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Clinical Evaluation of the Smart UnderWear

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Abstract:	<p>Purpose: We evaluated the performance of the smart underwear in detecting urine leakage from continence pads, their acceptability to users, and their effect on health related quality of life and psychosocial factors.</p> <p>Design: Prototype product evaluation.</p> <p>Subjects and Setting: Participants (females; pilot study: 8; mean age 62 years: main study 72; mean age 67 years) were recruited between October 2010 and February 2012 from out-patient clinics, GP surgeries, community Continence Services and through charities and networks.</p> <p>Methods: The Tact 3 project developed and manufactured prototype smart underwear designed to alert the wearer to a pad leak before it reached outer clothing or furniture. The clinical study was conducted in 2 stages: a pilot/feasibility study to assess general performance and acceptability of the smart underwear and a larger study to measure its performance, acceptability to users, health related quality of life and psychosocial impact. Participants were asked to wear the smart underwear for a period of two weeks, keeping a daily diary of leakage events for the first seven days. Health related quality of life questionnaires were completed before and after the trial period, and evaluation and psychosocial impact questionnaires completed at the end.</p> <p>Results: On average, 86% of the time participants were alerted to pad leakage events, and over 90% of participants thought the smart underwear to be "good" or "OK" and that it would or could give them more confidence. No symptom changes were recorded using the International Consultation on Incontinence Questionnaire - Urinary Incontinence Short Form; a significant difference was found in ability to travel using the International Consultation on Incontinence Questionnaire -Lower Urinary Tract Symptoms quality of life measure. The smart underwear were found to have a positive psychosocial impact using the self-reported PIADS tool.</p> <p>Conclusion: The smart underwear is an effective device in alerting pad wearers to leakage before it is visible to others, and is acceptable to users. Modifications are required to make the device suitable for a wider population of pad wearers who fear pad leakage.</p>

Introduction

The most common method of managing urinary incontinence (UI) is the absorbent pad or diaper; it is the choice for older people in care homes (1), and in general, women show a preference for disposable insert pads (2). Achieving effective and discrete containment of urine is paramount; five key characteristics are used to evaluate absorptive product effect. It must hold urine, contain smell, stay in place, be discrete, and be comfortable to wear (even when wet) (3). Despite having high absorbency, pads can leak for a variety of reasons, including a high volume challenge due to uncontrolled full bladder emptying, pads used past their absorbency level and movement of the pad within the fixation pant resulting in uneven absorbency. Although these factors can be mitigated, pad wearers report fear of pad leakage. The distinction between fear of leakage from the bladder and fear of leakage as a result of pad failure is not clear (4). Nevertheless, high levels of anxiety associated with perceived risk of poor pad performance, lack of discreteness, and complex regimes for pad management have been reported (3). The Simon Foundation (based in the US) and the Bladder and Bowel Foundation (based in the UK) have also reported that fear of visible leakage is present even when absorbent pads are used. This fear is not related to the severity of incontinence (5), and can be a major social constraint (6) leading to restricted participation in both leisure and work activities (7).

The “Tackling Ageing Continence through Theory. Tools and Technology” (TACT3) consortium (a non-commercial collaboration funded by the UK Research Councils) developed smart underwear (SUW) designed to detect urine leakage from the absorbent pad and alert the user before urine spreads onto outer clothes and furnishings (8). The purpose of the SUW is to improve pad user’s confidence by reducing the anxiety and embarrassment associated with visible leakage and the burden of coping with the extra washing, changing and cleaning involved in a major pad leakage.

The SUW comprises a pair of washable fixation pants with sewn-in conductive threads that track where pads are known to leak most frequently, i.e. gusset (the section between the legs) and back (Figure 1). These sensor threads are connected to a removable signalling unit that vibrates three times when any part of the conductive thread becomes wet. The SUW conforms to the required European device regulations, including CE marking, and the underwear is machine washable. For the study, removal of the signalling device was advised prior to washing. The SUW prototypes were made for women only for the purposes of initial evaluation.

The aims of the study were to test the performance of the SUW in detecting urine leakage from absorbent pads, the acceptability of the underwear to users, the influence on health related quality of life and the psychosocial impact on female wearers.

Methods

Study design

The study was a prototype product evaluation trial that was conducted in two stages. Stage 1 was a pilot/feasibility study to assess general performance and acceptability of the prototype. The pilot data were used to identify the need for any modifications to the SUW and study design. Data recorded in the pilot were not included in the final analysis. Stage 2 was a larger scale study to measure performance, acceptability, health related quality of life and psychosocial impact of the SUW.

Recruitment

The study sample was obtained from patients attending out-patient clinics at Southmead hospital, Bristol-based GP surgeries and community continence services, the Bladder and Bowel Foundation website and the Brunel Older Peoples' Reference Group. Participants were female, aged 18 years or over, regularly using continence pads (at least one pad per day), had

experienced leakage from the pad on at least one occasion within the previous month, and had sufficient manual dexterity and cognitive ability to operate a small electronic device, complete the questionnaires and give informed consent.

Women who expressed an interest were given a patient information sheet and offered the opportunity to discuss the study. Those willing to take part were requested to sign a consent form at their next clinic or study appointment, or were consented remotely. An initial questionnaire was completed to confirm eligibility and to collect data on age, type and make of continence pad used, frequency of use, frequency of leakage from the pad and size of underwear required.

Ethics

Study procedures were reviewed and ethics approval was granted from the North Bristol Research Ethics Committee (Ref 10/H0102/12) and governance approval from North Bristol NHS Trust which was the study sponsor. Participants' personal data were securely stored and accessible by the clinical study team only. Study codes were used to ensure anonymity of shared data.

Data collection

Stage 1: Feasibility Study

Women who met the inclusion criteria were invited to participate in the trial for a period of two weeks between October 2010 and February 2011. Five pairs of the underwear and one signalling unit were provided. Participants were advised to wear the SUW during the day for at least five days weekly, and to wash the underwear as many times as they wished. Participants were asked to complete a diary of all of pad leakage events. At the end of the two week period, they were asked to complete an evaluation questionnaire and return the diary and signalling unit.

Stage 2: Main Study

Data collection for the main study occurred from March 2011 to February 2012.

Performance

During the two-week trial period, participants were asked to complete a diary for the first seven days only. Details of pad leakage events, whether the signalling unit had alerted them, position at the time of the leakage (lying, sitting, standing or exercising) and how far the leakage had spread (underwear, outer clothing, furnishings) were recorded. Based on experiences in the pilot study, detailed event recording was limited to the first three events in any single day to keep the diary simple and the reporting burden to a minimum. Thus, for some participants the total number of leakage events on any day could exceed the number of events recorded in detail.

Acceptability

A questionnaire was constructed to obtain feedback on the acceptability of the SUW, it was completed by participants at the end of the study period. Questions included overall impression of the prototype, level of comfort and how discreet the SUW were to wear.. These questions required Good/OK/Poor responses with the opportunity to give additional free text comments. Other questions included when and where the SUW would be worn (e.g. at home, in the car, etc.), if they would purchase them (yes/no/maybe), place of purchase (e.g. supermarket), frequency of vibrations on the alert system (too often/OK/not often enough) and whether wearing the SUW improved confidence levels (yes/no/maybe).

Quality of Life

Participants were asked to complete two validated health related quality of life questionnaires, the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI-Short Form) and the ICIQ-Lower Urinary Tract

Symptoms Quality of Life (ICIQ-LUTSqol) (9;10) before using the SUW~~SUW~~, to provide baseline data, and again at the end of the study. The ICIQ-UI-Short Form measures incontinence frequency and severity and perceived causes and bothersomeness; the ICIQ-LUTSqol measures urinary specific quality of life issues, such as ability to take part in social activities.

Psychosocial impact

Psychosocial impact was evaluated using the Psychosocial Impact of Assistive Devices Scale (PIADS) questionnaire; it was completed at the end of the study. This 26-item self-rating scale is designed to provide a reliable and valid measure of how users perceive the impact of assistive devices on their quality of life and sense of well-being (11;12). The scale measures from -3 (negative impact) to +3 (positive impact).

Steps were taken to ensure adherence to study procedures including frequent contact with the participants by phone or email, and a compensatory payment of £25 was given after the completed documentation and signalling units were returned.

Data Analysis

The main study (Stage 2) was powered to detect changes in quality of life as primary outcome. An *a priori* power calculation for a two-sided analysis using the nonparametric Wilcoxon test indicated that a sample size of 57 complete records would be needed to detect a medium sized effect change (Cohen's $d=0.5$) or larger with 95% power using contemporary levels of significance ($\alpha=0.05$).

Outcome variables relating to the performance of the SUW, as measured by the participant's leakage event diaries were: the proportion of occasions participants' were alerted by the SUW; the proportion of occasions participants' were aware of leakage prior to being alerted; proportion of times participants' had sufficient time to change before leakage

became visible; and number of false alarms. Outcome variables relating to acceptability of the SUWSUW, as measured by the participant evaluation questionnaire were dichotomized owing to low counts: overall impression (Good v. OK/Poor); whether or not participants' would buy the SUW (Yes v. No/Maybe); and whether it increased their levels of confidence (Yes v. No/Maybe).

Outcome variables were examined for significant effects (at the 0.05 significance level) from the following potential explanatory variables; age, severity of incontinence (as measured by the number of pads worn per day) and dress size. Four more explanatory variables were included to examine for significant effects on acceptability; the proportion of time that the participants' were alerted by the sensor; the proportion of time participants were aware of leaks; the proportion of times participants had sufficient time to change; and the average number of false alarms/day.

Binary logistic regression (with correction for over dispersion) was applied using the statistical package **R (13)** for all variables modelled. Descriptive statistics were applied to all other data collected.

Results

Eight participants, with an average age of 62 years (range 55 – 85 years) gave informed consent to participate in the feasibility study; 7 entered and 6 completed the study. Participant's completion of the diary data was sporadic, so the diary was simplified and recording reduced to the first seven days of use and the detail of leakage events to three per day for the main study. The signalling unit also was changed from black to white to be more discreet against the white underwear and the underwear leg cut was altered to increase leg capacity.

Stage 2: Main Study

Two hundred and forty female pad-wearers were approached, 84 expressed an interest and 74 gave informed consent. Of these, eight were lost to follow-up and 10 withdrew (nine for reasons not related to the study and one whose carer found it too demanding). The remaining 56 participants completed the study. One participant was removed from the analysis since she thought the SUW was alerting her to urine leakage from the bladder, rather than from the pad. Thus, data from 55 respondents were included in the analyses.

The average age of participants was 67 years (range: 32 – 98 years). Their median dress size was 18-20 (range: size 10 - 26+), several sizes above the UK median of 12-14 (14). Sixty-two per cent of participants said they used 20 pads per week or less (<3 per day). Nineteen per cent of participants reported daily pad leakage, with the majority (67%) experiencing leaks between one and six times per week (Table 1). The Tena range (Svenska Cellulosa Aktiebolaget, Sweden) was the most commonly used continence pad (62%), followed by the Moli range (Paul Hartmann Ltd, UK; 11%), the Always range (Proctor & Gamble, UK; 9%) and the Euron range (Euron UK; 6%). All other manufacturers formed less than 2.5% of the participant's selection.

The baseline ICIQ questionnaires were completed by 74 participants and the post-study questionnaires by 56 participants. Data from the ICIQ-UI Short Form showed that over 77% of participants had incontinence episodes one or more times a day (Figure 2) and for 78% this was a moderate or large amount (Figure 3).

Self-reported impact further qualified the severity of reported symptoms; 55% of participants reported bother scores of 8 or above on a scale of 0-10 where 10 reflects 'a great deal' of interference with everyday life. Urgency and stress incontinence were perceived to be the greatest causes of symptoms (reported by 82% and 53% respectively), although 56% of respondents also reported that they experienced incontinence with no obvious cause.

Participants reported leakage from the pad on 77% (95% Confidence Interval (CI):69-86%) of the days that they completed their diaries. Participants were successfully alerted by the SUW on 86% (CI: 79-94%) of the occasions on which pad leakages occurred. Age, dress size and severity of incontinence were not significant factors in being alerted. On over half the occasions (59%) participants were not aware of leakage prior to the electronic alert. Age and severity of incontinence were not related to leakage awareness; however, dress size was significantly related ($p=0.046$); specifically, awareness of leakage decreased as dress size increased (Figure 4). In addition, there was an 82% (CI: 76-88%) success rate for participants being alerted in time to change their pad before leakage onto clothing or furnishings. Age, dress size and severity of incontinence were not significant factors for this outcome.

The number of false alarms recorded was highly variable, with some patients experiencing high numbers of false alarms and others none or very few. The average number of false alarms was 1.73 (0.79, 2.66) per day with a median of 0.5 false alarms per day.

Ninety-two per cent of participants' rated the overall impression of the SUW as Good (63%) or OK (29%). Participants' who were less aware of pad leakage were more likely to rate the SUW as Good than those who were always aware ($p=0.014$), and those who had 'moderate' severity of incontinence (11-20 pads per week) were more likely to rate the SUW as Good than those with mild (<10) or more severe incontinence (>21) ($p=0.033$) (Figure 5). More than 90% of participants thought the SUW would (62%) or might (30%) make them feel more confident. The proportion of participants who thought the SUW would make them feel more confident was not significantly affected by any of the explanatory variables.

Participants were generally willing to buy the SUW if it became commercially available, (46% yes; 31% maybe). Reasons for uncertainty included "would buy if the price [was] right", if the SUW were "sexier" or if they were "more reliable". The proportion of participants who stated that they would definitely buy the SUW was not significantly related

to any of the explanatory variables. When asked ‘where would you buy [your SUW]’, the most frequent choice (71%) was a pharmacy, although department stores, supermarkets and the internet were also mentioned.

Nearly all participants said they would wear the underwear at home during the day and some would wear it at night. Around 80% said they would wear it when going out, but fewer would wear it when using public transport or at work (Figure 6).

Results of participant opinion on the acceptability of the SUW are shown in Figure 7. The SUW was considered by many as “very comfortable to wear”. Although efforts were made to ensure participants had the correct size of underwear, several were not satisfied with the size or fit of the underwear used during the study. The majority (93%) of participants thought the underwear were easy to wash. A few thought the material took a long time to dry after washing due to the “material [being] too thick”.

The “press stud” mechanism for attaching the signalling unit to the underwear was the most criticised aspect of the design. Some participants found the press studs ‘stiff’ initially, but became easier with use, and those with arthritic hands found them difficult. Several reported that the signalling unit was too bulky, was too heavy to be properly supported by the underwear and showed through tight-fitting clothes. Many, but not all of those who commented that the signalling unit itself was poor, also thought that the position of the unit was poor.

The majority of participants found the vibration alert to be good, being sufficiently noticeable for the user, but discreet with correct number and delivery of vibrations (Figure 8). A minority reported concern that the vibrations could be heard by carers or, if they were in public; “the buzzer was audible to other people causing embarrassment”. Several commented that it sounded like a mobile phone, which although could be heard, did not give rise to

curiosity. Some participants were concerned about the level of false alarms, reporting that the signalling unit was “going off for no reason”, going off “when dry” or “when standing/exercising”. Several participants volunteered the explanation as being excessive sweating. Positive comments included “[the sensor is] very good in letting me know when [I am] wet”, “very useful and reliable” and “sensitive and accurate”. Almost all (98%) participants thought the instructions for use were good or OK.

Quality of Life and Psychosocial Impact

Mean scores for the ICIQ-UI SF indicated no change in the level of symptoms reported before or after the intervention (Pre-score 15.0; post- score 15.0, range 0-21).

The results from the ICIQ-LUTSqol revealed no significant changes in health related quality of life status over the two week intervention period, with the exception of travel restrictions. There was a significant difference in the ‘effect on ability to travel’ ($P < 0.05$, Wilcoxon signed ranks test) with most improvement observed in those who initially reported ‘moderate’ effects on travel. Those reporting ‘a lot’ of travel restriction remained as affected after use of the device.

The PIADS evaluation indicated a positive impact in all 3 domains, with mean scores of +0.44 for competence, reflecting perceived functional capability, independence and performance, +1.1 for adaptability, reflecting inclination or motivation to participate socially and take risks and +0.93 for self-esteem, reflecting self-confidence, self-esteem, and emotional well-being.

Discussion

The purpose of the prototype underwear was to improve confidence levels in women who wear continence pads. Although leakage from continence pads is considered avoidable, our study confirms that leakage can and does occur in a disparate female population. With

85% of participants being alerted to leakage before it reached outer clothing and thus visible to others, and 59% being warned prior to becoming aware of the leakage themselves, the SUW can provide useful information to the continence pad wearer and reduce the burden of additional laundry due to severe leakage episodes.

A major consideration in the introduction of a new assistive device is sustainability of use. Abandonment is associated with user dissatisfaction; this can arise for a variety of reasons including inadequate performance, failure to bring increase function for the user, discomfort in use and cost (15). The PIADS has been demonstrated to show a high correlation between positive scores and sustained adoption of an assistive device or product (16).. The highest PIADS score was for adaptability indicating that wearing the SUW makes an individual feel more able to engage in social activities and take risks. Increased competence and self-esteem were also shown when using SUW even though incontinence symptoms remained unaltered. Over 90% of participants also reported that the SUW did, or could, make them feel more confident, indicating that the device was successful in helping continence pad wearers to feel in control and that a commercial product has a good chance of being adopted.

The ICIQ-LUTSqol is a measure of change due to quality of life alterations. In this study the use of this instrument was considered expedient as it was the only available fully validated incontinence-specific evaluation of quality of life that included items of potential relevance when considering the device to be implemented. The only significant difference reported was in the ability to travel. This suggests that the SUW afforded a quality of life improvement in that better leakage detection may have enhanced the ability to travel among those who experienced a moderate level of incontinence, although this finding should be interpreted with caution.

The magnitude of this positive impact might be better observed over a longer follow-up period, as health related quality of life and psychosocial impact characteristics are not so readily observable within a short time period.

A significant minority of participants experienced problems with the SUW. Some of these can be addressed through design modifications, and discovering these was an important aspect of the study. Since the sensor threads respond to wetness, it is highly likely that participants' who, for any reason, suffer from bouts of excessive sweating (including during exercise) will experience false alerts.

Most participants reported that they were most likely to wear the SUW in the home and the least number would wear them at work. This is likely to be a reflection of the age profile of participants, with less than half of participants under 65 years of age and only a proportion of these still in paid work, rather than a reluctance to wear at work.

The statistical analysis suggests that the SUW was suitable for most women, with performance consistent across all ages, dress sizes and continence severity. The SUW was most acceptable to women who are the least aware of pad leakage and those with moderate incontinence. It should be noted that using the number of pads worn as a proxy measure for continence severity is not absolute, and although it seems likely that the SUW would be favored by women with moderate incontinence, this result would need to be verified.

Conclusions

The prototype underwear evaluated in this study was effective and acceptable to 5 out of every 10 wearers. Study findings suggest the prototype underwear area suitable for women of all ages, dress sizes and continence severity. The SUW had a positive psychosocial impact on wearers in the absence of any symptomatic changes and increased their level of confidence and ability to socialize and take risks.

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Figure Legends

Figure 1 Smart Underwear

Table 1 Profile of participants

Figure 2 ICIQ-UI SF data on frequency of urine leakage (not pad leakage)

Figure 3 - ICIQ-UI SF data on extent of urine leakage (not pad leakage)

Figure 4 Predicted proportion of time aware with 95% CI for dress sizes

Figure 5 Predicted probability of the overall impression of the SUW being rated as ‘Good’ (with 95% CI).

Figure 6 Occasions when Smart Underwear would be worn

Figure 7 Acceptability of different aspects of the smart underwear

Figure 8 Vibration of sensor alert

Fig 1

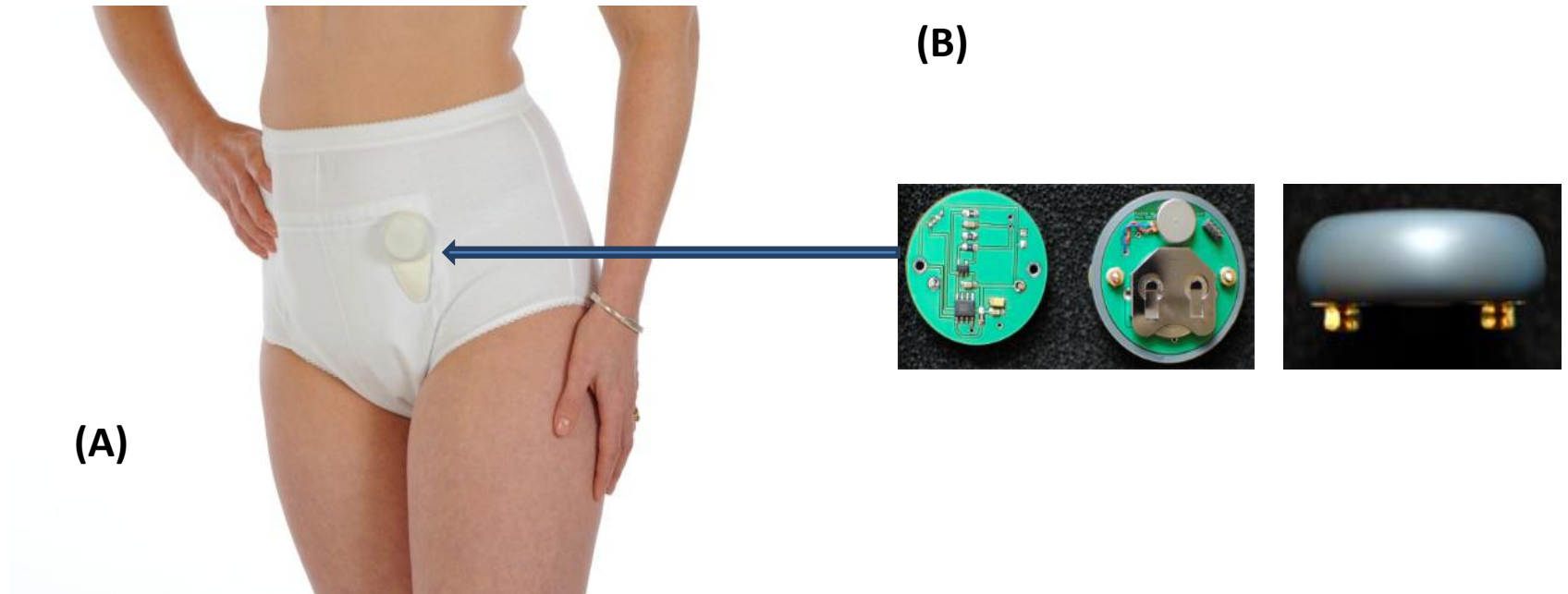


Fig 2

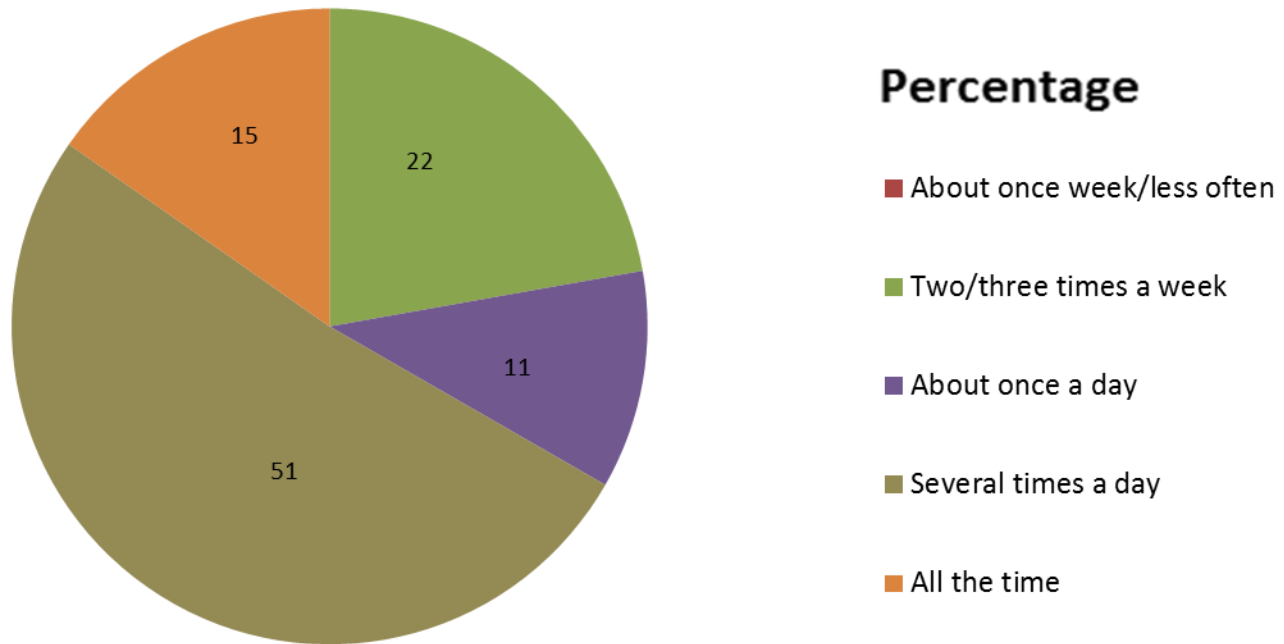


Fig 3

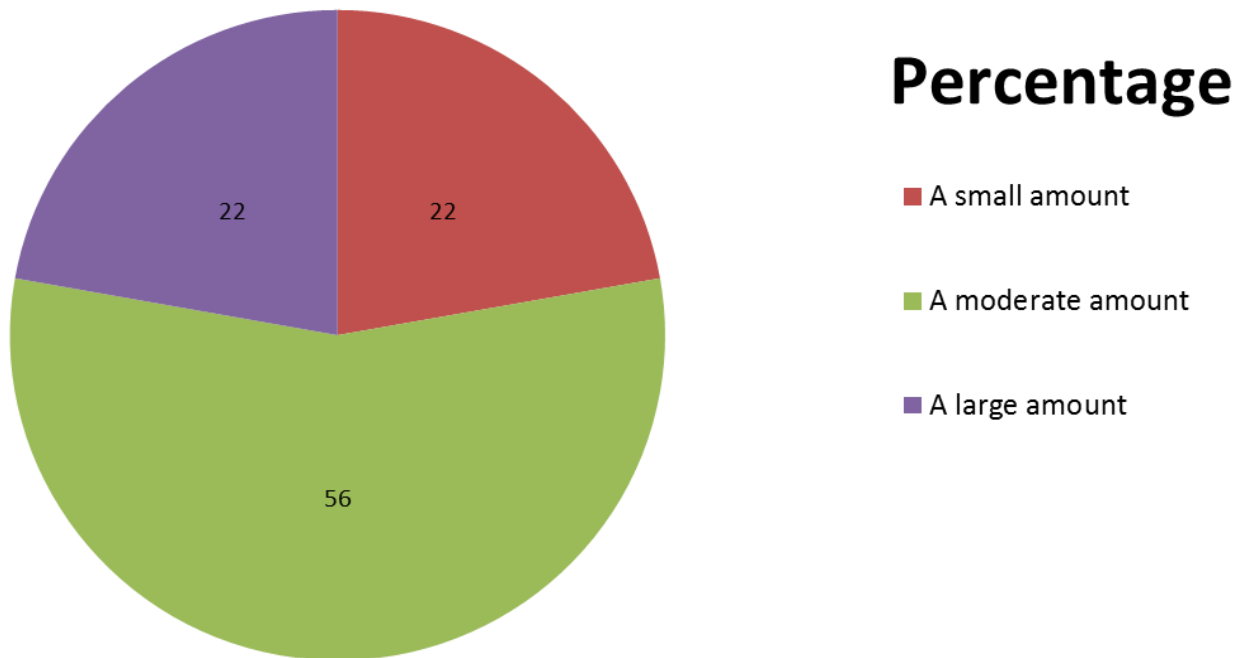


Fig 4

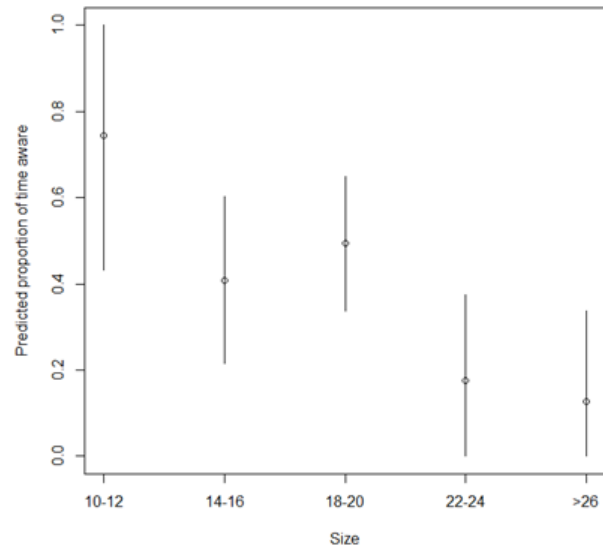


Fig 5

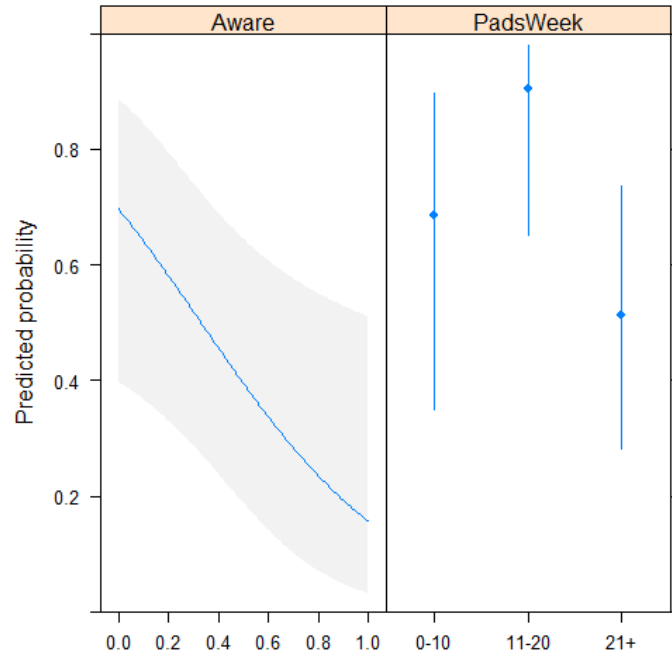


Fig 6

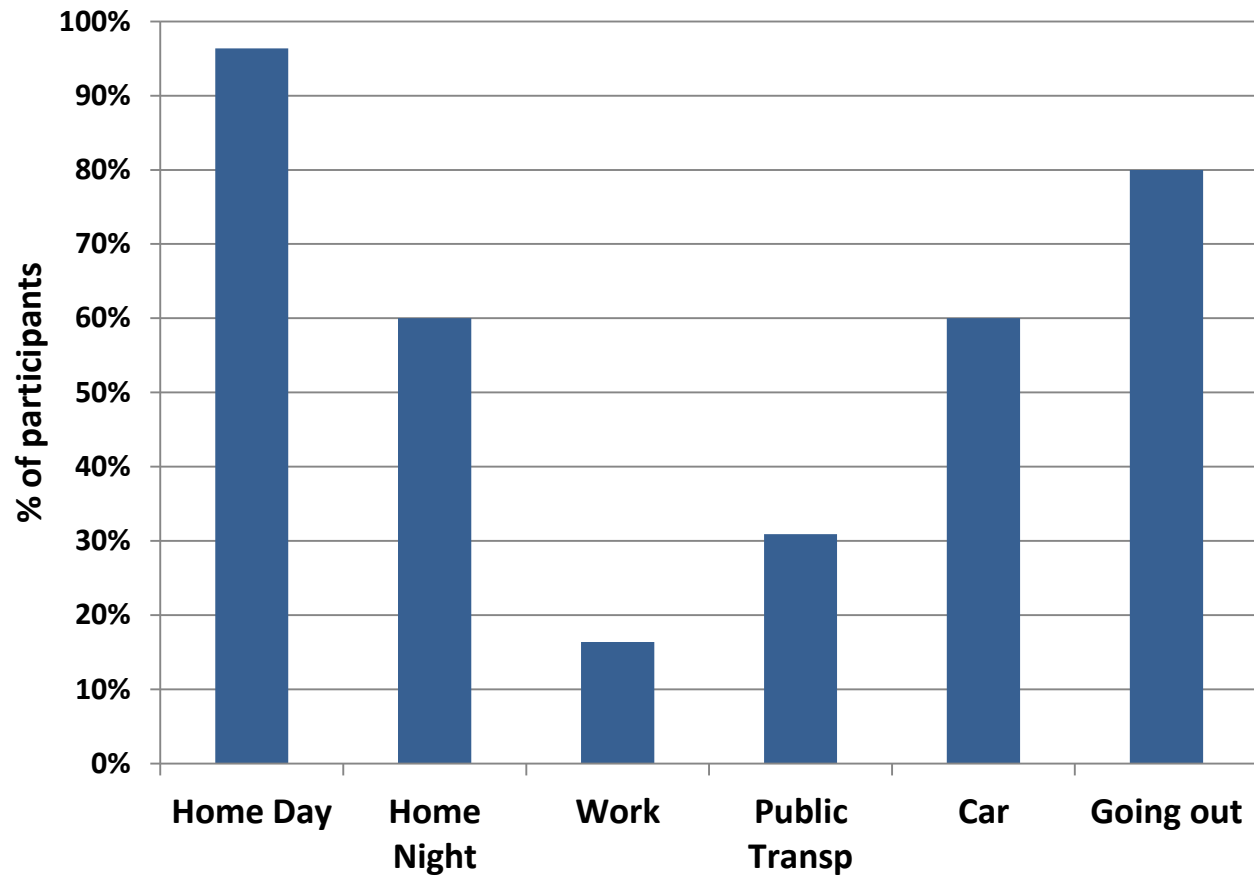


Fig 7

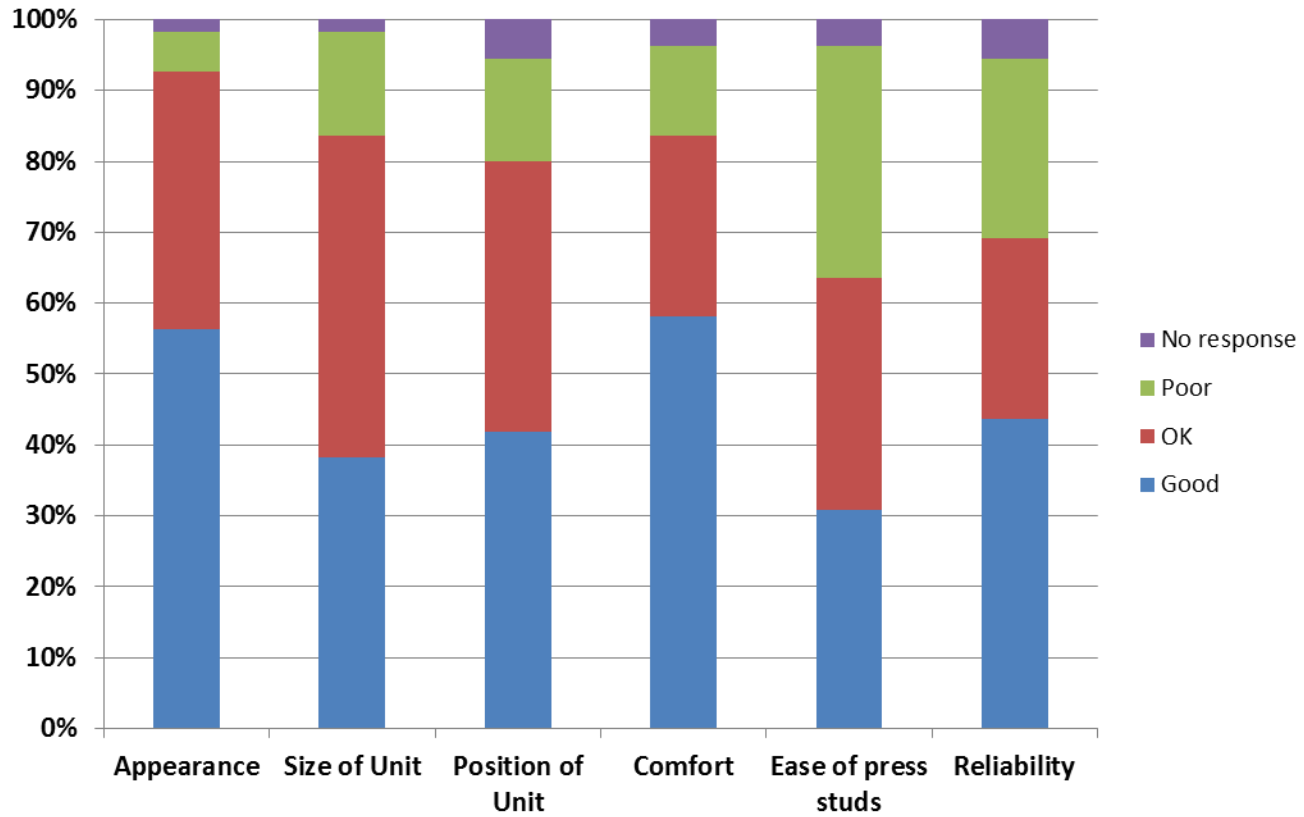


Fig 8

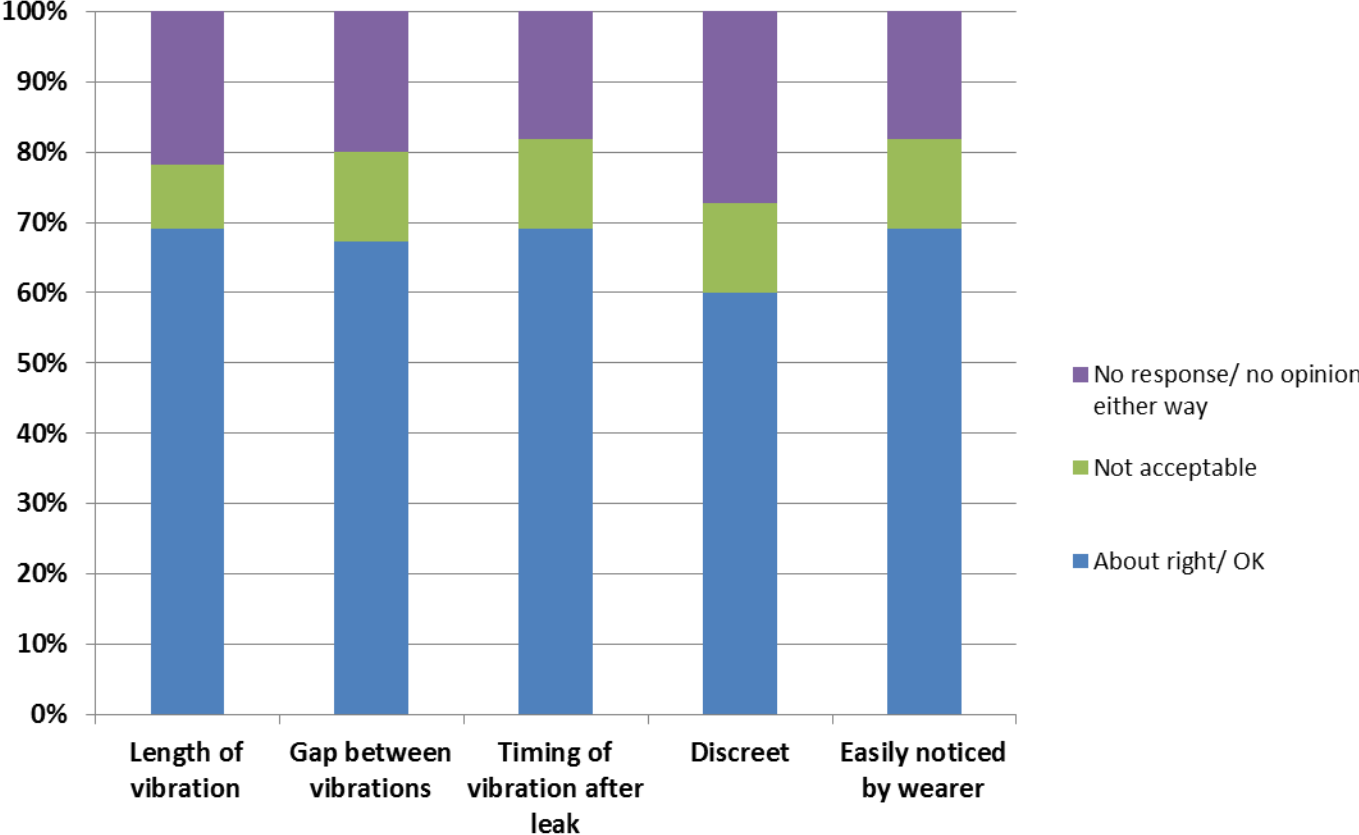


Table 1

Patient ID	Age	No. of pads/wk	Leak out of pad/wk	UK Dress Size
SU 02 78	32	21-40	<1	10
SU 02 76	38	11-20	>7	14-16
SU 02 04	40	21-40	3-6	10-12
SU 02 42	42	21-40	>7	18-20
SU 02 43	46	21-40	3-6	12
SU 02 28	48	<5	1-2	28
SU 02 80	48	21-41	>7	16-18
SU 02 05	49	6-10	3-6	10-12
SU 02 38	51	11-20	1-2	18
SU 02 81	52	ND	<1	18
SU 02 46	53	21-40	3-6	16
SU 02 06	56	6-10	1-2	14-16
SU 02 20	56	21-40	>7	20-22
SU 02 14	57	11-20	3-6	16
SU 02 16	57	6-10	>7	28
SU 02 37	57	ND	3-6	16-18
SU 02 48	57	6-10	1-2	14
SU 02 41	58	11-20	>7	18
SU 02 54	58	11-20	3-6	30
SU 02 12	59	21-40	3-6	18-20
SU 02 21	60	6-10	1-2	22
SU 02 45	60	11-20	>7	12
SU 02 77	60	6-10	1-2	12
SU 02 60	62	21-40	<1	18-20
SU 02 61	65	21-40	3-6	18-20
SU 02 82	65	<5	1-2	14-16
SU 02 15	66	21-40	3-6	18
SU 02 18	67	<5	1-2	26-28
SU 02 53	68	6-10	1-2	14
SU 02 63	68	6-10	1-2	16-18
SU 02 56	69	21-40	>7	28+
SU 02 62	69	6-10	3-6	22
SU 02 01	71	ND	ND	18-20
SU 02 17	71	21-40	1-2	12
SU 02 59	72	21-40	1-2	12
SU 02 67	72	11-20	1-2	18
SU 02 72	74	11-20	3-6	14
SU 02 73	74	11-20	3-6	24
SU 02 64	75	6-10	1-2	14
SU 02 22	76	11-20	3-6	22
SU 02 35	76	6-10	3-6	16
SU 02 50	76	21-40	>7	14-16

SU 02 57	76	11-20	1-2	18-20
SU 02 58	78	11-20	1-2	14-16
SU 02 74	78	11-20	>7	20-22
SU 02 24	79	11-20	1-2	16
SU 02 26	79	21-40	1-2	22
SU 02 29	79	11-20	<1	12-14
SU 02 33	80	11-20	1-2	18
SU 02 39	80	>40	<1	20-22
SU 02 25	84	21-40	>7	16
SU 02 49	84	6-10	<1	18 or 20
SU 02 75	85	21-40	3-6	ND
SU 02 47	87	11-20	3-6	16
SU 02 27	88	11-20	3-6	16-18
SU 02 83	98	>40	3-6	22

ND = No Data

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