Introducing iPad-Based Multimedia Education During Informed Consent for Image-Guided Breast Procedures

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Glossary of Abbreviations
Arm A - Study arm with traditional paper consent
Arm B - Study arm with iPad-based consent form
Arm C - Study arm with provider-led presentation of imaging and iPad-based consent form
Arm D - Study arm with informational video and iPad-based consent form
MacCAT-T - MacArthur Competence Assessment Tool for Treatment
ANOVA - Analysis of variance
BI-RADS - Breast Imaging-Reporting and Data System
HTML5 - HyperText Markup Language Version 5 (web programming language)
PDF - Portable Document Format
Abstract

Purpose: To determine whether multimedia education during informed consent for image-guided breast procedures improves patient understanding and experience.

Methods: 240 women having ultrasound-guided or stereotactic breast biopsy at Beth Israel Deaconess Medical Center were included in the study. Each was randomized to one of four study arms (A-D). Arm A consisted of standard paper informed consent by the radiology resident, fellow, nurse practitioner, or breast imaging attending. Arm B added informed consent on an iPad. Arm C added real-time review of the patient’s breast imaging. Arm D consisted of a prototype iPad application in which the patient watched an educational video discussing the standard informed consent followed by iPad consent. Objective understanding was assessed for all patients using the MacArthur Competency Assessment Tool for Treatment (MacCAT-T). Subjective patient experience, including anxiety, provider trust, and user experience with the multimedia was assessed through pre-consent, peri-consent, and post-procedure surveys. One-way ANOVA, Pearson’s r correlation, and chi-squared analysis was performed to evaluate for a difference between the 4 study arms.

Results: The mean age of study participants was 53.3 years (± 12.4 years SD). The study population to date was 59.6% White, 17.5% Black, 7.5% Hispanic, 12.1% Asian, 0.4% Pacific Islander, 1.7% Biracial, and 1.3% Other. 78.3% of patients spoke English and did not use an interpreter, and 21.7% of patients required an interpreter. There was no significant difference between study arms in MacCAT-T understanding summary rating among all patients (P = 0.19). Among all patients, patients in arm D were more likely to agree that the video improved their understanding of procedure steps than those in the imaging arm reported about the imaging presentation (χ² = 9.8, P=0.04). Non-White patients in arm C reported improved subjective understanding (9.8 ± 0.7 SD) than those in arm B (9.0 ± 1.6 SD, P = 0.05). Non-White patients in arm C also reported improved overall experience (9.8 ± 0.5 SD) compared to those in arm B (9.2 ± 0.9 SD, P = 0.02). Non-English-speaking patients in arm C reported improved post-procedure comfort with the provider who performed the procedure (9.9 ± 0.6 SD vs. 8.8 ± 1.7 SD, P = 0.04) and overall experience (9.9 ± 0.3 SD vs. 9.0 ± 0.9 SD P < 0.01) than those in arm B. Non-White patients in arm B experienced increased anxiety between the pre-consent and peri-
consent surveys (0.6 ± 0.9 SD) as compared to those in arm A whose anxiety decreased between those two points in time (-0.2 ± 1.1 SD, \( P = 0.03 \)).

Conclusions: Viewing an informational procedure video detailing the benefits, risks, alternatives and steps of the procedure has no effect on objective patient understanding, but significantly improves subjective understanding of the steps of the procedure among all patients and overall patient experience among non-White patients. Review of imaging as part of the consent process significantly improves subjective understanding among non-White patients, as well as post-procedure comfort with the provider who performed the procedure and overall experience among non-English-speaking patients. Future studies should evaluate the utility of the informational procedure video during the informed consent process for image-guided breast procedures in patients who speak languages other than English.
Introduction

Tablet computers like the iPad (Apple Inc., Cupertino, California) are well-equipped devices for patient education given their seamless image and video display capability, ease of Internet connectivity, secure access to online medical records, and simple means of user input. These features make the iPad an appealing option for supplementing the process of informed consent for medical, surgical and diagnostic procedures. The use of multimedia presented on an iPad has shown promise for improving patient understanding during the written informed consent process for interventional radiology procedures,¹ but has yet to be evaluated in the context of image-guided breast procedures. Thus, the specific aims of this study were to: 1) Evaluate whether providing written informed consent on an iPad improves patient understanding compared to written informed consent on paper for image-guided breast procedures (the standard of care); 2) Evaluate whether a provider-led presentation of patient’s clinical images prior to the informed consent process on an iPad improves patient understanding for image-guided breast procedures; 3) Evaluate whether viewing a video that describes the procedure as well as the traditional information disclosed during the informed consent process improves patient understanding for image-guided breast procedures; and 4) Evaluate patient experience with multimedia-enhanced informed consent on an iPad for image-guided breast procedures. Achieving these aims will provide evidence for or against the use of easily implementable imaging- and multimedia-enhanced informational tools in support of the informed consent process for image-guided breast procedures.

Hypothesis

We hypothesize that viewing a video that explains the procedure, its benefits and risks, alternatives, and post-procedure activity restrictions will improve patient understanding during the informed consent process as compared to traditional and image-enhanced methods.

Defining Informed Consent

Informed consent refers to both the idea and the legal standard that physicians are obligated to disclose enough information relevant to a procedure or treatment which any lay person would find critical to making an informed decision about how to proceed or (depending on the jurisdiction) which by consensus a body of physicians has agrees should be disclosed, such that a
patient may play an active role in the decision making process through a non-coercive discussion with the physician about any further information or clarification that the patient desires.\textsuperscript{2-4} While multiple elements of the informed consent process are common across state and international borders, the legal requirements for informed consent vary between states. Current practice standards for physicians obtaining informed consent are largely the result of prior rulings within state courts in cases of patients who felt that adequate informed consent was not obtained before undergoing a procedure. Collectively, individual rulings along with input from the professional organizations to which physicians belong clarified not only what level of information should be disclosed to patients, but also the importance of patient involvement in the informed consent process and understanding of the disclosed information.\textsuperscript{2}

More than a patient signature on a consent form, informed consent is a process consisting of two parts: the disclosure of information from which a patient can decide whether or not to proceed with the procedure, and the actual provision of consent by the patient. Although there is variation between professional organizations and states in how this process is performed, the disclosure portion of the informed consent process typically consists of a discussion of the nature of the procedure, associated benefits and risks (including the magnitude, imminence, and probability of these benefits and risks), alternatives to the procedure, the right to refuse the procedure, and the right to revoke consent at any time. There is currently no universal standard for exactly how much information to disclose for each individual procedure requiring informed consent, but it is standard practice for providers to disclose any information that a sensible person would want to know before making the decision.\textsuperscript{2,4} After this information is disclosed, it is typically the duty of the provider to ensure patient understanding of the disclosed information, and to ensure that their decision is made completely voluntarily without coercion. After the provider has ensured patient understanding and voluntariness, she may request that the patient indicates her willingness to undertake the associated risks of the procedure and forego the pursuit of any alternatives by signing an institutional consent form. In addition to multiple legal precedents which helped promote these practice standards, the American College of Radiology, the Society for Interventional Radiology, and the Society for Pediatric Radiology all promote these standards in their joint “Practice Parameter on Informed Consent for Image-guided Procedures.”\textsuperscript{5-7}
Patient understanding is a critical element of the informed consent process for both patients and providers. Often facing significant time constraints, providers may have difficulty ensuring patient understanding while they verbally describe a procedure, its indications, potential diagnostic benefits, and risks. Some providers simply request the patient’s signature on a consent form with little effort to ensure patient understanding and minimize coercion. As a result, not only do patients undergo procedures they potentially would not have undergone had they been more informed, but providers also make themselves more vulnerable to litigation. The informed consent process should ideally be a conversation between the patient and the provider in which patient questions and concerns about the information disclosed are addressed with objective language to avoid any coercion and verify that patients have a clear grasp of the procedure they are about to undergo. This idealized, interactive informed consent process may not be fully realized due to provider concerns about time constraints and inherent bias against any courses of action chosen by the patient which contradict with what the provider believes to be the best course of action.

In an observational study of the informed consent process in both inpatient and outpatient settings at a university hospital, Lidz, et al. identified multiple barriers patient involvement in decision making. Prominent barriers included an attitude among most physicians that the quality of the informed consent process does not influence the quality of patient care, and reluctance among inpatients to question their providers and take a greater role in clinical decision-making. As a result, approximately 90% of patients in this study felt removed from the decision-making process.

Patients undergoing the informed consent process for image-guided breast procedures are particularly susceptible to poor understanding given that confusion and concern about current diagnoses, anxiety about the procedure and ultimate diagnosis, the meaning of prior imaging studies and the diagnostic effectiveness of both invasive and non-invasive procedures in diagnosing serious breast disease are common. A cross-sectional study of patient understanding of abnormal mammogram results among women in the San Francisco Bay area by Karliner, et al. highlighted the need for improved communication of breast imaging results. Full understanding of their physician’s explanation of the abnormal results was reported by only 70% of women surveyed in the study. Furthermore, 49% of those with mammograms classified as suspicious or
highly suggestive of malignancy (BI-RADS 4 or 5) were not aware of their abnormal results.\textsuperscript{9} Similarly, many women awaiting breast biopsy after an abnormal mammogram experience confusion and anxiety surrounding the actual procedure which they will undergo, since the details of the procedure are often not discussed by the provider.\textsuperscript{10} Women referred to have a breast biopsy may also experience levels of anxiety and depression in the days leading up to their biopsy similar to those diagnosed with breast cancer when details communicated about their imaging findings remain ambiguous.\textsuperscript{11} A systematic review of the literature on anxiety due to breast disorders in women by Woodward and Webb showed that similar levels of anxiety are seen among women with breast disorders regardless of whether the disorder is benign or malignant. Similarly, this study showed that clear communication is critical in reducing anxiety in these women while they undergo further diagnostic workup and treatment.\textsuperscript{12} A prospective longitudinal study of the impact of communication on short-term follow-up of abnormal mammograms by Poon, et al. showed that among women who had a documented conversation with their physician about their abnormal test result, 26\% had no recollection of what the physician told them.\textsuperscript{13} Thus, an effective means of improving patient understanding during the informed consent process for diagnostic breast procedures would be beneficial.

\textit{Innovation}

This is the first study of patient understanding after imaging- and video-enhanced informed consent for image-guided breast procedures. Multiple prior studies examined the effect of multimedia-enhanced informed consent on patient understanding and experience, but none of these studies examined informed consent for diagnostic procedures within radiology. Of these prior studies, only one evaluated the utility of multimedia during the informed consent process for a diagnostic procedure, for which patient understanding may be more difficult given the lack of a formal diagnosis. This prospective randomized trial by Mednick, et al. in 2016 of the use of a supplemental narrated white board animation video detailing the information typically disclosed during the informed consent process for intravenous fluorescein angiography showed that video-enhanced informed consent significantly improved both patient understanding and subjective patient experience. Whereas our study examined the use of video displayed on an iPad, the video used in this study was displayed on a computer. The 6-question knowledge assessment used in this study did not assess patient comprehension of details about the procedure.
such as what will happen during the procedure and any alternatives that exist. This study also excluded those patients who do not speak English, making it difficult to determine if this tool could be beneficial in non-English-speaking populations.¹⁴

Other studies of multimedia-enhanced informed consent showed differing effects on patient understanding, yet had notable flaws in study design. A 2013 study of iPad-based multimedia for informed consent prior to interventional radiology procedures showed that clinical images and drawings improve subjective patient understanding and confidence in the provider. Patients in this study were asked to rate whether the interventions were significantly helpful in understanding the reasons for the procedure, but no objective metric of patient understanding was used. Patients in this study were also surveyed after the interventional procedure during which they had received conscious sedation, raising concern that patients might not have had full decision-making capacity at the time they were answering the survey questions. Similarly, there was no analysis of potential differences between patients of different ethnicities, education levels, or primary languages. Lastly, given that diagnostic procedures require additional understanding from patients regarding the likelihood of diagnostic success and the possibility of a non-diagnostic sample, the results of this study are likely not applicable to diagnostic procedures since 75% of the procedures included in this study were exclusively therapeutic.¹ A 2016 randomized controlled crossover trial by Winter, et al. of an iPad-based video supplement to the informed consent process for cystoscopy and ureteric stent insertion showed similar results. Patients who watched the video during their informed consent process had better objective understanding as measured by a true or false questionnaire than those who underwent standard verbal consent. The questionnaire used to evaluate patient understanding, however, was not a validated tool and it is unclear what specific questions were included.¹⁵ A 2015 randomized controlled trial of patient understanding after iPad-based multimedia during the informed consent process for minimally invasive vascular procedures by Bowers, et al. showed that multimedia-enhanced informed consent improves patient understanding of details about the procedure and overall satisfaction. The questionnaire used, however, was not a validated tool for assessing patient understanding during the consent process.¹⁶ A randomized controlled trial by Ham, et al. in 2016 of a mixed multimedia (illustrations, animations, and videos) informed consent supplement for patients requiring photo-selective vaporization of the prostate, however, showed
no effect on patient understanding compared to patients who underwent conventional written informed consent. A non-validated test of objective understanding was used in this study, but questions included in the test covered most important elements of informed consent. Also, patients whose education level was below middle school were excluded from the study, limiting the applicability of this study to that population of patients.17

Methods

Subject Selection

Informed written consent is required from all patients undergoing an image-guided breast procedure at Beth Israel Deaconess Medical Center (Boston, MA), therefore all patients scheduled to undergo a breast biopsy in the radiology department were eligible for inclusion in this study. Patients were excluded from the study if they had significant visual impairments that precluded them from viewing the multimedia displayed on the iPad, if there was a language barrier that could not be adequately overcome with the aid of an interpreter, or if they refused to have the iPad supplement their informed consent procedure. Patients were excluded from the video arm of the study if they did not speak English, as the video was not available in other languages. Patients included in this study were those scheduled to undergo ultrasound-guided core needle biopsy or stereotactic core needle biopsy who verbally consented to participate.

Prototype iPad Application Development

A prototype iPad application (Figure 1) was developed for this study using Apple Xcode version 8.2.1 (Apple, Inc., Cupertino, CA), the Swift programming language, as well as HTML5. Two procedure videos, one for ultrasound-guided core needle biopsies and the other for stereotactic core-needle biopsies, were created to be used as interventions within the video arm of the study. These videos consisted of still images of the procedure, text detailing the reason for the procedure, steps of the procedure, potential benefits, risks, alternatives, and post-procedure instructions for each respective procedure, all accompanied by voice narration. The content for the procedure videos was agreed upon via consensus input from five members of the breast imaging division at the institution with 5-30 years of clinical experience. The stereotactic core needle biopsy video had a duration of 323 seconds (5 minutes, 23 seconds) and the ultrasound-guided core needle biopsy video had a duration of 271 seconds (4 minutes, 31 seconds). The
videos were then housed within the iPad application where they would be shown to patients in the video arm of the study. The iPad application also included one link to the REDCap-based pre-consent, objective understanding, peri-consent, and post-procedure surveys, one link to the PDF-version of our institutional informed consent form to be signed within a PDF reader by patients in the iPad only, imaging, and video arms of the study, and a timer to record the duration of the informed consent process for each patient.

Objective Measurement of Patient Understanding

Given the right that all patients have to receive information about a suggested procedure and play an active role in the decision-making process, the validity of informed consent obtained from patients with incomplete understanding of the information that was disclosed is questionable. Although such patients with incomplete understanding are unlikely to be deemed incompetent by the traditional legal standard of inability to communicate choices, the inability to understand information relevant to an important treatment decision greatly undermines a patient’s ability to provide truly informed consent. Thus, improving patient understanding during the informed consent process is of great importance to upholding the legal doctrine of informed consent.

Applebaum and Grisso assert in their 1988 article that true understanding of the information disclosed during the informed consent process should be assessed by a patient’s ability to paraphrase this information since multiple choice and true or false questionnaires mostly assess the patient’s ability to remember the information that was disclosed. To ensure adequate assessment of patient understanding in this study, we decided against using a questionnaire like most prior studies of patient understanding during informed consent in favor of a validated tool for evaluating how well patients can paraphrase the disclosed information, the MacArthur Competence Assessment Tool – Treatment (MacCAT-T). In a 2006 literature review of tools for assessing patient competence during the informed consent process for diagnostic or therapeutic procedures, Dunn, et al. found that the MacCAT-T has been validated in multiple different populations and has high interrater reliability, giving it the most support in the literature of all similar tools.

Study Protocol
This prospective randomized controlled trial was performed in the Linsey Breast Imaging Center of the Department of Radiology at Beth Israel Deaconess Medical Center. Consecutive patients presenting for breast biopsy were recruited to this study using a verbal consent script. Those that agreed to participate in the study were consented, enrolled, and randomized to undergo informed written consent process in one of four arms: A) traditional consent in paper format; B) traditional consent on the iPad; C) consent on the iPad enriched by patient images; or D) consent on the iPad enriched by a video tool (Figure 2). Randomization was performed in a sequential fashion based on the daily image-guided procedure schedule.

The informed consent process in the first and second arms of this study began with an explanation of what was known about the patient’s condition. Then, the provider explained the procedure, its benefits and risks, alternatives, and any post-procedure activity restrictions. In the third arm of this study, the informed consent process began with a provider-led presentation of patient clinical images on an iPad. Then, the provider explained the procedure, its benefits and risks, alternatives, and any post-procedure activity restrictions. The informed consent process in the fourth arm of this study began with a video viewed by patients on an iPad that explains the procedure, its benefits and risks, alternatives, and post-procedure activity restrictions.

Prior to signing the breast biopsy procedure consent form, patients in each arm of this study were asked a series of questions from the MacArthur Competence Assessment Tool for Treatment (MacCAT-T). Administration of the MacCAT-T is integrated into the traditional informed consent process. After the provider discloses information about the indication for the procedure, its steps, benefits, risks, and alternatives, the patient is asked to paraphrase the disclosed information through a standard series of questions. The full MacCAT-T tool includes separate sections of questions to gauge patient understanding, expressing reasoning about risks and benefits, appreciating the consequences of their decision, and expressing a decision. Since this study aimed to evaluate the effect of our interventions on patient understanding, we exclusively used the MacCAT-T questions for understanding (Table 1). Any areas of confusion which become evident through these questions are clarified by the provider, after which the patient may ask any other questions to receive further clarification before signing the institutional consent form. Since the MacCAT-T questions prompt patients to paraphrase information, those rating
patient responses must be trained to determine what constitute adequate, partially adequate, and inadequate responses. In this study, two research staff members (AT and JF) administered all survey questions, timed the informed consent process, and rated patient responses without interference from providers. These two staff members were trained using the MacCAT-T manual’s guidelines for the rating process, in which a framework for rating the adequacy of a patient’s paraphrasing of vital information disclosed during the informed consent process was presented. To provide a rating, each patient’s responses to the MacCAT-T questions were compared to keyword-based examples of responses which would be considered adequate, partially adequate, and inadequate in an attempt to maintain the objectivity of the rating system as much as possible (Table 1).

Patients were given a rating from 0 to 2 for each item within the three MacCAT-T categories of understanding: understanding the disorder (naming the disorder, and up to 4 features of the disorder), understanding the procedure (naming the procedure, and up to 3 features of the procedure), and understanding its benefits and risks (naming up to 2 benefits, and up to 2 risks). A rating of 2 was given to patients who recalled a clear version of the content of an item. A rating of 1 was given to patients who described the item content with incomplete clarity, even after an effort at clarification was made. A rating of 0 was given to patients who did not recall the content of an item, described it in a completely inaccurate manner, or distorted the meaning of the item content even after an effort at clarification was made. A subtotal rating was calculated by averaging the ratings across all items within a category. The MacCAT-T understanding summary rating was then calculated by adding together the subtotal ratings for understanding of the disorder, the procedure, and its benefits and risks.

After each patient answered the MacCAT-T questions, the provider provided any clarification necessary to fill in gaps in patient understanding, and an approved Beth Israel Deaconess Medical Center breast biopsy Informed Consent Form was signed. Those in study arm A underwent the standard consent process and sign a paper consent form. Those in study arms B-D underwent three different enhanced informed consent methods delivered via the iPad, signed a digital version of the standard breast biopsy consent form on an iPad, and then signed the paper consent form. Once the breast biopsy consent form was signed, each patient underwent the
scheduled image-guided breast procedure, after which she was given a short post-procedure survey to rate her comfort level with the informed consent process as performed, her satisfaction with the description provided of the procedure, and her satisfaction with the provider. Patient anxiety, comfort with the provider, subjective understanding and overall experience were assessed using a 10-point visual analog scale. Patient opinions on how helpful the informational video and presentation of images were in helping understand the reasons for the procedure, understand the steps of the procedure, reduce anxiety, and improve confidence in the provider performing the procedure were assessed using a 5-point Likert scale (Table 2).

Sample Size Justification
Assuming standard deviation of 1 within each group based on Grisso’s 1997 study \(^{21}\) and a difference in mean summary rating of 0.5 between the video group and the other groups, a total of 240 subjects were necessary to have power of 0.8 to detect this difference at the 0.05 significance level. A total of 240 subjects were enrolled in this study, all who were patients at Beth Israel Deaconess Medical Center.

Outcomes
The primary outcome of this study is patient understanding as measured by the MacCAT-T understanding summary rating, \(^{20}\) calculated by adding together the subtotal ratings for understanding of the disorder, the procedure, and its benefits and risks. The secondary outcome of this study will be patient reactions to multimedia-enhanced informed written consent for image-guided breast procedures as measured by a short, multi-question survey.

Biostatistical Methods
Data from this study was entered into a REDCap database that contains the following information for each patient: a coded identification number, age, ethnicity, use of an interpreter, procedure, understanding subtotal and summary ratings, and post-procedure survey ratings. All data was stored on the secure institutional intranet and accessed only by study personnel on approved institutional computers. One-way ANOVA was used to analyze the primary outcome, the MacCAT-T summary rating for understanding. One-way ANOVA, Pearson’s \(r\) correlation and chi-squared analysis were used to analyze the secondary outcomes of this study. All
statistical analysis was performed at Beth Israel Deaconess Medical Center using IBM SPSS Version 24 (IBM Corp., Armonk, NY) by medical student Andrew Taliaferro, BA.

IRB/Ethical considerations

There was no identifying patient information included in this study other than age, ethnicity, education level, and use of an interpreter. This study received Beth Israel Deaconess Medical Center IRB Approval on June 8, 2016.

Results

Patient Demographics (Table 3)

An overview of the demographic characteristics of the patients included in this study can be found in Table 3. Of the 240 patients who completed this study, the average age of those in arm A was 53.4 years, 52.9 years in arm B, 52.8 years in arm C, and 54.1 years in arm D. There was no significant difference between study arms in age ($P = 0.93$). 59.6% (143) of patients were White, 17.5% (42) were Black, 7.5% (18) were Hispanic, 0% (0) were Native American, 12.1% (29) were Asian, 0.4% (1) were Pacific Islander, 1.3% (3) reported other, and 1.7% (4) were biracial. 78.3% (188) of patients spoke English and did not use an interpreter, 5.8% (14) used a Spanish interpreter, 6.3% (15) used a Mandarin or Cantonese Chinese interpreter, 1.7% (4) used a French or Haitian Creole interpreter, 2.1% (5) used a Portuguese or Cape Verdean Creole interpreter, 2.1% (5) used a Russian interpreter, and 3.8% (9) required an interpreter for a language other than those listed (Vietnamese, Korean, Polish, Persian, Urdu, and Gujarati). 5.4% (13) of patients had less than a high school education, 16.3% (39) completed high school, 12.9% (31) completed an associate’s degree, 30.4% (73) completed a bachelor’s degree, and 35.0% (84) had graduate education. Among all patients, self-reported race other than White was significantly associated with lower education level ($\chi^2 = 50.4, P < 0.01$) and less pre-consent preparation before arriving for the biopsy ($r = 0.16, P = 0.01$). Speaking a primary language other than English was also significantly associated with lower education level ($\chi^2 = 67.8, P < 0.01$) and less pre-consent preparation ($r = 0.18, P < 0.01$).

Primary Outcome
There was no significant difference between study arms in MacCAT-T understanding summary rating among all patients \((P = 0.19, \text{ Figure 3})\), non-White patients \((P = 0.25)\), English-speaking patients \((P = 0.80)\), non-English-speaking patients \((P = 0.78)\), those with greater than a high school education \((P = 0.70)\) and those with less than a high school education \((P = 0.47)\). Of note, greater education level was significantly associated with greater understanding of the breast abnormality \((r = 0.19, P < 0.01)\), the procedure \((r = 0.34, P < 0.01)\), the benefits and risks of the procedure \((r = 0.38, P < 0.01)\), and understanding summary rating \((r = 0.40, P < 0.01)\) as measured with the MacCAT-T. Among White patients, a significant difference was observed between study arms in understanding of procedure benefits and risks measured with the MacCAT-T \((P = 0.05, \text{ Figure 4})\), but no significant difference was observed for MacCAT-T understanding summary rating in this group. A Tukey post hoc test revealed that White patients in arm D had greater understanding of procedural benefits and risks \((3.8 \pm 0.4 \text{ SD})\) than those in arm C \((3.5 \pm 0.7 \text{ SD}, P = 0.03)\) but not significantly greater than those in arm B \((3.7 \pm 0.5 \text{ SD}, P = 0.64)\) or arm A \((3.6 \pm 0.7 \text{ SD}, P = 0.41)\).

**Secondary Outcomes**

Among all patients included in this study, a significant difference was observed between study arms in the time taken to complete the informed consent process \((P < 0.01, \text{ Figure 5})\). The informed consent process for those in arm D \((584.4 \pm 125.3 \text{ seconds SD})\) took significantly more time than that for patients in arm C \((383.8 \pm 116.3 \text{ seconds SD}, P < 0.01)\), arm B \((305.1 \pm 118.4 \text{ seconds SD}, P < 0.01)\), and arm A \((292.6 \pm 121.4 \text{ seconds SD}, P < 0.01)\). Increased time for informed consent was negatively correlated with overall experience among all patients \((r = -0.19, P < 0.01)\). There was no significant difference between study arms in age \((P = 0.93)\), pre-consent preparation \((P = 0.13)\), pre-consent anxiety \((P > 0.99)\), peri-consent anxiety \((P = 0.73)\), anxiety reduction between the pre- and peri-consent surveys \((P = 0.13)\), peri-consent comfort with the provider \((P = 0.41)\), post-procedure anxiety \((P = 0.48)\), post-procedure comfort with the provider \((P = 0.37)\), subjective understanding after the procedure \((P = 0.11)\), and overall experience \((P = 0.27)\).

Among White patients, no significant difference was observed between study arms in age \((P = 0.39)\), pre-consent preparation \((P = 0.12)\), pre-consent anxiety \((P = 0.27)\), peri-consent anxiety \((P = 0.73)\), and peri-consent comfort with the provider \((P = 0.73)\).
anxiety reduction between the pre- and peri-consent surveys ($P = 0.65$), post-procedure anxiety ($P = 0.10$), post-procedure comfort with the provider ($P = 0.97$), subjective understanding after the procedure ($P = 0.16$), and overall experience ($P = 0.07$). ANOVA revealed a significant difference between study arms in peri-consent comfort with the provider ($P = 0.05$), but a Tukey post hoc test did not reveal any significant differences between specific study arms.

Among non-White patients, a significant difference between study arms was observed for anxiety reduction between the pre- and peri-consent surveys ($P = 0.03$, Figure 6), post-procedure comfort with the provider ($P = 0.03$), subjective understanding ($P = 0.04$, Figure 7), and overall experience ($P = 0.01$, Figure 8). Non-White patients in arm B experienced increased anxiety between the pre-consent and peri-consent surveys ($0.6 \pm 0.9$ SD) as compared to those in arm A whose anxiety decreased between those two points in time ($-0.2 \pm 1.1$ SD, $P = 0.03$). Those in arm B had lower post-procedure comfort ($8.9 \pm 1.6$ SD) with the provider than those in arm A ($9.7 \pm 0.6$ SD, $P = 0.03$). Those in arm C reported greater subjective understanding ($9.8 \pm 0.7$ SD) than those in arm B ($9.0 \pm 1.6$ SD, $P = 0.05$). Similarly, non-White patients in arm B had lower rating of overall experience ($9.2 \pm 0.9$ SD) than both those in arm D ($9.8 \pm 0.5$ SD, $P = 0.02$). These patients also had lower rating of overall experience than those in arm A ($9.8 \pm 0.5$ SD, $P = 0.01$). Otherwise, there was no significant difference between study arms in age ($P = 0.66$), pre-consent preparation ($P = 0.66$), pre-consent anxiety ($P = 0.25$), peri-consent anxiety ($P = 0.07$), peri-consent comfort with the provider ($P = 0.48$), and post-procedure anxiety ($P = 0.75$).

Among English-speaking patients, a significant difference was observed between study arms in pre-consent preparation level ($P = 0.03$). Patients in arm C had significantly greater pre-consent preparation ($1.7 \pm 1.0$ SD) than those in arm B ($1.2 \pm 0.9$ SD, $P = 0.05$) and arm A ($1.1 \pm 0.6$ SD, $P = 0.04$). There was otherwise no significant difference between study arms in age ($P = 0.82$), preparation sum ($P = 0.48$), pre-consent anxiety ($P = 0.85$), peri-consent anxiety ($P = 0.84$), anxiety reduction between the pre- and peri-consent surveys ($P = 0.30$), peri-consent comfort with the provider ($P = 0.14$), post-procedure anxiety ($P = 0.29$), post-procedure comfort with the
provider \( (P = 0.37) \), subjective understanding after the procedure \( (P = 0.11) \), and overall experience \( (P = 0.43) \).

Among non-English speaking patients, a significant difference was observed between study arms in post-procedure comfort with the provider \( (P = 0.03, \text{Figure 9}) \) and overall experience \( (P < 0.01, \text{Figure 10}) \). Those in arm C had greater post-procedure comfort with the provider \( (9.9 \pm 0.6 \text{ SD}) \) than those in arm B \( (8.8 \pm 1.7 \text{ SD}, P = 0.04) \). Overall experience was significantly greater for those in arm C \( (9.9 \pm 0.3 \text{ SD}, P < 0.01) \) and arm A \( (9.9 \pm 0.4 \text{ SD}, P < 0.01) \) than those in arm B \( (9.0 \pm 0.9 \text{ SD}) \). There was no significant difference observed between study arms for age \( (P = 0.47) \), pre-consent preparation \( (P = 0.28) \), pre-consent anxiety \( (P = 0.50) \), peri-consent anxiety \( (P = 0.56) \), and subjective understanding after the procedure \( (P = 0.13) \).

Among patients with education level greater than high school and those with education level of high school or less, there was no significant difference between study arms in age \( (P = 0.62 \text{ and } 0.27, \text{respectively}) \), pre-consent preparation \( (P = 0.18 \text{ and } 0.86, \text{respectively}) \), pre-consent anxiety \( (P = 0.28 \text{ and } 0.66, \text{respectively}) \), peri-consent anxiety \( (P = 0.90 \text{ and } 0.37, \text{respectively}) \), peri-consent comfort with the provider \( (P = 0.44 \text{ and } 0.56, \text{respectively}) \), post-procedure anxiety \( (P = 0.81 \text{ and } 0.49, \text{respectively}) \), post-procedure comfort with the provider \( (P = 0.33 \text{ and } 0.76, \text{respectively}) \), subjective understanding after the procedure \( (P = 0.15 \text{ and } 0.30, \text{respectively}) \), and overall experience \( (P = 0.31 \text{ and } 0.31, \text{respectively}) \).

Among all patients, those in the video arm were more likely to strongly agree with the statement that this intervention was helpful in understanding the steps of the procedure than those in the imaging arm reported about the respective intervention used in their arm of the study \( (\chi^2 = 9.8, P=0.04) \).

**Discussion**

To our knowledge, this is the first study of multimedia-enhanced informed consent for image-guided breast procedures. Multiple prior studies have evaluated the utility of various forms of media as an enhancement to the informed consent process for therapeutic procedures in a variety of other fields such as ophthalmology, urology, interventional radiology, and vascular surgery.
with mixed results,\textsuperscript{1,14-17} but this is the first study of its kind within the field of diagnostic radiology. Unlike therapeutic procedures, diagnostic procedures have an inherent degree of associated uncertainty about the purpose, potential benefits, and risks of the procedure which may lead to reduced patient understanding and increased anxiety during the informed consent process. Thus, studies specific to the informed consent process for image-guided breast procedures are necessary to determine how patient understanding and autonomy can be optimized, improving the overall quality of the informed consent process as a whole while also possibly reducing anxiety and improving the overall experience of women requiring these procedures.

In our study, watching an informational procedure video detailing information typically disclosed during the informed consent process improved patient understanding of the benefits and risks of the procedure compared to a provider-led presentation of imaging findings among White patients. Within this group, however, there was no significant difference in understanding of benefits and risks between the video arm, the iPad consent form only arm, and the traditional consent arm. Similarly, among all other patient groups there was no difference in objective understanding of information disclosed during the informed consent process between patients in each of the study arms as measured with the MacCAT-T. Multiple possible explanations exist for the overall inefficacy of multimedia-enhanced informed consent in improving objective understanding. Since a small but significant effect was only seen among White patients who watched the informational procedure video it is plausible that patients must have a certain level of literacy or education in order for the video to have a significant effect on understanding. Pearson’s $r$ correlation analysis showed that higher education level is significantly correlated with increased understanding as measured with the MacCAT-T. Similarly, chi-squared analysis indicated that White patients were significantly more likely to have a higher education level than non-White patients. Since the effect among White patients was small and limited only to understanding the benefits and risks of the procedure (and not the other elements of understanding which were tested), and since no effect was seen among patients who had greater than a high school education, it is unlikely that differences in education are to blame for the inadequacy of our multimedia tools in improving understanding among non-White and non-English-speaking patients. Furthermore, the two procedure videos used in this study contained
text and language almost identical to that used in the brochures typically given to patients before their image-guided biopsy, which are written for patients of any education level. Thus, education level should not be expected to play a role in how well patients understand the information disclosed during the informed consent process.

An alternative explanation for why the video and imaging interventions failed to improve understanding observed in this study involves the sensitivity and specificity of the MacCAT-T in detecting inadequate understanding. Although the MacCAT-T has been validated in multiple studies when compared to other tools and has low inter-rater variability,\(^\text{19}\) this tool was designed specifically to avoid providing a firm cutoff between adequate and inadequate understanding (as well as competency and incompetency), but instead to assist providers in identifying which patients have incomplete understanding of what was disclosed during informed consent.\(^\text{20}\) Without a cutoff for inadequate understanding, it is impossible to determine the sensitivity and specificity of the MacCAT-T. Thus, it is possible that the questions included within the MacCAT-T for understanding are inadequately constructed to detect subtle differences in understanding between patients.

Most prior studies of multimedia-enhanced informed consent showed that videos, animations, and images showed that these interventions increase patient understanding during the informed consent process as measured by true or false or multiple choice questionnaire.\(^\text{1, 14-16}\) While the use of a questionnaire does not require the training necessary for a rater to properly administer the MacCAT-T, questionnaires are better tools for assessing patient memory of what was disclosed rather than true understanding, which is best assessed by asking the patient to paraphrase what was disclosed.\(^\text{18}\) Furthermore, the questionnaires used in these studies were not validated and multiple studies did not ask questions about information critical for a patient to understand before providing informed consent such as the indication for the procedure.\(^\text{14-16}\) None of these prior studies included procedures performed in breast imaging, or even more specifically diagnostic radiology, so the results of these studies may be inapplicable to diagnostic procedures. Without further evidence to support our finding that watching a short video detailing basic procedural steps, benefits, risks, alternatives, and post-biopsy care instructions for stereotactic and ultrasound-guided core needle biopsies improves objective patient understanding of the
benefits and risks of these procedures, it remains unclear whether multimedia-enhanced informed consent actually improves objective patient understanding for image-guided breast procedures.

This study also found that there was no significant difference in either pre-consent, peri-consent or post-procedure anxiety between the four study arms. Among non-White patients, however, those in arm B experienced on average an increase in anxiety from the time that the pre-consent survey was performed to the time that the peri-consent survey was performed just before undergoing their stereotactic or ultrasound-guided core needle biopsy. Those in arm A experienced a significantly different reduction in anxiety level between those two points in time as compared to the increase in anxiety that those in arm B experienced. These findings suggest that not only are informational videos and provider-led explanations of imaging findings before the informed consent process begins ineffective in reducing anxiety among women of any race, primary language, or level of education undergoing image-guided breast biopsies, but also that the use of a digital consent form on the iPad for patients to sign may inadvertently increase anxiety among non-White patients during the consent process. Possible reasons for these findings include that the interventions used in this study did not actually address common causes of anxiety among women requiring breast biopsies, or similarly, that anxiety in the days before and during an image-guided breast biopsy is independent of the amount of information and understanding that a patient has acquired and is instead driven by other factors. Lebel, et al. identified multiple factors which impact the amount of distress that women experience while waiting for a breast biopsy. In addition to those with active emotional coping strategies, women with no family history of breast cancer or personal history of prior breast biopsies are better able to handle the marked distress which may accompany referral for a breast biopsy. Of note, these are all factors which could not be modified through the use of a video or imaging presentation aimed at improving understanding. Thus, patients with anxiety about the procedure and its results may likely remain anxious if the cause for their anxiety is not properly addressed. A systematic review of breast disorder-related anxiety among women by Woodward, et al. called into question the assertion that distress among women with undiagnosed breast disorders is due to inadequate information. Instead, this article’s review of multiple studies revealed that inadequate counseling, social support, and delayed communication of new findings and results are more likely drivers of anxiety and distress among these patients. Similarly, Ong and
Austoker showed in their 1997 article that inadequate communication even at the time of recall for an abnormal screening mammogram results in significantly increased distress, which may remain at the time of breast biopsy if no effort to improve communication with the patient has been made. Thus, even if the quality of information presented to the patient was improved by the use of our informational video or imaging presentation, patient anxiety may remain unaffected. Of note, multiple patients reported difficulty signing the iPad consent form within the document editor that was used, which may have contributed to the worsening of anxiety among non-White patients in arm B during the consent process due to a combination of frustration, embarrassment, and possibly feeling that the iPad was an unnecessary addition to the consent process.

Significant improvements among non-White and non-English speaking patients in post-procedure comfort with the provider, subjective rating of understanding, and overall experience were achieved through the use of our informational videos for stereotactic and ultrasound-guided core needle biopsies and provider-led presentations of patient imaging. Whereas showing an informational video resulted in improved overall experience among non-White patients compared to the traditional informed consent process with a digital consent form in arm B, the provider-led presentation of patient images used in arm C resulted in improved subjective understanding among this patient population. Of note, there was no significant difference in overall experience between non-White patients in the video arm and those in the traditional paper consent arm. Given the potential impact of having to sign the consent form on the iPad, however, data from patients in imaging arm should only be compared to those in the iPad consent only arm. Similarly, non-English speaking patients who received a provider-led presentation of their imaging findings reported higher post-procedure comfort level with the provider performing the procedure as well as higher overall experience compared to those in arm B who did not receive that intervention and signed the consent form on the iPad. Together, these findings suggest that multimedia-enhanced informed consent is particularly useful for improving the experience of non-White and non-English-speaking women who are undergoing image-guided breast biopsies. Women may experience significant emotional distress surrounding breast biopsies, which may be further exacerbated if they perceive a sub-optimal interaction with the team performing the biopsy. By viewing a video or imaging supplement to the informed consent process, minority patients and those who speak a language other than English may perceive improved effort on the
part of the staff performing the biopsy to accommodate their needs, and provide care at the standard which all patients regardless of race or language should receive, with the patient’s best interest at heart. Interestingly, non-White patients in arm B reported lower post-procedure comfort with the provider, as well as lower overall experience than those in arm A, as did non-English-speaking patients in arm B. These findings mirror our findings that patients in arm B experienced increased anxiety over the course of their appointment as compared to those who underwent the entirely traditional consent process in arm A. This further supports the claim that women undergoing breast biopsy may find signing an iPad-based version of the consent form significantly distressing, arguing against its use.

The total time for informed consent in the video arm of this study required significantly more time than that in all other arms. Much of the time used in the video arm, however, was dedicated to showing the video to the patient. In this study, patients were shown the video prior to beginning the actual informed consent process, which resulted in minimal disruption to normal workflow in the procedure rooms where patient biopsies were occurring and within the breast imaging division as a whole. Of note, however, increased time for informed consent was negatively correlated with overall experience among all patients. Thus, to preserve the quality of patient experience in the future, patients could be watch these videos from the comfort of their own homes or while waiting in the waiting room, limiting the time that is spent during the informed consent process within the procedure room (which may be an anxiety-provoking location for many patients) while also ensuring that no workflow interruptions occur.

Limitations
Since there is no universally accepted guideline for how much a patient should understand about a procedure and his or her illness before giving informed consent, we are also limited by our inability to assess patient understanding in the intervention groups as compared to a gold standard, paper consent group. In addition, even though providers were informed at the beginning of the study about what information should be disclosed during the informed consent process, inter-provider variability in how the consent process was performed was inevitable, introducing some potential biases. Adding to the potential bias of the providers was the potential for bias among the two authors (AT and JF) who served as raters of patient understanding during
this study. Although they were thoroughly trained in the methods of administering the MacCAT-T, using this tool to rate patient understanding is inherently subjective since it requires that patients paraphrase in response to a question as opposed to answering a multiple choice or true or false question which does little to gauge understanding. Despite this, we attempted to minimize any potential bias that existed due to inter-rater variability by having the raters rate patient responses against a set of pre-written responses which were deemed to display adequate, partially adequate, and inadequate responses. A subtle limitation of this study is that no attempt was made to designate whether patient anxiety levels, which were measured on a 10-point visual analog scale, were due to anxiety about the biopsy procedure, anxiety about the results of the biopsy, or anxiety about something unrelated to either the procedure or the results. Consequently, our finding that none of the interventions used in this study resulted in a reduction in patient anxiety may not be valid, especially since one intervention may have helped to reduce a certain type of anxiety but not others. Although non-White and non-English-speaking patients who underwent the traditional consent process supplemented with a digital consent form experienced worsened anxiety and reduced overall experience, much of this may have been the result of difficulty that many patients had with signing the digital form. Many patients had difficulty using a stylus to write on the iPad, and many were upset about the appearance of their signatures on the digital form appeared compared to their normal handwriting. Thus, proper evaluation of the utility of a digital consent form should involve a more user-friendly mechanism for obtaining patient signatures, possibly revealing a result different from ours. Lastly, since non-English-speaking patients were excluded from the video arm of this study, our results indicating the benefits of an informational procedure video for patient understanding and overall experience are not applicable to patients who do not speak English.

Conclusions
Viewing an informational procedure video detailing the benefits, risks, alternatives and steps of an image-guided breast procedure has no effect on objective understanding, but significantly improves subjective understanding of the steps of the procedure among all patients, and overall patient experience among non-White patients. Review of imaging as part of the consent process significantly improves subjective understanding among non-White patients, as well as post-procedure comfort with the provider who performed the procedure and overall experience among
non-English-speaking patients. Both of these approaches to enhancing the informed consent process for image-guided breast procedures require only modest increases in time allotment for consent, making their implementation into practice feasible. Since there is no universally accepted guideline for how much a patient should understand about a procedure and his or her illness before giving informed consent, however, we are limited by our inability to assess patient understanding in the intervention groups as compared to the gold standard, paper consent group. In addition, inter-provider variability and inter-rater MacCAT-T variability in the consent process likely introduced some potential biases. Lastly, since non-English-speaking patients were excluded from the video arm, we were unable to determine the effect of an informational video on patient understanding, experience, and anxiety on this subgroup of patients.

**Suggestions for Future Work**
The present study was unable to evaluate the utility of informational videos detailing information typically disclosed during the informed consent process for image-guided breast procedures among patients who do not speak English. To adequately evaluate this utility, the procedure videos should be translated into different languages and understanding, anxiety, and experience among patients who do not speak English and those who do should be compared. Improvements to the user-friendliness of the document viewer used to sign the digital consent form in arm B should be made so as to avoid any potential skewing of patient experience in that arm due to the frustration or embarrassment that results from having difficulty signing the digital consent form. Future studies should also evaluate whether the interventions used in this study affect patient anxiety as a whole, or specifically affects patient anxiety about the procedure any differently than patient anxiety about the results of the biopsy or their potential mortality. Doing so may further clarify the effect of multimedia-based informed consent on patient anxiety.

**Summary**
Patient understanding is a critical element of the informed consent process for image-guided breast procedures. Informational videos and review of imaging for patients improve patient comfort and experience, especially among non-White and non-English-speaking patients, but have little effect on anxiety and understanding during the informed consent process.
References


18. Appelbaum PS, Grisso T. Assessing patients' capacities to consent to


Tables and Figures

Table 1 – MacCAT-T questions and scoring.

<table>
<thead>
<tr>
<th>Question</th>
<th>Response Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Please explain in your own words what was said about the findings on your imaging that led to the biopsy. (What are some features of your condition?)</td>
<td>2 - Breast calcifications, breast mass, breast lump, architectural distortion 1 - Something in my breast 0 - Not sure/None of the above</td>
</tr>
<tr>
<td>What is the name of the procedure you are about to undergo?</td>
<td>2 - Ultrasound or stereotactic core biopsy, fine needle or cyst aspiration 1 - Taking tissue from my breast, taking a sample 0 - Not sure/None of the above</td>
</tr>
<tr>
<td>Why are you getting the procedure?</td>
<td>2 - Get a diagnosis, to find out whether I have cancer 1 - The doctor recommended it 0 - Not sure/None of the above</td>
</tr>
<tr>
<td>What will happen during this procedure?</td>
<td>2 - Putting a needle in the breast, taking tissue samples, and sending to pathology for study 1 - Taking a sample but can't describe any specific steps 0 - Not sure/None of the above</td>
</tr>
<tr>
<td>What are the potential benefits of this procedure?</td>
<td>2 - Diagnosis, certainty, knowing what it is 1 - Anything else but what is listed above 0 - Not sure</td>
</tr>
<tr>
<td>What are potential risks of the procedure?</td>
<td>2 - 2 or more of: bleeding, infection, insufficient sample, pain, allergic reaction 1 - Only 1 of the above 0 - Not sure/None of the above</td>
</tr>
</tbody>
</table>
Table 2 – Peri-consent and post-procedure survey questions.

<table>
<thead>
<tr>
<th>Peri-Consent Survey</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rate your anxiety on a scale of 1-10. 1 is not anxious at all, 10 is very anxious.</td>
</tr>
<tr>
<td>1 2 3 4 5 6 7 8 9 10</td>
</tr>
<tr>
<td>How comfortable are you with the person performing the procedure? 1 is not comfortable, 10 is very comfortable.</td>
</tr>
<tr>
<td>1 2 3 4 5 6 7 8 9 10</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Post-Procedure Survey</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rate your level of anxiety on a scale of 1-10. 1 is not anxious at all, 10 is very anxious.</td>
</tr>
<tr>
<td>1 2 3 4 5 6 7 8 9 10</td>
</tr>
<tr>
<td>How comfortable were you with the person performing the procedure? 1 is not comfortable, 10 is very comfortable.</td>
</tr>
<tr>
<td>1 2 3 4 5 6 7 8 9 10</td>
</tr>
<tr>
<td>How well do you feel you understood the procedure that was explained to you? 1 is not at all, 10 is very well.</td>
</tr>
<tr>
<td>1 2 3 4 5 6 7 8 9 10</td>
</tr>
<tr>
<td>Overall, please rate your experience during this visit. 1 is poor, 10 is excellent.</td>
</tr>
<tr>
<td>1 2 3 4 5 6 7 8 9 10</td>
</tr>
<tr>
<td>Was viewing your radiology imaging or the video helpful in UNDERSTANDING THE REASONS for your procedure?</td>
</tr>
<tr>
<td>Strongly disagree/Disagree/Undecided/Agree/Strongly agree</td>
</tr>
<tr>
<td>Was viewing your radiology imaging or the video helpful in UNDERSTANDING THE STEPS of the procedure?</td>
</tr>
<tr>
<td>Strongly disagree/Disagree/Undecided/Agree/Strongly agree</td>
</tr>
<tr>
<td>Was viewing your radiology imaging or the video helpful in REDUCING YOUR ANXIETY about the procedure?</td>
</tr>
<tr>
<td>Strongly disagree/Disagree/Undecided/Agree/Strongly agree</td>
</tr>
<tr>
<td>Was viewing your radiology imaging or the video helpful in INCREASING YOUR CONFIDENCE in the providers performing the procedure?</td>
</tr>
<tr>
<td>Strongly disagree/Disagree/Undecided/Agree/Strongly agree</td>
</tr>
<tr>
<td>How did viewing your radiology imaging or the video change your overall experience?</td>
</tr>
<tr>
<td>Study Arm</td>
</tr>
<tr>
<td>-----------</td>
</tr>
<tr>
<td>1</td>
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<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
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<td>4</td>
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Figure 1 - Screenshots of the prototype iPad application.

CONSENT SUPPLEMENT

Beth Israel Deaconess Medical Center
HARVARD MEDICAL SCHOOL TEACHING HOSPITAL

"iPad-based patient education during informed consent for image-guided breast procedures."

Possible Biopsy Complications:

• Bleeding
• Infection
• The need for more procedures or treatments
• Non-diagnostic sample
• Allergic reactions
Figure 2 – Study configuration.
There was no significant difference between study arms in MacCAT-T understanding summary rating among all patients ($P = 0.19$).
Figure 4 – Objective understanding of procedure benefits and risks among White patients (one-way ANOVA).

Among White patients, a significant difference was observed between study arms in understanding of procedure benefits and risks measured with the MacCAT-T ($P = 0.05$), but no
significant difference was observed for MacCAT-T understanding summary rating in this group. A Tukey post hoc test revealed that White patients in arm D had greater understanding of procedural benefits and risks ($3.8 \pm 0.4$ SD) than those in arm C ($3.5 \pm 0.7$ SD, $P = 0.03$) but not significantly greater than those in arm B ($3.7 \pm 0.5$ SD, $P = 0.64$) or arm A ($3.6 \pm 0.7$ SD, $P = 0.41$).

**Figure 5** – Time for completion of the informed consent process among all patients (one-way ANOVA).

![Figure 5](image)

Among all patients included in this study, a significant difference was observed between study arms in the time taken to complete the informed consent process ($P < 0.01$). The informed consent process for those in arm D ($584.4 \pm 125.3$ seconds SD) took significantly more time than that for patients in arm C ($383.8 \pm 116.3$ seconds SD, $P < 0.01$), arm B ($305.1 \pm 118.4$ seconds SD, $P < 0.01$), and arm A ($292.6 \pm 121.4$ seconds SD, $P < 0.01$).
Among non-White patients, a significant difference between study arms was observed for anxiety reduction between the pre- and peri-consent surveys ($P = 0.03$). Patients in arm B experienced increased anxiety between the pre-consent and peri-consent surveys ($0.6 \pm 0.9$ SD) as compared to those in arm A whose anxiety decreased between those two points in time ($-0.2 \pm 1.1$ SD, $P = 0.03$).
Among non-White patients, a significant difference between study arms was observed for subjective understanding ($P = 0.04$). Those in arm C reported greater subjective understanding ($9.8 \pm 0.7$ SD) than those in arm B ($9.0 \pm 1.6$ SD, $P = 0.05$).
Among non-White patients, a significant difference between study arms was observed in overall experience ($P = 0.01$). Non-White patients in arm B had lower rating of overall experience ($9.2 \pm 0.9$ SD) than both those in those in arm D ($9.8 \pm 0.5$ SD, $P = 0.02$). These patients also had lower rating of overall experience than those in arm A ($9.8 \pm 0.5$ SD, $P = 0.01$).
Figure 9 – Post-procedure comfort with the provider among non-English-speaking patients (one-way ANOVA).
Among non-English speaking patients, a significant difference was observed between study arms in post-procedure comfort with the provider ($P = 0.03$). Those in arm C had greater post-procedure comfort with the provider ($9.9 \pm 0.6$ SD) than those in arm B ($8.8 \pm 1.7$ SD, $P = 0.04$).

**Figure 10** – Overall experience among non-English-speaking patients (one-way ANOVA).
Among non-English speaking patients, a significant difference was observed between study arms in overall experience ($P < 0.01$). Overall experience was significantly greater for those in arm C ($9.9 \pm 0.3$ SD, $P < 0.01$) and arm A ($9.9 \pm 0.4$ SD, $P < 0.01$) than those in arm B ($9.0 \pm 0.9$ SD).