INTRODUCTION AND OBJECTIVE:

Biodurability can be defined as the ability of the stent material (polymer) to resist 1) the absorption of biomolecules (proteins) on the stent, 2) cellular interactions and 3) encrustation and surface penetration by chemicals within the urine. All of these lead to a degradation of the polymer and ultimately result in a loss of critical physical characteristics such as strength, flexibility and elasticity. Complications associated with this degradation include stent fracture, stent migration and patient discomfort (sometimes associated with stent hardness). The objective of this paper is to summarize and compare the biodurability of the InLay Optima® stent and Percuflex® Plus stent at six months through in-vitro testing.

METHODOLOGY:

Artificial urine was made per the specifications detailed in the British Standard for simulated/artificial urine formulation. Thirty (30) 6Fr Inlay Optima® stents and thirty 6Fr Percuflex Plus® stents were soaked in artificial urine for 180 days at 37°C. Testing was done following the 6-month exposure period. This testing was done based on ASTM F 1828 Standard Test Methods for Ureteral Stents and FDA Guidance Document for the Content of PreMarket Notification for Ureteral Stents. The tests that were completed included:

- **Tensile and Elongation Tests**: Post urine soaked samples were placed in a test fixture and pulled until the stent broke apart. The force required to break the stent, the amount the stent stretched before breaking and the location of the breakage were all recorded. Tensile and Elongation are tests that look at the stent’s strength. This, again, is important during the stent removal process. This test was conducted according to ASTM F 1828 – 97 Standard Specification for Ureteral Stents, 6.3 Break Strength.

- **Coefficient of Friction**: Test based on ASTM D 1894 – 95 Standard Test Method for static and kinetic coefficients of friction of plastic film and sheeting. The method is a sled test conducted in a wet environment utilizing a calibrated Chatillon Gauge. This test measures the overall lubriciousness of the stent.

- **Coating Durability**: All of the stents were tested for the presence of coating after 180 days. This was done using either cresol red or congo red stain.

- **Flexibility**: The test criteria were based on ASTM D 747-02 Standard Test Methods for Ureteral Stents and FDA Guidance Document for the Content of PreMarket Notification for Ureteral Stents. The standard test method is performed on a bending apparatus by means of a cantilever beam obtained from Tinius Olsen Testing Machine Company, Inc. Testing was done at body temperature.

- **Flow Rate**: Testing was completed to determine the flow rates after soaking. Flow rates are a function of a stent’s ability to pass fluid at a specified rate per minute.

- **Coil Retention**: Testing was done to look at the force needed to uncoil the stents respective pigtails and to determine if any changes occurred to stents after exposure to urine. Migration can occur if the coils do not have good coil retention. Stents were tested according to ASTM F 1828 – 97 Standard Specification for Ureteral Stents, 6.2 Retention Strength. This test method measures the ability of a Ureteral Stent to resist migration.

RESULTS:

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Tensile Strengths (Lbs)</th>
<th>Coefficient of Friction</th>
<th>Flexibility at Body temperature</th>
<th>Flow Rate (ml/min)</th>
<th>Coil Strength (lbs)</th>
<th>Coating Durability # Showing No Stain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bard® InLay Optima® Stent</td>
<td>3</td>
<td>6.61</td>
<td>0.180</td>
<td>0.055</td>
<td>96.5</td>
<td>0.165 (Bladder) 0.160 (Kidney)</td>
<td>0</td>
</tr>
<tr>
<td>Microvasive Percuflex® Plus Stent</td>
<td>3</td>
<td>4.84</td>
<td>0.278</td>
<td>0.120</td>
<td>85.1</td>
<td>0.156 (Bladder) 0.153 (Kidney)</td>
<td>30</td>
</tr>
</tbody>
</table>
Comparison of Biodurability: Bard® InLay Optima® Ureteral Stent and Microvasive Percuflex® Plus Ureteral Stent at 6 Months

CONCLUSIONS:
The Inlay Optima® stent after six months of soaking in artificial urine had greater flexibility at body temperature, was more lubricious, had higher tensile strengths and flow rate than the Percuflex® Plus stent. The InLay Optima® stent also had better coating durability with 30/30 samples showing coating after 180 days compared to the Percuflex® Plus stent, which showed no coating.

REFERENCES:
1. Stenting the Urinary System
   Daniel Yachia, MD

*Study performed by C. R. Bard, Inc.
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