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● *Original Contribution*

NAVIGATION-SUPPORTED AND SONOGRAPHICALLY-CONTROLLED FINE-NEEDLE PUNCTURE IN SOFT TISSUES OF THE NECK

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Abstract—In surgery, sonography has been a well-accepted means of orientation for years. The immediate vicinity of many vital structures in the head and neck region calls for a very exact visualization of the surgical instrument in the 2-D ultrasonic picture. We report on the development of a new method for navigation-supported and sonographically-controlled fine-needle puncture in soft tissues of the neck. Our system comprises a navigated ultrasound probe, a navigated fine-puncture needle and a coordinate sensor. A personal computer with specially-developed software assists calibration and surgical application. The applicability test for the system is described. *In vitro*, a model lymph node of 9 mm in diameter had been hit. It is shown that the target structure can be aimed at very precisely by the navigated puncture needle. An accuracy of 97% and a specificity of 99% could be demonstrated. The development of a very precise and easy-to-handle method for navigation-supported fine-needle puncture in the neck region is presented. The outstanding advantage of this method is that no rigid reference gadget fixed to the patient's body is necessary. That makes this method very suitable for surgery in the neck region. Contrary to other sonographically-supported navigation methods in the head and neck region, preoperative imaging (CT or MRT) is dispensable. (E-mail: Matthias.Helbig@kgu.de) © 2009 World Federation for Ultrasound in Medicine & Biology.

Key Words: **Navigated sonographically-controlled puncture, Soft tissue of the neck, Fine-needle.**

INTRODUCTION

The immediate vicinity of many vital structures in the head and neck region implies several surgical problems. In otolaryngology (ENT), therefore, there has long been the desire for improved visualization and orientation during invasive procedures to better differentiate between pathologically altered and sound tissues (Majdani 2006; Stamm 2006; Stelter et al. 2006).

The generally accepted imaging methods are computed tomography (CT) and magnetic resonance tomography (MRT) (Bootz et al. 2001; Schlaier et al. 2005; Stieve et al. 2006; van Velthoven 2003). These procedures are carried out before planned interventions and always represent a momentary status only. So, they are "still" in contrast to "dynamic" processes and cannot visualize changes or movements during and because of invasive procedures. Therefore, these imaging methods can only be used during navigated operations in close vicinity of bone structures serving as anatomical landmarks. For interventions in soft tissues far away from such landmarks, navigation because of soft tissue shift becomes quite inexact (Schlaier et al. 2004; Unsgaard et al. 2002).

Here, sonography offers an alternative. For years it has been indispensable as a potent instrument for visualization of pathologic findings and anatomical relationships in the head and neck region (Helbig et al. 2005; Reinacher et al. 2003).

The advantages of sonography are well known. This "dynamic" method offers the possibility of direct representation of the individual anatomy (Ecke et al. 2006; Stetter et al. 2006). This applies also to changes and movements of the *situs* as they occur during surgery. Further on, it is a simple, often used and economical procedure with high resolution and good depth of focus without exposure to radiation.

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The following examples illustrate the areas in which sonography is already used or where it could be applied.

Diagnostics

Noninvasive. Display of individual anatomical situations, visualization of pathologic conditions (extent, size, relation)

Invasive. Biopsy and puncture of suspicious structures (Helbig et al. 2008)

Surgical therapy. Intraoperative orientation (search and visualization of suspicious target structures) and definition of appropriate resection margins. This is of special importance in connection with minimally invasive interventions to best preserve organs and functions. Although the best possible view of the operation field has to be aimed for, any injury risk for neighboring structures must be avoided (Pappas et al. 2005; Ridder et al. 2005).

Nonsurgical therapy. Precise administration of therapeutics (*e.g.*, of drugs), use of laser high-frequency ablation or high-intensity focused ultrasound (HIFU) (ter Haar 1995).

In the head and neck region, a navigation-supported sonographically-controlled target approach of a surgical instrument has to comply with the following requirements:

1. Real-time visualization and examination of the individual anatomy based on the ultrasound data.
2. Planning and creation of a virtual access (successive alternative possibilities), with respect to the entrance point and the inclination of the surgical instrument, taking into account the necessary protection of neighboring structures.
3. Permanent surveillance of the position of the surgical instrument compared with the target structure.

The most critical problem arising during sonographically-controlled invasive measures by use of a surgical instrument (*e.g.*, a puncture needle) is the appropriate representation of the instrument tip in the 2-D ultrasound picture. Only when this tip is exactly level with the 2-D ultrasound image can a correct representation be expected (Helbig et al. 2008).

A further problem arises when a puncture needle bends, which can occur both during the calibration and during the puncturing process: the system only can calibrate the tip precisely when the needle is not bent. The same applies to the navigation process: bending of the needle leads to deviations and lowers the accuracy of hitting the target.

Here, we offer a new method that will be referred to as navigation-supported and sonographically-controlled fine-needle puncture of soft tissues in the head and neck region. By means of a navigated ultrasonic probe and a navigated fine-puncture needle, we are able to visualize the 3-D position of the needle tip in relation to the individual anatomy at any time. To achieve this, the position of the needle tip (3-D dataset) is integrated real-time into the 2-D ultrasonic image. Our navigation system makes it possible to virtually align the needle tip with the target structure with respect to penetration angle and penetration depth, even before the needle actually enters the body. So, the tip of the puncture needle can be guided exactly to the ultrasound scan plane with the target structure. Further, the system provides helpful information as to the direction and distance of the needle from the target.

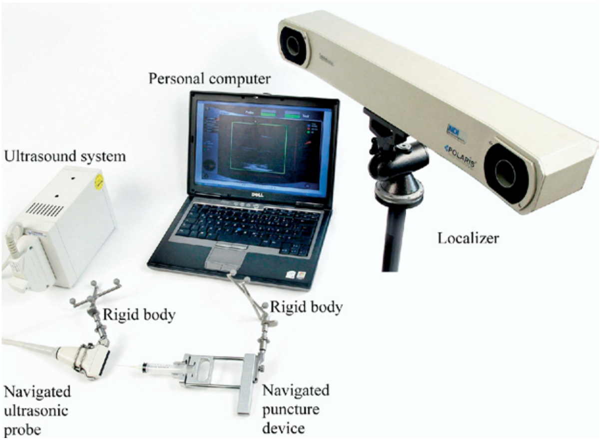

Fig. 1. The system comprises the following components: the ultrasound system with navigated ultrasonic probe, a navigated fine-puncture needle, a coordinate sensor (localizer) and two passive rigid bodies and a personal computer with custom-made software.

Following, the development of a prototype system for such navigation-supported and sonographically-controlled fine-needle puncture in soft tissues of the neck is described. Special emphasis is put on the operational exactness of the system.

MATERIALS AND METHODS

The system comprises the following components (Fig. 1): a navigated ultrasonic probe, a navigated fine puncture needle, a coordinate sensor and two passive rigid bodies and a personal computer with custom-made software. A rigid body consists of four infrared-reflecting spheres. When the localizer has spotted the position of these spheres, a coordinate system is constructed virtually around the rigid body. Within this coordinate system the position of a needle tip, for instance, can be determined.

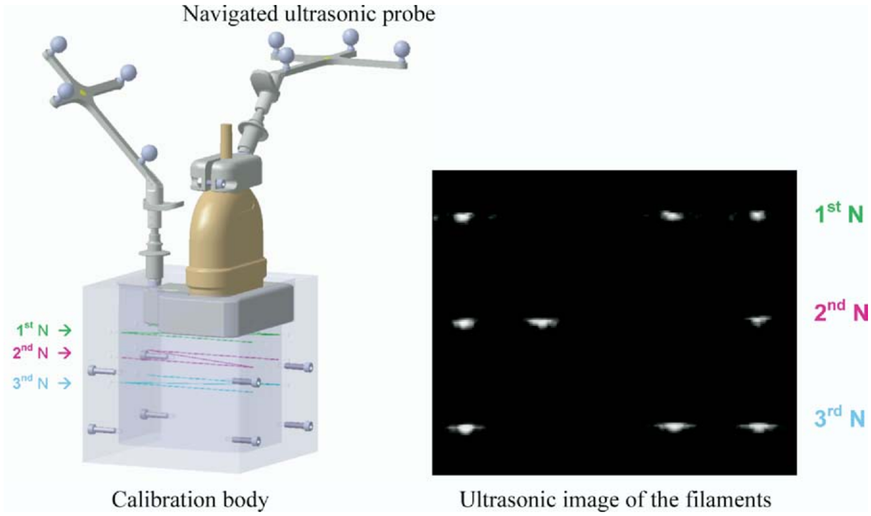

Fig. 2. Calibration procedure. Left: Calibration body and navigated ultrasound probe. Right: The ultrasonic image shows the "N-shaped" filaments in the calibration body. The exact position of the ultrasound probe in relation to the calibration body can be determined by the distances of the points from each other using a contour-seeking algorithm.

Ultrasonic device and navigated ultrasound scanner

We used a conventional ultrasound system (Echo Blaster 128 INT-1Z, Telemed, Vilnius, Lithuania) with a 9-MHz linear probe and a sound window of 40 mm. For navigation, the scanner is fitted with a fixed, unalterable interface to the rigid bodies. Consequently, only one calibration process is necessary (precalibrated 2-D B-mode), the data of which can be relied on afterwards. For practical application only, the passive bodies have to be exchanged.

Navigated puncture device

A rigid handle with an interface to the transmitter was attached to a commercial device for small-needle punctures (CAMECO LTD., London, UK). A 10-mL injection syringe (B. Braun, Melsungen, Germany) with a 20-G needle was fixed to the puncture device. This device has to be calibrated before use.

Computer and software

The hardware component was a DELL Latitude D620 computer with the following features: Intel Core Duo T2300E, 1.66 GHz, 1 GB RAM, Microsoft Windows XP. Graphic card: NVIDIA Quadro NVS 100 mol/L; Visual Studio C++. Special custom-made software was developed for calibration and application.

Localizer

The Polaris system (Northern Digital Inc., Waterloo, ON, Canada) was used to determine position and orientation of the ultrasound scanner and the puncture device relative to each other. The accuracy of the system in finding a target point in a 3-D space is 0.24 mm (RMS = rms) according to manufacturer's declarations.

Calibration of the ultrasonic probe

The aim of the calibration process is to correlate the 2-D image obtained with the navigated ultrasound probe with the coordinates of navigation (Lohnstein et al. 2007; Schlaier 2004). This is achieved by the Polaris system by generating a calibration matrix between ultrasound scan plane and rigid body on the probe. There is just one calibration process necessary, because the position of the probe rigid body is unchanging. Data collected and saved on disk can be used for all following applications. The calibration process described later, as well as custom-made software for this purpose, were developed specially for this application. The calibration body consists of nine parallel threads (fishing lines, Silicone-PTFE tempered, Diameter: 0.05 mm; Waku GmbH, Reinfeld, Germany) arranged in the shape of an N in three different levels. First, the position of the threads in this body was determined by means of a UMM 850 coordinate-measuring machine (Zeiss, Oberkochem, Germany). For calibration, the ultrasound probe was positioned into a holder of the calibration body. This calibration body, as well as the ultrasound probe, were each fixed to a passive rigid body. The coordinates of the ultrasound probe and of the calibration body were then transmitted to the coordinate tracking system (Fig. 2). The calibration software determines the coordinates of the nine threads of the calibration body and of the ultrasound probe. A transformation matrix is calculated from these data and the coordinates of the intersections of the threads in the ultrasound image to describe the position of the ultrasound plane in the rigid body coordinate system. The whole calibration process is performed under water in the calibration device. Because the speed-of-sound in water depends on the water temperature, we chose a water temperature of 37° C, matching fairly well that of the human body. At this temperature, the speed-of-sound of 1540 m/s was taken as baseline.

To determine the exact position of the crossing points, our custom-made software (contour tracking algorithm) automatically calculated the center of the thread outline (Kozak et al. 2005). The position of the ultrasound probe in relation to the calibration body could be determined exactly by the distance between these points.

Calibration of the needle

The calibration process is based on the fact that the coordinates of the rigid bodies of the puncture device are unknown. The coordinates of the needle tip are calculated by means of vector addition. The commercial needles (serial production) do not match our requirements of accuracy with respect to the needle tip position, because accurate specifications as to the interface between syringe and needle do not exist. Depending on how the needle is adjusted to the syringe, the position of the needle tip may vary slightly from needle to needle and from syringe to syringe. This makes it necessary to calibrate each needle–syringe combination individually.

Furthermore, we have to make sure that the orientation of the needle tip is approximately perpendicular to the calibration transmitter during the calibrating process. Because both puncture needle and syringe have to be sterile, an intra-operative calibration procedure is necessary before each clinical application. For this, the needle tip of the navigated puncture device is placed into the indentation of the second sterile rigid body (Fig. 3). The coordinates of the needle tip are calculated automatically and saved into the system. After this procedure, the data are available for clinical application.

System workflow

Special custom-made software was developed for the application in the head and neck region, which is not identical with the software used for calibrating the ultrasound probe in the calibration body (see section *Calibration of the ultrasonic probe*). The image pixels are converted into distance in millimeters and then the ultrasound image is displayed in real time. The target structure is displayed sonographically and marked with a green circle. From now on a contour tracking algorithm follows this marked structure. Any movement of the target structure on the screen is followed by the green circle mark. The navigated surgical instrument is tracked by the navigation system as virtual image with six degrees of freedom. That is, the position of the needle tip and its 3-D relationship to the ultrasound image is always known and displayed on the screen: The distance between the arrow tip and the color bar (visible on the right side and below the ultrasound image) symbolizes the distance of the navigated instrument tip to the ultrasound scan plane.

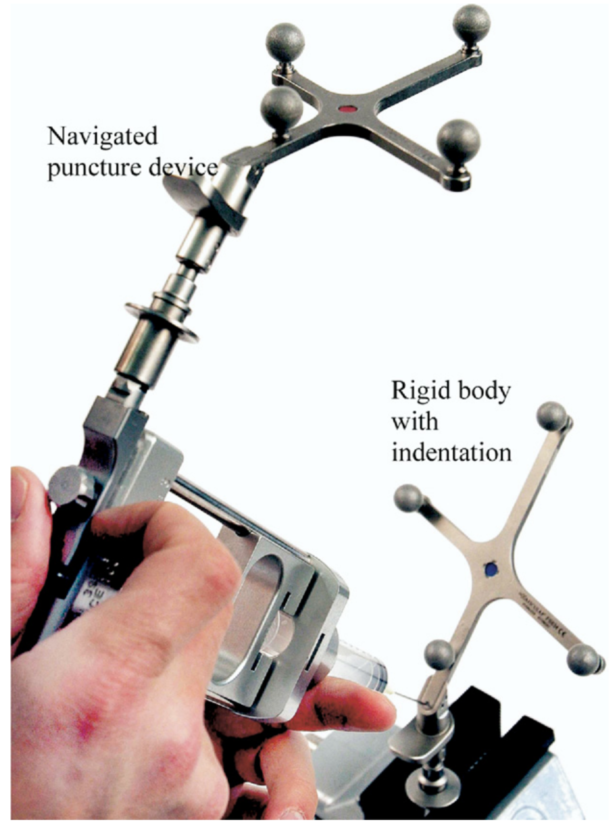

Fig. 3. Calibration of the needle. For this, the needle tip of the navigated puncture gadget is placed into the indentation of the second rigid body.

The third dimension is given by a dot using the following color codes:

Red: the instrument tip is in front (anterior) of the ultrasound scan plane,

Blue: the instrument tip is behind (posterior) the ultrasound scan plane, and

Green: the instrument tip is precisely in the ultrasound scan plane.

In addition, the direction of the arrows indicates the direction the instrument has to be moved to reach the target structure (Fig. 4). When the instrument reaches the target structure, the arrows are on the color bar and the color dot is exactly on the target, and all navigation indicators change to green. It is important to ensure that the needle is inserted along a straight path. Bending of

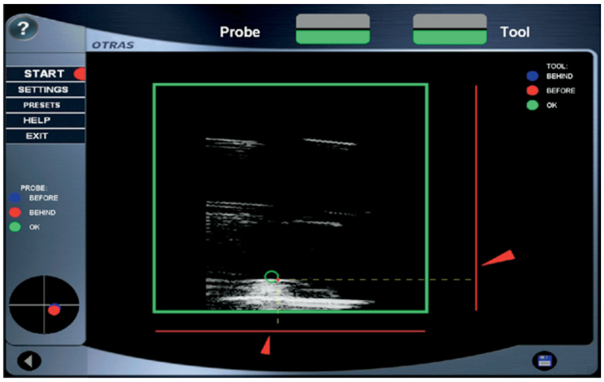

Fig. 4. Tracking. Target structure in the ultrasound image (green circle). The red navigation aids (bars, arrows, point) indicate the distance to the target structure and the proposed insertion channel for the surgical instrument. When the target has been successfully touched, the color of the navigation aids will change to green.

the needle must be avoided because this would have negative effects on the targeting accuracy (the degree of bending of the needle is proportional to the 3-D error). That is why the path of insertion is determined before puncturing the skin and has to be followed according to the system instructions.

Determination of targeting accuracy

The targeting rate of the navigation has been investigated *in vitro* 50 times each by two ENT surgeons. On the inner surface of a piece of meat (50 mm thick), a small ball of plasticine was positioned (Fig. 5). This ball had a diameter of 9 mm (Fig. 6). We chose this size because of its relevance in practice. So, lymph nodes of

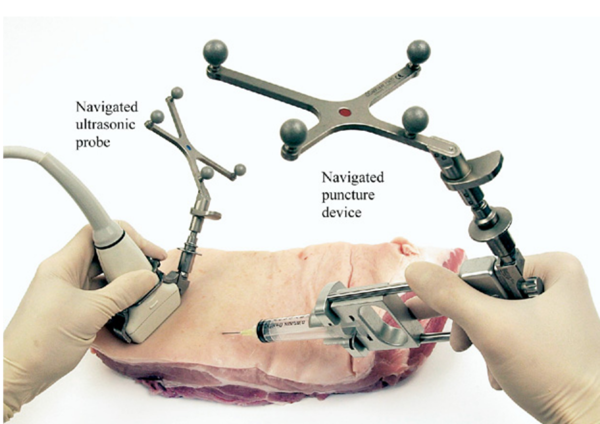

Fig. 5. Test setup. On the inner surface of a piece of meat (50 mm thick), a small ball of plasticine was positioned. Aim of these tests was to touch the plasticine ball with the needle tip only by means of sonographic navigation. Afterwards, an indentation in the ball had proven the success.

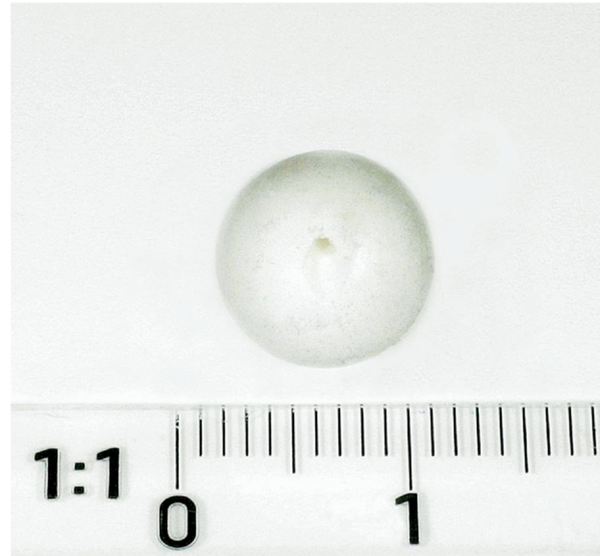

Fig. 6. Test ball. The hitting rate of the navigation has been investigated with a small ball of plasticine.

the neck of ≥10 mm would be an indication for puncturing, because from this volume on they are classified as “to be controlled”. The aim of these tests was to touch the plasticine ball with the needle tip by means of sonographic navigation only. Afterwards, an indentation in the ball had proven the success.

Four possible results were defined:

(1) Virtual display ⇒ ball touched, result⇒ ball shows indentation
(2) Virtual display ⇒ ball touched, result⇒ ball shows no indentation
(3) Virtual display ⇒ ball not touched, result ⇒ ball shows indentation
(4) Virtual display ⇒ ball not touched, result ⇒ ball shows no indentation

One-hundred trial results were evaluated by direct inspection of the plasticine ball, with respect to their sensitivity of the navigation display.

RESULTS

Two ENT surgeons each conducted 50 trials, the results of which are shown in Table 1. Sensitivity is understood as the probability that the hit ball was indicated as “hit.” The positive prediction value (accuracy) of this test is understood as the probability that all balls marked as hit by the navigation system actually showed an indentation.

We demonstrated a sensitivity of 99% and an accuracy of 97% for our navigation system.

These values of sensitivity and positive prediction value show that this technique of navigated sonopuncture

Table 1. Results of two sets of 50 trials conducted by two ENT surgeons

		Visual result as "gold standard"		
		Indentation	No indentation	
Navigation display of the 9-mm ball	Hit	94	3	Accuracy: 97%
	No hit	1	2	
		Sensitivity: 99%		

Sensitivity is understood as the probability that the hit ball was indicated as hit. The positive prediction value (accuracy) of this test is understood as the probability that all balls marked as hit by the navigation system actually showed an indentation.

(ultrasonic puncture) matches the requirements of accuracy in ENT surgery for structures >10 mm.

DISCUSSION

We have developed an easy-to-use prototype device for navigated sonopuncture in the head and neck region that meets all minimally-invasive surgery needs. The ultrasonic probe and the puncture needle are navigated. So, their 3-D orientations are known at any time of the surgical intervention. The distance of the instrument and its relationship to the ultrasound picture level, as well as to the target, are integrated into the 2-D ultrasound image by a specific presentation. This makes possible a precisely-directed access of the puncture needle tip to the target structure. The advantage of this navigation method is the real-time visualization. Every movement or change of the target is shown immediately and can be reacted to by redirecting the ultrasound probe.

In practice, ENT surgery requires accurate targeting of suspected target tissues with diameters of at least 1 cm. Lymph nodes of the neck, for instance, are classified as "to be controlled" from this size on. Such tissue volumes would be an indication for puncturing as described in this paper and can be targeted at very accurately by our navigated puncture needle. Even volumes of 9 mm can be hit precisely, with an accuracy of 97%.

Puncturing with fine needles is a commonly accepted diagnostic means. The surrounding tissues are spared and spread of malignant tissue parts is minimized. On the other hand, the use of very fine–puncture needles calls for special sensibility and caution of the doctor (Ridder et al. 2005; Weerda et al. 2000).

Inaccuracies in applying a new needle to the syringe inevitably lead to deviations. In such cases, a new calibration process has to be performed. To avoid such deviations caused by bending of the needle, it is crucial to insert it following a straight insertion path. Any correction of this insertion path during the procedure would result in deviation. The insertion path of the needle is determined before actually penetrating the skin and has to be followed according to the system instructions. When these rules are followed, our novel navigation system allows a very precise and safe targeting. On the one hand, the operator sees the anatomical structures in the sonographic image; on the other hand, supported by the system, he can navigate the needle so exactly that vital tissue structures are not injured.

The navigation system described here promises several advantages with respect to other *in vivo* applications.

For all navigation systems known up to now, *e.g.*, in cranial base surgery or in bone surgery (Majdani et al. 2003; Nijmeh et al. 2005; Plinkert 2002; Schipper et al. 2004; Stamm 2006; Stetter et al. 2006), rigid fixing of a reference transmitter to the patient's body in the very neighborhood of the operation site is obligatory. Its aim is to guarantee a safe navigation even when the coordinate tracking system or the target changes position. To avoid inaccuracies or deviations during the navigation, the coordinate sensor must be positioned very near to the rigid body of the navigated needle (West et al. 2001). Our novel navigation system described in this paper does not need an additional reference transmitter: ultrasound probe and needle are navigated in real-time. Any change of the situs and movement of the needle tip are immediately displayed on the ultrasound screen. The definite advantage of this navigation method is emphasized by the fact that in close vicinity to the operation site there are no anatomical structures serving as ultrasound landmarks.

Our procedure meets the requirements of minimally-invasive diagnostics: the puncture instrument can be manipulated safely to the target tissue under sonographic control (real-time). Changes and movements of the target structure are immediately displayed correctly. Injury to neighboring tissues can be minimized by use of a fine-puncture needle. The procedure is easy, practicable, without exposure to radiation and economically reasonable. Any ENT doctor will be able to work with it. Expensive examinations or interventions by radiologists (biopsies controlled by CT or MRT) can be avoided.

Furthermore, this procedure meets the requirements of minimally-invasive therapy. Very precisely–applied medication or high-intensity focused ultrasound therapy (HIFU) are possible future applications. These options are made possible by the precise visualization of the respective instrument and its 3-D position.

A prototype device for navigation-supported and sonographically-controlled fine-needle puncture in soft tissues of the head and neck region is presented here. It is a very precise and easy-to-handle instrument for minimally-invasive procedures. Tests with corpses and animal experiments are planned for the near future.

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