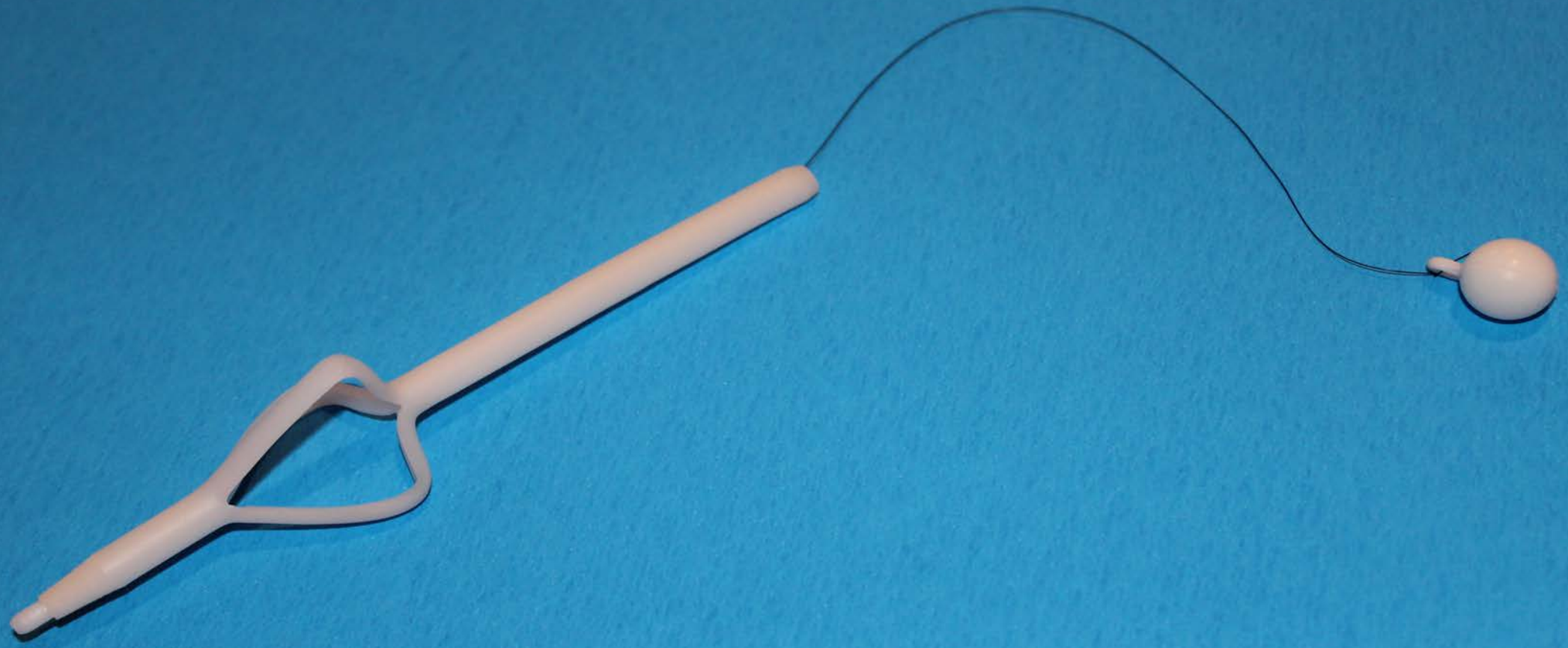
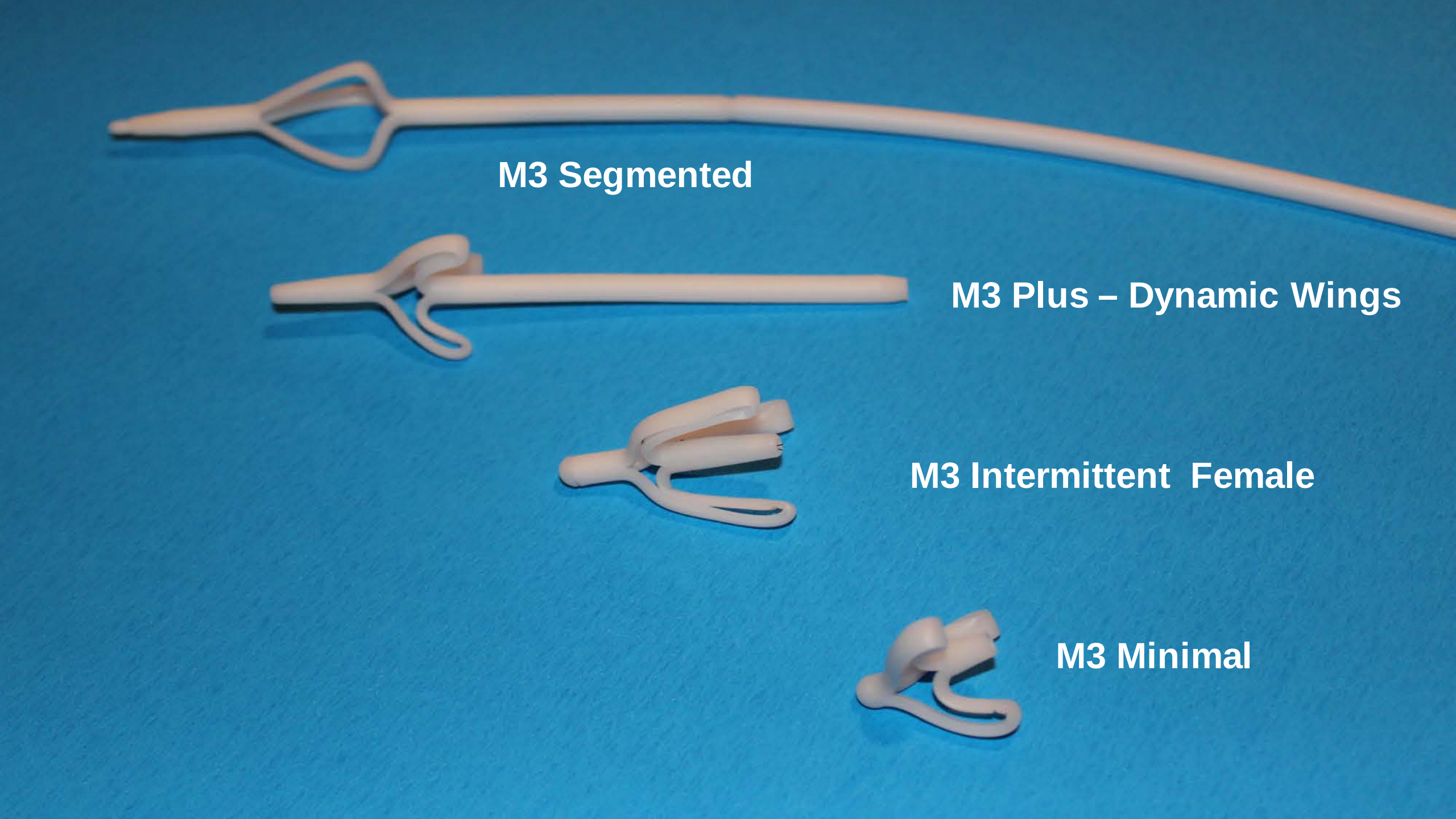
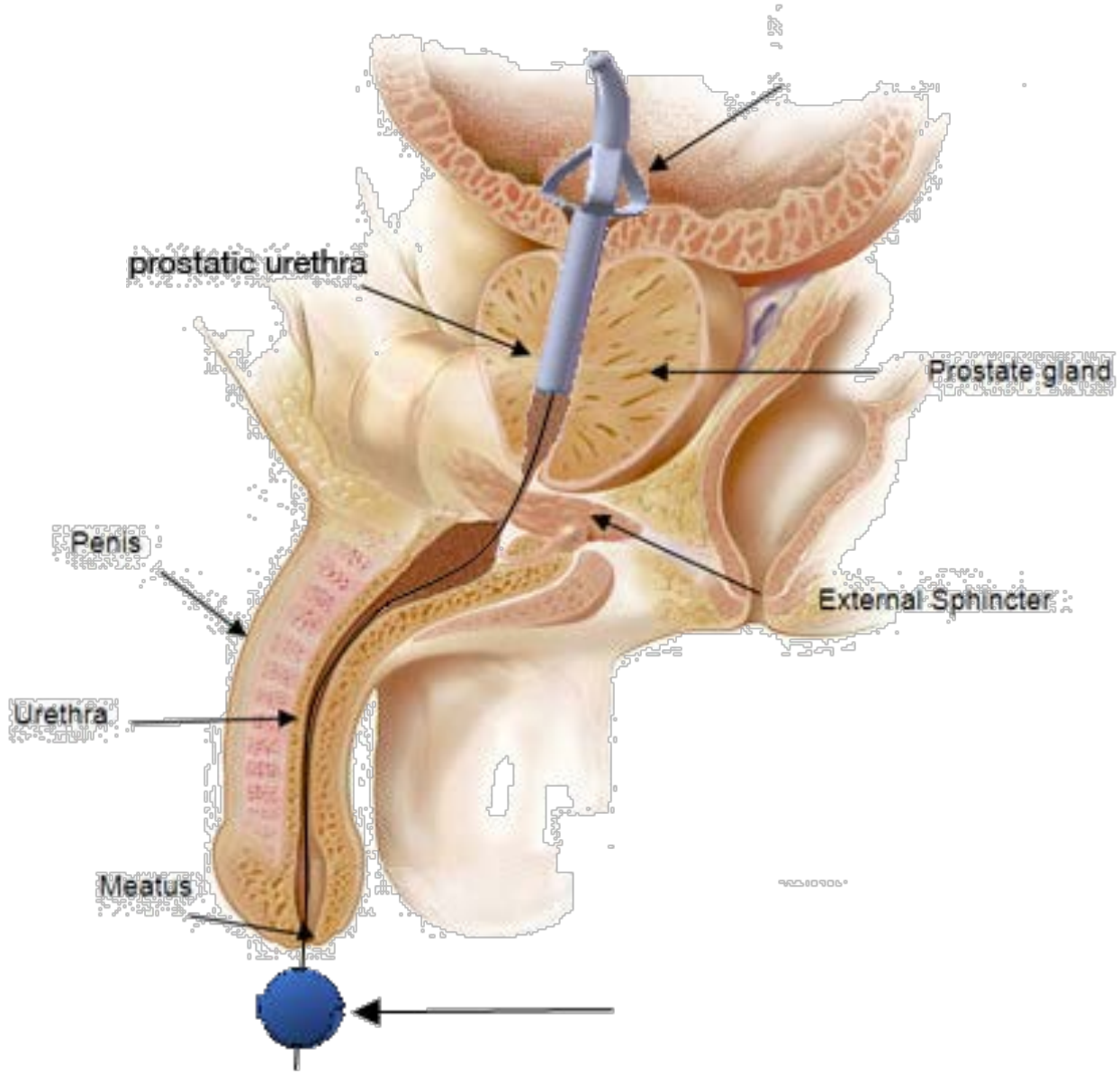
MP73-06 - A Prospective Evaluation of the Catheter Science M3 “Mini Catheter” for Patients with Prostatic Obstruction

Gaines W. Hammond Jr. MD FACS

M3 “Mini Catheter”




M3 Segmented
M3 Plus – Dynamic Wings
M3 Intermittent Female
M3 Minimal


prostatic urethra
Prostate gland
Penis
External Sphincter
Urethra
Meatus

Abstract

The M3 is a short catheter segment attached to a monofilament suture which runs thru the urethra and is attached to an external anti-migration “bobber.” The device has a Coude tip, guide wire channel and 3 wings used to stabilize and prevent expulsion. This temporary device bridges the obstructed prostate and with a contractile bladder coupled with a functioning urethral sphincter, normal volitional voiding is achieved.

Methods: This is an IRB approved single arm, prospective study is designed to produce valid scientific evidence regarding:

1. Safety and efficacy of the M3 “Mini Catheter” in establishing urinary drainage.

2. The study purpose is to measure the rate of catheter-related urinary tract infections in patients with the M3 in place as compared to the known anticipated infection rate for patients with a Foley in place for over a similar period of time.

3. Monitor the following:

- **Voluntary Micturition**
- **Post Void Residual**
- **Continence**
- **Retrograde or Ante-grade Migration of the device**
- **Ease of removal**
- **Comfort while in place**

4. To determine the rate of each anticipated Urinary Tract Adverse Event requiring intervention and unanticipated adverse device effects through 2 weeks post removal of the device.

Inclusion Criteria

- **Males > 50 years of age**
- **Signed subject informed consent**
- **Patients with actual urinary retention dependent on Foley Catheter or Intermittent Catheter**
- **Inclusion will start once the M3 is placed and a functioning bladder and sphincter are demonstrated.**

Exclusion Criteria

- **Inability to undergo bladder catheterization**
- **Gross hematuria**
- **Hypotonic Neurogenic Bladder (the placement of the M3 may isolate the cause of the retention with the bridging of the prostate as bladder dysfunction rather than prostate obstruction).**

The M3 allows for the bladder to fill since the sphincter is not bridged. Volitional micturition is initiated with bladder contraction coordinated with a relaxation of the external striated sphincter. The flow of urine is thru and around the M3 rather than only intraluminal in the Foley. This allows for an evaluation of the bladder as well as the sphincter function.

The direction of urine flow with the M3 is in one direction in contrast to the Foley catheter and external collection device which is bi-directionally. The flow of urine back into the bladder has long been viewed as a significant contributor to the CAUTI.

The Foley is a passive drainage device which simply drains the bladder with negative pressure produced in a closed system aided with gravity.

The retention balloon inflation channel impacts the internal diameter of the Foley. The Balloon prevents complete emptying of the bladder with resultant residual of 10-100cc reported.

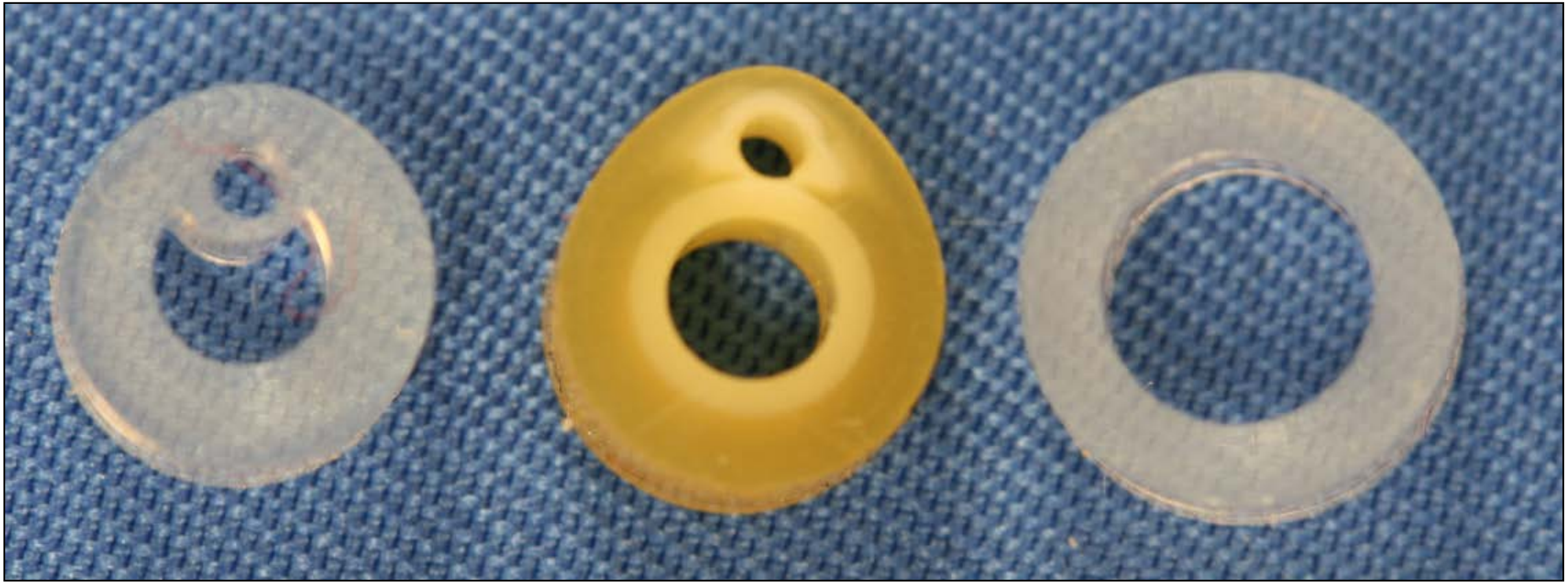
Since there is no consistent flow of urine around a Foley to help "wash out bacteria" the formation of biofilm is accelerated. The Foley violates the anatomical protective points (penile meatus, sphincter, prostatic urethral and bladder neck) which help prevent bacterial contamination.

The device was reported as comfortable which was reflected with improvement on IPSS scores.

No devices were removed due to hematuria or encrustations.

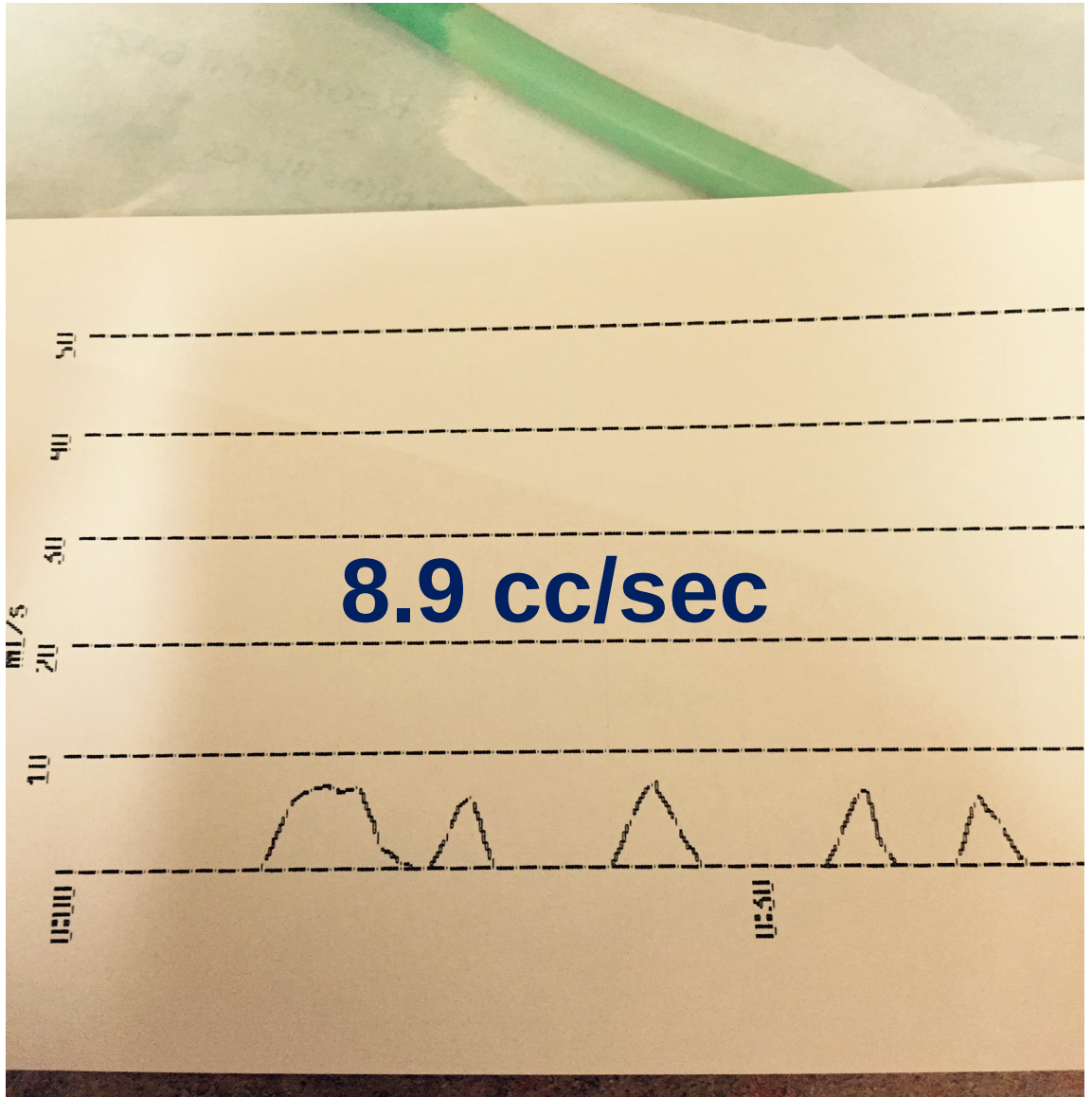
No incontinence was reported in patients with a device placed proximal to the urinary sphincter.

Flow Rate Improvements

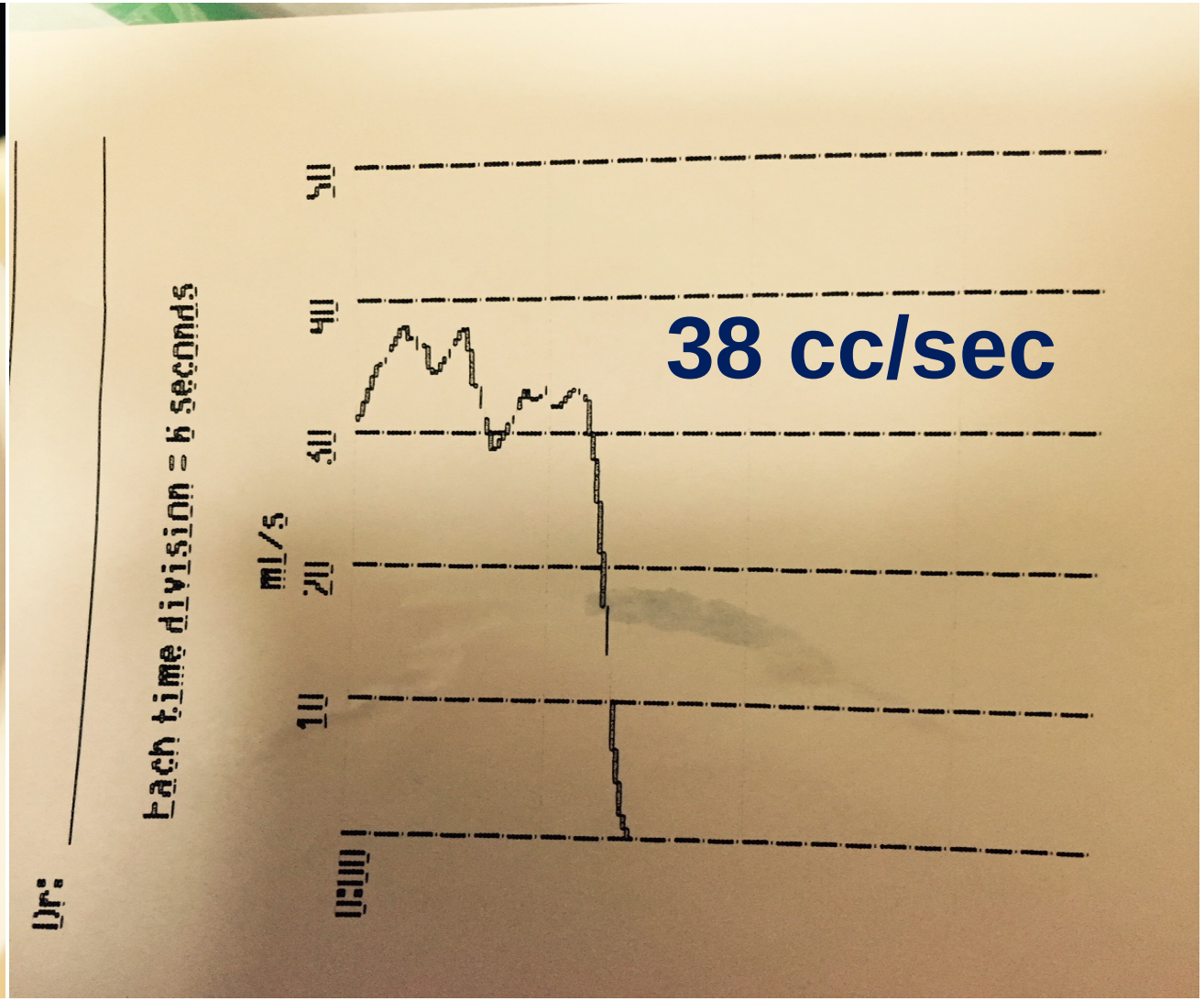


Silicone Foley **Latex Foley** **M3 Catheter**

Foley Catheter – Flow Rate 8.9 cc/sec



M3 – Flow Rate 38 cc/sec



M3 Reduction in Infection Rate

- **Increased flow rate thru and around device minimizing encrustations and biofilm**
- **Sphincter and Penile Meatus are not bridged**
- **Reduced PVR**
- **Wings prevent bladder mucosal trauma**
- **No external collection device**

Group 1 **Combined Infected and uninfected at day 0 of study**

Patients >3 days to 28 or greater days of insertion of M3

Total M3 Catheter Days = 871 days

Group 2 **Patients Infected at day 0 of study**

Patients >3 days to 28 or greater days of insertion of M3

Total M3 Catheter Days = 369 days

Group 3 **Patients with NO infection at day 0 of study**

Patients >3 days to 28 or greater days of insertion of M3

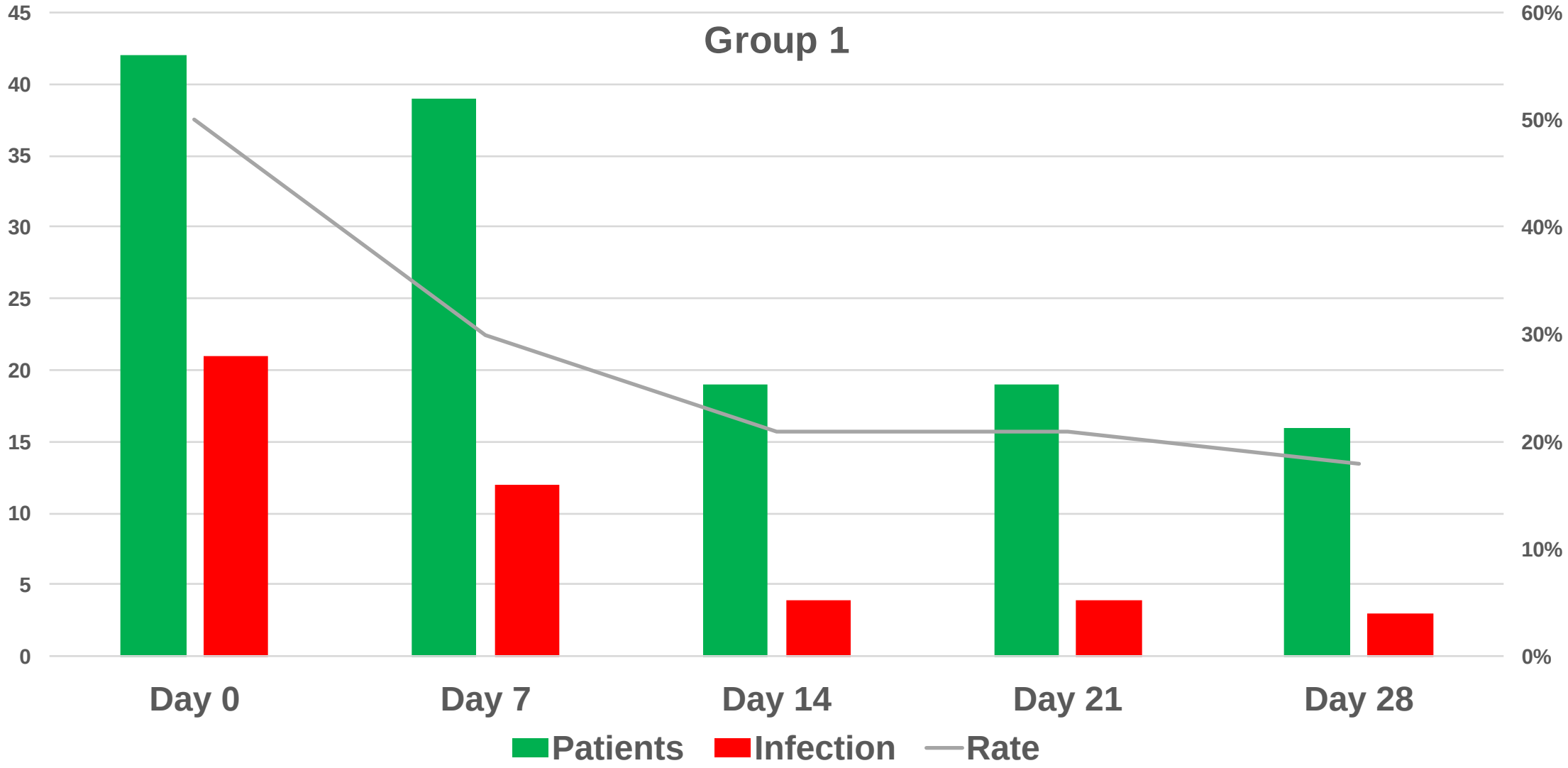
Total M3 Catheter Days = 502 days

M3 Catheter Days

Group 1	Day 0	Day 7	Day 14	Day 21	Day 28	871
Patients	42	39	19	19	16	
Infection	21	12	4	4	3	
Rate	50%	30%	21%	21%	18%	

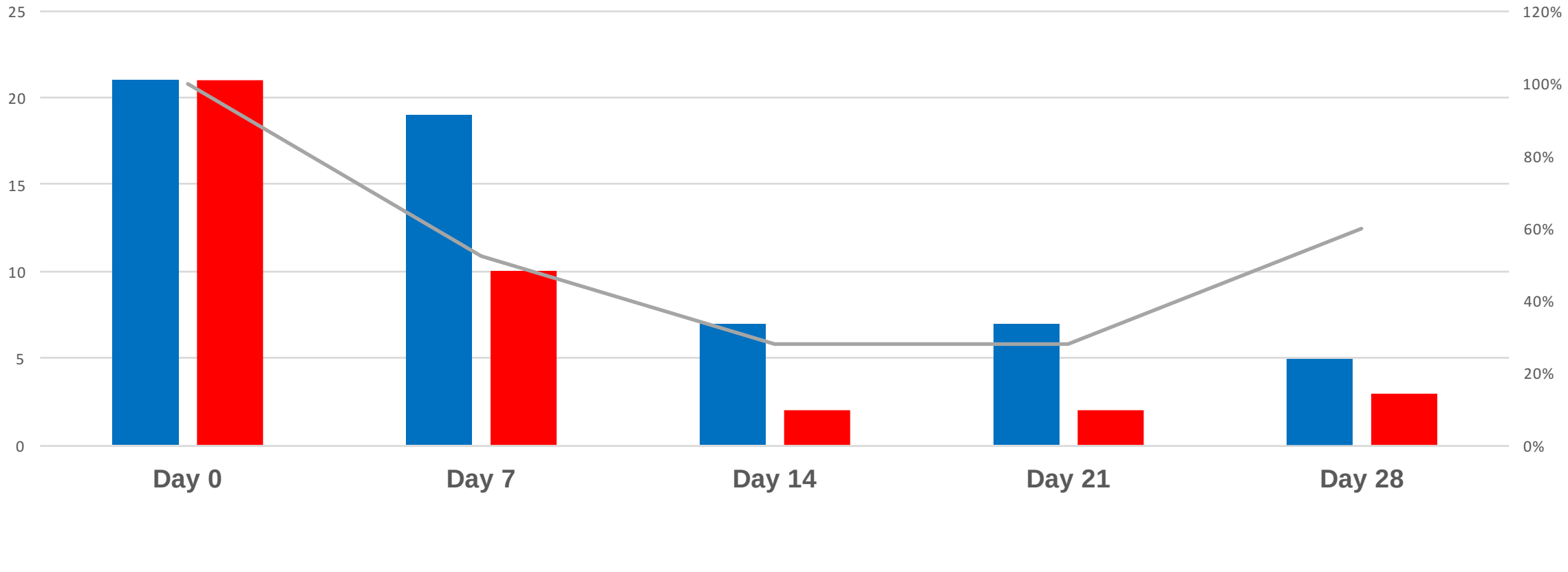
Group 2	Day 0	Day 7	Day 14	Day 21	Day 28	369
Patients	21	19	7	7	5	
Infection	21	12	4	4	3	
Rate	100%	63%	57%	57%	60%	

Group 3	Day 0	Day 7	Day 14	Day 21	Day 28	502
Patients	21	20	12	12	11	
Infection	0	0	0	0	0	
Rate	0%	0%	0%	0%	0%	

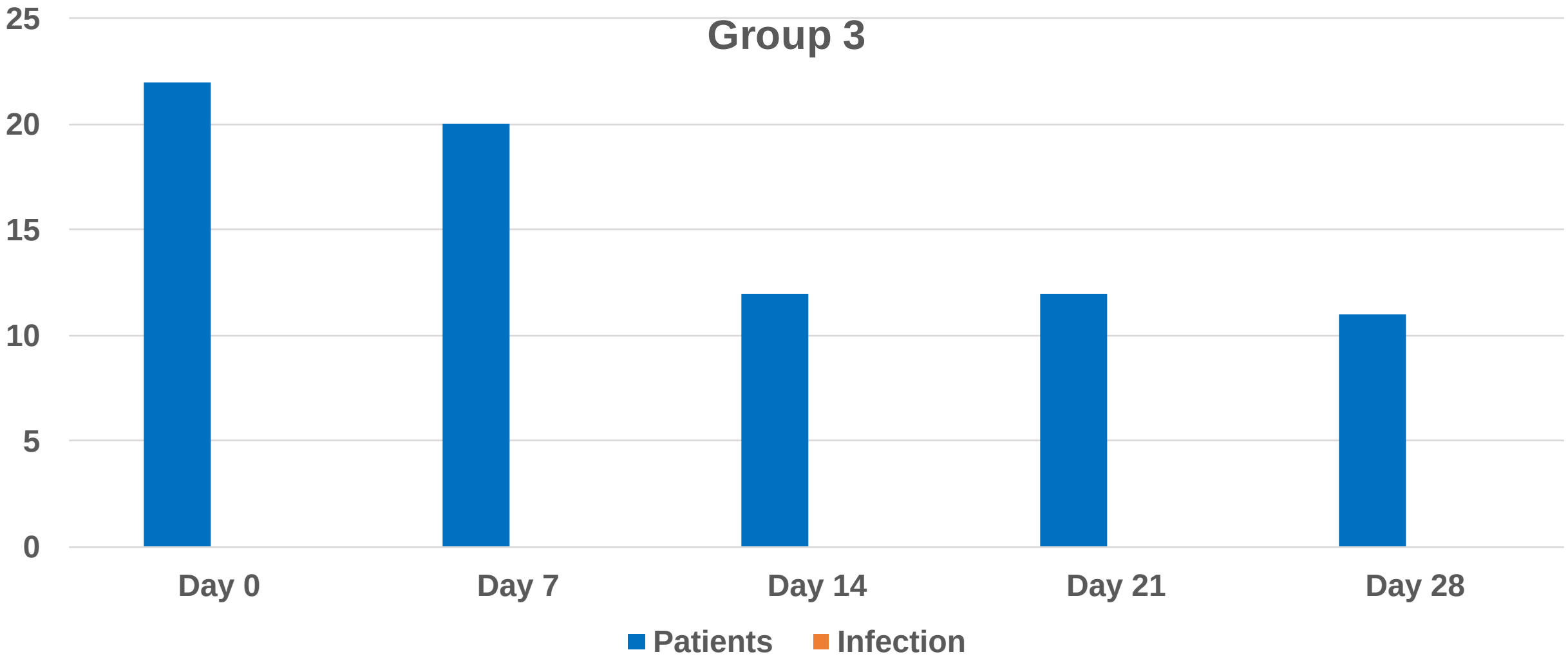


Group 1	Day 0	Day 7	Day 14	Day 21	Day 28	M3 Days
Patients	42	39	19	19	16	871
Infection	21	12	4	4	3	
Rate	50%	30%	21%	21%	18%	

Group 2



	Day 0	Day 7	Day 14	Day 21	Day 28	M3 Days
Patients	21	19	7	7	5	359
Infection	21	12	4	4	3	
Rate	100%	52%	57%	57%	60%	



	Day 0	Day 7	Day 14	Day 21	Day 28	M3 Days
Patients	21	20	12	12	11	502
Infection	0	0	0	0	0	

Study Population and Time Interval

	Patients	Days M3	Average Days
M3	42	879	20.9

Voiding Metrics

Voiding Metric						
Voided Volume	Q max	PVR	IPSS	M3 - IPSS	QOL	QOL
385 cc	9.1 cc/sec	51 cc	24	13.1	4.8	3

Summary

	Urinary Tract Infection				
	Day 0	**Day 7**	**Day 14**	**Day 21**	**Day 28**
M3	**50%**	**30%**	**21%**	**21%**	**18%**
Foley	**0%**	**35%**	**70%**	**>95%**	**>95%**

M3 Comparison to Foley

	28 Days			
	Infection	Encrustation	Retention	Migration
M3	<18%	0	<5%	<5%
Foley/CIC	>95%	>38%	>38%	N/A

Conclusions:

The M3 “Mini Catheter” demonstrated a substantial reduction in infection rate over the 28 day period as compared to anticipated infection rates with either a Foley or CIC. (>95% vs <18%)

The device is easy to place and remove and does not require an external collection device.

The device was not spontaneously expelled and infrequently migrated in a retrograde fashion back into the bladder which simply required repositioning of the device.


No Encrustations 28 Days


No Encrustations 28 Days