

18th Annual

PERSPECTIVES IN UROLOGY
POINT COUNTERPOINT 2009

Thursday, November 5, 2009

Ballroom E-F

The Scottsdale Plaza

Scottsdale, Arizona



Agenda

Wednesday, November 4

6:00 – 8:00 pm Registration

Thursday, November 5

Page

7:00 – 7:55 am Registration and Continental Breakfast in Exhibit Hall

7:55 – 8:00 am Welcome and Introduction
~ E. David Crawford, MD

Robotic Surgery

8:00 – 8:30 am The Role of Robotics in Urologic Surgery 1.3
~ Paul D. Maroni, MD

8:30 – 9:00 am Point-Counterpoint: Prostate Cancer 2.1

Robotic Surgery is Hype ~ E. David Crawford, MD 2.1

Robotic Surgery is the Mainstream ~ Paul D. Maroni, MD 2.16

9:00 – 9:10 am Questions & Answers

Renal Cell Carcinoma

9:10 – 9:30 am Histologic Subtypes of Renal Cell Carcinoma 3.1
~ M. Scott Lucia, MD

9:30 – 9:55 am Point-Counterpoint: Small Renal Masses 4.1

Best to Remove ~ Paul D. Maroni, MD 4.1

Best to Watch ~ Donald L. Lamm, MD 4.2

9:55 – 10:00 am Questions & Answers

10:00 – 10:15 am Break in Exhibit Hall

Female Urology, Part I

10:15 – 11:15 am Female Urology “Potpourri” 5.1
~ Brian J. Flynn, MD

11:15 – 11:25 am Questions & Answers

Clinical Challenges

11:25 – Noon Case Presentations and Discussion

Noon Adjourn for the day

Brief history of robotic surgery

- 1993 – AESOP approved for surgery
- 1997 – daVinci begins use
- 1998 – ZEUS first fully robotic surgery (Computer Motion)

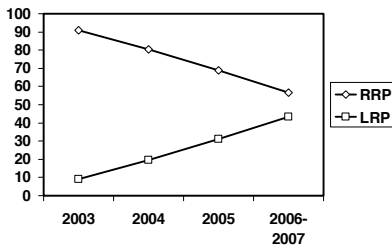


- 2000 – daVinci approved by FDA (Intuitive Surgical, Inc)
- 2003 – Computer Motion merged with Intuitive Surgical, Inc.

JAMA

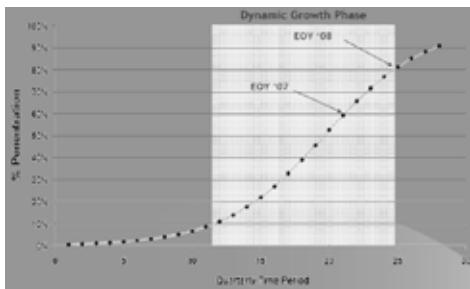
Comparative Effectiveness of Minimally Invasive vs Open Radical Prostatectomy

Jin C. Hu, Hsuehwei Gu, Stuart R. Lipsitz, et al
 JAMA. 2009;302(14):1507-1508 (doi:10.1001/jama.2009.1481)



Adapted from Hu et al.

**Adoption of robotic prostatectomy
 Market estimate**



Robotic assisted Cystectomy

- Around 300 cases published (size 1 to 67 patients)
- Complications (10-30%)
 - data largely incomplete
- Avg blood loss <300 ml
- Avg OR time ~ 7 hours
- Oncologic data remains to be seen

Hemal Curr Opin Urol 2009

Robotic assisted cystectomy Questions

- Will it decrease hospital stay? Complications?
- Can the OR times be shortened?
- Can an equivalent LND be done?
- How to handle the urinary diversion?
- Oncologic outcomes?

Opinion:

Long way to go. Probably good for benign disease.

Robotic assisted urinary diversion

- Intracorporeal ileal conduit and orthotopic bladder substitution have been done
 - OR time >10 hours
- Most make 8 cm incision to remove specimen and create urinary diversion.

Hemal Curr Opin Urol 2009

Robotic assisted adrenalectomy

- Case series and a few comparison studies (1 RT)
- About 150 patients published
- Complications inconsistently published
- Most metrics similar to lap adrenalectomy
- Longer OR time and more expensive for robot
- "subjective improvement" with robot
- Use in malignant disease TBD

Hyams and Stifelman Curr Opin Urol 2009

Robotic assisted simple prostatectomy

- Technically feasible
- Case series x 2, 3 and 7 patients
- Millin’s technique
- Modest EBL <600, 300 respectively
- 3-4 hours!!!

Opinion

Learn HoLEP. Probably not for robot.

Sotelo et al J Urol 2008, Yuh et al Can J Urol 2008

Robotic assisted bladder diverticulectomy

- Little in literature
- Easy to do robotically
- Curl guidewire in diverticulum
- Unproven for cancer
- Can do PVP simultaneously

Opinion

Excellent training case. Quick and handles all comers. Not for malignancy yet.

Robotic assisted lymph node dissections

- Pelvic
 - Well described and can do extended lymph node dissections, but tedious
- RPLND
 - Only 2 patients in PubMed
 - Expect more will come
- Inguinal LND
 - Believe it or not (Josephson et al Urology 2009)
 - Leave this to the few

Medical Ethics

- | | |
|----------------------|--------------------------|
| ■ Commercial | ■ Professional |
| ■ Caveat emptor | ■ Primum non nocere |
| ■ Equal relationship | ■ Fiduciary relationship |
| ■ Self-interest | ■ Self-sacrifice |

**University of Colorado Hospital
Robotic Credentialing**

- 3. Experience pathway
 - 20 cases as surgeon and 10 within last year.
 - List of complications
 - Verification of robotic privileges at other medical center
 - Supportive letter of recommendation from Chair of Surgery/Department.

Ways for practicing physician to train

- Fellowship
 - 6 months to 3 years
 - Hands-on required
- Mini-fellowships
- Self-directed
 - Dry-lab
 - Courses – hand-on and video observation

Prerequisites

- Experience with laparoscopy
- Understand an investment is necessary
- Discuss with partners (if any)
- Willingness to start slowly

How to incorporate

- Case observation
- Video observation
- Basic training
 - Online module
 - Hands-on off-site certification
- Dry-lab time (very helpful)
- Honesty is the best policy/dispel myths/expectations
- Start with simpler procedures soon after training
 - Nephrectomy
 - Bladder diverticulectomy

Point-Counterpoint: Robotic Surgery

Prostate Cancer Robotic Surgery is Hype ~ *E. David Crawford, MD*

Robotic Surgery is the Mainstream ~ *Paul D. Maroni, MD*

Robotic prostatectomy? HYPE

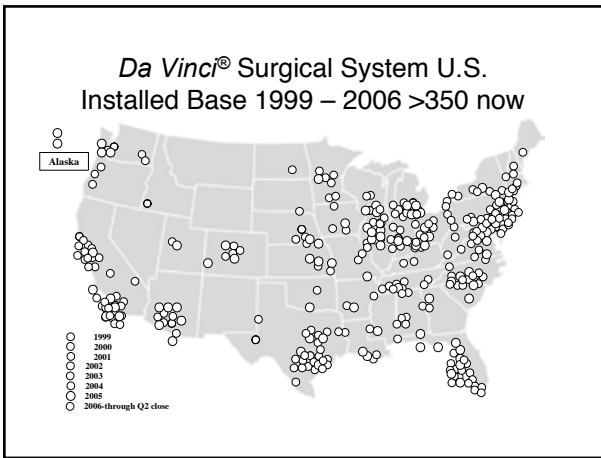
E. David Crawford, MD
Professor of Surgery (Urology) and Radiation Oncology
University of Colorado Health Sciences Center

ARS
Do you believe that the robot has significantly improved the care of patients undergoing a radical prostatectomy

1. yes
2. no

Just because you have a Ferrari does not make you a race car driver





Boston Globe -continued

- "It's unbelievable how good it was," said Philip Bedard, 59, a Boxford construction company "In five days I was back in the office, and in 10 days I was operating a backhoe."

The result - if a hospital does not have a robot you loose market share, even if not cost effective

Prostate Cancer Surgery

Google: Prostate Cancer Treatment

www.rcog.com	Comprehensive info from a world leader in treatment and research Prostate Cancer Surgery
www.laprp.com	America's longest running program for lap prostate cancer surgery Prostatectomy
www.CityofHope.com	Leading Treatment options including Robotic-Assisted Cancer Surgery

Do an internet search for prostate cancer:

Web | CNN News | CNN Videos
 Web results for "prostate caner" | Results 1-10 of 3,970
 Sponsored Links
 Prostate Health

www.ProstateCare.com Important Information About Determining Your Prostate Health. Robotic prostate surgery

www.StJosephsAtlanta.org Minimally invasive robotic surgery Saint Joseph's Hospital in Atlanta.

Marketing

- You will be left out
- Hospital against hospital
- Mid size cities where there are 5 robots
- Hospitals loose money
- When is the last time you were detailed on a perineal prostatectomy?

'The ideal way to compare
 Robot,LPR, RRP,RRP
 is a randomized clinical study
 using common clinical pathways'

In 2009

A man undergoing open RRP can expect:

- Uncomplicated surgical procedure
- A short and uneventful hospital stay
- The lack of allogeneic blood transfusion
- Early removal of the urinary catheter
- Full return to activity within 3 weeks
- Restoration of urinary continence within 3 weeks

Only long term problem is ED

Shekarriz et al Urol Clin North Am

Outcomes After Radical Prostatectomy: Ranked Order Based on Clinical Importance

- Cancer control
- Technical complications
- Postoperative complications
- Urinary continence
- Erectile function
- Cost
- Blood loss
- Timing of catheter removal
- Length of hospital stay
- Postoperative pain

Hospital Stay

- No difference

Functional Outcomes

- No difference

Urinary Control

- AUA Abstract # 1605-Vanderbilt
- Robot-320 90% 1 year
- RRP- 195 88% 1 year
- No difference and this is what other series report, though not all at the same institution.
- Patients are led to believe better

Table 1: Surgical outcomes of radical prostatectomy performed in series

Center	Approach	No Pts	Mean op time	Mean EBL	Transfusion %	Mean LOS	Complications	Positive Surgical Margin
Rassweiler et al ¹	TLRP	219	288	1100	30.1	12	19.6	21
	ELRP	219	218	800	9.6	11	10.5	23.7
Goeman et al ²⁰	TLRP	165	240	678	1.2	6.7	9.1	23
Elden et al ²¹	TLRP	100	238.9	310.5	2	3.8	8	16
Guillonneau et al ³	TLRP	550	200	380	5.3	5.8	10	15
Cathelineau et al ²²	ELRP	600	173	380	1.2	6.3	11.5	17.7
Tuerk et al ²³	ELRP	174	169	176	0	1.67	9.9	14.5
Goeman et al ²⁰	ELRP	550	188	390	4.7	4.6	10.9	pT2 17.9 pT3 44.8 pT4 71.4
Elden et al ²¹	ELRP	100	190.6	201.5	0	2.6	4	16
Stolzzenberg et al ²⁴	ELRP	700	151	220	0.9	-	2.4	19.8
Menon et al ²⁵	RAR P	1142	154	142	0	1.14	2.3	13
Patel et al ²⁶	RAR P	200	141	75	0	1.1	2	10.5
Joseph et al ²⁷	RAR P	325	130	196	0.09	-	9.8	13
Rassweiler et al ¹	ORP	219	196	1550	55.7	16	35.6	38.7
Zincke et al ²⁸	ORP	3170	-	600-1030	5-31	-	-	24
Lepor et al ²⁹	ORP	1000	-	819	9.7	2.3	7	19.9

Table 2: Oncologic and Functional Data in series

Center	Technique	No. pts	PSA Non-Recurrence	Urinary Continence	Potency
Rajawwiler et al ¹⁸	TLRP	438	94% (3 mos)	90.3% (12 mos), 95.8% (18 mos)	Not reported
Guillemot et al ¹⁹	ELRP	550	p12a 92.3% (36 mos) p12c 86.9% (31 mos)	82.9% No pad (12 mos)	BNS 85% (spontaneous erections), 66% (intracavernosal)
Geerman et al ²⁰	ELRP	550	p12 89.7% (5 yr) p13 58.6% (5 yr)	91% (24 mos)	BNS 64%, 78, 66, and 90.9% (12 & 24 mos) if pre-60 years old
Steinberg et al ²¹	ELRP	700	Not reported	92% complete (12 mos) 98% 1 pad or less	BNS 47.1% (6 mos)
Memon et al ²²	RARP	1142	Overall: 97.7% (36 mos) Gleason 6 - 98.5% Gleason 7 - 95.4% Gleason 8 & 9 - 60.1%	95.2% 1 pad or less (12 mos) 94% no urine leak	Bilateral vein technique 93% (48 mos) BNS 70% (intracorporeal at 5 yrs)
Mikhail et al ²³	RARP	100	Not reported	84% return to baseline function (12 mos) 89% subjective continence (12 mos)	89% return to baseline sexual function (12 mos)
Dink et al ²⁴	RARP	700	95% (5.7 mos)	88% (12 mos)	Not reported
Chou et al ²⁵	RARP	325	97% (6 mos)	90% (6 mos)	Not reported
Camblon et al ²⁶	ORP	1325	97% (6 mos)	93%	BNS 68% IENS 47%
Geary et al ²⁷	ORP	458		80.1% No pads 8.1% 1 - 2 pads 6.6% 3 - 5 pads 2.2% totally incontinent	71% w/ incontinence
Leandri et al ²⁸	ORP	670		85% complete control	71% w/ incontinence

Complication Rates Associated With Radical Prostatectomy, According to Prospective Studies

Complications	Open RRP	LRP (%)	
	Lepor & Kaci N = 500	Guillemot et al N = 567	Ruiz et al N = 330
Rectal injury	0	1.4	1.8
Ileocolonic injury	0	0.9	0
Rectal fistula	0	NR	NR
Ureteral injury	0.2	0.7	NR
Bladder injury	0	NR	NR
Nerve injury	0	0.5	NR
Vascular injury	0	0.5	0
Wound complication	0.2	0.7	1.5

Guillemot et al. J. Urol 2002;167: 51
Ruiz et al. Eur Urol 2004; 46: 50
Lepor et al. Urology 2004; 63:499

Complication Rates Associated With Radical Prostatectomy, According to Prospective Studies

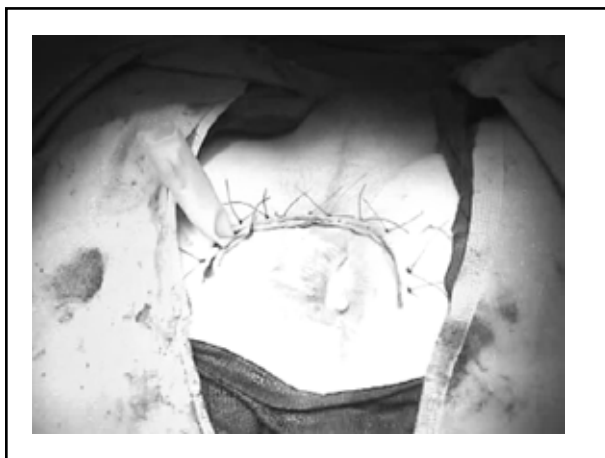
Complications	Open RRP	LRP (%)	
	Lepor & Kaci N = 500	Guillemot et al N = 567	Ruiz et al N = 330
Urinoma	0	NR	NR
Myocardial infarction	0.4	NR	NR
Pulmonary embolus	0	NR	NR
DVT	0.4	0.3	NR
CVA	0	NR	NR
Prolonged ileus	0.4	1	1.5
Lymphocele	0	0	0.3

Guillemot et al. J. Urol 2002;167: 51
Ruiz et al. Eur Urol 2004; 46: 50
Lepor et al. Urology 2004; 63:499

Positive Surgical Margins After Radical Prostatectomy

Author(s)	Institution	Patients, N	Positive Margins (%)		Study Period
			pT ₁ Disease	pT ₂ Disease	
Open radical prostatectomy					
Lepor ²⁹	New York University	1000	2.9	31.2	2000-2005
Baumgartner et al	Emory Hospital	77	2.3		1999-2001
Chen et al	Cleveland Clinic	152	7.4	28.6	1994-1996
Laparoscopic radical prostatectomy					
Rajawwiler et al	University of Heidelberg	438	9.7	33.1	1999-2002
Guillemot et al	Montebello Institute	1000	15.5	31.1	1998-2002
Memon et al	Honey Ford	100	0	40	2001-2002
Ruiz et al	Harriet Manter	330	16.3	44.3	2000-2002
Baumgartner et al	Emory Hospital	85	7.8		1999-2001

²⁹Unpublished data.
Concurrent studies at same institution.



Advantages of a Perineal Prostatectomy

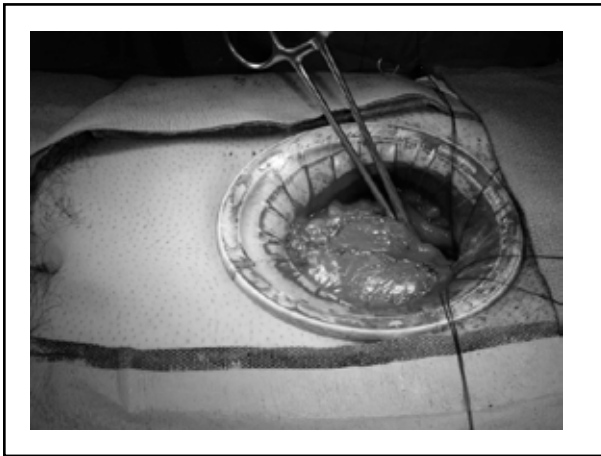
- Avoidance of an abdominal incision
- Avoidance of blood transfusion
- Apical dissection is facilitated and margin rate decreased (7%)
Weldon et al. J Urol -1995
- Ease of anastomosis – Watertight
- Early and immediate continence rates better
 Overall continence similar.
Weldon – J. Urol 1997, Bishoff – J. Urol 1998

Advantages of a Perineal Prostatectomy

- Oral pain. No epidural or PCA
- Postoperative convalescence : Regular Diet Ambulation in 12 to 18 hours.
- Discharge same day or next.
- Outpatient series – only 12% wished >23 hr stay
Ruiz-Deya et al. J urol. 2001.
- Prior surgery and obesity
- Potency: theoretical advantage due to better visualization but no clear evidence.
- WWW.medscape.com/viewarticle/551746

Perineal

Surgeon
 Similar results as Robot, Lap,
 RRP
 Go home the same day



The Incision



From: Stacy Childs <stacychilds@yahoo.com>
Date: Wed, 20 Jun 2007 15:20:18 -0700 (PDT)
To: "E. David Crawford M.D." <edc@edavidcrawford.com>
Subject: "Your Patient"

Took his foley out today. Voids well, good sphincter control. He was driving at p.o. day #5, back at work at day #7. You're right, tiny incision. Impressive. Are you using all laparoscopic instruments and not fingers?

Stace

Stacy J. Childs, M. D.
 (970) 870-6684 hm
 (970) 871-9710 wk
 (970) 870-6698 fx hm
 (970) 871-9709 fx wk

Postoperative complications Last 400 cases

	Number of patients
Bladder Neck Contracture	27
Meatal stricture	7
Wound Infection	3
bladder neck stricture	2
Bladder infection	2
Rectal Tear	1
Penile Pain	1
Epididymitis	2
Hydronephrosis	1
Penile pain	1
Hydroureteronephrosis	1
Suprapubic postoperative hematomas	1
wound granuloma	1

Demographics

Variable	Number	Mean (sd)	Median
Age	406	57.2 (7.1)	57.0
WM Gleason sum	373	6.5 (1.05)	7.0
Preoperative PSA (ng/dl)	406	6.9 (7.8)	5.6
Estimated Blood loss (ml)	341	406.2 (240.6)	350.0

Pathological stage

Pathological Stage	Frequency	Cumulative %
T1a	16	1.57
T1c	64	16.71
T2a	77	20.10
T2b	122	31.85
T2c	47	12.27
T3a	16	4.18
T3b	48	12.53
T3c	2	0.52

Advantages of LRP

Claims by LRP Surgeons	Rebuttal by open Surgeons
<ul style="list-style-type: none"> Magnification improves visualization 	<ul style="list-style-type: none"> Magnification achievable with surgical loops
<ul style="list-style-type: none"> Less blood loss 	<ul style="list-style-type: none"> Not clinically relevant, based on similar transfusion rates
<ul style="list-style-type: none"> Improved visualization allows for more precise dissection of the prostatic apex and NVB 	<ul style="list-style-type: none"> Quality of life outcomes fail to show advantages for continence or potency

Advantages of LRP

Claims by LRP Surgeons	Rebuttal by open Surgeons
<ul style="list-style-type: none"> Avoidance of lower abdominal incision decreases postoperative pain and facilitates return to activities 	<ul style="list-style-type: none"> Postoperative pain is comparable, and men can return to activities just as quickly despite an incision
<ul style="list-style-type: none"> Watertight urethrovesical anastomosis allows for earlier catheter removal 	<ul style="list-style-type: none"> No difference in achieving watertight Vesicourethral anastomosis at postoperative day 3; urinary catheters typically removed at 1 week after both approaches

Mistakes were made

- 2003 FTC allows purchase of Computer Motion, Inc by Intuitive Surgical, Inc for ~\$65M
- Price of daVinci surgical robot 2009
 - \$1.75M
- Estimated price with competition
 - Less than \$500,000
 - Source: Richard Satava MD FACS, lecture at Univ of Colorado General Surgery Grand Rounds, 2009

More mistakes

- Systematic problems force hospitals to compete
- Underserved areas think this will be an attraction
- Cancer reimbursed more favorably than other diseases
- Procedures reimbursed more favorably than most other options

- Isn't there enough other urologic disease?

Has the robot been oversold?

- Google.com search "robotic prostatectomy"
 - 127,000 hits
 - 11 paid sites on first page
- Intuitive Surgical, Inc.
 - Provides marketing advice/toolkits
- Strong incentives for medical centers' ROI
- Lost focus on patients during "dynamic growth curve" aka Gold Rush

Were there false expectations?

- Schroeck et al Eur Urol 2008
 - 400 patients surveyed from RRP and RARP 2000-2007
 - Equivalent functional outcomes and bother (EPIC) between RRP and RARP
 - More regret in RARP (24.1% v. 14.9%)

Patients who underwent RALP were more likely to be regretful and dissatisfied possibly because of high expectations of a new procedure. We suggest that urologists carefully portray the risks and benefits of new technologies during preoperative counseling to minimize regret and maximize satisfaction.

Is one approach better?

available at www.sciencedirect.com
journal homepage: www.europeanurology.com



Review – Prostate Cancer

Retropubic, Laparoscopic, and Robot-Assisted Radical Prostatectomy: A Systematic Review and Cumulative Analysis of Comparative Studies

Vincenzo Ficarra^{a,*}, Giacomo Novara^a, Walter Artibani^a, Andrea Cestari^b, Antonio Galiano^c, Markus Graefen^d, Giorgio Guazzoni^e, Bertrand Guillonneau^d, Mani Menon^f, Francesco Montorsi^g, Vipul Patel^h, Jens Rassweiler^b, Hendrik Van Poppelⁱ

- Published 2009 - 103 references

Is one approach better?

- LRP/RARP – less blood loss and transfusions
- Few or poor quality comparative studies

“...the data from this systematic review did not allow us to prove the superiority of any surgical approach...we do believe that it will never be shown that an LRP performed by a qualitatively poor surgeon would be better than an RRP done by a skilled surgeon (and vice versa).”

Is one approach better? Salvage treatment

- Hu et al J Clin Oncol 2008 – need for salvage treatments – Medicare database
 - MIRP 27.8% v. Open RP 9.1%
- Chino et al BJU Intl 2009 – 904 RP (536 open)
 - No difference in indication or referral for RT
- Hu et al JAMA 2009 (adapted)

Can Tx/100y	MIRP	RRP	P
Overall	8.2	6.9	.35
Radiation	5.1	4.9	.67
Hormone	5.3	3.7	.21

Is one approach better? Continence and Potency

Incontinence*	MIRP	RRP	P
Diagnosis	15.9	12.2	.02
Procedures	7.8	8.9	.24
Erec Dysfunc*			
Diagnosis	26.8	19.2	.009
Procedures	2.3	2.2	.78

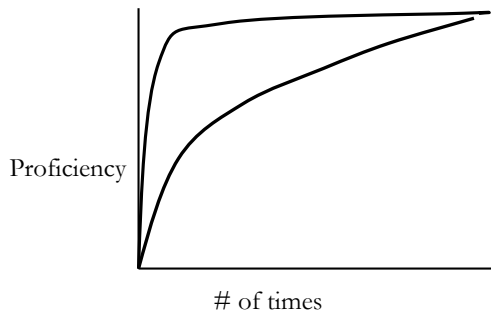
- Medicare dbase study – MIRP > SES
- No questionnaires used, early in learning curve

* - per 100 person years, adapted from Hu et al JAMA 2009

Is robotic assistance or laparoscopy necessary?

- Most metrics appear equal
- Device is costly
- Costs are important
- Why use it?

The learning curve



The learning curve

The Learning Curve for Coil Embolization of Unruptured Intracranial Aneurysms

Vineta Singh, Deep R. Goss, Randall T. Higdon, Christopher F. Dowd, Van V. Halbach, and S. Claiborne Johnston

AJNR Am J Neuroradiol 23:768-771, May 2002

- First 5 cases – 53% complications, after that 10%

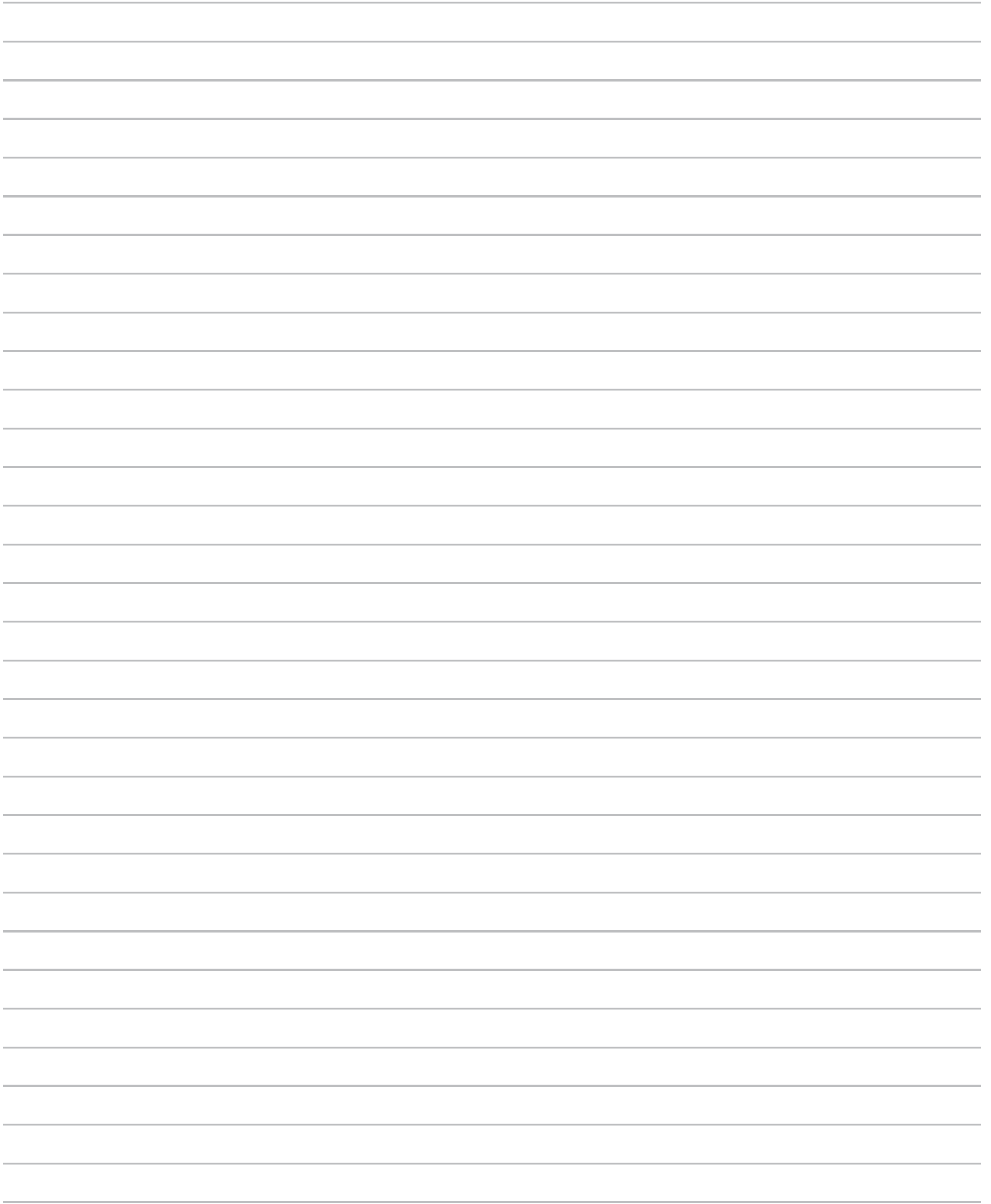
Analysis of the Learning Curve in Telerobotic, Beating Heart Coronary Artery Bypass Grafting: A 90 Patient Experience

Richard J. Nowick, MD, Stephanie A. Fox, RRCF, Bob B. Kiani, MD, Larry W. Sitt, MS, Reiza Rayman, MD, Kojiro Kodera, MD, Alan H. Menkis, MD, and W. Douglas Boyd, MD

- Ann Thorac Surg 2003 – 9 of first 18 with major complications, 9 of next 72 with major complications

Learning curve important for open radical prostatectomy

- All outcomes improve with surgeon experience
- Critical number 200-500 cases
 - Catalona et al J Urol 1999 (single surgeon)
 - Klein et al J Urol 2008 (multiple surgeons, 4 centers)
- Argument for regionalization
- Fellowship training may reduce the learning curve
 - Rosser et al Cancer 2006
 - First 66 patients post fellowship, same outcomes



Histologic Subtypes of Renal Cell Carcinoma

~ M. Scott Lucia, MD

Histologic Subtypes of Renal Cell Carcinoma



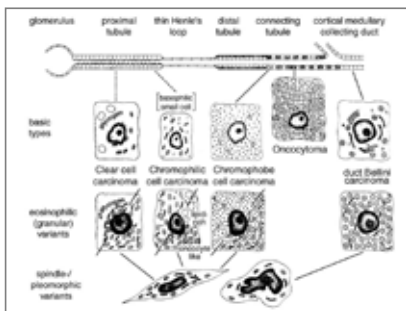
M. Scott Lucia, MD
 Associate Professor
 Chief of Genitourinary and Renal Pathology
 Director, Prostate Diagnostic Laboratory
 Dept. of Pathology
 University of Colorado Denver SOM

History of Classification of Renal Cell Neoplasms

- First case in literature reported by G. Miriel in 1810
- First classification in 1826, proposed by König, on basis of gross morphologic appearance into four types: Fungoid, Medullary, Scirrhus, Steatomatous
- Many subsequent classifications – many based upon descriptive histologic features of tumors (architectural and cytologic)
- Mainz classification proposed by Thoenes 1986
 - based upon cytologic features of tumors
 - first to correlate the subtypes of tumors with cell of origin in nephron

Delahunt B, Eble JN. History of the development of the classification of renal cell neoplasia. Clinics in Laboratory Medicine. 2005;25:231-46.

The Mainz Classification 1986



From: Delahunt B, Eble JN. Clinics in Laboratory Medicine. 2005;25:231-46. © 2005 Elsevier Inc.

Studies have confirmed cytogenetic differences between major tumor subtypes in Mainz classification

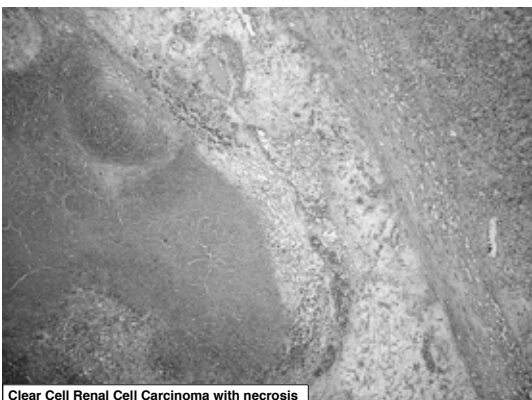
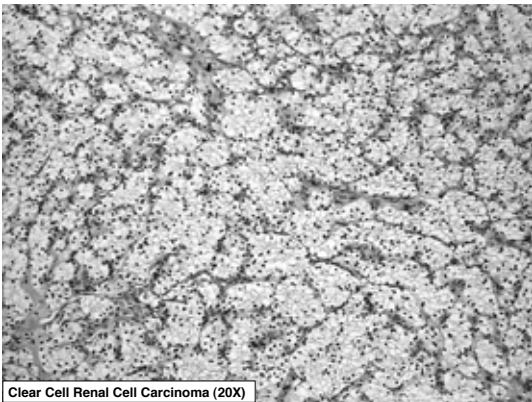
Tumor type	Freq	Histopathology	Cytogenetics
Clear cell RCC	70%	-Clear cytoplasm -Alveolar, tubular and cystic architecture -Vascular stroma	-3p, +5q, -6q, -8p, -14q
Chromophil RCC	15%	-Papillary architecture -basophilic, low N:C (type I) -eosinophilic, high N:C (type II)	Trisomy 7, 17, -Y, +3q
Chromophobe RCC	5%	-Solid architecture -Pale or granular cytoplasm -Prominent cell membranes -Occ. Bizarre nuclei	-1, -2, -6, -10, -13, -17, -21
Collecting duct Carcinoma	1-2%	-Medullary location -Tubuloglandular architecture -Hobnail cells -Desmoplastic stroma	-1q, -6p, -8p, -13q, -21q

Heidelberg Classification 1997¹

Expanded on Mainz classification; based upon cytogenetics

- Clear cell – “conventional RCC”
- Papillary RCC – to replace “Chromophil”
- Chromophobe RCC
- Collecting duct carcinoma
 - Medullary carcinoma – associated with sickle cell trait

1. Kovacs et al. J Pathol 1997;183:131-3.



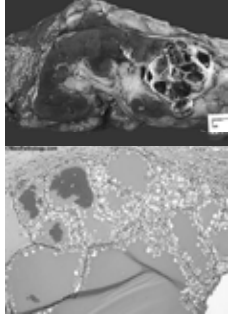
**2004 World Health Organization
Classification of Renal Cell Tumors**

Expanded on Mainz and Heidelberg classifications to account for cytogenetics, behavior, and associated conditions

- Clear cell RCC
- Multi-locular clear cell RCC (VHL gene mutation, good prognosis)
- Papillary RCC (Type I=basophilic, good prognosis; type II=eosinophilic, worse prognosis)
- Chromophobe RCC
- Carcinoma of the collecting ducts of Bellini
- Renal medullary carcinoma
- Xp11 translocation carcinoma
- Carcinoma associated with neuroblastoma
- Mucinous, tubular, and spindle cell carcinoma
- Renal cell carcinoma, unclassified
-
- Papillary adenoma
- Oncocytoma

Multilocular cystic renal cell carcinoma

- Good prognosis
- Most low grade (Fuhrman I or II)
- Usually stage I or II
- Mets not reported
- VHL mutations



**2004 World Health Organization
Classification of Renal Cell Tumors**

Expanded on Mainz and Heidelberg classifications to account for cytogenetics, behavior, and associated conditions

- Clear cell RCC
- Multi-locular clear cell RCC (VHL gene mutation, good prognosis)
- Papillary RCC (Type I=basophilic, good prognosis; type II=eosinophilic, worse prognosis)
- Chromophobe RCC
- Carcinoma of the collecting ducts of Bellini
- Renal medullary carcinoma
- Xp11 translocation carcinoma
- Carcinoma associated with neuroblastoma
- Mucinous, tubular, and spindle cell carcinoma
- Renal cell carcinoma, unclassified (5% of RCC)
-
- Papillary adenoma
- Oncocytoma

Conclusions

- The classification of renal cell carcinomas is expanding
- Classification has morphological and cytogenetic basis
- Proper classification important for prognosis

**Small renal mass
Best to remove**

- Definition – enhancing renal mass ≤ 4 cm (clinical T1a)

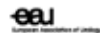
SRMs - Best to remove

Why?

- Minimal risk
- Effective treatment
- A real medical threat
- Improvements in peri-operative care

Risk of partial nephrectomy

available at www.eurospine.com
Journal homepage: www.eurospine.com



Urology – Kidney Cancer

**Laparoscopic versus Open Partial Nephrectomy:
Analysis of the Current Literature**

Francesco Porpiglia*, Alessandro Velje, Michele Billo, Roberto Mario Sarigo
Department of Urology, San Luigi Hospital, University of Turin, Turin, Italy

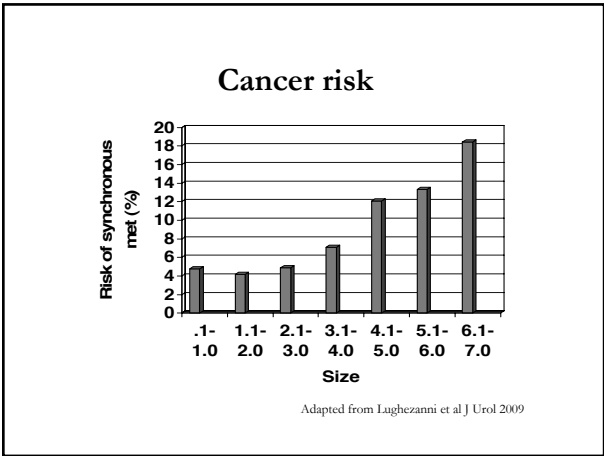
	# Pts	Size	Compl.	Medical	Leak
Open	2756	3.2	21.3%	10%	3.9%
Lap	1062	2.7	21.4%	9.6%	4.2%

Adapted from Porpiglia et al Eur Urol 2008

Contemporary reality

- 1-3 day hospital stay (even with open surgery)
- 3-4 weeks of convalescence
- 98% 10-yr cancer specific survival
 - 100% with smaller tumors?
- ~4% local recurrence

***Exceptionally low-risk in
healthy patients with excellent
cancer control***



- ### Cancer Risk
- Crispin et al Cancer 2009
 - 173 patients with enhancing renal mass on AS
 - 24 month median f/u
 - 1.3% developed metastasis
 - 15% exhibiting growth still had benign tumors
- Development of metastasis in 2-yrs as high as 10-yr CSS for PN.***
Growth a poor indicator of cancer.

Cancer Risk

Growth Kinetics of Renal Tumors/Crispin et al

low risk of disease progression, the excellent oncologic outcomes obtained with prompt surgical intervention continue to indicate that extirpative therapy in acceptable candidates should remain standard. Identification of clinical, radiographic, pathologic, and molecular correlates of a tumor's biologic potential is essential to avoid potential overtreatment of otherwise indolent asymptomatic tumors.

- ### Real-life case
- 1987 – 63 yo male with abnormality on IVP in upper pole of right kidney
 - 2004 – 81 yo male has 3-4cm mass identified in upper pole of right kidney. Cardiologist told him his cardiac risk was too high. Urologist told him his heart would kill him first.
 - 2005 – 4cm – continue to watch
 - 2006 – 5cm – continue to watch

Real-life case

- 2007 – 7cm, losing weight. Thinking more seriously about surgery. Saw cardiologist, PCP – all said not to operate.

UROLOGY 64: 909–913, 2004.

MANAGEMENT OF RENAL MASSES IN PATIENTS
MEDICALLY UNSUITABLE FOR NEPHRECTOMY—NATURAL
HISTORY, COMPLICATIONS, AND OUTCOME

GAVIN W. A. LAMB, EMMA J. BRONWICK, PAUL VASEY, AND MICHAEL AFFRISON

- 36 patients with renal masses 3.5-20cm in size (median 6)
- 23 had biopsy confirming RCC
- No deaths from cancer progression
- Generally slow growth (0.4cm/year)

Real-life case

- 2007 – 7cm, losing weight. Thinking more seriously about surgery. Saw cardiologist, PCP – all said not to operate.
- 2008 – 10 cm, flank pain. Local spread to liver and lung.
- August 2008 – dead from kidney cancer.

Acceptable candidates?

- How old is too old?
- How ill is too ill?

Example: elective abdominal aortic aneurysm repair in people over 80 years old

- Mortality 5.6% at one year

Example: Hypertrophic cardiomyopathy

- In hospital death – 6.7%

Ballotta et al Minerva Med 2009; Hreybe et al Clin Cardio 2006

Needle Biopsy of SRM

- Old Concept: Risk of bleeding, risk of seeding; necrosis, false negative biopsy common.
- New Concept (the facts):
 - Small cores or FNA rarely produce bleeding or AV fistula
 - Only 6 reported cases of tumor seeding (<0.01%); none recently with canula technique, small needles
 - FNA and core biopsies are accurate with experience: (97% sensitivity, 100% specificity)

Rodriguez, Sem Urol Oncol. 1995; Jewitt, Urol. Clin N Amer. 2008

Does Delay Affect Outcome?

Rais-Bahrani: BJU Int. 103:1355-8, 2009

- 32 with SRM, mean 2cm; 5 yr follow
- 3 or more month delay (mean 16 months) in LPN compared with standard
- Mean growth .56cm/yr
- No increase in operative complications, blood loss or time.
- No local or distant recurrence

How Effective is Cryoablation of SRM?

Stein: J Endourol. 22:2433-9, 2008.

- 30 SRM underwent lap cryoablation
- 84% had no enhancing mass at 3 months
- 90% by 6 months, only 1 (3%) of these 3 persisted by 9 months
- Lap partial nephrectomy on this mass showed no remaining carcinoma
- 100% short term (one year) complete response.
- Residual enhancement by 9 months may not indicate failure

Meta-analysis: Cryo vs RFA

Kunkle: Cancer. 113:2671-80, 2008

- 47 series, 1375 SRM's
- Local progression: Cryo 5%, RFA 13% ($p < .0001$)
- Repeat ablation: 1% Cryo, 8% RFA ($p < .0001$)
- Metastasis: 1% Cryo, 2.5% RFA ($p = 0.06$)
- Response criteria and short term follow up favor cryoablation over radio frequency ablation, though RFA is more frequently done percutaneously

Female Urology "Potpourri"

~ Brian J. Flynn, MD

Female Urology/Urogynecology Potpourri

Brian J. Flynn, MD
Director of Urogynecology, Reconstructive
Urology and Urodynamics

Associate Professor of Urology/Surgery
University of Colorado Denver
Denver, CO



Perspectives in Urology 2009

Urinary Tract Infections (UTIs) in Women

Perspectives in Urology 2009

UTI Introduction

- 8 million visits to health care providers annually *
- lead to more than 1 million admissions
- more than \$1.6 billion annually in health care dollars
- wide spectrum of disease from mild cystitis to life-threatening urosepsis

* Gupta K, et al: Ann Intern Med 2001

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**UTI
Complicated Cystitis**

patients predisposed to recurrent infection or treatment failure
anatomic or functional factors
DM, pregnancy
h/o pyelonephritis
men > 50 years of age
urine culture necessary
oral fluoroquinolone 1st line
10-14 day course

* Clin Infect Disease 1999;29:745

Perspectives in Urology 2009

**UTI
Recurrent: Same or organism or different***

symptomatic UTI that follows clinical resolution of an earlier UTI
common in post-menopausal women
- residual urine
- changes in microflora
college women
- 27% experience at least 1 Cx proven recurrent UTI within 6 months of tx

* Orenstein R, et al: Am Fam Physician 1999

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**UTI
Prophylactic/Suppressive/Self-Start ABX
Therapy**

If a women experiences > 3 UCx proven UTIs/year

Options
- postcoital abx therapy if occurs following sex
- self-start (3-day) therapy if no causal relation
- suppressive abx therapy if more severe infections
Suppressive abx therapy x 3 -6 months, stop then re-asses
- Nitrofurantoin 50 mg daily
- Bactrim DS ½ tablet daily
- TMP 100 mg daily
- Norfloxacin 200 mg daily

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**Vulvovaginal Candidiasis
'Vaginal Yeast Infection'**

Uncomplicated VVC Treatments
- short courses of treatment (1-3 days) adequate for most uncomplicated cases; improved compliance
- Clotrimazole 1% cream 1 applicator intravaginally for 7-14 days
- Clotrimazole 500 mg vaginal tablet x 1 dose
- Terconazole 6.5% ointment one applicator x 1 dose
- Terconazole 0.4% cream one applicator QD x 3 days
- Terconazole 80 mg vaginal suppository x 3 days
- Fluconazole 150 mg tablet PO x 1 dose

Perspectives in Urology 2009

Catheter Associated UTI (CAUTI)

Saint, S. et. al. Ann Intern Med 2009;150:877-884

Table 2. Hospital-Acquired Conditions Not Eligible for Additional Payment*

- Effective 1 October 2008**
- Catheter-associated urinary tract infection
 - Decubitus ulcer (pressure ulcers)
 - Vascular catheter-associated infection
 - Severe gastrointestinal "repose events"
 - Foreign object retained after surgery
 - Air embolism
 - Blood incompatibility
 - Falls and trauma
 - Manifestations of acute glycemic control
 - Exacerbated brachyitis
 - Neuroleptic malignant syndrome
 - Hyperglycemia, severe
 - Secondary diabetes with ketoacidosis or hyperosmolality
 - Deep venous thromboses or pulmonary embolism after certain orthopedic surgeries
 - Surgical site infections after certain surgical procedures
 - Mediastinitis after coronary artery bypass surgery
 - Certain orthopedic surgical site infections
 - Certain bariatric surgical site infections
- Considered for future implementation:**
- Ventilator-associated pneumonia
 - Staphylococcus aureus septicemia
 - Clostridium difficile-associated disease
 - Intraventricular hemorrhage
 - Legionnaire disease
 - Deltacrisis

* Adapted from references 4 and 29–31.

Hospital-Acquired Conditions Not Eligible for Additional Payment

Catheter Associated UTI (CAUTI)

- UTI is the most common hospital acquired infection
- 1 in 5 patients in the hospital receive a Foley catheter
- 1 day of catheter use = 5% increase in bacteriuria
- CAUTI costs at least \$600 and each episode of urinary tract-related bacteremia costs at least \$2800
- Short-term catheterization was defined as up to and including 14 days

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CAUTI Microbiology

- 40% - E coli
- 30% - Pseudomonas aeruginosa,
- 30% -gram positives, staph/strep and Candida
- the investigators did not include fungal urinary tract infections as part of their study

Wagenlehner FM et al.: Int J Antimicrob Agents 2008

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CAUTI

Recommendations for Hospitals to Address the Centers for Medicare Medicaid Services Rule Changes Regarding Catheter-Associated Urinary Tract Infection

- Use only when medically indicated
 - retention or high risk of retention
 - monitoring of urinary output
 - incontinence associated with risk of skin breakdown
 - specific surgical procedures (RRP, cryo, reconstruction)
- Proper insertion techniques
 - training standards for insertion and managing catheters
 - hand hygiene, aseptic catheter insertion, and proper maintenance by using a closed urinary drainage system
 - daily review of necessity "reminders and stop orders"
 - Develop systems for removal of catheters without physician order

Saint, S. et. al. Ann Intern Med 2009

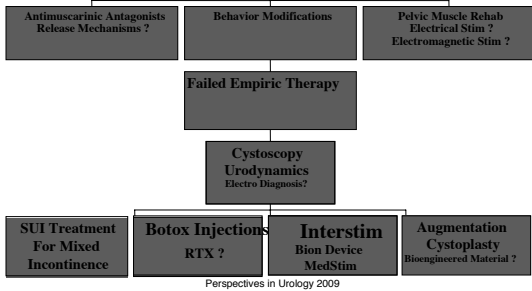
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OAB

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**of Responsive and Refractory
Evaluation and Management of OAB**

OverActive Bladder



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BOTOX

Perspectives in Urology 2009

**Some Published Uses of
Botulinum Toxin Type A**

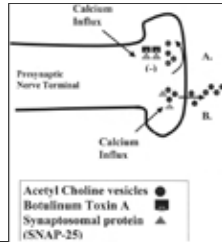
- Achalasia
- Blepharospasm
- Cervical Dystonia
- Essential Tremor
- Headache & Migraine
- Hemifacial Spasm
- Hyperhidrosis
- Myofascial Pain
- Occupational Dystonia
- Pain (muscle spasm)
- Spasmodic Dystonia
- Strabismus
- Spasticity
 - Cerebral Palsy
 - Multiple Sclerosis
 - Stroke
 - Traumatic Brain Injury

Cosmetic use is the most common application

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Management of Refractory OAB Intravesical Botulinum Toxin (botox)

- Botox is derived from the organism *C. botulinum*
- Inhibits the vesicular neuronal blockade up to 9 mos
- Increasing data on the benefits of botox in patients with
 - Non-neurogenic DO
 - Neurogenic DO
 - DSD
 - Interstitial cystitis?

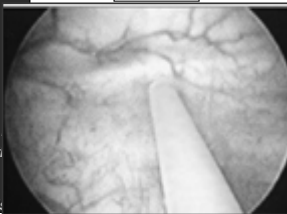


Schurch B, et al.: J Urol 2000
Smith CP and Chancellor MB: J Urol 2004

Management of Refractory OAB Intravesical Botulinum Toxin Type-A (botox)

- Urethra
 - 100 units in 2-3 ml of NS
 - Collagen needle used to inject 3, 6, 9 and 12 o'clock positions in striated sphincter
- Bladder
 - 200-300 units in 30 ml of
 - Inject 30-40 sites within the detrusor, targeting the trigone, base of the bladder and lateral wall.

Technique



Schurch B, et al.: J Urol 2000
Smith CP and Chancellor MB: J Urol 2004

Management of Refractory OAB Intravesical Botulinum Toxin (botox)

Open label pilot-study of 7 patients with refractory OAB that underwent detrusor injection with 150 units of botox

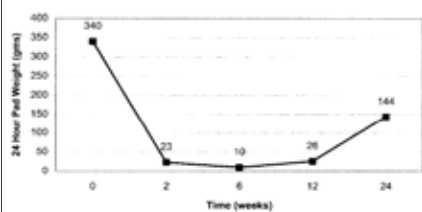


FIG. 4. Median 24-hour pad weights

Flynn, MK, Webster, GD and Amundsen, CL: J Urol 2005

Who is a candidate for intravesical Botox injection?

Typical Candidate

- MS, SCI, spina bifida patients
- Neurogenic OAB refractory to meds
- DSD

Other Potential Candidate

- Non-neurogenic OAB
- IC
- Parkinson's

As a Test

- Is the incontinence due to the bladder or a deficient outlet?
- Will they respond to bladder augmentation
 - Will they be able and willing to cath the urethra?
 - Will they be dry, or do they need a procedure on the outlet

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How close are we to approval of Botox for idiopathic OAB?



- I have used Botox in neurogenic OAB
 - MS
 - SCI
 - Spina bifida
- NOAB studies completed enrollment 3-09
 - An additional 12-18 months will be required before FDA approval may be anticipated, once studies completed

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Neuromodulation

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**Management of Refractory OAB
Sacral Neuromodulation**

- Introduced after the pioneering work of Tanagho and Schmidt for voiding dysfunction
- Neuromodulation of the micturition reflex manages urinary symptoms through the stimulation of the afferent pelvic nerves

Therapy



- Beneficial in patients with refractory OAB demonstrating a reduction in frequency, urgency, urge incontinence
- Treatment modality is based on unilateral or in some cases bilateral stimulation of the sacral nerves, most commonly S3

Tanagho EA, Schmidt RA and Orvis BR: J Urol 1989
Schmidt RA, et al.: A: J Urol 1999
Hassouna MM, et al.: J Urology 2000

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**How much stimulation is necessary?
Unilateral vs. Bilateral**

- For urge-incontinence stimulation of the S3 nerve root unilaterally is often sufficient
- For direct motor stimulation to produce micturition, bilateral stimulation of the motor roots is necessary
- For management of chronic pelvic pain, bilateral stimulation of the S3-4-5 dorsal roots is often necessary

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Who do I Implant

Characteristics

- Women respond better than men
- Younger patients (< 65) respond better than elderly
- Non-neurogenic do better than neurogenics
- Urge, frequency and urge incont. responds better than retention

Ideal Candidate

- Young female with urge, frequency, urge incontinence (without IC/PPP or neurologic condition) refractory to anti-muscarinics

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Management of Pelvic Organ Prolapse

Perspectives in Urology 2009

Anatomy of Vaginal Support POP Location ¹

- Anterior only 40%
- Anterior and apex 20%
- Posterior only 7%
- Posterior and apex 10%

- Anterior compartment involved 78%
- Highest failure in anterior compartment 30-70% ²⁻⁶

¹ Olsen et al. *Obstet Gynecol* 1997;89:501-506
² Shull et al. *Am J Obstet Gynecol* 1992;166:1764-1768
³ Holley et al. *South Med J* 1995;88:547-549
⁴ Samuelsson et al. *Am J Obstet Gynecol* 1999;180:299-305
⁵ Shull et al. *Am J Obstet Gynecol* 2000;183:1365-1373
⁶ Weber et al. *Int Urogynecol J Pelvic Fir Dysfunct* 2001;12:178-186

How are we doing with our current surgical procedures?

- 11.1% lifetime risk of surgery
- 29-40% patients require reoperation within 3 years^{1,2}
- 60% of the recurrences are at the same site³
- 32.5% of the recurrences are at a different site³

¹ Olson et al. *Obstet and Gynecol* 1997;89:501-506
² Marchionni et al. *J Reproduct Med* 1999;44:679-684
³ Clark et al. *Am J Obstet and Gynecol* 2003;189:1261-1267

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Pelvic Floor Reconstructive Surgery Use of Synthetics

Advantages

- Readily available
- Less expensive
- Surgical "kit"
- Predictable in vivo response
- No disease transmission
- Inert
- Not biodegradable

Disadvantages

- Urinary tract erosions
- Vaginal wall extrusions
- Graft contraction

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Management of Vaginal Vault Prolapse

Dependent on patients age, overall health and degree of physical and sexual activity *†

Patient that is physically and sexually active with minimal comorbid conditions



Abdominal sacral colpopexy

'Older' patient that is physically inactive with some comorbidities



Polypropylene mesh reinforced pelvic floor repair and vaginal vault suspension (Total Prolift)

* Flynn, BJ and Webster, GD: Curr Opin Urol 2002
† Amundsen, CL, Flynn, BJ and Webster, GD: J Urol 2003
Perspectives in Urology 2009

Analysis of Polypropylene Mesh Properties

			ETHICON	ETHICON	ETHICON	AMG	AMG	AMG	AMG	AMG
			STRONG	STRONG	STRONG	PROLIFT	PROLIFT	PROLIFT	PROLIFT	PROLIFT
			STRONG	STRONG	STRONG	PROLIFT	PROLIFT	PROLIFT	PROLIFT	PROLIFT
Meshing Surface Area	cm ²	cm ²	400	400	400	400	400	400	400	400
Mesh Weight	g/m ²	g/m ²	40	40	40	40	40	40	40	40
Mesh Pore Size (µm)	µm	µm	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0
Mesh Density	% air	%	96.0	96.0	96.0	96.0	96.0	96.0	96.0	96.0
Meshing Surface Area	cm ²	cm ²	400	400	400	400	400	400	400	400
Mesh Weight	g/m ²	g/m ²	40	40	40	40	40	40	40	40
Mesh Pore Size (µm)	µm	µm	2.0	2.0	2.0	2.0	2.0	2.0	2.0	2.0
Mesh Density	% air	%	96.0	96.0	96.0	96.0	96.0	96.0	96.0	96.0

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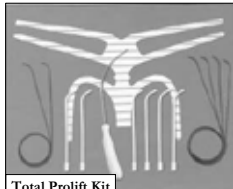
Data on file, Ethicon, Inc.

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Reinforced Vaginal Repairs for POP "Prolapse Kits"

Consists of a transvaginal extraperitoneal SSLF accomplished by placement of polypropylene mesh in the vaginal apex, anterior (vesicovaginal space) and/or posterior (rectovaginal space) compartments

- Minimally invasive
 - Trocar driven approach
 - Vesicovaginal space
 - Paravaginal space
 - Pararectal space
 - Obturator canal
- Minimal evidence
- Safety profile
 - Intraoperative
 - Postoperative



Total Prolift Kit

Perspectives in Urology 2009

PROLIFT System: Early Outcome Data¹

Author	# Pts.	Mean Age	Site	Complications	Exposure	Length of Follow Up	"Success" (≤ Stage II)
Cosson M et al. (France)	90	65.3	A-1 T-89	Rectal perf.-1 Hemorrhage-2 VVF-1	9 (10%) S=5 (56%)	12 mo.	74 (81.6%)
Fallon BF et al. (France)	110	63.2	A-22 P-29 T-59	Cystotomy-1 Hematoma-2 Vd. Dysfcn.-6	5 (4.7%) S=2 (40%)	3 mo.	105 (95.3%)
Murphey M et al. (USA)	89	65	A-48 P-11 T-30	Cystotomy-2	0 (0%)	5 mo.	84 (94.4%)
Hinoul P et al. (France)	29	62	A-29	Cystotomy-1	2 (6.9%) S=N/A	6 mo.	28 (96.5%)
Withagen MJ et al. (Netherlands)	43	66	A-11 P-16 T-5	Cystotomy-2 Rectal perf.-1 Vd Dysfcn-1	2 (4.7%) S=N/A	6 mo.	35 (81.4%)

¹IUGA – Fallon - 2006 Abstracts all published in: Int Urogynecol J 2006;

PROLIFT System: Early Outcome Data^{1,2}

Author	# Pts	Mean Age	Site	Complications	Exposure	Length of Follow Up	"Success" (≤ Stage II)
Groenen MJC et al. (Netherlands) ¹	26	61	A-6 P-10 T-10	Vd.dysfcn-5	1 (3.8%) S=N/A	2 mo.	26 (100%)
Perscheier M et al. (Austria) ¹	80	N/A	N/A	Cystotomy-2 Hematomas-2	8 (10%) S=5 (50%)	N/A	N/A
Rivera JM et al. (USA) ²	82	63	P-19 T-63	Hematoma-1 Hemorrhage-1	7 (11.7%) S=N/A	3 mo.	Not well defined
Compiled Data	549	64	A-109 P-85 T-256	Cystotomy- 1.7% Rectal perf. 0.4% Hemorrhagic- 1.3% Void dysfcn- 6.7%	34 (6.2%) S=12 (2.6%)	6 mo.	81.4-100%

¹IUGA – Fallon - 2006 Abstracts all published in: Int Urogynecol J 2006;17(S.2):S212
²AUGS 2006 Abstract published in: Int Urogyn J 2006;17(S.3):S460

NICE Review



Systematic review of the efficacy and safety of using mesh or grafts in surgery for anterior and/or posterior vaginal wall prolapse

Xueli Jia, Cathryn Glazener, Graham Mowatt, Graeme MacLennan, Cynthia Fraser, Jennifer Burr

October 2007

Perspectives in Urology 2009

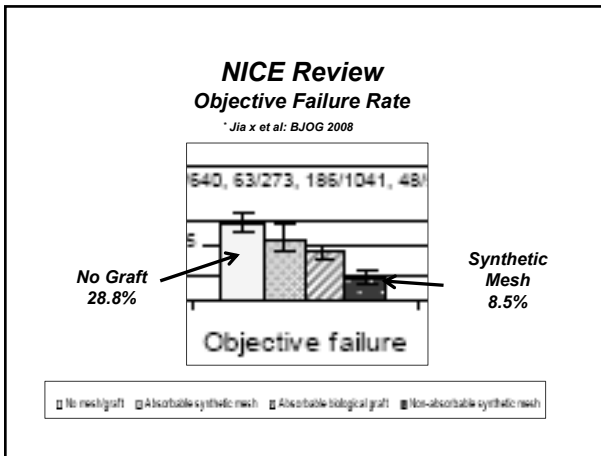
¹Jia x et al: BJOG 2008

NICE Review

- National Institute for Health and Clinical Excellence (NICE) report
- Provides national clinical guidelines in the UK
- Examined surgical repair of vaginal prolapse using mesh
- 199 page document
- Evaluated 446 reports - 49 studies selected
- 4589 patients in total

¹Jia x et al: BJOG 2008

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Management of Pelvic Organ Prolapse
Mesh Complications

	Erosion rate	Dyspareunia
Amrute, 2007	2.1%	10%
Hiltunen 2007	17.3 (most asymptomatic)	
Fatton 2007	4.7	10
DeTayrac 2007	6.3	12.8
DeVita 2008	3.8	1.3
Nguyen 2008	5 (all txd in office)	Mesh 9% No mesh 16%

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Polypropylene mesh reinforced pelvic floor repair and vaginal vault suspension (Prolift)
Flynn BJ, et al: SC AUA 2007

28 women with Stage III POP or greater treated with Prolift ± TVT in a 12 month period were evaluated

Prolapse Outcome

- Prolapse was cured in 27 of 28 patients (Stage 0-I prolapse)
- 1 rectocele following anterior implant only

Continence Outcome

- SUI cured in 13 of 13 patients that underwent TVT
- 5 of 12 that did not undergo TVT developed de novo SUI
- 2 of 3 urethrolysis patients remained dry

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Polypropylene mesh reinforced pelvic floor repair and vaginal vault suspension (Prolift)
Flynn BJ, et al: SC AUA 2007

Convalescence

- All patients were discharged within 24 hours of surgery
- All patients returned to normal activity, with the exception of heavy lifting, in < 7 days

Complications

- No urinary tract erosions, bowel, ureteral, vascular or nerve injuries
- 1 patient with delayed bleeding required replacement of vaginal pack for additional 48 hours
- 2 vaginal mesh extrusions noted with in 3 months of surgery
 - Local excision of mesh and multi-layer closure performed
 - No recurrent extrusion

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**Incidence of vaginal erosion following anterior prolapse repair with polypropylene mesh
Single vs. double layer vaginal wall closure**

Terlecki RT and Flynn BJ et al. AUGS 2009

75 cases of mesh reinforced anterior repair (anterior Prolift™) for cystocele performed by a BJF (2005-2008) were analyzed

Closure	Mean age (y)	Prior Repair (%)	Prior Hystx (%)	Mean LOS (d)	Mean DOC (d)	Mean F/U (mos)
SL	65	42	64	1.0	1.8	25
DL	63	59	67	1.2	2.8	10

Comparison of mesh extrusion rate following a single layer vaginal wall closure (n = 39) v. double layer closure (n = 36)

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Full-Thickness Vaginal Incision

- Identify the true vesicovaginal and rectovaginal spaces
- Consensus of experience- full thickness leads to lower extrusion rates
- 3-5 cm length with effort to keep incisions small
- Avoid the apex
- transverse incision

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**Incidence of vaginal erosion following anterior prolapse repair with polypropylene mesh
Single vs. double layer vaginal wall closure**

Terlecki RT and Flynn BJ et al. AUGS 2009

Outcome

Closure	POP Cure (%)	Erosion (#, %)
SL	97	6/39 (15%)
DL	97	0*

All vaginal wall extrusions were on the anterior incision

- 2 healed after office excision
- 4 required multiple OR excision, reclosure of vaginal incision

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**What to do with the opposite compartment?
Concomitant Repairs**

Anterior/Posterior Compartment

- Treat if
 - Prolapsed
 - Significant apical prolapse, large enterocele
- No prolapse in opposite compartment –No consensus
 - Treat with standard repair
 - Reinforced repair in lesser compartment
 - Leave untreated if asymptomatic

Perineal body

- Not advisable to treat asymptomatic perineal relaxation
- If symptomatic and there is laxity
 - repair separately "distal" to the mesh

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**What to do with the urethra?
Concomitant TVT**

SUI Surgery

- **Sling if**
 - History of SUI
 - UDS evidence of SUI with prolapse reduced
 - Stage III or IV cystocele and no prior sling
- **Stage patient if**
 - No history or UDS evidence of SUI
 - Prior successful sling in patient with large cystocele
 - No SUI in patient with posterior or apical prolapse only
 - Bladder incomplete emptying/retention in patient ± prior sling

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**Management of Complications of
SUI and Prolapse Surgery**

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**Complications
What could happen?**



Intraoperative

- Hemorrhage
- Bowel injuries
- Bladder and Urethral injuries
- Ureteral Injuries

Postoperative

- | | |
|---------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> • Erosion/extrusion • Fistula • Urinary retention • Pain | <ul style="list-style-type: none"> • Osteitis Pubis • Infection • Voiding dysfunction • Failures |
|---------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|

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**Vaginal Wall Extrusion and Urinary Tract Erosion
Incidence**

Midurethral tape composed of polypropylene mesh has become the new gold standard for treatment of female SUI^{*}

- Vaginal wall mesh extrusion occurs in 0.5 - 3% of patients and is usually amenable to tranvaginal partial mesh excision^{†‡}
- Urinary tract erosion is a more severe complication (< 1%) and may be treated with endoscopic or open partial excision

^{*} Bemelmans BLH and Chapple, CR: Cur Opin Urol Urol 2003
[†] Meschia M, et al: IntUrogynecol J Pelvic Floor Dysfunct 2001
[‡] Giri SK, et al: Urol 2007

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Graft Complication

CU Criteria for Simple v. Complex Graft Complications

	Simple	Complex
Mesh Type	Type 1 mesh early < 6 weeks	Type 2, 3, 4 mesh especially if mesh has been withdrawn from market delayed ≥ 6 weeks
Timing to presentation	suture line	remote from suture line
Location of extrusion	deep	embedded in vaginal wall, "cobblestone vagina"
Depth of mesh	none	≥ 1
Prior excisions	none/minimal	obvious purulence
Associated inflammation	vagina only	bladder, urethra, rectum
Affected organ		

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Vaginal Wall Mesh Erosion

Predisposing Factors

Etiology →

Ischemia, infection, iatrogenic

Patient characteristics

- Elderly
- Post-menopausal
- Radiation
- Vaginal infection

Surgical factors

- Button holes
- Unrecognized trocar injury
- Hematoma, infection, wound closure
- Mesh too superficial in vaginal wall

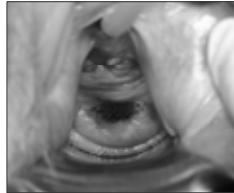
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Vaginal Wall Mesh Extrusion

Diagnosis

Diagnosis

- High index of suspicion
vaginal bleeding > 6 wks
dyspareunia
'scratchy vaginal wall'
partner pain on intercourse ('hispareunia')
- Meticulous follow-up
6 wks, 3 mos, 1 yr and PRN
- Clear plastic speculum



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Vaginal Wall Mesh Extrusion Prevention During Prolapse Surgery

Intra-operative

- generous hydrodissection
- transverse incisions
- careful tissue handling
- full-thickness dissection
- avoid button holes, trocar injury
- avoid incision over the vaginal cuff
- avoid concomitant hysterectomy
- avoid redundancy of mesh, no tension
- proper incision closure
- do not excise redundant vaginal wall

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Urinary Tract Sling Erosion
Urethrolysis: Contemporary Outcomes

Study	No.	Type	Management	Outcome
Kobashi et al 1999	7/34	ProteGen	Sling removal Martius (4) Delayed PVS (6)	25/34 (74%) SUI
Clemens et al 2000	6/14	ProteGen	Sling removal Urethral repair or prolonged drainage Immediate PVS (1) Delayed PVS (1)	5/6 (83%) SUI
Golomb et al 2001	1/1	Autograft	Bilateral partial excision	1/1 Dry
Amundsen et al 2003	6/6	Nonsynthetic 3/3 Synthetic	Sling incision Sling removal Martius (2) Delayed PVS (1)	6/6 Dry 2/3 (67%) SUI

Polypropylene Bladder Erosion
Prevention/Diagnosis

Prevention

- Avoid tunneling the trocar if the retropubic space is scarred
- Meticulous intra-op cystoscopy (70° lens), inspect anterior wall at 2 and 11 o'clock
- Postop Foley for 3 days if bladder is perforated

Diagnosis

- ↓
- High index of suspicion in patients with
 - Hematuria, bladder pain, urgency, recurrent incontinence, adherent calculus to the bladder wall

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Polypropylene Bladder Erosion
Case Reports: Endoscopic Approach

Endoscopic Laser Excision *

- 3 patients had bladder erosion due to polypropylene mesh
- Eroded tape successfully excised, 355 µm holmium laser in 20 mins

* Giri, SK, et al: J Urol 2005

Suprapubic Assisted Endoscopic Excision †

- 1 patient underwent successful endoscopic excision
- 5 mm suprapubic trocar, 24 Fr transurethral nephroscope
- Forceps inserted through the trocar used to stretch the tape
- Endoscopic scissors inserted through the nephroscope used to excise the tape

† Jorion, JL: J Urol 2002

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Management of Urinary Tract Erosions
Synthetic Erosion

Combined Abdominal and Vaginal Explantation *

- 5 patients with polypropylene mesh erosion
 - 3 with urinary tract erosion underwent explantation
 - ALL required subsequent anti-incontinence surgery

* Sweat SD, McGuire EJ and Lightner DJ: J Urol 2002

Mesh Explantation and Concomitant Sling †

- 19 patients with polypropylene mesh erosion underwent explantation
 - 53% had recurrent SUI
 - 5 underwent simultaneous autologous or porcine dermis sling

† Starkman, JS, et al: J Urol 2006

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**Institutional Sling Extrusion Data
April 2003-Present**


Vaginal Wall extrusion and urinary tract erosion

Vaginal wall extrusion/pain

- retropubic tape 1 of 72 (1.4%)
- TVT-O, 4 of 190 (2.1%)
- TVT-S, 1 of 119 (0.8%)
- Biological PVS, 0 of 60
- AUS, 0 of 9

Urinary tract erosion

- retropubic tape 1 of 72 (1.4%)
- TVT-O, 1 of 190 (0.5%)
- TVT-S, 0 of 119
- Biological PVS, 0 of 60
- AUS, 0 of 9



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2010 SUFU Abstract: MANAGEMENT OF POLYPROPYLENE MESH COMPLICATIONS (VAGINAL WALL EXTRUSIONS AND URINARY TRACT EROSIONS) AFTER SURGERY FOR SUI AND POP
Flynn BJ et al, Denver, CO

39 patients that underwent mesh explantation due to recurrent vaginal wall extrusions and/or urinary tract erosions performed by BJF (2003-2009) were analyzed

- treatment based upon CU algorithm for mesh complications
- patients classified as "simple" or "complex" graft complication
- simple graft complications treatment
 - in office partial mesh excision
 - OR excision, washout, and primary closure
- complex graft complications treatment
 - near total mesh excision, washout, repair of the urinary tract/vaginal wall, and concomitant placement of biological graft

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**Polypropylene Mesh Complication Algorithm
Location and Severity**

Minor (n = 17)	Severe (n = 22)
<p>Vaginal wall extrusion</p> <ul style="list-style-type: none"> Partial mesh excision Primary vaginal wall closure <p>Recurrent (n = 4)</p>	<p>Recurrent vaginal wall extrusion or urinary tract erosion</p> <ul style="list-style-type: none"> Abd/vag mesh explant Urethral/bladder repair Biological re-implant

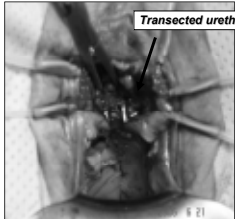
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**Polypropylene Mesh Complication Algorithm
Operative Technique for Severe Graft Complication**

- Abdominal/vaginal removal of mesh straps
- total explant of retropubic tapes, mini-slings
- removal of vaginal portion of TOT, prolapse mesh
- Urinary tract repair

↓

- Biological re-implant
 - autologous RF PVS for slings
 - allderm for prolapse kits
- 12 Fr foley (10-14 days) if urinary tract erosion



Transected urethra

* Flynn BJ et al: SUFU 2010

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Salvage Protocol
Near Total Mesh Explant, Washout, Re-implant with Biological

- Step 1: EUA, cysto, DRE, procto, CT scan in complex cases
- Step 2: Remove eroded mesh with 1 cm ring of vaginal epithelium
- Step 3: Complex cases continue explanting remaining body of the vaginal mesh
- Step 4: Repair defects in the viscera, consider flap if a fistula is present
- Step 5: Cysto to asses repair, r/o ureteral injury or residual FB
- Step 6: Irrigate with four solutions
 - bacitracin 50,000 units
 - gentamicin 80 mg in 1 l of 0.9% NS
 - 1/2 strength povidine-iodine, (500 ml)
 - 1/2 strength H2O2 (500 ml)
 - vancomycin 1 gm and gentamicin 80 mg, in 1 liter of 0.9% NS
- Step 7: Change gowns and gloves
- Step 8: Implant biological material
- Step 9: Close wound in 2 layers
- Step 10: Premarin vaginal pack
- Step 11: Treat with oral abx (based on culture results) for 1 month

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Management of Mesh Complications: Vaginal Wall Extrusions and Urinary Tract Erosions Results

Convalescence	Graft Complication Resolution
<ul style="list-style-type: none"> • mean f/u, 14 mos. • mean age, 55.5 yrs • mean length of stay <ul style="list-style-type: none"> - simple <23 hrs - complex 2.4 days 	<ul style="list-style-type: none"> • Simple group, n = 17 <ul style="list-style-type: none"> - trimming, n = 4 <ul style="list-style-type: none"> • 1 of 4 (25%) successful - OR excision/reclosure, n = 13 <ul style="list-style-type: none"> • 12 of 13 (92%) successful • Complex group, n = 22 <ul style="list-style-type: none"> - 21 of 22 (95%) successful

* Flynn BJ et al: SUFU 2010

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Management of Mesh Complications: Vaginal Wall Extrusions and Urinary Tract Erosions Continence Outcome

Post-operative	Image
<ul style="list-style-type: none"> • 30 patients with data regarding pad usage • 25 of 30 (83%) dry, 0 ppd • 3 required sling lysis for prolonged retention • 1 required prolapse repair • 1 required urethroplasty • 1 required Interstim for UUI 	

* Flynn BJ et al: SUFU 2010

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Management of Vesicovaginal Fistula (VVF)

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