397

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AN ADAPTABLE TELEMETRY CONTROLLED SPHINCTER FOR THE TREATMENT OF SEVERE STRESS URINARY INCONTINENCE IN MALE AND FEMALE PATIENTS

Hypothesis / aims of study

Urinary incontinence (UI) is a devastating physical disability affecting more than 15 million people only in the USA.
Artificial urinary sphincters (AUS) are used in the treatment of SUI and functions by occluding the urethral striated sphincter. Whereas AUS have become the gold standard for the treatment of male severe UI (SUI), the implantation of the same device in women remains limited. A potential downside of AUS is the need for periodic revisions.
Myopowers has developed a novel Artifical Urinary Sphincter. This active medical implant has features to permit an adaptive therapy over time. The Control Unit (CU) consists of the microdrive, the Cuff and its Transmission, the electronics, the antenna, the software and a battery. The silicone-made cuff is to be placed around the urethra of a female or male patient. There are two remote controls: one for the patient and one for the urologist (see Fig 1).
The Objectives of this study were to test in a relevant animal model the functionality of such a device and to see if the intra urethral pressure can be modulated over time using a telemetry.

Fig 1: View of the Artificial Sphincter. The motor pulls on the cuff to modulate its diameter. The cuff is closed around the urethra.

Study design, materials and methods

Animal Models and study design

Twelve (12) female pigs weighting from 170 to 160 lbs were enrolled in the study.
The animals we divided in 3 groups and euthanized at 3, 6 and 9 weeks postoperatively.
At implantation and prior euthanasia the implant functionalities (Remote control and urodynamic testing) were tested. Under general Anaesthesia, the abdominal cavity was opened through a 10 cm longitudinal incision. The trigone was localized and the urethra was dissected 2-3 cm from the ligament toward the distal end. The cuff was positioned at the distal end to the right of the urethra. The locking position was adjusted to the urethra. The bladder and the urethra were replaced into the abdominal cavity. A subcutaneous pouch was prepared to place the Control Unit on the midline.

Urodynamic measurement

Urodynamic pressure measurements were performed using a Solar Blue urodynamic system from Medical Measurement System. This device was used with a three-way urodynamic catheter.

Results

One animal died due to a stress related gastric ulcus.
The cuff could be controlled with the telemetry at various closing pressure. The intrinsic sphincter could be well identified on the urodynamic profile. The cuff was seen on the urodynamic profile just before the intrinsic sphincter.
After 3, 6 and 9 weeks the cuffs could be still manipulated via telemetry and the intra urethral pressure could be increased while closing the cuff. Those variations were similar than at implantation. Starting at 6 weeks the cuffs were covered by a thick granulation tissue. This reactive tissue had no effect on cuff mechanical behaviour, neither the change in the intraluminal urethral pressure induced while closing the cuff. Histological analysis is ongoing.

Interpretation of results

The present results demonstrate the functionality of the telemetry in the modulation of the Artificial Sphincter Invivo.
The Intra urethral pressure can be modulated by the variation of the diameter of the cuff upon time. The tissue reaction around the cuff does not impege cuff motion.

Concluding message

This novel urinary sphincter device permits intra urethral pressure modulation over time by controlled urethral compression. The device produces intra urethral pressure patterns that are similar to natural sphincter pressure behaviour. The device is controlled by telemetry. The present animal study demonstrates the proof of concept of this new device for the treatment of severe stress incontinence.

Disclosures
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