Study Protocol

The Nordic Consensus Study – Evaluation of the consensus guidelines in clinical practice

Study ID: CP339

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1. Background

Leakage is a big concern for ostomates. In a global survey conducted by Coloplast (n=5187) (1) - the Ostomy Life Study 2019 – 32 % experienced leakage once a week and 27% experienced leakage onto their clothes every month. 92 % of people living with an ostomy worry about leakage. Leakage has severe consequences such as skin complications and social isolation. If ostomates have skin complications, 58 % consider output under the baseplate to be the cause, 66 % say it to some degree impacts their ability to work and 20 % rarely leaves home due to fear of leakage. 26% say that difficulties getting a good fit of the stoma appliance is the main reason for leakage.

The Body Assessment Tool has been created to help better understand what products to use for individual peristomal body profiles. Individuals with a stoma have very different peristomal body profiles which sometimes require ostomy products that are designed to meet special shaping needs. The Body Assessment Tool is a 6- step assessment tool based on the newly developed consensus guidelines among stoma care nurses.

An article has been published in *British Journal of Nursing* (2) about the consensus guidelines to encourage nurses to choose ostomy products based on assessment of the individual body profile of the user. The paper shows how the consensus guidelines were developed and presents concept and purpose of the 6 steps in the Body Assessment Tool in hope of providing nurses a more structured and "right from the start" approach when choosing ostomy products. However, the Body Assessment Tool needs to be evaluated in clinical settings to document the usability among nurses and to explore its impact on selection of ostomy product(s) together with a potential improvement of leakage incidences and the user's leakage-related quality of life using the validated OLI score (Ostomy Leakage Impact Tool)(3).

Furthermore, it is of interest to explore usability of The Body Assessment Tool in the group of newly stoma patients (i.e. newly patient discharged (NPD)) as they may have a potentially larger extent of change of their peristomal body profile post-surgery compared to experienced people with a stoma (i.e. veterans). A subgroup of NPDs will therefore be recruited at one clinical site,
Meilahden tornisairaala, Finland
.

2. Hypothesis

The hypothesis is that with the Body Assessment Tool in combination with the use of the current guidelines and practices, nurses will be able in a standardised way to choose the most appropriate ostomy product(s) for the given user and may thereby help improving the QoL of the user by reducing the users concerns about leakage and preventing the incidences of leakage.

3. Objectives

3.1. The primary objective

- To evaluate the usability of the 6- step Body Assessment Tool in clinical settings (performed by the nurse) – see appendix A. For the usability evaluation a questionnaire has been prepared, theNurse Evaluation Form – see appendix B.

3.2. The secondary objectives

- To explore if the use of Body Assessment Tool and related change of ostomy product(s) have an impact on the leakage associated QoL (based on the OLI score)- see appendix C. The OLI score includes three domain scores:
  - emotional impact
  - usual and social activities
  - coping and in control
- To evaluate the incidences of leakage before and after change of ostomy product(s) (the question will be included in a leakage questionnaire in addition to the OLI score – see appendix D).

4. Study design

The study is a 1-sequential, 1-arm, non-randomised, non-blinded, multi-center (between 20 to 40 sites in total) non-interventional 4-5-week clinical investigation in which the Body Assessment Tool will be evaluated for its usability by ostomy nurses using the Nurse Evaluation Form and to explore if the change of ostomy product(s) can reduce the user's concerns about leakage and have a positive impact on QoL related to leakage (estimated by the OLI score). For evaluation of the number of leakage incidences the last 7 days pre- and post-change of ostomy products a questionnaire is prepared including a definition of leakage and images for support.

Blinding is not applicable as change of ostomy product(s) cannot be blinded for either the user or nurse. Randomization is not applicable as there will be no comparison to a specific ostomy product or control group. The subjects will change their ostomy product(s) based on their individual body profile assessment and the selection of ostomy products will vary in between subjects and will not be dictated by this protocol.

The NPD subgroup will follow the same protocol as the veterans. However, the data (NPDs vs. veterans) will not be compared due the potentially difference in the change of peristomal body profile. The NPD data will be regarded and handled as exploratory.

All assessments will be based on questionnaires either completed by the nurse or user. Usability data will only be analyzed using descriptive methods. Whereas the OLI score results will be analyzed by descriptive methods (sub-questions in OLI score) and paired t-test (domain scores). The number of leakage episodes will be analyzed by paired t-test.

The study will include 1 visit at the clinic and at least 1 phone call visit to the user (end-of study phone visit). The number of phone calls will vary depending on the user's need for support.

Prior to screening the nurse identifies potential patients who require a re-evaluation of their current ostomy products due to ongoing product issues (please refer to section 5 *'In- and exclusion criteria'*). If the patient is interested in study participation the subject must sign an informed consent after having received verbally and written information about the study. When signed the subject can undergo the screening assessment and if found eligible the subject can be enrolled in the study.

Following enrollment, the nurse will perform body profile assessment (the stoma and peristomal area) of the subject using the Body Assessment Tool. Based on the result the nurse will select the most appropriate ostomy product(s) for the subject. The body assessment tool that has been filled out for each participant will be stored in the study participant file. At the visit the subject will also be asked to evaluate the impact of leakage and fear of leakage on their QoL using the OLI-score together with recalling the number of leakage incidences the last 7 days. This questionnaire will also be stored in the study participation file. The participant

will leave the clinic with new ostomy products and be instructed to use them for the next 4-5 weeks. The participant will also receive a second questionnaire to be filled in at home after 4-5 weeks.

After 4-5 weeks, the nurse will contact the subject by phone or in a new scheduled visit to the clinic to remind the participant, if needed, to evaluate the impact of leakage on QoL/fear of leakage using the OLI score together with recalling the number of leakage incidences in the last 7 days. The subjects will send the questionnaires with a patient code directly to Coloplast. Patients will be encouraged to send in the second questionnaire even if they have discontinued using the recommended ostomy products also to know the reason for discontinuation.

After all subjects at a given study site have been included, the nurse will evaluate the Body Assessment Tool based on his/her experience of the tool in the clinic, using the Nurse Evaluation Form.

Anonymous data – including the questionnaire and the body assessment tool for each participant and the Nurse Evaluation Form will be sent to Coloplast for analysis.

5. Inclusion- and exclusion criteria

5.1. Inclusion criteria for veterans

- Adult, aged: ≥18
- Male or female individual with a stoma
- Stoma debut for ≥ 3 months
- Individual who require a re-evaluation of ostomy product(s) in a stoma care clinic due to issues with leakage
- Must have provided a written informed consent for participation in the study prior to any specific procedures

5.2. Inclusion criteria for NPD subgroup

- Adult, aged: ≥18
- Male or female individual with a stoma
- Stoma debut for < 3 months
- Must have provided a written informed consent for participation in the study prior to any specific procedures

5.3. Exclusion criteria for veterans and NPDs

The subject will not be eligible for enrollment if the subject:

- Requires a caretaker to change ostomy product(s) on the user
- Is pregnant (mainly due to substantial change of body profile during intervention)
- Is lactating (mainly due to potential weight loss and substantial change of body profile during the intervention)
- Does not have the resources personally, mentally, or physically to participate in the intervention (judged by the ostomy nurse)
- Changes his/her ostomy products (bag or plate) during the intervention period (withdraw of data)

6. Number of patients with rationale for choice

A minimum of 160 subjects will be enrolled in the study. At least 40 individuals with a stoma will be enrolled from each Nordic country (i.e. Denmark, Sweden, Norway and Finland). The subjects will be recruited from at least 3 clinics in each country and each clinic will recruit at least 5 participants to the study. The total number of participants is based on what seems feasible to enroll. As the primary endpoint will be presented using descriptive methods there is no requirements on the sample size.

The OLI score results are not the primary outcome of the study and the >160 numbers of subjects are sufficient.

7. Statistical considerations

Data from the Nurse Evaluation Form will be presented using descriptive methods.

The OLI score will be presented using both descriptive methods (i.e. sub-questions) and quantitative methods (i.e. the 3 domain scores: 'emotional impact', 'usual and social activities' and 'coping and in control').

Change of the domain scores 'emotional impact', 'usual and social activities' and 'coping and in control' and number of leakages pre-and post-transition of ostomy products will be analyzed by using paired t-test. All three domain scores are designed to range from 0-100. Higher scores represent better levels of functioning. The domain scores will be calculated as mean of the responses to each question or item within a domain (the method to estimate the domain scores is described in Appendix C).

The number of leakage episodes/7 days) will be analysed by quantitative methods (paired t-test).

The exploratory NPD data from the clinical site Meilahden tornisairaala, Finland will not be pooled with the veteran data as the two groups can be potentially very different in the change of peristomal body profiles during the study period. This makes the two groups less comparable and the NPD data will therefore be analysed separately.

There will be no comparison to other types of products or body assessment tools. In case subjects change to other ostomy products during the intervention period the data of the given subject will not be included in the final data of the study.

8. Primary and secondary outcomes

8.1. Primary outcome

- The usability of the Body Assessment Tool will be based on the Nurse Evaluation Form including the following questions (evaluation performed by the nurse) (6-point scale):
  - How well does the Body Assessment Tool work in a clinical setting?
  - How well does the assessment of the user's body profile work prior to selecting ostomy product(s)?
  - Do you experience that the Body Assessment Tool supports you to increase the quality of the treatment?

8.2. Secondary outcomes

- Rating of the user's leakage associated QoL the last 7 days (i.e. 4-point scale sub-questions) before and after ostomy product change
- Change in domain scoring of fear of leakage and the impact on QoL pre- and post-transition of ostomy product(s):
  - emotional impact
  - usual and social activities
  - coping and in control
- Number of self-reported retrospective incidences of leakage the last 7 days on prior to and after transition to more appropriate ostomy product(s)
-
- Analysis of connection between body profile, product solution and incidence of leakage

9. Comparison or control group

There will be no comparison to other types of products, body assessment tools or control groups.

Each subject will act as their own control when analysing the difference in the OLI score and number of leakage incidences pre-and post-transition of ostomy product(s).

10. Study follow-up schedule

No follow-up visits or contact with the users are included in the study

11. References

1. Ostomy Life Study 2019, Global Report, Data-on-file, PM-10499
2. James-Reid S, Bain K, Hansen AS, Vendelbo G, Droste W, Colwell J. Creating consensus-based practice guidelines with 2000 nurses. Br J Nurs. 2019; 28: S18-S25
3. Nafees B, Störling Z, Hindsberger C, Lloyd A. The Ostomy leak impact tool: development and validation of a new patient-reported tool to measure the burden of leakage in ostomy device users. Health and Quality of Life Outcomes. 2018; 16:231

12. Appendix A - Body Assessment Tool

Datum_____ Patient XXXX

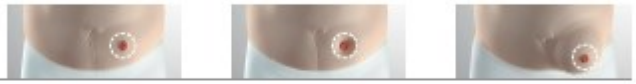
Kroppsprofil

Utvärdering av den peristomala kroppsformen för att säkerställa det bästa produktvalet

Coloplast

1	Formen på området runt stomin. Formen kan ändra sig när du sitter, ligger eller rör på dig.	Platt	Området är mer eller mindre i nivå med buken, även om stjälva huden kan vara ojämn.
		Inbuktad	Området sjunker ner i buken och bildar en grop.
		Utbuktad	Området reser sig från buken och bildar en topp.

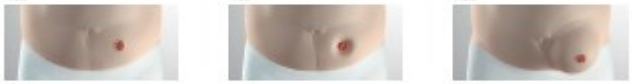
Platt Inbuktad Utbuktad



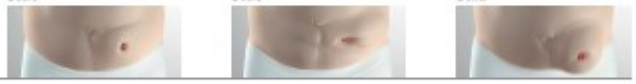
2	Den valda ytan kanske inte täcker hela området runt stomin	Helt	Formen täcker hela området runt stomin.
		Delvis	Formen täcker delar av området runt stomin.

Platt Inbuktad Utbuktad

Helt



Delvis

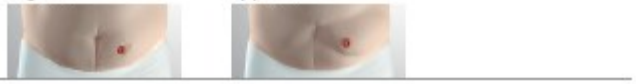


3	Är magen mjuk eller fast?	Mjuk	Ytan ger vika för tryck (som motsvarar tryck på en vattenmadrass).
		Fast	Ytan motstår tryck (som motsvarar tryck under hälen).

Mjuk mage Fast mage

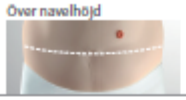
4	Är det ytliga eller djupa veck?	Ytliga	Huden omkring stomin har linjer, är förrod eller rynkig.
		Djupa	Huden omkring stomin har djupa veck av löst skinn eller fett.

Ytliga veck Djupa veck

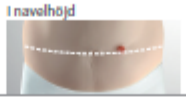


5	Stomins placering		Över navelhöjd	Stomin är placerad över navelhöjd.
			I navelhöjd	Stomin är placerad i navelhöjd.
			Under navelhöjd	Stomin är placerad under navelhöjd.

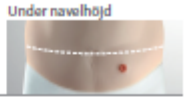
Över navelhöjd



I navelhöjd

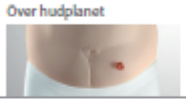


Under navelhöjd

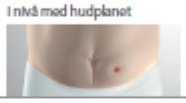


6	Stomimynningens placering i förhållande till huden		Över hudplanet	Stomimynningen är över hudplanet.
			I nivå med hudplanet	Stomimynningen är i nivå med hudplanet.
			Under hudplanet	Stomimynningen är under hudplanet.

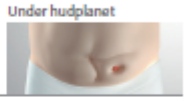
Över hudplanet



I nivå med hudplanet



Under hudplanet



Konsistensen på det som kommer ut från stomin

Konsistens:		Tjock avföring	
		Lös avföring	
		Urin	

Val av produkt

Typ av häfta		Typ av system		Typ av påse	
	Platt		1-delssystem		Tömbar påse
	Convex Soft		2-delssystem (klick/mekanisk koppling)		Sluten påse
	Convex Light		2-delssystem (häftkoppling)		Urostomipåse
	Convex Deep				
	Konkav				
	Annat				

Tillbehörsprodukter

Övriga faktorer som har haft betydelse vid val av produkt (markera gärna med flera kryss)

	Den peristomala huden		Patientens tillgång till hjälp i hemmet
	Patientens allmänna tillstånd		Patientens förmågor

13. Appendix B - Nurse Evaluation Tool

Utvärdering

Nordisk Konsensus Studie

Sjukhus: _____

Avdelning: _____

Stomiterapeut: _____

Datum: _____

1	Hur många stomiopererade har deltagit i studien? _____					
2	Hur väl upplever du att verktyget ***Kroppsprofil*** fungerar i klinisk praxis (där 6 är bäst). *Markera med x*					
	1	2	3	4	5	6
3	Hur väl upplever du att det fungerar att utgå ifrån patientens kroppsprofil, när du ska välja stomiprodukter? (där 6 är bäst). *Markera med x*					
	1	2	3	4	5	6
4	Upplever du att verktyget ***Kroppsprofil*** hjälper till att lyfta kvaliteten på behandlingen? (där 6 är bäst). *Markera med x*					
	1	2	3	4	5	6

5

De Internationella Consensus Guidelines rekommenderar att man, utöver att välja produkt baserat på kroppsprofil, även tar patientens peristomala hud och övergripande situation i beaktning. Genom att överföra det antal gånger de fyra faktorerna har påverkat valet av produkt från det ifyllda verktyget ***Kroppsprofil***, kan vi bestämma, vilka faktorer utöver kroppsprofil, som har varit viktigast i valet av produkt.
*Överför från verktyget **Kroppsprofil** det antal gånger de fyra faktorerna har haft påverkan på produktval*

Den peristomala huden	Patientens allmänna tillstånd	Patientens tillgång till hjälp i hemmet	Patientens förmågor

Andra förhållanden du har tagit i beaktning:

6

Beskriv med egna ord hur du upplever att verktyget ***Kroppsprofil***, som baserar sig på de Internationella Consensus Guidelines, har fungerat i klinisk praxis ?

7

Vill du rekommendera verktyget ***Kroppsprofil*** till andra stomiterapeuter/vårdpersonal?
Markera med *X*

JA	NEJ	Varför?

Tusen tack för hjälpen!

14. Appendix C – The OLI Score

The below tables show the scoring weights for each item from the OLI score questionnaire.

Domain score 1. Emotional impact

When you thought about your ostomy device and the risk of leakage, what emotions did you feel?

In the last 7 days, due to leakage or worry about leakage…	**All of the time**	**Often**	**Sometimes**	**Rarely or never**
1. I felt panic	0	1	2	3
2. I felt stressed out	0	1	2	3
3. I felt more afraid about leaks in the future	0	1	2	3
4. I felt worry	0	1	2	3
5. I felt frustrated	0	1	2	3
6. I felt embarrassed	0	1	2	3
7. I felt worried that I might leak	0	1	2	3
8. I couldn't sleep	0	1	2	3
9. I kept waking up at night to check my stoma	0	1	2	3
10. I kept checking my ostomy bag to see if I have leaked	0	1	2	3

Domain score 2. Usual and Social activities

When you thought about your ostomy device and the risk of leakage, how did it affect your activities?

In the last 7 days due to leakage or worry about leakage…	**All of the time**	**Often**	**Sometimes**	**Rarely or never**	***Not applicable***
11. I decided to stay at home	0	1	2	3	9
12. I couldn't do light activities	0	1	2	3	9
13. I changed my plans	0	1	2	3	9
14.I was unable to go out and meet family and friends	0	1	2	3	9
15. I avoided close physical contact with family and friends	0	1	2	3	9
16. I did not want to see people	0	1	2	3	9
17. I avoided people	0	1	2	3	9
18. I tried to avoid meeting new people	0	1	2	3	9

Domain score 3. Coping and in control

When you thought about your ostomy device and the risk of leakage, how did it affect your ability to cope?

In the last 7 days, due to leakage or worry about leakage…	**All of the time**	**Often**	**Sometimes**	**Rarely or never**
19. I felt in control	0	1	2	3
20. I was able to cope	0	1	2	3
21. I felt calm	0	1	2	3
22. I saw my friends as I usually do	0	1	2	3

All three domain scores are designed to range from 0-100. Higher scores represent better levels of functioning. A domain score is estimated as a mean of the responses to each question or item within a domain. This is then divided by the arithmetic difference between the minimum score (0) and the maximum score (3) so that this number then varies between 0 and 1. This is then rescaled between 0 -100. It is important to note that some items in the questionnaire are effectively reversed scored. The need to do this is accommodated by in the scoring algorithm itself rather than in the scoring weights for each question. Scoring formulae for the three domain scores is provided here:

Emotional impact

$$Score = \left(\frac{\sum(Q1, Q2, \dots Q10)}{10} \div 3 \times 100\right)$$

Usual & social activities

$$Score = \left(\frac{\sum(Q11, Q12, \dots Q18)}{8} \div 3 \times 100\right)$$

Coping & in control

$$Score = 100 - \left(\frac{\sum(Q19, Q20, \dots Q22)}{4} \div 3 \times 100\right)$$

Not applicable & Missing data
Where responses are classified as Not applicable then this should be noted in the descriptive summary of the data in any study report. In addition, though for the purposes of scoring the domains these responses should be coded as missing data.

A domain score can be estimated when at least 50% of the items within a domain have been completed. The scale score is estimated in the same way by taking the mean of the items that have been completed. If less than 50% of the items have been completed, then the domain should not be scored for that individual. If there are a high number of participants who fail to complete all the items in the survey, then this should be noted as a limitation in the study report.

References:

(1) *Creating consensus-based guidelines with 2000 nurses*, Sara James-Reid et al., British Journal of Nursing 2019: https://www.magonlinelibrary.com/doi/full/10.12968/bjon.2019.28.22.S18

15. Appendix D – The Leakage Questionnaire

2. Antal läckage och dess storlek

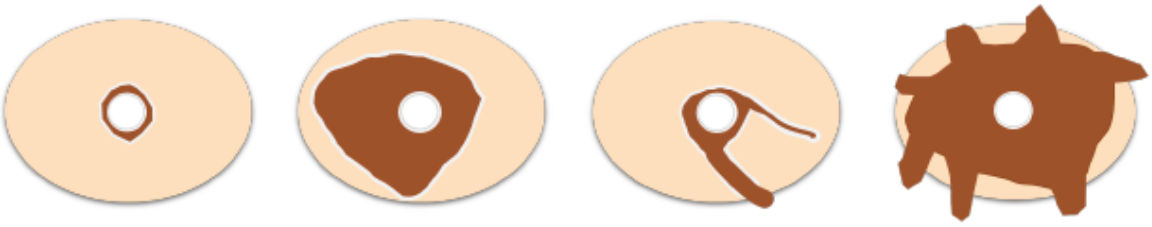
Hur många läckage har du haft de senaste 7 dagarna? _____
(se definitionen av läckage nedan)

Vad menar vi med läckage?

När du ska bedömma hur många gånger du har haft läckage under de senaste 7 dagarna, vill vi be dig att titta på exemplen nedan. Alla exempel nedan beskriver **läckage**. Allt från det lilla läckaget intill stomin; när huden kommit i kontakt med avföring eller urin, till stora läckage där det har läckt ut på kläderna.

Om du under de senaste 7 dagarna kan komma ihåg hur mycket läckage du har haft vid varje läckagetillfälle ber vi dig att även fylla i antal läckage nedan under varje exempel:

Läckage - avföring



Antal _____ Antal _____ Antal _____ Antal _____

Läckage - urin

Antal _____ Antal _____ Antal _____