

Paper 1

Comparison of Laparoscopic and Open Sacral Colpopexies

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OBJECTIVE: To compare laparoscopic and open sacral colpopexies for efficacy and safety.

METHODS: A cohort of 56 patients who underwent laparoscopic sacral colpopexy with and without other reconstructive pelvic procedures from 1998 thru 2003 was compared with 58 patients who underwent open sacral colpopexy and concomitant reconstruction during the same period. The charts were reviewed for demographic data, previous and concurrent surgical procedures, hospital parameters, short-term and long-term complications, follow-up POPQ examinations, visceral and sexual dysfunction, and subsequent surgery. Statistical analysis was performed. **RESULTS:** Demographic data did not differ between cohorts with mean follow-up of 13.3 +/- 12.1 months (range 1-46) in the laparoscopic sacral colpopexy group and 14.9 +/- 16.4 months (1-58) in the open group. Both groups were similar with respect to concomitant procedures performed except more adhesiolyses (59% vs 25%; p=.0002) and fewer Burch colposuspensions (35% vs 61%; p=.006) in the laparoscopic group compared to the open group. Mean operating time was significantly greater in the laparoscopic versus open cohort, 269 ± 65 minutes (range 150-467) and 218 +/- 60 minutes (95-372), respectively (p<.0001). Estimated blood loss (172 +/- 166 vs 234 +/- 149 ml; p=.04) and hospital stay (1.8 +/- 1.0 vs 4.0 +/- 1.8 days; p<.0001) were significantly less in the laparoscopic group than the open group. Intraoperative, short-term, and long-term complications did not differ between cohorts. There were 5 versus 2 cystotomies in the laparoscopic versus open group. One laparoscopic procedure was converted to open because of bleeding during laparoscopic rectopexy. There were one enterotomy and one postoperative small bowel obstruction in each group. Two patients in the laparoscopic group and one in the open group experienced mesh erosion. Subsequent reoperation for pelvic floor dysfunction were 10.7% in the laparoscopic group versus 5% in the open group. **CONCLUSIONS:** Laparoscopic sacral colpopexy is comparable to open sacral colpopexy with respect to clinical outcome and complications. Although laparoscopic sacral colpopexy requires longer operating time, hospital stay is significantly decreased.

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Paper 2

The Incidence of Urinary Tract Injury during Hysterectomy: A Prospective Analysis Based Upon Universal Cystoscopy

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OBJECTIVE: To evaluate the incidence of injury to the bladder and ureter using intra-operative cystoscopy after hysterectomy for benign disease at a teaching institution.

METHODS: Patients were enrolled prospectively from three separate gynecology clinics from August 2000 to November 2003. All patients undergoing abdominal, vaginal, or laparoscopic hysterectomy for benign disease were eligible. At the completion of the hysterectomy, comprehensive diagnostic

cystourethroscopy was performed in each patient. Indigo carmine was administered to evaluate ureteral integrity. Statistical analysis was performed using ANOVA, Chi-square, and regression as appropriate.

RESULTS: A total of 471 patients enrolled in the study with 278 having had abdominal hysterectomies, 144 having had vaginal hysterectomies, and 49 having had laparoscopic/ laparoscopic-assisted hysterectomies. All known urinary tract injuries were detected intra-operatively. There were 8 cases of ureteral injury (1.7%) and 16 cases of bladder injury (3.4%). Ureteral injury was more likely to occur when hysterectomy was coupled with a vaginal vault suspension (7.1% vs. 1.1%; $p<0.005$). Although increased patient age was associated with an increased risk of ureteral injury ($p<0.01$), this relationship was mainly attributed to the increased likelihood of prolapse surgery in older patients. While nulliparity (3.8%), intra-operative hemorrhage (3.2%), and performance of oophorectomy (2.5%) were associated with increased risk of ureteral injury, these findings were not significant. There was no correlation between ureteral peristalsis and injury; five of six injured ureters detected after abdominal or laparoscopic cases were noted to have had peristalsis. Bladder injury was associated with concurrent anti-incontinence procedures (10.7% vs. 2.9%; $p<0.025$) and blood loss greater than 400cc (6.4% vs. 2.1%; $p<0.025$). No other associations approached significance. Abdominal hysterectomy was associated with a higher incidence of ureteral injury (2.2% vs. 1.2%) and lower incidence of bladder injury (2.2% vs. 5.2%) when compared to vaginal and laparoscopic hysterectomies; however, these differences were not significant. Intra-operative injury detection prior to cystoscopy was only 12.5% for ureteral injury and 31.3% for bladder injury ($p<0.005$ for both). The occurrence of urinary tract injury was associated with a longer operative time ($p<0.005$).

CONCLUSIONS: The overall incidence of urinary tract injury during hysterectomy is 5.1%. Surgery for prolapse or incontinence clearly increases the risk of injury. Traditional means of evaluating the integrity of the ureter and bladder, such as the presence of ureteral peristalsis, are unreliable. More liberal use of cystoscopy can improve detection of urinary tract injuries to avoid a delay in diagnosis and allow for more prompt treatment.

Disclosure – Nothing to disclose

Paper 3

Low Risk of Ureteral Obstruction with “Deep” Uterosacral Ligament Fixation for Transvaginal Apical Suspension

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OBJECTIVE: The transvaginal use of the uterosacral ligaments (USL) to suspend the apex of the vagina is widely performed by numerous techniques. The term most often used to describe this operation is “high” USL fixation. Ureteral obstruction is a complication that can occur with this procedure. The course of the ureter diverges from the course of the USL as it travels back to its insertion over the lateral aspect of S2 and the sacroiliac articulation. In the supine position a transvaginal approach would lead one to reach “high” (cephalad) toward S2 in order to access the appropriate USL tissues. Placement of the patient in the lithotomy position for vaginal surgery rotates the pelvis so that these tissues now travel more dorsal than cephalad to their insertion on S2. Reaching “deep” (dorsally) accesses the USL component of the uterosacral-cardinal complex which may increase the margin of safety for the ureter. The purpose of this study is to examine the rate of ureteral obstruction when this concept of anatomy guides the “deep” placement of uterosacral sutures during transvaginal apical suspension. **METHODS:** All patients underwent a Mayo culdoplasty-type USL fixation vaginal vault suspension, with concomitant procedures as needed, utilizing a minimum of three USL sutures on each side. Each suspension stitch was placed “deep” on the USL (i.e., dorsal to the 3-9

o'clock horizon) in its para-rectal portion. After tying of all sutures and completion of the apical suspension, intraoperative cystoscopy utilizing intravenous Indigo Carmine was performed on all patients. **RESULTS:** 411 consecutive patients of one author (MPA) who underwent the above procedures between August 1990 and December 2003 are included. Demographic data was available for 364 of the 411 patients. The subjects' mean age was 61.9 ± 13 years (SD) and median parity was 3 ± 2 (IQR). 96.4% (351/364) of subjects had Grade 2, 3 or 4 prolapse (to or beyond the introitus) by the system of Baden and Walker. 82.1% (299/364) had Grade 3 or 4 prolapse. Thirty-nine percent had previously undergone hysterectomy. One patient out of 411 (0.24% [.01%, 1.35%]) had unilateral obstruction attributable to the USL fixation apical suspension procedure. This was treated with release of the obstructing USL sutures. A second patient had unilateral obstruction that was due to involvement with a uterine artery vaginal hysterectomy pedicle and not with the USL sutures. All other ureters were found to be patent. **CONCLUSIONS:** The course of the ureter diverges from the course of the USL as it approaches the sacrum. Rotation of the pelvis into lithotomy position for vaginal surgery changes the anatomic relationship of surgical landmarks relative to the operator. Conscious placement of USL fixation sutures "deep" (more dorsal) on the USL may increase the margin of safety for the ureter when utilizing the USL in apical vaginal suspension operations.

Disclosure – Nothing to disclose

Paper 4

A Randomized Controlled Trial Comparing Povidone-Iodine and Chlorhexidine to Prepare the Operative Field for Vaginal Hysterectomy

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OBJECTIVE: To compare the efficacy of two commonly used antiseptic solutions for cleansing the vagina prior to hysterectomy.

METHODS: Between October 2002 and September 2003, fifty-one patients undergoing vaginal hysterectomy were randomized to receive a surgical scrub with either povidone iodine or chlorhexidine. Standard prophylactic techniques including preoperative intravenous antibiotics were used for both groups. Quantitative aerobic and anaerobic bacterial cultures of the entire vaginal field were obtained from both groups preoperatively; 30 minutes after the surgical scrub; and hourly thereafter throughout each operation. A specimen was considered contaminated if the total bacterial colony counts were ≥ 5000 colony forming units/ml. Aerobic cultures were performed using 5% sheep blood agar and chocolate agar plates. Anaerobic cultures were performed using brucella blood agar, phenylethyl alcohol agar kanamycin vancomycin agar, and *Bacteroides* bile esculin agar. The staff in the microbiology lab was blinded as to the randomization scheme. At each time interval, the proportions of contaminated specimens in each group were compared using the 2-sided Pearson Chi square test. The two groups were compared in terms of age, BMI, gravity, parity, race and exogenous hormone use using the independent samples T-test. A prospective power calculation was performed based on a pilot study in which 52% (16 of 31 patients) of vaginal cultures obtained 30 minutes after povidone iodine surgical scrub resulted in a contaminated vaginal field. We decided that a reduction in the proportion of "contaminated" specimens from 52% to 10% would be significant. With 22 patients in each arm we had an 80% power to detect that reduction with an alpha of 0.05.

RESULTS: As expected, there were no significant differences between the groups with respect to age, BMI, gravity, parity, race, or exogenous hormone use. Mean preoperative colony counts for the povidone iodine and chlorhexidine groups were 211,957 and 172,296 respectively ($p=0.104$). At TIME 1 (30 minutes after scrub), 63% (17/27) of culture specimens from the povidone iodine group and 22%

(5/23) of the chlorhexidine group were classified as contaminated ($p=0.003$) $RR=6.12$; 95% $CI = 1.73, 21.61$. At TIME 2 (90 minutes after scrub), 36% (4/11) of the povidone iodine and 14% (2/14) of the chlorhexidine groups were classified as contaminated ($p=0.12$) $RR3.43$; 95% $CI = 0.49, 23.8$.

CONCLUSIONS: Chlorhexidine was more effective for decreasing the bacterial colony counts in the operative field during vaginal hysterectomy. Widespread use of chlorhexidine rather than povidone iodine to prepare the vagina for surgery might reduce the rate of operative site infections following vaginal hysterectomy.

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Paper 5

The Safety and Efficacy of Laparoscopic Surgical Staging of Apparent Stage I Ovarian and Fallopian Tube Cancers

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OBJECTIVE: To compare the safety and efficacy of laparoscopic staging of adnexal cancers to staging via laparotomy for epithelial ovarian carcinoma. **METHODS:** We performed a case-control study of all patients with apparent stage I adnexal cancers who underwent laparoscopic staging from 10/00-3/03. The control group consisted of all patients with apparent stage I epithelial ovarian carcinoma who underwent staging via laparotomy during the same time period. Standard two-sided statistical tests were used. **RESULTS:** Twenty patients who underwent laparoscopic staging were identified. Primary sites of disease and histologies were as follows: epithelial ovarian carcinoma, 12; borderline epithelial ovarian carcinoma, 3; tubal carcinoma, 2; granulosa cell tumor, 2; and immature teratoma, 1. The control group consisted of 30 identified patients with epithelial ovarian carcinoma who underwent staging via laparotomy. There were no significant differences in the mean lymph node counts for the laparoscopy vs laparotomy group—right pelvic, 6.5 vs 7.6 ($P = 0.31$); left pelvic, 5.8 vs 7.1 ($P=0.30$); right para-aortic, 3.8 vs 4.4 ($P = 0.36$); and left para-aortic, 2.9 vs 4.8 ($P = 0.08$). There were also no differences in the size of the omentectomy specimen (186 vs 347 cm^3 ; $P = 0.09$) and body mass index (24.6 vs 25.4; $P = 0.64$). The estimated blood loss (199 vs 345 mL; $P < 0.01$) and length of stay (2.9 vs 5.4 days; $P < 0.01$) were lower for patients undergoing laparoscopic staging. There were no complications in the laparoscopy group compared to 3 minor complications (10%) in the laparotomy group ($P = 0.27$). Based on the biopsies performed during the staging procedures, 10% of patients in both groups were upstaged to stage II or III disease. **CONCLUSION:** In this preliminary analysis, it appears that patients with apparent stage I adnexal cancer can safely and adequately undergo laparoscopic surgical staging. Larger studies with long-term follow-up are needed to identify the appropriate indications and limitations of this approach.

Disclosure – Nothing to disclose

Paper 6

Outcomes of Urethropexy Added to Paravaginal Defect Repair: A Randomized Trial of Burch versus Marshall-Marchetti-Krantz

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OBJECTIVE: The purpose of our study was to determine whether a Burch urethropexy or a Marshall-Marchetti-Krantz (MMK) urethropexy, both with a concurrent paravaginal defect repair (PVDR), is more effective in correcting stress urinary incontinence. Additionally, our aim was to determine if pre-operative urodynamic studies (UDS) make a difference in the success of either urethropexy group.

METHODS: A prospective randomized study was done on women who underwent surgery for anterior vaginal wall prolapse and genuine stress incontinence. The surgeries were performed by one physician at a medical school-affiliated private hospital between 1998 and 2003. Exclusion criteria included patients with a prior retropubic urethropexy or a cough leak point pressure less than 60 cmH₂O. Pre-operative UDS were either initiated by the referring physician or at the discretion of the surgeon when intrinsic sphincter deficiency or urge incontinence was clinically suspected. All patients underwent a PVDR and were randomized to receive a Burch or MMK urethropexy, using permanent sutures at all sites. Other ancillary procedures were performed as indicated. Follow-up was done by questionnaire (mail or interview). Based upon the responses, patients were categorized as cured, improved or failed.

RESULTS: There were 138 patients in the study, with 72 patients being randomized to the MMK urethropexy and 66 to the Burch urethropexy. There were no differences between the groups in terms of age, race, smoking, weight, follow up (87.7%), pre-operative need for protection (pad use), and the percentage of patients receiving pre-operative UDS (59.7% vs. 65.7%). After controlling for the difference in months of follow-up (MMK – 28.8 months, Burch - 24.2 months), the MMK group had a higher failure rate compared to the Burch group (MMK – 24.6%, Burch – 8.3%, p=0.0238). In the MMK group, women who had pre-operative UDS had a higher failure rate (35%) compared with those who did not have UDS (4.8%). Pre-operative UDS did not result in different failure rates in the Burch group. **CONCLUSION:** In women needing an incontinence procedure in addition to a PVDR, the Burch urethropexy was associated with a lower failure rate compared to the MMK urethropexy. It is unclear why the MMK group failure rate was even higher in the women having UDS.

Disclosure – Nothing to disclose

Paper 7

Levator Contraction Strength and Genital Hiatus as Predictors for Recurrent Pelvic Organ Prolapse

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OBJECTIVE: To evaluate the ability to predict surgical failure in surgery for pelvic organ prolapse (POP) and stress urinary incontinence (SUI) using two key elements of the physical examination, the levator ani contraction strength and the measurement of genital hiatus (GH). **METHODS:** This was a retrospective cohort study of patients having undergone surgery for POP or SUI from February 1997 to June 2003. All subjects had a comprehensive evaluation with ensuing surgery by one of the two senior authors who both specialize in the treatment of female pelvic floor disorders. Data was abstracted from the office charts. Levator contraction strength, determined by digital examination during a voluntary maximal pelvic floor contraction, was scored based upon the Oxford 0-5 Classification Scale of muscle strength. GH was measured in accordance with the Pelvic Organ Prolapse Quantification (POP-Q) examination. Statistical analysis was performed using ANOVA and Chi-square. **RESULTS:** Of 505 total cases during this time interval, levator contraction strength and GH were recorded in 426 and 156 cases respectively. There were 104 cases of recurrent pelvic organ prolapse (24.4%). Diminished levator strength (<5) was associated with an increase in recurrent POP (30.9% vs. 0%; p<0.025). A genital hiatus of 5 cm or greater was also associated with an increased risk of recurrent prolapse (44.2% vs.

27.8%; $p < 0.05$). There were 77 cases of subjectively reported recurrent or de novo urinary incontinence after surgery (22.0%). Patients unable to voluntarily contract the pelvic floor had an increased risk of post-operative urinary incontinence (35.0% vs. 20.4%; $p < 0.05$) and an increased risk of additional surgery for POP or incontinence (20.0% vs. 9.4%; $p < 0.05$). Patients requiring additional surgery for prolapse or incontinence (8.7%) tended to have a weaker levator contraction although the difference was not significant ($p = 0.097$). These patients did however have an increased genital hiatus (5.6 vs. 4.4; $p < 0.005$). Patients with a normal levator contraction tended to have a lower parity (2.2 vs. 3.8; $p < 0.025$) when compared to those with weaker contractions. This relationship did not hold for GH. There was no difference in body mass index, cesarean section rate, hysterectomy rate, or number of previous pelvic reconstructive procedures among patients with different degrees of levator function. **CONCLUSION:** Diminished levator ani contraction strength and a widened GH correlate with an increase in surgical failures and need for recurrent surgery. This information can help the surgeon counsel the patient with regards to recurrence and failure rates when attempting surgery for POP or SUI. Further study is necessary to assess whether modification of these variables can improve surgical outcomes.

Disclosure – Nothing to disclose

Paper 8

Structure of the Perineal Membrane in Females: Histologic, Anatomic, and MRI Findings

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OBJECTIVE: Traditional depictions of the perineal membrane describe a) a trilaminar musculo-fascial structure that is b) “perforated by the urethra and vagina” This does not correspond well with anatomy seen in cadaver dissection or imaging studies of living women. Our objective was to re-examine the anatomy of this area in serial cadaver sections and MR images of living women. **METHODS:** Serial histologic sections (trichrome) of 5 female pelvic specimens (0 to 37 years old) were examined. Specimens included the urethra, perineal membrane, vagina and surrounding structures. Macroscopic whole pelvis sections of 3 adults 28 to 56 years in axial, sagittal and coronal sections were also studied. Multiplanar proton-density MR images at 5 mm intervals from 20 normal nulliparous women were studied and 3-D reconstruction made from selected MR series. Serial histologic sections were used to define tissue types (smooth muscle, connective tissue, striated muscle) and to define the detailed spatial relationships of various structures. Whole pelvic cross sections were used to study overall topography. 3-D reconstructions of selected MR scans permitted *in-situ* analysis of normal living women not distorted by muscle tone loss or postmortem changes. **RESULTS:** The perineal membrane is a complex structure with many parts. It is composed of 2 regions, one dorsal and one ventral. The **dorsal portion** consists of bilateral transverse fibrous sheets that attach the lateral wall of the vagina and perineal body to the ischio-pubic ramus. This portion is devoid of striated muscle. The **ventral portion** is a solid 3-dimensional tissue mass in which several structures are embedded. It contains the compressor urethra and the urethra-vaginal sphincter muscle of the distal urethra with the urethra and its surrounding connective. The ventral margin of this mass is continuous with the insertion of the arcus tendineus fascia pelvis into the pubic bone. The levator ani muscles are attached to the cranial surface of the perineal membrane. The vestibular bulb and clitoral crus lie on the caudal surface of the membrane and are fused with it; there being no natural plane of cleavage between these erectile structures and the membrane. **CONCLUSION:** The structure of the perineal membrane is not a trilaminar sheet with perforating viscera, but a complex 3-dimensional structure with 2 distinctly different dorsal and ventral regions.

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Paper 9

The Effect of Hormone Replacement on the Biomechanical Properties of the Uterosacral and Round Ligaments in the Macaque Monkey Model

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OBJECTIVE: To determine the effects of ovariectomy (OVX) compared to two hormone replacement regimens on the biomechanical properties of the uterosacral (USL) and round (RL) ligaments in the postmenopausal monkey.

METHODS: Study Design: Randomized, triple blind, placebo-controlled. Surgically postmenopausal cynomolgus monkeys were randomized to receive for 12 months either no treatment (OVX) (control, n = 19), or conjugated equine estrogens plus continuous medroxyprogesterone acetate (CEE/MPA) (n = 19), or ethinyl estradiol plus norethindrone acetate (EE/NA) (n = 21) at doses that were scaled from those doses taken by women. USL and RL were harvested and mechanically tested, by the same blinded tester, via a series of step strains ranging from 2% to 30% while continuously bathed in physiological saline. The specimens were allowed to stress-relax at each strain level and the equilibrium strains were curve-fitted using an exponential function to obtain the strain-dependent tensile modulus from 0% to 30% strain. Oneway ANOVA with treatment as the factor was used to determine if there were statistically significant differences in the tensile moduli between treatments. A Student-Newman-Keuls multiple comparisons test was used to discern differences between treatment regimens.

RESULTS: 1) USL: The tensile moduli for both treatment groups were statistically larger than that of OVX monkeys for strains ranging from 0% through 12% (e.g. 0.08 ± 0.05 Megapascals (Mpa) OVX, 0.32 ± 0.28 MPa EE/NA, 0.35 ± 0.47 MPa CEE/MPA at 12% strain ($p < 0.04$)). No differences were found between treatment regimens. 2) RL: The tensile moduli for both treatment types were found to be statistically smaller than that of the OVX monkeys for strains ranging from 12% through 30% (e.g. 3.19 ± 2.62 MPa OVX, 1.33 ± 1.07 MPa EE/NA, 1.28 ± 0.88 MPa CEE/MPA at 12% strain ($p < 0.05$)). No differences were found between treatment regimens.

CONCLUSIONS: Both CEE/MPA and EE/NA affect the functional biomechanical properties of both the USL and RL in the monkey model in a similar manner. Treatment greatly increases stiffness in the USL while decreasing stiffness in the RL. This study supports the hypothesis that hormonal status plays a role in pelvic support. Continued application of these methodologies to the supporting structures of the pelvic organs is likely to provide a mechanistic understanding of pelvic organ prolapse.

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Paper 10

Are Differences in Urinary Incontinence (UI) Prevalence among Black v. White Women Explained by Differences in Risk Factors? A Multivariate Analysis.

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OBJECTIVE: Previous studies have reported a lower prevalence of stress UI and a higher prevalence of urge UI in black women compared to white women. We sought to determine if differences in UI by

type could be explained by differences in the distribution of UI risk factors between black and white women. **METHODS:** The Reproductive Risks for Incontinence Study at Kaiser (RRISK) is a population-based cohort of 2109 women age 40 to 69 randomly selected from age and race strata. Variables, including UI, were assessed by self-report questionnaires, in-person interviews, and 7-day voiding diaries. Labor and delivery and surgical data were abstracted from medical records archived since 1946. Differences in risk factor distribution between groups were tested using Student's t-test (continuous variables) or chi-square (categorical variables). Logistic regression was used to adjust for differences. **RESULTS:** Compared to white women (n=1003), Black women (n=383) were substantially less likely to report at least weekly stress UI (7.9% vs. 15.5%, p<.0001), and more like to report urge UI (13.5% v. 9.5%, p<.05). Blacks and whites differed on the proportion exposed to several UI risk factors, including hysterectomy (32% v. 22%, p<.001); current estrogen use (36% v. 23%, p<.001); body mass index (B>W, p<.001); history of breach presentation (4.6% v. 1.6%, p<.01); augmented labor (18% v. 12%, p<.01), prolonged 1st stage (14% v. 9%, p<.01), forceps (72% v. 64%, p<.01), diabetes (11% v. 5%, p<.001); health status fair/poor (17% vs. 10%, p<.001); and smoking (17% vs. 9%, p<.001). Adjustment for multiple potential risk factors (demographic and medical, reproductive and parturition variables, including those listed above) increased the difference in stress UI but did not change the difference in urge UI.

Table: Odds Ratios (ORs) and 95% Confidence Intervals (CIs) for UI by Type in Black v. White (ref) Women

UI by type	Unadjusted	95% CI	p-value	Adjusted	95% CI	p-value
Stress UI	0.42	0.27-0.64	<0.0001	0.34	0.20-0.55	<0.0001
Urge UI	1.49	1.04-2.14	<.05	1.51	0.95-2.34	0.09

CONCLUSIONS: The nearly 3-fold difference in prevalence of stress UI and the nearly 50% greater prevalence of urge UI in Blacks vs. whites cannot be explained by differences in commonly recognized risk factors for incontinence.

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Paper 11

Results of Urine Cytology and Cystoscopy in Women with Irritative Voiding Symptoms

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OBJECTIVES: The role of urine cytology in evaluating women with lower urinary tract symptoms remains unclear. The purpose of this study is to assess the rates of urine cytology abnormalities in women presenting to a tertiary Urogynecology clinic with irritative voiding symptoms, and to evaluate cystoscopy outcomes in a subset of these women.

METHODS: As part of an ongoing, IRB-approved cross-sectional study evaluating the utility of urine cytology in women presenting to a tertiary Urogynecology clinic with irritative voiding symptoms, all urine cytologies sent between 1/1/00 and 7/31/03 were reviewed. Irritative voiding symptoms were defined as urgency, frequency, nocturia, and/or dysuria. Cytology results were interpreted by Cytopathology as normal, atypical, suspicious, or malignant. Consistent with prior studies, normal and atypical cytologies were classified as low risk, and suspicious and malignant cytologies were classified as high risk. Data were then extracted from 200 consecutive charts from this large cohort to evaluate cystoscopy outcomes. Demographics, risk factors for urothelial cancer, cytology results, urinalysis and microscopy results, and cystoscopy results were analyzed.

RESULTS: 1783 total urine cytologies were reviewed; of these, 1661 were read as normal (93.2%), 119 (6.7%) were abnormal, and 3 (0.2%) were unsatisfactory. Among the 119 abnormal cytologies, 112 (94.1%) were classified as atypical or indeterminate. The remaining 7 cytologies were categorized as suspicious or malignant (5.9% of the abnormalities), accounting for only 0.4% of all cytologies sent. Of the 200 women chosen for subanalysis, the mean age was 57.4 ± 14.0 years, 54% were postmenopausal, 38.5% had a history of estrogen use, 7% had a documented urinary tract infection, 2% had microscopic hematuria on urinalysis, and 35% had a history of smoking. Cytology results for the 200 women were normal in 88.5% and atypical/ indeterminate in 11.5%. No cytologies were suspicious or malignant. 8.5% of smokers had an atypical urine cytology compared with 13% of nonsmokers. Cystoscopy was normal in 194 of the 200 women (97%) and demonstrated cystitis in 5 patients and bladder stones in 1 patient. No suspicious bladder lesions were noted on cystoscopy.

CONCLUSIONS: In our population of women with irritative voiding symptoms, urine cytology was classified as high risk in only 0.4% of cases. The low rate of suspicious or malignant urine cytologies brings into question the usefulness of urine cytology in the initial evaluation of women with irritative voiding symptoms. Furthermore, the routine use of cystoscopy in the initial evaluation of irritative voiding symptoms may be of limited value. The utility of these diagnostic tests is currently being evaluated in an ongoing, large cross-sectional study.

Disclosure – Nothing to disclose

Paper 12

Efficacy of Botulinum-A Toxin in the Treatment of Motor Urge Incontinence: A Prospective Non-Randomized Study

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OBJECTIVE: Botulinum-A toxin (BTX) injections into the detrusor muscle in spinal cord injured patients with reflex incontinence has recently gained worldwide acceptance. It was the purpose of this study to evaluate the efficacy of this treatment in patients suffering from overactive bladder/wet syndrome (OAB). **METHODS:** Since February 2003 21 patients (p) (mean age 66; 50-83) entered this ongoing open label prospective non-randomized study. Inclusion criteria were urodynamically proven motor and sensory urge incontinence not effectively treatable by different and high dose of anticholinergic medication (ACH) and a high impact on quality of life (QoL). Pretreatment evaluation consisted of history, urodynamic evaluation, voiding diary, urinalysis and urine culture. Special attention was given to maximal bladder capacity (MBC), compliance (C), residual volume (RV), volume during first desire to void, daytime frequency and urge incontinence episodes frequency (IEF). Under cystoscopic control a total amount of 100 units of BTX (Botox[®]) were injected into the detrusor muscle at 30 different sites, sparing the trigone. Clinical and urodynamic controls were performed at 4, 12 and 36 weeks after treatment. QoL assessment was performed by the King's Health Questionnaire (KHQ) validated in German language. **RESULTS:** BTX treatment was completed in all 21 p without any major immediate or late complication. Presently all p have been fully evaluated after 4 weeks, 13 after 12 weeks and 2 after 36 weeks. At 4 week follow-up urodynamic evaluation in 19/21 p revealed a significant increase of MBC (from mean 224 to mean 343ml), C (from mean 14 to mean 43ml/cmH₂O), volume during first desire to void (from mean 103 to mean 191ml) and a decrease of daytime frequency (from mean 12 to mean 4 voids per day). 2 p needed self-catheterization for one week (RV 130-230ml). All p were without any incontinence episodes. Evaluation of bother by the KHQ before/after treatment showed: scale "no bother at all" in 0/6 p, scale "a little bother" in 0/8 p, scale "moderate bother" in 10/5 p and scale "a lot of bother" in 9/0 p. 2/21 p had no benefit in terms of urodynamics and QoL. Data

analysis of urodynamic parameters and incontinence at the 12 week and 36 week follow-up is ongoing. So far 2 p were reinjected after the effect of BTX had diminished 5 and 10 months after initial injection. All successfully treated p (19/21) would be willing to undergo a second BTX injection if efficacy diminishes. **CONCLUSIONS:** This is one of the first pilot-studies indicating that BTX injections into the detrusor muscle in p with idiopathic motor or sensory urge incontinence and failed conventional treatment offers at least short-term efficacy. Patients' acceptance and satisfaction are high and recruitment of p is ongoing.

Disclosure – Nothing to disclose

Paper 13

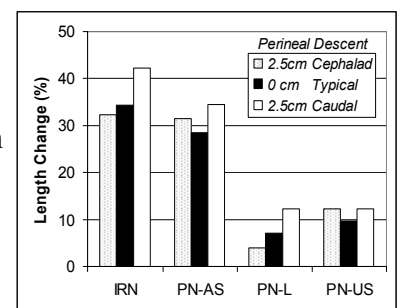
Pudendal Nerve Anatomy and 3-D Computer Simulation of Pudendal Nerves Stretch during Vaginal Birth

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OBJECTIVE: When a peripheral nerve is stretched more than 15% it can sustain permanent damage¹. To investigate pelvic nerve stretch during the second stage of labor, we determined (a) the anatomic 3-D course of the pudendal nerve relative to pelvic landmarks, and (b) the increase in pudendal nerve length during simulated birth using computer modeling.

METHODS: The three branches of the pudendal nerve (inferior rectal, IRN; perineal, PN; dorsal nerve of clitoris, DCN) were dissected in 12 hemi-pelves from six female cadavers. Their 3-D course was digitized from the S2-4 sacral roots to their insertions using an Optotrak 3020TM optoelectronic system. The two branches relevant to the external anal sphincter (IRN and PN) and striated urethral sphincter (PN) were selected for analysis. The data was imported into an existing 3-D computer model² of the pelvic floor in I-DEASTM. Each nerve was represented by a stretchable cord routed through defined anatomic landmarks (i.e., ischial spine, Alcock's canal, and perineal membrane). The model was used to quantify the pudendal nerve branch length changes distal to the ischial spine as a model fetal head of average molded diameter dilated the pelvic floor structures. Pudendal nerve branches were stretched around the fetal head as it descended through the pelvic floor. Length change percentages were calculated ($[\text{final length} - \text{original length}] / \text{original length} \times 100$) for three perineal descents: typical descent from the literature, 2.5 cm caudal and 2.5 cm cephalad.

RESULTS: Anatomy: The IRN terminated in the dorsal portion of the external anal sphincter, while a branch of the PN terminated in the ventral portion (PN-AS). A deep PN branch terminated in the striated urethral sphincter (PN-US), while the remaining PN branch terminated in the labia (PN-L). **Nerve Stretch:** The maximum change in nerve length is shown in the graph for each nerve (black bar: typical perineal descent; grey: 2.5 cm cephalad; white: 2.5 cm caudal). The IRN exhibited the maximum length change (34%), and this varied by 15% from the scenario with the least perineal descent to that with the most perineal descent. The percentile length change of the PN-AS was 28% while PN-L and PN-US reached 7% and 10%, respectively. The graph showed these length changes were influenced by the degree of perineal descent.



CONCLUSIONS: These observations suggest that (1) nerves innervating the anal sphincter are stretched beyond the threshold for permanent damage during the second stage of labor, and (2) the degree of perineal descent appears to influence pudendal nerve stretch. *Supported by NICHD HD R01 38665 & 44406.*

¹*Clin Orthop* 296:288-294, 1993; ²*Obstet Gynecol* 103:31-40, 2004

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Paper 14

Pudendal Neuralgia: A Severe Pain Syndrome

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OBJECTIVES: To describe the clinical and electrodiagnostic findings, the therapies and therapeutic outcomes of patients with pudendal neuralgia.

STUDY DESIGN: A retrospective, descriptive study of all patients diagnosed with pudendal neuralgia treated by the author from March 19, 2003 to December 22, 2003.

RESULTS: 66 patients were studied. The major clinical findings were pudendal nerve distribution of pain (66, 100%), pain aggravated by sitting (64, 97%) and relieved by standing or lying (59, 89%) and mis-diagnosis (55, 83%)

Pudendal nerve clinical neurophysiologic findings were: normal in 23 (35%), demyelination in 17 (26%), axonal loss in 5 (7.5%) and both demyelination and axonal loss in 21 (32%).

Therapies, described in text, were basic conservative in all, nerve injection therapy in 38 (57%), pudendal neurostimulation implant therapy in 2, and pudendal decompression surgery in 10 (15%). Pain improvement occurred slightly or moderately in all with conservative therapy, in 12 (31%) with nerve injection therapy, in both patients with nerve stimulation and in six patients (60%) with surgical decompression.

CONCLUSION: Pudendal neuralgia is a poorly recognized and poorly treated syndrome. Slight to moderate improvement is gained with conservative therapy. Injection therapy is beneficial in one third of cases, and surgical decompression has some benefit in one half of patients. Pudendal neurostimulation therapy needs further evaluation.

Disclosure –Consultant: J.T. Benson, Medtronic

Paper 15

The Effect of Pudendal Nerve Blockade on Vaginal and Anal Pressures

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OBJECTIVE: Recent studies have questioned whether the pudendal nerve innervates the levator ani muscle. We sought to determine the effect of pudendal nerve blockade on the resting and squeeze pressures in the vagina and anal canal.

METHODS: Seven nulliparous women without symptoms of anal or urinary incontinence were studied using vaginal and anal manometry with simultaneous electromyography (EMG) of the external anal sphincter (EAS) and puborectalis muscle (PRM). Concentric needle electrodes were placed transcutaneously into the EAS and the PRM for EMG recording. Pudendal Nerve Blockade (PNB) was performed transvaginally with 10cc of 1% lidocaine on each side. Pressure measurements were made at rest and during a sustained maximal contraction of the pelvic floor before and after PNB. The blockade was assessed by sharp-dull discrimination. Our previous work has demonstrated that contraction of the

PRM and EAS increases pressure in the proximal and distal areas of the anal canal respectively. Data are shown as mean +/-SD.

RESULTS: A complete bilateral block was achieved in 5 subjects. One subject had a complete block on one side with a partial block on the other side and one subject had a partial block bilaterally. Data are shown including all 7 subjects. Before PNB: Vaginal pressure increased from a baseline pressure of 33 mmHg to 58 mmHg (p<0.05) with squeeze. Proximal anal pressure increased from 35 to 48 mmHg (p<0.05) and distal anal pressure increased from 87 to 118 mmHg (p<0.05) with squeeze. After PNB: Vaginal pressure at rest decreased to 6 mm Hg (p<0.05) and squeeze vaginal pressure decreased to 24 mmHg (p<0.05). Proximal anal pressure at rest decreased to 19 mmHg (p<0.05), and during squeeze it decreased to 33 mmHg (p<0.05). Distal anal pressure at rest decreased to 53 mmHg (p<0.05) and during squeeze it decreased to 70 mmHg (p<0.05). The resting and squeeze EMG amplitude of the PRM and the EAS were markedly reduced by PNB.

		Before Block	After Block
Vaginal Pressure (mmHg)		Rest	33 +/-22
		Squeeze	58 +/-30
Anal Pressure (mmHg)	Proximal	Rest	35 +/-17
		Squeeze	48 +/-12
	Distal	Rest	88 +/-21
		Squeeze	118 +/-34

CONCLUSIONS: Pudendal nerve blockade significantly decreases vaginal and anal resting and squeeze pressures. The pudendal nerve innervates the portion of the pelvic floor (levator ani) muscle that contributes to vaginal pressure.

Disclosure – Nothing to disclose

Paper 16

Evaluation of the Role of Pudendal Nerve Integrity in Female Sexual Function Using Non-invasive Techniques

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Objective: Using quantitative sensory testing (QST), we sought to explore the role of pudendal nerve integrity in sexual function in women. **Methods:** After IRB approval, women were prospectively recruited from the Urogynecology and Gynecology clinics at our institution. Consenting patients were asked to complete the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-31) on their first visit. The PISQ is scored such that a lower score reflects poorer sexual function. QST is a validated diagnostic modality for the evaluation of peripheral nerve sensation using vibratory and tactile stimulation. QST has been proven to be reliable for assessing the female genital innervation. Biothesiometry and pressure thresholds were conducted at the S2 dermatome regions of the vulva, clitoris, external urethral meatus, and the right and left sides of the perineum, reflecting pudendal nerve distribution. Vibratory thresholds were determined using the method of limits at a fixed frequency of 120 Hz and pressure thresholds were conducted using Semmes-Weinstein monofilaments. Sensory thresholds were recorded and increased sensory thresholds indicate worsening neurological function. Descriptive data was analyzed using means, standard deviations and percentages. Categorical data was compared using Student's t- test. **Results:** Fifty-five women underwent neurological testing and completed the PISQ- 31. The mean age, parity and BMI of all participants were 38± 10.3 years, 1.8± 1.5, and 29.3 ± 6.1 kg/m², respectively. Thirty patients (55.5%) were asymptomatic and constituted the control group and twenty five (45.5%) had one or more forms of female sexual dysfunction (FSD). The percentage of women with FSD included: Desire disorder (DD) 17%, Arousal disorder (AD) 23.6%, Orgasmic disorder (OD) 26.4% and Pain disorder (PD) 13.7%. There was no significant difference between asymptomatic controls and the symptomatic group regarding age, parity, menopausal status and

BMI. When patients were categorized according to the type of sexual dysfunction reported, PISQ scores were significantly lower in each group compared to controls. ($p < 0.01$) Additionally, sensory deficits were found in the symptomatic groups. Women with DD had increased vibratory thresholds at the clitoris ($p = 0.04$) and vulva ($p = 0.04$) as well as increased pressure thresholds at the right perineum. ($p = 0.002$) Women with AD had increased vibratory thresholds seen at the clitoris ($p = 0.03$) and increased pressure thresholds at the right perineum. ($p = 0.003$)

Conclusion: There is a statistically significant increase in quantitative sensory thresholds in the genital region in women with sexual dysfunction when compared to normal controls. Pudendal nerve integrity may play a role in FSD. Further studies are needed to support these preliminary findings.

Disclosure – Consultant: G. Lazarou, Ortho McNeil, Pfizer, Bard, Mentor; Speaker’s Bureau: K. Powers, Ortho-McNeil

Paper 17

Immunohistochemical Evidence for the Interaction between Levator Ani and Pudendal Motor Neurons in the Coordination of Pelvic Floor and Visceral Activity

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OBJECTIVE: Neuromuscular integrity is essential in maintaining normal pelvic floor support and continence, but the neuronal control of the levator ani (LA) muscle is poorly understood. The purpose of this study was to characterize the afferent and efferent pathways that innervate the LA muscle in the female squirrel monkey. Specific attention was given to compare the morphology and locations of LA motor neurons with pudendal motor neurons to determine any contribution of the pudendal nerve to LA muscle innervation and anatomical substrates that might mediate physiological coordination of the rhabdosphincter and pelvic floor.

METHODS: Cholera toxin B (CTB) was injected unilaterally into the LA muscle of 4 squirrel monkeys to identify primary sensory neurons in the dorsal root ganglia (DRG) and motor neurons in the spinal cord that contribute fibers to the LA nerve. Fluoro-Gold (FG) was injected into the external anal sphincter to label pudendal motor neurons in the spinal cord ($n = 2$; 1 animal had concomitant CTB and FG injections). Animals were sacrificed 3-7 days following the injections to allow for the retrograde transport of the neurotracers. Spinal cord and DRG were dissected into segments and processed for immunohistochemistry.

RESULTS: Retrograde transport of CTB from the LA muscle labeled primary afferent neurons in the ipsilateral DRG, their central afferent projections, and motor neurons in the medial portion of the ipsilateral ventral horn of the spinal cord (L7-S2 segments). Importantly, CTB-labeled LA motor neurons were virtually absent in Onuf’s nucleus, where all pudendal nerve motor neurons are located. Injection of FG into the external anal sphincter resulted in labeled cells in Onuf’s nucleus primarily in L7, confirming the location of this nucleus in the squirrel monkey. Extra-somatic CTB-labeling within Onuf’s nucleus was observed adjacent to FG-labeled pudendal motor neurons. This CTB labeling appeared to be contiguous with LA motor neuron somata suggesting dendritic arborization and direct contact between LA motor neurons and pudendal motor neurons.

CONCLUSIONS: Results from this study indicate that the LA muscle has a distinct innervation with very little or no contribution from the pudendal nerve. The intriguing labeling of LA neural elements within a nucleus that innervates the external urethral and anal sphincters (involved in pelvic visceral control) may represent the neuroanatomical substrate for physiological integration with spinal and supraspinal inputs in the coordination of pelvic floor and visceral activity.

Disclosure – Other: K.B. Thor: paid speaker for Eli Lilly; employed by Dynogen Pharmaceuticals, Inc.

Paper 18

A Blinded, Sham-Controlled Trial of Postpartum Extracorporeal Magnetic Innervation to Restore Pelvic Muscle Strength in Primiparous Patients

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OBJECTIVE: To determine the effects of postpartum extracorporeal magnetic innervation (ExMI) on pelvic muscle strength of primiparous patients for the year following childbirth. **METHODS:** Primigravid patients were recruited from our community. Eligible patients were enrolled during their first pregnancy – between 20 and 34 weeks gestation. They were randomized to receive either active or sham ExMI treatments beginning during their 6th postpartum week. Our main outcome measure was pelvic muscle strength as measured by perineometry in cmH₂O. These assessments were made by a single independent observer blinded as to patients' group assignments. Baseline measurements were obtained at the enrollment visits (i.e. while the patients were pregnant), and follow-up measurements were made 6 weeks (prior to ExMI or sham treatment), 14 weeks, 6 months and 12 months postpartum. Between 6 and 14 weeks postpartum, patients completed a course of 16 treatment sessions in either the active or sham ExMI chair (NeoControl®, NeoTonus Inc., Marietta, GA). Our sample size estimate called for 19 patients in each arm to have 80% power of detecting a 40% difference in mean perineometry measures between groups at any point during the study ($\alpha = 0.05$). Mixed randomized-repeated measures analysis of variance was used to analyze the mean perineometry values between the two treatment groups and across all five time periods. Accordingly, group, time and group cross-time interaction effects were tested. **RESULTS:** Fifty-one patients enrolled, and 38 patients returned for their postpartum treatment sessions. As expected, there were no demographic differences between the active and sham groups. Likewise, there were no differences between the groups with respect to delivery characteristics (i.e. instrumented or C-section delivery, length of labor stages, damage to the perineum, baby birthweight, or episiotomy use). The analysis of variance procedure indicated no main effect difference between the active or sham ExMI treatments, $F(1,31)=0.02$, $p=0.89$. Also, there was no significant group cross-time interaction, $F(3,88)=2.5$, $p=0.07$, indicating no difference between groups at any given time period. When measures from both groups were combined, an overall time main-effect was found, $F(3,88)=4.4$, $p=0.01$. Namely, mean perineometry measures at baseline were significantly higher (mean = 52.2 cmH₂O) than those at 6 weeks postpartum (mean = 42.3 cmH₂O), $p=0.02$. However, all subsequent perineometry measurements (14 weeks, 6 months and 12 months postpartum) were similar to baseline measurements, $p=0.29$, $p=0.53$, $p=0.59$, respectively. **CONCLUSIONS:** We found no differences in pelvic muscle strength among primiparous patients who received active or sham ExMI treatments in the early postpartum period.

Disclosure – Grant/Research Support: P.J. Culligan, Neotonus Inc., Mentor Corp, Gynecare; Consultant: M.H. Heit, Indevus; P.J. Culligan, Eli Lilly; Speaker's Bureau: P.J. Culligan, Eli Lilly; Paid Instructor: P.J. Culligan, CR Bard; M.H. Heit, CR Bard

Paper 19

Obstetric Antecedents to Symptoms of Pelvic Floor Dysfunction

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OBJECTIVE: To prospectively study the association between symptoms of pelvic floor injury in primiparous women up to 6 months after childbirth and selected obstetric antecedents. **METHODS:** All nulliparous women who presented for delivery between June 1, 2000 and August 31, 2002 were interviewed to determine symptoms of urinary and anal incontinence prior to and during pregnancy. Following delivery, those women who returned to our healthcare system for postpartum, contraceptive, or subsequent prenatal care were surveyed regarding symptoms indicative of persistent pelvic floor dysfunction. This standardized survey, an adaptation of a previously validated Urogenital Distress Inventory, was administered at each subsequent postpartum visit with the aid of trained bilingual assistants. Pregnancy outcomes for all women are entered routinely into a computerized database by research nurses. Responses from all women with a postpartum survey within 6 months of delivery were analyzed. Obstetric antecedents to stress, urge, and anal incontinence were identified. Attributable risks for each factor were calculated through logistic regression using women who delivered spontaneously without: 1) oxytocin, 2) a prolonged second stage of labor, 3) an episiotomy or perineal laceration, 4) regional anesthesia, or 5) macrosomia (birthweight > 4000 g), as the referent group. **RESULTS:** Since completion of enrollment on August 31, 2002, 3,887 (37%) of 10,643 primiparous women have returned within 6 months of delivery. The mean age of women enrolled was 22 ±5 years and the average BMI was 30. The average birthweight was 3287 ± 539 grams. The mean number of days elapsed between delivery and postpartum survey was 56 (range 14-219 days). The prevalence of symptoms of stress and urge urinary incontinence in the reference group was 4.2% (34/810) and 3.8% (31/810), respectively. The prevalence of symptoms consistent with anal incontinence was 1.5% (12/810). Regarding **stress urinary incontinence**, symptoms were reduced by 52% (P = 0.006) in women with a cesarean delivery. When considering **urge urinary incontinence**, symptoms were doubled in women who underwent a forceps delivery (P = 0.04) and were reduced by 63% (P = 0.01) in women with a cesarean delivery. Concerning **anal incontinence**, symptoms were increased by 57% (P = 0.006) in women who delivered an infant > 4000 grams and were increased 3-fold (P = 0.003) in women who received oxytocin and had an episiotomy performed. **CONCLUSIONS:** The likelihood of symptom(s) of pelvic floor dysfunction up to 6 months after delivery was greater in women who received oxytocin, underwent a forceps delivery, delivered an infant > 4000 grams, or had an episiotomy performed. Women who underwent a cesarean delivery had fewer symptoms of urge and stress urinary incontinence when compared to those women delivered spontaneously. (Supported by NICHD, #RO1 HD038663)

Disclosure – Grant/Research Support: J. Schaffer, Eli Lilly; Consultant: J. Schaffer, Yamanouchi & Eli Lilly

Paper 20

Is There a Correlation Between Postoperative Vaginal Dimensions and The Risk for Dyspareunia Following Pelvic Reconstructive Surgeries?

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OBJECTIVE: Only few studies have so far addressed the question of whether vaginal dimensions following pelvic reconstructive surgeries affect the long-term risk for post operative dyspareunia. The current study aimed to answer this question based on a large cohort of patients.

METHODS: We comprehensively reviewed office and hospital charts of sexually active patients who had undergone pelvic reconstructive surgeries at the Evanston Continence Center between July 1988 and June 2002 and returned for follow-up one year postoperatively. For each patient, we recorded the surgical procedures done as well as pre- and postoperative pelvic exams by the POP-Q technique.

Transvaginal length (TVL) and genital hiatus (GH) values were used to estimate pre- and postoperative vaginal dimensions. The relative changes in these dimensions were calculated as: (preoperative value – postoperative value)/ preoperative value. All patients completed questionnaires regarding the presence and severity of dyspareunia before and one year after surgery. If present, they were asked to rate its severity on a Likert scale from 1 to 4. Data were analyzed using the Pearson’s correlation test, student t-test for continuous variables and Chi-square test for non-parametric variables. We used a logistic regression model, with dyspareunia as the dependent variable, in order to screen each risk factor separately for an association with this outcome.

RESULTS: Two hundred and twenty eight patients aged 44-83 years were included in this study. Surgeries included transvaginal hysterectomy (33%), anterior and/or posterior colporrhaphy (92%), vaginal vault suspension (32%), transvaginal sling procedures (78%) Burch retropubic urethropexy (6%) and paravaginal repairs (6%). Overall dyspareunia rates were significantly higher postoperatively than preoperatively (16% vs. 7%, $p = 0.001$). No specific surgery was associated with higher rates of postoperative dyspareunia. TVL (7.6 vs. 8.8 cm, $p=0.001$) as well as GH (2.7 vs. 3.5cm, $p=0.001$) dimensions were significantly shorter postoperatively than preoperatively. No correlation could be demonstrated between either TVL ($p=0.81$), GH ($p=0.41$) or the relative changes in these dimensions ($p=0.92$ and 0.18) and the risk for postoperative dyspareunia. No low threshold values were found for any of these parameters below which dyspareunia was more likely to occur.

CONCLUSIONS: The risk for dyspareunia increases significantly following pelvic reconstructive surgery. Postoperative vaginal dimensions are reduced following these surgeries, however, these changes may not account for the increased risk of postoperative dyspareunia. Other etiologies for dyspareunia (such as vaginal scarring, altered innervation and blood supply) should be investigated in future studies.

Disclosure – Grant/Research Support: P.K. Sand, Ortho McNeil, Watson, AMS, InDevus, Yamanouchi, Pfizer, Roche, Eli Lilly, Mentor, Bioform; Consultant: P.K. Sand, Ortho McNeil, Watson, AMS, InDevus, Yamanouchi, Pfizer, Boston Scientific, Roche; Speaker’s Bureau: P.K. Sand, Ortho McNeil, Watson, AMS, Boston Scientific

Paper 21

Incidence of Perioperative Complications of Urogynecologic Surgery in Elderly Women

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OBJECTIVE: To determine the prevalence of, and risk factors for, peri-operative complications in women over age 75 undergoing urogynecologic surgery.

METHODS: A retrospective chart review was performed on all patients 75 years or older undergoing urogynecologic surgery at an academic medical center between January 1999 and November 2003. Demographics, comorbidities, and major intra-operative and post-operative (≤ 6 weeks) complications were recorded. Charlson Comorbidity Index was calculated to summarize the patients overall peri-operative risk. Logistic regression was used to identify independent risk factors for peri-operative complications.

RESULTS: Two hundred seventy-eight patients 75 years or older underwent urogynecologic surgery during the study period. Seventeen patients had either incomplete follow up or missing records leaving 261 patients for final analysis. The mean age of patients was 79 ± 3.5 years (range 75-91). Ninety-five percent of patients were white with a mean BMI of 26.5 ± 4.4 (range 18-42), and a median Charlson Comorbidity Index of 1 (range 0-10). Seventy-one percent had ASA Classification 3 or greater. Surgery was performed using the vaginal approach in 81.2% of patients, abdominal approach in 3.8%,

laparoscopic approach in 3.1%, and a combined approach in 11.9%. Overall, 25.7% (95% CI 20.8-31.3%) of patients had one or more major peri-operative complication. The intra-operative and post-operative complication rates were 5.4% (95% CI 3.2 to 8.9%) and 24.1% (95% CI 19.3-29.7%) respectively. The most common peri-operative complications were blood transfusion or significant blood loss (HCT < 24%) in 7.7% (95% CI 5-11.6%), pulmonary edema in 6.5% (95% CI 4.1-10.2%), and post-op congestive heart failure in 4.6% (95% CI 2.6-7.9%). Readmission rate was 2.3% (95% CI 1.1-4.9%). Re-operation rate was 2.7% (95% CI 1.3-5.4%). There were no deaths within 6 weeks of surgery (peri-operative mortality 0%; 95% CI 0-1.1%). Independent risk factors predictive of a patient having one or more peri-operative complication were length of surgery, coronary artery disease, peripheral vascular disease, and chronic obstructive pulmonary disease. Charlson Comorbidity Index was not an independent predictor of peri-operative complications in this population.

CONCLUSION: Pre-existing cardiopulmonary disease increases the risk of a major peri-operative complication in elderly women undergoing urogynecologic surgery. However, overall the peri-operative mortality rate in elderly women undergoing urogynecologic surgery is low.

Disclosure – Grant/Research Support: M.F.R. Paraiso, Organogenesis Corp.; Consultant: M.F.R. Paraiso, Gynecare, Boston Scientific, American Medical Systems; Speaker's Bureau: K.J. Stepp, Wyeth Pharmaceuticals; Other: M.F.R. Paraiso, is an Advisor for BrainTree Laboratories Inc.

Paper 22

Does Information Bias Threaten the Validity of Surgical Outcomes in a Randomized Trial?

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OBJECTIVE: To determine if information bias exists when postoperative exams are performed by surgeons who are unblinded to allograft type and had a vested interest in the organic allograft working as well as the synthetic allograft during vaginal vault prolapse repairs. **METHODS:** This is a retrospective chart review of 58 patients who participated in a randomized surgical trial to determine if organic allograft worked as well as synthetic allograft for vaginal vault prolapse repairs. POP-Q points and stage of prolapse were estimated based on established criteria (Bump 1996) which have been shown to have high inter and intra-rater reliability during the preoperative period (Hall 1996). Participants were examined 6wks, 3mos, 6mos, and 1 year after surgery by a blinded investigator who had no vested interest in the results of the trial other than the internal validity of the POP-Q measurements. POP-Q measurements obtained by the blinded investigator were therefore considered accurate and reflective of the true state of pelvic organ support during the postoperative period (gold standard). The surgeon who operated on the patient examined the patient after the blinded investigator but was unaware of the POP-Q measurements obtained by the blinded investigator. We estimated the level of agreement between POP-Q measurements and prolapse stage obtained by the surgeon and POP-Q measurements obtained by the blinded investigator using intraclass correlation coefficients (two way mixed model, absolute agreement) when data were continuous, and Gamma coefficients when data were ordinal (Points Aa, Ba, Ap, and Bp @ 6wks). We also estimated the mean difference in POP-Q measurements (in mm) obtained by the surgeon and blinded investigator to assess agreement using Bland-Altman plots (Bland, Altman 1986). **RESULTS:** Agreement between POP-Q stage measurements declined over time as prolapse worsened postoperatively (ICC@6wks 1.0, ICC@3mos 0.733(95%CI 0.538, 0.864), ICC@6mos 0.657 (95%CI 0.413, 0.812), and ICC@1yr 0.604 (0.254, 0.814). We found a similar decline in agreement with time for all POP-Q measurements. POP-Q points Aa, Ba, Ap, and Bp @ 6wks, 3mos, and 1yr were measured similarly between the blinded investigator and the vested surgeon. The blinded investigator estimated greater degrees of pelvic organ prolapse over time, as measured by all remaining POP-Q points, compared to the vested surgeon. Clinically, the estimated mean difference in POP-Q

measurements obtained by the blinded investigator compared to the vested surgeon were small ranging from 0.13mm for Point Aa @ 3mos to 6.81mm for GH @ 1yr. **CONCLUSION:** Information bias may threaten the validity of surgical outcomes in a randomized trial because systematic error was introduced by a vested surgeon who estimated lower degrees of prolapse compared to a blinded investigator. Agreement between POP-Q stages can be affected by small differences in POP-Q measurements.

Disclosure – Grant/Research Support: M. Heit, Mentor Corporation

Paper 23

Evidence-Derived Protocol and Anticipatory Management Facilitate Safe Same Day Discharge after Vaginal Hysterectomy

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OBJECTIVE: To analyze the demographics, indications, complications and cost-effectiveness associated with outpatient vaginal hysterectomy in a community setting.

METHODS: Current literature related to pre and postoperative care was reviewed to design a program of anticipatory management to optimize patient management after hysterectomy. Outpatient vaginal hysterectomy has been reported in small numbers with seemingly good results. Based on the literature review, a protocol was derived and implemented to permit outpatient vaginal hysterectomy in our same day surgery unit. A prospective outcomes database was established to detail the demographics, indications, surgical approach, operative time, blood loss, surgical pathology, length of stay and post-operative complications associated with all hysterectomies performed in a single-surgeon general gynecology practice. Ambulation and oral intake were begun as soon as the patients were released from the post-anesthesia recovery area and medically stable. The data for all vaginal hysterectomies performed between January 1, 2000 and December 31, 2003 were analyzed to confirm the safety and feasibility of same-day discharge.

RESULTS: 411 of the 439 hysterectomies performed during this 4-year timeframe were performed vaginally. The patients ranged in age from 27 to 86 years. 389 (95%) of the patients were discharged home within 12 hours of admission to the same-day surgery center. There were no readmissions or emergency room encounters for bleeding, pain management, urinary retention or nausea and vomiting. 3 patients were readmitted within 30 days of surgery for fever and abdominal pain.

CONCLUSIONS: Using evidence-based criteria and incorporating anticipatory management in the postoperative care of patients undergoing vaginal hysterectomy, same day discharge can be implemented safely and effectively in the vast majority of patients. Proactive management included intensive counseling prior to surgery with a focus on patients' prior experiences with surgery and anesthesia. Previous problems were addressed prospectively and written pre and post-operative instructions were reviewed with patients at the office visit before surgery. Patients were contacted daily for several days after discharge to discuss patient questions and reinforce strategies for optimal healing. Eliminating nausea and vomiting while optimizing pain management with balanced analgesia were key factors in permitting early discharge.

Disclosure – Consultant: B. Levy, Conceptus, Inc., American Medical Systems, Inc., Cooper Surgical; Speaker's Bureau: B. Levy, Valleylab, Inc. (TycoHealthSystems), Aventis, Proctor and Gamble, Wyeth; Other: L. Emery is an employee of Myogen, Inc.

Paper 24

Pelvic Organ Support Study (POSST): The Posterior Pelvic Floor Descends as Constipation Complaints Multiply in a General Gynecologic Population

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OBJECTIVE: To evaluate the prevalence of constipation and its association with pelvic organ prolapse in a general gynecologic population. **METHODS:** In this multi-center, prospective, observational study, 1004 women presenting for routine gynecologic healthcare underwent POPQ measurements and completed an English or Spanish survey. Questions included: need to digitate, <2 bowel movements (BMs)/week, >25% frequency of straining, >25% hard or lumpy stools, and >25% incomplete emptying. Constipation scores reflected the sum of positive responses. Scores were examined continuously and dichotomously (0 or 1 vs 2). Bivariate relationships were assessed using Pearson and Spearman correlation coefficient, independent group t-test, and chi-square. The association between POPQ measurements (Ba, C, Bp, gh+pb) and constipation scores was evaluated using multivariable regression, with Bonferroni adjustment for multiple comparisons. **RESULTS:** 1003 of 1004 subjects were analyzed due to conflicting data. The mean age was 43y (SD=14, range=18-83), mean BMI 29kg/m² (SD=7, range=14-61), median vaginal deliveries 2 (0-13), self-reported race: 43% Caucasian, 24% African-American, 29% Hispanic, and 3% other. Annual household income was 35% ≤\$10,000, 29% \$10,001-\$35,000, 14% \$35,001-\$60,000, 14% and ≥\$60,001. Of 119 women with Bp ≥-1.00, 47% reported no constipation symptoms. Overall, hard/lumpy stools (26%), incomplete emptying (24%), and straining (24%) were more prevalent, while fewer women reported <2 BMs/week (15%) or need to digitate (7%). Constipation scores were significantly correlated with Bp (r=.07, P=.03), and gh+pb (r=.07, P=.02) but uncorrelated with C (r=-.01, P=.64) and Ba (r=.04, P=.24). Women reporting 2 or more symptoms had greater gh+pb measurements (M=6.8) than women reporting 0 or 1 symptom (M=6.5), P=.02. At the bivariate level, ≥2 symptoms were associated with income (P<.01), BMI (P=.04), age (P<.01), previous hysterectomy (P=.03) and NVD (P=.03), but not with race (P=.35). POPQ measurements were regressed separately onto (1) total constipation scores, (2) dichotomized scores, and (3) individual symptoms with BMI, age, NVD, race, previous hysterectomy, and income included in all models. (1) and (2) were nonsignificant in all models. Significant single symptom predictors were as follows: Mean gh+pb was 6.7 for non-digitators and 7.0 for those who did, P=.04. Mean gh+pb was 6.7 for non-strainers vs 7.0 for strainers, P=.03. Mean Ba was -1.8 for non-strainers and -1.6 for strainers (P<.01). Mean C was -6.5 for non-strainers, and -6.0 for strainers, P<.01. **CONCLUSIONS:** Although a large minority of women with Stage 2 or 3 posterior wall prolapse were asymptomatic, number of constipation symptoms was associated with increasing posterior wall prolapse and perineal descent [gh+pb] only. Straining was associated with apical and anterior wall prolapse and perineal descent only. Digitation was associated with perineal descent only.

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Paper 25

The Impact of Occiput Posterior Fetal Head Position on the Risk of Anal Sphincter Injury in Forceps-Assisted Vaginal Deliveries

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OBJECTIVE: A forceps-assisted vaginal delivery is a well-recognized risk factor for anal sphincter injury. Some studies have shown that occiput posterior fetal head position is also associated with an increased risk for third or fourth degree lacerations. The objective of this study was to assess whether occiput posterior position confers an incrementally increased risk for anal sphincter injury above that present with forceps deliveries.

METHODS: This was a retrospective cohort study of 588 singleton, cephalic, forceps-assisted vaginal deliveries performed at our institution between January 1996 and October 2003. Maternal demographics, labor and delivery characteristics, and neonatal factors were examined. Statistical analysis consisted of univariate statistics, Student's t-test, Chi-square and logistic regression.

RESULTS: The prevalence of occiput anterior (OA) and occiput posterior (OP) positions was 88.4% and 11.6% respectively. The groups were similar in age, marital status, BMI, use of epidural, frequency of inductions, episiotomies and shoulder dystocias. The OA group had a higher frequency of rotational forceps (16.8% versus 5.9%, $p = 0.019$), greater birth weights ($3307g \pm 526$ versus $3093g \pm 777$, $p = 0.003$), and a larger percentage of African Americans. Overall, 35% of forceps deliveries resulted in a third or fourth degree laceration. Anal sphincter injury occurred significantly more often in the OP group as compared to OA group (51.5% versus 32.9%, $p = 0.002$), giving a relative risk of 1.6 (CI: 1.2 – 2.0). In a logistic regression model that controlled for maternal BMI, length of second stage, fetal head position, birth weight, and the incidence of episiotomy and rotational forceps, OP head position was 2.5 (CI: 1.4 - 4.3) times more likely to be associated with anal sphincter injury than OA head position.

CONCLUSIONS: Forceps-assisted vaginal deliveries have been associated with a greater risk for anal sphincter injury. Within this population of forceps deliveries, an occiput posterior position further increases the risk of third or fourth degree lacerations when compared to an occiput anterior position.

Disclosure – Nothing to disclose

Paper 26

Decreased Anal Sphincter Lacerations Associated with Decreased Episiotomy Use

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OBJECTIVE: To determine if a decrease in the episiotomy rate over time is associated with a corresponding decrease in the anal sphincter laceration rate.

METHODS: Our institution began use of restrictive episiotomy in 1998, with decreasing rates over 4 consecutive academic years (1998-99 to 2001-02). We obtained data from all women delivered during this period, and excluded cesarean and vaginal twin or breech deliveries. Rates of episiotomy, anal sphincter laceration (3rd and 4th degree tears), and other confounding variables were compared between 1998-99 and 2001-02. Logistic regression was used to estimate the odds ratio of anal sphincter lacerations due to episiotomy and other variables in the first and last years of the study.

RESULTS: The episiotomy rate decreased each of the 4 years, from 37.4% in 1998-99 to 16.5% in 2001-02 ($p < .001$). Similarly, the anal sphincter laceration rate decreased from 9.7% to 5.4% ($p < .001$). There were no changes in age, race, nulliparity, duration of the second stage of labor, birthweight, or macrosomia, but oxytocin use decreased (37% to 31%, $p = .002$), epidural use decreased (80% to 76%, $p = .02$), and operative vaginal deliveries increased (8.9% to 11.2%, $p = .03$). At spontaneous vaginal delivery, the episiotomy and anal sphincter laceration rates decreased over four years from 33% to 14% ($p < .001$), and from 6.6% to 2.8% ($p < .001$), respectively. Similarly, at operative vaginal delivery, the episiotomy and anal sphincter laceration rates decreased from 81% to 37% ($p < .001$), and from 42% to 27% ($p = .007$), respectively. Between the first and last years of the study, the adjusted odds ratio of anal

sphincter laceration due to episiotomy decreased from 6.5 (95% CI 3.8, 11.1) to 2.9 (95% CI 1.7, 5.0). Conversely, the adjusted odds ratio for operative vaginal delivery increased from 4.4 (95% CI 2.7, 6.9) to 6.3 (95% CI 3.6, 11.1), but did not change for the other independent risk factors for anal sphincter laceration: nulliparity (from 2.9 to 2.9), prolonged second stage (from 2.0 to 2.1), and macrosomia (from 1.9 to 2.6).

CONCLUSION: With restricted use of episiotomy, our episiotomy rate at vaginal delivery decreased by 56%, and our anal sphincter laceration rate decreased by 44%. These decreases occurred for spontaneous vaginal delivery as well as operative vaginal delivery. In addition, the risk of anal sphincter laceration due to episiotomy was reduced

Disclosure – Consultant: J. Clemons, American Medical Systems; Speaker’s Bureau: J. Clemons, Pfizer

Paper 27

Anal Incontinence in Women Presenting for Gynecologic Care: Prevalence, Risk Factors and Impact upon Quality of Life

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OBJECTIVE: To determine the prevalence, risk factors and impact upon quality of life of anal incontinence (AI) in women aged 18 to 65. **METHODS:** Consecutive women presenting for general gynecologic care to one of 6 tertiary centers were given a self-administered, anonymous bowel function questionnaire. Women responding positively to the question “Have you had any accidental leakage of bowel movements or gas in the last 12 months?” were prompted to complete the Fecal Incontinence Severity Index (FISI, 51 point scale) and the Fecal Incontinence Quality of Life Scale (FIQL, 0-5 point scales). A higher score on the FISI indicates worsening incontinence and a higher score on the FIQL indicates better function. Constipation and irritable bowel syndrome (IBS) were defined according to ROME II criteria. **RESULTS:** A total of 457 women, with a mean age of 39.9 ± 11 years, comprised the cohort. The racial background of the cohort was 66.1% white, 23.2% black, 1.8% Asian and 8.9% other/unknown. The prevalence of AI was 29% [95% CI, 24.7- 33.6]. Of these women, 29.3% had only flatal incontinence, 54.3% reported liquid loss and 54.8% had solid loss. The prevalence of combined anal and urinary incontinence (UI) was 9.9%. Significant risk factors after univariate analysis were UI, vaginal delivery, constipation, IBS, and increasing age and BMI. After logistic regression, the presence of IBS (OR 3.2, 1.7-5.8), constipation (OR 2.0, 1.2-3.5), increasing age (OR 1.04, 1.02-1.07 per year) and BMI (OR 1.04, 1.01-1.08 per unit) remained significant. The mean FISI score was 20.6 ± 12.3. There was significant correlation between the FISI scores and the FIQL scores for liquid and solid stool loss, but not flatal incontinence. Women with only flatal incontinence score higher and women with liquid stool loss score lower on all four scales of the FIQL.

FIQL scale	Flatus only (n=36)	Solid +/- flatus (n=30)	Liquid +/- flatus (n=57)	P value
Lifestyle	3.9 ± 0.3	3.7 ± 0.4	3.5 ± 0.6	0.003
Coping	3.8 ± 0.4	3.5 ± 0.7	3.2 ± 0.7	<0.001
Depression	4.3 ± 0.5	3.9 ± 0.6	3.5 ± 0.8	<0.001
Embarrassment	3.8 ± 0.5	3.5 ± 0.7	3.1 ± 0.8	<0.001

Most women (64.3%) reported AI symptoms had been present for 3 years or less. Only 11.4% of women with AI had sought care and only 17.1% of women had ever been asked by a health care provider about AI. **CONCLUSION:** The prevalence of anal incontinence in women presenting for gynecologic care is high. Liquid stool incontinence has the greatest impact upon quality of life. AI continues to represent a large area of unmet medical need.

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Paper 28

Prevalence of Voiding Dysfunction in Patients with Obstructed Defecation

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The relative contributions of rectal contraction, pelvic floor relaxation and voluntary straining to normal and disordered defecation are unclear. The lower urinary tract and rectum retain and empty contents by similar mechanisms; impaired pelvic floor relaxation during evacuation may cause obstructive defecation and/or impaired voiding. Moreover, the mechanism of impaired pelvic floor relaxation is unknown.

OBJECTIVE: Assess the prevalence of voiding dysfunction in patients with obstructive defecation to understand mechanisms of pelvic floor dysfunction and impaired pelvic floor relaxation during evacuation.

METHODS: 31 healthy controls without constipation, urinary incontinence, or pelvic organ prolapse and 28 patients with obstructed defecation as defined by Rome Criteria III were evaluated by 48 hour voiding diary, symptoms questionnaire, uroflowmetry and postvoid residual measurement.

RESULTS: When queried women with obstructed defecation complained of difficulty initiating a stream compared to controls (57% vs 0%, $p < 0.0001$). Straining to initiate voiding (20% vs 0%, $p = 0.01$). Straining to empty (47% vs 3%, $p < 0.001$). Weak or prolonged stream (53% vs 0%, $p < 0.001$). Sensation of incomplete emptying (50% vs 3%, $p < 0.001$). Stream starting and stopping (40% vs 3%, $p < 0.001$).

Table I Comparison of Uroflowmetry and 48 hour Voiding diary

Patient Variables	Obstructed defecation	Controls	p – value
Abnormal flow pattern*	13	8	p = 0.15
Voiding time (sec.)	30	20	p = 0.02
Time to max flow (sec)	12	4	p = 0.0003
Max flow (ml/sec)	29	31	p = 0.50
48 hr intake (ml)	5737	4454	p = 0.06
Average voided volume (ml)	375	301	p = 0.02
Postvoid residual (ml)	30	50	p = 0.15

* Interrupted, intermittent, prolonged, or superflow

CONCLUSION: Women with obstructed defecation have symptomatic voiding dysfunction and significant differences in uroflow and voiding diaries compared to controls. This relationship supports impaired pelvic floor function in women with obstructed defecation. Studies are needed to dissect whether voiding dysfunction is attributable to a hypocontractile bladder, pelvic floor tension, or normal pelvic floor tone with impaired relaxation in patients with disordered defecation.

Disclosure – Nothing to disclose

Paper 29

Histopathologic Changes of Porcine Dermal Implants used for Transvaginal Suburethral Slings

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INTRODUCTION: Porcine dermal xenografts are commonly used in urogynecologic procedures, but few data exist regarding their in vivo behavior. The purpose of this study was to examine the histopathologic changes in grafts that required subsequent removal, and to correlate these findings with clinical outcomes.

METHODS: Among 63 women undergoing transvaginal sling placement with HMDI cross-linked porcine dermis, 10 patients had subsequent urinary retention requiring urethrolysis and 2 patients had recurrent stress urinary incontinence leading to sling revision and graft removal. Tissue specimens were available for histopathologic evaluation in 8 patients (retention specimens at 6, 15, 19, 21, and 42 weeks and failures at 58 and 67 weeks after surgery). A specimen of porcine dermis before implantation was also prepared for analysis as a control. Graft specimens underwent paraffin embedding according to protocol, and hematoxylin and eosin staining was performed. A single pathologist reviewed the slides blinded to clinical outcomes.

RESULTS: Pathologic analyses of the specimens from patients with retention showed a consistent trend toward graft preservation with minimal remodeling and tissue ingrowth. In these patients, the collagen structure of the graft was almost completely maintained up to 42 weeks after implantation. Layered collagen deposition was mostly limited to the periphery of the implants. Minimal fibroblast infiltration of the grafts was noted, yet only one graft demonstrated any new collagen through the entire thickness of the graft. This collagen ingrowth was limited to a small area of the retrieved material. More concerning, there was evidence of an immune reaction in 4 specimens, suggested by lymphocytic infiltrates at the interface of the new collagen and the graft. Histiocytes and multinucleated giant cells engulfing the porcine collagen matrix were present in 2 specimens suggesting a more vigorous foreign body reaction directly to the graft. In surgical failures, no remnant of graft was found within the resected suburethral tissue. The graft appeared to be completely replaced by dense fibroconnective tissue and moderate neovascularization without evidence of inflammation.

CONCLUSIONS: HMDI cross-linked porcine dermal implants result in variable tissue reactions that may have unpredictable clinical outcomes in different patients. In cases of postoperative urinary retention, the original graft structure was mostly intact with minimal collagen remodeling up to 42 weeks after surgery. Evidence of an immune reaction was also present. In contrast, surgical failures assessed at longer-term follow-up (58, 67 weeks) revealed no evidence of graft remnants or significant inflammatory reaction. This variability in response to the graft raises questions about the overall tolerability and efficacy of HMDI cross-linked porcine dermal xenografts in pelvic reconstructive surgery.

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Paper 30

A Double-Blind, Randomized Controlled Trial Comparing Solvent-Dehydrated Cadaveric Fascia Lata and Polypropylene Mesh for Sacral Colpopexy

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OBJECTIVE: To compare the surgical outcomes after sacral colpopexy performed with solvent-dehydrated cadaveric fascia lata and polypropylene mesh. **METHODS:** From July 2001 through June 2003, patients scheduled for sacral colpopexy in our institution were offered enrollment. Eligible

patients were randomized to receive either fascia lata (Tutoplast® processed Suspend® fascia lata, Mentor Corp, Santa Barbara, CA) or polypropylene mesh (Trelex®, Boston Scientific, Boston, MA). A computer-generated random assignment technique was used to determine the allocation sequence, and opaque sealed envelopes were used to conceal the group assignments until the time of surgery. Only the surgical team was aware of the patients' group assignments. All outcome measures were obtained by a single independent observer who was blinded as to which material was used. Likewise, patients were not told which material was used until they had completed the study. Data was collected at 6 weeks, 3 months, 6 months and 1 year postoperatively. The main outcome measures were POP-Q stage and individual POP-Q points over time. Objective surgical failure was defined as POP-Q stage ≥ 2 at any point during the follow-up period. Our study design called for 30 patients in each arm to have 90% power ($\alpha = .05$) to detect a 30% difference in mean POP-Q stage over a 1 year period using a repeated measures analysis of variance test. Also, mean POP-Q points and stage at 1 year were compared using the independent samples t-test. Baseline group characteristics were compared using Chi-square for proportions and either Mann-Whitney U tests or t-tests for numerical data as appropriate. **RESULTS:** One hundred patients were randomized to receive either fascia (n=46) or mesh (n=54). Currently, 67 patients have completed their 1 year follow-up period. Data on the entire 100 patients will be accrued prior to the AUGS/SGS meeting. As expected, there were no significant differences between the groups with respect to pre-operative POP-Q points, age, BMI, gravity, parity, race, prior prolapse or incontinence surgery, or hormone use. Mean pre-operative POP-Q stage was $2.3 \pm .7$ (fascia) and $2.6 \pm .6$ (mesh) $p = 0.1$. For the group of 67 at one year, mean point C measurements were -8.1 ± 3.1 (fascia) and -9.1 ± 1.2 (mesh) $p=0.1$; mean Aa measurements were -2.0 ± 1.4 (fascia) and $-2.6 \pm .9$ (mesh) $p=0.06$; and mean Ba measurements were -2.0 ± 1.3 (fascia) and -2.5 ± 0.9 $p=0.07$. POP-Q stage at 1 year was 0.9 ± 0.9 (fascia) and 0.6 ± 0.7 (mesh) $p=0.08$. Results from the repeated measures analysis of variance will be calculated when the entire group has completed the study. **CONCLUSIONS:** In the group with available data so far, there were no statistical differences in objective surgical outcomes at one year for sacral colpopexies performed with either Tutoplast® processed fascia lata or Trelex® polypropylene mesh.

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