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Comparison of encrustation between silicon-covered and polytetrafluoroethylene-covered metallic stent, *in vitro* experimental study

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Purpose: To compare encrustation resistance between silicon- and polytetrafluoroethylene (PTFE)-covered metallic ureteral stents (MUS) in an *in vitro* infection model and to determine the most effective material for reducing biofilm formation and encrustation.

Materials and Methods: A total of 52 MUS were prepared: 26 silicon-covered and 26 PTFE-covered stents. Each sample was immersed in artificial urine inoculated with *Proteus mirabilis* in a biofilm reactor for 48 hours. After immersion, the stents were weighed to measure their encrustation level. Scanning electron microscopy (SEM) and energy dispersive X-ray spectroscopy (EDS) were used to assess the surface morphology and elemental composition of the encrustation deposits.

Results: Silicon-covered stents showed a statistically significant reduction in weight gain due to encrustation compared to PTFE-covered stents (9.50±5.77 mg vs. 16.75±10.61 mg; p=0.004). Additionally, encrustation per unit length was lower in silicon-covered stents (0.76±0.45 mg/mm vs. 1.30±0.81 mg/mm; p=0.004). SEM and EDS analyses demonstrated lower calcium salt deposition on the silicon-covered stents, indicating greater resistance to encrustation.

Conclusions: Silicon-covered MUS demonstrated superior resistance to encrustation compared to PTFE-covered stents, supporting silicon as a more suitable covering material for long-term MUS applications. This finding may lead to extended stent lifespans and a reduced frequency of stent replacements, benefiting both patients and healthcare systems.

Keywords: Hydronephrosis; Stents; Ureter

INTRODUCTION

Ureteral stents are widely used in urological practice to ensure urine flow from the renal pelvis to the bladder, particularly in cases involving obstructive conditions such as tumors, stones, and injuries within the urinary tract [1]. These stents help preserve renal function in patients with endogenous or exogenous ureteral obstructions and offer critical support in various clinical scenarios, including both temporary and permanent placement [2]. An ideal ureteral stent must not only maintain urine flow and provide ease of insertion and removal, but also demonstrate high biocompatibility and long-term patency by resisting biofilm formation, encrustation, and subsequent occlusion [3].

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Despite significant advancements, biofilm formation remains a major limitation in long-term stent use [4]. Continuous exposure to urine promotes biofilm accumulation, which over time leads to the deposition of microorganisms, proteins, and calcium salts on the stent surface, a process known as encrustation [5]. Encrustation can impair the patency of ureteral stents and necessitate frequent replacements, thus increasing patient discomfort, healthcare costs, and the risk of complications [6,7].

To address these challenges, metallic ureteral stents (MUS) have been developed as a more durable alternative to traditional polymer stents [8]. MUS, particularly those with external coatings, are less prone to tissue ingrowth and blockage, and offer a longer functional lifespan in the urinary tract. Among MUS designs, those covered with biocompatible materials such as silicon and polytetrafluoroethylene (PTFE) are designed to reduce encrustation by limiting bacterial adhesion and biofilm formation [9,10]. However, to date, no study has thoroughly compared the encrustation resistance of silicon- and PTFE-covered MUS under controlled conditions, leaving uncertainty regarding the optimal coating material for long-term stent durability.

In this study, we compared encrustation formation on silicon- and PTFE-covered MUS using an *in vitro* biofilm reactor model.

MATERIALS AND METHODS

1. Study design and sample preparation

In this study, we employed an *in vitro* model to evaluate the encrustation of MUS with two different cover materials: silicon and PTFE. A total of 52 MUS segments (12.5 mm in length) were prepared, including 26 silicon-covered and 26 PTFE-covered stents.

2. Preparation of artificial urine solution

Artificial urine (AU) was prepared to mimic human urinary conditions. The solution composition included calcium chloride (0.49 g/L), magnesium chloride (0.30 g/L), sodium chloride (4.60 g/L), sodium sulfate (2.30 g/L), potassium dihydrogen phosphate (2.80 g/L), potassium chloride (1.60 g/L), ammonium chloride (1.00 g/L), urea (25 g/L), and creatinine (1.10 g/L). Each component was weighed precisely and sequentially dissolved in distilled water under constant stirring. The solution was stirred continuously at 600 revolutions per minute (rpm) for 12 hours to ensure complete dissolution and homogeneity of the AU solution. The pH of the AU was adjusted to 6.5 using hydrochloric acid. To induce encrustation, *Proteus mirabilis* (ATCC 12453) was cultured in AU, reaching a concentration of approximately 10^3 CFU/mL [11].

3. Biofilm reactor setup

A CDC Biofilm Reactor (BioSurface Technologies Corp.) was used for the controlled immersion of the stent samples. Each stent was suspended in a biofilm reactor chamber. The continuous flow of AU with *P. mirabilis* was maintained at 1 mL/min and placed on a stir plate at 50 rpm, ensuring consistent exposure to the bacterial solution over the immersion period.

4. Immersion protocol

The stent samples, biofilm reactor chamber, tube, and bottles were sterilized by autoclaving at 121°C and 15 lbs pressure for 15 minutes before immersion testing to ensure no pre-existing contamination. Each stent segment was placed individually within the biofilm reactor for a total immersion time of 48 hours. The immersion experiment was conducted using a closed system (Fig. 1).

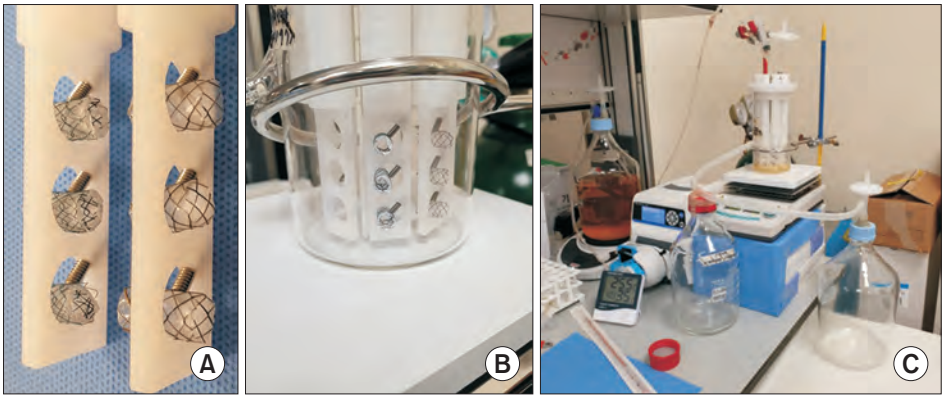

Fig. 1. Biofilm reactor setting. (A) Placement of metallic ureteral stents (MUS) in a biofilm reactor. Left: polytetrafluoroethylene-covered MUS. Right: silicon-covered MUS. (B, C) Settings of the biofilm reactor using artificial urine.

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5. Post-immersion analysis

Upon completion of the 48-hour immersion period, the stents were removed from the reactor and washed gently with sterile distilled water to remove loosely attached deposits. The samples were then dried in a desiccator at room temperature for 24 hours before weight measurements and surface analysis.

• Weight measurement: Each weight of each stent was measured pre- and post-immersion using a precision analytical balance (±0.1 mg accuracy). Weight differences were calculated to quantify the encrustation levels.

• Surface morphology: Scanning electron microscopy–energy dispersive X-ray spectroscopy (SEM-EDS) (Sigma 500; ZEISS) was performed to observe the stent surfaces after the immersion test. The samples were cut along the vertical axis to investigate the interior of the tubes. To minimize the charging problems under the electron beam, 5 nm of platinum was sputtered. SEM images at ×50, ×5,000, and ×10,000 magnifications were analyzed to identify encrustation patterns and structural changes on the stent surfaces.

• Elemental composition: EDS was performed at ×10,000 magnification to analyze the elemental composition of the encrustation deposits. Elements, such as calcium, phosphorus, and sulfur, were quantified to confirm the presence of calcium salts and other inorganic deposits associated with encrustation. Images were acquired three times using the ImageJ program.

6. Statistical analysis

Data are expressed as mean±standard deviation. The weight differences between the silicon- and PTFE-covered stents were compared using independent t-tests. The significance level was set at $p<0.05$. All statistical analyses were conducted using the IBM SPSS software version 25.0 (IBM Corp.).

RESULTS

A total of 52 MUS were tested, with 26 covered in silicon and 26 covered in PTFE. Each stent was immersed in AU containing *P. mirabilis* in a biofilm reactor for 48 hours to evaluate encrustation.

1. Weight change and encrustation

Following immersion, the weight gain due to encrustation was significantly lower in the silicon-covered stents than in the PTFE-covered stents. The mean weight gain for silicon-covered stents was 9.50±5.77 mg, while PTFE-covered stents exhibited a mean weight gain of 16.75±10.61 mg ($p=0.004$). When weight gain was normalized by stent length, silicon-covered stents showed a mean encrustation of 0.76±0.45 mg/mm, whereas PTFE-covered stents had a mean of 1.30±0.81 mg/mm ($p=0.004$) (Table 1).

2. Surface morphology analysis via SEM

SEM was performed at magnifications of ×50 and ×5,000 to visualize the surface morphology and assess encrustation coverage. Before immersion, both the silicon-covered stent and the PTFE-covered stent exhibited smooth inner and outer surfaces. However, the inner surface of the PTFE-covered stent was exposed to the metal material. After immersion, salt deposition was observed on the inner and outer surfaces of both stents. Silicon-covered stents exhibited a smoother surface with sparse and minimal encrustation. In contrast, the PTFE-covered stents showed denser and thicker encrustation layers with visibly larger salt deposits, suggesting increased mineral adherence on the PTFE-covered surface (Fig. 2).

3. Elemental composition analysis via EDS

EDS was conducted on ×10,000 SEM images to identify the elemental components of the encrustations on both the silicon- and PTFE-covered stents. The EDS analysis was per-

Table 1. Comparison of the weight gain after immersion test

Parameter	Silicon-covered (n=26)	PTFE-covered (n=26)	p-value
Weight (mg)			
Pre-immersion	37.64±3.70	65.89±5.13	<0.001
Post-immersion	47.14±8.24	82.64±12.72	<0.001
Weight difference (mg)	9.50±5.77	16.75±10.61	0.004
Length (mm)	12.50±0.60	12.89±0.70	0.038
Weight difference per length (mg/mm)	0.76±0.45	1.30±0.81	0.004

Values are presented as mean±standard deviation.
p-values by Student t-test.
PTFE, polytetrafluoroethylene.

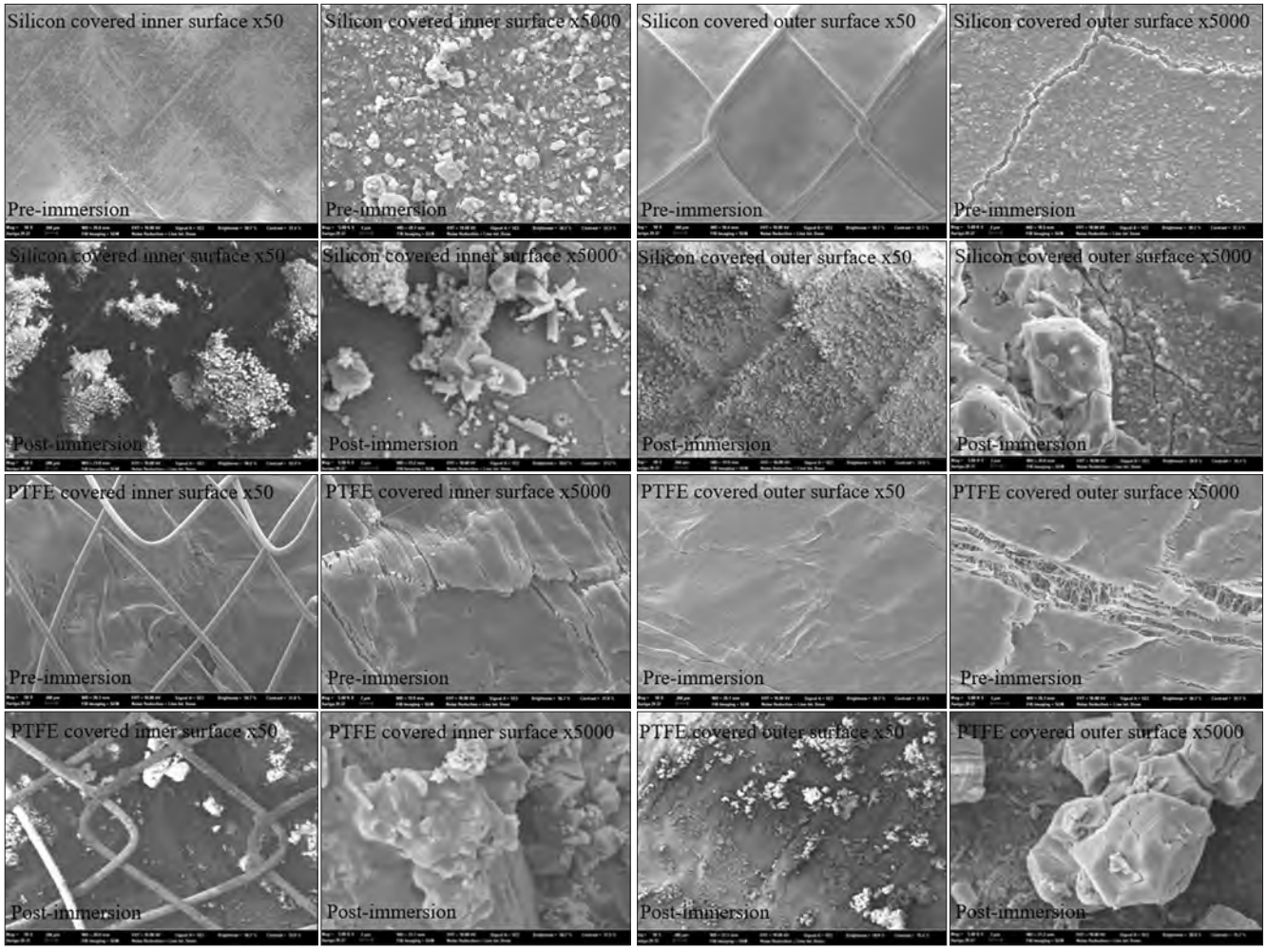

Fig. 2. Scanning electron microscopy images. Polytetrafluoroethylene (PTFE)-covered metallic ureteral stents (MUS) showing extensive encrustation. Silicon-covered MUS with minimal deposits.

formed on the areas with the largest encrustation in each sample. In the EDS examination, the elemental composition was assessed using the high peaks from salt deposition. For both stents, the main components of deposition were magnesium, calcium, phosphorus, and sulfur (Fig. 3).

DISCUSSION

The PTFE-covered stents showed more weight gain from encrustation, and a more extensive surface was displayed in SEM images at ×50 magnification compared to the silicon-covered stent.

Ureteral stents are essential for alleviating ureteral obstruction and maintaining urinary flow [12]. Traditional polymer stents are widely used because of their ease of placement, low cost, and accessibility [13]. These stents are particularly suitable for short-term applications, such as before and after lithotripsy or endoscopic procedures [14]. However, long-term stent placement is often required in cases of ureteral obstruction caused by malignancies, long-term stent placement is often required [15]. Frequent replacement of polymer stents in these patients increases the risk of pain, complications, and healthcare costs [16]. These limitations highlight the need for permanent ureteral stents leading to the development of MUS [17]. Durable MUS is expected to be a viable solution for managing malignant ureteral obstructions while minimizing the need for repeated interventions. However, clinical experience has revealed that these MUS are prone to rapid encrustation and tissue hyperplasia, leading to obstruction and compromised patency [18,19]. Moreover, tissue ingrowth in MUS makes endoscopic removal of the MUS difficult [20].

To address these limitations, MUS has been explored. First, a PTFE-covered MUS is introduced. PTFE-covered MUS has shown promise in maintaining ureteral patency while reducing tissue ingrowth [9]. According to Chung et al. [21], PTFE-covered MUS showed an improved patency rate compared with double-J stents in patients with malignant

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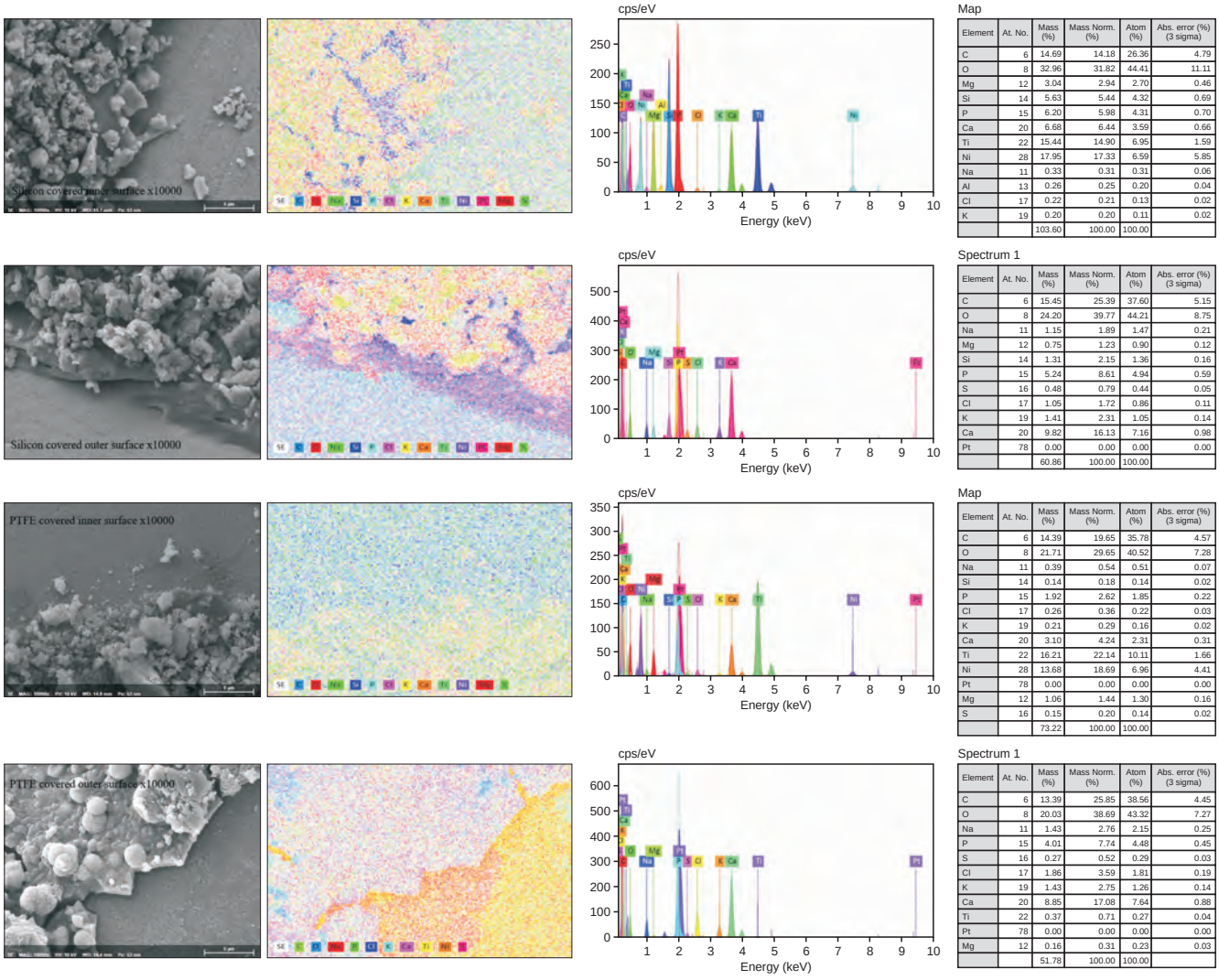

Element	At. No.	Mass (%)	Mass Norm. (%)	Atom (%)	Abs. error (%) (3 sigma)
C	6	14.69	14.18	26.36	4.79
O	8	32.96	31.82	44.41	11.11
Mg	12	3.04	2.94	2.70	0.46
Si	14	5.63	5.44	4.32	0.69
P	15	6.20	5.98	4.31	0.70
Ca	20	6.68	6.44	3.59	0.66
Ti	22	15.44	14.90	6.95	1.59
Ni	28	17.95	17.33	6.59	5.85
Na	11	0.33	0.31	0.31	0.06
Al	13	0.26	0.25	0.20	0.04
Cl	17	0.22	0.21	0.13	0.02
K	19	0.20	0.20	0.11	0.02
		103.60	100.00	100.00	

Spectrum 1

Element	At. No.	Mass (%)	Mass Norm. (%)	Atom (%)	Abs. error (%) (3 sigma)
C	6	15.45	25.39	37.60	5.15
O	8	24.20	39.77	44.21	8.75
Na	11	1.15	1.89	1.47	0.21
Mg	12	0.75	1.23	0.90	0.12
Si	14	1.31	2.15	1.36	0.16
P	15	5.24	8.61	4.94	0.59
S	16	0.48	0.79	0.44	0.05
Cl	17	1.05	1.72	0.86	0.11
K	19	1.41	2.31	1.05	0.14
Ca	20	9.82	16.13	7.16	0.98
Pt	78	0.00	0.00	0.00	0.00
		60.86	100.00	100.00	

Map

Element	At. No.	Mass (%)	Mass Norm. (%)	Atom (%)	Abs. error (%) (3 sigma)
C	6	14.39	19.65	35.78	4.57
O	8	21.71	29.65	40.52	7.28
Na	11	0.39	0.54	0.51	0.07
Si	14	0.14	0.18	0.14	0.02
P	15	1.92	2.62	1.85	0.22
Cl	17	0.26	0.36	0.22	0.03
K	19	0.21	0.29	0.16	0.02
Ca	20	3.10	4.24	2.31	0.31
Ti	22	16.21	22.14	10.11	1.66
Ni	28	13.68	18.69	6.96	4.41
Pt	78	0.00	0.00	0.00	0.00
Mg	12	1.06	1.44	1.30	0.16
S	16	0.15	0.20	0.14	0.02
		73.22	100.00	100.00	

Spectrum 1

Element	At. No.	Mass (%)	Mass Norm. (%)	Atom (%)	Abs. error (%) (3 sigma)
C	6	13.39	25.85	38.56	4.45
O	8	20.03	38.69	43.32	7.27
Na	11	1.43	2.76	2.15	0.25
P	15	4.01	7.74	4.48	0.45
S	16	0.27	0.52	0.29	0.03
Cl	17	1.86	3.59	1.81	0.19
K	19	1.43	2.75	1.26	0.14
Ca	20	8.85	17.08	7.64	0.88
Ti	22	0.37	0.71	0.27	0.04
Pt	78	0.00	0.00	0.00	0.00
Mg	12	0.16	0.31	0.23	0.03
		51.78	100.00	100.00	

Fig. 3. Energy dispersive X-ray spectroscopy at ×10,000 magnification of scanning electron microscopy images. PTFE, polytetrafluoroethylene; At. No., atomic number; Mass Norm., mass normalized; Abs. error, absolute error.

ureteral obstruction (81.7% vs. 64.8%). However, PTFE-covered MUS has some complications, such as persistent stent migration and encrustation [22]. Second, silicone-covered MUS has introduced significant advancements in the treatment of malignant ureteral obstructions [23]. Silicone, which has a non-reactive smooth surface, can reduce the risk of tissue ingrowth [24]. Silicon-covered MUS showed superior protection against stent occlusion without sacrificing stent stability compared with traditional polymer stents [10,23-25]. However, previous studies that assessed the efficacy of silicon-covered MUS had small sample sizes and short-term follow-up. Moreover, no study has compared the efficacy of PTFE-covered MUS and silicon-covered MUS.

Because MUS is placed in the human body for a long period of time, its durability must be guaranteed. In a long-term follow-up study of PTFE-covered MUS, an overall success rate of 78.7% was reported over a mean follow-up period of 41.4 months [26]. This long-term follow-up study demonstrated the durability of PTFE-covered MUS. However, a long-term follow-up study of silicon-covered MUS has not yet been reported.

MUS is indicated for patients with malignant ureteral obstruction, where long-term ency is crucial, not for stone surgeries. To simulate a high-risk environment for encrustation, this study used AU inoculated with *P. mirabilis*. *P. mirabilis* is a key pathogen in urinary stone formation primarily because of its ability to induce stone formation via urease. Urease hydrolyzes urea into ammonia and carbon dioxide, a reaction that increases urinary pH, creating an alkaline environment. This alkalinity facilitates the precipitation of mineral crystals such as struvite (magnesium ammonium phosphate) and calcium phosphate. Furthermore, *P. mirabilis* forms biofilms that adhere to the surfaces of ureteral stents or catheters, thereby providing protection from external de-

fense mechanisms. These biofilms promote stone formation, leading to urinary obstruction and stent blockage [11]. This model effectively mimics the conditions that lead to encrustation *in vivo*, providing a robust platform for assessing the performance of different stent-covered materials under clinically relevant conditions [27]. In this study, silicon-covered MUS showed superior resistance to encrustation compared with PTFE-covered stents, as evidenced by lower weight gain and reduced surface deposition. These findings suggest that silicon coverings may be more effective in preventing encrustation, thereby potentially reducing the need for frequent stent replacement and improving patient outcomes.

Although the results of this study are promising, several limitations should be considered. The *in vitro* model used here does not fully replicate the complex dynamics of the human urinary tract, where factors such as urine composition variability, flow rates, ureteral peristalsis and patient-specific variables can affect encrustation behavior differently than those in a controlled laboratory environment. Additionally, our model utilized *P. mirabilis* as a representative uropathogen; however, other common bacteria such as *Escherichia coli* and *Klebsiella pneumoniae* may also influence encrustation outcomes in clinical settings. Testing against a broader range of bacterial species could provide more comprehensive insights into the stent performance. However, this study is the first to provide direct comparative data on the encrustation behavior of PTFE and silicon-covered MUS. This study may serve as a foundational reference for future research and development of ureteral stents aimed at maximizing patency while minimizing patient discomfort and health care costs.

CONCLUSIONS

The silicon-covered MUS demonstrated superior resistance to encrustation compared to the PTFE-covered MUS in an *in vitro* setting, suggesting that silicon may serve as a more effective covering material for MUS intended for prolonged use.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

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AUTHORS' CONTRIBUTIONS

Research conception and design: Deok Hyun Han and Jae Hoon Chung. Data acquisition: Jae Hoon Chung. Statistical analysis: Jae Hoon Chung. Data analysis and interpretation: Deok Hyun Han and Jae Hoon Chung. Drafting of the manuscript: Deok Hyun Han and Jae Hoon Chung. Critical revision of the manuscript: Deok Hyun Han and Woo Jin Bang. Obtaining funding: Jae Hoon Chung. Administrative, technical, or material support: Deok Hyun Han and Jae Hoon Chung. Supervision: Deok Hyun Han and Woo Jin Bang. Approval of the final manuscript: all authors.

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