

THE ELECTRONIC MODULAR ARTIFICIAL SPHINCTER ARTUS: RESULTS OF THE CADAVER STUDY

Hypothesis / aims of study

The AMS 800 sphincter is considered to be the gold standard in the treatment of severe stress incontinence. However the permanent pressure on the urethra can result in severe complications, i.e. tissue atrophy, urethral arrosion. A new electronic device which can compress successive parts of the urethra intermittently can reduce these risks. Based on the animal studies we start the usability test in cadavers.

Study design, materials and methods:

In 6 cadavers (3male,3 female) with different BMI we implant the electronic modular system ARTUS.

The cuffs were implanted by a perineal incision. The cuffs were located in the peno-bulbar in male and in the proximal urethra in female. The battery and control unit were implanted in the right lower abdomen, therefore it was performed a subcutaneous pouch. The guiding wires were passed lateral to the spermatic cord to the cuffs. After that the system was connected. The cuff size and the length of wires were measured, the localisation of the control and battery unit were documented.

Results

The implantation of the new sphincter is easily done by the same technique than the AMS 800. The cuff size is 4.5 cm in male and 6 cm in female. The average length of wires is 12 cm (10.5-14cm). The subcutaneous pouch for the battery and control unit has to be bigger than the space for the tubes of AMS 800. There is no difference in implantation in cadavers with low, middle and high BMI.

Interpretation of results

Our results show that the new sphincter ARTUS can be implanted easily in cadavers.

The technique is almost the same like in the AMS 800 sphincter. Only the length of wires shows a difference according to BMI.

Concluding message

The results of the cadaver study show the usability of the new sphincter ARTUS.

The clinical investigation will start in the near future.

<i>Specify source of funding or grant</i>	first author is clinical director of myopowers SA.
<i>Is this a clinical trial?</i>	No
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	No
<i>This study did not require ethics committee approval because</i>	the study was a cadaveric study, the legal medicine was responsible for approval by the ethics committee.
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	No