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# One- piece foldable intraocular lens versus 3- piece IOL in scleral fixation Running title

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ORIGINAL STUDY

# One-piece foldable intraocular lens versus three-piece intraocular lens in scleral fixation

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**Abstract**

*Purpose*: **To assess the stability of postoperative intraocular lens (IOL) between the one-piece foldable and three-piece IOLs by the surgical technique of scleral fixation and so the efficacy of usage of one-piece IOL in this technique.**

*Material and method*: **This is a randomized controlled study that includes 118 eyes, which is divided into two groups. Group A includes 59 eyes that have implanted one-piece foldable IOL, while group B has an equal number of cases, implanted three-piece foldable IOL. Cases were followed up for 12 months every 3-month duration. Ultrasound biomicroscopy has evaluated the horizontal and vertical IOL optic tilt. The best-corrected visual acuity, refractive including cylindrical errors, and IOL position were compared.**

*Results*: **The IOL inclination differences were not significant for horizontal tilt ($P = 0.888$) nor for vertical tilt ($P = 0.14$) between the two groups. No statistically significant differences for postoperative spherical error ($P = 0.530$), cylindrical error ($P = 0.179$), and best-corrected visual acuity ($P = 0.160$) between the two groups.**

*Conclusion*: **One-piece IOL achieves the advantage of good postoperative stability as well as three-piece IOL in the scleral fixation technique. It also has another advantage over three-piece IOL as it has less incidence of haptic breakage during surgical manipulations.**

*Keywords:* Aphakia, Foldable intraocular lens, Intraocular lens tilt, Lens subluxation, One-piece intraocular lens, Scleral fixation, Three-piece intraocular lens scleral fixation

## 1. Introduction

The intraocular lens (IOL) is an artificially designed lens inserted in the eye after cataract extraction for postoperative visual rehabilitation. This IOL is composed of one optic and two haptics. The best position for this IOL is inside the capsular bag. This allows for the good stabilization and centration of the IOL on the pupillary axis, which results in the best postoperative refractive outcome [1]. There are many conditions associated with inadequate support of the capsular bag, such as complicated cataract surgery, ocular trauma, and inherited zonular weakness [2]. In these situations, the surgeon must have another surgical solution to place the IOL in the eye, such as using iris fixated IOL, anterior chamber IOL, or scleral fixated IOL [3]. Anterior chamber IOL and iris fixated IOL can be used in limited indications because of their higher risk of complications such as corneal decompensation, glaucoma, and uveitis, while if the patient has any corneal problems such as edema, dystrophy, a previous corneal transplant or shallow anterior chamber, the scleral fixated IOL will be the best option [4].

Different types of IOLs can be scleral fixated. Recently, the foldable IOL has become the IOL of choice due to its advantage of being inserted through a small incision; hence, better postoperative visual acuity, as well as maintaining the intraoperative stability of the anterior chamber depth, which is of great significance [5]. These foldable

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IOLs are mainly of two types: single-piece and three-piece IOLs. Currently, three-piece IOLs are more popular to be used in scleral fixation technique as it provides good postoperative stability [6]. One of the limitations of this type of IOL is its higher incidence of haptic breakage that causes serious harm to the eye [7–9].

In developed countries, nearly 1–2% of cataract operations were complicated by interrupted capsular bag and vitreous loss, which in turn may hinder the placement of a new IOL in the capsular bag [10,11]. Considering around 10 million cataract surgeries are conducted annually worldwide [12], even a 1 % rate of complicated cataract surgery would result in a significant number of eyes that may need a placement of a scleral fixed IOL [11]. Since scleral suturing IOL was introduced, the techniques and materials have been modified to enhance the efficacy and mitigate the likelihood of adverse complications. One of the most important factors affecting the success rate of this technique is the postoperative IOL stability [3], which has a direct impact on the visual acuity of the patient and decreases the incidence of postoperative complications such as glaucoma and retinal detachment [13].

Many previous studies have investigated different novel surgical techniques for using both types of foldable IOLs in scleral fixation technique [8,10], but currently, no comparative studies have been carried out between both types of foldable IOLs to evaluate their degree of stability in scleral fixation technique; hence, no conclusive evidence is available to recommend the use of one type of foldable IOLs rather than the other in scleral fixation technique. So, in the current study, we introduce the model of foldable one-piece IOL to ensure optimum postoperative stability the same three-piece foldable IOL. We can introduce the foldable one-piece IOL model for ideal postoperative stability and less incidence of haptic breakage. As such, this study aims to recommend one-piece IOL rather than three-piece IOL in the scleral fixation technique, considering both have the same postoperative stability, but one-piece IOLs have a less incidence of haptic breakage. While our specific aim is to assess the postoperative IOL stability after one-piece and three-piece IOLs in the scleral fixation technique.

## 2. Methodology

### 2.1. Study design

This is a single-center, randomized clinical trial comparing the foldable single-piece IOL to the foldable three-piece IOL in patients indicated for scleral fixation technique. This study was conducted at the Giza Memorial Institute of Ophthalmic Research (MIOR). This institute serves nearly 600 patients per day and more than 10 000 procedures for cataract extraction annually. All patients have been randomized (1 : 1) using the sealed envelope method to either group A patients had implanted hydrophobic acrylic one-piece IOL, the Acriva UDB 625 (VSY Biotechnologies, Amsterdam, the Netherlands) acts as the intervention group. While group B received the three-piece IOLs (AcrySof MA60AC/MN60AC) (conventional group). The randomization code was generated by utilizing a random number generator. Patients were blinded to the IOL type. Regular ophthalmic examinations and assessments were performed by the clinical staff and an expert investigator. Both were masked to group allocation. The surgeries were exclusively conducted by three expert surgeons who could not be masked. For a total of 12 months, all cases were monitored every 3 months.

#### 2.1.1. Study population/methods

The study included 118 eyes of 118 patients between the ages of 18–70 years old. Sample size estimation: assuming that the mean vertical IOL tilt in the case of the three-piece foldable IOL implantation is 0.24 ± 0.21. As we anticipate no significant difference from one-piece foldable IOL implantation, so we assume the mean vertical IOL tilt of one-piece IOL is 0.14 ± 0.17, with ~80 % power and two-tailed alpha of 0.05, the calculated sample size is 118 ($n = 59$ in each group). This estimation is based on the previous estimated mean [14].

#### 2.1.2. Inclusion criteria

Patients with a diagnosis of aphakia and no capsular support after complicated cataract surgery; patients have traumatic subluxated lenses associated with zonular rupture of more than 180°, the age from 18 to 70 years old, patients who can sign an informed consent to participate in the study.

#### 2.1.3. Exclusion criteria

Patients having any of the following: corneal disorders such as keratoconus or corneal opacities or dystrophies, corneal endothelial cell count less than 1500 cells/mm$^2$, collagen diseases associated with scleritis (systemic lupus erythematosus, polyarteritis nodosa, psoriatic arthritis), chorioretinal disorders, glaucoma, previous refractive or retinal surgery.

The study is approved by the Scientific and the Ethical Committee at MIOR. The patients had had an informed written consent about all benefits and risks of the surgery after an explanation of both

procedures and agreed to be randomized to one of them by chance.

### 2.2. Intraoperative and postoperative procedures

In group A, foldable one-piece IOL was implanted through sutured scleral fixation, and two scleral flaps of 3 mm were created at 3 and 9 clock hours, with the base on the limbus. Beneath the center of either scleral flap 1.5 mm from the limbus, a 10/0 straight needle double-armed polypropylene suture was introduced inside the eye while exited at the center of the other flap using a 24-G cannula. The polypropylene suture was passed outside the eye across the scleral sulcus, cut in two parts. Then each part was securely tied to the haptic. As previously described the implantation and centration of the IOL by Marianelli and colleagues. The transscleral sutures were positioned beneath each scleral flap. In group B, foldable three-piece IOL was implanted through a sutureless scleral fixation technique. The two ab-externo sclerotomies have been taken using a 24-G cannula, about 1.5 mm distance from the limbus at 3 and 9 clock hours. Then, a tunnel that is parallel to the limbus, was set at approximately half of the scleral thickness, starting at the sclerotomies site and terminating 3 mm at the exit site of the cannula. The injector was used for implanting the three-piece IOL. Using end-gripping 25-G forceps, the leading haptic's tip was grabbed via the sclerotomy (Schariot Scleral Fixation forceps 25 G, Dorc). The IOL haptic was drawn into the tunnel, while the forceps were inserted into the distal end of the tunnel to grip the externalized tip. Eventually, after the other haptic was similarly handled, the IOL centration and position were adjusted. Postoperative topical antibiotics and anti-inflammatory treatment were prescribed as usual.

### 2.3. Study protocol

All patients' demographic data (sex, age, and race) are recorded. Preoperative routine evaluation of all patients, including measuring best-corrected visual acuity by the Snellen chart which was transformed to LogMar for statistical analysis, measuring the refraction in diopter and K readings by autorefractometer, anterior segment examination using slit-lamp, measurement of intraocular pressure using Goldman applanation tonometer, dilated-fundus biomicroscopy, endothelial cell count and biometry for IOL power calculation. All cases were followed up every 3 months for clinical assessment, evaluation of visual acuity, and assessment of IOL stability for 12 months. Ultrasound biomicroscopy (UBM) was used to measure and evaluation of the postoperative stability of the IOL via assessing the vertical and horizontal IOL optic tilt by the iris plane measured in millimeters using Loya *et al.* [15] technique. One expert ophthalmologist has performed the 50-MHz transducer UBM scans by the VuMax II (Sonomed Escalon, New Hyde Park, New York, USA). The patients were examined in a supine position without medriatic administration. An eyecup with a normal saline solution and topical proxymetacaine hydrochloride at a 5 mg/ml concentration was applied. In the first step, we used the pupil's margins as a reference plane and drew an imaginary line with the hyperreflective iris pigment epithelium. In the next step, an imaginary line corresponds to the anterior surface of the IOL central optic. Eventually, we measured the smallest distance between those imaginary lines utilizing the integrated UBM system calliper tool at the following sites: medially (9 clock on left; or 3 clock hours at the right eye), laterally (at 3 clocks on the left, or 9 clock hours at the right eye), superiorly (12 clocks), inferiorly (6 clocks) (Figs. 1 and 2). The horizontal tilt was determined as the difference between the medial and lateral distances, while vertical tilt was deemed as the difference between the superior and inferior distances.

### 2.4. Statistical approach and power calculation

Statistical analyses compare the main outcome (horizontal and vertical and IOL tilt in mm) between one-piece IOL group and three-piece IOL group at the 12th month after surgery using two sample *t*-test. The test was significant when *P* value less than or equal to 0.05. The results were determined as mean ± SD. To determine the correlation between the primary predictor and the primary continuous

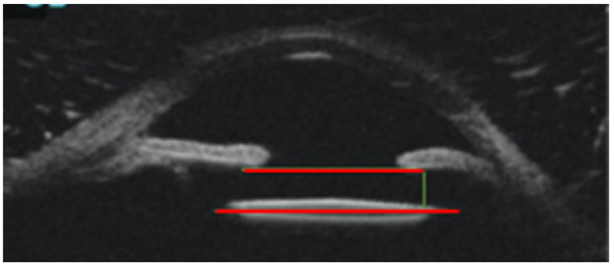

*Fig. 1. Representative image taken by ultrasound biomicroscopy (UBM). Imaginary lines utilizing the integrated caliper tool represent the reference lines in the IOL inclination detection method in the study. The horizontal superior red line is placed at the posterior iris surface, while the inferior red line is along the IOL optic axis. The vertical green line represents the distance in mm between the two imaginary lines at a particular axial quadrant. IOL, intraocular lens.*

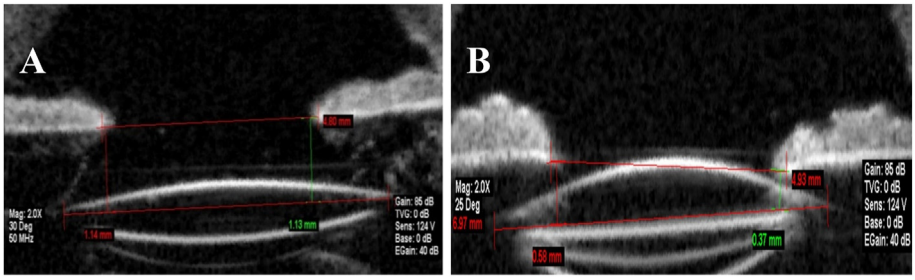


*Fig. 2. IOL inclination by UBM in a representative case. (A) Vertical axial image demonstrating the vertical axial tilt. (B) Horizontal axial image demonstrating the horizontal IOL tilt. The horizontal superior red line is placed at the posterior iris surface, while the inferior red line is along the IOL optic axis. The vertical green line represents the distance in mm between the two imaginary lines at a particular axial quadrant. IOL, intraocular lens; UBM, ultrasound biomicroscopy.*

outcome, multiple linear regressions were used (type of the foldable IOL, as one-piece IOL is the main exposure, three-piece IOL is the reference), adjusting for covariates of interests (age, sex, and surgical duration). All statistical analyses were conducted using STATA (Stata Statistical Software, Release 18. College Station, TX, USA), version 16, for Windows.

## 3. Results

One hundred eighteen eyes of an equal number of patients have been included. The age of the group A was 62.6 ± 21.33 years, while the group B was 60.5 ± 12.5 years ($P = 0.888$). Regarding sex in group A, 35 were female, while 24 males. In cohort B, 32 were female, while 27 were male, with no statistically significant difference sex ($P = 0.835$). There was no statistically significant difference regarding the eye side among groups ($P = 0.759$).

The primary rationale for scleral fixation in both groups was the consequence of a complication during phacoemulsification and failure of primary implantation, with a prevalence of 60 % in group A and 80 % in group B. Additional indications included lens subluxation resulting from ocular trauma (Table 1).

In the one-piece IOL group, the mean axial distances between IOL optic and the iris pigment epithelium were 0.96 ± 0.65 mm at 12 clock, 1.06 ± 0.61 mm at 6 clock, 0.94 ± 0.70 mm at 9 clock, and 1.01 ± 0.47 mm at 3 clock hours, while in the three-piece IOL group, the mean axial distances were 0.90 ± 0.45 mm at 12 clock, 0.85 ± 0.40 mm at 6 clock, 0.90 ± 0.60 mm at 9 clock, and 0.91 ± 0.42 mm at 3 clock hours.

In both one-piece and three-piece IOL implanted groups, there was a vertical and horizontal tilt; the mean vertical tilt was 0.17 ± 0.12, and 0.20 ± 0.23 mm, while the mean horizontal tilt was 0.20 ± 0.13, and 0.22 ± 0.15 mm, respectively. No significant differences were detected between both groups for any of these positions ($P = 0.778$ at 12 clock, $P = 0.597$ at 6 clock hours). Collectively, the IOL inclination differences were not statistically significant between groups for both vertical and horizontal tilt ($P = 0.14$ and 0.88, respectively) (Table 2).

In the three-piece IOL group, 112 (94.9 %) of 118 haptics were properly positioned in the intrascleral

*Table 1. Patient's demographic data.*

| Parameters | Group A (one-piece IOL) ($N = 59$) (mean ± SD) | Group B (three-piece IOL) ($N = 59$) (mean ± SD) | $\chi^2$ | $P$ value |
|---|---|---|---|---|
| Sex | | | 0.31 | 0.57 |
| Male | 24 | 27 | | |
| Female | 35 | 32 | | |
| Age (years) | 62.6 ± 21.33 | 60.5 ± 12.5 | – | 0.02 |
| Indication for scleral fixation | | | | |
| Complicated cataract | 60 % | 80 % | | |
| Traumatic lens subluxation | 40 % | 20 % | | |

*Table 2. Differences in the intraocular pressure inclination in patients who underwent scleral fixation surgery.*

| Parameters | Group A (one-piece IOL) ($N = 59$) (mean ± SD) | Group B (three-piece IOL) ($N = 59$) (mean ± SD) | $P$ value |
|---|---|---|---|
| Vertical IOL inclination (mm) | 0.17 ± 0.12 | 0.20 ± 0.23 | 0.14 |
| Horizontal IOL inclination (mm) | 0.20 ± 0.13 | 0.22 ± 0.15 | 0.88 |

tunnel; however, six (5.08 %) displaced to ciliary sulcus. Also, in this group, eight of 118 haptics were broken during the surgical manipulation during the procedure, which forced the surgeon to exchange the IOL with another one. In the one-piece IOL group, 82 (69.5 %) of the 118 haptics has been posterior to the ciliary body, 15 (12.7 %) of 118 haptics have been anterior to the ciliary body and 21 (17.7 %) were in the ciliary sulcus. The postoperative centration of implanted scleral fixation IOL by both techniques was similar (as shown in Fig. 3).

As regard the outcome of postoperative refraction and visual acuity, the cylindrical error ($P = 0.18$), spherical error ($P = 0.53$), and spherical equivalent ($P = 0.16$) were no significant differences between both groups (Table 3). The mean postoperative best-corrected visual acuity was 0.40 ± 0.30 (logMAR) in the sutureless group and 0.55 ± 0.30 (logMAR) in the suture group ($P = 0.439$).

There were no significant statistical differences between the groups for postoperative spherical error ($P = 0.530$), cylindrical error ($P = 0.179$) and spherical equivalent ($P = 0.160$). Visual acuity results and postoperative refraction data are shown in Table 4. Postoperative spherical and cylindrical error (diopters), spherical equivalent (diopters), and

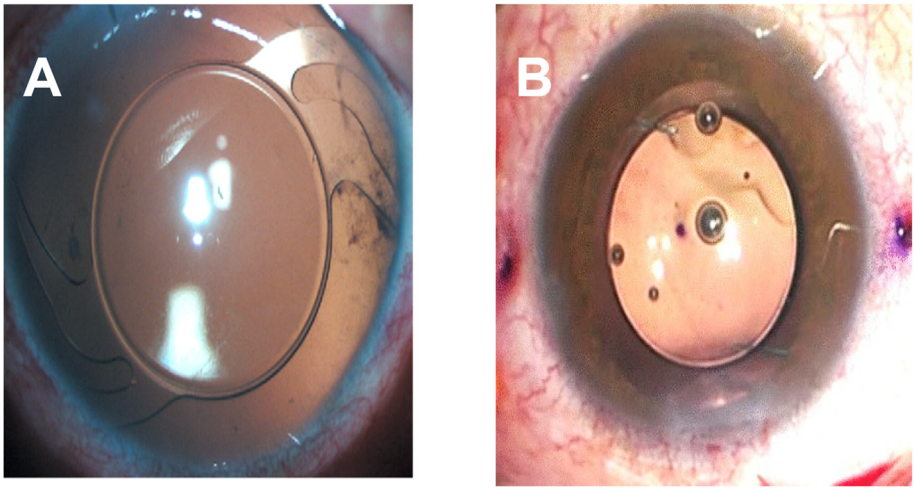


*Fig. 3. Postoperative centration of implanted scleral fixation IOL by both techniques. (A) Postoperative scleral fixation of one-piece IOL. (B) Postoperative scleral fixation three-piece IOL. IOL, intraocular lens.*

*Table 3. Long-term postoperative outcome and refraction in patients who underwent scleral fixation surgery.*

| Parameters | Group A (one-piece IOL) ($N = 59$) (mean ± SD) | Group B (three-piece IOL) ($N = 59$) (mean ± SD) | *P* value |
|---|---|---|---|
| Spherical error | −0.20 ± 1.80 (−0.55) | 0.30 ± 2.10 (0.00) | 0.52 |
| Cylindrical error | −3.34 ± 1.80 (−2.47) | −2.15 ± 1.05 (−2.10) | 0.18 |
| Spherical equivalent | −1.90 ± 1.65 (−2.00) | −0.73 ± 2.00 (−0.25) | 0.16 |
| Best-corrected visual acuity (LogMAR) | 0.50 ± 0.30 (0.45) | 0.45 ± 0.32 (0.30) | 0.43 |

*Table 4. Regression data.*

| Parameters | Vertical tilt coefficient (95 % confidence interval) | *P* | Horizontal tilt coefficient (95 % confidence interval) | *P* |
|---|---|---|---|---|
| Type of IOL | | | | |
| 3-piece IOL | Reference | – | Reference | – |
| 1-piece IOL | 0.080 (−0.110 to 0.275) | 0.380 | 0.054 (−0.125 to 0.235) | 0.526 |
| Sex | | | | |
| Female | Reference | | Reference | |
| Male | −0.103 (−0.290 to 0.080) | 0.246 | −0.155 (−0.330 to 0.015) | 0.070 |
| Age | −0.004 (−0.010 to 0.001) | 0.081 | −0.001 (−0.005 to 0.006) | 0.821 |
| Surgical duration | −0.001 (−0.003 to 0.002) | 0.581 | 0.001 (−0.001 to 0.003) | 0.164 |

best-corrected visual acuity (LogMAR): mean ± SD, median, and *P* value.

## 4. Discussion

Scleral fixed IOLs are designed to address aphakia caused by insufficient capsular support, positioning the lens near the anatomically required location. Many studies have investigated the different surgical techniques for using foldable IOLs in scleral fixation technique [8,10], but till now, no comparative studies have been carried out between the main types of foldable IOLs to evaluate their degree of stability and outcome in scleral fixation technique.

Yamane and colleagues described a technique for implanting a scleral fixed IOL with suture-less prolene haptic. This involves using cautery to create a flange at the end of the haptic and then inserting the haptics into the scleral tunnel. This method demonstrates the challenges of second haptic grasping, the potential for first haptic slippage, the risk of haptic deformation or breaking, the possibility of IOL dislocation into the vitreous, and the extended learning curve [16].

Currently, three-piece IOLs are more popular to be used in scleral fixation technique as it provides good postoperative stability [6]. However, one of the main disadvantages of this type of IOL is its higher incidence of haptic breakage [7,8]. Kelker and colleagues, have discussed the advantage of using one-piece IOL instead of three-piece IOL. They have reported that one-piece IOL reduces the chances of IOL haptic slippage or breakage [8]. As they have ordinary soft haptics, they are synthesized using the same material as the optic; however three-piece IOLs have rigid haptics are formed of another material than its optic [7]. A broken haptic can cause serious harm to the anterior and posterior segments of the eye [9]. In such cases, the IOL exchange is the best solution, but this will expose the patient to an additional risk of corneal endothelial cell loss and corneal decompensation [17].

Additionally, the critical advantages of the one-piece foldable approach that can eliminates the risk of IOL dislocation or haptic slippage by continuously securing the lens with a suture. This technique can be easily learned. Canabrava *et al.* [18] described nonfoldable PMMA IOL eyelets with the haptics. They used 5/0 prolene suture with flanges to secure the lens to the sclera.

In this trial, we inserted the foldable IOL via a 2.8 mm sutureless corneal incision, reducing the overall corneal astigmatism and improving visual outcomes compared to techniques requiring larger incisions. These larger incisions, however, are linked to many complications, including intraoperative and postoperative hypotony, choroidal detachment, and wound closure complications such as leaking, anterior chamber loss, and increased infection risk [19]. Interestingly, in this study, a single-piece foldable IOL was utilized, which is commonly used, eliminating the necessity for a specialized lens design or a three-piece lens.

Stem *et al.* [20] reported that the prevalent postoperative consequences of scleral fixated IOL are cystoid macular edema and vitreous hemorrhage. In this study, we have not reported any cases of intravitreal hemorrhage, macular edema, or postoperative endophthalmitis. Additionally, there was no suture breakage over the mean follow-up period of 12 months. In the literature, the younger individuals had a higher incidence of postoperative suture breakage, up to 24 % [16,18]. We believe that the 10-0 polypropylene suture offers certain advantages. As the 10-0 polypropylene suture knot is quite tiny and may result in lesser complications, such as scleral atrophy at the suture knots or erosion by the stiff ends [9].

### 4.1. Limitations

In this study, we have chosen a single design for each type of the two examined foldable IOLs, anticipating that both designs will provide the best postoperative stability. Further studies are needed to evaluate other different designs.

### 4.2. Conclusion

Aphakia correction using scleral fixated single-piece foldable IOLs is a safe and effective approach. It is a simple method that avoids difficult haptic manipulation, breakage, or slippage.

## Ethics approval

The experiment was approved by the Memorial institute of ophthalmic research Ethics Committee. Institutional rseceview board (IRB) approval number : Mior 2117. All procedures has been adhere to the Declaration of Helsinki ethical principles for medical research.

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## Author contributions

G.S.M. contributed to the design, acquisition, and interpretation of data, as well as drafted the manuscript. M.G.A. contributed to the statistical analysis and edited the manuscript. All authors have read and approved the final manuscript.

## Availability of data and materials

The data used in this research can be accessed through contact with the corresponding author.

## Institutional rseceview board (IRB) approval number

Mior 2117.

## Conflict of interest

There are no conflicts of interest.

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