

Methodological Approach to Accuracy Assessment in CAD-CAM Mandibular Reconstruction

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Conflict of Interest

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ABSTRACT

Introduction: Assessing accuracy in CAD-CAM mandibular reconstruction poses significant challenges but is essential for ensuring reliable outcomes. Existing methods are often operator-dependent, lacking repeatability and reproducibility. This study introduces the Global Positioning Layout (GPL) method, an accuracy assessment technique integrated into the reconstruction protocol based on CAD-CAM and additive printing technology. We describe the methodology and process for applying this approach in detail.

Materials and Methods: The GPL method was developed at the University of Padova, Italy. Key principles of accuracy assessment were identified and structured as Requirements, Data input, Data reference system, and Data output. The necessary 3D virtual models were defined: planned mandible, reference mandible, patient-specific implant (PSI), postoperative mandible, and postoperative PSI. A unique coordinate system (GPL-RS) was built on the reference mandible. Three Roto-Translational Matrices (RTMs) were applied to measure movements and deviations between the designed and postoperative models to assess reconstruction accuracy.

Results: A case study of mandibular reconstruction with a CAD-CAM titanium PSI is presented to showcase the GPL methodology. Geomagic Wrap ® software is used, utilizing its Python programming tools and GEO and API libraries.

Conclusion: The GPL method represents a significant advancement in assessing the accuracy of CAD-CAM reconstructions, providing valuable insights that can improve surgical outcomes.

INTRODUCTION

Computer-aided design and manufacturing (CAD-CAM) is an emerging technology in head and neck reconstructive surgery, which provides patient-specific devices, both implantable and non-implantable, to improve the surgeon's ability to restore facial symmetry and volumes. (Chang et al., 2016)

The introduction of additive manufacturing and three-dimensional (3D) printing technologies in medicine has profoundly changed how head and neck surgeons plan the resection and the reconstruction of challenging cases. (Largo and Garvey, 2018; Tang et al., 2019)

Virtual surgical planning (VSP) provides surgeons with a clear 3D visualization of the patient's anatomy to develop a personalized surgical plan before entering the operating room. (Pucci et al., 2020)

The progress of computer-assisted surgery (CAS) not only expands the surgeon's ability and precision intraoperatively but also decreases their learning curve and enhances the reproducibility of surgery. (Tran et al., 2022)

Ideally, the application of CAD-CAM technology offers head and neck surgeons objective data to measure the consistency of their work and make them available for comparison and quality check.

On the other hand, VSP is likely to amplify patient expectations before surgery. (Davey et al., 2019) Given these advancements, ensuring precision throughout the entire planning and execution workflow becomes increasingly critical. Evaluating the accuracy of CAD-CAM mandibular reconstruction presents significant challenges but is crucial for ensuring reliable results. No standardized protocols exist for virtual surgical planning (VSP), virtual design, engineering, or additive printing production in customized reconstructive surgery. (Barr et al., 2020)

To enhance the reproducibility of surgery and optimize mandibular reconstruction outcomes, the performance of computer-assisted surgery (CAS) needs to be quantitatively evaluated. (van Baar et al., 2018; Betancourt et al., 2023)

Several methods for assessing the accuracy of CAD-CAM mandibular reconstruction have been developed. Some compare two-dimensional (2D) CT images, while others compare the virtually planned surgery with the final postoperative result based on 3D CT imaging. (Peters et al., 2024)

Some methods rely on linear and angular measures based on the distance between anatomical landmarks. Such landmarks are drawn as single points on two-dimensional CT images or 3D virtual model surfaces (Mascha et al., 2017) (El-Mahallawy et al., 2023; Annino et al., 2022; Wilde et al., 2015; Metzler et al., 2014; Goormans et al., 2019) (Chernohorskyi et al., 2021)

Overall, these methods compute linear measurements through operator-dependent steps and might lack repeatability.

Recently, a guideline has been developed to standardize evaluation methods. It suggests strategies for imaging, defect classification, data comparison, and volume assessment of 3D models, and includes a quantitative accuracy assessment method. (Van Baar et al., 2019)

The GPL method was initially developed to quantify the 3D spatial deviation between the planned reconstruction and the postoperative result using roto-translational matrices. (Menapace G., 2019) (Bettini G, 2021) During this early phase, certain steps required operator intervention, which introduced variability into the results. Since then, the method has been refined to eliminate any operator-dependent variability.

This study aims to establish the metrological principles for computer-aided accuracy assessment of CAD-CAM mandibular reconstruction and to present a methodological approach called Global Positioning Layout (GPL). This method is designed to be independent of both the "application software" and the operator, ensuring consistent and reliable outcomes across various types of mandibular defect reconstructions.

MATERIALS AND METHODS

Study setting

The GPL method was developed at the Departments of Neuroscience-DNS and of Management and Engineering of the University of Padova (Italy)

Basic principles of accuracy assessment

The basic principles of accuracy assessment are listed as follows:

- A. Requirements:
 - a. Functionality: computing of spatial relationships between the planned mandibular reconstruction and the postoperative result.
 - b. Independency: results shall be independent of the operator (Operator uncertainty principle), thus minimizing human error and variability in measurements.
 - c. Compatibility: input and output data shall be given in a format suitable for any CADbased system.
 - d. Generality: the methodology should apply to various mandibular defects and reconstruction procedures, allowing for broad clinical use.
 - e. Rigid workpiece: any patient-specific device is a rigid part of infinite stiffness or whose distortion does not exceed specified tolerances by applying pressure or forces during and after standard surgery. It provides a stable reference for accuracy assessment.
- B. Data input:
 - a. any kind of mandibular bone defect.
 - b. any kind of VSP of mandible reconstruction.
 - c. any kind of CAD patient-specific device.
- C. Data reference system:
 - a. a defined and unique, intrinsic, 3D coordinate system (X-Y-Z), called "reference system", is used to describe the spatial position and orientation of any model.

D. Data output:

- a. a three-dimensional assessment of spatial errors, according to the reference system
- b. errors concern the position and orientation of the patient-specific device.

Definition of operational models for GPL applications

The Digital Imaging and Communications in Medicine (DICOM) data obtained from the preoperative CT scans are imported into a given virtual planning software and converted into surface models in a Standard Tessellation Language (STL) file format.

The virtual 3D model (i.e. CAD model) of the facial skeleton is segmented to obtain the "*native mandible*", which consists of the entire mandible, including both the diseased and healthy parts. The native mandible is used to extract the "*planned mandible*", which consists of the healthy portion of the native mandible devoid of the diseased bone.

For bone defects limited to half of the mandible, the native mandible is mirrored and fitted to obtain the *"reference mandible"*. In case of gross deformation of the mandible exceeding the midline, the reference mandible is obtained through superimposition, scaling, and fitting of healthy 3D models of the mandible taken from a virtual image library of lower jaws.

Then, the reference mandible is used to design the patient-specific implant (PSI). The final virtual 3D model of the device is called "*designed PSI*". The combination of the planned mandible and the designed PSI is called the "*designed model*".

The virtual 3D model of the postoperative result is obtained from the postoperative CT scans using the same approach and is called the "*postoperative model*". This latter consists of the combination of two features: *the "postoperative mandible"*, which is the remaining portion after surgical resection of the diseased bone volume, and *the "postoperative PSI"*, which is the patient-specific implant following surgical implantation. The sequence of the operational models is depicted in Figure 1:



Figure 1: Sequence of models obtained from the Virtual Surgical Planning and the Postoperative follow-up.

In conclusion, the following virtual 3D models are required to apply the GPL method: planned mandible, reference mandible, designed PSI, postoperative mandible, and postoperative PSI.

GPL data coordinate reference system

In the GPL method, the virtual 3D models of the VSP are positioned and aligned in a unique coordinate (X-Y-Z) reference system (GPL-RS). GPL-RS is based on the reference mandible through an automated process of identification of specific geometric features (see § Step 2: Reference system (GPL-RS) definition).

The virtual 3D postoperative model is positioned and oriented in a coordinate reference system that originates from CT data acquisition. Therefore, alignment of the virtual 3D postoperative model to GPL-RS is essential to perform the analysis and comparison according to the GPL methodology.

GPL workflow

The GPL workflow is depicted in Figure 2:



Figure 2: Global Positioning Layout workflow.

In the following, a brief description of the main steps is presented:

Step 1: Data import

Five 3D virtual models are imported into the application software: a) planned mandible, b) reference mandible, c) designed PSI, d) postoperative mandible, and e) postoperative PSI.

Step 2: Reference system (GPL-RS) definition

The GPL-RS is constructed on the reference mandible.

In brief, 3 intra-mandibular geometric features are computed: the *centre of gravity (i.e. barycentric point)*, a *symmetry plane*, and a *plane tangent to the inferior edge of the mandible*.

The application software computes the centre of gravity.

The symmetry plane of the reference mandible intentionally passes through the centre of gravity. The tangent plane to the inferior edge of the mandible is set through an optimization algorithm, which minimizes the distance from the centre of gravity.

To define the GPL-RS, the intra-mandibular geometric features are then associated with the common coordinate reference system (i.e. cartesian coordinate system, XYZ) following the ordered sequence:

- 1. centre of gravity \rightarrow OO origin of axes
- 2. symmetry plane \rightarrow YZ plane
- 3. tangent plane to inferior mandibular edge \rightarrow XY plane

This sequence aligns (i.e. translates and rotates) the *reference mandible* onto the GPL-RS coordinate system.

Step 3: First roto-translational matrix (RTM) computing and designed model alignment

The quantitative estimation of the above-mentioned movements of the reference mandible is described by 3 rotational and 3 translational components according to the X, Y, and Z axes of the GPL-RS, which define the 1st roto-translational matrix (RTM): positive rotation angles cause a counterclockwise rotation around the axes while positive translations cause a movement along the axes.

Below is provided the general form of the roto-translation matrix:

$$RTM = \begin{bmatrix} r_{11} & r_{12} & r_{13} & t_x \\ r_{21} & r_{22} & r_{23} & t_y \\ r_{31} & r_{32} & r_{33} & t_z \\ 0 & 0 & 0 & 1 \end{bmatrix}$$
(1)

It's a 4x4 matrix where the upper-left 3x3 sub-matrix represents the rotation matrix, and the last column (3x1) of the matrix represents the translational vector.

The 1st RTM is then applied to align *the designed model (planned mandible + designed PSI)* to the GPL-*RS*.

Step 4: Postoperative PSI alignment

The *postoperative PSI* is then aligned to the *designed PSI* through two consecutive steps using ICP algorithms. The initial step involves the superimposition of the prosthetic model onto the design model. This is achieved using a best-fit method that minimizes the distance between the two models by automatically selecting corresponding points. In the second step, a more detailed ICP-based alignment is employed to improve the preliminary superimposition.

Step 5: Second roto-translational matrix (RTM) computing and postoperative mandible alignment

The quantitative estimation of the *postoperative PSI* movements is the 2nd RTM. The 2nd RTM is then applied to align the *postoperative mandible* to the *GPL-RS*.

Step 6: Third roto-translational matrix (RTM) computing: measure of deviations

For the assessment of the accuracy in CAD-CAM mandibular reconstruction, the computation of the deviation between the postoperative model and the designed model requires the superimposition of the postoperative mandible onto the designed mandible.

Similarly to the procedure conducted for prosthetic models, it is necessary to undergo two alignment phases.

The quantitative estimation of the *postoperative mandible* movements is the 3rd RTM.

The 3rd RTM represents the deviations (rotational and translational errors) and measures the accuracy of the reconstruction. The general form of the rotation-translation matrix is given by equation (1). The rotational movements along the X, Y, and Z axes performed by the mandible in the postoperative follow-up can be computed employing Euler's formulas:

$$\theta_x = a \tan^2(-r_{23}, r_{33})$$
 (2)

$$\theta_{\rm y} = {\rm a}\sin(r_{13}) \tag{3}$$

$$\theta_z = \operatorname{a} \tan 2(-r_{12}, r_{11}) \tag{4}$$

The translations, instead, can be directly extracted from the roto-translational matrix.

$$\mathbf{T} = \begin{bmatrix} tx \\ ty \\ tz \end{bmatrix} \tag{5}$$

CASE STUDY PRESENTATION

The case study of a patient who underwent mandibular reconstruction of a condylar-containing lateral defect with a CAD-CAM titanium patient-specific device at the Unit of Maxillofacial Surgery of the University Hospital of Padua (Italy) is used to showcase the GPL methodology.

Data imaging (DICOM) is obtained from the preoperative and 1-month postoperative CT scans of the selected patient. A detailed description of the VSP and computer-aided mandibular design and fabrication developed at the Unit of Maxillofacial Surgery of the University of Padua (Italy) in collaboration with CAD-CAM specialists (Sintac s.r.l, Biomedical Engineering, Trento, Italy, and 3D-Fast s.r.l, Padova, Italy) has been previously published. (Bedogni et al., 2021)

On purpose, Geomagic Wrap ® (Oqton Inc., South Carolina, US) is used to present the procedure, taking advantage of its built-in Python programming tool and associated GEO and API libraries. All steps previously described are reproduced with the software, including the roto-translation matrices results for the selected patient.

First, the five 3D virtual models depicted in Figure 3 (planned mandible, reference mandible, designed prosthesis, postoperative prosthesis, and postoperative mandible) are imported into the application software.

Virtual Surgical Planning models



Figure 3: Five 3D models imported in Geomagic Wrap to apply the GPL method: 1) planned mandible 2) reference mandible 3) design prosthesis 4) postoperative prosthesis 5) postoperative mandible.

The reference system (GPL-RS) definition and first roto-translational matrix (RTM) computing are shown in Figure 4.



Figure 4: Reference system (GPL-RS) definition and first RTM computing. 4A: Computing of the intra-mandibular geometric features. 4B: World reference system used to align the reference mandible. 4C: Alignment of the reference mandible to the world reference system and first roto-translational matrix computing.

In detail, the intra-mandibular geometric features (centre of gravity, symmetry plane, and tangent plane) are used to align the reference mandible to the reference system called *'World'* in Geomagic; thus, the first RTM is obtained. The rotations and translations extracted from the first roto-translational matrix are reported in Table 1.

The first roto-translational matrix is applied for the alignment of the designed model (Figure 5A). In this way, all VSP models are located on the same reference system (Figure 5B). Next, the postoperative prosthesis is aligned to the designed prosthesis through '*Best Fit Alignment*' and '*Global Registration*' commands (Figure 5C); then the second roto-translational matrix is obtained (Table 1).



Figure 5: Alignment of the designed model, superimposition of the postoperative prosthesis onto the designed prosthesis, and second RTM computing. 5A: Application of the first roto-translational matrix to the designed models. 5B: VSP models in the same reference system. 5C: Alignment of the postoperative prosthesis to the designed prosthesis and second roto-translational matrix computing.

The second roto-translational matrix is applied for the alignment of the postoperative mandible (Figure 6A). In this way, all 3D models are located on the same reference system (Figure 6B). Once aligned with the GPL-RS, the model must be reoriented using the *'reorient model'* function to reset the previously applied movement. Then, the postoperative mandible is aligned to the designed mandible through 'Best Fit Alignment' and 'Global Registration' commands (Figure 6C).



Figure 6: Alignment of the designed model, superimposition of the postoperative prosthesis onto the designed prosthesis, and second RTM computing. 6A: Application of the second roto-translational matrix to the postoperative mandible. 6B: All 3D models in the same reference system. 6C: Alignment of the postoperative mandible to the designed mandible and third roto-translational matrix computing.

Finally, the third roto-translational matrix is obtained to assess the deviations between the designed model and the post-operative model, which quantifies the accuracy of mandibular reconstruction (Table 1).

	Rot X	Rot Y	Rot Z	Trans X	Trans Y	Trans Z
		[Deg]			[mm]	
1 ^{rt} RTM	-19,440	0,026	0,009	4,589	210,497	507,899
2 nd RTM	-17,553	-1,272	6,614	-33,448	264,291	136,173
3 rd RTM	-3,115	2,112	-2,477	2,213	0,719	-1,922

Table 1: Rotations and translations obtained from the three roto-translational matrices. 3rd RTM quantifies the distortion of the mandibular reconstruction.

To visualize the displacement of the prosthetic implant during the mandibular reconstruction process, it is necessary to apply the third roto-translational matrix to the postoperative prosthesis (Figure 7).



Figure 7: Application of the third roto-translational matrix to the postoperative prosthesis.

DISCUSSION

Recently developed computer-assisted reconstructive surgery techniques integrate advanced 3D imaging, computer simulation software, and CAD/CAM technologies. (Largo and Garvey, 2018) These systems aim to enhance the quality of surgical results and ideally ensure method reproducibility on a larger scale. The entire process of computer-assisted surgery (CAS) consists of sequential phases: 1) image data acquisition and elaboration/segmentation, 2) virtual surgical planning (CAD), 3) manufacturing of the final construct (CAM), 4) surgical treatment, and 5) evaluation of the surgical result. Each phase is susceptible to errors that can negatively impact the expected surgical outcome and, importantly, the quality of life of treated patients. (van Baar et al., 2018)

This study introduces the Global Positioning Layout (GPL) method as a systematic approach for assessing the accuracy of CAD-CAM mandibular reconstructions. The GPL method addresses various challenges in CAS by comparing distortions between the postoperative virtual model and the planned model. Instead of using the native mandible as a reference, which can be altered by underlying conditions, it relies on the planned model. This approach aligns with the views of other authors who have recognized the importance of comparing the postoperative STL model to the preoperative STL virtual model, including the planned reconstruction. (Zhang et al., 2016) (Mascha et al., 2017) (Tarsitano et al., 2018) (van Baar et al., 2018)

A key feature of the GPL method is its assumption that the titanium device used in the reconstruction maintains its geometry post-implantation. By first superimposing the titanium device, the method provides a consistent basis for accuracy assessment over time, which is crucial for enhancing precision and reproducibility. For this reason, we chose to present the GPL method using a case of mandibular reconstruction with a CAD-CAM titanium patient-specific implant, given its rigidity as a workpiece.

Some authors have discouraged superimposing pre- and postoperative STL models to generate a colorimetric map of deviations between the two models. This is because the scattering of the overlying reconstruction hardware on the postoperative mandibular CT image can make it difficult to align the postoperative result with the virtual plan. (van Baar et al., 2018) (Schepers et al., 2016) (Hanken et al., 2015)

Currently, all accuracy methods developed so far, including GPL, are limited by their dependence on the quality of image data acquisition. Preoperative and postoperative CT scans are often obtained using different CT scanners and acquisition parameters across various institutions. (van Baar et al., 2018)

However, the GPL method was developed specifically to address the accuracy assessment process, rather than to define strategies for improving image data acquisition. The latter has been the focus of

recent studies by several authors and requires dedicated efforts (Ghani and Karl, 2019) (Jeon and Lee, 2023) (Amirian et al., 2024) (Selles et al., 2024)

Unlike methods that rely on colorimetric maps, which are more susceptible to scattering effects, GPL evaluates accuracy without using these maps. In addition, GPL uses an ICP algorithm with *Auto-deviation Elimination* during the alignment of preoperative and postoperative PSI models. This function automatically identifies and excludes anomalous or erroneous points from the alignment process, preventing them from adversely affecting the outcome. As a result, even though scattering is present, the overall accuracy remains unaffected.

Alternatively, Van Baar et al. (2019) suggested starting the alignment from the condylar processes of the mandible on the postoperative STL model. (van Baar et al., 2019)

However, the condylar unit is often included in the resection plan due to direct disease involvement or for reconstruction purposes. In cases where the remaining condylar fragment is too small or has poor bone quality to accept plates and screws for stable fixation of the bone flap or alloplastic reconstructions, it may not always be available for superimposition. (Bedogni et al., 2021) (Kumar et al., 2016) (Jagtiani et al., 2024)

This makes the use of the condylar process for the initial alignment of the postoperative STL model non-reproducible across the full spectrum of mandibular bone defect reconstructions.

Again, the mandibular condyle is not a rigid workpiece and can undergo displacement and deformation when mechanical overload occurs. (Wong et al., 2010)

When the condylar unit is preserved, some degree of displacement can occur, regardless of the reconstructive technique used to address the mandibular defect. (Wang et al., 2024)

Post-operative malposition of one or both condylar processes can result from several factors, including the simultaneous loss of dental elements, detachment or resection of masticatory muscles, postoperative bleeding, or soft-tissue edema. (Lim et al., 2016) (Casap et al., 2008) These factors may resolve within a few weeks or months, potentially altering the postoperative anatomical conditions during follow-up.

Accuracy evaluation methods are primarily used to compare the initial postoperative result (within 1 month after surgery) with the planned reconstruction. (Barr et al., 2020)

However, it will soon be necessary to verify the long-term stability of reconstructions and, more importantly, to identify which clinical factors may influence the outcome, given the same reconstruction. This distinction will help differentiate between true operative errors and perioperative clinical conditions that may resolve over time, such as postoperative edema.

To achieve this, it will be necessary to compare the immediate postoperative result with the late result, at least 6 months after surgery, once adjuvant treatments have been completed. For this purpose, the

method employed must be as automated and operator-independent as possible and meet all the requirements outlined in the GPL.

Superimposing 3D virtual models usually requires a manual selection of anatomical landmarks and reference points to align preoperative/planned and postoperative models. (Schepers et al., 2015)

Van Baar et al. (2019) also suggest manually selecting reference points to align both condylar processes on the postoperative STL model by drawing a plane from the most caudal point of the mandibular notch, perpendicular to the posterior edge of the border between the condyle and ramus. (van Baar et al., 2019)

Even though the final alignment is performed using an ICP algorithm, the initial superimposition, conducted through point-pair alignment, remains subject to variability due to operator involvement. This manual step introduces inconsistencies that can affect the overall accuracy of the alignment, despite the subsequent refinement by the automated process. This is also true for the resulting linear and angular measurements, which can be further influenced by postoperative factors such as tissue edema or muscle detachment. (Lim et al., 2016) (Casap et al., 2008)

Furthermore, while the ICP algorithm provides a relatively automated alignment process, it has significant limitations. The information it generates often lacks spatial 3D orientation, potentially leading to less clinically relevant data. Specifically, the alignment produced by the ICP algorithm might not accurately reflect the true anatomical positioning and orientation of the reconstructed mandible. This can be particularly problematic in clinical decision-making, where precision in spatial orientation is critical for evaluating the success of complex reconstructions and planning further treatment.

After the superimposition of the two 3D virtual models, some evaluation methods use a 3D analysis for comparison, and the differences are shown with a colorimetric map. (Roser et al., 2010) (Hanken et al., 2015) (Schepers et al., 2015) (Zavattero et al., 2021) (Chernohorskyi et al., 2021)

In this way, the distortion between anatomical areas before and after surgical reconstruction can be visualized through different colors. However, a clear quantitative and spatially oriented measure of the deviation is still missing.

To address the limitations of linear, angular, and volumetric measurements, GPL was developed from the outset to quantify the 3D spatial deviation between the planned reconstruction and the postoperative result using roto-translational matrices. (Menapace G., 2019) (Bettini G, 2021) This approach quantitatively describes and spatially orients errors.

Bevini et al. (2023) recently proposed a similar approach, employing roto-translational matrices to evaluate mandibular reconstruction accuracy in three dimensions. (Bevini et al., 2023)

However, their method lacks a standardized reference system, relying on the inherent coordinate system of the 3D software, which limits reproducibility and increases measurement uncertainty. Additionally, their method involves manual selections for PSI superimposition, introducing further variability.

The GPL method presented here addresses these limitations by employing a unique 3D coordinate system, referred to as the 'reference system' (GPL-RS), to describe the spatial position and orientation of any model for any patient. This standardized coordinate system ensures consistent measurement results, enhancing reproducibility and comparability across various types of mandibular defect reconstructions, regardless of operator and software variability.

Future directions

GPL requires testing and validation across a large cohort of patients, including all types of mandibular defects and CAD-CAM mandibular reconstruction procedures. Additionally, the GPL workflow requires full automation of the entire process, which will offer significant advantages such as reduced processing times, speeding up accuracy evaluation, and enabling comparisons across large groups. Despite the comprehensive description provided by the matrix components, visualizing the computed deviations between the planned and postoperative mandible remains challenging to translate into a clinical context. Accurate clinical interpretation is crucial, as it allows surgeons to identify errors in reconstructive procedures and implement corrective measures, potentially preventing future mistakes. Enhancing the clinical interpretation of the resulting matrices is an essential task that must be addressed in the future.

Conclusion

In conclusion, the GPL methodology represents a significant advancement in the precision assessment of CAD-CAM reconstructions. It offers highly informative insights and is poised to significantly enhance surgeons' ability to evaluate reconstruction accuracy. This methodological innovation is likely to improve surgical outcomes and establish new standards in the field of mandibular reconstruction.

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