

## Sexual Medicine

11:00am - 12:00pm Tuesday, 2nd November, 2021

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### **SEX MED PODIUM Surgical Outcomes of Infrapubic Insertion of the Inflatable Penile Prosthesis in Transmen after Phalloplasty**

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#### **Abstract**

##### **INTRODUCTION AND OBJECTIVE:**

To review the surgical outcomes of the infrapubic approach to the insertion of inflatable penile prostheses (IPP) after phalloplasty in transmen.

##### **METHODS:**

The infrapubic prosthesis insertion after phalloplasty (IPIP) technique involves a horizontal incision anterior to the pubic symphysis, which allows dissection of the neophallus channel, the Space of Retzius, and the scrotal pocket. Surgical outcomes using the Titan (Coloplast, Minneapolis, MN) IPP were analyzed between October 2017 and November 2020. Complications were reviewed and categorized into erosions, infections, device malposition and malfunction, and less common events like necrosis.

##### **RESULTS:**

The IPIP technique was performed on 74 phalloplasty patients by a single surgeon (MLC): 68 patients had a prior RF phalloplasty, and 6 had a prior ALT phalloplasty. The mean followup was 66 weeks (range 1.4 - 164 weeks). Surgical revision was required in 9 patients (12%). There were 5 pump erosions through the neoscrotum, 5 infections, 2 pump malpositions in the neoscrotum, 1 cylinder malposition in the neophallus, 1 mechanical malfunction with broken

tubing, and 1 glans necrosis. There were no implant detachments from the pubic bone anchor site, no osteomyelitis, no neophallus erosions, and no urethral injuries.

##### **CONCLUSIONS:**

Preliminary data for the IPIP technique using the commercially available Coloplast Titan IPP suggest a reduction in neophallus prosthetic surgical revision rates. Longer term studies with patient reported outcomes are required for further evaluation.

#### **If funding provided, type in source company / entity name(s):**

GU Recon

## **207 Plant-based Dietary Patterns and Erectile Dysfunction in the Health Professionals Follow-Up Study**

Heiko Yang MD, PhD

UCSF, San Francisco, CA, USA

### **Abstract**

#### **Introduction and Objectives**

Healthy dietary patterns have recently been linked to a lower risk of erectile dysfunction (ED) in men. However, it remains unknown whether plant-based diets, which are beneficial to both health and the environment, contribute to lower ED risk. The aim of this study was to evaluate the longitudinal association between plant-based diet index scores and incident ED.

#### **Methods**

We conducted a prospective analysis of 21,942 men age 40 to 75 years who were enrolled in the Health Professionals Follow-Up Study, with "good" or "very good" self-reported erectile function at baseline. Erectile function was assessed with questionnaires in 2000, 2004, and 2008 and ED was defined as "poor" or "very poor" function. Dietary data was collected via validated food-frequency questionnaires completed every four years and was used to calculate total, healthy, and unhealthy plant-based diet index scores. We used multivariable Cox proportional hazards models to compute hazard ratios (HR) for incident ED and all models were stratified by age (<60, 60-70, ≥70 years).

#### **Results**

Higher healthy plant-based diet scores were associated with a lower risk of incident ED among men age 60-70 and ≥70 years. Men age 60-70 years in the highest quintile of healthy plant-based diet score had an 18% lower risk of ED (HR = 0.82; 95% CI 0.73-0.91; P-trend<0.001) compared to those in the lowest quintile. Men age ≥70 years with the highest healthy plant-based diet scores also had an 9% lower risk of ED (HR = 0.91; 95% CI 0.84-0.99; P-trend=0.06). Conversely, men age <60 years in the highest quintile of unhealthy plant-based diet score had a 27% higher risk of ED (HR = 1.27; 95% CI 1.01-1.60; P-trend=0.02) compared to the lowest quintile.

#### **Conclusions**

We found that a healthy plant-based diet was associated with lower risk of incident ED in older men. Among younger men, a healthy plant-based diet was not associated with higher or lower risk of ED, but an unhealthy plant-based diet was associated with increased risk of ED. Healthy-planted based diets may represent an environmentally sustainable intervention for men interested in maintaining erectile function.

#### **If funding provided, type in source company / entity name(s):**

Dr. Bauer was supported by grant 1K12DK111028 from the National Institute of Diabetes, Digestive, and Kidney Disorders.

## SEX MED PODIUM Inpatient Opioid Utilization After Implementation of a Standardized Analgesia Pathway for Gender Affirming Vaginoplasty

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### Abstract

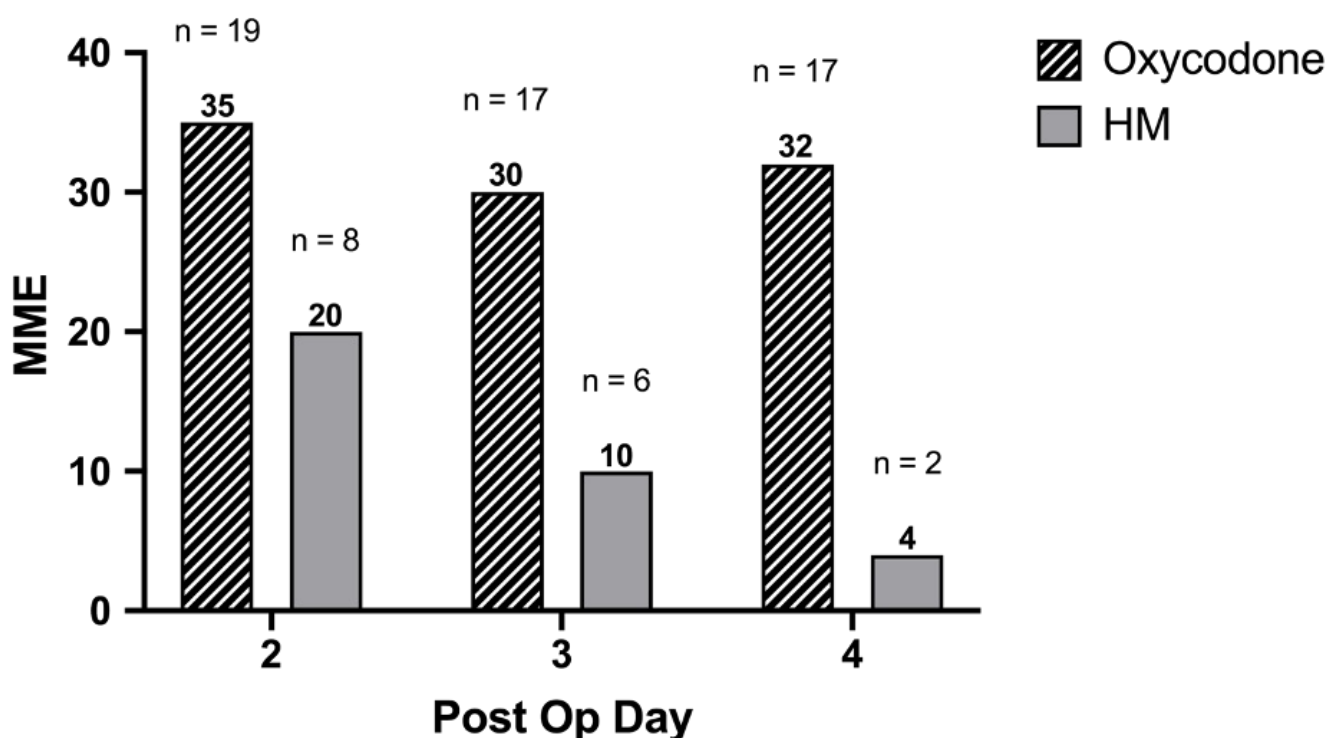
**Introduction:** There is sparse published literature on opioid use after gender affirming vaginoplasty (GAV). With creation of a neovagina and extensive external genital rearrangement, significant post-operative pain and opioid use would not be unexpected. We aimed to characterize inpatient opioid utilization after implementation of a standardized analgesia pathway.

**Methods:** An IRB-approved study was conducted on consecutive patients who underwent GAV by two surgeons from June 2020 to January 2021. Those on chronic narcotics (daily narcotic use  $\geq$  45 days pre-operatively) were excluded. As Patient-Controlled Analgesia was used POD0-1, data was only evaluated for POD 2-4. Opioid use was converted to morphine milligram equivalents (MME).

**Results:** 22 patients were included; 9 were robotic-assisted (41%). Median age 36 (range 19-79, IQR 30-48). BMI median 27, range 19-79 (IQR 30-48) Total MME was variable (median 104, IQR 45-164 MME) and equivalent to 30-110 oxycodone 5mg tablets. Robotic patients used less total MME (median 19 vs 154). 91% of patients received at least one dose of oral narcotic (n=20) while 55% used  $\geq$ 1 intravenous (IV) dose of hydromorphone (n=12). Urethral flaps were used in creation of labia minora in 9 patients (41%). These patients used much higher MME than those who underwent creation with penile skin flaps (median 52 vs 161 MME). There was no increased narcotic use with abdominal skin graft harvests (Median 60 vs 120 MME).

**Conclusions:** Our findings highlight the wide range of narcotic MME utilized by these patients. Oral narcotic use was utilized by more patients than IV. Patients who underwent the robotic approach used less total narcotic. Creation of the labia minora with urethral flaps was correlated with much higher narcotic use, while abdominal skin flap harvest was not. This may be due to urethral venous congestion and edema.

## Inpatient Opioid Use



**If funding provided, type in source company / entity name(s):**

Oregon Health & Science University

## **SEX MED PODIUM Testosterone Nasal Gel in Hypogonadal Men with Extreme Obesity**

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### **Abstract**

**Objective:** Most men prescribed testosterone have adult onset hypogonadism, and are overweight. Nevertheless, there is little published information on the benefits and risks of testosterone treatment for hypogonadal men with extreme obesity. This study was conducted towards filling that knowledge gap.

**Methods:** Post hoc analysis of a phase 3 multicenter, randomized trial to assess efficacy and safety of intra-nasal testosterone. Men age 28-80 with a baseline testosterone level of <300 ng/dL entered a 2-arm 90-day trial, and were randomized to either a fixed-dose (tid, 5.5 mg/nostril, 11 mg/dose, 33 mg/day) or a titration, starting at bid (22 mg/day) with adjustment to tid (33 mg/day) if the C<sub>avg</sub> testosterone level was <300 ng/dL on day 30. Results at baseline and day 90 were compared among men with BMI <30 (group 1; n=150), 30-35 (group 2; n=114) and >35 kg/m<sup>2</sup> (group 3; n=10).

**Results:** Age (52.2±12.7 yrs; M±SD), baseline total (206±44 ng/dL) and free (5.3±1.7 ng/dL) testosterone, DHT (16±3 ng/dL), estradiol (21±7 pg/mL), LH (5.7 ± 3.0 mIU/mL) and FSH (6.3±3.3 mIU/mL) levels in group 3 men were similar to groups 1 and 2. Testosterone nasal gel increased 24h C<sub>avg</sub> total testosterone levels in group 3 men (8 tid/2 bid) by 106% to 413±95 ng/dL on day 90 (range 257-611 ng/dL). These values were similar to groups 1 and 2. In Group 3, free testosterone rose 53.3%, DHT 100% and estradiol 45%, while LH (-54.6%) and FSH (-51%) declined, with percent changes similar to those of groups 1 and 2. The hematocrit in group 3 remained unchanged (45±2.9%), and none developed polycythemia. HDL cholesterol (-4.1 mg/dL) declined (p<0.05 in group 3 only), triglycerides (+122 mg/dL) rose (p<0.05 in all three groups), while PSA, total and LDLc levels were unchanged at 90 days.

**Conclusions:** Testosterone nasal gel restored testosterone 24h concentration profiles in men who were hypogonadal and extremely obese into the eugonadal range, producing values that were similar to those of normal or overweight men. Safety profiles were similar in all BMI groups.

**If funding provided, type in source company / entity name(s):**

Acerus Pharmaceuticals

## **SEX MED PODIUM Effects of 2-Years Oral Testosterone Undecanoate (TU) Administration (JATENZO) on Liver Function and Other Safety Measures in Hypogonadal Men**

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### **Abstract**

**INTRODUCTION:** Oral testosterone (T) replacement therapy (TRT) is the preferred choice for many hypogonadal men. Historically, the only oral TRT approved in the US was methyl-T but it is associated with hepatotoxicity. Recently, the FDA approved the first, oral TU formulation, JATENZO®. The safety of this novel, oral TU formulation was evaluated in hypogonadal men dosed for up to 2 years.

**SUBJECTS AND METHODS:** Two trials were conducted in hypogonadal men (serum T  $\leq$  300 ng/dL) age 18-75 years. Trial 1 was 2-arm, 12-month, active-controlled study, while Trial 2 was a 12-month extension. Statistical analyses were conducted with the subjects who completed Trial 1 and continued treatment in Trial 2, thus providing up to 2 full years of data.

**RESULTS:** Overall, up to 81 subjects participated in both studies. T concentration increased from  $208.3 \pm 102.4$  ng/dL (Mean  $\pm$  SD) at baseline (BL) to  $470.1 \pm 396.5$  ng/dL after 24 Mo with oral TU. There were no serious adverse events. There were no clinically significant changes in liver function tests – ALT ( $28.0 \pm 12.3$  to  $26.6 \pm 12.8$  U/L), AST ( $21.8 \pm 6.8$  to  $22.0 \pm 8.2$  U/L), ALP ( $64.05 \pm 1.95$  to  $52.95 \pm 1.49$  U/L), and bilirubin ( $0.58 \pm 0.22$  to  $0.52 \pm 0.19$  mg/dL). At d270, one subject had an ALT level of 227 U/L, which was  $> 5x$  the ULN (ULN for ALT = 45 U/L). Despite continued use of oral TU, his ALT dropped to 87 U/L,  $< 2x$  ULN, at d290. There were no other LFT elevations. Systolic BP consistently showed a mean increase from BL between 3-6 mmHg. Prostate-related and CV measures changed initially, then stabilized in all subjects.

**CONCLUSION:** This oral TU formulation is an effective, long-term therapy for hypogonadal men and has a safety profile consistent with other approved T products. Notably, no evidence of liver toxicity was observed. The long-term efficacy and safety profile of oral TU may provide a treatment option that avoids issues associated with other TRTs, such as injection site pain or transference to partners and children.

### **If funding provided, type in source company / entity name(s):**

Clarus Therapeutics

## **SEX MED PODIUM Thematic Analysis of the Psycho-sexual Symptoms in Patients with Peyronie's Disease Present on Online Forums**

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### **Abstract**

**Objectives:** To investigate the psycho-sexual impacts of Peyronie's Disease (PD) on patients and their partners.

**Methods:** The three largest online forums on PD were selected through Google search for thematic analysis. We compiled threads focusing on the psycho-sexual impacts of PD (2011-2021). First, we analyzed our sources sentence by sentence and generated appropriate labels pertaining to the experiences and emotions of PD patients and their partners. Second, we combined open codes into consolidated, analytic categories. Finally, we sorted categories into broader themes. Thematic analysis was performed in Dedoose (Los Angeles, CA. v8.3.45 2020).

**Results:** There were 277 unique posters, including 225 patients and 52 partners. We developed 179 open codes and applied them 2543 times to 853 threads. 84 categories and 5 themes were developed. Due to anonymity, participants openly shared their experiences (n=87, 31.4%) and provided anecdotal knowledge (n=79, 28.5%). Curvature was the most commonly discussed physical symptom (n=96, 42.7%), followed by pain (n=54, 24.0%). Emotional distress and depressive symptoms were prevalent among those with PD, including depressed mood (n=75, 33.3%), feelings of isolation (n=41, 18.2%), and body image dysmorphia (n=27, 12.0%). Of note, 23 patients (10.2%) expressed suicidal ideation and 15 (6.7%) patients reported developing substance abuse. Partners developed sexual dysfunction as well, including sexual dissatisfaction (n=11, 21.2%), dyspareunia (n=4, 8%) and decreased libido (n=2, 3%). PD impacted relationships, resulting in relationship disruption (n=14, 5.1%) or termination (n=10, 3.6%). A large portion of partners felt hopeless (n=11, 21.2%), undesired (n=7, 13.5%), and anxious (n=6, 11.2%).

**Conclusion:** Psychological symptoms ranging from mild depression to substance abuse and suicidal ideation are common in patients with PD. PD also impacts partners and intimate relationships leading to sexual dysfunction, psychological burden, and relationship termination. Further research is needed to identify strategies for effective psychological management of PD patients.

**Figure 1: Specific content of online health forums**

Theme	Category	No.	%
Information and social support	Showing support	90	32.5
	Sharing own experience	87	31.4
	Providing own anecdotal knowledge	79	28.5
	Encouragement	44	15.9
	Showing empathy	41	14.8
Physical symptoms	Curvature	96	42.7
	Pain	54	24.0
	Erectile Dysfunction	37	16.4
Psycho-sexual symptoms	Depressive symptoms	75	33.3
	Feelings of isolation	41	18.2
	Body image dysmorphia	27	12.0
	Loss of sexual confidence	24	10.7
	Suicidal ideation	23	10.2
	Difficulty with sex	22	9.7
	Avoidance of sex	19	8.4
	Substance abuse	15	6.7
Treatment and effect	Psychotherapy	20	8.9
	Antidepressants	17	7.6
	Improvement in curvature after non-surgical treatment	17	
	Psychological improvement after psychological treatment	14	
	Improvement in curvature after surgery	5	
Impacts on partnership and relationship	Sexual dissatisfaction	11	21.2
	Hopelessness	11	21.2
	Partner feeling undesired	7	13.5
	Anxiety	6	11.2
	Dyspareunia	4	7.7
	Relationship disruption	14	5.1
	Relationship termination	10	3.6
	Decreased libido	2	3

Footnote: percentages based off number of patients for symptoms, partners for relationship disruption/termination, and posters for all other themes