Individualized Surgical Templates and Titanium Microplates for Le Fort I Osteotomy by Computer-Aided Design and Computer-Aided Manufacturing

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Abstract: The authors report the use of novel individualized surgical templates and titanium miniplates for Le Fort I osteotomy and evaluate the accuracy of this technique in vitro. Nine three-dimensional stereolithographic skull models were used to design the templates and titanium microplates and to simulate the operation. Cone beam computed tomography (CBCT) scans of the skulls were acquired preoperatively and were used to generate virtual models. The surgical plans were made based on three-dimensional cephalometric analyses, and osteotomies were then performed virtually. Cylinder-shaped markers were placed to permit the correct location of titanium screws, and individualized surgical templates were designed. The bony segments were then repositioned virtually according to the surgical plans to correct the skeletal deformities. Resin surgical templates were produced by stereolithography rapid prototyping and the titanium miniplates by three-dimensional cutting. Le Fort I osteotomy was performed under the guide of the surgical templates and fixed with the titanium miniplates. Postoperatively, CBCT scans of each skull model were taken, and the differences between the actual and planned surgical outcomes were measured by superimposing the planned and postoperative virtual models generated from CBCT images. The authors demonstrated that the average linear difference between the planned and actual outcomes was <1 mm and the average orientation difference was $<1^\circ$. The individualized surgical templates and titanium microplates designed in this experimental study permitted the repositioning of the maxillary segment to the correct planned positions during Le Fort I osteotomy, making this technique a promising alternative to the conventional split method.

Key Words: Computer-aided surgical simulation, individual templates, individual titanium miniplates, Le Fort I osteotomy

(*J Craniofac Surg* 2015;26: 1877–1881)

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Received September 5, 2014.
Accepted for publication April 27, 2015.

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This study was supported by the new technique and new treatment modality fund of Peking University School and Hospital of Stomatology and by the National Natural Science Foundation of China (81250006).
The authors report no conflicts of interest.

ISSN: 1049-2275
DOI: 10.1097/SCS.0000000000001938

Le Fort I osteotomy is commonly used to correct dental and maxillofacial deformities. As a part of the conventional Le Fort I osteotomy, preparation for surgery involves using alginate impressions of the patient's dentition to generate dental casts. These are mounted to the articulator by facebow transfer. Individual surgical plans are determined using 3 key resources: the clinical examination, the cephalometric analysis, and dental models.[1] Following confirmation of the surgical model, the operation is performed using the dental casts which are detached from the articulator and reattached in the planned position. Following this, surgical wafers are constructed. These serve as the template to assist the surgeons in fixing the maxilla to the desired position following down-fracture.[2]

Although the process and functional outcome of the conventional Le Fort I osteotomy is widely accepted, it has been demonstrated that clinical outcomes may differ from the planned outcome when either two-dimensional (cephalometric analysis) or three-dimensional (computer assisted analysis) methods are used.[1,3,4] It is essential to move the maxilla to the new position during the surgery, and there are inherent errors in this that influence the precise transfer of the surgical plan to the patient. These errors may result from several aspects. The current articulator system used for model surgery was originally designed for prosthetic dentistry, and the upper arm of the articulator does not represent the Frankfort horizontal (FHP) but rather the axis (middle of the condyle)-orbital plane. This results in a difference between the occlusal plane inclination of the models and the actual occlusal plane inclination in the patient, thereby inducing a discrepancy in model surgery.[4] The other source of error is the change of the patient's body position. The occlusal relationship between the maxillary and mandibular teeth is recorded in the upright position to generate the mandibular model, yet when the patient is in the supine position under general anesthesia, the location of the condyle and the mandible are likely to be more posterior. This may disturb the placement of the maxilla to a new position.[4] In addition, when the intermediate wafer is used intraoperatively to reposition the maxilla, it can be difficult to establish the correct horizontal and vertical movement of the maxillary segment; and errors may arise as a consequence of the lack of anatomical reference points outside the osteotomy cuts against which a check can be performed.[5,6]

More recently, three-dimensional surgical planning has been used in the field of oral and maxillofacial surgery, and computer-aided surgical simulation (CASS) has been employed in various orthognathic surgical processes, including diagnosis, surgical planning, and predicting clinical outcomes.[7,8] Le Fort I osteotomy may also be subject to surgical simulation, with the use of virtual surgical template design.

The most commonly used virtually designed surgical template for Le Fort I osteotomy is the tooth-supported intermediate occlusal splint, with the shape of the conventional surgical splints made in plaster dental models.[9] Several kinds of bone-supported or tooth-bone-supported surgical templates for Le Fort I osteotomy

generated by computer-aided design and computer-aided manufacturing (CAD/CAM) have been reported and proposed as alternatives to conventional intermediate splints.[10–12] However, individual microplates virtually designed for Le Fort I osteotomy have been reported only in 1 study.[13]

In this study, we report the design of a novel surgical template and individualized microplates for Le Fort I osteotomy. We evaluated the feasibility and accuracy of this new method in vitro with a view to possible future assessment in patients.

MATERIALS AND METHODS

Subjects

This in vitro study was performed on 9 stereolithographic skull models. These models were generated using photoactivated resin based on spiral CT data (BrightSpeed, GE Medical Systems, Fairfield, CT) of the corresponding patient. A typical stereolithographic skull model is shown in Figure 1.

Each of the models had been used for the preoperative design of orthognathic surgery or distraction osteogenesis in the Oral and Maxillofacial Surgery Department, School and Hospital of Stomatology, Peking University. The characteristics of the studied models were described in Table 1. All the skull models still had a complete maxilla following their use in preoperative design.

This study was exempt from ethical approval by the institutional review board, because it would exert no harm on patient health and would not infringe patient privacy. Informed consent for the use the skull models in this study was obtained from all patients.

Data Acquisition

Four 4 mm long microscrews (Biomet Microfixation, USA) were applied to each skull model on the subspinale, between the right and left incisor, and the mesial buccal tips of the left and right first molar. These served as measurement marks for three-dimensional cephalometric analysis. All the skulls were scanned by CBCT (NewTom VGi; NewTom, Verona, Italy) with a 15×15 cm field of view. The Frankfort horizontal (FH) plane of each model was arranged parallel to the horizontal plane, assisted by the horizontal reference line of the CBCT machine, which was arranged to cross the Frankfort horizontal (FH) plane through the right and left portion and the right orbital of the models.[14] The central reference line of the CBCT machine was arranged to cross the midsagittal plane (MSR) passing through the basion and the nasion of the models.[14]

The acquired CBCT data in DICOM format were imported into the Mimics software (Materialise, Belgium) to generate three-dimensional digital skull models in stereolithography (STL) format.

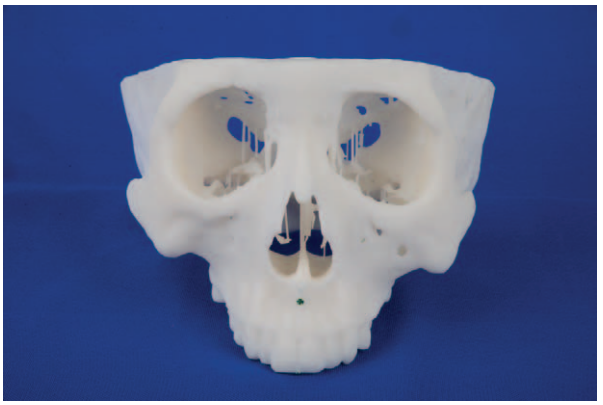

FIGURE 1. A stereolithographic skull model used in this experimental study.

TABLE 1. The Characteristics of the Studied Models and the Virtual Surgical Plans

No.	Diagnosis	3D Model Initially for	Virtual Movement
1	Hemifacial microsomia	Unilateral mandibular distraction	4.5 mm forward 1.5 mm downward rotation
2	Hemifacial atrophy	Unilateral mandibular distraction	1.5 mm forward rotation
3	Temporomandibular joint ankylosis	Bilateral mandibular distraction	6 mm forward rotation
4	Hemifacial microsomia	Unilateral mandibular distraction	1 mm forward 2 mm downward rotation
5	Hemimandibular hyperplasia	Orthognathic surgery	1 mm backward 3 mm downward rotation
6	Temporomandibular joint ankylosis	Unilateral mandibular distraction	2 mm forward 1 mm leftward
7	Temporomandibular joint ankylosis	Bilateral mandibular distraction	3.5 mm upward rotation
8	Temporomandibular joint ankylosis	Unilateral mandibular distraction	2 mm backward 2 mm downward
9	Condylar osteoma	Orthognathic surgery	4 mm forward 1 mm downward rotation

Virtual Design of the Surgical Templates

Using the Mimics software, three-dimensional cephalometric analyses were performed on every digital skull model for the development of surgical plans. The osteotomy lines for Le Fort I were labeled on the anterior wall of the maxilla (Fig. 2A). The surgical plans included the movements of the maxilla in the 3 planes of space (mediolateral, anteroposterior, and superoinferior), and the movements of each centroid of the maxillae were listed in Table 1.

A 10 mm long two-layer cylinder (TLC) model was generated in the FreeForm Modeling Plus software (Geo Magics SensAble, USA). The outer layer of the cylinder (OLC) was a pipe, the external diameter of which fitted the diameter of the surgical drill. The inner layer of the cylinder (ILC) was of a diameter to fit the microscrew used in this study (Biomet, USA) (Fig. 2B).

In the FreeForm software, the TLC model was imported and 16 TLCs were placed at the medial and lateral buttresses where the microscrews would be drilled (Fig. 2C). TLCs were manually placed perpendicular to the location sites on the anterior wall of the maxilla using the multiplanar view, since this could not be automatically accomplished by the software.

Next, a 2 mm thick "clay" (a virtual material in the FreeForm software) was placed on the anterior wall of the maxilla on the left and the right side to generate a novel surface template (Fig. 2C). The extensions of the novel templates were fitted to the area that would be exposed in the Le Fort I osteotomy. The nasal side of the template had a novel structure that partially covered the edge of the apertura piriformis and the anterior nasal spine. The osteotomy lines were projected onto the templates and labeled with 4 holes. After this, 10 mm long pipes were generated around the TLCs to form the directional drill pipes. The Boolean operation was performed to subtract the TLCs and the skull model, then the final surgical template was constructed (Fig. 2D). The data describing the template were exported and saved in STL format.

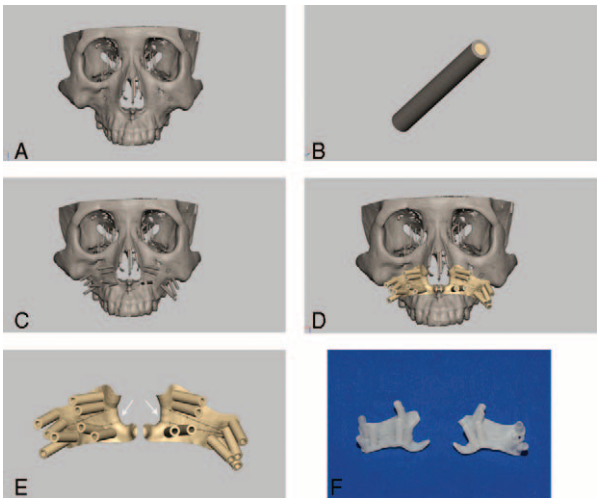

FIGURE 2. Virtual design of the surgical template. (A) Digital skull model generated from CBCT data, and the osteotomy lines for Le Fort I labeled on the anterior wall of the maxilla in Mimics software. (B) Two-layer cylinder (TLC) constructed in FreeForm software. (C) Sixteen TLCs were placed at the medial and lateral buttresses where the microscrews would be drilled. (D) "Clay" was placed on the anterior wall of the maxilla and around the directional pipes to generate the individual templates. (E) The front view of the virtual individual templates. The nasal side of the templates covered the edge of the apertura piriformis and the anterior nasal spine (white arrows). (F) The surgical templates generated by three-dimensional printing.

Computer Aided Surgical Simulation Protocol

In Mimics software, after the OLCs were hidden and the ILCs were merged to the virtual skull model, the maxillary segment with 4 TLCs inferior to the osteotomy line was virtually cut using the osteotomy tools of the Mimics software, and was moved to the desired position according to the corresponding surgical plan. The desired position served as the planned outcome.[15]

Virtual Design of the Microplates

The postoperative virtual skull model plus the ILCs were imported into the FreeForm software (Fig. 3A). Four 0.6 mm thick microplates were designed on every buttress according to the scale of commercial microplates (Biomet) (Fig. 3B). The microplates were cut from the ILCs through the subtraction Boolean operation to calculate the final virtual microplates (Fig. 3C). The data describing the microplates were exported and saved in STL format.

Fabrication of the Surgical Templates and Microplates

The data describing the virtual surgical templates in STL format were imported to a three-dimensional printing machine (ProJet 3510, 3D Systems, USA) to produce the final templates using a resin material (Fig. 2F). The data for the virtual microplates were imported to a five Axis Milling Machine (DMU 70, DMG MORI, Germany) for three-dimension cutting with titanium alloy (Fig. 3D).

Operation In Vitro

The Le Fort I osteotomies on the skull models were performed in the same manner as in the normal clinical setting. The surgical templates were fitted on the maxillary anterior wall, the apertura piriformis, and the anterior nasal spine, using light digital pressure. Eight holes were drilled on each side of the skull model through the directional drill pipes. The osteotomy lines were marked on the

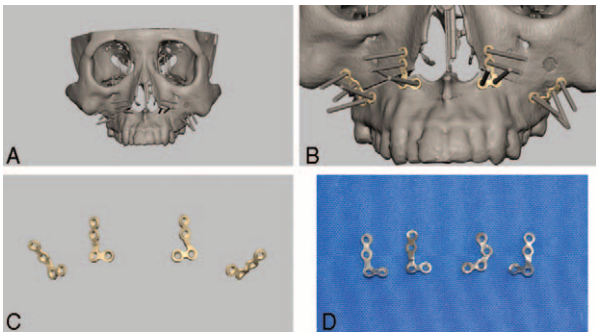

FIGURE 3. Virtual design of the individual microplates. (A) The postoperative virtual skull model plus the ILCs was imported into the FreeForm software. (B) Four microplates were designed on every buttress. (C) The front view of the virtual individual microplates. (D) The individual titanium microplates generated by three-dimensional printing.

skull models by drilling through the 4 holes on the osteotomy lines of the surgical templates. Next, removed the surgical templates, and Le Fort I osteotomy was carried out with drills and chisels. Individual templates were fixed with microscrews (Biomet) in the predrilled holes and the maxilla was repositioned. The postoperative skull models were scanned with CBCT to generate the virtual postoperative skull models that served as the actual outcome data.[15]

Outcome Analysis

The accuracy of the individual surgical templates and titanium microplates designed and produced in this study was assessed by comparing the planned outcomes with the actual surgical outcomes. This method was modified according to previous reports.[15,16]

Planned outcome and the actual outcome data were imported into the Geomagic Studio software (3D Systems, Rock Hill, SC) (Fig. 4A), and the linear and orientation differences between the planned outcomes and actual outcomes of the Le Fort I segments were measured.

First, the postoperative skull models were automatically registered to the planned models by using the surface-best-fit method (Fig. 4B). The cranium area of the postoperative models and the planned models were selected and superimposed. Second, the Le Fort I segments of the planned and postoperative models were displayed and the remaining parts of the models were eliminated. The areas of the planned and postoperative Le Fort I segments that

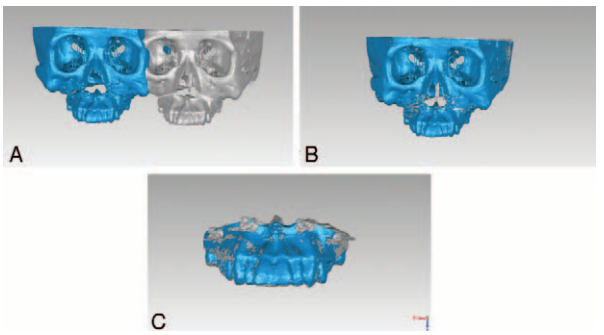

FIGURE 4. The method used for the measurement of accuracy. (A) The data of the planned outcome (gray) and the actual outcome were imported into the Geomagic Studio software. (?B) The postoperative skull model was automatically registered to the planned models using the surface-best-fit method. (C) Only the Le Fort I segments of the planned and postoperative models were displayed. The postoperative Le Fort I segments were registered to the planned models. The linear movements and orientation of the centroid position of the postoperative Le Fort I segments during the registration could be automatically calculated by the software.

were not affected by the surgery (namely the alveolar bone and the nasal base), and the individual microplates and microscrews on the postoperative Le Fort I segments were selected and superimposed. The postoperative Le Fort I segments were then aligned to planned data, while the planned Le Fort I segments served as targets (Fig. 4C). The linear movements and orientation of the centroid position of the postoperative Le Fort I segments during the registration were automatically calculated by the software, and described the position differences and orientation differences between the planned and actual postoperative Le Fort I segments.

The differences were presented in 2 aspects: first, the linear differences between the planned and postoperative centroid positions in the x (mediolateral), y (anteroposterior), and z (superoinferior) directions; and second, the orientation presented by the rotation around the x axis (mediolateral direction), the y axis (anteroposterior direction), and around the z axis (inferosuperior direction), which could be represented by pitch (mediolateral direction), roll (anteroposterior direction), and yaw (anteroposterior direction).[15,16]

The absolute values of the differences were recorded. The measurement was completed by the same examiner after an interval of 1 month. The average values of the 2 measurements of every case were accepted as the experimental results and used for statistical analysis.

Statistical Analyses

Mean values and standard errors of the mean of the differences in the position and rotation of the Le Fort I segments were presented. A difference of <2 mm in position and $<4^\circ$ difference in rotation were considered to be clinically insignificant.[15,17–19]

RESULTS

All the surgical guides and individual microplates made an excellent fit with the anterior walls of the maxilla. Surgery was successfully performed on the skull models in each case, and the maxillary segments were moved to their planned positions.

The linear and orientation accuracy between the actual positions and the planned positions are shown in Table 2. The average linear difference was 0.39 ± 0.30 mm, 0.81 ± 0.54 mm, and 0.44 ± 0.30 mm in the x, y, and z axes, respectively, representing the mediolateral, anteroposterior, and superoinferior directions. The largest linear difference was 1.78 mm, while the smallest linear difference was only 0.03 mm (Table 2).

The average orientation differences were $0.58^\circ \pm 0.30^\circ$, $0.30^\circ \pm 0.16^\circ$, $0.49^\circ \pm 0.31^\circ$ in the x, y and z axes, respectively, representing the pitch, roll, and yaw. The average orientation differences value was within 4°. The largest orientation difference was 1.10°, while the smallest orientation difference was only 0.07° (Table 2).

All the differences were clinically insignificant and acceptable according to the previously defined criteria.

TABLE 2. The Linear and Orientation Accuracy Between the Actual Position and the Planned Position

	X ± s, mm	Min, mm	Max, mm
Linear			
Mediolateral	0.39 ± 0.30	0.06	1.12
Anteroposterior	0.81 ± 0.54	0.03	1.78
Superoinferior	0.44 ± 0.30	0.16	1.11
Orientation			
Pitch	0.58 ± 0.30	0.07	1.09
Roll	0.30 ± 0.16	0.04	0.49
Yaw	0.49 ± 0.31	0.11	1.10

DISCUSSION

The increasingly widespread use of CASS provides a new clinical method for surgeons to simulate orthognathic surgery virtually, and to transfer surgical planning to the actual operation. After virtual Le Fort I osteotomy, the methods used to transfer the virtual surgical plan to the physical operation vary. Three-dimensional surgical wafers, similar to those conventionally used, have been widely reported,[20–22] and are considered to be efficient and cost-effective.[21] The accuracy of this kind of wafer is good, with clinically insignificant discrepancies (1.0 mm and 1.5° discrepancies in linear and rotational orientations, respectively).[15]

However, the preoperative preparation needed to generate such a wafer is complex.[11,16] Moreover, the need to position it on the unstable mandible to reposition the maxillary segment means that it shares some of the disadvantages described for conventional procedures.[4]

Several investigators put their concentrations on the front wall of the maxilla which were exposed during Le Fort I surgery and designed bone-supported surgical templates with or without the assisting support of the dentition. Clinically acceptable precision for the position of the maxilla (<1 mm) can be achieved this way.[11] Although the virtual design permitted appropriate positioning of the osteotomy template, the anterior maxillary wall forms a comparatively flat surface such that the templates must be fixed with screws on the maxilla to avoid slippage. Since the templates must leave space for the fixation of the Le Fort I segment with commercial microplates, they cannot cover the full area of the front wall; this may make it difficult to decide on the correct location of the templates.

To overcome these difficulties, we used virtual design to generate a new and previously unreported type of bone-supported surgical template and individual microplates for Le Fort I osteotomy. This novel surgical template was separated into 2 parts that were positioned on each side of the anterior maxillary wall. This kind of template had many advantages. The template covered the edge of the apertura piriformis and the anterior nasal spine. This special structure placed limits on the location of the template to enable best fit on the maxilla, and to maximize the ease of the location of the templates during the surgical procedure. The template was stable with only light digital pressure, and no extra fixation was needed. The surgeon can decide the osteotomy line, the location of the microscrews, and the planned amount of bone to be excised with the same template. Our template could cover almost all the exposure area of the maxillary anterior wall ensuring the correct placement and stability of the template. This surgical template was placed on the anterior maxillary wall but not the mandibular dentition, thus avoiding any discrepancy caused by the instability of the mandible.

In this study, the Le Fort I segment was finally fixed with the virtually designed microplates that fit to the outer surface of the maxilla. The individual microplates followed the repositioning template to guarantee the precise movement of the Le Fort I segment to the planned position.

No additional repositioning template was required, and no exchange between an osteotomy template and repositioning template was required. To bent the commercial microplates can be time-consuming, especially for surgeons with limited experience, and the use of virtually designed microplates can avoid this step, and reduce operating time. In our preliminary experiment, the locations of the microscrews were labeled with a series of holes on the surgical template, and obvious internal stress was caused to the microscrews and microplates during the fixation process. This is likely to be a consequence of failure to limit the direction of drilling, and we modified the design of the template to include directional

pipes to ensure the direction of insertion of each microscrew was approximately perpendicular to the microplate on which it was located. Following this modification, no serious internal stress was observed.

Statistical analysis showed that the mean linear and orientation accuracies of the individual templates and microplates in this study were within 1 mm and 1°, respectively, with even the maximum differences (1.8 mm and 1.1°) being still within the bounds of clinical acceptability. The results illustrated that this new digital method achieved satisfied precision in transferring the virtual surgical plan to the actual surgery and in controlling the movement of the maxilla in Le Fort I osteotomy. This experimental study therefore sets a firm foundation for the future clinical application of this technique.

In this in vitro study, we avoided the fusion of data from the dental model, the CBCT data from the skulls, and the normal head position. This does not affect the evaluation of the errors of the maxillary movement in this study but was essential for CASS to develop the surgical plan.[12]

The surgical template in this study could only label the designed osteotomy line on the anterior wall of the maxilla for the operation; the other osteotomy lines on other walls of the maxilla could not be transferred. Bony disturbance still needed to be trimmed after the down-fracture. Inaccuracies arising from treatment of the bony disturbance would influence the repositioning of the Le Fort I segment and may cause surgical discrepancies, in turn affecting the postoperative outcome.

Despite the advantages of this new digital method in our study, such as achieving precise movement of the maxilla owing to the best fit and limited location of the template and reducing the surgery time as mentioned above; this study could not reach the conclusion that this new method has better benefits over the conventional split method, because it was not a comparative study. This needs to be studied in our following clinical research.

This study may have some possible limitations for clinical application. This method involved many steps and much time-cost, so whether it is more efficient or not compared with the conventional method still need to be evaluated. Errors may arise from the virtual design, CASS, and fabrication procedures, then conventional surgical splits should be prepared in case this method could not reposition the maxilla to the desired position precisely,[10] especially in the initial phase of the clinical application. Moreover, the tension of the soft tissue attached to the maxilla might affect the clinical precision of this new method. Other limitation of the method we outline here is similar to those previously described,[11] including the unsuitability of the procedure for maxillary multiple-segment osteotomy.

To conclude, the individualized surgical templates and titanium miniplates designed in this experimental study permitted reliable positioning of the maxilla according to surgical plans. They may provide a promising alternative to the conventional split method to simplify the surgical procedure and to decrease operation times for Le Fort I osteotomy.

ACKNOWLEDGMENTS

The authors thank the new technique and new treatment modality fund of Peking University School and Hospital of Stomatology and by the National Natural Science Foundation of China (81250006).

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