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Abstract: AIM
We present a newly designed, localiser-free, head-mounted system featuring augmented reality as an aid to maxillofacial bone surgery, and assess the potential utility of the device by conducting a feasibility study and validation.
METHODS
Our head-mounted wearable system facilitating augmented surgery was developed as a stand-alone, video-based, see-through device in which the visual features were adapted to facilitate maxillofacial bone surgery. We implement a strategy designed to present augmented reality information to the operating surgeon. LeFort1 osteotomy was chosen as the test procedure. The system is designed to exhibit virtual planning overlaying the details of a real patient. We implemented a method allowing performance of waferless, augmented-reality assisted bone repositioning. In vitro testing was conducted on a physical replica of a human skull, and the augmented reality system was used to perform LeFort1 maxillary repositioning. Surgical accuracy was measured with the aid of an optical navigation system that recorded the coordinates of three reference points (located in anterior, posterior right, and posterior left positions) on the repositioned maxilla. The outcomes were compared with those expected to be achievable in a three-dimensional environment. Data were derived using three levels of surgical planning, of increasing complexity, and for nine different operators with varying levels of surgical skill.
RESULTS
The mean error was 1.70 ± 0.51 mm. The axial errors were 0.89 ± 0.54 mm on the sagittal axis, 0.60 ± 0.20 mm on the frontal axis, and 1.06 ± 0.40 mm on the craniocaudal axis. The simplest plan was associated with a slightly lower mean error (1.58± 0.37 mm) compared with the more complex plans (medium: 1.82 ± 0.71 mm; difficult: 1.70 ± 0.45 mm). The mean error for the anterior reference point was lower (1.33 ± 0.58 mm) than those for both the posterior right (1.72 ± 0.24 mm) and posterior left points (2.05 ± 0.47 mm). No significant difference in terms of error was noticed among operators, despite variations in surgical experience. Feedback from surgeons was acceptable; all tests were completed within 15 minutes and the tool was considered to be both comfortable and usable in practice.
CONCLUSION

*Title Page

Augmented reality as an aid in maxillofacial surgery: Validation of a wearable system allowing maxillary repositioning

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Summary

AIM

We present a newly designed, localiser-free, head-mounted ~~wearable~~ system featuring augmented reality as an aid to maxillofacial bone surgery, and ~~we~~ assess the potential utility of the device by conducting a feasibility study and validation.

METHODS

Our head-mounted wearable system facilitating augmented surgery was developed as a stand-alone, video-based, see-through device in which the visual features were adapted to facilitate maxillofacial bone surgery. We implement a strategy designed to present augmented reality information to the operating surgeon. LeFort1 osteotomy was chosen as the test procedure. The system is designed to exhibit virtual planning overlaying the details of a real patient. We implemented a method allowing performance of waferless, augmented-reality~~,~~ assisted bone repositioning. In vitro testing was conducted on a physical replica of a human skull, and the augmented reality system was used to perform LeFort1 maxillary repositioning. Surgical accuracy was measured with the aid of an optical navigation system that recorded the co~~-~~ordinates of three reference points (located in anterior, posterior right, and posterior left positions) on the repositioned maxilla. The outcomes were compared with those expected to be achievable in a three-dimensional environment. Data were derived using three levels of surgical planning~~s~~, of increasing complexity, and for nine different operators with varying levels of surgical skill.

RESULTS

The mean error was 1.70 ± 0.~~51~~ 51 mm. The axial errors were 0.89 ± 0.~~54~~ 54 mm on the sagittal axis, 0.60 ± 0.~~20~~ 20 mm on the frontal axis, and 1.06 ± 0.~~40~~ 40 mm on the cranio~~-~~

caudal axis. The simplest plan~~ning~~ was associated with a slightly lower mean error (1.58± 0.~~37~~ 37 mm) compared with the more complex plan~~s~~~~nings~~ (medium: 1.82 ± 0.~~71~~ 71 mm; difficult: 1.70 ± 0.~~45~~ 45 mm). The mean error for the anterior reference point was lower (1.33 ± 0.~~58~~ 58 mm) than those for both the posterior right (1.72 ± 0.~~24~~ 24 mm) and posterior left points (2.05 ± 0.47– mm). No significant difference in terms of error was noticed among operators, despite variations in surgical experience. Feedback from surgeons was acceptable; all tests were completed within 15 min~~utes~~ and the tool was considered to be both comfortable and usable in practice.

CONCLUSION

We used a new localiser-free, head-mounted, wearable, stereoscopic, video see-through display to develop a useful strategy affording surgeons access to augmented reality information. Our device appears to be accurate when used to assist in waferless maxillary repositioning. Our results suggest that the method can potentially be extended ~~to aid~~ for use ~~in~~ with many surgical procedures ~~conducted~~ on the facial skeleton. Further, our positive results suggest that it would be appropriate to proceed to in vivo testing to assess surgical accuracy under real clinical conditions.

KEYWORDS: Augmented ~~Reality~~reality; Computer-~~Assisted~~ assisted ~~Surgery~~surgery; Image-~~Guided~~ guided ~~Surgery~~surgery; Maxillofacial ~~Orthognathic~~ orthognathic ~~Surgery~~surgery; Maxillofacial ~~Abnormalities~~abnormalities

Introduction

Augmented reality (AR) is an innovative technology allowing merger of data from the real environment with virtual information. The virtual data may be simply informative (~~i.e.~~such as textual or numerical values relevant to what is under observation) or may consist of three-dimensional virtual objects inserted within the real environment in spatially defined positions.

In the context of image-guided surgery, improvements based on AR may represent the next significant technological development in the field, because such approaches complement and integrate the concepts of surgical navigation based on virtual reality. AR provides a surgeon with a direct perception of how virtual content, generally obtained via medical imaging, is located within an actual scene (Ferrari et al. 2009; Freschi et al. 2009). This is particularly valuable in the context of head-and-neck surgery, in which the extreme anatomical complexity has encouraged the development of several innovative devices. However, the sophistication of such surgery and the longer operative times required have compromised the widespread implementation of such devices. Moreover, the necessary equipment is expensive (Hupp, 2013; Turchetti et al., 2010). For these reasons, the technology demands both methodological and economic rationalisation.

In recent years, tools (or defined applications) employing AR have been designed and tested in the context of several surgical and medical disciplines, including maxillofacial surgery (Marmulla et al., 2005b; Marmulla et al., 2005a; Mischkowski et al., 2006; Zinser et al., 2013b), dentistry (Bruellmann et al., 2013), ENT surgery (Caversaccio et al., 2008; Nakamoto et al., 2012), neurosurgery (Inoue et al., 2013; Mahvash and Besharati Tabrizi 2013) and general surgery (Kowalczuk et al., 2012; Azagury et al. 2012; Marzano et al., 2013). The user experiences an AR view presented with the aid of various technical

modalities, ~~(e.g.~~such as a traditional display, a tablet display, or a wearable display~~)~~ (Freschi et al., 2009; Mischkowski et al., 2006; Mezzana et al., 2011; Shenai et al., 2011; Gavaghan et al., 2012; Deng et al., 2013; Suenaga et al., 2013). Nevertheless, as is true of many emerging technologies, no standard method by which AR technology could/should be transferred to clinical practice has yet been developed (Dixon et al., 2013).

Bearing these facts in mind, we used a new localiser-free, head-mounted, ~~wearable,~~ stereoscopic, video see-through display to develop a useful strategy for delivery of AR information to the surgeon. Our study is the result of ~~a~~ collaboration between the EndoCAS Laboratory of the University of Pisa (Italy) and the Maxillofacial Surgery Unit of the S. Orsola-Malpighi University Hospital of Bologna (Italy).

For brevity, the system will be termed the "wearable augmented reality for medicine" (WARM) device. The aim of the present study was to describe our new tool and to validate the accuracy thereof when used as an aid during surgery on facial bones. We also explore the potential for its wider application~~s~~ in ~~the discipline of~~ maxillofacial surgery ~~-~~in general.

Materials and Methods

The WARM ~~Device~~device

The device (**Fig. 1**) is based on a lightweight, stereoscopic head-mounted display (HMD) that is widely available; this is the Z800 instrument of eMagin (Bellevue, WA, USA). A support placed in front of the HMD holds two USB SXGA cameras (uEye UI-1646LE; IDS, Obersulm, Germany) and a 1/3'' image sensor placed precisely in front of the user's eyes. Two optics (mounted on either camera) ensure an anthropometric field of view. Augmented reality is provided by software that runs on conventional personal computers (Ferrari et al., 2009).

Alignment between the real and virtual world is achieved in the absence of an external tracking system, via processing of video frames grabbed by the cameras. In particular, a machine vision algorithm is used to superimpose the virtual content onto real data provided by the cameras, with subpixel accuracy, using small coloured spheres that do not compromise the surgeon's view of the real scenario **(Fig. 2**).

In vitro setup

The test was conducted on a replica of a cadaveric human skull. The real skull underwent CT scanning and the DICOM files were segmented using a semi-automatic segmentation tool integrated into the ITK-Snap open-source platform (Ferrari et al., 2012). Manual segmentation refinement (using a touch screen) was performed to obtain detailed information on small anatomical structures (e.g. the foramen rotundum, foramen spinosum, lamina cribriformis, and hypoglossal canal). The 3D virtual model distinguished pneumatised bones very well. In particular, the nasal cavities and the paranasal sinuses were computer-generated in minute detail.

The virtual model of the skull was cut along the LeFort 1 osteotomy line. The two resulting virtual objects (the upper skull and maxilla) were exported as STL files and replicated in ABS using a 3D printer (Stratasys Elite; Eden Prairie~~ina~~, MN, USA). LeFort 1 osteotomy and repositioning of the upper maxilla were chosen as test procedures featuring the principal features of maxillofacial surgery. Thus, the technique involves surgery on facial bones; the approach is a form of "semi-buried" surgery when performed under real clinical conditions; the technique involves complex three-dimensional movements of a rigid object in space; and the technique is often performed in clinical practice worldwide.

Before printing, three 6~~-~~ mm-diameter balls were inserted into the virtual model as marker references for the WARM device. Further, three reference holes were drilled into the

vestibular cortical bone, over the teeth (*anterior* in the premaxillary region; *posterior left* and *posterior right* in the respective molar regions). The holes were used as references to evaluate the position of the maxilla. Thus, each hole was designed to receive the tip of the tester probe used for validation (~~please~~ see below), to guarantee unique selection of each reference point.

The upper skull was fixed on a wooden holder. The maxillary piece was connected to the upper skull with plasticine (this material is highly malleable but rigid when shaped). This construction served as a fixing device for the maxilla once the planned position was attained, yet allowed the maxilla to be manually adjusted in space.

To evaluate the accuracy of our system, we used a traditional navigation platform (the eNlite Navigation System running iNtellect Cranial Navigation Software version 1.0; Stryker, Freiburg, Germany) featuring an active infrared localiser. Our setup is shown in **Fig~~ure~~ 3**, which identifies the tracking and pointing instruments of the navigation system.

AR Visualisation: ~~E~~e~~E~~rgonomic ~~E~~e~~E~~valuation

A preliminary assessment was conducted to evaluate the ergonomics of the device, actual usability in a surgical environment, and (in particular) the best method of displaying the virtual content. One surgeon (GB) and three engineers (VF, FC, and CF) collaborated in this work. Tests were conducted using different display modalities in an attempt to define a modality that was optimally comfortable and that had the smallest perceived parallax error. We commenced with the display modality most frequently adopted in similar work (Mischkowski et al. 2006; Suenaga et al. 2013); thus, a rendered virtual reality was superimposed on the real camera frames. We found that this display modality, although allowing us to change the transparency settings, did not satisfactorily establish the relative

positions of the real and the virtual (planned) maxilla, particularly in terms of depth, and was thus unable to aid in correct performance of the surgical task.

The display modality that we finally selected is shown in **Fig.~~ure~~ 4**. The virtual information consists of green asterisks drawn in positions defined during planning. For each virtual asterisk, a coloured landmark was fixed on the maxilla. Use of this display modality allowed us to study how to move the maxilla to replicate planning, and also if a planned position had been attained with high precision. Coloured landmarks can be fixed (for example) on the brackets of an orthodontic appliance, as shown, or on a CAD/CAM splint or guide.

Accuracy ~~Evaluation~~ evaluation ~~Testing~~testing

VIRTUAL SURGICAL PLANNING

Using Maya (Autodesk; Toronto, Canada), the virtual maxilla was moved in space as dictated by three surgical plan~~ning~~s of increasing complexity **(Fig. 5)**.

1) Maxilla 6 mm forward;
2) Maxilla 5 mm forward and 1 mm downward;
3) Maxilla 6 mm forward, 1 mm downward, and with 15° roll and 10° pitch.

Each plan~~ning~~ was saved as an STL file.

TEST

Three maxillofacial surgeons (AB, GB, and LP); three trainees in maxillofacial surgery (SA, EB, and FR); and three engineers (VF, FC, and CF) were involved in the testing; we evaluated interobserver variability. Hence, the three groups included appropriate representatives of users with different levels of surgical skill (from unskilled engineers to highly skilled surgeons). After only one warm-up session, during which each subject was trained to use the WARM device, the subject was asked to manually reposition the maxillary segment, using guidance afforded by the device. The procedure was repeated by each subject for

each of the three virtual plan~~ning~~s; the maximum test duration was 15 minutes. After completion of each test, the position of the maxillary segment was confirmed using the navigation system described in the following paragraph.

ACCURACY MEASUREMENT

The CT scan of the skull was imported into the navigation system as a DICOM file and the three plans, defined in the CT reference system, were loaded into the navigation system as STL files **(Fig. 6)**. The tracker of the navigation system was fixed on the model of the skull and the registration process featured a point-based procedure (using defined anatomical points) with subsequent surface refinement; the target registration error was 0.~~3~~ 3 mm. After each trial session, the navigation system probe was inserted into each of the three reference holes on the maxilla and the probe tip positions were saved **(Fig. 7)**. We next determined, for each subject, the linear distances between the real positions of the reference holes (measured using the navigation system) and the expected positions (defined during planning).

Statistical ~~Analysis~~analysis

The linear distances between the expected and real positions were computed with the aid of MatLab (Mathworks Inc.; Natick, MA, USA) to obtain descriptive statistics.

Results

The results are shown in **Table 1**. The mean error was 1.70 ± 0.51 mm. The axial errors were 0.89 ± 0.54 mm on the sagittal axis, 0.60 ± 0.20 mm on the frontal axis, and 1.06 ± 0.40 mm on the cranio-caudal axis. The simplest plan~~ning~~ was associated with a slightly lower mean error (1.58 ± 0.37 mm) than the more complex plans (medium:

1.82 ± 0.71 mm; difficult: 1.70 ± 0.45 mm). The mean error for the anterior reference point was lower (1.33 ± 0.58 mm) than those for the posterior right (1.72 ± 0.24 mm) and posterior left (2.05 ± 0.47 mm) points. No significant difference was noted among operators, despite variation in surgical experience **(Fig. 8)**. Feedback from surgeons was acceptable; all procedures were completed within 15 minutes and the tool was found to be both comfortable and usable.

Discussion

In recent years, the discipline of maxillofacial surgery has undergone a remarkable rate of technological innovation ~~among all surgical specialties~~. This is because the complex three-dimensional anatomy of the face, together with the need for surgical precision and the increasing number of requests for morphological surgery, have resulted in surgeons demanding advanced technological assistance. Thus, virtual planning software and navigation systems are today widely used by maxillofacial surgeons (Mazzoni et al., 2010; Zinser et al., 2013a). However, substantial room for improvement remains. The accuracy afforded by the technology must increase, as must the usability of devices in real clinical practice.

AR represents an important step toward the practical integration of several ground-breaking technologies. AR fuses navigational surgery and virtual planning with the real surgical field. AR can be displayed on a traditional monitor, or directly in front of the eyes of a surgeon who uses a wearable system such as WARM.

Our results suggest that wearable AR is both comfortable and functional, permitting a surgeon to maintain ~~his/her~~their natural operative posture during surgery performed ~~from~~ at different angles, without losing the three-dimensional relationship between the real

scene and that afforded by virtual planning. This is of particular importance. We found that ~~the~~ surgeon~~s~~ frequently change~~s his/her~~their line of view during an operation~~,~~ to control the three-dimensional position of the maxilla from all angles. Further, the use of a stereoscopic device obviates any need for an external localiser, because the device can serve as both a frame-grabber and a localiser.

Our system has other significant features; these are the registration and tracking modalities. Indeed, WARM does not require an external infrared camera or an electromagnetic field generator (unlike standard navigation systems), but ~~rather~~ use~~s~~~~ing~~ visible light. The head-mounted cameras grab the scene and use frames both to track the patient's skull and to realise the AR environment. In our laboratory setup, three coloured (red) spheres were placed on the skull surface to simplify the experimental conditions, but, in the clinic, a skull-mounted tracker with coloured spheres could be used. This would obviously require that a patient-specific registration process be conducted.

In terms of validation, our results suggest that the device affords an average accuracy of 1.70 ± 0.51 mm, which is good in the context of maxillofacial surgery. This result is even more significant because waferless surgery was planned. Considering the axial error components, the lowest error (0.60 ± 0.20 mm) was measured along the frontal axis, the next-largest error (0.89 ± 0.54 mm) along the sagittal axis, and the greatest error (1.06 ± 0.~~40~~ 40 mm) along the vertical axis. Thus, use of the device is associated with very small errors (below ~~1~~ 1 mm) in terms of frontal and sagittal malposition of the maxilla; ~~these are~~this is very good ~~values~~ compared with orthognathic surgical standards. Further, even the error on the vertical plane (around ~~1~~ 1 mm) is excellent, because the vertical dimension remains the most complex in terms of intraoperative control (Song and Baek, 2009). Such

errors are not discernible when a patient is evaluated after intervention, and surgery can thus be considered as having been performed optimally.

No significant difference in errors was evident when the three planning modes were compared. The simplest plan~~ning~~ was associated with error values slightly lower, on average, than the others; this is quite understandable. This suggests that our method could be extended to aid in the performance of any orthognathic procedure on the maxilla, regardless of the complexity of the required movements.

Average errors measured to the anterior reference hole were lower than those to the posterior hole. This is probably because the position of ~~only~~ the anterior reference hole is the only one that can be controlled from every viewpoint.

Another interesting result is the non-dependency of accuracy on user experience; all of the experienced surgeons, trainees, and (even) engineers obtained comparable results. All test procedures were completed within 15 minutes after a single 15~~-~~ minute warm-up session.

The use of small virtual asterisks, corresponding to coloured landmarks fixed on the brackets of the orthodontic appliance or onto splints, turns out to be an efficient way to present ~~an~~ AR guidance to the surgeon. Our device is simple and easy to use, and shows promise for assisting in maxillofacial orthognathic procedures.

Conclusion

We used a new, localiser-free, head-mounted, ~~wearable,~~ stereoscopic, video see-through display to develop a useful strategy affording the surgeon access to AR information. Our results suggest that the WARM device would be accurate when used to assist in waferless maxillary repositioning during the LeFort 1 orthognathic procedure. Further, our data

suggest that the method can be extended to aid ~~in~~ the performance of many surgical procedures on the facial skeleton. Also, in vivo testing should be performed to assess system accuracy under real clinical conditions.

Conflict of interest statement

This work was partially supported for EndoCAS by Opera Project (Advanced OPERAting room). ~~(~~ Tuscany Regional Funds: PAR FAS 2007~~-~~2013 Azione 1.1 P.I.R. 1.1.B~~)~~.

The authors have no financial interest~~s~~ or personal relationships with other people or organizations that may have inappropriately influenced the work presented here.

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Figure Legends

Fig. 1

The WARM system features the mounting of two external cameras on top of a commercial 3D visor.

Fig. 2

The WARM system. The two external cameras acquire real video frames. Our software application merges the virtual 3D model derived during surgical planning with real data from the camera frames and sends the result to the two internal monitors. Alignment between real and virtual information is obtained by calculating the positions of coloured markers relative to camera data, with respect to their known positions (recorded during planning), using detailed pre-operative CT images.

Fig. 3

Our setup: A physical replica of the human skull is fixed onto a wooden holder, and the three coloured spheres on the model (the black dashed arrows) ensure alignment between the real and virtual world in the absence of any external tracking system. We used a machine-based vision algorithm. The coloured brackets on the teeth (the black asterisks) are the reference markers for the AR display modality; three of the six holes on the maxilla (the red arrows) were used to evaluate accuracy with the aid of an external navigation system. The tracker of the navigation system is fixed onto the model in (a). In (b), the pointer of the navigation system, used to assess the position of reference holes, is shown beside the model.

Fig. 4

Different approaches to presentation of AR information: (a) A real video frame; (b, c) A traditional approach, presenting the virtual model on real camera frames. Using the approaches of (b) and (c), it was not possible to completely perceive the relationship between the real and virtual world. (d) A more ergonomic form of visualisation, ultimately selected by us to permit the subject to determine if the real maxilla was positioned correctly. The virtual information consists of a green asterisk for each coloured landmark on the maxilla.

Fig. 5

The virtual maxilla (a) was moved in space as dictated by three surgical plans of increasing complexity: b) ~~6~~ 6 mm forward; c) ~~5~~ 5 mm forward and ~~1~~ 1 mm downward; d) ~~6~~ 6 mm forward, ~~1~~ 1 mm downward, with 15~~°~~° roll and 10~~°~~° pitch.

Fig. 6

A screenshot of the navigator. The blue planning scenario is loaded together with the original CT scan.

Fig. 7

The accuracy evaluation process is shown in detail. On the left, the pointer slides into a reference hole of the maxilla (the hole termed “anterior one”); on the right, the navigation system shows where the tip of the pointer is actually located (compared with the planned

location). The co-ordinates of the real position are recorded and used to estimate errors in linear measurements.

Fig. 8

Mean errors in mm (over three trials and three reference holes) for each of the nine participants. No difference between engineers and physicians is evident.

<TYPESETTER: Fig 8. on vertical axis please change the commas in the numbers to decimal points, e.g. 2,50 should be 2.50 >

~~The English in this document has been checked by at least two professional editors, both native speakers of English. For a certificate, please see:~~

~~http://www.textcheck.com/certificate/QXiJZ3~~

Table 1. Errors for each target and plan for all operators, and the relative means

	Plan 1	Plan 2	Plan 3	Mean
Target 1	1.71 mm (±0.24)	1.80 mm (±0.18)	1.63 mm (±0.34)	1.72 mm (±0.24)
Target 2	1.07 mm (±0.17)	1.47 mm (±0.12)	1.45 mm (±0.45)	1.33 mm (±0.58)
Target 3	1.96 mm (±0.32)	2.18 mm (±0.69)	2.02 mm (±0.49)	2.05 mm (±0.47)
Mean	1.58 mm (±0.37)	1.82 mm (±0.71)	1.70 mm (±0.45)	**1.70 mm (±0.51)**

Figure 1

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Figure 2

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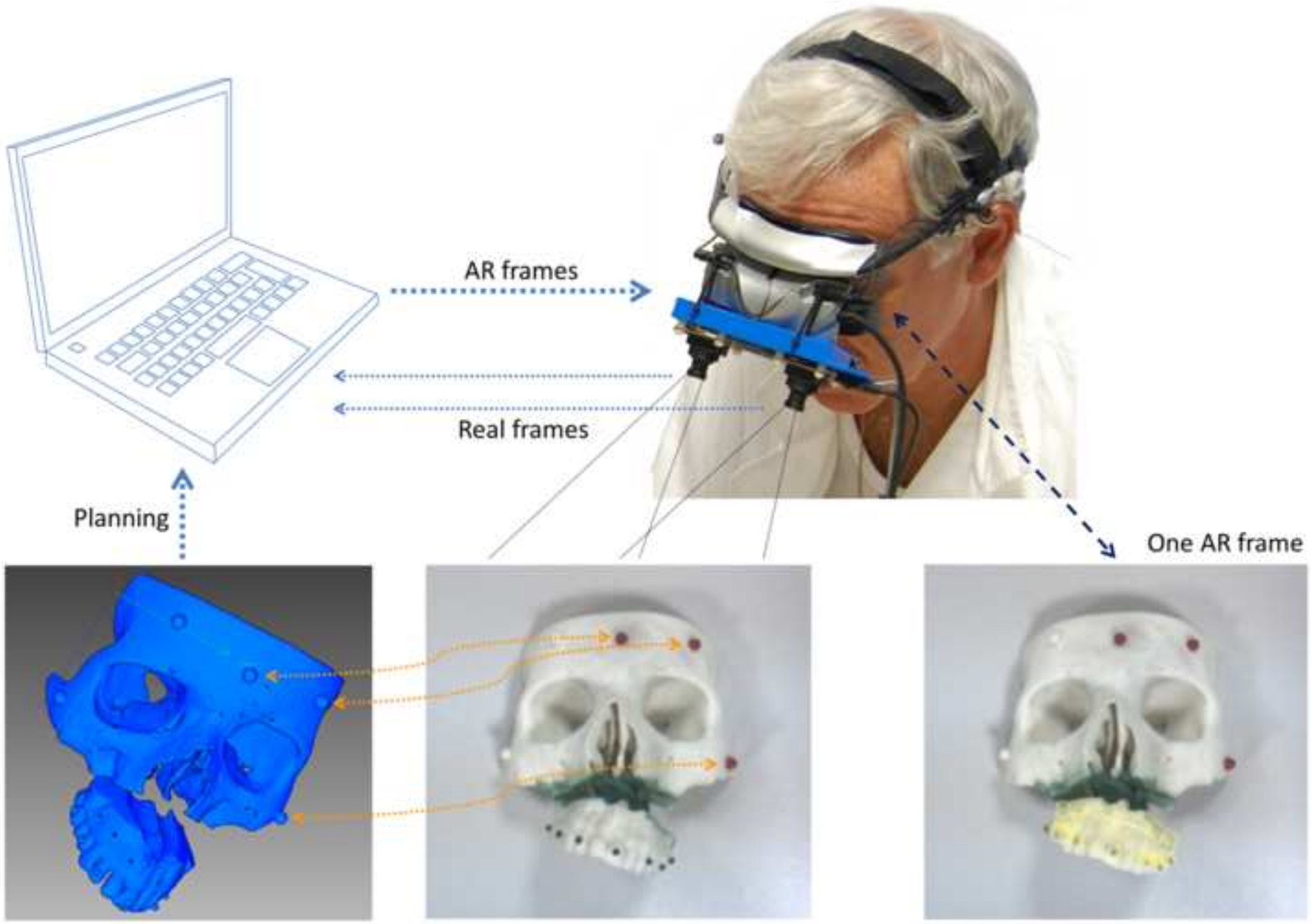

Figure 3

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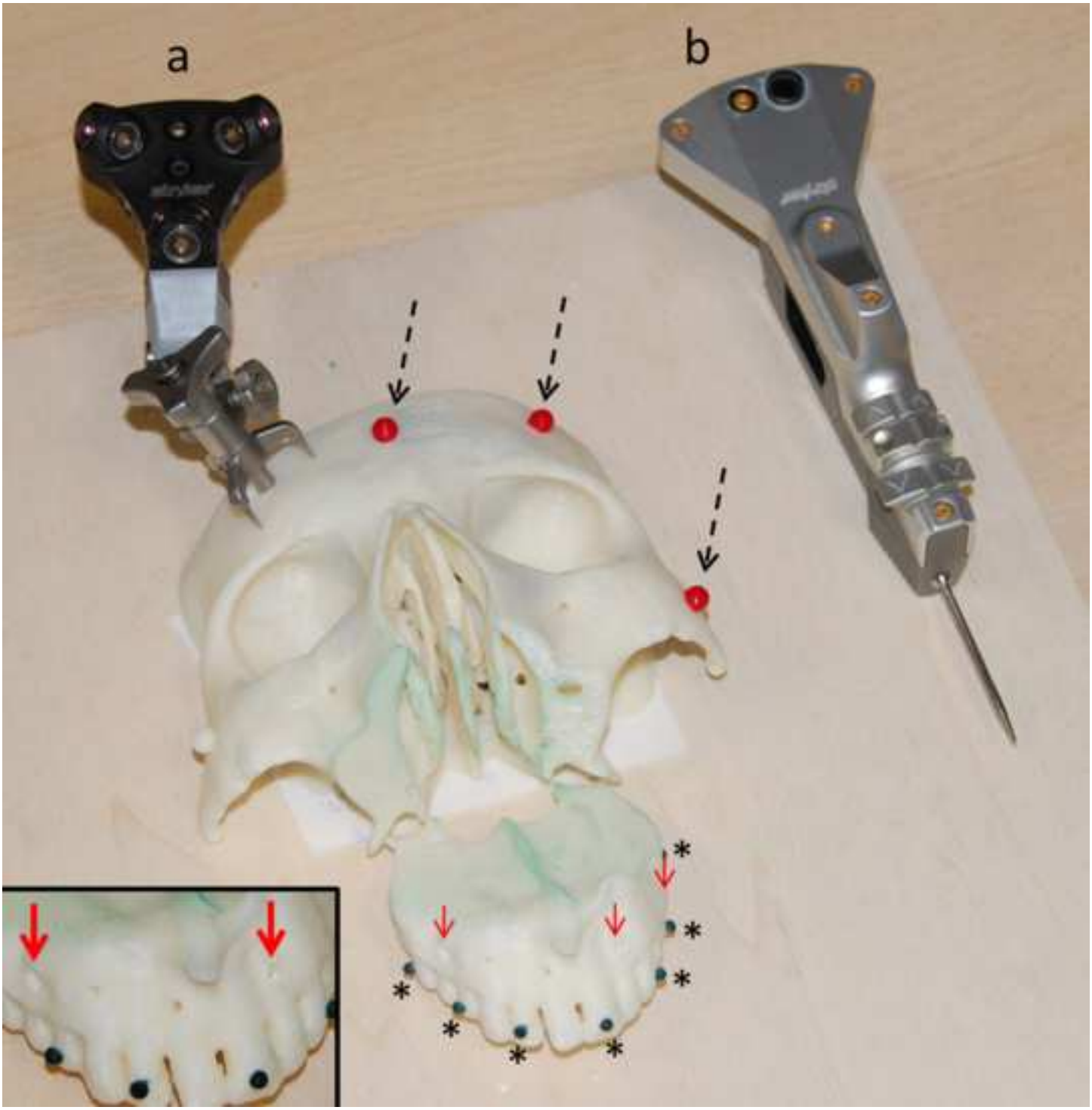

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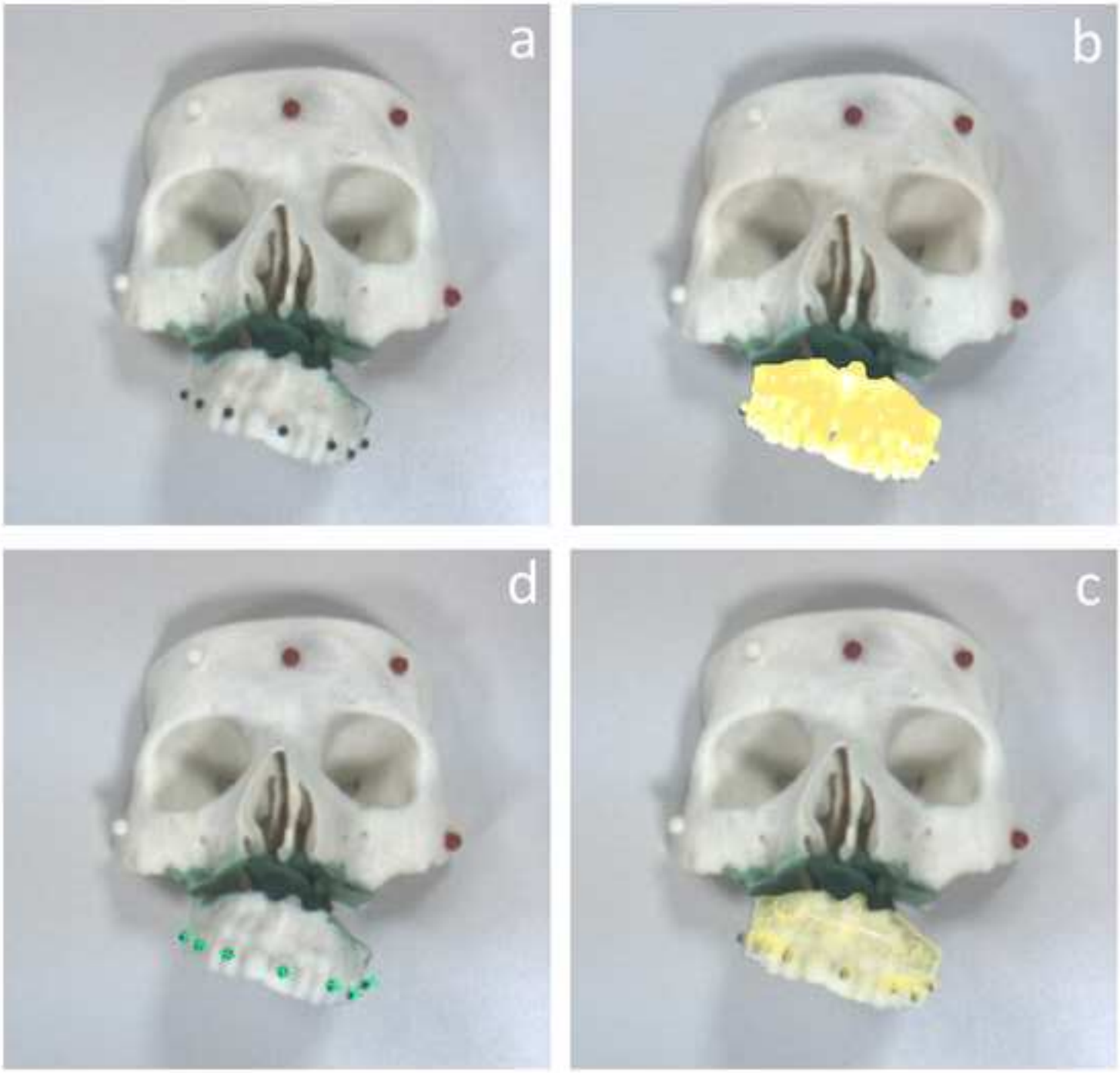

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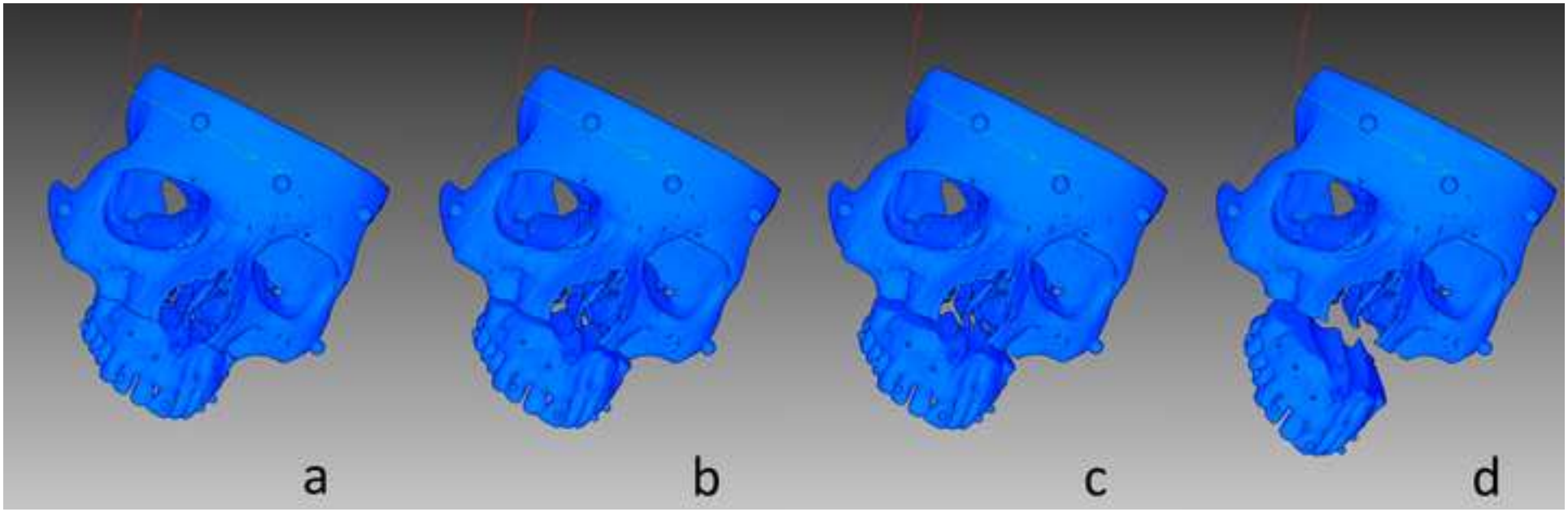

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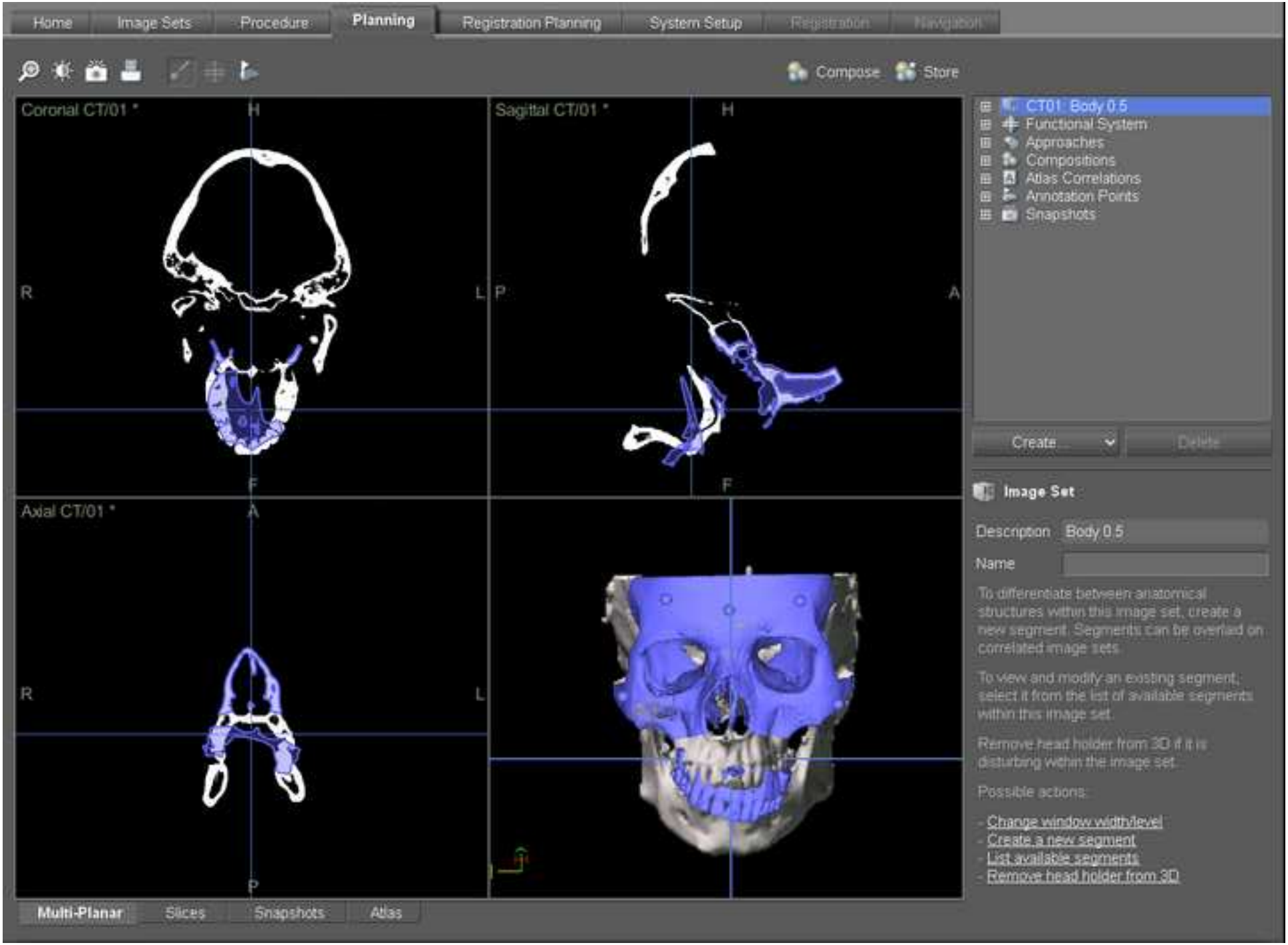

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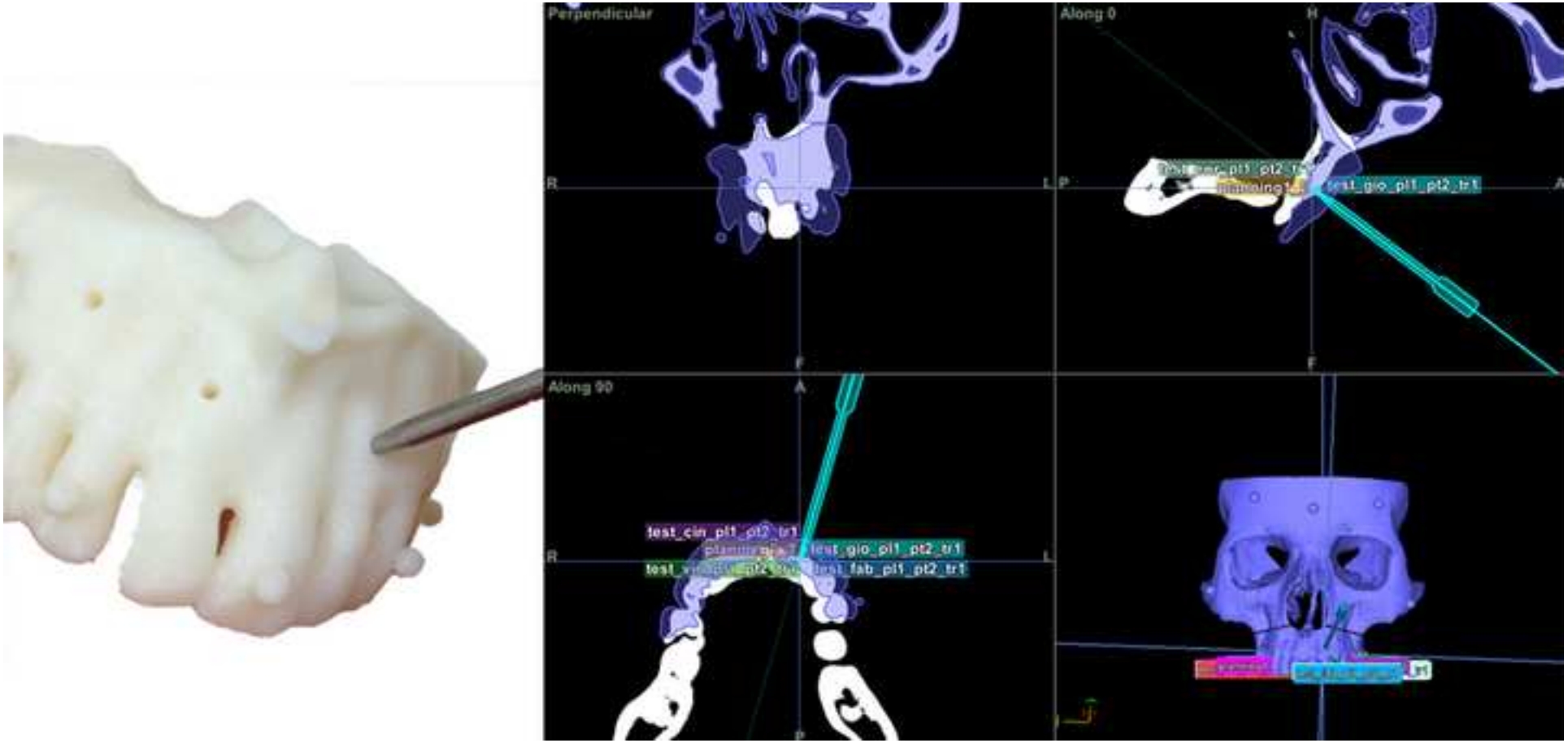

Figure 8

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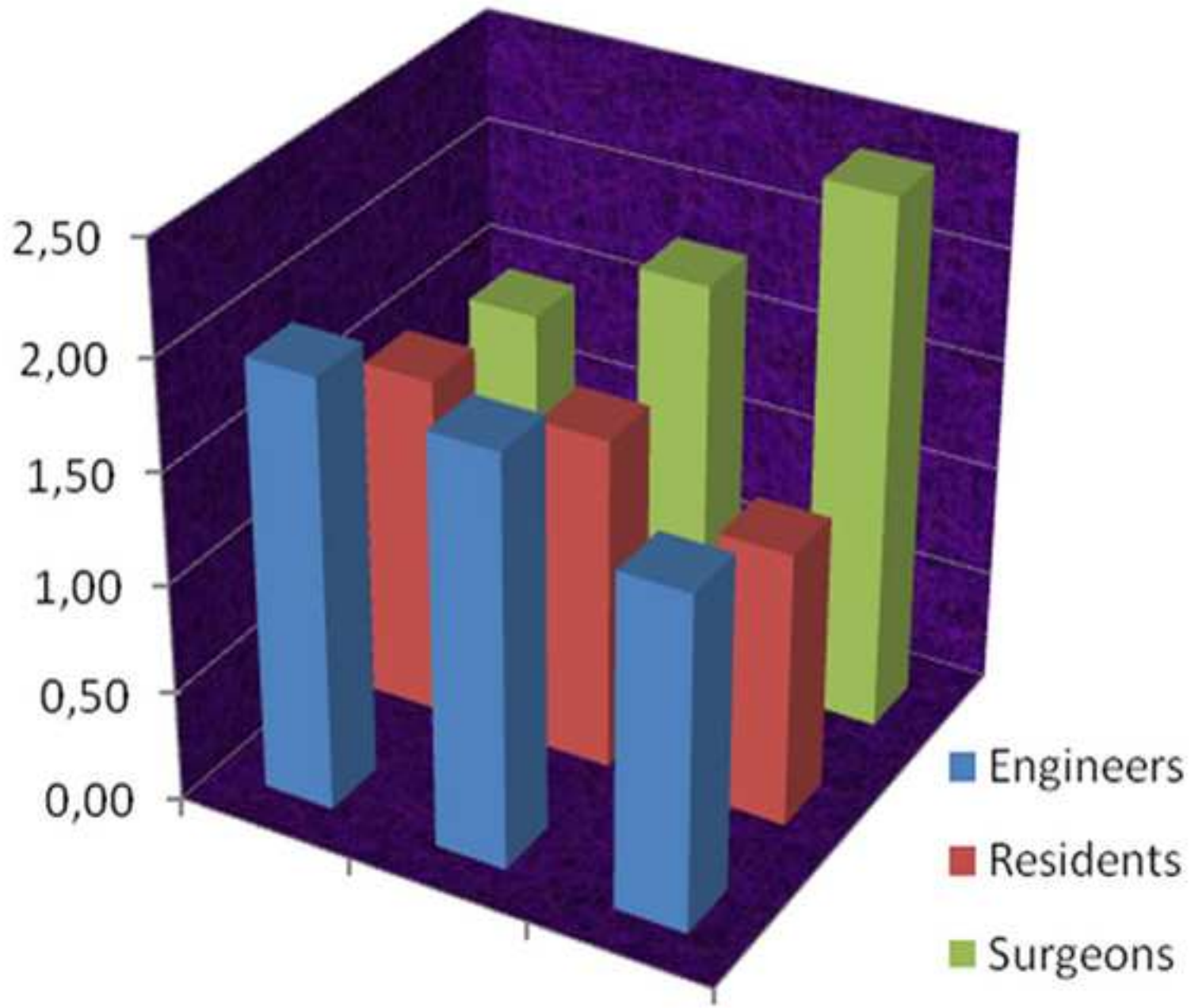

ALMA MATER STUDIORUM
UNIVERSITÀ DI BOLOGNA

ENDOCAS
CENTER FOR COMPUTER ASSISTED SURGERY

Highlights

1- Stand-alone, video see-through, head-mounted system for augmented reality
2- Visual features were adapted to facilitate maxillofacial bone surgery
3- LeFort1 osteotomy was chosen as the in vitro test procedure
4- We implemented a method for waferless, augmented-reality, assisted bone repositioning
5- The method can be extended for use in many surgical procedures on the facial skeleton