

EVALUATION OF 3D PRINTED STENTS FOR GUIDED INTRABONY MAXILLOFACIAL BIOPSIES

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ABSTRACT

BACKGROUND: Biopsies may be difficult to do if the lesions are too small, too near to vital tissues, or too tough to access. Examples include excision and incision, fine needle (with or without US guidance), core biopsy (with or without US guidance), and other traditional biopsy procedures.

OBJECTIVES: To evaluate the efficacy of the 3D printed tooth-supported stent in biopsy for intra-bony lesions.

MATERIALS AND METHODS: 12 individuals with intra-bony lesions in the jaw. All participants were recruited at random from the Oral and Maxillofacial Surgery outpatient clinic at the University of Alexandria's School of Dentistry. The sample size was calculated by G Power, version 3.1.9.2 with the following criteria: 80% study power and 5% alpha error. The sample size was determined to be 6 patients per group based on the difference between two independent means using pooled SD=0.48 mm to account for missing follow-up cases. Biopsies were obtained using a surgical guide and a trephine bur, and the findings were examined by Cone beam computed tomography (CBCT) following the surgery.

RESULTS: The planning software and the related (digitally created) biopsy cylinder were used to test the precision of the postoperative low-dose CBCT. The horizontal angle of departure between a drill's virtually planned location and its actual placement ranged from 0.38 degrees to 0.95 degrees, with a mean of 0.70 degrees and a standard deviation of 0.18 degrees.

CONCLUSION: Template-guided biopsy of the jawbone seems to be an alternative to a conventional approach with possibility of obtaining predictable and safe biopsies with comparatively low invasiveness and risk.

KEYWORDS: 3D printed surgical template, Intra bony lesion, CBCT.

RUNNING TITLE: Evaluation of 3D stents for intrabony maxillofacial biopsies.

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INTRODUCTION

Several biopsies may be utilized to diagnose maxillofacial lesions. To categorize lesions based on their size, location, cause, and so on. When the lesion is smaller than 1 cm in diameter, we do an excisional biopsy. For tumors larger than 1 cm, an incisional biopsy is performed, during which a part of the tumor and some surrounding healthy tissues are surgically removed (1).

Tissues were biopsied using a small needle aspirator and a 21-gauge needle. It is unlikely that it is guided by ultrasonography. A Core biopsy, on the other hand, which may or may not be guided by ultrasonography, makes a clean incision with a 2 mm needle. The most serious concern is that it might spread the malignant tumor (2).

The most effective therapy for lesions on bones and teeth is decalcified and ground section. A

specialized saw is required to grind the enamel after it has been softened in acid for days or weeks. After dragging a round, stiff bristle on a finger across the lesion's surface until bleeding occurs, the cells under the bristle are collected in a brush biopsy. A punch biopsy involves extracting an apple-shaped cylinder of tissue from a skin lesion by punching through all layers of skin (3).

An intraoral lesion can cause bone, skin, or oral mucosal injury. All or any of these might be cancerous. Origin and behavior may also differ. A biopsy is the only accurate technique to determine this.

Intra-bony lesions include cysts, vascular malformations, vascular tumors, malignancies (both odontogenic and non-odontogenic), and cancer (both metastatic and denovo) (4).

If a lesion is discovered after a biopsy, extreme caution should be exercised. Even though we can collect many biopsies for the same lesion at the same time, they must originate from worrisome and representative locations. Furthermore, the lesion's mucosa and submucosa should be entirely excised, therefore tissue should be extracted from the lesion's perimeter rather than its core. Include normal tissue for comparison and identification (5). To alleviate pain, a local anesthetic should be injected directly into the lesion or just outside of it (a field block or nerve block). Local anesthetic injection into a lesion causes tissue oedema and specimen distortion, which can lead to false diagnoses such as Cron's disease or orofacial granulomatosis. It is critical to protect blood vessels and nerves during a biopsy (5).

Surgical stents have been used in implant surgery for alignment, angulation, and depth monitoring since the discovery of CT technology. We can now correctly assess the implant's or stent's (guide) length, width, position, anatomical variation, and faults before making a 3D model using a 3D scanner and a 3D printer (6).

Because of the danger of damaging adjacent tissues such as dental roots and nerves, careful monitoring is preferred over biopsy. Furthermore, conventional techniques often need general anesthesia to get a representative biopsy, and patients frequently complain of discomfort in the days after surgery (7).

Because of guided implantology and 3-dimensional (3D) imaging techniques like cone beam computed tomography (CBCT) and dental scans, less invasive guided bone biopsies may be performed in the clinic. This technique improves the predictability of potentially hazardous and invasive bone biopsies conducted under local anesthetic (8).

However, anatomical concerns such as the location of the lesion, the mouth opening, and the presence of soft tissue may restrict its use. Computer-assisted treatments allow for shorter operating times and improved patient results in other maxillofacial operations as well (9).

Aim of the study: to evaluate the efficacy of the 3D printed tooth-supported stent in safe and easier biopsy for intra-bony lesions nearby vital anatomical structures.

MATERIALS AND METHODS

Study Design and Setting

This clinical investigation included 12 individuals with intra-bony lesions in the jaw (7 males and 5 women). All participants will be recruited at random from the Oral and maxillofacial surgery outpatient clinic at the university of Alexandria's School of Dentistry. distribution of biopsy {drilling site}: maxilla 3 cases {25%} anterior maxilla 2 cases {16.6%} anterior mandible 2 cases {16.6%} rous of mandible 3 cases {25%} and body of mandible 2cases {16.6%}.

Sample size calculation

G Power, version 3.1.9.2, was used to calculate the sample size, with the following criteria: 80% study power and 5% alpha error. The sample size was determined to be 6 patients per group based on the difference between two independent means using pooled SD=0.48 mm to account for missing follow-up cases. The total sample size is 12 patients (12 persons divided into two groups).

Ethical consideration

The study was approved by the University of Alexandria's Dental Research Committee. Each participant was told about the aims, risks, and possible benefits of the study, and written informed permission will be acquired before any therapy is administered.

Eligibility

Inclusion criteria

- Radiopaque intrabony lesions like central osteoma or cementoma.
- Radiolucent intrabony lesions like fibrous lesions.
- Mixed intrabony lesions.
- Lesions with difficult access or nearby important anatomical structures like the inferior alveolar nerve, maxillary sinus, floor of the nose and pterygoid plexus.
- The size of the lesion is more than 5 mm.

Exclusion criteria

- Small lesions (less than 5mm as the trephine bur is 4 mm in diameter).
- Accessible & easily biopsied lesions.
- Vascular tumour and vascular malformation as there will be no tissue to be taken and risk of severe complications.

Pre-surgical phase

Clinical examinations comprised visual inspection and palpation of the oral field and lesion after a complete dental and medical history.

The radiographic assessment also included periapical, occlusal, and cone beam computed tomography (CBCT) X-rays.

Fabrication of surgical guide

Cone beam computed tomography for the affected jaw was made then impression and model fabrication. Then scanning for the model with ceramill map 400 {AMMAN CIRBACH, Austria}. Then the CBCT and the scanned cast merged together by mimics innovation suite 19 tm software {materialize mimic software 3d medical imaging, Belgium} the cast give the soft tissue architecture and teeth dimensions, the CBCT give the bone architecture and lesion location. Virtual planning is designed with 3D cast on to make osteotomy for the trephine bur with depth, diameter and angle desired. Then it transformed to STL {system tessellation language} then it exported to the 3dprinter {dent 1dip, mogassam}which is DLp type{digital light printer}with 4K optical engine {conventional light

source similar to arc lamp}with liquid crystal display panel{LCD}.with wave length 405 nm, XY resolution 31micron ,build volume{XxYxZ}134.4x75.6x130mm.the light source illuminate in the desired location in the 3d design to photopolymerize the resin in the resin passing layer by layer. The resin composed of photopolymer fused with photoinitiator which cure with light to be rigid or flexible according to the resin type layer by layer {0.05:0.15 mm for each} this is called photopolymerization. After build up completed the stent removed and immersed in alcohol to remove excess unpolymerized resin and finished and polished as necessary.

Clinical evaluation

appropriate for the patient was evaluated for pain before procedure which was negative for all of them then once daily for 7 days then at 14th day after the biopsy was removed. The Numerical Rating Scale (NRS), created by Downie in 1978, is made up of a vertical or horizontal line and 11 numbers, ranging from 0 to 10, which, respectively, represent the absence of pain and the worst conceivable agony. The accuracy of earlier investigations employing the NRS is very high. The NRS is a straightforward evaluation tool that is simple to score. It can be administered verbally or in writing, but it is not elderly or very young children because it does not distinguish between words and numbers (21). NRS were estimated every day for 7 days then at 14th day during the first week then once a week thereafter. (Fig. 1)

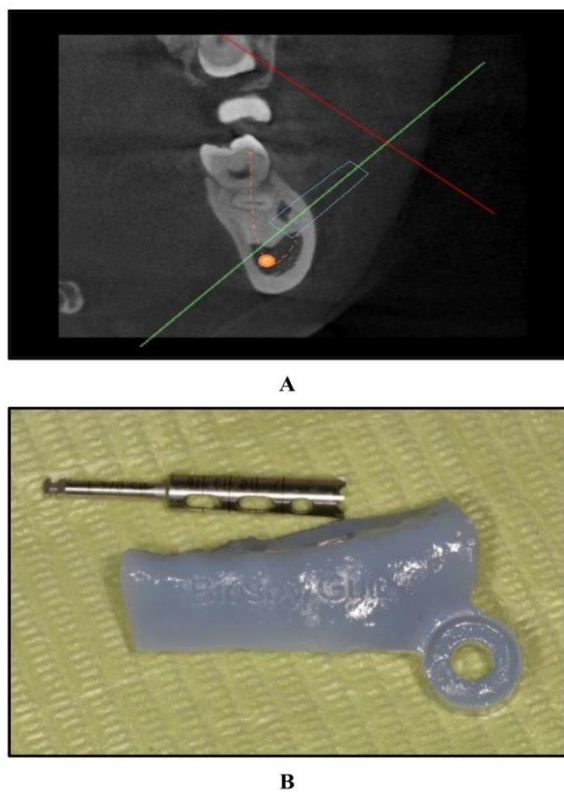


Figure (1): Numerical rating Scale (NRS).

Surgical phase

The stent was seated in place and verified for accuracy and seating and trephine bur canal. The region was cleansed during the patient's anesthesia to simulate a mucoperiosteal flap. After positioning the trephine bur, 150 rpm biopsy drilling was performed with adequate irrigation. After the lesion was biopsied, a biopsy core was placed in 10% formaldehyde for analysis. When the therapy was done, the incision was stitched. (Fig. 2)

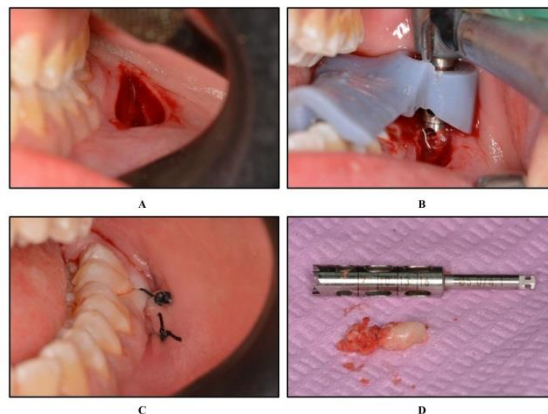


Figure (2): Surgical phase (A) Incision (B) Drilling with trephine bur (C) Suturing (D) Core Biopsy with the Drilling trephine bur

Postoperative phase

Patients were instructed to apply cold fomentation for 24 hours following surgery and were given antibiotics. Every day, a povidone-iodine mouthwash was used four times.

Radiographic evaluation

Cone beam computed tomography pictures taken before and after a trephine biopsy can be compared (11). (Fig. 3)

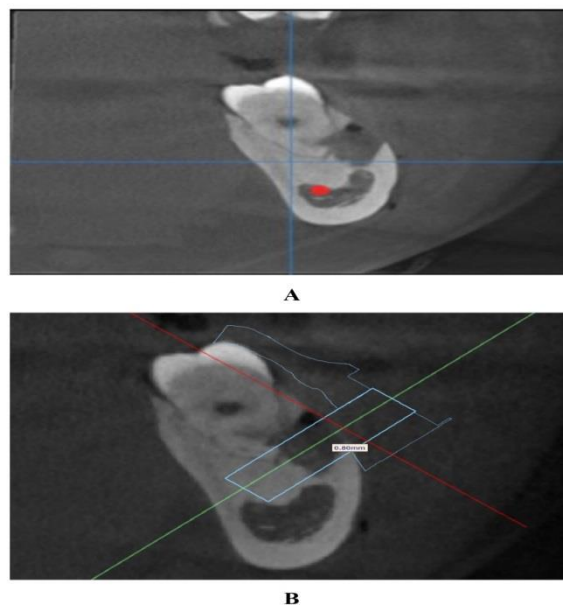


Figure (3): Postoperative (A) CBCT (B) real trephine Bur position

Histopathologic evaluation

Semi serial (5 m) histologic slices were created from core samples preserved in 10% buffered neutral formalin and embedded in paraffin blocks. To complete the diagnosis, tissue slices were stained with hematoxylin and eosin (H&E).

Statistical analysis

IBM SPSS 20.0 (Armonk, NY: IBM Corp.) was used to analyze the data. Percentage and numerical descriptions were used to describe qualitative data. To evaluate if the data were regularly distributed, the Kolmogorov-Smirnov test was utilized. Minimum and maximum values, mean, median, and standard deviation were used to characterize the quantitative data. We measured the angle and depth discrepancies between the drill's virtually planned placement location before surgery and its actual placement position after surgery. The paired t-test was performed to compare the differences between the two times. The significance level was set at $p \leq 0.05$.

RESULTS

Postoperative pain

The pain was measured every day during the first week, then once a week thereafter, using a Numerical analogue scale (NAS) ranging from 0 to 10 (where "0" represents no pain and "10" signals significant pain. 1,2,3 mild pain.4,5,6 moderate pain.8,9,10 severe pain). Following surgery, most patients show tolerable pain. where about 16% of patients had NAS2 and 32% had NAS3 32 % VAS4 16 had NAS2 at the First and second day which decrease gradually till 14 day {NAS 0 for all}.Table (1)

Accuracy of biopsy removal

Total variations between electronically planned and inserted drills were used to determine biopsy removal accuracy. The average difference between the virtual intended placed drill and the realized put drill was 0.70 degrees, or 0.18 degrees, according to the data, with horizontal angular deviations ranging from 0.38 degrees to 0.95 degrees. The average vertical angle between a drill that was put in and one that was practically planned for varied from 0.38 to 0.62 degrees, with a standard variation of 0.13 degrees. **Table (2) and (Fig. 4).**

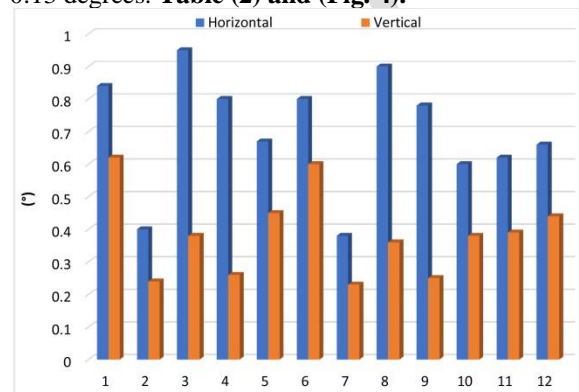


Figure (4): Descriptive analysis of the studied cases according to different parameters

Table (1): Distribution of pain among patients

No. of patient Day	1 2 3 4 5 6 7 14							
	vas 0					2	6	1
vas 1				3	1	5		
vas 2	2	2	3	3	3	1		
vas 3	4	4	3	3	5			
vas 4				1	1			
vas 5	4	4	4	2				
vas 6	2	2	1					
vas 7								
vas 8								
vas 9								
vas 10								

Table (2): Descriptive analysis of the studied cases according to different parameters

No.	Angle (°)	
	Horizontal	Vertical
1	0.84	0.62
2	0.40	0.24
3	0.95	0.38
4	0.80	0.26
5	0.67	0.45
6	0.80	0.60
7	0.38	0.23
8	0.90	0.36
9	0.78	0.25
10	0.60	0.38
11	0.62	0.39
12	0.66	0.44
Mean ± SD	0.70±0.18	0.38±0.13
Median	0.72	0.38
Min.	0.38	0.23
Max.	0.95	0.62

Histopathologic findings

The results of core biopsies revealed a wide variety of diagnoses, including inflammatory, fibro-osseous, and odontogenic disorders. Meanwhile, a malignant grade 2 chondrosarcoma was identified (Fig. 5).

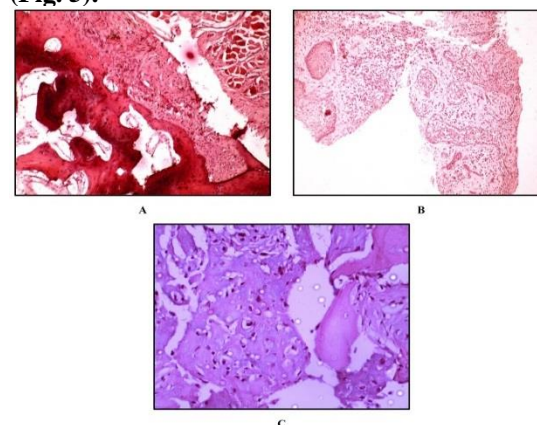


Figure (5): Histopathologic findings (A) Periapical cemental dysplasia showing mature cancellous

bone trabeculae lined by osteoblasts together with areas of cemental-like calcification. **(B)** Odontogenic cyst lined by irregular hyperplastic odontogenic epithelium. Islands of squamous odontogenic-like proliferation are detected in a heavily collagenized stroma. **(C)** Chondrosarcoma grade 2 showing a mass of malignant cartilage forming lobules of chondroid matrix containing variable size malignant chondrocytes

Case presentation (Fig. 6)

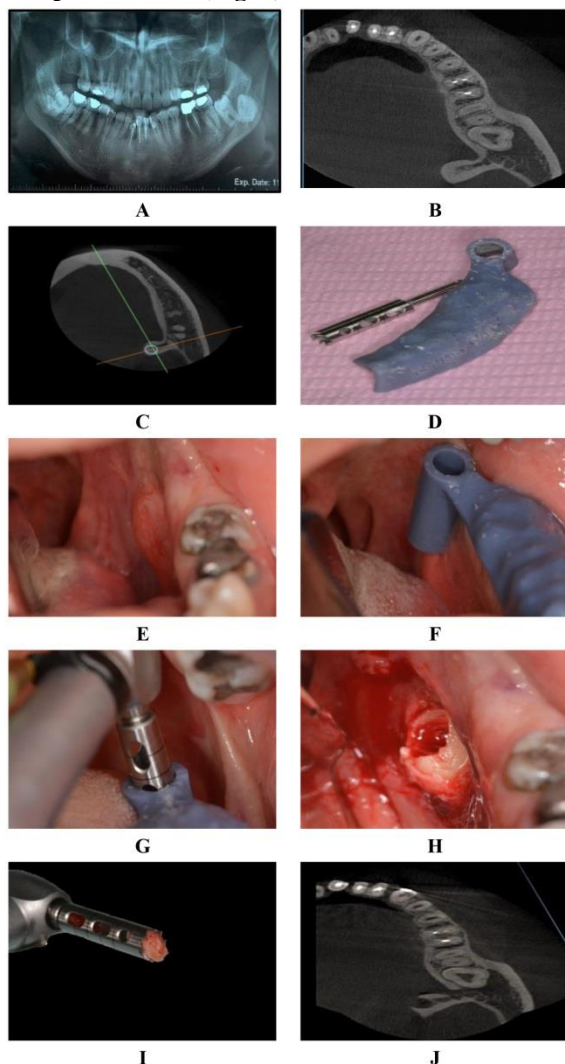


Figure (6): Case presentation **(A)** Panoramic view (radio opaque lesion). **(B)** Axial view CBCT. **(C)** 3D planning. **(D)** Fabrication of stent. **(E)** Clinical picture. **(F)** Stent in place. **(G)** Drilling. **(H)** Osteotomy completed. **(I)** Specimen completed. **(J)** Postoperative CBCT.

Materials printing parameters: Printer and paper were used in our study.

DISCUSSION

To examine the precision with which biopsies were extracted, scientists assessed the average difference between drills that were digitally designed and those

that were positioned in this study. The discrepancy between the real drill that was put in and the simulated drill that was supposed to be inserted ranged from 0.38 degrees to 0.95 degrees, with an average of 0.70 degrees, plus or minus 0.18 degrees. The average vertical angle discrepancy between the drill's actual placement and its virtually planned location varied from 0.38 to 0.62 degrees (with a standard variation of 0.13 degrees), on average.

These findings are consistent with those of a recent study that looked at the effectiveness of guided biopsy approaches for detecting jawbone osseous abnormalities. The standard variation of angles was 4.35 degrees. Guided biopsy appears to be a viable alternative to the standard procedure for doing a less invasive, exceptionally precise jawbone biopsy. The differences found here were significantly larger than those found by Lotz et al (12).

According to this study, a stereolithography (STL) file of CBCT images was obtained with specialized planning software and layered with an STL file of a dental cast to construct a virtual surgical guide, according to this study. This application also allows for a 3D (three-dimensional) view of the guide from a variety of angles and planes. The present guide's high accuracy, outstanding predictability, time-effectiveness, and flexibility should encourage doctors to utilize this minimally invasive surgical approach; nevertheless, controlled clinical trials are needed to determine both the benefits and any potential downsides (13).

Recent research has validated the accuracy of utilizing virtual planning to evaluate the drilling location, and the outcomes of using this software for guided implant surgery on actual patients have been favorable. As a result, guided biopsy procedures have become more popular (14).

These findings corroborated the findings of another study, which found that guided biopsies conducted using a drilling template supported by a tooth were a timesaving, less invasive surgical approach with enhanced accuracy and predictability. The requirement for bone biopsies in difficult-to-reach areas near sensitive tissues is the motivating motivation behind this novel method. Following surgery, the pathologist obtains additional useful information from radiological assessment of the trephine drill site utilizing a low-dose cone beam computed tomography (CBCT) scan (15).

The disclosed approach also has the added benefit of shortening the surgical process. This is especially important when selecting whether to use local or general anesthesia for a surgical procedure on a patient who is not cooperative. The approach is suitable for use on youngsters and improves access to deep-seated components in difficult anatomical locations. While preoperative preparation saves time while operating on a patient, it still takes about the same amount of time as traditional approaches. It's also vital to keep in mind that reducing

application faults necessitates prior planning experience (7).

This study confirmed what many people previously knew: there is a link between biopsy accuracy and dental implant implantation accuracy. Even if recent implantology research shows that improved accuracy values for the angle and position of the apex may be achieved, our experiment yielded promising outcomes for guided biopsies (16).

Our results agree with this, and accuracy is rated good when a unique approach is used. The usual angular deviation results from comparable in vivo implantology tests range between 2.70 and 4.30 degrees (17).

According to the current findings, the range acquired with an implant that is drilled, guided, and implanted without guidance ($4.30^{\circ} \pm 3.3^{\circ}$) is within the range obtained with a horizontal angular variation of $0.70^{\circ} \pm 0.18^{\circ}$ and a vertical angular deviation of $0.38^{\circ} \pm 0.13^{\circ}$.

Because the printed sleeve must slide into place, certain variations from the right position are to be expected. Although the majority of people thought the template fit well, slight positioning adjustments during drilling must be taken into account. There were no reports of bone warming following surgery in any of the individuals studied. Intraosseous biopsies entail a high risk of significant bleeding due to the chance of artery injury. However, problems during the surgery are quite unlikely (19). Our understanding of guided surgical methods is useful in oral and maxillofacial surgery, where precise bone drilling is necessary for successful surgeries such as apicoectomy and tooth auto transplantation (20).

In conclusion, assuming there are no budgetary constraints, a template-guided jawbone biopsy appears to offer an alternative to the standard procedure. The ability to get biopsies using minimally invasive procedures that are both predictable and safe benefits both patients and surgeons. Biopsies can be conducted with sufficient precision and little annoyance to the patient. This enables effective therapy to be planned by the diagnosis.

CONCLUSIONS

Template-guided biopsy of the jawbone seems to be an alternative to a conventional approach. The possibility of obtaining predictable and safe biopsies with comparatively low invasiveness is a great advantage for both patients and surgeons. However, biopsies can be performed with sufficient accuracy and minimal invasiveness. Thus, by a patient's diagnosis, adequate treatment can be planned. Guides that were produced with a stereolithographic desktop 3D printer allow significantly higher accuracy of biopsies.

CONFLICT OF INTEREST

There are no competing interests, contrary to what the authors assert.

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The writers did not get any specific funding.

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