

National vs. OCT White Paper Reoperation Rates

Adjunct intraoperative optical coherence tomography imaging and reoperation rates after breast-conserving surgery

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WHITE PAPER

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ABSTRACT

Background: Breast-conserving surgery (BCS) has become standard of care for treating early-stage breast cancers, including both invasive carcinomas and ductal carcinoma in situ (DCIS). However, when negative surgical margins are not achieved during the primary BCS procedure, re-excision may be necessary. In the U.S., optical coherence tomography (OCT) is available as an imaging modality with a general indication for use as an imaging tool in the evaluation of excised human tissue microstructure. In October 2022, our institution adopted use of the Perimeter 5-Series OCT (Perimeter Medical Imaging AI, Inc., Dallas, Texas) for obtaining adjunct imaging data from all specimens excised during BCS procedures. The purpose of the present study was to perform a retrospective, quantitative assessment of reoperation rates among patients in our practice who underwent OCT imaging during BCS in order to gain insight into the potential benefits and limitations of OCT for patient outcomes.

Methods: This was a retrospective, single-center, observational cohort study using existing data from all eligible BCS procedures that were performed in our practice in the era after adjunct, intraoperative OCT imaging was adopted into our routine practice. Patients were adults (≥ 18 years of age) who underwent primary BCS for a biopsy-proven breast malignancy, with adjunctive OCT imaging for intraoperative margin assessment between 11 OCT 2022 and 21 NOV 2023. Patients who had undergone prior BCS in the same breast, or whose procedure was performed outside of the study date range, were excluded. During each operation, the surgeon decided whether to excise additional margin shaves based on their clinical judgment and the interpreted results of both OCT and any standard-of-care intraoperative assessments. Postoperative decisions to excise remaining residual solid tumor were made by the surgeon based on the results of standard-of-

care final histopathology, performed by a pathologist. The primary endpoint was the rate of reoperation for close or positive margins among patients in our practice compared to the most recent published national average range of 14.9%–21.1%.^{1,2}

Results: Out of 95 records assessed for eligibility, 72 patients (66.2 \pm 9.96 years of age, 100% female) met eligibility criteria and were included in the analysis (Tables 1 and 2). Two patients underwent bilateral BCS at the time of index procedure, for a total of 74 surgical procedures. Reoperation for close or positive margins, as determined by final pathology, was performed in 4/72 patients for a patient-level reoperation rate of 5.6% (4/74 individual breasts, 5.4%). Final pathology for the four reoperations confirmed DCIS in three patients and DCIS/IDC/ucinous carcinoma in one patient.

Conclusions: In the era after OCT was adopted into our practice, the reoperation rate after BCS (5.6%) was lower than the most recent published national average (14.9%–21.1%).^{1,2} Our results provide insight into the potential use of intraoperative OCT imaging as an adjunctive margin assessment tool to achieve negative margins during primary BCS. Further research is warranted to ascertain how our results may be generalized to help address the current BCS reoperation epidemic.

KEY WORDS

Breast-conserving surgery; intraoperative margin analysis; optical coherence tomography; reoperation; re-excision

ABBREVIATIONS

ASBrS – American Society of Breast Surgeons
ASCO – American Society of Clinical Oncology
ASTRO – American Society for Radiation Oncology

This white paper is intended for an investor audience and not for use by healthcare professionals. The data contained herein have not undergone peer review nor evaluation by FDA and should not be used to guide clinical practice.

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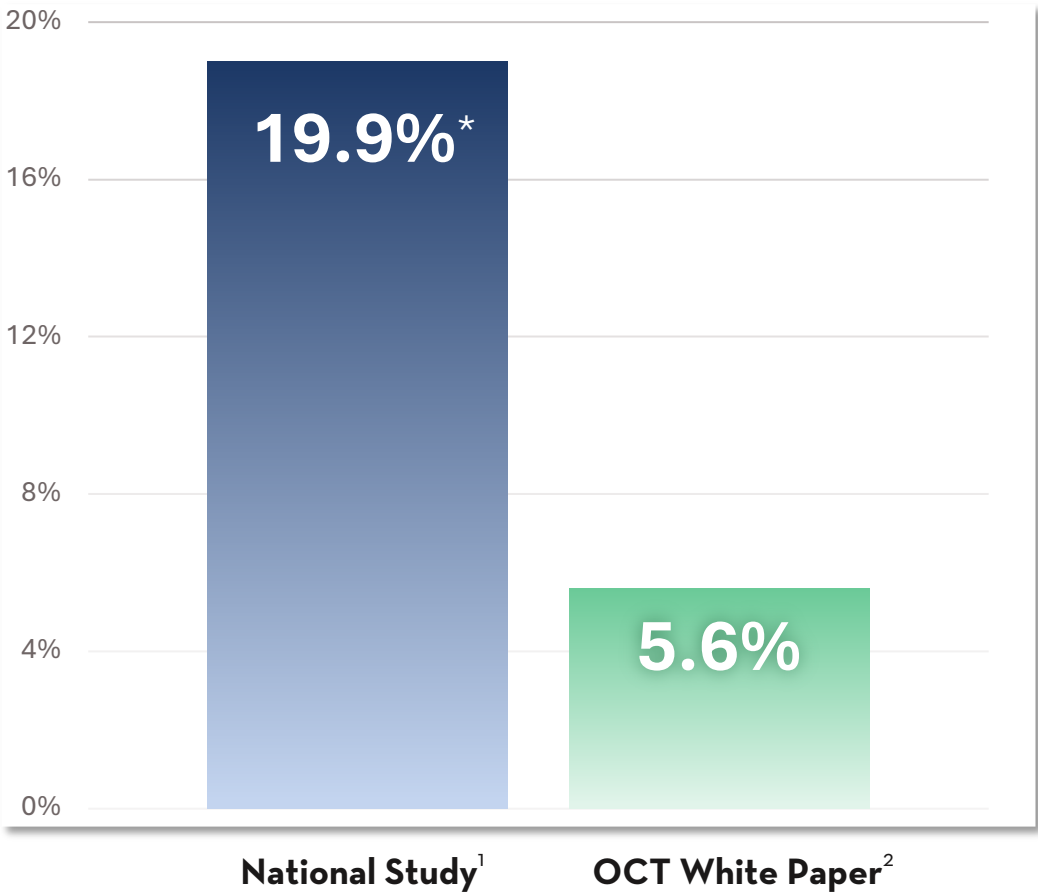
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National Study vs. OCT White Paper BCS Reoperation Rates



SAMPLE SIZES	
National Study ¹	24,106 patients
OCT White Paper ²	72 patients



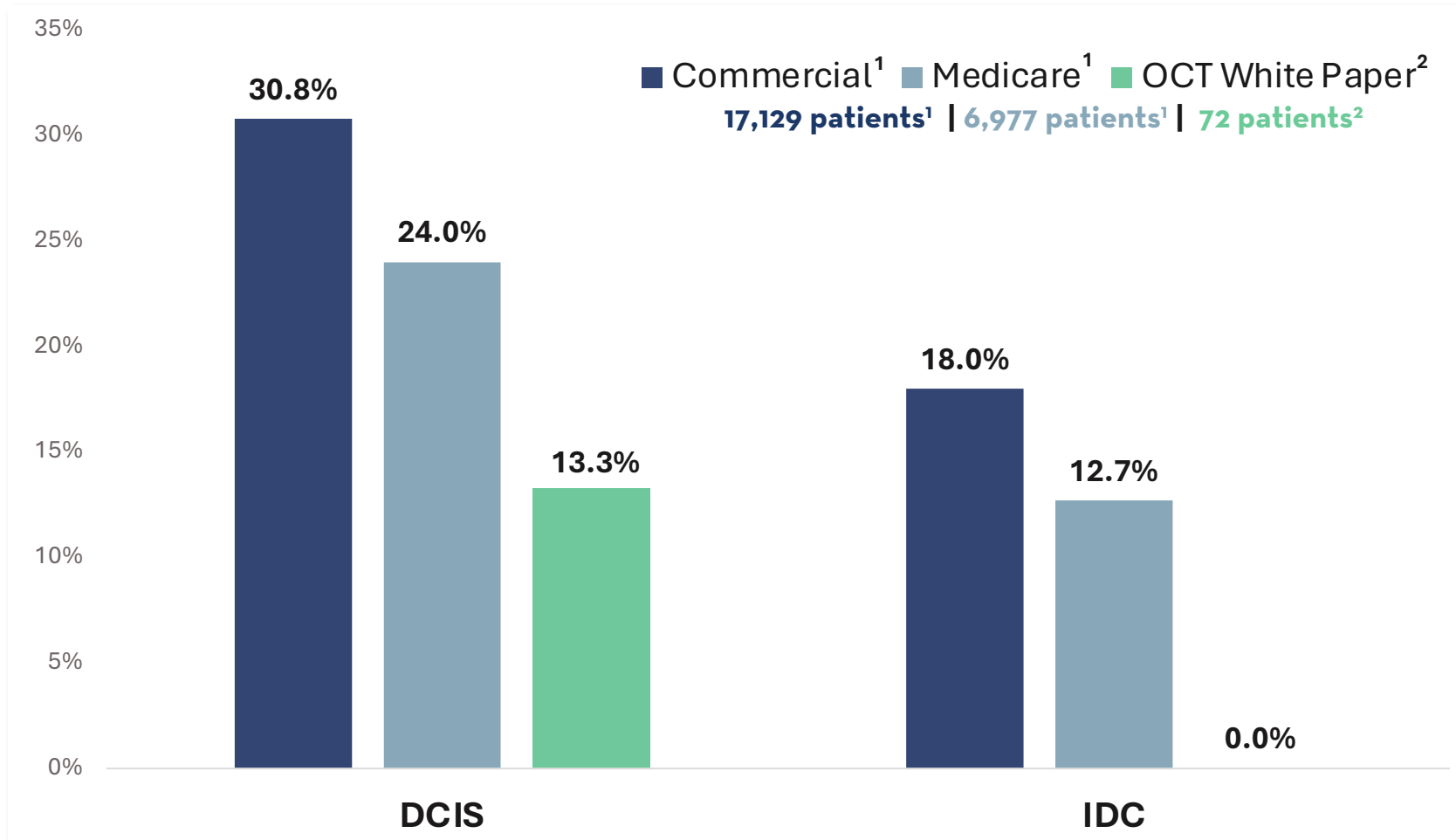
1) Kim Y, Ganduglia-Cazaban C, Tamirisa N, Lucci A, Krause TM. Contemporary Analysis of Reexcision and Conversion to Mastectomy Rates and Associated Healthcare Costs for Women Undergoing Breast-Conserving Surgery. Ann Surg Oncol. 2024; doi: 10.1245/s10434-024-14902-z

2) Gunter, Amelia. Adjunct intraoperative optical coherence tomography imaging and reoperation rates after breast-conserving surgery. The Center for Cancer and Blood Disorders, Weatherford, TX. June 3, 2024

BCS = Breast-conserving surgeries (BCS) for ductal carcinoma in situ (DCIS) or invasive ductal carcinoma (IDC)

*National reoperation rate calculated based on weighted rates in Commercial and Medicare cohort in MD Anderson study¹ and overall percent of U.S. patients covered by Commercial versus Medicare insurance in U.S. Census health insurance coverage report. <https://www.census.gov/library/publications/2023/demo/p60-281.html>

National Study vs. OCT White Paper DCIS & IDC Reoperation Rates



**Ductal carcinoma in situ (DCIS):
25% of cases nationally³**

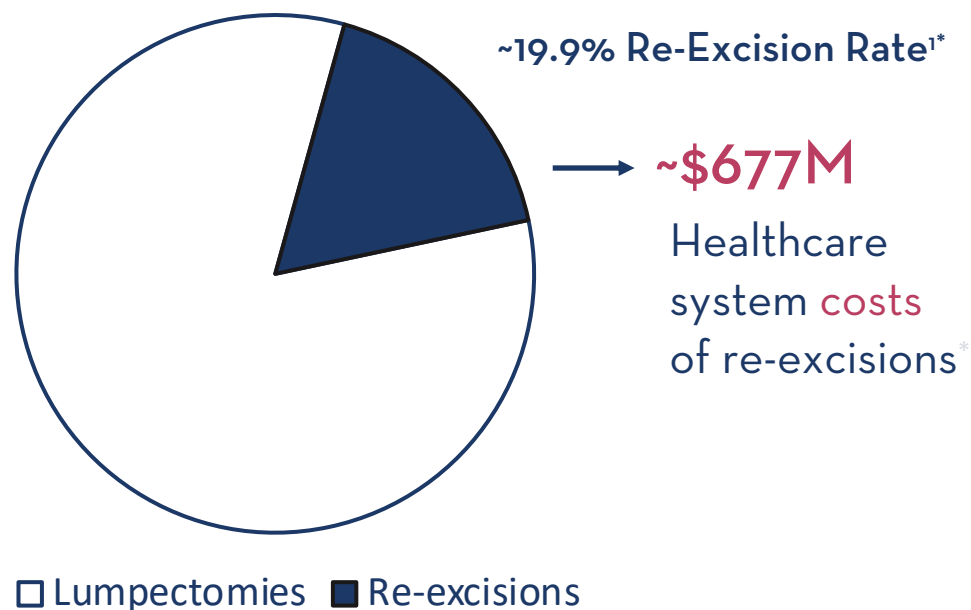
**Invasive ductal carcinoma (IDC):
75% of cases nationally⁴**

- 1) Kim Y, Ganduglia-Cazaban C, Tamirisa N, Lucci A, Krause TM. Contemporary Analysis of Reexcision and Conversion to Mastectomy Rates and Associated Healthcare Costs for Women Undergoing Breast-Conserving Surgery. Ann Surg Oncol. 2024; doi: 10.1245/s10434-024-14902-z
- 2) Gunter, Amelia. Adjunct intraoperative optical coherence tomography imaging and reoperation rates after breast-conserving surgery. The Center for Cancer and Blood Disorders, Weatherford, TX. June 3, 2024
- 3) Tomlinson-Hansen, S. et al. Breast Ductal Carcinoma In Situ. Feb. 27, 2023. <https://www.ncbi.nlm.nih.gov/books/NBK567766/>
- 4) DePolo, J. Invasive Ductal Carcinoma (IDC). <https://www.breastcancer.org/types/invasive-ductal-carcinoma>

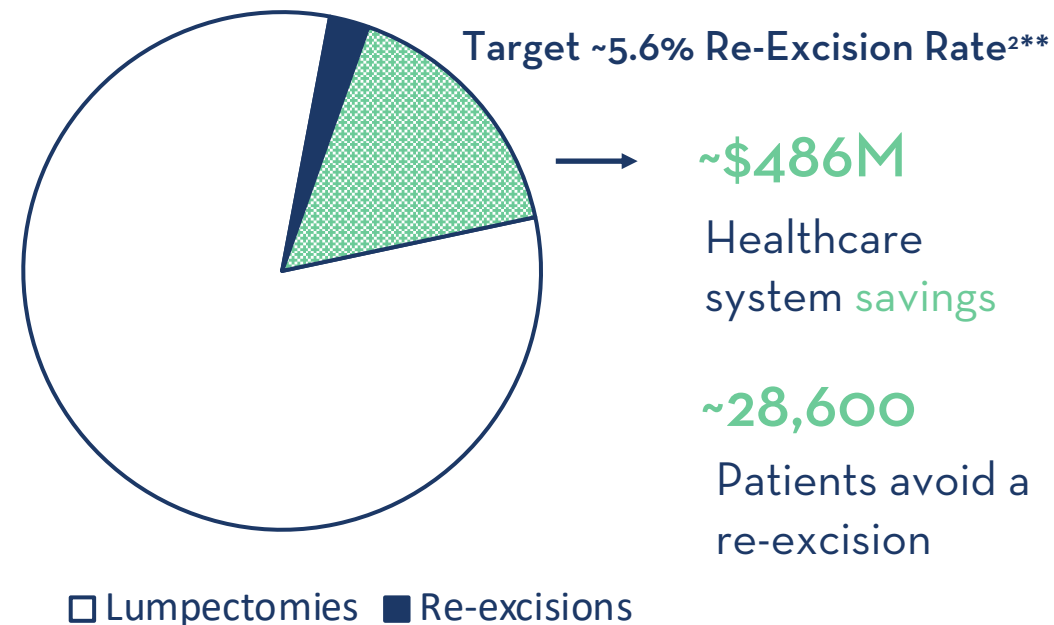
Large Economic Opportunity: Breast Cancer Surgery Use Case



Current Standard - HIGH COST



OCT White Paper - SIGNIFICANT SAVINGS



~\$17K cost per re-excision^{1*}

^{*}Re-excision rate and cost per re-excision are based on rates and costs in Commercial and Medicare cohort in MD Anderson study¹ and overall percent of U.S. patients covered by Commercial versus Medicare insurance in U.S. Census health insurance coverage report. <https://www.census.gov/library/publications/2023/demo/p60-281.html>

^{**}Perimeter calculation for U.S. illustration purposes only. Re-excision rate is based on white paper results² with a patient n=72.

1) Kim Y, Ganduglia-Cazaban C, Tamirisa N, Lucci A, Krause TM. Contemporary Analysis of Reexcision and Conversion to Mastectomy Rates and Associated Healthcare Costs for Women Undergoing Breast-Conserving Surgery. Ann Surg Oncol. 2024

2) Gunter, Amelia. Adjunct intraoperative optical coherence tomography imaging and reoperation rates after breast-conserving surgery. The Center for Cancer and Blood Disorders, Weatherford, TX. June 3, 2024

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Disclosures



Information About the White Paper

- Perimeter Medical Imaging AI intends the sharing of this research and associated data for an investor audience and not for use by healthcare professionals. The data collected have not undergone peer review nor evaluation by FDA and should not be used to guide clinical practice.
- Perimeter Medical Imaging was involved in the study design, data collection, analysis & interpretation, and the writing of the paper. Additionally, Perimeter funded professional medical writing support.

Information about the S-Series OCT Device

Intended Use

The S-Series OCT is indicated for use as an imaging tool in the evaluation of excised human tissue microstructure by providing two-dimensional, cross-sectional, real-time depth visualization with image review manipulation software for identifying and annotating regions of interest.

Unapproved Uses

The S-Series OCT has 510(k) clearance under a general indication and has not been evaluated by FDA specifically for use in breast tissue, breast cancer, other types of cancer, margin evaluation, and reducing re-excision rates. The safety and effectiveness of these uses has not been established.

For full information on unapproved/off-label uses, visit:

<https://perimetermed.com/disclosures> or contact medicalaffairs@perimetermed.com.