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Abstract

Background

Wound healing after surgery may be complicated by surgical site infection (SSI). SSI development may be influenced by surgical techniques surrounding primary wound closure; for example, the standard to which surgical wounds are closed at the end of an operation.

Aim

This study aimed to identify indicators of the quality of wound closure, and factors influencing this, to enable the future development of a tool to measure the quality of wound closure in the context of abdominal surgery.

Methods

This study was undertaken within the context of an ongoing feasibility study comparing dressing strategies for patients undergoing abdominal surgery. Content analysis of published literature, non-participant observations of wound closure in the operating theatre, and semi-structured interviews with clinicians were used to identify indicators of the quality of wound closure.

Results

A long list (n=38 domains) was categorized into visible markers indicating the quality of wound closure (e.g. suture visibility, apposition of wound edges, evidence of gaps in the wound or tethering of the skin edges), factors that might influence this (e.g. surgeon's expertise, time taken to closure the wounds) and patient factors (e.g. obesity, skin conditions).

Conclusions

This is the first study to investigate what is meant by 'good wound closure' and factors

that might influence it. Findings will result in the development of a tool to assess quality of

primary wound closure.

Keywords: surgery, surgical site infection, wound closure

Word count: 4179 (including all qualitative quotes)

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Introduction

Wound healing after surgery may be complicated by surgical site infection (SSI). This common problem prolongs hospital stay, increases healthcare costs and may have a detrimental impact on patients' well-being (Alias, 2017; Cromi, 2012). Multiple interventions delivered before, during and after surgery (such as nutrition and bathing, warming devices, blood glucose control, wound dressings and anti-microbial treatments), have been developed to try and minimize SSI. Evidence relating to these interventions has been summarised in several reviews (Allegranzi, 2016a; Allegranzi, 2016b). However, there has been relatively little focus on surgical techniques themselves, even though they have the potential to influence the development of SSI (Liu, 2015). Exceptions include evidence from randomised controlled trials (RCTs) suggesting that subcuticular sutures (skin stitches) should be performed in a continuous rather than interrupted manner (Gurusamy, 2014a). Similar studies investigating the role of subcutaneous sutures (an extra layer of stitches beneath the skin) found them to be of no benefit, through the quality of evidence was poor (Gurusamy, 2014b).

Another aspect of surgical technique that may influence the development of SSI is the quality of wound closure. Inadequate closure of primary surgical wounds may increase the likelihood of SSI through several mechanisms. The presence of gaps in the wound may lead to contamination; excess suture material may act as a nidus for bacterial colonization; and tension may reduce blood flow and oxygen delivery, leading to poor wound healing (Gottrup, 2005). Obtaining consensus about indicators of good quality wound closure could provide the basis for developing a tool to measure this endpoint. Such a tool would be

useful for studies examining interventions to minimise SSI, and in surgical training to assess the quality of wound closure. These issues have not previously been considered.

The overall aim of this study was to a) identify indicators of good quality wound closure and factors that may influence this, and b) establish the feasibility of measuring them. Results from this study will inform the development and validation of a tool to assess the quality of wound closure. Here we describe the development and feasibility testing of the tool.

Methods

The study comprised literature reviews and mixed qualitative methods to enable in-depth exploration of closure of surgical wounds (a complex phenomenon) in the operating theatre (the most common setting). Qualitative methods of data collection included non-participant overt observations of wound closure in the operating theatre and semi-structured interviews with clinicians. These methods were selected to establish i) what the surgical community understand by 'good wound closure', and the factors that influence this, ii) the feasibility of taking photographs of wounds in the operating theatre and iii) perceptions of the feasibility of capturing attributes of good wound closure in a photograph.

This study was undertaken in the context of the Bluebelle study (HTA 12/200/04) – feasibility work comprising preliminary mixed methods research (phase A) (Bluebelle study group, 2016), which in turn informed an external pilot RCT (phase B) (Bluebelle study group, 2017). The pilot randomised patients to receive a standard 'simple' dressing, 'glue-as-adressing', or 'no dressing' following abdominal surgery (gastrointestinal and obstetrics). The feasibility study sought to address several objectives, including the ability to recruit and the

development and validation of a patient-reported SSI tool. It also provided the opportunity to develop a metric for assessing the quality of wound closure (i.e. the focus of this paper) for use in a future, large, definitive RCT. The study was approved by the Camden and King's Cross Research Ethics Committee (14/LR/0640) on 10 April 2014.

Literature reviews

We searched published literature using snowballing methods (Greenhalgh, 2005) to identify concepts and theories about factors that constitute 'good wound closure'. Specifically, we investigated issues related to how the quality of wound closure might influence wound healing and/or the development of SSI. We chose snowballing instead of conventional search methods because of the difficulty (and inefficiency) in designing specific and sensitive search terms for a nebulous topic such as 'good wound closure'. Traditional search methods would have likely yielded vast numbers of largely irrelevant articles and still have risked missing relevant articles.

- a) *Snowballing:* Preliminary searches in PubMed identified an RCT in which the quality of wound closure was assessed (Lies, 2015). Starting with this citation, forwards and backwards snowballing identified further relevant articles. 'Forwards snowballing' refers to the identification of relevant articles based on papers citing the paper being examined. 'Backwards snowballing' involved searching reference lists of included papers to identify new papers of relevance to the review. The snowballing process ended when no new information about wound closure emerged from the papers.
- b) 'Grey literature' such as training videos and surgical text books were searched as part of the snowballing process.

Text relating to wound closure quality, and the factors potentially influencing this, were extracted verbatim and grouped into themes. Extracted data were summarised in diagrams and tables (Figure 1) and used to inform the interview topic guide and observation schedule.

Semi-structured interviews and observations

Sampling and recruitment

For the observations, surgical procedures performed at three centres were purposively sampled, to include a variety of approaches (laparoscopic and open surgery), disease types (cancer and non-cancer) and anatomical areas (upper and lower gastrointestinal tract, and caesarean section). Sampling of cases for observation was constrained by the parameters of the Bluebelle study, which focused exclusively on abdominal surgery. Non-participant observations of operations were undertaken to document the operative steps of wound closure and how these varied across surgeons, as well as contextual factors potentially influencing the quality of wound closure. As the project progressed, visits to the operating theatre provided an opportunity to establish the feasibility of using photographs to capture the characteristics of a well-closed wound.

Following the observations, surgeons were invited to take part in a brief interview, which explored their perceptions of whether the wound closure had progressed smoothly, and the reasons behind any unusual events or deviations that the researchers had noticed compared to their observations of other operations (in this study) and knowledge obtained from the literature. Additional surgeons (from the same three centres) who had not been observed were also invited for interview to obtain a wider range of views to address the study objectives. These additional potential interview participants were purposefully

sampled, with the aim of including informants with a range of clinical experience (e.g. consultants and trainee level) from a range of disciplines (e.g. orthopaedics and plastic surgery). Questions encouraged surgeons to reflect on their wound closure (and incision) practices, their rationale for these, and whether they felt these affected wound healing. Surgeons were also asked for their interpretations of what constitutes a well closed wound and whether (and how) this may be assessed in a photograph of a newly closed wound. Observations and interviews continued up to the point of data saturation (i.e. where additional data were not adding any new insights).

Data collection

Interviews and observations were conducted by two medically qualified trainees with limited direct surgical experience of wound closure. These researchers were not familiar with the participants or the operating theatre environments in which the research was conducted.

Observations were recorded by hand onto an observation schedule, which was developed during preparatory visits to the operating theatre. The focus of observations included steps in operative processes relating to skin incision and wound closure (prompted by the literature), and deviations from previously observed patterns and/or unexpected events. The term 'unexpected' was defined in relation to patterns across surgeons who had already been observed and the medical knowledge of the observer.

Interviews were semi-structured and conducted face-to-face between 2014 and 2015. Both interviewers worked from the same topic guide, which had been developed based on the literature review (described above) and the researchers' clinical knowledge. The guides were sufficiently flexible to enable unanticipated topics to be proposed by participants and

fully explored. Interviews were also an opportunity to confirm, challenge and clarify findings from the observations.

Data analysis

Data collection and analysis ran in parallel. Notes from the observations were electronically written up as soon as possible following each observed procedure, and interviews were transcribed verbatim. NVivo 10 (QSR International, Melbourne, Australia), Microsoft Excel and Word were used to aid the storage and analyses of all types of data, which were analysed thematically using constant comparison methods. Transcripts of interviews were coded by ascribing key words or phrases that captured the meaning of the text. Similar or related codes were then grouped into themes, forming an early coding framework. The coding framework was added to, and coded material regrouped, with further data collection and analysis. Descriptive accounts of the interview findings were considered in relation to observation notes.

Particular attention was paid to emerging themes/patterns in subsequent observations and interviews, with a view to refining key findings pertaining to the study objectives. As data collection and analysis was undertaken iteratively, emerging information from the literature findings was used to update the topic guides for the interviews. Literature knowledge was also likely to have influenced the observations that the observers were primed to record.

Synthesising findings

To integrate the findings from above, a 'long list' of all potential factors was created. After removing overlapping or duplicate information, remaining factors formed the basis of the draft tool for assessing the quality of wound closure. Factors were categorised either as a)

describing the appearance of the wound at the end of the procedure, and b) a characteristic that might influence the appearance of the wound.

Patient involvement

Patients were not directly involved in this component of the Bluebelle study.

Results

Literature reviews

Two recent articles summarizing World Health Organisation (WHO) recommendations about the pre- and peri-operative prevention of SSI were identified, together with other non-systematic reviews (Allegranzi, 2016a; Allegranzi, 2016b; Korol, 2013). Hypotheses about how the quality of wound closure might influence wound healing and the development of SSI were identified (Figure 1).

Semi-structured interviews

Seventeen interviews were undertaken at two NHS Trusts (Table 1). Interviews lasted between 05:52 and 20:41 minutes and were conducted face to face either immediately after the wound closure observation (n=6), or independently (n=11).

Non-participant observations

Twelve observations (six with interviews) involving general surgery and obstetric teams were undertaken (Table 1). Types of surgical procedures observed included laparoscopic cholecystectomy, inguinal and incisional hernia repair, caesarean section, and staging laparoscopies for the assessment of gastrointestinal cancer.

Wounds were predominantly closed with subcuticular suturing, although use of steri-strips (without sutures) and interrupted sutures were also observed. Subcutaneous (i.e. below the skin surface) suture layers were seldom used before the final closure layer.

Three major themes emerged across the data sources (literature review, interviews and observations): i) making the incision, ii) closing the wound and iii) other factors that influence wound healing and the quality of wound closure, which surgeons often referred to interchangeably. Findings from each theme category are summarised below.

Making incisions

Many surgeons believed that several aspects of the initial incision could influence wound closure quality, including the choice of tool for the incision, how it was used, and the length of the incision.

Choice and use of tools for wound closure

Most surgeons were observed using a scalpel to make the initial incision. Thereafter a cauterising tool (diathermy) was used to cut the deeper layers of skin. Interview data corroborated this (13 of 17 interviewees). In contrast, a systematic review of 14 RCTs found that incisions made with a diathermy (rather than a scalpel) were associated with reduced blood loss and pain (Ly, 2012). One justification for using the scalpel rather than a diathermy was to avoid de-vascularising the area:

S: "...you need a clean vertical cut so that's why I think a knife is a good thing to use ... I personally have concerns about that (using diathermy) because if you burn the skin edges I don't think it will heal as well." (Consultant, Plastic Surgery)

S: "Ideally an incision should be made with an appropriate blade. There's different sized blades depending on whether you're doing fine or a large laparotomy incision" (Trainee, General Surgery)

Many others felt that using diathermy to incise the skin might result in inadvertent damage by burning:

S: "You want to go through just uh the first layer of the skin really with the knife and then I always swap straightaway after that to using the diathermy to use the fine tipped monopolar and then use, use that to get through the other layers including the fat..." (Trainee, General Surgery).

All surgeon interviewees mentioned the importance of cutting the skin with the knife at 90 degrees to optimise healing:

S: "I think it's important to make sure your knife is at 90° to the skin so that you don't have an overhang of skin which isn't well vascularised on top." (Trainee, General Surgery)

Length and width of the wound

Cutting out (excising) or avoiding existing scars was deemed essential by some when making the initial incision, to improve the chances of having healthy-to-healthy skin edges at the point of wound closure:

S: "Previous scars, going across scars that have been previously made, excising tissue where you're not cutting through virgin skin - those are clearly factors that are gonna impact how nicely wounds heal." (Trainee, General Surgery)

By contrast, observations suggested that some surgeons incised directly through scar tissue. This may relate to the fact that some surgeons recognised that excision would present challenges at the point of wound closure, because excised skin edges would subsequently require tighter pulling together, potentially resulting in a wound with tension:

S: "it has to be tension free at the end of the procedure so if you're excising skin that's an issue." (Consultant, Plastic Surgery)

Creating tension-free wounds at the point of closure was discussed in terms of planning the size or length of the incision:

S: "I would rather make a longer incision and have relaxed wound edges when I'm retracting than have a smaller incision and put significant tension on the wound edges" (Consultant, Orthopaedics)

Closing wounds

Aspects of wound closure that surgeons felt might impact upon wound healing were the choice of tools, materials and techniques used for closing wounds.

Choice of tools and materials

Researchers observed that tools, such as forceps, were used to hold the skin edges while the surgeon closed the wound. Preferences for using 'toothed' or 'non-toothed' forceps were found to be related to the perceived trauma instruments might cause (e.g. bruising):

- **S:** "Using toothed forceps on the outside of the skin can cause it to be damaged and not heal particularly well." (Trainee, General Surgery)
- **S:** "I like to use toothed forceps...I know some people will think that you get less tissue damage with non-toothed forceps but I think you have to crush the skin to use this so I don't favour that." (Consultant, Plastic Surgery)

Wound closure techniques

A range of techniques were perceived to be important for optimal wound healing, including: suturing and knotting, achieving 'good apposition', and closure of deep skin layers. These were felt to minimise infection, devascularisation of the epidermis, and tension across the wound.

i) Suturing and knotting

Using too much suture material for wound closure was considered by some surgeons to be a potential source of infection:

S: "it can take a long time to re-absorb or could be a source for infection" (Trainee, General Surgery)

Surgeons related the importance of neat suturing, without visible or excess suture material, to achieving good wound closure. Some were mindful of 'burying' knots to avoid them becoming a nidus for infection. Other surgeons preferred to leave the suture material unknotted and instead used glue to hold it in place.

ii) Techniques for achieving 'good apposition'

Interviewees described 'good apposition' as the wound edges 'matching up' without any gaps or visibly exposed subcuticular tissue, which they believed to be achieved by evenly placing and spacing each needle entry and exit point (referred to as 'bites'). Gaps or steps could occur if the skin was not well apposed. Surgeons considered that a well 'apposed' wound would be tension free and therefore more likely to heal well:

- **S:** With skin closure it's just achieving tension free skin apposition, in a way that will allow good healing...." (Trainee, General Surgery)
- **S:** "More likely if you get good apposition of the skin edges you will more likely get good healing of the skin by primary intention rather than by secondary intention and so you are more likely to get good skin healing which as a secondary thing will also give you good cosmesis." (Consultant, Upper GI Surgery)

'Eversion' was a technique used by some surgeons to support good apposition of the skin edges. By slightly everting both skin edges, surgeons ensured that the epidermal tissue coming together was well vascularised, avoiding the creation of a "cavity or a sinus" and thus promoting wound healing.

iii) Closure of 'deep layers'

Some surgeons considered closure of the deep layers to be more important than the skin closure itself, in terms of favourable wound healing and cosmetic outcome:

S: "The skin's quite fragile, quite gentle edge opposing really. With a dermal layer, you can get a bit more tension and make sure it's uh well held...! think the dermal layer is probably more important than the subcuticular cos subcuticular often we use glue and steri strips." (Consultant, Plastic Surgery)

Other factors

Other contextual factors were thought to influence wound healing, including patient factors, the type and complexity of procedure, grade of surgeon, supervision of trainees, time taken to close the wound, and hygiene levels in theatre. Patient factors and hygienic conditions appeared to be most important to surgeons (which was mirrored in the literature findings) but there was less consensus around issues such as the grade of surgeon or time pressures.

Age, diabetes, obesity, skin conditions, and drugs (such as steroids) were commonly mentioned patient factors. Surgeons associated many of these with poor blood supply and/or or higher infection risks. Procedures involving groin surgery or intra-abdominal perforations were considered high risk. These peri-operative factors are reported in the literature as having the potential to increase SSI and wound healing (Allegranzi, 2016a; Allegranzi, 2016b). Interviewees described various preventative strategies as beneficial: for example, peri-operative antibiotics, antibiotic-impregnated sutures, and warming the patient during the procedure. Other interventions - incise drapes, pre-operative hair removal by shaving, and drain insertion – were evaluated in systematic reviews as ineffective.

Most surgeons agreed that the level of surgical experience impacted the quality of wound closure. Some associated this with the ability to anticipate and prevent wound healing problems. Others thought it was more relevant for the final cosmetic outcome. The time taken to close the wound seemed to be inextricably linked to experience. One surgeon thought that a balance between being slow enough to be careful and quick enough to decrease the length of time the wound was open and exposed to infection was important. Others did not think that the time taken for wound closure affected healing. This view was corroborated by the literature, as there is no evidence to suggest a correlation between surgical experience and the quality of wound closure.

Integration of literature, observation and interview data

"The 'long list' included 38 factors that might influence wound healing (Table 2). This long list was condensed to remove overlapping factors through iterative discussions amongst the study team, which comprised clinicians, clinical and non-clinical researchers and methodologists. Factors were then categorised as those relating to the appearance of the newly closed wound (termed 'metrics') and those influencing the appearance of the wound i.e. not visible at the end of an operation but nevertheless important to consider when assessing the quality of wound closure (termed 'mediators'). Mediators were further categorised as 'technical' or 'non-technical' factors and assimilated into a draft tool for assessing the quality of wound closure (Table 3). Care was taken to ensure that all factors from the original long list were captured within the tool."

Practicalities of taking photographs in the operating theatre, and using them to assess the quality of wound closure

The feasibility of taking a photograph of the wound was found to be influenced by the height of the operating table, the levels of overhead lighting, the distance away from the patient and the angle at which it was possible to take the photograph. In general, despite these challenges, photographs were found to reflect the *in situ* findings (except for one case where a tiny amount of suture material was visible in the wound, which was not visible on the corresponding photograph).

Surgeons identified several potential limitations of using a photograph to assess wound closure quality. Some expressed uncertainty about whether photographs could convey three-dimensional detail (e.g. uneven skin). Other areas they were sceptical about included the visibility of the tissue deep to the skin, and whether it would be possible to visually assess how the closure/non-closure of this layer might impact wound closure. The amount of tension across the wound closure was also seen as being problematic to assess from a photo:

S: "I think photographs could show the wound looked very well closed but you can't really assess hmm the soft tissue tension just by looking at a clinical picture, uh just my thoughts." (Consultant, Orthopaedics)

Some surgeons were mindful of the personnel who might be assessing the photos. They thought that a certain number of observations of the procedure, or a certain level of training, might be required:

S: "I don't think they'd have to be an expert but I think they would have to have seen it done a few times. I would have thought they'd have to have seen it done by someone who is appropriately good at it, perhaps about five times to know what is standard."

Surgeons noted certain factors that had potential to influence wound closure quality could not be assessed using a photograph, such as patient demographics.

S: "I think it would be important for you to be collecting demographics of the patient and also comorbidities and also risk factors related to that wound, so are they coming in critically unwell, in anaerobic metabolism with high lactate, which means their circulation is directed

to their heart and brain so their peripheries including their wound tissue planes will not be getting good blood supply, because that might impact on wound healing." (Consultant, Upper GI Surgery)

This mixed-methods study collected data from the literature, observations in the operating

theatre and interviews with surgeons, to identify i) metrics (factors influencing wound

Discussion

closure quality, which are possible to visualize in a freshly closed wound) and ii) mediators (factors influencing wound closure and healing). It is anticipated that these metrics and mediators will be amalgamated into a tool to be used in future studies to investigate the relationship between wound closure quality and the development of surgical site infection, as an outcome measure in clinical research and to facilitate surgeon training. Further work is now required to develop a scoring system for the tool and to test reliability and validity. Existing literature relating to the value and assessment of the quality of wound closure is limited, and methods to assess this have not currently been identified. By contrast, there are many reports of rating scales for assessing scar quality and cosmesis, for example, the Vancouver Scar Scale, the Manchester Scar Scale, the Patient Scar Assessment Scale, and the Observer Scar Assessment Scale (Fearmonti, 2010). None of these scales are recommended for use in the newly closed wound. One article, describing an RCT to investigate the effect of music on the efficiency of wound closure, involved grading the quality of wound closure by an independent assessor (Lies, 2015). Although the paper reported factors that were taken into consideration in this judgement (e.g. apposition, stepoffs, overlapping, gaping, and suture visibility), the final scoring used a single rating expressed as compilation of the overall appearance and it was unclear how this was calculated. Moreover, the study was undertaken in a simulated setting, solely including trainee surgeons. It also used non-human material for the assessments. In view of these limitations, our study team considered that further work in this area was required building upon this early experience.

To our knowledge, this study is the first to investigate what is meant by 'good wound closure' and the range of factors that might influence it. We interrogated multiple data sources and employed recognized research methods for investigating complex interventions. Despite this, there are several potential limitations. Firstly, the literature review did not use conventional 'systematic' search strategies and it is therefore possible that relevant articles were missed although the team have extensive knowledge of the surgical literature in this area. Given the anticipated difficulties associated with designing a specific and sensitive search strategy in this area, we concluded that a snowballing technique would yield more relevant information than conventional searching would have done. Secondly, the observations and interviews were undertaken in three centres in one city and did not include data from all surgical specialties. It is possible that surgeons in the city had similar training and other surgeons and centres may have very different approaches and theories about wound closure and SSI, meaning that these may have been overlooked or missed completely. This is unlikely, however, since the surgeons did not train in the same hospitals, regions or specialties (and within this region, there are at least nine hospitals in which surgeons undergo training). A third limitation is that surgical trainees, rather than trained photographers, were responsible for taking photographs of wounds at the end of operations. Although this may have influenced the quality of the photograph obtained, it reflects 'real life' as it would not be possible for a photographer to take photos for every patient in a multicentre study involving thousands of patients. Finally, the qualitative findings may have been influenced by the two researchers' medical backgrounds, even

though there was no evidence of this and furthermore their direct experience of wound

closure was limited.

In summary, this study identified metrics representing the quality of wound closure, and

mediating factors that may be responsible for influencing this quality. Feasibility testing

suggested that it may be possible to assess the metrics using digital photography, and to

collect data relating to the mediating factors within the operating theatre. Collectively,

these will enable a tool to assess wound closure quality to be developed. Further work to

finalise the tool, develop a rating scale and to assess reliability and validity, has started.

Once completed, we expect this tool to be used as a clinical endpoint in RCTs and other

research studies, as well as teaching and training. Other future possibilities include

automated image assessment using artificial intelligence to maximise efficiency, which is of

particular importance in large multicentre RCTs.

Contributor statement: Members of the Bluebelle Study Group contributed to the study

design and read the final version of this manuscript. Other author roles are as follows: NB,

LR, DE, BR and JB designed the study. KB and HGB undertook the literature work,

observations and interviews under NB and LR's supervision. ZT undertook the qualitative

analysis with LR and wrote the first draft which was revised by NB. All authors contributed

to further iterations and approved the final version for submission.

Competing interests: None to declare

Data sharing: No further data available

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- Table 1. Overview of the specialty and grade of surgeons interviewed
- Table 2. Summary of all factors identified from surgeon interviews, observations and the literature
- Table 3. Final list of proposed metrics and mediators of 'good wound closure'
- Figure 1. Literature review findings, summarizing theories relating to wound closure, wound healing and SSI