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Author(s) R Dmochowski[1], D Galen[2]

Institution, city, country Urology Associates of North Texas, Dallas TX USA[1] and Reproductive Science Center of the San Francisco Bay Area, San Ramon, CA USA[2]

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EVALUATION OF SUBACCUTE TISSUE RESPONSE IN AN ANIMAL MODEL TO EVALUATE A NOVEL THERAPY TO TREAT STRESS URINARY INCONTINENCE

Aims of Study For over 30 years, it has been recognized that the collagen in tissue when heated to between 60°C to 100°C will denature and shrink This characteristic of collagen has been used successfully in other medical specialties such and orthopedics and neurology It has been proposed that using radio frequency (RF) energy to shrink the endopelvic fascia using a novel electrosurgical device would result in the elevation of the urethrovesical junction which would improve stress urinary incontinence (SUI) This study characterized the amount of shrinkage, the tissue injury and healing response following RF shrinkage of tissue in an animal model Since this device is intended to treat SUI, the safety of RF energy applied directly to the urinary bladder was also evaluated

Methods: Porcine peritoneal fascia was used as a tissue response model to evaluate injury and healing using a low power RF energy delivery system (SURx, Inc , Pleasanton, CA) Six adult pigs were anaesthetised and laparoscopically treated at 36 separate sites of the internal abdominal wall Additionally, in four animals the thermal effect was evaluated on the peritoneal surface of the urinary bladder Animals also received additional treatments immediately prior to sacrifice to evaluate acute thermal injury response Animals were sacrificed at 0, 7, 21, and 42 days Histologic evaluations were performed using standard Hematoxylin and Eosin straining of Paraffin embedded tissue samples Thermal injury and healing over time were described using quantitative measurement of tissue shrinkage and by measurement of depth of collagen denaturation and tissue injury response

Results: Gross tissue shrinkage of 25% to 50% was noted at the time of the procedure Degree of denaturation was quantified and depth of penetration was measured The average depths of injury repair for treatments were

	Acute	7 days	21days	42 days
Tissue response depth	1 0-2 0mm	2 2mm	4 5mm	4 7mm

Histologic outcomes included total reperitonealiztion of treatment site, acute followed by chronic inflammatory changes and finally resolution of inflammatory response and chronic fibrotic replacement of denatured cell matrix with reabsorption of acute cell debris at 30 days of longer Treatment of the urinary bladder surface resulted in rapid healing with no internal mucosal damage and no significant lesions

Conclusions: The use of precisely delivered low power RF energy shows substantial tissue shrinkage and controlled treatment depths Wound healing response was comparable to that seen with other more expensive or more traumatic surgical modalities such as laser, electrosurgery or scalpel approach No adverse effects of this treatment on the urinary bladder were noted RF tissue shrinkage may hold promise for the treatment of SUI in humans

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