ORIGINAL ARTICLE

MAYO CLINIC PROCEEDINGS: DIGITAL HEALTH

MAYO CLINIC

Effect of a Novel Digital Leakage Notification System (Heylo) for Ostomy Care on Quality of Life and Burden of Living With an Intestinal Ostomy: The ASSISTER Trial, A Randomized Controlled Cross-Over Trial

Peter Che Ambe, MD, MBA; Elin Brunckhorst, PhD; Helle Doré Hansen, PhD; Johanne Louise Gotfredsen, PhD; Martin Vestergaard, PhD; and Teresa Adeltoft Ajslev, PhD

Abstract

Objective: To investigate the effect of a novel digital leakage notification system (Heylo) on quality of life (QoL) and burden of living with an intestinal ostomy.

Patients and Methods: A randomized, controlled, open-label, cross-over trial was conducted in Germany with people having intestinal ostomies, who were cared for by 13 ostomy care specialists. Participants with fecal leakage problems were randomized by a centralized system to either Heylo + Standard of Care (SoC) or SoC alone for 8 weeks, whereafter participants crossed over to the opposite treatment for an additional 8 weeks. Primary and secondary end points were: *Emotional impact* domain score of the Ostomy Leak Impact tool and *Participation* domain score of the WHO Disability Assessment Schedule 2.0, respectively. Primary comparisons between Heylo and SoC were evaluated using linear mixed models, taking time and study period into account. The trial is registered with ClinicalTrials.gov, NCT05200416.

Results: A total of 144 participants were allocated to a treatment sequence after giving informed consent (safety population). Analyses included randomized participants who had been exposed to at least 1 product and with information on at least 1 end point (intention-to-treat population, n=139). Both the *Emotional impact* and *Participation* domain scores improved significantly after 8 weeks use of Heylo compared with SoC (LS mean difference of 11.4; 95% CI, 7.8-15.0; $P<.001$ and −4.2; 95% CI, −6.7 to −1.6; $P=.001$, respectively). Few adverse events related to Heylo were reported (n=5, 3.5%; all related to skin irritation).

Conclusion: Use of Heylo reported positive effects on quality of life and the overall burden of living with an intestinal ostomy.

 ■ Mayo Clin Proc Digital Health 2023;1(3):438-449

From the Department of General, Visceral Surgery and Coloproctology, Universität Witten/Herdecke, Bergisch Gladbach-Bensberg, Germany (P.C.A.); Coloplast GmbH, Hamburg, Germany (E.B.); and Coloplast A/S, Humlebæk, Denmark (H.D.H., J.L.G., M.V., T.A.A.).

There are no global estimates for the number of people living with an ostomy; however, ∼700,000 people in Europe, more than 1 million in the United States, and ∼1 million in China live with an ostomy.[1,2] Stoma formation may be a life-saving intervention but often exposes patients to complications that may compromise their quality of life (QoL).[3] Living with an ostomy means lifelong use of ostomy care products (baseplate, bag, and supporting products) for the safe collection of effluent. Albeit ostomy care products have evolved considerably since their inception in the 1950's,[4] many people with an ostomy still struggle with leakage of stomal effluent seeping underneath the baseplate, sometimes progressing outside the baseplate, for example, soiling clothes or bedsheets, which is distressing for the individual and may lead to embarrassing situations.[1,5]

People living with an ostomy may not be able to feel stomal effluent seeping underneath

the baseplate and only become aware of this after effluent has soiled clothes or bedsheets. In a recent multinational survey among people living with an ostomy, 3 out of 4 respondents experienced effluent seeping underneath the baseplate monthly or more frequently, and moreover, 1 out of 4 experienced effluent progressing outside the baseplate at least once during this time period.[5,6] Within a year approximately 2 out of 3 experienced leakage outside their baseplate.[5,6]

Leakage incidents may have profound negative emotional consequences, with 9 out of 10 reporting worry about leakage.[5,6] Four out of 10 have reported that they often or all the time check their pouching system (bag and baseplate) for leakage, and even 1 out of 4 did so during the night.[5,6] Up to 1 out of 5 have stated that their worry about leakage made them stay at home and limited their social interactions.[5,6] The survey also investigated the impact of leakage frequency on QoL using the Ostomy Leak Impact (OLI) tool.[5,6] The frequency of leakage incidents outside or underneath the baseplate was negatively correlated with emotional wellbeing, participation in usual and social activities, and feeling of coping and control. Especially people who experienced leakage incidents outside the baseplate weekly, monthly, or every third month showed marked reductions in QoL.[5,6] This indicates that leakage of stomal effluent and worrying about it represent major mental burdens for many people living with an ostomy. Although advances in pouching systems, accessory products, and patient care have helped to improve fitting and attachment of the baseplate to the body,[4,7] there is still an unmet clinical need with regard to early leakage detection before effluent progresses outside the baseplate and soils clothes or bedsheets.

Previously, 2 exploratory single-arm trials have been conducted, namely a study in Denmark including 25 participants,[8] and 1 in the United Kingdom including a support service (NCT05135754, data not yet published),[9] both investigating health benefits of the digital leakage notification system (Heylo) in people with intestinal ostomies. In the 2 studies the use of Heylo reduced the number of leakage incidents progressing outside the baseplate, reduced worry about leakage, improved QoL, and improved stoma self-management[8,9] and NCT05135754.

We hypothesized that the use of Heylo as a stand-alone solution (without an online support service) would be associated with positive care effects in people with intestinal ostomies by enabling detection of an imminent leakage and thereby reduce the worry hereof. The aim of this randomized controlled cross-over trial (the ASSISTER trial) was therefore to investigate the effect of Heylo on QoL and burden of living with an intestinal ostomy.

PATIENTS AND METHODS

Study Design—Randomization and Masking

The study was conducted from January 2022 to November 2022 in Germany. The study is listed on www.ClinicalTrials.gov with ID NR: NCT05200416 and follows the CONSORT Statement.[10] The study was designed as a randomized, controlled, open-label (due to visual appearance of Heylo), cross-over investigation with 2 test periods (Figure 1A). During each test period, participants either used Heylo in combination with their usual pouching system (baseplate and bag) or Standard of Care (SoC) alone, being subject's usual pouching system. Participants were randomized into 1 of the 2 test sequences (1:1) by centralized randomization performed by Smart-Trial (version 2021.4) with random block sizes of 2, 4, 6, 8, or 10. Each study period was 8 weeks ±3 days. Four visits were scheduled during the study: an inclusion visit (V0) and 3 study visits—V1 (baseline), V2 (cross-over), and V3 (termination). Study visits were conducted by 13 ostomy care specialists at participant's own home or via remote virtual calls.

Heylo

The Heylo leakage notification system consists of; a bespoke smartphone software application (installed on the user's smartphone), an adhesive sensor layer (to be applied underneath the user's own baseplate), and a transmitter, which is attached to the sensor layer, and sends status messages by Bluetooth to the smartphone application. Based on the incoming data, the application decides when and how to notify the user of a change in the status of their baseplate. Heylo is

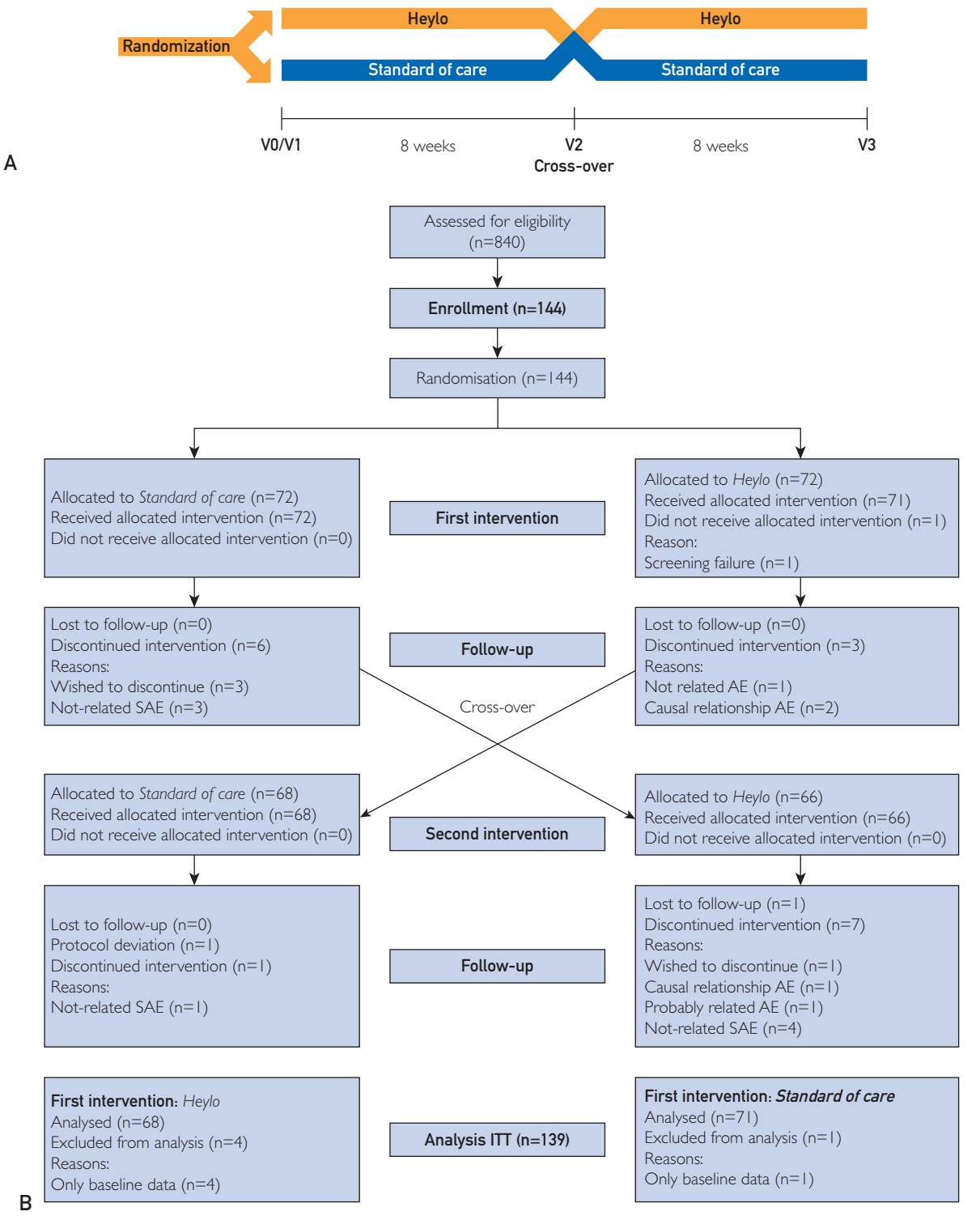

FIGURE 1. Overview of study and study flow-chart. (A) The study was designed as a randomized, controlled, open-label, cross-over investigation with 2 test periods, with each test period being 8 weeks. Participants were allocated to use either Heylo or Standard of Care in randomized order. Each participant had 1 inclusion visit (V0) and 3 study visits (V1, V2, and V3). AE, adverse event; SAE, serious adverse event; ITT, intention-to-treat.

Mayo Clin Proc Digital Health ■ September 2023;1(3):438-449 ■ https://doi.org/10.1016/j.mcpdig.2023.06.013
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CE-marked (regulatory approved for European markets).

Participants were provided a Heylo starter kit (consisting of 1 transmitter, 1 charger, and 10 sensor layers), an additional transmitter, and enough sensor layers for users to change pouching systems to a similar routine as they would normally do. Participants were instructed to install the bespoke Heylo application on their personal smartphones. Heylo was delivered with a remote technical support service.

Selection of Study Participants

Potential study participants being 18 years or older with a colostomy or ileostomy were found through a local Coloplast database and were contacted by either letter, email, or telephone as their first contact. All participants who were interested and found eligible as per study inclusion and exclusion criteria were consecutively enrolled in the investigation.

Inclusion criteria identified those with an ileostomy or a colostomy being 18 years or older and presenting with liquid to mushy effluent (Bristol scale type 5-7).[11] Participants should have experienced leakage underneath the baseplate at least 3 times in the past 2 weeks and should worry about leakage to *some*, *high* or *very high* degree on a 5-point Likert scale. Participants had to present a smartphone compatible with the bespoke Heylo application and be willing to refrain from using ostomy paste during the study. The participant should be able to follow study procedures for 4 months. Exclusion criteria included those having a pacemaker, those with known hypersensitivity to any components of the product, females being pregnant or breastfeeding, and failure to provide written consent.

End Points and Data Collection

The primary objective of this trial was to investigate the effect of Heylo on the *Emotional impact* domain score of the OLI tool compared with SoC. The OLI tool is an ostomy-specific measurement specifically designed to assess the impact of leakage on QoL.[12] The OLI tool comprises 3 domains and is based on a total of 22 questions, and each domain is scored on a scale ranging from 0 to 100, with higher scores reflecting lower impact.[12] The remaining 2 domains of the OLI tool: *Usual and social activities* and *Coping and in control*, were also assessed.

The secondary objective was to evaluate the effect of Heylo on subjects' participation in everyday life and social life activities measured by the World Health Organization Disability Assessment Schedule 2.0 (WHODAS 2.0) *Participation* domain score (domain 6) compared with SoC. WHODAS 2.0 is a generic instrument for assessment of health and disability.[13,14] The 36-item version was used, and it consists of 6 domains, which can be summed into a total score. Each domain is scored on a scale ranging from 0 to 100, with lower scores reflecting lower disability.[13,14] Also, here the remaining 5 domains (*Cognition*, *Mobility*, *Self-care*, *Getting along*, and *Life activities*), and the total score of the WHODAS 2.0 tool were assessed.

To support the results of the primary and secondary objectives, the feeling of security was assessed on a 5-point Likert scale (*Very poor*, *poor*, *acceptable*, *good*, and *very good*), and the number of times participants experienced leakage of stomal effluent outside the baseplate within the past 2 weeks was also investigated.

Patient demographic characteristic (sex, ostomy type, time since ostomy surgery, reason for ostomy surgery, etc.) were recorded at baseline (V1). Participants completed full questionnaires at baseline evaluation (V1) and after 8 weeks (V2), and 16 weeks (V3). Furthermore, participants completed the OLI tool[12] and reported the number of leakages outside the baseplate every second week, whereas WHODAS 2.0[13,14] was completed every fourth week. Participants answered the questionnaires through a clinical trial application on their private smartphones, independent of nurse visits and follow-up calls. Adverse events were recorded continuously throughout the study.

Statistical Analyses

Sample Size. Sample size calculation was based on a simplified model (paired 2-sided *t* test) on the primary end point. The result of the analysis was adjusted for multiple testing (primary and secondary end point), and therefore a significance level of $P<.025$ was applied to the sample size calculation. It was assumed that the total standard deviation

of the primary end point was 20.6 and that the total variation 20.6^2 was divided so that the residual variation was 14.4^2 (based on unpublished data from an explorative clinical trial, NCT04374890).

On the basis of the above assumptions, and considering that the true difference between the 2 treatments (with and without Heylo) was at least 6 on the *Emotional impact* domain (minimum clinically important difference is in the range of 5.4-10.4 according to the validation of the OLI tool),[12] a total of 108 participants should answer the questionnaires at the end of each test period to ensure a power of 81%. Taking a potential dropout (25%) into account, it was recommended to enroll 144 participants in the study.

Analyses. Statistical analyses were performed using SAS version 9.4 (SAS Institute Inc) after data transfer from a validated data management system (Smart-Trial version 2021.4.). Statistical analyses were performed according to the approved statistical analysis plan, and all members of the clinical analysis team were blinded to treatment sequences until after database lock.

The intention-to-treat (ITT) population (full analysis set) consisted of all randomized participants with valid informed consent who had been exposed to at least 1 product and with information on at least 1 end point. The safety population consisted of all participants who had given informed consent. All statistical analyses were based on the ITT population, whereas adverse events and device deficiencies were based on the safety population.

The primary end point score of the *Emotional impact* domain (OLI tool), measured every second week, was analyzed by a linear mixed model. The model included a fixed effect of product (SoC, Heylo), a fixed effect of time (2, 4, 6, and 8 weeks), a fixed interaction between product and time, a fixed period effect (test periods 1 and 2) and a random effect of subject (as each subject has tried both products the random effect of subject is included in the model to be able to devide the total variation in intra and inter variation). Additional OLI domain scores, the WHODAS domain scores and the total WHODAS 2.0 score were all analyzed by a similar model as the primary end point except that the WHODAS questions were only filled out after 4 and 8 weeks in each test period. Primary comparisons between Heylo and SoC were evaluated at week 8, which is also the end of treatment for each test period. Both test periods were included in these analyses, and the potential period effect was accounted for through adjustments.

Feeling of security evaluated at the end of each test period (5-point Likert scale) was analyzed by a generalized linear mixed model, namely a proportional odds model. The model included a fixed effect of product (SoC, Heylo), a fixed effect of period (test periods 1 and 2) and a random effect of subject.

Due to a potentially low number of leakage incidents within a 2-week period, a Poisson distribution was used for modeling these data instead of approximating a normal distribution. Comparison between the mean number of leakages after 8 weeks for the 2 products was performed by a generalized linear mixed model. The model included a fixed effect of product (SoC, Heylo), a fixed effect of time (2, 4, 6, and 8 weeks), a fixed interaction between product and time, a fixed period effect, and a random effect of subject. By using a negative binomial distribution, we allowed for overdispersion of the Poisson parameter.

For all statistical analyses, a 2-sided significance level of 5% was applied. The analyses of the primary end point and secondary end point were adjusted for multiple testing by a Bonferroni correction where the 2 individual results were tested at a 2.5% test level to keep the family-wise error rate at a 5% test level.

Ethical Consideration

The study was carried out in accordance with the Declaration of Helsinki, and approval was received from the ethics commission of Witten/Herdecke University, Germany (Application number 201/2021) before study initiation. All participants were fully informed about the investigation, both verbally and in writing, and all gave written informed consent to participate in the study. Participation in the study was voluntary, and participants could withdraw from the study at any time. The participants received a small gift voucher for participation in the study.

Role of the Funding Source

The study was funded by Coloplast. The sponsor was involved in study design, in collection, analysis, and interpretation of

data, in writing the report, and in the decision to submit the paper for publication.

RESULTS

Baseline Characteristics

A total of 144 participants were enrolled in this investigation (safety population) between January 13, 2022, and November 4, 2022. All 144 participants were randomized to a treatment sequence, with SoC switching over to Heylo or vice versa (Figure 1B). In all, 20 participants did not complete the study as planned (see Figure 1B for reasons). Eleven of the participants who did not complete the study as planned exited the study while using Heylo, and 8 participants exited while using SoC. One participant was a screening failure and did not test any products. A total of 5 participants were omitted from the ITT population because only baseline data were collected for these participants. Data from the ITT population (n=139) were included in the final analyses.

The mean age of the participants was 50.7 years (13.5 [SD]; range 18-81) and 51% (n=71) were female. Sixty-three percent (n=88) had an ileostomy, and 37% (n=51) had a colostomy. Stomas had been created due to cancer (n=43, 31%), ulcerative colitis (n=19, 14%), or Crohn's disease (n=47, 34%), whereas the remaining participants had their stoma formed due to other causes (Table). Participants on an average had their stoma surgery 6.1 years (8.2 [SD]; range 0-35) before enrollment and 22% (n=31) of the participants had their stoma surgery within the past 3 months.

Most of the participants (n=134, 96%) used a pouching system from Coloplast A/S as SoC and the remaining participants used pouching systems from other manufacturers. There was an almost even split between participants using 1-piece products (n=61, 44%) and 2-piece products (n=78, 56%). Most of the participants used a convex (n=88, 63%) product type, and the remaining used a flat (n=34, 24%) product or a concave product type (n=17, 12%).

TABLE. Baseline Characteristics of ITT population

Characteristic	ITT population N=139
Age (y), mean ± SD; (range)	50.7±13.5; (18-81)
Sex, n (%)	
Females	71 (51.1%)
Males	68 (48.9%)
BMI (kg/m^2); mean ± SD	25.9±5.5
Type of ostomy, n (%)	
Ileostomy	88 (63.3%)
Colostomy	51 (36.7%)
Time since ostomy surgery (y), mean ± SD; (range)	6.1±8.2; (0-35)
Ostomy surgery within the past 3 mo	31 (22.3%)
Reason for ostomy surgery, n (%)	
Ulcerative colitis	19 (13.7%)
Cancer	43 (30.9%)
Crohn's disease	47 (33.8%)
Other	30 (21.6%)

BMI, body mass index.

Impact of Leakage on Quality of Life

All 3 domain scores of the OLI tool were significantly higher when using Heylo for 8 weeks compared with SoC (Figure 2A). The primary end point, *Emotional impact* domain score, increased from 62.0 to 73.4 (LS mean difference, 11.4; 95% CI, 7.8-15.0; $P<.001$) with Heylo compared with SoC. The score for the *Usual and social activity* domain increased from 73.4 to 81.1 (LS mean difference, 7.7; 95% CI, 3.5-11.9; $P<.001$), and the score for the *Coping and in control* domain increased from 65.9 to 73.6 (LS mean difference, 7.8; 95% CI, 3.8-11.7; $P<.001$) with Heylo compared with SoC.

The positive impact of Heylo on the *Emotional impact* domain score significantly improved after 2 weeks of use compared with SoC and remained stable during the first test period (Figure 2B). Among participants in the treatment sequence starting on Heylo and switching to SoC, the *Emotional impact* domain score decreased already after 2 weeks back on SoC to a similar level as observed for participants starting on SoC in test period 1 (Figure 2B).

Health and Disability

WHODAS 2.0 covering 6 domains of day-to-day functioning was used to assess participants' health and disability. Five out of the 6 domain scores and the total score significantly improved when using Heylo compared with SoC: *Cognition* (LS mean difference, -3.4; 95% CI, -6.1 to -0.6;

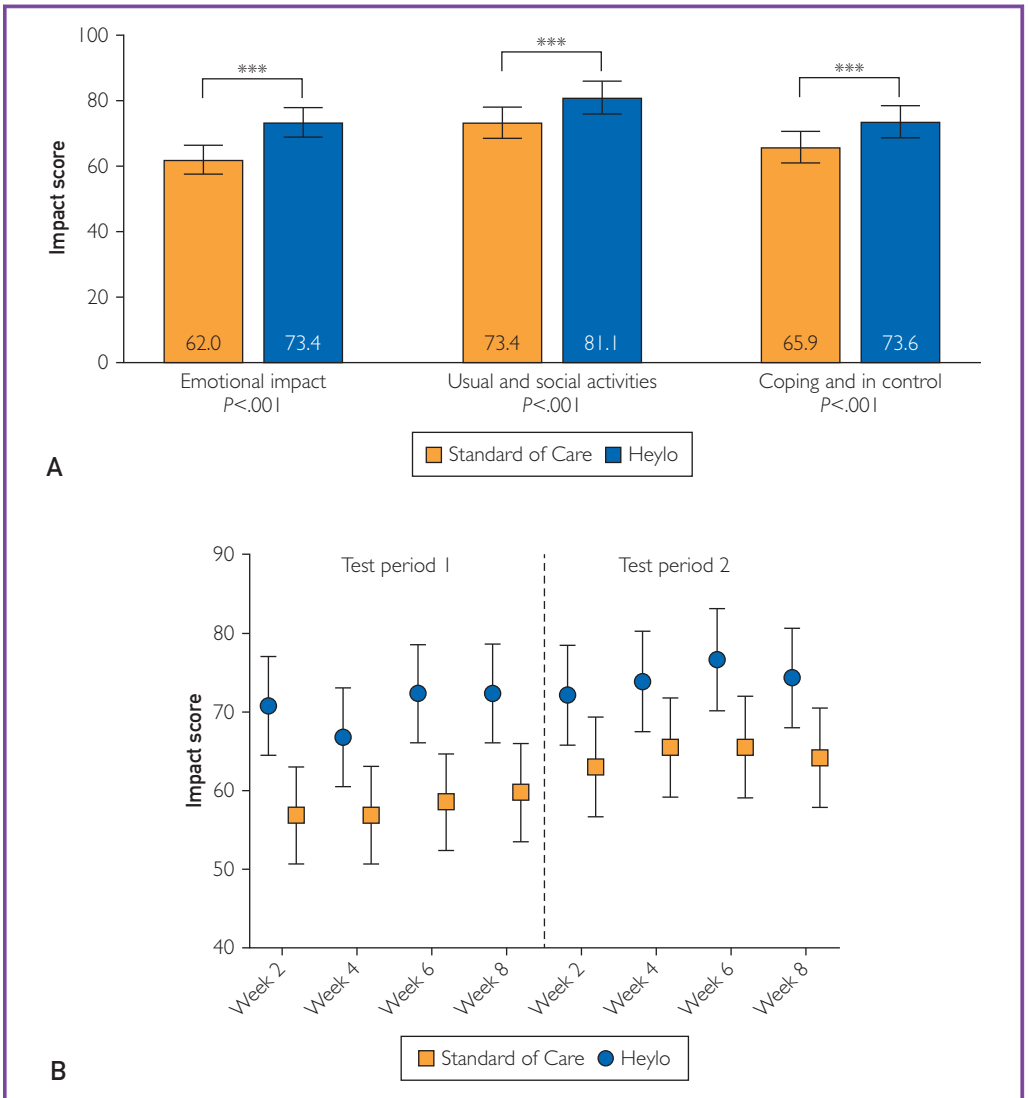

FIGURE 2. Ostomy leakage impact. (A) LS mean values are displayed for the 3 individual OLI domain scores for Standard of Care and Heylo. (B) LS mean values for the *Emotional impact* domain evaluated every second week in the 2 test periods. LS means in Figure B are from an extended model where also the interaction between product and period, and the interaction between product, period, and time are included. Error bars represent the 95% CI of the LS means. *$P<.05$, **$P<.01$, and ***$P<.001$. Each domain has a range of 0-100, where a score of 100 equals no impact and a score of 0 represents full impact.

$P=.018$), *Mobility* (LS mean difference, -3.6; 95% CI, -6.5 to -0.7; $P=.014$), *Getting along* (LS mean difference, -3.2; 95% CI, -5.9 to -0.5; $P=.020$), *Life activities* (LS mean difference, -4.8; 95% CI, -8.3 to -1.25; $P=.008$), and *Participation* (LS mean difference, -4.2; 95% CI, -6.7 to -1.6; $P=.001$), and the total score (LS mean difference, -3.5; 95% CI, -5.5 to -1.5; $P<.001$) (Figure 3). Only the *Self-care* domain did not significantly change among groups (LS mean difference, -2.1; 95% CI, -4.6-0.5; $P=.120$).

Episodes of Leakage Outside the Baseplate

Number of leakage incidents outside the baseplate decreased significantly from 2.26 leakage incidents with SoC to 1.56 leakage incidents per 2 weeks with Heylo ($P<.001$),

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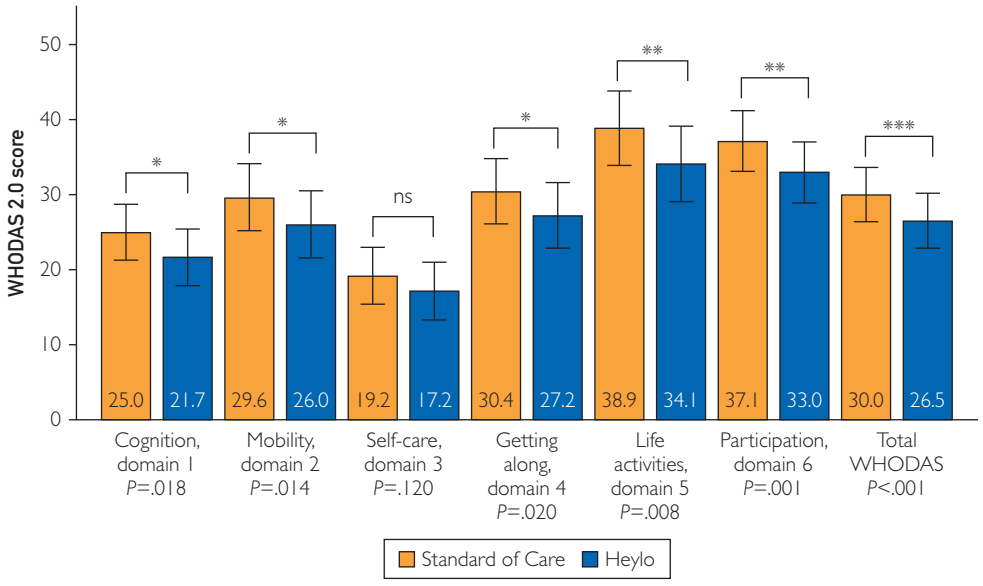

FIGURE 3. Health and disability. LS mean values are displayed for the 6 individual WHO Disability Assessment Schedule (WHODAS) 2.0 domain scores and for the total score for Standard of Care and Heylo. Error bars represent the 95% CI of the LS means. *P<.05, **P<.01, and ***P<.001. Each domain has a range of 0-100, where low scores equal better health and high scores indicate greater disability.

corresponding to a 31% reduction (95% CI, 15-44) (Figure 4A).

Feeling of Security

Feeling of security increased significantly when using Heylo compared with SoC (P<.001) (Figure 4B). In all, 76% of the participants reported a *good* or *very good* feeling of security with Heylo and 58% with SoC. This corresponds to a 31% increase in participants with a *good* or *very good* feeling of security with Heylo.

Safety and Device Deficiencies

During the study, a total of 20 adverse events were recorded in 18 of the 144 enrolled participants. Adverse events that were classified as being causally related, probably related, or possibly related to a device were all treated as related. Eleven of the adverse events were serious, however, none of the serious adverse events were assessed by the investigator to be related to Heylo or to SoC (including 3 deaths [n=2 while on SoC and n=1 while on Heylo], Crohn's disease flare-up [n=2], peritonitis [n=1], hepatobiliary disorder [n=1], pneumonia [n=1], stomal prolapse [n=1], and surgical or medical procedures [n=2]). Nine of the adverse events were nonserious, of which 5 were assessed to be related to Heylo. All of the adverse events related to Heylo (n=5 recorded in 5 participants, corresponding to 3.5% of the safety population) were associated with skin irritation, including 4 of moderate intensity and 1 of severe intensity. Peristomal medical adhesive-related skin injury may be an unfortunate side effect of using a baseplate.[15,16] Hence, Heylo showed no unanticipated adverse events considering that the participants used a new type of ostomy product with a different adhesive area and material.

In all, n=2 device deficiencies (transmitter defects) were observed in this study. None of the reported device deficiencies could have led to any severe adverse effect. Consequently, no corrective actions were taken.

DISCUSSION

In the present randomized controlled crossover trial, multiple positive care effects were identified for participants while using a novel digital leakage notification system. When using Heylo, participants experienced a

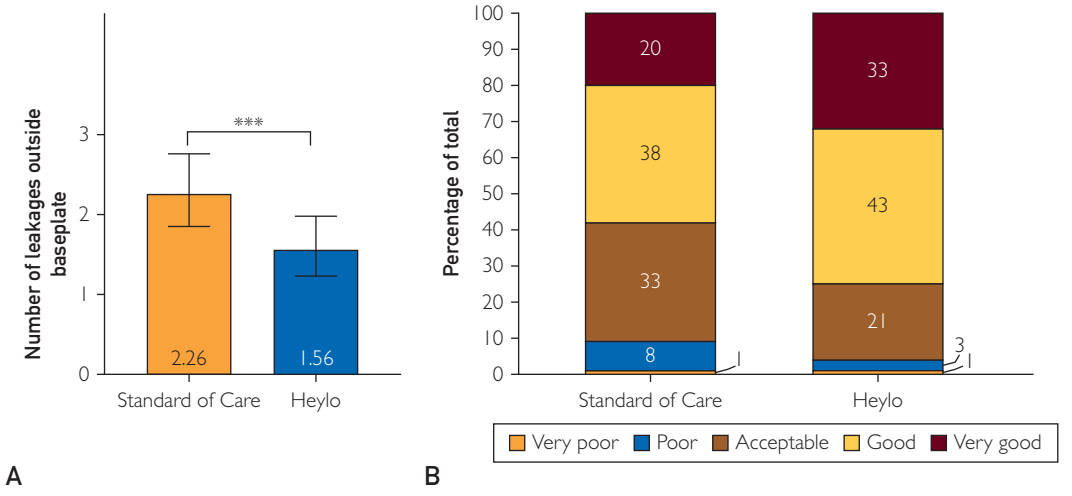

FIGURE 4. Leakage incidents and feeling of security. (A) LS mean values are displayed for number of leakage incidents per 2 weeks for Standard of Care and Heylo. Error bars represent the 95% CI of the LS means. *P<.05, **P<.01, and ***P<.001. (B) Participants were asked to rate their feeling of security on a 5-point Likert scale when using Standard of Care or Heylo. The proportion of participants in the 5 categories is displayed for Heylo and Standard of Care. Only participants with measures from both test periods (n=117) were included in the figure, whereas participants with at least 1 data point (n=133) were part of the statistical analysis.

significant improvement in the *Emotional impact* domain of the OLI tool compared with SoC (Δ11.4 points), which is higher than the previously described minimal clinically important difference (MCID) value of Δ7.6 (mean of 3 MCID values derived from different methods).[12] Translating this finding into clinical practice implies that Heylo provided a meaningful change for participants and that they felt less frustration, embarrassment, worry, and panic and had better sleep while using Heylo.

Besides having emotional consequences, leakage and the worry associated with it can also affect people's ability and willingness to participate in everyday activities.[5] In this trial, the domain scores for the other 2 OLI domains *Usual and social activities* (Δ7.7 points) and *Coping and in control* (Δ7.8 points) also improved significantly with Heylo compared with SoC, and the improvements were higher than the MCID values of Δ6.6 and Δ7.2, respectively.[12] This implies that participants who used Heylo felt calmer and in control, and they were better able to participate in social activities. That participant's ability to participate in social activities became better when using Heylo was also supported by the observed improvement in the *Participation* domain score (Δ-4.2 points) measured by the generic WHODAS 2.0 disability assessment tool as compared with SoC. Together, these results indicate that while using Heylo, participants reported a lower tendency to isolate themselves from other people, and they were better able to participate in community activities and to do so with dignity.

Even though WHODAS 2.0 was developed more than a decade ago,[13,14] only few studies have established MCID values for the individual WHODAS 2.0 (36-item) domain scores, and for the total score.[17,18] MCID values are sensitive to different populations and clinical scenarios; thus, a range of MCID value estimates exist for a given domain depending on the context for which it is used.[19,20] In 2 studies of patients with lower back pain and of hip and knee osteoarthritis (using the Polish 36-item version of the WHODAS 2.0), the reported MCID values for the *Participation* domain were Δ2.55[18] and Δ4.62,[17] respectively. The improvement in the *Participation* domain score in our study was 4.2 points after 8 weeks with Heylo, which is higher than the average MCID value of the 2 above-mentioned studies (Δ3.59).

Mayo Clin Proc Digital Health ■ September 2023;1(3):438-449 ■ https://doi.org/10.1016/j.mcpdig.2023.06.013
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This indicates that the use of Heylo, even when measured by a more generic disability tool, still provided a clinically meaningful change to participants' ability to participate in society and to live with dignity.

A previous study assessing disability among colorectal cancer survivors living with or without an ostomy reported that survivors living with an ostomy scored significantly worse in the *Participation* domain compared with the group living without an ostomy. This finding highlights the observation that people with an ostomy generally experience more difficulties when participating in society and joining social activities,[21] which again suggests that people living with an ostomy have a poorer QoL compared to those without. The effect sizes recorded in the present study for the WHODAS 2.0 domains were generally in the range of the MCID values previously established,[17,18] indicating that Heylo has the potential to reduce disabilities, and provide meaningful change across multiple domains for individuals living with intestinal ostomies and thereby provide beneficial effects to overall QoL. Finally, the total WHODAS 2.0 score also decreased by 3.5 points with Heylo compared with SoC. This observed improvement was within the range of previously reported MCIDs for the total WHODAS 2.0 (36-item version) of 3.3-4.9 points.[17,18]

The positive impact of Heylo on QoL and the reduced burden of living with an ostomy was supported by a significant (31%) reduction in episodes of leakage progressing outside the baseplate with Heylo compared with SoC. The result of this randomized, controlled trial supports the outcomes of 2 previous single-arm clinical trials, which both reported that participants experienced considerably fewer incidents of leakage outside the baseplate when using Heylo,[8,9] and NCT05135754). The impact of Heylo on participants' QoL and their ability to participate in social activities suggests that the information provided by the application regarding an imminent leakage constitutes a relevant difference to users, which is also supported by an observed increased feeling of security when using Heylo.

Multiple studies have previously highlighted that the frequency with which participants experience leakage outside the baseplate is associated with negative impacts on QoL,[5,22,23] and disutility.[24] Participants use different means to mitigate the risk of experiencing future leakage incidents, such as increasing the use of ostomy care products (bags, baseplates, and supporting products), and some rely on consultations with health care professionals.[25] This is in accordance with findings from a recent study on an international ostomy population reporting a positive correlation between the degree of worry about leakage and the consumption of specific accessories (ie, rings or seals, paste, tapes, and belts). The more individuals worried about leakage, the more accessories they used.[5] Early interactions with ostomy care nurses following stoma formation and access to annual reviews have previously been shown to ensure proactive health management that can reduce the need for consultations with general practitioners, outpatient attendances and accident and emergency visits, and reduce inappropriate use of supporting products.[26] Implementation of ostomy care innovations that can reduce the number of leakage incidents outside the baseplate, as shown in the present study with Heylo, may potentially limit inappropriate use of ostomy care products.

Wearables and connected health care solutions have a great potential to complement health care professionals in improving care for patients, particularly because health care systems worldwide have constrained resources partly because of an aging population. Providing users with information on when and in which direction a leakage emerges, can supplement the user and ostomy care nurse in finding the right fitting pouching system going forward.

Strengths and Limitations

The results of this study should be interpreted considering strengths and limitations of the study design.

A key strength of this study is the randomized cross-over design. The randomization of participants to the treatment sequences limits bias and, thus, potential influence from confounders. Moreover, the cross-over design allowed participants to serve as their own control, thereby allowing us to disregard the between subject variability. No carry-over effect was expected in the study, as the study

duration was 2 times 8 weeks and the main evaluation was done at the end of each test period.

The investigation was conducted in a real-world setting, as all study visits were performed by ostomy care specialists at the participants' homes or remotely by a telehealth call. Moreover, participants were not instructed on when to change their ostomy product, which means that they could follow their normal change routine or change owing to a notification from the application, if relevant. Therefore, the actual observed care effect of Heylo is close to what can be expected in real life. All patients completed questionnaires individually on their smartphones every second week without external aid and independently from nurse visits and follow-up calls. Thus, questionnaires have been filled in consistently across the study periods, and therefore nurses are not expected to have showed any influence on participants' responses to the questionnaires. Hence, the outcomes reported in this investigation are truly patient reported. Still, a limitation exists in the nonblinded study design. The fact that both the participants and the nurses were not blinded could potentially, consciously or subconsciously, have affected the participants' responses to the questionnaires.

Distribution of the study participants in terms of underlying pathology for intestinal ostomy surgery is largely in accordance with the current literature.[27] Therefore, the study population was a true reflection of the general ostomy population. This is also true with respect to the demographic characteristics of the study population. An inclusion criterion for study eligibility was patient-reported worry about leakage to *some*, *high* or *very high* degree (on a 5-point Likert scale). Participants who worry about leakage to a lower degree may not necessarily benefit from this solution to the same extent as reported in this trial. However, 2 out of 3 people with an ostomy worry about leakage to *some* degree or higher degree,[5] indicating that the population of this study still represents a large proportion of the global population of people with intestinal ostomies. Furthermore, study participants were recruited from a prospectively maintained Coloplast care database, and thereby most participants used a pouching system from Coloplast as their current solution (Standard of Care). Thus, the proportion of participants using Coloplast appliances is higher in the present investigation than for the general ostomy population. However, it has previously been shown that Heylo works as well with baseplates from other brands (based on currently unpublished results from NCT05135754),[9] and thereby the results generated in this study are not expected to be influenced in any direction.

CONCLUSION

This is the first randomized, controlled clinical trial to demonstrate that sensor technology embedded in supporting ostomy solutions can notify users about leakage seeping underneath the baseplate and thus secure timely change of the baseplate before effluent may reach outside the baseplate soiling clothes or bedsheets. Overall, Heylo showed great potential in increasing QoL in people with an ostomy who used to struggle mentally and being at risk of isolating themselves. Use of Heylo improved participants' capability to participate in society and to engage in everyday life activities. The system ultimately enables monitoring of leakage data to identify struggling users, which can complement stoma care nurses in helping struggling users and provide individualized care based on specific user data.

POTENTIAL COMPETING INTERESTS

P.C.A. received consultation fee from Coloplast and is a member of a Coloplast advisory board. E.B., H.D.H., J.L.G., M.V. and T.A.A. are employees of Coloplast.

ACKNOWLEDGMENTS

The authors wish to express their gratitude to all patients and health professionals who participated in the study.

Abbreviations and Acronyms: **CE,** conformité européenne; **ITT,** intention-to-treat; **LS mean,** least squares mean; **MCID,** minimal clinically important difference; **OLI,** ostomy leak impact; **QoL,** quality of life; **SoC,** Standard of Care; **WHODAS,** World Health Organization Disability Assessment Schedule

Correspondence: Address to Teresa Adeltoft Ajslev, PhD, Coloplast A/S, Humlebæk, 3050 Denmark (dkteaa@coloplast.com).

ORCID

Teresa Adeltoft Ajslev: https://orcid.org/0000-0003-3129-0568

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