Prosthetic joint infections: new diagnostic and therapeutic strategies
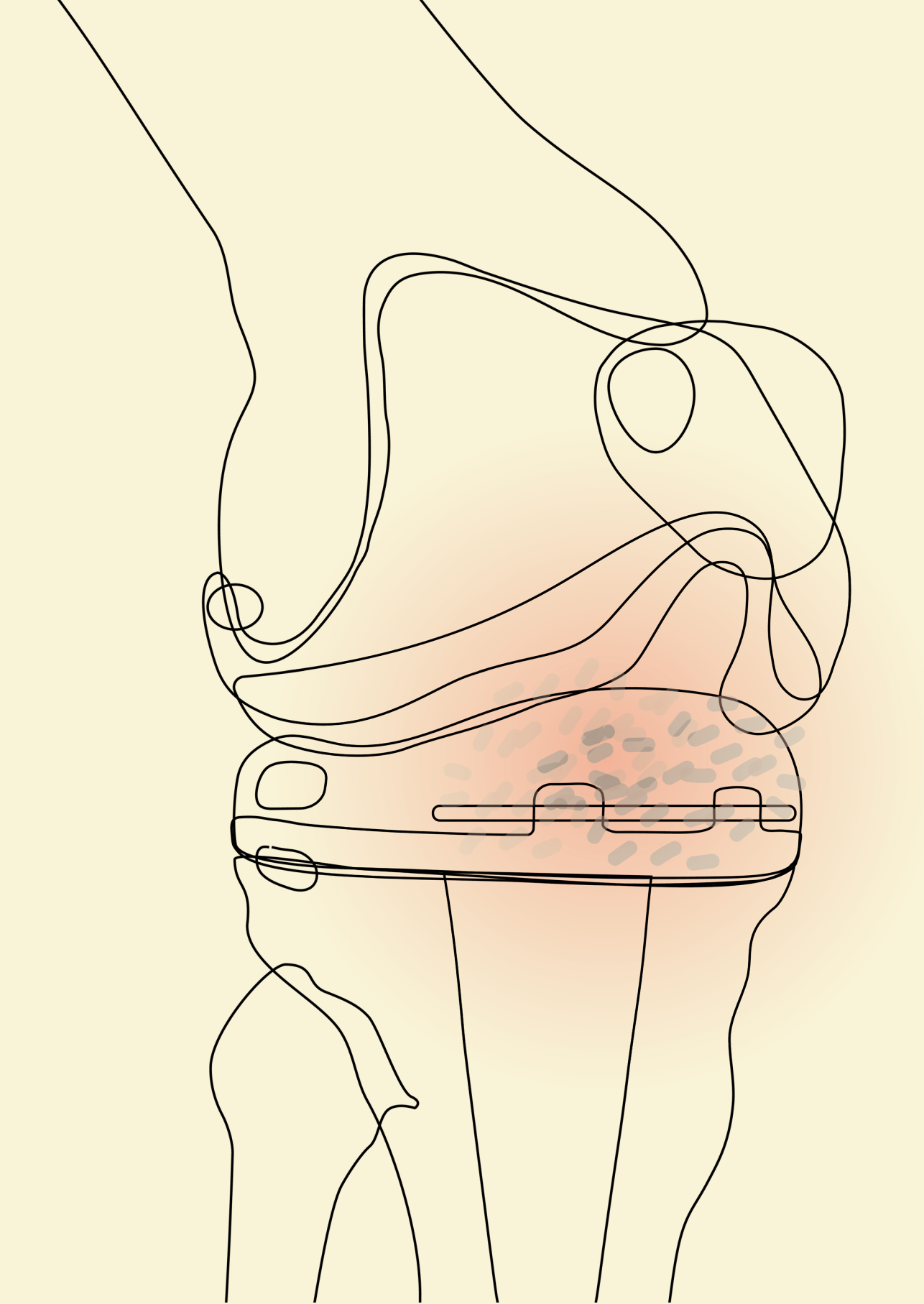
Scheper, H.

Part I. The use of E-health to detect prosthetic joint infections

CHAPTER 2

A mobile app for postoperative wound care after arthroplasty: ease of use and perceived usefulness

Henk Scheper, Roxanne Derogee. Rachid Mahdad, Robert J.P. van der Wal, Rob G.H.H. Nelissen, Leo G. Visser, Mark G.J. de Boer

Abstract

Background
Early postoperative discharge after joint arthroplasty may lead to decreased wound monitoring. A mobile woundcare app with an integrated algorithm to detect complications may lead to improved monitoring and earlier treatment of complications. In this study, the ease of use and perceived usefulness of such a mobile app was investigated.

Objective
Primary objective was to investigate the ease of use and perceived usefulness of using a woundcare app. Secondary objectives were the number of alerts created, the amount of days the app was actually used and patient-reported wound infection.

Methods
Patients that received a joint arthroplasty were enrolled in a prospective cohort study. During 30 postoperative days, patients scored their surgical wound by daily answering of questions in the app. An inbuilt algorithm advised patients to contact their treating physician if needed. On day 15 and day 30, additional questionnaires in the app investigated ease of use and perceived usefulness.

Results
Sixty-nine patients were included. Median age was 68 years. Forty-one patients (59.4%) used the app until day 30. Mean grade for ease of use (on a Likert-scale of 1 to 5) were 4.2 on day 15 and 4.2 on day 30; grades for perceived usefulness were 4.1 on day 15 and 4.0 on day 30. Out of 1317 days of app use, an alert was sent to patients on 29 days (2.2%). Concordance between patient-reported outcome and physician-reported outcome was 80%.

Conclusions
Introduction of a woundcare app with an alert communication on possible wound problems resulted in a high perceived usefulness and ease of use. Future studies will focus on validation of the algorithm and the association between postoperative wound leakage and the incidence of prosthetic joint infection.

Introduction

A prosthetic joint infection (PJI) is a feared complication for patients with a total joint arthroplasty. The reported incidence of PJIs ranges between 0.5-1.0% and 0.5-2.0% for hip and knee arthroplasty, respectively. This incidence is largely underestimated due to inadequate registration of infections[1]. Inadequate treatment of wound complications results in hospital readmission, revision surgery, long term antibiotic treatment and, in the worst case, removal of the prosthesis[2]. In The Netherlands, most patients are discharged the first or second postoperative day after arthroplasty, which is associated with faster functional recovery and lower costs[3]. Consequently, patients are responsible for monitoring their post-operative wound at home. This put them at risk for a delayed diagnosis of wound infections. This delay may lead to chronic PJI with extensive revision surgery with removal of the implant[4].

A mobile woundcare app used by patients after joint arthroplasty underscores the importance of adequate wound monitoring. Daily revision of the wound by patients may lead to improved monitoring, increased awareness for complications and, consequently, earlier consultation of the treating physician. There is evidence for distant postdischarge monitoring of postoperative patients. Reports have shown that post-operative telephone review is cost-effective and acceptable for patients with no underreporting of complications[5,6]. Another report showed a significant reduction in unnecessary emergency room visits by using email with smartphone photography in post-hypospadia patients[7]. The use of smartphones for monitoring recovery in post-operative patients at home has been shown to be feasible and acceptable to patients and surgeons, although patients were concerned about the lack of timely responses from healthcare[8,10]. To the best of our knowledge, no studies have been performed yet in which a mobile woundcare app was used with an integrated alert system for patients when to contact their physician. We hypothesized that a mobile woundcare app after joint implantation is useful for patients. We hypothesized that using such an app may lead to increased patient involvement, early detection of wound problems and prevention of chronic PJI[9]. In this prospective study we investigated the ease of use and perceived usefulness of using such a mobile woundcare app in patients after joint arthroplasty.

Methods

All patients having a primary or revision total joint arthroplasty during the period July to December 2017 were eligible for participation in a prospective cohort study conducted at an academic hospital (Leiden University Medical Center) and a large regional teaching hospital (Alrijne Hospital). The primary objective was to investigate the ease of use and the patient's perceived usefulness of the woundcare app. Secondary objectives were the number of alerts, the number of calls to the treating physician during the study period, the amount of days the app was actually used, patient-reported wound infection and the concordance between patient-reported outcome and physician-reported outcome. The study was approved by the institutional Medical Ethical Committee (protocol nr. P17.091).

All patients scheduled for total joint arthroplasty were asked to participate during their hospital admission. Inclusion criteria were at least 18 years old, able to provide written informed consent and ownership of an android or iOS 9.0-or newer smartphone. Informed consent was obtained by the study coordinator who also guided each patient with downloading of the app. Instructions were given to patients how to use the app and how to fill in the daily review tasks. The study coordinator was available for the first 2-3 postoperative days for practical assistance and could be called during the study if needed. People who were unable to understand or read Dutch were excluded. After 30 days, patient files were reviewed to check for concordance between patient-reported and physician-reported outcome with respect to wound complications. All patients were seen in the outpatient clinic two and six weeks postoperatively. Clinicians were instructed about the underlying algorithm in the app and the alert system that could prompt patients to call them. It was left to the judgment of the treating clinicians to decide whether patients needed a clinical review or that a telephonic review was sufficient. The nurses on the ward were instructed about postoperative use of the app so they could help patients with filling in. Statistical analysis was done using SPSS (IBM SPSS Statistics version 24.0, Armonk, USA).

Mobile woundcare app
A woundcare app (figure 1) was developed by a digital innovation company (Innovattic, Delft, The Netherlands) with intellectual input from the authors.

All data entered in the app were pseudonomised and stored on a local ISO 27001 certified data management server at the coordinating hospital. A key for disclosure was stored on a local data safety folder. The app consisted of an introductory page collecting basic patient characteristics followed by daily short questionnaires regarding the patient's wound. Patients recorded redness, pain (by visual analogue score, VAS), wound leakage, fever and a picture of the wound could be taken (Appendix 1). After 30 days, the patient-

reported outcome was scored by the patient (i.e. PJI). Based on the daily questionnaires, an algorithm created daily a risk-score. A threshold score, developed by consensus meetings of the authors (HS, MB, RG, LV) defined above which the wound was thought to be at risk for being infected (Appendix 2). If the score exceeded this threshold, an alert message on the smartphone advised patients to contact their treating physician within 24 hours. The orthopaedic ward could be called directly via a push button in the app. Prior to the study, caregivers were instructed to register every contact in the electronic patient files. Apart from using the app, postoperative wound care did not differ between study participants and patients who were not included.
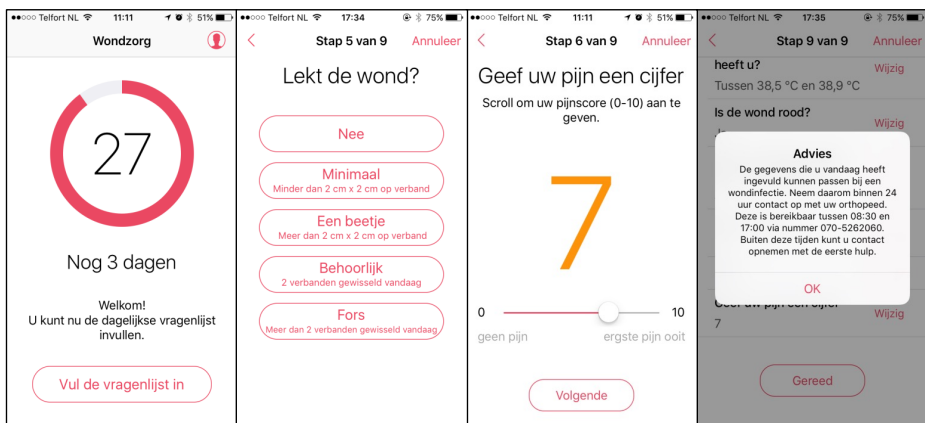
Figure 1. Screenshots of the woundcare app (with Dutch language)

English translation. Screen 1: Woundcare. Three days to go. You can now fill in the daily questionnaire. Screen 2: Does the wound leak? No, minimal (less then 2x2cm on the bandage), a little (more than 2x2cm on the bandage), fair (exchange of two bandages), strong (exchange of more than two bandages). Screen 3: Give your pain a score (Visual Analogue score 0-10). Screen 4. Advice: Your scores of today may fit with a wound complication. We advise you to contact your orthopaedic surgeon within 24 hours or (if out-of-office hours) with the emergency department

Ease of use and perceived usefulness

The questionnaires that were used to test for perceived usefulness and ease of use (Likert scale) were adapted from questionnaires that were developed for user acceptance of information technology[10] (Appendix 3). The app provided a link to the online questionnaires on day 15 and day 30 of the study. Additionally, patients received a reminder for the questionnaire by email. Responses followed a 5-point Likert scale from "strongly agree" to "strongly disagree." Results of day 15 and day 30 were compared for both questionnaires with a paired-samples T test. Patients who did not manage to fill in one of the questionnaires were contacted by telephone after 30 days to grade the app and to explore the reasons for not filling in the questionnaire.

Results

Of 127 eligible patients, thirty patients (24%) did not own a smartphone. Of the remaining 97 patients, 69 patients (71%) were included (Figure 1).
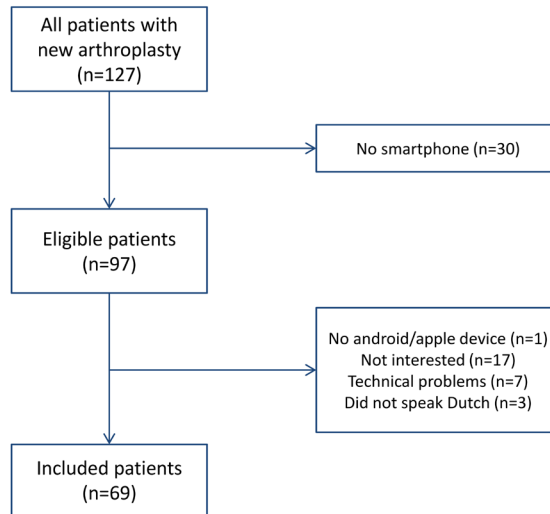
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        ┌─────────────────┐
        │  All patients with │
        │  new arthroplasty  │
        │     (n=127)        │
        └─────────────────┘
                 │                    ┌─────────────────────────┐
                 ├───────────────────▶│  No smartphone (n=30)   │
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        ┌─────────────────┐
        │ Eligible patients │
        │     (n=97)        │
        └─────────────────┘
                 │                    ┌──────────────────────────────────┐
                 │                    │ No android/apple device (n=1)     │
                 ├───────────────────▶│ Not interested (n=17)             │
                 │                    │ Technical problems (n=7)          │
                 │                    │ Did not speak Dutch (n=3)          │
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        ┌─────────────────┐
        │ Included patients │
        │     (n=69)        │
        └─────────────────┘
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Figure 2. Selection and inclusion of patients.

Baseline characteristics of the included patients are shown in Table 1.

Table 1. Baseline characteristics of 69 patients who used the Woundcare app

Age (median, range)	68 (33-90)
Female/Male	46/23
University Medical Center (n)	19 (28%)
Regional hospital (n)	50 (72%)
Operating System Mobile Device	
iOS (n, %)	33 (48%)
Android (n, %)	36 (52%)
Joint arthroplasty	
Hip	32 (46%)
Knee	37 (54%)
Past medical history	
Diabetes mellitus	9 (13%)
Rheumatoid arthritis	8 (12%)
Megaprosthesis	2 (3%)

The median age was 68 years (range 33-90). Forty-one patients (59.4%) used the app until day 30. Nine patients (13.0%) stopped using the app immediately after the first or the second day of use. On average, the app was used by 43 patients per day. In total, the app was used on 1317 postoperative days (64% of the total amount of 30 postoperative days in 69 patients). The overall amount of responses tended to decline slowly over time (Figure 3).
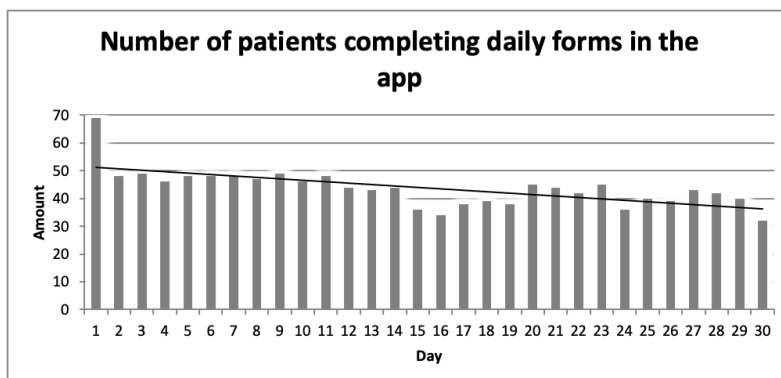
Figure 3. Number of patients completing daily forms in the app.

Perceived ease of use and perceived usefulness
The additional questionnaires about ease of use and usefulness were filled in by 31 patients (44.9%) on day 15 and by 37 patients (53.6%) on day 30. Fifteen patients (21.7%) filled in both questionnaires. The mean score for ease of use at day 15 was 4.2 (on a scale of 1 to 5) and 4.1 for perceived usefulness (Figure 4 and 5).

Figure 4. Patient-reported ease of use on day 15 and day 30

Mean scores (range)^	Day 15 (n=31) Mean (range)	Day 30 (n=37) Mean (range)
Daily entry is easy	4.7 (3-5)	4.5 (4-5)
Questions are understandable	4.7 (4-5)	4.5 (4.5)
Size of text is right	4.6 (4-5)	4.4 (4.5)
App takes little time	4.3 (1-5)	4.4 (2-5)
Alerts are understandable*	4.3 (3-5)	3.9 (3.5)
Easy to fill in every day	4.2 (2-5)	4.1 (2-5)
Help the first day is useful	3.1 (1-5)	3.6 (1-5)
Questions easy to understand	4.5 (4-5)	4.5 (3.5)
App looks good	3.8 (2-5)	3.9 (3-5)
Daily reminder is useful	4.0 (1-5)	3.8 (1-5)
App is easy to use	4.4 (2-5)	4.3 (3-5)

*16 patients scored 'not applicable'

^Scores: 1. strongly disagree, 2. disagree , 3. neutral, 4. agree , 5. strongly agree

Figure 5. Patient-reported perceived usefulness on day 15 and day 30

Mean scores (range)^	Day 15 (n=31)	Day 30 (n=37)
	Mean (range)	Mean (range)
Using app feels safe	4.2 (2-5)	4.1 (3-5)
Feels more engaged with app	4.0 (3-5)	3.9 (3-5)
Feels more responsible for recovery	3.7 (2-5)	3.8 (1-5)
Feels more engaged with hospital	3.8 (3-5)	3.7 (2-5)
Clear why app has been used	4.2 (3-5)	4.2 (4-5)
Feels more in control of wound	3.8 (2-5)	3.8 (2-5)
App is useful	4.3 (3-5)	4.2 (3-5)
App does not give stress	4.5 (3-5)	4.4 (3-5)
Sensible to fill in every day	4.1 (2-5)	4.0 (1-5)
Alerts are useful	4.1 (2-5)	4.2 (2-5)
Recommend app	4.4 (2-5)	4.2 (3-5)
Hospital took calls seriously*	3.7 (3-5)	3.6 (3-5)

* 16 patients scored 'not applicable'

^Scores: 1. strongly disagree, 2. disagree , 3. neutral, 4. agree , 5. strongly agree

The scores on day 30 were comparable to day 15 for ease of use (score 4.2, p=0.43) and perceived usefulness (score 4.0, p=0.40). The average satisfaction with the app at day 15 was 8.2 (on a scale of 1 to 10; range 6 to 10). Sixteen patients (23%) who did not fill in a questionnaire at all were contacted by telephone, to have information on user-friendliness or hick-ups when using the app. Eight of them could be reached and were interviewed with predefined questions. The mean satisfaction-score of the app among them was 7.9 (range 7-10). The majority of these patients had stopped using the app prior to reaching the day of the questionnaire (day 15). Reasons for discontinuation were malfunction of the smartphone (n=1), the app had stopped giving reminders (n=2) or patients had forgotten to fill in the app (n=6).

Alerts
An alert was sent to patients on 29 (2.2%) of the 1317 days the app was used. Ten alerts were sent because the score exceeded 5 points, three alerts because the score exceeded four points on two consecutive days and 16 alerts because the score exceeded three points on three consecutive days (see also Appendix 2). Thirteen patients responded on the question of the online questionnaire specifically asking if the hospital took their calls, based on alerts, seriously (score 3.7 on day 15 and 3.6 on day 30, figure 4). No single record of patient calls was found in the electronic patient files. Also, it appeared that in the iOS version of the app there was a technical flaw in the algorithm resulting in only sending alerts when the score exceeded five points. Due to this flaw, 28 out of 57 alerts were not sent to the patient.

Postoperative course

Forty-one patients filled in the outcome score on complications on day 30. Concordance of patient-reported and physician-reported outcome was reached in 33 patients (80%) (Table 2).

Table 2. Concordance between patient-reported and physician-reported outcome in 41 patients who used the app until day 30

		Physician-reported outcome			
		I don't know	No infection	Suspicion PJI	PJI
	I don't know	0	7	0	0
Patient-reported outcome	No infection	0	33	0	0
	Suspicion PJI	0	0	0	1
	PJI	0	0	0	0

Discordance occurred in seven patients who did not have a complication, but scored "I don't know" as outcome. The only patient (1.5%) in our study that developed a PJI on day 30 scored a "suspected PJI, but appeared to be no infection".

One patient (1.5%) had revision surgery because of repeated dislocations of the hip joint. Two patients (2.9%) developed a deep venous thrombosis of the leg. Four patients (5.8%) reported a temperature >38.0°C at least once during the 30 day postoperative period. Postoperative wound leakage was reported by thirty-seven patients (53.6%); the majority of the patients reported this on the second and third postoperative day (Figure 6).
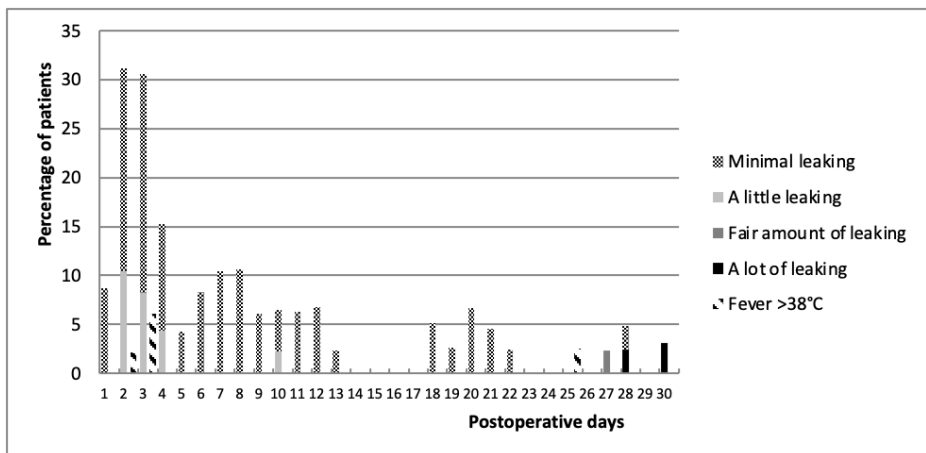

Figure 6. Proportion of patient-reported amount of wound leakage and fever (>38.0°C).

Wound leakage duration was present during a mean 2.2 days (range 1 to 11). From day 18 onwards, five patients reported new wound leakage for one to five days. The leakage reported in the fourth postoperative week corresponded with the patient who developed a prosthetic joint infection. This patient scored an unchanged wound for four weeks and leakage and fever since one day before admission with a PJI.

Discussion

We found that introduction of a mobile woundcare app resulted in a high perceived usefulness and ease of use. Patients felt engaged with their health and with the care provided by the hospital. This involvement was consistent during the use of the app. The number of patients completing daily forms in the app declined only mildly, confirming patient engagement with their own woundcare.

Clinical applications of mobile e-health by patients can be a valuable tool in health care management. With the increasing use of medical apps, it is important to develop e-tools that support patients and clinicians in improving health care. The high inclusion rate in this study stresses patient willingness to use mobile apps for postoperative wound monitoring. This is in line with recent surveys showing that using an app for surgical wound monitoring, including taking digital wound photographs, is supported by most patients[11,12]. Of all eligible patients aged 65 years or more, smartphone ownership in this study was 76%. Most likely, this will increase over the next years resulting in more patients who may benefit from medical apps.

In our woundcare app postoperative follow up care by patients themselves is integrated with an (wound)risk assessment that supports the patient when to contact their physician. Other studies have suggested that the use of mobile e-health led to more engagement of patients with their treatment[13-15]. Importantly, negative experiences might arise when daily asked to monitor a postoperative wound; however, these were not reported by patients. The response rate for the questionnaires on day 15 and 30 of only 77% might introduce a selection bias with skewed positive responses. Therefore, patients who did not fill in a questionnaire were interviewed later by telephone and, using the same grading system, those non-responders showed comparable high satisfaction rates as responders.

Cost-effectiveness
If postoperative infections can be treated at an earlier stage, devastating chronic PJI can be prevented. The costs of revision surgery for one patient (estimated costs around

30.000 euro) are about the same as the costs for the development of this app[16]. The app may be cost-effective by preventing diagnostic delay but larger studies need to be done to show cost-effectiveness. The app worked well for the only patient who developed a PJI; this patient scored eight points on the day of admission (score based on heavy leakage and a high pain score). She had not used the app on the day prior to admission; two days before admission her score was four. Good compliance is needed in order to really benefit from the app. Of all included patients, 59% used the app as intended until day 30. One of the main - understandable - reasons for discontinuation was that patients deemed further use of the App irrelevant, since their postoperative recovery went uneventful. For these patients, further use of the app would obviously not have resulted in improved clinical outcome.

Patient-reported and physician-reported outcome
Concordance between patient-reported and physician-reported outcome on wound healing is important in order to estimate the accuracy of patients to determine their own diagnosis. The discordance rate of 20% in this study is probably secondary to outcome options that were not presented clearly in the app. The 'I don't know' category (table 2) was too vague in hindsight and will be omitted in the next version of the app. We estimate that, when adjusting the options in the app, the concordance comes close to 100%, but reliable estimation of concordance can only be addressed in a larger study.

One of the objectives of this study was to determine the number of alerts that led to a call to the treating physician resulting in a change in treatment. The one patient that developed a PJI did receive an alert and was admitted to the hospital on the same day. Although physicians were instructed to report all app-based phone calls by patients in the electronic patient files, this apparently did not happen. This can partly be explained by the reduced number of alerts (due to the technical problems) but also by underreporting. The technical problems underscore the importance of pilot studies like this to find and resolve these issues. Visual integration of all app data into patient's electronic files may lead to improved registration, as this supports physicians to interpret a clinical situation more accurate when called by their patients. Currently, real-life visual integration of the clinical data of the app in the electronic patient files is implemented in our hospital.

Scoring system for wound infection
As far as we know, there is no validated grading system to score a postoperative wound. A systematic review of surgical infection scoring systems found one scoring system for postoperative sternal wounds, but this was developed for scoring by physicians and not suited for patient monitoring[17]. We developed a grading system based on the classical criteria for wound infection after arthroplasty (pain, fever, leakage, redness) that is easy

to use for patients (Appendix 2). To avoid false-negative results the threshold for sending an alert was put low, resulting in alerts in ten individual patients, while only one patient developed a PJI. Most of these alerts were based on a high VAS score; for these patients a mobile app may lower the threshold tot contact the treating physician to optimise their pain medication.

Wound leakage and infection
Currently, the importance of postoperative wound leakage as risk factor for PJI is largely unknown[16]. Differentiation between wound leakage as being part of normal postoperative course or being a symptom of a PJI is essential. Maathuis et al. reported that 10% of all wound leakages resulted in a PJI (unpublished results). Currently, a multicenter study on the treatment of postoperative wound leakage in elective hip and knee arthroplasty is done[16]. Immediate extensive surgical debridement is the cornerstone of treatment for an acute PJI but if done unnecessary it exposes patients to an additional risk for infection. Many patients in this study (59.4%) reported postoperative wound leakage, the majority on the second and third postoperative day. The true incidence of wound leakage may be higher, since not all patients completed the app every day. The recurrence of leakage on day 18 in five patients might be explained by easier wound monitoring after removal of the plaster at two weeks postoperative. This study was not powered for finding an association between the length and severity of wound leakage and a postoperative PJI. This association should be addressed in a large cohort study. A causal relationship would underscore the need for strict wound monitoring for which postoperative wound care with this app may have an additional value.

Funding

Acknowledgments

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Appendix A.

Daily reviews to be filled in by patient in Woundcare App

Questions	Response options
Do you have a fever?	yes/no/not measured
How high is your fever?	<37.5 ℃/37.5-37.9/38-38.4/38.5-38.9/ >39
Is the wound red?	yes/no/not judgeable
How is the redness compared to yesterday?	more red/less red/unchanged/not judgeable
Is the wound leaking?	no/ minimal (<2x2cm on dressing)/ a little (>2x2cm on dressing)/ fairly (2 dressing changes today)/ a lot (>2 dressing changes today)
Give your pain a number. (VAS score)	0-10

Questionnaires at day 30

Question	Response options
What was the date of discharge?	date
Have you had another surgery?	Yes/no
When did you have another surgery?	date
Did you receive antibiotics?	Yes/no
Which antibiotics did you receive?	
What was the diagnosis?	No infection / Superficial infection (Spontaneous recovery) / Superficial infection (Recovery with antibiotics) / PJI (operation and antibiotics received) / Suspected PJI (operation proved otherwise) / I don't know
Did you answer the previous question with your physician?	Yes/no

Appendix B.

Underlying algorithm in woundcare App in order to send alerts to patients with a possible postoperative complication

Question	Answer options	Points
Do you have a fever?	T > 38.5	5
	T 38-38.5	2
	T>2 days T 38-38.5	5
	T<38	0
Is the wound leaking?	No	0
	Minimal	1
	A little	2
	Fairly	3
	A lot	4
Is de wound red?	More red than day before	2
VAS score	VAS >7	4
	VAS 6 or 7	3
	VAS ≤ 5	0
	VAS > 2pts compared to day before	3
	When >3 days VAS>3	3
	Total amount of points:	

Woundcare App calculates amount of points per day:

· If score ≥ 5 points: an alert will appear on the smartphone: "the symptoms that you filled in on your app today might fit with a wound problem. We advise you to consult your orthopaedist within 24 hours."

· If for ≥ 2 consecutive days 4 points: same alert message on smartphone

· If for ≥3 consecutive days 3 points : same alert message on smartphone

· If none of above mentioned points: message: "thank you for using the app today, You can use the app tomorrow again."

Appendix C.

Questionnaires perceived ease of use and perceived usefulness

Perceived ease of use-questionnaire

1. Filling in the daily form of the App is easy for me
2. The questions are understandable
3. The sizing of the text in the App is right
4. Filling in the daily form takes a lot of time
5. If I received the advice to call my physician, it was clear to me what I had to do
6. I find it difficult to keep filling in the daily form
7. It is good to receive help with filling in the app on the first day
8. The questions in the App are difficult to understand
9. The design, in other words the look of the App is attractive
10. The daily reminder to fill in the App is useful
11. The use of the App is easy

Strongly disagree / disagree / neutral / agree / strongly agree

(answers question 5: Strongly disagree / disagree / neutral / agree / strongly agree / Does not apply)

Perceived usefulness -questionnaire

1. It feels safe to use this App to monitor my wound
2. I feel more involved in my woundcare by using the App
3. I feel more responsible for my own wound by using the App
4. I feel more involved with the hospital by using the App
5. It is clear to me why I need to use the App
6. Using the App makes me feel more in control of the wound
7. I think the Woundcare App is useful
8. Using the App makes me feel stressed
9. I think it is useless to fill in the daily forms every day
10. I think it's useful to get the advice to call the hospital at certain scores
11. I would recommend the App to others
12. I was taken seriously when the App advised me to call the hospital

Strongly disagree / disagree / neutral / agree / strongly agree

(answers question 12: Strongly disagree / disagree / neutral / agree / strongly agree / Does not apply)

What grade do you give the App?
(1 = very bad, 10 = very good)
1 2 3 4 5 6 7 8 9 10

Open question: What could be improved in the App according to you?