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Review

Digital Support for Patients Undergoing Bariatric Surgery: Narrative Review of the Roles and Challenges of Online Forums

Anna Robinson¹, MPharm, PGDip (Adv); Andrew K Husband¹, PhD; Robert D Slight², PhD; Sarah P Slight¹, PhD

¹School of Pharmacy, Institute of Population Health Sciences, Newcastle University, Newcastle Upon Tyne, United Kingdom

²Institute of Population Health Sciences, Newcastle University, Newcastle Upon Tyne, United Kingdom

Corresponding Author:

Sarah P Slight, PhD

School of Pharmacy

Institute of Population Health Sciences

Newcastle University

King George VI Building

Queen Victoria Road

Newcastle Upon Tyne, NE1 7RU

United Kingdom

Phone: 44 191 208 2358

Email: Sarah.Slight@newcastle.ac.uk

Abstract

Background: The internet has become an important medium within health care, giving patients the opportunity to search for information, guidance, and support to manage their health and well-being needs. Online forums and internet-based platforms appear to have changed the way many patients undergoing bariatric surgery view and engage with their health, before and after weight loss surgery. Given that significant health improvements result from sustained weight loss, ensuring patient adherence to recommended preoperative and postoperative guidance is critical for bariatric surgery success. In a patient cohort with high information needs preoperatively, and notoriously high attrition rates postoperatively, online forums may present an underutilized method of support.

Objective: The aim of this study was to conduct a narrative review focusing on the developing roles that online forums can play for patients with bariatric conditions preoperatively and postoperatively.

Methods: A literature search was conducted in October-November 2019 across 5 electronic databases: Scopus, EMBASE, PsycINFO, CINAHL, and MEDLINE. Qualitative or mixed methods studies were included if they evaluated patients undergoing bariatric surgery (or bariatric surgery health care professionals) engaging with, using, or analyzing online discussion forums or social media platforms. Using thematic analysis, themes were developed from coding patterns within the data to identify the roles and challenges of online forums for patients undergoing bariatric surgery.

Results: A total of 8 studies were included in this review, with 5 themes emerging around (1) managing expectations of a *new life*; (2) decision making and signposting; (3) supporting information seeking; (4) facilitating connectedness: peer-to-peer social and emotional support; and (5) enabling accessibility and connectivity with health care professionals.

Conclusions: Online forums could offer one solution to improving postoperative success by supporting and motivating patients. Future research should consider how best to design and moderate online forums for maximal effectiveness and the sharing of accurate information. The surgical multidisciplinary team may consider recommendations of online peer-support networks to complement care for patients throughout their surgical journey.

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KEYWORDS

bariatric surgery; online forums; patient support; digital support; eHealth; mHealth

Introduction

Digital technologies are recognized as an integral part of modern life. National Statistics estimate that 78% of adults own a smartphone, 90% of people regularly access home internet, and 20% of the population use wearable technologies such as smart watches and fitness trackers [1]. Not only are individuals readily using these technologies in their day-to-day lives [2], but also many are turning to them for support in managing their health and well-being. In the United States, 86% of the population are now connected online, with estimates reporting that 1 in 2 adults use the internet to seek information about their health [3].

One particular cohort that has benefitted from the advancing support of digital technologies is patients undergoing bariatric surgery. Obesity has been recognized as a global health concern, described as an *epidemic* by the World Health Organization (WHO). It is a chronic, life-limiting disease, which is associated with numerous serious health conditions including type 2 diabetes, cardiovascular disease, hypertension, sleep apnea, osteoarthritis, and some types of cancer (such as prostate, breast, ovarian, and pancreatic) [4,5]. The prevalence of bariatric surgery has increased alongside the rising trend in obesity across the Western world [4]. Bariatric surgery is often regarded as the most effective treatment for severely obese individuals [6], in whom evidence has suggested that weight loss can be up to 62% following the procedure [7]. However, it is well recognized that despite these promising outcomes, patients with bariatric conditions commonly experience challenges beyond the procedure itself in their bid for surgical success. Individuals may need to overcome social (eg, stigma), physical (eg, surgical complications), and psychological (eg, depression and negative body image) hurdles throughout their journey, in addition to adjusting to their new lifestyles (eg, recommendations for improved dietary intake and physical activity) following the procedure [8-10]. Furthermore, weight regain and inadequate weight loss have been recognized as obstacles impacting longer-term postsurgical outcomes [11]. This is where online forums have come into play, supporting patients throughout their surgical journey and beyond.

Online forums and telehealth platforms appear to have changed the way patients with bariatric conditions view and engage with their health before and after weight loss surgery [9,12]. The internet has become an important medium within health care, giving patients the opportunity to search for information, guidance, and seek social support. Previous studies have found links between social support and successful weight maintenance [13,14], improved quality of life, and increased patient empowerment [15-17].

We conducted a narrative review focusing on the developing roles that online forums can play for patients with bariatric conditions preoperatively and postoperatively. We also considered the broader challenges associated with online forums and the wider use of digital health technologies when it comes to supporting surgical patients.

Methods

Search Strategy

We conducted our search of the literature in October–November 2019 across 5 electronic databases: Scopus, EMBASE, PsycINFO, CINAHL, and MEDLINE. No limits were applied on publication dates. Bibliographies of all included studies were hand-searched and gray literature (using Google Scholar) identified additional papers. Keywords used in the searches covered the themes of bariatric surgery, online forums, and qualitative methodology. The full database search strategy and MeSH terms are available on request. All articles were exported to EndNote X9 (Clarivate Analytics) for data management.

Inclusion Criteria

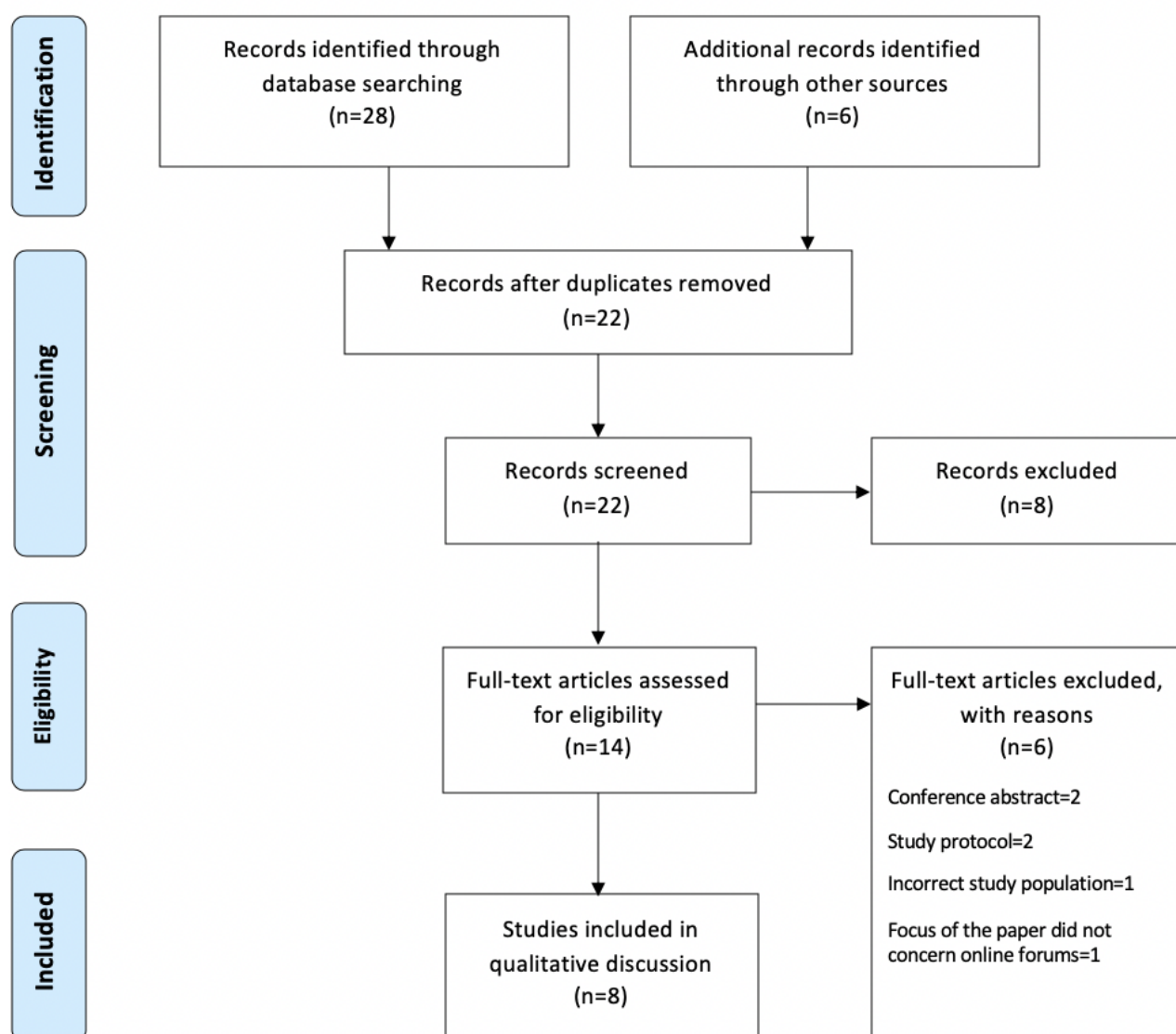
We included studies that had (1) included an investigation of patients undergoing bariatric surgery (or bariatric surgery health care professionals) engaging with, using, or analyzing online discussion forums or social media platforms, such as Facebook; (2) reported findings in the English language; and (3) conducted a qualitative or mixed methods study with qualitative transcripts of data available for analysis.

Review and Thematic Analysis

Two authors (AR and AKH) reviewed the papers from the database search. Full texts were retrieved for articles that met the inclusion criteria or those that could not be rejected without certainty. The full texts were independently screened by AR and AKH. Any disagreements were resolved through discussion or by a third reviewer (SPS) where necessary. Figure 1 demonstrates the inclusion flowchart for this discussion.

Thematic analysis, as defined by Braun and Clarke [18], was performed by 2 researchers (AR and AKH) to identify patterns of themes in the data. Significant phrases and sections of available transcripts were coded with initial codes; these were then sorted and clustered into common coding patterns, which enabled the development of themes (derived from the data). Working iteratively and reflexively, the themes were reviewed and refined until they were coherent and distinctive [18]. Any discrepancies were resolved through discussion (AR and AKH) and, if agreement was not reached, by consensus with a third author (SPS). NVivo version 12 software (QSR International) was used for the organization of data and thematic analysis.

Figure 1. Flowchart of included studies.



Results

Analysis of Search Data

The database searches returned a total of 28 papers. A further 6 records were included through gray literature and bibliography hand-searching. Following the removal of duplicates ($n=12$), 22 papers were screened and, of these, 8 were excluded based on their title and abstract. The remaining 14 full-text papers were assessed for eligibility, of which 6 were excluded with reasons. Eventually, 8 studies were included in this review. All 8 were published in the last 6 years and were conducted in the United States ($n=4$), Norway ($n=2$), Sweden ($n=1$), and Canada ($n=1$). Mixed methods were employed in 2 studies and the remaining used a form of qualitative methodologies, such as content analysis.

Findings

Five themes relating to the roles of online forums in supporting patients undergoing bariatric surgery emerged: (1) managing expectations of a *new life*; (2) decision making and signposting; (3) supporting information seeking; (4) facilitating

connectedness: peer-to-peer social and emotional support; and (5) enabling accessibility and connectivity with health care professionals.

Managing Expectations of a New Life

Life following bariatric surgery often requires a multitude of interpersonal adjustments, resulting in individuals creating expectations or goals for themselves to achieve following surgery. It is well-known within the literature that prior to surgery, patients with bariatric conditions may display unrealistic expectations of a *new life* following the procedure [19-21]. This appears to be a common finding among online forum preoperative postings, primarily with expectations focusing on the degree of weight loss individuals are hoping to achieve [22]. These patients have been known to perceive surgery as a *fix* or as a last chance for them to regain control over their weight when previous attempts by themselves in managing their weight have been unsuccessful [23]. This thinking may well link to poorly managed expectations from the side of the clinical team, but may also be a result of meeting certain eligibility criteria in order to qualify for the surgery [6].

Regardless of which, it was a common theme to see preoperative forum posts underpinned with emotions around excitement for an upcoming *new life* following surgery. Willmer and Salzman-Erikson reported patients perceiving their surgery as a journey, whereby they change from their current weight and end with a happier, *lighter-weight life* [22]. These ambitious preoperative expectations appeared to go hand-in-hand with anticipation and nerves relating to undergoing the surgery itself. Willmer and Salzman-Erikson reported how common it is for patients to anticipate dramatic changes of body and mind following weight loss surgery: “I look forward to the new me and my new life, I can barely wait”, and “Just think how unbelievably good it will feel afterwards” [22].

Decision Making and Signposting

This is a common theme in posts on preoperative forums related to surgical decision making; for instance, the suitability of surgery, the types of surgery on offer, and the impact of surgery on patient lifestyles [24]. Online forums enabled patients to seek relatable and supportive advice from other forum members. Atwood et al. [25] reported that responders reflected personally to these posts around decision making, using their own real-life examples to contextualize their choices: “I went with a bypass because I already had bad GERD [gastro-esophageal reflux disease], and the sleeve has been known to increase the amount of reflux you have”.

Deciding whether to undergo bariatric surgery is a big task for a patient to undertake, without considering the psychosocial impact that the surgery may have [26,27]. Online forums can play a role in supporting this decision making, where peers have come together to offer their thoughts and (often very personal) first-hand experiences of having gone through the surgery [25]. In their work, Ferry and Richards [24] acknowledged that patients felt similarities between themselves and other members’ stories, enabling them to put a real-life context behind their decision making: “I think my story is similar to many others I’ve read here ... I think I’m finally ready to seriously consider surgery, but I don’t know where to start”, and “I’m hoping to hear from all of you how surgery worked for you, so I can see if it can work for me”.

Preoperative patients were able to post and share information to help them weigh up the benefits and risks of going through the surgery; responders were seen to signpost their peers to alternative online sources of information to support their decision making “look at the National Institute of Health (NIH) website and journals such as New England Journal of Medicine” and “I looked at the percentage of probable weight loss. I thought this was a great tool for that: [website address]” [25]. Proactively seeking out digitally delivered information demonstrates the preoperative motivation of patients undergoing bariatric surgery and their acceptance of using online tools for support [28].

Preoperatively, patients also utilized online forums to seek advice and support about their choice of whether to *go public* with their surgery. The stigma of undergoing weight loss surgery is a common, and often underappreciated, hurdle that patients with bariatric conditions face [27,29]. With this in mind, it was not unusual to find posters reflecting on their personal decisions

with other forum users: “I’ve chosen not to go public with this, except to family and certain friends. What have you done, have you told many people?” and “I’ve also chosen not to go public with what I’m about to do ... will do it little by little” [22]. It appears that emotional support closely links to surgical decision making, possibly affecting individuals more than is recognized within routine clinical practice. Having a way to openly and freely discuss this using online forums appears to be cathartic and beneficial for patients, with peers showing empathy and respect for those seeking preoperative support.

Supporting Information Seeking

Online forums can play a facilitative role in empowering patient engagement with their own care [30,31]. Having educational tools and support at their fingertips means that patients with bariatric conditions can actively seek out information at various stages of their surgical journey. For instance, this information may support patients to change their health behaviors prior to surgery, to learn about managing common symptoms following their surgery, or to normalize any ongoing emotions in postoperative life.

Preoperative and postoperative patients have been seen to readily post in online forums and lead discussion threads online [25,32,33]. Despite both sets of patients posting, there was a clear contrast between the nature of information being sought by preoperative and postoperative patients [22,32]. This mainly related to their own personal stage and accompanying information needs within the surgical journey. Preoperative patients used online forums for advice regarding physical preparation for their journey ahead, while also seeking information to normalize their emotions and nerves in the build-up to surgery [32]. Furthermore, it was common to see preoperative posts displaying a close affinity to the motivation and anticipation of a *new life* following surgery [22]. The patients were particularly keen to seek information about how they can improve the outcomes of their surgery. Preoperatively, patients were particularly receptive to advice given by postoperative patients who had recently gone through the surgical process.

These motivated information-seeking behaviors are demonstrated by patients postoperatively too; however, the content and type of information being sought differed. Unsurprisingly, following surgery many patients utilized the online forums to seek information to support their new diet and lifestyle. In a study by Das and Faxvaag [32], postoperative patients reported that they preferred to seek information via the online forum in comparison to liaising directly with their own medical team: “it’s easier to go on here [online forum] ask questions and get answers”. Their preferences may be related to the speed and ease with which answers can be obtained, given the high rate of engagement by forum users and their readiness to share information. In addition to this, postoperative patients have referred to more readily discussing sensitive issues on the forums as opposed to sharing these in a traditional face-to-face group or clinic appointment: “I think it is easier to talk about them [sensitive issues] in a place like this than face-to-face” and “you can be much tougher on the net, write things that you might not want to say to people because they are difficult to

talk about. This becomes easier when you have a screen you can hide behind” [32].

Facilitating Connectedness: Peer-to-Peer Social and Emotional Support

It appeared that examples of peer support on online forums can take 2 forms, informational and emotional, with both types offered among preoperative and postoperative users [25,33]. Posts containing supportive advice aimed at those awaiting surgery appeared to feature heavily in American and Canadian preoperative forums [24,25,33-35]. They covered a range of content from advice on managing preoperative diet plans to tips relating to medicines following surgery, “you may want to pick up a pill crusher and a pill splitter in the drug store ... I had to crush and mix with drink in order to take [my medicines]”, and how to be best prepared for the emotional journey ahead of them, “keep your sense of humour. It’ll all be worth it in the end” [25]. Koball et al. [33] reflected in their mixed methods study, which analyzed content on a bariatric surgery Facebook page, that most preoperative patients used the forum to solicit answers to nutritional and medical questions ($P<.001$ for both). Postoperative patients were also seen to post on preoperative forums, offering their personal support as a *buddy* to someone who would be going on the journey: “I would be happy to make this journey with you” [25], “I would love to be your buddy” [25], “Believe me, I’ve been there ... feel free to message me with any questions” [24]. In their qualitative analysis of postoperative patients, Geraci et al. [34] reported the thoughts and perspectives of females who were 2 years postsurgery. Participants noted that their engagement with online support groups came from a want to inspire and give hope to the newbies (newly postoperative patients): “I want to give people hope that are just starting out and are thinking, ‘Will I ever lose the weight?’” [34]. It would be interesting to compare the prevalence of these posts on US forums with those from other countries, to assess possible cultural social norms.

Enabling Accessibility and Connectivity With Health Care Professionals

This is a smaller, yet significant, theme identified in the literature related to online forums connecting patients to health care professionals. In their study, Das et al. [36] evaluated the impact of an online forum on interactions between health care professionals and patients. They recognized the benefits in connecting the two groups to allow for easier access to evidence-based advice, as well as offering a convenient and geographically independent platform to promote patient engagement: “if we can get hold of them through this, then it’s really good. Because we want everyone to succeed”.

A lower threshold for information seeking by patients was also reported, with sensitive questions being more readily asked online as opposed to in face-to-face settings [36]. The forum also gave the health care professionals insight into the *day-to-day* lives of patients undergoing bariatric surgery, something that they would not normally see in a traditional, time-limited clinic appointment: “it’s obvious that one can capture things in the portal that I cannot capture during a consultation” and “you get more information about them here [online] than on the phone”.

Discussion

Preliminary Findings

This review has synthesized the findings from 8 studies focusing on the role and value of online forums for patients undergoing bariatric surgery. These early qualitative studies have shown how online forums can assist in supporting patients’ emotional and informational needs [37]. The value of peer-to-peer connectedness has been well documented in previous settings, with authors acknowledging benefits in quality of life and care satisfaction [38-40]. Not only does connectedness with peers allow for informational support, but it also provides emotional support and reassurance [41]. Online forums offer the opportunity to engage with a vast community of peers, which can be particularly beneficial for anyone who feels socially isolated [22].

Preoperatively and postoperatively, patients acknowledged the benefits and value of peer support in helping to maintain their own responsibility and motivation. This is not a new theme in the literature, where social connectedness and peer support have been linked to enhanced postoperative weight loss [14,42]. Atwood et al. [25] discussed that the frequency of informational peer support was higher in postoperative forums. They reported that posters readily shared their personal strategies as topics of information, such as ways to manage physical side effects or symptoms following surgery, and posting nutritional advice for adhering to lifestyle adjustments. The authors hypothesized that this information was likely to be reiterated from information provided at bariatric specialist appointments [25]. Given that a previous work has found that patients struggle with retaining information provided at specialist appointments [43], online forums could help to reinforce the ongoing educational messages throughout the surgical pathway.

It is well-evidenced that attendance at postoperative bariatric follow-up assessments is poor, with contributing factors relating to travel burden, geographical isolation, and time commitments [44-46]. Furthermore, patients have reported not seeing the value in postoperative clinics because the surgery had already been completed [47-50], and some preferred not to share sensitive information about their surgical journey in front of others [49]. Online forums can play a role in complementing traditional care and providing ongoing postoperative support, while helping to overcome these challenges. Studies have demonstrated that the content of online forums closely matched that of face-to-face clinics, meaning that patients are seeking support in the same subject areas [13]. Perhaps delivering this support via an online forum could be a way of overcoming these barriers, providing patients with the peer-support exposure they would be given if it were face-to-face, but ensuring anonymity for information sharing.

Internet-based forums, involving both health care professionals and patients, also existed in the wider literature, previously termed *online health communities* [31]. Patients have reported the benefits of utilizing these online forums for many health-related conditions, as well as for bariatric surgery [25,36,51,52]. In their review into the *empowerment effects* of online forums and support groups, Bartlett and Coulson [30]

discussed the benefits of promoting active collaboration between the patient and their personal doctor [30]. The authors concluded that online forums increase patient empowerment and positively affect patient-provider encounters, leading to beneficial impacts on health-related outcomes and behavior change. Patients reported increased feelings of accountability and responsibility to adhere to healthier lifestyles and treatment plans as a result of digitally enabled connectivity with health care professionals [30]. These findings are also echoed in the wider health-related literature [37,53,54]. This receptivity toward positive health behaviors has also been associated with the concept of *teachable moments* [55,56]. A teachable moment is defined as “an event that creates an opportunity for positive behavioural change” [57]. Perhaps digital technologies and online forums hold value in this, where engagement with providers can opportunistically exploit patient insight to encourage healthy behaviors and empower to improved postoperative outcomes.

Despite the advantages of online forums, and digitally enabled health care, there are notable challenges too, particularly in understanding the digital divide and ensuring the accuracy of content and information being shared [51,58]. The digital divide refers to a gap in the access and use of technology [59,60], but with recent statistics supporting regular internet use by over 90% of the UK population, perhaps it could be better interpreted as “inequalities in understanding and interpreting the information” [1,61]. The digital divide has been acknowledged as a threat specifically to disadvantaged, minority, and older patients, as well as to those with lower sociodemographics and educational attainment [60,62,63]. In their review concerning the digital divide in health care, López et al. [62] call for the careful design and implementation of digital health interventions with the potential to eliminate disparities and bridge the digital divide, “we should ensure that disparities are not simply an afterthought for digitally enabled health care.” Despite increases in the integration of digital and online interventions, the digital divide is important to acknowledge in order to best support patients [61,64,65].

Sanders et al. [66] identified barriers to using online forums, reporting the main factors to be low health literacy, disinterest, and increased costs. Findings from a related study reiterate similar barriers as recognized challenges when it comes to the role of online forums for patients undergoing bariatric surgery [32]. We must not forget that there continues to be a population who prefer to use face-to-face contact with health care professionals or forms of traditional media (such as leaflets or books) as their primary source of health information [3,38,67]. Understanding the reasons behind this could be a pivotal finding in overcoming barriers to usability and uptake. This cohort should not be forgotten when it comes to introducing technology-delivered health care solutions; there is a risk of minorities falling further behind and widening the gap. Perhaps this supports the argument for implementing digital technologies

(such as online forums) to complement traditional care, instead of replacing it.

Given the high acceptability (and engagement) of online forums, it would be prudent to consider the nature of the information shared, and the credibility and accuracy of the posts [31,33,35,68]. Many bariatric surgical forums are dominated by peer-to-peer communication without professional supervision or involvement. In their review, Li and Suh [69] reported that users associated credibility of posts with certain factors; increased presence of particular users (mainly how often they interact with posts) and posts that share anecdotes of personal experiences are perceived to be of higher credibility [69]. In another study, the content and accuracy of nutrition posts in a bariatric surgery Facebook group were evaluated [35]. The authors of that study raised concerns about the fidelity of the information posted, and encouraged health care professionals to caution patients when interpreting forum discussions [35]. They recognized benefits that may come from a greater presence of health care professionals in online groups, referring to potential roles in moderation of posts and provision of evidence-based recommendations [35]. Further to this, Lindsay et al. [70] reported that having a moderator in an online support group for heart disease meant patients were more likely to adhere to advice, and thus more readily maintaining healthy behaviors. Similar findings were reported by Graham et al. [9], but this time from the perspective of a bariatric surgical health care professional [9]. Members of the surgical team specifically acknowledged that information shared which originates from other countries may conflict with the advice from UK recommendations, and that discussions about dietary intake may not be adequately tailored for those recovering from bariatric surgery [9].

It is clear that online forum content is an area that would benefit from further research in order to systematically review the data and better appreciate the place of digital support in a modern health care system. Surgical team members should consider the availability of digital support, and the possibilities or detriments this could have on patients before and after surgery.

Conclusion

In a patient cohort with notoriously high attrition rates at postoperative follow-up, and vastly changing needs during their surgical journey, the potential of online forums may well be an untapped method of support. Online forums could offer one solution to improving postoperative success by supporting and motivating patients. Future research should further explore the value of online forums and their place within modern health care systems. Involving patients to determine the optimal design and moderation of online forums will help to maximize usefulness and effectiveness. Members of the bariatric surgery multidisciplinary team may consider recommendations of peer-support networks to complement care for patients throughout their surgical journey.

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Authors' Contributions

AR led the writing of this manuscript as part of her PhD doctoral candidature, with all coauthors commenting on various drafts and approving the manuscript for submission.

Conflicts of Interest

None declared.

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Review

Usability of Mobile Health Apps for Postoperative Care: Systematic Review

Ben Patel¹, BA, BMBCh; Arron Thind², BA, BMBCh

¹Guy's and St Thomas' Hospital National Health Service Foundation Trust, London, United Kingdom

²East Surrey Hospital, Redhill, United Kingdom

Corresponding Author:

Ben Patel, BA, BMBCh

Guy's and St Thomas' Hospital National Health Service Foundation Trust

Westminster Bridge Road

London, SE1 7EH

United Kingdom

Phone: 44 7720994804

Email: benjpatel@gmail.com

Abstract

Background: Mobile health (mHealth) apps are increasingly used postoperatively to monitor, educate, and rehabilitate. The usability of mHealth apps is critical to their implementation.

Objective: This systematic review evaluates the (1) methodology of usability analyses, (2) domains of usability being assessed, and (3) results of usability analyses.

Methods: The A Measurement Tool to Assess Systematic Reviews checklist was consulted. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses reporting guideline was adhered to. Screening was undertaken by 2 independent reviewers. All included studies were assessed for risk of bias. Domains of usability were compared with the gold-standard mHealth App Usability Questionnaire (MAUQ).

Results: A total of 33 of 720 identified studies were included for data extraction. Of the 5 included randomized controlled trials (RCTs), usability was never the primary end point. Methodology of usability analyses included interview (10/33), self-created questionnaire (18/33), and validated questionnaire (9/33). Of the 3 domains of usability proposed in the MAUQ, satisfaction was assessed in 28 of the 33 studies, system information arrangement was assessed in 11 of the 33 studies, and usefulness was assessed in 18 of the 33 studies. Usability of mHealth apps was above industry average, with median System Usability Scale scores ranging from 76 to 95 out of 100.

Conclusions: Current analyses of mHealth app usability are substandard. RCTs are rare, and validated questionnaires are infrequently consulted. Of the 3 domains of usability, only satisfaction is regularly assessed. There is significant bias throughout the literature, particularly with regards to conflicts of interest. Future studies should adhere to the MAUQ to assess usability and improve the utility of mHealth apps.

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KEYWORDS

postoperative monitoring; postoperative care; mobile health app; telemedicine; smartphone; mobile phone

Introduction

Industry experts have forecasted significant growth in mobile app users [1]. Given this projected surge, mobile health (mHealth) apps offer a unique and readily accessible platform to the patient, surgeon, and innovator. mHealth apps are now being integrated into various sectors of health care, with over 318,000 [2] apps currently helping to track, educate, and diagnose [3].

One area of particular growth is the use of mHealth apps as a means of monitoring patients in the important postoperative period. Well-designed apps have the potential to encourage earlier discharge, reduce in-person follow-ups [4,5], rehabilitate [6], aid clinicians in picking up surgical complications [7], and improve communication between patient and health care professional [8]. In addition to the economic and medical benefit of early discharge, postoperative monitoring apps have the potential to empower patients, giving them autonomy over their

own health, which in turn might improve patient satisfaction and motivation for recovery [9].

The usability of mHealth apps is important [10,11] because those with poor usability will be less commonly used [12,13]. This is particularly significant in the postoperative period, given the focus of mHealth apps on rehabilitation, for which patient engagement is critical. One study revealed that around half of all mHealth app users stop engaging for various reasons, including loss of interest [14]. Despite this, little empirical research is undertaken to analyze the usability of mHealth apps before they are launched [15].

Several definitions and domains of usability have been previously defined without clear unification [11,16,17], but with several recurring themes. For example, the International Organization for Standardization (ISO) 3-pronged definition includes effectiveness (ie, whether users can use the product to complete their goals), efficiency (ie, the extent to which individuals expend resource in achieving their goals), and satisfaction [18]. Another definition [19] has been designed specifically for mHealth apps and includes factors such as mobility, connectivity, and additional cognitive load.

Different methods have been proposed for assessing domains of usability, such as the Post-Study System Usability Questionnaire [20] and the System Usability Scale (SUS) [21]. However, these tools were not originally created to evaluate mHealth apps. The Mobile App Rating Scale [22] was recently created for researchers and clinicians to assess the quality of mHealth apps, with the simpler user version of the Mobile App Rating Scale (uMARS) [23] being proposed shortly after. While quality of an mHealth app shares several components with usability, there are important differences.

Given the heterogeneity in definitions and methods used for assessing the usability of mHealth apps, one group has recently

developed and validated the 21-item mHealth App Usability Questionnaire (MAUQ) [24]. This tool explores 3 domains of usability, which are in line with the ISO definition: (1) ease of use and satisfaction, akin to ISO satisfaction; (2) system information arrangement, akin to ISO efficiency; and (3) usefulness, akin to ISO effectiveness. This systematic literature review aims to determine whether the usability of postoperative mHealth apps is being rigorously assessed, using the validated MAUQ as the gold-standard reference. We consider which empirical methods are being used and analyze whether postoperative mHealth apps are indeed usable.

Methods

Database Search

The A Measurement Tool to Assess Systematic Reviews checklist [25] was analyzed before conducting this review, with all methodology being established prior to the review being conducted. A university librarian experienced in the field of systematic literature review methodology was consulted. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [26] reporting guideline was adhered to for this review. Rayyan (Qatar Computing Research Institute) [27] software was used for the search.

Textbox 1 shows the questions that were defined.

The Medline, Embase, and Association for Computing Machinery Digital Library databases were searched. The search string was generated and aimed to provide maximum coverage while maintaining manageability. We defined 4 broad themes for our search. Terms within a theme were combined using Boolean operator OR, as seen in Table 1. Themes were then combined using Boolean operator AND.

Textbox 1. Search questions.

1. Which dimensions of usability are dealt with most often?
2. Which empirical methods are used to evaluate usability?
3. In which surgical specialties are mobile health apps' usability being evaluated?
4. What types of operating systems have been used?
5. What are the results obtained by the usability evaluation of the apps?

Table 1. Search strings for the 4 themes.

Theme	String
Mobile context	Smartphone OR smart phone OR mobile phone OR mobile device OR mHealth ^a OR tablet
Software	App OR application OR operating system OR OS ^b OR ios OR android OR windows OR google play
Postoperative	Postoperative OR post-operative OR surgery OR surgical OR operation OR perioperative OR peri operative
Usability	Usab* OR understandab* OR learnab* OR operab* OR attractive* OR user experience OR engag* OR satisf* OR adher* OR willing* OR accepta* OR effectiv* OR aesthetic OR intuitive*

^amHealth: mobile health.

^bOS: operating system.

Screening of Papers for Inclusion and Exclusion

Each study recruited from the initial search was evaluated to determine whether it should be admitted for analysis. The inclusion and exclusion criteria are shown in [Textbox 2](#).

Screening of article titles and abstracts was performed by 2 authors independently. In situations where eligibility of a study

could not be determined based on abstract alone, the full-text article was retrieved. We executed a full-text review of the remaining studies after title and abstract screening to further analyze appropriateness for inclusion. We analyzed all review articles to identify any other appropriate studies. We also reviewed the reference list of included papers.

Textbox 2. Inclusion and exclusion criteria.

Inclusion Criteria

- The paper uses a mobile health app, defined as an application (rather than a web-based tool) on a portable device (including smartphones and tablets). We include apps designed both for the patient and for the health care professional. We include all types of apps, including monitoring, educational, and rehabilitation apps
- The paper analyzes the postoperative period, defined as the point at which the patient leaves the operating theater, having undergone a surgical procedure
- The paper studies usability of the mobile health app. Any level of assessment is included, from structured questionnaire to analysis of engagement or time spent on the app
- The paper must be a full paper (not an abstract)

Exclusion Criteria

- The paper is not written in English
- The paper was published before 2000, in keeping with the launch of the first smartphone, the Ericsson R380 (Ericsson Mobile Communications)
- The paper only uses web-based, text-based, or email-based technologies (no mobile health app). We want to concentrate on mobile health apps, given that they are the subject of such traction in the market
- The app is not targeted to the postoperative period. For example, surgical apps monitoring patients following trauma or burns are excluded if no operative intervention is used. Furthermore, nonsurgical papers (eg, monitoring patients with chronic pain) are excluded. In addition, apps only used for education of surgeons are excluded
- Inappropriate study types, including reviews, case reports, and feasibility/pilot studies without any real-life postoperative analysis
- App is not designed for humans

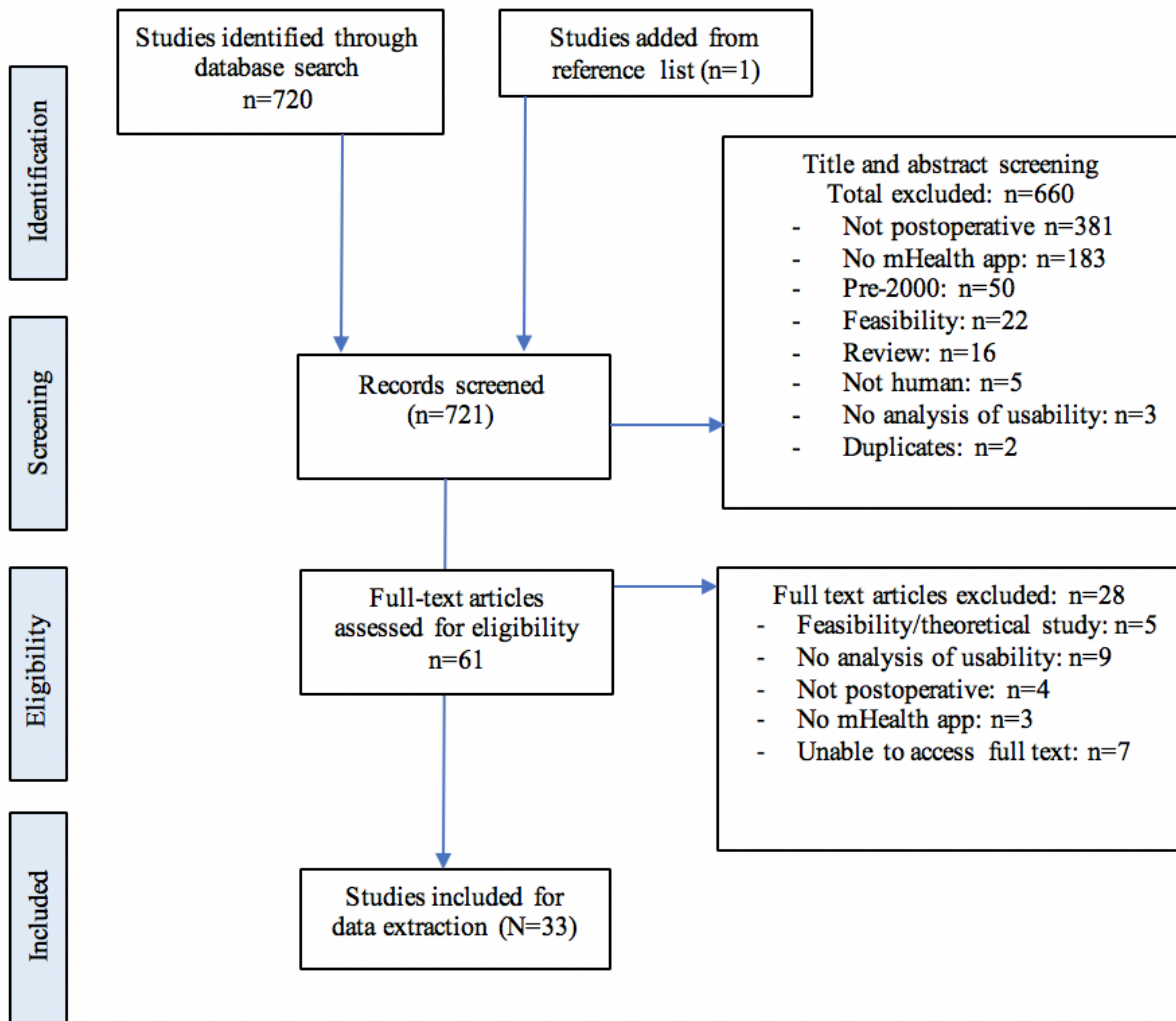
Results

Database Search Results

The initial search and reference list screening identified 721 studies. After title and abstract screening, 660 were excluded,

leaving 61 full-text studies to be assessed. Of these, 28 were excluded, leaving 33 studies included for data extraction. The PRISMA summary of the database search is presented in [Figure 1](#).

Figure 1. PRISMA summary of the literature search and exclusion process. mHealth: mobile health. PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses.



Study Characteristics

A total of 33 studies were included. Of the 33 studies, 21 were from North America (14 from the United States and 6 from Canada), 9 were from Europe, 2 were from Asia, and 1 was from South America. Most studies specified the type of mobile device used by participants. Smartphones were used in 22 studies, tablets were used in 9, smartwatches were used in 1, iPod touch (Apple Inc) devices were used in 2, and 3 studies did not specify. Regarding the operating system, 11 studies used iOS (Apple Inc), 5 used Android, 1 used Windows (Microsoft Corp), and 17 did not specify.

Among the included studies, mHealth apps were used within a wide range of surgical subspecialties, including orthopedics (8 studies), general surgery (6 studies), head and neck (4 studies), transplant (3 studies), pediatrics (2 studies), breast (1 study),

vascular (1 study), neurosurgery (1 study), and others/multiple (7 studies).

Functionality was divided into 5 clear categories; 26 studies included monitoring of symptoms or wounds, 8 included educational content, 5 provided a communication platform, 5 included physiotherapy and rehabilitation, and 2 enabled medication management. App details are presented in [Table 2](#).

Study characteristics are presented in [Table 3](#). With regards to study design, 5 studies were randomized controlled trials (RCTs), 25 were prospective noncontrolled studies, and 3 were retrospective reviews. Sample sizes ranged from 4 to 494, with a median of 39 patients and a mean of 81 patients. Follow-up ranged from 30 minutes postoperation to 12 months postdischarge. The follow-up period was less than 7 days in 4 studies, between 1 week and 1 month in 15 studies, greater than 1 month in 9 studies, and not declared in 5 studies.

Table 2. App details, including the study, country of origin, type of mobile device used, app name, surgical subspecialty, and app function.

Study	Country	Primary mobile device (operating system)	App name	Surgical subspecialty	Function
Timmers et al [28]	Netherlands	Smartphone and tablet (— ^a)	Patient Journey App (Interactive Studios)	Orthopedics (elective total knee replacement)	Personalized educational information regarding pain; Physiotherapy; Wound monitoring; Self-care
Yadav et al [29]	India	Smartphone (—)	WhatsApp (Facebook Inc)	Endocrine surgery	Tele-follow-up including wound check and communication
Ramkumar et al [30]	United States	Smartphone (iOS)	TKR (Focus Ventures)	Orthopedics (elective total knee replacement)	Monitoring of mobility and range of movement using wearable sleeve; PROMs ^b ; Analgesia need; Home exercise program compliance
Argent et al [31]	Ireland	Tablet (Android)	—	Orthopedics (elective total knee replacement)	Rehabilitation using an inertial measurement unit ^c , consisting of wearable sleeve; PROMs monitoring, including pain and perceived exercise difficulty
Brunner et al [32]	United States	Tablet (iOS)	Proloquo2Go (AssistiveWare)	Head and neck surgery	Augmentative and alternative communication in patients who are unable to speak postoperatively
van der Meij et al [33]	Netherlands	Smartphone (—)	—	Abdominal surgery (laparoscopic cholecystectomy, inguinal hernia surgery, laparoscopic adnexal surgery)	Information about surgical procedure; Insight into convalescence plan; Recovery monitor
Felbaum et al [34]	United States	Smartphone (—)	TrackMyRecovery	Neurosurgery	Postoperative instructions; Pain reporting; Wound monitoring
Goz et al [35]	United States	Smartphone (—)	—	Spine surgery	Postoperative communication through messaging app
Gunter et al [36]	United States	Smartphone (iOS)	WoundCheck	Vascular surgery	Wound monitoring using photographs and questionnaire
Gustavell et al [37]	Sweden	Smartphone and tablet (—)	Interaktor (Health Navigator)	Pancreatic surgery	Symptom monitoring; Education links to evidence-based care advice
Harder et al [38]	United Kingdom	Smartphone (iOS)	bWell	Breast surgery	Rehabilitation (arm exercises); Symptom monitoring
Higgins et al [39]	Canada	Smartphone (—)	QoC Health (QoC Health Inc)	Orthopedics (ACL ^d reconstruction)	Symptom monitoring; QoR-9 ^e questionnaire
Highland et al [40]	United States	Smartphone (—)	mCare	Surgery using peripheral nerve block	Symptom control using DVPRS ^f
Khanwalkar et al [41]	United States	Smartphone (—)	HealthLoop	ENT ^g (septoplasty and FESS ^h)	PROMs, including VAS ⁱ pain score, PROMIS ^j , and SNOT-22 ^k

Study	Country	Primary mobile device (operating system)	App name	Surgical subspecialty	Function
Mata et al [42]	Canada	Tablet (iOS)	SeamlessMD (Seamless Mobile Health Inc)	Colorectal surgery	Milestones checklist; Symptom-monitoring questionnaires; Educational content
Nilsson et al [43]	Sweden	Smartphone (—)	Recovery Assessment by Phone Points	Day surgery	SwQoR ¹ questionnaire
Pecorelli et al [44]	Canada	Smartphone (—)	SeamlessMD	Colorectal surgery	Milestones checklist; Symptom-monitoring questionnaires; Educational content
Sousa and Turrini [45]	Brazil	Smartphone (iOS)	OrtogApp	Orthognathic surgery	Educational content; Communication platform
Sun et al [46]	Canada	iPod touch (iOS)	Panda (Balsamiq Solutions)	Pediatric surgery	Postoperative pain monitoring; Medication management
Tsapepas et al [47]	United States	Tablet (—)	Medication Regimen Education	Kidney transplant	Educational content
Scott et al [48]	United States	Smartphone (—)	SeamlessMD	Colorectal surgery	Symptom tracker; Photograph of wound; Temperature recording
Warren-Stomberg et al [49]	Sweden	Smartphone (iOS and Android)	Medipal (Novatelligence AB)	Day orthopedic surgery	Symptom questionnaire
Debono et al [50]	France	Smartphone and tablet (—)	—	Lumbar discectomy	Symptom monitoring
Gunter et al [51]	United States	— (iOS)	WoundCheck	Vascular and general surgery	Symptom monitoring; Photograph of wound
Ponce et al [52]	United States	— (iOS)	HelpLightning	Orthopedics and neurosurgery	Virtual examination
Jiang et al [53]	United States	Smartphone (Windows)	PocketPATH	Lung transplant	Data entry of health indicators; Self-monitoring
Chai et al [54]	South Korea	Tablet (iOS)	Self-Reporting Application	Thyroid surgery	Self-reporting of symptoms
Shellmer et al [55]	United States	— (Android)	Teen Pocket PATH	Solid organ transplant	Monitoring of medications
Sun et al [56]	Canada	Smartphone (—)	Panda	Pediatric surgery	Postoperative pain monitoring using electronic versions of FPS-R ^m and CAS ⁿ
Jaensson et al [57]	Sweden	Smartphone (—)	Recovery Assessment by Phone Points	Day surgery	SwQoR questionnaire
Symer et al [58]	United States	Smartphone (iOS and Android) with paired smartwatch ^o	—	Colorectal surgery	Pain monitoring; Symptom monitoring; Patient reminders/alerts; Photograph of wound
Semple et al [59]	Canada	Smartphone or tablet (Android)	QoC Health	Breast and orthopedic surgery	Mobile version of the QoR-9 questionnaire

Study	Country	Primary mobile device (operating system)	App name	Surgical subspecialty	Function
Bini and Mahajan [60]	United States	iPod touch (iOS)	CaptureProof	Orthopedic surgery	Physiotherapy videos

^aNot available.

^bPROMs: patient-reported outcome measures.

^cShimmer3; Shimmer.

^dACL: anterior cruciate ligament.

^eQOR-9: quality of recovery 9.

^fDVPRS: Defense and Veterans Pain Rating Scale.

^gENT: ear, nose, and throat.

^hFESS: functional endoscopic sinus surgery.

ⁱVAS: visual analog scale.

^jPROMIS: Patient-Reported Outcomes Measurement Information System.

^kSNOT-22: Sino-Nasal Outcome Test 22.

^lSwQoR: Swedish Web Version of Quality of Life.

^mFPS-R: Faces Pain Scale – Revised.

ⁿCAS: color analog scale.

^oFitbit; Fitbit Inc.

Table 3. Study characteristics, including study design, number of patients included, duration of follow-up, method of usability analysis, usability domain, and selected usability results.

Study	Study design	Number of patients	Duration follow-up	Method of analysis of usability /outcome measure	Aspects of usability measured	Selected quantitative measure of usability
Timmers et al [28]	Multicenter RCT ^a	213	4 weeks	Measurement of patient usage; Interview of small group of patients (n=6)	Usefulness	App used 26 times/patient; Videos watched 36 times/patient; Qualitative reporting of usefulness
Yadav et al [29]	Prospective study (no control)	107	6 months	Self-created questionnaire	Satisfaction; Usefulness	1% unsatisfied across the questionnaire; 53% very satisfied with effectiveness; 78% very satisfied with app overall; Comfortable: 78% very satisfied; Convenience: 86%-91% very satisfied
Ramkumar et al [30]	Prospective study (no control)	22	3 months	Semi-structured interview	Satisfaction; Usefulness	A1: average score 2.6/10 (1=easiest to use; 10=most difficult)
Argent et al [31]	Mixed methods, including prospective study	15	2 weeks	Questionnaires (SUS ^b and uMARS ^c); Semi-structured interview	Satisfaction; System information arrangement; Usefulness	uMARS average score 4.1/5 (SD 0.39); SUS average score 90.8 (SD 7.8)
Brunner et al [32]	Prospective preintervention and postintervention study	38	4 days	Self-created questionnaires; Measurement of usage	Satisfaction; Usefulness	66% used the app; 60% satisfied with the app; 85% felt it was helpful
van der Meij et al [33]	RCT	344	3 months	Measurement of usage; Self-created questionnaire; Semistructured interviews	Satisfaction	49.6% had used the app; Mean score for app 7.6/10
Felbaum et al [34]	Prospective study (no control)	56	— ^d	Self-created questionnaire	Usefulness	Usefulness ranged from 8.39-9.0 out of 10 (Likert scale)
Goz et al [35]	Prospective study (no control)	21	2 weeks	Measurement of usage/engagement; Self-created questionnaire	Satisfaction; Usefulness	82% satisfied (would recommend to others); 75% found useful (felt the app made it less likely for them to call the clinic); Engagement: 3.38 messages/person over 2 weeks
Gunter et al [36]	Prospective study (no control)	40	2 weeks	SUS (questionnaire); Measurement of usage	Satisfaction; System information arrangement	SUS average score of 87.2
Gustavell et al [37]	Prospective study (no control)	6	4 weeks	Measurement of usage; Semistructured interviews	Satisfaction; System information arrangement; Usefulness	Adherence to reporting daily was 84%; Other measurements qualitative
Harder et al [38]	Prospective study (no control)	4	8 weeks	Measurement of usage; Self-created questionnaire	Satisfaction; System information arrangement; Usefulness	Overall rating (Likert scale) 4.6/5; All used the app almost daily or several times/day
Higgins et al [39]	Retrospective case series	32	6 weeks	Interview; Self-created questionnaire	Satisfaction	Overall satisfaction was reported as excellent (43%), good (40%), fair (10%), poor (7%); 94% would use the app again

Study	Study design	Number of patients	Duration follow-up	Method of analysis of usability /outcome measure	Aspects of usability measured	Selected quantitative measure of usability
Highland et al [40]	RCT	24 (only 12 assessed usability)	10 days	SUS questionnaire; Additional questionnaire	Satisfaction; System information arrangement; Usefulness	SUS average score 76.26/100; No difference in convenience between intervention and standard of care (telephone follow-up)
Khanwalkar et al [41]	Prospective study (no control)	249	3 months	Measurement of usage	None	77.4% response rate (usage)
Mata et al [42]	RCT	50	4 weeks; Satisfaction measured at discharge	Measurement of usage; Self-created questionnaire using 4 items from S-CAHPS ^e	Satisfaction	Usage: postoperative day 0=94%, day 1=82%, day 2=72%, day 3=48%; 4/5 satisfaction across all 4 questions
Nilsson et al [43]	Prospective study (no control)	494	14 days	Measurement of usage (response rate)	None	Usage: day 1=86.8%, day 7=69%, day 14=57.5%
Pecorelli et al [44]	Prospective study (no control)	45	4 weeks	SUS questionnaire	Satisfaction; System information arrangement	SUS average score 87/100
Sousa and Turriani [45]	Prospective study (no control)	30	—	SUS questionnaire; Satisfaction measured according to experience sampling method technique; Usage	Satisfaction; System information arrangement	SUS average score 79.8/100, 73.3% >68 (cutoff), 100% >50 (acceptable); Satisfaction 82.9%; Usage: 100% used at least once, 40% used 2-3 times, 10% used 5 times, 20% used >5 times
Sun et al [46]	Prospective study (no control)	29	—	CSUQ ^f Unstructured interviews	Satisfaction; System information arrangement; Usefulness	Median CSUQ score 2 (IQR ^g 1-3); 93% found app easy to use; 59% would use the app at home
Tsapepas et al [47]	Retrospective study	282	—	Self-created questionnaire	Satisfaction	Satisfaction rated 4 or 5 in 92%
Scott et al [48]	Prospective study (no control)	20	14 days	SUS questionnaire; Semi-structured interview; Measurement of usage	Satisfaction; System information arrangement; Usefulness	Median SUS 95/100; Usage: 30% did not use after discharge
Warren-Stomberg et al [49]	Prospective study (no control)	101	1 week	Measurement of usage	None	55/101 used the app; Of those that used the app, 53% used >13 times out of possible 15
Debono et al [50]	Prospective study (no control)	60	15 days	Telephone interview	Satisfaction; Usefulness	1 (poor) to 4 (excellent) scale: Overall satisfaction 3.4 Usability 3.5 Usefulness at home 3.2 Facilitating return at home 3.1; 91.6% would use the device again
Gunter et al [51]	Prospective study (no control)	9	—	SUS questionnaire	Satisfaction; System information arrangement	Average SUS score 83.3/100; 55.6% were able to complete the tasks independently
Ponce et al [52]	Prospective	31	24 days	15-point questionnaire	Satisfaction; Usefulness	Reassurance 4.6-4.8/5; Useful 4.5-4.8/5; Satisfaction 4.2-4.6/5

Study	Study design	Number of patients	Duration follow-up	Method of analysis of usability /outcome measure	Aspects of usability measured	Selected quantitative measure of usability
Jiang et al [53]	Secondary retrospective analysis of previous RCT data	96	12 months	Technology acceptance subscales used to measure: intention to use (1 item); perceived usefulness (4 items); and perceived ease of use (4 items)	Satisfaction; Usefulness	85% strongly agree with intention to use item; 80% gave high rating of perceived usefulness (>24/28); 82% gave high rating of perceived ease of use (>24/28)
Chai et al [54]	Prospective comparison study (nonrandomized)	54	14 days	Self-created questionnaire	Satisfaction; Usefulness	Satisfaction was >7.2/10 across all 4 items on questionnaire
Shellmer et al [55]	Prospective study	7	6 weeks	8/16 questions from PSSUQ ^h survey	Satisfaction; System information arrangement; Usefulness	Satisfaction 1/7 (1=strongly agree); Ease of use 1/7; Felt comfortable using application 1/7; "I could clearly tell when I missed my medication" 1/7; Liked tracking medications 3/7; Helpful to track medications 2/7
Sun et al [56]	Prospective study	66	30 minutes postoperation	Single question asked regarding preference of monitoring (app vs paper version of questionnaire)	Satisfaction	76%-81% preferred the app over the paper version
Jaensson et al [57]	Prospective study	10	—	Self-created questionnaire on system layout and technical issues, satisfaction, and usefulness	Satisfaction; System information arrangement; Usefulness	—
Symer et al [58]	Prospective study	31	30 days	Measurement of usage; Self-created questionnaire	Satisfaction; System information arrangement; Usefulness	83.9% used the app 70% of the time; 89.3%: easy to navigate; 88.9%: easy to use; 85.2%: survey questions relevant for identifying problems related to readmission; 66.7% found reminders useful; 92.9% would recommend to others
Semple et al [59]	Prospective study	65	30 days	Self-created survey; Interview; Usage	Satisfaction	Satisfaction 3.7-3.9/4; 100% willing to use in future; 100% surgeons found platform intuitive and easy to use; Usage: mean number of logins 19.3-23.9/30 days; Mean number of photographs uploaded 38-63/30 days

Study	Study design	Number of patients	Duration follow-up	Method of analysis of usability /outcome measure	Aspects of usability measured	Selected quantitative measure of usability
Bini and Mahajan [60]	RCT	29	24 weeks	Self-created survey; Free-form feedback; Usage	Satisfaction	Ease of use: 3.9-4.4/5; Satisfaction 4.2/5

^aRCT: randomized controlled trial.

^bSUS: System Usability Scale.

^cuMARS: user version of the Mobile App Rating Scale.

^dNot available.

^eS-CAHPS: Surgical Care Consumer Assessment of Healthcare Providers and Systems.

^fCSUQ: Computer System Usability Questionnaire.

^gIQR: interquartile range.

^hPSSUQ: Post-Study System Usability Questionnaire.

Usability Analysis

Regarding the method of usability analysis, usage (ie, monitoring of user engagement with the app) was used in 15 studies and was the only usability analysis employed in 4 studies. Interviews were used in 10 studies. Self-created questionnaires were used in 18 studies. Validated questionnaires were used in 9 studies. Of these, 7 used the SUS questionnaire, 1 used the uMARS questionnaire, 1 used the technology acceptance subscale, and 1 used the Computer System Usability Questionnaire (CSUQ).

We have categorized the domains of usability according to the MAUQ. A total of 28 studies covered ease of use and satisfaction, 11 studies covered system information arrangement, and 18 studies covered usefulness.

Average SUS scores ranged from 76 to 95 out of 100, with a median score of 87. The uMARS score was 4.1 out of 5. The CSUQ score was 2 out of 7 (whereby a score of 1 would indicate greatest usability).

Bias

There is significant potential for bias in studies evaluating the usability of mHealth apps. Hidden agenda bias and secondary gains bias were common and seemingly underreported in the literature. Of the 33 included studies, 8 officially reported authors' conflicts of interest, stating that they held shares in the app. Furthermore, several of the study groups were provided with the apps free of charge [28], which has clear implications on the usability domain of satisfaction; users who have paid for an app might be expected to have higher expectations than those who have been given an app for free. Perhaps more worryingly, a number of groups [38] declared no conflict of interest, despite seemingly being founders of their app.

Nonresponse bias is a further concern. Some studies, such as Pecorelli et al [44], had high response rates (96%) to usability analyses. However, others, such as Nilsson et al [43], had much lower rates (57.5% on day 14), and some [51] did not disclose the proportion of responders. Nonresponders to usability analyses are more likely to have reported poor usability. Therefore, studies with high rates of nonresponders are likely to have inflated usability results.

Population bias is a further issue. Younger audiences are likely to be more adept at using mobile technologies. Therefore, studies that include a younger demographic are likely to demonstrate inflated usability results. Additionally, the generalizability of results from studies [44] that included patients that were not used to mobile technologies may be limited and may change in the future, when greater numbers of older patients are used to mobile technologies.

Discussion

Principal Findings

To our knowledge, this is the first comprehensive systematic review to assess usability of mHealth apps in postoperative management. This review identified 33 studies evaluating the usability of mHealth apps in the postoperative period across a broad range of surgical subspecialties, demonstrating the growing interest in this area. Most of the included studies were derived from the United States and Europe, which appear to be hubs of innovation in the field. Unsurprisingly, smartphones were the most commonly used devices. However, we suspect that wearable devices such as smartwatches, which have additional monitoring capabilities such as electrocardiogram monitors, will play an increasingly important role in the future [61].

With respect to study designs, 25 of 33 studies were prospective noncontrolled trials. There were 5 RCTs, but usability was never a primary end point in these studies. We feel RCTs comparing mHealth apps to normal practice (eg, in-person follow-up, telephone follow-up, or no follow-up) would be particularly beneficial in assessing the domains of satisfaction and usefulness. It has also been suggested that mHealth app interventions are associated with a falsely heightened level of user satisfaction due to patients' affinities for their digital devices [62]. This could be minimized by comparing postoperative mHealth apps to a sham app. However, we also acknowledge that RCTs have previously been described as an impractical evaluation methodology for mHealth apps, due to their prolonged duration from recruitment to results and their high costs [63].

The methodology for assessing usability was generally poor. The majority of analyses used simplistic self-created

questionnaires that asked rudimentary questions focusing on the domain of satisfaction (28/33 studies) rather than other domains of usability. Indeed, only 11 of the 33 usability analyses assessed the domain of system information arrangement. We would argue that formal usability analyses should cover all 3 common domains of (1) satisfaction, (2) usefulness, and (3) system arrangement, according to the ISO definition of usability [18]. Validated questionnaires are helpful in assessing these areas reliably. Only 9 of the 33 included studies used validated questionnaires, most of which used the SUS. The SUS is a Likert scale made up of 10 questions. The average SUS score is 68 out of 100, meaning that all 7 studies that used the SUS scored above average in terms of usability. Although the SUS is a quick and cheap means of assessing usability, it was created in 1986, before the first smartphone or the concept of an app was realized. The SUS has not been validated for assessing mHealth apps. In comparison, the MAUQ was recently proposed and validated for use in mHealth apps in a population of English-speaking adults [64]. This is the gold-standard reference for analysis of mHealth app usability. While scores on the MAUQ have previously been shown to correlate with the SUS, this is not a strong correlation ($r=0.643$), thereby highlighting the inadequacy of studies that have only used the SUS.

A major concern in these studies is the risk of bias. A number of the studies' authors have a financial interest in the usability of their apps, with high user satisfaction making adoption by hospitals and investors more likely. Furthermore, devices were sometimes provided free of charge, which could influence the feedback from users.

Conclusions

mHealth apps have significant potential during the postoperative period for encouraging earlier discharge, improving patient engagement, and offering a safety net for early identification of complications. Thorough analysis of usability is critical to the adoption of these novel technologies in the postoperative period; those with poor usability will have little impact in health care. According to this review, usability analyses to date have been substandard. They have focused on satisfaction, a narrow dimension of usability, with simplistic self-created questionnaires. Furthermore, there is a significant risk of bias, given the common conflicts of interest among authors of published studies. We hope this review changes future practice, with researchers undertaking more robust assessments of usability by employing validated questionnaires, such as the MAUQ, in blinded RCTs.

Authors' Contributions

BP contributed the study conception and design. BP and AT performed the acquisition of data and analysis of data. BP drafted the manuscript. All work was self-funded.

Conflicts of Interest

None declared.

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Abbreviations

CSUQ: Computer System Usability Questionnaire

ISO: Organization for Standardization

MAUQ: mHealth App Usability Questionnaire

mHealth: mobile health

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

SUS: System Usability Scale

uMARS: user version of the Mobile App Rating Scale

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Original Paper

Perioperative Tablet-Based Telemonitoring After Abdominal Wall Hernia Surgery: Pilot Prospective Observational Cohort Study

Alexander Gräfitsch^{1,2*}, MD; Philipp Kirchhoff^{1,3*}, MD; Henry Hoffmann^{1,3}, MD; Ralph F Staerke¹, MD; Savas D Soysal⁴, MD; Philippe M Glauser^{1,5}, MD

¹Department of General and Visceral Surgery, University Hospital Basel, Basel, Switzerland

²Department of Visceral Surgery, Kantonsspital Aarau, Aarau, Switzerland

³ZweiChirurgen GmbH-Center for Hernia Surgery and Proctology, Basel, Switzerland

⁴Visceral Surgery Research Laboratory, Department of Surgery, Clarunis University Center for Gastrointestinal and Liver Diseases, Basel, Switzerland

⁵Department of Visceral Surgery, Spital Dornach, Dornach, Switzerland

*these authors contributed equally

Corresponding Author:

Philippe M Glauser, MD

Department of Visceral Surgery

Spital Dornach

Spitalweg 11

Dornach, 4143

Switzerland

Phone: 41 617044227

Email: philippe.glauser@spital.so.ch

Abstract

Background: Hernia repairs account for millions of general surgical procedures performed each year worldwide, with a notable shift to outpatient settings over the last decades. As technical possibilities such as smartphones, tablets, and different kinds of probes are becoming more and more available, such systems have been evaluated for applications in various clinical settings. However, there have been few studies conducted in the surgical field, especially in general surgery.

Objective: We aimed to assess the feasibility of a tablet-based follow up to monitor activity levels after repair of abdominal wall hernias and to evaluate a possible reduction of adverse events by their earlier recognition.

Methods: Patients scheduled for elective surgical repair of minor abdominal wall hernias (eg, inguinal, umbilical, or trocar hernias) were equipped with a telemonitoring system, including a tablet, pulse oximeter, and actimeter, for a monitoring phase of 7 days before and 30 days after surgery. Descriptive statistical analyses were performed.

Results: We enrolled 16 patients with a mean overall age of 48.75 (SD 16.27) years. Preoperative activity levels were reached on postoperative day 12 with a median of 2242 (IQR 0-4578) steps after plunging on the day of surgery. The median proportion of available activity measurements over the entire study period of 38 days was 69% (IQR 56%-81%). We observed a gradual decrease in the proportion of available data for all parameters during the postoperative course. Six out of ten patients (60%) regained preoperative activity levels within 3 weeks after surgery. Overall, patients rated the usability of the system as relatively easy.

Conclusions: Tablet-based follow up is feasible after surgical repair of minor abdominal wall hernias, with good adherence rates during the first couple of weeks after surgery. Thus, such a system could be a useful tool to supplement or even replace traditional outpatient follow up in selected general surgical patients.

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KEYWORDS

tablet-based follow up; day-case surgery; hernia surgery; telehealth; digital health; perioperative activity

Introduction

Background

As health care costs are rising worldwide, member states of the European Union spend on average 10% of their annual gross domestic products on health care [1]. Developing countries are facing even greater challenges due to population growth and lifestyle changes [2]. General surgical procedures are a significant contributor to these expenditures; for example, approximately 20 million inguinal hernia repairs are performed annually worldwide [3].

Due to rising pressure to reduce costs and ongoing efforts to increase patient comfort, more and more surgical procedures have been performed in a day-case setting since the 1990s [4]. The International Association for Ambulatory Surgery encourages that various procedures, including groin hernia repairs, be performed in an outpatient setting [5,6]. Correspondingly, the United Kingdom considers the day-case approach as the standard of care for most surgical procedures [7]. Furthermore, offering outpatient procedures is also encouraged in contemporary guidelines for the repair of groin hernias [8,9]. Switzerland recently started to follow this international trend. However, in 2010, only 8% of all inguinal and femoral hernia repairs were performed as day cases, which is far lower than the rates in France and Sweden with about 62% and 72%, respectively [10].

Although outpatient surgery is considered safe, we question whether surgeons might be losing personal contact with their patients too early [11]. Traditionally, nurses and surgeons have been monitoring complications and encouraging early mobilization in the ward. This inpatient setting will be diminished in the near future in Switzerland, and is already the exception for minor procedures in many countries.

Different approaches utilizing technical innovations such as virtual clinics or electronic devices have been successfully introduced to improve follow up, rehabilitation, and disease management in numerous fields, including for the outpatient management of inflammatory bowel disease, congestive heart failure, or diabetes [12-15]. In cardiovascular surgery, a digital health kit-based follow up after discharge is feasible [16]; however, its use did not reduce the readmission rate after cardiac surgery compared to traditional follow up [17].

Objectives

We aimed to study the feasibility of tablet-based monitoring perioperative activity 7 days before and 30 days after surgery for minor abdominal wall hernias and to assess whether this could reduce adverse events due to facilitated recognition. Postoperative pain and the occurrence of surgical site infections (SSI) were assessed as secondary outcomes.

Methods

Recruitment

Patients undergoing elective open or laparoscopic repair of abdominal wall hernias between October 2017 and September 2018 were eligible for enrollment in this single-center,

prospective, observational cohort study. Approval by the regional ethics committee was granted before the study was initiated (Ethics Commission Northwest and Central Switzerland, Project ID 2017-00787) and written informed consent was obtained from all patients. Exclusion criteria were aged below 18 years, emergency procedures, pregnancy or breastfeeding, and inability to use the devices. No remuneration was awarded for participation. The recruitment took place in our outpatient clinic, in which oral and written informed consent was obtained, and the patient was familiarized with the equipment. To gain optimal compliance, the same scientific assistant was responsible for enrollment in all cases and handed out an information leaflet.

Equipment

A digital health kit (Santiago Telemonitoring Kit, provided by Health In Sight Solutions, GmbH, Munich, Germany) was used in this study. The telemonitoring kit contained a Santiago R tablet, actimeter to be worn on the wrist, and pulse oximeter. The activity was assessed continuously by the actimeter, counting the patient steps per day and per week. The device was equipped with a Swiss SIM card, which provided internet coverage within Switzerland's national borders.

Measurement of Parameters

Patients had to measure pulse, blood oxygen saturation, and pain levels at rest, twice daily. The pain level was measured using the visual analog scale (VAS). The actimeter had to be worn continuously. To allow patients to adapt to the measuring routines and to generate a baseline, we set a preoperative observation period of 7 days. As we conducted this study as a pilot trial, we decided to set a postoperative follow-up period of 30 days to gain information about adherence for further trials. As the risk for postoperative SSI in clean procedures is negligible [18,19], we asked participants to send wound pictures only for 7 days after surgery. Furthermore, they were free to take pictures of a suspected wound infection as they wanted. A study assistant monitored the incoming results and data to spot possible complications after surgery. Moreover, this assistant identified adverse events and intervened if requests from the system for data input were ignored.

Procedures and Follow Up

Procedures were conducted typically with an overnight stay, and the anesthetic regime was left to the discretion of the attending anesthetists. The pain management consisted of nonsteroidal anti-inflammatory drugs. Follow-up appointments in the clinic were not scheduled as we do not see our patients routinely after repair of minor abdominal wall hernias. At the end of the observation period, each patient was asked to fill in a short questionnaire to evaluate the functionality of the provided tablet and actimeter.

Statistical Analysis

After completion of enrollment, patients' baseline characteristics such as comorbidities, type of procedure, and length of stay were recorded. Finally, descriptive statistical analyses were performed.

Results

Patient Characteristics and Procedures

We enrolled 16 patients from October 2017 to July 2018, including 11 (69%) men and 5 (31%) women, with a mean overall age of 48.75 (SD 16.27) years (Figure 1, Table 1). Three

patients were retired, one patient was currently unemployed, and 12 patients were employees (see Multimedia Appendix 1 for the complete details).

Twelve repairs of groin hernias and four repairs of ventral abdominal wall hernias were performed (Table 2). In cases of trainees delivering the operation, an assisting specialist was always present for supervision.

Figure 1. Study flowchart.

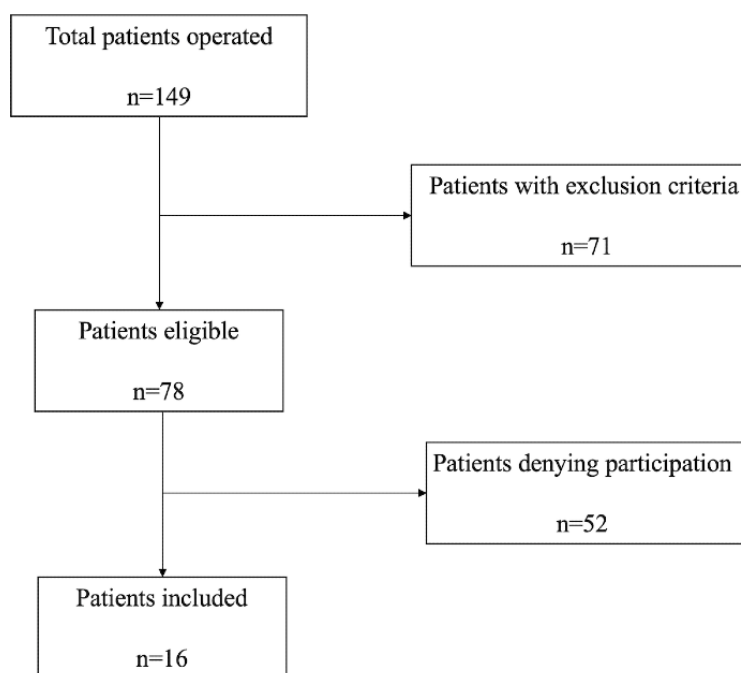


Table 1. Baseline characteristics of the participants (N=16).

Characteristic	Females (n=5)	Males (n=11)
Age (years), mean (SD)	45.80 (11.81)	50.09 (18.31)
BMI (kg/m ²), mean (SD)	24.80 (2.39)	26.55 (4.93)
ASA ^a score (1-5), mean (SD)	1.80 (0.45)	2.27 (0.65)
Aspirin ^b , n (%)	0 (0)	1 (9)
Smoking history, n (%)		
Active smokers	3 (60)	4 (36)
Exsmokers	0 (0)	3 (28)
Nonsmokers	2 (40)	4 (36)
LOS ^c (days), mean (SD)	2.40 (0.55)	2.27 (0.47)

^aASA: American Society of Anesthesiologists' classification of physical status.

^bOngoing treatment with Aspirin or generic equivalent.

^cLOS: length of stay in hospital.

Table 2. Type of interventions (N=16).

Procedure	Females (n=5), n (%)	Males (n=11), n (%)
TAPP ^a one side	3 (60)	5 (46)
TAPP both sides	1 (20)	0 (0)
TEP ^b one side	1 (20)	1 (9)
Lichtenstein repair one side	0 (0)	1 (9)
Direct closure, umbilical	0 (0)	1 (9)
Open sublay repair	0 (0)	1 (9)
Laparoscopic IPOM ^c	0 (0)	2 (18)

^aTAPP: transabdominal preperitoneal plasty.

^bTEP: total extraperitoneal plasty.

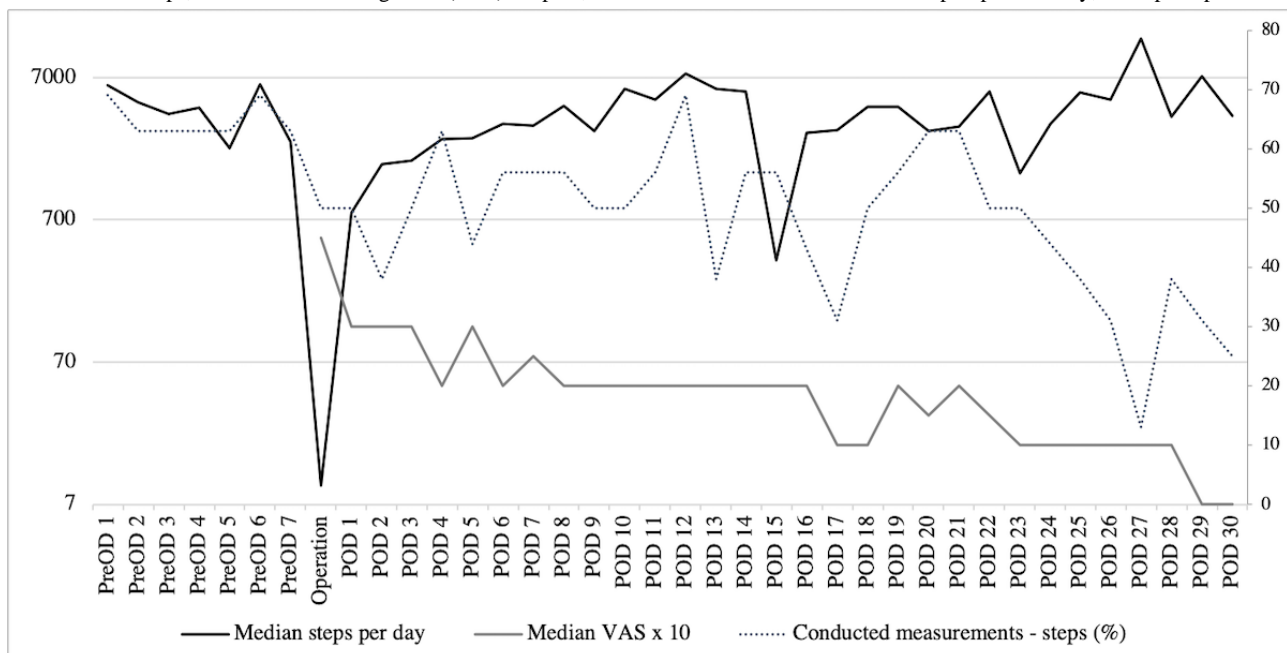
^cIPOM: intraperitoneal onlay mesh.

Activity

Our patients showed a wide range of activity levels over the study period and a considerable amount of activity data were not transferred (Figure 2). Preoperatively, the median step count per day ranged from 2242 (IQR 0-4578) to 6230 (IQR 96-8173) with up to 11 (69%) patients transferring data. Unsurprisingly,

daily steps plunged on the day of the procedure but gradually rose from postoperative day 1 and surpassed preoperative levels by postoperative day 12 with a median 7469 (IQR 3314-9126) steps. Subsequently, the step count remained fairly stable, but we noted a remarkable decrease in data transfer over the next few weeks.

Figure 2. Median steps, median visual analog scale (VAS) for pain, and conducted measurements. PreOD:preoperative day; POD:postoperative day.

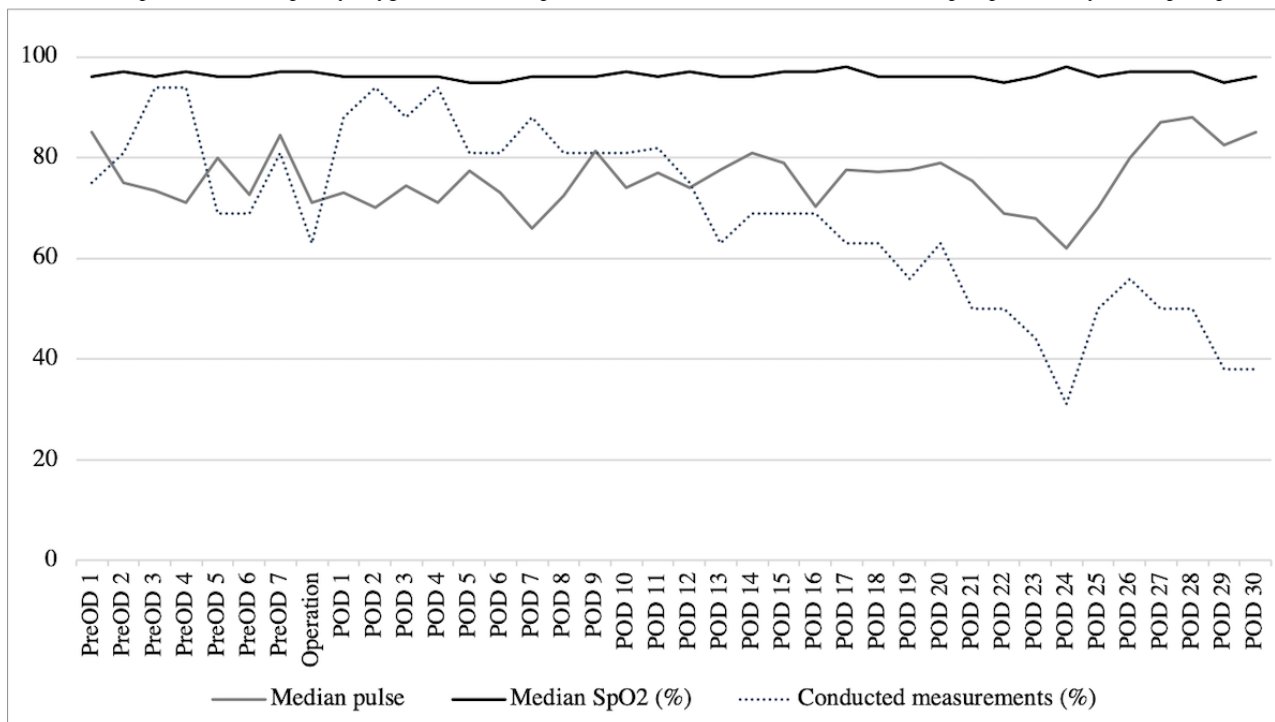


With regard to recovering preoperative activity levels, 9 out of the 16 datasets included sufficient information for analysis. Among these patients, 6 (66%) achieved their preoperative levels within 3 weeks after surgery (after 1 week for two patients, after 2 weeks for three patients, and after 3 weeks for one patient).

Pain levels peaked on the day of surgery with a median VAS of 4.5 (IQR 2.25-6) and subsequently decreased over the following weeks with similar rates of transferred data as found for the activity data.

Pulse Oximeter and SSI

Average oxygen saturation and pulse levels remained stable throughout the perioperative observation period (Figure 3). Again, the rate of transferred datasets declined steadily, falling below 50% on postoperative day 22. Seven (44%) patients sent wound pictures on postoperative day 3, which was the highest number over the planned 7 postoperative days, but dropped down to as low as 2 (13%) on postoperative day 6. No SSI occurred during the study period.

Figure 3. Median pulse, median capillary oxygen saturation (SpO₂), and conducted measurements. PreOD: preoperative day; POD: postoperative day.

General Feedback

Several patients stated that the actimeter was sometimes uncomfortable to wear, and that data transfer from the pulse oximeter and actimeter to the tablet was quite long in some instances. Taking photographs of the wound site was considered to be a laborious task. It was suggested to add a field for further information on pain besides the VAS (eg, pain medication was taken, localization of the pain, quality of pain).

Participants noted varying reasons for missing data input, such as personal and professional commitments abroad, inability to wear the actimeter at work, problems with the photo and VAS apps, and issues with transferring actimeter data. Additionally, one patient received the set on postoperative day 1 and one patient lost his actimeter during the postoperative period.

Nine participants (56%) completed the questionnaire, rating the usability of the tablet interface overall and the different apps as relatively easy (mean 1.8, SD 0.93), rated on a score of 1 (easy) to 5 (difficult). All 9 (100%) patients stated that they would participate in such a trial again and 4 (44%) would recommend friends to take part in studies with this system.

Discussion

Principal Results

Our single-center, prospective, observational cohort study showed, in principle, the feasibility of a tablet-based follow up after repair of small hernias of the abdominal wall. The majority of patients achieved their preoperative activity levels within 3 weeks. The usability of the system was rated as relatively easy.

Limitations

Some limitations of our study have to be considered. The number of included patients was relatively low, and selection

bias cannot be excluded. For example, our pragmatic inclusion criterion of “being able to handle a smartphone” has to be mentioned in this context. A setback was that some patients had to travel abroad for professional commitments, while others went on vacations, which led to further loss of data due to the chosen SIM card that was valid only in Switzerland. Additional technical issues such as problems with the connection between the devices or difficulties taking pictures also reduced the transferred data volume. As no SSI occurred, our secondary hypothesis regarding the possible advantages of a photograph-based follow up to minimize the impact of SSI could not be evaluated.

Comparison With Prior Work

Regarding our primary outcome, we managed to monitor our patients’ activity over the study period. However, surprisingly, the overall completeness of the datasets was quite low; for example, only 25% of the activity datasets were transferred on all 7 days before the procedure. These findings are in sharp contrast to another study in which adherence rates ranged from 59% to 69% for 12 months while monitoring various parameters in patients with chronic conditions [20]. Colleagues studying the use of electronic diaries in patients with chronic pain found even higher rates, with 92% to 96% compliance over a study period of 3 weeks [21]. Interestingly, the rate of the gathered information from the pulse oximeter was consistently higher than that for the actimeter. The reason may be related to technical issues, as the actimeters did not always transfer data to the tablet. Moreover, it had to be worn all the time, in contrast to intermittently using the pulse oximeter. For example, one person was not allowed to wear the actimeter during working hours as a chef.

It is striking that the transferred pulse oximeter information gradually declined as of postoperative day 11 from its highest

level of 90% directly after the intervention. In our opinion, this loss of adherence may be due to well-controlled postoperative pain and the return to regular social and professional commitments. These findings are underpinned as 6 out of 9 patients (67%) managed to reach or surpass their preoperative weekly step count within only 2 weeks after surgery. Another possible explanation for the decreasing data transfer may be technical issues reported by the participants.

We found high satisfaction with the system among our patients; additionally, the system's usability was rated as relatively easy. These findings reflect results of previous studies in which patients showed high acceptance rates for the tested remote monitoring devices [16,17]. As 100% of the patients who filled in the final questionnaire in our trial stated that they would again

take part in a trial with this system, we suspect that a shift to an electronic follow up might be feasible on a broad basis.

Conclusion

Our study shows that a tablet-based follow up with a primary focus on mobilization can be implemented after minor general surgical procedures. Further studies with control groups should be conducted to evaluate possible cost and adverse event reductions compared with traditional follow up. Moreover, we would suggest studying this or similar systems after major abdominal surgery or complications following previous procedures. Finally, smartphones, instead of tablet-based apps, could possibly enhance adherence in younger patients in future trials.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Professions of participants.

[\[DOCX File , 13 KB - periop_v3i2e15672_app1.docx \]](#)

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Abbreviations

SSI: surgical site infection

VAS: visual analog scale

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Original Paper

Wireless Remote Home Monitoring of Vital Signs in Patients Discharged Early After Esophagectomy: Observational Feasibility Study

Martine J M Breteler^{1,2}, MSc; Lieke Numan^{1,3}, MSc; Jelle P Ruurda⁴, MD, PhD; Richard van Hillegersberg⁴, MD, PhD; Sylvia van der Horst⁴, MSc; Daan A J Dohmen², PhD; Mathilde C van Rossum^{3,5}, MSc; Cor J Kalkman¹, MD, PhD

¹Department of Anesthesiology, University Medical Center Utrecht, Utrecht, Netherlands

²Luscii Healthtech BV, Amsterdam, Netherlands

³Department of Technical Medicine, University of Twente, Enschede, Netherlands

⁴Department of Surgery, University Medical Center Utrecht, Utrecht, Netherlands

⁵Biomedical Signals and Systems Group, University of Twente, Enschede, Netherlands

Corresponding Author:

Martine J M Breteler, MSc

Department of Anesthesiology

University Medical Center Utrecht

Heidelberglaan 100

Utrecht, 3584CX

Netherlands

Phone: 31 623112514

Email: m.j.m.breteler@umcutrecht.nl

Abstract

Background: Hospital stays after major surgery are shorter than ever before. Although enhanced recovery and early discharge have many benefits, some complications will now first manifest themselves in home settings. Remote patient monitoring with wearable sensors in the first days after hospital discharge may capture clinical deterioration earlier but is largely uncharted territory.

Objective: This study aimed to assess the technical feasibility of patients, discharged after esophagectomy, being remotely monitored at home with a wireless patch sensor and the experiences of these patients. In addition, we determined whether observing vital signs with a wireless patch sensor influences clinical decision making.

Methods: In an observational feasibility study, vital signs of patients were monitored with a wearable patch sensor (VitalPatch, VitalConnect Inc) during the first 7 days at home after esophagectomy and discharge from hospital. Vital signs trends were shared with the surgical team once a day, and they were asked to check the patient's condition by phone each morning. Patient experiences were evaluated with a questionnaire, and technical feasibility was analyzed on a daily basis as the percentage of data loss and gap durations. In addition, the number of patients for whom a change in clinical decision was made based on the results of remote vital signs monitoring at home was assessed.

Results: Patients (N=20) completed 7 days each of home monitoring with the wearable patch sensor. Each of the patients had good recovery at home, and remotely observed vital signs trends did not alter clinical decision making. Patients appreciated that surgeons checked their vital signs daily (mean 4.4/5) and were happy to be called by the surgical team each day (mean 4.5/5). Wearability of the patch was high (mean 4.4/5), and no reports of skin irritation were mentioned. Overall data loss of vital signs measurements at home was 25%; both data loss and gap duration varied considerably among patients.

Conclusions: Remote monitoring of vital signs combined with telephone support from the surgical team was feasible and well perceived by all patients. Future studies need to evaluate the impact of home monitoring on patient outcome as well as the cost-effectiveness of this new approach.

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KEYWORDS

remote monitoring; wireless monitoring; vital signs monitoring; telemonitoring; wearables

Introduction

Monitoring in high-care settings (eg, intensive care units) includes continuous measurement of different vital signs and frequent visual observations of the patient's clinical status by the nurse. In low-care settings, such as surgical wards, the current standard is intermittent measurement of vital signs only, usually once every shift [1,2]. By contrast, when patients are discharged after major surgery, vital signs are no longer monitored at all, while it is known that more than 29% of deaths after noncardiac surgery occur after patients are discharged from the hospital [3]. Although the risk of patient deterioration has decreased by the time the patient is discharged from hospital, the risk that patient deterioration will go unnoticed increases.

At present, patients are discharged after major surgery earlier than ever before. In part, this is facilitated by the introduction of enhanced recovery after surgery programs that have shown to accelerate patient recovery, resulting in shorter hospital lengths of stay [4-6]. Although recovery within the patient's own home has many benefits, it increases the risk that early warning signs will be missed; some late major complications might first manifest themselves in the home setting.

Recognizing the early signs of deterioration in the first few critical days at home might be improved with the availability of remote monitoring of vital signs for patients at high risk for complications, such as patients discharged home early after esophagectomy. Hospital readmissions after esophagectomy occur frequently, ranging from 5%-19%, and are associated with poor outcomes [4,7-9]. Advances in telemonitoring technology have now resulted in wearable and wireless sensors for remote unobtrusive vital signs monitoring. Such technology could provide patients the opportunity to recover at home, with the patient knowing that the hospital team will capture any possible deterioration early. At least in theory, this should allow safe early discharge after surgery and may reassure patients and their family.

Several studies have demonstrated the feasibility of wireless vital signs monitoring in patients admitted to the hospital [10-13], but monitoring patients at home in the first days after hospital discharge with wearable sensors is largely uncharted territory. It is unknown whether it is feasible to monitor patients remotely at home or whether remotely observing vital signs positively impacts clinical decision making.

Therefore, the objective of this study was to assess the technical feasibility of patients, discharged after esophagectomy, being remotely monitored with a wireless patch sensor as well as their experiences. In addition, we aimed to determine whether observing vital signs with a wireless patch sensor in these patients influenced clinical decision making.

Methods

Study Design and Setting

This was an observational feasibility study in which patients were monitored after esophagectomy with a wearable patch sensor (VitalPatch, VitalConnect Inc) on the general ward of the University Medical Center Utrecht, the Netherlands, and at home during the first 7 days after hospital discharge. The University Medical Center Utrecht ethics committee waived the need for formal ethical approval, since patients were not subject to procedures or required to follow extensive rules of behavior.

Study Population

Patients receiving care after esophagectomy at the surgical oncology ward were included. Patients were recruited from July 2019 to December 2019. All patients were informed about the study 1 week before surgery by phone. Exclusion criteria were known skin allergies, pacemaker or implantable cardioverter defibrillator, or a wound near the application site of the patch. After written informed consent was obtained from the patient on the surgical ward, the wireless patch sensor was applied and vital signs recording started.

Description of the Wireless Patch Sensor

The VitalPatch wearable biosensor consists of a disposable adhesive patch that incorporates 2 electrocardiography electrodes, a triaxial accelerometer, and a thermistor. It is designed to facilitate remote monitoring of patients on the ward as well as in the home setting after hospital discharge. Heart rate and respiratory rate measurements of a previous version of the VitalPatch sensor (HealthPatch, VitalConnect Inc) have been validated in high-risk patients in a clinical environment [14,15]. The patch can be applied on the patient's chest, and it records heart rate, heart rate variability, respiratory rate, and skin temperature (every 4 seconds) and body posture and steps continuously (every second) for up to 5 days. Data were sent via Bluetooth to a mobile phone (Cubot King Kong 3, Shenzhen Huaifurui Technology Co Ltd), which uploaded the data over cellular networks to the HealthStream (MedioBioSense Ltd) cloud platform. This app can display vital signs data in real time but was not designed to view long-term vital signs trends. Data could be stored for up to 18 hours on the sensor if connection between the patch sensor and mobile app was lost. Afterward, it would take half of the upload time of the live data to upload this offline data to the cloud platform. No identifiable patient information was entered on the mobile device or in the app to ensure compliance with European General Data Protection Regulations.

Data Collection

Patients wore a patch sensor on the surgical ward and during the first 7 days after hospital discharge. In-hospital measurements were solely used to generate baseline data prior to discharge, and the patient's vital signs were observed intermittently through care as usual. A new patch was applied

upon discharge, and patients were taught how to replace a new patch after 5 days at home. In addition, they were instructed to keep the mobile phone charged and within a range of 10 m. It was made explicit that wearing a patch at home does not mean that the patient's vital signs would be continuously observed. Instead, their vital signs trends were checked once every 24 hours.

Each morning, for 7 days postdischarge, vital sign trends over 24 hours and vital signs trends over 7 days were shared with the gastrointestinal oncology surgical team (3 surgeons, 2 surgical residents, 1 physician assistant) in a secure medical messaging app (Siilo, Siilo Holding BV). Examples are shown in Figure 1 and Figure 2. Surgeons were asked to check the patient's condition each morning by phone using a short

structured format with questions, such as "how do you feel?", and asking about pain and fever. Phone calls were used as a safety net to prevent cases of missed patient deterioration, since the added value of remote vital signs monitoring had not been established. After each phone call, surgeons scored the patient's condition with a 0 (no cause for concern), 1 (slightly worried), or 2 (significant concern). Conservative wait-and-see treatment was applied if a score of 1 was given, and the general practitioner was informed if a score of 2 was given. Thereafter, a surgical team member checked the vital sign trends and used that information to reassess their score. An X was scored if not enough vital signs data were available. This approach allowed the surgical team to adapt treatment policy, if needed, after taking into account information from the vital signs data trends.

Figure 1. Example of vital sign trends over 24 hours, showing (A) heart rate, (B) respiratory rate, (C) skin temperature, and (D) cumulative step count. The shaded area indicates night-time.

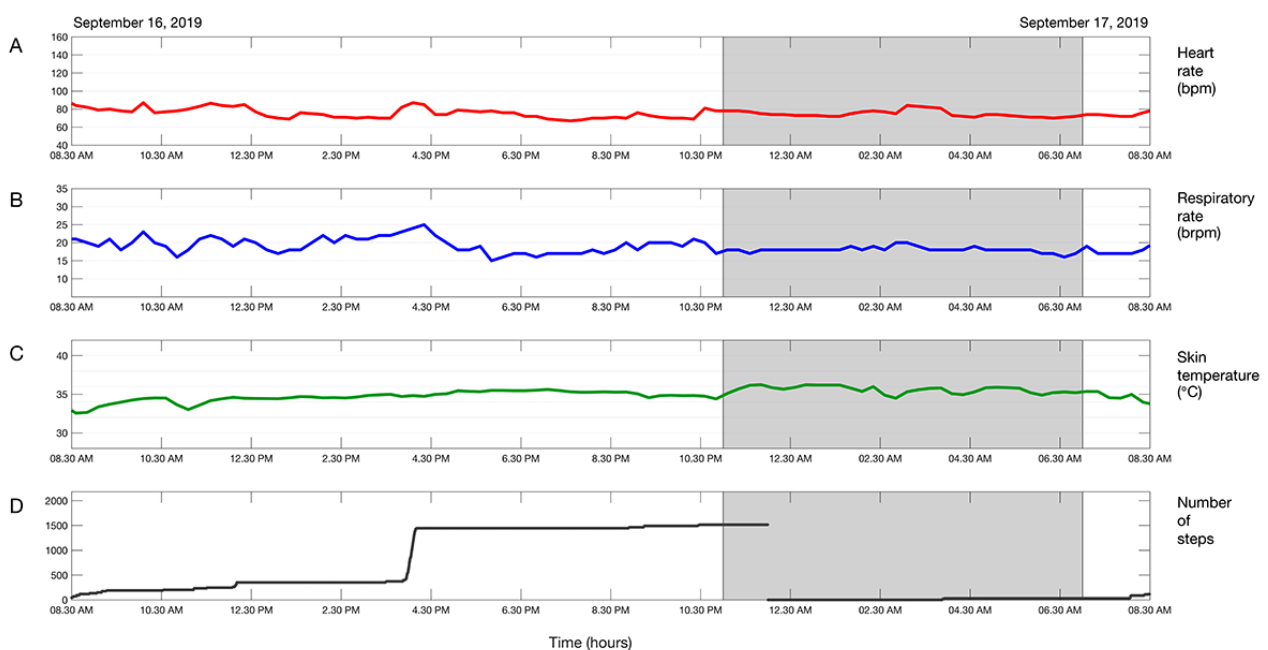
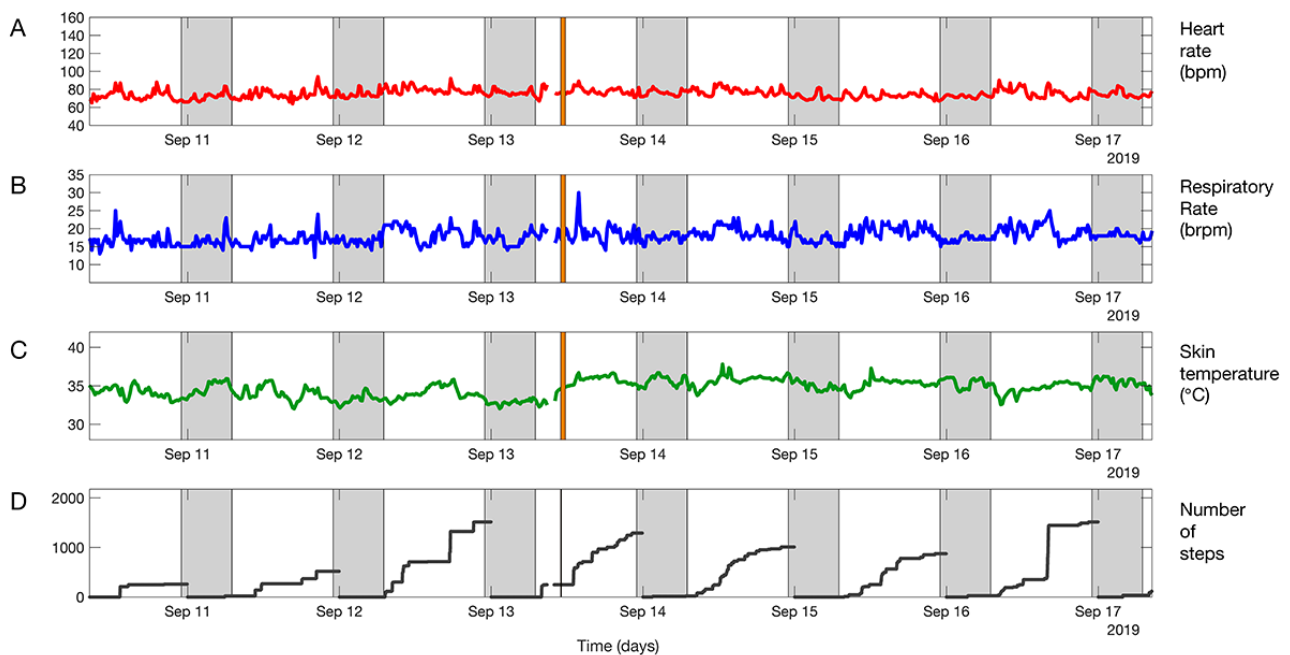


Figure 2. Example of vital sign trends over 7 days, both within hospital and at home after hospital discharge, showing (A) heart rate, (B) respiratory rate, (C) skin temperature, and (D) cumulative step count. The orange line indicates the time of hospital discharge. The shaded area indicates night-time.



Signal Analysis

Wireless sensor data were retrieved in comma-separated variable (.csv) text files and stored in a secured local research database. Data reports were processed using Matlab (MathWorks Inc). A median filter over nonoverlapping epochs of 15 minutes was applied to eliminate artifacts from transients and to increase clarity and readability of the vital signs trend overviews. The number of steps was reset to zero at midnight to allow easy visual verification of each patient's daily activity level.

Outcome Measures

Patient experiences of being remotely monitored at home and sensor wearability were assessed with a questionnaire, completed after the study. This questionnaire consisted of 8 questions using a 5-point Likert scale, 2 open answer questions, 1 yes or no question, and 1 question with 3 possible answers. The technical feasibility of remote home monitoring with a wireless sensor was assessed on a daily basis as the percentage of useful data available for vital signs interpretation. In addition, maximum duration of data loss was defined as gap durations less than 15 minutes, less than 1 hour, 1-4 hours, or 4 hours or longer. We distinguished data loss observed between the time of vital signs assessment (each morning) and observed at the end of the entire measurement period.

Another outcome measure was the number of patients in which a change in clinical decision was made based on the results of remote vital signs monitoring. This was measured by registering the number of times a score was adapted from 0 to 1, or from 1 to 2 following inspection of the vital signs trend overviews

and compared with the check of the patient's condition by phone each day. In addition, trend patterns of heart rate, respiratory rate, skin temperature, and number of steps during the week were also assessed.

Statistical Analysis

Descriptive statistics were used to evaluate patient demographics and to assess feasibility of home monitoring. Since this was an observational feasibility study not designed to assess whether remote home monitoring could improve patient outcome, we refrained from a formal sample size calculation. Given the much lower probability of postdischarge adverse events [16], very large sample sizes would likely be needed to demonstrate statistically significant differences in outcome.

Results

Patient Population

Of 29 patients screened, 23 gave informed consent and 6 patients declined to participate, either because they already had "too much on their mind," did not want to stay connected with the hospital once back home or thought they would not be able to cope with such modern technology. Two patients withdrew before the home monitoring period started because they were no longer willing to participate. One patient died during hospital admission. In total, 20 patients completed a combined total of 140 days (7 days each) of home monitoring with the wearable patch sensor. None of these patients were readmitted to the hospital within 30 days, and only 1 event after discharge home was observed (Table 1).

Table 1. Patient characteristics.

Characteristic	Patients (N=20)
Age (in years), median (IQR)	70 (7)
Sex	
Male	16 (80)
Female	4 (20)
BMI, median (IQR)	25 (2)
Living status, n (%)	
Living alone	4 (20)
Living with someone	16 (80)
Comorbidities^a, n (%)	
Hypertension	9 (45)
Cardiovascular disease	5 (25)
Chronic obstructive pulmonary disease	4 (20)
Diabetes	3 (15)
Length of stay (days), median (IQR)	11 (7)
Readmission within 30 days, median (IQR)	0 (0)
In-hospital postoperative events^a, n (%)	
Pneumonia	13 (65)
Atrial fibrillation	6 (30)
Anastomotic leak	7 (35)
Chyle leak	2 (10)
Pneumothorax	1 (5)
No events	2 (10)
Postdischarge postoperative events, n (%)	
Severe dyspnea	1 (5)
No events	19 (95)

^aMore than one event per patient possible; therefore, percentages do not add to 100%.

Patient Experiences

Patient experiences were collected via a questionnaire as shown in Table 2. Overall, patients reported very high satisfaction rates. They appreciated that physicians checked their vital signs daily and they were happy to be called by the surgical team each day. The wearability of the patch sensor in the outpatient setting was high; patients were not aware of wearing a patch. Furthermore, no reports of skin irritation were mentioned, and the patch stayed in place most of the time, even during sweating and showering. One patient lost the patch twice at home, due to excessive sweating. Replacing the patch themselves at home was considered very easy. No information was visible on the dedicated mobile phone that acted as a gateway for the vital signs data, but patients were asked to keep the phone in close proximity to ensure uninterrupted data transmission. Interestingly, 95% of patients (19/20) reported they did not miss the absence of data on the mobile phone regarding current vital signs values or the proper functioning of the entire system. Thus, it did not bother them that they could not see anything on the

mobile phone. Only 1 patient mentioned it would be reassuring to show the vital signs and additional information whether their vital signs data is being transferred to surgeons correctly. 75% of the patients (15/20) reported feeling safer at home knowing that their vital signs trends were checked and being called by a physician daily.

In addition, all patients were asked to imagine a future scenario in which they would be offered the option to go home 1 day earlier with a wireless patch sensor. Most patients (15/20, 75%) indicated they would prefer to be discharged earlier with the assistance of a remote patient monitoring solution. The main reasons given for this preference were a belief that they would recover more quickly at home and the fact that it is much more convenient to recover in one's own home than in a hospital bed. A few patients mentioned that they felt quite uncertain being discharged home after such a major surgical procedure. As 1 patient noted: "It is quite a transition from a hospital where they constantly keep an eye on you, to home. It gives you reassurance when you have the feeling that your condition is being checked remotely." Most of the patients reported the necessity of having

home care properly organized, and ideally, having the possibility of access to home care 24 hours a day. Of note, the amount of home care received by these patients was dependent on their need for assistance with tube feeding or wound care. Three patients did not like the idea of being discharged sooner with assistance of a remote patient monitoring solution, either because

they felt they were discharged quite quickly already (while they were still recovering from adverse events that occurred in-hospital) or they had experienced that their medications or home care was not adequately organized at the time they were discharged.

Table 2. Questions on patients' experience of being remotely monitored at home with the VitalPatch sensor.

Question	Patient response (n=20)
1 How did you experience wearing the patch in the first week after hospital discharge? ^a , mean	4.1
2 How did your partner experience the fact that you wore this patch and that your vitals were checked by physicians remotely? ^a , mean	4.5
3 To what extent did you find it pleasant or not pleasant that physicians were able to see your vital signs once daily? ^a , mean	4.4
4 To what extent did you find it pleasant or not pleasant that physicians called you each day to ask how you were doing? ^a , mean	4.5
5 Nothing was visible on this mobile phone you had in proximity. Would you have preferred to see any data on this mobile phone, or you haven't missed this? , n (%)	
Yes	19 (95)
No	1 (5)
6 Your vitals were checked and you were called once daily. To what extent did this make you feel safer or not? , n (%)	
Yes	15 (75)
No	5 (25)
7 Imagine you have a choice to go home one day earlier with such a wireless patch sensor in the future. What do you think of this? , n (%)	
Yes	15 (75)
No	5 (25)
8 What would you need for this, to make yourself comfortable at home? (open answer)	— ^b
9 To what extent were you aware of wearing this patch? ^c , mean	4.4
10 To what extent caused this patch irritation on your skin? ^d , mean	5
11 To what extent stayed this patch in place, even during sweating and showering? ^a , mean	4.8
12 To what extent was it easy to replace the patch at home? ^a , mean	4.8

^aOn a scale of 1 (disagree/disagreeable) to 5 (agree/agreeable).

^bThis was an open answer question.

^cOn a scale of 1 to 5, where a higher score indicates less awareness.

^dOn a scale of 1 to 5, where a higher score indicates less skin irritation.

Feasibility of Home Monitoring

Overall data loss of all vital signs at the time of assessment each morning and after the entire measurement period were a mean of 25% (SD 24%) and a mean of 14% (SD 19%), respectively. The amount of data loss varied considerably among patients as can be seen in [Figure 3](#). At the time of patch replacement at

home (by the patient themselves), most patients showed a preceding period with data loss. More than 77% of the gap durations at the time of vital signs assessment were less than 1 hour, with the majority of gaps lasting less than 15 minutes. An overview of frequency and duration of data loss is shown in [Table 3](#).

Figure 3. Percentage of available data (green) and data loss (red) of all patients per hour during each day of home measurements. Each star indicates the first measurement of a new patch.

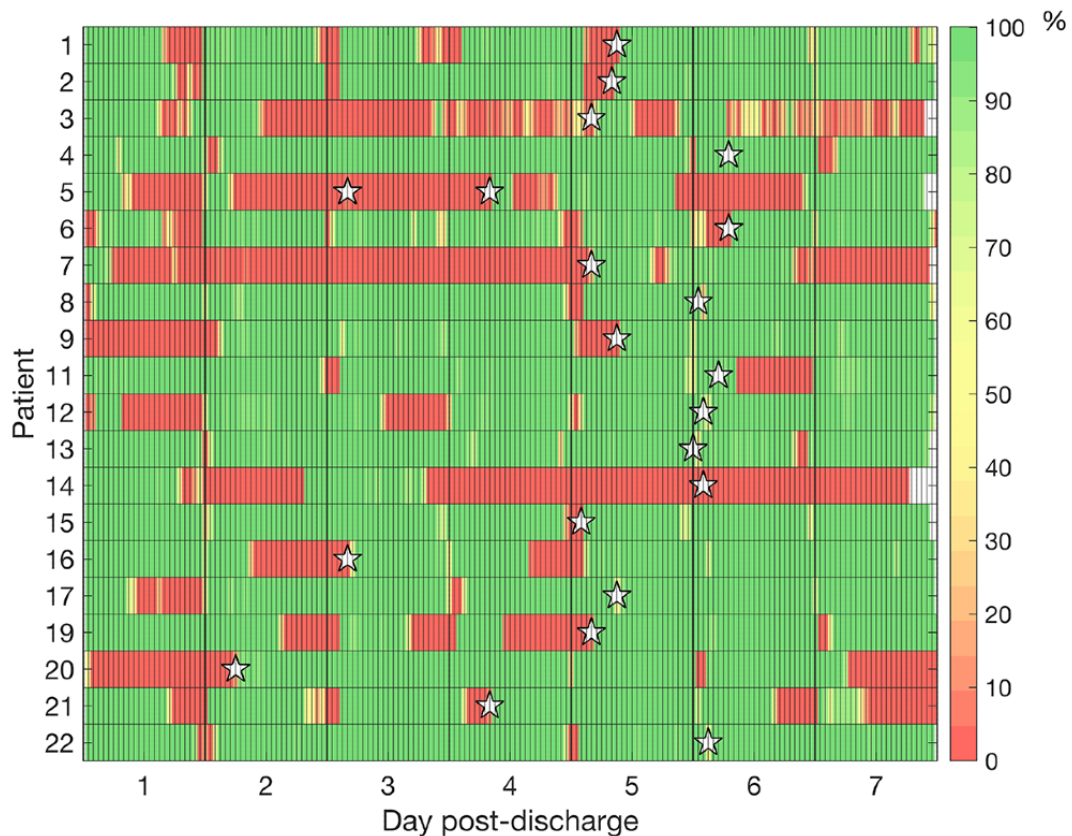


Table 3. Amount of known data loss at the time of daily assessment (around 8:30 AM) and total amount of data loss as recorded at the end of the entire measurement period.

Type of data loss	Within previous 24 hours (observed at the time of assessment)	Within entire measurement period
Overall percentage, mean (SD)	25 (24)	14 (19)
Gaps, n (%)		
<15 minutes	235 (55)	245 (67)
15-60 minutes	93 (22)	66 (18)
1-4 hours	66 (15)	37 (10)
>4 hours	35 (8)	19 (5)

Scoring of Vital Signs Trends in Patients at Home

Table 4 shows an overview of scores provided after each call and vital signs observations. In 4/140 (3%) occasions, the surgeon was slightly worried about the patient’s condition after the phone call, but this did not result in an increased score after checking the vital signs trend overviews. As a result, clinical decision making was not changed based on observing vital signs. During 1 phone call the patient complained about severe dyspnea and coughing, after which a score of 2 (concern) was given and the general practitioner was asked to check on the patient’s

condition and prescribed bronchodilator treatment. However, the vital signs trend overviews were not scored as worrisome (Figure 4 and Figure 5). Although no clear diagnosis could be found at this point in time, this patient continued struggling and was admitted to the hospital with atelectasis 4 weeks later. On 8/140 occasions (6%), a score of 1 (slightly worried) was assigned after checking the vital signs trends, most often related to a high heart rate at rest shortly after hospital discharge. Overviews of vital signs trends were not available on 9/140 (6%) occasions due to data loss.

Table 4. Overview of scores after phone calls and vital signs observations.

Observation	Value, n (%)
Phone calls	137 (98)
Missed calls	3 (2)
Phone calls	
Slightly worried score, 1	4 (3)
Concerned score, 2	1 (1)
Vital signs observations	
Slightly worried score, 1	8 (6)
Concerned score, 2	0 (0)
Unable to judge, X	9 (6)

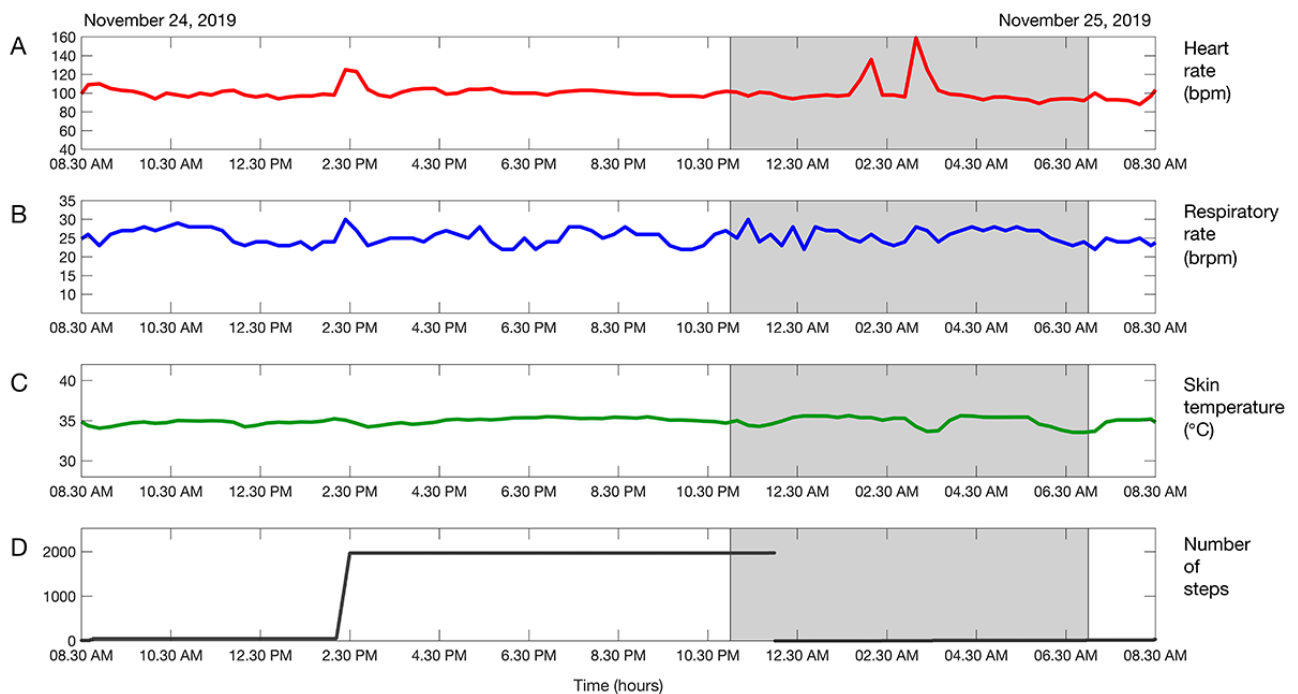
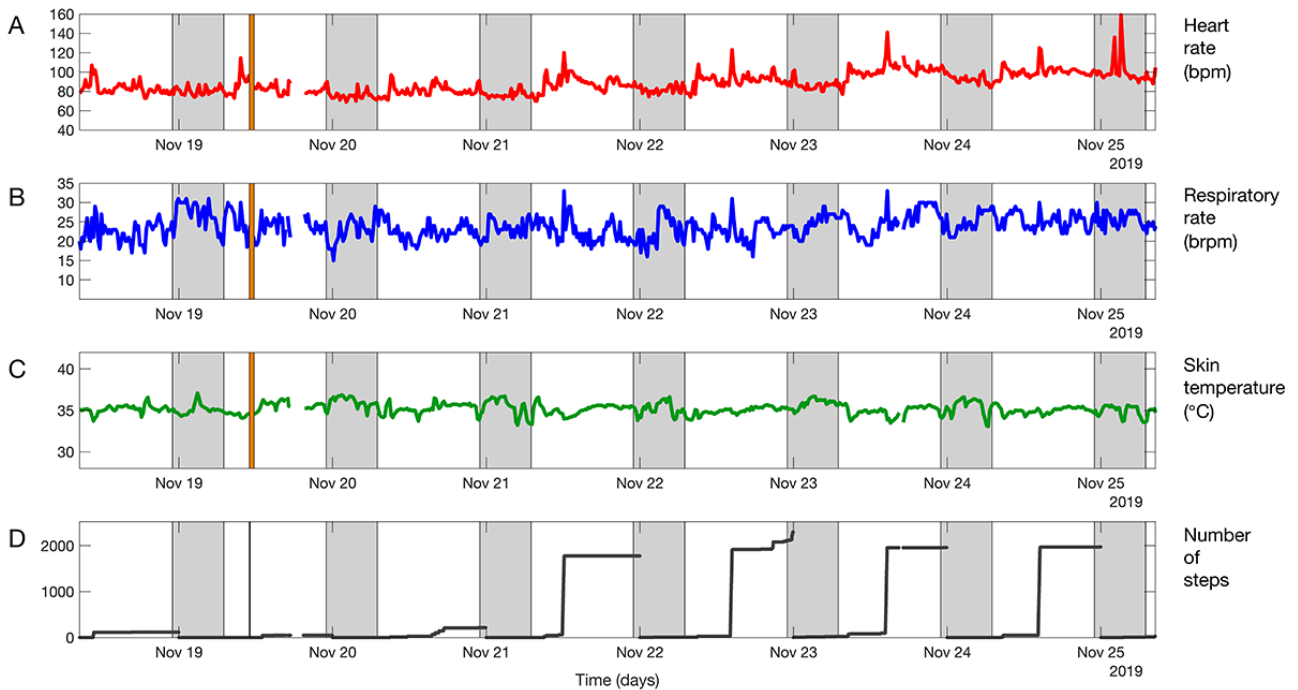
Figure 4. Vital sign trends over 24 hours, showing (A) heart rate, (B) respiratory rate, (C) skin temperature, and (D) cumulative step count of a patient who complained of severe dyspnea and coughing, when called at 8:30 AM (end of graph). Two episodes of increased heart rate can be seen during the night, but no clear vital signs deterioration occurred over the 24-hour period. The shaded area indicates night-time.

Figure 5. Vital sign trends over 7 days, showing (A) heart rate, (B) respiratory rate, (C) skin temperature, and (D) cumulative step count of the patient who complained of severe dyspnea and coughing on November 25. The orange line indicates the time of hospital discharge. Until November 22, heart rate fluctuated around 80 bpm at night and most respiratory rate values remained between 20 and 25 brpm. From November 22 until November 25, heart rate slowly increased from 80 to 100 bpm at night, while respiratory rate slightly increased to 25-30 brpm on November 23. The surgical team member asked the general practitioner to check the patient at home and prescribed bronchodilator treatment. The shaded area indicates night-time.



Observing Vital Sign Trends Over Time

Figure 6 provides an overview of the mean heart rate, respiratory rate, and skin temperature during night-time hours (11 PM to 7 AM) in the 4 days before hospital discharge until the first 7 days at home. Heart rate decreased from 89 bpm in-hospital to 85 bpm at home, whereas no change in respiratory rate was visible between the hospital and home period. Overall, high

variation in heart rate and respiratory rate among patients at night could be seen. Skin temperature was slightly increased in the first days at home. Figure 7 shows a boxplot of the number of steps in the first 7 days after hospital discharge. The mean number of steps increased from 500 to 1300, suggesting that patients’ daily activity increases gradually as recovery progressed at home.

Figure 6. Mean (blue line) and SD (shaded red area) during night-time hours (for a period starting 4 days before hospital discharge until 7 days after discharge) of (A) heart rate, (B) respiratory rate, and (C) skin temperature of all patients.

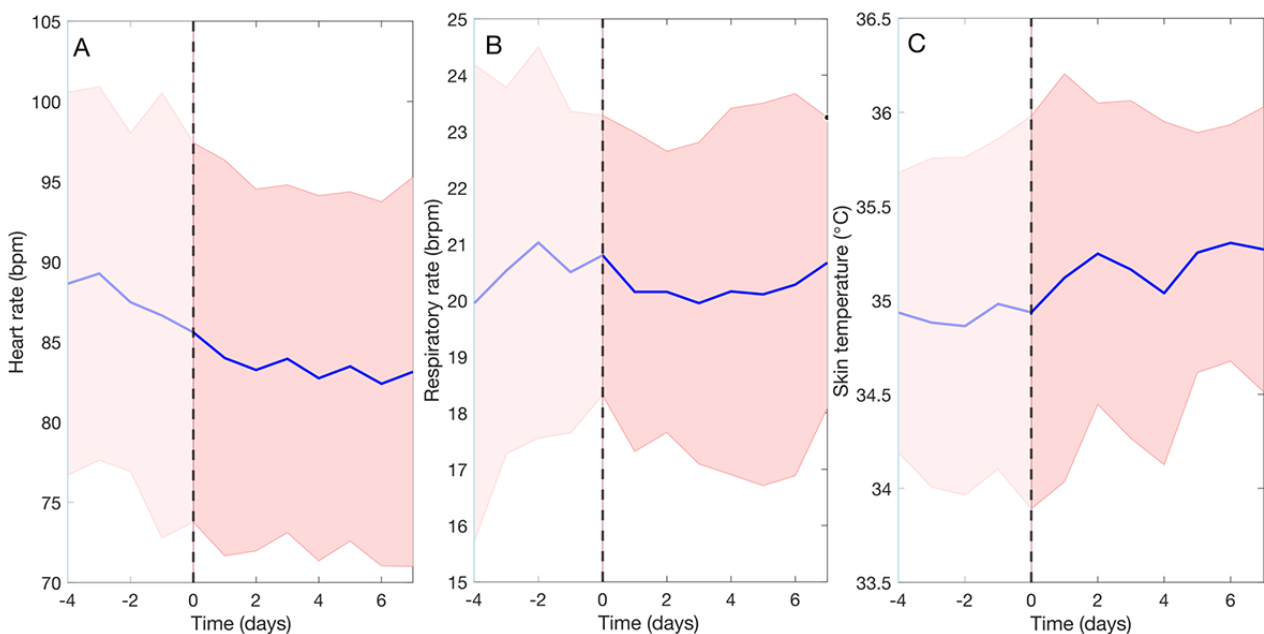
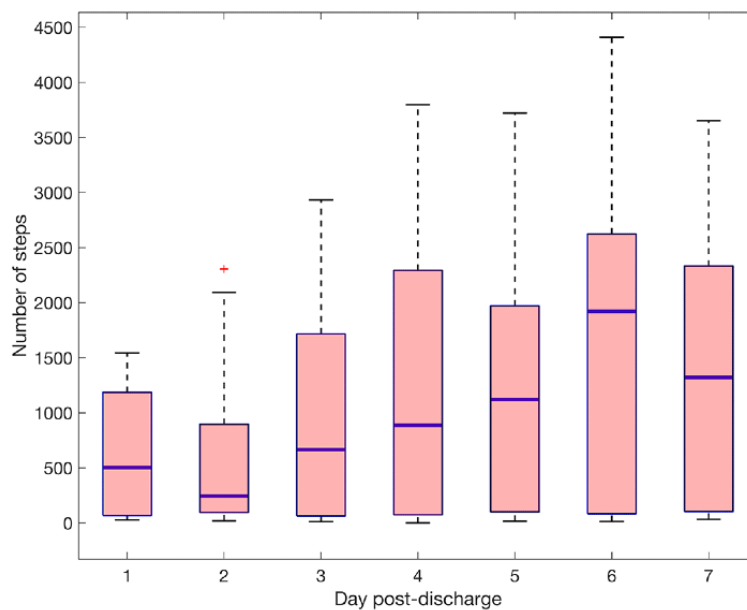


Figure 7. Box plots showing median daily number of steps for the first 7 days after hospital discharge.

Discussion

Principal Findings

We investigated the feasibility of remote vital signs monitoring with a wireless patch sensor in patients after esophagectomy in the first week home after hospital discharge and assessed patient experiences. Each of the 20 patients who were monitored at home had a good recovery, and remotely observed vital signs trends did not directly alter clinical decision making, although it supported clinical judgments regarding the patients' condition derived by the surgical team from the patient's comments during the daily phone calls. In general, remote home monitoring was well perceived by patients and reported satisfaction scores and usability rates were very high. For the sensor used in this study, average data loss of vital signs measurements at home was 25%; both data loss and duration of data gaps varied considerably among patients. In this select group of patients recovering from major surgery, we observed a decrease in heart rate and an increase in number of steps during the first 7 days at home.

Strengths and Limitations

When interpreting the findings of this study, some limitations should be taken into account. Based on previous studies, we had anticipated a 10% readmission rate in patients after esophagectomy [9,17]. However, we observed only 1 event after discharge at home, and none of the 20 study participants were readmitted to the hospital. Only much larger studies can demonstrate how vital signs trend patterns vary among patients with and without clinical deterioration after hospital discharge. As a result, we were unable to determine whether observing vital signs trends remotely changed clinical decision making. However, we cannot entirely eliminate the possibility that patients who decided to participate in this study had a better baseline prognosis or that a Hawthorne effect—the awareness of being observed remotely and daily phone contact with the

surgical team—had positively influenced study outcomes [18,19].

A second limitation was our inability to discern the causes of the positive patient experiences. Both the fact that the patient's vital signs were remotely checked and their daily telephone contact with a surgical team member might have contributed. In any case, patients highly appreciated being remotely monitored at home and having daily contact with the team, and as a result, they felt more reassured. Studies have shown that structured telephone calls following discharge can reduce readmission rates in elderly patients [20]. Although these findings cannot be translated to the our study, it seems likely that the ability to communicate with a patient to verify the presence of any deteriorating symptoms, together with abnormal vital signs, may improve recognition of patient deterioration in the home setting.

A score of 1 (slightly worried) was assigned in 6% of the vital signs trend reviews (8/140), most often related to a higher heart rate, especially shortly after hospital discharge or due to high respiratory rates. Elevated heart rates—possibly related to the process of recovery and postoperative fatigue—have been noticed in an earlier study after major surgery [21]. We observed that average heart rate slightly decreased in the days following discharge home. In contrast, average respiratory rate remained high in these patients monitored at home. One possible explanation could be technical in nature since the measurement approach in this particular sensor tends to overestimate respiratory rate. In a previous study [14,15], we validated a precursor of the VitalPatch sensor in surgical patients and observed considerable overestimation of respiratory rate. Carefully performed validation studies in clinical practice are therefore of crucial importance for a sustainable long-term implementation of remote wireless monitoring [22].

Nobody knows how often one should measure a full set of vital signs in patients discharged after major surgery. The VitalPatch

sensor used in this study measures each of the vital signs in a nearly continuous (every 4 seconds) fashion. This seems redundant for measuring patients in a home setting who are no longer at high risk for deterioration and may increase the rate of false alarms. In addition, transmitting these continuous data streams consumes valuable energy and may easily contribute to data loss. In this study, 35/429 (8%) of the data gaps were longer than 4 hours which may result in difficulties interpreting vital signs trends appropriately. Reasons for data gaps may be the fact that the VitalPatch relies on Bluetooth technology and a smartphone acting as a gateway between the patch and remote medical server. Patients did not always remember to keep the phone in close proximity, for example during the night-time. Furthermore, they may have forgotten to keep the phone charged all the time, which may not always have been reported to us. Other reasons might be the inability to automatically restore connection with the cloud server after Bluetooth disconnection occurred or to transfer piled amounts of data after repetitive periods of connection loss. The high number of long duration data gaps is possibly related to the data transmission protocol of the mobile app used in this study. Data could be stored for 18 hours on the patch sensor if Bluetooth connection was transiently lost, but it took an additional 50% of time on top of the upload time of the live data to transfer this offline data to the cloud platform. Although this data transmission protocol could be improved, it is unknown to what extent the duration of such data gaps results in the inability to capture clinical deterioration on time in the home setting. However, it seems likely that a reduced monitoring frequency might be a necessary trade-off to minimize the number of alerts due to missing data. As soon as an alert is generated, a dedicated 24/7 medical call center could initiate video communication, for example, to verify the presence of any signs that might give reason for rapid medical attention and exclude trivial causes for the alert such as exercise. These approaches are especially relevant since the majority of patients at home will not deteriorate but may develop unimportant vital signs abnormalities which should not trigger intervention.

Comparison With Prior Work

Studies that evaluate the feasibility and patient experiences of remote home monitoring are limited. A recent study of Tonino et al [23] demonstrated high wearability and good usability of the VitalPatch sensor worn by a small number of patients in the outpatient setting receiving blood cell transfusions or immunotherapy. The results of our study confirm these findings. Another study [24] reported high wearing comfort of the HealthPatch sensor in senior participants after long-term monitoring of 50 days in their home setting. Although the study [24] hints at the convenience of wireless monitoring of patients in the home care setting, the results were obtained in healthy volunteers and may therefore differ when used in patients discharged home.

Despite the fact that hospital-to-home initiatives are still in its infancy, the increasing pressure from payers force hospitals to develop less expensive alternatives to hospital care. A recent randomized controlled trial [25] compared direct costs of acute care in patients admitted to an emergency department, who were randomized to either usual hospital care or hospital-at-home care while vital signs were continuously monitored via the HealthPatch sensor. Although the sample, with 20 patients, was small in size and recruited within a highly selected patient group, the authors found that patients who received hospital-at-home care were readmitted less frequently within 30 days (7% vs 23%), and their health care costs were 38% lower on average. Nonetheless, large well-controlled studies in patients at risk for deterioration are needed to evaluate the impact of remote monitoring on patient outcomes.

Conclusions

A daily 24-hour vital signs trend evaluation combined with a phone call from the surgical team were feasible and highly appreciated by all patients. The minimal requirements regarding optimal measurement frequency and data continuity for adequate home monitoring need to be further investigated. Remote patient monitoring at home is feasible. Future studies need to evaluate the impact of home monitoring on patient outcome as well as the cost-effectiveness of this approach.

Conflicts of Interest

At the time of the study, MB was a part-time employee of Luscii Healthtech BV. DAJD is founder and chief executive officer of Luscii Healthtech BV.

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Original Paper

A Smartphone App With a Digital Care Pathway for Patients Undergoing Spine Surgery: Development and Feasibility Study

Madison Ponder^{1*}, BSPH, MPS; Abena A. Ansah-Yeboah^{1*}, BSc; Lefko T. Charalambous², BSc; Syed M. Adil², BSc; Vishal Venkatraman², BSc; Muhammad Abd-El-Barr², MD, PhD; Michael Haglund², MD, PhD; Peter Grossi², MD; Chester Yarbrough², MD, MPHS; Rajeev Dharmapurikar¹, MSc; Ziad Gellad¹, MD, MPH; Shivanand P. Lad², MD, PhD

¹Higgs Boson Health, Durham, NC, United States

²Department of Neurosurgery, Duke University Medical Center, Durham, NC, United States

*these authors contributed equally

Corresponding Author:

Lefko T. Charalambous, BSc

Department of Neurosurgery

Duke University Medical Center

30 Duke Medicine Circle

Durham, NC, 27710

United States

Phone: 1 919 613 0444

Email: lefko.charalambous@duke.edu

Abstract

Background: There is a great unmet clinical need to provide patients undergoing spinal surgery and their caregivers with ongoing, high-quality care before and after surgery in an efficiency-focused health care environment.

Objective: The objective of this study is to design, develop, and evaluate the acceptability and feasibility of a novel planning-, outcomes-, and analytics-based smartphone app called ManageMySurgery (MMS) in patients undergoing elective spine surgery (MMS-Spine).

Methods: The development process of the MMS app was conducted over 2 sequential stages: (1) an evidence-based intervention design with refinement from surgeon and patient feedback and (2) feasibility testing in a clinical pilot study. We developed a novel, mobile-based, Health Insurance Portability and Accountability Act-compliant platform for interventional and surgical procedures. It is a patient-centric mobile health app that streamlines patients' interactions with their care team. MMS divides the patient journey into phases, making it feasible to provide customized care pathways that meet patients' unique needs. Patient-reported outcomes are easily collected and conform to the National Institutes of Health Patient-Reported Outcomes Measurement Information System (PROMIS) standard.

Results: We tested the feasibility of the MMS-Spine app with patients undergoing elective spine surgery at a large academic health system. A total of 47 patients undergoing elective spine surgery (26 cervical spine and 21 lumbar spine surgeries) downloaded and used MMS-Spine to navigate their surgical journey, quantify their baseline characteristics and postoperative outcomes, and provide feedback on the utility of the app in preparing for and recovering from their spinal surgery. The median age was 59.0 (range 33-77) years, 22 of the 47 patients (47%) were women, and 26 patients (55%) had commercial insurance. Of the 47 patients, a total of 33 (70%) logged in on an iOS device, 11 (23%) on an Android device, and 3 (6%) on a computer or tablet. A total of 17 of the 47 patients (36%) added a caregiver, of which 7 (41%) logged in. The median number of sign-ins was 2. A total of 38 of 47 patients (81%) completed their baseline preoperative PROMIS-29 outcomes, and 14 patients (30%) completed at least one PROMIS-29 survey during the postoperative period. Of the 24 patients who completed the MMS survey, 21 (88%) said it was helpful during preparation for their procedure, 16 (67%) said it was helpful during the postoperative period, and 23 (96%) said that they would recommend MMS to a friend or family member.

Conclusions: We used a patient-centered approach based on proven behavior change techniques to develop a comprehensive smartphone app for patients undergoing elective spine surgery. The optimized version of the app is ready for formal testing in a larger randomized clinical study to establish its cost-effectiveness and effect on patients' self-management skills and long-term outcomes.

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KEYWORDS

development; digital interventions; digital health; smartphone app; surgery; behavior change; mobile app; technology; mobile phone; mHealth

Introduction

Disorders of the spine are among the most prevalent medical conditions worldwide. In the United States, over US \$85 billion is spent annually on spine-related problems, which are the second leading cause of hospital-related visits after the common cold [1]. When conservative options have been exhausted, many patients undergo spine surgery to relieve their pain. Recently, increasing efficiency and cost pressures have significantly impacted postoperative care. Patients are being discharged earlier, and symptoms that would have previously prompted a longer postoperative stay are now being managed remotely. Moreover, without easy access to reliable remote medical information and risk assessment, patients may delay seeking care, experience unnecessary anxiety, or seek unnecessary care. Given the ubiquity of smartphone use, mobile apps are actively being implemented as platforms to connect care providers with patients and provide information and communication outside of a traditional medical office visit.

A number of studies have demonstrated that digital health solutions and patient-reported outcomes (PROs) improve the results of chronic medical conditions [2]. Some mobile apps have been developed to use as perioperative care tools to communicate presurgical and postsurgical instructions and

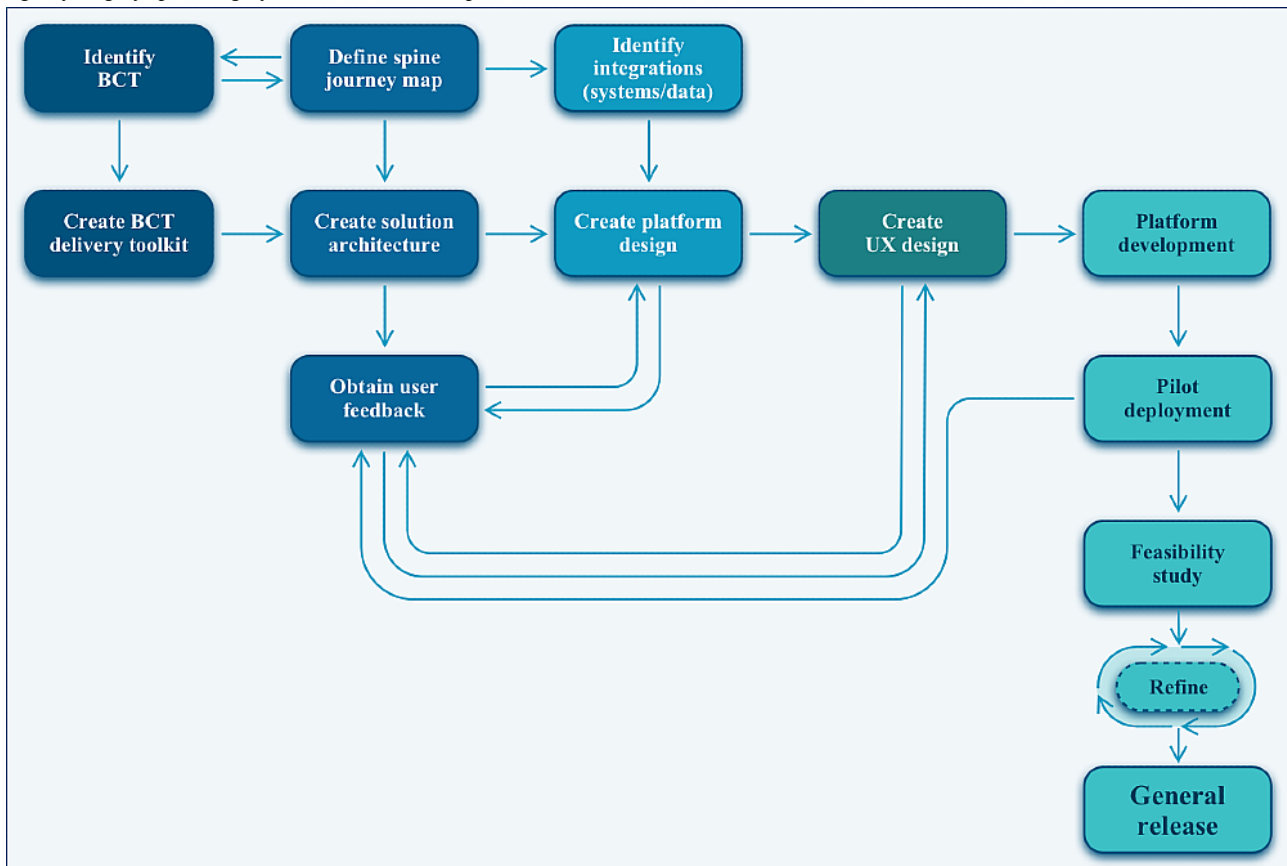
concerns. Feasibility studies for apps for abdominal and orthopedic surgeries have shown that they are convenient for patients to use and can reduce the need for follow-up visits [3-5]. However, there are currently no validated solutions aimed at acute spinal surgical time points, which are among the most stressful health care experiences in the lives of patients and their caregivers. There is a great unmet clinical need to provide patients undergoing surgery and their caregivers with ongoing high-quality care before and after surgery in an increasingly efficiency-focused health care environment. To address this need, we created a novel planning-, outcomes-, and analytics-based platform called ManageMySurgery (MMS), which includes a specific module for spine surgery (MMS-Spine), and conducted feasibility testing in patients undergoing elective spine surgery.

Methods

MMS Development

We developed the MMS app in 2 stages: (1) an evidence-based intervention design with refinement by health care providers using the MMS app (Figure 1) and (2) feasibility testing in a clinical pilot study. This section presents the procedures and key findings used to inform the next stage of the iterative development process.

Figure 1. Development overview process of the creation and implementation of the MMS-Spine app. BCT: behavior change technique; MMS-Spine: ManageMySurgery spine surgery module; UX: user experience.



Stage 1: Consultation With Experts, Intervention Design, and Outcomes

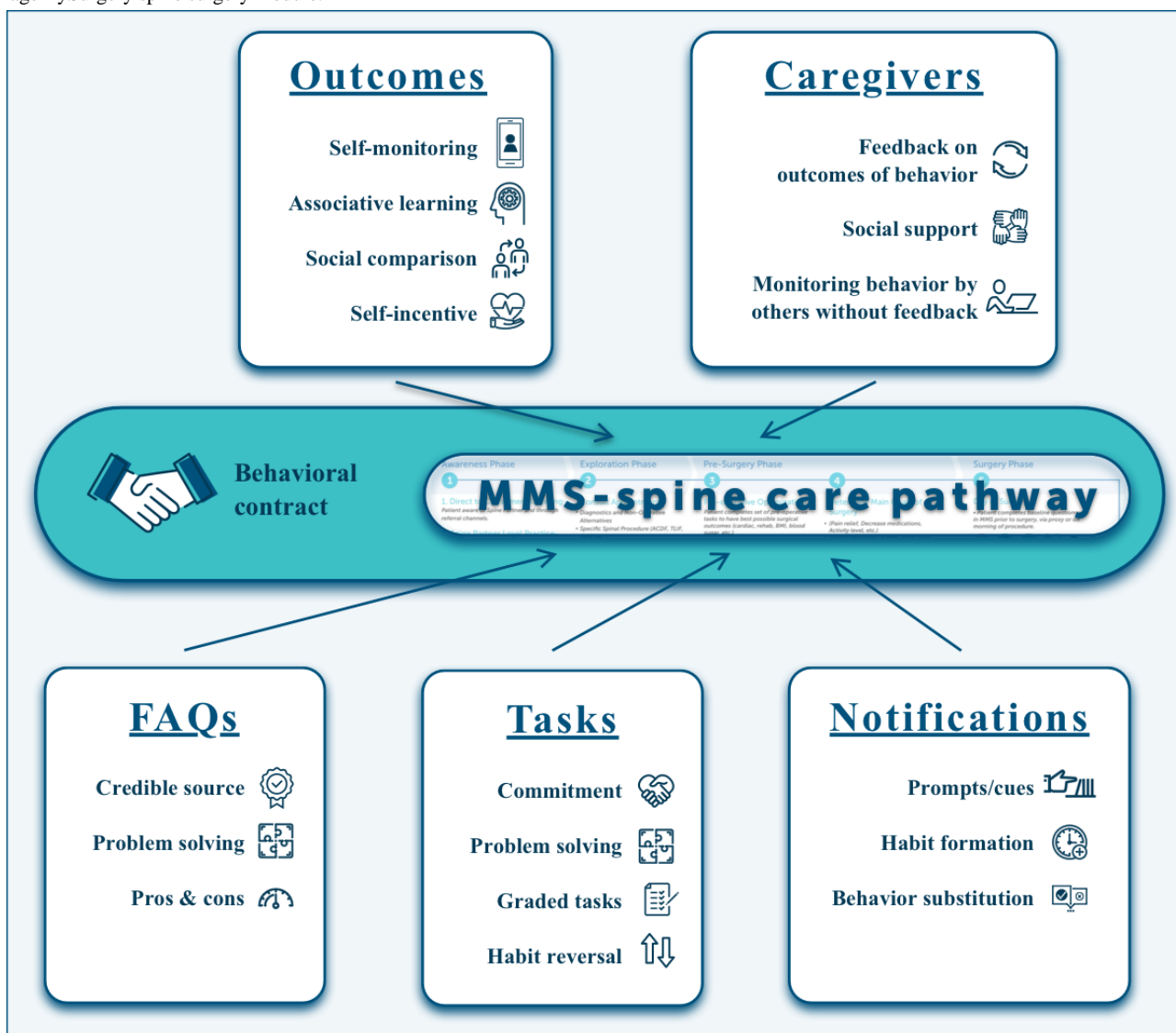
App Overview

MMS is a cloud-based, Health Insurance Portability and Accountability Act–compliant solution that provides a platform that acts as an extension of the clinical care team for patients undergoing surgical procedures and their caregivers. The goal of MMS is to provide a solution that provides patients and their families the best possible surgical experience while tracking quantifiable outcomes from surgery. MMS does this by providing a way for patients and their caregivers to prepare for procedures and make shared decisions, leading to lower overall

anxiety, increased satisfaction, and increased retention of patients in their digital care pathway. In short, better patient engagement and better workflows can lead to overall better outcomes at a lower cost. The app was designed to function on mobile operating systems, including Android (Google Inc) and iOS (Apple Inc), and as a web application to allow for the widest possible use.

Behavior change techniques (BCTs) are designed to enable behavior change by augmenting factors that facilitate behavior change or by mitigating factors that inhibit behavior change [6]. MMS was designed to administer BCTs that fit within the clinical workflow (journey map, frequently asked questions, tasks, notifications, and outcomes; see Figure 2) [6,7].

Figure 2. MMS-Spine features incorporating behavior change technique methods applicable to clinical care. FAQ: frequently asked question; MMS-Spine: ManageMySurgery spine surgery module.



The design of MMS-Spine was informed by an interdisciplinary group of experts in surgery, behavior change, psychometrics, and computer science. Sources for app content included evidence-based guidelines from national societies that specialize in spine care and surgery (North American Spine Society, American Association of Neurological Surgeons, and the American Association of Orthopedic Surgeons). Importantly, the wording of questions, responses, and other content in the app was developed through an iterative design process with a scientific writing team so that all information was presented at a sixth-grade reading level at maximum. Literacy evaluation was performed by the Duke Patient Education Governance Council. The goals of this process were to make the app accessible and patient centered while also improving communication and patient knowledge. This design process was also iterative, involving collaborative decision-making between the clinical and app development teams. Any discrepancies between the different sources of data from evidence-based guidelines were solved in a collaborative manner and with team consensus.

Patient-Reported Outcomes

Approximately 2 to 4 weeks prior to elective spine surgery, patients were invited to download the app, receive structured preoperative information, and complete baseline surveys. Perioperative information was delivered based on the timing relative to the day of surgery. Postoperative surveys were automatically available to patients after discharge, and reminders were given via automated notifications on their smartphones. All items were closed questions with predefined answers. Patients received surveys that were selected or created by the spine surgeons at Duke Spine Center. These surveys were specifically designed to capture baseline and postoperative PROs via the platform. Standardized surveys that were used included the 29-item Patient-Reported Outcomes Measurement Information System (PROMIS-29), Oswestry Disability Index, and Neck Disability Index. These are the most common outcomes collected in spine surgery, and each is well validated in multiple clinical studies in quantifying the impact of spine surgery. In addition, 4 surveys—the numerical pain assessment, the lumbar fusion approach assessment, the percent pain reduction lumbar survey, and the percent pain reduction anterior

cervical discectomy and fusion (ACDF) survey—were created and used by the surgical team and are defined in [Multimedia Appendix 1](#).

Stage 2: Evaluation of the MMS-Spine Module Feasibility Study

Participants and Setting

Institutional review board approval was obtained prior to beginning the study. We performed a descriptive feasibility study in which patients were prospectively invited and enrolled to participate if they were scheduled to undergo elective spine surgery at Duke University Health System. Consent was performed electronically and obtained at the time of enrollment. A total of 47 continuous patients were included in this feasibility study. Inclusion criteria were English as the primary language, availability of a smartphone, and capacity to consent. Procedures supported by the MMS-Spine module included the most common spine surgeries, such as lumbar laminectomy and discectomy, lumbar fusion, and ACDF. Patients who did not have a phone or could not use one could assign a family member as a caregiver to operate the app on their behalf. After identification of patients via weekly operating room schedule reviews, patients were invited to download MMS via email. For this study, patients were considered engaged with and benefiting from MMS if they had downloaded and logged in to the app. Informed consent was obtained, and each patient went through a brief, standardized walk-through orientation within the app.

Data Collection and Analysis

Two members of the research team independently reviewed the results of the outcomes data, patient responses, and associated electronic health record data. Descriptive statistics for the surveys were calculated using Google Sheets (Google Corp) and SAS 9.4 (SAS Institute Inc). Continuous variables were reported as means, standard deviations, medians, first quartiles, third quartiles, minimum values, and maximum values. Categorical variables were reported as numbers and percentages.

Data gathered throughout the entirety of the patient's engagement with MMS from this cohort were collected and stored securely via Amazon Web Services. Measures that were continually collected included the number of account sign-ins, task completion, the addition of a caregiver or caregivers, the device used to access MMS, and the frequently asked questions (FAQs) viewed. Additional data gathered at specific time points

included PROs, collected through surveys and patient feedback regarding their experience with MMS. The PROs were requested prior to the surgery, once the patient's procedure was added to MMS, and at various time points that were set based on when the procedure was completed. These postoperative time points included 6 weeks, 3 months, 6 months, and 12 months. Patient feedback was collected 30 days postoperatively. MMS also automatically sends push notifications to patients for tasks at various time points to gather data (eg, appointment confirmation, completion of preoperative screening, etc). This is designed to reduce the burden on the clinical staff and allow for more consistent and predictable follow-up. Descriptive statistics for the self-administered survey completion were also collected.

Results

Stage 1: Consultation With Experts and Intervention Design

Key features and design elements were used to develop a clinically seamless workflow in MMS-Spine ([Figure 3](#)). The app was designed to serve as a virtual patient navigator through the various phases of the surgical journey, from awareness to exploration, presurgery, surgery, and ultimately, recovery. Patients can self-report their outcomes and access FAQs, receive notifications, and connect to a variety of multimedia resources to educate them about their procedure and ways in which they can prepare for and recover from their surgery in order to optimize outcomes ([Figure 4](#)).

One of the key challenges was the need to adapt technical medical language when communicating within a multidisciplinary team. The scientific writing team was critical to ensuring all content conveyed complex medical knowledge at an appropriate reading comprehension level. After continuous refinement, we arrived at a viable app that guides the patient throughout the preoperative, perioperative, and postoperative periods and serves to ease the anxiety commonly encountered during surgical procedures. Additionally, by leveraging analysis of task completion and PRO results, the app can assist in identifying patients who may need attention sooner or those who do not need to be seen at all. For example, if a patient has not completed any of their preoperative tasks, they are less likely to be engaged in their upcoming procedure and potentially more likely to have a poor outcome or a complication.

Figure 3. Step-by-step road map of the MMS-Spine patient care pathway. ACDF: anterior cervical discectomy and fusion; MMS: ManageMySurgery; OLIF: oblique lateral interbody fusion; rehab: rehabilitation; TLIF: transforaminal lumbar interbody fusion.



Figure 4. Functionality of the MMS-Spine app. FAQs: frequently asked questions; PROs: patient-reported outcomes.



Stage 2: Evaluation of the MMS-Spine Module Feasibility Study

Patient Characteristics

A total of 47 patients e-consented and participated in the feasibility study. Patients from 5 spine surgeons contributed to the study. Of the 47 patients, 21 (45%) underwent lumbar fusion and 26 (55%) underwent ACDF. The median age was 59.0 (range 33-77) years, and 22 of the 47 patients (47%) were women, 26 (55%) had commercial insurance, and 40 (85%) had

surgery on 1 to 3 spinal levels (Table 1). A total of 17 of the 47 patients (36%) added a caregiver (friend or family member), of which 7 (41%) logged in (Table 2). Compared with the patients who underwent lumbar fusion, patients who underwent ACDF were younger (56.4 years vs 62.3 years), more frequently female (13/26, 50% vs 9/21, 43%), used more commercial insurance (17/26, 65% vs 9/21, 43%), used fewer iOS phones (17/26, 65% vs 16/21, 76%), added more caregivers (17/26, 65% vs 13/21, 62%), and had fewer patients who did not view any FAQs (10/26, 38% vs 14/21, 67%) (Table 1 and Table 2).

Table 1. Patient characteristics by procedure type (N=47).

Patient characteristics	ACDF ^a (n=26)	Lumbar fusion (n=21)	Total (N=47)
Age at surgery (years)			
Age (years), mean (SD)	56.4 (9.3)	62.3 (12.2)	59.0 (11.0)
Age (years), median (IQR)	58.5 (50.3-62.0)	63.0 (56.0-72.0)	59.0 (52.5-67.0)
Age (years), range	37.0-73.0	33.0-77.0	33.0-77.0
Gender, n (%)			
Female	13 (50)	9 (43)	22 (47)
Male	13 (50)	12 (57)	25 (53)
Payor group, n (%)			
Commercial	17 (65)	9 (43)	26 (55)
Medicare	6 (23)	11 (52)	17 (36)
Other	3 (12)	1 (5)	4 (9)
Procedure, n (%)			
ACDF	25 (96)	1 (5)	26 (55)
ALIF ^b	0	1 (5)	1 (2)
Lumbar laminectomy	0	3 (14)	3 (6)
Posterior cervical fusion	1 (4)	1 (5)	2 (4)
SI ^c fusion	0	1 (5)	1 (2)
TLIF ^d or PLIF ^e	0	13 (62)	13 (28)
XLIF ^f	0	1 (5)	1 (2)
Surgery levels, n (%)			
1	6 (23)	8 (38)	14 (30)
2	10 (38)	6 (29)	16 (34)
3	6 (23)	4 (19)	10 (21)
4	2 (8)	1 (5)	3 (6)
5	0	1 (5)	1 (2)
8	1 (4)	0	1 (2)
Missing	1 (4)	1 (5)	2 (4)

^aACDF: anterior cervical discectomy and fusion.

^bALIF: anterior lumbar interbody fusion.

^cSI: sacroiliac.

^dTLIF: transforaminal lumbar interbody fusion.

^ePLIF: posterior lumbar interbody fusion.

^fXLIF: extreme lateral interbody fusion.

Table 2. Patient usage results by procedure type (N=47).

Usage	ACDF ^a (n=26)	Lumbar fusion (n=21)	Total (N=47)
Patient sign-in count, n (%)			
1-4	23 (88)	16 (76)	39 (83)
5-9	2 (8)	3 (14)	5 (11)
10+	1 (4)	2 (10)	3 (6)
Patient sign-in count, mean (SD)	3.0 (4.7)	3.5 (2.8)	3.2 (3.9)
Patient sign-in count, median (IQR)	2 (1-3)	2 (2-4)	2 (1-4)
Caregiver added, n (%)			
No	17 (65)	13 (62)	30 (64)
Yes	9 (35)	8 (38)	17 (36)
Added caregivers that logged in, n (%)	3 (33)	4 (50)	7 (41)
Device, n (%)			
iOS	17 (65)	16 (76)	33 (70)
Android	9 (35)	2 (10)	11 (23)
Web or notifications off	0	3 (14)	3 (6)
Viewed questions, n (%)			
0	10 (38)	14 (67)	24 (51)
1-10	3 (12)	2 (10)	5 (11)
11-20	5 (19)	0	5 (11)
21-30	4 (15)	4 (19)	8 (17)
31-40	1 (4)	1 (5)	2 (4)
51-60	2 (8)	0	2 (4)
81-90	1 (4)	0	1 (2)
Viewed questions, mean (SD)	16.0 (20.8)	7.4 (12.5)	12.2 (17.9)
Viewed questions, median (IQR)	12.5 (0.0-22.5)	0.0 (0.0-9.0)	0.0 (0.0-21.5)
Viewed questions, range	0.0-85.0	0.0-36.0	0.0-85.0

^aACDF: anterior cervical discectomy and fusion.

App Use

During the feasibility study, 100% (47/47) of patients interacted with the app by downloading and logging in, meeting our definition of feasibility (Table 2). Screenshots of the patient- and provider-facing interface of the MMS-Spine app are shown in Figure 5. A total of 33 of the 47 patients (70%) used an iOS phone or tablet device to access the app, 11 (23%) used an Android device, and 3 (6%) used a web browser or phone with notifications turned off (Table 2).

The median number of log-ins into the app was 2, with 83% (39/47) of patients signing in 1 to 4 times (a log-in was defined as any time the patient input their username and password to access their account) (Table 2). Among the 47 patients, the top

3 most-viewed FAQs were (1) How soon can I start driving again after the procedure? (20/47, 43%); (2) What serious symptoms should I watch for during my recovery? (16/47, 34%); and (3) How will I feel after the surgery? (16/47, 34%) (Table 3).

Of the 47 patients, 24 (51%) provided feedback on the MMS-Spine app. Among these 24 patients, 12 (50%) found the app very helpful and 9 (38%) found the app somewhat helpful in preparing for their surgery. In addition, 8 of the 24 respondents (33%) found it very helpful and 8 (33%) found it somewhat helpful in recovering from their surgery. A total of 23 of the 24 respondents (96%) stated that they would recommend MMS to a friend or family member (Table 4).

Figure 5. Screenshot of the MMS-Spine patient (mobile app) and provider (desktop, laptop, or tablet) interfaces.

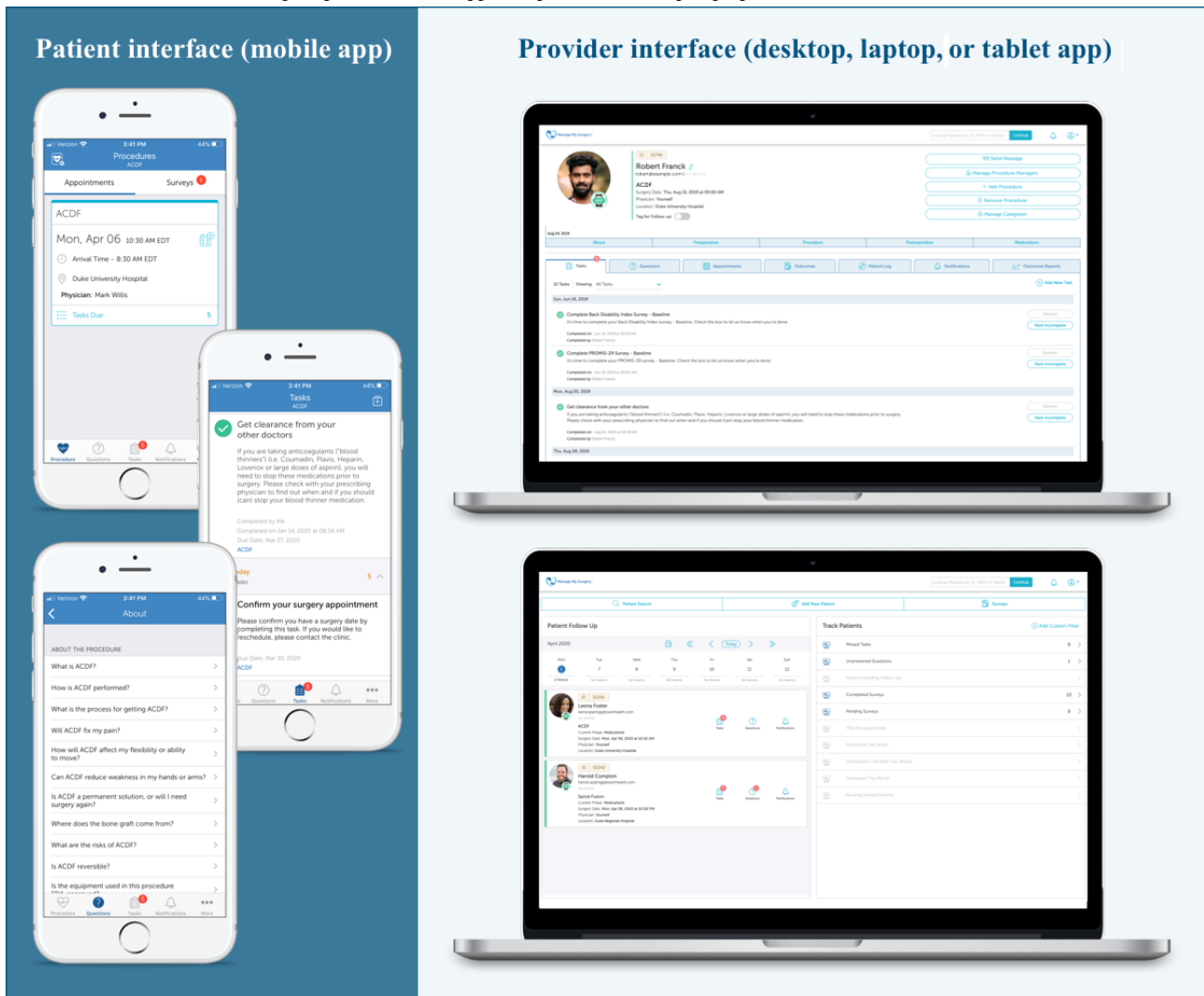


Table 3. Most viewed frequently asked questions by procedure type (N=47).

Procedure type and question	Views, n (%)
ACDF^a (n=26)	
What are the risks of ACDF?	13 (50)
What is ACDF?	8 (31)
Lumbar fusion (n=21)	
How will a spinal fusion affect my flexibility or ability to move?	5 (24)
What are the risks of spinal fusion?	4 (19)
What is the process for getting a spinal fusion?	4 (19)
Both ACDF and lumbar fusion (N=47)	
How soon can I start driving again after the procedure?	20 (43)
What serious symptoms should I watch for during my recovery?	16 (34)
How will I feel after the surgery?	16 (34)
How long will I be in the hospital?	13 (28)
Are there restrictions on eating or drinking after the procedure?	13 (28)
How long will I be in the hospital?	13 (28)

^aACDF: anterior cervical discectomy and fusion.

Table 4. MMS patient feedback survey results (N=47).

Feedback	ACDF ^a (n=26)	Lumbar fusion (n=21)	Total (n=47)
Survey completion, n (%) ^b	14 (54)	10 (48)	24 (51)
MMS^c helpfulness in procedure preparation, n (%)^{d,e}			
1	6 (43)	6 (60)	12 (50)
2	7 (50)	2 (20)	9 (38)
3	1 (7)	2 (20)	3 (13)
4	0 (0)	0 (0)	0 (0)
5	0 (0)	0 (0)	0 (0)
MMS helpfulness in procedure recovery, n (%)^{d,e}			
1	5 (36)	3 (30)	8 (33)
2	5 (36)	3 (30)	8 (33)
3	4 (29)	3 (30)	7 (29)
4	0 (0)	1 (10)	1 (4)
5	0 (0)	0 (0)	0 (0)
MMS recommendation to a family or friend, n (%)^{d,e}			
Yes	13 (93)	10 (100)	23 (96)
No	1 (7)	0 (0)	1 (4)

^aACDF: anterior cervical discectomy and fusion.

^bSignifies the number of surveys completed out of the entire cohort of 47 patients.

^cMMS: ManageMySurgery.

^dSignifies the number of specified responses out of the total number of 24 surveys completed.

^eKey: 1=very helpful, 2=somewhat helpful, 3=neither helpful nor unhelpful, 4=somewhat unhelpful, 5=very unhelpful.

A total of 38 of 47 patients (81%) completed their baseline preoperative PROMIS-29 outcomes. At 6 weeks, 3 months, 6 months, and 12 months postoperatively, the number of patients who completed PROMIS-29 surveys out of the 47 total patients was 13 (28%), 8 (17%), 6 (13%), and 1 (2%), respectively. A total of 14 of 47 patients (30%) completed at least 1 PROMIS-29 survey during the postoperative period, with the highest response rate at 6 weeks (13/47, 28%) (Table 5). The MMS-Spine app has the capability of converting PROMIS-29 T-score data into graphs (Figure 6) or visualizations to clearly compare a patient's

baseline and postoperative outcome measures at specified time points. Figure 6 gives one example of this by comparing T-scores at baseline and 6 months post procedure for 16 cohort members in the PROMIS-29 domain of social roles and activities and the domain of physical function, showing an average score increase from 41.3 (mild) to 48.9 (normal) and 37.0 (moderate) to 44.1 (normal), respectively. For a full list of T-scores collected from baseline through 12 months post operation across all PROMIS domains, see Multimedia Appendix 2.

Figure 6. PROMIS-29 outcome measures for social roles and activities and for physical function compared at baseline and 6-month time points for 16 members of the cohort. PROMIS: Patient-Reported Outcomes Measurement Information System.

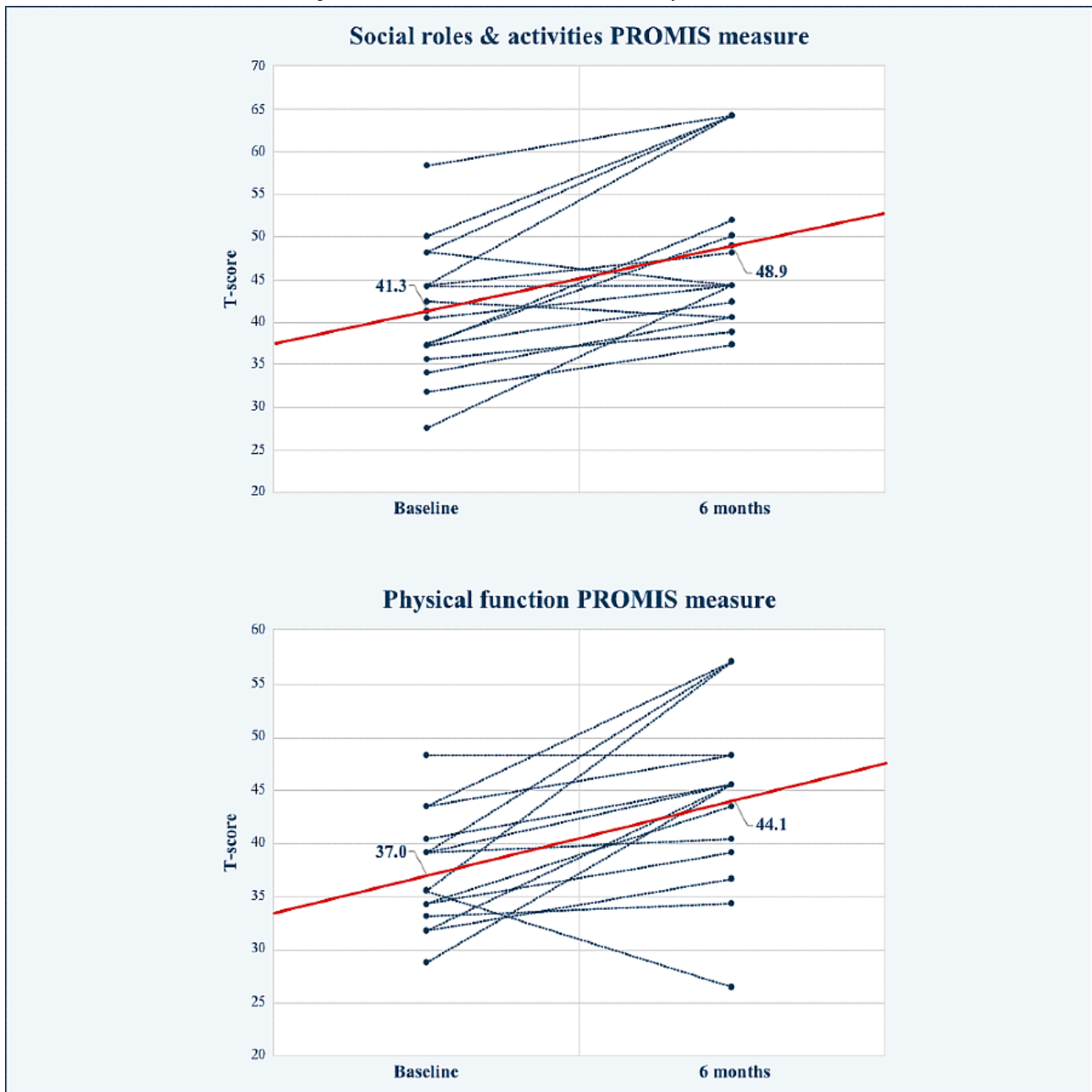


Table 5. Completion rate of self-administered Back Disability Index, Neck Disability Index, percent pain reduction, and PROMIS-29 surveys.

Procedure and survey	Baseline	Postoperative time point				
		6 weeks	3 months	6 months	12 months	At least one completed
ACDF^a, n (%) (n=26)						
Neck Disability Index	22 (85)	5 (19)	3 (12)	3 (12)	0 (0)	6 (23)
Percent pain reduction	N/A ^b	5 (19)	4 (15)	3 (12)	0 (0)	7 (27)
Lumbar fusion, n (%) (n=21)						
Back Disability Index	15 (71)	6 (29)	3 (14)	3 (14)	1 (5)	6 (29)
Numerical pain assessment survey	16 (76)	6 (29)	3 (14)	3 (14)	1 (5)	7 (33)
Lumbar fusion approach assessment	N/A	7 (33)	2 (10)	3 (14)	1 (5)	7 (33)
Percent pain reduction	N/A	5 (24)	4 (19)	5 (24)	1 (5)	6 (29)
Both ACDF and lumbar fusion, n (%) (N=47)						
PROMIS-29 ^c	38 (81)	13 (28)	8 (17)	6 (13)	1 (2)	14 (30)

^aACDF: anterior cervical discectomy and fusion.

^bN/A: not applicable.

^cPROMIS-29: 29-item Patient-Reported Outcomes Measurement Information System.

Discussion

Principal Findings and Future Work

Our results demonstrate that it is feasible to use a novel mobile health app (MMS-Spine) to engage patients in their spine surgery journey. The majority of patients tracked outcomes, completed tasks, and engaged with the FAQs at some point through their surgical journey, decreasing the burden on clinical and research staff.

This study is one of the first to report a patient-centered approach to developing a smartphone-based platform for patients undergoing elective spine surgery. Previous health care applications have primarily focused on chronic medical conditions [2] or symptom monitoring [8], and there has been little research regarding how the applications can be integrated into clinical practice. Prior mobile app studies have shown effectiveness in promoting behaviors for surgical recovery by recording patient adherence to postsurgical instructions, providing rehabilitation exercises, and monitoring medication use [4,9,10]. MMS incorporates a focus on short-term behavior change, as demonstrated in this feasibility study for spine surgery.

Engagement, defined as how a user interacts with technology and their emotional response to it, was a key metric of success. There are a number of metrics to evaluate engagement, from user satisfaction to more complex user engagement scores [11] and, on the commercial side, net promoter scores [12]. Because of the relatively short duration of use for this app, we decided to focus more on short-term user experience metrics and tended to avoid longer-term or patient loyalty metrics such as net promoter scores. Thus, for this initial feasibility study, we tracked overall patient satisfaction with the app and patient completion of key PROs. Overall, 96% of patients (23/24) found the app easy to use and would recommend it to a friend or family

member. Additionally, participants expressed that the clear, concise presentation of information and the timely tasks and notifications were beneficial. Finally, we noted that patient engagement was extremely high prior to surgery, with 38 of 47 patients (81%) completing their baseline preoperative PROMIS-29 outcomes. During the postoperative period, however, only 14 of the 47 patients (30%) completed at least one postoperative PROMIS-29 survey, indicating that additional strategies are needed to maintain patient engagement after the surgical event.

Future iterations will incorporate strategies to improve patient engagement and the number of postoperative outcomes that are collected. Several strategies for increasing patient engagement are possible when designing mobile health apps, including design-thinking techniques, improved notifications and messaging, and the incorporation of opportunities for feedback [13]. We aim to increase engagement by both increasing log-in rates and by improving our reminder and notification system. To increase the initial log-in rate, patients who were invited but did not log in to the program will be polled, and their reasons for not using MMS will be analyzed and addressed. In order to improve reminders and notifications, patients who began using MMS but did not complete the long-term follow-up surveys will be polled to better understand their reasons for not returning to the app. App updates will be designed and implemented with this feedback in mind. Preliminary options to increase follow-up response include sending reminders via additional mediums, collecting PROs via email and text from patients who have not downloaded the app, using artificial intelligence to optimize notification delivery, and sending messages to patients who have been less engaged around the time of their procedure. Finally, we plan to provide greater value to patients. To accomplish this, we agree with the conclusions of Bombard and colleagues [14] that making patients feel heard is hugely important to maintaining their engagement with the platform.

We plan to integrate messaging or system alerts for patients with suboptimal outcomes who may need more attention from a care provider. The downside to this approach is the higher technical cost and potential to overwhelm providers. We are also considering sharing outcome reports directly with patients at certain milestones. This can naturally incentivize future survey completion, as patients have direct knowledge about their health. Sharing data and comparisons with national averages with patients would be at the discretion of the provider and require contextualized explanations of PROs to maximize value and understanding by the patient.

Enhancing usability and engagement is another crucial element of the effectiveness of mobile apps in health care [13]. Higher-stress interventions, such as surgery, may lead to higher user engagement (measured through log-ins and repeated use), which has been associated with better health outcomes [10,15]. However, patients will not actually use a beneficial tool with a poor user experience. Consumer expectations for mobile health care apps are high and only increasing; a recent survey demonstrated that peoples' tolerance for poorly performing apps has reduced over time, even just in recent years [16,17]. Thus, we have been careful to maintain a collaborative workflow between clinicians, developers, and scientific writers, with a constant focus on functional design. Development of future features that continue improving usability and engagement will iterate on these foundational principles and simultaneously add value to patients by enabling them to stay on care pathways that lead to the best possible surgical outcomes.

Usability from the provider perspective is also crucial in health care app development. Recent studies have highlighted the importance of user experiences for both the patient and provider [18]. As such, we optimized the app for ease of use for the provider while also providing maximum flexibility to adapt to new procedures and surgeries. The MMS app is built as a platform that can be used for any interventional or surgical procedure, with the focus of the current feasibility study being spine surgery. It can accommodate many different patient care pathways, is highly configurable to fit a health system's workflow, and facilitates the transition of therapy and care. MMS was made available to patients through a web application, but for increased usability and adoption rate, both iOS and Android phone apps are also available and were primarily used in this feasibility study. Finally, MMS was designed to be compatible with any electronic health record, thus facilitating implementation for the hospital. Moreover, MMS is available with out-of-the-box content that is fully customizable to meet the client's needs.

Despite the rapid expansion of the field of mobile health, there have been few studies in surgical patients, especially spine surgery. Any studies focusing on ambulatory surgeries have focused entirely on postoperative care. For example, mobile apps have been demonstrated to reduce 30-day readmission rates in ambulatory breast reconstruction [19] and reduce in-person follow-up for lumbar discectomies [20]. Taken together, these data suggest that a comprehensive app that

includes preoperative, perioperative, and postoperative values could be effective on a larger scale. MMS-Spine is unique in the breadth and variety of information it provides to the patient and caregiver. The proper use of prespecified tasks and notifications allows one to rapidly identify which patients are off track and anticipate problems that might require patient-provider communication. In an increasingly telemedicine- and efficiency-focused US health care system, patients often come inadequately prepared for their surgical procedure or leave the surgical center experiencing symptoms that were previously attended to by the health care team. Without information and risk awareness, patients may delay seeking care, experience unnecessary anxiety, or seek unnecessary care, which can all lead to increased costs. These scenarios put additional strain on the health care system through the need for potentially expensive unplanned hospital readmissions, corrective procedures for complications that could have been addressed more easily at an earlier stage, or the burdening of medical personnel with hospital visits for minor complaints that could have been addressed remotely. Research regarding digital health solutions remains scarce, and more studies with larger sample sizes and longer follow-ups are needed to evaluate the impact of mobile health apps on surgical outcomes.

Limitations

Participation bias may have influenced the feasibility study. For example, all study participants were computer literate and had ready access to smartphones. We considered this limitation by alternatively developing the application as a web application that could run on a desktop or laptop (using modern browsers, including Chrome, Firefox, Safari, and Internet Explorer). In addition, the ability to add a caregiver helps minimize the barrier to technology adoption, as usually one or more members of a family have access to a smartphone (>80% of the US population [21]). The data collection was limited to counting the number of log-ins and not the number of times the app was opened. This number could be much greater than the number of log-ins indicates because 1 log-in allows a patient to access their account for up to 2 weeks when the smartphone has an enabled locking mechanism. Additionally, our data are limited to descriptive usage statistics, and future comparative studies will need to be performed to examine the effects of MMS usage on clinical outcomes and health care resource utilization. Finally, further refinements of the app may be needed to help engage patients who are less familiar with technology.

Conclusions

In summary, we used a patient-centered approach to develop one of the first comprehensive smartphone apps for patients undergoing elective spine surgery. This study summarizes the sequential and iterative process of developing the MMS-Spine app, which is aimed at navigating the spine surgery journey. Feasibility testing provided useful information regarding users' experiences with the app. The optimized version of the app will be ready for formal testing in a larger randomized clinical study to establish its cost-effectiveness and effect on patients' self-management skills and long-term outcomes.

Conflicts of Interest

SPL is a consultant for Higgs Boson Health. ZG and RD are the cofounders of Higgs Boson Health. MP and AA are employees of Higgs Boson Health. All other authors had no conflicts of interest to declare.

Multimedia Appendix 1

Additional survey instruments created and used by Duke Spine Center to assess patient pain during recovery.

[[DOCX File , 16 KB - periop_v3i2e21138_app1.docx](#)]

Multimedia Appendix 2

PROMIS-29 outcomes results (self-administered and proxied) at individual and aggregated timepoints.

[[DOCX File , 16 KB - periop_v3i2e21138_app2.docx](#)]

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Abbreviations

ACDF: anterior cervical discectomy and fusion

BCT: behavior change technique

FAQ: frequently asked question

MMS: ManageMySurgery

MMS-Spine: ManageMySurgery spine surgery module

PRO: patient-reported outcome

PROMIS-29: 29-item Patient-Reported Outcomes Measurement Information System

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Original Paper

Comparing Computed Tomography–Derived Augmented Reality Holograms to a Standard Picture Archiving and Communication Systems Viewer for Presurgical Planning: Feasibility Study

David Dallas-Orr^{1,2*}, MTM, MBA; Yordan Penev^{1,2*}, MTM; Robert Schultz^{1,2}, MTM, MD; Jesse Courtier^{3,4}, MD

¹Department of Bioengineering and Therapeutic Sciences, University of California, San Francisco, San Francisco, CA, United States

²Department of Bioengineering, University of California, Berkeley, Berkeley, CA, United States

³Department of Radiology, Mission Bay Hospital, University of California, San Francisco, San Francisco, CA, United States

⁴Department of Radiology and Biomedical Imaging, University of California, San Francisco, San Francisco, CA, United States

* these authors contributed equally

Corresponding Author:

Jesse Courtier, MD

Department of Radiology

Mission Bay Hospital

University of California, San Francisco

1975 4th Street C1758L

San Francisco, CA, 94127

United States

Phone: 1 415 476 1364

Email: jesse.courtier@ucsf.edu

Abstract

Background: Picture archiving and communication systems (PACS) are ubiquitously used to store, share, and view radiological information for preoperative planning across surgical specialties. Although traditional PACS software has proven reliable in terms of display accuracy and ease of use, it remains limited by its inherent representation of medical imaging in 2 dimensions. Augmented reality (AR) systems present an exciting opportunity to complement traditional PACS capabilities.

Objective: This study aims to evaluate the technical feasibility of using a novel AR platform, with holograms derived from computed tomography (CT) imaging, as a supplement to traditional PACS for presurgical planning in complex surgical procedures.

Methods: Independent readers measured objects of predetermined, anthropomorphically correlated sizes using the circumference and angle tools of standard-of-care PACS software and a newly developed augmented reality presurgical planning system (ARPPS).

Results: Measurements taken with the standard PACS and the ARPPS showed no statistically significant differences. Bland-Altman analysis showed a mean difference of 0.08% (95% CI –4.20% to 4.36%) for measurements taken with PACS versus ARPPS' circumference tools and –1.84% (95% CI –6.17% to 2.14%) for measurements with the systems' angle tools. Lin's concordance correlation coefficients were 1.00 and 0.98 for the circumference and angle measurements, respectively, indicating almost perfect strength of agreement between ARPPS and PACS. Intraclass correlation showed no statistically significant difference between the readers for either measurement tool on each system.

Conclusions: ARPPS can be an effective, accurate, and precise means of 3D visualization and measurement of CT-derived holograms in the presurgical care timeline.

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KEYWORDS

augmented reality; mixed reality; picture archiving and communication system; presurgical planning; new technology evaluation; medical imaging; surgery

Introduction

Picture archiving and communication systems (PACS) allow for easy storage and viewing of medical imaging information. Traditional PACS viewers present images in x-ray, computed tomography (CT), and magnetic resonance imaging (MRI) data on a 2-dimensional (2D) workstation screen to be examined by a surgical team in preparation for a complex procedure [1,2]. While these systems have been shown to be accurate and easy to use for the analysis of medical images [3], they are also limited by their requirement of a desktop computer, laptop, or smartphone screen [4]. Dias et al [5] report that 2 of the most common problems of traditional PACS are the mismatch between the 2D viewing screen and the real world and the accompanying lack of flexibility and efficiency of use.

Augmented reality (AR) and virtual reality (VR) technologies have the potential to address these shortcomings. AR and VR alike allow for the realistic and interactive digital representation of objects in a 3D space. As such, both technologies are already successfully deployed across a diverse set of applications, including terrestrial navigation [6], architectural modeling [7], automotive engineering [8], and education [9]. The same properties could be applied to present a realistic overlay of medical devices and tools on patients' anatomy in 3D space on a portable, shared visualization method.

Whereas VR presents an entirely digital representation of objects and their environment, AR allows for the overlay of digital holograms on a live real-world scene. In addition, many VR systems require a dedicated physical play space to allow for the experience of the completely immersive digital experience [10]. These characteristics make AR a more likely candidate for the development of interactive tools assisting the dynamic clinical workflow.

The potential of AR systems to assist in clinical tasks has been extensively reviewed by Uppot et al [11]. Possible use cases include supplementing radiology training; communicating with colleagues, referring clinicians, and patients; and aiding in interventional radiology procedures. Additional uses for AR in medicine include providing simulations for advanced life support training [12], visualizing patient anatomy including tumors [13], and guiding assistants during robotic surgery [14]. The increased spatial understanding of anatomy with AR has been shown to positively impact surgical care during laparoscopic surgery for

visualizing hidden patient anatomy [15], resection of neurological tumors without causing new neurological deficit [16], and breast tumor resection by maximizing breast conservation [17]. Multiple other non-patient outcome benefits have been proposed, including overall operating room efficiency [18,19], and more specifically—reduced operating room time, increased surgical precision, and reduced radiation exposure [20].

In order to create an AR model suitable for presurgical planning, the medical image from a CT or MRI scan must first be segmented using a DICOM viewer to visualize only the object or organ of interest. The resulting image is passed onto an image processing software that renders the object's volumes and surfaces into a 3D scalar field model. This model can later be loaded in a dedicated AR software designed for projecting the image onto an AR or mixed reality headset display. Similar technologies have evaluated the use of AR systems for the visualization of MRI data [21]. However, the focus of this study is the validation of CT-derived holograms. Although the visualization of CT-derived holograms has been assessed, measurement systems for these CT-derived holograms are rarely evaluated or utilized.

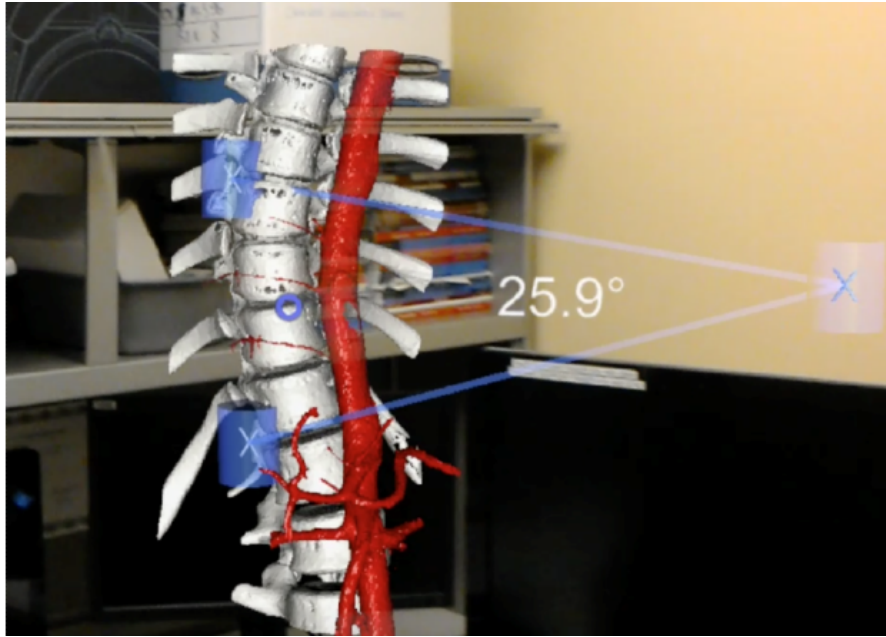
As AR becomes more widely used in presurgical planning, it is crucial to know that these systems meet the gold standard for medical image measurement. This study aims to validate the feasibility, safety, and efficacy of a novel ARPPS, compared to a standard-of-care PACS viewer, in order to support its use in the presurgical visualization and measurement of CT-derived imaging of patient anatomy and surgical tools.

Methods

Materials

A CT image data set was generated using Discovery CT750 HD (GE Healthcare). The object imaged was a CT dose meter phantom (model 137856101, GE Healthcare) compliant with the American College of Radiology standards. The PACS used for standard-of-care comparison was Osirix MD version 10.0 (Pixmeo SARL; FDA 510(k) K101342) [22]. The experimental PACS was the RadHA ARPPS version 3.3 (University of California, San Francisco) (Figure 1), as viewed on HoloLens generation 1 headset (Microsoft Corp). A MT-912 Digital Light Meter (Urceci) was used to measure the background light intensity.

Figure 1. The RadHA ARPPS version 3.3 displaying a spine model with a vascular model overlay and an angle measurement of thoracic kyphosis.



Procedure

The CT dose meter phantom DICOM (digital imaging and communications in medicine) file was converted to an OBJ file (object file, Wavefront Technologies) and uploaded to the

ARPPS for viewing on the HoloLens. The circumference and angle measurement tools of both the standard PACS and the ARPPS were used to measure diameters (Figure 2) and angles, respectively, with reference to the manufacturer-specified parameters of the CT dose meter phantom (Figure 3).

Figure 2. The RadHA ARPPS version 3.3 displaying a computed tomography (CT)-derived 3D hologram of a CT dose meter phantom with diameter and circumference measurements and selectable icons.

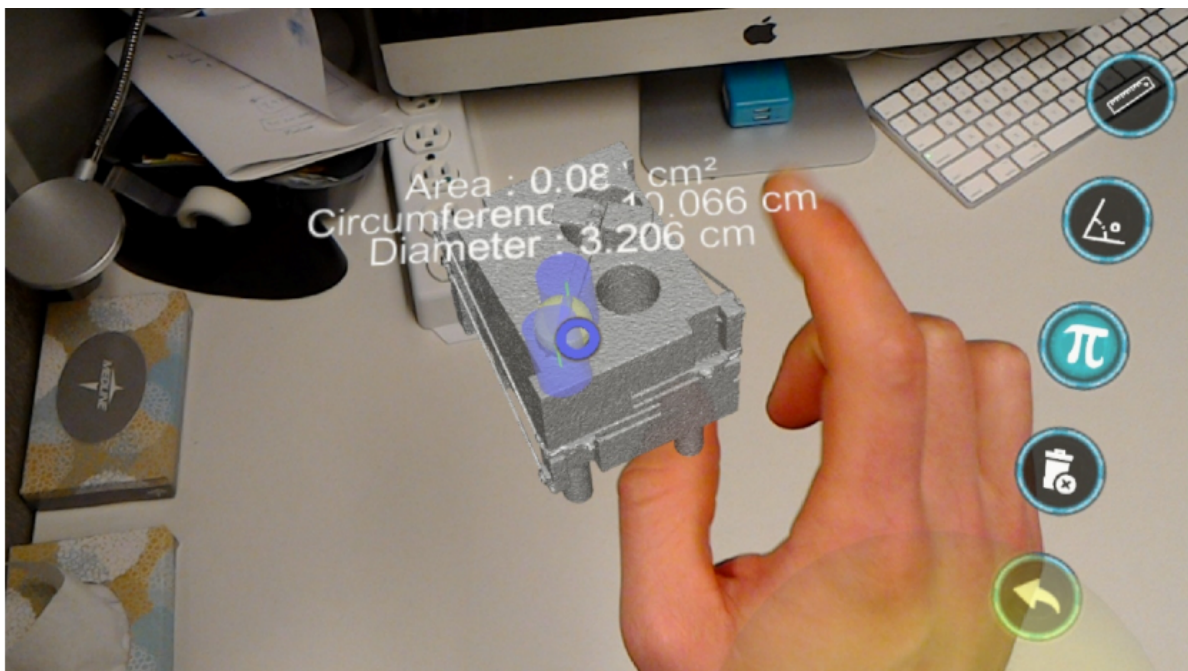
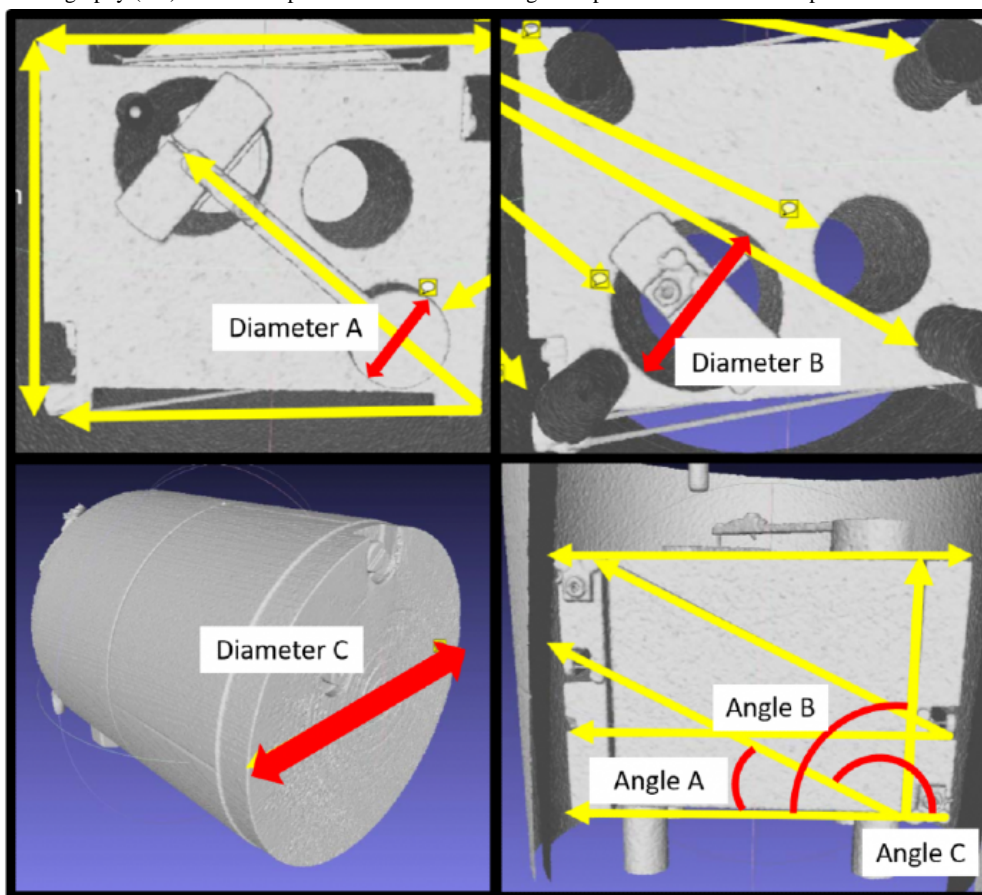


Figure 3. Computed tomography (CT) dose meter phantom diameters and angles as per the manufacturer's specifications.



A range of low, medium, and high clinical measurements were selected for anthropomorphic correlation of the phantom's diameter and angle parameters (Table 1). Two readers measured each of the phantom parameters 10 times independently of each

other starting with the ARPPS. The readers were blinded to the manufacturer-provided measurements. Testing was completed in an office with a background light intensity of 152.1 lux.

Table 1. Clinical significance of the CT dose meter phantom measurements.

Object	Manufacturer-specified size	Clinical guideline
Diameter A	3.215 cm	Mitral valve repair valve sizing [23] (mitral annulus diameter 3.15 cm)
Diameter B	5.0 cm	Elective abdominal aortic aneurysm repair in women [24] (5.0-5.4 cm)
Diameter C	21.31 cm	Pediatric abdominal diameter
Angle A	26.57°	Scoliosis evaluation [25] (bracing Cobb angle 29-40°)
Angle B	90.0°	Proximal tibial alignment [26] (normal lateral distal tibial angle 90°)
Angle C	153.43°	Pediatric hip evaluation [27] (normal pediatric femoral shaft angle 160°)

Statistical Analysis

All statistical analyses were performed using Microsoft Excel version 1903. The interrater reliability of the readers was verified using Lin's concordance correlation coefficient for both the circumference and angle tools [28]. Shapiro-Wilk test was performed to verify the normality of the differences of each set of measurements in order to satisfy the requirements of performing a nonparametric method of analysis such as a Bland-Altman analysis [29]. Bland-Altman analysis was used to evaluate the agreement between measurements taken with the standard PACS and the ARPPS.

Results

Lin's concordance correlation coefficient showed almost perfect concordance of the standard PACS viewer and the ARPPS (Figure 4, Table 2). Additionally, no significant difference in interrater reliability was observed for the circumference and angle tool measurements for both the PACS and ARPPS separately (Figure 4, Table 2).

The Shapiro-Wilk tests failed to reject the null hypothesis of normality (Table 3). Bland-Altman plots evaluating the circumference tool showed an average bias of 0.08% with a 95% CI -4.20% to 4.36%. Bland-Altman plots evaluating the

angle tool showed an average bias of -1.84% with a 95% CI -6.17% to 2.14% . The bias and confidence intervals of each of the 3 measures for the circumference and angle tools are reported in Table 3. The Bland-Altman plots of each of the measurements, as well as the combined measurements are shown

for the circumference tool (Figure 5 a-d) and angle tool (Figure 5 e-h).

The variability of the percent error of each of the measurements using the ARPPS as compared to using the standard PACS are visualized in individual box plots in Figure 6.

Figure 4. Lin's concordance plots of a) circumference tool, b) angle tool; interrater reliability plots of c) circumference tool for the picture archiving and communication system (PACS), d) circumference tool for augmented reality presurgical planning system (ARPPS), e) angle tool for PACS, f) angle tool for ARPPS.

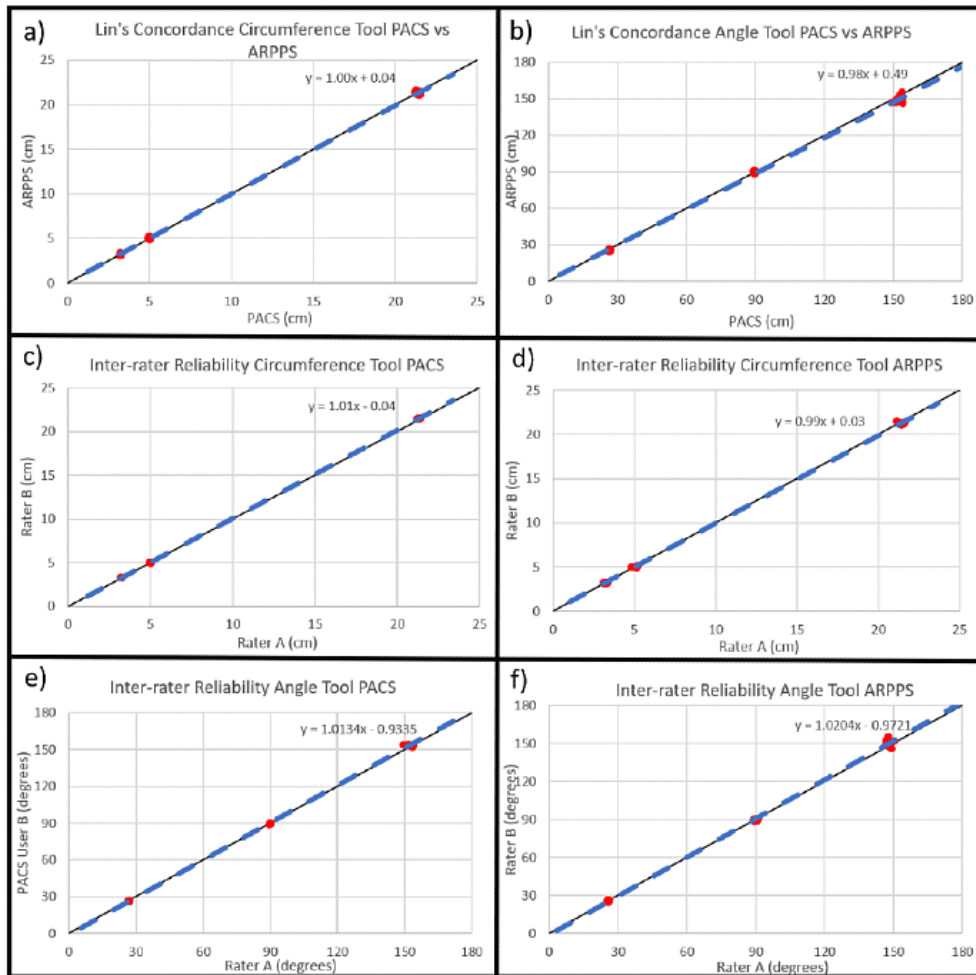


Table 2. Lin's concordance correlation coefficients and interrater reliability.

Tools	Concordance correlation coefficient	Interrater reliability PACS ^a standard DI-COM ^b viewer	Interrater reliability ARPPS ^c
Circumference tool	1.00	1.01	0.99
Angle tool	0.98	1.01	1.02

^aPACS: picture archiving and communication system.

^bDICOM: digital imaging and communications in medicine.

^cARPPS: augmented reality presurgical planning system.

Table 3. Shapiro-Wilk test for normality of differences and Bland-Altman analysis.

Tools and measurements	Shapiro-Wilk test <i>P</i> value	% Bias	Lower limits of agreement, %	Upper limits of agreement, %
Circumference tool				
Diameter A	.5607	-0.59	-5.56	4.39
Diameter B	.4528	1.16	-3.36	5.69
Diameter C	.3325	-0.33	-2.44	1.78
Combined	N/A	0.08	-4.20	4.36
Angle tool				
Angle A	.8304	-3.30	-7.78	1.19
Angle B	.9685	0.14	-1.66	1.93
Angle C	.7211	-2.36	-5.42	0.71
Combined	N/A	-1.84	-6.17	2.49

Figure 5. Bland-Altman plots for the circumference tool measurements for a) diameter A, b) diameter B, c) diameter C, d) all diameters combined, and of the angle tool measurements for e) angle A, f) angle B, g) angle C, h) all angles combined.

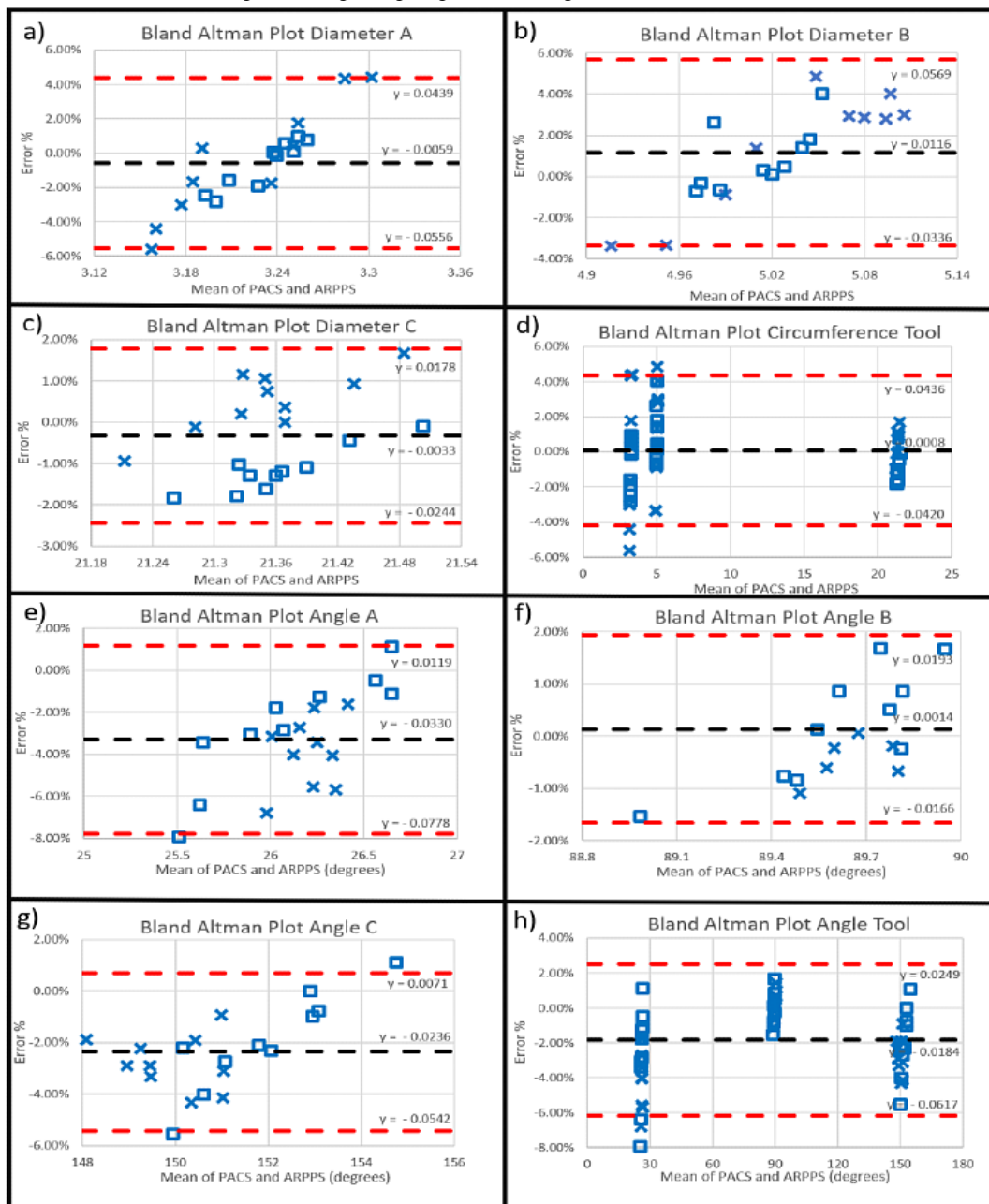
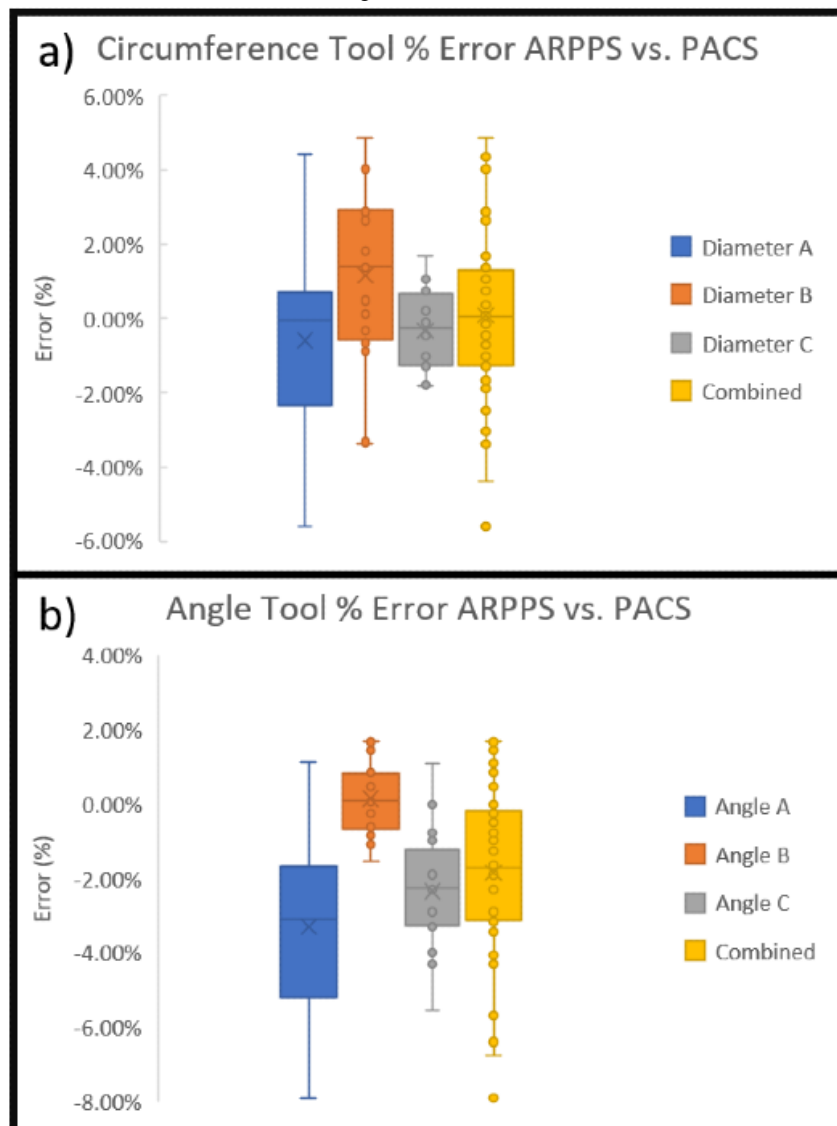


Figure 6. Whisker plot comparisons of percent error of the augmented reality presurgical planning system (ARPPS) versus the standard picture archiving and communication system (PACS) for a) circumference tool, b) angle tool.



Discussion

Principal Results and Comparison to Prior Work

Both the circumference and angle measuring tools of the ARPPS had an accuracy that was not significantly different as compared to the PACS measurements used in traditional preoperative settings. The circumference tool had an overall bias of 0.08%, which is more accurate than the 0.3% previously reported for a comparable AR system [30]. Similarly, the angle tool had an overall bias of -1.84% , which is more accurate than that previously reported for another 3D reconstruction software already on the market [31].

Interestingly, a decrease in percent error in either circumference or angle tool measurements was associated with an increase in the size of the object and ray length, respectively (Figure 6). This was consistent with a corresponding increase in the ease of manipulation of the hologram for larger objects as reported by both readers. AR and mixed reality-viewing hardware with higher resolution and responsiveness is likely to significantly improve the usability of such systems.

Limitations

Manipulating objects on the HoloLens can be technically challenging and contain a systematic error. Both readers reported difficulties in determining a clear vertex for angles A and C. However, angle B, which had no reported difficulties in measurement, showed a bias of only 0.14%. In addition, readers reported significant improvements in hologram manipulation dexterity with experience.

Conclusions

ARPPS can be an effective, precise, and accurate tool for the realistic visualization, manipulation, and measurement of clinically significant angles and circumferences in 3D space. ARPPS measurements are of substantially equivalent accuracy and precision as compared to standard-of-care PACS, similar systems that have previously been awarded the Food and Drug Administration (FDA) clearance as class II medical devices for presurgical planning, and other systems with published data [30,31]. Nonetheless, technological difficulties remain a major barrier to the adoption of such technologies in medical and surgical care settings. To realize the full potential of AR and

similar technologies, it is important that the medical community works in concert with device manufacturers to ensure the devices' real-world feasibility, usability, safety, and efficacy.

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Conflicts of Interest

JC is an Associate Clinical Professor in Pediatric Radiology at the University of California, San Francisco and creator of the ARPPS but did not participate in the collection or analysis of the data.

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Abbreviations

- 2D:** 2-dimensional
- AR:** augmented reality
- ARPPS:** augmented reality presurgical planning system
- CT:** computed tomography
- DICOM:** digital imaging and communications in medicine
- FDA:** Food and Drug Administration
- MRI:** magnetic resonance imaging
- PACS:** picture archiving and communication system
- VR:** virtual reality

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Original Paper

Feasibility of Using a Single Heart Rate–Based Measure for Real-time Feedback in a Voluntary Deep Breathing App for Children: Data Collection and Algorithm Development

Christian L Petersen¹, PhD; Matthias Görge^{1,2}, PhD; Evgenia Todorova^{3,4}, MD; Nicholas C West¹, MSc; Theresa Newlove^{3,4}, PhD, Rpsych; J Mark Ansermino^{1,2}, MBBCh, MMed (Anaesth), MSc (Info), FRCPC

¹Department of Anesthesiology, Pharmacology & Therapeutics, The University of British Columbia, Vancouver, BC, Canada

²Research Institute, BC Children's Hospital, Vancouver, BC, Canada

³Department of Psychology, The University of British Columbia, Vancouver, BC, Canada

⁴Department of Psychology, BC Children's Hospital, Vancouver, BC, Canada

Corresponding Author:

Matthias Görge, PhD

Department of Anesthesiology, Pharmacology & Therapeutics

The University of British Columbia

Rm V3-324, 950 West 28th Avenue

Vancouver, BC, V5Z 4H4

Canada

Phone: 1 6048752000 ext 5616

Fax: 1 6048752668

Email: mgorges@bcchr.ca

Abstract

Background: Deep diaphragmatic breathing, also called belly breathing, is a popular behavioral intervention that helps children cope with anxiety, stress, and their experience of pain. Combining physiological monitoring with accessible mobile technology can motivate children to comply with this intervention through biofeedback and gaming. These innovative technologies have the potential to improve patient experience and compliance with strategies that reduce anxiety, change the experience of pain, and enhance self-regulation during distressing medical procedures.

Objective: The aim of this paper was to describe a simple biofeedback method for quantifying breathing compliance in a mobile smartphone app.

Methods: A smartphone app was developed that combined pulse oximetry with an animated protocol for paced deep breathing. We collected photoplethysmogram data during spontaneous and subsequently paced deep breathing in children. Two measures, synchronized respiratory sinus arrhythmia (RSA_{sync}) and the corresponding relative synchronized inspiration/expiration heart rate ratio ($HR-I:E_{sync}$), were extracted from the photoplethysmogram.

Results: Data collected from 80 children aged 5-17 years showed a positive RSA_{sync} effect in all participants during paced deep breathing, with a median (IQR; range) $HR-I:E_{sync}$ ratio of 1.26 (1.16-1.35; 1.01-1.60) during paced deep breathing compared to 0.98 (0.96-1.02; 0.82-1.18) during spontaneous breathing (median difference 0.25, 95% CI 0.23-0.30; $P < .001$). The measured $HR-I:E_{sync}$ values appeared to be independent of age.

Conclusions: An $HR-I:E_{sync}$ level of 1.1 was identified as an age-independent threshold for programming the breathing pattern for optimal compliance in biofeedback.

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KEYWORDS

pediatric pain; respiratory sinus arrhythmia; biofeedback; pulse oximetry; mobile health; anxiety; diaphragmatic breathing; self-regulation

Introduction

As a child's psychological well-being during hospital visits is associated with improved health outcomes, it is imperative to find ways to minimize the stress and anxiety that children experience during medical procedures [1]. Studies have shown that decreased anxiety is associated with not only decreased distress but also decreased pain and less negative attitudes toward future medical procedures [2]. Therefore, providing developmentally appropriate strategies to support children's coping before, during, and after medical procedures should be considered an important element of care.

Deep diaphragmatic breathing (sometimes referred to as belly breathing in pediatric settings) typically produces a relaxed state and is considered a behavioral coping strategy to reduce anxiety in children undergoing medical procedures [3]. Teaching deep diaphragmatic breathing is a popular behavioral intervention used by health care professionals, which affects both the physiological and psychological outcomes of patients. This technique has been found to ease procedural distress in children with cystic fibrosis [4] and anxiety in children with asthma [5]. In addition to the psychophysiological benefits of deep diaphragmatic breathing, intermittent periods of a slow respiratory rate (in the range of 6 breaths/minute) can have a direct positive impact on the cardiorespiratory health of patients. They increase the resting oxygen saturation [6] and baroreflex sensitivity [7-9] while reducing chemoreflex activation [10] and muscle nerve sympathetic activity [11].

Compliance with breathing protocols is optimized when children are taught through instruction, modelling, and in-vivo coaching by a health care provider typically assigned to support the child during a medical procedure. Children who have previously been identified as having significant difficulties in participating in medical procedures are often referred to Child Life specialists or other providers assigned to support children; however, many children who experience distress during medical procedures are not recommended interventions and do not have the opportunity to access coping strategies. In the absence of this active teaching and coaching to belly breathe during a procedure, children are often unable to belly breathe successfully, instead focusing on the procedure that is the source of distress and discomfort. As children are increasingly surrounded by technology, both at home and in educational settings, teaching deep breathing through a smartphone app can increase accessibility to coping strategies for children undergoing medical procedures. The smartphone app acts as a biofeedback game that simultaneously enables children to successfully engage in belly breathing while also providing active distraction that can further help reduce the experience of pain [12].

There is limited research published on using biofeedback apps to teach relaxation to children in clinical settings; however, evidence supports the effectiveness of biofeedback as an intervention for invasive procedures in children with cancer [13], in patients post cardiac surgery [14], and in children with asthma [15]. A systematic review of apps for the management of pain and stress, including 11 breathing-related apps, cautioned that a majority were developed by lay-professionals, were

intended to be used by adults, and had not been formally evaluated [16]. Furthermore, few of these apps used sensors for feedback; those that did, used the phone's accelerometer placed on the xiphoid process or, more recently, obtained the heart rate from an Apple Watch [16].

Respiratory sinus arrhythmia refers to the heart rate variation that occurs during the respiratory cycle, by which the heart rate increases during inspiration and decreases during expiration [17,18]. This effect is especially pronounced in children [19] and decreases with age and declining cardiovascular health [20]. The change in rate is due to respiratory-induced changes in intrathoracic pressure. The change in pressure leads to changes in cardiac output that lead to a reflex-mediated change in heart rate. Deep diaphragmatic breathing enhances the respiratory sinus arrhythmia amplitude, as activation of pulmonary stretch receptors increases pulmonary vagal inhibition. The photoplethysmogram (PPG) waveform, obtained from a pulse oximeter, contains detailed information about heart rate variability. Although heart rate variability is traditionally extracted from an electrocardiogram, the PPG can be used to extract equivalent measures [21]. It is therefore plausible that PPG-derived respiratory sinus arrhythmia could be the basis of a deep breathing biofeedback system for children.

This study uses a previously developed smartphone audio-based pulse oximeter [22] as a biofeedback measure for a smartphone game that teaches and promotes deep diaphragmatic breathing in children. The aim of this paper was to describe the creation of a simple indicator to quantify compliance with deep breathing patterns, which can be used in the fully programmed biofeedback app.

Methods

Study Design

We prospectively collected PPG data from a cohort of volunteer child participants during sequential spontaneous breathing and paced deep breathing, guided by a smartphone app, in order to establish an appropriate measure that can be implemented for future use in real-time smartphone-based biofeedback.

Ethical Approval

The study was approved by the University of British Columbia/Children's and Women's Health Centre of British Columbia Research Ethics Board (H14-02577). All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed parental consent and child assent was obtained from all individual participants included in the study.

Equipment

A smartphone app for iOS and Android was developed using the cross-platform open source LambdaNative framework [23,24]. In an effort to engage children, the app features a happy protagonist, named Johnny Bellybreath, in a hot air balloon [25], who inhales and exhales bubbles. As he inhales, animated

bubbles enter his nose. As he exhales, the bubbles reappear from his mouth; during the pause between inhalation and exhalation, there are no bubbles shown on the screen. The goals of the biofeedback game are as follows: (1) to teach a voluntary deep breathing protocol; (2) to detect compliance to the breathing protocol using an attached audio-based pulse oximeter sensor; (3) to raise the hot air balloon as the child belly breathes successfully, as determined by the relative synchronized expiration to inspiration heart rate ratio (see Data Analysis section); and (4) to reinforce continued belly breathing by keeping the balloon rising while exponentially increasing altitude and increasing the “altitude score” of the game, reaching 1,000,000 m after approximately 2 minutes. In the final

application, the scenery changes as the balloon rises driven by biofeedback, until it eventually reaches outer space.

For the purpose of data collection, the smartphone app contains two nonfeedback modes of operation: Blank mode and Training mode. In Blank mode, the screen is blank, and the app simply measures and records the PPG using the pulse oximeter sensor. In Training mode, the app displays a stationary hot air balloon (no biofeedback), and the character blows bubbles in accordance with the slow breathing protocol at 6 breaths per minute (3 seconds inhale, 3 seconds hold, 3 seconds exhale, and 1 second pause/transition) while PPG data is recorded. The Training mode also shows the 3-step breathing instructions on the screen as “Breathe-2-3,” “Hold-2-3,” and “Blow-2-3” (Figure 1).

Figure 1. Pulse oximetry sensor– and smartphone–based animated deep breathing trainer. The animated character inhales bubbles through the nose and exhales them through the mouth at 6 breaths per minute.



Participants and Data Collection

A kiosk was set up in the hallways of the British Columbia Children’s Hospital to recruit participants. The smartphone app was installed on an iPad (Apple Inc) and mounted on a stand adjusted to be at eye level for a seated child. Inclusion criteria for children to participate in the study were (1) age, 5-17 years; (2) ability to speak English; (3) no significant developmental or intellectual disability; and (4) no severe cardiovascular or respiratory condition that could either inhibit their ability to perform deep breathing or significantly affect their heart rate variability.

Participants were seated in a chair in front of the iPad with the audio pulse oximeter placed on an index finger. During spontaneous breathing, the PPG was recorded for 1 minute using the Blank mode of the smartphone application; participants did not receive specific instructions, as the purpose was to emulate random breathing when children were not paying attention to the game. After collecting spontaneous data, the deep diaphragmatic breathing technique was explained to the participants and the Training mode of the application was demonstrated by a hospital volunteer using a script and accompanying pictures. Then, the smartphone app was put into Training mode and the PPG was collected for 2 minutes of

paced deep breathing. The phase of the deep breathing cycle was fixed for all collected data sets, allowing a systematic comparison of the heart rate between participants at different phases of the breathing cycle.

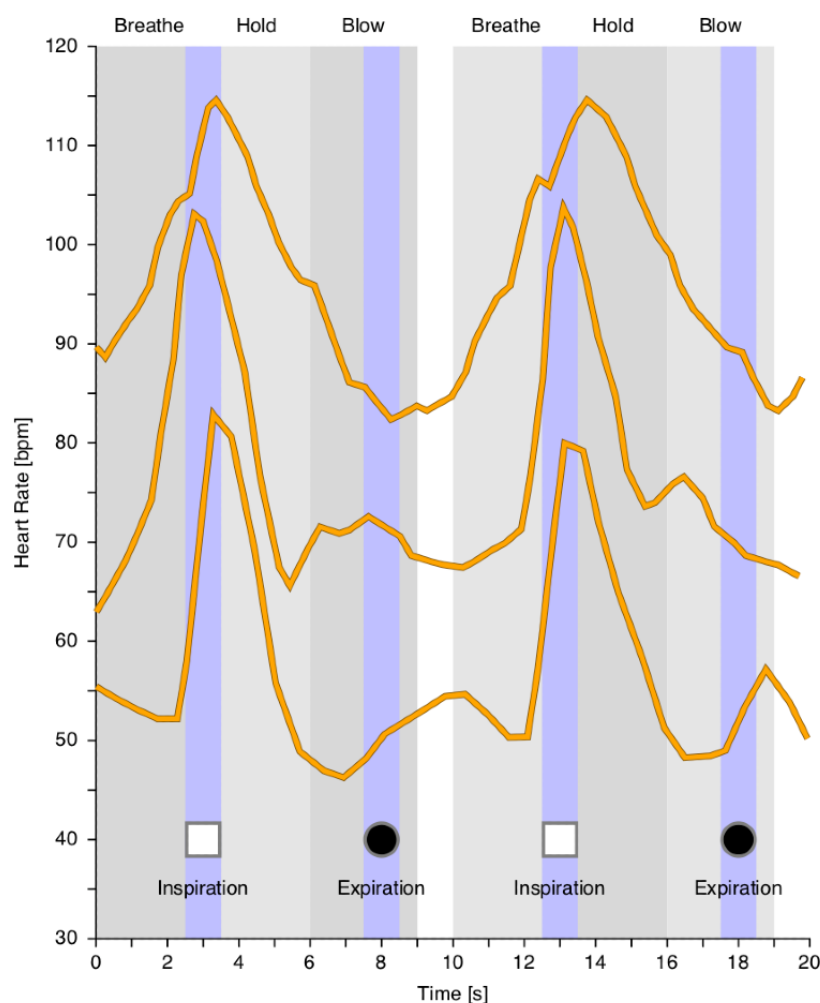
Data Analysis

Heart rates were extracted from the PPG signal on a beat-to-beat basis to quantify the variability of respiratory sinus arrhythmia in children. A 1-second window of heart rate was recorded 2.5-3.5 seconds (typically the end of the inspiratory cycle in spontaneously breathing children) into the breathing cycle for inspiration, and a second 1-second window of heart rate at 7.5-8.5 seconds for expiration (typically the middle of the expiratory cycle). The timing of 1-second windows corresponded to the timing of the animated pacing bubbles in the game and, when successfully playing the game, the children should have been in inspiration/expiration at those moments. The width of the window was a compromise, rewarding

compliance to the animation while at the same time allowing for natural variations in each breathing cycle. Finally, during spontaneous breathing, the animation was not shown, but the heart rate window timing was identical to that used during paced deep breathing.

The heart beats were extracted using a standard peak detection method; specifically, using zero-crossings in the difference signal after band-limiting it to 0.5-4Hz using a fourth-order filter (Figure 2). This sampling gives an equitemporal distribution of the inspiration/expiration updates (5 seconds), which is convenient for the real-time feedback implementation. The difference between the average heart rates (HR) recorded during $HR_{\text{inspiration}}$ and $HR_{\text{expiration}}$, was used to determine a synchronized respiratory sinus arrhythmia measure, $RSA_{\text{sync}} = HR_{\text{inspiration}} - HR_{\text{expiration}}$, and the corresponding relative synchronized expiration/inspiration ratio, $HR\text{-}I:E_{\text{sync}} = HR_{\text{inspiration}}/HR_{\text{expiration}}$.

Figure 2. Example tachograms from 3 separate participants for two consecutive breathing cycles, illustrating interpatient variance in respiratory sinus arrhythmia slope and maxima/minima. The signal is sampled in two 1-second windows (highlighted in blue), during inspiration (white) and expiration (black) respectively, to extract the synchronized respiratory sinus arrhythmia measure.



For each participant, the average $HR\text{-}I:E_{\text{sync}}$ ratio was obtained. Results were grouped according to the participants' ages: 5-7 years, 8-10 years, 11-13 years, and 14-17 years. The median

and IQR were also determined. Finally, $HR\text{-}I:E_{\text{sync}}$ ratios for all participants were compared using the Wilcoxon signed-rank test with the 95% confidence interval of the median difference

to identify the nonoverlapping area between groups, to be used as a threshold for the breathing pattern performance.

Results

A total of 109 children entered the study over the course of 53 days. Of these, 16 participants did not complete the study, 9

participants were excluded because of respiratory conditions, and 4 met other exclusion criteria. The remaining 80 eligible participants (34 boys, 46 girls) were separated into 4 age groups: 5-7 years (n=18), 8-10 years (n=20), 11-13 years (n=21), and 14-17 years (n=21) (Table 1).

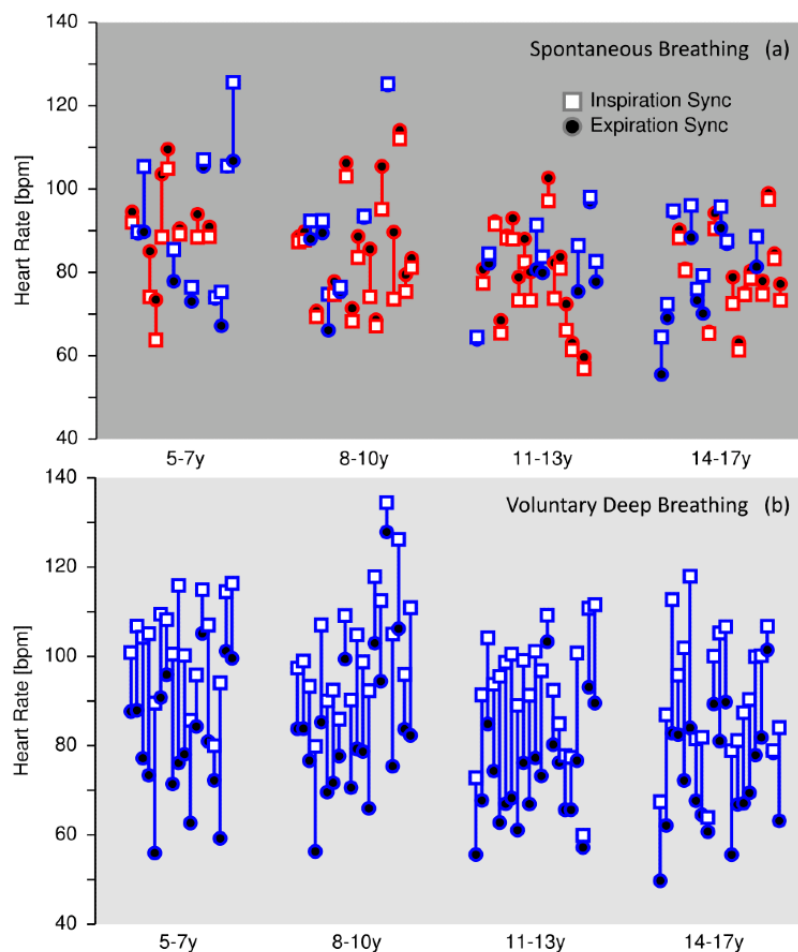
Table 1. Age groups characteristics. Data are reported as median (IQR).

Age group (years)	Age (years)	Participants (N=80), n	
		Female (n=46)	Male (n=34)
5-7	7 (6-7)	12	6
8-10	9 (8-10)	12	8
11-13	11 (11-13)	7	14
14-17	15 (15-16)	15	6

During the spontaneous breathing (Blank mode), there appeared to be no systematic difference between the inspiration and expiration synchronization, as the participants' natural breathing patterns did not synchronize with the paced breathing pattern

(Figure 3a). On the other hand, during paced deep breathing (Training mode), all participants exhibited a higher heart rate at inspiration than at expiration, equivalent to a positive RSA_{sync} response (Figure 3b).

Figure 3. Measured heart rates at inspiration (white square bullets) and expiration (black round bullets) using (a) spontaneous breathing (Blank mode), and (b) the paced deep breathing at 6 breaths per minute (Training mode). Positive response is indicated in blue color, and negative response is indicated in red color.



All 80 participants exhibited a positive RSA_{sync} value in the Training mode of the app, with a median 26% increase in heart rate at inspiration over expiration, compared to a 2% decrease

in the Blank mode of the app (Table 2). The timing of the peak heart rates at inspiration was well determined across participants and located at the end of the inspiratory segment of the breathing

cycle. The minimum heart rate at expiration was dependent on the individual dynamic inter-breath heart rate variations, but generally located in the middle of the expiratory segment of the cycle.

Table 2. Heart rates observed at inspiration and expiration, synchronized respiratory sinus arrhythmia measure (RSA_{sync}), and relative synchronized expiration/inspiration ratio ($HR-I:E_{sync}$), split by age groups and feedback mode (spontaneous and deep breathing). Data are reported as median (IQR).

Age group (years)	HR ^a inspiration (bpm ^b)		HR expiration (bpm)		RSA _{sync} (bpm)		HR-I:E _{sync}	
	Spontaneous	Deep breathing	Spontaneous	Deep breathing	Spontaneous	Deep breathing	Spontaneous	Deep breathing
5-7	82.5 (73.3-88)	95.5 (89.0-100.8)	80.7 (75.4-88.0)	73.2 (65.6-77.3)	-2.8 (-5.5 to 1.2)	22.0 (12.2-24.1)	0.97 (0.95-1.01)	1.30 (1.19-1.35)
8-10	79.2 (73.3-88.6)	90.3 (81.5-101.9)	80.3 (73.3-88.3)	72.2 (64.5-82.5)	-0.4 (-1.9 to 3.3)	18.3 (13.9-23.3)	0.99 (0.98-1.05)	1.28 (1.19-1.36)
11-13	88.6 (76.4-104.9)	105.1 (95.8-109.4)	90.5 (77.9-103.6)	81.0 (72.2-90.8)	0.0 (-4.7 to 3.4)	18.8 (13.2-29.1)	1.00 (0.96-1.05)	1.21 (1.14-1.41)
14-17	82.4 (74.6-92.7)	98.9 (92.4-109.6)	88.3 (77.2-90.6)	80.8 (74.5-87.5)	-2.1 (-3.4 to 0.3)	19.8 (14.6-22.2)	0.98 (0.95-1.00)	1.24 (1.16-1.30)

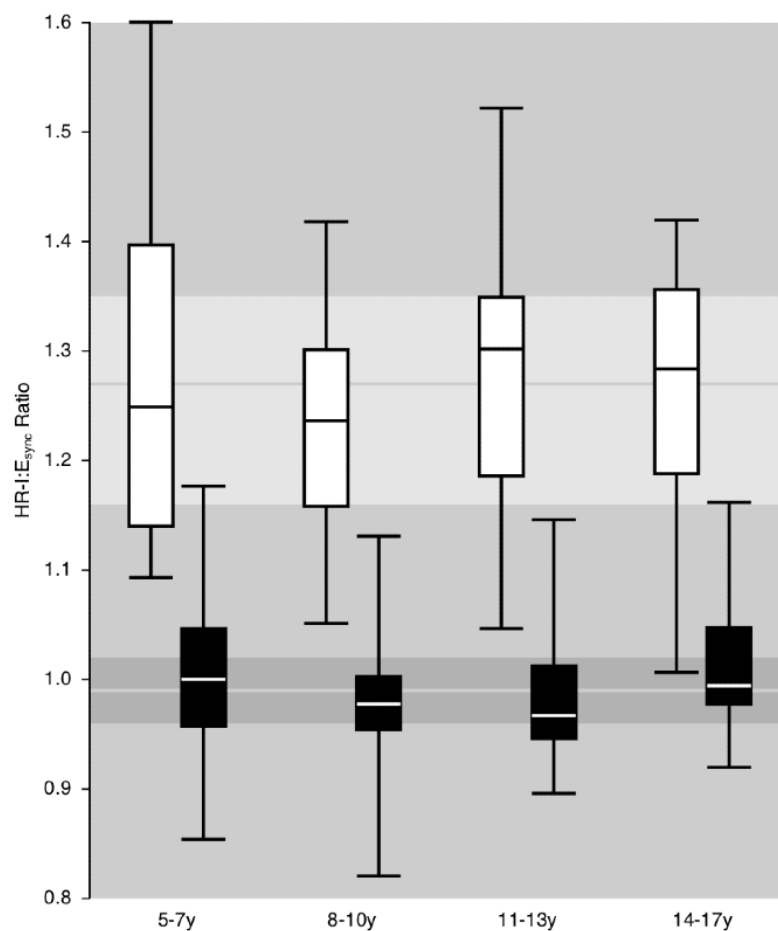
^aHR: heart rate

^bbpm: beats per minute

The median (IQR; range) $HR-I:E_{sync}$ across the entire population was 1.26 (1.16-1.35; 1.01-1.60) during paced deep breathing and 0.98 (0.96-1.02; 0.82-1.18) during spontaneous breathing (Figure 4); the median difference was 0.26 with a 95% CI of 0.23-0.30 ($P<.001$).

The measured $HR-I:E_{sync}$ values appeared to be age independent (Figure 4). Hence, a single $HR-I:E_{sync}$ threshold of 1.1 was selected as a reasonable threshold for breathing compliance during biofeedback.

Figure 4. Age group–specific median synchronized inspiration/expiration heart rate ratios during paced deep breathing (Training mode; white) and spontaneous breathing (Blank mode; black). The horizontal bands indicate the total first to third quartile for the two data sets, with the median indicated using a horizontal line.



Discussion

In this study, we observed a pronounced RSA_{sync} during paced deep breathing and lack of synchronization during spontaneous breathing. The synchronized differences were sufficiently distinct to identify a single heart rate–based measure ($HR-I:E_{sync} = 1.1$) for biofeedback in all participants. This $HR-I:E_{sync}$ threshold can be universally applied to children of all ages, despite the large inherent interpatient variability in this demographic. It is unexpected that the RSA_{sync} magnitude is relatively constant between age groups, as it is known that respiratory sinus arrhythmia naturally decreases with age. Instead, results show a moderate reversal, with a slightly lower effect in the youngest age group and an elevated effect in the oldest age group. This could be due to differences in compliance, increased respiratory effort by older children, or the smaller data sets in the two limiting age groups.

The fact that the RSA_{sync} effect is pronounced even in the youngest age group demonstrates that the visual breathing instructions in the Training mode of the app is an effective way of pacing deep breathing in small children. It suggests that the smartphone biofeedback app could be used in a wide age range of children, possibly even in children younger than the participants recruited in this study.

The particular shape of the respiratory sinus arrhythmia response was found to be different between participants, without any clear age dependence or other systematic relation. Some participants exhibited a broad sawtooth-like response in heart rate during the cycle, while others showed a narrow response characterized by a rapid increase and decrease of heart rate at inspiration and a reproducible substructure in between breaths. It is unclear whether this difference is due to physiological differences between participants, individual variations in interpretation of the breathing protocol, or a combination thereof.

The conventional method for extracting respiratory sinus arrhythmia from the heart rate tachogram involves resampling and performing a Fourier transformation on a long temporal window. However, this frequency domain method does not suit the purposes of biofeedback, as a real–time response that can be updated during each breathing segment is required. The proposed RSA_{sync} measure underestimates true respiratory sinus arrhythmia, as the true heart rate extrema may fall outside of the sampling windows. However, the advantage of using RSA_{sync} for biofeedback is that spontaneous breathing should yield a net RSA_{sync} of zero due to the lack of synchronization, while compliant deep diaphragmatic breathing is expected to yield a value of RSA_{sync} approaching the full arrhythmia effect.

Limitations

This study presents preliminary data. The biofeedback process and threshold selected for belly breathing protocol compliance feedback were not evaluated as part of this study. The children involved in this study were volunteers not undergoing any medical procedure while they were participating in the study. Further research is required to evaluate whether these results will translate to children experiencing the pain and/or stress of a medical condition or procedure, which paced deep breathing (belly breathing) is intended to alleviate.

Conclusions

The use of PPG as biofeedback for deep breathing in children was investigated. Our results suggest that this is a feasible approach and that a single universal threshold in HR-I:E_{sync} ratio of 1.1 will be sufficient to encode real-time feedback in the app for all ages evaluated.

The next phases of the study involve programming the smartphone biofeedback in accordance to these findings, and

comparing the app to traditional teaching methods by measuring the respiratory sinus arrhythmia magnitude in both groups to determine its effectiveness in reinforcing effective deep diaphragmatic breathing in children. Subsequently, the app will be investigated as a tool to improve self-regulation and coping and to minimize pre-procedural anxiety and the experience of pain in children undergoing medical procedures. The fully programmed biofeedback deep breathing application represents a new tool that can encourage children to engage in a simple behavioral intervention with the potential to reduce the experience of pain and anxiety of medical procedures during hospital visits and in other settings. It may provide children with an opportunity to engage in a proactive, child-friendly activity, giving them a sense of control during painful, but necessary, medical procedures. This is important, as children who experience distress even during routine medical procedures can carry this negative experience into subsequent health care interactions. Thus, this tool may provide children with a coping strategy that could improve their health care journey.

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Authors' Contributions

CLP, ET, and TN designed the study and obtained ethical approval to conduct the research. CLP developed the app software. ET supervised the data collection. CLP, TN, and MG analyzed the data. CLP, ET, MG, NW, and JMA interpreted the findings and drafted the manuscript. All authors critically reviewed the manuscript, and read and approved the final version.

Conflicts of Interest

Two of the authors (CLP and JMA) are co-inventors of the audio phone oximeter, the rights to which have been transferred to LionsGate Technologies Inc in exchange for equity.

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Abbreviations

HR: heart rate

HR-I:E_{sync}: synchronized inspiration/expiration heart rate ratio

PPG: photoplethysmogram

RSA_{sync}: synchronized respiratory sinus arrhythmia

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Original Paper

Efficacy of a Novel Intraoperative Engineered Sharps Injury Prevention Device: Pilot Usability and Efficacy Trial

Hillary Jenny¹, MPH, MD; Maria Reategui Via y Rada², BSc; Pooja Yesantharao¹, MSc; Helen Xun¹, BSc; Richard Redett¹, MD; Justin Michael Sacks¹, MBA, MD; Robin Yang¹, MD, DDS

¹Department of Plastic & Reconstructive Surgery, Johns Hopkins Hospital, Baltimore, MD, United States

²Geisel School of Medicine at Dartmouth, Hanover, NH, United States

Corresponding Author:

Hillary Jenny, MPH, MD

Department of Plastic & Reconstructive Surgery

Johns Hopkins Hospital

1800 Orleans St

Baltimore, MD

United States

Phone: 1 410 955 5000

Email: hjenny@jhu.edu

Abstract

Background: The American College of Surgeons reports 88,320 intraoperative needlestick injuries (NSIs) per year, resulting in US \$376 to US \$2456 in costs per NSI. Engineered sharps injury prevention (ESIP) devices protect against NSIs. To our knowledge, no study has been published to date to demonstrate clinical effectiveness of an intraoperative ESIP device. Operative Armour is a wearable arm cuff that can be donned during surgical closure to allow surgeons to keep a suture pack and sharps protection container on their forearm.

Objective: We characterize Operative Armour's ESIP device effectiveness in a tertiary hospital, hypothesizing that this device will decrease NSI risk by decreasing behaviors associated with NSIs: needle passing and handling.

Methods: A prospective case-control study was conducted with institutional review board quality improvement designation in which authors observed skin closures of plastic surgery procedures. To ensure accuracy, one surgeon was observed at a time. Control surgeries were purely observational; intervention cases involved surgeon use of the device during skin closure. Outcomes of interest included needle passing, needle handling, lost needles, and loaded waiting needles.

Results: Surgeons were observed in 50 control and 50 intervention cases. Operative Armour eliminated needle passing during skin closure. One NSI occurred in one control case; no NSIs were observed in intervention cases ($P=.36$). The mean number of loaded and unprotected waiting needles was also significantly decreased in the intervention group from 2.3 to 0.2 ($P<.001$). Furthermore, a multivariable linear regression established that Operative Armour significantly decreased the number of needle adjustments by hand per stitch observed ($F_{4,21.68}=3.72$; $P=.01$). In fact, needle adjustments by hand decreased overall (1 adjustment per 10 stitches vs 1 adjustment per 5 stitches, $P=.004$), and adjustments occurred half as frequently with use of Operative Armour in free flap reconstruction (1 adjustment per 10 stitches vs 1 adjustment per 5 stitches, $P=.03$) and a quarter as frequently in other breast reconstruction cases such as mastopexy (1 adjustment per 20 stitches vs 1 adjustment per 5 stitches, $P=.002$).

Conclusions: Operative Armour effectively functions as an ESIP device by decreasing intraoperative needle passing and handling. Although sample size prohibits demonstrating a decrease in NSIs during observed cases, by decreasing behaviors that drive NSI risk, we anticipate an associated decrease in NSIs with use of the device.

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KEYWORDS

needlestick injuries; sharps injuries; needles; safety; perioperative safety; intraoperative safety; quality improvement; case-control studies; tertiary care centers; plastic surgery; surgeons

Introduction

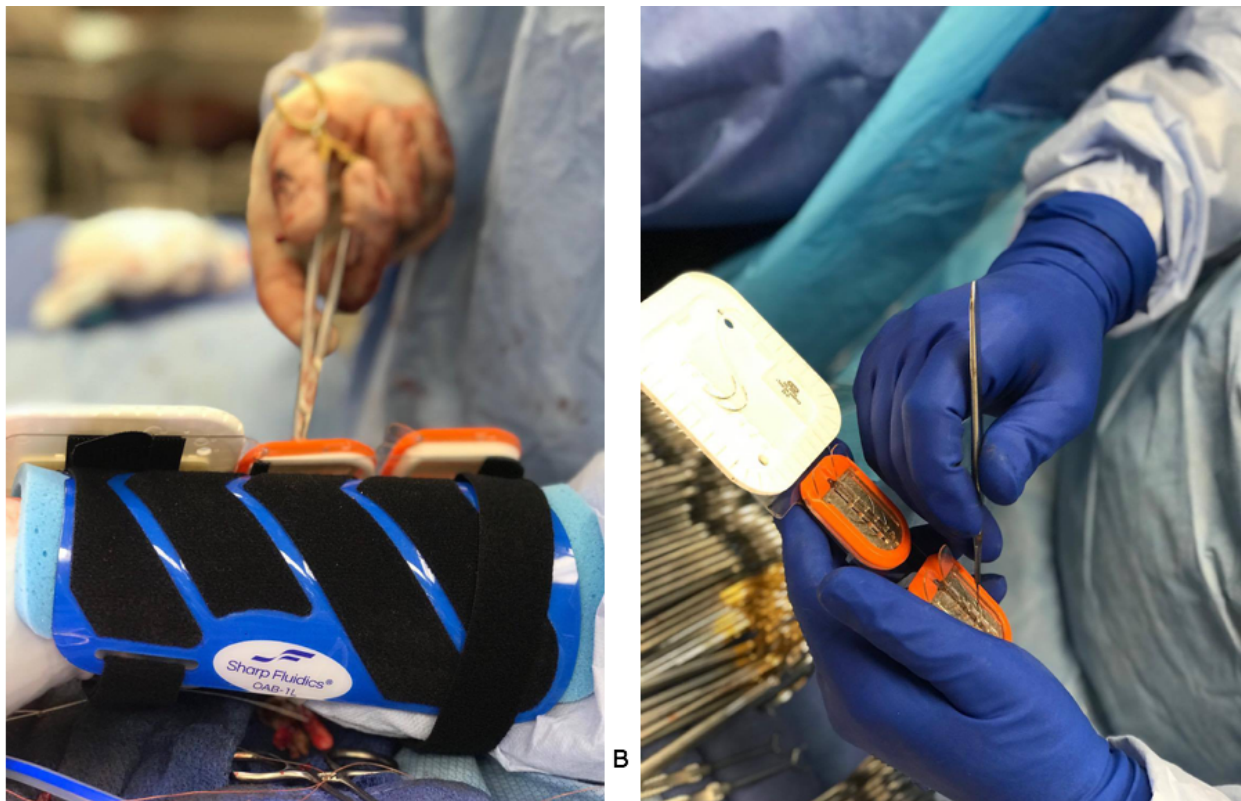
Needlestick injuries (NSIs) have been estimated to occur at a rate of 1.55% per surgeon per operation [1]. Other studies estimate that NSIs occur in 1.7% to 15% of all procedures [2], with the American College of Surgeons reporting 88,320 NSIs a year [3]. Surgeons or their first assistant are at the highest risk of injury, accounting for 59% of NSIs, followed by scrub personnel (19%), anesthesiologists (6%), and circulating nurses (6%) [2]. The most common cause of sharps injuries in surgeons are suture needles, of which over half occur during suturing of fascia or muscles [4]. Up to 16% of injuries have been found to occur while passing sharp instruments hand to hand [2]. These needle handoffs occur frequently in the operating room as needles are loaded by the scrub tech, passed off to the surgeon, and handed back to the tech once the stitch is thrown.

NSIs pose a significant health risk to employees. After NSI from an infected source, the risk of acquiring hepatitis B virus is between 2% to 40% [5], hepatitis C virus 3% to 10%, and HIV 0.2% to 0.5% [6]. In addition to the health risk these NSIs

present, they pose a significant financial burden: each NSI costs anywhere from US \$376 to US \$2456 for an estimated yearly national cost from US \$33 million to US \$2 billion [7]. Under these circumstances, there is a pressing need to reduce needlestick injuries, particularly in the surgical setting [8].

Operative Armour is a wearable arm cuff that allows surgeons to keep a suture pack and a sharps protection container on their forearm. The arm cuff is worn by the surgeon on their nondominant forearm, strapped on by adjustable Velcro. The surgeon positions a suture pack and the Operative Armour sharps protection container on the forearm cuff through adhesives and Velcro (Figure 1A). The surgeon is then able to use their needle driver to directly pick up needles from the cuff. The surgeon then stores the needle by sliding the needle into the sharps protection container, which features shelves that trap the unprotected needle. When the surgeons reload, the suture pack and sharps protection container are exchanged for a new set, allowing the scrub technician to perform the needle count with the returned Operative Armour sharps protection container (Figure 1B).

Figure 1. Operative Armour is a wearable arm cuff allowing the surgeon to reload and protect needles, reducing the number of handoffs between the surgeon and scrub technician. (A) The surgeon wears the arm cuff (blue), upon which the Operative Armour sharps container storage (orange) and any suture pack (white) can be placed using adhesives and Velcro. Here, the surgeon is sliding the needle into the storage container. (B) Following exchange of the needle pack, the scrub technician performs the needle count of the needles protected in the sharps storage container.



By allowing the surgeon to have the suture pack and needle storage container on their own forearm, passing unprotected needles between surgical technician and surgeon will no longer be needed. Needle handling is also decreased as the surgeon can load the needle themselves and does not need to protect the needle after suturing as it is no longer passed off to the surgical technician. We aim to characterize Operative Armour's effectiveness as an intraoperative sharps protection device in a

tertiary hospital, hypothesizing that this device will decrease NSI risk by decreasing behaviors associated with NSIs: needle passing and handling.

Methods

Study Design

A prospective case-control study was conducted with Johns Hopkins School of Medicine institutional review board quality improvement designation (IRB00207584, approved April 24, 2019) in which authors observed skin and soft tissue closures of plastic surgery procedures. Data were collected from August 1 to December 1, 2019. Cases were included if they were plastic surgery procedures with long closures (>10 cm total length) and multiple surgeons (2 or more). These surgeries included abdominal hernia repairs, panniculectomies, breast reconstruction with free tissue transfer, breast reconstruction with implants, and breast reductions and mastopexies for both macromastia and breast reconstructive purposes. To ensure accuracy, one surgeon was observed at a time.

Case/Control Grouping

Control surgeries were purely observational. Study outcomes were observed and noted without intervention. Case surgeries (intervention surgeries) involved surgeon donning and using Operative Armour during skin closure. For analysis, procedures were grouped into 3 cohorts: abdominal surgery (abdominal hernia repairs, panniculectomies), breast reconstruction (free tissue transfer or implant-based), and mastopexy/breast reduction or revision (mastopexies, reduction mammoplasties, and breast reconstruction revision procedures).

Outcomes

The primary outcome of interest was needle passing, which was defined as the needle being passed hand to hand between two people. Secondary outcomes included needle handling; needles that were dropped, temporarily misplaced, or permanently lost; loaded waiting needles; and needlestick injury occurrence. Needle handling was defined as surgeon hand contact with the needle. Dropped needles were dropped on the floor during any

part of the suturing process, either realized in the moment or later during count. Temporarily misplaced needles were needles that were temporarily absent from the needle count and caused significant search and recount efforts before they were found; these were typically either dropped or misplaced in a less visible area of the sterile field. Permanently lost needles were never found. Loaded waiting needles were defined as needles that were loaded on a needle driver with the sharp edge exposed, waiting to be used for suturing. The washout period during acclimation to the device was determined on a case by case basis, with the observer and surgeon coming to an agreement that the surgeon is acclimated and suturing with a similar speed and facility with Operative Armour as without. Cases were observed by nonscrubbed authors HJ, MLR, PY, and HX from within the operating room at a safe distance to maintain surgical field sterility. All observers were trained in outcome definition and key data points for observation and documentation.

Statistical Analysis

All statistical analyses were completed using Stata version 13 (StataCorp LLC). Schapiro-Wilk testing was used to determine normality of all continuous variables. Descriptive statistics by case type were calculated using analyses of variance and chi square analyses where appropriate. Multiple linear regression was used to analyze the impact of intervention (Operative Armour vs control) on the number of needle adjustments, after adjusting for surgeon and case-level covariates. The 2-tailed threshold for statistical significance was set at an alpha value of .05. The Bonferroni correction was used for multiple comparisons. Post hoc power analyses were completed using G*Power software (IDRE Statistical Consulting).

Results

Surgeon and Case Characteristics

In total, 4 attending surgeons and 13 surgical residents were observed in 50 control and 50 intervention cases (Table 1).

Table 1. Surgeon/case characteristics for control and Operative Armour groups.

Characteristic	Control (n=50)	Operative Armour (n=50)	P value
Case type, n (%)	N/A^a	N/A	.02
Abdominal surgery	11 (22)	8 (16)	N/A
Breast reconstruction	26 (52)	38 (76)	N/A
Surgeon level of training, n (%)	N/A	N/A	.27
PGY1-3 ^b	13 (26)	9 (18)	N/A
PGY4-6 ^c	30 (60)	8 (16)	N/A
Fellow	3 (6)	8 (16)	N/A
Attending	3 (6)	9 (18)	N/A
Other	1 (2)	1 (2)	N/A
# Surgeons at site, mean (SD)	1.6 (0.7)	1.7 (0.6)	.87
# Surgeons in case, mean (SD)	2.7 (0.7)	2.9 (0.9)	.38
Length of incision in centimeters, mean (SD)	29.1 (1.7)	33.3 (2.2)	.13
Right-handed, n (%)	50 (100)	47 (94)	.08

^aN/A: not applicable.

^bPGY 1-3: postgraduate year 1-3.

^cPGY4-6: postgraduate year 4-6.

While the distribution of case types differed significantly between control and intervention groups (Table 1, $P=.02$), breast reconstruction was the most frequent case type in both groups. All other surgeon and case characteristics, including surgeons' level of training, number of surgeons per case, number of surgeons at each surgical site during a case, and mean length of incision did not significantly differ between control and intervention groups. Most surgeons in both groups were right-handed (15/15, or 100% in the control group vs 15/16, or 94% in the Operative Armour group).

Control Versus Operative Armour Needle Use Outcomes

Across all 100 cases, 2234 needles were observed (1037 needles in control cases and 1197 needles in intervention cases). On average, users required 4.8 needles to acclimate to the use of Operative Armour (Table 2). The number of needles used per incision, stratified by case type, did not significantly differ between control and intervention groups.

Table 2. Needle use statistics for control and Operative Armour cohorts, stratified by case type.

Characteristic	Control (n=1037)	Operative Armour (n=1197)	P value
# Stitches for acclimation, mean (SD)	N/A ^a	4.8 (3.5)	N/A
# Stitches used per incision, mean (SD)	N/A	N/A	N/A
Abdominal surgery	21.3 (14.4)	20.8 (7.1)	.93
Breast reconstruction—breast site	20.1 (11.1)	24.4 (11.8)	.50
Breast reconstruction—donor site	44.4 (17.2)	44.6 (19.9)	.34
Mastopexy/breast revision	24.4 (11.8)	28.2 (9.1)	.54
# Passes per stitch, mean (SD)	2.0 (0.3)	0 (0)	<.001
Abdominal surgery	2.0 (0)	0 (0)	<.001
Breast reconstruction	2.0 (0.1)	0 (0)	<.001
Mastopexy/breast revision	2.1 (0.6)	0 (0)	<.001
# Needle adjustments per stitch, mean (SD)	0.2 (0.4)	0.1 (0.3)	.004
Abdominal surgery	0.1 (0.3)	0.1 (0.4)	.53
Breast reconstruction	0.2 (0.4)	0.1 (0.3)	.03
Mastopexy/breast revision	0.2 (0.4)	0.05 (0.2)	<.001
# Needles waiting, mean (SD)	2.3 (1.0)	0.2 (0.5)	<.001
Abdominal surgery	1.9 (0.8)	0 (0)	<.001
Breast reconstruction	2.7 (1.0)	0.2 (0.6)	<.001
Mastopexy/breast revision	1.7 (0.8)	0.2 (0.4)	<.001
Proportion of needles dropped, n/N (%)^b	4/1037 (0.4)	2/1197 (0.1)	.32
Abdominal surgery	0/234 (0)	0/207 (0)	>.99
Breast reconstruction	2/557 (10.4)	2/845 (0.2)	.34
Mastopexy/breast revision	2/246 (8.1)	0/145 (0)	.28
Proportion of needles temporarily misplaced, n/N (%)^b	8/1037 (0.8)	4/1197 (0.3)	.11
Abdominal surgery	1/234 (0.4)	0/207 (0)	.36
Breast reconstruction	4/557 (0.7)	2/845 (0.2)	.14
Mastopexy/breast revision	3/246 (1.2)	2/145 (1.4)	.87
Proportion of needles lost, n/N (%)^b	0/1037 (0)	1/1197 (0.1)	.87
Abdominal surgery	0/234 (0)	0/207 (0)	>.99
Breast reconstruction	0/557 (0)	0/845 (0)	>.99
Mastopexy/breast revision	0/246 (0)	1/145 (0.7)	.11
Proportion of needlesticks, n/N (%)^c	1/50 (2)	0/50 (0)	.36
Abdominal surgery	1/11 (9)	0/8 (0)	.38
Breast reconstruction	0/26 (0)	0/38 (0)	>.99
Mastopexy/breast revision	0/13 (0)	0/4 (0)	>.99

^aN/A: not applicable.

^bProportions reported out of total number of needles used.

^cProportion reported out of total number of cases.

Overall, Operative Armour led to significant decreases in the mean number of needle adjustments by hand per stitch (1 adjustment per every 5 stitches in control cases vs 1 adjustment per every 10 stitches in Operative Armour, or intervention, cases, $P=.004$). In fact, needle adjustments occurred half as

frequently with use of the device in free flap breast reconstruction cases (1 in 5 stitches in control vs 1 in 10 stitches with intervention, $P=.03$) and one-fourth as frequently for mastopexy/breast revision cases (1 in 5 stitches in control cases vs 1 in 20 stitches in Operative Armour cases, $P<.001$). A

multivariable linear regression established that intervention (Operative Armour) significantly decreased the number of needle adjustments by hand observed, after adjusting for surgeons' level of training and for case type ($F_{4, 21.68}=3.72$; 95% CI 1.82-5.98; $P=.01$).

Control Versus Operative Armour Needle Safety Outcomes

Use of Operative Armour eliminated needle passing during skin closure ($P<.001$ compared with control cases). The mean number of loaded and unprotected waiting needles per case was also significantly decreased in the Operative Armour group (2.3 needles in control cases vs 0.2 in intervention cases, $P<.001$). However, there was no significant difference in overall proportion of needles dropped (41/1037, or 0.4% in control vs 2/1197, or 0.1% with Operative Armour; $P=.32$), temporarily misplaced (8/1037, or 0.8% in control vs 4/1197, or 0.3% with Operative Armour; $P=.11$), and permanently lost (0/1037, or 0% in control vs 1/1197, or 0.1% with Operative Armour; $P=.87$). Out of all 100 cases, one Operative Armour case required an x-ray to locate a lost needle (not found in the patient) and one NSI occurred in a control case; both findings did not represent a significant difference between groups ($P=.36$ for both).

Post Hoc Power Analyses

Post hoc power analyses were conducted for all analyses. Based on the number of cases observed (50 control, 50 intervention) and the effect size with regard to needle use and safety observed between case and control study groups, we determined that our study had a power greater than 0.8 for all analyses conducted.

Discussion

Principal Findings

Observations of 50 control and 50 intervention surgeries using the Operative Armour device showed a significant decreased in the number of needle adjustments by hand with use of the device. Although no significant difference was seen in NSI incidence, the device eliminated needle passing during skin closure and decreased the number of loaded and unprotected waiting needles. No significant difference was observed in dropped, temporarily misplaced, or lost needles.

NSIs pose a significant occupational health risk over the course of a surgeon's career. Given the potential for a needlestick to transmit an infectious blood borne disease such as HIV, in 2000, the Needlestick Safety and Prevention Act was signed into law, which required the US Occupational Safety and Health Administration to revise their Bloodborne Pathogens Standard to include additional requirements to prevent NSIs [9]. Under this revised standard, employers are required to identify and use engineered sharps injury prevention (ESIP) devices or devices that are engineered to have a higher level of safety [10-12]. As needlesticks are inversely related to experience and age, teaching hospitals have a particular responsibility to adopt devices and programs that may help prevent these occupational injuries [10,13].

Previously attempted tactics to decrease NSIs include double gloving [14] and creating a neutral zone on the surgical field in which sharps are placed, eliminating the direct hand-to-hand technique [15]. However, having contaminated needles on the field still elevates the risk of NSIs. Hitchhiker sharps, in which needles hitchhike with other instruments or materials (such as gauze), can still injure an unknowing party, even when left in a neutral zone [1]. Additionally, in cases in which there are multiple operative sites and numerous surgeons, it is challenging to identify an appropriate neutral zone location that is accessible for both scrub techs and surgeons. It is therefore unsurprising that although it is common practice to double glove, many institutions do not regularly employ any additional needlestick prevention protocols.

Safety-engineered devices are designed to improve safe handling of sharps by incorporating a built-in protection mechanism. Safety-engineered devices are used predominantly in nonsurgical settings and have been found to have mixed efficacy in reducing NSIs, with some studies finding that safety-engineered devices actually increase risk of these injuries [16,17]. In fact, a Cochrane review analyzing 24 studies investigating devices for preventing NSIs in nonsurgical settings reported uniformly low-quality evidence with inconsistent results [18]. ESIP devices are a class of safety-engineered devices that provide mechanical protection from sharp injuries. However, there are currently no studies to demonstrate the effectiveness of intraoperative ESIP devices in preventing needlestick or sharps injuries. Consequently, there is a need for more high-quality, controlled studies, especially in surgical settings.

To our knowledge, this study is the first to date to study and demonstrate clinical effectiveness of a wearable intraoperative ESIP device. First, although not significantly different, the only NSI that occurred during the conduction of this trial occurred during a control case. Second, as Operative Armour was not associated with any difference in dropped, temporarily misplaced, or lost needles, the device demonstrates noninferiority compared with current practices. Third, by minimizing sharps behaviors that drive NSIs such as the manipulation, handling, and passing of intraoperative sharps, Operative Armour demonstrates superiority over current practice in the potential to significantly decrease sharps injuries. Therefore, Operative Armour functions effectively as an intraoperative ESIP device.

In addition to efficacy, ease of device incorporation is also critical to assess for any new device. The attendings and residents involved in the study were initially given a training session outside of the operating room in which they were taught how to wear the device and secure needles within the holder. Each surgeon's intraoperative acclimation period was also observed and averaged fewer than 5 needles, indicating surgeons were able to efficiently adjust to the device during the first case of its use. Interestingly, surgeons with more years of operative experience (eg, chief residents, fellows, and attendings) typically required a longer period of time to acclimate to the device when compared with younger surgeons (eg, junior residents). This could potentially represent the concept of conscious versus unconscious competence—as younger surgeons are still honing their basic technical suturing skills, they are likely more

consciously competent during the conduction of these tasks. However, more experienced surgeons are unconsciously competent with skin closure, so introducing a new device may have required a temporary shift back to more mindful suturing practices.

In addition to the device's impact on needlestick risk, it may also have the potential to improve operative efficiency by introducing parallel processing in which two or more separate processes are conducted simultaneously rather than in series [19-22]. When the surgery team is closing the wound at the end of a surgical case, the scrub tech and circulator nurse are usually kept occupied making sure the surgeons have the sutures and dressings needed to finish the case, including loading and unloading the needle driver each time a surgeon needs a new suture. Often, it is not until the surgery is finished that the scrub tech and circulator can do their final count and begin breaking down the room. However, if the scrub tech and circulator were free to do those tasks while the surgeon is closing independently, those processes could therefore be conducted in parallel. Operative Armour may have the potential to facilitate this parallel processing by allowing the surgeon to manage their own sutures. When the surgeon is ready to close, the scrub tech can give the self-service device to the surgeon and then begin the final count as the surgeon has all the equipment needed to finish the case. Future studies could therefore look at the effect of Operative Armour on operative efficiency, ideally through the use of paired time measurements of same-surgeon same-facility closure times with and without the device, as well as overall turnover time. This analysis would in turn enable a more accurate cost/benefit ratio analysis of this device. Included procedures used an average of two Operative Armour barrier kits (US \$130 each, including 1 barrier arm band and 6 needle holder pieces) for a total of US \$260 per case. Future research may determine whether Operative Armour affects the financial considerations associated with operative efficiency, as well as costs associated with NSIs.

Limitations

This study has a few limitations. First, due to the setting in an academic environment, the teams of circulator and scrub tech frequently varied. Although staff was typically familiar with plastic surgery cases, more familiarity with the device due to consistent staffing may have further affected needle handling and use of the device. As the trainees studied also moved on or off this service throughout the 4 months of observation, we were unable to do paired measurements of same-surgeon closure times with and without the device. However, as trainees in academic environments experience a higher risk for NSIs, this was the environment we were most interested in investigating. Last, although we were able to find statistically significant differences in behaviors that increase NSI risk, we were not powered to find a difference in NSIs due to the rarity of these occurrences.

This study is the first clinical review of an ESIP device to prevent NSIs in the operating room. By addressing needle passing and handling—key contributors to intraoperative NSIs—Operative Armour has the potential to decrease the risk of NSIs for both surgeons and perioperative staff. These findings are especially important for academic teaching hospitals to consider as younger practitioners are at the highest risk for NSIs. Further research may be done to identify the impact of this device on operative efficiency as well.

Conclusions

Operative Armour effectively functions as an ESIP device by decreasing intraoperative needle passing and handling. Although sample size prohibits demonstrating a decrease in NSIs during observed cases, by decreasing behaviors that drive NSI risk, we anticipate an associated decrease in NSIs with use of the device. By decreasing these injuries, we can safeguard the health of health care workers at all levels, from attending to nurse to medical student.

Acknowledgments

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Authors' Contributions

HJ, RR, RY, and JS designed the study, and HJ and MR obtained institutional review board approval. HJ, MR, PY, and HX collected all data. HJ and PY analyzed the data, and HJ, PY, and HX wrote the first manuscript draft. All authors contributed to editing and manuscript revisions to compose the final published manuscript.

Conflicts of Interest

HJ served as a consultant for Sharp Fluidics and received partial salary support from Sharp Fluidics for time spent on this study. JS is a cofounder of LifeSprout.

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Abbreviations

ESIP: engineered sharps injury prevention

NSI: needlestick injury

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