Journal of Tissue Viability 34 (2025) 100889

Contents lists available at ScienceDirect

Journal of Tissue Viability

journal homepage: www.elsevier.com/locate/jtv

Modification and validation of the Bluebelle Wound Healing Questionnaire (WHQ) for assessing surgical site infection in wounds healing by secondary intention

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https://doi.org/10.1016/j.jtv.2025.100889
Received 9 August 2024; Received in revised form 25 February 2025; Accepted 14 March 2025
Available online 18 March 2025

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ARTICLE INFO

Keywords:
Surgical site infection
Wound assessment
Secondary intention healing
Surgical wounds
Patient reported outcome (PRO)

ABSTRACT

Background: Surgical wounds healing by secondary intention are common. Healing is often complicated by surgical site infection (SSI). SSI assessment is important to guide treatment but existing methods generally require in-person assessment, making them resource intensive. A validated patient-reported SSI outcome measure may be useful to overcome this limitation.
Aim: To modify and validate the Bluebelle Wound Healing Questionnaire (WHQ) for wounds healing by secondary intention.
Methods: The 18-item Bluebelle WHQ developed for wounds healing by primary intention was modified to make it applicable to secondary healing wounds. Testing was performed as part of the SWHSI-2 randomised trial assessing negative pressure wound dressings versus standard care. Participants completed the WHQ at five timepoints; in-person (baseline, post-healing) and by post (3, 6, 12 months). A reference SSI assessment was performed by a research nurse at the time of wound healing. Acceptability and criterion validity (ability of the Bluebelle WHQ to discriminate between SSI/no SSI) were explored by examining questionnaire return rates, levels of missing data and total score sensitivity/specificity values (receiver operating characteristic curve (ROC)).
Results: Baseline in-person questionnaire return rates were highest (672/686; 98 %), with postal return rates of 428/615 (68.5 %), 274/416 (65.9 %) and 186/296 (62.8 %) at follow up points. Overall, low levels of item-missing data were observed with few problems completing the questionnaire reported. Ability to discriminate between SSI/no SSI was good (Area under ROC = 0.796).
Conclusion: The modified Bluebelle WHQ is a valuable tool for post-discharge assessment of wounds healing by secondary intention. It is recommended for use in research and clinical practice.

1. Introduction

Approximately 10 million surgical procedures are performed annually in the UK [1]. Most procedures result in a surgical wound(s) and the majority of these are closed with sutures, staples or a tissue adhesive (healing by primary intention). A proportion of wounds cannot be safely closed or break down and reopen after primary closure. In such cases, the wounds are usually left open with healing occurring by the formation of granulation tissue and epithelisation over time (healing by secondary intention). Figures from UK survey data demonstrate surgical wounds healing by secondary intention have prevalence estimates of 4.1 per 10,000 population [2]. Highest frequencies are observed in colorectal, plastics and vascular surgeries [2] because of high rates of contamination, swelling, infection and insufficient tissue to cover a wound.

During healing of an open wound several problems may occur. These include wound leakage, pain, and infection [3]. This interferes with patients' daily activities, has a detrimental impact on quality of life and can result in substantial costs to the NHS [2,4]. If infection does occur, then interventions and/or readmission may be required. Understanding surgical site infection (SSI) in wounds healing by secondary intention is therefore important but we have not been able to identify a validated measure of SSI specifically for these wounds [5]. The most common methods for assessing SSI are those used by the U.S. Centers for Disease Control and Prevention (CDC) and UK Health Security Agency (formally Public Health England) surveillance [6,7]. The definitions and criteria for determining SSI, however, have limitations due to inconsistencies in data and the need for intensive follow methods such as telephone calls and/or home visits to capture SSI incidences that occur post-discharge [7,8].

More recently the Bluebelle Wound Healing Questionnaire (WHQ), a patient- or observer-completed SSI outcome measure, has been developed and validated in patients with closed primary wounds following abdominal surgery [9,10]. The measure includes items to assess signs, symptoms, and wound care interventions for SSI. It is to be completed after hospital discharge with a recall period of approximately 30 days or less (the expected timeframe within which an SSI occurs for closed surgical wounds). The Bluebelle WHQ has been widely used [11–15]. It is unknown, however, whether this tool or an adapted version of it is suitable for patients with wounds healing by secondary intention. The aim of this study was to modify and validate the Bluebelle WHQ for patient report of SSI in wounds healing by secondary intention.

2. Methods

2.1. Study design

This Bluebelle WHQ validation study was embedded within the SWHSI-2 trial, a UK multi-centre, randomised controlled trial (RCT)

[1] Denotes Principal Investigator.

with an internal pilot phase [16]. This two-arm superiority trial was designed to assess the clinical and cost-effectiveness of negative pressure wound therapy (NPWT) compared to standard care for patients with a surgical wound healing with secondary intention (SWHSI). The primary outcome was time to wound healing [16]. Wound infection assessed using a modified Bluebelle WHQ was a planned secondary outcome in the SWHSI-2 trial. Modification of the Bluebelle WHQ, adapted for relevance to patients with open wounds, was part of the SWHSI-2 trial design process and is described in the published protocol [16] and in further detail below. Assessment of the acceptability and measurement properties of the modified Blubelle WHQ, therefore, was required to validate its use for this patient population. This work was performed alongside the main trial.

A total of 686 participants were recruited for the SWHSI-2 trial from 29 NHS Trusts and primary care centers across the UK between May 2019 and January 2023. Included were patients over 16 years old, with an acute SWHSI on any part of the body considered to be ready for NPWT. A detailed description of participant eligibility, recruitment processes and study procedures have previously been reported [2]. Ethics approval was granted by Yorkshire and the Humber - Leeds East Research Ethics Committee (reference 19-YH-0054).

2.2. Adaptations to the Wound Healing Questionnaire (WHQ)

The original 18-item Bluebelle WHQ (developed and validated for patients with closed surgical abdominal wounds) was reviewed in detail by members of the SWHSI-2 study team (IC, CA) to determine whether it was suitable for patients with wounds healing by secondary intention, for example, identification of redundant or irrelevant items and consideration of face validity. It was modified in two ways: i) removal of items not applicable to SWHSI, and ii) changes to the recall period. Adaptations were proposed by the SWHSI-2 trial investigators and agreed by the Bluebelle WHQ developers (JMB, RM).

(i) Modifications to items

Three items were considered not to be applicable to patients with secondary wound healing. These included: (i) a symptom item assessing spontaneous dehiscence; (ii) a wound care intervention item assessing whether the wound was deliberately reopened by a healthcare professional (because wounds were not closed), and; (iii) a wound care intervention item assessing whether a dressing had been applied (because dressings were applied to all wounds in the SWHSI-2 trial). These items were removed, meaning the adapted Bluebelle WHQ therefore had 15 items: nine relating to signs and symptoms of the wound and six relating to wound care interventions. A comparison of the original and modified items, and the version of the Bluebelle WHQ as used in the SWHSI-2 trial, are included in Supplementary Table 1.

(ii) Modifications to the recall period

The recall period was modified because patients with wounds healing by secondary intention receive treatment for many weeks or even months. The expected healing process takes time and therefore infection may occur after a prolonged period. At baseline, and at the time of wound healing (which may have occurred at any timepoint between randomisation and 12-month follow-up in the SWHSI-2 trial), participants were asked to complete the Bluebelle WHQ considering the time since first having the open wound (i.e., overall timeframe). At the 3-, 6- and 12-month assessment timepoints, participants were asked to complete the Bluebelle WHQ considering the previous three months; the equivalent of approximately 90 days (Supplementary Table 2).

2.3. Response categories and scoring

Response categories and scores were not changed. Categorical options for the nine sign/symptoms items were “Not at all” = 0, “A little” = 1, “Quite a bit” = 2 and “A lot” = 3. Binary options for the six wound care intervention items were “No” = 0 and “Yes” = 1. A total score was obtained by adding the item scores together, providing a total score ranging between 0 and 33. A lower score represented fewer problems.

2.4. Data collection

2.4.1. Bluebelle Wound Healing Questionnaire

The Bluebelle WHQ was administered to participants as a self-assessment questionnaire at the following timepoints:

(i) Baseline/pre-randomisation, administered in-person and completed by all participants at the time of recruitment.
(ii) Three, six and 12-months post-randomisation, completed by participants who had reached any of these timepoints prior to their wound healing. It was administered via a pre-paid postal questionnaire, or via telephone when a response to postal questionnaires was not received or COVID-19 lockdown restrictions were in place. Partway through the SWHSI-2 trial (October 2022) the Bluebelle WHQ ceased to be collected at the 6- and 12-month assessments. This decision was made by the Trial Management Group, as a strategy to increase response rates, based on anecdotal evidence from participant telephone calls that the presence of multiple patient-reported questionnaires as part of a follow-up booklet was reducing response rates.
(iii) At the time of wound healing (post-healing assessment), completed by all participants whose wound had healed within the 12-month study timeframe. It was administered in-person, or via telephone when COVID-19 lockdown restrictions were in place or the study coordinating centre were required to undertake participant follow-up due to local capacity issues. Healing was defined as complete epithelialisation with no eschar (scab) and confirmed by a healthcare professional in accordance with the SWHSI-2 protocol [16]. At this timepoint, the research nurse also collected Bluebelle WHQ acceptability data, recording any issues reported by the participant regarding items that were difficult to understand, not applicable, problems with being unable to recall events and insufficient response options.

2.4.2. Reference surgical site infection (SSI) assessment

A face-to-face SSI assessment was performed at the post-healing assessment, conducted by the research nurse [16]. The assessment was performed after the participant had completed the self-assessment Bluebelle WHQ. Documented data included (i) whether the participant had experienced any wound infection(s) during the trial (yes/no), (ii) date of infection onset, and; (iii) a checklist of features that had been present based on the Centers for Disease Control and Prevention (CDC) infection criteria [17] (Supplementary Box 1). Information was mostly obtained by asking the participant, with other sources to verify/supplement information including medical notes, study adverse event (AE)/serious adverse event (SAE) forms and contact with other healthcare professionals. During COVID-19 lock down periods post-healing assessments were conducted remotely by York Trials Unit and no reference SSI assessment was completed for these patients.

2.5. Analysis

2.5.1. Acceptability

Acceptability of the modified Bluebelle WHQ for patients with wounds healing by secondary intention was explored in three ways: (i) questionnaire return rates at the different assessment timepoints, (ii) levels of missing data, (iii) answers to additional questions about acceptability collected as part of the study at the post-healing visit.

Missing data were summarised at questionnaire and item-level (i.e.

whole missing questionnaires or missing individual items). Demographic and clinical characteristics (including age, gender, ethnicity, socio-economic deprivation score, wound location, and co-morbidities) for participants completing at least one item compared to the rest of the study cohort (i.e., those who did not return a questionnaire at all and those that returned one without completing any Bluebelle WHQ items) were examined. Socio-economic deprivation was based on the Index of Multiple Deprivation Decile (IMD), where a lower number signifies higher deprivation [18]. Statistical tests for differences were examined using t-tests for continuous variables, chi squared for categorical variables and an ordered trend test for ordinal data (number of comorbidities and IMD decile). Patterns in item-level missing data were examined to explore whether there were Bluebelle WHQ items with a higher level of missing data that may indicate specific difficulties for patients with SWHSI to answer.

This study did not examine scores by trial randomised group with all participants analysed together.

2.5.2. Criterion validity

Criterion validity was assessed by comparing participants' Bluebelle WHQ total score with the SSI reference assessment (based on the CDC criteria for defining of SSI [17]). Data were used to examine the capability of the total scores for discriminating participants who had or had not experienced a wound infection during the trial, compared to the SSI reference assessment. A contingency table (cross-tabulation) of total score and a binary SSI/no SSI reference assessment was examined. Sensitivity (the probability of correctly classifying a participant as having had an SSI; i.e. the proportion of true positives) and specificity (the probability of correctly classifying a participant as not having had an SSI; i.e. the proportion for true negatives) values with 95 % confidence intervals for a series of incremental Bluebelle WHQ score cut-off thresholds (dichotomised variables created by a cut-off score of, for example, less than or equal to seven) were calculated. Sensitivity and 1-specificity values were used to plot a Receiver Operating Characteristic (ROC) curve. The ability of the Bluebelle WHQ score to discriminate between participants who had/had not experienced an SSI was measured by the area under the ROC (AUROC). An AUROC value approaching 1.0 is considered to indicate good discrimination with high sensitivity and specificity, whereas a value of 0.5 is interpreted as not being able to discriminate at all [19]. Analyses were performed using R® statistical software version 4.4.0 [20].

3. Results

Participant socio-demographic and clinical data are summarised in Table 1. For participants whose wounds healed within the study timeframe and had a post-healing assessment (n = 312/686; 45.5 %), median time between recruitment and the post-healing assessment was 146 days (interquartile range: 98–211 days).

3.1. Acceptability

Questionnaire return rates at each timepoint are presented in Table 2. Baseline assessment return rates (in-person assessments) were highest (672/686; 98.0 %). At the 3-, 6- and 12-month assessments the return rate from participants (postal questionnaires) was 428/615 (68.5 %), 274/416 (65.9 %) and 186/296 (62.8 %), respectively. The challenges with low response rates were discussed by the SWHSI-2 Trial Management Group partway through the study (October 2022). It was considered that the administration of multiple patient-reported questionnaires as part of a follow-up booklet may have reduced responses. Attempted measures to improve response rates at the 6- and 12-month follow-up assessments were agreed. The Bluebelle WHQ (alongside other PROMs) was removed from the follow-up booklet to reduce participant burden, therefore, no participants were followed up with the Bluebelle WHQ at 6- and 12-months after October 2022.

Table 1
Participant sociodemographic and clinical details for all participants (n = 686).

Characteristic	
Mean age at time of recruitment, years (s.d.)	62.42 (12.61)
Not reported	3
Sex, n (%)	
Male	513 (75.1 %)
Female	170 (24.9 %)
Not reported	3
Ethnicity, n (%)	
White	630 (92.8 %)
Asian or Asian British	28 (4.1 %)
Black or Black British	20 (2.9 %)
Other ethnicity	1 (0.1 %)
Not reported	7
Location of wound(s)	
Foot	551 (80.3 %)
Leg	69 (10.1 %)
Abdomen	24 (3.5 %)
Other	42 (6.1 %)

For questionnaires that were returned at baseline, 3- and 6-month assessments, almost all participants completed at least half of the items (>98 %), with only very few (<2 %) returning questionnaires with missing data from all items (Table 2). At the 12-month assessment, these figures remained low (n = 176/186; 95 % completing at least half of the items, n = 10/186; 5 % missing all items). Overall, no difference in participant socio-demographic and clinical characteristics was observed between those that returned a questionnaire and those that did not across all timepoints (Supplementary Table 3). The exception was deprivation score, with higher proportions of non-responders observed in those from areas with higher deprivation ($p = 0.008$, $p = 0.006$ and $p < 0.001$ at the 3-, 6- and 12-month timepoints, respectively). A comparison of mean age between responders and non-responders was also statistically significant ($p < 0.001$ at all timepoints) with responders being slightly older, however the actual difference in years was small (3 or 4 years; Supplementary Table 3).

Item-level missing data at the different timepoints are presented in Table 3. Overall, very low levels of item-missing data were observed. More responses were missing in the baseline assessments (in-person, at the time of randomisation) than subsequent follow up points (Table 3). Specific items with missing data at this timepoint most commonly were those that related to wound care interventions (e.g., antibiotics, drainage of pus/abscess, reoperation, seeking advice and debridement). At the 3-, 6- and 12-month assessments (completed by post/via telephone), all items had less than 3.0 % of responses missing (Table 3). The post-healing assessment (completed in-person/via telephone) also had low levels of item-missing data (<3.5 %).

Data from the additional questions assessing acceptability collected at the post-healing assessment demonstrated few problems completing the Bluebelle WHQ or the individual items (31/312; 10 % participants). The majority (16/312; 5 %) were problems recalling events. Some 6/312 (2 %) participants reported difficultly in understanding an item(s). Other reported problems (n = 8) included difficulty completing the Bluebelle WHQ because participants did not routinely look or touch the wound (n = 3; e.g., due to dressings) or did not want to look at the wound (n = 1). One participant had problems completing the item assessing pain due to reduced sensation in their foot as a result of their condition (n = 1) (Supplementary Table 3).

3.2. Criterion validity

Reference SSI assessments were available for 277/302 (91.7 %) participants whose wound had healed during the trial and had a post-healing follow-up assessment. Of these, 256 had completed the Bluebelle WHQ with no missing items at the same timepoint and therefore it

Table 2
Number of returned and completed Bluebelle WHQ at different timepoints.

Timepoint	Number of questionnaires administered	Number of questionnaires returned[a] (%)	Number with all items completed (%)	Number with at least half (≥ 8) items completed (%)	Number with all items missing i.e., no items completed (%)
Baseline	686	672 (98.0 %)	528/672 (78.6 %)	665/672 (99.0 %)	4/672 (0.6 %)
3-month	615	428 (68.5 %)	387/428 (90.4 %)	418/428 (97.7 %)	6/428 (1.4 %)
6-month[b]	416	274 (65.9 %)	252/274 (92.0 %)	268/274 (97.8 %)	5/274 (1.8 %)
12-month[b]	296	186 (62.8 %)	162/186 (87.1 %)	176/186 (94.6 %)	10/186 (5.4 %)
Post-healing	N/A	312	276/312 (88.5 %)	301/312 (96.5 %)	10/312 (3.2 %)

[a] Questionnaires at baseline and post-healing timepoints were returned from recruiting centers as part of the study case report form, questionnaires at 3-, 6- & 12-month timepoints were returned directly by participants by post.
[b] WHQs were excluded from the 6- and 12-month follow-up assessments after October 6, 2022 as part of a SWHSI-2 trial study amendment to reduce participant burden and improve response rates. The number expected is therefore lower for these timepoints, restricted only to those who were sent the WHQ prior to the amendment.

was possible to calculate a total score. Overall, patterns in the relationship between the Bluebelle WHQ total scores and reference assessment SSI data were as expected, with the majority of participants classified as not having had an SSI from the reference assessment also having low scores (WHQ ≤ 6, n = 145/185; 78 %) and the majority of participants classified as having had an SSI from the reference assessment having higher scores (WHQ ≥ 8, n = 46/71; 65 %) (Table 4). The exceptions were a small number of participants (for example, n = 3/185; 2 %) classified as not having had an SSI from the reference assessment but, however, had relatively high total scores (i.e., ≥ 14). Conversely, some discrepancies were also indicated for a small number of participants (for example, n = 8/71; 11 %), whose reference assessment indicated that an SSI had occurred but the total score was zero or one (indicating no/few problems). When data were used to plot a ROC curve, the AUROC was 0.796 (Fig. 1). This indicates good sensitivity and specificity of the Bluebelle WHQ for discriminating between participants who had and had not had an SSI as determined from the reference assessment. Sensitivity and specificity values at different Bluebelle WHQ cut-off thresholds are presented (Table 5).

4. Discussion

This study examined the acceptability and validity of a modified Bluebelle WHQ for use as a patient-reported tool to assess SSI in patients with wounds healing by secondary intention. Data were collected as part of a wider RCT evaluating the effectiveness and cost-effectiveness of NPWT for this patient group (the SWHSI-2 trial). The modified Bluebelle WHQ was found to be acceptable with overall low levels of item-missing data and few problems with understanding items and recall reported. Similar response rates across the socio-demographic and clinical characteristics of the participants were observed, with the exception of UK areas of deprivation. The modified Bluebelle WHQ demonstrated good sensitivity and specificity for discriminating between SSI and no SSI compared to a face-to-face reference assessment using the CDC criteria for defining SSI. Data in this study, therefore, demonstrates sufficient criterion validity of the modified Bluebelle WHQ according to established guidelines for assessing PROM measurement properties [21]. Findings suggest the modified Bluebelle WHQ is a valuable tool for post-discharge assessment of SSI in wounds with secondary intention healing. It is a suitable alternative to traditional resource intensive methods for collecting SSI data, such as telephone calls or face to face

Table 3
Item-level missing data at the different timepoints, for those who completed at least one item in the Bluebelle WHQ.

Item		Baseline (N = 668)	3-month (N = 422)	6-month (N = 269)	12-month (N = 176)	Post-healing (N = 302)
		Missing response[a]				
		n (%)	n (%)	n (%)	n (%)	n (%)
1	Was there redness spreading away from the wound? (erythema/cellulitis)	22(3.3 %)	9(2.1 %)	3(1.1 %)	2(1.1 %)	3(1 %)
2	Was the area around the wound warmer than the surrounding skin?	27(4 %)	9(2.1 %)	5(1.9 %)	4(2.3 %)	10(3.3 %)
3	Has any part of the wound leaked clear fluid? (serous exudate)	21(3.1 %)	11(2.6 %)	2(0.7 %)	2(1.1 %)	5(1.7 %)
4	Has any part of the wound leaked blood-stained fluid? (haemoserous exudate)	16(2.4 %)	11(2.6 %)	3(1.1 %)	1(0.6 %)	3(1 %)
5	Has any part of the wound leaked thick and yellow/green fluid? (pus/purulent exudate)	20(3 %)	9(2.1 %)	3(1.1 %)	1(0.6 %)	3(1 %)
6	Has the area around the wound become swollen?	15(2.2 %)	6(1.4 %)	2(0.7 %)	0(0 %)	2(0.7 %)
7	Has the wound been smelly?	8(1.2 %)	8(1.9 %)	2(0.7 %)	2(1.1 %)	2(0.7 %)
8	Has the wound been painful to touch?	15(2.2 %)	8(1.9 %)	4(1.5 %)	4(2.3 %)	3(1 %)
9	Have you had, or felt like you have had, a raised temperature or fever? (fever >38°C)	9(1.3 %)	5(1.2 %)	1(0.4 %)	0(0 %)	2(0.7 %)
10	Have you sought advice because of a problem with your wound, other than at a planned follow-up appointment?	43(6.4 %)	2(0.5 %)	2(0.7 %)	1(0.6 %)	1(0.3 %)
11	Have you been back into hospital for treatment of a problem with your wound?	15(2.2 %)	2(0.5 %)	1(0.4 %)	1(0.6 %)	2(0.7 %)
12	Have you been given antibiotics for a problem with your wound?	51(7.6 %)	2(0.5 %)	3(1.1 %)	0(0 %)	4(1.3 %)
13	Has your wound been scraped or cut to remove any unwanted tissue? (debridement of wound)	43(6.4 %)	5(1.2 %)	3(1.1 %)	1(0.6 %)	3(1 %)
14	Has your wound been drained? (drainage of pus/abscess)	46(6.9 %)	4(0.9 %)	1(0.4 %)	1(0.6 %)	3(1 %)
15	Have you had an operation under general anaesthetic for treatment of a problem with your wound?	45(6.7 %)	2(0.5 %)	1(0.4 %)	0(0 %)	5(1.7 %)

[a] Percentages of missing responses calculated as the proportion missing in an otherwise completed WHQ.

Table 4
Cross tabulation of WHQ total score and reference SSI assessment at the post-healing timepoint, for participants with complete data from both assessments (n = 256).

	WHQ total score[a]																									
	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	16	17	18	19	20	21	22	27	28	29	**Total**
Reference assessment																										
No SSI	37	16	29	27	13	12	11	11	7	6	7	4	2	0	1	0	0	0	0	1	0	0	0	1	0	185
SSI of any type	4	4	1	3	4	3	3	3	3	8	5	6	3	2	2	2	5	1	3	0	2	2	1	0	1	71
Total	41	20	30	30	17	15	14	14	10	14	12	10	5	2	3	2	5	1	3	1	2	2	1	1	1	256

[a] Higher WHQ score indicates more problems with wound healing/indications of SSI.

assessments conducted by a trained healthcare professional. It is therefore recommended for use in research and clinical practice.

In this study we observed better Bluebelle WHQ response rates when data were collected in-person (baseline and post-healing assessments) compared to by post/telephone. Response rates for postal/telephone assessments were less than <70 %. Although this is commonly seen in trials it would be insufficient for obtaining outcome data in a trial in which SSI is the primary endpoint. A recent Cochrane review summarised the RCT evidence of strategies to improve response for postal and electronic questionnaires [22]. It found that effective strategies included financial and non-financial incentives, personalising documentation, and shortening questionnaires as much as possible. The review, however, included a broad range of studies and participant populations and it is unknown which strategies might be effective specifically for patients with wounds healing by secondary intention. In SWHSI-2 unconditional incentives (£5) were included with the 6- and 12-month questionnaires. An attempt to reduce participant burden by removing questionnaires was undertaken partway through the SWHSI-2 trial which demonstrated slight improvement in response rates (Arundel et al., manuscript submitted for publication). A previous study has administered the Bluebelle WHQ electronically (eWHQ) as part of a mobile health intervention for SSI surveillance after caesarean (primary closed wounds) in an Australian population [11]. Some 382/730 (52 %) participants completed the eWHQ administered by text message/smartphone, including an automated reminder. Ongoing work is exploring the use of electronic methods for collecting Bluebelle WHQ data in a UK population [23]. Surveys are being sent to patients via an automated survey 30 days after surgery across nine different specialties in one UK NHS Trust. Findings will inform whether collecting Bluebelle WHQ data through an online, remote method may help to increase response rates for studies involving patients with SWHSI who often struggle with reduced mobility [4] and may, therefore, find in-person visits or even being able to return a postal questionnaire challenging.

Patients with wounds left for secondary intention healing and the associated, underlying clinical conditions are different to patients with primary closed surgical wounds. It was the latter group in which the original Bluebelle WHQ was developed and validated. Findings from the current study suggest that the modified Bluebelle WHQ items are relevant to patients with SWHSI, and this tool can be completed without problems. Overall, item-level missing data was low at the follow-up assessments, across all items assessing signs/symptoms and wound care interventions. This study, however, has some limitations. Firstly, the modifications made to the Bluebelle WHQ before it was used in this study were based on expert opinion alone. It is possible that earlier input from patients would have been valuable for content validity and acceptability. Secondly, this study was limited by the impact of the COVID-19 pandemic. During this period, it was not possible to collect reference SSI assessments as face-to-face visits and post-healing assessments had to be conducted by telephone. Thirdly, the use of the CDC criteria as a reference SSI assessment is known to have limitations [8,24]. However, this was chosen as the best available reference standard and the most common and widely regarded assessment of SSI [25,26]. For a small number (n = 8) of participants, the reference assessment indicated that the participant had had an SSI but the Bluebelle WHQ total score was zero or one (indicating no/few problems). Conversely, some participants had a relatively high total score (e.g., n = 3 participants had total scores greater than 14) but no indication that SSI had occurred from the reference assessment. It is uncertain whether these discrepancies were due to, for example, inaccuracies in data collection or in discrepancies/misunderstanding of the recall period. Further investigation is warranted to explore and understand this observation in more detail. Qualitative methods and patient interviews, for example, could be used and may provide an explanation. Lastly, the SWHSI-2 trial in which this data was collected was pragmatic with broad inclusion criteria. The study sample, however, had a significantly higher number of participants (80 % of the study sample) with wounds on the foot than

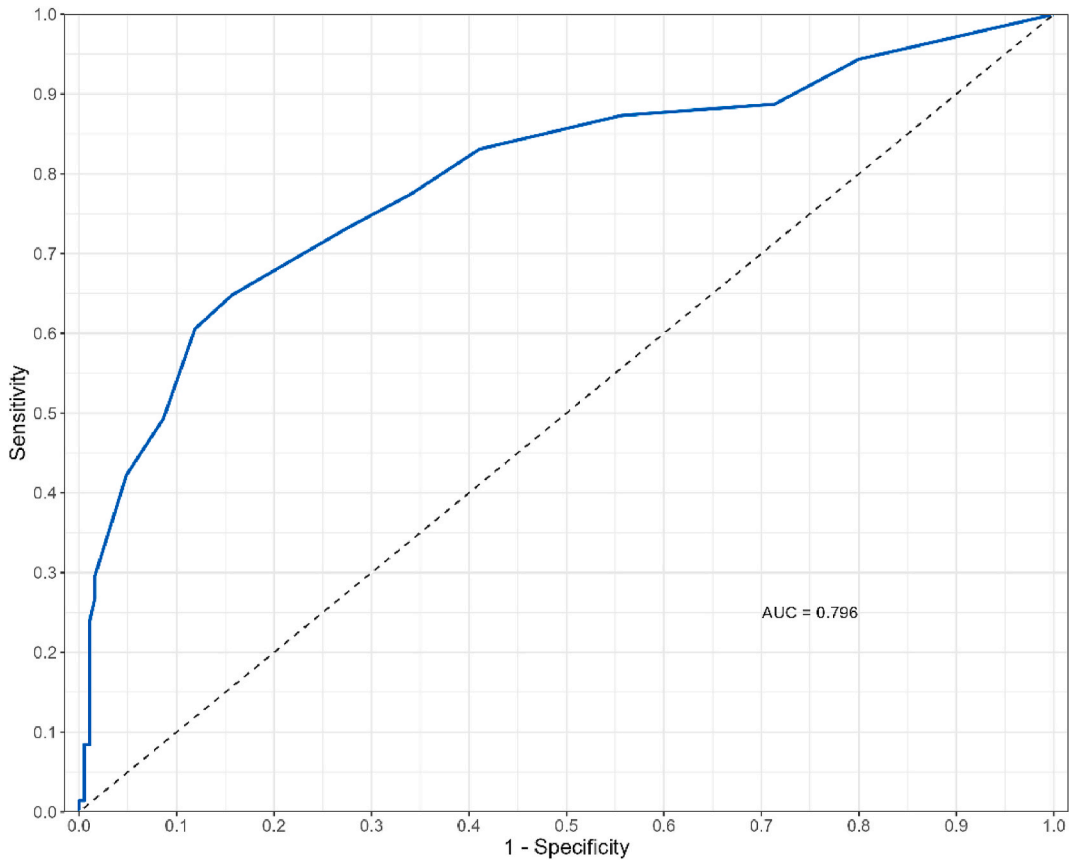

Fig. 1. Receiver operating characteristic (ROC) curve.

Table 5
Sensitivity and specificity of selected self-assessment Bluebelle WHQ total score cut-off thresholds compared to the reference SSI assessment.

WHQ score cut-off threshold	Sensitivity % (95 % CI)	Specificity % (95 % CI)
≥3	87.3 (77.3–94)	44.3 (37–51.8)
≥4	83.1 (72.3–91)	58.9 (51.5–66.1)
≥5	77.5 (66–86.5)	65.9 (58.6–72.7)
≥6	73.2 (61.4–83.1)	72.4 (65.4–78.7)
≥7	69 (56.9–79.5)	78.4 (71.7–84.1)
≥8	64.8 (52.5–75.8)	84.3 (78.3–89.2)
≥9	60.6 (48.3–72)	88.1 (82.6–92.4)
≥10	49.3 (37.2–61.4)	91.4 (86.3–95)
≥11	42.3 (30.6–54.6)	95.1 (91–97.8)
≥12	33.8 (23–46)	97.3 (93.8–99.1)
≥13	29.6 (19.3–41.6)	98.4 (95.3–99.7)
≥14	26.8 (16.9–38.6)	98.4 (95.3–99.7)
≥15	23.9 (14.6–35.5)	98.9 (96.1–99.9)

any other location on the body. This is a higher proportion compared to previous UK cohort study data (59/393 participants; 15 %) [16]. It is unknown whether this higher representation of patients with wounds on the foot and the associated comorbidities may have affected, for example, overall response rates or WHQ scores.

Further work is warranted to explore the reliability and validity of the modified Bluebelle WHQ in patients with wounds healing by secondary intention in more detail. We have previously demonstrated a WHQ total score between 6 and 8 may be a suitable cut-off score for indicating an SSI [10]. This was using the original 18-item measure for patients with closed primary wounds. The current study is the first study using the modified WHQ in patients with wounds healing by secondary intention. It shows promising early data although further investigation to explore sensitivity and specificity thresholds for SSI cut-off scores is still needed. Research is also needed to explore the acceptability and validity of the Bluebelle WHQ in a more diverse sample of participants including, for example, those with different skin tones as highlighted in other applications of the tool in low- and middle-income countries (LMICs) [27]. Work is warranted to further explore groups identified as having lower response, such as those from areas of higher deprivation, to explore what may be done in these specific groups to improve response rates in future studies or surveillance, for example. This validation study was conducted within the constraints of a wider trial. Results of the wider RCT, including the number of SSIs reported in the intervention and control groups separately, are not included in the current report and will be published separately. The current study was limited to examining acceptability and criterion validity. We did not examine other psychometric properties of the Bluebelle WHQ in this patient group, for example, test-retest reliability. Similarly, examination of scale structure and internal reliability were not performed. A more detailed analysis is warranted to explore these measurement properties further. Despite the scope for this further work, the modified Bluebelle WHQ is recommended for assessment of SSI in patients with SWHSI. It can be used as a patient reported tool or completed by observers (healthcare professionals) and can be used in the outpatient setting. It is recommended for use as an outcome measure for trials, clinical practice or for SSI audit/surveillance.

Ethics approval and consent to participate

Ethical approval for this trial was granted by the Leeds East Research Ethics Committee – reference 19-YH-0054 (Approval dated: April 05, 2019). Participants were required to provide informed consent prior to participation.

Consent for publication

Not applicable.

Availability of data and materials

Anonymised datasets generated and analysed during the current study will be stored in a publicly available open research repository (https://osf.io/echxv). Data is anticipated to be available via this repository by end 2024, following completion of analysis and subsequent publication. Sharing of this anonymised data is covered by original participant consent for the SWHSI-2 trial which permits sharing of data to support future research via sharing anonymously.

Authors' contributions

IC, CA, JB, BC, SD, JD, CF, CH, ML, RM, AO, TP, PS, NS and DT conceived the idea for the SWHSI-2 study, obtained funding for the study, and contributed to the trial design, intervention, and outcome measures. KB and AG contributed to the SWHSI-2 statistical analysis and KB, JH, AM, SS, JW, LW and SZ contributed to SWHSI-2 trial design, intervention, and outcome measures.

LM completed the statistical analysis, RM, JB, LM, CA, IC, CF and KB drafted the manuscript, and this was revised with input from all writing committee members. The collaborative group has read and approved the final manuscript.

Funding

This project was funded by the National Institute for Health Research (NIHR) Health Technology Assessment Programme (Project Reference: 17/42/94) and supported by the National Institute for Health and Care Research Bristol Biomedical Research Centre. The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Licence requests for the Bluebelle Wound Healing Questionnaire are available from Oxford University Innovations https://innovation.ox.ac.uk/outcome-measures/bluebelle-wound-healing-questionnaire/.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgments

We would like to thank the study participants who kindly agreed to take part in this study and our patient and public involvement representatives (D Butler, D Smith and B Alleyway) whose input has been indispensable in developing study documentation.

We would also like to thank all participating site staff at each site involved in the study and staff who have supported the delivery of the SWHSI-2 study at York Trials Unit, University of York (J McCaffery, H Rodrick, V Exley, S Rodgers, C Peck) and Hull University Teaching Hospitals NHS Trust (C Acey, J Long).

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jtv.2025.100889.

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