Introduction

Complex wounds, either chronic or acute, are wounds that do not progress through the normal wound healing process, and may include one or more of the following criteria: (1) extensive loss of the integument, (2) presence of infection, (3) compromised viability of tissue and supporting structures, and/or (4) systemic conditions that impede normal healing. The treatment of complex wounds is challenging due to the complexity of these criteria and how their interactions affect the healing process. [1,2]

Complex wounds have a significant impact on both the affected individual and on society as a whole.[3,4] For the individual, complex wounds can cause physical discomfort, pain, and emotional distress, leading to an overall decreased quality of life, and may require extensive medical treatment and rehabilitation, which can be costly and time-consuming.[3,4] In some cases, complex wounds may result in permanent disability or disfigurement, which can affect daily function and the ability to engage in activities and employment. On a societal level, the cost of treating complex wounds puts a strain on healthcare resources and budgets. Furthermore, the loss of productivity due to disability or time spent seeking medical treatment can have an economic impact on society.[3-5]

Bordered foam dressings are frequently used to treat complex wounds due to their unique features.[6-8] In 2021, the global market size for foam dressings was estimated at $1.67 billion and is expected to grow at a compound annual rate of 4.7% from 2021 to 2028, driven by factors such as an aging population, and an increase in chronic diseases.[9] Foam dressings are typically composed of a hydrophilic foam non-adherent layer that absorbs fluids through to the foam body of the dressing, a waterproof adhesive backing, and in the case of bordered foam dressings, a margin that surrounds the wound and helps keep the dressing in place. There may also be a superabsorbent layer adjacent to the foam, containing superabsorbent particles to further retain the wound exudate. The foam material in these dressings provides mechanical protection for the wound through its tensile stiffness and strength. However, the conformability and exudate management capabilities of foam dressings are also affected by the bending stiffness of the foam.[10]

Foam dressings offer several advantages over other types of wound dressings.[6-8] The layer which is in contact with the wound bed is designed to maintain a moist wound healing environment by transporting wound exudate into the foam. Additionally, the lower risk of adhesion to fragile wound bed tissue makes foam dressings attractive for use on complex wounds. Other benefits include thermal insulation for the wound, and ability to adapt to the contours of the body.[11] Foam dressings can be used on both acute and chronic wounds, as well as partial and full thickness wounds, and can serve as either primary or secondary dressings.[12] Compared to the non-bordered variants, bordered foam dressings do not require an additional secondary dressing. Adhesion to the surrounding skin is designed to keep the dressing in place, which helps to reduce the risk of the dressing coming loose or shifting, and prevents leakage from causing skin irritation and maceration. Another benefit of bordered foam dressings is that since the introduction of silicone adhesives they can be easily removed with a lower risk of causing pain and skin stripping. Additionally, depending on the amount of exudate, they can be worn for a wear time of one to seven days, which helps to reduce the frequency of dressing changes and thereby, the treatment costs (dominated by the clinical labor time).[10]

The benefits of bordered foam dressings, such as improved wound management with respect to basic (e.g., gauze) dressings, reduced tissue maceration with respect to simple dressings, and atraumatic application and removal, make them a valuable option for the treatment of complex wounds, offering a combination of absorbency, conformability, and ease of use.[13-15] However, foam dressings differ

considerably across manufacturers and brands, by materials and composition and by the method of production, and therefore, foam dressings from different suppliers have difference performance, both in the laboratory and clinically.[10,14] Hence, to assess the impact of bordered foam dressings in the treatment of complex wounds, specific comparative, measurable effectiveness and safety outcomes are needed.[16,17] Outcomes are defined as variables that are measured during and/or at the end of a study or treatment period to document the impact, efficacy, and safety of a particular intervention on the health of a specified population.[1,16] For example, in wound management, outcomes may include changes in wound status, reduction in wound size, exudate control, and improvements in healthcare efficiency.[18]

There is a significant heterogeneity in which outcomes measures are reported and what definitions are used in clinical trials[19], which makes its challenging to draw definite conclusions about their relative effectiveness in the treatment of complex wounds. By identifying a standardized set of measurable outcomes, called a Core Outcome Set (COS), it is possible to synthesize and systematically compare results across clinical trials, to reduce the risk of bias, and pool results to be used in evidence-based practice.[16,20] Measuring a COS does not limit researchers if they wish to include additional outcomes and measurements, but ensures that the outcomes that are broadly agreed as essential for inclusion are indeed represented. The development of COS is a collaborative process that involves input from researchers (from different relevant disciplines, clinicians, patients, and potentially other stakeholders such as regulators.[16]

Although validated and reliable outcomes, such as dressing wear time and the decrease in wound size, have been recommended[19], there is no agreement on a COS for clinical effectiveness studies of bordered foam dressings in the treatment of complex wounds. Therefore, our study aims to develop a COS, which recommends the outcomes that should be measured and reported as a minimum, for clinical effectiveness trials of bordered foam dressings in the treatment of complex wounds. Future developments in COS development will involve creating measurement instruments and relevant endpoints for these outcomes. The development of the COS has the potential to improve the design and analysis of effectiveness studies, take into account the characteristics of bordered foam dressings, and ensure that the outcomes measured are relevant and meaningful to patients and stakeholders. The absence of agreement on a COS highlights the need for this study.

Methods

Aim

The aim of this project was to develop the first core outcome set (COS) for clinical effectiveness studies of bordered foam dressings in the treatment of complex wounds.

Study design/methods

The project team (PT) consisted of three researchers (C.R., D.B., J.T.) responsible for the design and coordination of the project and for making final decisions. The International Wound Dressing Technology Expert Panel (IWDTEP), consisting of experts in the field of dermatology, wound care, surgery, podiatry, clinical trials, biomedical engineering, and nursing, provided guidance throughout the development of the COS.

The research project consisted of two phases, based on the procedure of the initiative Core Outcome Measures in Effectiveness Trials (COMET).[16] The first phase included the preparation of the background and process. The second phase involved three steps: (1) the generation of a list of outcomes gathered via a systematic review and a qualitative study, (2) a Delphi consensus study, and (3) a consensus

meeting. The research methods of the study are outlined briefly as they have been described in detail in the previously published protocol[21].

Systematic review

Four databases were systematically searched using a combination of key terms, including; wounds, bordered foam dressing, and treatment. Studies were included if they (1) targeted an adult population, (2) addressed the treatment of complex wounds with a bordered foam dressing as the primary wound dressing, (3) were retrieved from original research, and (4) were published between 2000 and 2022. There were no restrictions on language or study design. Studies that focused primarily on the prevention of complex wounds were excluded. A total of 24 outcome domains and 82 outcomes were identified. The process and results of the systematic review were published previously.[19]

Qualitative study

A descriptive qualitative study[22-24] was employed to capture outcomes that were not identified through the systematic review. Additional outcomes were obtained via individual semi-structured interviews with healthcare providers, researchers and patients. The topic guide included open-ended questions focusing on the use of bordered foam dressings in treating complex wounds and how to evaluate them. To minimise bias, all interviews were conducted by the same researcher (C.R.) experienced in qualitative research. Variation sampling was chosen to facilitate a broad range of perspectives and a variety of meanings within the sample. Eligible participants (Table 1) were recruited via the network of the PT and the IWDTEP. The interviews were analysed using the thematic analysis framework described by Braun and Clark.[25] Decisions regarding sampling, data collection and data analysis were discussed with the IWDTEP members and recorded in an audit trail.

Table 1 Inclusion criteria participants qualitative study

Stakeholder group	Inclusion criteria
Healthcare providers	- Adults (≥18 years) - Minimum 3 years of experience treating patients with complex wounds such as DFU VLU, etc - Used a bordered foam dressing to treat complex wounds at least once - Able to give informed consent - Speak and understand English
Healthcare researchers	- Adults (≥18 years) - Research background in wound care and wound dressings - Took part in/conducted a clinical trial - Able to give informed consent -
Patients	- Adults (≥18 years) - Able to give informed consent - Able to communicate verbally - Have/had one or more complex wound(s) - Treated with a bordered foam dressing at least once

Delphi procedure

The Delphi procedure was based on the recommendations of the initiative Core Outcome Measures in Effectiveness Trials (COMET).[16] The list of outcomes generated from the systematic review and the qualitative study was reviewed by the PT and IWDEPT. Following the development of the online questionnaire using Qualtrics software Version 2022 (Qualtrics, Provo, UT), the questionnaire was pilot tested to assess validity, comprehension and acceptability. Three patients, three healthcare providers,

and two researchers from the network of the PT were contacted to participate in the pilot test. Based on the pilot test and discussions with the IWDEPT members, outcomes with similar meanings but subtle differences in wording or outcomes that referred to the same concept were grouped into single outcomes.

After the evaluation and adjustment of the questionnaire, a two-round Delphi study was conducted with a global stakeholder group, composed of (1) healthcare providers, (2) researchers, (3) both researcher and healthcare providers, and (4) patients. The inclusion criteria are provided in Table 2. The study aimed to invite a minimum of 60 participants to accomplish a minimum of 50 experts completing the two rounds of the Delphi study, considering an 80% response rate. The minimum representation for each stakeholder was a pragmatic choice discussed within the PT team to achieve a diverse group of experts in terms of discipline and expertise, academic or industry background and years of experience, country of origin, and other relevant factors such as gender balance and clinical versus laboratory research work. However, research indicates that recruiting patients into COS studies can be challenging.[26] Therefore, the PT decided to set a minimum of five patients for participation in the Delphi study.

Table 2 Stakeholder groups Delphi study

Stakeholder group	Group characteristics	Number of participants
Healthcare providers	This group is composed of healthcare professionals and health care providers (facilities) who have experience treating complex wounds with bordered foam dressings	Minimum 15
Healthcare researchers	This group is composed of professionals working in all areas of clinical research relevant to complex wound care, as well as methodologists or statisticians currently working only as researchers	Minimum 20
Patients	This group is composed of individuals who have/had at least one complex wound	Minimum 5
Healthcare researchers and providers	A separate category is created for these professionals who are involved in both healthcare and research, as they may have different perspectives on key outcomes than professionals who are involved in only one of the two activities	Minimum 20

The questionnaire with the specific inclusion criteria mentioned was distributed within the network of the PT and the IWDTEP and through the network of the wound care organisations European Pressure Ulcer Advisory Panel (EPUAP), EWMA (European Wound Management Association) and ISTAP (International Skin Tear Advisory Panel). Although not all organisations focus specifically on complex wounds, the members of the organizations may have access to a broad network of patients, healthcare providers, and researchers who may also have experience with complex wounds and bordered foam dressings.

At the beginning of round one participants were asked to indicate which of the four stakeholder groups they belonged to and to complete their demographic information. All participants were then asked to evaluate the given outcomes using a 9-point Likert scale. Scores were considered to be of 'low importance' (one to three), 'important' but 'not critical' (four to six), and 'critical' (seven to nine). To prevent possible weighting of the results by order, outcomes were arranged alphabetically. To ensure

potential outcomes were not missed, participants could propose additional outcomes to be included in the second Delphi round. Three weeks after completing Delphi round one, participants were invited to the second round and were asked to rate the outcomes again on the same scale. Additionally, participants were given the opportunity to explain their scoring. All outcomes were retained in round two to enable participants to score and prioritise the list of outcomes in totally. To provide an updated evaluation regarding each outcome in the light of the collected feedback, results of the first round were displayed by the cumulative rating for each outcome per stakeholder group.

Consensus was defined as at least 70% of all panellists rating the outcome as 'critical' and maximum 15% of all panellists rating the outcome as 'of low importance'. Outcomes rated as 'of low importance' by at least 70% of the panellists and as 'critical' by maximum 15% of the panellists were excluded. All other outcomes were categorised as no consensus.[20]

A 2-hour online consensus meeting was held with IWDTEP members to discuss the results and decide on the final number of outcomes. Eight participants who completed both rounds of the Delphi survey were invited to participate in the consensus meeting. Invited participants who could not attend the meeting were provided with the conclusions of the meeting and given the opportunity to provide feedback on the results. All outcomes that were rated as 'critical' or 'no consensus' in the Delphi survey were up for discussion. During the online meeting, participants were given the opportunity to share opinions on the importance of each outcome under the guidance of the moderator.

Data analysis

Demographic data of the qualitative and Delphi study, as well as responses to the questionnaire were described using frequency distributions. All analysis were performed using SPSS statistical package version 25 (SPSS, Inc., Chicago, IL, USA).

Ethical considerations

The study was approved by the Ethical Committee of Ghent University Hospital (B6702020000296). Written informed consent was provided by all participants. Participants' information was treated anonymous and confidential. The study has been registered in the Core Outcome Measures in Effectiveness Trials (COMET Initiative) database.

RESULTS

Characteristics of the participants

In total five researchers, eight clinicians and five patients were interviewed. An overview of their demographics in provided in Table 3.

Table 3 Participants interviews

	Group 1[a]	Group 2[b]	Group 3[c]
N (%)	**5**	**8**	**5**
Country			
Africa[d]	0 (0.0)	0 (0.0)	1 (20.0)
Asia[e]	1 (20.0)	0 (0.0)	0 (0.0)
Europe[f]	1 (20.0)	1 (12.5)	3 (60.0)
North America[g]	0 (0.0)	1 (12.5)	0 (0.0)
Oceania[h]	0 (0.0)	4 (50.0)	1 (20.0)
South America[i]	2 (40.0)	0 (0.0)	0 (0.0)

Gender				
	Female	2 (40.0)	7 (75.0)	1 (20.0)
	Male	3 (60.0)	1 (25.0)	4 (80.0)
Age				
	mean (SD) years	53.3 (14.1)	48.8 (11.6)	72.4 (11.9)
Professional experience[j]				
	mean (SD) years	23.4 (11.8)	24.9 (12.9)	

[a] Researchers [b] Clinicians [c] Patients [d] South Africa [E] Israel [f] Belgium, Ireland, United Kingdom [g] Canada [h] Australia [I] Brazil [j] in current function

Table 4 provides the participant characteristics for the Delphi survey. In total 157 panellists completed the first Delphi round, of which 111 (70.7%) completed the second round. Across all rounds participants were recruited from 23 countries and 6 regions. Most of the panellists reported living in Europe (n = 65), followed by Oceania (n = 17). The largest stakeholder group was formed by the 'clinicians' (n = 66). Clinicians were mainly nurses, either within or without an additional researcher role (n=70).

Table 4 Participant characteristics for the Delphi survey

			Round 2	
	Group 1[a]	**Group 2**[b]	**Group 3**[c]	**Group 4**[d]
N (%)	9	66	7	29
Country				
Africa[e]	0 (0.0)	6 (9.1)	0 (0.0)	2 (6.9)
Asia[f]	1 (11.1)	2 (3)	0 (0.0)	2 (6.9)
Europe[g]	8 (88.9)	34 (51.5)	5 (71.7)	18 (62.1)
North America[h]	0 (0.0)	12 (18.2)	0 (0.0)	1 (3.5)
Oceania[i]	0 (0.0)	12 (18.2)	2 (28.3)	3 (10.3)
South America[j]	0 (0.0)	0 (0.0)	0 (0.0)	3 (10.3)
Gender				
Female	1 (1.11)	11 (16.7)	4 (57.1)	11 (37.9)
Male	7 (77.8)	54 (81.8)	3 (42.9)	17 (58.6)
Non-binary/third gender	0 (0)	1 (1.5)	0 (0.0)	0 (0.0)
Prefer not to say	1 (1.11)	0 (0)	0 (0.0)	1 (3.5)
Age				
mean (SD) years	47.8 (15.2)	50.6 (11)	53.4 (8.6)	47.7 (11.4)
Education				
High school	0 (0.0)	0 (0.0)	1 (14.3)	0 (0.0)
College degree	0 (0.0)	4 (6.1)	0 (0.0)	0 (0.0)
Bachelor's degree	0 (0.0)	21 (31.8)	3 (42.9)	4 (13.7)
Master's degree	4 (44.4)	34 (51.5)	2 (28.6)	17 (58.6)
Doctoral degree	5 (55.6)	4 (6.1)	0 (0)	5 (17.4)
Other	0 (0)	3 (4.5)	1 (14.3)	3 (10.3)
Role				
Clinician (nurse/ANP[k]/…)	0 (0.0)	52 (78)		18 (62.1)
Clinician (medical doctor)	0 (0.0)	5 (7.5)		1 (3.5)
Clinician (other)	0 (0.0)	1 (1.5)		1 (3.5)
Research	3 (33.3)	2 (3.0)		2 (6.9)

	Round 2			
	Group 1[a]	**Group 2[b]**	**Group 3[c]**	**Group 4[d]**
Professor/lecturer	5 (55.6)	2 (3.0)		3 (10.3)
Director	0 (0.0)	2 (3.0)		4 (13.7)
Other	1 (11.1)	2 (3.0)		0 (0.0)
Field of work				
Bioengineering	1 (1.1)	0 (0.0)		0 (0.0)
Dermatology and wound care	5 (55.6)	50 (75.7)		19 (65.5)
Emergency/Intensive care	1 (11.1)	1 (1.5)		1 (3.4)
General medicine* / (community) Nursing	0 (0.0)	8 (12.3)		3 (10.3)
Geriatrics	1 (11.1)	3 (4.5)		0 (0.0)
Pediatrics	0 (0.0)	0 (0.0)		2 (6.9)
Rehabilitation Care	0 (0.0)	2 (3.0)		1 (3.4)
Surgery	1 (11.1)	2 (3.0)		0 (0.0)
Other	0 (0.0)	0 (0.0)		2 (6.9)
Professional experience[l]				
mean (SD) years	14.5 (10.9)	14.9 (10.6)		16.9 (10.5)

[a] Researchers [b] Clinicians [c] Patients [d] Researchers and clinicians

[e] India, Israel, Malaysia, State of Palestine, Turkey [f] South Africa [g] Belgium, Denmark, Ireland, Italy, Malta, Netherlands, Norway, Portugal, Serbia, Spain, Sweden [h] Canada, United States [i] Australia, New Zealand [j] Brazil [k] Advanced Nurse Practitioner [l] in current function *including cardiology and oncology

Delphi study

The systematic review resulted in 82 outcomes, and 20 additional outcomes were obtained during the interviews. The initial list of outcomes is presented in Supplementary Table S1. After the pilot test, outcomes with similar meanings but subtle differences in wording or outcomes that referred to the same concept were discussed with the IWDTEP members and refined into single outcomes. For example, the outcomes 'trauma to wound edges', 'trauma to the wound bed, and 'trauma to the surrounding skin' were grouped into 'dressing-related trauma'. After this refinement, 51 outcomes were included in the Delphi study. The two Delphi rounds took place between September and November 2022. After the first round, six outcomes ('absorption capacity', 'access to wound specialist', 'healing time (days) level of itching', 'level of patient knowledge', 'presence of sinus') were added to the list.

Of the 57 outcomes, 45 were rated 'critically important' by all groups with mean scores ranging from 6.8 (SD = 1.4) to 8.5 (SD = 0.6). Of these, 22 outcomes were rated to be 'critically important' by >90% of all groups. The outcome 'ability to stay in place' reached consensus on 'critically important' by all participants. Ten outcomes had an average mean score of ≥8. For patients, the outcome 'overall satisfaction had the highest mean score (M = 8.14; SD = 0.69). The outcome 'ability to stay in place' had the highest mean score for researchers (M = 8.44; SD = 0.73), clinicians (M = 8.55; SD = 0.612) and the combined group of researchers and clinicians (M = 8.52; SD = 0.688). Twelve outcomes did not reach the threshold and were rated as 'of low importance'. The results of the Delphi study are provided in Supplementary Table S2.

Consensus meeting

The consensus meeting took place on 22 December 2022 with 11 IWDTEP members, one researcher and two clinicians of the Delphi study. The almost concordant results made the participants realize that some outcomes had a close overlap in terms of their definition and scope, such that certain outcomes were captured by other outcomes; indicating that they could be consolidated and merged into a single outcome measure. Additionally, discussions arose about which of the outcomes were able to evaluate the unique features of bordered foam dressings in the treatment of complex wound.

'**Ability to stay in place**' was identified as the outcome of highest importance. Its inclusion was approved by all participants both in the Delphi study as well during the consensus meeting. During the meeting participants agreed this outcome captures the main feature of a bordered foam dressing.

A similar opinion was shared for the outcome '**leakage'** which was likewise considered critical unanimously by the expert group and which directly relates to the fluid handling characteristics of dressings.[14] Further, there was agreement that 'pain during wear and pain while removing or changing the dressing' are very important but are strongly interrelated. Therefore, the participants agreed both outcomes could be merged into the single outcome '**pain'**. Capturing outcomes on 'quality of life, overall satisfaction and comfort' as core outcomes seemed relevant to some from a patient perspective. Others countered that these outcomes are important, but it is challenging to capture these outcomes without losing the subjective nature. It was therefore agreed that it was justified to not include them as a part of the COS due to their subjective nature. There were further discussions about some possible overlaps, for example between the outcomes 'dressing related trauma, maceration, allergic reaction and periwound skin condition'. It was noted that, although they represent separate outcomes, they strongly interrelate. Therefore, participants agreed to group these outcomes in a separate outcome '**dressing related periwound skin changes'.** Several participants raised the question whether an outcome on wound healing should be included and which outcome was considered most suited. It was found that this outcome should not be limited to a visual aspect (e.g. size or depth) but should include a time aspect as well. This led to the suggestion to evaluate wound healing by the outcome '**change in wound size over time'**. Finally, participants indicated that economic outcomes are infrequently reported in wound care research and that inclusion of the outcome '**cost effectiveness'** in the COS would increase the awareness and the standardization of reporting economic outcomes. The remaining outcomes were considered important but not as a part of the minimum set. The selected Delphi study participants who did not attend the meeting had no further feedback on the results.

After the consensus meeting, the discussion regarding including a patient-reported outcome was reopened within the group. Given the tremendous impact that complex wounds and their treatment may have on a patient's daily life, the IWDTEP members and the selected Delphi study participants of the patient group decided to include the outcome '**overall satisfaction'.**

In total, seven core outcomes were determined for clinical effectiveness studies of bordered foam dressings in the treatment of complex wounds.

Table 5 Core outcomes for clinical effectiveness studies of bordered foam dressings in the treatment of complex wounds

Core outcome	Description
Ability to stay in place	The ability of a bordered foam dressing to remain securely adhered to the wound site without shifting or coming loose during wear but also without causing skin damage while removing it (once or multiple times).

Core outcome	Description
Leakage	The ability of a bordered foam dressing to prevent fluid or exudate from escaping the wound and coming into contact with skin and other surroundings such as the clothing or bedsheets when the dressing is in its intended place on the wound, as determined by the wound care clinician.
Pain	The level of discomfort or pain experienced by the patient when the bordered foam dressing is applied or removed, or when the dressing is worn for an extended period of time.
Dressing related periwound skin changes	Any changes in the condition of the skin surrounding the wound, caused by the use of the bordered foam dressing. These changes can include erythema, maceration, medical adhesive related skin injury or other signs of irritation.
Change in wound size over time	Change in the size of the wound, measured over time, as a result of using the bordered foam dressing.
Cost effectiveness	Cost effectiveness includes several aspects such as the cost of the dressing itself and the cost of any additional wound care products needed, and the cost of clinical labor time associated with use of the product/s, in relation to the effectiveness of the dressing in healing the wound, such as change in wound size over time, the number of wound healing complications, and the overall improvement in the patient's overall satisfaction.
Overall satisfaction	The degree to which the individual considers the dressing or the way in which the wound care with the dressing is provided as useful, effective or beneficial. This includes the allowance of normality of daily routines and the comfort of the dressing during wear or sleep.

Discussion

The aim of our study was to develop a COS for clinical effectiveness studies of bordered foam dressings in the treatment of complex wounds. The final COS compromises seven core outcomes: 'ability to stay in place', 'leakage', 'pain, 'dressing related periwound skin changes', 'change in wound size over time', and 'overall satisfaction'. The first six outcomes all correlate, directly or indirectly, with quantitative engineering performance metrics related to the fluid handling and mechanical and contact characteristics of foam dressings, which reflects bordered foam dressings their unique features. he seventh outcome reflects the complex impact of wounds and their treatment on a patient's daily life.

The development of this COS followed a multi-stage process according to the current standards of COS development.[16] However, our starting point was an intervention/treatment, whereas a COS usually is developed from and for a specific health condition. The reasoning behind this are the specific features that bordered foam dressings offer.[6-8] Bordered foam dressings are only one type of dressing in a range of wound dressings and we agree that it is impractical and even impossible to develop a COS for each of these wound dressings. However, the unique aspect, and the reason for this COS, of bordered foam dressings is that they combine multiple features of different dressings into one (e.g. exudate handling, malodour control, comfort for the patient, and ability to shower).[6-8,13-15] This is also reflected in the prioritized outcomes, 'ability to stay in place' and 'leakage'. Their relevance for practice is also reflected in the global market statistics. However, despite their relevance in practice and the expected increase

in use, it is challenging to evaluate their effectiveness, due to the variety and lack of consistency in terms of outcomes across different reported studies.

This is reflected in the comprehensive list of outcomes initially obtained through our systematic review[19] (n = 82). Moreover, individual interviews with clinicians, researchers and patients identified 20 additional outcomes. To examine the conceptual complexity of those outcomes, a pilot study with different stakeholders was conducted. Based on their input, the 102 outcomes were refined to 51, and ambiguous outcomes were clarified with a definition. Nevertheless, the results indicate that despite those measures, some definitions were insufficient or some outcomes remained closely related to another.[27] This was reflected during the consensus meeting, where the interrelation between the outcomes 'dressing related trauma, maceration, allergic reaction and periwound skin condition' was highlighted. Therefore, participants agreed to group these outcomes in a separate outcome 'dressing related periwound skin changes'. The results indicate also that our criteria to withdraw outcomes have been too strict, as none of them were excluded. Scoring an outcome to be 'of low importance' (scores 1-3) may be a barrier and the large list of outcomes may have been a burden on participants. A suggestion may be to reduce the number of outcomes from one round to the next by grouping closely related outcomes after the first Delphi round and classify them in overarching outcomes. In future studies, it could be considered to label the scores 1-3 differently, for example 'somewhat important'.[28]

Contrary to expectations, no outcome on wound healing had a mean score of 8 or higher in contrast to outcomes on the dressings' features such as durability. This finding may indicate that the participants were able to comprehend the objective of this COS, specifically the evaluation of the specific features of a bordered foam dressing. However, it was determined through consensus that the inclusion of an outcome on wound healing was needed. Discussions ensued regarding which of the evaluated outcomes would be most suitable for this purpose. Based on the results, it was agreed that the chosen outcome should be capable to capture both the visual aspect of wound healing and the time aspect. As such, the outcome of "wound size over time" was chosen. As indicated previously the cost of treating complex wounds puts a strain on healthcare resources and budgets. However, there has been more attention in research to the context of effectiveness rather than costs in the treatment of complex wounds. Therefore, consensus was reached to include the 'cost-effectiveness'.

Another important finding was that the outcome 'overall satisfaction', which had the highest mean score for patients in the Delphi survey, was not included as a core outcome during the consensus meeting. This may be reflected by the patients' absence from the consensus meeting. They received the conclusions of the meeting via email, and they agreed that capturing outcomes on 'quality of life, overall satisfaction, and comfort' are challenging without losing the subjective nature. Nevertheless, it is important to recognize that disagreeing through email added an extra barrier. Additionally, there was an agreement to include the outcome 'pain' as a core outcome. Despite 'pain' constituting only one important factor determining quality of life, it has a detrimental effect on every aspect of the life of individuals.[29,30] and the outcome may be more easily captured compared to the outcomes of 'quality of life' or 'overall satisfaction'. However, given the tremendous impact that complex wounds and their treatment may have on a patient's daily life, the discussion to include a patient-reported outcome was reopened. As a result, the outcome 'overall satisfaction' was added to the COS.

This study has some limitations. Based on the systematic review and qualitative interviews, 102 outcomes were identified. This long list was considered not feasible to be presented in the Delphi survey. Therefore, multiple outcomes were grouped into single outcomes, which may have made the outcomes more abstract for participants. Additionally, the choice to group outcomes may have introduced subjectivity,.

Nonetheless, we provided clear definitions to mitigate the above challenges. It is worth noting that there is no guidance on grouping similar outcome terms into a single unique outcome and that there is a need for further methodological guidance.[31] Another limitation of the study could be that the total number of participating patients might be considered low specifically because none of them could attend the consensus meeting. However, the study included more patients in the Delphi study than initially anticipated and reported the final outcome set via email. More research is needed on how to engage patients in Delphi procedures and consensus meetings involving different experts from multiple disciplines.[26] In addition, it should be investigated whether there is a need for patient core sets.

A strength of this COS project is that throughout the different stages of the study, great efforts were made to ensure a high and representative sample of participants. Through the inclusion of various international stakeholder groups in the interviews, Delphi survey and online consensus meeting we aimed to increase the number of ideas, perspectives, and issues considered, to ensure credibility, relevance, and significance to diverse groups; and to increase acceptance and dissemination of this COS. To date, this is the first study ever conducted to obtain international and multidisciplinary consensus on a core outcome set (COS) for clinical effectiveness studies of bordered foam dressings in the treatment of complex wounds. We would recommend that researchers evaluating the treatment of complex wounds with bordered foam dressings should report the COS-outcomes identified here as a minimum, along with any other outcomes of interest to their research questions. In this way, we believe this COS will enhance the comparability of study results worldwide, facilitate data synthesis and meta-analyses, decrease possible outcome reporting biases, and stimulate evidence-based practice and decision-making. The next steps entail the development of a set of measurement instruments and relevant endpoints in order to measure these outcomes.

Conclusion

The COS for evaluating the effectiveness of bordered foam dressings in treating complex wounds includes 7 outcomes: ‘ability to stay in place’, ‘leakage’, ‘pain’, ‘dressing related periwound skin changes’, ‘change in wound size over time’, and ‘overall satisfaction’. These identified outcomes are correlated with contemporary bioengineering testing and evaluation methods for dressing performance, which underpins the need for a close multidisciplinary collaboration to advance the field of wound dressings. The outcome ‘overall satisfaction’ reflects the impact that complex wounds and their treatment may have on a patient's daily life. The use of these outcomes is recommended to improve data synthesis and promote evidence-based practice. Future developments in COS development involve creating measurement instruments and relevant endpoints for these outcomes.

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Declaration of competing interest

None.

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