Using Patient-Generated Health Data to Facilitate Preoperative Decision Making for Breast Cancer Patients

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***Abstract* – Approximately 1 in 8 U.S. women will be diagnosed with new invasive breast cancer over the course of her lifetime. An estimated 252,710 new cases of invasive breast cancer are expected to be diagnosed in women in the U.S. in 2017. Mastectomy is recommended in over a third of early-stage breast cancer patients. Those women who elect to undergo breast reconstruction are counseled on surgical risks and benefits of implant-based and autologous reconstruction. Currently, there is limited patient-centered information about course of recovery, which is a major consideration when deciding between types of reconstruction. Patient recovery estimates are often anecdotally related to the length or invasiveness of the surgical procedure rather than patient-centered, evidence-based data on implant versus autologous surgical recovery. This deficit in information on patient recovery comes at a time when real-time digital devices are used to track vitals, sleep-wake cycles, and steps taken for personal convenience without being used to guide treatment. The primary objective of this paper is to present a system framework for modeling the surgical recovery process. We also outline preliminary results from a pilot study with two breast cancer patients who each underwent one of the two reconstruction surgeries.**

Index Terms – breast cancer, mobile sensing, reconstruction, remote health monitoring

INTRODUCTION

In the United States, about 12% of women will develop invasive breast cancer, a rate second only to skin cancer [1]. Annually, approximately 69,000 women in the U.S. have a mastectomy to remove the cancerous tissue so it does not metastasize and spread to the rest of the body [2]. Physicians are currently unable to give accurate, detailed information on when women may expect to resume their regular activities based on their personal characteristics, and furthermore, are uncertain which aspects of recovery are most important. Thus, surgeons and breast cancer patients need more evidence-informed knowledge about the recovery process to aid in the surgical decision-making process. The ability to monitor patients' mobility and physiological responses before and after surgery will give clinicians a better understanding of what the recovery process looks like for the different surgical choices, enabling them to give personalized advice on which surgery a patient should choose. Eventually, this will give patients an understanding of their recovery process for different surgical options based on their specific health profile and personal values.

Previous studies have been conducted to understand the recovery process based on patient-reported qualitative data. Elder et al. used the SF-36 Health Survey questionnaire to assess patients' quality of life before and after mastectomies with immediate reconstruction surgery [3]. Weichman et al. utilized the Numerical Pain Rating Scale (NPRS), McGill Pain Questionnaire, and Breast-Q to measure pain and fatigue preoperatively, and at one week and three months postoperatively [4]. However, the data presently collected are not enough to develop personalized reconstruction recovery estimates across the different surgeries.

Granular health data have shown promising results in understanding recovery processes. Jiang et al. indicated that accelerometer and gyroscope data collected and analyzed from consumer wearable devices, such as smartwatches, can accurately recognize activities and correctly generalize to new users [5]. Sun et al. identified the importance of collecting both physical and emotional data to differentiate between activity-related and mental stressors [6].

The present work aims to design a system framework for surgical recovery monitoring combining patient-reported data and objective sensor data on mobility and physiology collected from a smartwatch. We also present the results of a pilot study with two breast cancer patients who each underwent one of the two reconstruction surgeries. The end-goal of this work is to use the patient-generated data to develop holistic models of recovery that can be used as a decision-aid for the patient and physician regarding the type of reconstruction surgery. Ideally, these models will provide tailored recovery estimates based on the type of reconstruction surgery, patient demographics, and baseline activity profiles.

POST-MASTECTOMY RECONSTRUCTION OPTIONS

After a mastectomy, patients can decide to not have reconstruction or can choose to undergo one of many breast reconstruction surgeries [7]. The two types focused on in this study are tissue expander with an implant and autologous tissue transfer (flap) from the abdomen or buttocks. Implants can be subglandular with the implant over the pectoral muscles, or submuscular with the implant over the pectoralis minor muscle but under the pectoralis major muscle [8].

Implants are the most popular form of reconstruction, as three quarters of women choose implants over flap surgeries [9]. Implant surgery with a tissue expander requires two operations. Temporary tissue expanders are inserted and incrementally filled with saline every one to two weeks until the desired volume is reached. Permanent silicone implants are then inserted either under or over the pectoralis major muscle a few months after the final expansion. Following both procedures, drains are placed in the prosthetic space and remain in for several days to collect fluid from the incision site. Additionally, patients remain in the hospital for one night after each procedure to recover [10]. While the surgery requires two operations, it is considered less invasive and risky compared to the flap surgery. Patients are expected to return to normal activity four to six weeks after each of the operations.

The flap procedure uses tissue and fat from other parts of a patient's body to replace the breast tissue removed during surgery. In the past, the surgery involved taking abdominal muscle as well as autologous tissue; however, the reconstruction can now be done using tissue alone. Fewer patients are eligible for this method of reconstruction due to factors such as breast size, amount of abdominal tissue, and lifestyle choices like tobacco use [11]. This procedure is done in a single surgery lasting four to five hours for each side of a patient's chest. Patients stay in the hospital for three to four days after the surgery and the incision site drains come out later than with the implant surgeries [12]. Patients are expected to return to their normal activities two months after their operation.

Researchers have investigated quality of life for patients who undergo breast reconstruction and addressed the differences in immediate versus delayed reconstruction [3]-[4]. However, little is known about the recovery process with regard to differences in recovery between no reconstruction and reconstruction surgeries (implant and flap). Without this information, it is difficult for the patient to make an informed decision about which surgical path to choose.

DESIGN CONSIDERATIONS

We first collected qualitative data from patient focus groups to better understand the patient recovery process in terms of its key experiential factors. We then used these results to guide a pilot study collecting data from newly diagnosed breast cancer patients undergoing one of the two surgical options.

Patient Focus Groups

With the approval of the Institutional Review Board for Health Sciences Research (IRB-HSR) at the University of Virginia, focus groups were conducted with women who went through mastectomies and reconstruction surgeries. Each focus group included one facilitator and five to six women who had undergone mastectomies in the past. Focus group participants were recruited through our established patient population: women who were between six months and one year out from their mastectomy or completion of their reconstruction. Women were asked to discuss the choice they made, how they made that choice, what they experienced post-surgery, what they would have liked to know, what were the hardest and easiest parts of recovery, what helped them recover, what delayed their recovery, and what were the pivotal points in the recovery process. We used the patient focus groups to determine what postoperative recovery outcomes were important.

The first focus group comprised of women who had opted out of reconstruction surgery. Most of the women said that they opted out of the reconstruction procedure because they wanted to get back to normal life quickly and did not believe that the reconstruction would be worth the extended recovery period. One aspect of the mastectomy recovery process that stood out as most uncomfortable was the drains that the patients had to wear for around three weeks post-surgery. Once the drains were removed, the women said they felt markedly better. When asked what milestones in the recovery process the women felt were most significant to them, they said showering, sleeping lying down, and removing the drains. Most women were able to return to work after about four weeks. However, even though the women could generally return to work after four to six weeks, the emotional recovery took much longer.

The second focus group consisted of six women who had undergone double mastectomies followed by implant reconstruction. Some of the women admitted they did not originally want to undergo reconstruction, but after talking to doctors and friends who had been through the surgery, decided it was worth it to regain their previous body shape. When asked why they chose implants over the flap surgery, most said that they were not candidates for the flap surgery due to a lack of available tissue or other medical concerns. Similar to the mastectomy-only women, it was about four weeks before the women were allowed to return to work. However, the women said that getting back to a normal, pain-free life took six to eight months. The aspects of recovery that stood out as the worst to the women were discomfort during sleep and muscle spasms that occurred long after the four-week mark. This set of women also said that while implants were uncomfortable at first, the tissue expanders put in during the first surgery were extremely painful.

We used the focus group feedback to develop postoperative questionnaires regarding patient-recovery and guide our hypotheses about the recovery processes of the reconstruction surgeries. The focus groups allowed us to create a rough outline of what we hypothesized the recoveries would look like, as well as gather input on whether or not breast cancer patients would be willing and able to take part in the study.

Technology-Enabled Monitoring

In order to provide evidence-based guidelines about the recovery process, objective data were required to compare recovery between post-mastectomy and reconstruction patients. In order to quantitatively evaluate activity and return-to-function, we used smartphones and actigraphy devices to collect patient self-reported data on activity, sleep, pain, and mood as well as objective measures of mobility (e.g., steps, activity level) and physiological parameters (e.g. heart rate, heart rate variability). We used these data to characterize each patient's return to preoperative activity after surgery. We hypothesized that measurements from actigraphy devices would reveal objective differences between reconstruction modalities and mastectomy alone, and would thus guide recommendations and patient decisions.

For the study, we chose the Sensus application [13] and the Microsoft Band 2 smartwatch, which contains ten sensors to collect health vitals. The relevant sensors to monitor recovery were the accelerometer, heart rate, R-R interval, skin and air temperature, pedometer, and galvanic skin response (GSR). We used the Sensus smartphone application to collect patient self-report data *in situ* and to collect data from the smartwatch using Bluetooth. This allowed for continuously sampled data streams in addition to hourly and daily measures from the Microsoft Health application (steps taken, floors climbed, calories burned, heart rate, and sleep). The sampling rates for the sensors were all configured to 1 Hz within Sensus to maximize the battery life and the amount of gathered data.

Requirements

Before developing an initial design, requirements were created to ensure the feasibility of the design. The device and applications should be straightforward and easy to use by patients. If difficulties or confusions arise, then the patients should be able to easily access help from a research coordinator. Additionally, the self-report surveys should be unbiased and administered regularly, but should not be burdensome to patients. The only data collected should be necessary to track the recovery process and should be de-identified.

Hypotheses

Based on prior research and patient focus groups, we developed a set of hypotheses about patient recovery for the two reconstruction surgery types: (1) Patients who undergo implant reconstruction have an overall longer recovery time due to the multiple operation. Thus, these patients will return to their preoperative routines within four to six weeks following each surgery, but will not fully return to their baseline physical and emotional states until four to six months following their initial surgery; (2) Patients who undergo flap reconstruction will have a shorter recovery time and will return to their baseline levels within six to eight weeks following surgery.

STUDY DESIGN

To evaluate activity and return-to-function with actigraphy devices, a study was designed to collect subjective and objective pre and postoperative data from breast cancer reconstruction patients. In this design, baseline (preoperative) information was tracked one to two weeks before mastectomy, and postoperative recovery was monitored for three to four weeks. We implemented a nonrandomized parallel group cohort study, where each woman's choice of treatment was determined by herself and her doctor. This study design allowed for analysis of patient outcomes when treatment decisions were made based on routine care (i.e., there was no influence of the study on the decision of treatment). The smartwatch devices were used to measure activity metrics and sleep. Patient data were analyzed during and after the data collection period to look for progress and patterns in the recovery process.

The study tracked the recovery processes of patients undergoing implant or flap breast reconstruction in order to model the recovery process of each surgery. Recovery was defined by the patient milestones found in the focus group discussions (i.e. getting back to work, sleeping through the night, and getting all drains removed) and our quantitative measures: mobility, sleep, pain, and stress. These parameters were measured through data collected from the smartwatch. To allow for a holistic view of the patient's recovery, we captured data from the smartwatch sensors that would allow us to characterize both activity levels and physiological state. Figure I displays the interconnectivity between the patient, data, and analysts and clinicians.

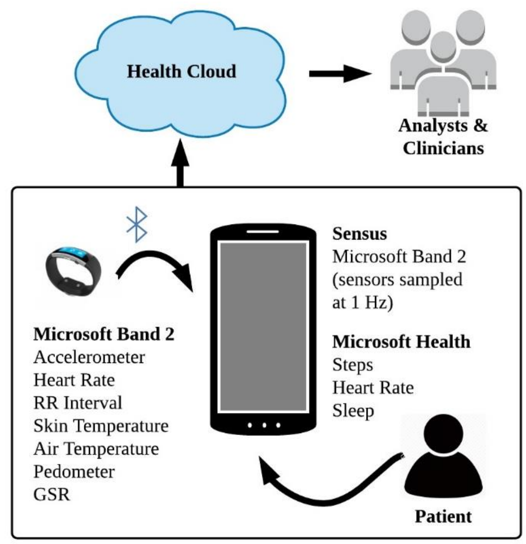

FIGURE I
PATIENT SYSTEM DESIGN

Patient Setup and Recruitment

Each new patient that met the inclusion criteria (early-stage breast cancer 0-3a, smartphone, Wi-Fi, and willingness to wear a smartwatch) was eligible for the study. Patients who underwent chemotherapy were excluded due to possible confounds with their reconstruction surgery. Women were identified and recruited when a mastectomy was chosen, typically during the first or second clinic visit. Upon joining the study, patients were allotted a smartwatch to collect baseline measures on activity. Sensus was installed on patient smartphones and loaded with pre and postoperative protocols. Figure I shows the enabled technology as well as the data that were collected.

Data from the smartwatch permitted the measurement of changes in activity and sleep patterns over the course of recovery for a given patient in comparison to baseline measures. Each patient was introduced to and trained on the smartwatch device and Sensus and Microsoft Health applications at the time of enrollment and was acclimated to the device during the first week of use. Problems with the device (e.g., difficulty charging the device or syncing the device for data capture) were addressed during this time. Patients who experienced difficulty using the device were able to meet with a research coordinator when meeting with the plastic surgeon or during the preoperative visits before they returned for their mastectomy.

PRELIMINARY RESULTS

Data Analysis

Given time, patient recruitment, and technology constraints of the study, we narrowed our focus to two metrics: mobility and sleep. While we continued to collect data for pain and stress, our analysis focused on mobility and sleep and their respective sensors. R was the primary tool used for data analysis [14]. Analysis included data cleaning, metric computation, visualization, and statistical analysis. The analysis is broken into two sections: expected results and statistical analysis of two patients' recovery processes. While a larger patient sample size was preferred, we present the results from two patients with the most comprehensive pre and postoperative data.

Expected Recovery

Based on information gathered from the patient focus groups, we created a recovery timeline (Figure II) for the two reconstruction surgery types. As a reference, we included the expected recovery for mastectomy-only patients. Since patients who undergo implant reconstruction with tissue expanders have two surgeries, there are additional milestones associated with these surgeries compared to no reconstruction and flap reconstruction.

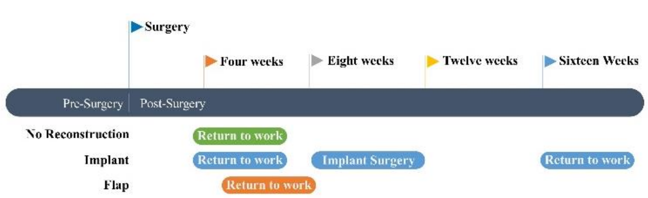

FIGURE II
EXPECTED RECOVERY FOR EACH RECONSTRUCTION SURGERY TYPE

To compare the difference in surgery types, we analyzed patient mobility measured by total steps taken per week and overlaid the information with the expected recovery timetable. The lines in Figure III represent the expected recovery based on the recovery timeline (Figure II), and the circles represent actual patient data collected in the study. For the three weeks of collected postoperative data, the implant patient and the flap patient followed the expected number of steps taken during the recovery process.

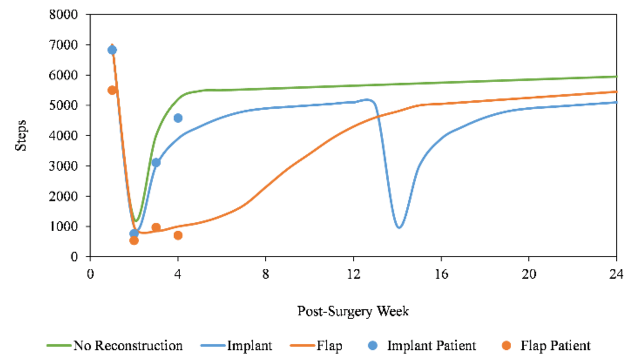

FIGURE III
EXPECTED MOBILITY RECOVERY IN TERMS OF STEPS FOR NO RECONSTRUCTION, IMPLANT, AND FLAP PATIENTS

Patient Recovery Analysis

We analyzed patient recovery with respect to mobility and sleep. We defined mobility in terms of total steps, heart rate, and an activity index, and sleep in terms of variance in the total duration. First, we examined total steps taken per day for an implant patient and a flap patient, as seen in Figure IV. As expected, there is a drop in steps after surgery for both patients, but there is an upward trend as time passes. Consistent with the expected recovery, in which implant patients recover faster than flap patients, the total number of steps taken postoperatively is increasing at a faster rate for the implant patient than the flap patient. Additionally, we analyzed patient activity levels between two patients before surgery and after surgery. The first patient took more steps before surgery than the second patient. This carried over into the postoperative stage, in that the first patient also took more steps than the second patient.

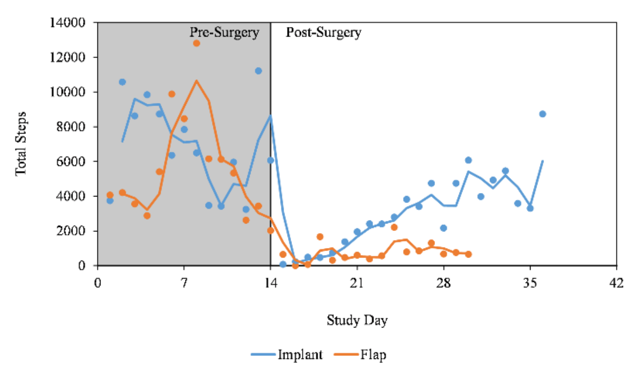

FIGURE IV
TIME SERIES PLOT OF IMPLANT AND FLAP PATIENT TOTAL STEPS PRE AND POSTOPERATIVELY

Second, we analyzed mobility in terms of the implant patient's mean heart rate and mean activity index values, and sleep in terms of variance in the total duration. Mobility was measured by calculating an activity index proposed by Bai et al. from the raw accelerometer data collected from Sensus [15]. The index is a weighted average of the variance in the accelerometer data in the X, Y, and Z directions for a given time interval. We used the modified index proposed by Bai et al. to normalize the metric using the stationary variance, which was found by calculating the accelerometer variance when the band was idle [15]. As seen in Figure V, the patient's mean daily activity index drops below preoperative levels after surgery and gradually increases with time.

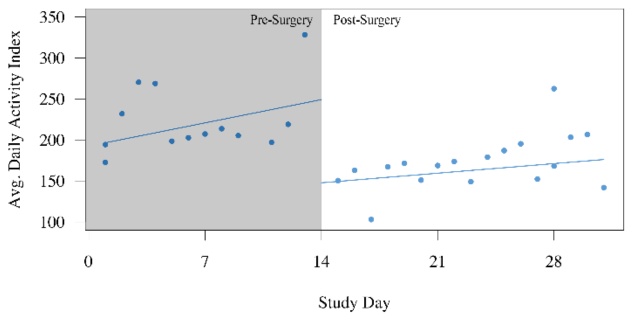

FIGURE V
TIME SERIES PLOT OF PATIENT ACTIVITY INDEX PRE AND POSTOPERATIVELY

The implant patient's heart rate also showed a marked change after surgery. As seen by the center black line in Figure VI, the patient's mean daily heart rate steadily increased above preoperative levels for the first week after surgery, then gradually decreased in the following ten days, eventually stabilizing to preoperative levels. Additionally, for the first four days after surgery, the variance in hourly heart rate, as seen by the boxplots, is quite narrow. As the patient's recovery progressed, the variance increased, as expected.

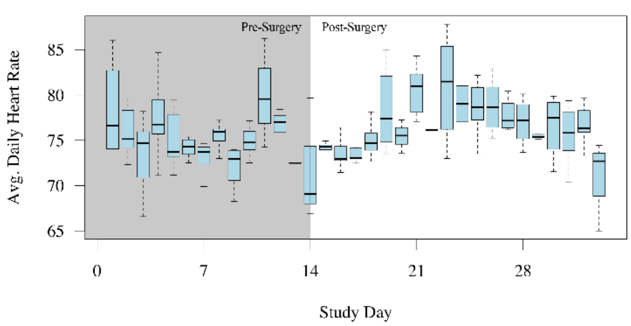

FIGURE VI
TIME SERIES BOXPLOT OF PATIENT HEART RATE PRE AND POSTOPERATIVELY

While many different sleep metrics were collected, sleep duration proved to be the most indicative metric of a shift in sleeping habits. As seen in Figure VII, the variance of sleep duration for the implant patient increased significantly after surgery. A chi-squared test on the data showed that the preoperative and postoperative sleep duration variances were significantly different (p=0.06241).

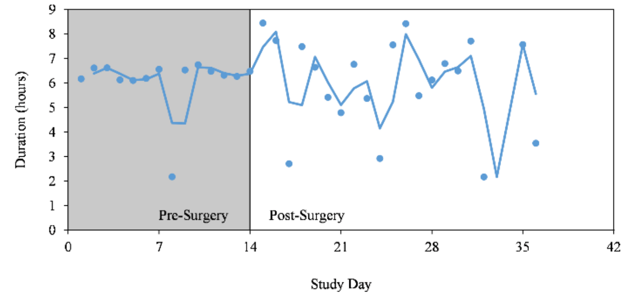

FIGURE VII
TIME SERIES PLOT OF PATIENT SLEEP DURATION PRE AND POSTOPERATIVELY

DISCUSSION

Limitations

This study faced limitations that impeded data analysis. Due to the brevity of the recruitment period, there were four patients enrolled in the study, with only two collecting data on a daily basis, making the sample too small to accurately assess the differences in surgery recoveries. iPhone users had more difficulty maintaining smartwatch connectivity to the Sensus application and submitting data to study servers. Patient compliance with data and survey submission also limited data collection and analysis.

Interpretations and Implications of Results

When analyzing mobility in terms of steps, the total number of steps for both patients dropped after surgery, as expected. There was a clear upward trend after surgery with the implant patient increasing faster than the flap patient, suggesting that mobility for both patients was returning to preoperative levels. This is further supported by the variance in hourly heart rate for the implant patient. For the first few days after surgery, the patient was inactive due to the narrow heart rate variance. Similar to daily steps, as the patient's recovery progressed, the variance increased, due to increasing activity levels. Additionally, the patient's mean heart rate spiked in the week following surgery, then gradually returned to baseline over the next ten days. Considering the patient's activity level dropped substantially after surgery, this spike could be due to psychological reasons, such as increased stress levels.

Looking at sleep, the variance in the total duration increased significantly between preoperative and postoperative periods. These results suggest that the variance in sleep duration is a key predictor of patient recovery. If patient data is collected for a longer period of time postoperatively, then a decrease in sleep duration variance suggests patient recovery.

Furthermore, patient preoperative baselines extend to postoperative activity levels no matter the type of reconstruction surgery patients choose. Patients who are more active before surgery, will likely be more active after surgery. This further enhances the need for individualized recovery models, since patient recoveries need to be tailored to individuals' baseline levels.

CONCLUSIONS AND FUTURE WORK

This research served as a pilot study to assess the feasibility of monitoring and analyzing patient recovery experiences. In this respect, the study proved successful in providing a better understanding of the recovery process for each respective surgery. Analysis between pre and postoperative data revealed a significant difference in patient mobility and sleep.

In future efforts, we hope to extend this work to include self-report data on sleep, pain, and mood, in which two daily postoperative surveys would be delivered to assess these attributes. Additionally, a longer postoperative data collection period would allow for an in-depth study of the course of recovery and follow-up of each surgical option.

The long-term goal of this work is to inform patients of their expected recovery for different surgical choices based on their own patient profile. As we continue to analyze additional patient recovery trajectories, models will be developed to estimate recovery times based on patients' current health and lifestyles, further empowering patients with better-informed decision making. In turn, this data can also be used by clinicians to help their patients make more informed surgical decisions.

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