# Phantom-based prospective analysis of the accuracy of photo registration technology in electromagnetic navigation of the frontal skull base

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**Abstract. – OBJECTIVE: This prospective study compared the accuracy of two different company-specific registration methods (Fiagon GmbH, Hennigsdorf, Germany) in the electromagnetic navigation of the frontal skull base. A newly developed photo registration technology (Fiagon tracey©) promises an increase in accuracy and user-friendliness, but there is no phantom-based prospective study comparing the new method with the classic approach of tactile surface registration.**

**MATERIALS AND METHODS: A phantom skull was prepared with 27 markers in the sagittal, axial and coronary planes, and their reference coordinates were determined using a navigational CT (low dose, slice 0.6 mm). Subsequently, 20 runs of automatic photo registration and tactile surface registration were carried out, and the resulting marker coordinates were compared with the reference coordinates. The target registration error (TRE) of the 27 markers was assessed and compared between the two methods using a 2-factor ANOVA with repeated measures.**

**RESULTS: The mean TRE using surface registration was 1.97 mm ± 0.57, while the mean TRE of the automatic photo registration was 1.54 mm ± 0.24 (*p* < 0.001). In a subgroup analysis limited to markers in anatomical regions of clinical relevance in terms of paranasal sinus surgery, the mean TRE for the photo registration procedure can even be reduced to 1.29 mm (± 0.43) compared to tactile registration (1.80 mm; ±0.50; *p*=0.01).**

**CONCLUSIONS: Photo registration is a promising new technology in the field of electromagnetic navigation in paranasal sinus surgery. This prospective phantom-based study showed that the photo registration method achieves a significantly lower target registration error (1.29 mm) compared to the surface-based tactile registration procedure (1.80 mm).**

*Key Words:*
Endoscopic sinus surgery, FESS, Image guided surgery, Navigation, Photo-registration, Target registration error.

## Introduction

Within the otorhinolaryngology branch of medicine, the rhinologists at the beginning of the 20$^{th}$ century, first saw the need for a system of navigation in the paranasal sinuses because of the complexity of their anatomical structures. Mosher et al[1], therefore, established the original form of navigation as early as 1902 by meticulously measuring numerous distances within the nasal and sinus cavities of a total of 64 human skulls. Based on these findings, Mosher performed the first endonasal ethmoidectomy in 1912 – notably in the pre-endoscopic era. In 1987 Schlöndorff et al[2,3] at the Rheinisch-Westfälische Technische Hochschule (RWTH Aachen University) performed the first computer-assisted paranasal sinus surgery (CAS, Computer-Assisted Surgery).

The successive further development of the hardware and software for image-guided surgery



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(IGS) systems made the technique increasingly reliable and user-friendly. In most ENT surgical departments nowadays, interventions in the area of the frontal skull base and its adjacent anatomical structures can be supported by intraoperative navigation. Numerous studies[4,5] have shown the advantages of IGS in paranasal sinus surgery, ranging from reduced intraoperative blood loss to a decrease in the intraoperative complication rate (bleeding, skull base defect, etc.) as well as less revision procedures. Last but not least, IGS, for example, has made it progressively easier to meet the surgical challenge regarding the anatomical diversity of the frontal recess[6].

While in the early years mainly opto-electrical (OE) navigation systems were used, in recent years, electromagnetic (EM) systems have become increasingly popular due to their improved clinical applicability in everyday clinical practice with comparable accuracy[7,8].

Current studies[9-12] show that the accuracy of IGS systems in paranasal sinus surgery is in the range of 1.5 mm to 2 mm. The aim is therefore to further improve accuracy by using technical innovations. Consideration of the core processes required for IGS leads to potential starting points. A navigated operation schematically consists of three parts[13]:

**1.** The therapeutic object (the patient's habitus);
**2.** The virtual object (preoperative imaging); and
**3.** The navigator (the navigation system used).

The navigation system synchronizes the therapeutic and the virtual object during an operation.

Three processes are necessary for this:

**1.** Calibration (records the instruments in the coordinate system);
**2.** Registration (matches the therapeutic object with the virtual object);
**3.** Referencing (ensures that registration is maintained).

Calibration only needs to be performed once per operation and is usually automated. The registration procedure must be carried out by the surgeon before each operation. Referencing is again carried out automatically after registration. Thus, the registration process represents the critical point of navigation[14] and up till now has not been carried out automatically.

The accuracy of navigation depends mainly on the registration process. In principle, the registration process deals with finding structures in the preoperative imaging of the operative site and matching their locations. This can be done using preoperatively defined anatomical landmarks (marker-based registration) or surfaces (surface-based registration)[12]. Optimizing the registration procedure is therefore a promising approach for improving the accuracy of navigation.

A new photo registration technique (Fiagon Tracey©, Fiagon GmbH, Hennigsdorf, Germany) for electromagnetic (EM) navigation recently became available for clinical application. The aim of this innovation is to improve the accuracy of the registration process, while at the same time optimizing user-friendliness.

The objective of this prospective study is to compare the accuracy of the two different company-specific registration methods (marker and surface-based registration *vs.* photo registration technology) using a phantom skull with predefined marker positions.

## Materials and Methods

The prospective phantom-based study was performed at the Department of Otorhinolaryngology, Head and Neck Surgery of the Friedrich-Alexander University of Erlangen-Nürnberg (FAU).

### Basic Functioning of Electromagnetic (EM) Navigation

As a first step, a computed tomography of the object to be navigated has to be created. After registration, the preoperatively performed imaging can be used for navigation. The object to be navigated (e.g., phantom skull) is centrally located on a magnetic field generator. This generator, which is integrated in the headrest, generates magnetic fields at a fast frequency with a strength of about 6 mT. The excitation frequency for field generation is between 7 and 14 kHz. Current is induced in the coil of the navigable instruments (pointer, suction cup, curette, wire, shaver, etc.) as soon as the instrument's position in the magnetic field changes. According to Lenz's law, the current strength depends on the magnetic field strength and the orientation of the coil. Thus, the induction current can be used to determine the position of the instrument in the magnetic field. Due to the previously performed registration process, the position of the instrument can now be displayed in real time in preoperative imaging (CT). In a prospective accuracy study on a phantom skull, the new photo registration (Fiagon

GmbH, software version 3.7.5.3171.0) was compared with the previously used tactile registration (Fiagon GmbH, software version 3.7.5.3171.0). The clinically relevant parameter used in most accuracy studies is the so-called target registration error (TRE). The TRE describes the distance between the actual position of the instrument (e.g., pointer) and the position displayed in the CT after the registration process[15]. To determine the TRE of both registration procedures, a phantom skull was provided with a total of 27 markers in the sagittal, axial and coronal planes in the area of the main nasal cavity, paranasal sinuses and the posterior fossa. Markers 1 to 9 were located in the sagittal plane, markers 14 to 21 in the axial plane and markers 10 to 13 and 22-27 in the coronal plane (Figure 1). The CT markers were drilled in the center, so that an exact approach with the pointer was possible. The phantom skull was an anatomically realistic replica made of CT real plastic. The localizer of the navigation system was permanently fixed to the phantom in the area of the frontal bone (Figure 1). A removable silicone mask was mounted on the skull. The mask was made by a make-up artist in such a way as to approximate the physiognomy of a real face and is suitable for both photo registration and tactile registration (Figure 2).

A low dose computed tomography (CT) (SOMATOM Definition AS, Siemens Healthineers, Germany) of the paranasal sinuses was per-

**Figure 2.** Phantom skull with silicone mask. Phantom with removable silicone mask suitable for photo registration and tactile registration.

formed on the phantom for navigation purposes (phantom skull with silicone mask) (Figure 3).

The phantom skull was positioned on the headrest including the magnetic field generator in the operating room and covered with adhesive tissues in a standardized way in keeping with endoscopic paranasal sinus surgery. The caudal border of the cover was just below the upper lip to avoid distortion of the facial soft tissue, and the cranial cover was just below the

**Figure 1.** Phantom skull with a total of 27 firmly anchored markers (1-9 in the sagittal, 14-21 in the axial and 10-13 and 22-27 in the coronal plane) and localiser *(in green)*.

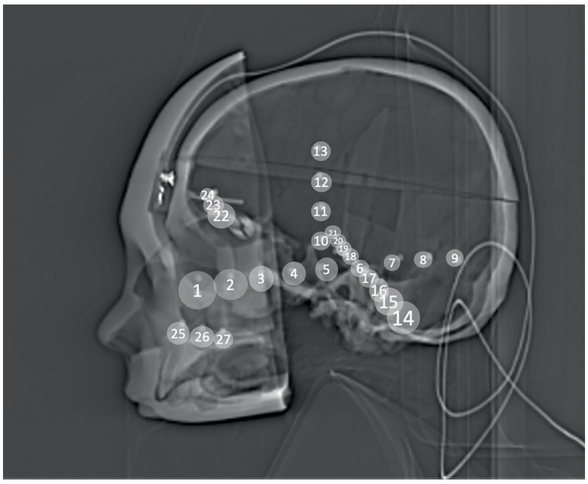


**Figure 3.** CT of the phantom with highlighted markers. CT protocol: layer thickness 0.6 mm; tube voltage 100 kV; tube current 35 ref. mAs; CTDI vol 1.79; DLP 36.6; CARE DOSE 4D switched on, CARE kV switched off; pitch 0.9; rotation time 1 s; SAFIRE thickness 2, kernel J70h; field of view (FoV) 248; increment 1.0.

hairline (Figure 4). In the next step, 20 tactile registrations (measurements n=1080; 2 × 20 measurements × 27 markers) and 20 registrations each were performed sequentially with the photography based Fiagon Tracey© system, and the respective TRE of the corresponding registration mode was determined. The complete data set of these measurements can be found as a **Supplementary Table I.**

### Tactile Registration Method

The tactile registration of the system used by Fiagon© is a hybrid procedure consisting of marker-based and surface-based registration. In this procedure, a localizer must first be fixed with an adhesive onto the head below the hairline in the median line, and then, three markers (recommended: lateral canthus left and right, philtrum) must be placed manually in the CT data set. If the root-mean-square error (RMSE) of the so-called "matching" between the three defined and probed points is greater than 6 mm, the registration is automatically discarded by the system and has to be performed again.

If the marker positions are approached correctly, the next step is the surface-based registration with a so-called pointer. The manufacturer recommends that the eye area is circumscribed in a spectacle shape, including the bridge of the nose. Once the system has acquired 170 points, the registration is finally calculated automatically.

### Photo Registration Process

Attaching the localizer for photo registration is done in the same way as for tactile registration (see above). In the second step, the patient's head is positioned centrally in a mapper frame (Figure 5). Subsequently, three frontal images of the patient's face are taken from slightly offset angles using a tablet computer (iPad air, 2nd generation 2014, Apple Inc., Cupertino, CA, USA). The software shows the user the required distance and angle. From the image data, the navigation system automatically creates the registration.

**Figure 5.** Phantom in the mapper frame. Intraoperative view of the phantom skull with corresponding cover for a paranasal procedure positioned in a mapper frame.

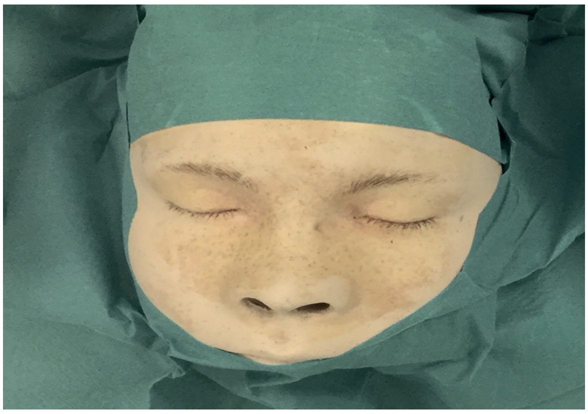

**Figure 4.** Phantom with sterile cover. The cover is located just below the upper lip to avoid distortion of the facial soft tissu.

### Procedure of the Study

First, the positions of the 27 markers were determined manually in the CT in relation to the localizer and defined as a reference using 3D Slicer (Version 3.6.3)[16]. 3D Slicer is software which was specially developed for clinical image processing. The position of each marker was determined three times by two persons independently. The mean value of each of the 6 determined positions was used as a reference coordinate for each marker position in the study.

The further course of the study can be divided into two steps. In the first step, a registration of the phantom was created in the respective technique. Both the tactile and the photo registration were carried out according to the above-mentioned procedure. The silicone mask was fixed with plastic snap fasteners. The sterile cover was glued to the phantom once and was not changed between the individual registrations. All registrations were carried out under identical conditions in an operating room with the ceiling lighting switched on. In the second step, the mask was removed from the phantom in order to approach each of the 27 CT markers individually with a pointer. Sequentially, 20 measurement repetitions were performed with tactile registration and 20 repetitions with the photo registration Fiagon Tracey© system (measurements n=1080; 2 procedures × 20 measurements × 27 markers) and the deviation of the measured coordinates from the reference coordinates was calculated in mm. Finally, two groups were formed. Group 1 (green circles in Figure 6) comprises markers 1-4 and 22-27, which are of clinical relevance in the field of paranasal sinus surgery (frontal sinus to sphenoid sinus). Group 2 (black circles in Figure 6) comprises markers 5-21 in the region of the middle and posterior fossa.

### *The Calculation of the TRE (Target Registration Error)*

The target registration error (TRE, mm) is the difference between the measured and the reference position. The TRE was calculated according to the following formula:

$$TRE_i - \sqrt{}\,(x_{Ci} - x_i)^2 + (y_{Ci} - y_i)^2 + (z_{Ci} - z_i)^2$$

where:

| | |
|---|---|
| $TRE_i$ | Target registration error for marker number $i$ |
| $(x_{Ci}, y_{Ci}, z_{Ci})$ | Reference position of a marker $i$ n the CT scan defined using 3D Slicer |
| $(x_i, y_i, z_i)$ | Position of a marker $i$ measured by a pointer after registration |

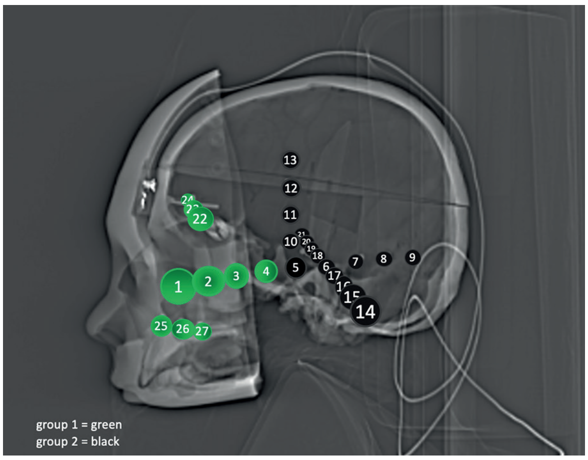


**Figure 6.** CT of the phantom with classification of the markers into Group 1 and Group 2. Group 1 (green; markers 1-4 and 22-27) comprises the anatomical regions relevant for paranasal sinus surgery. Group 2 comprises markers 5-21 in the mid and posterior fossa.

The mean TRE across all 27 marker positions and all 20 measurement runs (grand mean) is used as an estimate for the accuracy of the respective registration technique.

### *Statistical Analysis*

We analyzed the registration data of all 20 repetitions using a 2-factor repeated measures ANOVA with the factor's marker and type of registration or marker group and type of registration in Statistica 8 (StatSoft, Hamburg, Germany). The significance level was chosen at $p<0.05$. In addition, we performed post-hoc comparisons using Tukey tests.

## Results

The grand mean TRE (± standard deviation) of tactile surface registration was 1.97 ±0.57 mm and 1.54 ±0.24 for photo registration (Table I). This difference was statistically significant ($p<0.001$) (Figure 7).

However, at the single marker level, only marker positions 5 and 9 were significantly different in both registration procedures in this analysis, probably due to the relatively low number of repeated measurements (n=20) for the number of groups within the analysis.

In the subgroup analysis (Group 1, Group 2), repeated measurement ANOVA shows that the distance of the marker from the localizer in the sagittal plane (frontal/anterior or occipital/posterior markers) has a significant effect on the TRE [factor group, F (1.50) = 10.994 $p=0.002$].

The interaction between the two factors (group and registration method) is not significant (Figure 8b). In other words, Groups 1 and 2 differ in the same way in both registration methods.

The average TRE for Group 1 is 1.80 ± 0.50 mm for tactile surface registration and 1.29 ± 0.43 mm for photo registration. This difference is significant (Tukey post-hoc test $p=0.01$). For Group 2, the average TRE for tactile registration is 2.07 mm and for photo-based registration 1.68 mm. This difference is also significant (Tukey post-hoc test $p= 0.01$). However, the difference between Groups 1 and 2 is only significant for photo registration (Tukey post-hoc test $p= 0.035$), but not for the tactile measurement method ($p>0.05$) (Table II).

The subgroup analysis thus reveals two clinically relevant aspects. Firstly, photo registration (TRE 1.29 mm) has significantly lower TREs than tactile registration (TRE 1.80) (Figure 8a).

**Table I.** Grand mean TRE (in mm) of tactile and photo registration.

| Tactile registration – results | | | Photo registration – results | | |
|---|---|---|---|---|---|
| **Reg-ID** | **M** | **SD** | **Reg-ID** | **M** | **SD** |
| 1 | 2.38 | 0.90 | 1 | 2.23 | 0.40 |
| 2 | 1.80 | 0.73 | 2 | 1.55 | 0.40 |
| 3 | 2.50 | 0.77 | 3 | 1.39 | 0.49 |
| 4 | 1.83 | 0.76 | 4 | 1.55 | 0.40 |
| 5 | 1.70 | 0.41 | 5 | 1.99 | 0.49 |
| 6 | 1.79 | 0.44 | 6 | 1.28 | 0.47 |
| 7 | 1.60 | 0.65 | 7 | 1.19 | 0.47 |
| 8 | 1.72 | 0.75 | 8 | 1.40 | 0.30 |
| 9 | 2.81 | 1.08 | 9 | 1.54 | 0.39 |
| 10 | 3.96 | 1.26 | 10 | 1.50 | 0.94 |
| 11 | 1.41 | 0.52 | 11 | 1.33 | 0.33 |
| 12 | 1.73 | 0.78 | 12 | 1.58 | 0.52 |
| 13 | 2.04 | 0.77 | 13 | 1.55 | 0.64 |
| 14 | 1.62 | 0.66 | 14 | 1.77 | 0.98 |
| 15 | 1.48 | 0.62 | 15 | 1.39 | 0.47 |
| 16 | 2.09 | 0.73 | 16 | 1.47 | 0.39 |
| 17 | 1.81 | 0.72 | 17 | 1.64 | 0.38 |
| 18 | 1.59 | 0.83 | 18 | 1.46 | 0.46 |
| 19 | 1.62 | 0.39 | 19 | 1.28 | 0.52 |
| 20 | 1.94 | 0.73 | 20 | 1.62 | 0.44 |
| **ALL** | **1.97** | **0.57** | **ALL** | **1.54** | **0.24** |

Furthermore, photo registration was more accurate for navigation in the anterior base of the skull (Group 1), since dorsally located anatomical regions, such as the posterior fossa (Group 2) showed a significantly higher TRE (TRE 1.68 mm, *p*=0.035) (Table II).

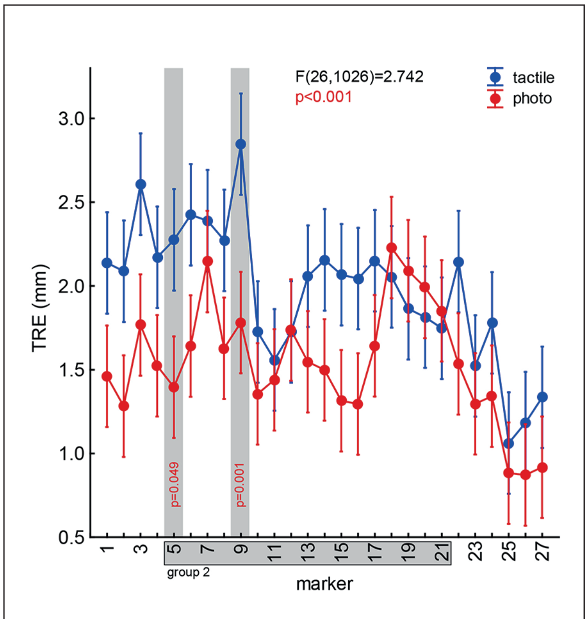


**Figure 7.** Interaction of the factors registration type (tactile/photo) and marker on grand mean TRE.

## Discussion

In this phantom-based study it was shown that the TRE can be significantly reduced by a novel photo registration method compared to a conventional tactile registration method. With a TRE of 1.97 mm (tactile) and 1.54 mm (photo), the two compared registration methods are in the range of the previously published results for surface-based registration methods[2].

For the use of intraoperative navigation in the area of the frontal skull base, a reduction of the TRE below 1.5 mm is desired, due to the proximity to critical anatomical structures[9]. In a subgroup analysis limited to those markers in anatomical regions of clinical relevance in terms of paranasal sinus surgery (Group 1), the mean TRE for the photo registration procedure can be reduced to 1.29 mm, thus significantly undercutting the desired 1.5 mm. This effect is also clearly visible in the subgroup analysis of the tactile registration method, where the mean TRE for Group 1 was significantly reduced from 2.07 mm to 1.80 mm.

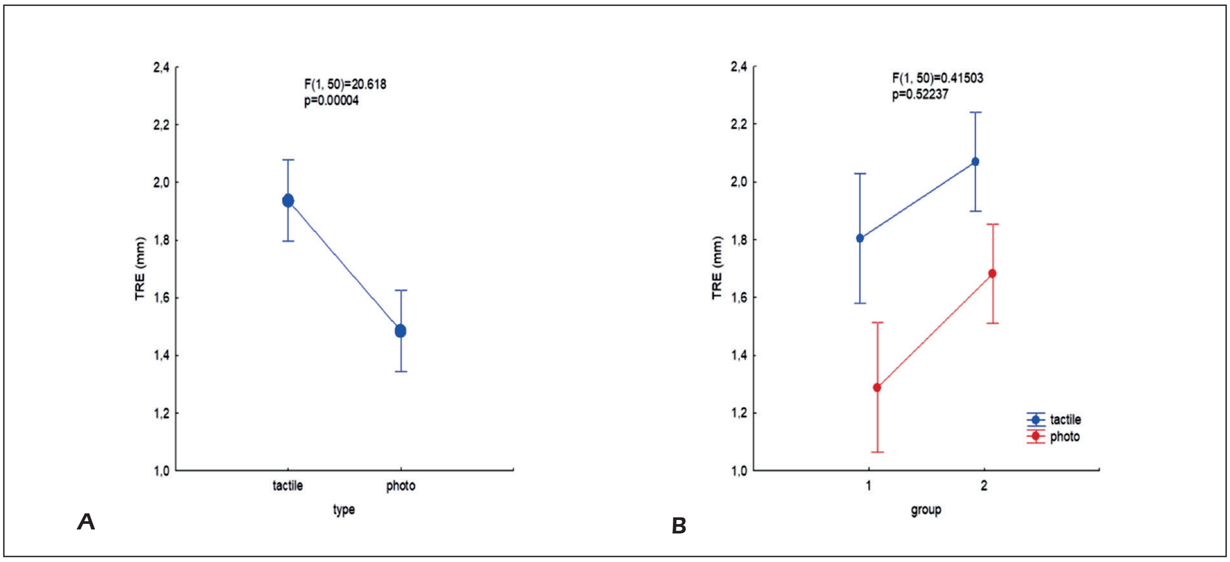


**Figure 8.** **A,** Grand mean TRE of tactile and photo-registration. **B,** Interaction of factor group and registration type on grand mean TRE.

The fact that accuracy of surface-based registration decreases with increasing distance from the registered surface has already been described in other studies[17] and could also be confirmed in this study for both registration procedures. The reason for this is that the registration process deviations are within the translational and rotational degrees of freedom. This means that the registered virtual object might be slightly shifted and tilted to the physical object (face). Where a translational deviation results in a constant TRE in the complete phantom, it is the rotational deviation that causes a higher TRE on targets with distance to the registration surface with the tilt axis.

In addition, we showed that photo registration allows more consistent registration results, as evidenced by the significantly lower standard deviation. This could be due to the fact that the simplification of the procedure and thus the lower potential for human error. One source of error inherent to tactile registration is the registration process of the patient's surface. This may result in incorrect data being entered into the registration. This may be caused, for example, by a "soft tissue shift", i.e., a shift of the facial soft tissue through sterile drapes or an endotracheal tube that is not medially centered in the area of the lower lip. The process of scanning the patient's surface can also influence the registration and thus the accuracy, depending on both the patient and the registrar. This sometimes depends on the thickness and flexibility of the cutaneous and subcutaneous tissue in the area of the registration area. On the phantom, this effect can be simulated only to a limited extent by the soft silicone mask. It is therefore expected that this effect of tactile registration will be even more pronounced under real conditions on a patient in the OR. With contactless photo registration, however, these sources of error can be completely eliminated. This also explains the lower standard deviation of ±0.24 mm for photo registration compared to the tactile method of ±0.57 mm in this study.

**Table II.** Grand mean TRE (in mm) of Group 1 and Group 2.

| | Group 1 | Group 2 | *p*-value |
|---|---|---|---|
| TRE tactil | 1.80 | 2.07 | n.s. |
| TRE photo | 1.29 | 1.68 | 0.035 |
| *p*-value | 0.01 | 0.01 | |

Glicksman et al[18] also demonstrated significantly better registration using the photo method compared to the tactile method in direct intraoperative comparison with four previously defined anatomical landmarks. However, in contrast to exactly defined markers with corresponding boreholes for the pointer tip and corresponding marker reference coordinates, as used in our study, the accuracy in the study by Glicksman et al[18] was only determined on the basis of four individual localizations (tip of the nose, head and axilla of the middle nasal concha, anterior sphenoidal sinus wall).

Nevertheless, it is clear from the available data that both surface registration methods are still susceptible to errors that are not automatically detected by the respective navigation system by the root mean square error (RMSE). This is particularly reflected in the relatively high standard deviation of the TRE of the tactile registration method, while the lower standard deviation of the TRE of the photoregistration seems to indicate that the photo-method is likely to be less error-prone overall.

The worst registration result for tactile registration was a TRE of 3.96 mm, but a TRE of 2.23 mm for photo registration is not acceptable either. Such values make it clear how important it is for the surgeon to visually check the registration. For this purpose, the surgeon should approach an anatomical structure with an instrument that is easily identifiable both in the CT and in the surgical site. If the position of the instrument is displayed with a TRE of > 2 mm in the navigation CT, it is recommended that the registration procedure should be repeated.

### *Limitations of the Study*

For technical reasons, it was not possible to fix the localizer on the silicone mask in the same way as for the real site, since the silicone mask had to be removed from the phantom to approach the CT markers. Since the silicone mask was to reproduce the surface of a face as realistically as possible (both optically for photo registration and haptically for tactile registration), it was deliberately decided not to make cut-outs to make the CT markers accessible without removing the mask. Since the relative position between the localizer and the CT marker point is determined during registration, the corresponding position of the localizer (bony skull vs. skin surface) has no influence on the measurement results themselves from a methodological point of view.

Even though user-friendliness was not systematically investigated in this study, we found that the photo registration process was significantly faster and easier to handle than the conventional tactile method. An additional optimization of photo registration by e.g., fixed, and standardized camera positions could make the registration process even more independent from the user, which in turn could have an additional positive influence on the TRE. Further developments of this kind should be the subject of future investigations.

## Conclusions

The photo registration procedure (Fiagon Tracey©) is a promising new technology for electromagnetic navigation in paranasal sinus surgery. In this prospective phantom-based study it was shown for the first time that this automatic registration method achieves a significantly lower target registration error (1.29 mm) compared to the company-specific (Fiagon GmbH, Hennigsdorf, Germany) surface-based tactile registration procedure (1.80 mm; $p$=0.01).

### *Declaration of Conflicting Interests*

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Schilke P, Tziridis K, Mantsopoulos K, Mueller S, Sievert M, Gostian A and Iro H have no conflicts of interest to declare. Bohr C and Traxdorf M have received financial support from Fiagon GmbH (Hennigsdorf, Germany) at national and international congresses and events. Anderssohn S is an engineer of the company Fiagon and has provided technical and methodical support. The author(s) received no financial support for the research, authorship, and/or publication of this article.

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