Tria™ Firm Ureteral Stent Calcium and Magnesium Urine Salt Accumulation:

Evaluation of Novel Anti-Adherence Materials on Tria Firm and Bard Inlay Optima™ Ureteral Stents Using the BEST™ Method

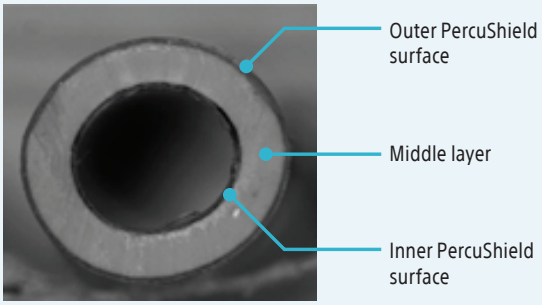
Testing conducted by Innovotech, Inc.
A pioneer in antimicrobial and anti-encrustation testing for coated medical devices.

Introduction and Purpose

Despite continued advances in ureteral stent design and materials, the problem of minimizing the encrustation of biomaterials in the urinary tract remains a challenge. It is well documented that both major and minor stent encrustations can lead to stent blockage and adverse effects, including flank pain, infection, irritative urinary symptoms, hydronephrosis, etc.[1] Encrusted stents can also be difficult to remove and may require additional, often complicated, surgical procedures.[1,2] The cause and rate of encrustation is multifactorial and can include factors such as body chemistry and medical condition of the patient, stent in-dwell time, and surface material or properties of the stent.[2-4]

The Tria Ureteral Stent is designed with a unique tri-layer design, including a proprietary PercuShield™ technology on both the outer and inner stent surfaces that minimizes the adherence of calcium and magnesium salts. The PercuShield technology is designed with an inert, non-polar copolymer material composition, which has a low surface energy. Consequently, the surface is less reactive to aqueous solutions, and less compatible with ionic materials such as urine calcium and magnesium salts,[5] which is one of many factors impacting encrustation.[4,6]

Cross-section view of Tria™ Stent



The purpose of this paper is to summarize the findings of a laboratory study evaluating the ability of Tria Firm Ureteral Stent's inner and outer surface layers to minimize the accumulation of calcium and magnesium urine salt deposits on the stent surface compared to Bard Inlay Optima™ Stent.

Since the presence of a urinary tract infection may also correlate with a higher degree of distal coil encrustation,[7] the adherence of calcium and magnesium salts to the stent surface was analyzed both in the presence and in the absence of bacteria.

Materials and Methods

Testing was performed by Innovotech, Inc. using the in-vitro BEST™ (Biofilm Eradication Surface Testing) platform to evaluate calcium and magnesium salt accumulation of the ureteral stents.[5]

A total of 30 samples from each ureteral stent family (Tria Firm and Bard Inlay Optima), cut into 3.5cm pieces, were tested in a sterile Artificial Urine Model and a Bacterial Infection Model (n=15 in each model). All samples tested contained side holes, allowing the urine to flow in and out of the side holes freely.

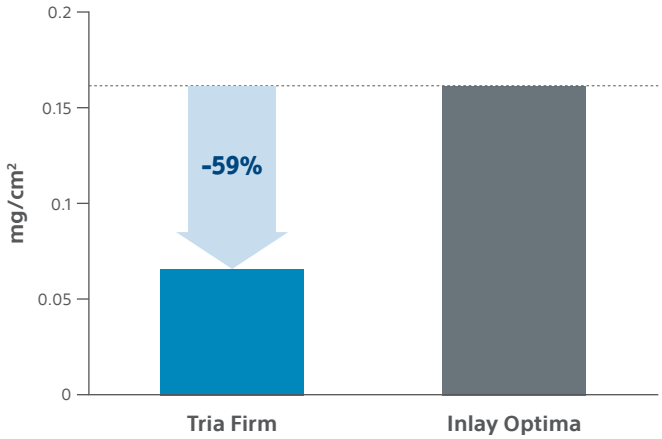
Units tested in the “Sterile Urine” group were soaked in artificial urine, filtrated through 0.2 µm filter units and stored at 4°C until required. Before use, a sterility check was performed. Units tested in the “Bacterial Infection Model” group were soaked in sterile artificial urine with a *Proteus mirabilis* spike. *Proteus mirabilis* was used as the microbial challenge in the Bacterial Infection Model due to its known urease production and involvement in struvite formation.[8] Artificial urine was replaced every 48 hours. Units in both models were secured to pegs in the BEST™ 12 well plate, ensuring they were in a "U" shape, with a simulated 0.5 ml/min physiological flow rate; incubated at 37+/-2°C for 2 weeks.

Upon completion of the 2-week exposure, salt crystals were disrupted by sonicating in nitric acid solution for 30 min and left for 24 hours, and solutions were analyzed for calcium and magnesium content by atomic absorption spectroscopy (AAS).

Results

After 2 weeks of soaking (artificial urine was changed every 48 hours), the recovered magnesium (Mg) and calcium (Ca) salt accumulation in nitric acid was measured. In the "Bacterial Infection Model" the adhered microbial biomass was recovered first, then the recovered Mg and Ca salt accumulation in nitric acid was measured. For both conditions, the mean material (mg/cm^2), as well as comparative difference calculated as [(Tria™ Firm Stent – Competitor Stent) / Competitor Stent] * 100 was analyzed. Results

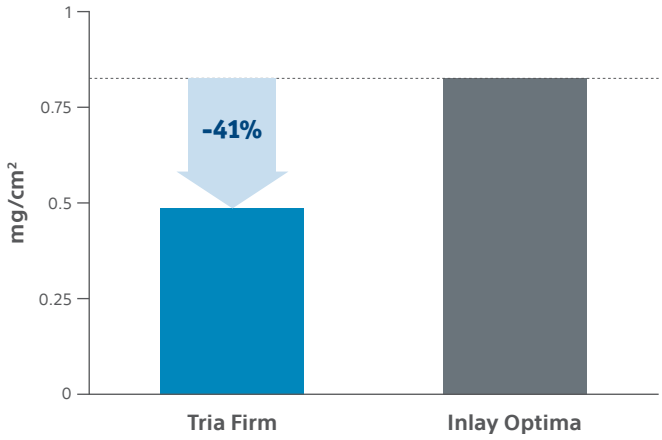
Sterile Artificial Urine Study



The Tria Firm Stent reduced the combined Ca and Mg Urine Salt Accumulation by 59% compared to the Bard Inlay Optima Stent in the sterile urine model. The mean difference of salt crystal material was a statistically significant reduction.

Device	Mean Material (mg/cm^2)	St. Dev	P-Value	Difference (mg/cm^2)	% Difference
Tria Firm	0.0658	0.0117			
Bard Inlay Optima	0.1612	0.1332	< 0.05*	-0.0954	-59%

Proteus Spiked Artificial Urine Study



The Tria Firm Stent reduced the combined Ca and Mg Urine Salt Accumulation by 41% compared to Bard Inlay Optima Stent in the bacterial infection urine model. The mean salt crystal material was a statistically significant reduction.

Device	Mean Material (mg/cm^2)	St. Dev	P-Value	Difference (mg/cm^2)	% Difference
Tria Firm	0.4856	0.1579			
Bard Inlay Optima	0.8244	0.1491	< 0.05*	-0.3388	-41%

* For each condition, the difference between the Tria Stent and the Bard Inlay Optima stent on mean amount of salt crystal material was assessed at the 0.05 level of significance using a (one-sided) two-sample t test.

Conclusion

In conclusion, the data collected and analyzed as part of this study provide evidence that Tria™ Firm Stent's unique tri-layer design, with the PercuShield™ technology on both the outer and inner surfaces of the stent, significantly reduced the combined accumulation of magnesium and calcium deposits when compared to the Bard Inlay Optima™ stent both in the presence and in the absence of bacteria (Proteus mirabilis).[5]

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2. Bultitude MF, Tiptaft RC, Glass JM, et al. Management of encrusted ureteral stents impacted in upper tract. *Urology.* 2003 Oct;62(4):622-6.
3. Elwood CN, Lo J, Chou E, et al. Understanding urinary conditioning film components on ureteral stents: profiling protein components and evaluating their role in bacterial colonization. *Biofouling.* 2013;29(9):1115-22.
4. Vanderbrink BA, Rastinehad AR, Ost MC, et al. Encrusted urinary stents: Evaluation and endourologic management. *J Endourol.* 2008 May;22(5):905-12.
5. Data on file with Boston Scientific. Bench Test results may not necessarily be indicative of clinical performance.
6. Bruce A, Clark A, Awad S. Clark , Albert & Awad, Sana. (1974). The problem of catheter encrustation. *Can Med Assoc J.* 1974;111:238-8
7. Sighinolfi MC, Sighinolfi GP, Galli E, et al. Chemical and mineralogical analysis of ureteral stent encrustation and associated risk factors. *Urology.* 2015 Oct;86(4):703-6.
8. Brooks T, Keevil CW. A simple artificial urine for the growth of urinary pathogens. *Letters in Applied Microbiology.* 1997, 24, 203–206.

The testing was performed by or on behalf of BSC. Data on file.

CAUTION: US Federal law restricts this device to sale by or on the order of a physician.