

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

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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



Robot and LPR Primary Advantages

- Faster recovery – no lower abdominal incision
- Less blood loss – pneumoperitoneum
- Better preservation of the NVB – magnification
- Better Vesicourethral anastomosis – direct vision

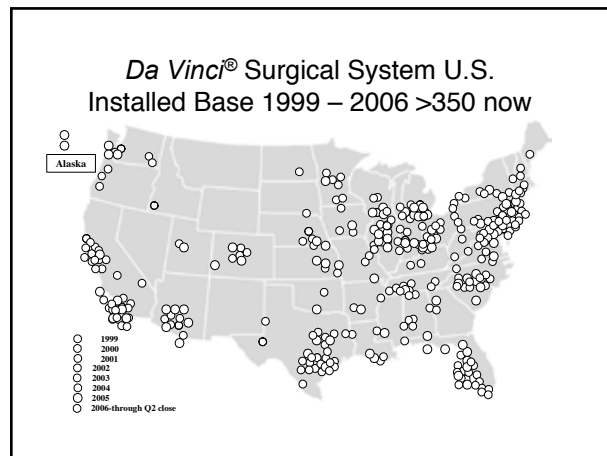
Robot

- Supposed improvement over lap
- 3-D up-close
- Wristed motions
- Tremor and movement scaling

Conclusions

- A lot of marketing hype
- Skill trumps any technique
Robot=RRP=RPP=Lap RRP
There is no difference in any parameter with the robot (even blood loss)
- Too much time wasted at meetings
- Has done nothing to advance care

Marketing



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

The Surgeon Makes the Difference

Not the technique
Robot, RRP, RPP, Lap

Operative time

- Lap longer
- Robot less
- RRP less
- With experience all about the same

Blood loss

- Lap and robot less
- But experience trumps all

Complications

- No difference
- Perhaps more bladder neck contracture with lap/robot
- Disasters with Robot/Lap
vascular injuries, rectal, anastomosis

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
Stolzberger 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
Guillonneau 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
Stohrberg et al ²¹	ELRP	700	Not reported	92% complete (12 mos) 98% 1 pad or less	BNS 47.1% (6 mos)
Memon et al	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 ²²	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 ²³	RARP	700	95% (5.7 mos)	88% (12 mos)	Not reported
Chou, Albert et al ²⁴	RARP	325	97% (6 mos)	90% (6 mos)	Not reported
Camblon et al ²⁵	ORP	1325	97% (6 mos)	93%	BNS 68% IENS 47%
Geary et al ²⁶	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 ²⁷	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	Guillonneau 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

Guillonneau 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

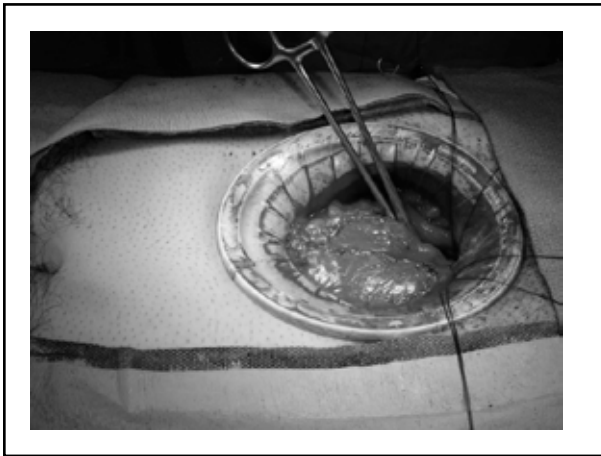
Complications	Open RRP	LRP (%)	
	Lepor & Kaci N = 500	Guillonneau et al N = 567	Ruiz et al N = 330
Urinoma	0	NR	NR
Myocardial infarction	0.4	NR	NR
Pulmonary embolus	0	NR	NR
DVT	0.4	0.3	NR
CVA	0	NR	NR
Prolonged ileus	0.4	1	1.5
Lymphocele	0	0	0.3

Guillonneau 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 ²⁸	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
Guillonneau et al	Montebios Institute	1000	15.5	31.1	1998-2002
Memon et al	Honey Ford	100	0	40	2001-2002
Ruiz et al	Harriet Mauder	330	16.3	44.3	2000-2002
Baumgartner et al	Emory Hospital	85	7.8		1999-2001

²⁸Unpublished data.
Concurrent studies at same institution.



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
Hydrourteronephrosis	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

Point-Counterpoint: Prostate Cancer Robotic Surgery is Mainstream

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Department of Surgery/Urology



Merriam-Webster Definition

Mainstream

Pronunciation: \mān-strēm\

Function: *noun*

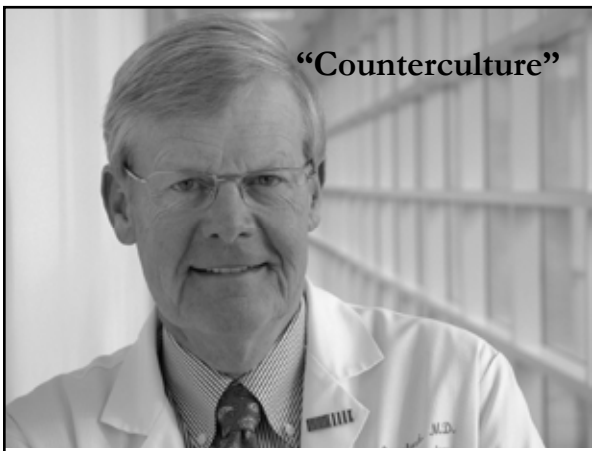
Date: 1599

: a prevailing current or direction of activity or influence

— **mainstream** *adjective*

Wikipedia definition - Mainstream

- the common current of thought of the majority.
- something that has ties to corporate or commercial entities.
- includes all popular culture, typically disseminated by mass media.
- The opposite of the mainstream are subcultures, countercultures, cult followings, underground cultures and (in fiction) genre.
- It is often used as a pejorative term.



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

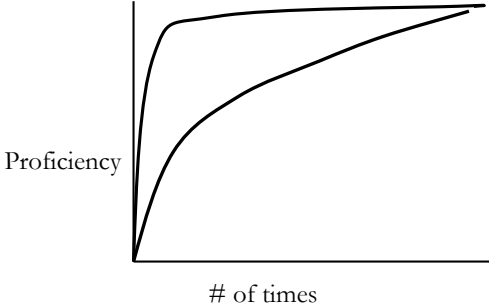
- Medicare dbase study – MIRP > SES
- No questionnaires used, early in learning curve

* - 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
Vincent Singh, Deep R. Gnan, Randal T. Hignault, 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. Novick, MD, Stephanie A. Fox, RBCF, Bob B. Kiani, MD, Larry W. Sitt, MS, Reiza Rayman, MD, Kojiro Kodera, MD, Alan H. Menkis, MD, and W. Douglas Bord, 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

Learning curve robotic assisted radical prostatectomy

- Are patients hurt by the learning curve?

Learning curve robotic assisted radical prostatectomy

- White et al Urol 2009
 - First 50 RARP compared to 50 historical RRP by same community surgeon (2005-2008)
 - Surgeon had performed >1200 RRP in career

	Margin positive	T2 (margin positive)
RRP	36%	34%
RARP	22%	19%

Adapted from White et al Urology 2009

Learning curve robotic assisted radical prostatectomy

- Atug et al Eur Urol 2006
 - First 100 RARP divided into thirds
 - 3 advanced laparoscopic surgeons

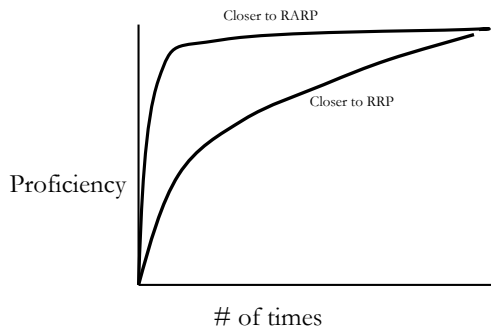
#	1-33	34-66	67-100
+ margin	45.4%	21.2%	11.7%
T2 + margin	38.4%	13.7%	3.6%

Adapted from Atug et al Eur Urol 2006

Learning curve robotic assisted radical prostatectomy

- Patel et al J Urol 2005 (positive margins – PSM)
 - First 100 – 13%
 - Second 100 – 8%
 - T2 – 5.7%
- Ahlering et al Urology 2004 (PSM)
 - First 45 – 35%
 - Next 60 – 16.7%
 - Next 60 - T2 – 4.5%

The learning curve



Cost issues

- Technological costs decrease with time
- Must calculate in context of other treatments for PCa
 - RT highest cost (Crawford et al, presented at SCS AUA, 2009)
- Incremental cost will decrease as other specialties use more frequently

Why robot assisted radical prostatectomy?

- Patients deserve the procedure with the steepest learning curve (and hopefully proficiency is achieved in training).
- It allows what only a few could do well to be done by a wider array of surgeons.