Breast conservation surgery re-excision rates improved with utilization of the MarginMap specimen orientation charms

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Abstract:

There are many roles that a breast imaging radiologist has: a champion for the use of screening mammography to identify breast cancers early, performing diagnostic examinations to help rule in or out cancers, assessing for the extent of disease or response to neoadjuvant chemotherapy, and a comforter and guide for our patients who have questions about their diagnosis and disease process. However, a major role played by the radiologist that is sometimes overlooked is that of a guide to the surgeon on the day of surgery for patients who choose to have breast conservation surgery or a lumpectomy. The aim of this article will be to briefly review the different specimen markers that are available at the surgeon's disposal. We will then illustrate that after implementing a standardized methodology for orienting lumpectomy specimens with the MarginMap® specimen orientation charms, Beekley Medical®, Bristol, CT, by our team that it is the most reliable and efficient way for the radiologist, pathologist, and surgeons to communicate on the day of the breast conservation surgery.

Keywords: MarginMap® charms, breast conservation surgery, breast cancer screening, specimen orientation

Introduction:

In 2024, breast cancer was noted as the most common cancer diagnosed in women in the USA and the second leading cause of cancer death after lung cancer.[1] It is well established that approximately 1 in 8 women will get invasive cancer in their lifetime.[2] Together with lung and colorectal cancer, the second and third most common cancer diagnosis in women, these three diseases account for 52% of all cancers diagnosed in women. Data from the National Cancer Institute (NIH) estimate that approximately 310,720 women will be diagnosed with breast cancer, with a mortality rate of 42,250 women.[3]

There are many risk factors that are associated with the potential development of breast cancer, ranging from one's diet to the environment, but not a single factor has been scientifically proven to cause a genetic mutation leading to breast cancer.[4] Due to the initial developmental phase of this disease when a woman can be asymptomatic, it is the power of mammographic imaging, the gold standard when it comes to mass screening, that has demonstrated a strong role in early detection, which can lead to a better prognostic outcome.[5]

The outcome for many women is breast conservation surgery (BCS), which may be used as part of a treatment plan. This procedure is also sometimes referred to as a lumpectomy or a partial mastectomy, depending on how much of the breast tissue is removed.[6] BCS is an alternative to a mastectomy, which removes a woman's entire breast. BCS is often followed by radiation therapy, which serves to reduce the risk of cancer returning.[7] But how is the decision made regarding which procedure the patient should undergo? The prerequisites are based on an interplay of many factors that starts with a fully informed discussion about all the possible surgical options available to the patient, the extent or burden of disease that was demonstrated after the original histologic diagnosis, and a review of the patient's medical history and physical examination.[8] Analysis of the overall survival for BCS and mastectomy indicates a similar survival rate if all tumor margins are negative. When radiation therapy is added to BCS and then compared to mastectomy at the 3, 5, and

10-year intervals, the survival rate is 96.5% vs. 93.4%, 92.9% vs. 88.3%, and 80.9% vs. 67.2 %, respectively.[9] Therefore, in the long run, BCS appears to be a greater benefit to the patient, but only if the breast cancer tissue margins are free of tumor.

Tumor at the margins of a surgically excised breast cancer leads to local recurrence of breast cancer. Therefore, the accurate assessment for clear margins radiologically at the time of surgery is imperative to decreasing the possibility of need for re-excision, which is necessary to decrease the risk of local recurrence.[10]

The only remedy to positive margins is a second operation, sometimes as long as 1-3 weeks after the initial surgery, to re-excise the margins when pathologically detected cancer cells are present at the edge of the resected breast cancer specimen. Re-excision rates for breast cancer lumpectomies vary widely across institutions from 12% to as high as 20-40% for an individual surgeon.[11]

When re-excision surgeries are performed, there are potential complications that can impact patient care. These include, a delay in other essential components of treatment of the cancer, including radiation therapy and possibly chemotherapy; an increased risk of infection, hematoma, seroma, fat necrosis; prolonged postoperative pain; increased scarring and potential deformity at the re-excision site and an increased in anxiety secondary to all of the factors stated, which can undermine the patient's trust in her ongoing and future health care delivery.[12] In addition, there is an increased cost to the healthcare system as described later in this paper.

In their paper Metcalfe et al discussed how women undergoing repeated surgery to achieve clear margins after lumpectomy had a 47.6% higher risk of at least one complication, and 89.1% risk of multiple complications compared with patients undergoing only a single lumpectomy. At 3 months following lumpectomy, complications were twice as likely for those patients having repeated breast surgery.[12]

Logically, avoiding re-excision is the best patient quality care. Several techniques exist for decreasing the need for re-excision, including but not limited to various surgical techniques, utilization of injectable agents and intraoperative probes.[13,14]

The pilot study presented in this paper presents an inexpensive tool utilized at the critical point of radiologic evaluation at the time of the initial excision of the breast cancer with collaboration of the radiologic evaluation of the tissue. This tool is shown here to decrease the need for re-excision of positive breast cancer margins by providing a more accurate means of identifying the orientation of the specimen margins on radiograph of the breast cancer specimen, thus proving critical orientation to the pathologist who will examine the tissue microscopically.

However, there are two fundamental steps that provide the greatest assistance to surgeons that increases accuracy at the time of surgery. First, is the initial evaluation of all of the patient's radiologic imaging that demonstrates the cancer. Second, is the critically important collaborative communication with the radiologist who evaluates the excised breast cancer specimen radiologically in real time while the patient is in surgery.

This pilot study demonstrates that the MarginMap® facilitates the radiologist's accuracy in describing the margins to the surgeon to determine if additional tissue is to be excised at the time of the initial surgery, and if so, which specific margins.

As patients are prepared for their BCS, options to approach the targeted area for the surgeon can be based on a wire or wire-free approach. Many surgeons have transitioned to the wire-free method as it presents many benefits. It decouples the radiological procedure from the surgical procedure as it allows placement of the wire-free device before the day of surgery; it improves patient comfort since a metallic wire is not extending out of their breast, which in turn decreases the risk of the wire being pulled out of the breast. Most importantly, the surgeon is not confined to a set incision approach or direction.[15] By tradition, many believed that this is where the radiologist plays the most important role as they serve as the guide for the surgeon to indicate where the target resides through localization. However, this belief overlooks the crucial role that imaging plays in assessing the accuracy of the specimen that is subsequently excised. This first-look assessment facilitates the intricate coordination between the surgeon and the radiologist before the pathologist is called in to demonstrate their skillset and more or less confirms what the radiologist reported on the margins.

But how can the radiologist best accomplish communicating with the surgeon, if the margins are close or cleared on the excised tissue? What tools do they have available in their arsenal? There are many different methods for specimen evaluation to communicate the specimen orientation to the pathologist for margin assessment during BCS.

One of these methods includes dyes or inks applied to the specimen edge. However, this presents a limitation for the radiologist, who cannot visualize the dyes or inks on a specimen radiograph to effectively communicate with the surgeon to minimize the amount of tissue removed from the lumpectomy bed. Also, most pathologists would prefer that dyes and inks not be placed on the specimen before it arrives in the pathology lab, as they perform special staining on the specimen. For example, the University of Chicago Department of Pathology lab applies inks as follows: anterior – orange, posterior – black, medial – green, lateral – yellow, superior – blue, and inferior – red. (Fig. 1A)

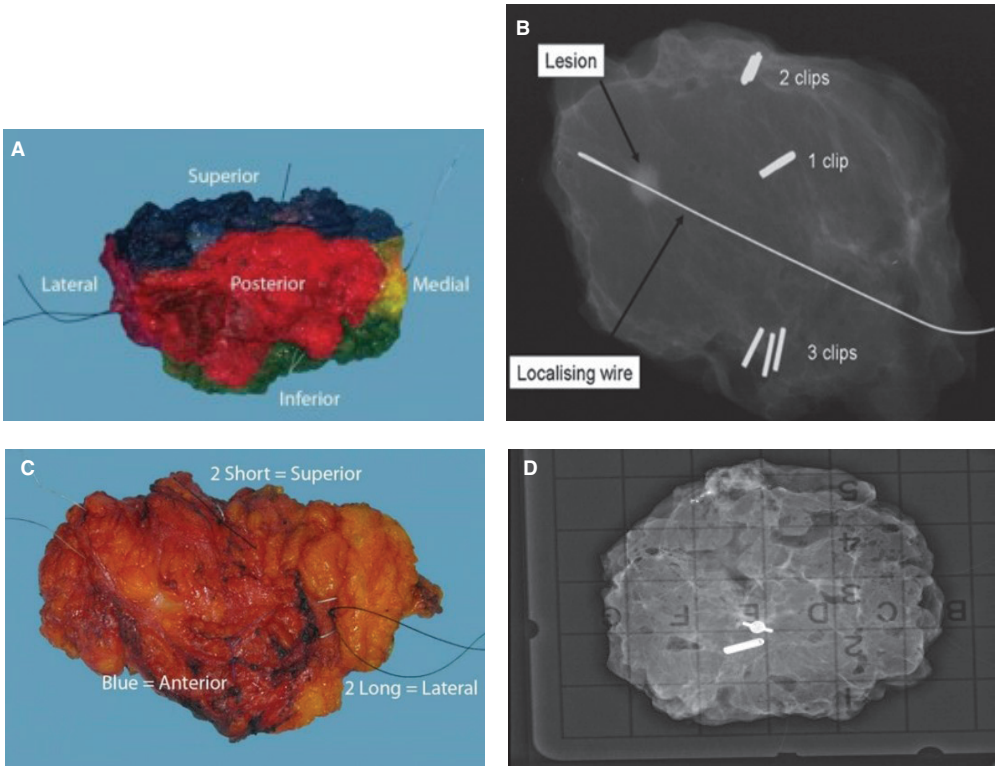

Figure 1. (A) Ink application to mark the specimen in the pathology department. (B) Surgical clips to mark the specimen. (C) String technique to mark the specimen - gross. (D) String technique to mark the specimen - radiograph.

Another method involving using surgical clips in varying numbers to mark the specimen can result in errors if clips overlap on the radiograph. During the radiograph assessment, the radiologist is once again given the tedious task of having the technologist repeat multiple images to unveil the correct position and orientation of the surgical clips. (Fig.1B)

Similarly, using surgical sutures of different lengths to indicate margin locations also has limitations. For instance, the pathologist can infer the medial and inferior margins of the specimen when two strings are utilized – one short to indicate the superior margin and one long to indicate the lateral margin. (Fig.1C) But if the radiograph cuts off the long string, making both strings appear the same length (Fig. 1D), what is the radiologist left to interpret? How can the radiologist effectively discuss with the surgeon in real-time while in the operating room whether additional tissue needs to be removed from the patient's breast?

In switching from the string method, our team was able to implement a standardized methodology for orienting lumpectomy specimens using MarginMap® specimen orientation charms.

Implementation of this new orientation system improved communication between surgeons, radiologists, and pathologists, improved the speed of reporting the specimen state, reduced the risk of errors in reading the specimens, and in turn decreased the re-excision rate. (Fig. 2)

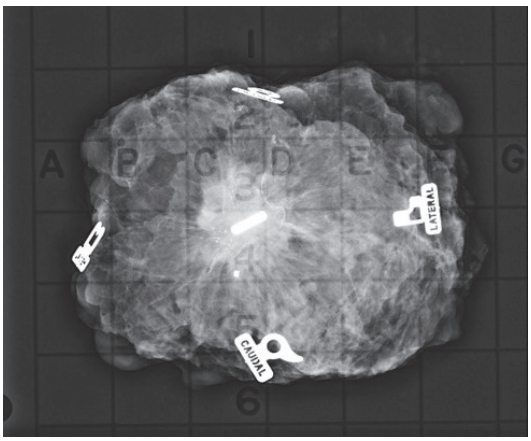

Figure 2 – Radiograph of MarginMap® Specimen Orientation Charms used to label the specimen

This ultimately leads to improved overall patient care for women with breast cancer by decreasing the number of patients requiring a second potentially avoidable operation. By avoiding a second surgery, patients benefit from not having to be exposed to the increased risk of infection and increased scarring and deformity, which can be seen with re-excision. Patients are also prevented from the increased mental and physical stress, and anxiety of facing a delay in the other vital components of their treatment of radiation, and, for many chemotherapy. Economically, patients benefit from shorter recuperations with a single surgery, and thus sooner return to their life

routines and less time away from work. The health care system benefits from avoidance of the medical costs of a second procedure.

Launched in 2003 by Beekley Medical®, the MarginMap specimen orientation charms system was invented by a surgery and radiology team at Bristol Hospital in Bristol, CT. It is an effective and accurate method for helping the radiologist quickly and easily communicate the specimen's margins to the surgeon. MarginMap consists of six distinctly shaped radiopaque charms that identify their corresponding margins at a glance. (Fig. 3) These charms help clarify specimen orientation, reducing miscommunication among the surgery, radiology, and pathology teams. The charms are clearly visible on the radiograph.

Figure 3. MarginMap® Specimen Orientation Charms.

Results:

The charms play a crucial role in reducing the re-excision rate for a large majority of patients. The case illustrated in Figure 4 A-C, on page 5, demonstrates the identification of a small cancer and how, with the precision of the marker clip placement and using the charms, the surgeon is able to acquire minimal tissue with negative margins. (Fig. 4D on page 5) Before switching to the MarginMap® charms, our facility utilized the string method as previously described. At our institution, we performed 130 lumpectomies in 2022, with 8 re-excisions, for a re-excision rate of 8/130 or 6.2%. After implementing the MarginMap® specimen orientation charms in 2023, the number of lumpectomy cases for that year was 122, with 4 re-excisions for a re-excision rate of 4/122 or 3.3%. (Fig. 5 on page 6) Within that one year, we were able to reduce the re-excision rate by almost half.

Of the 4 cases reported to have positive margins, only one is considered a true positive as there was residual disease, and the radiologist did not think that the margins were too close to request additional tissue. (Fig. 6 on page 6) The second case was reported to be positive at the skin. However, when the patient had her MRI imaging to assess for the extent of the disease prior to lumpectomy, it was reported that there was skin thickening and enhancement, which was suspicious for dermal invasion. Therefore, we would consider this a false positive as we cannot assess the skin on the specimen when the radiograph is obtained. The third and fourth cases are somewhat similar. The radiologist correctly called the margins as close and additional tissue was requested and retrieved in real-time. (Fig. 7 on page 6) In the third case, the additional tissue was positive, and the patient had a re-excision that subsequently cleared the additional area for DCIS high grade. For the fourth case, additional tissue was harvested in real-time, and the pathology report indicated that the additional tissue still had DCIS throughout. The patient was taken for a second re-excision surgery, and the tissue still had positive margins with DCIS. At that point, the patient was taken to surgery again but for a full mastectomy. The latter two cases illustrate some of the difficulties that we encounter when it comes to breast conservation surgery, especially for DCIS of the high-grade pattern, even when the charms are used correctly.

Breast conservation surgery that results in re-excision carries a cost not only to the patient and hospital, but it is a burden to the healthcare system. Prior to utilizing the string method, the hospital system calculated that the average cost for a re-excision was $7,500. At an average of 8 re-excisions per year, the hospital system incurred an average cost of $60,000. In transitioning to the MarginMap® specimen orientation charms, we reduced the re-excision rate to 4 per year at a cost of only $30,000 to the hospital.

The cost for MarginMap is only $20.33 per patient. The cost to cover the hospital's yearly lumpectomies (130 lumpectomies x $20.33) is $2,642.90. Since the cost of lumpectomy re-excision was reduced from 60k to 30k we can subtract the cost of MarginMap ($2,642.90) from the total savings (30K) to get the adjusted savings of $27,357.10. (Fig. 8 on page 7) The transition to the MarginMap specimen orientation charms led to an almost 50% reduction in our hospital expenses. (Fig. 9 on page 7)

Discussion:

There is a clinical need for intraoperative surgical specimen margin assessment to augment pathological analysis, given the prevalence of BCS. BCS accounts for approximately 65% of all operations for breast cancer.[16] The current standard of care for BCS involves a preoperative wire or wire-free localization device of the tumor core, guided by mammography or ultrasound.[17] The utilization of specimen margin devices is utilized with the hopes of curbing the high rates of re-excision procedures on subsequent days following the initial surgery. Performing minimal surgery with greater accuracy is

encouraging in that less invasive surgeries are completed as compared to a full mastectomy. There is increased pressure to accurately ensure that there are mechanisms in place to help in obtaining a complete excision with no remaining residual cancer in the body. However, an unavoidable consequence of BCS is that a subset of women will ultimately have positive margins and require re-operation. Re-excision surgeries to obtain additional tissue that are performed secondary to positive margins diagnosed from a resected specimen are performed at an added cost to the patient and healthcare system and increase the patient's morbidity risk.[18]

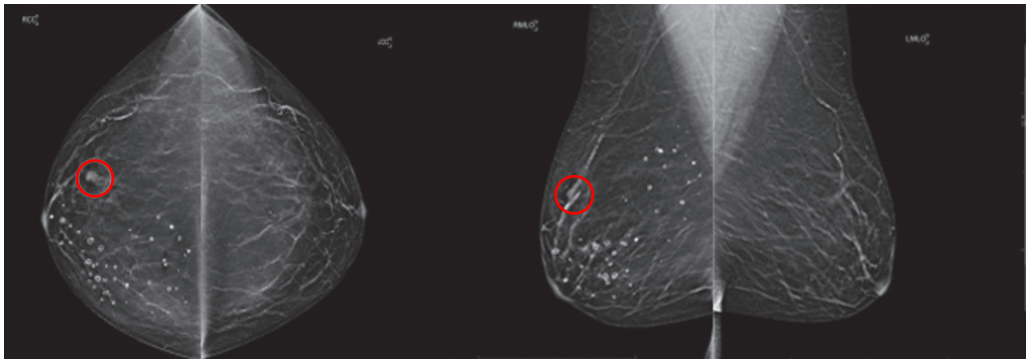

Figure 4A. Screening mammogram with findings of a focal asymmetry in the right breast.

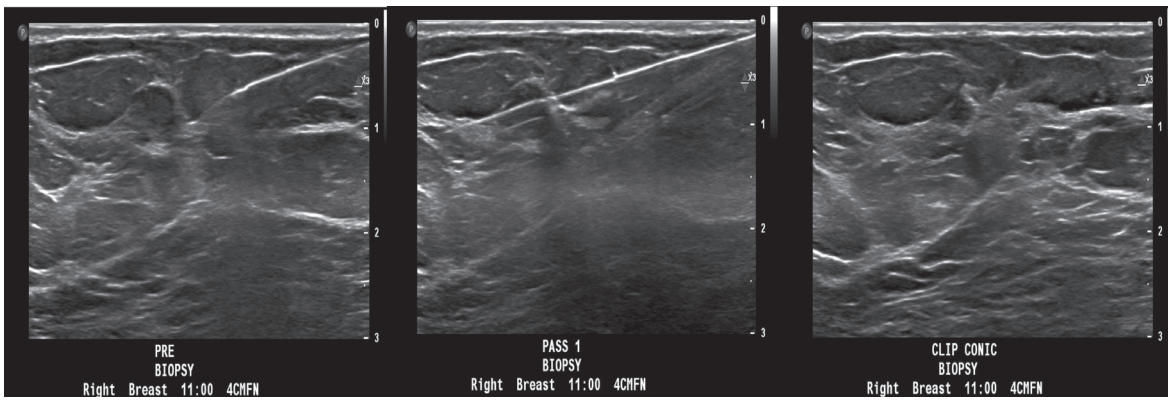

Figure 4B. Ultrasound of the right breast demonstrating a hypoechoic mass at the 11 o'clock location, followed by U/S guided biopsy and clip placement of the same mass.

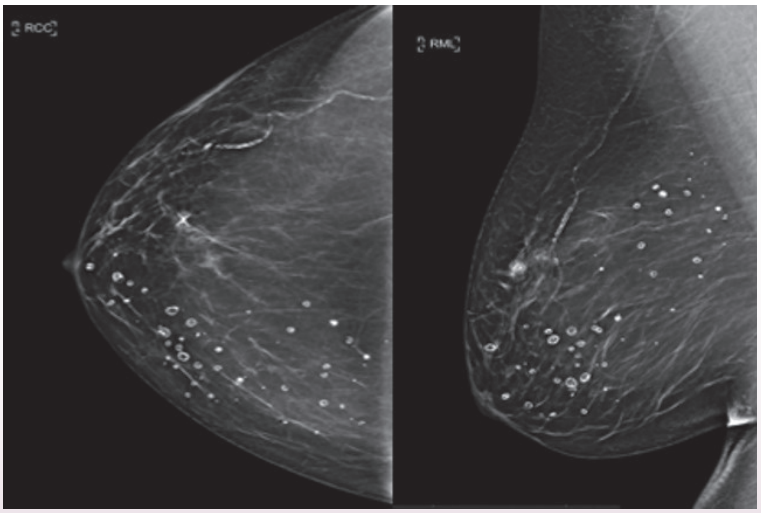

Figure 4C. Post clip placement mammogram right breast.

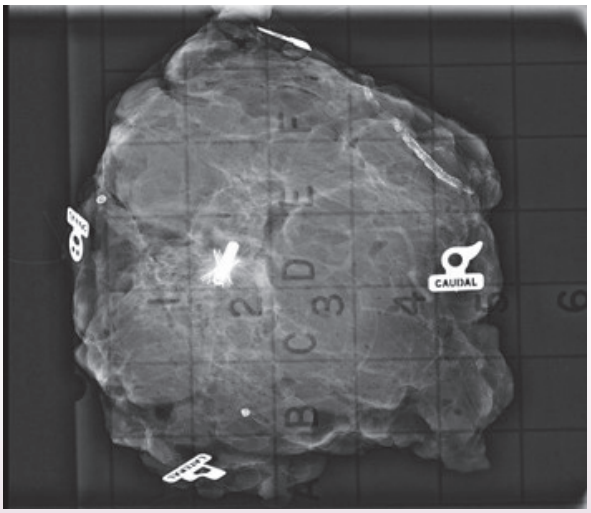

Figure 4D. Specimen radiograph of lumpectomy specimen right breast.

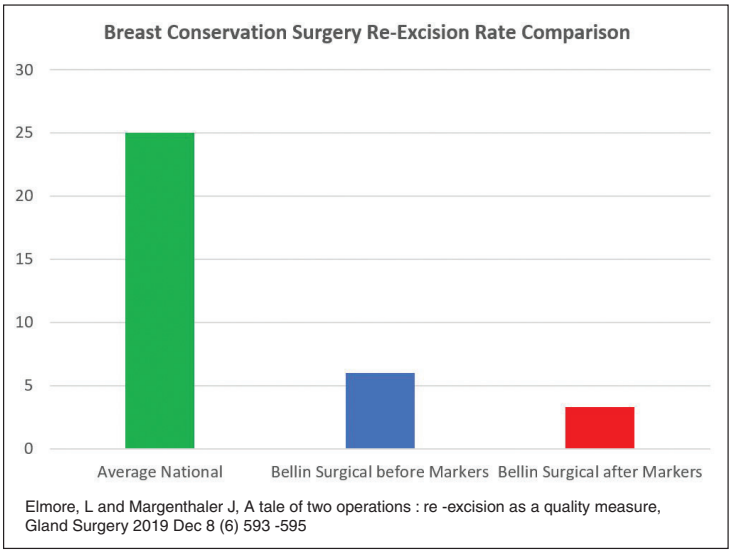

Figure 5. Comparison of breast conservation surgery re-excision.

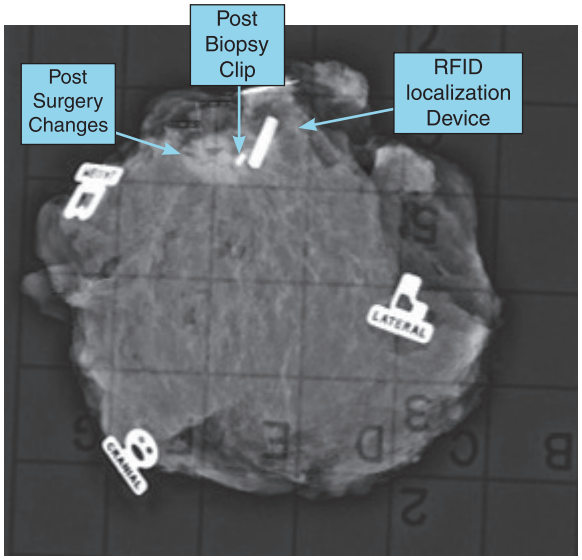

Figure 6. Specimen radiograph with orientation charms. Margins called negative by radiologist had residual disease of IDC and DCIS along the medial and caudal regions.

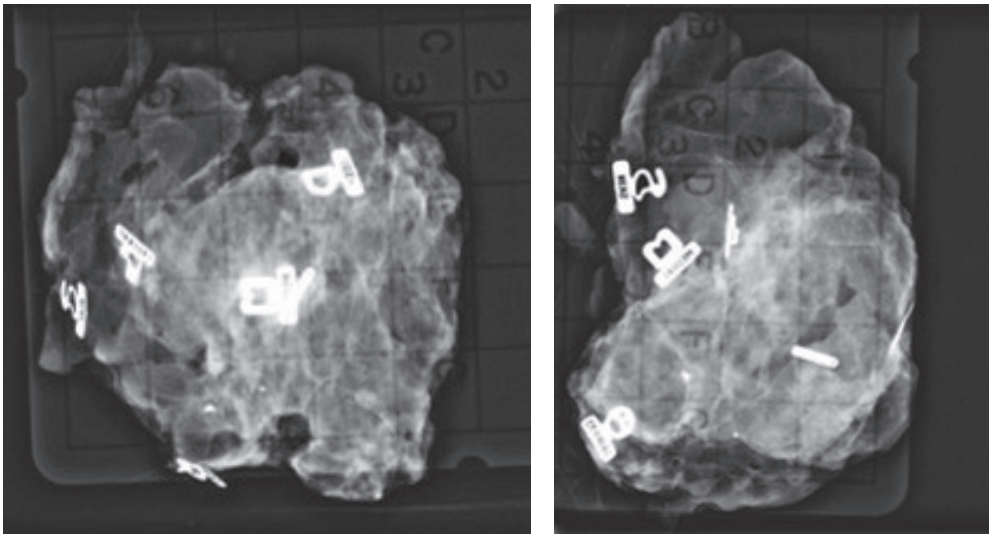

Figure 7. Specimen radiograph 2 views showing residual calcifications along the cranial margin. A request for additional tissue was made by the radiologist.

The research shows that the re-excision rates vary greatly between institutions because of the many different protocols that are used to constitute a negative margin. There is a wide variation in the literature as to what a negative margin constitutes. Common definitions have included no tumor on ink, tumor > 2 mm from ink, tumor > 5 mm from ink, and tumor > 10 mm from ink.[6] The selection can vary according to the surgeon's preference, the institutional policies, and the histopathologic evaluation. The re-excision rate for BCS has been reported to be as high as 20-40%.[19] At our facility, we were able to utilize the MarginMap® specimen orientation charms to help increase the accuracy of our assessment of the specimen in real time for patients undergoing BCS and simultaneously reduce the re-excision rate. At the time of implementing the MarginMap charms we were limited by the fact that only one of the eight reading radiologists had any prior experience with the charms, and none of the surgery and pathology teams members had any prior exposure to the charms. However, after a short trial, the learning curve was shallow for the radiologists, pathologists, and surgeons, and we all quickly learned how to utilize the charms.

The radiologist's job was to ensure that there was enough normal appearing tissue surrounding the lesion, using the charms to inform the surgeon as to whether the margins were clear. The specimen orientation charms quickly oriented

the pathologist to the exact location where the tissue was extracted from the breast – no longer were we reliant on trying to orient the specimen based on the string length. In addition, the charms attached to the specimen in no way impeded the pathologist, who could easily remove them without altering the tissue in any manner. The surgeons quickly learned that by using the Mayo table, this led to faster placement of the charms. The decrease in the re-excision rate was paramount since a positive margin diagnosed from the resected specimen after the procedure led to a second re-excision surgery at an added cost to the patient and healthcare system.

At our facility, the transition to a new specimen marker, the MarginMap specimen orientation charms, led to a collaborative effort between the three medical teams who play an integral role during a patient's BCS and served to decrease the re-excision rate. Due to the current environment of healthcare reform where accountability and transparency are paramount in assessing patient care to decrease morbidity and mortality, the MarginMap specimen orientation charms have proven to be a valuable asset to help decrease the cost to the healthcare system.

Yearly lumpectomies	130
Average cost of re-excision	$7,500
Re-excisions per year without MarginMap	8
Yearly cost of re-excisions w/o MarginMap	$60,000
Re-excisions per year with MarginMap	4
Yearly cost of re-excisions w MarginMap	$30,000
MarginMap supplied 15 per box at	$305/bx or $20.33 per patient
Cost to cover 130 lumpectomy pts	$2,642.90 (130 x $20.33)
Initial savings minus cost of MarginMap	$27,357.10 ($30,000 - $2,642.90)
Total savings	**$27,357.10**

Figure 8. Re-excision cost analysis after implementing the MarginMap® Specimen Orientation Charms.

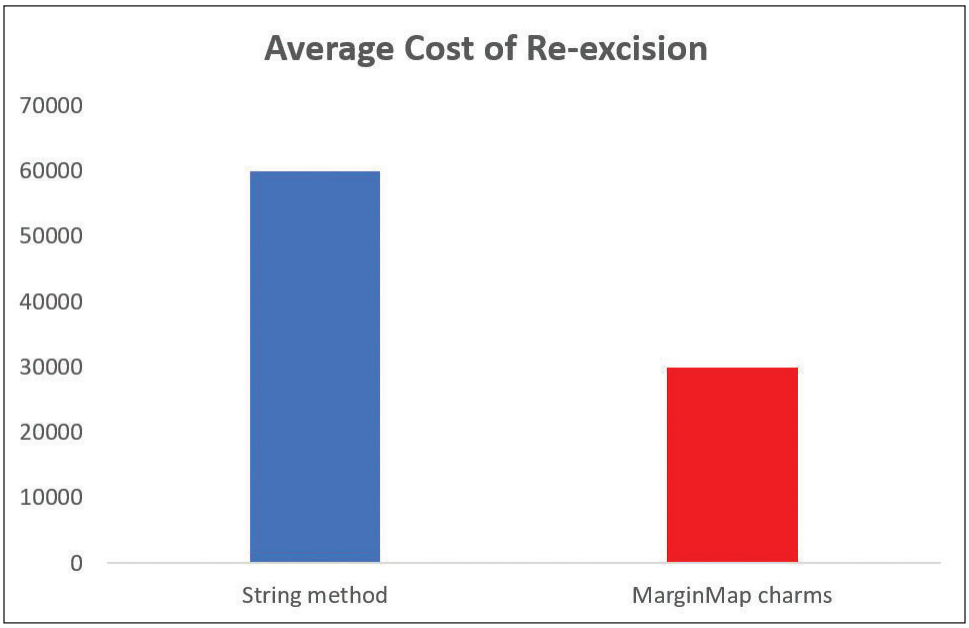

Figure 9. Re-excision cost after implementing the MarginMap® Specimen Orientations Charms.

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Dr. Zarfos served as Clinical Assistant Professor of Surgery at the University of Connecticut School of Medicine, Emeritus Director of the Saint Francis Comprehensive Women's Health Center and Senior Attending in General Surgery at the Saint Francis Hospital and Medical Center, Hartford, Connecticut.

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