**Conclusion**

We achieved sub-degree and sub-millimeter TRE accuracy in a laboratory application of EM tracking with personalized guides. The guides provided anatomical registration and the EM provided information usable in an IGS system. The reported values are consistent with previously published error and, together, suggest that accurate characterizations were achieved [3, 4]. The FLE numbers are much lower than might be expected from EM tracking; the accuracy results from the registration that accounts strongly for direction.

The algorithm is an improvement on Rasquinha’s “crossing lines” algorithm [3], removing the need for geometric intersection. This facilitated a better guide design while maintaining high accuracy. The result is an ergonomic system, with personalized guides for registration in a conventional IGS setting.

Results were limited to a laboratory study on the shoulder. The metal retractors used in shoulder arthroplasty may interfere with the EM field; further investigation is warranted. The tracked guides still require preoperative imaging, both segmented and preoperatively planned. However, the intraoperative calibration time suggests that it could be done by a perioperative assistant during surgery, so it would not likely add to intraoperative time.

The primary contribution of this work is a method to help mitigate the challenges of reliably registering personalized guides to difficult anatomy. Currently, if a guide fits poorly, there is no way to verify the registration. A tracked guide enables intraoperative verification and, if necessary, conversion to IGS navigation.

EM was used for tracking because its devices are small and light, so they can be incorporated into personalized guides with minimal interference. Future work will include cadaveric studies and pilot clinical trials.

**References**


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**Safety and feasibility study for real-time electromagnetic navigation in breast-conserving surgery**

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**Purpose**

Breast cancer, the most common cancer in women, is ideally treated with breast-conserving surgery in its early stage. Precise delineation of the tumor margins is difficult as lesion margins are commonly not physically palpable, and breast tissue moves and deforms during the procedure [1]. The presence of a positive margin is linked with an increased local recurrence rate despite adjuvant radiotherapy, and therefore leads to the patient requiring additional surgeries and treatment. Current strategies have a reexcision rate for positive margins as high as 25% [2]. We have developed a real-time electromagnetic (EM) navigation system via ultrasound (US) to register the tumor resection volume from a tracked needle fixed in the tumor, allowing tumor movement to be followed in real-time during surgery [3]. This method has the potential to reduce the incidence of positive margins, while reducing the amount of healthy tissue removed. A previous study done on breast phantoms showed a decrease in positive margin rate from 42.9% (wire-localization) to 19.0% (EM navigation). The goal of this prospective phase 1 study was to assess the feasibility of using our electromagnetic navigation system in the operating room.

**Methods**

Female patients with a single palpable tumor were recruited to undergo a partial mastectomy. Intraoperatively, the SonixGPS Tablet (Ultrasonix, Vancouver, CA) ultrasound with its built-in EM tracker was used to register the tumor resection volume (Fig. 1). The surgeon inserted a wire-localization needle in the tumour under ultrasound guidance (Fig. 2A) and performed tumour contouring via an intraoperative touchscreen interface (navigation tablet). The SlicerIGT navigation software (www.SlicerIGT.org) provided real-time visualization of the resection volume and curvature position with respect to the tumor. The resulting real-time navigation was displayed on a laparoscopy monitor (Fig. 2B). In this study, feasibility was assessed via three components: confirmation of safety and sterility, measurement of the duration of operation and tumor registration, and completion of a surgeon questionnaire.

**Fig. 1 Operating room setup of the breast surgery electromagnetic navigation system.** The black coils are electromagnetic position sensors. The navigation tablet allows the surgeon to manually select the tumor resection volume in a sterile fashion. The resulting real-time navigation is also displayed on a laparoscopy monitor.
Ten patients with a mean age of 58.9 years (range 29–92 years), diagnosed with a stage IA to IIIA breast cancer (n = 8) or a benign breast lesion (n = 2) were recruited. The mean operative time was 62.5 min (range 48–82 min) for the cases of partial mastectomy with sentinel node biopsy (n = 8), and 35.5 min (range 29–42 min) for the cases of partial mastectomy alone (n = 2). Mean registration time was 8.25 min (range 5–12 min). There were no EM-specific complications or breach in sterility during surgery. Feedback questionnaires stated that none of the participants found that the EM sensors interfered with the surgical procedure. Using the 5-point Likert scale, participants stated that it was somewhat easy to complete the registration process (n = 7)(n = 1 very easy; n = 1 neither easy/difficult; n = 1 somewhat difficult) and to use the electromagnetic system to guide the surgery (n = 7)(n = 2 very easy; n = 1 neither easy/difficult), even without formal prior ultrasound training.

Conclusion

This study shows that EM navigation is feasible and safe to use intraoperatively in breast-conserving surgery. This technology could provide real-time feedback to surgeons that may improve treatment outcome. These encouraging results support the next phase of research: a trial on non-palpable tumors.

References

