

Pre-clinical Evaluation of a Variable Length and Conforming Peritoneal Dialysis Catheter Weighted Anchor: In Vitro Analysis and Cadaver Feasibility Study

Christopher Scott Morris (✉ christopher.morris@uvmhealth.org)

University of Vermont Medical Center <https://orcid.org/0000-0001-8780-4586>

Gregory P. Johnston

University of Vermont College of Medicine

Michael J. DeSarno

University of Vermont

Appala Raju Badireddy

University of Vermont

Research article

Keywords: peritoneal dialysis catheter, cadaver study, tungsten, catheter migration, weighted anchor

Posted Date: August 22nd, 2020

DOI: <https://doi.org/10.21203/rs.3.rs-33928/v2>

License: © ⓘ This work is licensed under a Creative Commons Attribution 4.0 International License.

[Read Full License](#)

Abstract

Purpose Peritoneal dialysis (PD) catheters function best when residing within the retrovesical space of the peritoneal cavity, but they frequently migrate and fail. A novel variable length and conforming PD catheter weighted anchor to prevent migration has been evaluated.

Methods Test devices were placed in normal saline for 21 months. The effluent was periodically measured for heavy metals, including tungsten. The water-tight property of the device was also tested separately. Four cadavers were subjected to three-dimensional imaging and maneuvering to evaluate percutaneous insertion, function, stability within the retrovesical space, and percutaneous retrievability in 10 test devices.

Results Liquid leakage was low, with a mean absorbance of the test device effluent saline of 0.015. Mean methylene blue absorbance of the test device was significantly lower than the positive control (p-value = 0.01). Leakage of tungsten from devices made with medical grade Silastic tubing was also low, with a mean of 0.362 mg/L in the effluent saline, compared to a background concentration of 0.166 mg/L. Each test device was successfully inserted into the retrovesical space and retrieved percutaneously and remained completely intact following placement and insertion. No test device migrated as shown on axial cone beam CT imaging. Mean flow times and volumes were satisfactory at 3 minutes and 0.92L, respectively, for all test devices. For all catheters, the mean flow rate was 312 cc/min. No significant difference was found between the pre-roll and post-roll mean flow rates of the test devices (p-value = 0.35).

Conclusion This PD catheter weighted anchor showed stability, with minimal leakage of tungsten. All test devices were successfully inserted and retrieved percutaneously, with no damage or migration, and mean flow rates were satisfactory. Further investigation is warranted.

Background

Peritoneal dialysis (PD) is a low cost, and often physiologically beneficial, option for many patients with end stage renal disease (ESRD). However, its utilization has decreased in the United States, as 9.7% of prevalent ESRD patients were being treated with PD in 2014, whereas only 7.1% were utilizing PD in 2017. [1, 2] This recent decrease in PD utilization has occurred despite a previous increase related to economic incentives. The Centers for Medicare and Medicaid Services ESRD Prospective Payment System was introduced in 2011, which highlights the fact that PD is more cost-effective than in-center hemodialysis. [3]

The two most common reasons that PD fails, requiring many patients to transfer to hemodialysis, are infectious and mechanical complications of the PD catheter.[4] Optimal function of the PD catheter is often dependent on its ability to reside within the retrovesical space of the pelvis in men, or cul de sac

(pouch of Douglas) in women.[5, 6] The retrovesical space is a dependent portion of the peritoneal cavity in the supine or upright body positions, where fluid tends to accumulate. In addition, the retrovesical space is free of omentum and small bowel, which can impede PD catheter function. Unfortunately, catheter migration out of the retrovesical space of the pelvis is a common cause of PD failure.[7] Catheter migration has been reported to occur as high as 35%.[8] Revision of PD catheter migration is often unsuccessful, usually resulting in PD catheter replacement.[9] PD catheter malfunction is one of the major barriers to increasing the utilization rate of PD.

This study has evaluated multiple variations of a prototype PD catheter device which combines an effective weight effect at the intraperitoneal terminus of the catheter with other features, such as maintaining the same low profile throughout the PD catheter length. The device, when combined with a coiled PD catheter, creates a variable length catheter which conforms to the retrovesical pouch of the peritoneal cavity. This PD catheter weighted anchor can be retrofitted to modify any commercially available existing PD catheter, or it can be fabricated into a new PD catheter design. It can be placed percutaneously, laparoscopically, or with open surgery. It is low profile so that it can be placed through the same 18-French peel away sheath as the currently available standard PD catheters, which allows it to be placed percutaneously, and it will adjust the effective length of a coiled PD catheter by preventing elastic recoil out of the retrovesical space in larger patients.

The evaluation of this prototype PD catheter consisted of two parts. First, the stability of the device to prevent leakage of tungsten and other heavy metals over a 21-month period was measured. Second, the application of three-dimensional radiographic imaging to monitor percutaneous insertion, function, stability within the retrovesical space, and percutaneous removal in cadavers was performed.

Methods

The University of Vermont Research Protections Office determined that this project was exempt from review by the Institutional Review Board.

The University of Vermont and the University of Vermont Medical Center protocols governing the use of cadavers in research were followed in all cases. The first three cadavers came from the University of Vermont Anatomy Department, through the Anatomical Gift Program. This program has a robust registration process, which includes the consent of the live donor to comply with their wishes to allow the University of Vermont to use their body for teaching and research, including the development of new and innovative techniques and devices. The Anatomical Gift Program maintains a file of these signed consent and registration documents. The fourth cadaver was procured through the University of Vermont Medical Center Department of Pathology, after obtaining written consent from the next of kin prior to expiration, in

keeping with the patient's wishes. This consent form is on record at the University of Vermont Medical Center.

All methods and experiments were carried out accordance with relevant guidelines and regulations (Declaration of Helsinki).

Benchtop in vitro study

Test devices were created under sanitary conditions by inserting five 4mm diameter tungsten-carbide ball (ACER Racing, Los Angeles, CA) into the center of 4cm long sections of Silastic tubing, four with medical grade tubing (Merit Medical, South Jordan, UT) and two with laboratory grade tubing (Tri-anim Health Services, Dublin, OH).(Fig. 1A) The ends of each column of tungsten-carbide balls were bordered by two 4mm in diameter stainless steel balls (VXB, Anaheim, CA), which were secured with 0 Prolene sutures to create a water-tight fit.

A single 4cm long section of medical grade Silastic tubing was filled with 1% methylene blue and sealed at both ends with 4mm in diameter stainless steel balls and 0 Prolene sutures to create a water-tight fit.

Eight Erlenmeyer flasks were filled with 500ml of medical grade normal saline and A) normal saline negative control, B) 0.1ml of 1% methylene blue for a concentration of 0.02% as a positive control, C) Five 4mm in diameter tungsten-carbide and two 4mm in stainless steel balls as a positive control, D) the methylene blue device, E) one test device, F) one test device, G) two test devices, and H) two test devices. The flasks were stored in the dark at room temperature for 21 months.(Fig. 1B) Two ml effluent saline samples were drawn from each flask at the following time points: 1 day, 14 days, 3 months, 6 months, 9 months, and 21 months. Samples A, B, and D were tested for methylene blue (668 nm) by ultraviolet visible photometry. Samples A, C, E, F, G, H, I, and J were digested with 0.280ml of nitric acid (TraceMetal Grade, Thermo Fisher Scientific, Waltham, MA) and then analyzed for tungsten, iron, cobalt, and chromium (6, 9, and 21 month measurements) by inductively coupled plasma mass spectrometry (ICP-MS) by the Meadowlands Environmental Research Institute (Rutgers University, Newark, NJ).

Cadaver study

10 test devices of varying designs (flexible straight, segmented, and curled), lengths (8 to 16cm), and weights (10.5 to 20.6g) were attached to the terminal coiled ends of 8 Merit (Merit Medical, South Jordan, UT) and 2 Swan Neck Missouri Covidien (Covidien LLC, Mansfield, MA) curled PD catheters using 0 Prolene sutures.(Fig. 2) The devices were created by inserting multiple 4mm diameter tungsten-carbide balls into the center of medical grade Silastic tubing, with a 4mm in diameter stainless steel ball bordering each end. The ends were tied securely with 0 Prolene sutures. This created a water-tight attribute of each device, which remained intact throughout the study.

Four non-embalmed male cadavers were used within 24 hours from the time of expiration. Percutaneous insertion of all PD catheters and devices were successfully accomplished using the following percutaneous image guided technique. A needle was used with ultrasound guidance to enter the peritoneal cavity through the anterior abdominal wall and rectus muscle. A fluoroscopic and digital acquisition peritoneogram was obtained to ensure an intraperitoneal position and to delineate the retrovesical space. A 0.035-inch diameter guide wire was advanced into the peritoneal space and the needle was removed. Then, a 4-French angled angiographic catheter was used with the guide wire, to enter the retrovesical space. A 0.035-inch guide wire was coiled in the retrovesical space, the 4-French angiographic catheter was removed, and an 18-French peel away sheath (6.5mm outside diameter) was directed into the retrovesical space. The guide wire was removed and the PD catheter with attached device was pushed through the peel away sheath and into the retrovesical space. The peel away sheath was removed and the PD catheter was attached to the skin without creating a subcutaneous tunnel.

For each cadaver, one liter of normal saline was attempted to be infused and drained through each PD catheter via gravity. Flow rates and volumes were recorded. Table (Philips Allura table level at -9cm for infusion, +18 cm for drainage, and +6cm for cone beam CT), infusion pole (normal saline bag 6 feet above floor), and drainage bag (bag placed on floor) heights were standardized and consistent for all cadavers and all infusions and drainages. Between infusions and drainages for each PD catheter, each cadaver was manually rolled 360 degrees around the vertical axis to provoke migration. Peritoneograms in multiple 3-dimensional projections, as well as axial cone beam CT scanning (XperCT, Philips Medical Systems, The Netherlands) were obtained before and after each roll to detect migration. Images were recorded and archived.

Finally, each PD catheter and device were removed percutaneously. Each catheter and device were examined for tears and ruptures, and any breach in integrity was noted.

Statistical analysis for benchtop in vitro and cadaver studies

Comparisons of tungsten concentrations between the normal saline negative controls and the devices made of medical grade silastic tubing, as well as between the medical device made with laboratory grade silastic tubing and the devices made with medical grade silastic tubing, were performed with repeated measures mixed model analyses of variance. All effluent metal data was log transformed for normality. Comparison of the positive methylene blue control to the saline effluent of the methylene blue device was done using the Wilcoxon rank sum test. Cadaver study catheter flow rate comparisons were done using repeated measures mixed model analyses of variance. P-values ≤ 0.05 were considered to be statistically significant. All statistical analyses were performed using SAS version 9.4 statistical analysis software (SAS Institute, Inc., Cary, NC).

Results

Benchtop in vitro study

Heavy metal and methylene blue assay measurements are shown in Table I.

Over the 21-month evaluation period, mean methylene blue absorbance of the saline negative control measurement, 0.02% methylene blue positive control, and water-tight methylene blue test device using medical grade silastic tubing were 0.000, 0.520, and 0.015, respectively. Mean methylene blue absorbance of the test device was significantly lower than the positive control (p-value = 0.01). This confirmed that liquid methylene blue leakage from the test device was low.

Leakage of tungsten from the test devices using medical grade silastic tubing over 21 months was also low, although the difference of the mean tungsten concentration leakage amount between the saline negative control and the tungsten devices made with medical grade silicone did not reach statistical significance (p-value = 0.16). Concentration of free-floating tungsten in saline baths with bare tungsten-carbide balls (positive control) increased with time, as expected, from a low of 12.3 µg/L to a high of 610 µg/L, with a mean of 353 µg/L. In test devices with medical grade silastic tubing, the leakage of tungsten increased with time, from a low of 0.03 µg/L to a high of 2.24 µg/L, with a mean of 0.362 µg/L. However, the leakage of tungsten from the test devices made with laboratory grade silastic tubing was higher, ranging from a low of 0.14 µg/L to a high of 2.55 µg/L, with a mean of 1.09 µg/L. The ambient concentration of tungsten in normal saline ranged from a low of 0.10 µg/L to a high of 0.529 µg/L, with a mean of 0.166 µg/L. However, the difference of the mean tungsten concentration leakage amount between devices made with laboratory grade Silastic tubing and medical grade Silastic tubing did not reach statistical significance (p-value = 0.10). The percent increase in concentration of tungsten leaked from the test devices compared to the ambient concentration in medical grade normal saline was 218% for medical grade silastic tubing versus 657% for laboratory grade silastic tubing. The concentrations of the constituent heavy metal components of stainless steel (iron, cobalt, and chromium) within the saline baths of the test devices, also tended to increase with time.

Cadaver study

Each test device was easily and successfully inserted into the retrovesical space using percutaneous image guided technique with an 18-French peel away sheath. In addition, each test device was successfully retrieved intact using percutaneous technique. No tear, rupture, or breach in integrity was visualized on any of the test devices, post retrieval. No test device migrated, as depicted on biplane radiographic imaging, peritoneography, and axial cone beam CT scanning, despite filling the peritoneum with saline and provocative maneuvering (360-degree rolls of the cadavers for each test device). (Figs. 3–6)

Saline flow rates for each test device and cadaver are shown in Table 2. All in-flow and out-flow rates (total volume within 10 min) and volumes (greater than 0.7L in or out) were acceptable, except for a low

volume of 0.2L drained out of the Merit catheter with no device after the roll in cadaver 1, low volume of 0.6L out of the Covidien catheter with an 8 cm straight device prior to the roll in cadaver 2, and a low volume of 0.5L out of the Merit catheter with an 8 cm straight device prior to the roll in cadaver 3. For test devices, all volumes were infused or drained within a mean time of 3 minutes and the mean volume was 0.9L. For all catheters, the mean flow rate was 312 cc/min, which is well above the threshold rate of 100 cc/min. (Table 3)

No significant difference was found between the pre-roll and post-roll mean flow rates of the test devices (p-value = 0.35), signifying that the provocative maneuvering did not impede flow. Segregating the groups further, no significant difference was identified between the pre-roll and post-roll mean inflow (p-value = 0.41) or outflow (p-value = 0.53) rates, nor between the mean flow rates of the catheters with or without the devices (p-value = 0.23), indicating that device did not inhibit flow compared to catheters without the device located in an optimal position within the retrovesical space of the peritoneal cavity.

Discussion

Previous studies have shown that PD catheter migration out of the retrovesical space is a common cause of PD catheter dysfunction, occurring with a frequency between 12.7 and 35%.^[6–8] However, the true rate may be much higher, mainly because it may be under reported. These studies have not utilized the precision of three-dimensional imaging to determine if a PD catheter has migrated. In addition, without the use of imaging that records the position of the PD catheter at placement and three-dimensional imaging at follow up, the baseline position of the PD catheter and the true migration distance at follow up cannot be certain. If a frontal two-dimensional radiograph is used to determine migration distance, all of the PD catheters that migrate in an anterior direction will not be detected. Particularly in obese patients, PD catheters that migrate into the anterior abdominal recess and become dysfunctional due to wrap by omentum and small bowel will appear to be well placed on frontal radiographs.

Di Paolo, et al., attempted to ameliorate the problem of PD catheter migration by introducing the “self-locating peritoneal dialysis catheter” (SLPDC) in 1996.^[10] This PD catheter is similar to the straight Tenckhoff catheter in form, but is modified with a 12 g tungsten cylinder incorporated in the tip to keep the catheter tip in the retrovesical space through gravitational forces. Multiple studies have shown improved function, decreased migration, and longer catheter survival with the SLPDC.^[9–14] However, drawbacks of the SLPDC include the significantly increased diameter of the terminal tungsten cylinder compared to the nominal diameter of the catheter precluding the ability to place it percutaneously through small sheaths, its inability to vary the length of the effective catheter, and its restricted application to a straight catheter instead of a coiled catheter.

Some reports have made claims that PD catheter migration can be decreased or eliminated by applying various laparoscopic insertions techniques, such as using a three-cuff PD catheter with a low-entry technique, or “advanced laparoscopic” techniques consisting of rectus sheath tunneling and adjunctive procedures.^[15, 16] Many of these techniques can also be accomplished with the percutaneous method

of PD catheter placement. However, it does not appear that these investigations have documented initial PD catheter placement into the retrovesical space or analyzed migration at follow up by using three-dimensional imaging. Therefore, the true PD catheter migration rate remains unknown in these studies.

Like the SLPDC by DiPaolo, this device strives to prevent migration by the inherent anchoring effect of the tungsten, due to gravitational forces into the dependent portion of the pelvis. However, the device evaluated has multiple advantages over the SLPDC, which include its flexible design which conforms to the shape of the retrovesical space, its variable length when associated with a coiled PD catheter, and the applicability to all existing PD catheters as a modification. Most of all, it is low profile and designed to be placed percutaneously through an 18-French peel-away sheath. Besides the gravitational weight effect, another factor that stabilizes this device in the retrovesical space is its ability to conform to the shape of the retrovesical space and become interpolated due to its flexible properties. By associating this device with a coiled PD catheter, either as an ancillary attachment to a commercially available PD catheter or as an inherent part of a new modified PD catheter, the effective length of the active coil zone of the PD catheter will be increased, ensuring that the infusions and drainages will occur within the most dependent portion of the peritoneal cavity. Currently, proceduralists that place PD catheters rely on a “one size fits all” approach, or a limitation to two different lengths of commercially available coiled PD catheters, while the intraperitoneal distance between the anterior abdominal wall insertion site and the retrovesical space varies significantly among patients. In large patients, commercially available coiled PD catheters are not long enough to stay in place within the retrovesical space. The device tested may rectify this problem by increasing the effective length of the PD catheter and preventing elastic recoil out of the dependent portion of the pelvis.

One of the problems with the SLPDC is the large diameter of the tungsten terminus. This precludes percutaneous insertion and causes the entrance channel into the peritoneal space to be quite patulous, which increases the rate of dialysate leakage.[17] Other authors have reported additional complications with the SLPDC, including difficulty in removing it and pain.[18, 19] In contrast, the device evaluated is low profile and will not increase the size of the insertion channel into the peritoneal space when placed percutaneously. In addition, it can also be placed laparoscopically and surgically.

Cadavers were chosen to test the device with respect to feasibility of percutaneous insertion and retrieval, ability to stabilize within the retrovesical space following a provocative saline infusion into the peritoneal space and a 360-degree roll, and saline infusion and drainage rates of devices attached to two commercially available PD catheters. All test results were generally favorable, as all devices were successfully inserted through an 18-French peel-away sheath and retrieved. The device and PD catheter combinations remained in place within the retrovesical space at all times. They also exhibited acceptable infusion and drainage rates, which is a rate greater than 1L in within 10 minutes (100 cc/min) and 1L out within 12 minutes (83 cc/min), in 10 different device and PD catheter combinations and 42 out of 44 infusions or drainages. Human cadavers are the best in vitro model for testing this device, as they simulate the supine position of most patients undergoing PD. Four legged live animals are not ideal as a long-term test model, since they generally ambulate and sleep in the prone position. This weighted device

would tend to gravitate into a dependent position in most animals, which would place the PD catheter between bowel loops and omentum. Silastic tubing is already known to be biocompatible in humans, so a toxicology analysis in live animals would seem to be superfluous. Despite the inherent rigor mortis and unprepared bowel of the non-embalmed cadavers, acceptable flow rates were still observed.

This study shows that there was a minimal amount of tungsten that leaked out of the test devices made with medical grade silastic tubing. These test devices relied on a water-tight seal created with stainless steel balls and Prolene sutures. The minimal tungsten leak could be further reduced by incorporating the device into a PD catheter, so that the tungsten balls are completely encased by silicone during the fabrication process. In addition, some of the small amount of tungsten that might potentially leak out of this device in clinical use will be drained out of the peritoneal space during dialysate exchanges, in vivo. Tungsten is ubiquitous in the environment and has not been associated with toxic effects in humans. In the general population, tungsten blood and urine levels have been measured between 1 to 6 µg/L and 0.085 µg/L, respectively.[20] These “normal” blood levels of tungsten are generally much higher than the concentration of tungsten in the saline baths resulting from the minimal leak observed with test devices up to nine months, and similar to the concentrations in the saline baths observed at 21 months. U.S. Environmental Protection Agency does not require measurement of tungsten in surface water or groundwater, but tungsten levels have been measured up to 337 µg/L in well water.(20) No carcinogenic effect of tungsten in humans has been found.[21]

Limitations of this study are primarily related to the limited resources available in conducting the evaluation. Regarding the measurement of tungsten leak, variable time points were used for metal analysis up to 21 months, depending on funds available to perform the analyses. Likewise, only 10 different device and catheter combinations were evaluated in cadavers, as procedure room time, available test cadavers, and ancillary staff were restricted. Ideally, a larger number of cadavers, using a greater number of device and catheter combinations, with a randomized and controlled evaluation among commercially available PD catheter and device combinations could yield more meaningful results.

Conclusions

In summary, this novel and innovative device has the potential of improving function and durability of existing PD catheters as a modification or it can be fabricated into a new PD catheter design. This device works by anchoring the PD catheter into the retrovesical space through gravitational forces and interpolation, while increasing its effective length. This study has shown that this device is amenable to percutaneous insertion and retrieval and retains acceptable stability and flow rates in cadavers. Tungsten leak from this device is minimal and appears lower than the “normal” tungsten blood levels in humans. This device has the potential to benefit ESRD patients on PD. Further investigation in humans with a fabricated one-piece prototype is warranted.

References

1. United States Renal Data System. 2016 USRDS Annual Data Report | Volume 2 – ESRD in the United States. 2016 National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases. Available from: <https://www.usrds.org/2016/view/Default.aspx>. Accessed 4 Jun 2020.
2. United States Renal Data System. 2019 USRDS Annual Data Report: Epidemiology of kidney disease in the United States. 2019 National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases. Available from <https://www.usrds.org/2019/view/Default.aspx>. Accessed 4 Jun 2020.
3. Hansson, JH, Watnick S. Update on Peritoneal Dialysis: Core Curriculum. *Am J Kidney Dis*. 2016;67:151-64.
4. Crabtree JH, Shrestha BM, Chow K-M, Figueiredo AE, Povlsen JV, Wilkie M, et al. Creating and maintaining optimal peritoneal dialysis access in the adult patient: Update. *Perit Dial Int*. 2019;39:414-46.
5. Gokal R, Alexander S, Ash S, Chen TW, Danielson A, Holmes C, et al. Peritoneal catheters and exit-site practices toward optimum peritoneal access: 1998 update. *Perit Dial Int*. 1998;18:11-33.
6. Eklund B. Surgical implantation of capd catheters: Presentation of midline incision-lateral placement method and a review of 110 procedures. *Nephrol Dial Transplant*. 1995;10:386-90.
7. Chen WM, Cheng CL. A simple method to prevent peritoneal dialysis catheter tip migration. *Perit Dial Int*. 2007;27:557-9.
8. Bay WH, Cerilli GJ, Perrine V, Powell S, Erlich L. Analysis of a new technique to stabilize the chronic peritoneal dialysis catheter. *Am J Kidney Dis*. 1983;3:133-5.
9. Di Paolo N, Capotondo L, Brardi S, Nicolai G. The self-locating peritoneal catheter: Fifteen years of experience. *Perit Dial Int*. 2010;30:504-505.
10. Di Paolo N, Petrini G, Garosi G, Buoncristiani U, Brardi S, Monaci G. A new self-locating peritoneal catheter. *Perit Dial Int*. 1996;16:623-7.
11. Cavagna R, Tessarin C, Tarroni G, Casol D, De Silvestro L, Fabbian F. The self-locating catheter: Clinical evaluation and comparison with the Tenckhoff catheter. *Perit Dial Int*. 1999;19:540-3.
12. Bergamin B, Senn O, Corsenca A, Dutkowski P, Weber M, Wüthrick RP, et al. Finding the right position: A three-year, single-center experience with the “self-locating” catheter. *Perit Dial Int*. 2010;30:519-23.
13. Minguela I, Lanuza M, Ruiz de Gauna R, Rodado R, Alegría S, Andreu AJ, et al. Lower malfunction rate with self-locating catheters. *Perit Dial Int*. 2001;21Suppl3:S209-12.
14. Lanuza M, Minguela JI, Rodado R, Muriel J, Ruiz-De-Gauna R. Our nine-year experience with the self-locating catheter: Comparison of malfunction rate with other Tenckhoff catheter variants. *Int J Artif Organs*. 2006;29:138-141.
15. Al-Hwiesh AK. A modified peritoneal dialysis catheter with a new technique: Farewell to catheter migration. *Saudi J Kidney Dis Transpl*. 2016;27:281-9.
16. Shrestha BM, Shrestha D, Kumar A, Shrestha A, Boyes SA, Wilkie ME. Advanced laparoscopic peritoneal dialysis catheter insertion: systematic review and meta-analysis. *Perit Dial Int*.

2018;38:163-71.

17. Segura FC, Espejo JLM, Castilla ACG, Guerrero MÁO. Our experience with the self-locating catheter compared to other variants of the tenckhoff catheter. Multicentre study. *Enferm Nefrol*. 2013;15:283-9.
18. Russo R, Conte M, Corciulo R. Difficulties in removing the self-locating peritoneal catheter. *Perit Dial Int*. 2011;31:500-2.
19. Moreiras-Plaza M, Martin-Baez IM, Blanco-Garcia R, Beato-Coo LV, Cossio-Aranibar CR. New peritoneal catheters: New catheter problems? *Perit Dial Int*. 2014;34:556-61.
20. ToxGuide™ for tungsten. Agency for Toxic Substances and Disease Registry. 2020. Available from: <https://www.atsdr.cdc.gov/toxguides/toxguide-186.pdf>. Accessed 4 Jun 2020.
21. Environmental Protection Agency Federal Facilities Restoration U, Office R. Technical Fact Sheet – Tungsten. 2017. Available from: https://www.epa.gov/sites/production/files/2017-10/documents/ffrro_ecfactsheet_tungsten_9-15-17_508.pdf. Accessed 4 Jun 2020.

Declarations

Ethics approval and consent to participate

The University of Vermont Research Protections Office determined that this project was exempt from review by the Institutional Review Board. All methods and experiments were carried out accordance with relevant guidelines and regulations (Declaration of Helsinki). The University of Vermont and the University of Vermont Medical Center protocols governing the use of cadavers in research were followed in all cases. The first three cadavers came from the University of Vermont Anatomy Department, through the Anatomical Gift Program. This program has a robust registration process, which includes the consent of the live donor to comply with their wishes to allow the University of Vermont to use their body for teaching and research, including the development of new and innovative techniques and devices. The Anatomical Gift Program maintains a file of these signed consent and registration documents. The fourth cadaver was procured through the University of Vermont Medical Center Department of Pathology, after obtaining written consent from the next of kin prior to expiration, in keeping with the patient's wishes. This consent form is on record at the University of Vermont Medical Center.

Consent for publication

Not applicable

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing Interests

CSM declares a patent application (patent pending) on the device of interest described in this manuscript. No other author reports a conflict of interest.

Funding

A University of Vermont Medical Center Foundation Grant provided funding for data collection and analysis.

Author Contributions

CSM designed the study, collected and analyzed data, and wrote the manuscript. GPJ assisted in data collection and reviewed the manuscript. MJD performed the statistical analysis, assisted in writing the manuscript, and reviewed the manuscript. ARB assisted in the design of the study, data analysis, and reviewed the manuscript.

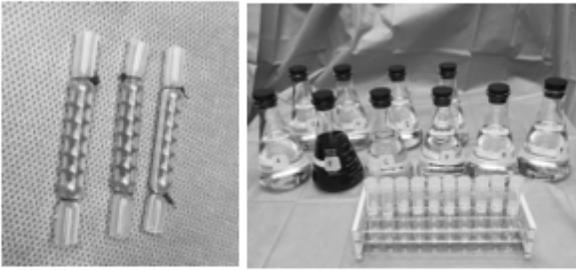
Acknowledgements

The authors gratefully acknowledge grant support from the University of Vermont Medical Center Foundation, technical support from the College of Engineering and Mathematical Sciences at the University of Vermont, and the generosity of the cadaver donors.

Tables

Please see the supplementary files section to view the tables.

Figures

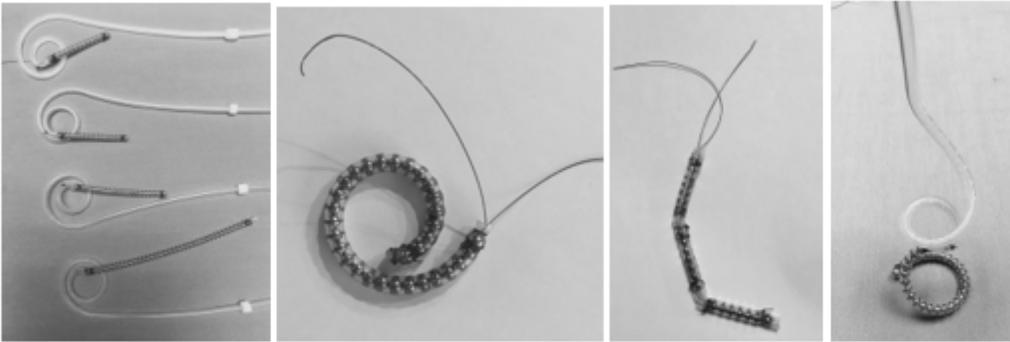


A.

B.

Figure 1

Devices and flasks tested for leak. A: Test devices; B: Test devices in flasks with normal saline and methylene blue control



A.

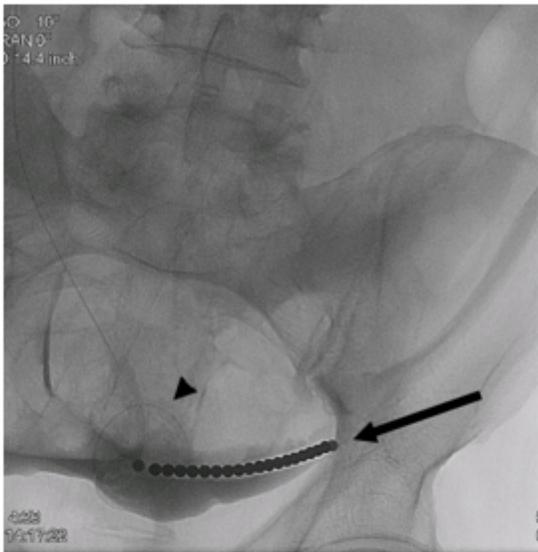
B.

C.

D.

Figure 2

Spectrum of devices tested in cadavers. A: Straight devices attached to coiled catheters; B: Curled device; C: Segmented device; D: Suspended curled device attached to coiled catheter and suspended in air, showing increase in effective length of coiled PD catheter.



A.

Figure 3

Imaging of device placed in cadaver 1. A: A-P radiograph of 8 cm straight device (arrow) and attached coil of PD cath (arrowhead) within retrovesical space post roll.



A.



B.

Figure 4

Imaging of device placed in cadaver 2. A: A-P radiograph of 8 cm device within retrovesical space prior to roll. B: Cone beam axial CT scan showing artifact created by 8 cm device and dense contrast media in retrovesical space (arrow) prior to roll.

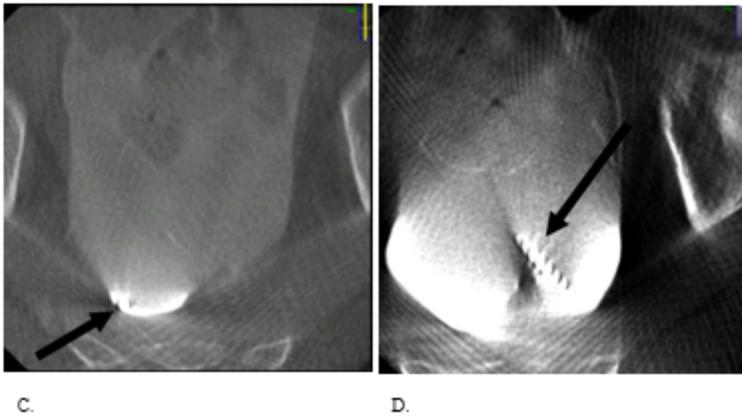
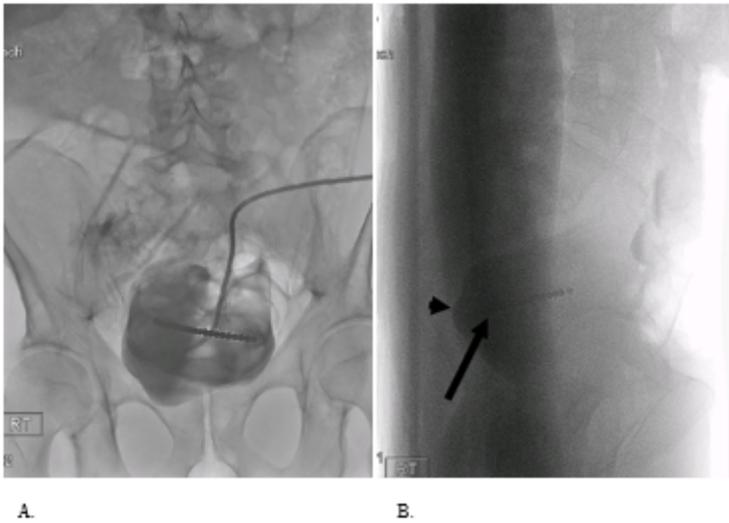


Figure 5

Imaging of device placed in cadaver 3. A: A-P radiograph of 8 cm device in rectovesical space pre roll. B: Lateral radiograph of 8 cm device (arrow) in rectovesical space (arrow head) post roll. C: Cone beam axial CT showing device (arrow) in rectovesical space pre roll. D: Cone beam axial CT showing device (arrow) in rectovesical space post roll.

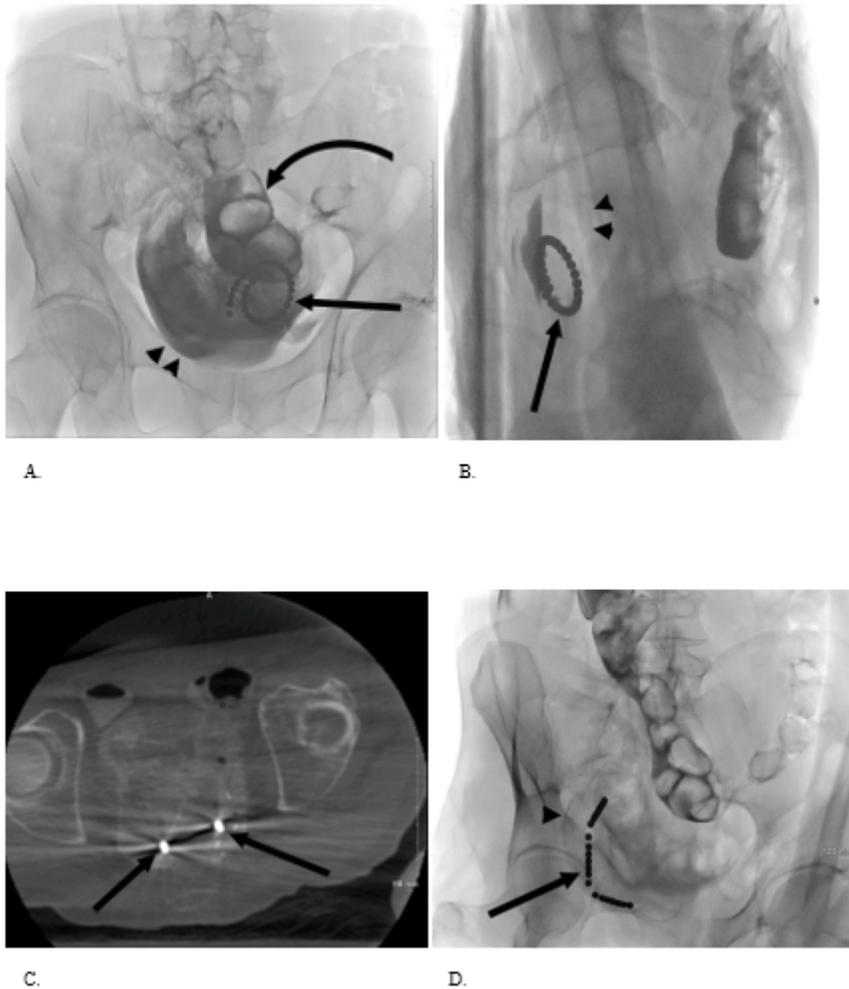


Figure 6

Imaging of device placed in cadaver 4. A: A-P radiograph demonstrating rectovesical space (arrowheads), coiled device in rectovesical space (arrow) and contrast media in sigmoid colon (curved arrow) pre roll. B: Lateral radiograph shows coiled device in posterior rectovesical space (arrow) attached to the PD catheter (arrowheads) pre roll. C: Cone beam axial CT shows coiled device (arrows) in rectovesical space post roll. D: Oblique radiograph depicting segmented device (arrow) in posterior rectovesical space (arrowhead) post roll.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [Tables.docx](#)