Efficacy and safety of a new adjustable artificial urinary sphincter (AROYO™) for the treatment of male stress urinary incontinence: RELIEF I study with 12 months follow up

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Hypothesis, Aims of Study:
1. to evaluate the feasibility of the new adjustable AROYO™ device for the treatment of male SUI
2. to provide enough information to power the global, multicenter, prospective RELIEF II study

Study Design, Materials and Methods:
RELIEF I: a prospective, single arm, feasibility study
10 men with SUI after RP or TURP in two centers 2013 – 2015
implanted via penoscrotal approach
activation 6 weeks after implantation
follow-up at 1, 3, 6 and 12 months after activation
repressurization at follow up visits and at any time between visits
Primary endpoint:
change in 24h PWT from screening to 3 months
Secondary endpoints:
changes in 1h PWT, number of incontinence episodes/day, average number of pads/day,
questionnaire scores (ICIQ, ICIQ-MLUTS, IIEF), subject opinion on ease of device use, and summary of the use of manual compression feature and surgical parameters
Primary safety endpoint:
occurrence of any major device-related complications

Results:
10 patients: 9 after RP and 1 after TURP (mean age 68.8 y)
mean implantation time 80 minutes with a relevant reduction of the last procedures
Two patient populations were defined:
Intent-To-Treat: 9 patients (1 patient explanted 3 weeks after implantation due to urethral injury)
Per Protocol: 7 patients (1 explanted, 1 with device malfunction, 1 with incorrect baseline data excluded)

Concluding Message:
The new adjustable artificial sphincter AROYO™ has shown to effectively and safely treat male SUI with a follow up of 12 months