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THE SPANISH REMEEEX SYSTEM IMPLANT REGISTRY.

Hypothesis / aims of study

The Spanish Working Group initiated a registry to be able to analyse and review the results with a large group of patients (683). Mid and long term follow up will be analysed to reach conclusions on the safety and efficacy of this particular technique.

Study design, materials and methods

A Registry of 683 patients that were operated on with a readjustable incontinence prosthesis (Remeex System) in 15 different Spanish Hospitals was created, to evaluate the safety and efficacy of the sling readjustability concept. For the surgical treatment of female urinary stress incontinence.

Mean age was 59.9 (range 21 – 87) with a mean follow up time of 23 months (6 - 93). As the technique was used initially in complicated patients, the group includes 30.2% of patients with clinical mixed incontinence, 33.1% of patients with urodynamic ISD, 35.7% had previous failed incontinence interventions, and 54.3% with associated pelvic floor surgery. All patients were analysed pre op by a clinical history, physical examination, urodynamic test including Valsalva Leak Point Pressure (VLPP) and/or Maximal Urethral Closure Pressure (MUCP) and an incontinence questionnaire. In every follow up, patients had an incontinence questionnaire, physical examination and cough test.

Results

The cure rate at last follow up was 92.2%, with additional improvement in 6.9% of the patients. 0.9% were regarded as failures. Immediate Post-op Adjustment was used in 416 (60.9%) of patients as an extension of the intervention during the next 24 – 48 hours, before patient hospital discharge. 80 patients (11.7%) were mid-long term readjusted (6 – 18 months after surgery) to recover full dryness. Of this 80 patients, 77 patients had a sling support level increase and three patients had a sling support level lowered (6 to 14 months after surgery). No other patient complained of long term voiding difficulties, 1.7% had an extraction of the varitensor due to a persistent abdominal seroma. 0.8% had sling exposure in the vaginal wall. Analysing results by specific diagnostic groups of patients (ISD and Recurrent patients) the results maintain consistent at the cure rate level of 86% and 89.1%.

Interpretation of results

The Remeex system implant was designed to treat stress urinary incontinence by recovering the urethral continence pressure. The sling urethral support level was able to be adjusted to very particular patient needs in every case 24 to 48 hours after the surgical procedure. Due to the edema after the intervention further adjustments 11,7% of the patients where needed to reach the cure rate of 92.2% at last follow up.

Concluding message

The Remeex System is a minimal invasive technique with good consistent results even in non homogenous groups of patients, including ISD, recurrent patients, mixed incontinence, and associated pathology, where other techniques have a lower success rate.