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Abstract: Purpose

In the present study we report on an innovative workflow using polyetheretherketone Patient Specific Implants (PEEK PSI) for aesthetical corrections in the facial region through the process of onlay grafting. The planning comprises implant design according to virtual osteotomy and generation of subtraction volume. Implant design was refined by stepwise changing the implant geometry according to soft tissue simulations.

Materials and Methods

One patient was scanned in a CT. PEEK implants were interactively designed and manufactured using rapid prototyping techniques. Positioning intraoperative was assisted by means of computer-aided navigation. Two months after surgery a 3D surface model of the patient's face was generated using photogrammetry. Finally, the Hausdorff distance calculation was used to quantify the overall error encompassing failures in soft tissue simulation and implantation.

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The implant positioning process during surgery was satisfactory. The simulated soft tissue surface and the photogrammetry scan of the patient showed a high correspondence, especially where the skin covered the implants. Mean total error (Hausdorff distance) was 0.81 +- 1.00 mm (median 0.48 , IQR 1.11). The spatial deviation remains below 0.7 mm for the vast majority of points.

Conclusion

The proposed workflow provides a complete CAD-CAM-CAS (Computer Aided surgery) chain for implant design, according soft tissue simulation, fabrication of patient specific implants as well as image- guided surgery to position the implants. Much of the surgical complexity resulting from osteotomies of the zygoma, chin or mandibular angle might be transferred into the planning phase of patient specific implants.

Original article

Patient specific PEEK facial implants in a computer-aided planning workflow

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Godoberto Guevara-Rojas MSc and Prof. DDr. Franz Watzinger contributed equally to this study. Godoberto Guevara-Rojas was responsible for the technical part, Franz Watzinger for the medical aspects.

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Godoberto Guevara-Rojas: Complete preoperative computer simulations for the rapid prototyping process, writing of main parts of the manuscript

Franz Watzinger: Surgical concept, carried out surgery and was responsible for the surgical aspects of the planning

Michael Figl: Mathematics: Evaluation method, calculations and data representations

Rudolf Seemann: Data analysis, virtual planning and editing of the manuscript;

Hannes Traxler: Responsible for anatomical details of the planning approach

Apostolos Vacariu: Substantial contribution to the writing of the manuscript

Claus-Christian Carbon: Contribution to the development of the photogrammetric evaluation method and utilization of photogrammetry in our specific clinical context.

Rolf Ewers: Chairman of the clinic, providing infrastructure and supervision of the team

Kurt Schicho: Organization of the funding, development of study concept, coaching of the team, management of the whole project.

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The proposed workflow provides a complete CAD-CAM-CAS (Computer Aided surgery) chain for implant design, according soft tissue simulation, fabrication of patient specific implants as well as image- guided surgery to position the implants. Much of the surgical

complexity resulting from osteotomies of the zygoma, chin or mandibular angle might be transferred into the planning phase of patient specific implants.

Introduction

Medical rapid prototyping is gaining significance in different areas of preoperative planning such as maxillofacial surgery, orthopedics, neurosurgery and orthognatic surgery. These 3D models allow the surgeon to become acquainted with the local anatomy and to support the surgeon's intraoperative "3D imagination" ¹. The surgeon has the possibility to plan the osteotomies and, if necessary, to bend the fixation plates onto the model prior to surgery. By this means it is possible to reduce surgical time and increase accuracy. Modern software such as MimicsTM (Materialise Inc., Leuven, Belgium) allows the planning of osteotomies or distractions based on computer tomography data of patients. Although this planning technology represents a mentionable advantage for surgical treatments, and the 3D representations of anatomy have reached a high quality and accuracy ², for the surgeon it is still more effective to handle with actual models of the patient's skull. This actually adds a haptic component to the process, and not even the most sophisticated 3D simulations can fully substitute the use of rapid prototyping models.

In many cases it is necessary to repair defects caused by trauma or tumour resection. For these purposes standardized implants are available that can be individually adapted to the defect during the operation. This can in some cases increase the surgery time and the results also strongly depend on the surgeon's experience and skills. Recent developments such as patient-specific implants (PSIs) ³ do not require adaptation of the implant's shape and geometry to the patient's anatomy during surgery. Instead, computer-aided implant design based on CT data of the patient is utilized. The PSIs are designed to fit precisely in the patient's defects or malformations. After having finalized the computer-aided implant design, the implant shape is controlled visually and - if needed – modified in the course of an iterative process, using a rapid prototyping model of the implant in combination with the patient's anatomy in order to

control and optimize the shape and fit of the implant on the bone. Models are commonly produced by means of stereolithography, 3D-printing or selective laser sintering.

Stereolithography has proven to be a highly precise rapid prototyping manufacturing method⁴, with the drawback that is expensive. Selective laser sintering (SLS) and three-dimensional printing (3DP™) provide acceptable accuracy and might be a useful method for maxillofacial surgery⁵. The material polyether-etherketon (PEEK) has already been used in several medical applications such as cranial vault reconstruction⁶⁷

Various materials have been used over time for reconstructing calvarial defects, including autograft, allograft, xenograft, metallic or non-metallic alloplastic implants⁸. New materials such as alloplastic implants have influenced treatment concepts and improved the outcome of calvarial defect reconstruction. Patient-specific alloplastic implants have reduced both the need for major manipulations during surgery and actual surgery time. In preparation for calvarial defects reconstruction a preoperative 3-D CT scan is performed and the images are sent to the implant manufacturer. An anatomically correct skull model and an implant are built by means of rapid prototyping and sent to the physician for review and approval. The company then delivers the definitive polyetheretherketone (PEEK)-PSI to the physician who will perform the implant procedure⁸. PEEK patient-specific implants (PSI) have been used recently for reconstructing calvarial defects⁷. There are reports on the reconstruction of complex orbito-fronto-temporal reconstruction using PEEK-PSIs⁸. PEEK polymers have been used in spine surgery and in orthopaedic surgery and these have shown to be a highly reliable material with advantageous characteristics⁹¹⁰¹¹. In the follow-up X-ray and CT imaging, translucency without artifacts have been observed⁸¹². The advantageous radiolucent material characteristics of PEEK make it a widely accepted alternative to metallic materials for spine implants⁹. Furthermore it is MRI compatible, as it causes no magnetic interference. In addition PEEK polymers have excellent chemical resistance and the degree of elasticity or

stiffness can be modified to fit the situation. The main drawback is the possibility of postoperative infection ⁸ .

In the present study we report on a new workflow using PEEK PSIs for aesthetic corrections in the facial region. The planning comprises implant design according to specifications derived from 3-dimensional simulation of soft-tissue behaviour.

Material and Methods

This study followed the Declaration of Helsinki on medical protocol and ethics and the Ethical Committee of the Medical Univ. Vienna, (approval No. EK 665/2008) approved the study

Patient

The patient described was female, 27 years old, suffering from dermatomyositis and a severe congenital midface hypoplasia. Figure 1 shows a preoperative 3D photogram of the patient.

We decided to offer her a treatment using PSIs for augmentation of the zygomatic prominence

The complete workflow comprised following steps:

- a) Computer-assisted treatment planning with soft tissue prediction following two different methods (to enable comparison) and manufacturing of the PEEK implants in an interactive iterative teleplanning process;
- b) Surgery (navigation-assisted insertion of the PEEK implants) and
- c) Evaluation of the concept (quantitative comparison of soft tissue prediction with post-operative 3D Photogrammetry).

Computer-assisted planning

The planning began with importing computer tomography data of the skull (CT: Philips Brilliance 64, Amsterdam, Holland) into the planning software Mimics™ 14.0 (Materialise, Leuven, Belgium). CT data was accessed via a secure ftp server for the rapid prototyping company (Synthes, Mesovico, Switzerland). Zygomatic protuberance was determined by a modified virtual LeFort III (Figure 2) osteotomy and consecutive virtual displacement of the maxillary fragment. Subtraction volume of primary anatomy and planned final situation according to the virtual LeFort osteotomy gave the initial geometry of the implant. The realization of this concept is illustrated in Figure 2. Further refinement – including edge removal and contour smoothing - was achieved with mesh distortion tools and vertex

removal. Different simulations of osteotomies and bone reposition were used for soft tissue simulation using Mimics™ and evaluated by the authors in an interactive teleplanning process. Finally, a small implant was manufactured by the rapid prototyping department of the Synthes company (Mesovicco, Switzerland).

The “expressiveness” of the simulation is a crucial goal. Pure 3D reconstructions from computed tomography data can not sufficiently provide a realistic impression especially for the patient (Figure 3).

Additionally, the same planning task was accomplished by means of Amira™ software (Visage Imaging GmbH, Berlin, Germany) by a team of Dr. Zachow at the scientific visualization department of the Konrad Zuse Center for information technology (Berlin, Germany). This planning process was provided as a kind of “stand alone process”, i.e. the team of experts delivered the final result independently from the Mimics™-simulation. The contribution of the Zuse Institute (Amira simulation and implant design attempts) was financed from the FFG grant.

Navigation assisted surgery

A coronary approach was employed in order to avoid visible scars. Two PEEK onlay implants were used to augment both zygomatic prominences. Micro screw positions were predefined by a hole through the PSIs in the course of the rapid prototyping process. Drilling in the bone for fixation screws was navigated using Fusion ENT Navigation © (Medtronic, Minneapolis, MN, USA), a customary computer-aided surgery (CAS) system using electromagnetic tracking technology. The patient reference frame was fixed to the calvaria using microscrews (Figure 4). Conventional registration procedure was performed on the base of anatomical landmarks. As an additional verification and to support the surgeon’s three dimensional imagination a non-sterile STL model and identical non-sterile PEEK implants were displayed during the surgery by an assistant - although this did not show any deviations of the predefined drilling plan.

Postoperative follow-up and photogrammetry

The patient's postoperative face was scanned using a 3D photogrammetry system (Dimensional Imaging Inc., Glasgow, Scotland, UK) two months after surgery. To evaluate simulation error using MESH 1.13 (open source,¹³), the photogrammetric surface dataset was first aligned with the simulated soft tissue data by surface registration using the planning software MimicsTM 14.0 (Materialise, Leuven, Belgium) on a defined region of interest outside the augmented area. In addition, another region of interest was defined in the zygomatic area on which the Hausdorff distances were computed ascertaining the quantitative measure of planning error.

Results

Handling revealed the feasibility for routine application using standard instruments. The duration of the surgical intervention was four hours including approach and wound closure. No complications were observed during and after the surgery. The patient expressed high satisfaction. Three weeks after the surgery the soft tissue swelling resolved.

The simulated soft tissue surface and the photogrammetry scan of the patient showed high correspondence, especially of the skin covering the implants. Mean total error (Hausdorff distance) was 0.81 ± 1.00 mm (median 0.48 , IQR 1.11). Figure 5 shows the soft tissue simulation model with colour-coding for the Hausdorff distance. A histogram of the latter (Figure 6) indicates that the spatial deviation (i.e. surface distance) remains below 0.7 mm for the vast majority of points. Outliers occurred only in the eyeball region; these were closed in the soft tissue simulation and opened during acquisition of photogrammetric data (i.e. red coloured areas). The patient's pre- and postoperative photos are shown in Figure 7.

Discussion

The present study evaluated a workflow for CAD-CAM (computer-aided design and - manufacturing) fabrication and CAS (Computer Aided Surgery) insertion of patient specific implants. Although this workflow comprised different software packages and several steps the evaluation of the soft tissue simulation revealed good correspondence with the postoperative appearance. The accuracies observed in the present study remain reliably within the ranges of accuracy known from computer-assisted surgery literature¹⁴⁻¹⁶. High correspondence between the predicted facial surface geometry and the actual surgical outcome was achieved within the competence of the MimicsTM software.

The interactive-iterative teleplanning workflow proved to be feasible for efficient preparation of the surgical intervention. Particularly the integration of 3D photogrammetry contributed mentionable to the “expressiveness” of the simulation (Figure 3).

However, there is one important shortcoming in the current workflow: the MimicsTM package allows only for soft-tissue simulations associated with osteotomies. In the concept we presented, the PSI design was based on the subtraction of the original data set from the simulated optimum surgical plan. Consequently, some deviations between simulation and outcome are inevitably caused by the method itself and cannot be eliminated (i.e. a systematic error). This problem is addressed by the concept in the AmiraTM software (Visage Imaging GmbH, Berlin, Germany). With AmiraTM the simulation is actually based on PSIs that are virtually attached to the bone. For comparison purposes the scientific visualization department of the Konrad Zuse Center for information technology (Berlin, Germany) provided soft tissue simulation using AmiraTM. Unfortunately, although this would be the ideal approach, in its current available stage of development the AmiraTM software does not perform acceptably and thus does not provide a sufficient approximation. In our clinical case the AmiraTM soft-tissue prediction generated an indentation on the facial surface above the PSI instead of the expected

convex shape. As the Amira™ simulation was carried out by a highly specialized and experienced expert, this result was not a consequence of mistakes in applying the software.

Computer-designed alloplastic implants might represent a milestone in the evolution of planning and realization of 3D reconstructions in surgery. They provide the potential to become a reliable and irreplaceable part of the surgical tools⁸. The present report covers the first clinical case of maxillofacial reconstruction using a computer-designed PEEK-PSI bilateral augmentation.

Reasons for reconstruction can be congenital dysplasia, traumatic fractures, defects due to inflammation or tumor resection. PEEK-PSIs enable an adequate reconstruction of the zygomatic region, thus resulting in an esthetic rehabilitation of the patient's face. Important expected advantages comprise improved predictability in surgery, geometrical optimization of the reconstruction and transfer of much of the intraoperative time to a rather complex planning process. On the other hand, the planning process itself also supports surgery preparation by providing realistic simulations without neglecting the haptic component for the surgeon. This can also be accomplished with the additional use of stereolithographic biomodels.²

The present study thus concludes that the proposed workflow provides a complete CAD-CAM-CAS chain for implant design that accords soft tissue simulation, fabrication of patient specific implants as well as image-guided surgery for positioning the implants. Much of the surgical complexity owing to osteotomies of the zygoma, chin or mandibular angle might be transferred to the planning phase of patient-specific implants.

Acknowledgements

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Legends

Fig.1: Preoperative 3D photogram of the 27 years old female patient. The midface hypoplasia is clearly perceptible.

Fig.2: Concept of our planning approach: Virtual LeFort osteotomy for achievement of the desired look according to soft-tissue prediction and subtraction of the original (i.e. real preoperative) situation gives an initial definition of PEEK-PSI design.

Fig.3: “Expressiveness” is an important measure for the quality of a simulation, especially in aesthetic surgery.

Left: 3D reconstructions from computed tomography data provide precise information on shape and geometry of the facial surface for the surgeon, but are obviously not sufficiently illustrative to inform the patient, primarily because hair, eyebrows and eyelashes are not visualized.

Middle: Merging of a (conventional) digital photo with the 3D reconstruction from computed tomography data clearly enhances the “natural and realistic” look, but lacks reliability and precision, because it’s accompanied by distortions of surface geometry due to the matching method.

Right: 3D photogrammetry outperforms the “expressiveness” of conventional photos. From the technical point of view, data from 3D photogrammetry can easily be integrated in virtual planning workflows.

Fig.4: OR site: Electromagnetic patient reference frame (left) fixed on the calvaria using microscrews, and PSI in situ (right). Obviously, a reliable and precise intraoperative positioning of the implant (i.e. corresponding with the preoperative plan) would be almost impossible without support from navigation.

Fig.5: Screenshot of the soft tissue simulation model with colour-coding for the Hausdorff distance, evaluated with software MESH. On the left part of the picture the colour coded

(“cold-warm”) point to surface distances are shown: As perceptible within the histogram on the far left side of the figure, almost all of the distances remain below 0.7mm.

Fig.6 Histogram shows the point to surface distances of points from the first to the second surface.

Fig.7: Preoperative (left) and postoperative photos (right) of the patient, showing the aesthetical benefit. Postoperative photos have been taken 3 weeks after surgery.

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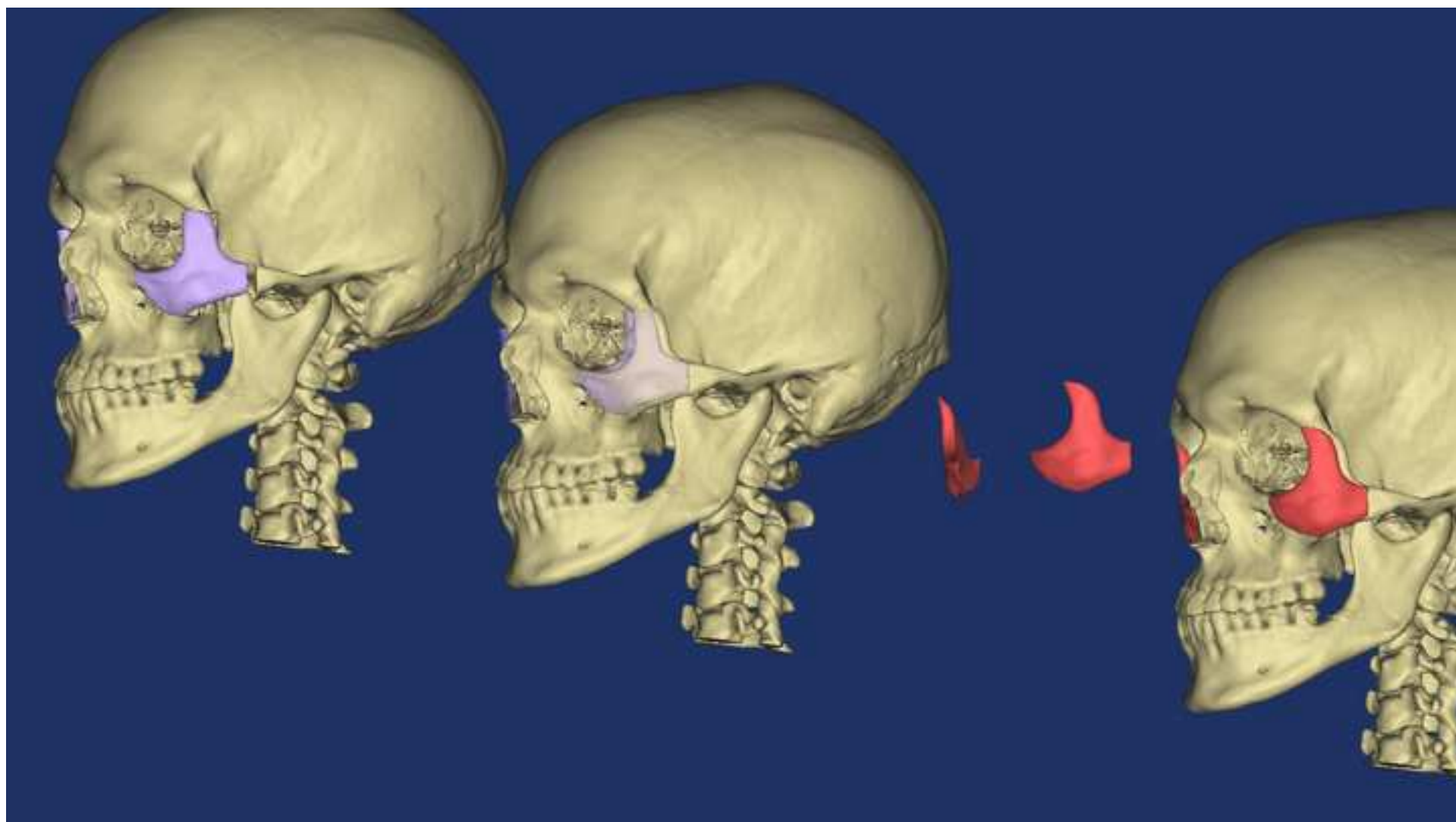
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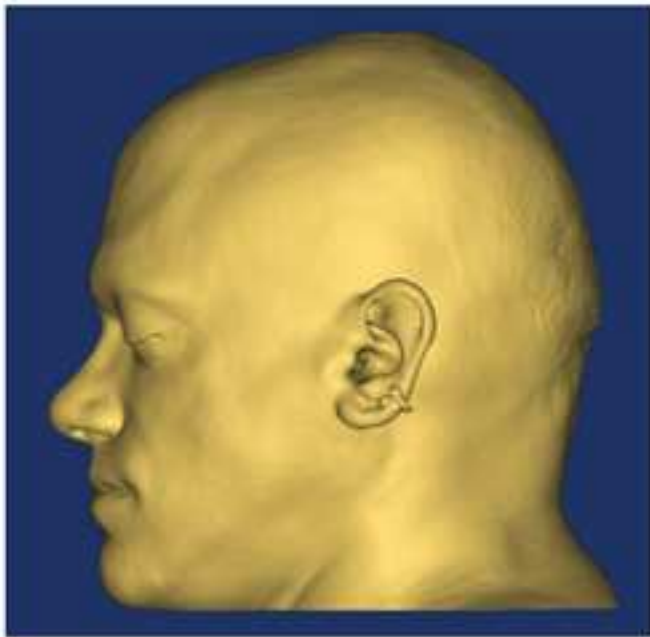
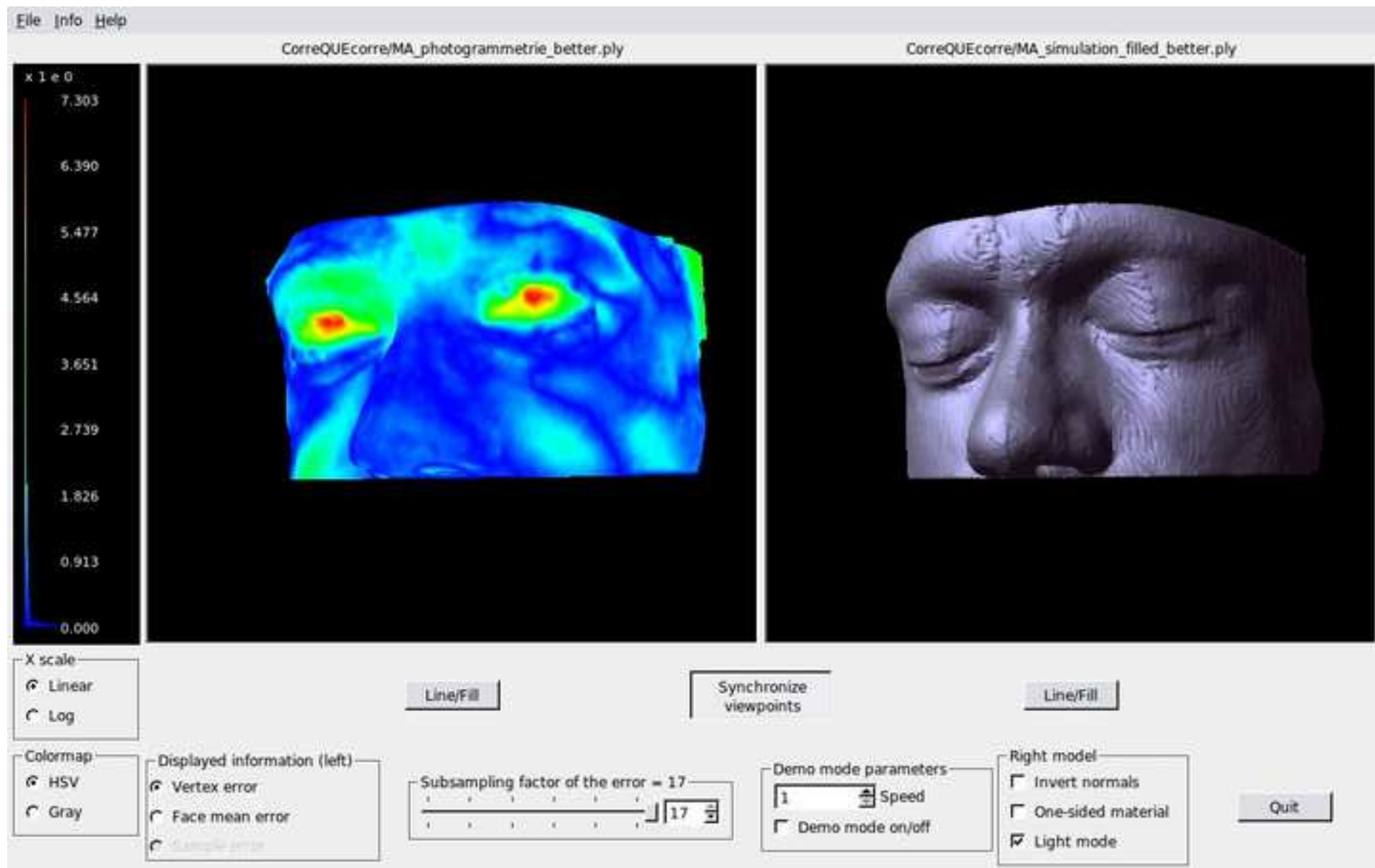


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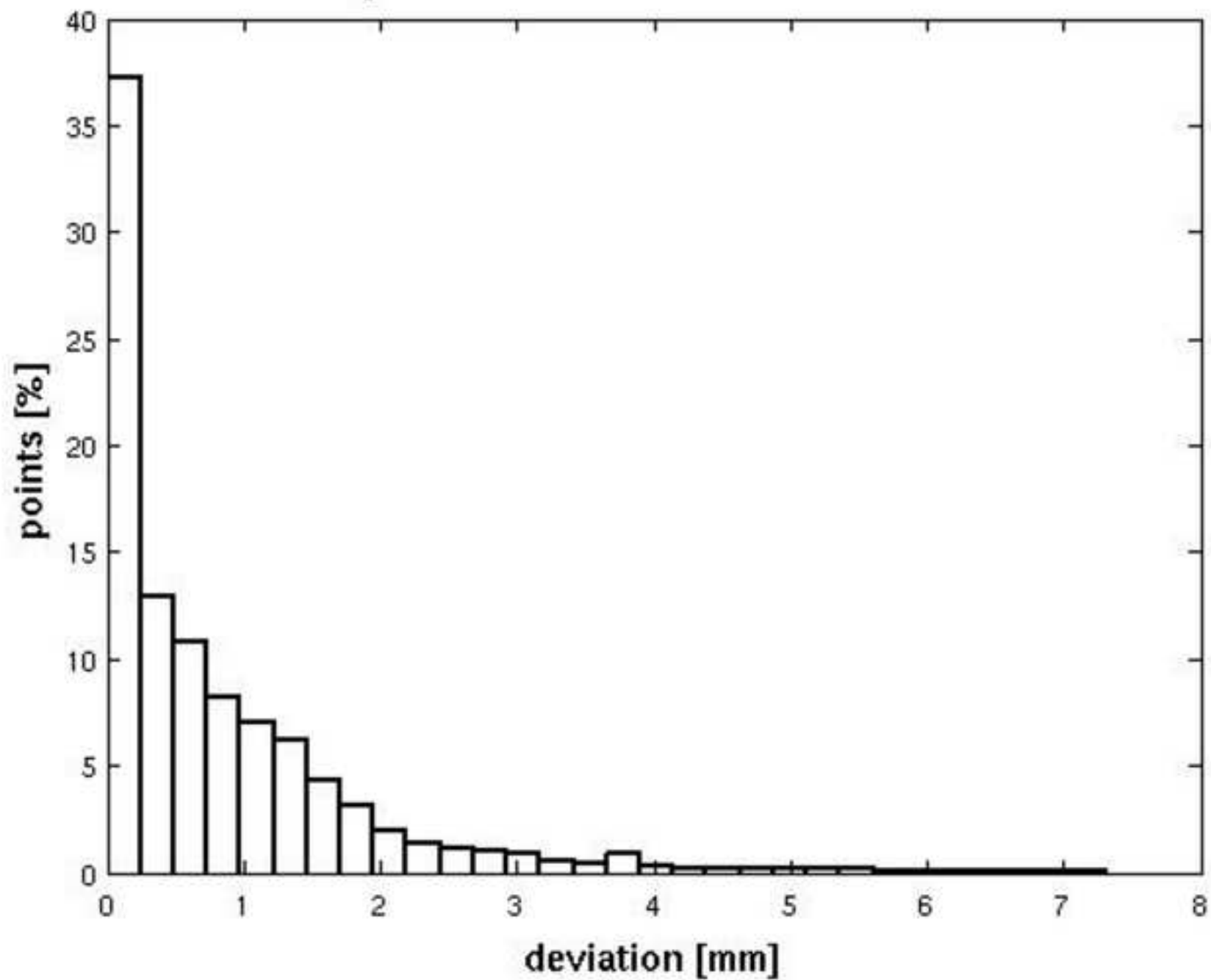


Figure

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point to surface distances



Figure

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