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Influence of Coil Number on the Retention Strength of Ureteral Stents: An Experimental Investigation

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Abstract

Ureteral stents are temporary implantable devices used to maintain urinary drainage and prevent obstruction. Most designs incorporate terminal coils to reduce migration; however, the influence of coil number on retention strength remains unclear. This study investigated the effect of coil number on ureteral stent retention under controlled conditions. Five commercial stents representing short (2 months), medium (6 months), and long-term (12 months) use were evaluated, including 1 coil and 1.5 coil configurations. Specimens were immersed in artificial urine for one month and tested according to ASTM F1828-22 using a custom tensile device. Results showed that 1.5 coil stents exhibited substantially higher retention forces (0.061–0.065 N) compared to 1 coil stents (0.010–0.034 N), representing an approximately sixfold increase. Statistical analysis confirmed significant differences among stent types ($F = 72.76$, $p = 4.665 \times 10^{-19}$). These findings demonstrate that increasing coil number significantly enhances retention strength, highlighting coil configuration as a key design factor for reducing migration risk.

1 Introduction

The ureter is a narrow duct responsible for transporting urine from the renal pelvis to the urinary bladder and plays a critical role in maintaining urinary tract function [1]. Ureteral obstruction caused by urolithiasis, inflammation, infection, or postoperative edema may compromise renal function and require temporary drainage support [2]. Ureteral stents are widely used to maintain urinary patency. However, indwelling stents are associated with complications such as pain, lower urinary tract symptoms, hematuria, infection, encrustation, and migration, which may reduce patient quality of life [3–6].

From 1990 to 2019, the global incidence of urinary tract disorders increased by approximately 2.4-fold, indicating a growing demand for improved medical interventions and implantable devices [7]. Recent epidemiological analyses reinforce this trend The worldwide burden of urinary tract infections (UTIs) has continued to rise, with the global age-standardized incidence rate increasing from approximately 4,700 per 100,000 population in 1990 to over 5,200 per 100,000 in 2019, corresponding to an estimated 400 million cases worldwide in 2019, according to global health data [7, 8]. Among mechanical complications associated with ureteral stents, proximal or distal migration remains clinically relevant, as stent displacement may compromise urinary drainage and necessitate secondary endoscopic intervention for retrieval or replacement [3, 5, 9, 10]. Classical clinical series have linked stent migration to inappropriate stent length and incomplete formation of the renal or bladder coil, underscoring the importance of terminal retention geometry [9, 10]. More recent biomechanical modeling further demonstrates that both stent length and implantation position influence the forces resisting migration [11].

The Double-J (JJ) stent, characterized by coiled ends in the renal pelvis and bladder, relies on terminal pigtail geometry to provide anchoring while allowing atraumatic insertion and removal [3, 4, 12]. Despite

their utility, ureteral stents are associated with complications, particularly stent migration, which unintended dislodgement may necessitate premature removal or lead to further medical issues [5], [6], [7]. An optimal balance of retention is required: excessive pull-out forces may exacerbate ureteral irritation or cause discomfort during removal, whereas insufficient retention increases the risk of stent migration [3, 4, 13]. Experimental pullout studies have demonstrated that retention force depends on frictional conditions, material properties, and geometric design [11].

In vitro retention testing of ureteral stents is commonly performed using standardized axial pullout methods, where the stent is drawn through a constricted funnel block or simulated ureteral lumen. ASTM F1828-22 provides detailed guidelines for such assessments, including immersion protocols to replicate physiological conditions and test velocity to simulate clinical removal rates [14]. These tests enable reproducible quantification of mechanical stability, supporting comparative evaluation across stent designs and informing regulatory and design decisions. The standard also emphasizes that retention is strongly influenced by tribology, particularly dynamic friction, and therefore surface chemistry and material stiffness should be considered alongside coil geometry [14].

The retention performance of a ureteral stent is closely related to its geometric design. In JJ stents, pigtail coil length contributes to anchoring, and increasing the number of coils may improve retention by enlarging the contact area and frictional resistance against axial displacement. However, design modifications must balance anchoring strength with patient comfort and ease of retrieval. Therefore, coil number represents a critical design parameter in preventing migration [15]. Although various stent materials, coatings, and configurations have been developed [4, 16–18], quantitative evidence regarding the influence of terminal coil number on retention strength remains limited. Most existing studies have focused on surface coatings to reduce encrustation or enhance biocompatibility rather than on the mechanical contribution of coil geometry [19, 20].

JJ stents available on the market vary in both intended duration of use (ranging from 2 to 12 months) and in terminal coil configuration. However, the clinical implications of such variations remain unclear. This study aims to investigate the influence of coil numbers on ureteral stent retention strength under controlled laboratory conditions. This research seeks to provide evidence-based guidance for optimizing stent design and to determine the minimum observed pullout (retention) force across tested samples as a baseline minimum study force for JJ stent design through evaluating five commercially available stents with either 1 or 1.5 coils. The study provides evidence-based guidance for optimizing stent geometry and improving clinical outcomes through reduced risk of migration while maintaining ease of removal by establishing this relationship [7, 14, 21].

2 Materials and Method

2.1 Study design and testing standard

This study was designed as a laboratory experiment in accordance with the ASTM F1828-22 standard, which specifies procedures for testing the retention force of ureteral stents. All experiments were conducted in a controlled laboratory environment to simulate relevant human physiological conditions.

2.2 Ureteral stent specimens

The ureteral stent specimens used in this study were commercially available products widely used in Indonesia. A total of five stent types from two brands, ARK and Marflow, were selected. The specimens included ARK White, ARK Black Silicone, Marflow Standard, Marflow Longlife, and Marflow Longlife 180. Among these specimens, ARK White, ARK Black Silicone, and Marflow Standard had one coil, whereas Marflow Longlife and Marflow Longlife 180 had 1.5 coils. The variation in coil number served as the primary basis for comparing the retention force of the ureteral stents.

b) Marflow Longlife, c) Marflow Longlife 180, d) ARK Black Silicone, and e) ARK White.

2.3 Artificial urine immersion protocol

Prior to testing, all ureteral stent specimens were carefully inspected to ensure the absence of defects or damage that could influence the test results. Only specimens that met the inspection criteria were used in the subsequent experimental procedures.

After preparation, the ureteral stents were immersed in artificial urine media to simulate physiological conditions within the human body. The artificial urine was maintained at a temperature of 37°C ± 3°C and a pH range of 5.5–6.5, which corresponds to the typical pH of human urine. The immersion period lasted for one month. During this period, the urine medium was regularly inspected and replaced when necessary to prevent degradation or volume reduction, thereby ensuring consistent exposure conditions. This immersion step was intended to replicate in-use conditions of ureteral stents without requiring in vivo implantation. Under these conditions, changes in material properties and geometry, such as stiffening or alterations in lumen diameter, may occur due to interactions between the stent material and urine.

2.4 Retention test apparatus

The retention test setup is shown in Fig. 2. The stent was pulled through the funnel block by a motor. A load cell connected to the pulling rod measured the pulling force, which was then defined as the retention force of the ureteral stent. The testing device consisted of three subsystems (Fig. 2a):

- *The pulling mechanism (red path)*,
- *The recording system (green path)*,
- *The sensor reading system (blue path)*.

The retention force recorded by the sensor system represented the maximum force measured before the stent coil passed through the funnel block. To ensure accurate synchronization, the recording system was synchronized with the sensor system. The fully assembled retention test apparatus is depicted in

Fig. 2b. The device used a motor connected to a controller for consistent pulling. This motor was directly linked to a load cell mount via a cylindrical shaft, which followed the upward motion of the ureteral stent. The mount's position was also used to determine the motor's pulling speed, in compliance with ASTM F1828-22. The pulling speed was calculated by dividing the pulling distance by the time taken. The load cell was recalibrated for each specimen to minimize sensor reading errors using a comparison and deviation analysis method.

a) Testing scheme, and b) Retention test apparatus.

2.5 Pullout testing procedure

Following the immersion period, the ureteral stents were subjected to a retention (pullout) test using a funnel block device. The stents were pulled at a constant speed until they were completely dislodged from the funnel block. The pulling speed was set at 20 inches per minute (8.5 mm/s), in accordance with ASTM F1828-22.

The maximum force required to extract each stent was recorded as the retention force using a calibrated load cell. This test was designed to simulate forces acting on ureteral stents during clinical use and to evaluate their ability to maintain positional stability.

2.6 Data acquisition and retention force calculation

The collected data included the equivalent load (in grams) required to extract the ureteral stent during the testing process. These readings reflected the maximum retention force under simulated conditions. The highest force recorded during the pullout process was identified as the ureteral stent's retention force. This information provided a clear indication of the stent's effectiveness and stability in a human-like environment, and it was crucial for evaluating performance and reliability in clinical applications.

2.7 Statistical analysis

The test results, consisting of repeated measurements under different treatments, were statistically analyzed using Analysis of Variance (ANOVA) to determine the factors affecting retention force. The influence of these factors was indicated by the F-distribution values in each analysis. A significance level (α) of **0.05** was used to determine the critical F value as the threshold for rejecting or accepting the null hypothesis. In this study, ANOVA was performed for three comparison sets to evaluate the effect of coil number on retention force with all analyses conducted at 95% confidence level.

- *Across all stents regardless of brand*,
- *Between ARK and Marflow brands*,
- *among Marflow Stents (Standard vs. Longlife vs. Longlife 180).*

3 Results

3.1 Retention test process and data conversion

The pullout process was recorded and documented, as illustrated in Fig. 1, which captures the retention testing process. From this figure, the point at which the stent disengages from its coiled shape and the location of coil unravelling can be identified. The results of the pullout process were recorded by the retention test apparatus. The readings from this device are presented in force-weight equivalent units, measured in grams. These readings indicate the force experienced by the ureteral stent, which is equivalent to the force exerted by a mass under gravity (9.81 m/s²). To convert the instrument readings to force values in Newtons, each value was multiplied by a factor of 0.00981 N/gram. The final retention force measurements for each ureteral stent in Newtons are shown in Table 1 and Fig. 3.

3.2 Retention force by stent type

Table 1
Retention Force Measurements of Ureteral Stents

Retention Force (N)	Marflow Standard	Marflow Longlife	Marflow Longlife 180	ARK Black	ARK White
Rep 1	0.00980	0.07468	0.06860	0.03058	0.03175
Rep 2	0.00951	0.05302	0.07066	0.03087	0.02871
Rep 3	0.01049	0.05537	0.06958	0.03920	0.03156
Rep 4	0.01019	0.06654	0.05096	0.03254	0.03058
Rep 5	0.00980	0.05645	0.06341	0.03528	0.03156

Table 1 and Fig. 3 shows that the Marflow Longlife and Marflow Longlife 180 stents exhibited significantly higher retention forces compared to Marflow Standard, ARK Black, and ARK White. The primary difference between the Marflow Longlife series and the other stents is the increased coil number 1.5 coils versus 1 coil. Additionally, stents from the ARK brand demonstrated lower retention force values compared to Marflow. When compared to Marflow Longlife and Longlife 180, ARK stents showed approximately a two-fold reduction in retention force.

3.3 Analysis of variance (ANOVA) across stent types

The data processing began by calculating basic statistics: treatment means, overall mean, sum of squares, and variance for each group. These statistical values were then used to compute the ANOVA results for significance testing. A null hypothesis (H_0) was defined stating that there is no difference among the group means prior to conducting the ANOVA. The null hypothesis is accepted if the treatment F-value is less than the F-critical value. The alternative hypothesis (H_1) assumes that at least one group mean is different.

The ANOVA results are presented in Table 2, which shows that no significant variation was observed among repeated measurements, indicating that repeated trials (five replicates) for the same stent type

did not significantly alter the data. Thus, five replicates were used for each stent type in further analysis to improve the statistical accuracy of the results.

Table 2
Analysis of Variance for Ureteral Stent Types

Source of Variation	SS	df	MS	F	P-value	F critical
Repetition	8.48513E-5	4	2.12127E-5	0.59266	0.67292	3.00691
Among Stents	0.01041	4	0.00260	72.76394	4.66517E-10	3.00691
Error	0.00057	16	3.57921E-5			
Total	0.01101	24				

Table 2 presents the analysis of variance for the experimental data. The F-value for differences among stents is 72.76394, which exceeds the F-critical value of 3.00691 at $\alpha = 0.05$ (with appropriate degrees of freedom). Since the F-value is outside the F-critical range, the null hypothesis is rejected, indicating a statistically significant difference among the stent types. The P-value for the comparison among stents is 4.665×10^{-10}, while the P-value for the repetition factor is 0.67292, showing consistency in repeated measurements.

3.4 Effect of coil configuration in Marflow stents

From this analysis, a significant difference in retention force is observed among the stent types. However, this result alone does not conclusively attribute the difference to the coil number. To investigate further, a direct comparison was performed among stents of the same brand (Marflow) but with different coil configurations. Marflow was chosen for comparison because it includes both 1-coil (Marflow Standard) and 1.5-coil types (Marflow Longlife and Longlife 180). Additional factors such as stent diameter, length, and manufacturing consistency are assumed to be controlled within the same brand.

Table 3
Analysis of Variance – Marflow Standard vs Marflow Longlife

Source of Variation	SS	df	MS	F	P-value	F critical
Between Groups	0.00656	1	0.00656	157.18973	1.53408E-6	5.31765
Within Groups	0.00033	8	4.178E-5			
Total	0.00689	9				

Table 3 indicates a significant difference in retention force between Marflow Standard and Marflow Longlife. The null hypothesis is rejected because the F-value exceeds the critical threshold, confirming that the increased coil number significantly improves retention force by approximately 5 to 6 times.

Table 4
Analysis of Variance – Marflow Standard vs Marflow Longlife 180

Source of Variation	SS	df	MS	F	P-value	F critical
Between Groups	0.00747	1	0.00747	225.21482	3.83920E-7	5.31765
Within Groups	0.00026	8	3.31943E-5			
Total	0.00689	9				

Table 4 also confirms a significant difference between Marflow Standard and Marflow Longlife 180, with the F-value well above the critical limit. This confirms that increasing the coil number results in a 5 to 7-fold improvement in retention force. Figure 4 shows the comparison of retention force by the number of coil.

4 Discussion

4.1 Biomechanical interpretation of retention force

A biomechanical standpoint defines retention force as the maximum axial force required to dislodge the stent from its position within the ureter under controlled conditions. Retention force is primarily influenced by geometric parameters (coil diameter, pitch, and number of turns), material properties (stiffness, durometer, and elasticity), and environmental factors such as ureteral wall compliance and lubrication. Studies have shown that stents with higher stiffness and coil strength provide better anchoring performance but may reduce patient comfort [12]. Clinical studies also indicate that proximal coil configuration can affect patient-reported symptoms, underscoring the balance required between retention and comfort [22]. A greater number of coils typically increases the surface area in contact with the ureteral wall, thereby enhancing frictional resistance and improving anchoring. However, excessive coiling may introduce complications such as increased patient discomfort, difficult insertion, or trauma to the urothelium.

4.2 Clinical retention force thresholds for functional effectiveness and safe removal

self-retaining capability. The self-retaining mechanism must strike a balance between sufficient retention force and ease of removal. According to Sheth et al. (2020), the average pullout force for ureteral stents ranged from 3.9 N to 4.73 N in benchtop dry models and from 0.17 N to 0.85 N in porcine models with urine flow [13]. These values serve as reference limits for stent application. The retention force must exceed the intravesical pressures yet remain below the force required for stent removal, as shown in Fig. 5.

4.3 Biological safety thresholds for ureteral tissue

Additionally, stent retention force must account for biological safety thresholds. Prior research has shown that the maximum longitudinal stress tolerable by ureteral tissue is 3.48 ± 0.47 MPa, and the circumferential stress is 2.31 ± 0.46 MPa, with peristaltic pressure ranging between 1.5 to 5 kPa [21, 23]. Based on this, the maximum tolerable longitudinal force for a 3–4 mm ureter is estimated to be 5 to 43 N. Exceeding this threshold may cause tissue damage, defining the upper safety limit of retention force for ureteral stents.

Therefore, the optimal retention force should be:

- *above 0.17–0.85 N for functional effectiveness*,
- *below 3.9–4.73 N to allow safe removal*,
- *remain well under 5–43 N to prevent ureteral injury.*

The study demonstrates a significant difference in retention force among various types of ureteral stents. The test results indicate that Marflow stents exhibit notably distinct retention force values. The Marflow Standard stent recorded a retention force of 0.00996 N, while the Marflow Longlife stent showed a higher force of 0.06121 N. The Marflow Longlife 180 stent exhibited the highest retention force among the three, at 0.06464 N. In comparison, stents from the ARK brand showed lower retention forces, with ARK Black registered at 0.03369 N, and ARK White slightly lower at 0.03083 N.

The strength of stent retention can be expressed in pressure units ranging from 1.5 kPa to 3.48 MPa using these retention force measurements. This range illustrates the stent's capacity to maintain its position within the ureter under varying pressure conditions. The addition of coils on the ureteral stent significantly affects its retention force. The data show that increasing the number of coils can enhance the retention force by nearly six times, especially when increasing from 1 coil to 1.5 coils. This addition demonstrates a significant effect on improving retention performance, with the 1.5-coil design, as seen in the Marflow Longlife and Longlife 180 stents, proving to be effective. This indicates that a higher number of coils can enhance the stent's ability to stay in place, reduce the risk of migration, and ensure clinical effectiveness.

Declarations

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Conflict of interest the authors declare that they have no conflict of interest.

Ethical approval This article does not involve any studies with human participants conducted by the authors.

Consent for publication Not applicable. This manuscript does not contain any individual person's data in any form (including individual details, images, or videos).

Availability of data and materials Not applicable. This study does not involve any datasets that require public access or repository submission.

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Figures

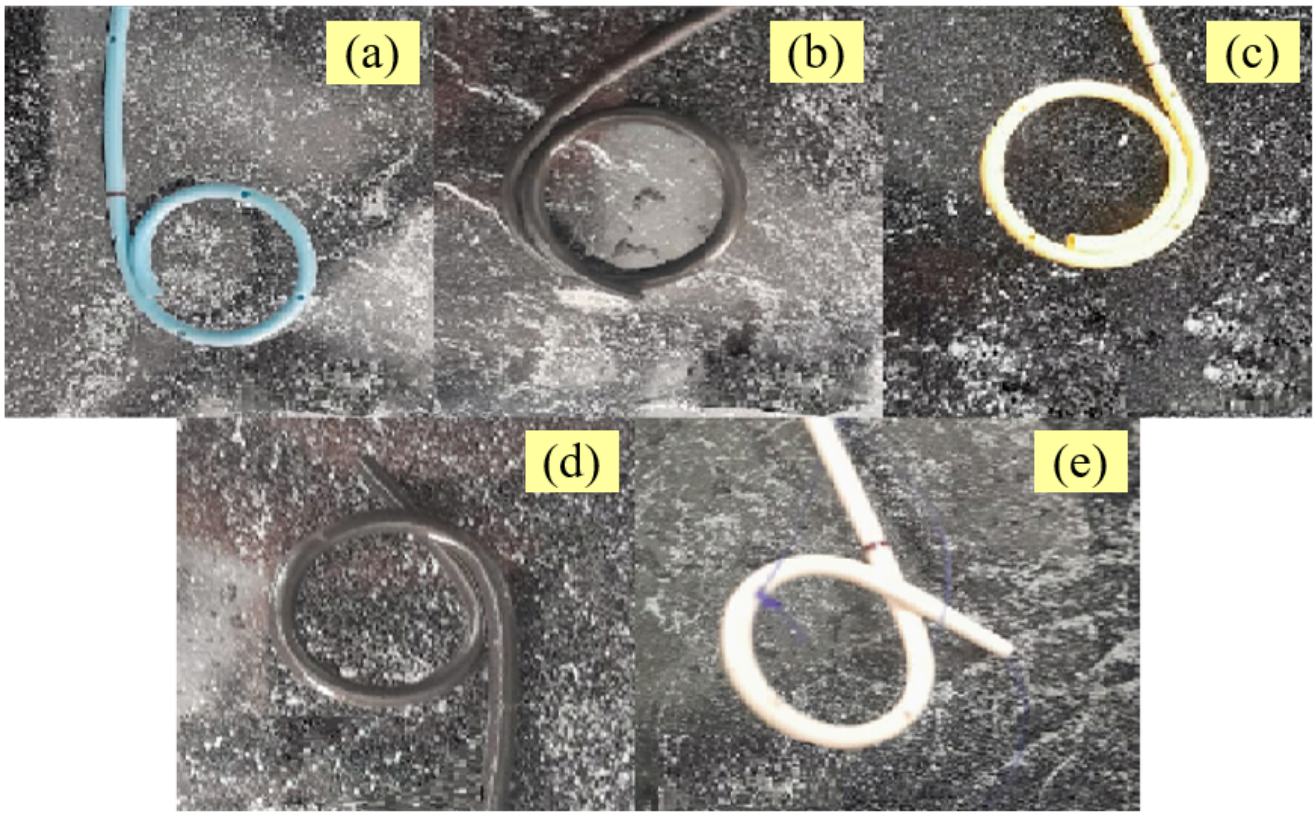


Figure 1

Variations in ureteral stent specimens selected for the experiment: a) Marflow Standard, b) Marflow Longlife, c) Marflow Longlife 180, d) ARK Black Silicone, and e) ARK White.

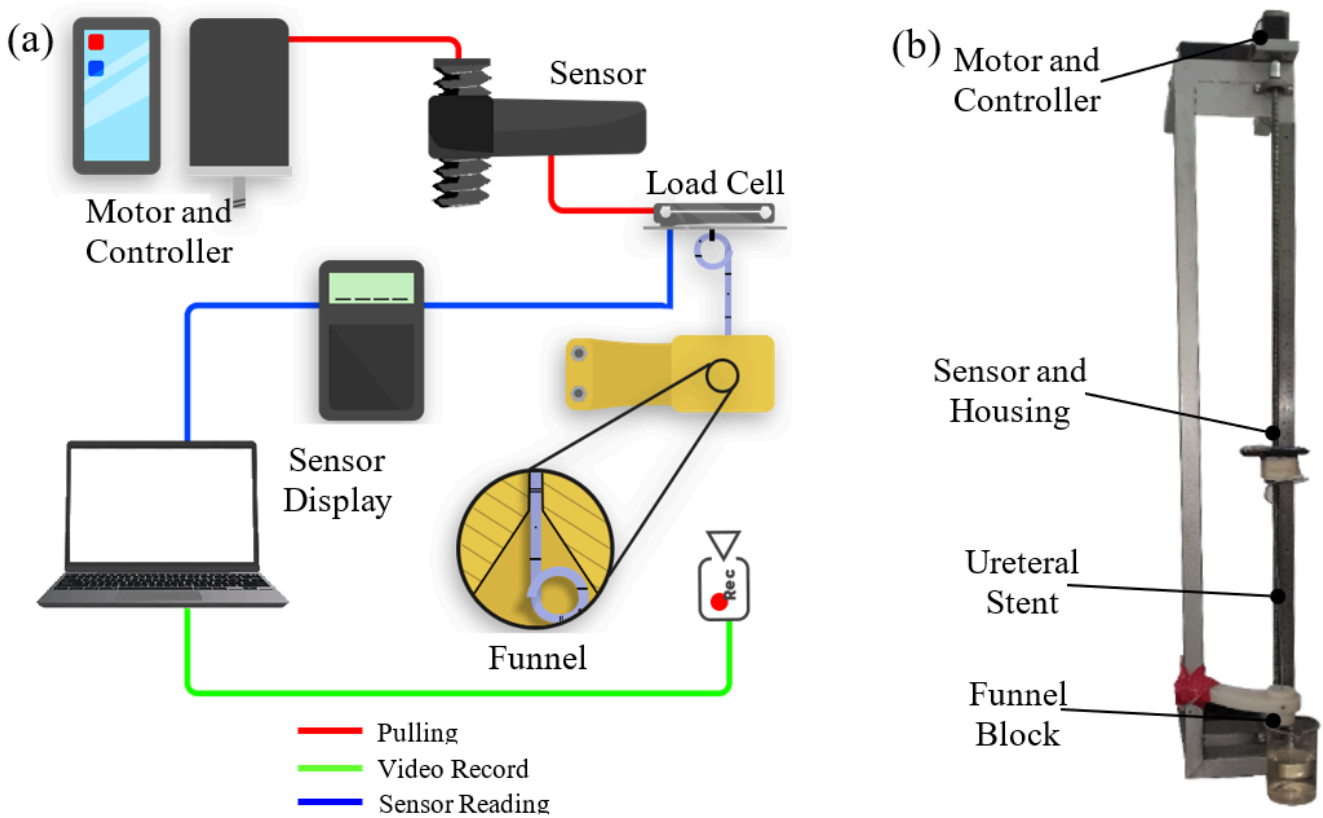


Figure 2

Experimental design for the retention test:
a) Testing scheme, and b) Retention test apparatus.

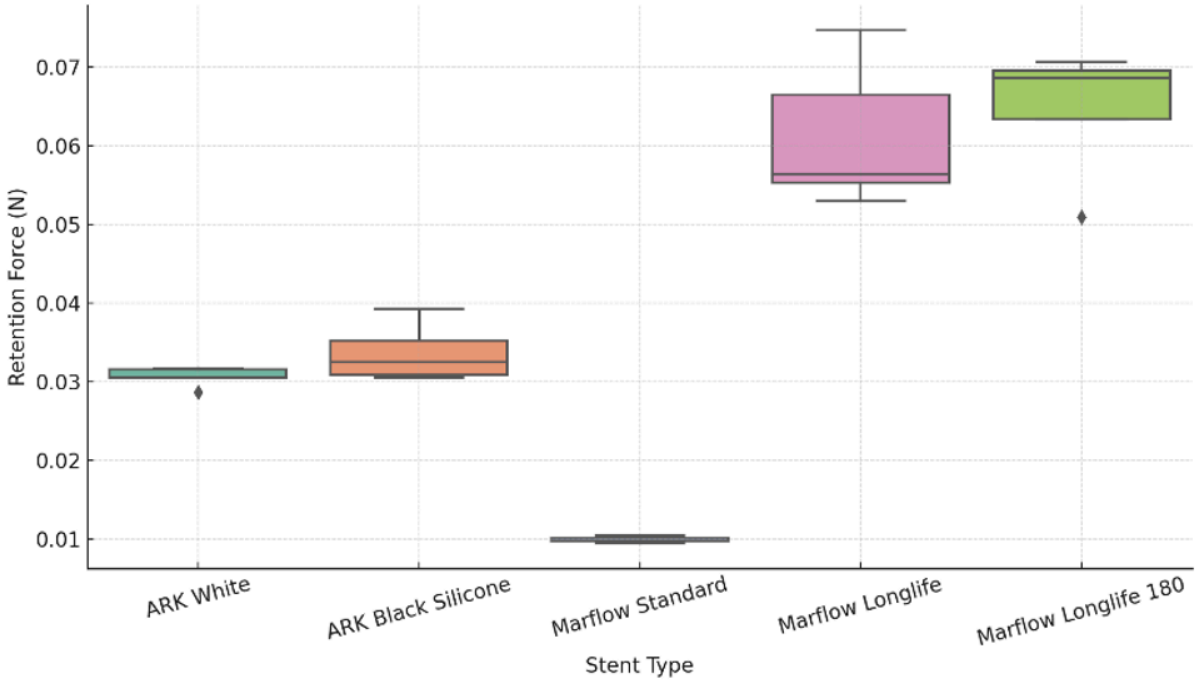


Figure 3

Visualization of Retention Force by Stent Type

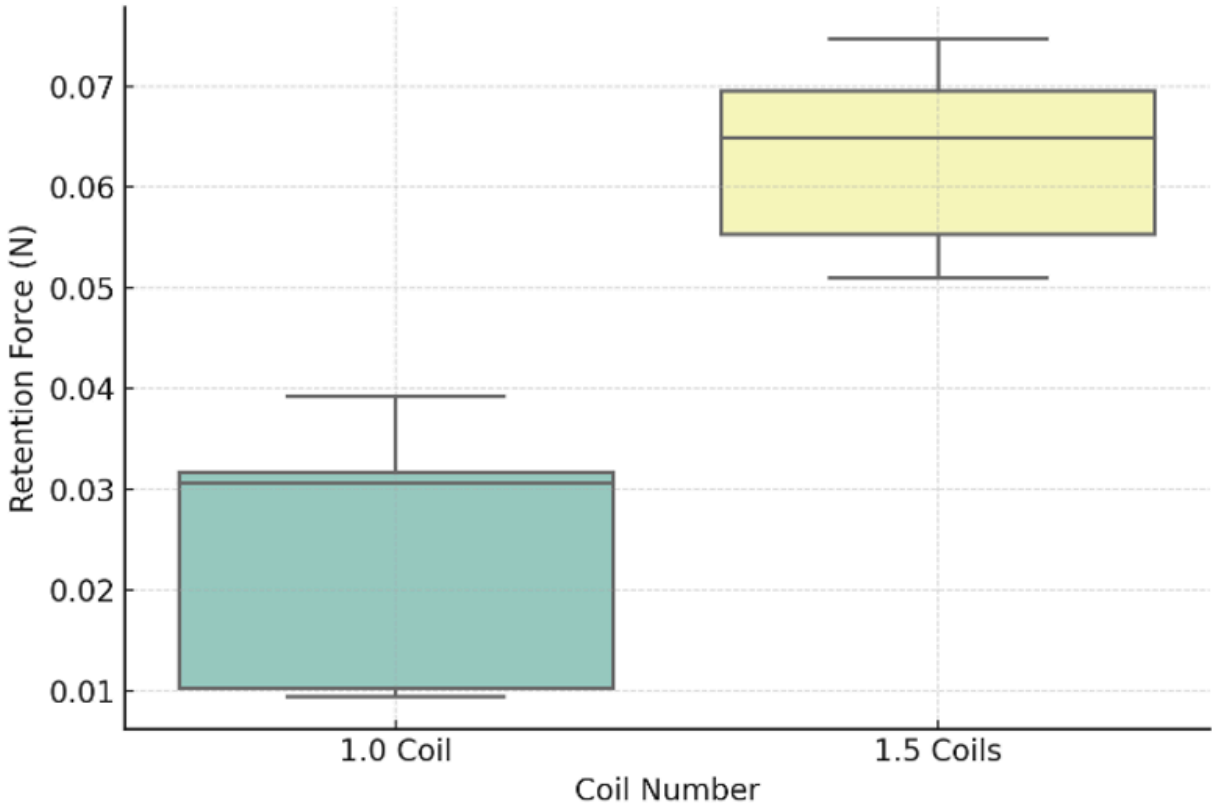


Figure 4

Clinical Retention Force Thresholds

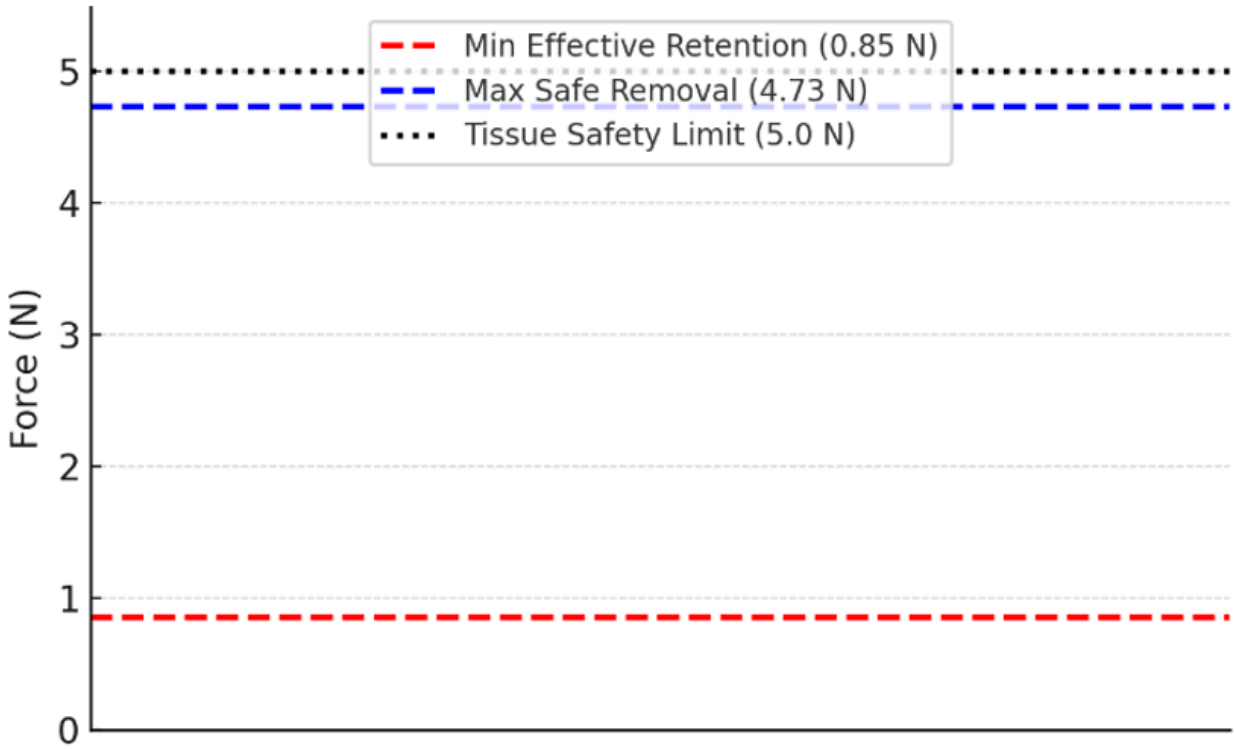


Figure 5

Clinical Retention Force Thresholds

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