Development of a Fiber-reinforced, Composite, Absorbable Ureteral Stent, Uriprene®

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Statement of Purpose: Ureteral stents are a common tool in urologic practice. Since the development of the non-absorbable, double-pigtail stent in 1978,[1] the search for the ideal ureteral stent continues and patients continue to suffer from stent-related morbidity ranging from irritation and discomfort to sepsis and renal compromise from encrusted "forgotten" stents. In their search for an ideal stent, a number of investigators and inventors attempted to use absorbable polymers to construct new stents that do not require a second procedure for their removal, among other attributes associated with their transient nature.[2-4] However, none of these attempts has led to clinically successful products due to faulty design and/or improper selection of absorbable polymers having the optimum absorption and breaking strength retention profiles for use as a safe and effective transient ureteral stent. In view of such an unmet need for an absorbable ureteral stent, Poly-Med's consistent interest in absorbable fibers and fibrous, single-component and composite constructs with modulated biological properties and recent development of radiopaque, hybrid, absorbable monofilaments[5-9] prompted the pursuit of the present study. This deals with the development of a novel ureteral stent featuring a load-bearing radiopaque coil and knitted scaffold in a flexible matrix.

Methods: Polymers for the mesh, coil, and matrix were produced as previously described.[5-9] Initially, a coil was prepared over a continuous support to provide control over internal diameter of the stent. A weft-knitted multifilament yarn[9] was placed over the coil and impregnated with a polymer matrix. The construct was subsequently dried, heat set into final shape and placed in a tray for final packaging and sterilization. Stents were packaged with a polyethylene pusher (for deployment) in a hermetically sealed pouch with desiccated nitrogen atmosphere. Packages were sterilized with 25 to 30 kGy γ-irradiation and tested for shape retention and mechanical properties before release.

Results: Early designs of the Uriprene® ureteral stent were refined to the current design and reflect changes to enhance the clinical relevance of the device. The current design includes (1) a coil providing axial integrity and radiopacity, (2) knitted scaffold to contain central coil and provide lattice for matrix, and (3) matrix to stabilize construct and maintain heat set. *Figure 1* depicts the typical shape of an Uriprene® Stent with two pigtail retaining loop ends.

Figure 2 better illustrates the interior coil that forms the load-bearing radiopaque component of the reinforcing scaffold of the stent that allows monitoring the fate of the stent by X-ray during the use period.

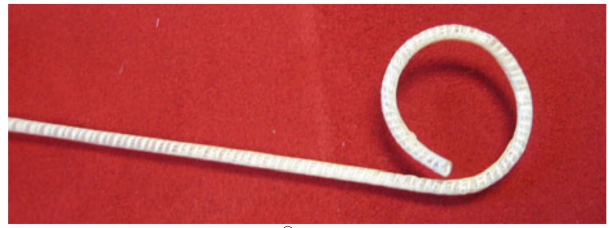

Figure 1: Uriprene® Proximal Pig Tail Loop

Figure 2: Uriprene® Reinforcing Radiopaque Coil

Mechanical testing was performed to evaluate stent functionality. Axial compression testing was used to verify the ability of the stent to be inserted using standard placement procedures, while radial compression testing was used to verify radial integrity. Pigtail loops are used to maintain implant position; curl retention strength was used as a measure of the ability to maintain initial position. Table I summarizes typical initial testing results for the 3rd generation Uriprene® stent. The current design is not visually detectable after 4 weeks and can be produced with 20, 22, 24, 26, 28, and 30 cm lengths.

Table I. Typical Uriprene® Mechanical Properties

Test	Range
Axial Compression	2.2 - 6.6 N
50% Radial Compression	53 - 98 N
Curl Retention Strength	> 0.5 N
Yield Strength	61 – 134 N

Conclusions: Results of the study demonstrate the ability to construct a composite, absorbable/disintegrated ureteral stent that is well-suited to overcome most of the clinical problems associated with its non-absorbable counterparts.

References:

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