The Performance of Patient-Worn Actigraphy Devices to Measure Recovery after Breast Reconstruction

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Introduction: Annually, over 250,000 women are diagnosed with breast cancer with over one-third undergoing mastectomy and contemplating reconstruction. Surgical breast reconstructive options vary in post-operative recovery, yet with a paucity of objective data to inform women of their expected recovery after flap or implant-based reconstruction. As a result, patient decision-making is based primarily on surgeon preference and subjective data regarding perceived invasiveness of surgical options. This study aims to identify recovery outcomes of interest to breast cancer patients and to determine the feasibility of objectively measuring patient recovery after mastectomy and reconstruction using patient-worn actigraphy devices.

Methods: Three survivorship focus groups for patients after mastectomy with and without reconstruction were used to identify recovery outcomes they considered relevant. Cloud storage systems and actigraphy devices were piloted to determine performance. Actigraphy devices were worn by patients peri-operatively to measure post-operative sleep quality and steps taken, normalized to individual patient pre-operative control data.

Results: Focus groups identified sleep quality, return to activity (measurable with actigraphy), and driving as variables impacting surgical decision-making. We prospectively measured outcomes for four women undergoing immediate prepectoral tissue expander placement and four women undergoing immediate free flap reconstruction. Actigraphy data demonstrated an initial decrease in activity, increase in sleep variability and increased heart rate that approached the patients' pre-operative normalized data as they recovered over time.

Conclusions: These data demonstrate that actigraphy data would be of interest to patients making breast reconstruction decisions and that the data can be successfully collected to inform decision-making. *(Plast Reconstr Surg Glob Open 2019;7:e2503; doi: 10.1097/GOX.0000000000002503; Published online 28 October 2019.)*

INTRODUCTION

An estimated 250,000 women were diagnosed with breast cancer in 2017 with over one-third undergoing a mastectomy as part of treatment, with mastectomy rates continuing to increase[1,2]. Breast reconstruction rates post-mastectomy have also increased from 12% in 1998 to upwards of 42% in 2016 and are continuing to rise[1].

Currently, information addressing recovery after implant or flap-based reconstruction is limited to subjective, patient-reported outcomes. Objective data assessing critical functions of daily living such as sleep and resumption of baseline physical activities is lacking[3]. The current literature describes the patient's perspective on long-term recovery and surgical invasiveness of individual reconstructive procedures, ignoring the importance of short-term recovery in surgical decision-making[3].

The purpose of this study is to use patient survivorship focus groups to identify outcome variables that patients

value that can also be assessed with patient-worn actigraphy devices. Secondly, we evaluated the performance of actigraphy devices to measure quantitative short-term post-operative data after mastectomy and reconstruction that can be used to inform patient decision-making.

METHODS

Patient-Defined Recovery Outcomes of Interest

This study was approved by a full institutional board review. Patients who had undergone mastectomy alone, mastectomy and implant-based reconstruction or mastectomy and autologous reconstruction less than one year previously were identified through our institution's survivorship program and invited to participate in one of three focus groups of 6 patients each to identify outcomes of relevance for surgical decision-making. With a standardized script and audio-recording, focus group facilitators asked patients to discuss their operative choice, post-operative experience, what they would have wanted to know, and the hardest aspects of their post-operative recovery to determine if the variables measured by the actigraphy device would be considered valuable to patients during surgical decision-making.

Perioperative Actigraphy

Women undergoing immediate free flap or pre-pectoral tissue expander placement after early stage breast cancer (Stage 0-II), who would not require axillary dissection, who owned a smartphone, had WiFi, and were willing to wear a smartwatch were eligible for inclusion. Recruitment occurred during a reconstructive consultation 2-3 weeks after receiving their breast cancer diagnosis. The Sensus application (SensusMobile UVA Apps LLC, Charlottesville, VA) and the Microsoft Band 2 (Microsoft Corporation, Redmond, WA) smartwatch were used to measure patient recovery at 1Hz measurement frequency combined with hourly and daily step and sleep measures from the Microsoft Health application.

Each patient wore an actigraphy device for a two-week baseline period followed by a three-month post-operative period to assess short-term recovery normalized to the patient's individual pre-operative data. Patient diaries were kept to help interpret the daily activities reflected by the actigraphy devices.

RESULTS

Focus Groups

Focus group discussions identified sleep quality, return of normal bowel function, ability to shower, drain removal,

narcotic dependence, and return to work, driving and exercise as important early post-operative variables that were important to patient recovery in all three focus groups. Focus group administrators subjectively noted a majority of patients who had mastectomy alone prioritized drain removal and return to driving and exercise. A majority of patients having had implant based surgery prioritized sleep quality while those having had flap based surgery emphasized sleep quality and return to prior exercise and work. Sleep quality and return to regular activity could be measured by the sleep and step counts of an actigraphy device.

Actigraphy Results

Actigraphy devices were worn by four women undergoing immediate implant-based breast reconstruction and four women undergoing immediate flap reconstruction (Table 1 describes their medical and demographic data). Steps taken decreased immediately post-operatively and then slowly improved over time to approach the patients' baseline state for both expander-based and flap-based reconstruction (Figures 1–2). By post-operative day 30, all patient's average steps were back within their baseline range. Variance in total and restful sleep initially increased after surgery, relative to baseline state, and then returned to baseline by post-operative day 20 (Figure 3). Heart rate variability decreased immediately following surgery and then gradually returned to baseline around post-operative day 35 (Figure 4). Patient compliance and device usability yielded post-operative data ranging from 2 weeks to 3 months of usable data per patient.

DISCUSSION

Through this pilot study, we were able to identify sleep quality, and return to activity as patient-selected variables important to surgical decision-making that can be captured quantitatively with actigraphy devices. Actigraphy data demonstrated a measurable decline in activity and heart rate variability as well as an increase in sleep variability after breast reconstruction that returned to patient-normalized baseline over a short-term recovery period.

Currently, reconstructive surgery consultations tend to focus on perioperative surgical risks, long term aesthetics, and revision rates with reportable data limited to subjective questionnaires[4]. By combining objective actigraphy data from women after reconstruction with subjective survey data, clinicians may provide a comprehensive picture of post-operative recovery focusing on outcome variables valued by patients[5–7].

Table 1. Medical and Demographic Data

| Patient Characteristics	Immediate Expander Placement (N=4)	Immediate Free Flap (N=4)
Age Mean (range)	56.8yr (46-67)	52yr (45-62)
BMI Mean (Range)	23.7 (18.7-27.8)	30.1 (21.8-35.9)
Laterality	3 Bilateral/1Unilateral	1 Bilateral/ 3 Unilateral
Prior Radiation	None	1 Patient Bilateral Radiation
Neoadjuvant Chemotherapy	2 of 4 Patients	2 of 4 Patients
Adjuvant Chemotherapy	None	1 of 4 Patients
Adjuvant Radiation	None	1 of 4 Patients
Smoking	None	1 of 4 Patients
Complications	1 Patient Complex Repair Under Local After Minor Dehiscence	None
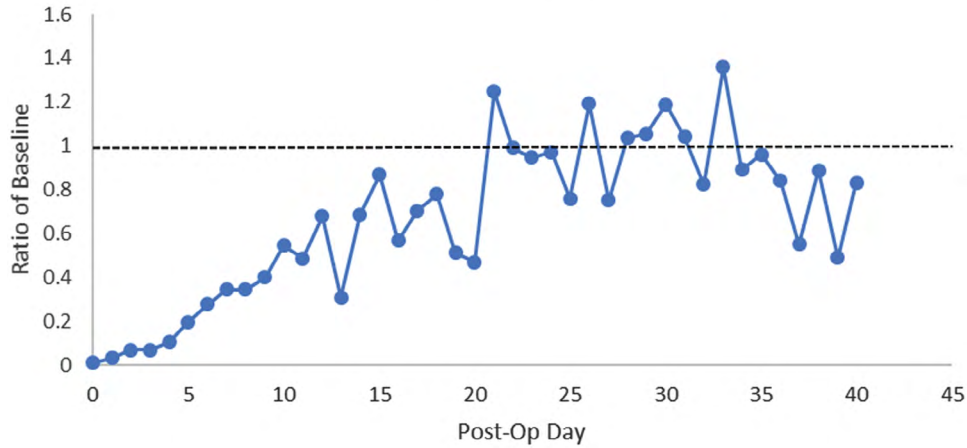
Figure 1. Post-operative steps taken after unilateral DIEP free flap breast reconstruction normalized to 2 week lead-in pre-operative data. Significant early decease in activity with reported pain index 6-10. Step frequency approached pre-operative baseline of 4899 steps per day or 2.1 miles traveled by Day 21 (transverse dashed line represents baseline activity). At 1 week appointment, patient was walking about the 1st floor of their house. At one month post-operative visit, she was performing all activities of daily living including walks in the neighborhood.
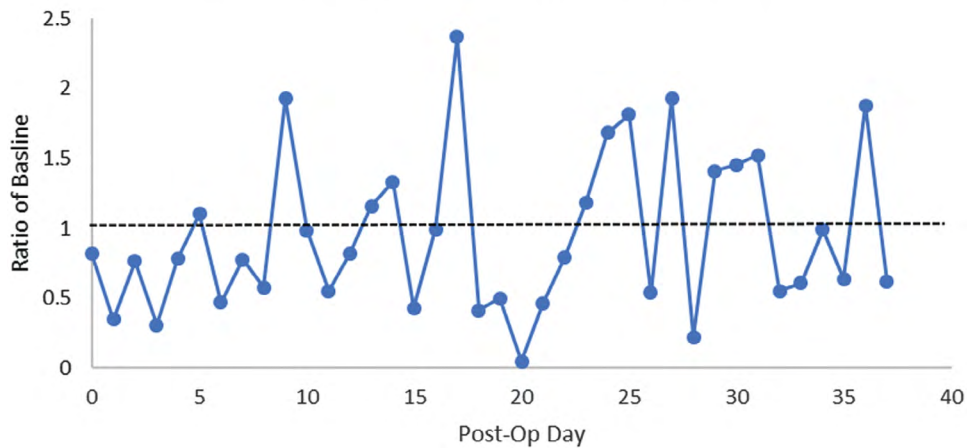

Figure 2. Post-operative steps taken after implant based reconstruction with bilateral pre-pectoral tissue expanders. Significant variability in steps taken after overnight stay in the hospital that correlated with self-reported pain ratings. By POD 12, over half of her days exhibited activity above pre-operative baseline level.

Fortunately, an interest in studying real-time patient data parallels patient interest in wearable devices used to measure function for their personal convenience. While different devices vary in performance, validity across devices has been reported for steps traveled, activity levels, and sleep, the main outcome variables of our investigation[8].

Patient-generated data and actigraphy devices have well-documented uses in other medical specialties[9,10]. However, the application of this technology to surgical patients, in general, is limited and in post-mastectomy breast reconstruction, specifically, has not been described. Our report demonstrates that sleep patterns and activity can be measured after breast reconstruction without distracting variability to mask the overall trend. Wearable technology appears to be a promising adjunct to traditional post-operative patient reported outcomes measures. The resultant objective data can be analyzed and compared with validated patient reported outcomes, allowing for predictive modeling and aiding in future patient decision-making.
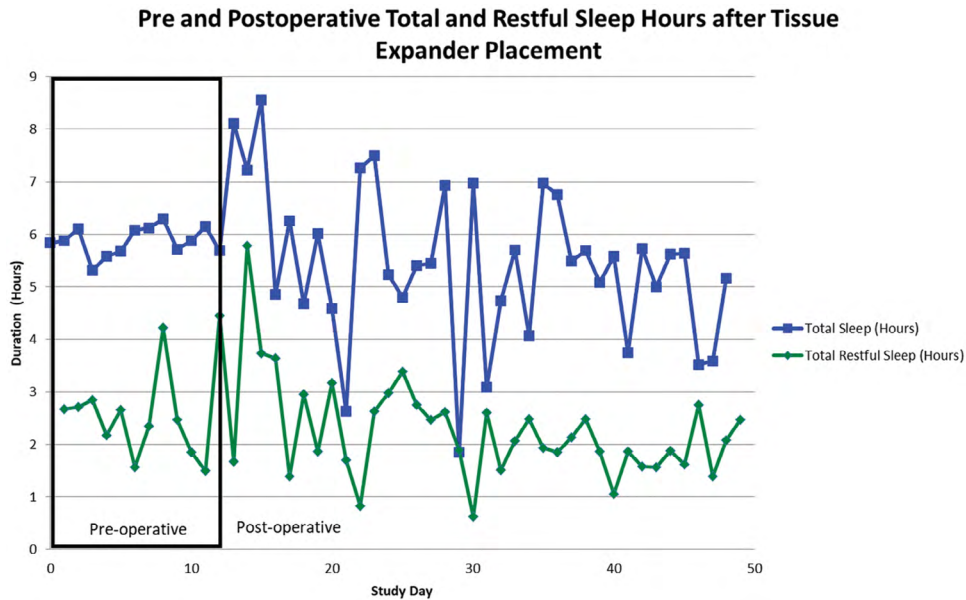
Pre and Postoperative Total and Restful Sleep Hours after Tissue Expander Placement

Figure 3. Pre and Post-operative Total and Restful Sleep Hours after Bilateral Tissue Expander Placement. Increased variability in total and restful sleep hours over POD 1-19. Patient endorsed 3 weeks of narcotic use and daytime naps and then returned to a diurnal schedule similar to baseline after that period.
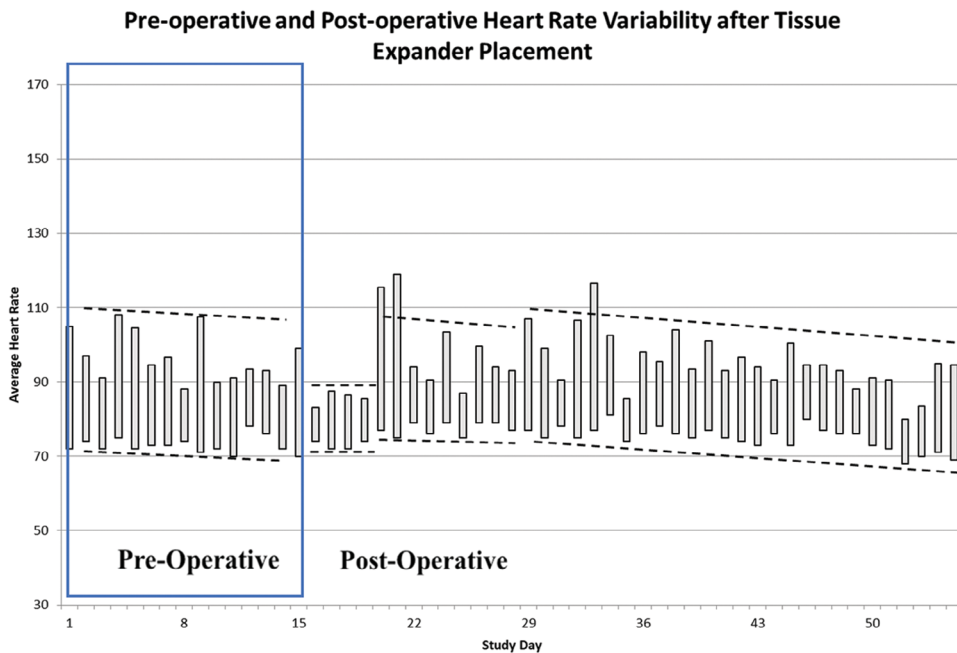
Pre-operative and Post-operative Heart Rate Variability after Tissue Expander Placement

Figure 4. Pre and Post-operative Heart Rate Variability after Tissue Expander Placement – Box Plots and Trend Lines. Heart variability decreases as exhibited by shorter box plots and narrower trend lines of heart rate range for first 4 days after surgery with patient documenting narcotic use for 7 days. Heart rate variability increases as calculated activity index increases (data not shown) over POD 5-13, and again POD 14-55.

The use of patient-worn actigraphy devices opens up an avenue for remote patient-monitoring to aid expeditious detection and treatment of surgical complications to help reduce health costs and detriment to the patient. We used remote, real-time monitoring to encourage compliance as the study progressed, similar to how patient care teams could monitor vital sign trends.

Further studies in a larger cohort of patients are indicated to compare outcomes of different types of reconstruction and draw further conclusions regarding average time to return of baseline activities, sleep, and other important quality of life measures as identified by patients. The current study makes the critical contribution of demonstrating the feasibility and utility of a system that

collects objective data of patient-valued outcomes, with the ultimate goal of using this data to improve surgical decision-making.

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