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A new automated electronic artificial urinary sphincter: Results of the first in man study at 3 months post-activation (SOPHIA study)

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Introduction & Objectives: UroActiveTM (UroMems, France) is an implantable artificial urinary sphincter made of an occlusive cuff(OC) connected to a Control Unit(CU) which includes a reservoir, a pump, a battery and electronic components able to communicate wirelessly(Fig). The OC is placed around the bulbar urethra and the CU is placed in the right part of the abdomen above the rectus aponeurosis. During follow-up visits, the clinician can download data recorded by the CU and set device parameters via a programmer. The patient can open the cuff to void and decrease device pressure when lying down using a dedicated remote control. A safety function named UroTimerTM automatically deactivate the device if the patient does not void during a certain period. UroactiveTM is neither CE Marked nor FDA approved yet.

Materials & Methods: This study was a prospective, open-label, multi-center, single-arm study designed to assess the safety and the effectiveness of UroActive™ device in 6 patients (NCT05547672, French ethical committee approved). After the implantation and a healing period of 5 weeks, the device is activated. Follow-up visits are planned at day 14; 1, 3 and 6 months post-activation to adjust device parameters according to patient feedback on continence. Primary Outcome Measures were rate of device activation successes and rate of explantation or revisions at 6months. Main Secondary Outcome Measures were the number of subjects with 50% reduction or greater in 24-hour pad weight test (24H-PWT) at 3 and 6 months after activation.

Results: The 6 patients (median age=69y; IQR=7) were incontinent after radical prostatectomy. All devices were successfully implanted and activated. No explantation were observed nor revision required. One patient had a hematoma following the surgery.
At 3 months after device activation:
· According to CU data, patients performed a mean of 8 micturition/day (IQR = 3) and spent a mean of 7hours/day (IQR=40minutes) with a low-pressure.
· All patients had a 24H-PWT reduction of more than 50% (median =84%, IQR = 8%). Median Qmax was 34ml/s (IQR = 10).
UroTimerTM safety function triggered 3 three times because of function setting (time too short) and once following an adverse event unrelated to the device. All devices were reactivated without difficulties.

Conclusions: UroActive™ met the safety and efficacy targets at 3 months post-activation, allowing the study to continue.