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Mechanical Limitations of Balloon Retention in Indwelling Urethral Catheters and Alternative Retention Designs: A Narrative Review

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Abstract

The balloon-retained (Foley) catheter was first described in 1937 and remains the standard device for indwelling urethral catheterisation. Research on catheter design has mainly concentrated on catheter-associated urinary tract infection (CAUTI), although non-infectious complications are reported more frequently by patients. This narrative review examines complications attributable to the mechanics of balloon retention and evaluates alternative retention designs. PubMed/PubMed Central, the Cochrane Library, guideline repositories, ClinicalTrials.gov, the International Standard Randomised Controlled Trial Number (ISRCTN) registry and the reference lists of included articles were searched using combinations of terms for urinary catheters and their mechanical complications and design, with the search updated on November 16, 2026. Original clinical studies were prioritised, and animal, ex vivo, in vitro and computational studies were included where they addressed a specific mechanism.

Unplanned intraurethral balloon inflation is the best-characterised balloon-specific injury: in a multi-institutional study, a pressure-relief safety valve activated during 22 of 994 catheterisations. Meatal pressure injury affected 9% of 200 adults with long-term urethral catheters. Ex vivo and porcine studies show that conventional drainage eyelets generate negative-pressure peaks that injure the urothelium and reported residual urine volumes during drainage vary widely between studies. Removal can also be complicated by deflation cuffing and balloon non-deflation. Alternative designs include low-profile and protected-tip balloon catheters, a dual-balloon catheter and a non-balloon catheter with deployable wings. However, the evidence for these designs is limited to animal studies, one randomised trial (n=80), one first-in-human study (n=15), one conference abstract and one feasibility study (n=50). None has shown superiority over the Foley catheter in an adequately powered comparative trial. We therefore propose six domains for the comparative evaluation of retention systems: retention, tissue safety, drainage, patient experience, removal and implementation.

Categories: Urology
Keywords: balloon anchoring, bladder drainage, catheter-associated urinary tract infection, catheter design, foley catheter, indwelling urinary catheter, mechanical injury, non-pneumatic retention

Introduction And Background

Foley described a self-retaining balloon catheter for continuous bladder drainage in 1937 [1], and the balloon-retained design remains the standard indwelling urethral catheter. Indwelling catheters are used widely: in National Health Service (NHS) Safety Thermometer data from England comprising 9,266,284 patient observations between 2012 and 2016, a urinary catheter was present in 12.9% of observations overall, 18.6% of observations in hospital and 76.6% of observations in critical care [2].

In a balloon-retained catheter, a separate inflation channel runs along the shaft to a balloon mounted close to the catheter tip. Once the catheter has been advanced into the bladder, the balloon is filled with fluid and rests against the bladder neck, preventing withdrawal [1,3]. Because the balloon is fixed close to the tip, its position also determines where the tip and drainage eyelets lie within the bladder [3,4]. This arrangement creates several points at which mechanical complications can arise. Inflation before the balloon has reached the bladder can injure the urethra [5,6]; traction on the catheter is resisted by the balloon at the bladder neck and transmitted to the urethra and meatus [7,8]; the tip and eyelets are in contact with the urothelium [9,10]; drainage depends on the position of the eyelets and on the configuration of the drainage tubing [11,12]; and removal depends on complete balloon deflation [13].

Complications of indwelling catheters are frequent and are not predominantly infective [14,15]. In a prospective multicentre cohort of 2,076 adults with an indwelling urethral catheter, 57% reported at least one complication within 30 days; non-infectious complications were reported by 55% and infectious complications by 11% [14]. Prospective surveillance of inpatients with indwelling catheters at a single centre found genitourinary trauma to occur at a frequency comparable to that of catheter-associated infection [15].

Most modifications to the Foley catheter leave the retention mechanism unchanged. In the largest randomised trial of antimicrobial urethral catheters, which included 7,102 adults, symptomatic CAUTI occurred in 12.6% of patients with a standard polytetrafluoroethylene-coated catheter, 12.5% with a silver alloy-coated catheter and 10.6% with a nitrofural-impregnated catheter, and routine use of antimicrobial catheters was not supported [16]. Pressure-relief valves and securement devices reduce specific deployment and traction injuries but do not alter the position of the tip and eyelets in the bladder or the dependence of removal on balloon deflation [17,18]. Complications that arise from these features can be addressed only by changing the retention design itself, and several alternative designs have been developed and tested [19-23]. This review therefore examines which complications arise from the mechanics of balloon retention and what evidence supports catheter designs that modify or replace the retention balloon.

Review

Methods: literature search and study selection

This is a narrative review; it was not designed or reported as a systematic review, and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 statement was therefore not applied. Targeted searches were performed in PubMed/PubMed Central, the Cochrane Library, guideline repositories, ClinicalTrials.gov and the International Standard Randomised Controlled Trial Number (ISRCTN) registry, and the reference lists of included articles and of relevant reviews and guidelines were screened for additional original studies. The searches combined terms for the device (urinary catheter, Foley catheter, indwelling urethral catheter) with terms for mechanical complications and design (non-infectious complication, mechanical injury, mucosal injury, pressure injury, meatal injury, catheter traction, balloon injury, balloon deflation, drainage eyelet, mucosal suction, residual urine, hydrodynamics, encrustation, biofilm, securement and catheter redesign). The searches were performed over several months during 2026 and were updated on November 16, 2026 to identify studies published since the initial searches.

Inclusion criteria were as follows: (1) original studies of any design, including clinical studies, case reports, and animal, ex vivo, in vitro and computational studies; (2) studies reporting on a mechanical aspect of balloon retention, contact between the catheter tip or eyelets and the urothelium, drainage, securement or removal of indwelling urethral catheters, or on a catheter with an alternative retention design; (3) studies of intermittent catheters only where they addressed the interaction between drainage eyelets and the urothelium; (4) trial registrations of ongoing or unpublished trials of alternative retention designs; and (5) publication in English. Evidence from adults with indwelling urethral catheters was prioritised. Exclusion criteria were as follows: (1) review articles, editorials, guidelines and consensus statements, although their reference lists were used to identify original studies; (2) manufacturer material without original data; (3) studies reporting infection outcomes without a mechanical design variable; and (4) studies limited to children. Both authors (PC and HU) screened the search results and assessed potentially relevant full texts against these criteria, with disagreements resolved by discussion. Because the searches were targeted rather than systematic, the numbers of records screened at each stage were not recorded. In total, 31 studies and two trial registrations were included; these comprise studies meeting the criteria above together with two studies cited as background, on the prevalence of urinary catheter use and on antimicrobial catheter coatings. Of the 31 studies, 21 were clinical (four randomised controlled trials, 15 observational, single-arm or non-randomised studies and two case reports), nine were laboratory, animal or computational studies (three ex vivo or cadaveric, three in vitro or bench, two animal and one computational), and one was the original description of the balloon catheter.

For each included study, the design, population or model, sample size, comparator and principal findings were extracted by both authors (PC and HU), and discrepancies were resolved by discussion. Because the included studies ranged from randomised trials to computational models, no single risk-of-bias tool could be applied across them. Instead, each study of mechanical complications or alternative retention designs was classified by design and its principal methodological limitation was recorded (Table *1*), and mechanistic evidence from laboratory and animal studies was distinguished from comparative clinical evidence throughout the review. No pooled analysis was performed because the studies differed in design, population and outcome; quantitative results are reported as given in the original studies, with sample sizes and measures of variance where these were reported.

Study	Design	Population or model	Principal finding	Principal limitation
Complications related to the balloon				
Davis et al. (2015) [5]	Ex vivo and cadaveric experimental study	Porcine urethras; human cadavers	Urethral rupture above 40% strain and 150 kPa; intraurethral inflation pressure 452±188 kPa	No clinical outcomes
Lawton et al. (2024) [6]	Retrospective analysis of prospectively collected data	98 traumatic catheterisation events at one centre	5.3 events per 1,000 catheters; urethral balloon inflation in 20%	Single centre; urology consultations only

Davis et al. (2018) [24]	Prospective single-arm study	100 men undergoing catheterisation	Valve activated in 7 cases of intraurethral balloon position	No comparator group
O'Connor et al. (2023) [17]	Prospective multi-institutional study	994 catheterisations	Venting in 22 cases without injury; 5.5 injuries per 1,000 catheterisations without valve	Injury rate from a separate period; not randomised
Munien et al. (2024) [8]	Cross-sectional study	200 adults with long-term urethral catheters	Meatal pressure injury in 9%	Association only; no longitudinal follow-up
Shenhar et al. (2020) [25]	Observational study	168 hospitalised men	Meatal pressure injury in 36%	Hospitalised men only
Subramanian et al. (2022) [26]	Case report	One patient with spinal cord injury	Nephrogenic metaplasia at site of balloon pressure	Single case; contributing fibroid
Parkin et al. (2002) [13]	Clinical audit and in vitro study	154 patients; 12 catheters in vitro	Removal problems in 14%; cuffing in 10 of 12 catheters	Audit based on patient report
Okorie et al. (2015) [27]	Prospective catheterisation record	337 catheterisations in 109 patients	Non-deflation in 5 of 21 catheters of one brand	Single brand implicated; small numbers
Complications related to catheter geometry				
Willumsen et al. (2024) [9]	Ex vivo experimental study	Porcine bladders; intermittent catheters	Suction peaks -806.8 vs -192.4 mbar; less urothelial damage with micro-holes	Ex vivo; intermittent catheters; manufacturer-affiliated authors
Stærk et al. (2024) [10]	Randomised animal study	9 pigs; 20 drainage cycles	Mucosal trauma with eyelets; none significant with micro-holes	Small sample; intermittent catheters; manufacturer-affiliated authors
Schrøder et al. (2024) [28]	Ex vivo experimental study	Porcine lower urinary tracts; intermittent catheters	Residual 38.1 vs 3.6 mL; suction in 12/15 vs 0/15	Manufacturer-funded; no histology
Miakhil et al. (2025) [29]	Case report	One 79-year-old man	Posterior bladder wall erosion with coudé-tip catheter	Single case; duration not reported
Ionescu et al. (2021) [30]	In vitro study	Bladder model; five bacterial species	Residual 0.20 vs 5.60 mL; reduced biofilm	In vitro only
Complications related to the drainage configuration				
Avulova et al. (2015) [11]	Imaging study	167 catheterised adults	Mean residual 13.2 mL; 2.4% ≥50 mL	Observational; single imaging measurement
Garcia et al. (2007) [12]	Ultrasound and bench study	150 inpatients; bench model	Mean residual 96 and 136 mL; tubing loops raise obstruction pressure	Observational measurements
Complications related to securement				
Calpe-Damians et al. (2024) [18]	Randomised controlled trial	350 intensive care patients	Lower CAUTI and meatal injury with securement; skin injury 7.1%	Intensive care setting only
Zhu et al. (2026) [31]	Randomised controlled trial	208 men after transurethral prostate resection	Meatal injury 8.6% with thigh taping vs 1.0% without	Single centre; short-term catheterisation
Alternative retention designs				
Greenberg et al. (2017) [19]	Animal study	Ovine model, 96 hours	Less ulceration and inflammation with low-profile catheter	Animal model; short duration
Ramezani et al. (2023)	Randomised controlled trial	80 comatose intensive care	Less haematuria and leukocytosis with low-profile catheter	Small sample; selected population

[20]		patients		
Drake et al. (2023) [21]	Preclinical and first-in-human study	15 patients	Device failures including spontaneous deflation and failed inflation	No comparator; small sample
Beilan et al. (2016) [22]	Non-randomised comparative study	385 neuroscience intensive care patients	CAUTI 1.1 vs 5.5 per 1,000 catheter-days	Conference abstract; seven events
Lockhart et al. (2017) [23]	Prospective feasibility study	50 patients	Residual 4.8 mL; dislodgement in 4%	No comparator; short durations

TABLE 1: Table 1: Design, principal finding and principal limitation of the studies of mechanical complications and alternative retention designs

CAUTI: catheter-associated urinary tract infection.

Complications related to the balloon

Intra-urethral Balloon Inflation

Inflation of the balloon before it has entered the bladder distends the urethra [5]. In ex vivo porcine bulbar urethras catheterised with 16 French (Fr) catheters, urethral rupture occurred consistently when internal diametric strain exceeded 40% and inflation pressure exceeded 150 kPa [5]. In a human cadaveric model, intraurethral inflation with a standard syringe generated a mean maximum pressure of 452±188 kPa, whereas a prototype safety syringe vented at a mean threshold of 153±3 kPa [5]. In clinical practice, a single-centre analysis of a prospectively collected urology consultation database identified 98 traumatic catheterisation events over 30 months, an incidence of 5.3 per 1,000 catheters placed; urethral balloon inflation was documented in 20 (20%) of these events, and treatment of the resulting complications required 52 additional hospital days [6].

A pressure-relief safety valve based on this threshold has been evaluated clinically [17,24]. In a prospective study of 100 men, the valve activated in seven cases (7%) in which the balloon was positioned in the urethra, and in each case the catheter was subsequently advanced and inflated in the bladder [24]. In a prospective multi-institutional study, the valve vented during 22 of 994 urethral catheterisations (2.2%) with no urethral injury in those episodes; during a three-month embedded period, 18 balloon inflation injuries occurred in catheterisations performed without the valve, corresponding to 5.5 injuries per 1,000 catheterisations [17].

Retention Force, Traction and Balloon Contact

Retention force depends on balloon volume: in an experimental study, the force required to extract a catheter increased as the balloon fill volume increased [7]. Traction applied to the catheter is therefore resisted at the bladder neck and transmitted along the urethra to the meatus. In a cross-sectional study of 200 adults with long-term urethral catheters, catheter-associated meatal pressure injury was present in 18 patients (9%) [8], and in a study of 168 hospitalised men with indwelling catheters, 36% developed meatal pressure injury [25]. Prolonged pressure from the balloon itself can also affect the bladder wall: one case report described nephrogenic metaplasia at a site where a uterine fibroid had pressed the catheter balloon against the bladder wall for more than seven years [26].

Balloon Deflation and Catheter Removal

Removal requires complete balloon deflation, and deflation can be incomplete or fail [13,27]. In a clinical audit of 154 patients with long-term catheters, 22 (14%) reported removal problems in the preceding year, and these were associated disproportionately with all-silicone and suprapubic catheters [13]. In the same study, 10 of 12 Foley catheters formed a cuff on deflation after six weeks of incubation at 37°C, and all-silicone catheters required retention forces up to 200% greater than their friction force during withdrawal through a simulated tract [13]. In a prospective record of 337 catheterisations in 109 patients, five of 21 catheters (24%) of one brand failed to deflate, and the problem resolved when that brand was withdrawn [27].

Complications related to catheter geometry

As the bladder empties, urothelium can be drawn into drainage eyelets by negative pressure [9,10]. In an ex vivo porcine bladder model, mean negative-pressure peaks were -806.8 mbar with conventional-eyelet catheters and -192.4 mbar with a micro-hole catheter, and histology showed urothelial damage with

conventional eyelets but only thinning and small breaches with the micro-hole design [9]. In a porcine study in which nine animals were randomised to conventional-eyelet or micro-hole catheters for 20 drainage cycles, conventional eyelets produced suction events with epithelial loss, oedema, haemorrhage and neutrophil infiltration, whereas no significant trauma was found with the micro-hole design [10]. In an ex vivo porcine lower urinary tract model, residual urine at first flow-stop was 38.1±26.7 mL with a conventional-eyelet catheter and 3.6±3.9 mL with a micro-hole catheter, and suction events occurred in 12 of 15 catheterisations with conventional eyelets and in none with the micro-hole design [28]. All three studies used intermittent catheters and included authors employed by the manufacturer of the micro-hole catheter, and their findings have not been tested in continuously draining Foley catheters [9,10,28]. Clinically, bladder wall erosion has been reported after prolonged use of a coudé-tip urethral catheter, found incidentally on the posterior bladder wall at cystoscopy [29].

Catheter geometry may also affect drainage [30]. In an in vitro bladder model, a modified catheter design reduced residual fluid from 5.60±0.43 mL with a Foley catheter to 0.20±0.03 mL and reduced biofilm formation by five bacterial species [30].

Complications related to the drainage configuration

Studies of residual urine during catheter drainage report divergent results [11,12]. In a computed tomography study of 167 catheterised adults, mean residual volume was 13.2 mL and only four patients (2.4%) had 50 mL or more [11]. In contrast, a bladder ultrasound study of 75 patients in an intensive care unit and 75 on hospital wards found mean residual volumes of 96 mL (range 4-290 mL) and 136 mL (range 22-647 mL), respectively; in a bench model from the same study, each centimetre of dependent loop height in the drainage tubing increased obstruction pressure in the artificial bladder by 1 cmH_2O [12]. Residual volume is therefore influenced by the configuration of the drainage tubing [12]. Residual urine and low-flow regions are relevant because urease-producing *Proteus mirabilis* forms crystalline biofilm that encrusts and obstructs catheters [32].

Complications related to securement

Securement is intended to reduce catheter movement, but its effect depends on the method and setting [18,31]. In a randomised trial of 350 patients in two intensive care units, a securement device was associated with lower risks of CAUTI and meatal pressure injury, and skin-related injury occurred in 7.1% of patients [18]. In contrast, in a randomised trial of 208 men after transurethral resection of the prostate, taping the catheter to the thigh was associated with more meatal pressure injury than no external fixation (8.6% versus 1.0%; P=0.010), with no difference in CAUTI and no unplanned catheter removal in either group [31].

Alternative retention designs

Low-Profile and Drainage-Focused Balloon Catheters

Low-profile designs reduce the length of catheter that protrudes beyond the balloon [19,20]. In an ovine model, a low-profile catheter produced less bladder-surface ulceration and inflammation than a Foley catheter after 96 hours [19]. In a randomised trial of 80 comatose intensive care patients, a low-profile catheter was associated with fewer cases of haematuria and leukocytosis than a Foley catheter, and the difference in elevated urinary colony counts (5% versus 12.5%) was not significant after adjustment for antibiotic dose and fluid intake [20]. The Optitip catheter, which has a shortened open tip and an additional drainage port below the balloon, is being compared with a Foley catheter in the CaDeT randomised trial in community-dwelling adults with long-term catheters; the trial has closed to recruitment, and results have not been published [3].

Protected-Tip Balloon Catheters

In the FLUME catheter, the inflated balloon envelops the tip, and the drainage apertures are inset at the base of the balloon [21]. In preclinical testing, FLUME caused less trauma than a Foley catheter in a model of forced evulsion and took longer to block with *P. mirabilis* than a latex, but not a silicone, Foley catheter [21]. In a first-in-human study of 15 patients, one balloon failed to inflate, one patient could not be catheterised, one balloon deflated spontaneously on day 14, and three catheters were removed early because of clot, bypassing and difficulty connecting the drainage bag [21]. A study of patient-reported comfort has been registered (NCT05785858) but has not been reported [33].

Dual-Balloon Catheters

Dual-balloon catheters use a proximal balloon for retention and a distal balloon to cushion the tip, with the drainage eyelets between the two balloons [22]. In a non-randomised 11-month study in a neuroscience intensive care unit, reported only as a conference abstract, 162 patients with a dual-balloon catheter had one CAUTI in 870 catheter-days (1.1 per 1,000 catheter-days), compared with six CAUTIs in 1,090 catheter-days (5.5 per 1,000 catheter-days) among 223 patients with Foley catheters [22].

Non-balloon Retention

The Lotus catheter replaces the balloon with soft, Malecot-like wings deployed by a proximal mechanical actuator [23]. In a single-centre prospective study of 50 patients without a comparator group, mean post-void residual volume was 4.8 mL (range 0-76), median removal discomfort was two on a 10-point scale, no gross haematuria or urinary tract infection was reported, and two catheters (4%) were dislodged without deactivation [23].

Proposed framework for comparing retention systems

On the basis of the failure modes described above, we propose that retention systems be compared across six domains (Table *2*): retention and removal, reflecting extraction force [7], dislodgement [23] and deflation failure [13,27]; tissue safety, reflecting intraurethral inflation [5,17], meatal pressure injury [8] and eyelet suction [9,10]; drainage, reflecting residual urine and encrustation [11,12,32]; patient experience; and implementation, reflecting device-specific failures such as drainage-bag connection problems [21].

Domain	Core question	Objective measures	Patient-important outcomes
Retention	Does the device remain reliably positioned?	Pull-out force; migration; deployment reliability	Accidental displacement; emergency replacement
Tissue safety	Where and how is force applied?	Contact pressure; traction; tissue imaging	Pain; haematuria; urethral or meatal injury
Drainage	Does the geometry support emptying in use?	Residual volume; flow; suction events	Blockage; bypassing; unplanned change
Patient experience	Is the device tolerable and manageable?	Validated PROMs; sleep and activity measures	Comfort; urgency; spasm; acceptability
Removal	Can retention be predictably deactivated?	Deflation or collapse time; failure testing	Traumatic removal; urgent intervention
Implementation	Can the device fit existing pathways of care?	Training; connector compatibility; workload	Errors; adoption; cost-effectiveness

TABLE 2: Proposed domains for comparative evaluation of indwelling catheter retention systems

PROMs: patient-reported outcome measures.

Implications for practice and research

Several of the mechanical factors described above can be assessed in patients with recurrent catheter problems. Because meatal pressure injury was present in 9% of adults with long-term urethral catheters, the meatus should be examined at each catheter review [8,25]. Recurrent blockage should prompt assessment for encrustation [32], the drainage tubing should be checked for dependent loops [12], and difficulty with balloon deflation should be anticipated with all-silicone and suprapubic catheters [13].

For research, comparative trials should specify the Foley comparator by material, size, balloon volume, securement method and drainage system, because each of these variables has been associated with complications [7,12,13,18]. Trials should report displacement, blockage, bypassing, pain, unplanned catheter change and removal complications alongside CAUTI, because these were the principal failure modes in the device studies reviewed here [13,21,23]. Securement should be evaluated by method and clinical setting, because thigh taping increased meatal injury after prostate resection whereas a securement device reduced it in intensive care [18,31]. The eyelet-suction findings from intermittent catheters should be tested in continuously draining indwelling catheters [9,10,28], and studies of long-term use should include community catheter changes, because failures such as spontaneous deflation appeared only after days of use [21].

Limitations

This is a narrative review and is susceptible to selection bias. The searches were targeted rather than systematic, did not include Embase or Scopus, were limited to English-language publications and did not record the numbers of records screened, so relevant studies may have been missed. No formal risk-of-bias assessment was performed because no single tool applies to the range of study designs included; the principal limitation of each study of mechanical complications or alternative designs is instead summarised in Table *1*. Much of the mechanistic evidence comes from animal, ex vivo and in vitro studies [5,9,10,28,30],

and the clinical evidence for alternative designs comprises small, single-centre or non-randomised studies and one conference abstract [19-23], so the comparative effectiveness of these designs cannot be determined from the current evidence.

Conclusions

This review identified five mechanical complications associated with balloon retention: intraurethral inflation injury, traction-related meatal injury, eyelet-related urothelial suction, incomplete drainage and failure of deflation at removal. Intraurethral inflation injury is the most clearly defined of these and the only one for which a preventive device has been evaluated in clinical practice. Low-profile, protected-tip, dual-balloon and non-balloon designs address some of these mechanisms, but the evidence supporting them remains preliminary. Future comparative trials should evaluate retention, tissue safety, drainage, patient experience, removal and implementation together.

Additional Information

Author Contributions

All authors have reviewed the final version to be published and agreed to be accountable for all aspects of the work.

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Disclosures

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