

Study into the displacement of tumor localization needle during navigated breast cancer surgery

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ABSTRACT

PURPOSE: Early stage breast cancer is typically treated with lumpectomy. During lumpectomy, electromagnetic tracking can be used to monitor tumor position using a localization needle with an electromagnetic sensor fixed on the needle shaft. This needle is stabilized in the tumor with tissue locking wire hooks, which are deployed once the needle is inserted. The localization needle may displace from its initial position of insertion due to mechanical forces, providing false spatial information about the tumor position and increasing the probability of an incomplete resection. This study investigates whether gravitational and mechanical forces affected the magnitude of needle displacement.

METHODS: Ten ultrasound scans were evaluated to measure needle displacement in vivo. Needle position was approximated by the distance between the needle tip and the tumor boundary on a 2D ultrasound image, and needle displacement was defined by the change in position. The angle between the localization needle and the coronal plane was computed in an open-source platform.

RESULTS: A significant relationship ($p = 0.04$) was found between the needle to coronal plane angle and increased needle displacement. Needles inserted vertically, pointing towards the operating room ceiling, tended to exhibit greater needle displacement. Average needle displacement was 1.7 ± 1.2 mm.

CONCLUSION: Angle between the needle and the horizontal plane has been shown to affect needle displacement, and should be taken into consideration when inserting the localization needle. Future works can be directed towards improving the clinical workflow and mechanical design of the localization needle to reduce slippage during surgery.

Keywords: lumpectomy, breast-conserving surgery, EM tracking, image guidance, surgical oncology

1. INTRODUCTION

Breast cancer is a prevalent disease affecting about 1.38 million women worldwide [Stewart and Wild 2014], and is the most common type of cancer diagnosed in women. Approximately 1 in 8 women will receive a breast cancer diagnosis in their lifetime [DeSantis et al. 2013]. Treatment typically involves surgical removal of the tumor, along with chemotherapy. If the cancer is detected early enough, a lumpectomy may be performed. Rather than removing the entire breast like a mastectomy, a lumpectomy procedure will only remove the tumor with a small amount of surrounding healthy tissue is removed. Lumpectomy is commonly preferred over mastectomy because it reduces the amount of healthy tissue resected and improves cosmetic and psychological results after the operation.

A current challenge with lumpectomy is optimizing cosmetic appearance while ensuring full tumor resection. Tumor location can be estimated with pre-operative imaging, although this approximated location is often not accurate enough to allow full excision of non-palpable tumors without tactile feedback. The non-palpable nature of the tumor poses an added challenge for surgeons to successfully locate tumors and perform a complete resection. Guidewire-localization is the standard method used in lumpectomy to locate non-palpable tumors. Prior to tumor resection, a needle is inserted into the tumor under image guidance and wire hooks are deployed in the tumor to estimate its position. However, the spatial information provided by this method is insufficient and may result in an incomplete resection. Cancer-positive margins are reported to occur in approximately 15%-60% of cases [Jung 2012 & Waljee 2008], often requiring the patient to

undergo additional surgery. The need for repeat operations defeats the benefits of performing a lumpectomy over a mastectomy, and this introduces additional cost, trauma and recovery time for the patient.

An intraoperative electromagnetic (EM) navigation system [Ungi 2016] incorporating ultrasound imaging can be used in lumpectomy to minimize the volume of resected healthy tissue while ensuring that the tumor is completely removed. This system has been clinically tested on 30 patients to date. In the methods described by Ungi *et al.*, a needle with wire hooks is pre-operatively inserted into the tumor under ultrasound image guidance. Hooks from the needle are deployed to secure the needle tip to the tumor and prevent needle slippage. A rigid relationship between the needle and tumor is assumed in the system by Ungi *et al.* The tumor contour is tracked with an EM sensor fixed on the needle shaft. Tracked surgical instruments and the tumor contour are visualized in a 3D navigation display to provide the surgeon with intraoperative feedback about the tumor location (Figure 1).

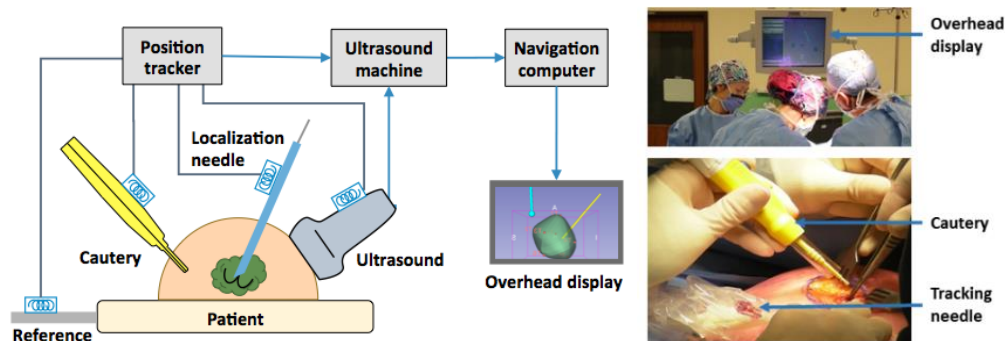


Figure 1. Lumpectomy navigation system: boxed coils represent EM sensors (left), navigation system in use (right).

The wire hooks deployed in the tissue will prevent the needle moving side to side, however gravity and various mechanical forces can cause the hooks to decompress, which allows the needle to slide outwards. These forces can be attributed to the mechanical pressure applied during ultrasound scanning motions and cauterization cutting in tumor resection. The weight of the EM sensor on the needle shaft and the connecting cable to the position sensor, covered by a sterile sleeve, may also cause the needle to be more sensitive to displacement from gravitational forces. Needle displacement can also be affected by breast tissue composition: a greater proportion of fibrous tissue is more effective at stabilizing needle position in comparison to breasts with greater fat tissue. Needle displacement can impact the overall outcome of the navigated operation, as excess needle migration may result in an incomplete tumor resection. The purpose of this study is to investigate needle displacement during ultrasound scanning of the breast prior to resection that can affect the magnitude of displacement.

2. METHODS

Images acquired from the beginning and end of the recorded ultrasound during tumor contouring were used to measure needle displacement. This is because once tumor excision begins, ultrasound images cannot be obtained and needle displacement cannot be measured, as acoustic coupling is lost due to air in the resection cavity. Mechanical deformation of the breast from scanning motions in different directions, applied pressure during resection, and the associated forces of the EM sensor and connected cable hanging from the needle, are likely causes of needle displacement. However, this displacement cannot be detected until the post-resection specimen X-ray, since the needle remains in the excised tissue. Therefore, utilizing ultrasound images obtained from tumor contouring was the feasible solution.

Ultrasound scans were collected with the Sonix Touch (Analogic Corp., Peabody, MA, USA) and tracking data was acquired through the Ascension 3D trakSTAR and Model 800 EM sensors (NDI, Waterloo, ON, Canada). Tumor location was monitored with the DuaLok hooked needle (Bard Biopsy, Tempe, Arizona, USA). An experienced radiologist pre-operatively inserted the localization needle (Figure 2), before performing an ultrasound scan to contour a 3D tumor volume. Tracked surgical instruments and ultrasound data were intraoperatively visualized in the open-source 3D Slicer application and its SlicerIGT extension (www.SlicerIGT.org) as described earlier⁵.

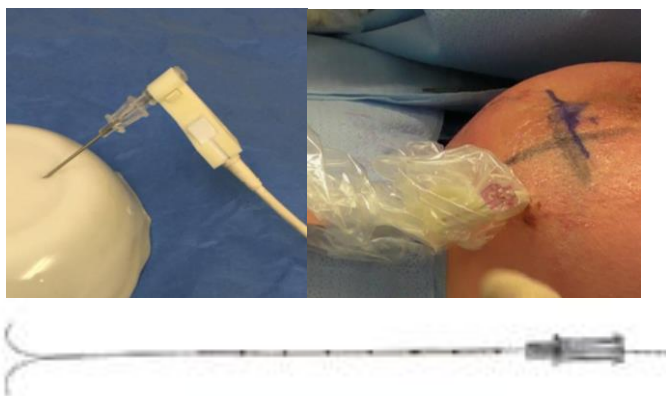


Figure 2: Inserted localization needle with attached sensor and cable without sterile sleeve (left), set-up used in operating room (right), hooked localization needle (bottom).

A custom software module was written using SlicerIGT¹ to visualize image and tracking data, and to calculate the angle between the needle to the coronal plane (NCA). The module automatically sets up a transform hierarchy (Figure 3) to translate the ultrasound images, needle model and tumor model into the same coordinate system. This allows visualization of the ultrasound images with the tracking data and NCA calculations.

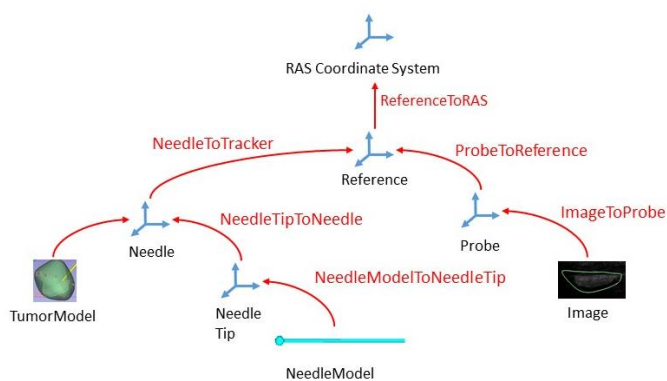


Figure 3: Transform hierarchy

¹ <http://www.slicerigt.org/wp/>

Intra-operative ultrasound scans were collected from 10 patients with non-palpable tumors. Ultrasound scans were evaluated by a physician to quantify needle displacement relative to visible tumor margins. Needle displacement was measured by the change in distance between the needle tip and tumor margins in the direction of the needle axis. Figure 4 illustrates the displacement measurement of interest. Once the software module set up the data for visualization, this measurement was performed manually after the physician identified the tumor boundary.

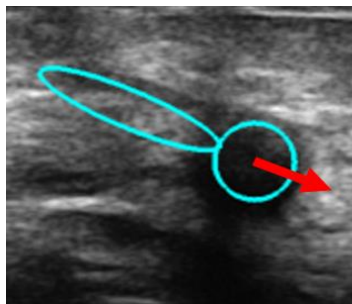


Figure 4: Distance between needle and tumor boundary (right)

An in-plane image (Figure 5) was defined as an ultrasound image that was parallel to the localization needle. In-plane image orientation was used so that displacement could be visualized with respect to the axis of the localization needle. Images that were not in the parallel orientation with respect to the localization needle axis were unable to visualize the needle, and thus were not used. Displacement was measured between two in-plane images, taken from the beginning and the end of the ultrasound recording from contouring the tumor. The two images were recorded approximately 1-3 minutes apart when pressure was applied on the patient's breast in different directions from continuous ultrasound scanning motions in tumor contouring.

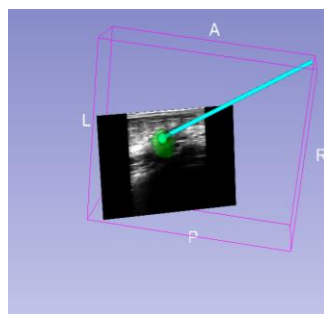


Figure 5: In plane image

The NCA was measured from the direction vectors of the localization needle and the coronal plane (Figure 6), using the first in-plane ultrasound image observed. The cosine of NCA represented the vertical component (anterior-posterior direction relative to the patient in supine position on the operating table), and was used to estimate needle displacement resulting from gravitational and mechanical forces.

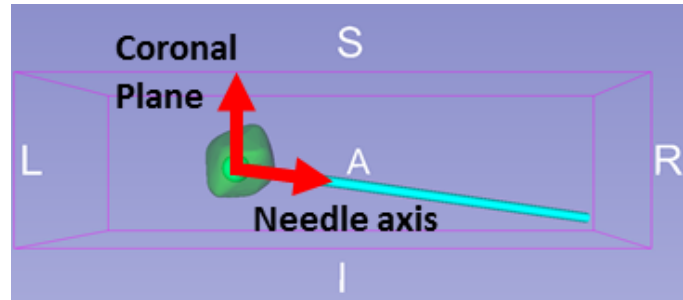


Figure 6: NCA measurement.

3. RESULTS

3.1 NCA Measurement

The needle displacements and NCA-s were measured in 10 cases with non-palpable tumors. Data were collected from 14 patients with non-palpable tumors. However, 4 cases were excluded due to lack of in-plane images with clear needle visibility both at the beginning and the end of the scan.

3.2 Needle Displacement Measurement

Average needle displacement was 1.7 ± 1.2 mm. It was determined that NCA was significantly correlated ($p = 0.04$) with increased needle displacement. As shown in Figure 7, localization needles inserted pointing towards the operating room ceiling tended to experience greater displacement. Average time between the first and last in plane image was 161.0 ± 89.3 seconds. Maximum needle displacement was 4.5 mm.

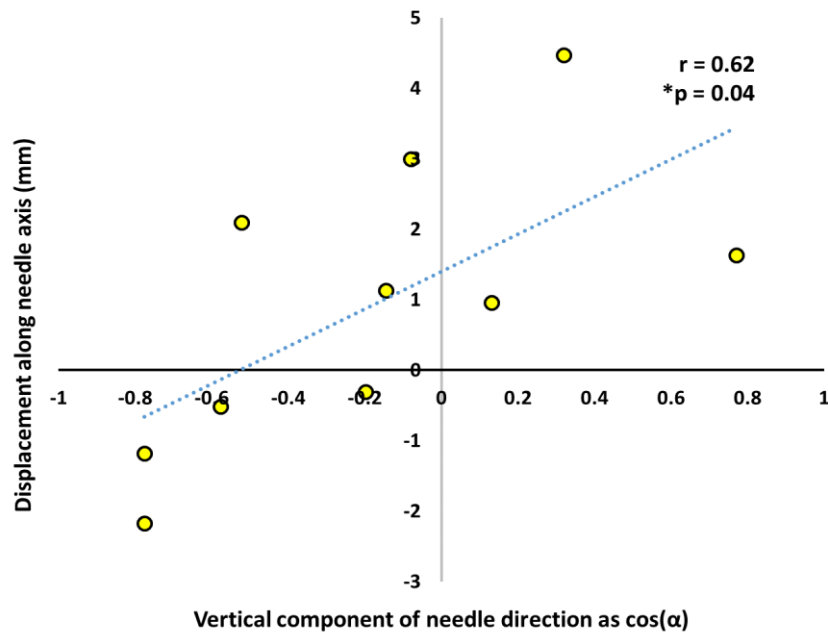


Figure 7: Scatter plot showing the relationship of needle displacement and needle orientation. Displacement is shown along the needle axis relative to the distal tumor margin, between the beginning and the end of ultrasound scan. Positive direction is towards the needle shaft; negative direction is towards the needle tip.

4. DISCUSSION

Three stages of the lumpectomy procedure are especially prone to needle slippage: tumor contouring with ultrasound imaging, tumor excision, and transportation to post-excision specimen X-ray. This study investigated needle displacement when the tumor was contoured. Some needle displacement was evident in this stage, and it is suspected that needle displacement continues during tumor excision. Continued displacement can occur when the surgeon cuts the skin at the insertion site of the needle, reducing the support from surrounding tissue that stabilizes needle position. However, it is not possible to monitor displacement during the resection phase with the methods outlined in this work. Air in the resection cavity interferes with the acoustic coupling needed to obtain informative ultrasound images and for needle displacement measurements. Needle displacement during tumor contouring and excision are the stages of interest, as the surgical outcome is not affected by needle migration that occurs in transportation to post-excision specimen X-ray. The needle may continue to slip once the tumor is removed from the breast because the needle remains in the excised tissue and the structural support from surrounding tissues stabilizing the needle is further reduced. It has been noted in some cases that the radiologist initially inserts the localization needle through the tumor and past the distal margin, and upon post excision X-ray the needle is shown to have partially slipped out of the tumor.

Results suggest that the clinical workflow can also be improved to reduce needle displacement. When the localization needle is initially inserted by the radiologist, the patient is in an angled supine position. However, this position may not be precisely replicated in the operating room during surgery, as surgeons prefer to operate on a fully supine patient for extra stability. Inconsistent positioning can cause errors during tumor contouring, as the mechanical forces deforming the breast tissue may have varying effects on needle displacement when the patient is oriented in different positions.

Prior to the use of tracking technology, using intra-operative ultrasound imaging resulted in a reduced volume of tissue resected in comparison to the guidewire localization technique [Rubio 2016]. The navigation system defined by Ungi et al. incorporates electromagnetic tracking with pre-operative ultrasound imaging and guidewire localization. While clinical results suggest the current lumpectomy navigation system to provide accurate spatial information intra-operatively, this still relies on a fixed needle position, and a rigid relationship between the tracking needle and tumor. As discussed in this work, when the needle can slip from its originally inserted position, the surgeon may be presented with incorrect spatial information that may lead to negative patient outcomes. Clinicians have expressed interest in modifying the current navigation system to remove the tracking needle altogether. Using wireless tumor tracking can monitor the 3D position of the tumor without the added inconvenience of an extra tracking needle. This helps maintain a clear resection cavity and more importantly eliminates the possibility of tracking error from a displaced needle. A wire with an electromagnetic sensor attached may also be used in the place of the tracking needle, and clipped at the skin surface to avoid obstructing the resection cavity.

Alternate methods to guidewire localization have also been explored. Radioactive seed localization has been shown to be a more effective technique to intra-operatively identify cancerous tissue in comparison to wire localization alone [Gray 2004]. However, radioactive seed localization is a more complex procedure. Approximately 0.3%-7.2% of deployed seeds are misplaced, often as a result of technical inexperience, and misplaced seeds cannot be pre-operatively repositioned [Goudreau 2015]. Although the associated radiation is not harmful to the patient, extensive safety training and patient monitoring is required when radioactive seed localization is used, creating additional but avoidable steps to the lumpectomy procedure.

An area of interest for further investigation is the mechanical design of the needle. The hooks on the localization needle are designed to fix the needle position in the tumor, however results suggest that the current DuaLok needle model and other similar tools can be improved to reduce migration. Additional hooks or alternate hooking mechanisms may be necessary to further secure the needle within the tumor. Using more rigid materials may also increase traction and better stabilize the needle.

NEW AND BREAKTHROUGH WORK TO BE PRESENTED

We investigated the displacement of an EM-tracked localization needle in lumpectomy using ultrasound imaging. An analysis of needle movement was performed, and the angle of needle insertion identifies a cause of needle displacement. Modifications to current clinical workflow and improvements upon the mechanical design of the localized needle will be vital in reducing needle displacement.

5. CONCLUSION

Tracking needle displacements from EM navigated lumpectomy procedures were measured. A significant relationship was found between vertically inserted localization needles and increased needle displacement. Results suggest that inserting the localization needle horizontally, parallel with the operating room floor may reduce needle displacement. Improved clinical workflow and mechanical design of the hooked needle, along with an optimal angle of needle insertion can reduce overall needle displacement. This information is valuable in suggesting how the overall navigation system can be improved to reduce needle displacement and the rate of cancer-positive margins.

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REFERENCES

- DeSantis C, Ma J, Bryan L, Jemal A., "Breast cancer statistics", *CA: a cancer journal for clinicians*. 1;64(1):52-62 (2013).
- Goudreau, S. H., Joseph, J. P., & Seiler, S. J. Preoperative radioactive seed localization for nonpalpable breast lesions: technique, pitfalls, and solutions. *Radiographics*, 35(5), 1319-1334 (2015).
- Gray, R. J., Pockaj, B. A., Karstaedt, P. J., & Roarke, M. C., "Radioactive seed localization of nonpalpable breast lesions is better than wire localization", *The American journal of surgery*, 188(4), 377-380 (2004).
- Jung, W., Kang, E., Kim, S. M., Kim, D., Hwang, Y., Sun, Y., Yom, C.K., and Kim, S. W., "Factors associated with re-excision after breast-conserving surgery for early-stage breast cancer", *Journal of breast cancer*. 15(4), 412-419 (2012).
- Rubio, I.T., Esgueva-Colmenarejo, A., Espinosa-Bravo, M., Salazar, J.P., Miranda, I. and Peg, V., "Intraoperative ultrasound-guided lumpectomy versus mammographic wire localization for breast cancer patients after neoadjuvant treatment", *Annals of surgical oncology*. 23(1), 38-43 (2016).
- Stewart B.W., Wild C.P., "World Cancer Report 2014", International Agency for Research on Cancer (IARC), ISBN. 978-92-832-0429-9 (2014).
- Ungi, T., Gauvin, G., Lasso, A., Yeo, C.T., Pezeshki, P., Vaughan, T., Carter, K., Rudan, J., Engel, C.J., Fichtinger, G., "Navigated breast tumor excision using electromagnetically tracked ultrasound and surgical instruments", *IEEE Trans Biomed Eng.* 63(3):600-6 (2016).
- Waljee, J.F., Hu, E.S., Newman, L.A., and Aldermann, A.K., "Predictors of re-excision among women undergoing breast-conserving surgery for cancer," *Annals of Surgical Oncology*, 15(5), 1297-1303 (2008).