Silicone-hydrocoated ureteral stents encrustation and biofilm formation after 3-week dwell time: results of a prospective randomized multicenter clinical study

Yazeed Barghouthy; Paris, France
Oliver Wiseman; Cambridge, UK
Eugenio Ventimiglia; Milano, Italy
Julien Letendre; Montreal, Canada
Jonathan Cloutier; Quebec, Canada
Michel Daudon; Paris, France
Francois Kleinclauss; Besancon, France
Steeve Doizi; Paris, France
Maria Corrales; Paris, France
Olivier Traxer; Paris, France

STUDY SUMMARY

Objective: To explore the risk of encrustation and biofilm formation for silicone ureteral stents compared to Percuflex™ polymer stents, through a randomized multicenter study.

Patients and methods: Design, setting and participants: A multicenter, prospective, randomized, single blind, comparative study of hydrocoated silicone stent (Coloplast Imajin® Hydro) versus Percuflex™ Plus stent (Boston Scientific), in 141 patients treated by flexible URS for a kidney stone. The study had ethical committee approval in the respective hospitals. Outcome measurements and statistical analysis: Endpoints related to encrustation were biofilm formation and mineral encrustation after a period of 3-week indwelling time. They were evaluated at removal through a scoring scale of ureteral stents encrustation, infrared spectroscopy and optical microscopy of inner and outer surfaces of tips, angles and along the stent's body. Comparison was performed using ANOVA.

Results: 119 stents were available after removal for analysis, 56 in the silicone and 63 in the Percuflex™ Plus group. Mean dwelling duration was 21.8 days for silicone, 22.1 days for Percuflex™ Plus. There was significantly more biofilm on Percuflex™ Plus compared to silicone (1.24 ± 0.08 vs 0.93 ± 0.09, p = 0.0021), and more mineral encrustation (1.22 ± 0.10 vs 0.78 ± 0.11, p = 0.0048), respectively.

Conclusions: This multicenter randomized study shows that silicone hydrocoated stents are less prone to encrustation than Percuflex™ Plus after a 3-week dwelling period and confirms the low encrustation potential of silicone.

Ref: Barghouthy Y, Wiseman O, Ventimiglia E, Letendre J, Cloutier J, Daudon M, Kleinclauss F, Doizi S, Corrales M, Traxer O. Silicone-hydrocoated ureteral stents encrustation and biofilm formation after 3-week dwell time: results of a prospective randomized multicenter clinical study. WJU. 2021 Mar 10: doi: 10.1007/s00345-021-03646-0

COLOPLAST KEY TAKEAWAYS

- The results of this prospective randomized controlled study of 119 stents demonstrates that Coloplast Imajin® Hydro silicone stents are associated with significantly less encrustation and biofilm formation after 20-day dwell time compared to Percuflex™ Plus stents from Boston Scientific.
- After 20-day dwell time, global biofilm formation at stent surface of the Coloplast ImaJin® Hydro silicone stent was 0.93 compared to 1.24 for the Boston Scientific Percuflex™ Plus stent. This represents a 0.31 or 25% reduction in biofilm formation in favor of Coloplast Imajin® Hydro.
- After 20-day dwell time, global mineral encrustation at stent surface of the Coloplast ImaJin® Hydro silicone stent was 0.78 compared to 1.22 for the Boston Scientific Percuflex™ Plus stent. This represents a 0.44 or 36% reduction in global mineral encrustation in favor of Coloplast Imajin® Hydro.
- 5 of the 56 Coloplast ImaJin® Hydro silicone stents studied demonstrated no signs of mineral encrustation after a 20-day dwell time.
- This study confirms the low encrustation potential of silicone and hydrocoated silicone stents.

Indications: Drainage of the upper urinary tract over fistulas or ureteral obstacles. Healing of the Ureter. Cicatrisation stent.

Contraindications: Untreated progressive infection of the upper urinary tract. Any known allergies to the medical device materials. These devices may particularly contain traces of silicone resulting from the manufacturing process. The evaluation of the allergic background of a patient is the healthcare professional's responsibility. Do not attempt stent placement in a patient with suspect ureteral avulsion. Do not use, when, in the judgement of the physician, such a procedure would be contrary to the best interest of the patient.

Warnings and Precautions: Reuse of this single use product may create a potential risk to the user. Reprocessing, cleaning, disinfection and sterilization may compromise product characteristics which in turn create an additional risk of physical harm to or infection of the patient. Formation of knots in lengthy stents have been reported as adverse events and may require surgical intervention to remove them.

Adverse Events: The following events have been reported although their occurrence greatly depends on patients' medical conditions. Adverse events include but are not limited to: migration or dislodgement, encrustation, infection, fragmentation, flank pain, mucosal irritation or inflammation, mucus secretion, frequency, urgency, dysuria, hematuria, reflux, stone formation, obstruction, erosion and perforation of the renal pelvis, ureter or bladder. Some events may be related to this procedure, amongst which those related to the guidewire: ureteral perforation or burns when in contact with an electrosurgical equipment.

The risks and benefits of using Imajin® Silicone Hydrocoated Double Loop Ureteral Stent Kits should be considered in patients.

The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings and precautions refer to the product's Instructions for Use. Alternatively, you may contact a Coloplast representative at 1-800-258-3476 and/or visit the company Website at www.coloplast.com.

Complications from the use of this device should be brought to the attention of your Coloplast Representative and your physician.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Coloplast Corp. Minneapolis, MN 55411 / Interventional Urology Surgical Support 1-800-258-3476
www.coloplast.us The Coloplast logo is a registered trademark of Coloplast A/S.

PM-10561 3.21

Coloplast