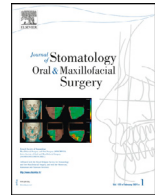




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Original Article

On the feasibility of minimally invasive Le Fort I with patient-specific implants: Proof of concept

Federico Hernández-Alfaro^{a,b}, Oscar Saavedra^{b,*}, Francesc Duran-Vallès^b,
Adaia Valls-Ontañón^{a,b,*}

^a Department of Oral and Maxillofacial Surgery, Universitat Internacional de Catalunya (UIC), Barcelona, Spain

^b Institute of Maxillofacial Surgery, Teknon Medical Center, Barcelona, Spain

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ABSTRACT

A novel approach to Le Fort I osteotomy is presented, integrating patient-specific implants (PSIs), osteosynthesis and cutting guides within a minimally invasive surgical framework, and the accuracy of the procedure is assessed through 3D voxel-based superimposition. The technique was applied in 5 cases. Differences between the surgical plan and final outcome were evaluated as follows: a 2-mm color scale was established to assess the anterior surfaces of the maxilla, mandible and chin, as well as the condylar surfaces. Measurements were made at 8 specific landmarks, and all of them showed a mean difference of less than 1 mm. In conclusion, the described protocol allows for minimally invasive Le Fort I osteotomy using PSIs. Besides, although the accuracy of the results may be limited by the small sample size, the findings are consistent with those reported in the literature. A prospective comparative study is needed to obtain statistically significant results and draw meaningful conclusions.

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1. Introduction

The last two decades have seen a paradigm shift in orthognathic surgery. The advancement of 3D technology has increased the predictability and accuracy of surgical outcomes and made surgical planning user friendly and simpler [1]. In this context, CAD/CAM patient-specific splints have proven to be accurate in transferring information from the 3D planning into the surgical field [2]. As they can be printed on an in-house basis, they are becoming even faster and cheaper to produce [3,4].

On the other hand, minimally invasive surgical techniques have been implemented in order to reduce morbidity and surgical time, thus improving patient recovery and satisfaction. In 2012, our group described a minimally invasive approach to the Le Fort I procedure, combining a reduced incision with an anterior pterygomaxillary disjunction or so-called “twist technique” [5]. More recently, we have added another modification involving a transmucosal pterygomaxillary osteotomy through the palatal mucosa using a piezoelectric device, thereby easing the down-fracturing maneuver and making the pterygomaxillary disjunction more precise, which facilitates isolation of the pedicles [6].

Recently, patient-specific implants (PSIs) have been advocated as an alternative to patient-specific splints [7,8]. The rationale behind this technology lies in the avoidance of condylar seating during maxilla and mandible repositioning. Some authors have also claimed a reduced surgical time and slightly more accuracy in bone repositioning [4,7,9]. However, the drawbacks of PSI include: I) the need for a third party (often distant) to design and manufacture the cutting guides and PSI; II) significantly increased costs; and III) the need for extensive approaches for placement of the cutting guides and fixation plates.

In order to avoid extensive approaches and unnecessary deperiostization, we propose a new design and the application of both cutting guides and PSIs in the context of minimally invasive Le Fort I osteotomy. Furthermore, the authors aim to evaluate if the proposed minimally invasive approach does not jeopardize the PSI inherent accuracy.

2. Materials and methods

2.1. Sample selection

The described protocol was applied in five consecutive patients with an underlying dentofacial anomaly (DFA) who underwent orthognathic surgery with maxillary PSI at the Maxillofacial Institute, Teknon Medical Center (Barcelona, Spain) between July 2023 to September 2023. All patients met the following inclusion criteria: 1) subjects having undergone bimaxillary surgery to correct any underlying

* Corresponding author at: Maxillofacial Institute, Teknon Medical Center, Carrer de Vilana, 12 (desp. 185), 08022, Barcelona, Spain.

E-mail address: avalls@institutomaxilofacial.com (A. Valls-Ontañón).

DFA following the described protocol; 2) age > 18 years; 3) completed growth of the maxillofacial complex; and 5) availability of a preoperative helicoid computed tomography (CT) scan (Revolution CT - 256, General Electric) and postoperative cone-beam computed tomography (CBCT) scan (iCAT, Imaging Sciences International, Hatfield, PA, USA).

The study was approved by the Ethics Committee of Teknon Medical Center (Barcelona, Spain) (Ref. 2023/103-MAX-CMT), and was conducted in accordance with the ethical standards laid down in the Declaration of Helsinki (1964 and later amendments). All participants signed an informed consent document prior to surgery.

2.2. Workflow protocol

The presurgical helicoid CT scan was taken, and 3D planning of the surgery was made with Dolphin software (Dolphin Imaging & Management Solutions 12.09, Chatsworth, CA, USA), as the standard virtual surgical planning protocol of the department.¹ On day one, a Standard Triangle Language (STL) file of the 3D surgical plan was shared online with the local company in charge of designing and manufacturing the PSI (Avinent, Barcelona, Spain). On day two after processing the information, a video conference between the surgeon (FHA) and one of the company engineers allowed them to agree on the cutting guide and plate design. One “inverted T” plate with 2 mm thickness on each anterior buttress was designed according to the planned maxillary movement and gap, and fixed where the major bone thickness was found with 8 holes (Fig. 1). Cutting guides were designed as follows to allow a minimally invasive approach (Fig. 2): the guides fitted the rim at the piriform aperture and extended just 2 cm distal to the rim. The guide holes themselves were subsequently used to fix the plates in order to double check the proper position of the fixation plates and screws within the bone (Figs. 1 and 2). On this same day the plan was sent to production, so the company could 3D

print the plates in titanium. Simultaneously, the cutting guides were printed in-house at our department. In all cases an intermediate and final splint with a maxilla first protocol was also printed as a backup to double check the treatment plan. On day three the plates were received from the company and the patient was operated on day four.

2.3. Surgery

All cases were operated upon by the senior surgeon of the team (FHA), and as opposed to the routine “mandible first” protocol, the “maxilla first” sequence was applied.

The procedure began with bilateral transmucosal pterygomaxillary disjunction with a piezoelectric device, through a minimally invasive (side-to-side) incision. Subperiosteal elevation of the anterior and lateral walls of the maxilla to the pterygoid region was performed. The nasal spine was separated from the maxilla with the piezoelectric saw, the nasal mucosa was detached from the nasal floor with a periosteal elevator, and the nasal septum was luxated laterally to separate it from the nasal crest of the maxilla. Subsequently, cutting guides on each side were fixed with two screws (Fig. 3), and holes for future fixation of the plates were predrilled at this stage. The standard Le Fort I osteotomies were performed using a reciprocating saw with a 4-cm blade, and then the cutting guides were removed. Pterygomaxillary disjunction was carried out through an anterior approach by driving a sharp, straight 2-cm osteotome from the nasal crest of the maxilla to the pterygomaxillary junction, or the so-called “twist technique”. Then, neurovascular pedicles were identified on both sides and soft tissue was stretched. At this point, both preprinted custom plates were fixed with screws in the mobile maxilla, and it was moved to meet the predrilled holes in the upper section of the osteotomy, thus replicating the planned 3D repositioning of the maxilla (Fig. 4). Grafting was applied in the posterior gaps with

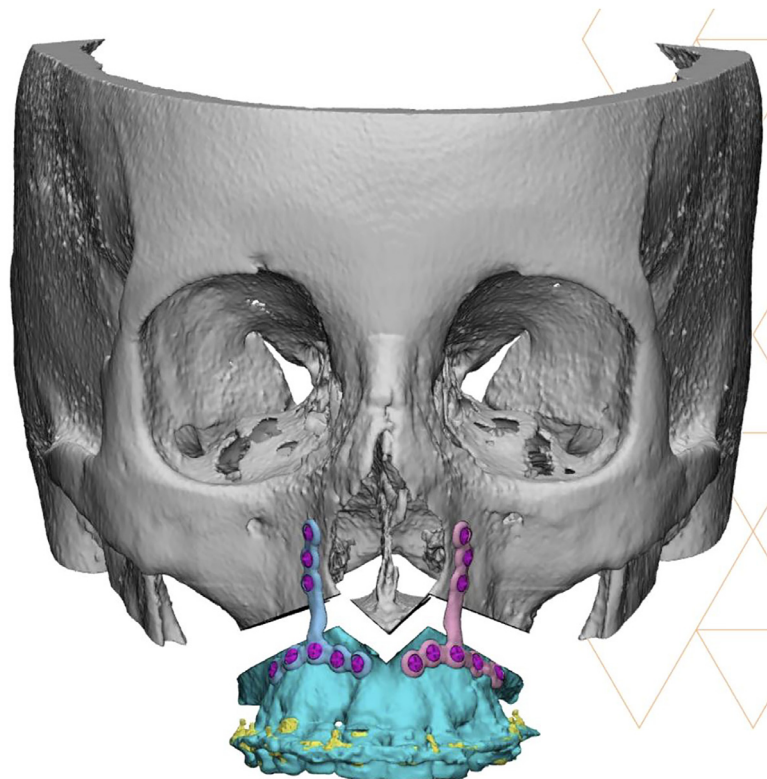


Fig. 1. The virtual planning is converted into an STL (Standard Triangle Language) file, which is then used by the company to design and fabricate the custom plates.

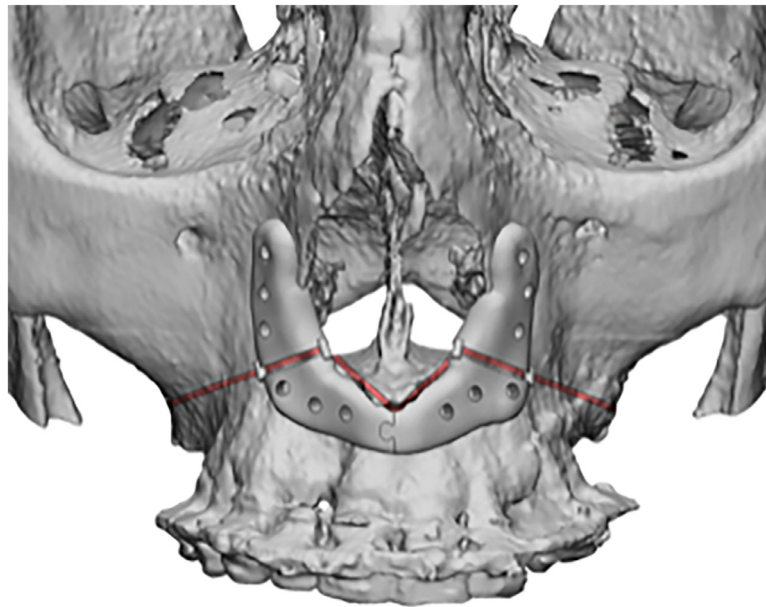


Fig. 2. Design of the cutting and drilling guide over the initial position of the maxilla. The design of the cutting and drilling guide feature an approximately 45° inclined posterior edge. The anatomical retention of the guide is located on its anterior edge, which aligns with the free margin of the piriform aperture and features three supports to provide rigidity during adaptation maneuvers. Both guides are assembled with a puzzle connection and are secured with two screws, one on each side of the osteotomy.

hydroxyapatite blocks, which were trimmed and adapted. Cross suturing of the muscles was performed with 4/0 Vicryl (Ethicon, Inc.), as published elsewhere [10], and the mucosa was closed with running 5/0 Monocryl suture (Ethicon, Inc.).

The backup intermediate patient-specific splint was seen to fit well in all cases. After maxillary repositioning, mandibular surgery was performed.

2.4. Accuracy evaluation

Differences between the surgical plan and the final outcome of the 5 cases were measured using 3D voxel-based cranial base superimposition in Dolphin software. A 2-mm color scale was established for assessment of the anterior surfaces of the maxilla, mandible and chin, as well as the condylar surfaces (Fig. 5). Furthermore, using the



Fig. 3. Intraoperative image showing the cutting guide in place, anchored to the piriform rim and fixed with two screws, while preserving the minimally invasive approach.

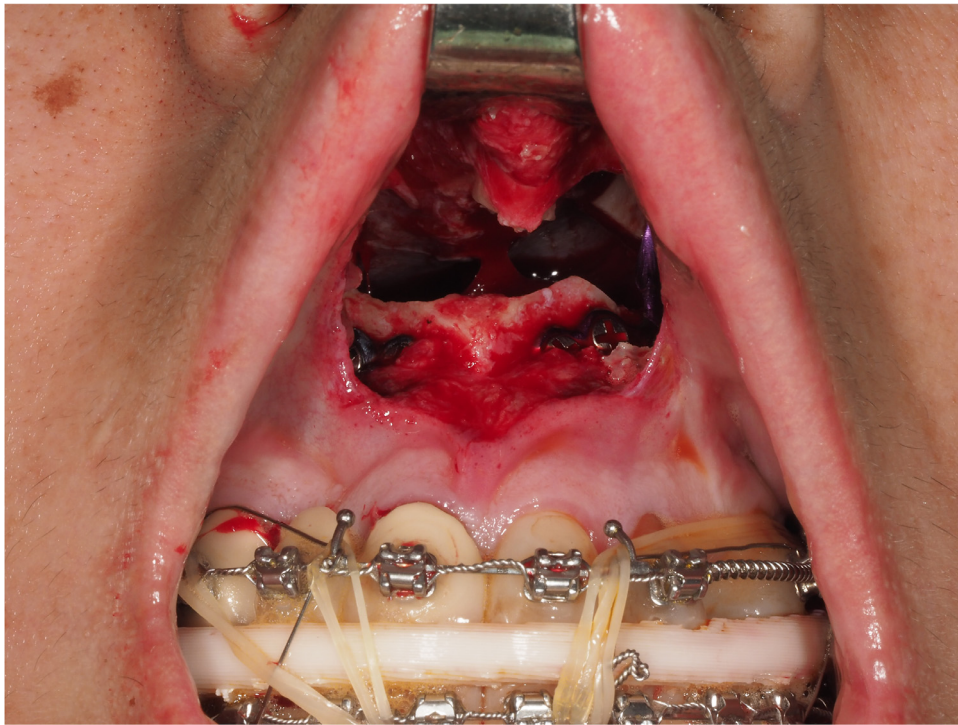


Fig. 4. Maintenance of the minimally invasive Le Fort I approach after placement of the fixation plates.

distance difference measurement tool of the Dolphin software, measurements were made at 8 specific landmarks: A point, pogonion, midpoint of the incisal surface of the upper right and left central incisors, tip of the upper right and left canines, and mesiobuccal cusp of the upper right and left first molars.

3. Results

The described Le Fort I protocol was applied in five patients (3 women and 2 men), with an average age of 24.8 years (range: 17

–45). Regarding the initial diagnosis, four patients presented class II malocclusion with a biretrusive facial profile, while one patient presented class III malocclusion with sagittal maxillary hypoplasia. All patients underwent bimaxillary advancement with counterclockwise rotation of the occlusal plane, and three of them received a genioplasty (Table 1).

Superposition images of the surgical plan and the final outcome of the 5 cases are reported in Table 2, as along with the landmark measurements. All 8 landmarks showed a mean difference of less than 1 mm - the right first molar being the one with the smallest

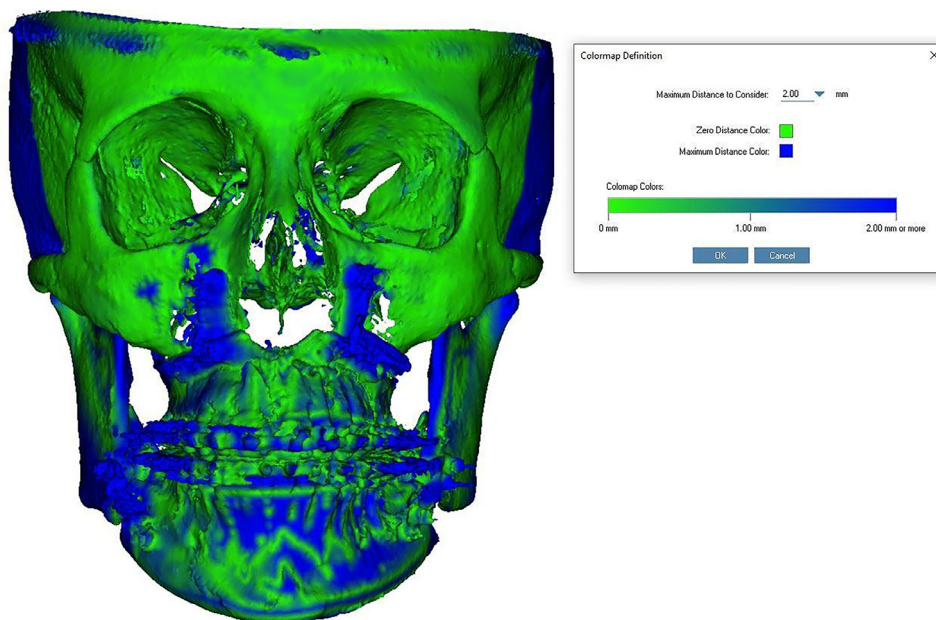


Fig. 5. Overlay of virtual planning STL and post-surgical CBCT STL using the Color Map tool of the Dolphin software, in which areas where the two meshes are perfectly aligned result in green color and differences ≥ 2 mm appear as solid blue.

Table 1
Demographic and surgical data of the study sample.

	Sex	Age	Diagnosis	Treatment	Surgical Time for Le Fort I (Minutes)
Case 1	M	19	Class III Maxillary Hypoplasia	MMA + CCWR	38
Case 2	F	17	Class II Biretrusion	MMA + CCWR	35
Case 3	F	45	Class II Biretrusion	MMA + CCWR + Genioplasty	33
Case 4	M	23	Class II Biretrusion	MMA + CCWR + Genioplasty	34
Case 5	F	20	Class II Biretrusion	MMA + CCWR + Genioplasty	35

*M: male; F: female; MMA: maxillomandibular advancement; CCWR: counterclockwise rotation.

discrepancy (0.20 mm), followed by the right upper incisor (0.28 mm). In contrast, the greatest difference corresponded to the pogonion (0.6 mm).

4. Discussion

The present case series shows that a minimally invasive approach is feasible when using PSI for Le Fort I osteotomy. All papers published to date describe larger incisions and degloving to fit cutting guides and customized plates [11,12]. However, the PSI protocol with small cutting guides with a puzzle connection adapted to the piriform rim and “inverted T” custom plates applied in the anterior buttress is compatible with a minimally invasive approach, while warranting sufficient rigidity thanks to the 2-mm profile customized plates.

On the other hand, the design and manufacturing protocol used in the present study was very brief compared to other protocols reported in the literature [13,14]. This is even more relevant in the case of international patients, who otherwise would require an extra trip weeks before surgery to allow for planning, design and production of the plates - thus complicating their personal logistics. Regarding the cutting guides material, they are made of rigid acrylic, which firmly adapts to the bone anatomy; more specifically to the piriform

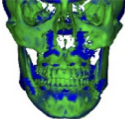
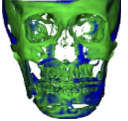
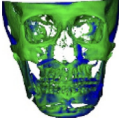
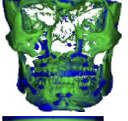
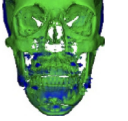
apertures, paranasal areas and nasal spine. This allows for a real minimally invasive approach avoiding the need of bulky guides with dental support which need to be made of rigid metal to avoid deformation, require a wider approach and make the system less user friendly and more expensive.

A described objection related to PSI is the increased cost of customized cutting guides and implants compared to conventional CAD/CAM splints and miniplates, tripling its price when both maxillary and mandibular plates are customized [15,16]. However, the described protocol cut expenses by reducing the customized hardware to two plates and being able to print the cutting guides on an in-house basis. Furthermore, when using the “maxilla first” sequence, the bilateral sagittal split osteotomy (BSSO) can be fixed with only one conventional plate per side [17], since the mandible is no longer the reference positioning bone [4,18].

It is relevant to highlight that PSI were not used in the mandible mainly because errors due to centric relation record during CT registration cannot completely be ruled out, which consequently could be transmitted to the mandibular cutting guides and customized osteosynthesis material. So, the authors trust more in the correct position of the condyle when using intraoperatively the bimanual technique than merely relying on the CT imaging and planning software.

Table 2

Individual measurements of the anatomical points that were evaluated to determine the accuracy of transfer from the virtual plan to the postoperative result.

Color Map at Specific Points in the Overlay Between Preoperative STL and Postoperative STL 7 Days After Surgery									
#Case	A Point (mm)	Right Upper Incisor Edge (mm)	Left Upper Incisor Edge (mm)	Right Canine Cusp (mm)	Left Canine Cusp (mm)	Right First Molar MV Cusp (mm)	Left First Molar MV Cusp (mm)	Pogonion (mm)	
Case 1	0.4	0.15	0.1	0.4	0.1	0.3	0.09	0.61	
Case 2	0.2	0.6	0.54	0.93	0.76	0.25	0.92	0.7	
Case 3	0.35	0.16	0.19	0.11	0.27	0.11	0.34	0.7	
Case 4	0.58	0.04	0.35	0.33	0.26	0.34	0.56	0.49	
Case 5	0.33	0.35	0.22	0.11	0.35	0.04	0.14	0.52	
Average	0.372	0.26	0.28	0.376	0.348	0.208	0.41	0.604	

Moreover, the direction of the tip of the saw during the BSSO is less predictable, even when a cutting guide is placed, which entails a less accurate osteotomy line in the most basal jawbone and therefore could induce unexpected cortical interferences. Finally, drilling holes of the proximal segment with the cutting guide does not allow perpendicular drilling through an intraoral approach. Otherwise, usually a transoral approach or drilling oblique holes in the proximal segment would be required. Therefore, the authors chose not to use PSI on the mandible and thus a final splint was used to position the mandible and finally place the conventional osteosynthesis hardware.

Hence, the major drawbacks related to PSI for Le Fort I osteotomy (extensive approach, long time to design and manufacture the material due to a distant third party dependence, and increased cost) have been partially overcome with the described protocol.

On the other hand, as previously mentioned, the literature suggests significant benefits related to PSI: reduced surgical time and slightly greater accuracy [17,18]. The high accuracy related to this protocol is obtained because there is no dependence on condylar seating for maxilla and mandible repositioning, thus eliminating potential errors in condylar position [16,19]. According to the literature, translation differences < 2 mm and rotation differences < 4° between the virtual plan and the surgical outcome are considered to constitute success, since these differences are clinically insignificant [20]. The literature suggests that customized plates match or even enhance this precision, making the implementation of this technology beneficial for patients and treating physicians [21–23]. The results reported in the present study are promising, with a mean magnitude of less than 1 mm - the right first molar showing the smallest discrepancy (0.20 mm), followed by the right upper incisor (0.28 mm). In contrast, the greatest difference corresponded to the pogonion (0.6 mm) (Table 2). As previously mentioned, PSI are not used for the BSSO and the genioplasty, so a higher discrepancy is expected in mandibular landmarks.

Regarding surgical time, although a comparative study could not be carried out due to the limited sample size, the mean time for Le Fort I surgery from incision to fixation was 35 min. Despite cutting guides placement is time-consuming, molding miniplates normally takes longer. Furthermore, using isolated nasomaxillary fixation (two plates alone) also reduces operative time. Susarla et al. in 2020 demonstrated stable maxillary position using this method at 1 year post-operative [24]. And if we take into account that the PSI osteosynthesis material is more rigid, the results should be even more stable.

The main limitation of the study is the limited sample size. Moreover, all patients underwent maxillomandibular advancement and counterclockwise rotation, which are simple and more predictable movements for maxillary osteotomies compared to maxillary impaction or asymmetry correction.

In conclusion, the described PSI design allows for minimally invasive Le Fort I osteotomy by using PSI. Besides, although the accuracy outcomes of our study may be limited by the small sample size involved, they are consistent with what has been reported in the literature. A prospective comparative study has been initiated in order to obtain statistically significant results and draw meaningful conclusions.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

CRediT authorship contribution statement

Federico Hernández-Alfaro: Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Project

administration, Methodology, Formal analysis, Data curation, Conceptualization. **Oscar Saavedra:** Writing – review & editing, Writing – original draft, Visualization, Validation, Software, Methodology, Investigation, Formal analysis, Data curation. **Francesc Duran-Vallès:** Writing – review & editing, Writing – original draft, Visualization, Software, Investigation, Formal analysis, Data curation. **Adaia Valls-Ontañón:** Writing – review & editing, Writing – original draft, Visualization, Validation, Supervision, Methodology, Investigation, Formal analysis, Data curation, Conceptualization.

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