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Utilizing post-imaging surveys to guide development of photoacoustic computed technology for breast imaging☆

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ABSTRACT

Objective: Current breast imaging has limitations. Mammography uses radiation and compression; ultrasound depends on user expertise; MRI requires time and intravenous contrast. Development of novel technologies for breast imaging may be improved with patient surveys.
Methods: Breast cancer patients scheduled for breast operations or undergoing neoadjuvant therapy were enrolled in studies to evaluate photoacoustic computed tomography (PACT) at a single institution. After each imaging session, the patients were surveyed. The survey included Likert scale, multiple choice, and open-ended questions.
Results: Of 49 patients, 86 % completed at least one survey with 42 % completing three. Survey completion took <10 min. Features assessed specific to the imaging technology included water bath, duration, positioning, and environment. Patients overwhelmingly reported ease of PACT over mammography and MRI. Suggestions included better cushioning, improved head support, well-fitting laser safety glasses.
Conclusion: Photoacoustic breast imaging is feasible to breast cancer patients. User feedback informs on clinical technology improvement.

1. Introduction

Early detection and treatment of breast cancer is crucial to reducing cancer-related mortality. Screening via mammography, widely implemented in the 1980s, is supported by randomized clinical trials (RCTs) such as the Swedish two-county trial and HIP Breast Cancer Screening Trial, which showed a correlation between mammogram screening and decreased breast cancer mortality.[1] Currently, mammograms are considered the primary tool for breast cancer detection due to their proven mortality reduction, relatively low cost, and ease in mass screening. However, performance issues produce false negatives approximately 15 % of the time,[2] caused by human error and lack of technology sensitivity, particularly in dense breasts. Additionally, a significant number of women report pain during imaging, with residual discomfort and unpleasantness even after completion of the scan.[3]

Other breast imaging modalities, such as ultrasound (US) and magnetic resonance imaging (MRI), are frequently used to supplement indeterminate mammograms or screen high-risk patients. However, US are highly operator dependent and provide limited views. MRIs require patients to lie still in prone position within an enclosed tube for 30–60 min. The positioning of the breast coil, limited space, and loud noises can cause physical discomfort, claustrophobia, and anxiety. Contraindications include implanted devices, shunts, metallic objects, and renal disease.[4] Additionally, the intravenous contrast can cause allergic reactions and accumulation of gadolinium.[5]

There is ongoing investigation into new technologies to improve breast imaging. Recently, photoacoustic technology has been tested by several groups.[6–8] Imagio is a portable photoacoustic device utilizing a probe, and the first photoacoustic device to receive FDA approval (2021). When used in the PIONEER study, diagnostic specificity improved by 14.9 % compared to ultrasound alone. This was further supported by the results of the READER-02 study.[9,10] Another multicenter study showed the ability of optoacoustic ultrasonography to appropriately downgrade benign BI-RADS 4a (47.9 %) or BI-RADS 4b

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masses (11.1 %) to BI-RADS 3 or 2.[11]

Station-based photoacoustic systems, such as the device used in our study, allow for larger images with increased depth, thereby improving image quality and diagnostic capabilities, while its design encourages reproducibility. We have previously reported on design and development of a full-ring photoacoustic computed tomography (PACT) system.[12] When distinguishing between suspicious and healthy quadrants, the area under the receiver operating characteristic curve (AUROC) of 0.89 is higher compared to mammogram or US (~0.8). Additionally, PACT's ability to differentiate between malignant versus benign lesions is comparable to mammogram and MRI, but ~44 % improved compared to ultrasound.[13] In 2023, photoacoustic imaging was included in the DICOM standard, suggesting its progressive acceptance in clinical applicability.[10]

During imaging, a patient lies in prone position with her breast inserted into a water-filled opening [Fig. 1]. Tissues exposed to laser light energy expand, generating acoustic waves that are detected by ultrasound arrays. Volumetric scanning is done to acquire 3D images. PACT imaging has potential imaging advantages including the use of hemoglobin as an endogenous contrast, enabling visualization of vasculature without exogenous contrast. In addition, PACT imaging is unaffected by breast density, requires minimal to no compression, does not use ionizing radiation, and is non-claustrophobic. Whole breast imaging is completed in a single breath hold.[12]

Imaging of each breast is completed in under 5 min. However, the entire imaging session, which includes dressing and positioning, takes approximately 30 min.

The potential impact of new medical technologies is underscored by their technical capabilities but also by clinical utilization. Clinical utilization is predicated on patient acceptance of the technology. As part of our ongoing studies to determine the performance of PACT in imaging the breast, we sought to analyze patient feedback via post-imaging surveys to inform on its perceived usability and to identify opportunities for improvement. The results of the performance of PACT will be reported separately.

2. Methods

Data was collected from two prospective studies conducted at a single institution. All participants were female patients newly diagnosed with breast cancer. Eligibility criteria included: age ≥18 years old, diagnosis of breast cancer, intact skin, weight <300 lbs. Exclusion criteria included: pregnancy. Consecutive new breast cancer patients seen at the institution were screened for eligibility and included in the study after consent. Studies were reviewed and approved by the regulatory committees at each of the imaging institutions.

The study participants were surveyed after each PACT imaging session. Group 1 included stage I-IV patients scheduled for upfront surgery who underwent one-time imaging session. Group 2 included stage I-III patients being treated with neoadjuvant chemotherapy (NAC), undergoing serial imaging – prior to the initiation of NAC, after two cycles, and after completion of NAC and before surgery (three sessions). Group 2 underwent one to three imaging sessions.

The surveys assessed multiple aspects of the PACT experience including the location and environment of the lab, comfort and ease of the imaging process and device, and the usability of PACT when compared to mammogram, US, and MRI. During these studies, the device was moved from a research facility to a clinical setting. Two survey versions were used: one for each location. The first version of the survey included 28 Likert scale questions and 3 open-ended questions (Supplement 1). The second version had 28 Likert scale questions, 5 multiple choice questions, and the 3 open-ended questions (Supplement 2). Patients were able to decline to answer any of the questions. The survey was available in an electronic or paper format. The survey completion time was between 5 and 10 min. Results were analyzed using descriptive and comparative analyses. Statistical analyses included parametric and nonparametric t-tests analyzed using Graphpad Prism 10.6.1. Excel was used to generate the figures.

3. Results

A total of 49 patients were accrued to the two clinical studies: 26 in the one-time imaging study (Group 1) and 23 in the neoadjuvant study (Group 2). Of the 49 patients, 42 patients completed a post-imaging survey: 23 patients from Group 1 and 19 patients from Group 2. Group 1 completed one survey each, while Group 2 completed one to three surveys each. A total of 64 surveys were completed.

Of those who completed a survey, the median age was 54.5 years, ranging from 33 to 74 years old. The study population was all female and represented the racial makeup of the population seen at our institution with 73.81 % White, 4.76 % Black or African American, 14.29 % Asian, 4.76 % other races, and 2.38 % declined to answer. In addition, ethnic makeup was 31 % Hispanic or Latino and 69 % non-Hispanic or Latino (Table 1). Other pertinent demographic information including BMI,

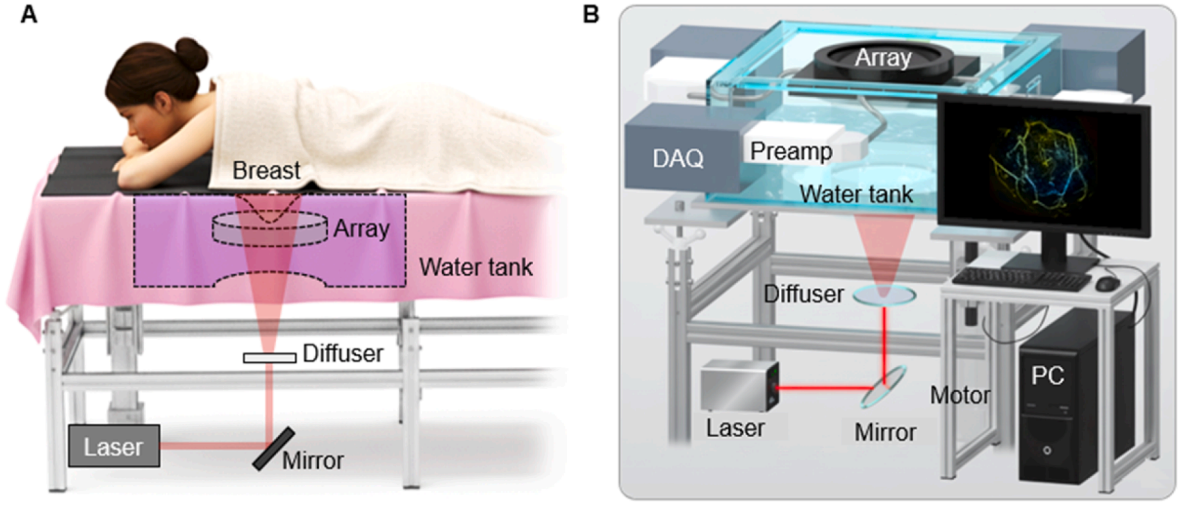

Fig. 1. The photoacoustic computed tomography (PACT) system. **A.** The patient lies prone on the imaging table with the breast pendant in a water tank. **B.** Schematic of PACT system. The patient's breast is inserted into the water tank. A ring-shaped ultrasound transducer array (array) is positioned inside the water tank and scans the breast illuminated by the laser (laser) energy source that is positioned below the water tank. The data from the imaging is processed through the computer (PC) and the image is displayed on the monitor.

Table 1
Patient demographics.

Demographics		Neoadjuvant (n = 19)	Newly diagnosed (n = 23)	Total (n = 42)
Age (median years, IQR)		50, 22	57, 17	54.5, 23
Sex (n)	Female	19	23	42
Race (n)	White	18	13	31
	Black	0	2	2
	Asian	0	6	6
	Other	0	2	2
	Unknown	1	0	1
Ethnicity (n)	Hispanic	8	5	13
	Non-Hispanic	11	18	29

breast cancer stage, and breast density is provided in Supplement 3. No socioeconomic data was reported.

In Group 1, 88 % completed a survey. Of the surveys completed, 22 of the 23 surveys were completed immediately after the imaging session. In Group 2, 83 % completed at least one survey and 42 % completed all three surveys. Four of the 19 patients (21 %) are still undergoing NAC. 36 of 41 surveys were completed immediately after. There were 42 respondents from Groups 1 and 2 resulting in an overall completion rate of 86 %. 58 surveys were completed immediately after the visit and 6 were completed within one week of the imaging session.

Ease of PACT compared favorably with other breast imaging tests with 80 % agreed or strongly agreed that PACT is easier than MRI; 59 % of patients agreed or strongly agreed that PACT is easier than US; and 83 % agreed or strongly agreed that PACT is easier than mammogram (Fig. 2). Positioning on the PACT system was assessed by age and experience. The responses of patients aged 50 years old and younger were compared to those of patients aged greater than 51 years old (Fig. 3). The responses of first time (Naïve) users were compared with second and third time (Non-naïve) users (Fig. 4). There was no statistical difference in Likert responses regardless of age or with serial imaging.

Patient responses to the open-ended questions identified opportunities for improvement in device design. Specific comments by the respondents have resulted in updated imaging procedures and device changes to minimize manual positioning, increase table cushioning and improve head support. Better fitting laser safety glasses were also obtained.

The complete results of the surveys are reported in Supplement 4.

4. Discussion

In summary, 42 patients completed a post-PACT survey – 23 from the one-time imaging study (Group 1) and 19 from the neoadjuvant chemotherapy study (Group 2) – for a total of 64 responses. Survey completion rate was 86 %. Our findings suggest that when asked to compare our novel technology with currently available breast imaging, patients responded favorably to the PACT imaging experience. Clinical utilization of technology is dependent upon patient acceptance, and our findings support the feasibility of performing PACT from a patient quality of life and experience perspective.

Presently, mammograms are the primary method for breast cancer screening as they are low-cost and have been validated through multiple clinical trials to reduce mortality from breast cancer. Screening mammograms detect asymptomatic and non-palpable breast cancers,[1] leading to a 25 % reduction in breast cancer mortality within the United States from 1975 to 2019.[14] However, breast compression during mammograms is frequently associated with discomfort and pain. The subsequent negative physical and psychological associations can lead to anticipatory anxiety for future scans, deterring patients from maintaining screening compliance. A 2013 study of several databases revealed that 25–46 % of participants cited pain as the reason that they did not undergo a repeat mammogram.[15] Other limitations include sensitivity in detection of breast masses in patients with high breast density. Dense breast tissue has a similar appearance to tumors on mammography, potentially obscuring malignant lesions resulting in delay of cancer diagnosis and worse cancer outcomes.[16] Lastly, mammograms utilize ionizing radiation, which, with repeated exposure, can increase the risk of breast cancer development.[17]

Breast US is better able to identify lesions in dense breast tissue, increasing detection by 1.9–4.2 %.[18] US is comfortable and painless. However, the accuracy of US is highly technician-dependent, and the US probes have limited field of view. These limitations result in overall specificity that is lower than mammograms.[19,20] US, not recommended as an exclusive screening test for breast cancer, is most commonly used as a supplement to mammograms.

MRI have much higher sensitivity than mammogram or US and are used for screening and surveillance in women with high risk for breast cancer.[1] However, the cost of contrast enhanced breast MRI prohibits

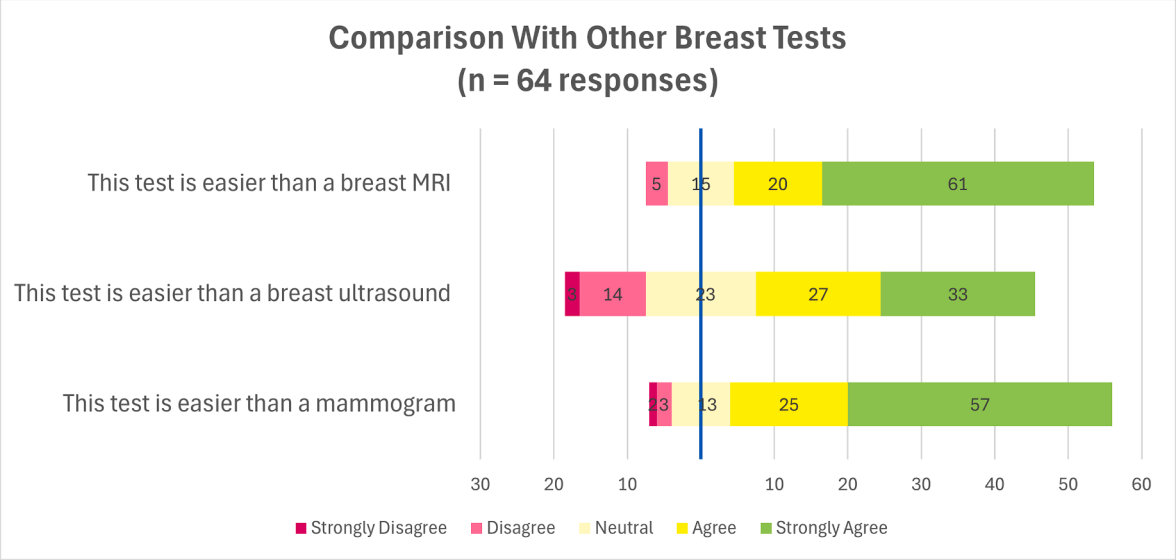

Fig. 2. Likert responses on Ease of PACT when compared to other breast imaging modalities. Responses in percentages are shown on the graphs. Numeric values are reported in Supplement 3. Percentages may not equal 100 % due to rounding.

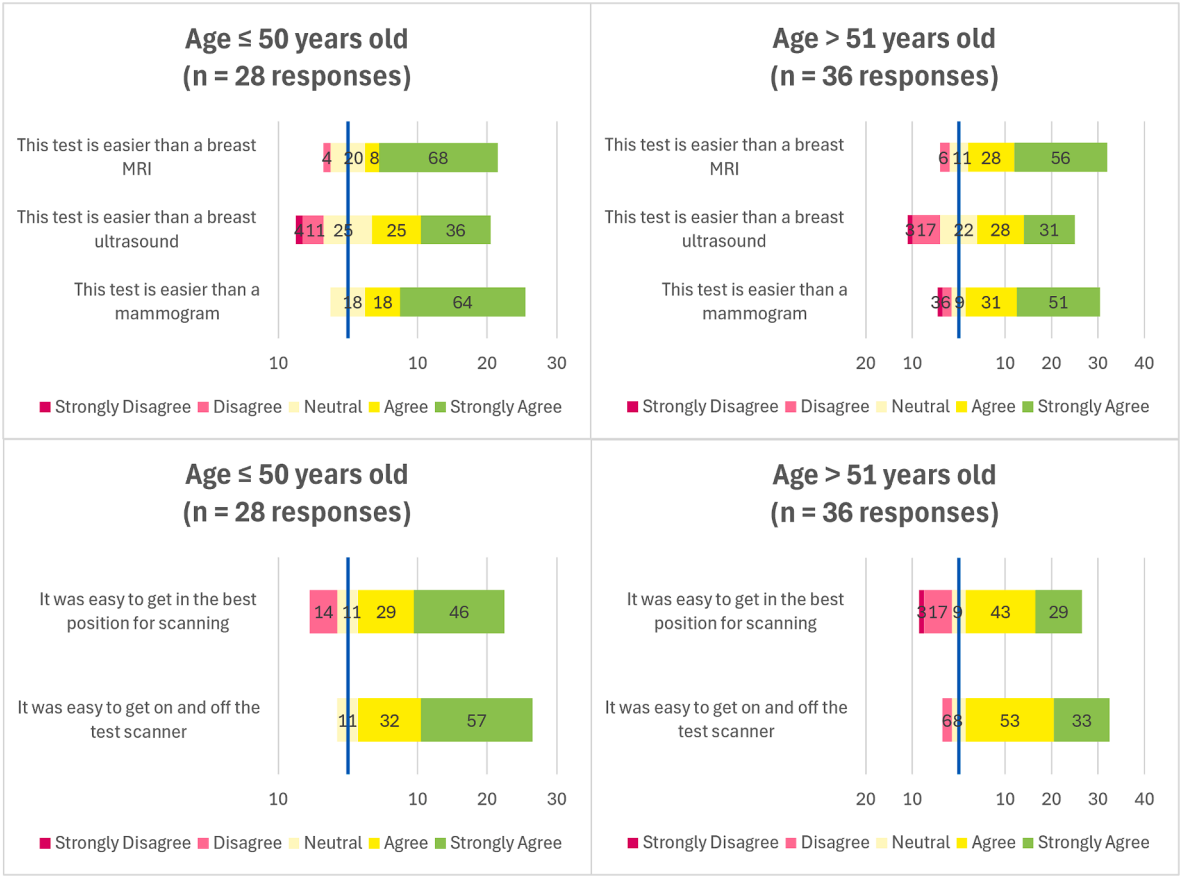

Fig. 3. Likert responses on Ease of PACT and PACT Positioning based on age. Responses in percentages are shown on the graphs. Numeric values are reported in Supplement 3. Percentages may not equal 100 % due to rounding.

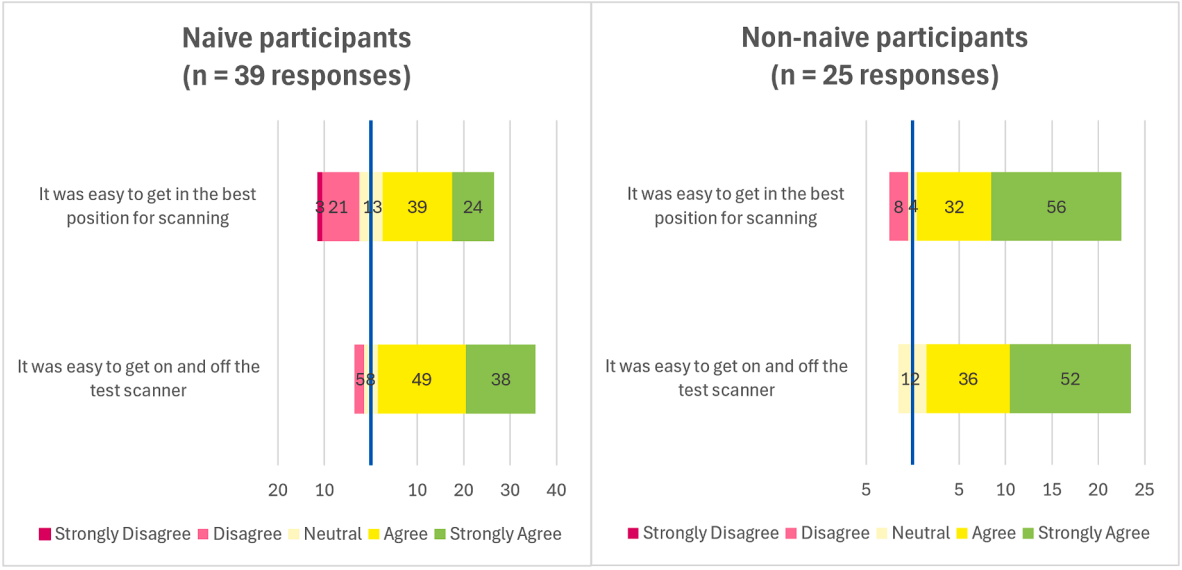

Fig. 4. Likert responses on PACT Positioning based on patients' first (Naïve) versus subsequent (Non-naïve) imaging studies. Responses in percentages are shown on the graphs. Numeric values are reported in Supplement 3. Percentages may not equal 100 % due to rounding.

wide adoption for mass screening. Furthermore, MRI has been shown to generate high rates of false positive findings resulting in marked increase in breast biopsies. In the DENSE trial, women with extremely dense breasts and negative mammograms underwent supplemental MRI. While this resulted in increased cancer detection, there was also an increase in MRI findings that resulted in additional biopsies. Nearly three-quarters of patients who completed a biopsy per the MRI recommendations had benign results.[21] Additionally, the loud noises and small, enclosed space during imaging can cause discomfort and even pain. The use of intravenous contrast can lead to allergic reactions and

gadolinium accumulation within the brain.

A novel panoramic PACT device was used in this prospective study. The PACT device uses a 1064 nm laser to illuminate breast tissue, causing thermal expansion and contraction. Acoustic waves are generated that can be detected by ultrasound elements and used to reconstruct photoacoustic images. Compared to pre-existing breast imaging modalities, PACT has high spatial resolution and deep penetration allowing for the clear visualization of vasculature irrespective of breast density, including increased angiogenesis around tumor sites. It is noninvasive and does not use ionizing radiation. Imaging of the whole breast can be completed in a single, 13-s breath hold.[13] Post imaging surveys allowed evaluation of PACT by patients as a novel imaging technology in the context of other existing modalities.

Recent research highlights the positive association between patient experience and clinical efficacy, including compliance with breast cancer screening and recommended treatments.[22] Therefore, there is growing emphasis placed on utilizing patient feedback to inform on technology acceptability. Other research groups investigating new breast imaging technologies are similarly surveying patients to guide device development.[23] Regulatory agencies such as the FDA Center for Devices and Radiological Health (CDRH) incorporate patient input for benefit-risk assessment of new medical devices into their regulatory reviews, to ensure that designs are considerate of the end user. This has been instrumental in determining the final FDA approved designs of new technologies.[24] Furthermore, incorporation of user-identified changes to product design and use before production results in improved efficiency and cost of manufacturing.

The post-PACT surveys identified a wide variety of features resulting in several device and imaging iterations. Changes in the device design incorporated comments from the patients and resulted in less manual positioning and patient movement during imaging. Comments from the patients improved the comfort of the imaging session through use of thicker table cushioning and better head support. In addition, laser safety glasses in different sizes and better fits were purchased to improve the overall patient experience.

There are limitations to our study. Our sample size is small although there was a high response rate with 86 %. As with all surveys, there is the potential for recall bias. Our recall bias was minimized by 91 % of surveys being completed immediately after the visit while the rest (9 %) were completed within one week of the visit.

5. Conclusion

Evaluation of user experience through surveys when developing new medical technology is feasible and valuable to ensure patient-centered design. Overall, the positive patient experience with PACT argues for continuing development of this novel imaging technology for breast imaging. The results of these surveys inform device iteration and usability. Future studies using a user-centered design approach will help to further focus in on patient adoption to new breast cancer imaging modalities via deeper understanding of patients' experiences, beliefs, barriers, and contexts.

CRediT authorship contribution statement

Stephanie Delos Santos: Writing – review & editing, Writing – original draft, Validation, Project administration, Investigation, Formal analysis, Data curation. **Marta Invernizzi:** Writing – review & editing, Validation, Project administration, Investigation, Data curation. **Cindy Liu:** Writing – review & editing, Project administration, Investigation. **Xin Tong:** Writing – review & editing, Project administration, Investigation. **Jodi Rosen:** Writing – review & editing. **Lihong V. Wang:** Writing – review & editing, Supervision, Resources, Investigation, Funding acquisition. **Lily L. Lai:** Writing – review & editing, Validation, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Conceptualization.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.amjsurg.2026.116828.

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