Anthem

Medical Policy

Subject: Intraoperative Assessment of Surgical Margins During Breast-Conserving Surgery with Radiofrequency Spectroscopy or Optical Coherence Tomography
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Description/Scope

This document addresses the use of radiofrequency spectroscopy (RFS) and optical coherence tomography (OCT) for the assessment of surgical margins during breast-conserving surgery (BCS, also known as lumpectomy or wide excision). These technologies have been proposed to detect the presence of malignant tissue on the excised tissue sample in the operating room during surgery.

Note: For other documents addressing breast surgery please see:

- SURG.00023 Breast Procedures; including Reconstructive Surgery, Implants and Other Breast Procedures

Position Statement

Investigational and Not Medically Necessary:

The use of radiofrequency spectroscopy or optical coherence tomography for intraoperative assessment of surgical margins during breast-conserving surgery is considered **investigational and not medically necessary.**

Rationale

Pathohistological evaluation of tissue samples is the standard of care for evaluating surgical margins in individuals undergoing BCS. When conducted concurrently with surgery, a significant amount of time is added to the procedure. Reoperation may be required if positive margin results are received after the surgical procedure. In an attempt to reduce surgical times and the need for reoperations, several technologies have been proposed to allow assessment of the surgical margins at the time of surgery. Two such technologies, using radiofrequency spectroscopy (RFS) or optical coherence tomography (OCT), may provide information regarding the presence or absence of malignant cells in real time during the surgical procedure.

Radiofrequency Spectroscopy

In 2010, Pappo and colleagues published a report addressing the sensitivity and specificity of RFS using the MarginProbe® system (Dilon Technologies, Inc., Newport News, VA) in 76 participants with ductal carcinoma in-situ (DCIS) or invasive carcinoma undergoing BCS or mastectomy. In total, 869 samples were collected and evaluated by RFS and histopathology. The results for relatively homogeneous sample sites indicated a sensitivity of 100% (95% confidence interval [CI], 0.85-1) and a specificity of 87% (95% CI, 0.83-0.90). For the full dataset, sensitivity was 70% (95% CI, 0.63-0.77) and specificity was 70% (95% CI, 0.67-0.74). The authors stated that sensitivity changed from 56% to 97% as the cancer feature size increased from 0.7 mm to 6.6 mm. No significant differences in sensitivity or specificity were noted between samples containing pure DCIS as compared to those with invasive cancer.

Several studies have investigated the impact of the MarginProbe system on reoperation or re-excision rates. The largest of these studies was the Pivotal Trial used as the basis for the premarket approval (PMA) from the U.S. Food and Drug Administration (FDA) and also published by Rivera (2012). This randomized controlled trial (RCT) involved 596 participants with either DCIS or invasive carcinoma undergoing BCS. Participants were assigned to standard of care (SOC) or SOC plus RFS (n=298 in each group). The results indicated that use of the device resulted in a 57% reduction in re-excision compared to the SOC group (MarginProbe group: 14.1% [42/298] vs. control group: 29.9% [98/298]; [p<0.0001]). As a result of true positive and false positive MarginProbe results, a small increase was noted in tissue volume removed during the primary procedure (15.6 cc and less than 2 shavings per subject). Among subjects requiring re-excision of positive margins at a second procedure, a 43.4% reduction in the volume of tissue was removed in the device arm (MarginProbe group, 28.4 cc; SOC group, 49.5 cc). When looking at all operations combined, the volume of resected tissue was slightly greater in the MarginProbe group arm (2.6% greater when normalized to bra cup size). MarginProbe readings were available for 1750 of 1788 margins with final histopathology results. Out of these data, 327 margins were histologically positive, with MarginProbe positivity for 246, resulting in a sensitivity of 75.2%. Of the 1423 negative margins, MarginProbe recorded negative results in 660, making specificity of the MarginProbe 46.4%.

Several limitations to this study exist. Participants were randomized after initial removal of the main specimen and any additional tissue on the judgment of the treating surgeon. Following additional excision, the surface of the main surgical specimen is no longer representative of the actual surgical margin. It is also important to note that in the analysis of the study, although all re-excision tissue was evaluated histologically to assess the ultimate margin, the study authors provided no information regarding whether this re-excision tissue was taken prior to randomization, subsequent to testing with MarginProbe, or subsequent to standard margin assessment. An additional unclear aspect of the study was whether or not pre-randomization re-excision cases counted as being appropriate responses to a positive main specimen margin in either study arm. The authors stated that a positive MarginProbe test required the surgeon to re-excise or address a positive test, but it is unclear if a pre-randomization additional excision qualified as a valid re-excision or whether further excision was required. Participants in the SOC group who underwent additional excision following randomization were censured. The number of participants censured is not given. Another potential source of bias is that the MarginProbe group was provided three opportunities for re-excision and the SOC group only two. This could have skewed the results regarding the thoroughness of the excision.

In another large RCT involving individuals with either DCIS or invasive carcinoma undergoing BCS, a total of 293 participants were assigned to receive either SOC (n=150) or SOC plus RFS with the MarginProbe (n=143) (Allweis, 2008). The ability to correctly and intraoperatively identify all of the involved margins on the main specimen and re-excise them was significantly higher in the MarginProbe group than in the SOC group arm, 60% (35/58) vs. 41% (25/61), respectively; p=0.044. Repeat operations were conducted for 17 MarginProbe participants, who had 18 total surgeries. In the SOC group, 23 participants underwent 28 repeat operations. Despite the overall reoperation rate being 32.3% lower in the MarginProbe group (12.6% [18/143]) as compared to the SOC group (18.6% [28/150]), the difference did not achieve statistical significance (p=0.098). When the data was reanalyzed

excluding participants who underwent mastectomy, the re-excision rate was significantly lower (56%) in the MarginProbe group (5.6% [8/143]) as compared to the SOC group (12.7% [19/150]); p=0.0027. No difference between groups was reported with regard to the average total tissue volumes excised during the first procedure (p=0.066). A sub-analysis was conducted involving participants with only non-palpable lesions. In this subgroup, the ability to correctly and intraoperatively identify all of the involved margins on the main specimen and re-excise them was significantly higher in the MarginProbe group compared to the SOC group (69% [20/29] vs. 39% [13/33] respectively; p=0.024). Reoperation rates were also significantly lower (53%) in the MarginProbe group compared to the SOC group in this subgroup (p=0.02). A similar significant 52% decrease in re-excision rates is observed when excluding mastectomy procedures. Finally, average tissue volumes excised during the first surgical procedure in the non-palpable lesions subgroup were significantly higher in the MarginProbe group vs. the SOC group (p=0.30).

Thill and others (2014) reported on the results of a case series of 42 participants with DCIS undergoing BCS with the MarginProbe device who were compared to historical controls. In comparison with the historical re-excision rate of 39% (26/67), the use of MarginProbe led to a significant 56% reduction in the re-excision rate, down to 17% ([7/42]; p=0.018). In 21% (9/42) of the MarginProbe participants, use of the device led to a direct conversion to mastectomy due to extensive disease identified, sparing an additional re-excision BCS. The authors concluded that use of the MarginProbe as an adjunctive tool to BCS significantly decreased the re-excision rate.

In 2016, two additional studies were published addressing re-excision rates as a result of the MarginProbe device. Coble and others (2016) studied 137 participants using the MarginProbe vs. 199 participants using full cavity shaves. The authors reported that the re-excision rate was reduced by 57% (p=0.026), from 15.1% to 6.6%. Overall tissue volume removed was also reduced by 32%, from 115 cc to 78 cc (p=0.0023). Blohmer and others (2016) reported on 150 participants treated with the MarginProbe device vs. a historical group of 172 participants treated with standard care. The authors reported that application of MarginProbe resulted in an overall decrease in re-excision rates of 14.6%. In a subgroup of participants with DCIS, the re-excision rate was reduced from 61.7% to 23.1 %. In another subgroup of participants with invasive lobular carcinoma (ILC), the re-excision rate decreased from 37.0% to 19.0 %. The authors stated that the MarginProbe results were not affected by grading, tumor size, breast density, age, BMI or marker-wire application.

In 2018, Kupstas reported the results of a retrospective chart review of 240 participants who underwent BCS both before (n=120) the institutional use of the MarginProbe who received the standard of care (SOC), and 120 cases after the use of the MarginProbe device was introduced into the study institution. Participants' information from the SOC group was collected retrospectively while the MarginProbe use group was prospectively gathered. There were 18 relumpectomies (15%) in the SOC group and 7 (5.8%) in the device group (p=0.20). The rate of conversion to mastectomy did not differ between groups, (n=4, 3.3%). The total reported re-excision rate was 18.2% in the control group vs. 9.2% in the MarginProbe group (p=0.039). Use of the MarginProbe represented a 50% reduction in the re-excision rate after the introduction into the study institution. This study has several limitations and the impact on long-term outcomes or recurrence rates was not reported.

Geha and colleagues (2020) published the results of an RCT evaluating the use of the MarginProbe in nonpalpable breast cancers. A total of 46 participants were enrolled and underwent randomization intraoperatively with 23 participants enrolled to the device arm and 23 to the control arm. The device arm included use of the MarginProbe to examine all six surfaces of the main lumpectomy specimen; the control arm underwent collection of shave margins based on intraoperative assessment and imaging. Histopathology evaluation was performed by a pathologist blinded to group assignment. A total of 8 participants (35%) in the control group required additional surgery for re-excision due to margin involvement versus 1 participant (4%) in the MarginProbe group (p=0.022). Further research using MarginProbe is necessary to ensure additional surgery for re-excision is reduced and to verify MarginProbe is accurate and consistent with complete removal of malignant tissue during initial surgery thereby decreasing local recurrence.

LeeVan and colleagues (2020) published the results of a clinical trial evaluating the MarginProbe as an adjunct to standard breast conserving operating procedures. This study followed a single breast surgeon with a low rate of re-excision and 60 participants qualified for enrollment. The re-excision rate of the control group was 8.6%, and the MarginProbe group had a rate of 6.6% (p<0.01). A total of 18 participants (30%) had at least 1 histologically close/positive margin on the initial lumpectomy specimen and 8 participants (13.3%) had a final close/positive margin on pathology. The MarginProbe performed as well as standard breast conserving operating procedures in regard to sensitivity and specificity. The false-positive rate was also comparable at 36%, which ultimately results in a greater amount of unnecessary tissue removal. This study is limited as it was a single-center utilizing a single surgeon to perform all procedures. Additional multi-center long-term studies are needed to further establish sensitivity, specificity, and recurrence rates.

In 2022, Hoffman published the results of a prospective study comparing MarginProbe results to pathology results in 51 tumors from 48 participants who underwent lumpectomy procedures. Both the surgeon and a MarginProbe representative examined each specimen to determine whether or not the use of the MarginProbe was appropriate. The authors reported that 12 lumpectomies yielded 13 tumors with involved or close margins requiring additional excisions. It was determined that of these 13 tumors, further margin shavings guided by MarginProbe would have avoided re-operation in 2 subjects. Overall, only 1.3% (4/306) margins were not assessed by MarginProbe and it was reported that none were involved or close margins on final pathological analysis. A total of 97 margins read as positive by MarginProbe were subsequently determined by pathology to be neither involved nor close. Those readings were determined to be false positives by the MarginProbe device and were estimated by the investigators to have resulted in 47 unnecessary margin resections. The sensitivity, specificity, positive predictive value and negative predictive value were calculated to be 23.1%, 66.4%, 3.0%, and 95.1% respectively. The authors concluded that, cancer detection rate by MarginProbe "is relatively low while high false-positive rate leads to unnecessary shavings in almost all patients."

A similar study by Qafiti (2022) involved 86 lumpectomy samples evaluated with the MarginProbe and intraoperative gross pathologic assessment. The authors reported that among all cases, intraoperative gross assessment alone reduced positive margins from 27.9% to 19.8% (29.2% relative reduction, p=0.28). Utilizing both gross assessment and MarginProbe together resulted in decreasing positive margins from 27.9% to 9.3% (66.7% relative reduction, p<0.01) representing a 46.9% relative reduction compared to gross assessment alone. A total of 68 cases of invasive cancer were reported and 14 of related samples were found to have at least 1 positive margin on final pathology. Of these 14, 10 (71%) were identified intraoperatively after using both gross assessment and MarginProbe. MarginProbe alone identified 8 tumors, missing 6, and gross assessment identified 7, missing 7. Overall, gross assessment averaged 1.0 false-positive margin assessments out of the 6 directional margins evaluated per case, MarginProbe averaged 1.7 false-positive margin assessments, and when both were used the mean per-case false positivity rate was approximately 1.3 margins. The authors reported that sensitivity for MarginProbe was 57.1% vs. 50.0% for gross assessment. Negative predictive value was 86.1% vs. 86.3%, respectively. Specificity was 68.5% and 81.5%, respectively, and positive predictive value was 32.0% and 41.2%, respectively.

Studies demonstrating the long-term net health benefits of using RFS following BCS are lacking and the available data regarding sensitivity and specificity is inconsistent. While data indicating decreased reoperations and re-excision rates is helpful, whether or not the use of RFS decreases the rate of cancer recurrence, the most important clinical outcome and goal of BCS specimen margin assessment, needs further investigation.

Optical Coherence Tomography

There are few studies in the published peer-reviewed literature evaluating the use of OCT in the clinical setting. Nyugen and others (2009) published the results of a study involving 37 participants with DCIS or invasive carcinoma undergoing BCS. For all cases, both OCT and histopathology were conducted on surgical specimens at the time of the procedure. Participants were divided into two groups, a training set and a study set. It is unclear from the report what, if any, time difference existed in data collection periods between these groups. The training group included the first 17 participants for whom OCT images were gathered and evaluated in real time by one of several researchers during the surgical procedure. The study group included 20 participants for whom OCT images were gathered during the surgery but were evaluated by a single researcher several months following the initial procedure. The trial group was intended to establish standard imaging protocols, coregistration procedures and imaging evaluation criteria. Once protocols and procedures were established, they were used to conduct the study group evaluations. Of the study group's 20 participants' lumpectomy specimens, 11 were identified with a positive or close surgical margin and 9 were identified with a negative margin under OCT. Comparing OCT results to the histologic findings, 9 true positives, 9 true negatives, 2 false positives, and 0 false negatives were reported, yielding a sensitivity of 100% and specificity of 82%. The authors concluded that their results demonstrated the potential of OCT as a real time method for intraoperative margin assessment in breast-conserving surgeries.

Erickson-Bhatt and others (2015) published the results of a translational study evaluating the results derived from an OCT device to those from standard postoperative histopathological assessment in 35 participants undergoing wide local excision surgery for breast cancer. The authors reported that the ex vivo images from the OCT device yielded a sensitivity of 91.7% (95% confidence interval [CI], 62.5%-100%) and specificity of 92.1% (95% CI, 78.4%-98%). Study limitations include ex vivo OCT analysis and a small sample size.

Schmidt and colleagues (2019) conducted a pilot study to evaluate wide-field optical coherence tomography (WF-OCT) to evaluate tissue margins. A total of 50 participants were enrolled with 185 tissue samples evaluated by WF-OCT. The initial diagnosis for 32 participants was invasive ductal carcinoma (IDC) with or without DCIS, pure DCIS for 14, ILC with or without DCIS for 3, and sarcoma in 1 individual. Final histopathology diagnosis was <2 mm in 17 specimens, and WF-OCT was consistent with final pathology results of the main lump and all shave samples in 178/185 (96.2% accuracy). However, for the main lump only, the accuracy was 86.0% (43/50). A total of 7/185 (3.8%) samples were inconsistent with final histopathology; WF-OCT had 1 false positive, and 6 false negatives. Margin re-excision was necessary for 7 participants, and 3 of these participants had additional disease identified by WF-OCT and confirmed by histopathology. Additional studies with a larger multi-institutional approach to further investigate the sensitivity and specificity of this technique are needed.

Further evidence in the form of more rigorously designed and conducted trials is warranted to demonstrate whether OCT devices provide net health outcomes for individuals undergoing BCS.

Nationally Recognized Guidelines

Neither RFS nor OCT for the treatment of individuals undergoing BCS are discussed in the most current breast cancer guidelines and position statements from several authoritative organizations, including the American Society of Breast Surgeons (ASBS, 2017), the National Comprehensive Cancer Network (NCCN, 2024), the Society of Surgical Oncology (SSO, 2014), and the American Society for Radiation Oncology (ASTRO, 2016). A lack of discussion would indicate that neither RFS nor OCT are standard tools in the care of individuals with breast cancer.

Background/Overview

BCS is an attractive and viable option for individuals with early stage cancer breast cancer. Unlike mastectomy, BCS removes only the tumor and a small area of normal tissue around it, and can potentially provide good cosmetic, functional and survival outcomes. According to the American Cancer Society, for most individuals with early stage breast cancer, BCS plus radiation therapy is as effective as mastectomy. With BCS, the margins around the tumor need to be adequately excised in an attempt to minimize the risk of leaving malignant tissue in the surgical field and potentially increasing the risk of cancer recurrence. Additional minimization of the risk of recurrence may be addressed with postoperative radiation therapy.

Radiofrequency Spectroscopy

RFS is a noninvasive and nondestructive method proposed for the detection of cancer in BCS specimens. The Margin Probe System, the only available RFS device on the U.S. market, received PMA status from the FDA on December 27, 2012, and is used as an adjunctive diagnostic tool for identification of cancerous tissue at the margins (≤1 mm) of the main ex-vivo lumpectomy specimen following primary excision and is indicated for intraoperative use, in conjunction with standard methods (such as intraoperative imaging and palpation) in individuals undergoing BCS for previously diagnosed breast cancer. The PMA document lists the following circumstances as contraindications to the use of the MarginProbe System:

- To replace standard tissue histopathology assessment.
- On ex-vivo lumpectomy specimens that have been exposed to saline, ultrasound gel or local anesthetic solutions.
- On in-vivo tissue (i.e., it should not be used within the lumpectomy cavity).
- On tissues other than breast tissue (i.e., it should not be used on Sentinel Lymph Nodes).
- Closer than 1.5 mm to a fine needle localization guidewire.

The MarginProbe is based on the principles of dielectric spectroscopy. Cancer cells and normal breast tissues produce different electronic signals when exposed to radiofrequency energy. The device involves the use of a single-use handheld probe attached to a computer. The probe is applied to a small area of the resected surgical specimen in the operating room, where it emits radiofrequency energy and receives feedback from the tissue. The computer analyzes the received data to determine whether it is likely malignant or benign. The results, either positive or negative, are provided in real time via an indicator on the probe. If any of the samples give a positive reading, the margin is considered to be positive for the presence of malignancy and should be considered for re-excision if possible. The device can only be used on the main specimen, and cannot be used on shavings or in the BCS cavity.

Optical Coherence Tomography

OCT is another noninvasive and nondestructive method for detecting cancer cells. OCT creates a real-time image of the microstructural detail of tissue in situ and has been proposed for the assessment of surgical margins in individuals undergoing BCS. The Optical Tissue Imaging System 2.1 (OTIS 2.1) (Perimeter Medical, Toronto, Canada) has received FDA 510(k) clearance. This device involves the use of a portable probe attached to a computer. The probe is applied to a small area of the resected surgical specimen in the operating room. This use of OCT may also be referred to as "computed optical margin assessment."

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
For the following procedure codes, or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT	
0351T	Optical coherence tomography of breast or axillary lymph node, excised tissue, each specimen; real-time intraoperative
0352T	Optical coherence tomography of breast or axillary lymph node, excised tissue, each specimen; interpretation and report, real-time or referred
0353T	Optical coherence tomography of breast, surgical cavity; real-time intraoperative
0354T	Optical coherence tomography of breast, surgical cavity; interpretation and report, real-time or referred
0546T	Radiofrequency spectroscopy, real time, intraoperative margin assessment, at the time of partial mastectomy, with report

ICD-10 Diagnosis	
	All diagnoses

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1. Allweis TM, Kaufman Z, Lelcuk S, et al. A prospective, randomized, controlled, multicenter study of a real-time, intraoperative probe for positive margin detection in breast-conserving surgery. Am J Surg. 2008; 196(4):483-489.
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Government Agency, Medical Society, and Other Authoritative Publications:

1. American Society of Breast Surgeons. Consensus Guideline on Breast Cancer Lumpectomy Margins. December 20, 2017. Available at: https://www.breastsurgeons.org/resources/statements. Accessed on February 8, 2024.
2. Morrow M, Van Zee KJ, Solin LJ, et al. Society of Surgical Oncology–American Society for Radiation Oncology–American Society of Clinical Oncology consensus guideline on margins for breast-conserving surgery with whole breast irradiation in ductal carcinoma in situ. J Clin Oncol. 2016; 34(33):4040-4046.
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    - Breast Cancer (V1.2024). Revised January 25, 2024.
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MarginProbe

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action

Reviewed	02/15/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised Rationale, Background/Overview, and References sections.
Reviewed	02/16/2023	MPTAC review. Updated Rationale and References sections.
Reviewed	02/17/2022	MPTAC review. Updated Rationale and References sections.
Reviewed	02/11/2021	MPTAC review. Updated Rationale and References sections.
Reviewed	02/20/2020	MPTAC review. Updated References section.
Reviewed	03/21/2019	MPTAC review.
Reviewed	03/20/2019	Hematology/Oncology Subcommittee review. Updated Rationale and References sections. Updated Coding section with 07/01/2019 CPT changes; added 0546T.
Reviewed	05/03/2018	MPTAC review.
Reviewed	05/02/2018	Hematology/Oncology Subcommittee review. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated Rationale and References sections.
Reviewed	05/04/2017	MPTAC review.
Reviewed	05/03/2017	Hematology/Oncology Subcommittee review. Updated Rationale and References sections.
Reviewed	05/05/2016	MPTAC review.
Reviewed	05/04/2016	Hematology/Oncology Subcommittee review. Updated Rationale and References sections. Removed ICD-9 codes from Coding section.
Reviewed	05/07/2015	MPTAC review.
Reviewed	05/06/2015	Hematology/Oncology Subcommittee review. Updated Background and References sections.
New	05/15/2014	MPTAC review.
New	05/14/2014	Hematology/Oncology Subcommittee review. Initial document development.

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