EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Curriculum Vitae

Personal information

Francisco Cruz

Work experience

01/01/1996 – CURRENT – Portugal
SENIOR CONSULTANT OF UROLOGY, PROFESSOR OF UROLOGY AND VICE DIRECTOR OF THE FACULTY OF MEDICINE – Faculty of Medicine and Hospital SJ

Senior consultant of Urology Since 1996
Full Invited Professor of Urology. Since 2011
Vice-Director of the Faculty of Medicine. Since 2018
Group leader of the research group "Translational NeuroUrology" at the University of
Vice-President of SINUG (Socied Ibero-Americana de Neuro-Urologia e Uroginecologia, Since 2015
Chairman of the European Section of Female and Functional Urology (ESFFU) since 2016
Expert for the International Consultation on Incontinence
Member of the Editorial Board at large of European Urology.
Member of the Editorial Board of the Neurourology and Urodynamics
Member of the Editorial Board of the British Journal of Urology
Member of the Academic Association of European Urologists since 2008
Previous relevamt activities>
Chairman of the Department of Urology, between 2003-2018
Member of the Scientific Office of the EAU between 2004 and 2012

Education and training

01/01/1996 – CURRENT – Portugal
SENIOR CONSULTANT OF UROLOGY AND FULL PROFESSOR OF UROLOGY. SEVERAL
POSITIONS IN THE AREA OF FUNCTIONAL UROLOGY IN EUROPEAN ASSOCIATION OF
UROLOGY AND SOCIEDAD IBERO/AMERICANA DE NEUROUROLOGY AND UROGYNECOLOGY – Hospital and Faculty of Medicine

Group leader of a reserch group in a large Institite of Biomedical research
Field(s) of study
Health and welfare
PhD (1993) and Habillition (1998) Morphology of thin primary afferents in Laminae I-II of the spinal cord. (1993)
EQF level 8

Additional information

Publications

Mini-Slings: Do They Stand the Test of Time? A 10-Year Cohort
Urol Int. 2020 Dec 2:1-5. doi: 10.1159/000511648.
2020
It is known that failures after midurethral slings increase with the follow-up time. Nevertheless, data concerning mini-slings are sparse. To clarify this statement, we analyze a mini-sling cohort with a median follow-up of 10 years. Although the brand used, MiniArc®, is no longer available, an identical device, Solyx™, can still be used, which makes the analysis of the cohort clinically

relevant.
A total of 172 women with predominant stress urinary incontinence (SUI) were consecutively treated with the mini-sling MiniArc® from 2006 until 2013. They were reevaluated in 2018. The primary outcome, treatment success, was defined as no self-reported SUI symptoms and no reintervention. Secondary outcomes included the response to patient-reported outcomes. Adverse events were assessed.
After a median follow-up time of 113 months, 115 (66.9%) women were available for reevaluation. Forty-four (38.3%) women self-reported SUI. Seventeen women had been reoperated, 14 (12.2%) due to the reappearance of SUI and 3 due to complications. Altogether, MiniArc® had an overall success rate of 47.0% at 10 years. Among those not reoperated, 63.3% stated that they were much better or very much better in Patient Global Impression of Improvement (PGI-I) and 71.4% affirmed that their continence problem was normal or mild in Patient Global Impression of Severity (PGI-S). Almost 85% would repeat the surgery. Reoperation due to complications was rare (2.6%). De novo urgency appeared in 30.6% of the patients and it was managed with anticholinergic drugs with favorable outcome This report adds evidence to the long-term outcomes of mini-slings, confirming that they can cure or improve SUI and give patients high satisfaction rates, at the expense of low morbidity.

Position of the Ibero-American Society of Neurourology and Urogynecology in relation to the use of synthetic suburethral meshes for the surgical treatment of female stress incontinence

Neurourol Urodyn. 2019. doi: 10.1002/nau.24178
2019
The aim of this paper is to stablish de position of the Ibero-American Society of Neurourology and Urogynecology (SINUG)
in relation to the use of suburethral meshes for the surgical treatment of female stress incontinence. SINUG has reviewed the
evidence and official position of different societies in relation to the safety and efficacy of MUS in the surgical treatment of
incontinence differentiating them from meshes used to repair POP. Data from synthetic mesh manufacturers indicate that in
2010, 300 000 women underwent surgical procedures to repair POP and approximately 260 000 were operated on for SUI.
According to these estimates, approximately more than 80% of the surgical techniques for UI treatment were performed
transvaginally with meshes. In conclusion, once reviewed evidence and position of different societies, the SINUG presents a
favorable position concerning its use.

Adjustable Transobturator Male System after Failed Surgical Devices for Male Stress Urinary Incontinence: A Feasibility Study

Urol Int. 2018;101(1):106-113. doi: 10.1159/000489316
2018
To evaluate the efficacy and safety of Adjustable Transobturator Male System (ATOMS) after failed surgical devices for male stress urinary incontinence (SUI).Thirty patients were implanted with ATOMS after they were implanted with surgical device/s previously. SUI severity was evaluated as dryness (0-1 pad/day), mild (2 pads/day), moderate (3-5 pads/day), or severe (≥6 pads/day). Change in pad-test and pad-count after adjustment, operative parameters, patient satisfaction, and number and grade of complications were investigated.Previous failed treatment methods were artificial urinary sphincter (AUS; n = 19), Advance (n = 10), and Virtue (n = 1). Six cases had multiple previous treatments. Preoperative SUI was mild 6 (20%), moderate 11 (36.7%), and severe 13 (43.3%). Median pad-test decreased from 435 mL baseline to 10 mL after adjustment and pad-count from 4 to 0. Dry-rate was 76.7 and 83.3% declared satisfied. Postoperative SUI distribution was mild in 3 (10%) and moderate in 4 (13.3%). No patient had urinary retention after catheter removal. Complications presented in 4 (13.3%; 3 grade-I, 1 grade-II). After a median of 24 months follow-up, no system experienced infection or urethral erosion and 1 (3.3%) was removed for inefficacy. Based on short-term efficacy and patient satisfaction, ATOMS can be a realistic alternative for male SUI after other failed systems, including AUS. The absence of urethral erosion and limited infective problems makes this alternative attractive for

cases with previous failed treatments.

Treatment of male stress urinary incontinence with the adjustable transobturator male system: Outcomes of a multi-center Iberian study

Neurourol Urodyn. 2018 Jan 9. doi: 10.1002/nau.23474.
2018

To evaluate effectiveness and safety of the adjustable transobturator male system (ATOMS) for male stress urinary incontinence (SUI).

A retrospective multicenter study was conducted in nine Iberian institutions using a board-approved database for 215 patients intervened between 2012 and 2017, with no case excluded. Continence status, patient satisfaction, number, and grade of complications (Clavien-Dindo) and factors affecting dry rate at adjustment were evaluated. Multivariate analysis defined the population at best success rate. Incontinence recurrence due to device failure and/or explant was evaluated and Kaplan-Meier curve for durability performed.

Adjustment was achieved at a mean 1.4 ± 1.9 fillings. Dry-rate after adjustment was 80.5% (96.2% mild and 75.3% moderate-severe), 121 (56.3%) used no pads, and 52 (24.2%) a security pad with urine loss under 10 mL. Mean basal daily pad-test and pad-count decreased from 484 ± 372.3 mL and 3.9 ± 2 pads to 63.5 ± 201.2 mL and 0.9 ± 1.5pads (both P < 0.0001). Satisfaction rate was 85.1% (94.3% mild and 82.1% moderate-severe). Factors associated to dryness were: lesser severity of SUI (P < .0001), absence of radiotherapy (P = 0.0002) and device generation (P = 0.05). Multivariate analysis revealed absence of radiation (OR = 3.12; 1.36-7.19), mild (OR = 19.61; 3.95-100), and moderate (OR = 2.48; 1.1-5.59) SUI were independent predictors. Complications presented in 33(15.35%); 66.7% grade 1, 9.1% grade 2, and 24.2% grade 3. At 24.3 ± 15 mo mean follow-up device was explanted in seven (3.25%) and SUI worsened after adjustment in nine (4.2%). Dryrate at follow-up was 73% and durability of device in dry patients at adjustment was 89.8% (82.9-94) at 2-years.

This study confirms ATOMS device is safe and achieves high treatment efficacy and patient satisfaction in a multicenter setting. Significantly better results are achieved in less severe and non-irradiated cases. Durability of the device is reassuring in the short-term.

Consensus Statement of the European Urology Association and the European Urogynaecological Association on the Use of Implanted Materials for Treating Pelvic Organ Prolapse and Stress Urinary Incontinence

Eur Urol. 2017. pii: S0302-2838(17)30279-8. doi: 10.1016/j.eururo
2017

Surgical nonautologous meshes have been used for several decades to repair abdominal wall herniae. Implantable materials have been adopted for the treatment of female and male stress urinary incontinence (SUI) and female pelvic organ prolapse (POP).

This document summarises the deliberations of a consensus group meeting convened by the European Association of Urology (EAU) and the European Urogynecological Association, to explore the current evidence relating to the use of polypropylene (PP) materials used for the treatment of SUI and POP, with reference to the 2016 EAU guidelines (European Association of Urology 2016), the European Commission's SCENIHR report on the use of surgical meshes (SCENIHR 2015), other available high-quality evidence, guidelines, and national recommendations. Current data suggest that the use of nonautologous durable materials in surgery has well-established benefits but significant risks, which are specific to the condition and location they are used for. Various graft-related complications have been described-such as infection, chronic pain including dyspareunia, exposure in the vagina, shrinkage, erosion into other organs of xenografts, synthetic PP tapes (used in SUI), and meshes (used in POP)-which differ from the

complications seen with abdominal herniae. When considering surgery for SUI, it is essential to evaluate the available options, which may include synthetic midurethral slings (MUSs) using PP tapes, bulking agents, colposuspension, and autologous sling surgery. The use of synthetic MUSs for surgical treatment of SUI in both male and female patients has good efficacy and acceptable morbidity. Synthetic mesh for POP should be used only in complex cases with recurrent prolapse in the same compartment and restricted to those surgeons with appropriate training who are working in multidisciplinary referral centres

Mini-arc for the treatment of female stress urinary incontinence: long-term prospective evaluation by patient reported outcomes.

ISRN Urol. 2014 Jan 20;2014:659-383.2014

Single-incision slings were introduced in the surgical treatment of female stress urinary incontinence (SUI) to lessen the morbidity associated with traditional midurethral slings. However, long-term reports on patient satisfaction are still scarce.

This study describes the outcome of women treated with Mini-Arc at a mean follow-up of 45 months. In a previous report on 105 women with 15-month mean follow-up, 84 (80%) were found cured and 12 (11%) improved. Now, with a mean follow-up of 45 months, cured/improved patients were reassessed by telephone and completed Patient Global Impression of Improvement (PGI-I), Patient Global Impression of Severity (PGI-S), rated their improvement in a 0–100 scale, and answered if they would recommend the procedure. At 45-month follow-up, 73 women cured/improved were available for evaluation. Over 80% of the cured patients rated the improvement of SUI by the PGI-I as “very much better” or “much better,” reported their urinary tract condition to be “normal” on PGI-S, and described their improvement >70%. Ninety percent would recommend this procedure to a friend. This study shows that the majority of patients cured/improved after Mini-Arc placement maintain a high degree of satisfaction at a long-term evaluation.

Exploratory Study Assessing Efficacy and Complications of TVT-O, TVT-Secur, and Mini-Arc: Results at 12-Month Follow-Up

Eur Urol. 2011;59(6):940-4. doi: 10.1016/j.eururo.2011.01.018

2011

Contemporary surgical treatment of female stress urinary incontinence (SUI) includes retropubic and transobturator (TO) midurethral slings (MUS). Case series of single-incision slings (SIS) have shown similar outcomes with lower morbidity. Our aim was to assess the cure rates, complications, and quality-of-life impact of one standard TO MUS and two SIS.

Ninety consecutive patients with clinically and urodynamically proven SUI were enrolled in an exploratory randomised phase 2 trial. Patients with previous SUI surgery, major pelvic organ prolapse, mixed incontinence, or detrusor overactivity were excluded.Patients were treated randomly with TVT-O, TVT-Secur, or Mini-Arc. Postoperative visits were scheduled at 6 and 12 mo. The King's Health Questionnaire (KHQ) was repeated at 6 mo. Cure was defined as the absence of urine leakage, no pad use, and a negative cough test at 12 mo. Pain and other complications were also investigated. Cure rate was 83% after TVT-O, 67% after TVT-Secur, and 87% after Mini-Arc. Improvement was found in 10%, 13%, and 7% of the patients, respectively. Failures were 7% after TVT-O and Mini-Arc and 20% after TVT-Secur. TVT-O and Mini-Arc improved at least 15 points in >80% of the patients in six KHQ domains, whereas TVT-Secur could only achieve improvement in three of the nine domains. The pain score was lower in the Mini-Arc group. Complications were more numerous after TVT-O. This study has the limitations inherent in a phase 2 trial with a follow-up limited to 12 mo.

Mini-Arc offers cure and improvement rates are similar to TVT-O, whereas TVT-Secur may yield an inferior outcome. These
findings recommend the urgent launch of large randomised phase 3 studies comparing conventional MUS with SIS, with
Mini-Arc the advised option.

Projects

IMI TRIPP project on pelvic pain funded by EU

Memberships

Other Relevant Information

HONOURS AND AWARDS

01/03/2011

Best non-oncological poster – European Associatiopn of Urology

Best non-oncological poster of the XXVI EAU Congress. Vienna. The subject was biomarkers for urinary incontinence
01/11/2018

1st Grunenthal Prize on Clinical Pain Research and Therapy – Grunenthal

1 Grunenthal Prize on Clinical Pain Research and Therapy, with the RCT study on Botulinum toxin bladder injection in
patients with Intertstitial Cystitis
11/08/2018

First prize of ICS 2018 abstracts on the topic of urethra – International Continence Society

First prize of ICS 2018 abstracts on the topic of urethra. Description of neuro-endocrine cells expressin 5HT in the urethra