Official measurement protocol and accuracy results for an optical surgical navigation system (NPU)

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Abstract— Image-guided surgical navigation is on the rise in many different areas of modern medicine and is already an established standard in some disciplines like ear nose and throat (ENT) or maxillofacial surgery. When evaluating surgical navigation systems the absolute accuracy of the device is of major concern to the surgeon. The following work presents two different ways of measuring the accuracy of surgical navigation systems using the example of the KARL STORZ *Navigation Panel Unit* (*NPU*). According to these protocols the FDA approval of the NPU navigation system was prepared. In a first series of experiments the accuracy under realistic surgical conditions is evaluated with a phantom of a human head, which is manufactured in rapid-prototyping processes. In another series of experiments a custom registration board is used, which provides means to evaluate the accuracy under optimal conditions and also allows further measurements regarding the registration error, that are not possible with the phantom. In the experiments an accuracy of 1.44 mm \pm 0.18 mm was measured in the surgical setup and 0.63 mm \pm 0.07 mm under ideal conditions.

I. INTRODUCTION

During many surgical procedures the surgeon has to locate and identify specific anatomical structures in order to perform biopsies, resections, drainages or implantations. Prior to the actual surgery, the surgeon needs to define the operating area and any connecting pathways in a way, which prevents injuries to sensible anatomy. Therefore the surgeon preoperatively creates a planning which has to be followed closely in the actual intraoperative procedure. Problems with the implementation of the preoperative planning arise from the fact, that in most situations the surgeon does not know the precise position and orientation of the intraoperatively used surgical instruments in relation to the preoperatively acquired image data. Therefore orientation within the operating field relies heavily on anatomical landmarks, which can be difficult due to the complex individual anatomy, pathological deformations, limited visibility caused by lesions or the minimally-invasive nature of the intervention in general.

Navigation systems assist the surgeon with the complex task of locating and identifying anatomical structures by projecting the position and orientation of surgical instruments into radiological image data [1]–[3]. Naturally, during the intraoperative use of image-guided navigation the absolute

accuracy of the navigation system is of major concern to the surgeon. The following work presents two reliable ways of measuring the absolute accuracy of a navigation system under surgical and optimal conditions.

II. MATERIAL AND METHODS

A. The navigation system

The *Navigation Panel Unit (NPU)* (KARL STORZ GmbH & Co.KG, Tuttlingen, Germany) is an optical navigation system with its main application in ear, nose and throat surgery [2]. The *NPU* consists of a *Polaris Vicra* (NDI, Waterloo, Canada) navigation camera, a *Slimbook* tablet PC (PaceBlade, Amersfoort, Netherlands) and the ENT navigation software. Various surgical instruments may be navigated, including pointing devices (probes), different suctions, mills and endoscopes. The navigated instruments either have integrated or separate, attachable optical localizers consisting of three or four glass spheres, which are tracked by the navigation camera with a frequency of 20 Hz. The patient is referenced by a patient localizer, which is attached via a headband. Among other modalities, CT- or MRI- images may be used as preoperative image data. During the surgical intervention the positions and orientations of the navigated instruments relative to the patient localizer are tracked by the navigation camera and projected into the preoperative image data in real time.

B. Evaluating the accuracy of the NPU

The overall accuracy of image-guided surgery is heavily dependent on the accuracy of image-to-patient registration, which transforms the location of real instruments in the operating room into the virtual space of the preoperatively acquired radiological images of the patient [4], [5], [10].

To calculate the image-to-patient registration the *NPU* employs a paired-point based registration technique. Prior to the operation the surgeon selects four registration points at distinct anatomical landmarks, which are clearly identifiable in the patients radiological data and marks them in the navigation software by placing virtual markers either on the surface of the 3D model that was generated from the radiological images or directly in the two-dimensional slices of the image data themselves. At the beginning of the intervention the surgeon registers the location of the patient in reference to the radiological images by touching exactly the same anatomical landmarks on the real patient with the navigated probe. By correlating the touched points with the previously defined virtual points the navigation software is able to calculate the homogeneous transformation matrix

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 $^{mod}T_{pat}$ which maps coordinates of the real instruments from the coordinate space of the patient localizer pat to coordinates in the virtual image space of the radiological data mod.

The accuracy with which the anatomical landmarks were touched during the registration process is commonly called Fiducial Registration Error (FRE) and is calculated as the distance between the virtual position of a registration point mod **p**_{FM} and the touched position pat **p**_{FM} transformed with the registration matrix (eq. 1) [8], [9]. The navigation software accepts the calculated transformation if the mean FRE across all registration points is less than 2 mm.

$$
\mathbf{FRE}\left(\mathbf{^{mod}}_{\mathbf{P}FM}\right) = \mathbf{^{mod}}_{\mathbf{P}FM} - \mathbf{^{mod}}_{\mathbf{T}_{pat}} \cdot \mathbf{^{pat}}_{\mathbf{P}FM} \quad (1)
$$

Since the accuracy of image-to-patient registration and therefore the overall accuracy of the navigation system depend on the precision with which the registration points have been planned and touched, two different series of experiments have been conducted to evaluate the accuracy of the *NPU*. In the first series of experiments the accuracy under conditions closely resembling surgical interventions was evaluated using a phantom of a human head. In the second series of experiments the accuracy under optimal conditions was measured using an artificial registration board which allows placing the registration points at milled indentations on the boards surface so they can be touched precisely with the navigated probe.

C. Measuring the accuracy under surgical conditions

In this series of experiments a phantom of a human head, which closely resembles the natural anatomy, along with a regular CT scan of the phantom provide realistic measurement conditions. The phantom is manufactured in a rapidprototyping process from an original CT-dataset of a real patient and therefore precisely mirrors the actual anatomy of the patient's head (fig. 1) [11]. The skin and bone parts of the phantom are constructed with two different kinds of materials with densities similar to their natural counterparts to make sure they show as skin and bone in the radiological images when scanning the phantom in a CT scanner. Since the material used for the skin is slightly soft, the probe indents the skin slightly when touching the anatomical landmarks. The scale of the head phantom is 1:1 the scale of the original CT-dataset of which it is manufactured, therefore the size of the phantom matches the dimensions of a natural human head, which also allows to attach the headband with the patient localizer exactly as it would be done in a real surgical intervention.

During the experiment all steps necessary to perform image-guided surgical navigation with the *NPU* are carried out. Image-to-patient registration is performed with registration points at anatomical landmarks (corners of the eyes, root of the nose, etc.) that are commonly used in ENT surgery. In order to allow measurement of the resulting accuracy close to the operation situs, five bone screws were drilled into the bone parts of the phantom at locations around and inside the paransal sinuses (fig. 1). The bone screws are clearly visible

Fig. 1. The phantom of a human head, which was used to measure accuracy under conditions similar to regular surgical interventions. The phantom consists of three bone parts (a) for FESS and temporal bone surgery, which are screwed to a common baseplate (b). The outer skin part (c) is manufactured from a soft, elastic material and covers the bone parts when it is attached to the baseplate. Several titanium bone screws (d) serve as measurement points during experiments. The patient localizer (e) is attached via an elastic headband (not shown), just like in a real surgical setup.

in the CT scans of the phantom and may be used as reference points.

The resulting accuracy of the navigation system is measured by touching each of the implanted bone screws with the navigated probe and subtracting the actual position of the measurement point at the bone screw mod \mathbf{p}_{MP} , within the radiological images from the measured position of the navigated probes tip pat **p** $_{TCP}$ (eq. 2). The distance between the position of a bone screw in the image data and the position of the probes's tip equals the Target Registration Error (TRE) at the touched point (eq. 3). The TRE depicts the absolute accuracy of the navigation system at a point of interest and includes the whole chain of errors influencing the accuracy of image-guided navigation, including the error of the navigation camera, the optical localizers, instrument geometries and image-to-patient registration [6]–[10].

$$
^{pat}\mathbf{p}_{TCP} = \left(\begin{matrix} cam\mathbf{T}_{pat}\end{matrix}\right)^{-1} \cdot ^{cam}\mathbf{T}_{probe} \cdot ^{probe}\mathbf{p}_{TCP} \tag{2}
$$

THE
$$
\binom{mod}{PMP}
$$
 = $\binom{mod}{T}_{pat}$ $\binom{pat}{PTP}$ = $\binom{mod}{PMP}$ (3)

During measurement the vector $^{pat}p_{TCP}$ is saved in a ringbuffers holding 50 values and is averaged over the last 50 consecutive positions measured by the navigation camera. Acquisition of a measurement point starts as soon as the standard deviation σ of the probes TCP falls below 0.3 mm. If σ raises above 0.3 mm during the next 50 transformation cycles, acquisition is canceled automatically. After all measurement points have been touched, the arithmetic mean and standard deviation of the TRE across all M measurement points are calculated with equations 4 and 5.

$$
\overline{TRE} = \frac{1}{M} \cdot \sum_{i=1}^{M} \left| \left| \mathbf{TRE} \left(\begin{matrix} \text{mod} \\ \mathbf{p}_{MP,i} \end{matrix} \right) \right| \right| \tag{4}
$$

$$
\sigma \left(TRE \right) = \sqrt{\frac{1}{M-1} \cdot \sum_{i=1}^{M} \left(TRE_i - \overline{TRE} \right)^2} \tag{5}
$$

D. Measuring the accuracy under optimal conditions

In order to be able to measure the accuracy under optimal conditions and also to allow studying of the image-topatient registration error in particular a registration board was constructed, which serves as an artificial phantom, replacing the patient in the regular surgical setup. The registration board is a rectangular metal board, with milled indentations at predefined locations across the boards surface, which act as artificial landmarks or measurement points. The diameter of the indentations matches exactly the diameter of the probes tip, allowing to precisely touch each of the points. The patient localizer can be screwed to a mounting post on the registration board therefore fixing it in an exactly defined position and orientation relative to the board (fig. 2) [11].

Fig. 2. 3D view of the registration board, which was used in the second series of experiments. The milled grooves and indentations on the board's surface allow for a multitude of different layouts of the registration points, which can also be touched precisely with any navigated instrument. The image shows the board and the navigated probe while touching a measurement point (close up).

Because the patient localizer can only be attached in one predefined orientation, once it has been fixed to the board the transformation between the patient localizer and the registration board itself is constant and can be calculated from the construction data of the registration board.

$$
^{mod}\hat{\mathbf{T}}_{pat} = const
$$
 (6)

The only error influencing this transformation is the inaccuracy of the manufacturing device used to create the registration board, which is below 0.1 mm and therefore negligible compared to the inaccuracy of the navigation system. This constant reference transformation allows to isolate the registration error (RE) introduced by image-topatient registration alone and to evaluate it exclusively, which is not possible in the regular setup with the phantom and bone screws.

First, the registration error at any point $^{pat}p_x$ relative to the patient localizer can be calculated by transforming the position of the point (e.g. the probes Tool-Center-Point (TCP) pat P $_{TCP}$) into image space both with the constant transformation $\binom{mod \hat{T}}{pat}$ and the variable transformation $^{mod}T_{pat}$ gained from a regular registration process (eq. 7).

$$
\mathbf{RE}\left(\begin{smallmatrix}pat\ \mathbf{p}_x\end{smallmatrix}\right) = \begin{smallmatrix}mod\ \mathbf{T}_{pat}\end{smallmatrix} \begin{smallmatrix}pat\ \mathbf{p}_x \end{smallmatrix} - \begin{smallmatrix}mod\ \mathbf{\hat{T}}_{pat}\end{smallmatrix} \begin{smallmatrix}pat\ \mathbf{p}_x \end{smallmatrix} \begin{smallmatrix} (7)\ \end{smallmatrix}
$$

Second the variable transformation from the registration process may be multiplied with the reference transformation to gain the transformation from the original image space to the slightly rotated and translated image space defined by the erroneous registration matrix. This allows to state the error introduced by image-to-patient registration alone for any point $^{mod}p_x$ in image space (eq. 8).

$$
\mathbf{RE}\left(^{mod}\mathbf{p}_x\right) = ^{mod}\mathbf{T}_{pat} \cdot \left(^{mod}\hat{\mathbf{T}}_{pat}\right)^{-1} \cdot ^{mod}\mathbf{p}_x \qquad (8)
$$

Finally the absolute accuracy of the navigation system can be measured analog to the phantom experiments by touching measurement points on the board's surface and calculating the TRE at the touched position with equation 3, without using the constant transformation. Since the TRE is of highest interest when evaluating the accuracy of image-guided surgical navigation, the experiments with the registration board were conducted in the same way as the phantom experiments. However the four registration points were planned at milled indentations on the board's surface, thus simulating optimal registration conditions and instead of bone screws the intersections of the milled grooves across the board's surface (fig. 2) were used as measurement points.

III. RESULTS

A. Accuracy under surgical conditions

The experiment with the phantom was carried out 20 times. The four registration points were defined at anatomical landmarks that are commonly used in navigated ENT surgery - at the outer corner of the left and right eye, as well as above and below the nose.

In the 20 experiments with the phantom an average FRE of 0.96 mm \pm 0.19 mm and an average TRE of 1.44 mm \pm 0.18 mm was measured. Table I lists the FRE, as well as the resulting TRE for each of the individual experiments. Figure 3 gives an overview of the mean accuracy and the standard deviation measured in each experiment.

B. Accuracy under optimal conditions

Since the registration points on the registration board can be touched with very low deviation, the experiment with the registration board was carried out only twice. In the first experiment the registration points were touched with a mean accuracy of 0.33 mm \pm 0.07 mm and an average positioning

TABLE I

MEAN, MAXIMUM AND STANDARD DEVIATION (σ) OF THE FRE AND TRE FOR THE PHANTOM-EXPERIMENTS. ALL VALUES IN MM.

Exp.	FRE	max(FRE)	TRE	$\sigma (TRE)$	max(TRE)
1	1.28	1.61	1.50	0.26	1.76
\overline{c}	0.78	1.10	1.66	0.37	2.13
3	0.93	1.57	1.21	0.29	1.54
$\overline{4}$	0.86	1.53	1.32	0.31	1.68
5	0.89	1.50	1.18	0.27	1.46
6	0.95	1.34	1.51	0.50	2.30
7	1.01	1.66	1.68	0.46	2.22
8	0.93	1.28	1.80	0.56	2.43
9	1.45	1.82	1.51	0.51	2.23
10	1.14	2.01	1.57	0.50	2.42
11	1.08	1.87	1.16	0.43	1.67
12	0.88	1.12	1.56	0.84	2.54
13	0.87	1.41	1.37	0.28	1.77
14	0.70	1.20	1.35	0.26	1.72
15	0.90	1.71	1.55	0.22	1.84
16	1.15	1.71	1.21	0.26	1.49
17	1.06	1.77	1.43	0.20	1.58
18	0.86	1.07	1.68	0.56	2.50
19	0.86	1.22	1.24	0.35	1.71
20	0.60	0.84	1.35	0.39	1.88

Fig. 3. Mean and standard deviation of the TRE for each of the experiments with the phantom.

error of 0.63 mm \pm 0.07 mm was measured. In the second experiment the registration points were planned at different positions. The experiment still showed similar results with an FRE of 0.35 mm \pm 0.17 mm which resulted in a TRE of 0.62 mm \pm 0.10 mm (see table II).

IV. CONCLUSION

With the *NPU* surgical instruments can be guided with three-dimensional visual feedback. During the operation the surgeon can observe the position and orientation of the navigated instruments relative to the patient in reality as well as relative to the preoperatively acquired CT- or MRIimage data on the computer screen. Besides other sources of error, like human control, the inaccuracies of the image data and the navigation system noise, the overall accuracy of the system is dominated by the image-to-patient registration error.

TABLE II

MEAN, MAXIMUM AND STANDARD DEVIATION (σ) OF THE FRE AND TRE FOR THE BOARD-EXPERIMENTS. ALL VALUES IN MM.

Two different methods to measure the absolute accuracy of the navigation system have been introduced. While the phantom provides means to evaluate the accuracy in a realistic surgical setup, the registration board allows to isolate the registration error from the remaining inaccuracies and study its particular contribution more closely. Experiments showed that under ideal conditions the *NPU* is capable of navigating instruments with a mean accuracy of 0.63 mm. Under conditions closely resembling those of real surgical interventions mean accuracies of 1.16 mm to 1.80 mm were measured. Here the accuracy depends heavily on how much care is taken when planning and touching the registration points at the anatomical landmarks.

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