CAD/CAM-based referencing aids to reduce preoperative radiation exposure for intraoperative navigation

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Abstract
Background: All intraoperative navigation systems need a referencing procedure prior to utilization, usually requiring an additional computed tomography (CT) or cone beam computed tomograph (CBCT) scan. As new techniques in the field of Computer-aided design / Computer-aided manufacturing (CAD/CAM) have evolved, it seemed favourable to develop a new referencing method not relying on additional CT or CBCT scans.

Methods: A digital maxillary dental scan was used to create a referencing splint by CAD/CAM containing four reference points. By matching scanned dental model and initial trauma-CT, the splints position and thus the reference points were digitally simulated. These splints data were imported into the navigation system in Standard Tessellation Language (STL) format. These data were also 3D printed and the resulting piece was placed on the anatomical models’ teeth. The methods accuracy was then assessed in vitro.

Conclusion: Our method for referencing of intraoperative navigation can be feasible to avoid an additional CT or CBCT prior to navigation.

KEYWORDS
3D-printing, CAD/CAM, navigation, radiation exposure, registration computer-assisted surgery, stereotactic surgery

1 | INTRODUCTION

Intraoperative navigation has been proven to be a useful instrument to increase surgical precision and patient safety. Several different methods utilizing infrared light, ultrasound or electromagnetic concepts exist in this field. They come with individual advantages and disadvantages and are used depending on the surgical procedure performed and the surrounding conditions. As for Craniomaxillofacial (CMF) surgery, infrared-based navigation systems have been used intensively for the last years, especially for procedures involving the mid-face and the orbit. The functions of these systems have been integrated in patient-specific implant design¹ and are commonly used to intraoperatively evaluate and predict surgical outcomes without the additional application of radiation.² Not relying on X-rays and thus being able to be used as often as desired by the surgeon, can be considered to be the major advantage of intraoperative navigation.

All systems have in common though, that they need a referencing procedure prior to utilization. For fields other than CMF, this can routinely be performed by procedures based on surface matching algorithms. In CMF, this has been shown to be a problematic
approach. On the one hand, there is a strong need for increased precision in this field, on the other hand posttraumatic and intraoperative swelling have been shown to compromise registration strongly. An alternative referencing method is the use of well-defined anatomical landmarks (e.g., bony prominences or dental cusps), which provide definite reference points for instrument tracking. However, this procedure is difficult to reproduce and less precise than using artificial applied markers. Thus, soft tissue independent and extrinsic dental based methods have been developed and established. These dental carried occlusion splints (dental registration splints [DRS]), usually equipped with four radiodense markers consisting of 2.0 mm osteosynthesis screws, however, need an additional radiographic examination, as these appliances are usually not used for the primary, most often the posttraumatic examination. Even though dose-saving CBCT has been shown to be suitable if it is matched with the markerless trauma CT, this still causes a significant increase of the radiation dose used. As most patients undergoing these procedures are young and the fact that the area exposed to radiation contains highly radiation sensitive structures, referencing was identified to be improvable. Besides the issues of radiation safety, this working group identified misplacement of navigation points when evaluating accuracy of navigation surgery. A main issue was shown to be preoperative digital malpositioning of referencing points, which can be attributed to artefacts caused by the osteosynthesis material, metallic dental restorations and to human error.

As new techniques in the field of CAD/CAM, especially 3D-printing and 3D-scanning, evolved, combining these to overcome the issues described afore seemed favourable. In digital planning of orthodontic procedures, several techniques for matching of dental surface data and radiographic images have been developed. They have been shown to be highly precise. Furthermore, easy to use software for computer-aided design (CAD) and precise, biocompatible and cost-efficient 3D printing have become available.

Thus, we aimed to develop a novel dental-based referencing aid overcoming the need for preoperative CT or CBCT just for navigation registration. Similar to splints for orthodontic surgery, this referencing aid was to be constructed in a defined position between the maxillary and mandibular teeth. It was planned to include at least four elements to serve as intraoperative referencing points. Their position should be defined precisely in CAD and be importable into the navigation software. CAD data were then to be printed on a precise 3D-printer. As the printed referencing aid was to be dental mounted, making it insertable in one position only, these points positions were assumed to be precisely transferable into the patient.

Instruments, to facilitate a smooth pivoting movement without pointer bending. They were digitally added onto a 5-mm-thick plate in the shape of a typical dental arch. This shape was chosen to allow digital individualization of the device by adding 3–4 mm deep impressions of the maxillary teeth, as described in detail below.

A standard anatomical skull model was used to develop this technique under standardized conditions. To simulate posttraumatic imaging, a CT scan was obtained in DICOM format and imported into Brainlab iPlan CMF 3.0.6 (Brainlab). iPlan CMF is a medical approved (FDA, CE) software that can be used for segmentation and navigation planning. The maxilla and its teeth were segmented using its threshold-based segmentation and an automated atlas-based segmentation. Segmented data were then exported as an STL file including its coordinate system with ‘high’ accuracy and imported into Geomag Freeform Plus 2019 (3D Systems) for further processing. The skull was not moved within the coordinate system during CAD. To generate a surface data set of the maxillary teeth, a full arch optical scan was performed using a Trios 4 intraoral scanner (3shape), exported as an STL file and consequently imported into the Geomag Freeform file described before.

The scanned dental model was then matched onto the segmented teeth by Geomag Freeform proprietary surface-matching algorithm. By this, the precise dental scan was moved into the correct position within the navigation systems coordinate system. Undercuts were digitally filled. The resulting model was then subtracted from the device described before by a Boolean operation, thus creating 3–4 mm deep impressions on it for a precise fit. The generated STL file was then re-imported into Brainlab iPlan CMF 3.0.6. As the same coordinate system was used, it was possible to import it in the same position as it was designed during CAD and as it would fit onto the maxillary teeth. Furthermore, the generated STL file was exported into PreForm, to be printed using a biocompatible Resin (Dental SG resin) on a Form2 using an LT tank with 50 µ layer thickness (each by Formlabs). The device was oriented in 20° deviation towards the perpendicular to the build platform to avoid any support structures within the cones for referencing and the dental impressions on it. This printer/resin combination is commonly used for dental implantology guides and has been shown to be able to achieve very precise printing results. The complete workflow for using the novel navigation aid in contrast to conventional DRS is displayed in Figure 1.

Subsequently, the novel CAD/CAM registration splint was placed on the standard anatomical skull model. The accuracy was measured using 20 predefined peribital points resulting in a mean deviation of 0.56 mm.

2 METHODS

The device to be constructed was supposed to contain at least four clearly identifiable landmarks for registration purposes. Most used navigation systems require a pivoting movement as these points are identified using a navigation pointer. Thus, they were designed as negative cones, similar to those used for registering generic surgical

3 DISCUSSION

In this technical note we describe a novel technique for registration of intraoperative navigation systems. The aim of this technique was to develop an instrument for registration of intraoperative navigation systems, which is independent of soft tissue swelling and soft tissue
Until now, the surgeon had to choose between different registration methods, all coming with certain disadvantages. Skin surface-based registration methods have been shown to be suboptimal for maxillofacial surgery, as re-registering is hardly possible due to intraoperative soft tissue swelling. All dental based methods need an additional CBCT or CT scan, methods based on anatomical landmarks were shown to be the least accurate and those based on artificial landmarks are invasive and dependent on prior inserted osteosynthesis material.

The combination of well-established, modern technologies enabled us to design the afore described concept of a virtual DRS for the navigation system and its 3D printed copy to be used with the patient. Its optimized geometry and the absence of metallic artefacts surrounding the registration points provide chances that this method may improve registration precision and accuracy. First results of the achieved accuracy of navigation in vitro are very promising. As requirements for CAD have decreased over the last years and biocompatible 3D printing has become readily available, the hurdles for implementing this method can be considered low.

Currently, preoperative imaging solely for navigation purposes still is a routine procedure in many places. Applying the described method within the clinical routine may overcome the need for these procedures, leading to a significant reduction of preoperatively applied dose of radiation. Software, that is able to (semi-)automatically create occlusal splints (i.e., exocad) and register dental scans with DICOM images (i.e., Dolphin, Dolphin imaging solutions) is already available. It is conceivable, that the combination and integration of the specific modules might be a feasible option to implement an automatic design process for the described registration aid into navigation software such as iPlan CMF.

The method described also has its limitations. First, a DICOM data set without major artefacts affecting the teeth surfaces is needed for precise matching DICOM and STL data. Owing to metallic restorations, this is not always given, even though metallic restorations are more and more replaced by composite or ceramic-based restorations leading to less artefacts. Furthermore, CBCT or dual-energy CT can generate images with significant artefact reduction. As with all dental based registration aids, its use for the mid-face cannot be encouraged for cases with a mobile maxilla. Second, familiarity of the surgeon with CAD is currently needed. Even though, this technique might overcome some sources of human error, such as the misplacement of registration points, it does not eliminate other sources of error such as pointer bending or limitation coming with the technology of navigation itself.

Certainly, this method has to be evaluated thoroughly before using it within the clinical routine. Most currently available studies addressing registration accuracy and other technical notes are hardly comparable, as they use very different set ups. Testing all currently available methods against the method described using identical artificial or cadaveric test set ups would go beyond the scope of this technical note, yet it will be the next step towards its clinical use.

We believe that the method described deserves consideration, as it might overcome the weaknesses and disadvantages of most currently used registration methods and avoid the additional application of radiation for navigation purposes.

4 CONCLUSIONS

We have introduced a new method for registration of intraoperative navigation systems. It is shown, that the combination of a virtual navigation splint and its 3D printed copy is likely to be feasible for registering navigation systems. Further studies are required to determine if this combination can prove its accuracy in vivo. If so, it might replace conventional registration methods and significantly reduce the amount of preoperative radiation applied.

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CONFLICT OF INTEREST

The authors declare to have no possible conflict of interest.
AUTHOR CONTRIBUTION
Alexander-Nicolai Zeller: Conception and design, construction of prototypes, manuscript writing and final approval of manuscript. Rüdiger Martin Zimmerer: Manuscript correction and final approval of manuscript. Sina Springhetti: Manuscript correction and final approval of manuscript. Björn Rahlf: Conception and design and final approval of manuscript. Michael-Tobias Neuhaus: Collection of literature, manuscript writing and final approval of the manuscript. Nils-Clausius Gellrich: Conception and design and final approval of manuscript.

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