Revista ENFURO
Asociación Española de Enfermería en Urología

index

ARTÍCULO ORIGINAL

T-Control®. A new leak-tight urethral catheter

T-Control®. Un nuevo catéter uretral hermético

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Abstract

Urinary catheterisation is an invasive technique that carries several associated risks and has a significant impact on the patient's quality of life. However, research on the different properties of urethral catheters that may affect patients' quality of life, such as the leak-tightness, are limited. T-Control® is a novel silicone catheter with an integrated fluid-control valve that allows voluntary control of urine flow. In addition, it can be used with a fixer called Holder, which prevents leakage, liquid entry and accidental valve openings. This study aims to evaluate the leak-tightness of the T-Control® catheter, both individually and when used with the Holder.

Keywords: Tightness. Quality of life. Urinary catheter. Fluid-control valve. Leakage prevention.

Resumen

El sondaje vesical es una técnica invasiva que conlleva varios riesgos asociados y tiene un impacto significativo en la calidad de vida del paciente. Sin embargo, la investigación sobre las diferentes propiedades de las sondas vesicales que pueden afectar la calidad de vida de los pacientes, como la estanqueidad, es limitada. T-Control® es una sonda de silicona novedosa con una válvula de control de fluidos integrada que permite el control voluntario del flujo de orina. Además, puede usarse con un fijador llamado Holder, que previene las fugas, la entrada de líquido y las aperturas accidentales de la válvula. Este estudio tiene como objetivo evaluar la estanqueidad de la sonda T-Control®, tanto de manera individual como cuando se utiliza con el Holder.

Palabras clave: Estanqueidad. Calidad de vida. Sonda vesical. Válvula de control de fluidos. Prevención de fugas.

Introduction

Urinary bladder catheterisation is a prevalent procedure utilised for both therapeutic and diagnostic objectives[1], typically overseen by nursing personnel[2]. Approximately 15.5% of hospitalised patients necessitate urinary catheterisation at some point[3], marking it a high-risk procedure for urinary infections. Various literature reviews conducted in hospital settings indicate that 16-23% of European patients[4,5,6] and 16-24% of American patients are prescribed urinary catheters[7,8].

Main indications for urinary catheterisation include relieving acute or chronic urinary retention; surgical preparation and post-operative urinary tract healing; bladder irrigation in case of haematuria or for medication administration; strict diuresis control; protecting skin lesions in incontinent patients; sterile urine sample collection; and palliative care[5].

Despite its widespread application, urinary catheterisation is an invasive technique that carries several associated risks[9]. These include an elevated risk of catheter-associated urinary tract infections (CAUTIs)[5], which are the most prevalent complication[10,11,12,13]. This increases not only morbidity[14,15] and mortality[14,15,18] but also healthcare costs[15,16,17,18]. Patients can also experience various catheter-related issues, such as obstructions[11,19], due to either encrustation or biofilm formation[20], bladder spasms[21], spillages[21,22], and even bladder trauma[23]. Furthermore, using urine collection bags can detrimentally impact bladder tone[24] by reducing its natural elasticity and expansion ability[25].

Additionally, patients frequently report negative emotional experiences, often stemming from the catheter and its associated complications such as infections, blockages or catheter bypassing[26, 27, 28]. These feelings of pain and lack of autonomy contribute to a diminished quality of life[27, 28]. Common emotional responses include catheter rejection, fear, anxiety, and

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Date of receipt: 03/16/2024
Date of acceptance: 03/16/2024
Publication date: 04/30/2024

Rev. Enfuro 2024; 143:32-39
www.revistaenfuro.com

concerns about personal appearance[29]. Patients also lament a lack of comprζensive information regarding catheter use and maintenance[30], as well as a deficit in the education on indwelling catheterisation received from healthcare professionals[31].

Despite the widespread use of catheters, there remains a limited number of studies focusing on the quality of life for catheterised individuals[21,32]. Moreover, a consensus is yet to be reached on the information that should be provided to patients about the lifestyle changes required post-catheterisation[33].

Indwelling catheters significantly disrupt patients' social lives, daily comfort and routines[30]. Concerns range from odour and clothing adjustments to social interactions and intimate relationships[27,34]. A qualitative study by our research group found that participants experienced negative emotions throughout the catheterisation process, such as rejection, fear, anger, shame, sadness and anxiety[30]. In addition to mentioning the negative impact of catheterisation, psychological support and heightened attention from healthcare professionals were also identified as factors that could facilitate better acceptance[30].

Limited research exists on the leak-tightness of urinary catheters, either as standalone devices or when used with external valves or plugs. A sealed device could potentially ameliorate patients' quality of life by mitigating the risk of leaks.

T-Control® is a novel silicone Foley catheter with an integrated valve that allows voluntary control of urine flow. The "control position", only available initially for the insertion process, prevents unwanted urine leakage thanks to a specific built-in membrane, whereas "open" and "closed" positions regulate urine flow without other additional accessories required by the conventional Foley catheter. The catheter enhances patient autonomy as it eliminates the need for constant connection to a urine collection bag, allowing recovery of their habits and an improved engagement in water-related activities, such as bathing, showering or rζabilitation programs.

Furthermore, the T-Control® catheter can be used in conjunction with an accessory called Holder, which prevents both residual leakage or liquid entry, and prevents accidental valve openings. This accessory also facilitates the attachment of the catheter to the patient's underwear or to a leg band, thereby enhancing mobility.

In our forthcoming experiment, we aim to evaluate the leak-tightness of the T-Control® catheter, both individually and when used with the Holder accessory, to observe the occurrence of accidental leaks and the liquid ingress into the device.

Materials and methods

Design

For this study, we used 20 T-Control® catheters and 10 Holder accessories. Half of the sample set, consisting of 10 T-Control® catheters and 5 Holders, was used to evaluate the entry of water into the catheters. The remaining samples were used to observe potential leakages from the catheters.

To assess the tightness of the T-Control® device, we designed a simulation that mimicked the conditions experienced by a catheter submerged in a simulation designed to mimic the conditions to which a catheter submerged in water would be exposed. The catheters were securely affixed to a circular support and submerged in a column of 30 cm of water under turbulent flow conditions for 24 hours. In the first experiment, the water was dyed red, without altering its physical properties, adding a small quantity of red food colouring (Direct Red BA 150%) to the water tank. Figure 1a shows the arrangement of the catheters on the circular support, while Figure 1b shows the circular support with the affixed catheters submerged in the dyed-water receptacle.

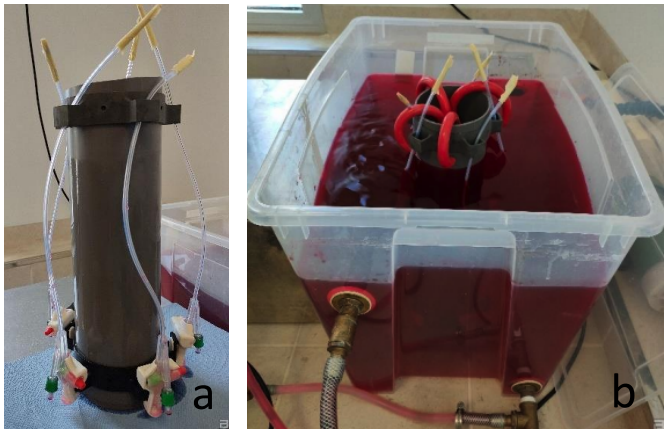

Figure 1. (a) Circular support with the catheters. (b) Circular support with the catheters fixed submersed in the container filled with stained water.

Two approaches were contemplated for simulating the fluid dynamics of water in interaction with catheters: either by moving the water around stationary catheters or by moving the catheters within a static water environment. After careful consideration, the chosen approach was made to circulate the water around immobile catheters using a series of motors and brackets. This was deemed to be the most cost-efficient and reproducible method.

To emulate the water movement, a pair of centrifugal pumps (UNO; HCM-75LX) were utilised. These pumps agitated the entire water volume within the tank, achieving a maximum flow rate of 62 litres per minute and a maximum driving force height of 5.6 metres. The ensuing vortex interacted uniformly with all installed catheters. To generate this vortex, two impulsion valves—each with an outlet diameter of 11 mm and an inlet diameter of 5 mm—were strategically positioned along the diagonal axes that delineate the overall dimensions of the tank when viewed from above, thus inducing clockwise turbulence. The efficacy of the vortex in creating agitation was directly related to the outlet velocity in the nozzles of each installed impulsion valve. An intake valve, responsible for allowing liquid into the tank, was situated at its base. A comprζensive illustration of the assembled system components is shown in Figure 2.

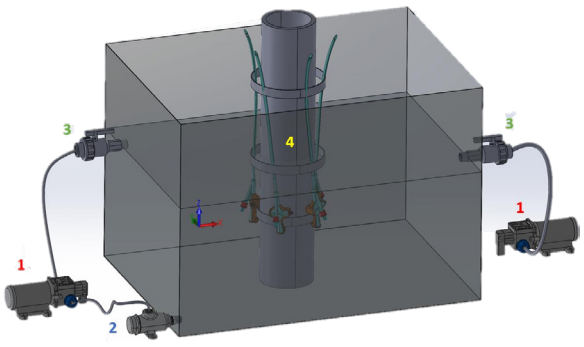

Figure 2. Assembly schematic featuring key components designated by numerals and distinct colours, ranging from 1 to 4. 1) Dual centrifugal pumps designed to circulate the water; 2) An inlet valve facilitating water entry into the tank; 3) A pair of discharge valves for water outlet; and 4) Samples affixed to the central fixation tube.

Analysis of the entry of liquid to the catheter

We evaluated the tightness of the T-Control® catheter by studying fluid ingress under turbulent flow over 24 hours. In this experiment, we tested five standalone T-Control® catheters and five attached to the Holder accessory, using dyed water for easier identification of potential filtration. We sealed the catheter tips opposite the external valves with air-permeable material to prevent water entry due to splashing.

Initially, a visual inspection was conducted to assess the catheter tightness, specifically looking for leakages. Subsequently, the catheter was detached from its circular mount. After drying its surface, any traces of red liquid within the catheter were meticulously examined by employing white absorbent paper, thereby enhancing the visibility of the red indicator dye. Following this, the catheters were disassembled, separating each component with utmost care, to scrutinise the presence of any liquid within, once again utilising white absorbent paper for this purpose.

Study of liquid leakage from the T-Control® catheter

After evaluating fluid ingress, we conducted a second experiment to check potential water leakage from the T-Control® catheter into the previously mentioned water tank. Differing from the first experiment where we coloured the tank water, here we added to the tested catheters 500 µl of a 10 mg/ml fluorescein solution (CAS number 2321-07-5), a fluorescent marker that exhibits fluorescence under UV light.

A set of five T-Control® catheters and five T-Control® catheters affixed to the accessory Holder were tested utilising a coaxial double cannula to mitigate the risk of external contamination. To prevent inadvertent water entry through splash effects, the distal tips of the catheters, opposite to the external valves, were sealed with an air-permeable material.

After removing the catheters from their mounts and drying them, we visually inspected their tightness within a cabinet illuminated under a fluorescent light. Should there have been any leaks, these would have been readily discernible due to the fluorescein that had been previously added within the catheters. Several droplets of fluorescein at various concentrations were also introduced into both the catheter and the Holder as positive control.

Subsequently, the fluorescein concentration was quantified both within the water tank and inside the catheters by spectrophotometry. Should leakage have occurred, the resulting concentration would be proportional to the volume of fluorescein that had escaped. Moreover, in instances of water infiltration into the catheter, one would anticipate a commensurate reduction in the concentration of the fluorescein solution contained within.

The procedure followed to measure the concentration of fluorescein within the water tank utilising spectrophotometry is described as follows:

1. Three 25 ml aliquots were withdrawn from the 40-litre tank.
2. The spectrophotometer settings were configured as detailed below, with a reading temperature of 24.6°C:

Excitation Wavelength	488 nm
Emission Wavelength	510 nm
Excitation Bandwidth	9 nm
Emission Bandwidth	20 nm
Gain	61 Optimal (100%)
Number of Flashes	25
Integration Time	20 µs

3. A calibration curve was prepared. The concentrations of the solutions included in the calibration curve were 0.005, 0.01, 0.02, 0.05, 0.1 µg/ml, which were prepared from a stock solution of fluorescein with a known concentration of 10 mg/ml. The water from the tank was used as the dilution solvent for the standard solutions and to measure the blank fluorescence of the calibration curve. Fluorescence was measured three times for each concentration, and the linear regression was determined using Microsoft Excel (Redmond, Washington, United States).

The procedure followed to measure the amount of fluorescein inside the catheters by spectrophotometry is described below:

1. Each catheter was cut (with the valve kept closed), and a sample of water with fluorescein solution (approximately 100 µl) was extracted from each of them for evaluation.
2. Each aliquot was diluted 1/625 with the tank water to fit within the calibration range.
3. The conditions for the spectrophotometer were as follows (temperature of the reading: 24.8 °C):

Excitation Wavelength	488 nm
Emission Wavelength	514 nm
Excitation Bandwidth	9 nm
Emission Bandwidth	20 nm
Gain	44 Optimal (100%)
Number of Flashes	25
Integration Time	20 µs

4. A calibration curve was prepared. The concentrations included in the calibration curve were 0.5, 1.0, 2.0, 5.0, 10.0, and 20.0 µg/ml, which were prepared from a stock solution of fluorescein with a known concentration of 10 mg/ml (the same concentration as that added to the catheters). The water from the tank was used to measure the blank fluorescence of the calibration curve and as a dilution solvent for the standard solutions. Fluorescence was measured three times for each concentration, and a linear regression was determined using Microsoft Excel.

Results

Analysis of the entrance of liquid to the catheter

After 24 hours immersed in water and the subsequent disassembly, no droplets were visually observed inside the tested T-Control® catheters. In the test performed with the catheter fixed to the Holder, some droplets were observed in the Holder, but not in the catheters. These results show that the valve alone can prevent liquid from entering the catheter, while the accessory Holder contributes to sealing the urine drainage port, in addition to facilitating catheter fixation.

Analysis of the liquid leakage from the catheter

1. Visual inspection of the catheters

Figure 3 shows the positive controls, one sample of a catheter and one sample of a Holder with different drops of fluorescein at several concentrations deliberately dropped in.

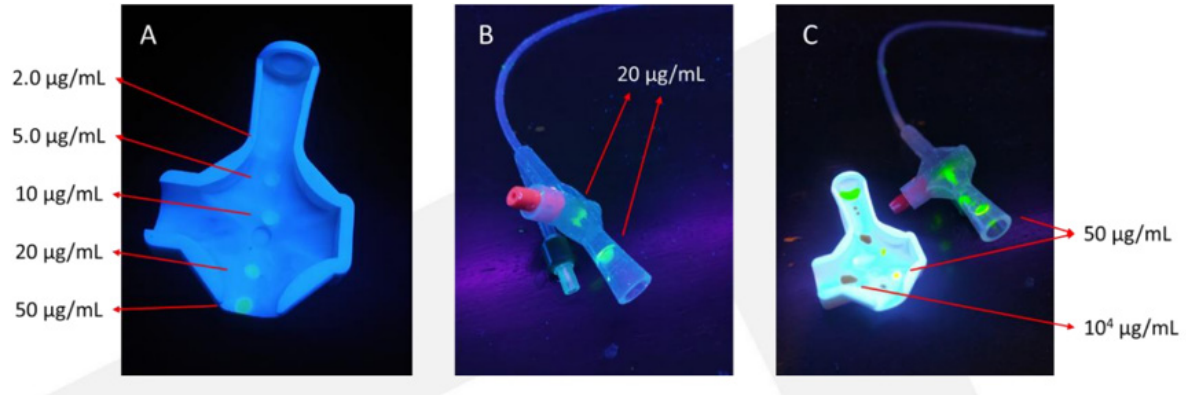

Figure 3. Images of the positive control of a catheter and a Holder under exposure to UV light. A) Holder with 50 µL drops of fluorescein solution at different concentrations, ranging from 2.0 to 50 µg/ml. B) Catheter with fluorescein at a concentration of 20 µg/ml added at the two points indicated. C) Photograph of both a Holder and a catheter with fluorescein added at different concentrations.

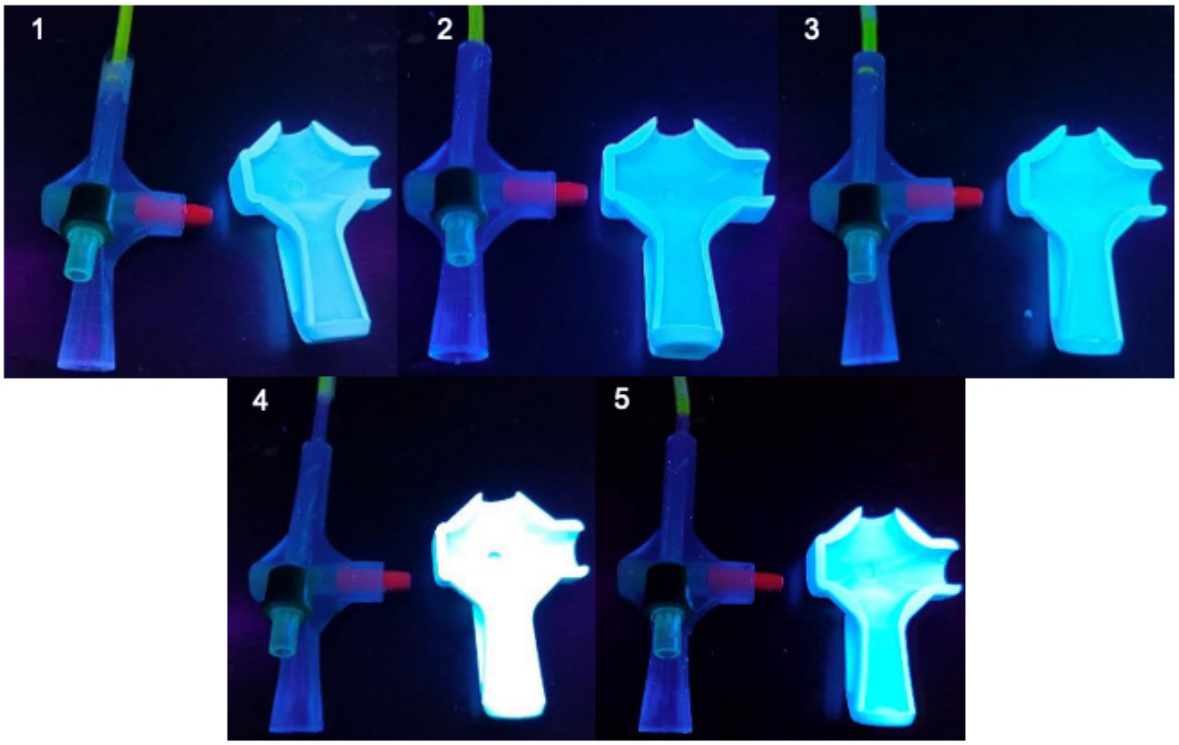

Figure 4. Images of the T-Control® catheters and the Holder under UV light.

After performing the test and subsequently disassembling the five T-Control® catheters affixed to the Holder, no presence of fluorescein was detected in either the catheters or the accessories, as shown in Figure 4.

Likewise, fluorescence was not observed around the valve area of the T-Control® catheters tested without the accessory Holder, as can be observed in Figure 5.

2. Determination of fluorescence in the tank

The calibration curve obtained to calculate the fluorescein concentration of the water tank aliquots is shown in Figure 6 The range was determined to encompass the expected results, covering fluorescein concentrations from 0.000 to 0.100 µg/ml. The Limit of Detection (LOD; the minimum concentration capable of being detected for fluorescence leakage from the catheter to the tank) was established at 0.008 µg/ml. Concentrations of fluorescein extracted from the tank samples were determined using the regression equation of this linear regression.

Table 1 shows the results of the spectrophotometry measurements of the 6 samples extracted from the water tank, 3 samples belonging to the water tank set of the T-Control® catheter fixed to the accessory Holder and 3 samples belonging to the water tank set of the T-Control® catheter without the accessory Holder.

The equation obtained in Figure 6 was used to calculate the concentration of fluorescein from the results obtained from the spectrophotometer (Table 1). Concerning the catheters affixed to the Holder, the concentration of fluorescein obtained was -0.0018 ± 0.003 µg/mL; whereas, the fluorescein concentration obtained for the catheters without the Holder was -0.0019 ± 0.002 µg/mL.

The negative results obtained indicate that the fluorescence from the tank is below the technique's limit of detection. Hence,

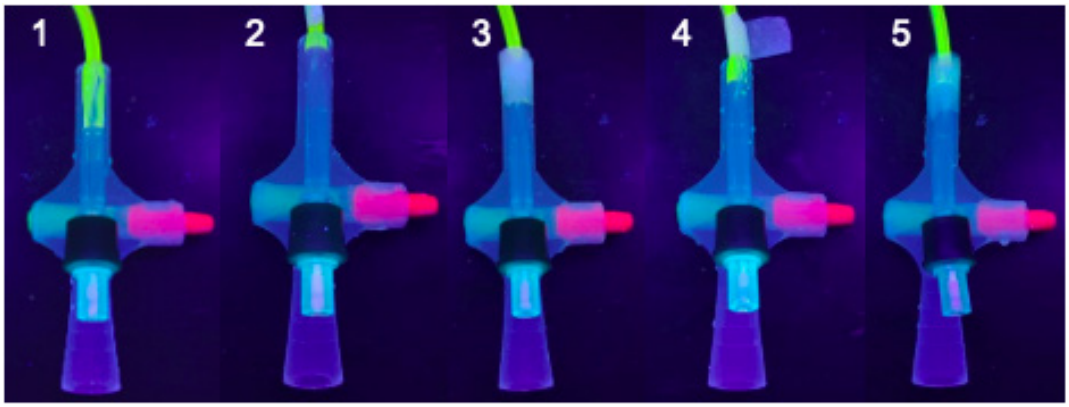

Figure 5. Images of T-Control® catheters, analysed without being fixed to the Holder, under UV light.

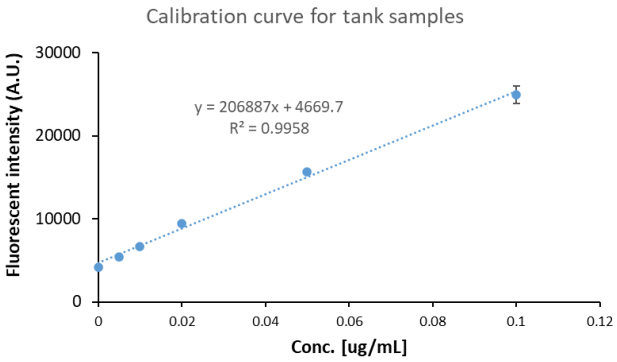

Figure 6. Calibration curve of the extracted solutions of the water tank.

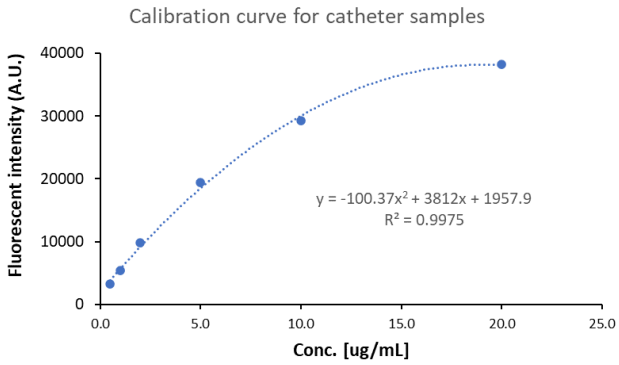

Figure 7. Calibration curve for the catheter samples.

Table 1. Measurements of the mean fluorescent intensity leaks to the water tank by spectrophotometer for the catheters with and without Holder.

	Fluorescent Intensity (A.U.) ± SD	
	Catheters with Holder	Catheters without Holder
Water tank (sample 1)	4205 ± 741	4498 ± 161
Water tank (sample 2)	4234 ± 112	4309 ± 19
Water tank (sample 3)	4442 ± 40	4013 ± 14
Water tank total	**4293 ± 355**	**4273 ± 230**

no leakage was detected from the catheter to the tank, both for T-Control® attached to the Holder and for T-Control® alone without being attached to the Holder.

3. Determination of fluorescence in the catheter

The calibration curve used to analyse the fluorescence within the catheters is shown in Figure 7. As can be observed, the curve encompasses the range of fluorescein concentrations from 0.5 to 20.0 µg/ml. The concentrations of fluorescein from the samples within the catheter were diluted and determined using parameters from the regression of the second-degree polynomial equation.

Table 2 shows the average fluorescence measurements in the fluorescein solutions extracted from inside the catheters.

The concentration of fluorescein was calculated by using the equation detailed in Figure 7. The results obtained are shown in Table 3.

The results show that the concentration within the catheters remains unchanged after 24 hours of turbulent flow under 30 cm of water. Hence, no leaking was detected from the catheters to the tank or vice versa.

Discussion

Research about the functional properties of urinary catheters remains scarce. Notable studies, including those conducted by Abdelrahman Mt et al.[41] and Stewart CA et al.[42], have focused on comparing the flow rates of various commercially available urinary catheters from different brands. These studies, in concurrence with prior research[43,44], underscore that structural variations among catheters lead to disparities in irrigation and flow characteristics. Similarly, there are hypotheses suggesting that these differences could also stem from the materials used in catheter manufacturing[45].

Investigations have been typically directed toward understanding the volume needed for the balloon to burst and how different materials influence the rate of free fragmentation formation, as explained in the studies of Gilbert C et al.[46] and Chung et al[47]. These studies revealed that the catheter type significantly contributes to catheter balloon cuffing, along with other factors like the duration of catheter usage and the methods of deflation employed.

In more innovative approaches, recent studies have used ex vivo models of porcine urinary tracts to explore catheters' effects on flow rates and mucosal damage[48]. However, we can

Table 2. Fluorescence detected in the solutions extracted from the T-Control® catheters.

Catheters fixed to the accessory Holder	Fluorescent Intensity (A.U.) ± SD	Catheters without Holder	Fluorescent Intensity (A.U.) ± SD
Catheter Holder 1	37428 ± 301	Catheter without Holder 1	37472 ± 45
Catheter Holder 2	37321 ± 42	Catheter without Holder 2	37031 ± 636
Catheter Holder 3	37626 ± 115	Catheter without Holder 3	36790 ± 793
Catheter Holder 4	37576 ± 113	Catheter without Holder 4	37285 ± 645
Catheter Holder 5	36716 ± 585	Catheter without Holder 5	36456 ± 365

Table 3. Concentration of fluorescein in the fluorescein solution extracted from the catheters.

	Catheter with Holder		Catheter without Holder	
	Concentration ± SD	%η* = $[conc]_f/[Conc]_0$	Concentration ± SD	%η = $[conc]_f/[Conc]_0$
1	16.30 ± 0.57 µg/mL	101.9	16.39 ± 0.09 µg/mL	102.4
2	16.11 ± 0.07 µg/mL	100.7	15.65 ± 0.99 µg/mL	97.8
3	16.70 ± 0.25 µg/mL	104.4	15.30 ± 1.13 µg/mL	95.7
4	16.59 ± 0.24 µg/mL	103.7	16.05 ± 1.20 µg/mL	100.3
5	15.21 ± 0.79 µg/mL	95.0	14.88 ± 0.44 µg/mL	93.0
Average	16.18 ± 0.59 µg/mL	**101.1 ± 3.7%**	15.65 ± 0.60 µg/mL	**97.8 ± 3.7%**

*Recovery percentage: percentual relation between the concentration of fluorescein in the catheter at the end of the essay and the concentration in the catheter before the assay.

identify a glaring gap in these investigations, the lack of focus on the catheter's tightness property, crucial for preventing the infiltration of external elements, be they fluids, particles, or air, as well as the unintended leakage of urine.

In this study, we aimed to investigate the leak-tightness properties of the new T-Control® catheter to gain a deeper understanding of urinary catheter characteristics. Findings distinctly indicate that the T-Control® catheter, wether tested independently or attached to the Holder, exhibited no evidence of filtration or leakage, regardless of the direction of the potential flow—inside-out or outside-in.

The functional properties of urinary catheters significantly impact the quality of life of catheterised patients. Unfortunately, there is a noticeable lack of evidence concerning how catheter functionalities affect patients' quality of life[39]. Only a handful of studies have delved into the life quality differences among patients based on the catheter materials used[39,49,50]. Furthermore, detailed information about these properties, including flow rate and flexibility, is often inaccessible to end-users. This lack of information handicaps healthcare professionals and patients in selecting the most suitable urinary catheter for their specific clinical needs. Prioritising research into these properties is crucial as they largely dictate the potential side effects a patient might experience.

The quality of life for catheterised patients is paramount. Existing literature concurs that the experience of living with a bladder catheter is cumbersome for patients, independent of the underlying medical condition[35]. Besides, multiple qualitative studies[38,39,40] document a decline in life quality among catheterised individuals, highlighting continuous discomfort, challenges in finding restful positions, and disruptions in daily activities. Common reported catheter-related complications include urinary leakage, pain, bladder spasms, and urinary tract infections[34].In addition to these physical inconveniences, emotional factors also play a significant role. Feelings of fear, anger, embarrassment, diminished confidence, and the social stigma associated with wearing a catheter profoundly affect patients' lifestyles. The stigma of wearing a bladder catheter often elicits negative emotions[32], with some narratives equating life with a urinary catheter to living with incontinence, largely due to the visibility of the device. While the stigmatisation of incontinence is known to contribute to depression and anxiety, research specifically investigating the catheter's stigma and its impact on quality of life is notably deficient[30].

Despite these challenges, there have been significant advancements in the development of innovative urinary catheters and related accessories, aimed at enhancing the quality of life for catheterised patients. These include external catheter valves[36] and novel catheter designs poised to minimise biofilm formation[37]. However, comprζensive studies assessing the functionality, effectiveness, and benefits of these new urethral catheters and accessories are still lacking.

Our research shows an in-depth evaluation of the unique feature of the new T-Control® catheter: its tightness prevents both inward and outward liquid flow. The implications of our results are profound, suggesting that T-Control® has the potential to forestall urine leakages, thereby enhancing catheterized patients' quality of life by making their condition less distressing. Moreover, T-Control® offers patients the freedom to engage in their usual daily activities with minimal restrictions, encompassing physical exercises and various forms of rζabilitation, including water therapies.

Funding

This work has been supported by grant Sodecan number EXP-INNO-0010-2021

Competing interests

PR Castellano-Santana declares no conflicts of interest for the present work.

C Armas-Moreno is a junior researcher at Rethink Medical SL, M Mòdol-Vidal is a Project Manager at Rethink Medical SL, M Serrano-Muñoz is the Technical Director, Scientific Director, and Regulatory Officer at Rethink Medical SL, J Ruiz-Canales is the Technical and Quality Manager at Rethink Medical SL. Both M Luque-González and Endrényi are co-founders and sharζolders of Rethink Medical SL. Rethink Medical SL, the company responsible for developing and holding the rights to T-Control®.

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