueK-RK) 6 and the double-K modification of the Holladay 1 formula7 are the options for prior radial keratotomy (RK). A recent systematic review8 demonstrated that Barrett True-K no history seems to have the best performance for IOL power calculations after laser vision correction, with some studies reported 70% of the eyes within ±0.50 D of the target. In eyes submitted to RK, Barret True-K, both history and no history versions, and Haigis formulas were found to have a good performance with 69.2% of the eyes within ±0.50 D of target.9 The Emmetropia Verifying Optical (EVO) Formula (free available at http://www.evoiolcalculator.com) is a new formula that has an option for previous myopic LASIK/PRK correction. The PEARL-DGS formula has a module for complex eyes, including post-laser vision correction (LVC), RK, non-physiologic corneas and implantable collamer lens, and, recently, it was shown to have a better performance than Hoffer-QST, Barrett True K, Shammas-PL, and Haigis-L for IOL power calculation in postmyopic LVC eyes without constant optimization.<sup>10</sup> So far, no study assessed the performance of these two formulas on prior double keratorefractive patients.

To our best knowledge, there are few cases in the lit-

erature concerning the IOL power calculation after two keratorefractive surgeries. In this work, we report the comparison of the ASCRS, and EVO formulas for six patients (7 eyes) with previous history of a RK later enhanced with LASIK/PRK.

#### **METHODS**

This is a case series enrolling all patients with history of double keratorefractive surgery submitted to phacoemulsification at a tertiary hospital center (Unidade Local de Saúde de Santo António, Porto, Portugal). This study was conducted in compliance with the Declaration of Helsinki and complied with the requirements of the institute's committee on human research. All patients signed informed consent for the procedure.

Demographics and clinical variables were retrieved from medical records. Keratometry and biometry data of these patients were collected using IOL Master 500 (case 1) and 700<sup>®</sup> (cases 2 to 6). The predicted refraction of each formula available at the ASCRS online calculator, including IOL calculation formulas for prior myopic LASIK/PRK condition (Shammas, Haigis-L and BTrueK-myopic), formulas for prior RK condition (Double K-modified Holladay 1 based on Oculus Pentacam® and IOL Master®, and BTrueK-RK) was found by changing the target refraction until the suggested IOL power matched the implanted IOL. For the EVO formula, the target refraction for each IOL power was retrieved from the online calculator (https://www.evoiolcalculator.com). For the PEARL-DG formula, the module for complex eyes post-myopic corneal refractive surgery was used in the online calculator (https://iolsolver.com/ main) and the target refraction for each IOL power was retrieved with (PEARL-DGS[RK]) and without (PEARL-DGS[LVC]) selecting the "radial keratotomy" option. Additionally, posterior keratometry data was retrieved from the IOL Master 700 as used for calculations in the BTrueK (using the online calculator from the Asia-Pacific Association of Cataract and Refractive Surgeons (APACRS)) and EVO formulas. The A-constant used was the recommended by that manufacturer for all cases at the time of the procedure. The refractive prediction error (PE) was calculated as the difference between the actual and predicted postoperative refractive spherical equivalent (actual refraction - predicted refraction).<sup>11</sup> For interpretation, positive and negative refractive prediction errors indicate that hyperopic and myopic results, respectively, were achieved when compared with the predicted refraction.<sup>11</sup> This study was conducted in compliance with the Declaration of Helsinki.

#### RESULTS

Seven eyes of 6 myopic patients (50% female) with previous double keratorefractive procedures were enrolled in this study. Six eyes have been submitted to RK and LASIK and one eye had a history of RK followed by PRK. Table 1 presents the ocular and biometric characteristics of the eyes and Table 2 presents the formula prediction results using only anterior keratometry. Table 3 presents the results of BTrueK and EVO formulas using posterior keratometry.

#### CASE 1

A 55-year-old woman has been submitted to refractive surgery for myopia with RK on her right eye (OD), later enhanced by PRK more than 20 years ago. On the left eye

(OS), she has undergone a single keratorefractive procedure (LASIK). The patient presented at our department complaining of reduced visual acuity OD. The best-corrected visual acuity (BCVA) was 20/60 OD and 20/25 OS. The subjective refraction was -8.00 D OD and -5.00 D OS. At slit-lamp examination, corneal haze and 8 radial keratotomies OD and cortical cataracts in both eyes (OU) were the main findings. No clinically significant changes in the posterior pole OU were found at fundoscopy. A pigmented scar due to laser photocoagulation of a peripheral retinal tear was evident on the right eye. After discussion with the patient, she was proposed for phacoemulsification with in-the-bag intraocular monofocal single-piece acrylic lens implantation with an A-constant of 118.7 (Alcon AcrySof IQ SN60WF) and a power of +12 D. Following the postoperative period, the patient presented a BCVA of 20/30 with spherical equivalent of +0.125 D. For this patient, the most accurate formulas were the PEARL-DGS[RK] and the Double K-modified Holladay 1, with prediction errors of -0.18 and +0.30 D, respectively. No other formula performed within ±1.00 D.

Table 1. Ocular and biometric characteristics of the included cases.									
	RK cuts (n)	AL (mm)	Kmean (D)	Cylinder (D)	ACD (mm)	LT (mm)	WTW (mm)		
Case 1	8	30.74	35.75	1.50	3.13				
Case 2	8	30.59	30.40	1.10	3.82	4.71	12.80		
Case 3 – OD	12	28.11	36.17	0.61	3.5	3.95	11.9		
Case 3 – OS	12	28.10	35.56	0.48	3.44	4.02	11.8		
Case 4	4	28.53	37.61	1.47	3.36	4.19	11.6		
Case 5	4	23.10	43.81	9.09	3.36	4.25	11.8		
Case 6	4	26.42	39.28	1.00	3.29	4.9	11.7		

ACD, anterior chamber depth, AL, axial length; D, diopter; K, keratometry; LT, lens thickness; RK, radial keratotomy; WTW, white-to-white.

 Table 2. Formula prediction results using formulas from ASCRS online calculator and Kane formula. Highlights correspond to ±0.50D prediction error.

			Prior myopic LASIK/PRK Prior RK			PEARL-DGS				
		Manifest SE	Shammas	Haigis-L	Barrett TK	Mod. Holladay 1	Barret TK	EVO	LVC	RK
Predicted refraction	Case 1	-	+2.30	+1.80	+2.25	-0.18	+1.44	+1.75	+1.71	+0.30
	Case 2	-	+1.83	+4.08	+1.88	-0.96	+0.64	+1.14	+1.56	-1.03
	Case 3 – OD	-	-0.76	-0.97	-1.31	-2.48	-2.28	-1.28	-1.23	-2.58
	Case 3 – OS	-	-1.22	-1.28	-1.84	-2.95	-2.87	-1.75	-1.69	-3.22
	Case 4	-	-0.12	-0.68	-0.41	-1.90	-1.29	-0.54	-0.58	-1.50
	Case 5	-	-0.20	+0.41	-0.20	-0.93	-0.49	-0.28	-0.45	+0.77
	Case 6	-	-0.28	-0.84	-0.61	-1.30	-1.32	-0.63	-0.54	-0.90
Refraction prediction error	Case 1	+0.125	-2.18	-1.68	-2.13	+0.30	-1.32	-1.63	-1.59	-0.18
	Case 2	+0.625	-1.20	-3.45	-1.25	+1.59	-0.01	-0.51	-0.93	+1.66
	Case 3 – OD	-2.25	-1.49	-1.28	-0.94	+0.23	+0.03	-0.97	-1.02	+0.33
	Case 3 – OS	-2.75	-1.53	-1.47	-0.91	+0.20	+0.12	-1.00	-1.06	+0.47
	Case 4	0	+0.12	+0.68	+0.41	+1.90	+1.29	+0.54	+0.58	+1.50
	Case 5	0	+0.20	-0.41	+0.20	+0.93	+0.49	+0.28	+0.45	-0.77
	Case 6	0	+0.28	+0.84	+0.61	+1.30	+1.32	+0.63	+0.54	+0.90
Range	Minimum		-2.18	-3.45	-2.13	+0.20	-1.32	-1.63	-1.59	-0.77
	Maximum		+0.28	+0.84	+0.61	+1.90	+1.32	+0.63	+0.58	+1.66

LASIK. laser-assisted in situ keratomileusis; LVC. laser vision. correction; PRK. photorefractive keratectomy; RK. radial keratotomy; SE. spherical equivalent.

Table 3. Formula prediction results of Barrett True-K and EVO using posterior keratometry data. Highlights correspond improvement of prediction error with the introduction of posterior keratometry.

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			Barrett TrueK-myopic		Barrett T	TrueK-RK	EVO		
		Manifest SE	К	K + KPost	К	K + KPost	К	K + KPost	
	Case 2	-	+1.88	+1.10	+0.64	+0.73	+1.14	+0.21	
	Case 3 – OD	-	-1.31	-1.99	K-myopic         Barrett TrueK-RK         EVO           K + KPost         K         K + KPost         K           +1.10         +0.64         +0.73         +1.14           -1.99         -2.28         -2.32         -1.28           -2.48         -2.87         -2.87         -1.75           -0.47         -1.29         -0.62         -0.54           -0.55         -0.49         -0.63         -0.28           -0.95         -1.32         -1.23         -0.63           -0.47         -0.01         -0.10         -0.51           -0.26         +0.03         +0.07         -0.97           -0.26         +0.03         +0.07         -0.97           -0.27         +0.12         +0.12         -1.00           +0.47         +1.29         +0.62         +0.54           +0.55         +0.49         +0.63         +0.28           +0.95         +1.32         +1.23         +0.63           +0.95         +1.32         +1.23         +0.63	-2.05			
Predicted	Case 3 – OS	-	$\begin{array}{ c c c c c c c c c c c c c c c c c c c$	-2.54					
refraction	raction Case 4	-	-0.41	-0.47	-1.29	-0.62	-0.54	-0.55	
Case	Case 5	-	-0.20	-0.55	-0.49	-0.63	-0.28	-0.77	
	Case 6	-	-0.61	-0.95	-1.32	-1.23	-0.54         -0.55           -0.28         -0.77           -0.63         -1.06           -0.51         +0.42	-1.06	
	Case 2	+0.625	-1.25	-0.47	-0.01	-0.10	E Dest K +1.14 -1.28 -1.75 -0.54 -0.28 -0.63 -0.51 -0.97 -1.00 +0.54 +0.28 +0.63 -1.00 +0.63 -1.00 +0.63	+0.42	
	Case 3 – OD	-2.25	-0.94	-0.26	+0.03	+0.07	-0.97	-0.20	
Refraction	Case 3 – OS	$\begin{array}{c c c c c c c c c c c c c c c c c c c $	+0.12	-1.00	-0.21				
error	Case 4	0	+0.41	+0.47	+1.29	+0.62	+0.54	+0.55	
	Case 5	0	+0.20	+0.55	+0.49	+0.63	+0.28	+0.77	
	Case 6	0	+0.61	+0.95	+1.32	+1.23	+0.63	+1.06	
Range	Minimum		-1.25	-0.47	-0.01	-0.10	-1.00	-0.21	
	Maximum		+0.61	+0.95	+1.29	+1.23	+0.63	+1.06	

#### CASE 2

A 70-year-old man has received refractive surgery for myopia with RK OU, later enhanced by LASIK OD more than 30 years ago. The patient presented at our department complaining of reduced visual acuity OU, having a BCVA of 20/50 OD and 20/40 OS. The subjective refraction was -3.75 D -0.50 D x 40° OD and -2.50 D x 80° OS. At slit-lamp examination, 12 radial keratotomies and cortical cataracts OU were the main findings. Fundus exam found peripapillary chorioretinal atrophy in both eyes and no significant macular changes. After discussion with the patient, he was proposed for OD phacoemulsification with in-the-bag intraocular monofocal singlepiece acrylic lens implantation with an A-constant of 119.26 (Alcon Clareon CNA0T0) and a power of +21.0 D. Following the postoperative period, the patient presented a BCVA of 20/30 with spherical equivalent of +0.625 D. For this case, the best formula was the BTrueK-RK (PE = -0.01 D).

#### CASE 3

A 49-year-old woman has been submitted to RK for myopia correction on both eyes at the age of 18, enhanced by LASIK seven years later. The patient presented at our service for a routine examination complaining of progressive decrease of visual acuity OU, having a BCVA of 20/40 OD and 20/40 OS. The subjective refraction was -4.00 -1.50x90° OD and -3.00 OS. The previous BCVA was 20/25 for each eye. At slit-lamp examination, 12 radial keratotomies in each eye and posterior subcapsular cataracts OU were the main findings. Fundoscopy was unremarkable. After discussion with the patient, she was proposed for phacoemulsification with in-the-bag intraocular monofocal singlepiece acrylic lens implantation with an A-constant of 119.26 (Alcon Clareon CNA0T0) and a power of +21.5 D OD and +23 D OS and a myopic target refraction (-2.50 D) aiming to provide glasses independence for near vision. Following the postoperative period, the patient presented a BCVA of 20/25 in each eye with spherical equivalent of -2.25 D OD and -2.75 D OS. For this patient, the best formulas for both eyes were those for prior RK conditions, namely Double Kmodified Holladay 1, BTrueK-RK and PEARL-DGS[RK], all performing within ±0.50 D prediction range.

#### CASE 4

A 55-year-old woman has been submitted to refractive surgery for myopia with RK on her amblyopic right eye, later on enhanced by LASIK more than 20 years ago. No surgery was performed on her left eye. The patient mentioned reduced visual acuity OD, having a BCVA of 20/60 OD and 20/25 OS. The subjective refraction was -4.50D -1.50D x 35° OD and +1.00 D +0.50 D x 20° OS. At slit-lamp examination, a LASIK flap and 4 radial keratotomies OD and nuclear cataracts OU with subcapsular component OD were evident. Fundoscopy was unremarkable. After discussion, she was proposed for phacoemulsification with in-the-bag intraocular monofocal single-piece acrylic lens implantation with an A-constant of 119.26 (Alcon Clareon CNA0T0) and a power of +17.5D. Following the postoperative period, the patient presented an uncorrected visual acuity of 20/30 with spherical equivalent of 0D. For this patient, the best formulas were those for prior myopic LASIK/PRK conditions, namely Shammas and the BTrueKmyopic, both performing within ±0.50 D prediction range. The EVO and Haigis-L formulas also presented a good performance, with a predicted refraction within ±1.00 D range.

#### CASE 5

A 59-year-old man has received refractive surgery for myopia 30 years ago with RK OD, later on enhanced by

LASIK. He presented at our department for clear lens exchange, having a BCVA of 20/30 OD and 20/40 OS. The subjective refraction was +2.00 D -6.00 D x 80° OD and -1.50D -0.50 x 60° OS. At slit-lamp examination, 4 RK, one of which with significant scarring associated with leukoma, and a LASIK flap OD were the main findings; OS was unremarkable. Fundus exam revealed no changes. Corneal tomography (Pentacam, Oculus®) revealed an irregular astigmatism of 6.8 D at 79.3° with a K max of 57.3 D due to the RK-associated scarring. After discussion with the patient, he was proposed for phacoemulsification of the right eye with in-the-bag intraocular toric monofocal single-piece acrylic lens implantation with an A-constant of 118.3 (Zeiss AT TORBI 709M), a sphere power of +17 D and a cylinder power of +11.5 D (+22.75 D of spherical equivalent), calculated with the Z CALC Online IOL calculator (https://zcalc.meditec.zeiss. com). Following the postoperative period, the patient was satisfied with the result and presented an uncorrected visual acuity of 20/25 with spherical equivalent of 0D. For this patient, all formulas assessed had a PE within ±1.00 D. The most accurate formulas were Shammas and BTrueK-myopic (P = +0.20 D for both). The Haigis-L, BTrueK-RK, EVO and PEARL-DGS[LVC] also performed within ±0.50 D.

#### CASE 6

A 77-year-old man has received refractive surgery for myopia with RK OU, later enhanced by LASIK OD more than 30 years ago. He presented at our department complaining of reduced visual acuity, having a BCVA of 20/100 OD and 20/30 OS. The subjective refraction was -1.00D x  $90^{\circ}$ OD and +4.00 x 130º OS. At slit-lamp examination, the main findings were 4 RK and a LASIK flap OD, 8 RK OS and cortical cataracts OU. Fundus exam revealed no changes. After discussion, the patient was proposed for phacoemulsification of the right eye with in-the-bag intraocular monofocal single-piece acrylic lens implantation with an A-constant of 119.26 (Alcon Clareon CNA0T0) and a power of +20.5 D. Following the postoperative period, the patient was satisfied with the result and presented an uncorrected visual acuity of 20/40 with spherical equivalent of 0D. For this patient, the most accurate formula was Shammas (PE = +0.28D). EVO and BTrueK-myopic performed within ±1.00D.

#### SUMMARY

Overall, the formulas for prior RK condition had higher predictability with 8 or more RK (cases 1 to 3) with each one performing within  $\pm 0.50$  D in 3 out of 4 eyes. For patients with only 4 RK, Shammas was the most predictable, performing within  $\pm 0.50$  D for cases 4 to 6, followed by BTrueK-myopic that stood within  $\pm 0.50D$  for two out of 3 eyes and within  $\pm 1.00$  D for the other. EVO and Haigis-L also performed better in the subgroup with only 4 RK, with a PE within  $\pm 1.00$  D for all those. The prediction errors of EVO formula were outside of  $\pm 0.50$  D range for all cases. The results of PEARL-DGS agreed with the findings in other formulas: the RK option had a better performance for eyes with more RK whereas the LVC module had a PE within  $\pm 1.00$  D for all eyes with few RK cuts.

The introduction of posterior keratometry data improved the performance of each formula in the subset of patients where they had worst results, i.e., in eyes with over 8 RK cuts for BTrueK-myopic and EVO and in eyes with few RK cuts for BTrueK-RK. Overall, the introduction of these data reduced the range of PE for both formulas studied in Table 3. Of note, leading to a performance of BTrueKmyopic with posterior keratometry performed within ±1.00 D for all eyes and BTrueK-RK and EVO had a similar result for 5 out of 6 eyes.

### DISCUSSION

In this manuscript, we present 6 challenging cases (7 eyes) of patients submitted to phacoemulsification with in-thebag IOL implantation years after a double keratorefractive procedure. This work contains important information and clinical experience on the discussion of IOL power calculation for these scenarios. Patients with past history of corneal refractive surgery will represent a significant proportion of those eligible for cataract surgery in the near future. In our cases, it seems that the number of RK greatly influences the formula predictability: for patients with 8 or more RK, the formulas for prior RK condition have a better performance than those for prior myopic LASIK/PRK condition; the opposite was verified for those with only 4 RK. EVO formula seems to have an acceptable performance in the group with only 4 RK, despite being worse than Shammas and BTrueKmyopic. The posterior keratometry seems to be of interest in these cases, reducing the range of prediction errors.

In the first three cases, no formula was found to be accurate for all patients. Although, each of those for prior RK conditions was among the most predictable in 3 out of 4 eyes. These results disagree with the hypothesis of Liu et al<sup>12</sup> that prior LASIK Haigis-L formula of ASCRS IOL power calculator may be sufficient and the information from the prior RK setting may be discarded. In cases 4 to 6, Shammas, BTrueK-myopic and EVO formulas were found to be the most predictable, having a maximum difference of 0.40D between them. For patients with few RK, these formulas seem to be the right choice. Christopher *et al*<sup>13</sup> suggested the use of BTrueK-RK formula for eyes with axial length less than 27.5 mm, and the BTrueK-myopic for eyes with axial length greater than 27.5 mm. Our series disputes this theory as for cases with axial length less than 27.5 mm (cases 5 and 6) BTrueK-myopic had a better predictability than BTrueK-RK. Instead, the number of RK cuts seems to provide a better explanation for results. This finding might be explained by the small ablations usually performed in the enhancements, leading to the effect of the RK to prevail over the laser vision correction (LVC) when those were in high number. For those with few RK, the effect of LVC might overshadow the previous RK. Christopher et al13 did not analyzed their eleven eyes according to the number of RK which could have also help to shed light on the role of this parameter on formulas' performance.

This is a case series; further large-scale studies are warranted to develop a better method for IOL power calculation in these scenarios. Second, the keratorefractive procedure of these patients were performed in other institutions, thus we did not have any preoperative data to complement the preparation of these calculations and surgeries.

# CONCLUSION

In summary, so far there is no consensus on the best method for IOL power calculation after keratorefractive surgery. A double corneal surgery further increases the complexity of these calculations. The results from this case series suggests that the number of RK is a relevant factor that needs to be considered in the choice of the formula for IOL power calculation. Thus, it is important to deal properly with preoperative patients' expectations and to inform them of the risk of miscalculation.

# CONTRIBUTORSHIP STATEMENT / DECLARAÇÃO DE CONTRIBUIÇÃO

AF: Study design, data collection and analysis, drafting and revising the manuscript.

ACA, SM and MCP: Study design; data interpretation; drafting and revising the manuscript.

JHM, NS: Data interpretation; drafting and revising the manuscript.

All authors approved the final version to be published.

AF: Desenho de estudo, colheita e análise de dados, redação e revisão do manuscrito.

ACA, SM e MCP: Desenho de estudo; interpretação dos dados; redação e revisão do manuscrito.

JHM, NS: Interpretação dos dados; redação e revisão do manuscrito.

Todos autores aprovaram a versão final a ser publicada.

# **RESPONSABILIDADES ÉTICAS**

**Conflitos de Interesse:** Os autores declaram a inexistência de conflitos de interesse na realização do presente trabalho.

Fontes de Financiamento: Não existiram fontes externas de financiamento para a realização deste artigo.

**Confidencialidade dos Dados:** Os autores declaram ter seguido os protocolos da sua instituição acerca da publicação dos dados de doentes.

**Proteção de Pessoas e Animais:** Os autores declaram que os procedimentos seguidos estavam de acordo com os regulamentos estabelecidos pela Comissão de Ética responsável e de acordo com a Declaração de Helsínquia revista em 2013 e da Associação Médica Mundial.

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# ETHICAL DISCLOSURES

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**Protection of Human and Animal Subjects:** The authors declare that the procedures followed were in accordance with the regulations of the relevant clinical research ethics committee and with those of the Code of Ethics of the World Medical Association (Declaration of Helsinki as revised in 2013).

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