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Clinical Translation of Real Time Cautery Navigation for Breast Surgery

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INTRODUCTION

Breast cancer is the most frequent surgically treated cancer in women. The recommended treatment for early stage breast cancer is breast-conserving surgery, which requires complete surgical excision of the tumor while conserving healthy breast tissue. If cancer is found at the excision margins (called positive margin), additional surgery is performed. Recent reported positive margins rates have been as high as 47% [1].

At the Hamlyn Symposium in 2014, we introduced the concept of a breast-conserving surgery navigation system using real time electromagnetic (EM) tracking [2]. The system features an EM-tracked tissue locking needle to serve as a local coordinate reference (Figure 1). Wire hooks lock the needle in the tumor, thereby achieving accurate tracking when the targeted tumor moves and deforms during surgery. The target is contoured in EM-tracked ultrasound and defined in the coordinate frame of the needle. The tracked surgical cutting tool (cautery device) is shown on the navigation display relative to the tumor margins. Phantom studies with this system have shown 50% reduction in positive tumor margins compared to conventional wire localization, while total excised tissue amount was equal in both groups [2]. In this paper, we present the clinical translation to breast-conserving surgery navigation and the outcomes of a clinical safety and feasibility study.

MATERIALS AND METHODS

Sterility is achieved by placing the EM field generator under the sterile drape (Figure 4) and by placing the EM sensors in sterile bags. Disposable 3D-printed fixtures house the EM sensors. The fixtures are clipped onto the needle and cautery (Figure 2). The needle tracking fixture is secured to the needle shaft and is compatible with a variety of needle brands. We use Sonic Touch GPS ultrasound scanner (Ultrasonix, Richmond, BC, Canada) with an L14-5gps probe that also includes an integrated EM sensor. The mechanical designs, editable printable models with user instructions are available on the PLUS software website (www.plustoolkit.org) [3].

For intra-operative segmentation of the tumor volume in tracked ultrasound, we model the tumors by an arbitrary number of margin points. A convex surface enclosing all tumor points is generated by Delaunay triangulation. Points are collected during systematic scanning of the tumor from multiple directions until the tumor in the ultrasound images is encompassed within the margins from all directions. Points can be added to update the tumor model at any time during the surgery. The cautery or any tracked pointer can be used to add points to the margin (Figure 3). This feature will be integrated with advanced intraoperative tumor detection methods such as mass spectrometry and optical coherence tomography in the future for tumors not completely visible in ultrasound.

The attention of the surgeons is usually focused on the surgical site, so the navigation display is out of their direct line of sight (Figure 4). The navigation system obtains the surgeon's attention when the tumor margin is breached. We developed a general purpose software module to provide visual and/or audio warning signals when the tools interfere with predefined tissue areas.

All software used in our navigation system is part of the

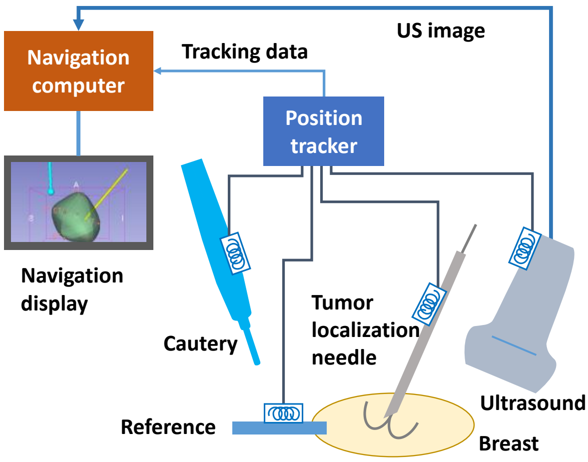

Fig. 1. Schematic view of the breast-conserving surgery navigation system. Blue coils represent EM tracking sensors.

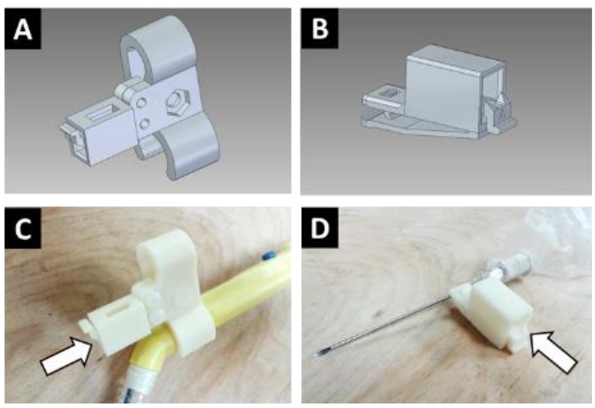

Fig. 2. Disposable tracking fixtures designed and 3D-printed for the cautery (A, C) and the needle (B, D). Arrows point at slots for EM tracking sensors.

SlicerIGT open-source framework. The source code is freely available from www.slicerigt.org, without any restriction of use. All modules are built on the 3D Slicer open source application framework (www.slicer.org) and they can be conveniently installed through the 3D Slicer extension manager. We provide online tutorials for the software modules on the SlicerIGT website. The tutorials do not require software coding knowledge. New features may be added by minimal Python scripting. Devices can be swapped out without programming by using PLUS [3]. The resulting navigation system was tested in a clinical safety and feasibility study on patients with palpable breast tumors. The study was approved by our institutional research ethics board, and written informed consent was obtained from all participating patients before surgery. We measured system setup time, calibration time, and the total procedure time. Surgeons were surveyed on the usability of the navigation system after the operations.

RESULTS

Six patients were included in the safety and feasibility study with stage IA to IIIA breast cancer. All margins were histologically confirmed as negative. There was no complication due to the navigation system, and no breach of sterility was detected in any of the cases. Clinical features and results of the study are shown in Table 1.

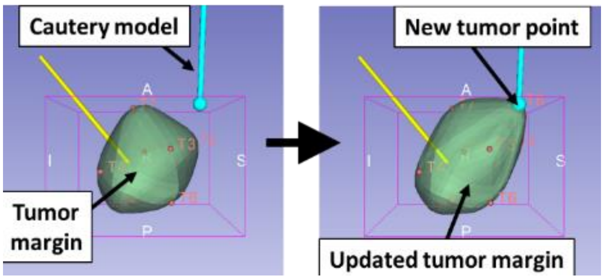

Fig. 3. Extending the tumor margin during surgery. The surgeon points at the tumor location with the cautery tip (left). The navigation software adds a new tumor point and extends the tumor margin with the new point set (right).

Fig. 4. The navigation system components (ultrasound and position tracker) are under the sterile draping. The navigation display is placed in front of the surgeons during the operation.

Questionnaires showed that the surgeons did not find the EM sensors to interfere with the procedure and the navigation system was generally easy to use. All surgeons rated the navigation system as "easy" or "very easy" to use, and considered it useful in maintaining safe and accurate tumor margins. The system setup and calibration time decreased from 15 minutes in the first case to only 6 minutes in the last case. Procedure times fell within the normal breast-conserving surgery times at our institution (Table 1).

Number of patients in study (N)	6
Age (range)	29 – 92 yrs.
Anesthesia (sedation / general)	3 / 3
Sentinel node biopsy in procedure (N)	4
Operation time (avg. ±SD)	51 ±16 min
Navigation setup time (avg. ±SD)	8.7 ±1.4 min
Margin histology (negative/positive)	6 / 0

Table 1. Clinical features and results of the clinical safety and feasibility study.

DISCUSSION

Our results suggest that real time navigation with EM tracking is safe and feasible in breast conserving surgery. No navigation system specific technical complications were experienced.

One person was needed in addition to the standard surgical staff to operate the navigation software. The surgeons indicated a strong need for sterile human-computer interface. We are planning to solve this problem by adding wireless touch-screen tablet in a sterile bag. With this, several workflow steps can be performed by the surgeons using the tablet device, such as tumor contouring and virtual viewpoint adjustment for the 3D navigation display. In one occasion the EM tracker slipped off of the needle and needed re-clamping, but tracking remained accurate because the fixture is clamped on the needle next to the hub reproducibly.

The breast surgery navigation system performed without any technical and clinical failure. A larger clinical study on non-palpable tumor cases is currently underway.

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