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## THE IMPACT OF AN ELECTROMAGNETIC SEED LOCALIZATION DEVICE VERSUS WIRE LOCALIZATION ON BREAST CONSERVING SURGERY: A MATCHED PAIR ANALYSIS

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### Abstract

**Background.**—For breast-conserving surgery(BCS), several alternatives to wire-localization(WL) have been developed. The newest, electromagnetic seed localization(ESL), provides three-dimensional navigation utilizing the electrosurgical tool. This study assessed operative times, specimen volumes, margin positivity, and re-excision rates for ESL and WL.

**Methods.**—Patients having ESL-guided breast conserving surgery between 8/2020 and 8/2021 were reviewed and matched one-to-one with patients having WL based on surgeon, procedure type, and pathology. Variables were compared between ESL and WL using Wilcoxon rank sum and Fisher's exact tests.

**Results.**—Ninety-seven patients who underwent excisional biopsy(n=20) or partial mastectomy with(n=53) or without(n=24) sentinel lymph node biopsy(SLNB) using ESL were matched. Median operative time for ESL vs WL for lumpectomy with SLNB was 66 vs. 69 minutes (p=0.76) and without SLNB was 40 vs. 34.5 minutes (p=0.17). Median specimen volume was 36 cm<sup>3</sup> using ESL vs. 55 cm<sup>3</sup> with WL (p=0.001). In those with measurable tumor volume, excess tissue was greater using WL as versus ESL (median=73.2 vs 52.5 cm<sup>3</sup>, p=0.017). Margins were positive for 10 of 97 (10%) ESL patients and 18 of 97 (19%) WL patients (p=0.17). In the ESL group, 6 of 97 (6%) had a subsequent re-excision, compared to 13 of 97 in the WL group (13%), (p=0.15).

**Conclusions.**—ESL is more accurate than WL, evidenced by decreased specimen volume and excess tissue excised despite similar operative times. Although not statistically significant, ESL resulted in fewer positive margins and re-excisions than WL. Further studies are needed to confirm that ESL is most advantageous.

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#### DISCLOSURES

Dr. Bleicher became a consultant for Elucent Medical after completion of the study and data analysis.

## INTRODUCTION

Breast cancer is the most common cancer diagnosed in women in the United States, and the most common cancer diagnosed globally as of 2021.<sup>1</sup> With the implementation of screening protocols for both average and high-risk women, many cancers are being found at an earlier stage, making them amenable to breast conserving surgery (BCS). This has become increasingly popular since BCS was proven to have a survival equivalent to mastectomy when combined with radiation<sup>2,3</sup> which together constitutes breast conserving therapy (BCT). Many of these newly diagnosed breast cancers are not palpable, and therefore require pre-operative localization prior to BCS.

Wire localization (WL), the first pre-operative radiographic localization technique developed nearly 50 years ago, remains the standard technique used today.<sup>4</sup> Since that time, WL has seen many changes, now with a variety of wires available and placement possible under mammographic, tomographic, sonographic, or magnetic resonance guidance. Wire localization has several advantages in that it is cost effective compared to non-wire options<sup>5</sup>, is not radioactive, and that multiple wires can be utilized for multifocal or extensive disease by bracketing the area in question. However, multiple disadvantages have been demonstrated with this technology as well. The wire may migrate or become fractured before and during surgery,<sup>5,6</sup> may cause significant discomfort or vasovagal symptoms in some patients<sup>8</sup>, and because one end sticks out of the patient, must be placed on the same day as surgery, which can lead to delays in operation start time. Over the past two decades, several non-wire localization alternatives have been developed including radioactive seed localization (RSL), magnetic seed localization (MSL), radiofrequency identification (RFID) guided localization, and reflector guided localization (RGL). Recently developed, wireless electromagnetic seed localization (ESL; EnVisio Navigation System, Elucent Technologies, Eden Prairie, MN) utilizes a percutaneously placed detection marker (“SmartClip”™, SC) to provide real-time, three-dimensional navigation during surgery.

The system is comprised of a console, display, patient pad, and foot pedal as well as a sterile navigator and calibration disk. Intraoperatively, the patient pad connected to the device is placed on the thoracic region of the operating room table, and the navigation probe, which is smaller than the electrocautery instrument, is attached to and calibrated on the electrocautery tool using a calibration disk. This allows distance to be measured and displayed in three dimensions between the tip of the electrocautery device (not the affixed probe) and the marker for ease of dissection. The probe communicates with the activated SC which emits a high frequency signal transmitted between the surgical bed pad and navigation tool.

Similar to Global Positioning System (GPS) navigation, it provides a continuous relative location between the clip and electrocautery pen so the surgeon need only focus on the location of the electrocautery for dissection to the SC, without having to move the cautery out of the way of a separate detection probe, as the two are attached. This differs from other wireless localization technologies that often require an optical direct sight line and show only distance to the tip of the detector necessitating movement of the detector to determine directionality. These distances are then pictured on a tablet display screen with constant

measurements of depth, distance, and superior/inferior, lateral/medial, and superficial/deep distances provided within millimeters of accuracy (Figures 2–3).

The SCs can be placed either into a breast primary or used to localize a lymph node for targeted axillary dissection after neoadjuvant chemotherapy. Up to three differentiated SCs can be utilized for multifocal disease or for bracketing.<sup>7</sup> This technology, to date, is the only one to provide both distance and three-dimensional directionality, as the other technologies provide distance to the marker alone.

While several studies have compared non-WL techniques to WL, to our knowledge, no data exists in the United States evaluating the newer ESL technology. This study was performed to assess the impact of this new localization method on operative times, specimen volumes, margin positivity, and margin re-excision rates, versus WL.

## METHODS

This study was evaluated and approved by the Fox Chase Cancer Center Institutional Review Board. Patients undergoing ESL-guided BCS between August 2020 and August 2021 by five breast surgeons at a single institution were reviewed. Inclusion criteria encompassed males or females over 18 years of age, those who underwent lumpectomy for invasive or *in situ* breast cancer, excisional biopsy for benign pathology, or lumpectomy with sentinel lymph node biopsy/axillary dissection. All operative procedures were performed between the specified dates using pre-operative localization using ESL and at least one SC or WL. Patients were excluded if they did not undergo BCS, underwent BCS in combination with reconstruction or mastectomy, their medical records did not contain critical variables, or could not be matched based on a minimum of surgeon and procedure.

Qualifying patients were then matched 1:1 to a patient who underwent BCS with WL between 2006 and 2021. WL was rarely performed after the implementation of ESL (August 2020), and only when ESL was felt to not be feasible. This was primarily because of body habitus of the patients, as there is a theoretical 35 cm anterior-posterior maximum thoracic distance in which the technology is guaranteed to work. Matching was based on surgeon, procedure type with stratification for those having or not having nodal procedures, and pathologic stage or benign pathology. When more than one match was identified, selection was randomized. If pathologic overall stage was not available, matches were based on pathologic T stage. For benign pathology, matches were determined by ICD-10 benign diagnosis codes grouped to include atypical ductal hyperplasia, atypical lobular hyperplasia, lobular carcinoma in situ, radial scar, intraductal papilloma, fibroadenoma and benign phyllodes tumor.

Data were collected and stored in a password protected RedCap Database. Operative times were determined by medical records review, to determine the time from incision to closure via the anesthesia record. Main segment volumes (cm<sup>3</sup>), defined as the total primary lumpectomy resection specimen encompassing the tumor, were calculated using specimen dimensions provided in the pathology report. When available, discrete tumor volume (cm<sup>3</sup>) was also determined using pathology documentation. Data was collected to account for

additional cavity shave margins which were taken at the time of surgery based on surgeons' practices and discretion. For some surgeons the preference was routine shave margins, while for others, shave margins were directed by findings based on intraoperative imaging. Total specimen size was calculated as lumpectomy volume plus shave margin volumes. Excess tissue excised was calculated as total specimen size minus tumor volume. Positive margin specifics and re-excisions required at a separate operation were recorded from the medical record.

Main segment margins were used to determine margin positivity as it was felt this best represented the accuracy of the localization technology and additional shave margins were based on surgeon discretion. Re-excisions were performed in accordance with indications as outlined in the SSO/ASCO/ASTRO consensus statements, where pure DCIS lesions necessitated re-excision for margins closer than 2 mm, and those having an invasive component >1mm necessitated re-excision for positive margins, unless the margin was on skin or chest wall.<sup>9-10</sup> Intra-operative x-ray was standardly used by all surgeons throughout the cohort to confirm the presence of the SC or wire(s) and the biopsy clip(s) during the entire period evaluated.

Continuous (e.g., operative times, specimen size, excess volume excised) and categorical variables (e.g., positive margin rates, re-excision rates) were compared between patients undergoing BCS with ESL as versus WL using Wilcoxon rank sum tests and Fisher's exact tests, respectively.

## RESULTS

Between August 2020 and August 2021, 179 patients were identified of whom 97 met inclusion criteria and were matched with a WL patient having surgery between 2006 and 2021 (Figure 1). Of the WL cohort, \*\*\* were performed after the implementation of ESL. Fifty-three ESL-WL matched pairs underwent partial mastectomy with sentinel lymph node biopsy (SLNB), 24 underwent partial mastectomy without SLNB, while 20 pairs had an excisional biopsy using ESL. Of the cohort, \*\*\* ESL patients had 2 or more SC placed while \*\*\* WL patients had more than 1 needle placed for bracketing. The matched set sample included 190 females and four males. Median age in the ESL group was 64 vs. 61 in the WL group ( $p=0.15$ , Interquartile Range (IQR) 57-71 and 53-69 respectively). In the ESL group, median body mass index (BMI) was 27.6 (IQR 24.2-34.7) compared to WL with a median BMI of 30.5 (IQR 25.2-34.3,  $p=0.34$ ). Race was not collected as utilization of ESL was implemented in patients across all races and ethnicities in August of 2020 and therefore not felt to be germane to the procedures or outcomes being evaluated (partial mastectomy operative case times, specimens resected, margins, and reexcisions). Benign pathology was seen in 25 pairs while 72 pairs underwent surgery for malignant pathology. Most malignant lesions were pathologic stage 0 ( $n=18$  ESL,  $n=16$  WL) or stage 1A ( $n=44$  ESL,  $n=53$  WL). (Table 1)

Median operative time for ESL vs WL for lumpectomy with SLNB was 66 vs. 69 minutes ( $p=0.76$ ) and without SLNB was 40 vs. 34.5 minutes ( $p=0.17$ ). Median specimen volume was 36 cm<sup>3</sup> in ESL vs. 55 cm<sup>3</sup> with WL ( $p=0.001$ ). In those with measurable tumor/

benign lesion volume (ESL n=79, WL n=83), median volume with ESL vs. WL was 0.39 cm<sup>3</sup> vs. 0.77 cm<sup>3</sup> (p=0.07). Excess tissue excised was larger with WL compared to ESL (median=73.2 vs 52.5 cm<sup>3</sup>, p=0.017). (Table 2)

Additional shave margins were taken in 63 ESL patients and 55 WL patients. Main segment margins were positive in 10 of 97 (10%) ESL patients compared to 18 of 97 (19%) WL patients (p=0.17). In the ESL group, 6 of 97 (6%) had margin re-excision at a separate procedure, compared to 13 of 97 (13%) in the WL group, (p=0.15).

Of those with positive main segment margins in the ESL group (n=10), 6 had a single positive margin [anterior (n=2), inferior (n=1), lateral (n=1), medial (n=2)] and 4 had multiple margins positive [inferior/posterior (n=1), inferior/superior (n=2), superior/medial (n=1)]. Final pathology for these patients included invasive ductal carcinoma (n=5), invasive lobular carcinoma (n=2), and ductal carcinoma in situ (n=3). Of the WL group with positive main segment margins (n=18), 11 had a single positive margin [anterior (n=3), lateral (n=2), medial (n=2), posterior (n=2), superior (n=2)] while 7 had multiple positive margins [anterior/lateral (n=1), anterior/Posterior (n=1), inferior/lateral/posterior (n=1), medial/posterior (n=1), superior/medial (n=2), superior/posterior (n=1)]. Final pathologies included invasive ductal carcinoma (n=7) and ductal carcinoma in situ (n=11). (Table 3)

In the ESL group, 6 of the 10 patients proceeded with margin re-excision. Four patients did not undergo re-excision due to no further tissue at that margin (n=1), a negative peripheral shave margin (n=1), or patient choice (n=2). In the WL group of main segment margin positive patients, 12 underwent margin re-excision. Of the 6 that did not, 4 had no further tissue at the positive margin, 1 had a negative peripheral margin, and 1 was unknown. There was one WL group patient who underwent margin re-excision after negative main segment margins due to positive peripheral margins.

## DISCUSSION

Satisfactory preoperative localization is paramount for performing safe and effective BCS for non-palpable breast lesions. The ideal pre-operative localization modality optimizes patient comfort, surgical efficiency, localization accuracy, and provides the potential to achieve adequate margins while removing the least tissue possible, while also being cost and time efficient. This study showed ESL to be superior to WL as evidenced by smaller overall specimen and excess tissue volumes excised while having comparable operative times.

Wire localization, changed the landscape of breast conserving surgery for non-palpable lesions. While proven to be cost effective and safe, this technique has been associated with patient discomfort, scheduling conflicts, operative delays, and is subject to wire migration or fracturing.<sup>5,6</sup> Several novel non-wire localization technologies have been developed to mitigate these disadvantages, including radioactive seed localization, magnetic seed localization, and reflector guided localization with radioactive seed localization waning because of regulatory requirements. General advantages of non-wire techniques include less tissue removal, improved workflow, and improved psychological effects of a visible wire.<sup>11</sup> Some disadvantages of these techniques involve migration of the seed, limitations

of placement, such as the fact that magnetic seeds are not MRI compatible and some seeds are limited to shallow depths of placement, and the inability to reposition the seed once placed. In addition, several have evaluated intra-operative ultrasound guided excision as an alternative to wire localization, but this is limited to lesions visible by ultrasound and is user dependent.

As with other non-wire techniques, workflow for SC placement differs than that of WL. The SC may be placed on any date prior to the operative procedure via 15G needle deployment under ultrasound or mammographic guidance and is FDA approved to stay in the breast. At our institution, the SC is typically placed the same date as preadmission testing to eliminate the need for multiple visits. Because the SC is placed on a date prior to the operative date, ESL cases could be performed as the first case. This was in contrast to WL being performed the morning of surgery which was prohibitive to performing WL cases at the start of the day. While requiring one additional visit, placement of the SC on a prior date removes the stress and potential delays of same day placement and logistical issues related to external wire discomfort for the patient.

One of the most dramatic findings from this study was the difference in both specimen volumes and excess tissue volumes between ESL and WL. Median specimen volume was 55 cm<sup>3</sup> with WL vs. 36 cm<sup>3</sup> in ESL (p=0.001) while excess tissue excised was larger with WL compared to ESL (median=73.2 vs 52.5 cm<sup>3</sup>, p=0.017). Differing results have been shown in studies comparing RSL and RFL to WL with Chagpar et al. finding no significant difference in specimen volume between the three modalities<sup>12</sup>. However, Srour et al. found that WL did result in greater volume of tissue excised when multiple markers or wires were used<sup>13</sup>. As technologies improve, more focus is being placed on aesthetic outcomes and oncoplastic techniques, making the amount of excess tissue excised increasingly important to consider. By removing less tissue while maintaining safe oncologic results, patients will have less tissue deficits, require fewer oncoplastic rearrangements, and have smaller noticeable discrepancies between breasts. Like other non-wire options, the SC-based, three-dimensional navigation also allows for variability with more aesthetically placed incisions whereas the location of the wire often times dictates incision choice in WL. Additionally, the ESL display indicates measurements in three dimensions (anterior-posterior, medial-lateral, and superior-inferior), providing localization information that is not available via WL or other current technologies.

Although not statistically significant, ESL resulted in a lower positive margins rate and fewer margin re-excisions compared to WL. This is consistent with other non-wire localization technologies, including RFID and RSL which have been shown to have improved to similar rates of positive margins and re-excisions without statistical significance<sup>12-15</sup>. Although in a recent randomized control trial, Taylor et al. reported statistically lower re-excision rates with RSL as versus WL although there was no statistically significant difference in positive margin rates<sup>16</sup>. Within our data, there was a difference between the number of positive main segment margins and those having re-excisions in both ESL and WL patients. This is explained by the presence of negative shave margins in the same patient, no further tissue to be excised at said margin due to



dissection down to chest wall or to skin, or patient preference to not proceed with further surgery.

There was also no significant difference seen in operative times between patients undergoing ESL vs WL for both lumpectomy/excisional biopsy without axillary nodal surgery and for those including axillary sentinel lymph node biopsy. This is somewhat unexpected as one of the advantages of this ESL technology is that it allows for a single tool, three-dimensional localization not afforded in wire localization. While unexpected, this is also consistent with other non-wire localization tools which have shown to have similar operative times when compared to WL<sup>13,14</sup>. This could be explained by the learning curve required for a new technology at a single institution that has classically utilized WL as well as the presence of training fellows and residents participating in surgical cases. Although ESL provides distinct benefits as versus wire localization, there are disadvantages, similar to those of other non-wire technologies. There is potential for seed migration, although this is exceedingly rare and was not encountered during the study period. While the bloom on MRI from the SC is not insignificant, it remains smaller than that caused by ferromagnetic seeds, making placement after post-neoadjuvant MRI imaging advisable. Additionally, while cost was not specifically analyzed, we do believe ESL to be more costly than wire localization and requires an investment in specialized equipment.

This study does have several limitations. First, this study is retrospective in nature and performed at a single institution. Additionally, the sample size was limited in order for us to meet strict matching and inclusion criteria. However, this is comparable to the standards set by previous studies evaluating other non-wire localization techniques, and was done in rigorous fashion to limit confounders by creating the matched cohort. Attempts were made to avoid the impact of confounding variables by matching patients one to one based on surgeon, procedure, and pathology. Additionally, cost analysis was not performed and would be a valuable addition to the data presented.

## CONCLUSION

ESL is superior to WL as it enables excision in similar time, but minimizes excess tissue resected without compromising margin status which has the potential to improve cosmesis. Although not statistically significant, ESL resulted in lower positive margins rates and margin re-excision compared to WL. The ESL technology allows for single-tool, three-dimensional localization with the patient convenience of pre-operative placement. Further assessment of ESL as versus other localization technologies should be evaluated to refine which localization technology is most advantageous in breast conservation surgery.

## ACKNOWLEDGEMENTS

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**SYNOPSIS**

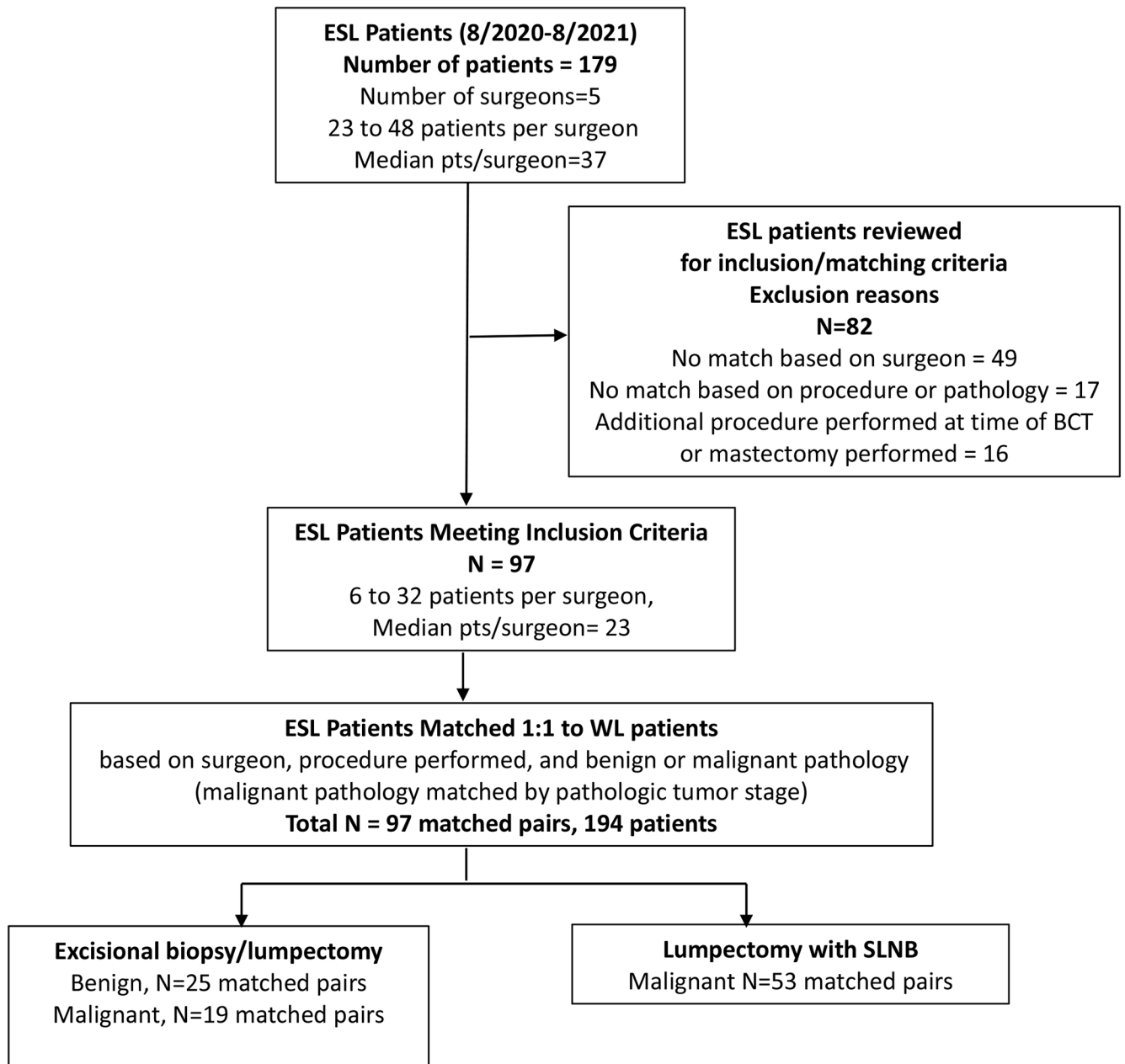
A new technique for breast conservation, electromagnetic seed localization (ESL), was evaluated versus wire localization. ESL results in statistically smaller specimen and excess tissue volumes without compromising operative times. Although not significant, ESL resulted in fewer positive margins and re-excisions.

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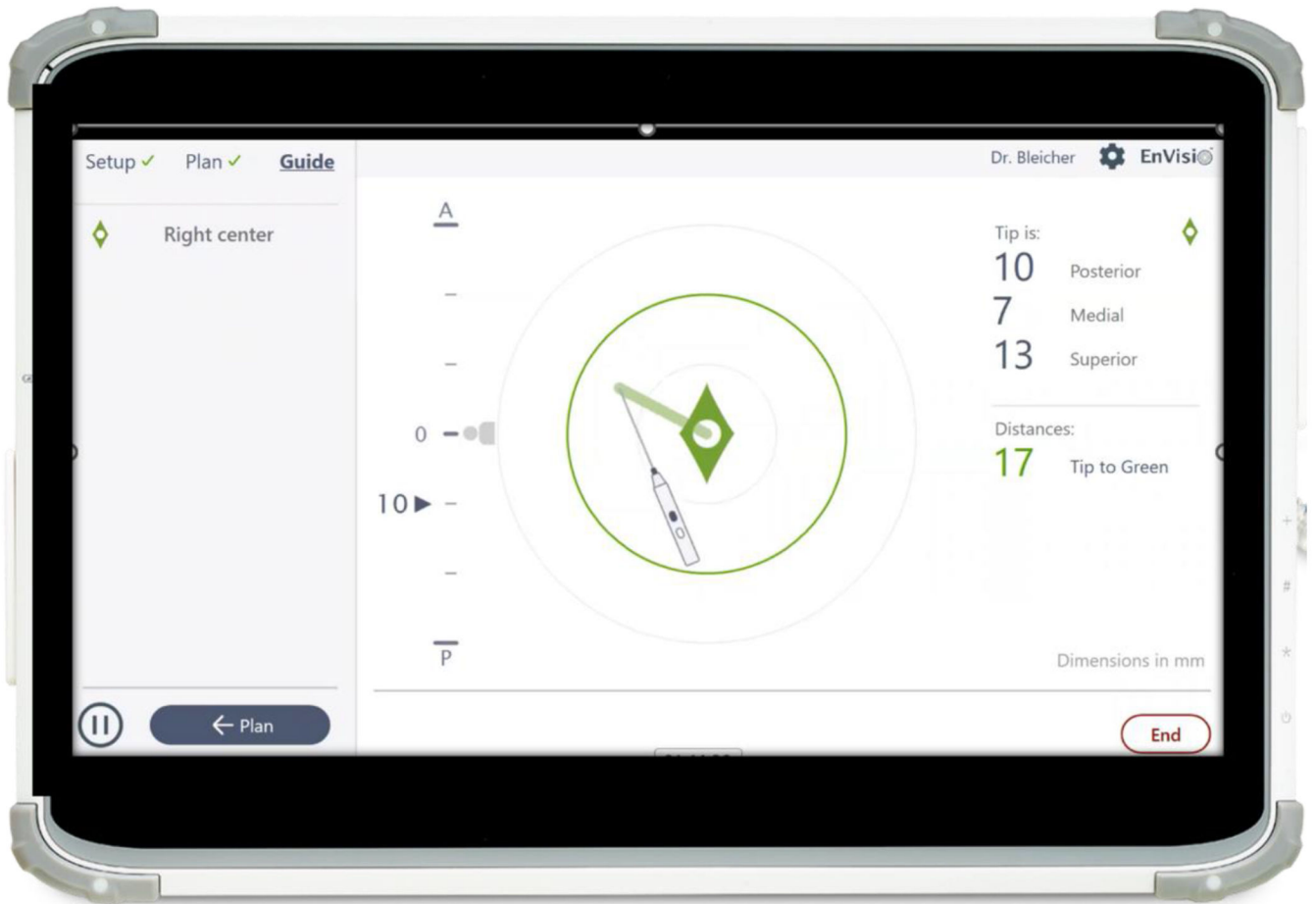
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**Figure 1:**  
Inclusion Criteria



**Figure 2:**  
Electromagnetic Seed Localization Navigator



**Figure 3: Electromagnetic Seed Localization Display**

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**Table 1:**

Characteristics by type of localization. Table shows frequency unless otherwise specified.

Characteristic	Wire Localization	Electromagnetic Seed Localization	p
Age (years), median [IQR]	61 [53-69]	64 [57-71]	0.15
BMI (kg/m <sup>2</sup> ), median [IQR]	30.5 [25.2-34.3]	27.6 [24.2-34.7]	0.34
Sex			0.62
Male	1	3	
Female	96	94	
Pathology*			
Benign	25	25	
ADH	4	2	
ADH, ALH	0	1	
ADH, Radial scar	1	0	
ALH	1	1	
ALH, Radial scar, Other	0	1	
Fibroadenoma	2	2	
LCIS	2	0	
LCIS, ALH	1	1	
LCIS, Papilloma	0	1	
Papilloma	3	8	
Papilloma, Fibroadenoma	1	0	
Papilloma, Other	1	0	
Radial Scar	4	1	
Radial Scar, Other	1	0	
Other	4	8	
Malignant	72	72	
Ductal carcinoma in situ	18	18	
Invasive ductal carcinoma	47	42	
Invasive lobular carcinoma	4	10	
Carcinoma other	3	1	
Procedure*			
Without SLNB			
Excisional biopsy	28	24	
Lumpectomy	16	20	
With SLNB			
Lumpectomy with SLNB	52	53	
Lumpectomy with SLNB/Axillary Dissection	1	0	
Neoadjuvant chemotherapy given	0	1	1.00
Grade			0.24

Characteristic	Wire Localization	Electromagnetic Seed Localization	p
1	16	17	
2	40	34	
3	10	20	
N/A	31	26	
Pathologic T-Stage			1.00**
Benign	25	25	
pT1mi	5	4	
pTis	15	15	
pT1a	8	9	
pT1b	16	17	
pT1c	21	21	
pT2	3	2	
No remaining tumor identified	4	4	
Pathologic Stage (benign omitted)			0.076
No clinical stage recommended/stage unknown	0	2	
Stage 0: Tis	16	18	
Stage IA	53	44	
Stage IB	1	7	
Stage IIA	2	1	

*IQR* Interquartile range, *BMI* Body Mass Index; *ADH* Atypical Ductal Hyperplasia; *ALH* Atypical Lobular Hyperplasia; *LCIS* Lobular carcinoma in situ; *SLNB* Sentinel lymph node biopsy

\* matching variables included pathology (benign vs malignant), procedure (without SLNB vs with SLNB)

\*\* p value compares pT distribution by localization type in non-Benign tumors (as benign /malignant was a matching criterion).



**Table 2:**

BCS surgery variables by type of localization

Variable	Wire Localization	Electromagnetic Seed Localization	p-value
Operative Times (Median-minutes)			
Excisional biopsy/Lumpectomy	34.5	40	0.17
Lumpectomy with SLNB	69	66	0.76
Specimen Volume (Median-cm <sup>3</sup> )	55	36	0.001
Excess Tissue Volume Excised (Median-cm <sup>3</sup> )	73.2	52.5	0.017
Main segment positive margins	18/97 (19%)	10/97 (10%)	0.15
Peripheral margins taken (same surgery)	55/97 (57%)	63/97 (65%)	0.30
Peripheral margins positive	5/55 (9%)	4/63 (6%)	0.73
Margin Re-excision	13/97 (13%)	6/97 (6%)	0.15

SLNB Sentinel lymph node biopsy

**Table 3:****Main Segment Positive Margins by Localization Technique**

	<b>Wire Localization</b>	<b>Electromagnetic Seed Localization</b>	<b>p-value</b>
Main Segment Positive Margins	18/97 (19%)	10/97 (10%)	0.15
One margin positive	11/18 (61%)	6/10 (60%)	
Anterior	3	2	
Posterior	2		
Inferior		1	
Superior	2		
Lateral	2	1	
Medial	2	2	
Two or more margins positive	7/18 (39%)	4/10 (40%)	
Inferior/Posterior		1	
Inferior/Superior		2	
Superior/Medial	2	1	
Anterior/Lateral	1		
Anterior/Posterior	1		
Medial/Posterior	1		
Superior/Posterior	1		
Inferior/Lateral/Posterior	1		
Pathology			
Ductal Carcinoma in Situ	11	3	
Invasive Ductal Carcinoma	7	5	
Invasive Lobular Carcinoma		2	