IMPROVEMENT OF INTERSTITIAL CYSTITIS SYMPTOMS AFTER CHRONIC PELVIC FLOOR ELECTROSTIMULATION: UPDATED RESULTS OF A MULTICENTRE STUDY.

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Hypothesis / aims of study
Interstitial Cystitis (IC) is a disabling non-malignant condition of the lower urinary tract, the etiology which is uncertain. IC typically presents as a syndrome of pain and lower urinary tract symptoms (frequency, urgency, dysuria, and/or nocturia) and poor quality of life (1,2).
There is no universally effective treatment for IC, but it typically includes a combination of methods such as multimodal behavioural and lifestyle modification, pharmacological treatment, bladder instillations and hydro-distension. However, these treatments may only provide temporary relief of symptoms.
The purpose of our study has been to assess the efficacy of chronic pelvic floor stimulation using a novel active implantable system, the miniaturo™-I system (BioControl Medical Ltd., Israel), on IC symptoms (3). This abstract presents the most recent data from the ongoing study.

Study design, materials and methods
The study is an international, multicentre, prospective observational trial. Adult women at six centres, diagnosed with IC for more than 12 months, who have failed to achieve acceptable benefit from conservative management were eligible for the study. After undergoing 6 - 24 hours of test stimulation, patients who derived a reduction in pain and urinary frequency underwent a simple surgical procedure (under epidural or local anesthesia) for chronic implantation of the system.
A pulse generator (size 53 x 47 x 11 mm) was implanted subcutaneously through a 4-5 cm suprapubic incision and secured to the rectus sheath. A bipolar stimulation lead was inserted paraurethrally and connected subcutaneously to the pulse generator. The system was activated via a telemetry device to deliver intermittent pulses through the lead to the pelvic floor with the intensity determined individually according to the patient's sensations.
Treatment success was measured by pain and voiding diary and response to quality of life questionnaires (QoL) including O'Leary-Sant symptoms and problem Indices (O'Leary-Sant Indices), Short-form McGill Pain Questionnaire (SF-MPQ) and Pelvic pain and Urgency/Frequency patient symptoms scale (PUF) at 1, 3, 6 and 12 months following implantation. Multi-centre research ethics committee approval has been granted for this study.

Results
Out of thirty-four patients, mean age 50.5 years (range 28-80 years) who were enrolled, five failed the test stimulation and so twenty nine women underwent the chronic implantation. Three women subsequently withdrew from the study 3 to 9 months post surgery because they did not feel significant improvement.
Data analysis was available for twenty-three patients who have completed a mean follow up period of 8 months (range 1 to 24 months). The remainder have completed less than one month follow up at the time of submission.