the placebo group (p=0.0457). The effect was maintained through the end of the study. The incidence of hot flashes and flushing reported as adverse events (reported by the patient as severe) was lower in the toremifene group (3.9%) compared to the placebo group (5.8%). This incidence showed a statistical trend in favor of toremifene (p=0.1188).
Conclusion: In this randomized placebo controlled trial toremifene 80 mg demonstrated the ability to reduce hot flashes in a subset population that experienced on average a higher number of hot flashes at baseline than that observed in the ITT population. Additionally, fewer subjects reported severe hot flashes and flushing as adverse events.

Moderated Poster Session VII: General Urology
Friday, October 9, 4:00 – 5:00 p.m.

P102
Research in Urology: A National Survey on Attitudes and Experience of Research in Urology Residency
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Introduction and Objective: Involvement in clinical or basic science research as one component of the scholar role is an important part of urologic residency training. The teaching and evaluation of this role is often observational, based on participation in research, and performance-related, with respect to production of research publications and attendance at conferences. We sought to access the experiences with and attitudes towards research endeavours in Urology residents across Canada.
Materials and Methods: An anonymous, self-report questionnaire was filled out by 26 chief residents in Canadian Urology programs in February 2009. The questionnaire was composed of 30 open and closed-ended questions set to evaluate the residents experience with and attitudes toward research, both prior to, and during residency. The closed-ended questions were based on a five-point Likert scale. Descriptive and correlative statistics were used to evaluate responses to the survey. For ease of reporting herein, an agreement score was given by combining two agreement points on the Likert scale.
Results: The response rate from the questionnaire was 100%. The vast majority of residents had some experience in research prior to residency and have published at least one paper (92.3% and 84.6% respectively), with the average resident publishing over 4 papers (mean=4.65, range 0 - 11). However less than half those surveyed believed that research during their residency was important to their overall training (42%). Over half (58%) admitted that their motives for doing research was mainly to increase their chances of obtaining their desired fellowship program. Thirty-eight percent of the respondents agreed that there was dedicated time set aside for research endeavours in their residency and 69% of those surveyed would be more inclined to take part in research. The greatest obstacle to participating in research in urology residency appeared to be dedicated time and available preceptors.
Conclusion: There is a wide range of medical research activity and opinion regarding research during a urologic residency-training program. A significant proportion of respondents feel research is unimportant in their training. Nonetheless, over two-thirds of residents believe that they would be more inclined to perform research if they were provided more protected research rotations and time constraints were identified as the most common and important self-reported limiting factor to participation in research during residency.

P103
Suprasacral Spinal Cord Injury Patients Managed by Reflex Voiding: Characterization of our Cohort
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Introduction and Objective: Suprasacral spinal cord injury patients require frequent urologic attention to prevent morbidity and mortality. Urodynamic studies can help the clinician formulate a safe management plan for bladder storage and emptying. We attempt to characterize our cohort of suprasacral spinal cord injury patients managed by reflex voiding.
Materials and Methods: The census of all patients studied in our urodynamics laboratory over the past twelve months was reviewed. The records of all patients (34) with suprasacral spinal cord injuries managed by reflex voiding for at least three years were chosen for retrospective review. Ten patients were excluded for incomplete data.
Results: Mean time from injury was 17.3 years. 23/24 patients were male. Location of injury: C1-C7 (14), T1-T12 (10), L1-L5 (0). 21/24 were complete spinal cord lesions, 3/24 were incomplete lesions. Eight patients had a transurethral sphincterotomy. Three required repeat transurethral sphincterotomy for persistent autonomic dysreflexia. Indications for initial sphincterotomy include autonomic dysreflexia (4/8), hydronephrosis with a poorly compliant bladder (3/8) and autonomic dysreflexia with poor compliance (1/8). Detrusor external sphincter dysynergia (DESD) was observed in 21/24 patients. Those with complete spinal cord lesions were more likely to have type II or type III DESD (16/20). Bladder capacity was 77-947mL. Intravesical storage pressures prior to flow were 10-58 cm H_2O. Intravesical leak point pressures were 43-144 cm H_2O. Patients with prior sphincterotomy had an average leak point pressure of 49 cm H_20. Patients without prior sphincterotomy had an average leak point pressure of 90 cm H_20. 8/8 patients managed with sphincterotomy had type II or type III DESD. Abnormal renal ultrasound was observed in 4/24 patients. One developed bilateral hydronephrosis and renal insufficiency from persistent high storage pressures and was refusing intervention, one presented with bilateral staghorn, ureteral and bladder calculi with renal insufficiency requiring rescue procedures, one had staghorn calculi and refused intervention and one had bilateral renal scarring from a history of chronic pyelonephritis.
Conclusion: Urodynamics are crucial to the routine follow-up of patients with suprasacral spinal cord injuries managed with reflex voiding. Sphincterotomy is an effective means of stabilizing those who develop complications from poor bladder compliance or autonomic dysreflexia.

P104
Surgical Treatment of Bladder Outlet Obstruction Improves Outcome in Male Interstitial Cystitis
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Introduction and Objective: Male interstitial cystitis continues to be a formidable challenge for urologists and an interesting subject for clinical research.Since the principal manifestation of this ailment is pelvic pain,current treatment is directed towards relief of pain with analgesics,alpha blockers,and antibiotics with outcome not worth duplicating.There is therefore a stimulus to look for another etiology and devise another treatment.
Materials and Methods: The medical records of 3015 male patients were reviewed over a 29 year poeriod with a view to discovering those with symptoms approximating interstitial cystitis.346 of these were judged

to have enough pain severity to be considered MIC.133 of these underwent surgical treatment for bladder outlet obstruction/distal urethral stenosis namely urethrotomy . 213 received nonsurgical management.
Results: The surgery group reported pain relief in 131 out of 133 to a degree that further treatment was not required.1 had hypospadias and the other had symptom severity of a higher magnitude on a scale of 1 to 10 and were continued on medical therapy.
Conclusion: Men with interstitial cystitis could very possibly have bladder outlet obstruction which could contribute to the magnitude of the pain. A careful search with a high index of suspicion may lead surgical treatment and improve the outcome. Lack of consensus among coders have led to labelling of urethrotomy until a new code can be assigned.

P105
Office-Based Urotelehealth—Bringing Urology Health Care Near to Home: A Work in Progress

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Introduction and Objective: Telemedicine involves the electronic transfer of medical and health information and services between distant sites and participants. This system provides a broad range of clinical services in various specialities as well as continuing medical education and preventive health. We assessed the role of telemedicine in the management of urology patients in remote communities.
Materials and Methods: Application to the Ontario Telemedicine Network (OTN) to build an office-based studio was approved. Urotelehealth Studio #0285 was certified in November 2006. The Clinic was planned to operate 4 hours/month. The OTN staff received referrals and scheduled these every 15 minutes. A schedule was faxed to the urologist 24 to 48 hours early. Patients were seen in hospital-based studios run by OTN nurses. Primary health care providers and family were welcome to attend. The urologist's and OTN records were reviewed to determine the number of clinics, patient encounter and type of clinical encounter. Patient demographics, diagnoses and time utilized were studied.
Results: There were 22 clinics between 2006 and 2008. A total of 389 patients: 276 males and 113 females between 3 and 96 (mean 64) years. Patient encounter included: counseling (35), consultation (85), and follow-up to review test results and surgical outcomes (269). There was a wide range of urological diagnoses. The time logged was 71 hours, average 3.2 hours/month. The average time per encounter was 11 minutes. Cancellation due to a technical problem occurred once.
Conclusion: Telemedicine resulted in rapid follow-up and review of test results and surgical outcomes. Counselling of patients and families enhanced care. Time management for the urologist was efficient exceeding the goal of 352 encounters by 37. Travel time for both the urologist and patient was greatly reduced.

P106
An Open-Label, Multi-Center Pharmacokinetic Study of Uracyst® 400 mg Following a Single Bladder Instillation in Subjects with Interstitial Cystitis/Painful Bladder Syndrome

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Introduction and Objective: Interstitial Cystitis/Painful Bladder Syndrome (IC/PBS) is a chronic bladder disease characterized by frequency, urgency, nocturia, and suprapubic pain. IC/PBS may result from the defect in the glycosaminoglycan (GAG) layer lining the urothelium. The GAG layer provides a protective barrier against insulting agents present in urine. Therapeutic agent such as chondroitin sulfate (CS) has been used to treat IC with positive results. In Canada, Uracyst® (2% CS solution) is approved as a medical device for the replenishment of the GAG layer when instilled in the urinary bladder. Human pharmacokinetic studies of oral CS demonstrate varying rates of absorption and bioavailability in healthy volunteers. A single oral dose of 4 g CS was quickly absorbed and plasma levels increased to 200 percent over baseline levels. No published data are available on the ADME studies after intravesical administration of CS in either animals or in humans. The aim of this study was to evaluate the extent of any absorption of Uracyst when Uracyst was administered to subjects with IC/PBS as an intravesical instillation.
Materials and Methods: The study was a multi-center, open-label, single-instillation design in 22 IC/PBS female and male subjects. Subjects were required to visit the study site to complete the screening process, and then to arrive at the study site approximately 2 hours before device administration. Following the collection of the pre-instillation blood sample, 6 additional blood samples were collected serially during the 4 hours following device instillation in order to determine plasma chondroitin sulfate concentrations. Each subject's total participation was up to 22 days (screening period, followed by a total of up to 6 hours on the day of device instillation and blood samples collection).
Results: Plasma concentrations of Uracyst could not be detected in any of the samples analyzed, as the concentration was below the lower limit of quantitation (LLOQ), suggesting that there was no significant systemic absorption of Uracyst. Safety evaluations revealed no adverse trends in any safety parameter measured during the study period. Only three subjects (13.6%) reported four adverse effects and all were mild in intensity, and non-related to the study device instillation.
Conclusion: Uracyst is not significantly absorbed from the bladder when given as a single instillation of Uracyst 400 mg to IC/PBS subjects, and is well-tolerated.

P107
Utility of an Ambulatory Pessary Trial to Unmask Occult Stress Urinary Incontinence

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Introduction and Objective: We aimed to demonstrate that an ambulatory pessary trial determines the need for anti-incontinence surgery in patients with advanced prolapse, even in patients whose leakage was missed on urodynamic testing.
Materials and Methods: Patients with Baden-Walker grade 2 or higher anterior vaginal wall prolapse and an unresolved diagnostic concern (occult stress incontinence, incomplete emptying, urge incontinence, etc.) were offered a pessary trial to predict response to reconstruction. Review of cases was performed from June 2005 to February 2009. All patients underwent a detailed evaluation including meticulous videourodynamics (VUDS) with and without reduction. Patients were followed with respect to clinical symptoms.
Results: 41 patients accepted the pessary trial and 26 were able to retain > 1 week. Mean age was 65 (range 44 to 80); median cystocele grade was 2 (range 2-4) and median vault grade was 2 (range 2-4). Mean degree of urethral hypermobility was 39 (range 0 - 45). Ten (38%) women showing no evidence of sphincteric incontinence by pessary trial, clinical report, VUDS, or physical exam underwent surgical repair of prolapse without anti-incontinence procedure. None had stress urinary incontinence postoperatively. Sixteen women (61%) were found to have stress urinary incontinence by pessary trial, clinical report, VUDS, or physical exam and underwent concomitant sling. 3/16 (19%) were identified by the pessary trial alone. 25/26 patients were without clinical stress incontinence after surgery at a mean follow up of 12 months (range 4- 37 months). The one failure was in the sling group, initially dry post-op, then markedly noncompliant with activity. The pessary trial correctly predicted persistent incomplete emptying in 5 patients and persistent urge incontinence in 6. There were no patients with SUI or persistent voiding difficulty whose symptoms were missed in a successful pessary trial.
Conclusion: A properly fitted pessary will approximate the anatomic result achieved by surgery during activities of daily life pre-operatively. This reversible test aids in the decision to perform anti-incontinence procedures and in setting appropriate post-operative expectations regarding urgency and emptying ability. In our series, 20% of patients in our stress incontinent group were identified by pessary trial alone.

P108

The Longitudinal Effects on Penile Oxygen Saturation from a Prospective Randomized Study of the Nightly Use of Intraurethral Alprostadil vs. Sildenafil Following Nerve-Sparing Radical Prostatectomy (NSRP)

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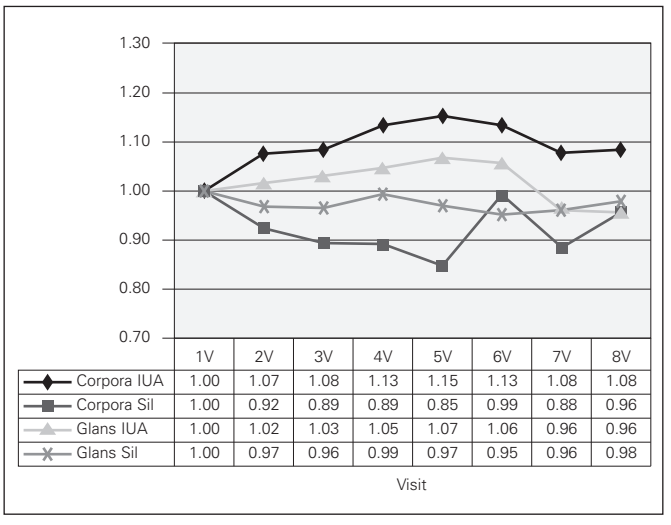
Introduction and Objective: Early penile rehabilitation is recognized as an important part of the recovery of erectile function after RP. Postoperative intracorporal and intraurethral alprostadil as well as oral sildenafil have been reported to improve recovery of erectile function. Enhanced penile oxygenation is believed to be an important factor in the observed beneficial effect. The purpose of this study was to examine the longitudinal effect of nightly sildenafil or intraurethral prostaglandin on flaccid penile oxygen saturation.

Materials and Methods: A subgroup of 50 men enrolled in a larger (78 men) randomized comparative 11 month penile rehabilitation trial of nightly alprostadil (MUSE®) 250 mcgm vs. sildenafil 50 mgs , underwent preoperative penile oximetry (V1), at post op visit week one (V2), month 1.25 (V3), month 3 (V4), month 6 (V5), month 9 (V6), month 10 (V7), and month 11 (V8). Medications were started at catheter removal and continued through month 9. After a one month washout men were challenged with 6 doses of Sildenafil 100 mg. At each visit oximetry was done with a FDA approved tissue oximeter at five sites, the right thigh, (RT), right corpora, (RC), glans penis, (G),left corpora,(LC) and left thigh,(LT).

Results: All men were preoperatively potent (Avg IIEF 29) and underwent nerve sparing prostatectomy by two surgeons (HL) and (ST). Average age was 55. Right and left thigh oximetry did not change significantly over the 11 month period. Corporal oximetry in the IUA cohort increased over 9 months, achieving statistical significance over the second visit nadir throughout the treatment period. Corporal gradually decreased from baseline in the Sildenafil group but returned to baseline by the end of the study (Fig. 1).



	1V	2V	3V	4V	5V	6V	7V	8V
Corpora IUA	1.00	1.07	1.08	1.13	1.15	1.13	1.08	1.08
Corpora Sil	1.00	0.92	0.89	0.89	0.85	0.99	0.88	0.96
Glans IUA	1.00	1.02	1.03	1.05	1.07	1.06	0.96	0.96
Glans Sil	1.00	0.97	0.96	0.99	0.97	0.95	0.96	0.98

Fig. 1. Percentage change from baseline in penile oximetry in intraurethral alprostadil vs. sildenafil.

Conclusion: Despite the short half life of intraurethral alprostadil, low dose nightly alprostadil increased flaccid penile oximetry throughout the study. Flaccid penile oximetry in the sildenafil cohort decreased in the same period. This supports the early incorporation IUA for penile rehabilitation after RP to maintain corporal oxygenation.

P109

The Impact of Clomiphene Citrate on Severe Idiopathic Oligospermia

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Introduction and Objective: Clomiphene citrate is recommended in the treatment of oligospermia and non-obstructive azoospermia in patients found to have low or low-normal testosterone levels. Multiple studies have debated its effectiveness in improving semen quality. Clomiphene citrate has been shown to improve semen quality in some men, however, predicting which patients will benefit has proven more difficult. Our goal was to evaluate the impact of clomiphene citrate on semen parameters, with a specific focus on patients with severe idiopathic oligospermia (≥ 5 million/ml) and non-obstructive azoospermia.

Materials and Methods: A retrospective chart review was performed on 632 male infertility patients from a single urologist's practice from 2004-2009. 501 patients underwent initial work up for infertility and were subsequently diagnosed with idiopathic oligospermia or non-obstructive azoospermia. 46 patients in this group were prescribed clomiphene citrate 25 mg PO daily x 3 months, based on semen parameters, FSH, and testosterone levels. Patients (n=15) excluded had used steroids or failed to complete testing. Abnormal semen analysis values were based on the WHO 1999 criteria. We performed paired t tests to statistically examine whether there was a difference in semen parameters after use of clomiphene citrate. In addition, a subgroup analysis of patients with severe oligospermia ((≥5 million/ml) was similarly completed.

Results: No difference between pre and post semen parameters (volume, sperm concentration, motility, morphology) was observed after treatment with clomiphene citrate. However, motility showed a trend toward statistical significance (p=0.08) both in the larger group and the subgroup analysis. Sperm concentration increased and also showed a trend toward statistical significance in the subgroup analysis (p=0.15).

Conclusion: The impact of clomiphene citrate on semen quality in men with oligospermia and non-obstructive azoospermia is not statistically significant in this small analysis. In men with severe oligospermia, mean sperm concentration and motility values increase and trend toward statistical significance. There may be a benefit of clomiphene citrate on this subgroup if studied in a larger group of patients. In addition, there is a suggestion in this trend that FSH may be a predictor, in combination with semen parameters, of who may benefit from clomiphene citrate therapy.

P110

A Comparison Between Composix™-based Slings, Tension Free Vaginal Tapes Tvt™ And Transobturator Tapes Tvt-o™ at a Median Follow-Up of 24 months

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Introduction and Objective: Suburethral synthetic sling procedures have become widely used as surgical treatment for female urinary stress incontinence. Since 2002, we have used in a non-randomized fashion, Composix™-based slings, tension-free vaginal tapes TVT™ and transobturator tapes TVT-O™. The Composix sling was cut from a mesh used for ventral hernia repair . It was positionned suburethrally with a Raz needle introduced through a suprapubic incision. The goal of this prospective study is to compare the success rate, the durability, and the complications of the three approaches.

Materials and Methods: Among the 103 women having SUI, 60 were assigned to Composix™, 21 to TVT™, and 22 to TVT-O™. patients presenting a complete set of data were included in the analysis. Preoperative workup included medical history, clinical examination, a 24-h pad test, FPSUND, satisfaction and impact incontinence quality of life questionnaires. Objective changes in SUI were the primary end point; whereas other outcome variables such as symptoms, quality of life questionnaires and satisfaction scale were our secondary end points. Clinical check ups were conducted at 3 months, each 6 months for 2 years and then annually up to 5 years. The objective result was considered favorable when the absolute value of incontinence after treatment was (≥ 2 g per 24 hours.

Results: The median follow up of the cohort was 24 months. The median I-QOL scores for the Composix, TVT™ and TVT-O™ prior to surgery were 57, 55, 49 respectively, and 106, 106, 109 at 24 months. Similarly, the FPSUND scores were initially 12, 11, 12 and 4, 1, 2 at follow-up, whereas the 11 point-scale satisfaction score improved from 2 to 9 for all groups. The median pad weight was 26g, 66g and 20 g prior to surgery; at 24 months all patients who had not failed int the first 6 months were dry. Complications were divided into three categories, voiding dysfunction, De novo urgency and erosions/extrusions, their respective rates were 13%, 3% and 7% which are comparable to the overall incidence rates reported in the literature.
Conclusion: This study did not detect any statistically significant difference between the Composix™, TVT™ and TVT-O™ slings for the cure of female SUI at a median follow-up of 24 months. The incontinence cure rate and improvement in quality of life is maintained over at least 2 years. Complications rate was similar to that reported in the litterature, knowing that the Composix™sling is significantly cheaper and might be a cost effective alternative.

P111

Clinical Phenotyping of Urologic Chronic Pelvic Pain Syndromes (UCPPS): Validation of the "Snowflake Hypothesis"

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Introduction and Objective: If there is only one thing learned from a decade of urological literature littered with well intentioned clinical trials it is that while they initially appear similar, each Chronic Prostatitis (CP) and Interstitial Cystitis (IC) patient is entirely unique. We have devised a clinical phenotyping strategy, categorizing patients into 6 "UPOINT" domains.
Materials and Methods: CP and IC patients were clinically categorized into one or more UPOINT domains: Urinary, Psychosocial, Organ Specific, Infection, Neurologic/Systemic, Tenderness. Symptoms were assessed using disease specific instruments. Clinically relevant associations were calculated.
Results: Ninety CP and 100 IC patients were categorized into one or more of the UPOINT domains. Percent of 90 CP and 100 IC patients positive for each domain (CP:IC) was Urinary 52:100, Psychosocial 34:34, Organ Specific 61:96, Infection 16:38, Neurologic/Systemic 37:45 and Tenderness 53:48. There was a significant stepwise increase in total symptom severity scores as number of positive domains increase. Symptom duration but not age was associated with more positive domains. Significantly increased symptoms were seen in patients positive for the neurologic/systemic and tenderness domains, while these domains along with the psychosocial domain most strongly impacted quality of life.
Conclusion: Categorization of IC and CP patients employing the UPOINT phenotype classification system clearly identifies multiple clinical phenotypes (validating the Snowflake Hypothesis for UCPPS). Domains which function outside of the bladder/prostate (psychosocial, neurologic, tenderness) predict significant impact on symptoms and quality of life. The UPOINT system explains our consistent failure in developing a standardized therapeutic algorithm and will have clinical utility in formulating phenotypically individualized dynamic treatment strategies. This is the future of UCPPS management.

P112

Mid-Term Results of Pelvic Organ Prolapse Repair Using a Transvaginal Mesh: The Sherbrooke Experience

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Introduction and Objective: Pelvic organ prolapse (POP) is a common problem in the ageing woman. Conventional treatment strategies for POP repair have a recurrence rate of 20-30%. A new surgical technique of pelvic reconstruction using a transvaginal mesh, the Prolift system, attempts to improve these results. The objective of this study was to report our experience on the implantation of the Prolift system since 2005.
Materials and Methods: The population of the study included 56 patients operated from July 29th 2005 to August 29th 2008 by one surgeon. The patients have all undergone the implantation of a transvaginal mesh, the Prolift system, for the treatment of recurrent or high grade (Baden-Walker stage 3 or 4) multiple compartment POP.
Results: The population had a mean age of 68,1 (46-88), a body mass index (BMI) of 27 (21-40), a parity average of 3,3 (1-16). Previous POP repair had been performed in 17 patients (30%) and a hysterectomy in 43 (77%). OR time was on average 98 minutes (70-135), blood loss 81 ml (50-300) and hospital stay 2,9 days (1-10). With a median follow-up of 21 months, the cure rate for pelvic organ prolapse was 91% (48/53). Perioperative complications included 1 anterior rectal wall laceration as well as 1 prolonged bleeding. Short-term postoperative complications comprised 10 episodes of transient urinary retention that required immediate tape release in 4 patients. Long-term complications included 5 POP recurrences, 2 low grade and 3 high grade. Of these recurrences, 4 required a reoperation.
Conclusion: Considering the results of this study and a review of literature, the Prolift system appears to be a safe and effective alternative to conventional surgeries for the treatment of recurrent or high grade multiple compartment POP, because of a high mid-term cure rate and a satisfactory complication profile. However, long-term follow-up is still needed in order to confirm these good results.

P113

An Autologous Tissue-Engineered Endothelialized Graft: A Possible Option in the Surgical Correction of Peyronie's Disease

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Introduction and Objective: Surgical treatment is indicated in severe cases of Peyronie's disease. Excision of the plaque with subsequent graft material is the option of choice. Ideal graft tissue is not yet available. The aim of this study is to evaluate the use of an autologous tissue-engineered endothelialized graft by the self-assembly method for tunica albuginea reconstruction in Peyronie's disease.
Materials and Methods: Two tunica albuginea models were created. Human fibroblasts were isolated from a small skin biopsy and cultured in vitro until formation of fibroblast sheets. Seven days before sheets have reached a state allowing manipulation, umbilical vein endothelial cells (HUVEC) were seeded on fibroblasts sheets. It was then wrapped around a tubular support to form a cylinder of about 10 layers. This model named endothelialized tunica albuginea (ETA) was placed in a bioreactor for one week. In the tunica albuginea model (TA), no endothelial cells were seeded before wrapping. After 21 days of tube maturation, HUVEC were seeded into the lumen of the fibroblast tubes. Constructions were placed in a bioreactor for one week with an internal perfusion of endothelial cells culture medium (EGM-2). External perfusion with DME supplemented with 10% SVF was used for fibroblast culture. Fibroblast-only constructions were used as controls. Histology, immuno-histochemistry and burst pressure were performed to characterize mature tubular graft.
Results: Histology showed uniform multilayer of fibroblasts. Extracelullar matrix, produced entirely by fibroblasts, presented a good staining of collagen I (positive anti-collagen 1). Some elastin fibers were also present. For the ETA model, anti-pecam 1 antibody revealed the endothelial cells forming capillary-like structures. Fibroblast-only tube had a mean burst pressure of 803 ± 22 mmHg after 2 weeks of maturation. After total maturation and perfusion, burst pression increased to 1761 ± 248 mmHg.
Conclusion: Tissue-engineered endothelialized tubular graft is structurally similar to normal tunica albuginea and presents an adequate mechanical resistance. The self-assembly method used and the autologous property of this model represent a real advantage in comparison to other available grafts. Further evaluation will be necessary to characterize *in vivo* implantation and behavior of the graft. Next experiences will include comparison of the two proposed models.

P114

Chondroitin Sulfate is a Promising Therapy for Interstitial Cystitis/Painful Bladder Syndrome (IC/PBS)

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Introduction and Objective: Chondroitin sulfate is a naturally occurring GAG in the bladder mucus layer implicated in the pathogenesis of IC/PBS in some patients. Small single center studies have suggested that intravesical chondroitin sulfate may have efficacy in IC. Two clinical studies, a preliminary real life clincal practice study followed by a pilot randomized placebo controlled trial (RCT), were performed to determine the potential efficacy of this intravesical agent.

Materials and Methods: Study 1 was a prospective multi-center, community based open label study designed to assess the efficacy and safety of intravesical sodium chondroitin sulfate in the treatment of patients with a clinical diagnosis of IC. IC patients were treated with sodium chondroitin sulfate solution (Uracyst®) 2.0% via urinary catheter weekly for 6 weeks and then monthly for 16 weeks for a total of 10 treatments. Study 2 was a multi-center randomized controlled trial evaluating the efficacy of 6 similar weekly treatments of chondroitin sulfate vs. vehicle control. The primary efficacy endpoint for both studies was the percent responders to treatment as indicated by a marked or moderate improvement on a seven-point patient Global Response Assessment scale at end of trial.

Results: In study 1, 47% and 60% of the 53 enrolled patients with long standing moderately severe IC were responders at 10 and 24 weeks respectively. In study 2, 65 IC patients were randomized to active or inactive control therapy. 39.4% of the 33 patients randomized to active therapy compared to 22.6% of 31 patients randomized to placebo were responders at 7 weeks (p not significant). There were no significant safety issues during either study.

Conclusion: These two studies (real life clinical practice study and pilot RCT) suggests that intravesical chondroitin sulfate may have a potential role in the treatment of IC/PBS and validates the rationale and provides the data for a definitive well powered randomized placebo controlled trial.

P115

MRI-Guided Transurethral Ultrasound Therapy with Real Time Thermal Mapping: Initial Studies

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Introduction and Objective: MRI guided transurethral ultrasound therapy is a novel minimally invasive treatment that has been developed at our Centre. Over the last 8 years, we have developed a system which uses MR derived temperature mapping to target and modulate transurethral ultrasound power and frequency enabling thermal ablation of the prostate with speed and precise control. This is the first report of our initial canine experiments. We report the correlation between initial planning, thermal injury as determined by MR, and subsequent histologic evidence of tissue injury and necrosis.

Materials and Methods: All experiments were performed in a clinical 1.5T MRI using an MRI compatible prototype treatment system. Transurethral planar ultrasound heating applicators were inserted through perineal urethrostomy and a target boundary was selected within the prostate gland, based on MR images. A rectal device was placed for cooling. A single transducer (9.1MHz) was used to distribute energy continuously. The spatial temperature distribution was measured continuously with MRI using the proton-resonant frequency shift method producing a temperature resolution of ±1ºC updated at 5 second intervals. This was used in a feedback control algorithm to achieve a spatial precision of 1-2mm in heating to a minimum of 55°C. Following treatment prostates were harvested, formalin fixed, sectioned and stained with H&E in whole-mount fashion. These sections were compared to the MR images using image-registration techniques.

Results: A targeted region of thermal damage was generated within the prostate gland by transurethral ultrasound. Comparison between thermal mapping, post treatment MRI and histology demonstrated that temperature information was highly predictive of thermal damage. T2-weighted and contrast-enhanced MRI depicts the evolution of thermal damage in the days following treatment. The greatest distance between the tissue targeted for ablation and histologic injury was 3 mm. Treatment time was below 20 minutes for all animals. There was no evidence of thermal damage to rectal tissue.

Conclusion: MRI guided transurethral ultrasound therapy using real-time MR thermal mapping to adjust the energy delivered and regulate the extent and degree of ablation, enables precise and rapid thermal ablation of the entire canine prostate. The deviation between targeted tissue and thermally ablated tissue was 0-3 mm. The success of these studies has led to development of a clinical study in men undergoing radical prostatectomy.

P116

Recovery of Erectile Function Following Nerve-Sparing Radical Prostatectomy After Penile Rehabilitation with Nightly Intraurethral Alprostadil vs. Sildenafil Citrate

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Introduction and Objective: Radical prostatectomy can cause long-standing erectile dysfunction. The current clinical trial was conducted to assess if early, consistent use of intraurethral alprostadil (IUA) vs. oral sildenafil citrate (SC) hastened return of erectile function after nerve sparing radical prostatectomy (NSRP).

Materials and Methods: Subjects with normal erectile function who were scheduled for a bilateral NSRP were enrolled in this prospective, randomized, open label, multicenter study. They initiated nightly IUA, 125 mcg, or oral SC, 50 mg, within one month of surgery and continued for 9 months. Subjects were seen throughout the study and completed the International Index of Erectile Function (IIEF) erectile function domain, global assessment question (GAQ) sexual encounter profile and measured stretched penile length (SPL). After one month washout period (month 9) they self-administered SC, 100 mg, 6 times prior to sexual activity. The Erectile Dysfunction Inventory of Treatment Satisfaction was completed at 11 months.

Results: 161 subjects (100 IUA, 61 SC) completed the trial. IUA increased the IIEF and GAQ by 12-14% and 11-27% at 3 and 6 months, respectively, vs. SC ($p<0.02$ for GAQ at 6 months). Intercourse success rate was improved by IUA, and the SPL decrease was less for the IUA group (months 6 and 9). There were no differences between IUA and SC at study termination. Treatments were well tolerated.

Conclusion: Early, consistent use of low dose IUA after NSRP produced a quicker return of erectile function than SC. Early initiation of IUA after RP may hasten penile rehabilitation, providing for a better, earlier sexual response.

P117

Provider Recommendation and Treatment Choice

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Introduction and Objective: When making a PCa treatment decision, men diagnosed with prostate cancer (PCa) turn to their physicians for information and guidance. Currently, there is insufficient evidence to support the superiority of one definitive treatment modality over another; however, each treatment option is associated with different benefits, risks, side effects, and complications. PCa patients' treatment decision-

making has reported to be hurried, base upon misconception and anecdotes, and not rational. It has been suggested that seeking opinions of multiple physicians from different specialties (e.g., urologists, radiation oncologists, and primary care physicians) serves to increase the information PCa patients receive and reduces the bias of this information. The objectives of this study were to determine the likelihood of men consulting with and receiving treatment recommendations from different providers (urologists, radiation oncologists [RO], and primary care providers [PCP]), the content of these recommendations, the perceived influence of recommendations and which recommendations, if any, were associated with PCa treatment decisions.

Materials and Methods: One hundred and fifty-eight participants with clinically localized PCa completed a survey regarding their treatment decision-making processes. Associations between treatment choice and perceived urologist recommendations, consultations with ROs and PCPs, influence of potential side effects and chance of removing all cancer, and treatment inconvenience were examined using multiple logistic regression analysis.

Results: Several men consulted multiple providers and of these, more than half perceived that they received at least one treatment recommendation. Most men chose a treatment recommended by at least one provider. The likelihood of choosing a treatment increased when the urologist recommended it (P value < .05). Consulting a RO decreased the odds of choosing radical prostatectomy, and increased the odds of choosing radiation (P value < .05). The odds of choosing watchful waiting increased if men gave greater consideration to treatment side effects (P value < .05).

Conclusion: Most men with newly diagnosed PCa consulted multiple providers and received multiple treatment recommendations. Recommendations appeared to have played a significant role in PCa treatment decision-making. Further research is required to better understand why one physician's recommendation might be more influential than another's, whether discordant recommendations increase decision-making distress and difficulty.

P118

Optimization of the Nanolantern™ Assay for Rapid Detection of Common Urinary Tract Pathogens

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Introduction and Objective: Urinary tract infections (UTI) are among the most commonly treated bacterial infections, and the most common nosocomial infections in the United States are catheter related UTI. Currently, the gold standard for UTI diagnosis is quantitative urinary culture. This provides objective evidence of specific uropathogens and their sensitivity, but is labor intensive and can take several days to provide a definitive diagnosis. As such, many UTIs are treated empirically, and this use of antibiotics not only has contributed to antibiotic resistance but has also consumed millions of healthcare dollars. Therefore, there is an urgent need for a rapid diagnostic tool that can identify uropathogens and their antibiotic sensitivity, preferably at the point of care. We present experimental evidence for the use of NanoLantern™ technology in the detection of common urinary tract pathogens.

Materials and Methods: The NanoLantern™ is a chip sensor that utilizes modified DNA hairpins immobilized onto a planar gold surface. In the presence of target DNA, the hairpin stem is opened, exposing a quantifiable fluorophore. To demonstrate the feasibility of the NanoLantern™ chip technology for the rapid diagnosis of uropathogens, single target NanoLantern™ sensitivity testing was performed for probes that were specific for Enterobacter cloacae, Klebsiella pneumoniae, and Pseudomonas aeruginosa. In parallel, polymerase chain reaction (PCR) primers were designed in conjunction with the NanoLantern™ probes to evaluate the utility of PCR-based diagnostic testing in combination with NanoLantern™ technology. The goal of this research project was to develop and validate both parts of the assay individually as an initial thrust towards developing an integrated solution.

Results: Single target NanoLantern™ sensitivity testing showed optimal binding at target DNA concentrations of 100 nM for all three bacterial probes. Initial PCR amplification studies demonstrated successful amplification of Entrerobacter cloacae with a limit of detection of 103 CFU/mL. The specificity of the Entrerobacter cloacae primers have been demonstrated in mixed cultures of Escherichia coli and Pseudomonas aeruginosa.

Conclusion: We have successfully demonstrated the utility of several new DNA hairpin probes and corresponding PCR protocols. Work is ongoing to continue the PCR assay design process and to begin testing the NanoLantern™ chip against the output of the PCR assays. Ultimately, these integrated assays will provide rapid analysis of urinary pathogens at clinically significant concentrations with specificity. Further work is ongoing to bring NanoLantern™ technology as part of an automated system to the clinical setting where urine culture information on the order of minutes would be valuable.