Received: 5 October 2022 | Revised: 22 February 2023 | Accepted: 27 February 2023

DOI: 10.1111/ijun.12362

ORIGINAL ARTICLE

BAUN BRITISH ASSOCIATION OF UROLOGICAL NURSES WILEY

Indwelling catheter patient experiences and the potential usability and acceptance of the T-Control® prototype urinary catheter

A. Toledo-Chavarri PhD[1] | A. Bassas-Parga Bsc[2] | S. Endrenyi Msc[3] | M. Luque Bsc[3,4] | C. Bezos-Daleske PhD[5] | V. Reyero MSc[5] | P. Serrano-Aguilar PhD[1] | J. E. Batista-Miranda PhD[2]

[1]Canary Islands Health Research Institute Foundation (FIISC), Santa Cruz de Tenerife, Santa Cruz, Spain

[2]Asociación "Continentia", Barcelona, Spain

[3]Rethink Medical, Las Palmas de Gran Canaria, Las Palmas, Spain

[4]Universidad de Las Palmas de Gran Canaria (ULPGC), Las Palmas, Spain

[5]Institute for Patient Experience—IEXP, Madrid, Spain

Correspondence
M. Luque, Calle Practicante Ignacio Rodríguez S/N, Edificio Polivalente II del Campus Universitario de Tafira, 35017, Las Palmas de Gran Canaria, Las Palmas, Spain.
Email: manuel.luque101@alu.ulpgc.es

Funding information
Rethink Medical SL

Abstract

The aim of this study was to analyse the experience of users of indwelling bladder catheters and evaluate the anticipated usability of a prototype of the T-Control® urinary catheter (without being inserted) by patients who were able to compare the differences between the T-Control® prototype and other urinary catheters and urinary catheter accessories. A qualitative study was conducted with people who had lived with an indwelling urinary catheter for at least 1 week. Two user-centred design techniques were applied: patient experience trajectory map and *Think Aloud*, a method where the participants were able to express their previous experiences, expectations and preferences while manipulating the devices. The experiential trajectory was collected based on a semi-structured following interviews. Participants were able to manipulate the new T-Control® and, based on their previous experiences, compare the potential usability of T-control® with Foley-type catheter and its accessories All the participants stated that they had experienced negative emotions concerning bladder catheterisation during the trajectory of use, from the initial prescription and adaptation to the follow-up, and the forced life changes that a permanent catheterisation implies. The most frequent emotions were rejection and sadness. The new T-Control® device could potentially improve the patient experience, as all participants perceived advantages related to the closure system, ease of use, safety and discretion. Participants also noted its closure system as an advantage and highlighted its ease of use, although one-handed operation required some learning. Catheters currently on the market are functional, but some patients do not always have a satisfactory experience. This might negatively affect their quality of life, so there is a wide market opportunity for new devices that improve clinical and psychological care. Based on patient evaluation, the new T-Control® device with a built-in valve could provide benefits for patients.

KEYWORDS
bladder catheters, patient experience, patient journey map, T-control®, user-centred design

This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made.
© 2023 Rethink Medical SL and The Authors. *International Journal of Urological Nursing* published by British Association of Urological Nurses and John Wiley & Sons Ltd.

What is known about this topic

Several previous studies point to the inconveniences and difficulties related to the use of bladder catheter. Although patients highlight the lack of information and the need to include psycological support to improve the clinical care of catheterised people, we have not been able to find any study focused on the emotional aspects that catheterised people show, such as fear, anxiety, sadness or anger.

What this paper adds

The research carried out in this study explores these emotionals aspects that are a key element for a better experience and quality of life for catheterised patients. Furthermore, the patient experience could be improved with new devices, such as T-Control®, that are designed to be easier to use and which are proposed to offer more safety and comfort through their design, thus meeting the necessary requirements to increase the quality of life of patients.

1 | INTRODUCTION

The most commonly used urinary catheters are permanent internal urethral catheters, allowing both short-term bladder drainage and the treatment of chronic urinary retention.[1] Permanent transurethral catheterisation with a Foley catheter is a widely used procedure both in hospitals and in the community, but is not without complications, the development of urinary tract infections (UTI) being the most frequent one.[2] The prevalence of UTI has been noted to be present in 80% of people with a catheter[1,3] and it is suggested that the bacterial colonization rate reaches an incidence of up to 95%, 4 weeks after insertion.[4] Other complications can include catheter obstruction, pericatheter leakage, bladder spasms, and trauma to the urethra or bladder endothelium, which can lead to perilesional stenosis.[5] Catheter-associated urinary tract infections (CAUTI) increase morbidity, mortality, the use of healthcare resources, and, consequently increased healthcare costs[6] with sources in the literature suggesting that more than 5340 years of life are potentially lost (2011–2012) and an annual cost of approximately € 549 000 000 in Europe alone.[7] Although the widespread use of the Foley catheter has demonstrated functional effectiveness in draining the bladder, it has also shown safety problems, among which are the high risk of CAUTI; contamination of urine samples; the blockage of the catheter; disconnection accidents and urine leaks; reduction of the bladder reflex; the reduction of the quality of life of the users (limitation of autonomy, stigma, pain); and occupational accidents of the healthcare professionals due to the exposure to biological fluids.[6]

Beyond the safety problems observed with the use of the Foley catheter, the limited professional adherence to the recommendations of the clinical practice guidelines to reduce the incidence of CAUTI has contributed to stimulating the search for safer alternatives for permanent bladder catheterisation.[8]

The T-Control® device (EP13735021.1-28540002EP PCT/EP2013/064520, Rethink Medical SL) is a new silicone Foley catheter that incorporates an innovative system for active fluid control through a three-position valve that is integrated into the proximal end of the catheter. The 'open' and 'closed' positions of the valve, available throughout the whole period of use, allow the control of the urinary flow without the need for the additional accessories required by the common Foley catheter. Meanwhile, the control position available just during the insertion of the device prevents the involuntary leakage of urine thanks to a specific in-built membrane. In this way, it is possible to regulate the flow of urine and reduce the risk of CAUTI.[9] T-Control® has an additional safety lock to prevent inadvertent or accidental catheter openings. These safety mechanisms allow T-Control®: (1) to keep the system closed and to reduce the risk of accidents due to contamination with biological fluids; (2) to fill the bladder, favouring the conservation of the bladder reflex and tone; (3) to reduce pressure injuries of the catheter tip on the bladder mucosa[10]; (4) to eliminate biofilm and microorganisms, by entrainment, during the intermittently emptying the bladder; (5) to reduce traction accidents and injuries; (6) to totally or partially dispense with the collection bag;[11] (7) to reduce accidental leaks due to bag disconnection when mobilizing the patient; and (8) to promote a more autonomous and active life of the patient, with the consequent improvement in quality of life.[12] T-Control® is also compatible with any type of collection bag and, like any other type of Foley catheter, is recommended to be used with a fixing device to avoid accidental tractions, a recommendation that is not always followed by conventional catheter users. T-Control®'s accessory allows it to be fixed to the patient's underwear avoiding both accidental tractions and involuntary opening of the valve.

Participatory methodologies focused on user preferences make possible to adapt the design of health technologies to the needs and expectations of the people who use them.[13] This study aims to identify and analyse the experience of users of indwelling urinary catheters, evaluate the usability of a T-Control® prototype, and improve the design of this new urinary catheter.

2 | METHODOLOGY

2.1 | Design

A qualitative study was conducted with two user-centred design techniques:[14,15] *Patient Journey Map*[16] and *Think Aloud*.[17–19] The study

1749771x, 0, Downloaded from https://onlinelibrary.wiley.com/doi/10.1111/jjun.12362 by Readcube (Labtiva Inc.), Wiley Online Library on [03/04/2023]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

was carried out in the period between December 2019 and February 2020. The important question at this stage of the research is to identify what matters most to bladder catheterised patients.[19] In the initial stages of this research, an exploratory approach that produces new knowledge is required.[20,21]

The methods used for inquiring were interviews and a workshop. As recommended by the European Association of Urology, it is important to gather the opinions of patient focus groups and relevant healthcare professionals. In 2012, the Association created an interprofessional workgroup called 'patient information' (http://patients.uroweb.org) where it is considered important to empower the patients by offering them a platform from which to express their needs and desires. The nature of these methods is inductive, and the accuracy depends on the right selection of participants.[22] The sample can be small, as in this present case, and does not aim to be fully representative, but is considered big enough to produce information that is both rich and coherent through research questions. It is only in the second phase that a quantitative approach is needed to assess validity and reliability with large samples.[23,24]

2.2 | Recruitment

The patients were selected in a specialized urology centre of Barcelona (Spain) among those who had lived with an indwelling bladder catheter for different reasons and at least 1 week in the 6 months prior to the start of the study (July–December 2019). The initial list of participants was made by verifying which patients who gave their consent to the medical team to review their clinical history for quality audit and clinical research activities, a practice previously recommended by the Clinical Research Ethics Committee. After an initial list, 16 patients were contacted by telephone, eight patients out of these 16 were initially contacted for the study. Those people under 18 years old, carriers of a suprapubic tube and those unable to understand the objectives of the study were excluded. The sample looked for balance in gender and age, taking into account that the most frequent profile of a urinary catheter carrier is middle-aged men.

2.3 | Data collection procedure

All participants signed informed consent on the content and aims of the study. The patients were divided into two separate session groups, and each of the data collection sessions was structured in two parts that were audio recorded. During the first part of the session, the experiential trajectory of the patients with a urinary catheter was collected based on a semi-structured script. Annexe I shows the questions included in the script, with their focus on first impressions and experiences, physical, social and psychological impact of the catheter, as well as their interactions with the catheter and with healthcare professionals.

In the second part of the session, the participants were able to evaluate different medical devices and accessories: conventional indwelling urinary catheter (Foley type), collection bag, flow closure plug, fixing tape and a flow closure valve, called Flip-flo®. The participants were able to compare these devices with a prototype of the new T-Control® device, having the opportunity to manipulate all the devices freely, intuitively and without receiving prior instructions to verify their usability. Through a *Think Aloud* technique, which is commonly used in the design of health technologies, participants were able to express their previous experiences, expectations and preferences while manipulating the devices. As in the first part, the different reactions were collected in a semi-structured script detailed in Annex II.

2.4 | Analysis

The information collected from the bladder catheterised patients in the first part made it possible to represent their experiences longitudinally in a *Patient Journey Map*. A descriptive content analysis was performed from the recordings and field notes of the sessions organized into topics and categories. To assure trustworthiness, interviews were transcribed and divided into different content topics, afterwards, units of meaning were obtained and introduced into each content topic. Following this, meaning codes were extracted and added to be categorized, and themes were created to link underlying meanings in the categories.[25]

The evaluation of the anticipated usability of the T-Control® prototype was reported descriptively, comparing it with the rest of the devices shown.

3 | RESULTS

Of the 16 initially contacted patients, 10 agreed to participate, and only 8 finally attended, who were divided into two groups of 2-h face-to-face sessions (five participants in the first session and three in the second) held at the specialized urology centre. The age of the sample was between 20 and 67 years old, including six men and two women. All the participants had had an indwelling catheter for at least 1 week for various reasons. Socio-demographic and clinical data are shown in Table 1.

All the participants stated that they had experienced negative emotions concerning the catheter during all the cycle, from the initial prescription and adaptation to the follow-up and the forced life changes that the permanent catheter entails. The *Permanent Bladder Catheter Patient Journey Map* with the situations, illustrative comments of the participants, main emotions and perceived needs can be seen in Table 2.

Positive emotions were only reported by two of the urinary catheter users and referred to as symptomatic relief from not having to get up at night. The most mentioned emotions were rejection ($N = 8$), fear (5), anger (4), shame (3), sadness (2), anxiety (2) and night-time relief (2).

Next, the experience, the preferences with the different devices used and the evaluation of the usability, functionality and innovation

1749771x, 0, Downloaded from https://onlinelibrary.wiley.com/doi/10.1111/jjun.12362 by Readcube (Labtiva Inc.), Wiley Online Library on [03/04/2023]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

TABLE 1 Demographic and clinical features of the participants

Variable		Total
Sex	Male	6
	Female	2
Age; median (years)		51
Reason for catheterisation	Acute urine retention	5
	High post-voiding residual	1
	Postoperative	2
Clean intermittent catheterisation		3
Plug users		2

of T-Control® catheter were studied in greater depth. The part of T-Control® that is inserted in the patient is the same as in other urinary catheters, therefore, it was considered enough to evaluate the usability of the integrated valve, which is the innovative part of T-Control®. The comments of the participants organized according to topic and category are shown in Table 3.

3.1 | The experiences of the people with catheters in greater detail

The prescription of the urinary catheter aroused negative feelings such as: uncertainty, fear, anxiety, sadness, helplessness and anger, shame and low self-esteem. The initial reaction is the rejection of the catheter and also some surprise since participants mentioned that they lacked information about the catheter devices themselves, their indications and how to use and maintain them. During the following period of time, negative emotions increase, worsening self-esteem and opinion of themselves due to having to live with a foreign body as is the catheter tube. The participants pointed out that psychological support and greater attention from health professionals would have facilitated the acceptance of the catheter. The catheter is taboo, some people with the catheter tried as much as possible to hide the device so that others could not see or smell them. Out of shame and/or fear of stigma, participants who used a bag hid this situation. Regarding previous catheterisation experiences, with already marketed devices, a perception of disability and/or lower worth was repeatedly expressed throughout the sessions and by all participants without being related to the type of catheterisation or characteristics or the use of the collection bag.

The lives of the participants changed in all cases after being catheterised, from the beginning of the catheterisation and regardless of its duration. For a few weeks or chronically either, the catheterised persons adapted to the new situation and changed some habits. Four participants commented that they had altered their habits in terms of water consumption and two of them confirmed that they had reduced their intake or practically eliminated it to avoid filling the bag. Two participants expressed having changed their way of dressing and another restricted their activities outside their home due to the shame that the catheter entailed, thereby affecting the normal progress of their social life.

All participants considered it important to maintain the desire to void, which is manifested through both physical (spasms, relief and peri-catheter losses) and psychological sensations (will to self-control). The insertion of the catheter can be a painful experience, three participants needed to receive urgent attention due to incidents with the catheter (accidental exit, pain, infection and obstruction). The care received by the participants in the emergency department during and after the catheterisation was highly variable. Some participants pointed out that the clinical care of catheterised persons could be improved with greater sensitivity by health professionals and psychological support.

3.2 | Previous experience and preferences with bladder catheterisation devices

All participants experienced problems with the usability of the bladder catheterisation products they had used. The main concerns of the participants were poor fixing, emptying of the bag and leakage due to disconnection of the plug. The connection of the bag to the leg was considered the main source of discomfort and concern, as well as the weight that the bag acquired as it filled. Emptying was a problem for the male participants in terms of handling in public spaces.

Most catheterised people preferred the use of a catheter plug to the use of the collection bag due to its discretion, because collecting bags can be an additional burden of care by having to empty them more repeatedly. Two participants considered that the use of the plug would increase their anxiety due to the fear of an accidental disconnection with a voiding leak and preferred the collection bag. All participants would change the design of the plug favouring the control of accidental urine leakage. Two participants acknowledged reusing the bags and plugs, despite being aware of the recommendation not to do so.

3.3 | Evaluation of the T-Control® catheter

When evaluating the T-Control® catheter prototype over conventional devices with a disposable plug, all participants perceived advantages related to the closure system, ease of use, safety and discretion. The closure system was rated positively for its visual aid of colour differentiation (red/green) compared to the Flip-flo® valve. Two patients mentioned that after a few months of using the valve, one would begin to forget more easily whether or not it closed properly, and a visual aid could help.

Participants manipulated the T-Control® product and agreed that the one-handed operation would require some learning. However, following instructions on how to use it with one hand, they were able to mimic the process without difficulty. T-Control® was rated as robust and less cumbersome than the Flip-flo® valve. The balance between hardness and flexibility in the closure was positive and all participants considered that it allowed easy handling and, in turn, most considered it safe to avoid leaks. One person was of the opinion that the end of the tube could be stiffer.

1749771x, 0, Downloaded from https://onlinelibrary.wiley.com/doi/10.1111/jjun.12362 by Readcube (Labtiva Inc.), Wiley Online Library on [03/04/2023]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

TABLE 2 Permanent bladder catheter patient journey map

	Prescription	Initial adaptation	Follow-up	Living with a catheter
Situation	Lack of knowledge about the handling and care required.	Great physiological and psychological impact.	Catheter change, visits to the emergency service for problems with the catheter.	Slow adaptation leading to forced life changes.
Comments	*When they told me my world fell apart… I thought it was for a few days, but when they told me it was for a long time … it was like a glass of cold water.*	*At first I was very sad. I was very depressed that they put a catheter in me.*	*Some professionals have golden hands … but others hurt you too much … I do not wish it on my worst enemy.*	*There are things that I like but I do not do anymore … I am comfortable as I am. And I'm happy at night … before I had a terrible time.*
Main emotions	Rejection, anger, surprise.	Shame, fear of stigma, sadness.	Pain.	Partial acceptance, night-time relief. Reduced self-esteem, perception of disability.
Needs	Lack of information.	Reduced quality of life. Lack of psychological care.	Feeling of dependency Finding the right care.	Reduced quality of life Loss of bladder reflex. Loss of bladder musculature.

TABLE 3 Additional topics, categories and comments

Topic: The experience of the catheterized persons in greater detail
Positive emotions *I was used to getting up 4 or 5 times a night due to prostate problems, and the difference between being able to sleep eight hours in a row, I would not take off my bag even if they pity me.*
Initial reaction to the catheter *My son sent me a WhatsApp a few days after I got the catheter to ask me how I was doing. My answer was: tired and angry.*
Stigma *As the bag is filling up, your leg looks as if it were swollen … and also since at the beginning it is very strange to have a bag of pee tied to your leg, I was walking a little strangely. And my neighbours asked me, what's wrong with your leg? And I told them that I had hurt myself…*
Perception of disability *At night I do use the bag, and I feel a little handicapped … a little handicapped compared to the others.*
Changes in habits *I began not to go out on the street. Because if I maintain my pee a lot, then it will not come out. And I was afraid to go out in case I could not find a bathroom and that I would end up having to go to the emergency service… So I stopped following my routine.*
Deficiencies in urgent care *There were some [health professionals] who had silver hands and you did not feel anything … But there are others who hurt you a lot … And some nurses pass by and others do not do it well … It's horrible!*
Topic: Experience and preferences with the bladder catheterisation devices used
General usability of the devices *It is quality of life because it is comfortable […] But you get tired of carrying the bag with you … I carry it day and night. The tube bends, it remains stagnant, you notice that the bag has been filled, it hurts … In bed it is not so much a problem. But during the day it is very uncomfortable and you always have to always pay attention.*
Plug leaks *But in the end I decided every hour to take the plug off. And it leaked a little bit, it was annoying to have to go every hour, but if I waited more it would get wet. If I get distracted and do not put the plug on properly, the pee leaks … This does not happen to me anymore because I make sure I tighten it well.*
A minority prefers the bag *It has happened to me while working, that without realizing it the plug came loose … and you get messy … Because of course, it is not that you get a little wet … it is that you get soaked! And of course, you have to be careful that they do not see you in the bathroom … and, well in the end I have always solved it as best I could. But now I always carry a whole change of clothes because of what might happen. Because you are always living in fear.*
Topic: T-Control® Catheter Assessment
Security *It gives me a sense of security because as this is blocked [the guillotine], nothing goes wrong here.*
Discretion *For men, you wear it down here, you hide it and you do not notice it with your trousers. And it gives me the feeling that it will hold better. […] More practical than with a bag … You do not have to take off your trousers, underpants …*

1749771x, 0, Downloaded from https://onlinelibrary.wiley.com/doi/10.1111/jjun.12362 by Readcube (Labtiva Inc.), Wiley Online Library on [03/04/2023]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

All considered discretion to be important. Along these lines, one of the participants who used a catheter with a bag commented that T-Control® seemed to be a more discreet and practical option. However, as the improvement in terms of discretion depends on the current conditions of each catheterised person, for some it was not an improvement on the already available device. Asked if they would use T-Control® with or without a bag, they all answered that they would prefer to use it without a bag.

4 | DISCUSSION

Negative emotions such as fear, anxiety, sadness or anger prevail related to permanent urinary catheterisation. Current products meet functional requirements, but entail limitations on the quality of life of their users due to daily living issues including problems with the catheter (size), bag (poor fixing and lack of discretion) as well as plugs (leak and accidents). Although we have not found any previous research focused on the emotional aspects of the experiential trajectory of the catheterised persons, other qualitative studies point to the difficulties of adaptation and the impact of catheters on the self-esteem, body image and social life of its users.[26,27]

This impact of urinary catheters stems from limitations in their design,[27] and this is where T-Control® could improve the patient experience, since patients valued the advantages of its closure system and highlighted its ease of use, although one-handed operation requires some learning. The device was perceived as safe, especially due to the visual aid (green/red) in opening or closing the valve, a novelty not available in other devices. In general, the robustness of the device and being not very bulky were valued positively, demonstrating that T-Control® would meet the fundamental requirements of functionality, safety and manageability.

The information needed by catheterised persons includes, in addition to those mentioned in this study, information about the prevention of problems and infections and the management of sexual and social life.[28] Despite this, users of indwelling catheters generally lack the necessary information on this type of product, as well as its care, making it difficult for them to adapt. For this reason, catheterised persons and their caregivers feel ill-prepared for catheter management, especially when faced with problem management.[29] The care of the catheterised patients could, therefore, improve with the involvement of the health professionals,[30] as well as providing them with more information and psychological support.

4.1 | Limitations

This study was conducted with a small sample of indwelling catheter users from just two medical centres. In addition, participants valued the new device without it being inserted, since it is in the development phase. This limits the experiential knowledge of the study. It is necessary to carry out a clinical trial that allows the evaluation of its clinical effectiveness and safety, as well as being able to quantitatively assess its usability with a larger sample. On the other hand, we highlight that the qualitative methodology has allowed us to discover preferences regarding the currently marketed products in order to improve the design of the T-Control® prototype.

5 | CONCLUSIONS

Current catheters are functional, but they do not provide a satisfactory quality of life experience, so there is a wide opportunity to improve such devices and thereby enhance the clinical and psychological care of these patients.

Patients discussed their experience with urine retention, their experience with traditional devices, and evaluated a prototype of T-Control® without inserting it, as a concept. In this evaluation, all the patients mentioned as attributes its ease of use, its safety (functional and psychological), the comfort and the improvement over intimacy that it provides. Similarly, all patients preferred not to use the device with a collection bag if there is a guarantee that there will be no urine leakage. These attributes belong to the sphere of quality of life, which is why—in a first assessment—T-Control® could meet the requirement of providing a better patient experience and its design can be optimized with the perceptions collected from the catheterised persons.

AUTHOR CONTRIBUTIONS

S. Endrenyi, M. Luque, C. Bezos-Daleske, P. Serrano-Aguilar and J. E. Batista-Miranda are responsible for the design of the study. Patients' recruitment was carried out by A. Bassas-Parga, C. Bezos-Daleske, V. Reyero and J. E. Batista-Miranda, while A. Bassas-Parga, S. Endrenyi, M. Luque, V. Reyero and C. Bezos-Daleske participated in the data collection. Results and data analysis were carried out by A. Toledo-Chavarri, S. Endrenyi, M. Luque and P. Serrano-Aguilar. A. Toledo-Chavarri, A. Bassas-Parga and V. Reyero are responsible for the manuscript writing, while S. Endrenyi, M. Luque, P. Serrano-Aguilar and J. E. Batista-Miranda carried out the principal revision of it. All authors made substantial contributions to the revising of the manuscript and approved the final version.

FUNDING INFORMATION

This study was funded by private funding contributed by Rethink Medical.

CONFLICT OF INTEREST STATEMENT

Ana Toledo Chavarri declares that she has no conflict of interest. Anais Bassas Parga declares that she has received financial contributions as an employee of Asociación Continentia. Szilvia Endrényi is co-founder and shareholder of Rethink Medical, a company that develops and owns the rights of T-Control®. Manuel Luque is co-founder and shareholder of Rethink Medical, a company that develops and owns the rights of T-Control®. Carlos Bezos Daleske declares that he has received financial contributions as an employee of Institute for Patient Experience—IEXP. Author Verónica Reyero declares that she has received financial contributions as an employee of Institute for Patient

1749771x, 0, Downloaded from https://onlinelibrary.wiley.com/doi/10.1111/jun.12362 by Readcube (Labtiva Inc.), Wiley Online Library on [03/04/2023]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

Experience—IEXP. Pedro Serrano-Aguilar declares that he has no conflict of interest. José Emilio Batista Miranda declares that he has received financial contributions as an employee of Asociación Continentia.

ORCID

M. Luque https://orcid.org/0009-0003-3804-2978

REFERENCES

1. Gilbert B, Naidoo TL, Redwig F. Ins and outs of urinary catheters. *Aust J Gen Pract*. 2018;47(3):132-136.
2. Krein SL, Fowler KE, Ratz D, Meddings J, Saint S. Preventing device-associated infections in US hospitals: national surveys from 2005 to 2013. *BMJ Qual Saf*. 2015;24(6):385-392.
3. Yu S, Marshall AP, Li J, Lin F. Interventions and strategies to prevent catheter-associated urinary tract infections with short-term indwelling urinary catheters in hospitalized patients: an integrative review. *Int J Nurs Pract*. 2020;26(3):e12834.
4. Kass EH, Finland M. Asymptomatic infections of the urinary tract. *J Urol*. 2002;168(2):420-424.
5. Durkin MJ, Keller M, Butler AM, et al. An assessment of inappropriate antibiotic use and guideline adherence for uncomplicated urinary tract infections. *Open Forum Infect Dis*. 2018;5(9):ofy198.
6. Dellimore KH, Helyer AR, Franklin SE. A scoping review of important urinary catheter induced complications. *J Mater Sci Mater Med*. 2013;24(8):1825-1835.
7. Cassini A, Plachouras D, Eckmanns T, et al. Burden of six healthcare-associated infections on European population health: estimating incidence-based disability-adjusted life years through a population prevalence-based modelling study. *PLoS Med*. 2016;13(10):e1002150.
8. Kuy S, Gupta R, Roy C, Awad S. Incidence of catheter-associated urinary tract infections with compliance with preventive guidelines. *JAMA Surg*. 2020;155(7):661-662.
9. Shbeeb A, Young JL, Hart SA, Hart JC, Gelman J. Lock-out valve to decrease catheter-associated urinary tract infections. *Adv Urol*. 2014;2014:765756.
10. Yates A. How to use a catheter valve. *Pract Nurs Pract*. 2017;113(5):25-27.
11. van den Eijkel E, Griffiths P. Catheter valves for indwelling urinary catheters: a systematic review. *Br J Community Nurs*. 2006;11(3):111-2, 114.
12. Dhariwal L, Chiu S, Salamon C. A urinary catheter valve is non-inferior to continuous bladder drainage with respect to post-operative UTIs: a randomized controlled trial. *Int Urogynecol J*. 2021;32(6):1433-1439.
13. Oliveira P, Zejnilović L, Canhão H. Challenges and opportunities in developing and sharing solutions by patients and caregivers: the story of a knowledge commons for the patient innovation project. *Governing Medical Knowledge Commons*. Cambridge University Press; 2017:301-325.
14. Woods L, Cummings E, Duff J, Walker K. Design thinking for mHealth application Co-design to support heart failure self-management. *Stud Health Technol Inform*. 2017;241:97-102.
15. Flood M, Ennis M, Ludlow A, et al. Research methods from human-centered design: potential applications in pharmacy and health services research. *Res Social Adm Pharm*. 2021;17(12):2036-2043.
16. Toledo-Chávarri A, Ramos-García V, Koatz D, et al. Co-design process of a virtual community of practice for the empowerment of people with ischemic heart disease. *Int J Integr Care*. 2020;20(4):9.
17. Long DL, Bourg T. Thinking aloud: telling a story about a story. *Discourse Process*. 1996;21(3):329-339.
18. Güss CD. What is going through your mind? Thinking aloud as a method in cross-cultural psychology. *Front Psychol*. 2018;13(9):1292.
19. Parise A, Güss D. *TAP: A Thinking-Aloud Analysis Program. Computer Program to Analyze Participants' Thinking Aloud Protocols to Develop State-Transition Diagrams*. University of North Florida, Department of Psychology; 2006.
20. Moser A, Korstjens I. Series: practical guidance to qualitative research. Part 3: sampling, data collection and analysis. *Eur J Gen Pract*. 2018;24(1):9-18.
21. KKorstjens I, Moser A. Series: practical guidance to qualitative research. Part 4: trustworthiness and publishing. *Eur J Gen Pract*. 2018;24(1):120-124.
22. Luciani M, Jack SM, Campbell K, et al. An Introduction to qualitative Health Research. *Prof Inferm*. 2019;72(1):60-68.
23. Weldring T, Smith SM. Patient-reported outcomes (PROs) and patient-reported outcome measures (PROMs). *Health Serv Insights*. 2013;4(6):61-68.
24. Kline RB. *Principles and Practice of Structural Equation Modeling*. 4th ed. Guilford Press; 2015.
25. Graneheim UH, Lundman B. Qualitative content analysis in nursing research: concepts, procedures and measures to achieve trustworthiness. *Nurse Educ Today*. 2004;24(2):105-112.
26. Chapple A, Prinjha S, Feneley R, Ziebland S. Drawing on accounts of Long-term urinary catheter use: design for the "seemingly mundane". *Qual Health Res*. 2016;26(2):154-163.
27. Fowler S, Godfrey H, Fader M, Timoney AG, Long A. Living with a long-term, indwelling urinary catheter: catheter users' experience. *J Wound Ostomy Continence Nurs*. 2014;41(6):597-603. 597, 603.
28. Prinjha S, Chapple A, Feneley R, Mangnall J. Exploring the information needs of people living with a long-term indwelling urinary catheter: a qualitative study. *J Adv Nurs*. 2016;72(6):1335-1346.
29. Mackay WG, MacIntosh T, Kydd A, et al. Living with an indwelling urethral catheter in a community setting: exploring triggers for unscheduled community nurse 'out-of-hours' visits. *J Clin Nurs*. 2018;27(3–4):866-875.
30. Carter EJ, Pallin DJ, Mandel L, Sinnette C, Schuur JD. Emergency department catheter-associated urinary tract infection prevention: multisite qualitative study of perceived risks and implemented strategies. *Infect Control Hosp Epidemiol*. 2016;37(2):156-162.

How to cite this article: Toledo-Chavarri A, Bassas-Parga A, Endrenyi S, et al. Indwelling catheter patient experiences and the potential usability and acceptance of the T-Control® prototype urinary catheter. *Int J Urol Nurs*. 2023;1-8. doi:10.1111/ijun.12362

ANNEX I: —Question script

First impressions and experiences

1. What was your reaction at the beginning?
2. What impact does the catheter have on your life in general (in the case of chronic use, what impact did it have at the beginning and what impact does it have afterwards?) Have you changed habits (specify: not drinking enough, leading a sedentary life, etc.)?

Physical Impact

3. How does the catheter affect you physically? sports wise/ dressing wise

1749771x, 0, Downloaded from https://onlinelibrary.wiley.com/doi/10.1111/ijun.12362 by Readcube (Labtiva Inc.), Wiley Online Library on [03/04/2023]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

Social impact

4. How does it affect you socially? work/hobbies/travel.
5. Does it affect the lives of the people around you? (family and friends) How?

Psychological Impact

6. Have you ever experienced embarrassment from the catheter? What happened? How did you experience it? How did you manage the situation? What did you feel?
7. How does it affect you psychologically? How have your attitude and emotions about the catheter changed since you started using it until today? (detailing: self-image, stress, mood, shame, stigma, feeling of loss of control, feeling of being sick and limited or older, worries, etc.).

Interaction with the product and healthcare professionals

8. Do you usually have adverse effects that force you to make an urgent appointment? (It can be leak, pain, infection, blockage, etc.).
9. Do you have any recommendations for improvement for health-care professionals in general when addressing this issue?

ANNEX II: Think Aloud question script

First Part: During this part, participants will be able to see and touch the following products:

- Conventional permanent urinary catheter, Foley type (product available in Spain).
- Collection bag (product available in Spain).
- Flow closure plug (product available in Spain).
- Fixing tape.

Questions:

1. How practical are these products for you on a day-to-day basis?
2. What are the three advantages and three disadvantages of these products?
3. What would you change in them, if you could?
4. Do you prefer to use a bag or a plug? (away from home and at home, day-night, sport-no sport, etc.).
5. How and how often do you change the bag and plug?
6. Do you feel any physical difference between the use of a bag or a plug? (pain Do you think that one of the two options generates more pain? Which one? Where do you get that information from? One or the other or the new solution?)
7. Do you feel any psychological difference between the use of a bag and a plug?
8. If you use a bag, what disturbs you? (size, sound, difficult fixing on the leg, etc.)
9. Have you suffered bag disconnections?
10. Have you experienced plug disconnections?

Second Part: Transition Question

- Have you ever been offered an intermittent catheter? If you do not currently use it, why is that?
- A flow shut-off valve, called Flip-flo® (probably unknown to patients as it is a product available only in other EU countries) is placed on the table, its use is explained and each participant can touch or examine it.

Questions:

1. What differences do you perceive with the product you are currently using?
2. What improvements would this product offer you, if available?

Third part: The T-Control® product is shown, its use is explained and each participant can touch or examine it.

Questions:

1. What differences do you perceive with the product you are currently using?
2. What advantages do you find?
3. What are its disadvantages?
4. How can it affect quality of life (physical, psychological, social, work, and family)?
5. What would you change in it? What risks do you see?
6. How would you use it (without or with a bag)?
7. How would you fix it?
8. How easy is it to use?
9. If they were available and you had to pay for them, what price range would you put (min-max)?
10. Would you like to try it one day?

1749771x, 0, Downloaded from https://onlinelibrary.wiley.com/doi/10.1111/jun.12362 by Readcube (Labtiva Inc.), Wiley Online Library on [03/04/2023]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License