




A surgical navigated cutting guide for mandibular osteotomies: accuracy and reproducibility of an image-guided mandibular osteotomy

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Abstract

Purpose 3D-printed cutting guides are the current standard to translate the virtual surgery plan to the intraoperative setting. The production of these patient-specific cutting guides is time-consuming and costly, and therefore, alternative approaches are currently subject of research. The aim of this study was to assess the accuracy and reproducibility of using a novel electromagnetic (EM) navigated surgical cutting guide to perform virtually planned osteotomies in mandible models.

Methods A novel 3D navigated cutting guide (dubbed Bladerunner) was designed and evaluated with a total of 20 osteotomies, performed on plaster mandibular models according to preoperative planning using EM navigation. The pre- and postoperative scans were registered, and the difference between the preoperatively planned osteotomy and the performed osteotomy was expressed as the distance between the planned and performed cutting planes, and the yaw and roll angles between the planes.

Results The mean difference in distance between the planned osteotomy and performed osteotomy was 1.1 mm (STD 0.6 mm), the mean yaw was 1.8° (STD 1.4°), and mean roll was 1.6° (STD 1.3°).

Conclusion The proposed EM navigated cutting guide for mandibular osteotomies demonstrated accurate positioning of the cutting plane according to the preoperative virtual surgical plan with respect to distance, yaw and roll angles. This novel approach has the potential to make the use of 3D-printed cutting guides obsolete, thereby decreasing the interval between diagnosis and surgery, reduce cost and allow for adaptation of the virtual plan in case of rapid tumor proliferation or unanticipated in situ deviations from the preoperative CT/MR imaging.

Keywords Surgical navigation · Electromagnetic · Oral and maxillofacial surgery · Computer-assisted surgery · Intraoperative navigation · Presurgical virtual planning · Cutting guide

Introduction

Computer-assisted surgery has become a common tool in head and neck surgery. With the use of 3D planning software in combination with rapid prototyping, a patient-specific

cutting guide can be created to improve precision and reduce the duration of bone reconstruction during head and neck surgery [1–3]. In addition, this approach allows for less experienced surgeons to conduct this type of surgery successfully.

Virtual surgical planning has made the outcome more predictable and accurate compared to the free-hand approach. However, several shortcomings and problems still occur using the virtual surgical planning. The time interval between the planning CT and the surgery should not exceed 2 weeks [4], but can take as long as 4 weeks or more due to production, shipping and designing difficulties. Even a 2-week delay may result in serious limitations for patients with rapidly growing tumors or acute trauma [3]. Positioning

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of the 3D-printed cutting guide can be inaccurate due to remaining soft tissue between the mandible and the cutting guide, resulting in aberrant cutting planes. Deviations from the virtual plan can also occur when the shape of the 3D cutting guide is not sufficiently patient specific, i.e., after placement on the mandible, it still allows for small shifts. If a non-perfect fit is noticed or an unexpected intraoperative finding occurs, the non-flexibility of the cutting guides does not allow for alterations of the original planning. In addition, the printed material lacks robustness, making it possible for the surgical saw to cut through the 3D-printed cutting guide and create a non-straight cut. The dependence on an external medical printing company and the frequently complicated and time-consuming logistics and communication between engineer, surgeon, operating department/nurses and sterilization department results in overall costly 3D-printed cutting guides [5]. A novel approach that overcomes the disadvantages of 3D-printed cutting guides is therefore required. One potential approach is the use of image-guided optical or electromagnetic navigation.

Recently, two research groups have been working on different navigated saws tracked with an optical navigation system, for performing mandibular osteotomies according to a virtual plan. The implementation of the navigated saw can be carried out exclusively by medical team members, thereby eliminating the need for bioengineer services, and the relatively long production and design time of the 3D-printed cutting guides [6, 8]. In an experimental setting, multiple osteotomies were performed on plaster or polyurethane model mandibles. Pietruski et al. [6] let a single operator perform the osteotomies, and two observers evaluated the difference in volume, the angular deviations and the differences between preoperative and postoperative marginal point positions. The mean difference between the planned and actual bone resection volumes was $8.55 \pm 5.51\%$, the mean angular deviation between planned and actual osteotomy trajectories was $8.08^\circ \pm 5.50^\circ$, and the mean difference between the preoperative and the postoperative marginal point positions was 2.63 ± 1.27 mm [6]. The study highlights the potential for image-guided resection, but the method requires further improvement and a comparison with the patient-specific cutting guide. In a study by Bernstein et al. [7], four surgeons (two attendings and two clinical fellows) performed unnavigated and navigated osteotomies and evaluated the distance and angular deviations (here, pitch and roll) between the planned and the cutting planes. The navigated cuts were significantly better than the unnavigated cuts in all evaluated measures. Mean distance from the virtual planned osteotomy was 2.65 ± 2.25 mm unnavigated and 1.3 ± 0.80 mm 3D navigated; mean pitch was $5.06^\circ \pm 4.24^\circ$ unnavigated and $4.11^\circ \pm 2.723^\circ$ 3D navigated; mean roll was $9.4^\circ \pm 8.3^\circ$ unnavigated and $3.5^\circ \pm 3.1^\circ$ 3D navigated.

However, no comparison is made with the patient-specific cutting guides. Both of these groups demonstrate the potential of surgical navigation in providing accurate osteotomies; however, a free-hand navigated saw requires good eye–hand coordination [6], and without a saw compelling cutting guide it is challenging to make a non-straight cut. These studies achieved a good accuracy (in general this should be less than 1 mm) in distance, but still have high angular deviations. During reconstruction, this angular and distance errors propagate over the entire length of the defect and can thus result in malocclusion and facial deformation. Navigating the cutting guide instead of the saw itself can overcome these shortcomings. A navigated cutting guide placed at the right position and fixed at the right angle is no longer dependent on the hand stability of the surgeon.

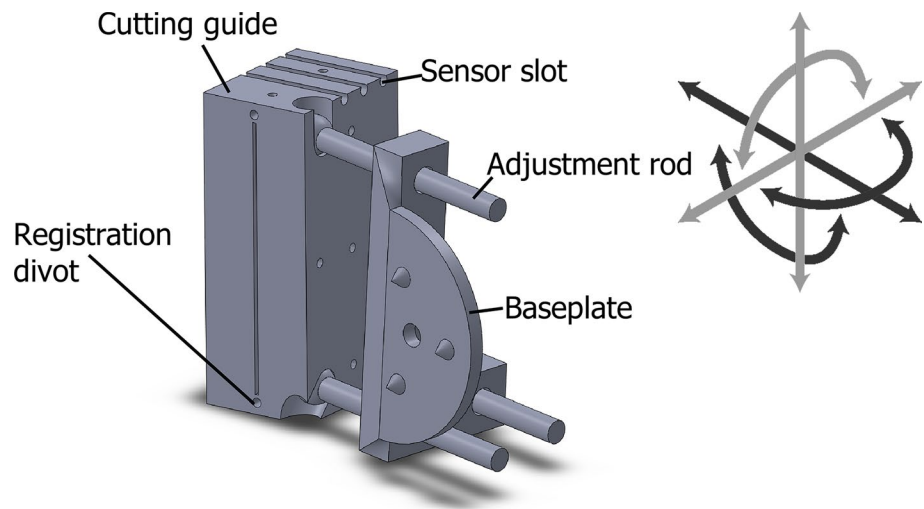
The aim of this study was to assess the accuracy and reproducibility of three-dimensional (3D) virtually planned osteotomies in mandible models using a novel electromagnetic (EM) image-guided navigated surgical cutting guide.

Methods

Bladerunner design

An experimental navigated cutting guide system (dubbed Bladerunner) was designed consisting of three elements; a baseplate for a rigid fixation to the mandible, a navigated cutting guide, i.e., a slot with thickness that corresponds to the saw blade thickness and adjustment rods (Fig. 1). The baseplate has three equidistant spikes with a screw hole in the center to provide the best kinematic constraint on an irregular surface such as the mandible and an L-shaped support with three holes for the adjustment rods. The connection and mobility provided by the adjustment rods are derived from a kinematic mirror mount, to provide 5-degree-of-freedom (DOF) movement. By elongating or shortening the adjustment rods, the navigated cutting guide is able to tilt and translate opposed to the baseplate. This is necessary for providing minute and larger adjustment options to obtain the best cutting plane alignment according to virtual planning. When the optimal position and orientation are obtained, the setup can be fixed using opposing nuts along the adjustment rods. The navigated cutting guide has a $30 \times 20 \times 1$ mm slit to adequately compel the saw, a trench for the EM sensor and fourteen widely spaced indentations on the outer surface which can be used for registration. The prototype was 3D-printed on a Formlabs Form 2 stereolithographic printer (Formlabs, Somerville, USA) using clear resin FLGPCL04. The design and material were approved by the in-house sterilization department for future clinical use.

Fig. 1 3D model of the navigated cutting guide, dubbed “Bladerunner.” In the upper right corner, displayed in black are the 3 degrees of freedom



3D navigation system

This study utilized in-house-developed navigation software, *SurgNav* [9], in combination with an EM tracking system, NDI Aurora (Northern Digital Inc., Waterloo, Canada). The system allows for real-time tracking of sensor coils locations and orientations inside a 3D measuring EM volume. The software accommodates the registration and a four-display mode (axial, sagittal, frontal and 3D) where the position and orientation of the tools relative to the imaging data are visualized.

Mandible phantoms

The plaster mandible cutting models were constructed as follows: a mandible model was extracted from a computed tomography (CT) scan of a dentate patient and split along the midsagittal plane, where the (healthy) left half was 3D-printed and used to create a mold. The 3D-printed mandible model was half submerged in silicone (Dragon Skin[®] 10; Smooth-On, Inc.; Easton, PA 18042; USA) and hardened in a 20° oven; thereafter, the other half was covered and hardened. After removal of the 3D-printed mandible model, this resulted in a reusable silicon mold. Using this mold, ten plaster mandible models were created using generic plaster. All of the plaster models were scanned individually using a CT scan (Somatom Sensation Open; Siemens Medical Solutions, Erlangen, Germany) with a resolution of 0.59 mm/pixel and a 1.5 mm slice thickness. Image data were saved in Digital Imaging and Communication in Medicine (DICOM) format.

Osteotomy planning

The segmentation of the plaster mandibles was performed with the 3D Slicer software platform [10] using a simple threshold and converted to a stereolithographic file (STL) format. Using computer-assisted design freeware Meshmixer (Autodesk, Inc., <http://meshmixer.com>), two osteotomies based on actual cases of osteotomy locations were planned and drawn in 3D for each plaster mandible model (Fig. 2).

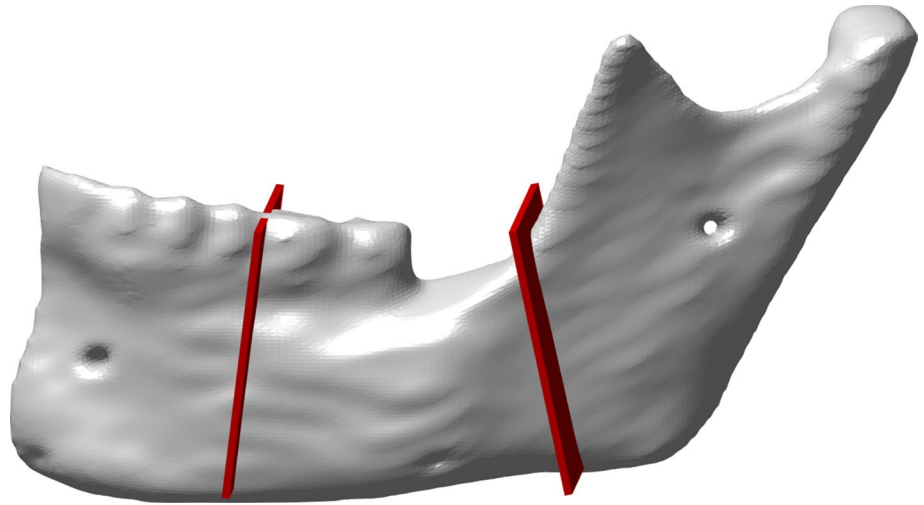
Calibration and registration

EM sensors were attached with tape in between the two osteotomies on the plaster models, and in the specifically designed grooves on top of the Bladerunner (Fig. 1). The Bladerunner and the plaster mandible were both registered using a point match registration. The plaster mandible models were registered to the 3D reconstructions using three widely spaced fiducials (condyle, mental foramen and mental protuberance) that were holes drilled into the models. Image-to-sensor paired-point registration was measured in the root mean square registration error to assess how closely the preoperative CT and physical plaster mandible model were registered. The Bladerunner was registered to the 3D model using fourteen widely spaced fiducials in the small indentations along its surface.

Osteotomies

All surgical procedures were performed in an operating theater setting, according to the same operating protocol. The baseplate was attached to the plaster mandible in the

Fig. 2 3D model of the plaster mandible with the planned osteotomies indicated in red



vicinity of the planned planes using a stainless steel screw. Next, the Bladerunner with predicted cutting plane was positioned using the 3D views of *SurgNav* in such a way that the predicted plane was superimposed on the virtually planned osteotomy plane (Fig. 3). Rigid fixation was attained by securing opposing nuts on the adjustment rods. A 0.1-mm-thin handheld sawblade was inserted through the Bladerunner and used to perform the osteotomies. All mandibular osteotomy cuts were made approximately 80% of the cut height so that each bone remained intact for the postoperative CT scan to facilitate accurate analysis.

Osteotomy plane analysis

After completing the osteotomies, the mandible models were CT scanned with identical imaging parameters to the preoperative scans and stored in DICOM file format. Segmentations were again performed with 3D Slicer using the same threshold value and stored in STL file format. Both pre- and postoperative STL files were registered in MATLAB R2018b (The MathWorks Inc., Natick, USA) using an Iterative Closest Point (ICP) algorithm. Model-to-model registration error was determined as the root mean square error between the planned and registered models, to confirm the accuracy of the quantitative outcome measures. The osteotomy was found in the model by determining the outward orientated normal vectors which intersected with the model, where the corresponding vertices had an intermediate distance of approximately the thickness of the osteotomy. This resulted in points on both sides of the osteotomy. Resection planes were defined by determining a plane of best fit through these points by minimizing the normal quadratic distance.

In order to quantitatively determine the difference between the planned (virtual) and postoperative (performed) resection planes, the distance and angles (yaw and roll) between the

planes were analyzed [mean and standard deviation (STD)]. The distance between the planned and postoperative resection planes was defined as the distance between the center of gravities of each plane intersecting with the mandibular bone model. The center of gravity was defined as the average of all 3D points of the cross section between the cutting plane and the jaw model. The postoperative plane was transformed to align the planned resection plane along the Z-axis, before performing a registration to determine the yaw and the roll between the planes.

Results

A total of 20 osteotomies guided with the Bladerunner were performed on ten plaster mandible models. The mean image-to-sensor paired-point registration error was 0.4 mm (STD 0.3 mm), and the mean model-to-model registration error was 1.0 mm (STD 0.1 mm).

The paired-point registration procedure only took 2–3 min; the accurate positioning of the 3D navigated Bladerunner took about 10–15 min. A single measurement including attachment of the sensors and performing the osteotomy lasted between 20 and 30 min.

Table 1 shows the difference between the virtually planned osteotomy and the 3D navigated performed osteotomy using the Bladerunner for anterior and posterior cutting planes in all 10 plaster mandible models. Mean distance between the planned and performed osteotomies was 1.1 mm (STD 0.6 mm), the mean yaw 1.8° (STD 1.4°) and mean roll 1.6° (STD 1.3°).

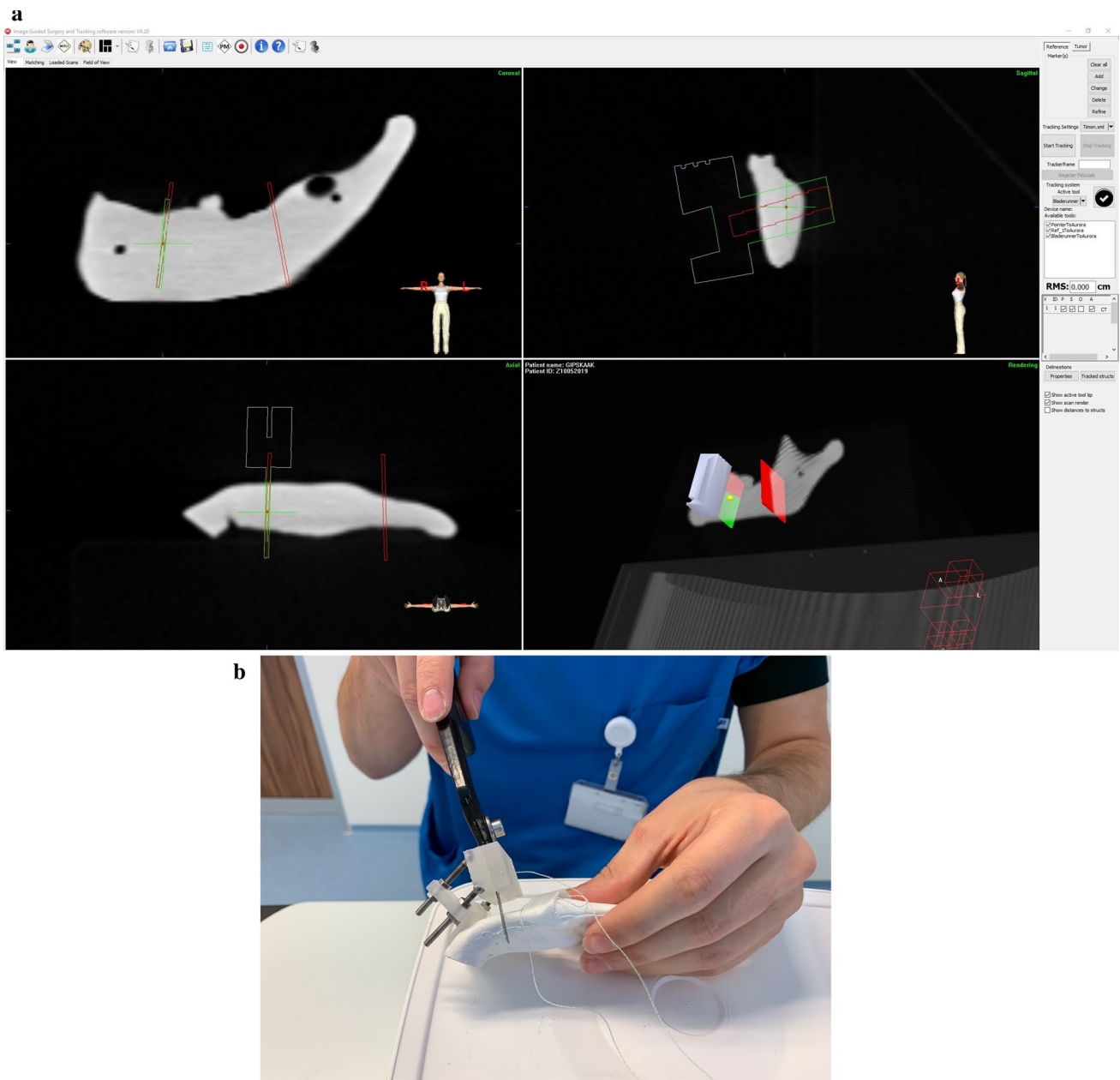


Fig. 3 An osteotomy being performed on a plaster mandible model using the 3D navigated cutting guide in combination with Surgnav and a 0.1-mm-thin handheld sawblade. **a** Performing the osteotomy. **b** Positioning the Bladerunner using Surgnav

Discussion

The current state-of-the-art 3D-printed cutting guides have shown to be a clear improvement on the traditional free-hand techniques [12]. However, these cutting guides come with their own shortcomings in the form of inflexibility during surgery, logistics, long production time and cost. Several research groups have started to look for alternative methods in the form of a navigated saw. In this study, the concept of a navigated cutting guide is introduced, and multiple navigated osteotomies were performed to evaluate the efficacy.

In this study, the navigated Bladerunner shows a high accuracy and the small standard deviations suggest that these results are reproducible. An average distance of 1 mm between planned and performed resection planes approaches clinically acceptable values. Furthermore, both the roll and the yaw indicate an accurate osteotomy.

The yaw and roll angles work over the entire length of the reconstruction; a small deviation in the angle can result in a multiple millimeter offset over the length of the bone segment. This is where the Bladerunner could provide the

Table 1 Distance, yaw and roll between the virtually planned osteotomy and the 3D navigated osteotomies using the Bladerunner

Mandible model	Plane	Distance (mm)	Roll (°)	Yaw (°)
1	Anterior	0.69	2.50	3.63
	Posterior	1.04	2.57	0.92
2	Anterior	1.01	1.37	0.84
	Posterior	0.60	1.19	3.02
3	Anterior	1.11	0.35	1.64
	Posterior	0.96	1.06	0.18
4	Anterior	0.36	0.97	1.55
	Posterior	0.86	0.70	1.13
5	Anterior	0.67	4.08	0.62
	Posterior	1.54	0.12	0.14
6	Anterior	2.06	1.05	1.88
	Posterior	1.73	0.23	0.07
7	Anterior	2.28	0.24	0.68
	Posterior	1.45	1.69	2.47
8	Anterior	0.23	2.49	3.28
	Posterior	0.29	0.46	4.82
9	Anterior	0.90	2.73	1.75
	Posterior	1.36	3.94	3.24
10	Anterior	1.33	0.68	3.98
	Posterior	0.76	4.11	0.77
Mean		1.06	1.63	1.83
STD		0.56	1.33	1.41

STD standard deviation

most improvement; the length and the shape of the excised bone segment will be more accurate.

Osteotomies performed with the navigated Bladerunner should at least achieve similar, and preferably better, accuracies compared to the currently used state-of-the-art 3D-printed rigid cutting guides. A study that was performed in house included seven patients and showed that the distance between preoperatively planned cutting plane and the performed cutting plane was 0.9 mm (STD 0.5 mm) for the anterior osteotomy and 2.0 mm (STD 1.0 mm) for the posterior osteotomy [11]. The angles ranged between 2.6° and 9.5°. Due to the difference in study setup, it is not possible to compare these results directly with the results of Bladerunner presented in this study. However, it shows a frame of reference to the order of accuracy that should be achieved when evaluating the use of the Bladerunner in a patient study.

Bernstein et al. [7] navigated on maxillary osteotomies in anatomical models, using a 3D navigated saw. Mean distance from the virtual planned osteotomy was 1.3 ± 0.80 mm, mean pitch was $4.11^\circ \pm 2.723^\circ$, and mean roll was $3.5^\circ \pm 3.1^\circ$ 3D navigated. This study included 144 osteotomies on the mandible, and it is therefore not possible to compare the results with the results obtained by the Bladerunner. This

study also provides an indication of the order of accuracy that should be achieved in our future studies.

Both of the navigated saw groups [6, 7] utilize an optical navigation system as EM navigation has demonstrated to be inaccurate in the vicinity of large metallic instruments such as the saw [13]. However, surgical navigation with a navigated cutting guide is only needed during the actual positioning of the Bladerunner that is manufactured from non-ferrous material (e.g., medical-grade stainless steel or titanium). During the navigated positioning of the Bladerunner, no interfering metallic instruments are needed that could affect the accuracy. When the correct position and orientation are obtained, the navigation system can even be turned off before using the metallic saw for the osteotomy. When using optical navigation, the required line of sight between the optical tracker and surgical tools limits the surgeons flexibility and this type of navigation is therefore challenging to use in practice, especially in small working areas like in head and neck surgery [14]. Therefore, EM navigation is the preferred system for the navigation of the navigated cutting guide.

The benefit of a navigated cutting guide versus a navigated saw is that the saw is compelled by the guide, making a curved cut impossible. The free-hand navigated saw requires good eye–hand coordination during the positioning and performing the osteotomy which could impact the performance [6]. The navigated cutting guide only requires this eye–hand coordination during positioning. When the cutting guide is aligned according to planning, the position of the Bladerunner can be fixed so the surgeon can focus on performing the osteotomy. Future studies could also evaluate the use of augmented reality (AR) while positioning the Bladerunner. Pietruski et al. recently published a promising study that AR could already be used for presentation of digital navigation data to enhance the surgeon's hand–eye coordination [15].

This is a proof of concept study and thus has some limitations. The Bladerunner setup requires that the baseplate is attached to the mandible at some distance from the planned osteotomy. As it is not feasible to position the baseplate on the tumor site, it is of yet difficult to perform an osteotomy near the condyle of the mandible. In further studies, this could be alleviated by providing multiple baseplates for different attachment locations. The fixation of the Bladerunner after cutting plane alignment is achieved by tightening opposing bolts on the adjustment rods. While this was fine for the proof of concept, this is not feasible during surgery as this is time and labor intensive. Different fixation options are required, which also provides room for improvement.

There are some future improvements planned for the Bladerunner. The 3D-printed material has some minor slack which could affect the osteotomy and is not suitable for an electric saw. Therefore, the next iteration will be from a

different material, including millimeter scales for alignment and fixation methods. A quantitative feedback on how well the virtual and actual planes coincide is required, to assist in the alignment and to eliminate possible inaccuracies caused by the hand–eye coordination. There is also future work in translating the angles and distances to a fibula cutting guide or virtual planning.

The focus of subsequent studies is to incorporate the previously stated improvements and assess the technology in a clinical patient study. The end goal would be to also eliminate the fibula 3D-printed Cutting Guide and use the virtual planning with the Bladerunner directly for the operation.

Conclusion

This study demonstrates the potential of image-guided EM navigated cutting guides for mandibular osteotomies. The distance, yaw, and roll were accurate, clinically acceptable and had a high reproducibility. The proposed method has the potential to make the use of 3D-printed cutting guides obsolete, thereby decreasing the interval between diagnosis and surgery, reduce costs and allow for adaptation of the virtual surgical preoperative plan in case of rapid tumor proliferation or unanticipated in situ deviations from the preoperative CT/MR imaging. Subsequent studies are focused on improvements to the navigated cutting guide setup and on evaluation of this novel approach in a clinical patient study.

Authors' contributions All authors have contributed to the research described in this manuscript.

Availability of data and materials The authors are willing to share the data and material for further research purposes.

Code availability The authors are willing to share the code and material for further research purposes.

Conflict of interest The authors declare that they have no conflict of interest.

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