Original Article

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Ophthalmology Section

Efficacy of Single-site versus Two-site Phacotrabeculectomy in Primary Open-angle Glaucoma: A Prospective Cohort Study

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ABSTRACT

Introduction: The prevalence of co-existing cataract and glaucoma is increasing in the adult population. Combined surgeries have become more popular. However, there is a conflict over which technique provides the best Intraocular Pressure (IOP) control with good postoperative outcomes.

Aim: To compare the efficacy of single-site versus two-site phacotrabeculectomy with mitomycin-C in patients with Primary Open-angle Glaucoma (POAG) and cataract.

Materials and Methods: A prospective cohort study was conducted in the Department of Ophthalmology, S.V. Medical College, Tirupati, Andhra Pradesh, India, over a period of one year from January 2019 to January 2020. A total of 50 cases of POAG co-existing with cataract were analysed in the present study. Twenty-five cases were included in each group (Group-1 and Group-2). Phacoemulsification and trabeculectomy were both performed through a superior scleral tunnel in the single-site approach. The two-site method combines a superior trabeculectomy with a temporal clear corneal phacoemulsification. A concentration of 0.2 mg/mL of MMC was applied in both groups for three minutes. Patients were followed-up for three months after surgery to evaluate Intraocular Pressure (IOP), the need for antiglaucoma medication, and postoperative best-corrected Visual Acuity (VA). Comparative analysis was done using the Student's t-test, and a p-value <0.05 was considered statistically significant.

Results: Throughout the three-month duration, the patients were monitored. In the single-site group, the average preoperative IOP was 21.880±8.4079 mmHg, which significantly decreased to 11.16±9.95 mmHg after three months (p<0.001). In the two-site group, the corresponding figures were 22.640±6.3040 and 10.8±1.19 mmHg, respectively (p<0.001), with no discernible statistical distinction between the two groups (p=0.486). At the final follow-up, the number of antiglaucoma medications was 0.24±0.5 in the single-site group compared to 0.16±0.24 in the two-site group. The mean postoperative Best Corrected Visual Acuity (BCVA) did not exhibit any significant variation between the two groups. Furthermore, there was no disparity in the occurrence rate of complications between the two groups.

Conclusion: Both single and two-site phacotrabeculectomy led to a significant reduction in IOP and improvement in BCVA. The final IOP was similar in the two procedures, although the two-site group needed less glaucoma medication. As both surgical procedures are equally effective, the choice of procedure remains at the discretion of the surgeon.

Keywords: Cataract, Intraocular pressure, Lens implantation, Mitomycin C, Visual acuity

INTRODUCTION

Cataract and glaucoma are the leading causes of blindness worldwide, with a prevalence of 51% and 8%, respectively. The concurrent existence of visually significant cataract and POAG is increasing in elderly patients [1]. A study by McGuigan LJ et al., has shown an IOP spike in two-thirds of patients undergoing cataract surgery with pre-existing glaucoma, compared to 10% in controls [2]. Brooks AM et al., demonstrated a 2.5 times increase in IOP after cataract surgery alone compared to combined surgery [3]. In eyes that have undergone trabeculectomy in the past, cataract surgery raises the likelihood of bleb failure, and this risk escalates when the interval between trabeculectomy and cataract surgery is shorter, as complications become more pronounced with each separate procedure [4]. Glaucoma surgery is indicated in patients who fail to respond to maximally tolerated medical therapy or who continue to have progressive optic nerve damage despite medical control. Glaucoma surgery alone can significantly increase the risk of developing cataract [5].

With advancements in phacoemulsification, combined trabeculectomy with phacoemulsification has become a popular and effective procedure [6,7]. IOP is significantly lowered when phacoemulsification with Intraocular Lens (IOL) implantation and trabeculectomy are combined (phacotrabeculectomy), with a reduced requirement for postoperative antiglaucoma drugs [8]. The effectiveness of phacotrabeculectomy has significantly increased with the use of Mitomycin C, an antimetabolite and antifibrotic drug, as a wound modulator [9].

Phacotrabeculectomy can be performed either through a single incision (phacoemulsification and trabeculectomy) or through two separate incisions (two sites). It has been suggested that using a separate phacoemulsification incision from the trabeculectomy incision improves the outcomes of the filtering procedure and reduces postoperative conjunctival and scleral scarring [10].

However, the decision to perform phacotrabeculectomy through one site or two sites is still a matter of debate. While VA results have been comparable [11,12], there is disagreement regarding which technique provides the best management of IOP and reduction in the need for glaucoma medication. The choice between the surgical approaches of phacotrabeculectomy has been a subject of debate, and present study provides valuable insights into the comparative effectiveness of the single-site vs. two-site approach.

The IOP management is a crucial aspect of glaucoma treatment. By tracking IOP changes over a three-month follow-up period, present study offers a comprehensive understanding of how these surgical methods influence IOP control. Additionally, it explores the postoperative reduction in the number of antiglaucoma medications required by patients in both groups, which is essential for patient comfort and long-term care. The present study also assesses whether one surgical technique provides better visual outcomes compared to the other.

The study meticulously records and compares the occurrence of postoperative complications between the single-site and two-site groups, providing essential insights into the safety profiles of these procedures.

The present study was aimed to compare the efficacy of both procedures in controlling IOP, the use of postoperative antiglaucoma medications, postoperative VA, and astigmatism.

MATERIALS AND METHODS

A prospective cohort study was conducted at the Department of Ophthalmology in SVRRGGH, S.V. Medical College, Tirupati, Andhra Pradesh, India, over a period of one year from January 2019 to January 2020. The research was conducted in adherence to the Principles of the Declaration of Helsinki and received approval from the Institutional Ethical Review Board of study institute (IEC No 47/2018). Written informed consent was obtained from all patients after providing a comprehensive explanation of the surgical procedure. The study focused on patients diagnosed with POAG accompanied by visually significant cataract.

Inclusion crietria: The inclusion criteria comprised patients with POAG presenting characteristic visual field defects, who had uncontrolled IOP despite using two different antiglaucoma medications, along with visually significant cataract. The severity of cataract was determined based on its impact on BCVA, specifically if it caused a decrease of more than five lines on the Snellen chart.

Exclusion criteria: Individuals with lens subluxation, secondary glaucomas, or neo-vascular glaucoma, patients with advanced visual field loss or advanced cupping of the optic disc, a history of prior intraocular surgery in the same eye, participants who experienced intraoperative complications that hindered the implantation of a foldable IOL, such as posterior capsular rent or vitreous loss, and individuals with co-existing ocular conditions that could potentially impact the final VA were excluded from the study.

Sample size calculation: A total of 54 eyes from 46 patients were enrolled in the study. The sample size calculation was done based on the formula:

$$n=\frac{2SD^2(Z\alpha/2+Z\beta)^2}{d^2}$$

Where SD=Standard Deviation from previous studies (13)=3.5 mmHg, Zα/2=1.96 (standard normal variate from Z-table at 95% confidence interval), Zβ=0.842 (from Z-table) at 80% power, d=expected difference between the means (IOP)=2 mmHg.

Study Procedure

The patients were randomly assigned to two groups: Group I (n=28 eyes) and Group II (n=26 eyes), which underwent single-site and two-site phacotrabeculectomy, respectively. However, four eyes of four patients were excluded from the analysis due to loss of follow-up. Specifically, three cases from Group I (single-site phacotrabeculectomy) and one case from Group II (two-site phacotrabeculectomy) were lost to follow-up. Therefore, the study included 25 cases in each group.

Method of randomisation: Sealed envelopes were used to conceal the sequence of random allocation for a single-site and two-site phacotrabeculectomy. The envelopes were unsealed on the day of surgery.

Data collection: Prior to the surgery, relevant baseline information such as patient demographics, diagnosis, IOP measured using Goldman applanation tonometry, and the number of antiglaucoma medications taken by the patient were documented. BCVA was assessed using the Snellen chart and converted to the logMAR scale for statistical analysis. Additionally, corneal curvature was measured using automated keratometry.

Preoperatively, topical moxifloxacin, flurbiprofen eye drops, and a combination of topical tropicamide 0.8% and phenylephrine 5% were instilled every 15 minutes for one and a half to two hours prior to surgery. All operated eyes received peribulbar anaesthesia with 2% lidocaine with or without epinephrine and 0.5% bupivacaine. All surgeries were performed by a single surgeon.

Single-site surgery [13]: A 4-0 silk bridle suture was placed beneath the superior rectus muscle to expose the superior surgical area. A superior fornix-based conjunctival flap was created by incising the conjunctiva at the limbus from the 11 o'clock to 1 o'clock position and dissecting posteriorly. Episcleral bleeding was controlled using wet cautery. A cotton pellet soaked in 0.2 mg/mL of mitomycin C (MMC) was positioned beneath the conjunctiva, ensuring it did not come into contact with the conjunctival edges, and left in place for three minutes. The area was thoroughly irrigated with a balanced salt solution.

A triangular partial-thickness scleral flap measuring 5×5×5 mm was fashioned and dissected anteriorly, for 1 mm into the cornea. A paracentesis was performed at the 11 o'clock position in the right eye and at the 1 o'clock position in the left eye, followed by the injection of a viscoelastic substance into the anterior chamber. A 2.8 mm keratome was used to enter the anterior chamber under the scleral flap. Phacoemulsification was then carried out using the direct chop technique [14], and a foldable, single-piece acrylic IOL was inserted into the capsular bag. After aspirating all viscoelastic material, the pupil was constricted with intracameral pilocarpine, and a trabecular block measuring 1.5×1.5 mm was excised using a Kelly Descemet's punch. Peripheral iridectomy was performed with the aid of iris forceps and Vanna's scissors.

The scleral flap was secured using three interrupted 10-0 nylon sutures: one placed on each side of the triangular scleral flap and one at the apex. The conjunctival flap was closed using the wing suture technique and 10-0 nylon suture material. To reduce the risk of leakage, postoperative conjunctival retraction, and exposure of the trabeculectomy site, the anterior edge of the conjunctiva was advanced at least 1 mm onto the cornea. The anterior chamber was reformed with a balanced salt solution through the paracentesis. The trabeculectomy site was assessed for excessive leakage, and if necessary, the scleral sutures were adjusted to achieve appropriate bleb elevation and prevent leakage. Finally, a subconjunctival injection of dexamethasone and gentamicin was administered inferiorly.

Two-site surgery [15]: A superior fornix-based conjunctival flap was made, and MMC application and creation of a triangular scleral flap were done as in the single-site group. Phacoemulsification with foldable IOL implantation (Ocuflex foldable single-piece Hydrophilic Acrylic manufactured by Care group sight solutions Private limited, Padra, Vadodara district, Gujarat) was performed through a separate temporal clear corneal incision. After performing cataract surgery, trabeculectomy, and the rest of the procedure were completed as in the single-site group.

The postoperative regimen was the same for both groups of eyes. Topical antibiotic-steroid eye drops (a combination of ciprofloxacin 0.3% and dexamethasone 0.1%) were applied four to six times per day for three weeks following surgery, depending on the degree of inflammation, and then tapered over the next two weeks. Cycloplegics (Cyclopentolate 1%) eye drops were used three times a day during the first week and then as necessary. In the follow-up, antiglaucoma medication was added if the target IOP was not achieved.

Operative data encompassed details such as the specific surgical technique employed (single-site or two-site phacotrabeculectomy) and any occurrences of operative complications.

Follow-up: All patients were followed-up on postoperative day seven, one month, two months, and 3 months. At each follow-up visit, BCVA, corneal curvature by automated keratometry, and IOP were recorded. Bleb assessment and the number of antiglaucoma drugs required to achieve the target IOP were noted. The Indiana classification was used for bleb grading [16]. Intraoperative and postoperative complications were also recorded at each follow-up visit. The Seidel test was performed to check for any bleb leak. Fundus examination was done with a 90D lens. Visual fields were done at the end of three months.

STATISTICAL ANALYSIS

The data were collected on a Microsoft Excel sheet, and Statistical Packages for Social Sciences (SPSS) software version 21.0 was used for analysis. The Student's t-test was used to establish significance. The paired Student t-test was employed to evaluate the pre- and postoperative parameters within a single group, whereas an unpaired t-test was utilised to compare parameters between two distinct groups. A p-value <0.05 was considered statistically significant.

Parameters	Group-1 (Single site), (n=25)	Group-2 (Two site) (n=25)	p-value*
Age (years) (Mean±SD)	**61.28±5.66**	**60.52±6.25**	**0.654**
Gender			0.286
Male	14	11	
Female	9	8	
Preoperative IOP (mmHg) (mean±SD)	21.880±8.4079	22.640±6.3040	0.719
Number of antiglaucoma medications (mean±SD)	2.4±0.816	2.360±0.5686	0.841
BCVA (LogMAR)[1] (mean±SD)	1.41±0.74	1.299±0.728	0.595

[Table/Fig-1]: Baseline characteristics of the two study groups.
*unpaired t-test; IOP: Intraocular pressure; BCVA: Best corrected visual acuity; SD: Standard deviation; [1]Independent sample t-test

RESULTS

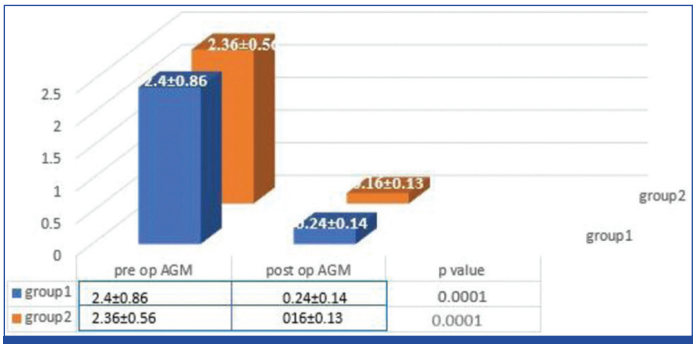
There were no statistically significant differences (p=0.670) in baseline characteristics, age (p=0.654), preoperative BCVA (p=0.595), preoperative IOP (p=0.719), and the number of antiglaucoma drugs used between the two groups (p=0.841) [Table/Fig-1].

Parameters	Group-1 (Single-site) mean±SD (mm of Hg)	Group-2 (Two site) mean±SD (mm of Hg)
Preoperative IOP	21.880±8.4079	22.640±6.3040
Postoperative IOP		
7 days	12.8±4.09	12.7±4.07
1 month	12.32±2.82	12.94±3.43
3 months	11.16±9.95	10.8±1.19
p-value[#]	<0.001	<0.001
Mean reduction in IOP[2]	10.72±8.127	11.84±6.196*
		p-value 0.586

[Table/Fig-2]: Mean IOP pre and postoperative follow-up.
*unpaired t-test, p-value: 0.586, [#]paired t-test- <0.001

At the 3-month postoperative follow-up, the mean IOP was 11.16±9.95 mmHg in the single-site group and 10.80±1.19 mmHg in the two-site group, with a statistically significant difference (p<0.001) [Table/Fig-2]. Although the two-site group had a lower IOP compared to the single-site group at the 3-month mark, there was no statistically significant difference in the mean reduction in IOP between the two groups (p=0.58).

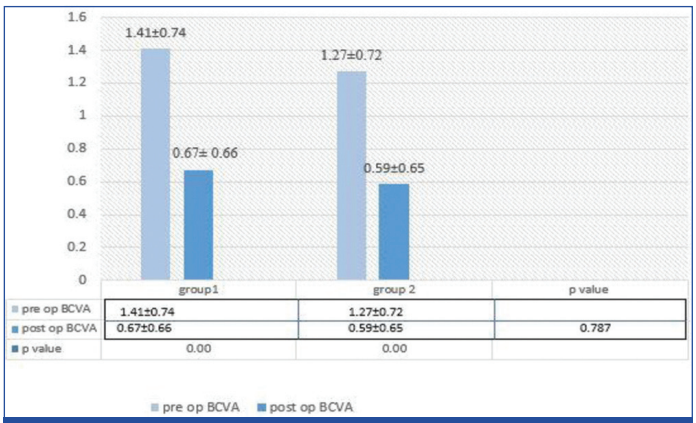
The number of antiglaucoma medications decreased from 2.4±0.86 preoperatively to 0.24±0.14 postoperatively in Group-1 and from 2.36±0.56 to 0.16±0.13 in Group-2. A statistically significant difference is noted in the usage of pre and postoperative antiglaucoma medications required to control the IOP in either group (p-value=0.0001). The target IOP was achieved with a single antiglaucoma medication in either group. A lower percentage of patients in the two-site group 4 (16%) compared to the single-site group 6 (24%) required postoperative antiglaucoma medication. The number of glaucoma medications used pre- and postoperatively by patients in each group is depicted in [Table/Fig-3,4]. The mean reduction in Antiglaucoma Medications (AGM) postoperatively in Group-1 was 2.16±0.987 and in Group-2 was 2.20±0.645 without any significant difference between the two groups (p=0.867).



[Table/Fig-3]: Number of antiglaucoma medications preoperative and at postoperative three months in two groups.
Student[1] paired t-test, p-value=0.867
AGM: Antiglaucoma medications; Group-1: single-site; Group-2: two site

[Table/Fig-4]: Number of patients using AGM at each follow-up visit in each group.

In the single-site group, the mean BCVA improved from 1.41±0.74 logMAR preoperatively to 0.67±0.66 logMAR postoperatively (p<0.001), and in the two-site group, it improved from 1.27±0.72 logMAR preoperatively to 0.59±0.65 logMAR postoperatively (p<0.001). The mean postoperative BCVA did not show a statistically significant difference between the two groups with a p-value of 0.787 [Table/Fig-5].



[Table/Fig-5]: BCVA (LogMAR) in two groups.
[1]unpaired t-test

Corneal astigmatism was calculated using an automated keratometer. Preoperative astigmatism was similar in both groups. At the three-month postoperative follow-up, the amount of surgically-induced

astigmatism was lower in both groups compared to preoperative values. Specifically, the induced astigmatism was 0.3 D±0.11 in the two-site group and 0.6 D±0.18 in the single-site group, with lower values observed in the two-site group. No intraoperative complications were observed in either group.

During the first postoperative week, two patients in the single-site group developed hyphema, and two eyes in the single-site group and one eye in the two-site group presented with a shallow anterior chamber. In the single-site group, three cases exhibited flat blebs in the early postoperative period, while at the 3-month follow-up, all blebs were diffusely elevated with mild vascularity, and the Seidel test was negative in all cases. In the two-site group, one case had flat blebs in the early postoperative week, and at the 3-month follow-up, all blebs were diffusely elevated with mild to moderate vascularity, and the Seidel test was negative in all cases. Additionally, one case of postoperative uveitis was reported in the single-site group.

DISCUSSION

Managing glaucoma with visually significant cataract presents a clinical challenge. The care of patients with co-existing cataract and glaucoma often involves considering combined surgery, such as phacotrabeculectomy. When this approach is considered, two main decisions need to be made regarding surgical strategy. The first is the location of the surgical incision for cataract extraction, and the second is the location of the conjunctival incision for trabeculectomy.

Early clinical studies of phacotrabeculectomy reported surgical outcomes using the same upper scleral incision for both the phacoemulsification and trabeculectomy portions of the operation. The introduction of the temporal incision for phacoemulsification allowed surgeons to perform a two-site phacotrabeculectomy, creating a second superior incision for trabeculectomy. It has been suggested that using this latter technique, by separating the incisions, lowers postoperative scarring of the scleral flap and conjunctiva, thereby enhancing the outcomes of the filtration procedure. Some surgeons believe that a temporal cataract incision allows for greater visualisation of the eye and surgical access, especially in patients with challenging anatomical features of the orbit [11,12,17].

However, there is no compelling evidence supporting the superiority of either surgical strategy. A meta-analysis of 12 randomised clinical trials comparing one-site versus two-site phacotrabeculectomy, with a minimum of 12 months of follow-up, found no observable difference in the reduction of IOP, use of glaucoma drugs, or change in BCVA from baseline [18].

The present study aimed to compare postoperative IOP reduction, the number of antiglaucoma medications required after surgery to reach the target IOP, postoperative BCVA, and corneal astigmatism between the two approaches and evaluate their superiority.

Several studies have reported better control of IOP when the surgical incisions were made separately, as in the two-site technique [9,15,19]. The benefit was measured as an additional reduction of 1 to 2 mmHg with two-site surgery. Other studies have reported only minor differences between the one and two-site approaches [7,11,20]. Similarly, in the present study, postoperative IOP at 3 months was lower than the preoperative IOP (p=0.001) in both groups, indicating that both techniques are effective in reducing IOP. However, IOP was consistently lower in Group-2 (two sites) compared to Group-1 (single-site), and the mean reduction in IOP was better in Group-2 compared to Group-1, although without statistical significance (p=0.586).

Significant reductions in the number of postoperative antiglaucoma medications were observed in both groups (p<0.001). At the 3-month follow-up, only six patients in Group-1 were using a single antiglaucoma medication, while in Group-2, only four patients required a single drug, and 21 patients did not require any medications. None of the patients in either group needed more than one drug. The mean reduction in antiglaucoma medications was not statistically significant between the two groups, which is consistent with the findings of Wyse T et al., [12]. Patients who required postoperative antiglaucoma medications belonged to the advanced glaucoma group and were on maximum medical therapy prior to surgery. In a study by Moschos MM et al., a higher proportion of patients in the two-site group did not require any medication postoperatively, and none of the patients needed more than one medication [13]. However, three patients in the one-site group required two glaucoma medications postoperatively, possibly due to increased fibrosis resulting from more manipulation of the conjunctival and scleral flaps. In contrast to the study by Moschos MM et al., present study findings suggest that the use of antimetabolites allowed for better IOP control with fewer medications in both groups.

All cases included in the study showed improvement in BCVA postoperatively. This improvement can be attributed to the absence of major complications in both techniques and the exclusion of patients with preoperative ocular pathology that could affect visual outcomes. There was no significant difference in the final visual outcome between the two groups, although Group-2 showed slightly better results. Similar findings of better BCVA with two-site surgery were reported by Baradaran-Rafiee A et al., although the difference was not statistically significant [21]. This observed difference may be due to the separation of surgical sites in two-site surgery, which potentially avoids the tissue weakening effect of antimetabolites on the temporal phacoemulsification incision, resulting in a more stable wound.

The current study observed a significant difference in surgically induced astigmatism between the groups, with the two-site group showing less astigmatism. This finding is consistent with the study by Moschos MM et al., which also reported less induced astigmatism in the two-site group [13]. Previous studies have similarly concluded that a temporal incision results in less astigmatism compared to an incision at the 12 o'clock position [11,22]. The higher astigmatism observed in single-site phacotrabeculectomy may be attributed to excessive manipulation of the wound.

Complications of phacotrabeculectomy with MMC were not influenced by the type of surgery. During early postoperative follow-ups, both groups experienced a shallow anterior chamber with bleb leak and choroidal detachment, with Group-1 experiencing more of these complications. In the single-site group, two cases of hyphema were treated conservatively. One case in Group-2 developed conjunctival recession, for which re-suturing was done. In Group-1, postoperative uveitis with fibrinous exudation was reported in one case. In a comparative study investigating one-site versus two-site phacotrabeculectomy, Borggrefe J et al., reported a 24% incidence of postoperative fibrinous uveitis [17]. Similarly, Allan BD and Barrett GD observed postoperative uveitis in 33% of eyes (3 out of 10 eyes) in the form of mild fibrinous exudate in their study [23]. The relatively higher occurrence of mild fibrinous exudation in patients with glaucoma and cataract may be partly attributed to dysfunction of the blood-ocular barrier. However, in the current study, the rate of fibrinous exudation was notably low (1 out of 50 eyes). This could be attributed to minimal tissue manipulation during the procedure, which likely contributed to reduced postoperative inflammation. Additionally, the overall complication rate was lower compared to previous studies. At the 3-month follow-up, all the blebs were functioning effectively, yielding similar outcomes in both groups.

Limitation(s)

The limitation of the current study was the short follow-up period. Only automated keratometry was used to measure pre- and postoperative corneal astigmatism. The use of corneal topography might have provided more reliable results.

CONCLUSION(S)

The present study suggests that both phacotrabeculectomy surgical procedures are clinically successful and equally effective in controlling IOP and minimising the requirement for antiglaucoma drugs. Adverse events are comparable between the two groups and are not influenced by the type of surgery. Because these differences did not have an impact on the clinical outcome, the authors conclude that selecting the incision sites for phacotrabeculectomy should remain at the discretion of the surgeon. Surgeons who believe that less scleral and conjunctival manipulation result in a good postoperative outcome prefer the separate-site procedure.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Jun 22, 2023
- Manual Googling: Sep 15, 2023
- iThenticate Software: Nov 18, 2023 (10%)

ETYMOLOGY: Author Origin

EMENDATIONS: 7

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

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