



Assessment of the efficacy of auricular conchal cartilage graft in repairing orbital floor fractures and its effect on diplopia: a nonrandomized clinical trial

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Background: Orbital fractures are a common sequela of maxillofacial zone trauma. Rapid assessment and management are essential for successful reconstruction. The selected treatment method depends on fracture types, accompanied injuries, and intervention time. Implantable grafts used to be from autologous materials. The study aimed to evaluate the effectiveness of using the auricular conchal cartilage taken from the ear to repair orbital floor fractures in cases of minimal bone loss, less than (2 × 2) cm.

Material and Methods: A prospective single-arm, nonrandomised clinical trial was conducted during the past 4 years (from 2018 to 2022). A total of 15 cases, who had visited the department of oral and maxillofacial surgery department with orbital floor fractures, were enrolled. The participants underwent conchal cartilage grafting for orbital floor fracture reconstruction. The time factor to perform the surgery after trauma had been considered. Patients were closely monitored for the development of double vision (diplopia) at 15 days, 1 month, and 3 months postsurgery.

Results: The results showed statistically significant differences during the follow-up period following the surgical procedure. They appeared to have complete restoration of eye movements, restoration of the normal positioning of the eyeball affected by the orbital floor fracture compared to the healthy eyeball, and regression of double vision (diplopia) throughout the follow-up period.

Conclusion: Using the auricular conchal cartilage graft in repairing fractures of the orbital floor resulted in the improvement of the functional aspect of the eyeball and the restoration of the esthetic aspect.

Keywords: cartilage graft, diplopia, ear, maxillofacial surgery, orbital floor fracture

Background

The maxillofacial zone is vital due to the functions it allows, such as breathing, chewing, articulation, and sight. The maxillofacial zone trauma can result in sequelae that may affect the patient and their lifestyle and that is due to the functional and esthetic importance of this area^[1]. The middle third of the facial skeleton is composed of many bones that rarely break apart. The structure of these bones is arranged to resist the chewing pressure from the jaw and protect the bio-structures, specifically the eye structure (the eyeball), as well as other bony structures, that are subjected to fractures to dissipate the pressures and protect the bones of the skull^[1]. Orbital fractures are usually caused by: traffic accidents, accidental falls, sports injuries and, quarrels. The injury may vary

HIGHLIGHTS

- The ideal implant used in repairing the orbital floor fracture should be non-reactive, available, biocompatible, and noncarcinogenic. In addition, it should be easy to place, free from any possibility of disease transmission, and provide good structural support.
- Cartilage graft taken from the ear is an efficient choice in the treatment of fractures of the orbital floor with minimal bony damage less than (2 × 2) cm.
- The use of cartilage graft in the repair of the orbital floor fractures led to improvement and regression of diplopia.

according to multiple factors such as the environment, sex, age, and socioeconomic status of patients^[2]. Many classifications have been developed to characterize this type of orbital fracture. However, they have not adopted a unified system that fits all orbits^[3]. Orbital floor fractures are usually included within other fractures, due to the complex geometry of the orbital bones, which makes it challenging to perform reconstruction after facial trauma, especially if more than one section is injured^[1]. Assessment of trauma to the facial bones is based on clinical examination and appropriate radiography. The fractures of the orbital floor can be managed surgically or nonsurgical. The correct and early clinical diagnosis determine the success of the treatment. Therefore, the functional examination and radiographs will help determine the suitable procedure. However, surgical intervention is usually indicated in patients with severe injury or dysfunction^[4]. The treatment pattern varies depending on fracture type, treatment timing, injury accompaniment and the

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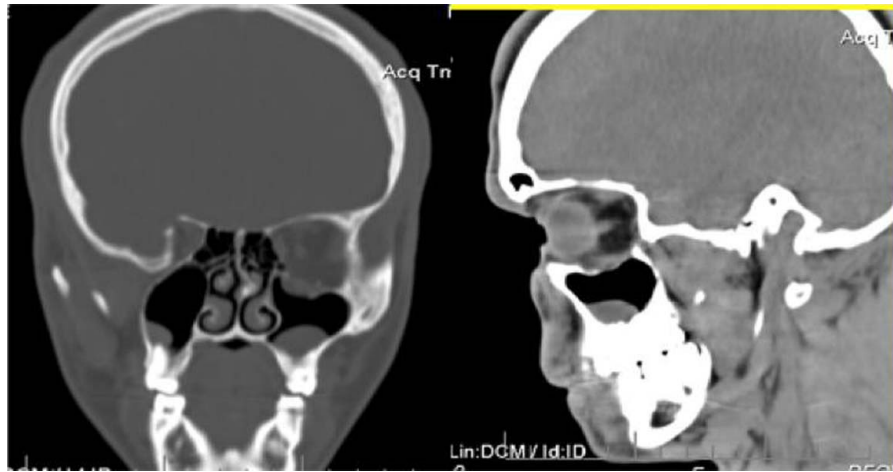


Figure 1. The computed tomography scan shows an orbital floor fracture and impaction of the inferior rectus muscle and orbital fat within the fracture line.

general condition of the patient^[5]. Controversial opinions appeared about the best implantable material that can be used in grafting the orbital floor. The ideal material must be biocompatible, noncarcinogenic, easily fixed in place and free of any potential disease transmitting hotbeds. Moreover, it must not require any surgical procedure to remove titanium implants and nets if they are used^[6]. Treatment of the orbital floor fracture is an advanced procedure, and it is well-known that regardless of the material used in the graft, it must aim to restore the anatomical shape of the orbital cavity, in addition to avoiding the severe rigid fixation that occurs with metal meshes and thick grafts. It is well-

documented in cases where rigidity fixation to the orbital floor is associated with recurrences of lesions occurring in the same eye due to increased pressure. Autologous materials such as bone, cartilage, and periosteum have the advantage of lower rates of infection and lower procedure costs. In contrast, these materials have the disadvantage of increased surgical time and morbidity associated with complications in the donating part. Cartilage and bone are the most commonly used autologous materials in orbital floor grafts. Apparently, they are easily obtained with minimal tissue trauma. Moreover, they show high rates of uptake and loss. On the other hand, artificial grafts reduce surgical time but increase the possibility of infection, rejection, fistulas, cysts, and treatment costs. In this regard, many studies have shown fewer complications with autologous grafts than with artificial ones^[7]. In our study, we use cartilage graft due to the high trauma, surgical duration, and possible non-anatomical reduction that is associated with rigid fixation of the orbital floor and also the absorption rates in the bone grafts. The mostly used autologous cartilages are the nasal septum and the auricular cartilage, which we adopt in this study. Here, we conducted a nonrandomized clinical trial to evaluate the safety and efficacy of selecting cartilage grafts taken from the ear to repair the orbital floor fractures. We hypothesize that cartilage grafts will enable doctors to use them as an alternative to metal meshes. In addition, we envisage their effectiveness in restoring the anatomical shape of the orbit and repositioning its components to their normal location.

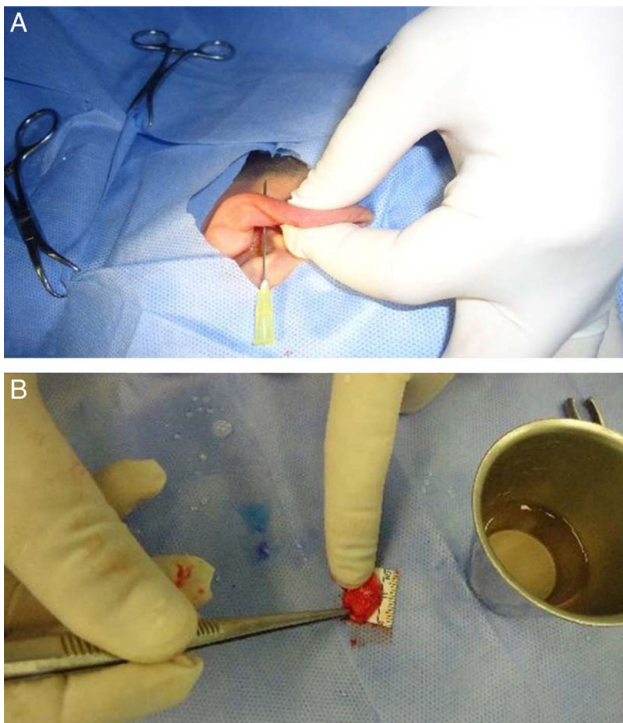


Figure 2. Graft borders estimation, then excision and determination of its dissemination to be finally saved in a container with a balanced electrolyte solution.

Materials and methods

Study design, and settings

A prospective, single-arm, nonrandomized clinical trial design was conducted during the past 4 years (from 2018 to 2022) in the Department of Oral and Maxillofacial Surgery. Patients who had a traffic accident or fight were initially assessed in the orthopedic and neurosurgery departments. Then they were transferred to be managed by the cooperation of oral and maxillofacial surgeons and ophthalmologists. The ophthalmologist evaluated the patient about the presence of diplopia, any change in the vertical dimension, and the enophthalmos. If diplopia was the only symptom, we waited until the bruising and edema around the eyeball were subsided, and we re-examined again to confirm the need for surgery.

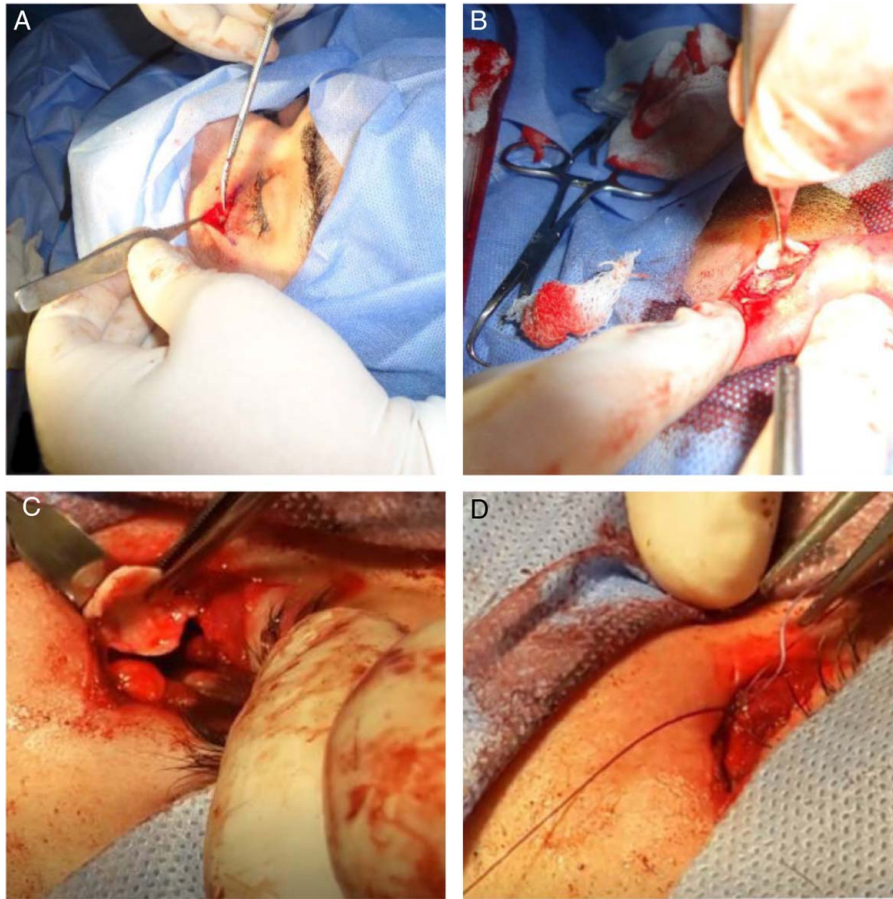


Figure 3. The surgical stages of the work: (A) making an incision at the lower edge of the orbit, (B) dissection of the orbicularis oris muscle, (C) placement of the graft at the fracture site, (D) sewing wound layers with sutures.

Participant

A sample size of 15 patients, who were diagnosed depending on clinical examination and computed tomography (CT) scan results that showed the fracture of the orbital floor and impacting of the inferior rectus muscle and orbital fat within the fracture line (Fig. 1), was required. Male patients aged

18–58 years complaining of diplopia and enophthalmos with confirmed orbital floor fracture and eye muscle impaction without additional complications were eligible for this study. Exclusion criteria included significant material loss of the orbital floor and patients with brain or other related injuries. Written informed consent was obtained from all participants.

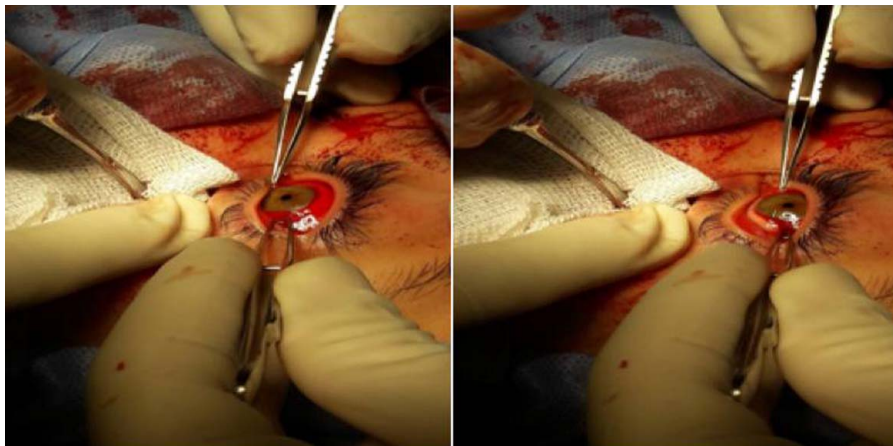


Figure 4. The assessment of the eye muscle function after the procedure by the Forced Ducting Test (FDT).

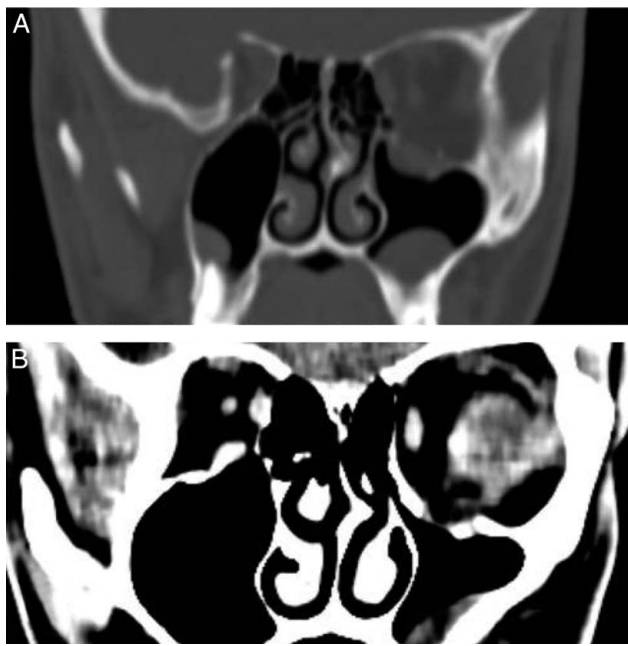


Figure 5. The computed tomography scan findings: (A) before surgery, (B) after surgery.

Interventions

Manufacture of an ear graft

Patients were scheduled to undergo interocular pressure measurement, visual field examination by Hess charts and ocular muscle contraction checking. Next, we determined the dimensions of the fracture by measuring the sagittal and frontal sections between the edges of the fractured bone. Then the Efilm Lite

program used at the hospital processed the CT images. The implanted ear graft was individually designed to reconstruct reconstruct the existing defect. All grafts were with a size of approximately 2 × 2 cm with an adjustment according to each patient’s ear size. Marking is carried out using methylene blue on the borders of the ear concha and is followed by determining the dimensions of the graft and the incision procedure. The removed graft was placed in a sterile container with a physiological fluid that a balanced electrolyte solution (Fig. 2) with protection of the anatomical units of the ear.

Surgical technique

We perform the procedure under general anesthesia and oral or nasal incubation. Depending on each patient’s condition, area preparation with the cleaning of the face and the affected area with dermal povidone is performed, in addition to placing sterile gauze and isolating the operation area where the graft is excised. After graft preparation, we palpate the lower edge of the orbit, and the incision site is determined using a sterile marker and made in the natural skin fold under the eyelid cartilage only. Secondly, we dissect the orbicularis oris muscle using dissection scissors until the periosteum is reached. The periosteum is cut to the bone and flayed by periosteum elevators until the lower edge of the orbit appears. Afterward, the orbital spatula is used to elevate the eyeball, and the cartilaginous graft is applied after releasing the wedged parts within the fracture line. In addition, we perform the fixation of bones with plates in the event of other fractures. Finally, the wound is closed using two layers; the periosteum using vicryl threads 0–4 and the skin using nylon threads 0–5 (Fig. 3). After graft insertion, the ophthalmologist performs forced duction testing to ensure the success of the implemented intervention (Fig. 4). Postoperative, we monitor vital signs, and the patient is given painkillers with antibiotics.

Postoperative follow-up

Each patient is evaluated after 15 days, after a month, and after 3 months by experienced maxillofacial surgeons and ophthalmologists, and a radiological evaluation with a CT scan is performed (Fig. 5). Ear appearance after one month of the procedure is shown in Figure 6. Figure 7 presents the follow-up of two cases before surgery, 15 days and 3 months after surgery.

Results

To assess the safety and efficacy of this clinical study, we used the following statistical methods: Kolmogorov–Smirnov test, the Freidman test to compare linked samples, and the Wilcoxon test for linked eyes. The statistical package for social sciences (SPSS v20) was used to carry out the analysis process and achieve the objectives set within the framework of this research with a significance level 5%, which is generally considered a satisfactory level for this type of study. Corresponding to a 95% CI in the results of the study.

Measurements of diplopia (Double Vision)

We evaluated the diplopia cases by requesting the patient to look directly at a small light source, placing a finger at an arm’s length from the patient’s eyes and asking him to follow its movement. Cases of diplopia were recorded in each of the nine eye positions.



Figure 6. The ear after a month from surgery.



Figure 7. The appearance of two cases: (A) after sustaining the injury demonstrating ecchymosis, (B) 15 days after surgery, (C) after a follow-up period of 3 months.

The (0) marker was given to indicate the absence of double vision and the degree (1) if any signs occurred. Table 1 shows the results of the diplopia measurements during the study periods. The clinical improvement of diplopia was noted with the progression of time after 15 days, a month, and 3 months of the following-up.

Statistical comparison

We used χ^2 to compare the follow-up periods when measuring the diplopia. The results of which are shown in Table 2. χ^2 (Freidman) was used to compare the averages of the diplopia levels during the follow-up periods. A decrease in the average levels of the follow-up periods until the complete absence of double vision in the 15 days postsurgery period was noted. It decreased further in 1 month and 3 months after surgery. Moreover, to infer the positions of these differences, a Z test (Wilcoxon) was conducted (Table 3).

Discussion

Fractures of the orbital base are relatively common injuries that happen after sustaining facial trauma or a tumoral injury. These fractures need urgent management to prevent accompanying eye

function impairment. The orbital floor reconstruction should be considered with paying attention to the successful reposting of herniated fat and tissue in the orbit and appropriate bone defect rebuilding. In addition, the orbital floor reconstruction should prevent diplopia development and infection spreading from the maxillary sinus, according to (Baumann *et al.*,^[6]). On the other hand, choosing and placing appropriate materials for reconstruction is the other significant factor. The ideal implant should be non-reactive, available, biocompatible, and noncarcinogenic. Also, it has to be easy to place, free from any possibility of disease transmission, and provide good structural support. In 1992, (Hendler *et al.*,^[8]) confirmed that auricular cartilage is an excellent source of autogenous tissue that is suitable for repairing orbital floor defects. The thickness of this cartilage and its concave shape are ideal qualities that allow an accurate fit of the concaved orbital floor, especially at the junction of the floor with the medial wall, which is the most common site for traumatic

Table 1
Measurement of diplopia case.

Period	Average levels	χ^2	P	Result
Presurgery	2.90	14.182	0.003	Statistically significant
15 days	2.77			
1 month	2.23			
3 months	2.10			

Table 2
 χ^2 results of diplopia during follow-up.

Period	Frequency	Double vision occurrence
Presurgery	Absolute	8
	Relative	53.3%
Postsurgery 15 days	Absolute	7
	Relative	46.7%
Postsurgery 1 month	Absolute	3
	Relative	20%
Postsurgery 3 months	Absolute	2
	Relative	13.3%

Table 3
Results of Z test comparing averages of diplopia levels during the follow-up period.

Period 1	Period 2	Z Test	P	Result
Presurgery	15 days	1	N.s 0.317	Not statistically significant
	1 month	2.236	*0.025	Statistically significant
	3 months	2.449	*0.014	Statistically significant
15 days	1 month	2	*0.046	Statistically significant
	3 months	2.236	*0.025	Statistically significant
1 month	3 months	1	N.s 0.317	Not statistically significant

dislocations. Long-term experimental and clinical studies have shown that cartilage grafts remain in place for long periods and maintain proper structure and size years after grafting. An additional advantage of using auricular cartilage is that the harvesting and grafting sites combine into a unique surgical field due to their proximity. That lends ease to the preparation and sterilization processes; cartilage can usually be obtained in less than 20 min via a simplified surgical technique, adding minimal time to the procedure. In addition, according to (Saluja *et al.*,^[9]), the low anaerobic metabolism and relative vasculature that allow cartilage grafts to survive with minimal oxygen/perfusion requirements make them preferable to other autografts. However, critics advised against auricular cartilage because the flexibility of cartilage does not provide adequate support for the orbital contents. A subsequent systematic review, which was conducted by (Gunarajah *et al.*,^[10]) proved that cartilaginous graft is a durable and flexible material, which makes it easy to adapt to the orbital floor. And it has a low resorption rate when compared to bone. Hence, it has shown more life capacity and structural integrity, as shown in animal studies. In our study, a total of 15 patients were included to undergo cartilage graft placement to repair the orbital floor fractures. The results of the analysis showed the following: 15 days post a follow-up of the surgical procedure, diplopia improved for only one case by 12.5% and did not decline for 88.5%. The traumatic edema and varying severity of surgery can explain this result.

Comparing the cases presurgery and 15 days after follow-up, it was noted that the P -value > 0.05 . Accordingly, no statistically significant in-kind differences between both average levels of diplopia between the two periods were recorded.

The results showed that in 14 cases, the diplopia measurement in both periods was the same, while only a case showed an improvement 15 days after follow-up.

After a follow-up period of 3 months of the surgical procedure, the absence of diplopia was noted in five cases by 62.5%, and it remained in three cases.

Comparing the cases presurgery and one month after follow-up, it was noted that the P -value < 0.05 , accordingly, statistically significant in-kind differences were recorded between both average levels of diplopia measurement between the two periods, and the average of diplopia measurement levels after a month is less than after the surgery by 22.99%. Given the results of this study, 10 cases had the same diplopia measurement in both periods, and only five cases in which diplopia measurement had improved a month after the follow-up.

3 months post the follow-up after the surgical procedure, diplopia was absent in six cases by 75% and remained in two cases. The persistence of the impaction of parts of the lower

rectus muscle can interpret these results. The involvement of the fracture for more than one tissue and the severity of the injury within the orbital cavity are another reasonable causes.

Comparing the cases presurgery and 3 months after follow-up, it was noted that the P -value < 0.05 ; accordingly, significant statistically in-kind differences were recorded between both average levels of diplopia measurement between the two periods, and the average of diplopia measurement levels after three months is less than after surgery by 27.59%. Given the results of the this study, nine cases had the same diplopia measurement in both periods, and only six cases in which diplopia measurement had improved a month after the follow-up.

In conclusion, after 3 months of follow-up, there were two cases in which diplopia remained mild, due to the delay in performing surgery after the injury and the occurrence of adhesions with the difficulty of dissecting them, in addition to the presence of partial impaction of the lower rectus muscle.

Conclusions

It was concluded that the use of a cartilage graft taken from the ear in grafting fractures of the orbital floor with minimal material loss (less than 2 cm) effectively contributed to the recovery of patients from diplopia due to the ability of cartilage to provide a new stable muscle rest and a good movement of the eyeball. Hence, we agreed with Andrea Castellani in 2002 and Leonardo de Souza in 2011 on the ability of the cartilage graft taken from the ear to maintain the new position of the muscles and restore the natural structure of the orbital cavity while protecting the eyeball. The cartilage graft from the ear can be used for fractures of the orbital floor with minimal bony damage of less than (2 × 2) cm.

Ethical approval

Ethical approval for this study was provided by the Ethical Committee of Tishreen University hospital, Lattakia, Syria with protocol (No.407) during session number (No.3) on 16 October 2018.

Informed consent

Written informed consent was obtained from the patient for publication and any accompanying images. A copy of the written consent is available for review by the Editor-in-Chief of this journal on request.

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NA.

Author contribution

M.D.: study concept or design, data collection, data analysis or interpretation, writing the paper; I.B.: writing – review and editing; M.A.: supervision; writing – review and editing.

Conflicts of interest disclosure

The authors declare that they have no financial conflict of interest with regard to the content of this report.

Research registration unique identifying number (UIN)

1. Name of the registry: researchregistry.
2. Unique identifying number or registration ID: research registry8795.
3. Hyperlink registration: <https://www.researchregistry.com/browse-the-registry#home/registrationdetails/6424b2ab96d6be0027759cd1/>

Guarantor

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Availability of data and materials

All data and material collected during this study are available from the corresponding author upon reasonable request.

Provenance and peer review

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