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LAPAROSCOPIC IMPLANTATION AND EVALUATION OF A TELEMETRIC SPHINCTER PROSTHESIS FOR URINARY INCONTINENCE IN PIGS – EVALUATION OF FIRST RESULTS.

Hypothesis / Study Objective

The first artificial sphincter was implanted in 1947 by Foley. Since then, sphincter prostheses have become a crucial instrument in the therapy of high-grade urinary incontinence. In fact, the currently most widespread systems, i.e. the AMS 800 [1] and the FlowSecure System [2], have been implanted over 100.000 times. These systems both entail at least 3 components that are implanted in different anatomical compartments. Also both systems use hydraulic mechanisms and are manually controlled.

In the past, we developed a fully telemetric sphincter prosthesis, the German Artificial Sphincter System (GASS). Here we report on the implantation of this prosthesis in two pigs. Our goal was to test whether continence can be achieved while at the same time providing adequate tissue protection. Furthermore, we tested a laparoscopic implantation technique.

Study Design, Materials and Methods

GASS consists of three distinct elements (Abb1): an inflatable cuff for around the urethra, a bidirectional micropump that works with Piezo technology, a microprocessor with an integrated pressure sensor, and a reloadable battery. Furthermore, GASS contains a unit for bidirectional signal transmission. Reloading the battery was achieved by tunnelling a cable subcutaneously.

The software for controlling GASS was programmed with Labview® (LabView Version 8, National Instruments Corporation, 11500 N Mopac Expwy, Austin, TX78759-3504) and run off a PC.

The implantation was performed laparoscopically in 6-month-old female pigs weighing roughly 35kg.

Ischemic tissue damage was quantified by continuous measurement of oxygen saturation and capillary blood flow using a Laser Doppler Remission Spectrophotometry sensor (O2C1111 System, LEA Medizintechnik, Giessen, Germany) that was placed in between the cuff and the urethra. Following explantation, the urethra was histologically examined.

Results

The implantation was achieved without complications, and the prosthesis was positioned immediately distal of the vesical cervix. The experiment lasted 6 days. Continence was successfully established over the duration of 12 hours, spontaneous micturition was allowed three times during this period. During the night, the system was deactivated. A suprapubic catheter was implanted to guarantee vesical relief in the case of a system shut-down. The control unit was implanted intramuscularly in the animal's flank, and the cable for reloading the battery was tunnelled subcutaneously and stowed in a special backpack.

The flow rate of the micro pump is 3,4 ml/min in vitro. The cuff has a volume of 4 ml thus leading to a continent state after roughly 2 minutes. Here, we illustrate that an increase of compression pressure to 160 mbar, which correlated with the continent state of the animal, only lead to a mild decrease of tissue oxygen saturation as well as blood flow. To support this, a histological post-mortem examination of the urethra showed no signs of ischemic or pressure-related tissue damage.

On the second postoperative day, the system became uncontrollable due to a disruption of the connection to the telemetric unit. The prosthesis and the control unit remained in vivo. The cuff remained in the continent state, micturition was guaranteed via the suprapubic catheter. Following explantation, we observed that fluid had entered the control module. Nonetheless, the system was telemetrically operational without technical intervention in our lab.

Interpretation of results

We illustrate that continence can be achieved with our telemetric system without compromising vital tissue in the animal model. Laparoscopic implantation is a feasible method. The system shut-down was most likely caused by a disturbance of the connection due to mechanical stress.

Concluding message

To conclude, laparoscopic implantation in the animal model was both feasible and secure. Furthermore, we illustrate that a telemetric sphincter prosthesis is indeed feasible. Our next objective is to redesign the telemetric components in order to provide a more stable and stronger connection with the control unit.

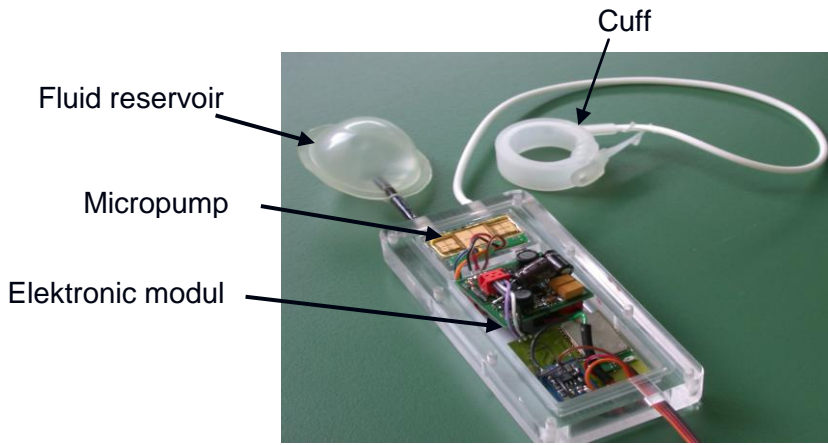
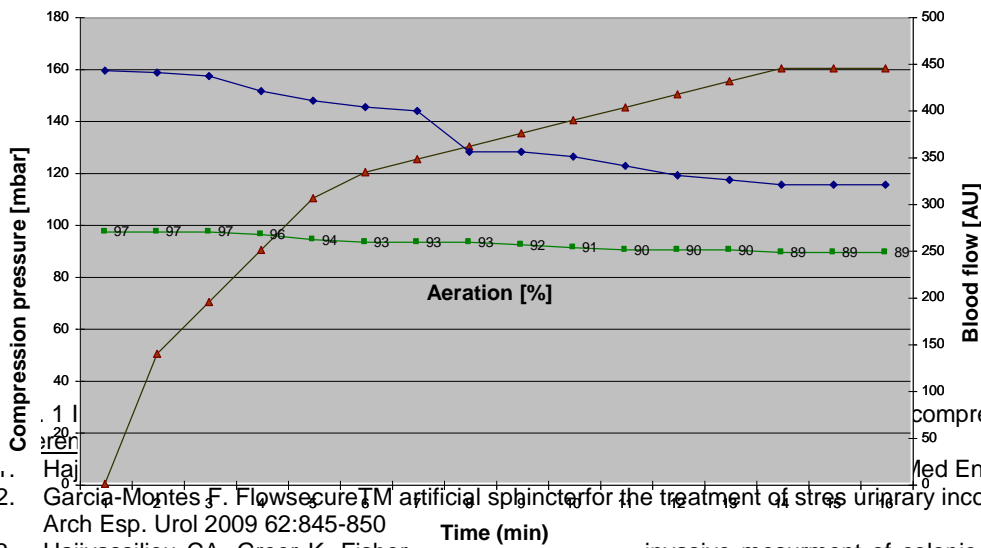


Abb. 1 GASS -Prototype



1. Hajivassiliou CA, Greer K, Fisher JA, et al. Non-invasive measurement of colonic blood flow distribution using laser Doppler imaging. 1998 Br J Surg; 85: 52 – 55.
2. Garcia-Montes F. Flowsecure™ artificial sphincter for the treatment of stress urinary incontinence after radical prostatectomy. Arch Esp. Urol 2009 62:845-850
3. Hajivassiliou CA, Greer K, Fisher JA, et al. Non-invasive measurement of colonic blood flow distribution using laser Doppler imaging. 1998 Br J Surg; 85: 52 – 55.

Specify source of funding or grant	We illustrate that continence can be achieved with our telemetric system without compromising vital tissue in the animal model. Laparoscopic implantation is a feasible method. The system shut-down was most likely caused by a disturbance of the connection due to mechanical stress.
Is this a clinical trial?	No
What were the subjects in the study?	ANIMAL
Were guidelines for care and use of laboratory animals followed or ethical committee approval obtained?	Yes
Name of ethics committee	Thüringen Lower Saxony Office for Consumer Protection and Food Safety, Germany Reg. Nr. 08-004/08