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Dincolo de Bisturiu: Măsurarea Nuanțată a Rezultatelor Raportate de Pacienti va Aduce Următoarea Rundă de Perfecționări în Tehnicile Chirurgicale

Liliana Bordeianou, MD, MPH, FACS, FASCRS
Professor of Surgery, Harvard Medical School
Chief, Mass General Colorectal and Pelvic Floor Centers

MGH 1811
MASSACHUSETTS GENERAL HOSPITAL
DIGESTIVE HEALTHCARE CENTER

- Am crescut in Chisinau, URSS
- Am plecat la SUA din URSS: 1990
- Am absolvit Universitatea: 1994
  - Queens College, CUNY (New York)
- Am absolvit Facultatea de Medicina : 2000
  - Harvard Medical School (Boston)
- Rezidentura chirurgicala / Fellowship :2006
  - Mas Gen Hospital (Boston)
  - Univ Minnesota (Minneapolis)
- Chirurg cu drepturi depline 2006- prezent
  - Massachusetts General Hospital
- Profesor de Chirurgie 2021
  - Harvard Medical School

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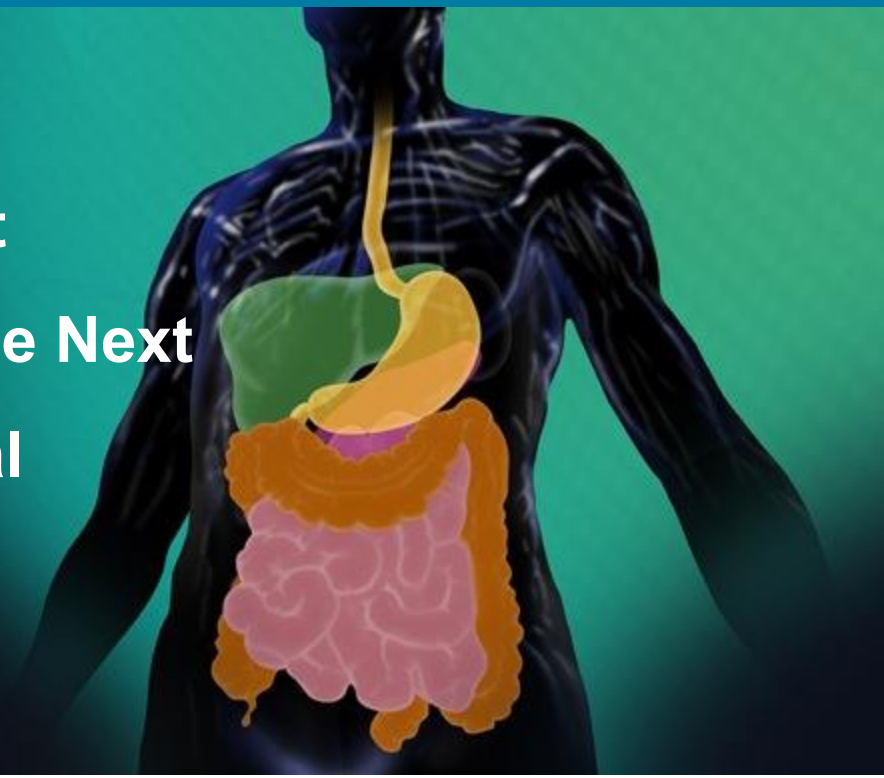
Beyond the Scalpel: Nuanced Measurement of Patient Reported Outcomes Will Bring the Next Round of Refinements in Surgical Techniques



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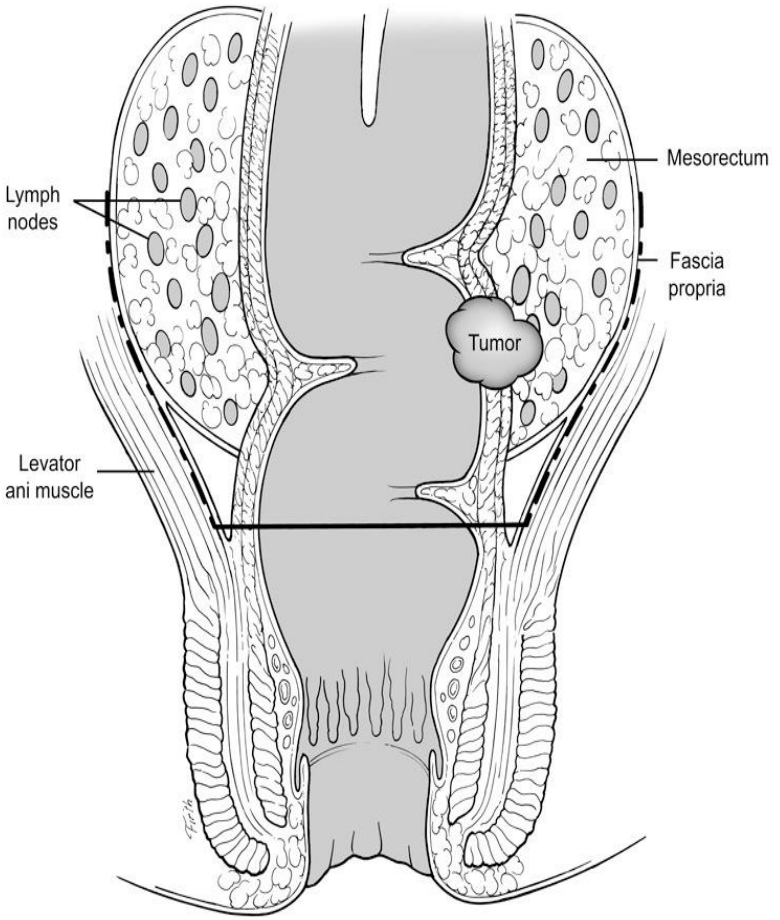
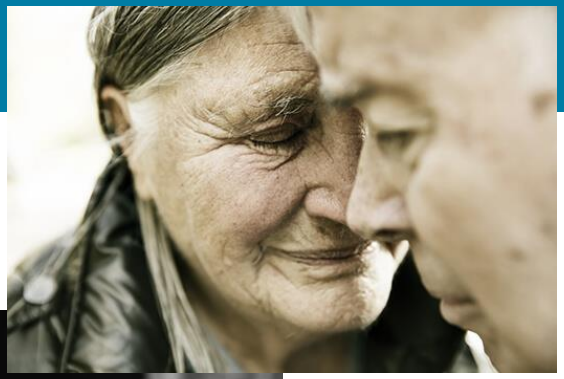
History of Refining Total Mesorectal Excision Techniques For Rectal Cancer Patients

- Pioneered by Richard Heald at Basingstoke District Hospital in UK in 1978
  - Postulated that leaving mesorectum at time of surgery leads to local recurrence
  - Advocated meticulous sharp excision of mesorectum without disruption of fascia propria
  - Data verified by an independent review by another surgeon who reviewed data in Lancet in 1992
  - Local recurrence: 4%



MacFarlane JK, et al. Lancet 1993; 341:457-460.

What do Patients Hope For?



- Cure
- Minimal pain
- Rapid recovery
- Avoidance of stoma
- Reasonable intestinal function
- Resonable bladder and sexual function
- Dignity
- Being whole

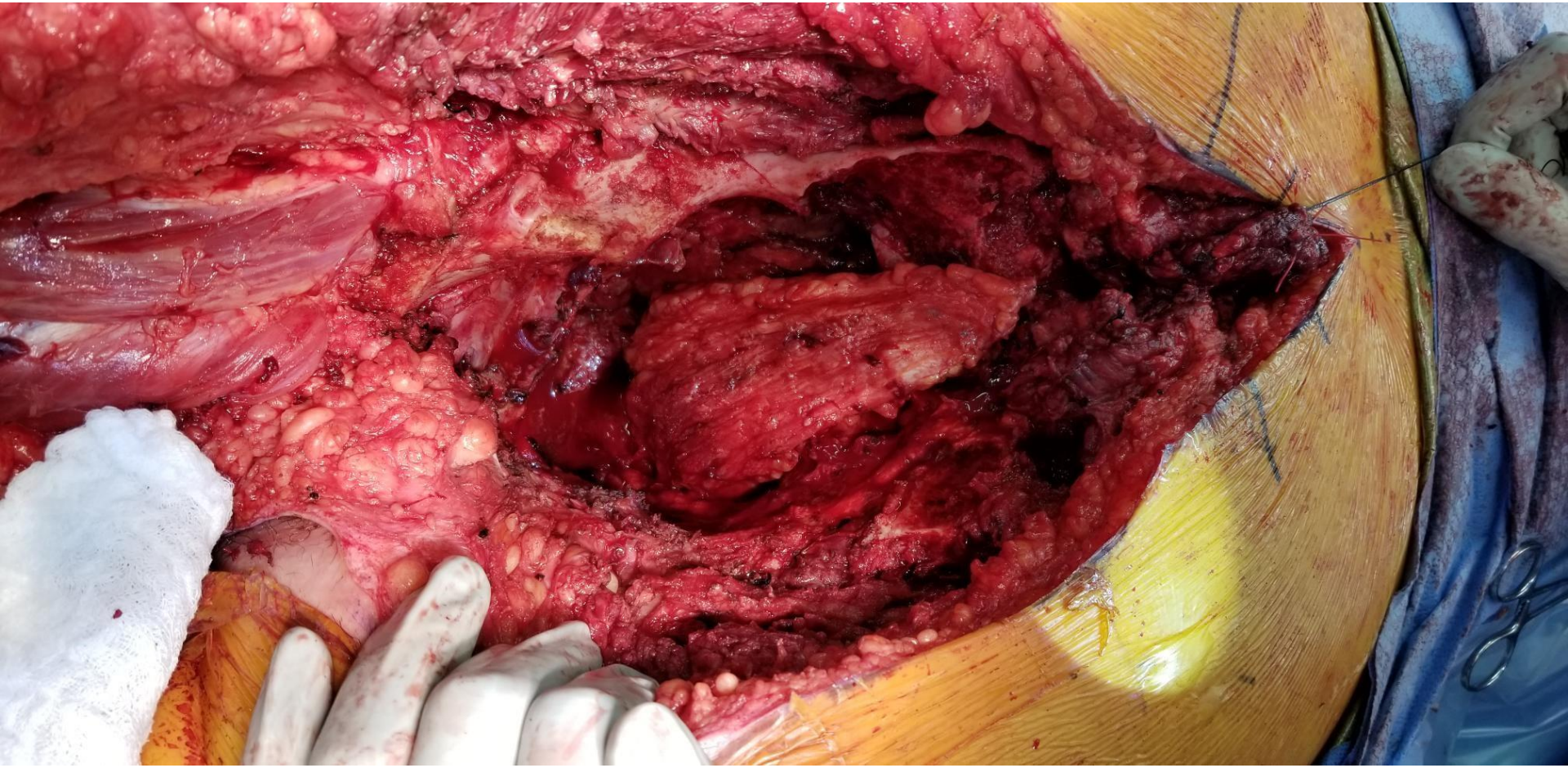
Advances in Medical and Radiation Oncology Allow for Improvements

Variable	Preoperative Chemoradiotherapy (N=415)	Postoperative Chemoradiotherapy (N=384)	P Value
Type of resection (%)			0.45
Low anterior, intersphincteric	69	71	
Abdominoperineal	26	23	
Other	3	2	
Unknown	2	3	

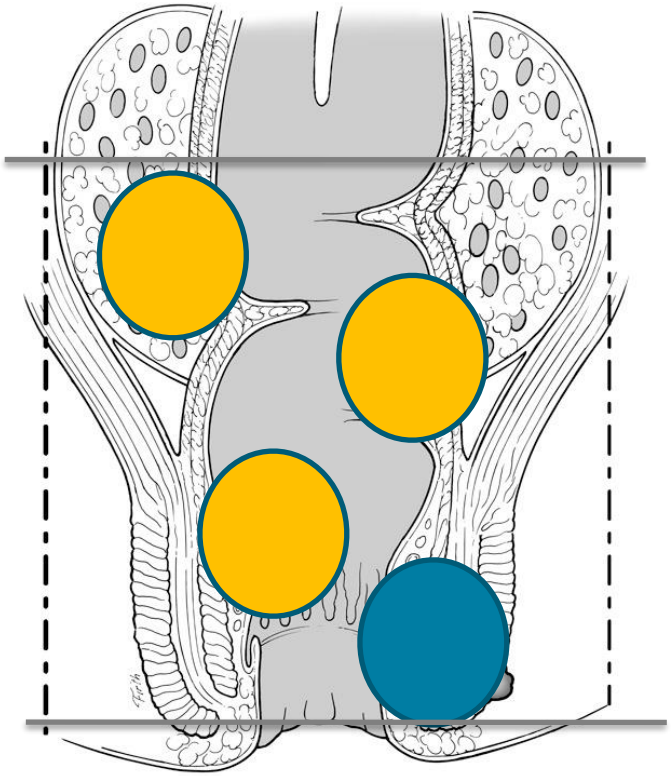
Variable	Preoperative Chemoradiotherapy (N=415)	Postoperative Chemoradiotherapy (N=384)	P Value
Abdominoperineal resection deemed necessary — no. (%)	116 (28)	78 (20)	
Sphincter-preserving surgery performed — no./total no. (%)	45/116 (39)	15/78 (19)	0.004

Greater rate of sphincter preservation in group pre-operatively felt to need APR

Avoidance of Abdominoperineal Resection Except for Late Stage Tumors



APRs Reserved For Low Tumors Involving External Sphincter Complex



"Most Controversial Segment of the Large Intestine"

Claude Dixon, MD

Ann Surg. 1948; 128(3):425-42.

Reproduced from Bordeianou, et al. *J Gastr Surg* 2015; 18:1358-1372

Options for the Super Low Tumors:

- Inter-sphincteric resection with colo-anal anastomosis (ISR)
- Transanal TME (TATME)
- Laparoscopic Surgery
- Robotic Surgery

MRI Assessment of Intersphincteric Plane is Key

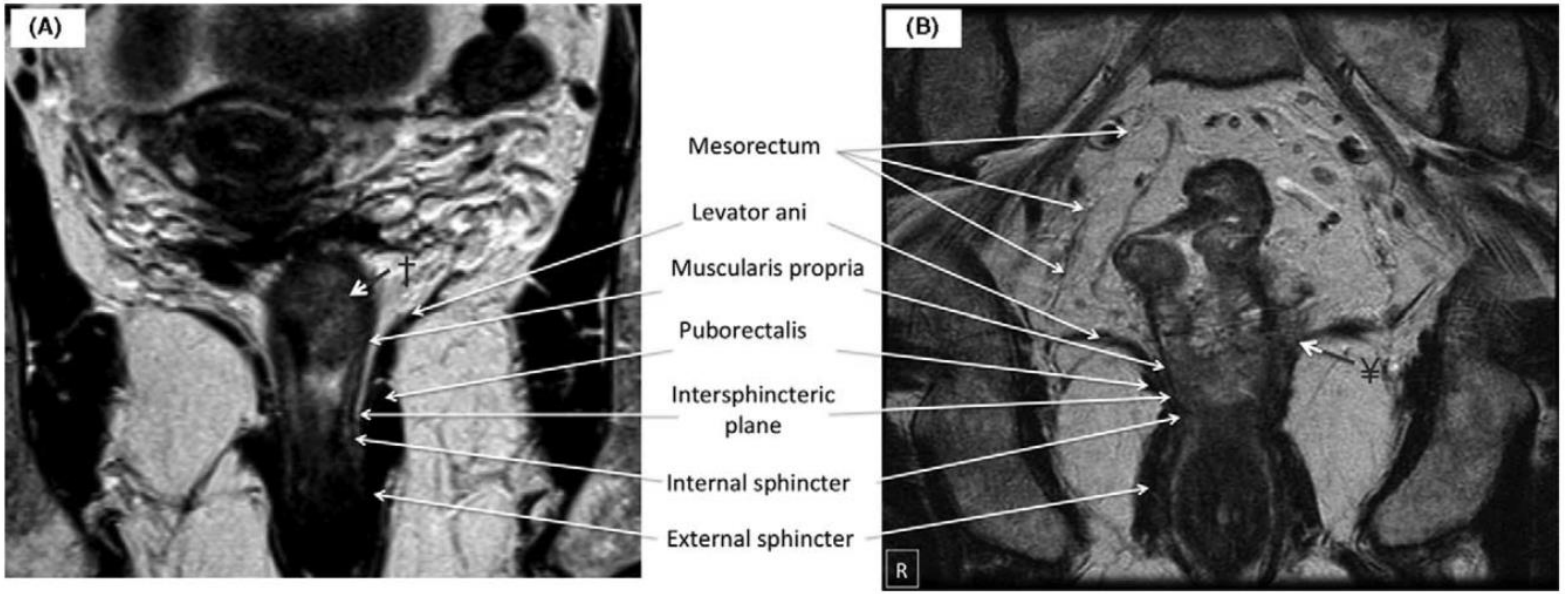
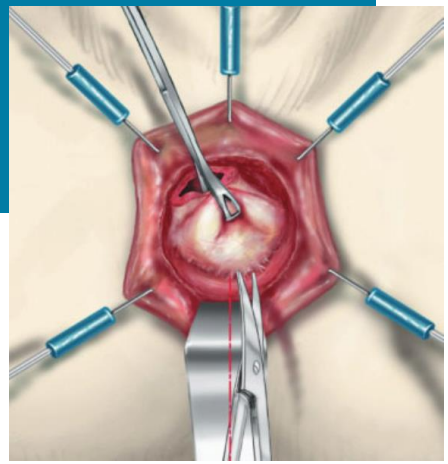
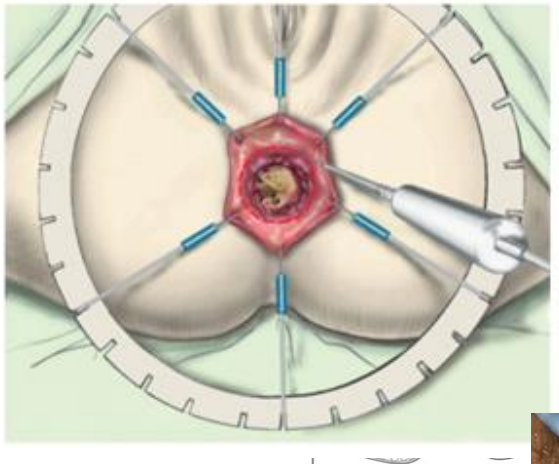
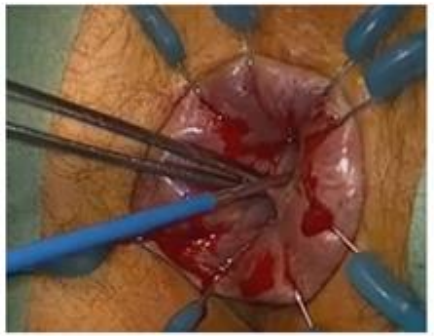
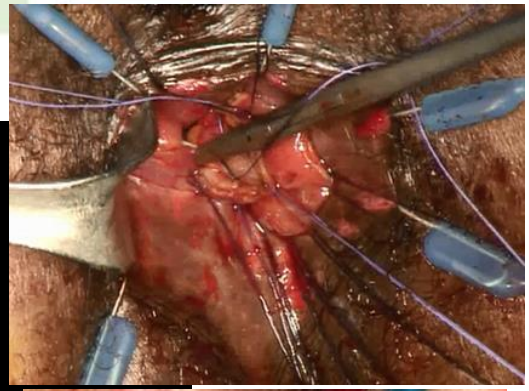


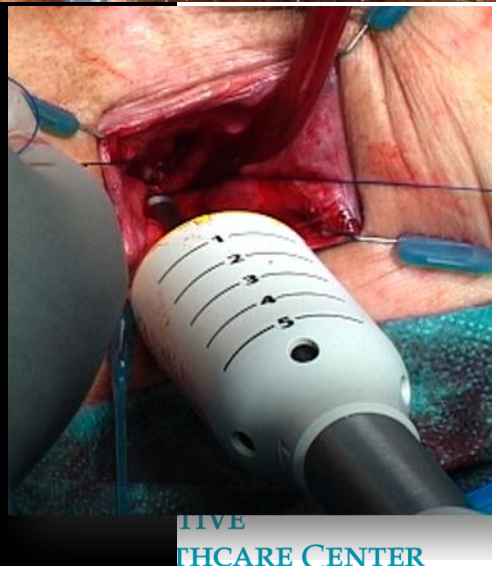
FIGURE 2. A, B, A high-resolution, coronal, oblique MRI image through long-axis of the anal canal for 2 different low rectal cancers. A, A tumor confined to the muscularis propria (†). The MRI assessed low rectal cancer resection plane (mrLRP) appears "safe," suggesting an intersphincteric resection is feasible. B, The tumor (¥) appears to breach the muscularis propria and is invading the distal mesorectum and intersphincteric plane. This tumor is mrLRP "unsafe" and an intersphincteric resection would be high-risk for pCRM involvement; therefore, an ELAPE was suggested.











Sphincter-Saving Resection for All Rectal Carcinomas

The End of the 2-cm Distal Rule

Eric Rullier, MD, Christophe Laurent, MD,* Frédéric Bretagnol, MD,* Anne Rullier, MD,† Véronique Vendrely, MD,‡ and Frank Zerbib MD, PhD§*

- N=92 patients
- Tumor 3 cm form anal verge (1.5-4.5)
- All underwent ISR

- R0 resection: 89%
- Positive distal resection margin: 2%
- Positive radial circumferential margin: 11% (vs. 17% in Dutch RCT)
- 5 yr local recurrence: 2% (vs. 4% in Dutch RCT)
- 5yr survival : 81%

TABLE 1. Patients Treated by Intersphincteric Resection for a Low Rectal Cancer (n = 92)

Age* (yrs)	65 (25–86)
Sex (M:F)	57:35
Tumor distance from anal verge* (cm)	3.0 (1.5–4.5)
Tumor distance from anal ring* (cm)	0.5 (−1.5–1.5)
Tumor stage	
T1	2
T2	12
T3	72
T4	6
Preoperative radiotherapy	81

*Values are median (range).

Rullier, et al. *Ann Surg* 2005; 241:465-469

Oncologic Outcomes better than APR

TABLE 4. Pathologic Stage, Resection Margins, and Recurrence According to Surgical Procedure

Factor	LAR + Stapled Coloanal Anastomosis n = 41 (28)	LAR + Intersphincteric Resection + Handsewn Coloanal Anastomosis n = 44 (29)	APR n = 63 (43)	*P*
Pathologic TNM stage				0.12
0 (pCR)	10 (24)	11 (25)	6 (10)	
I	13 (32)	16 (36)	15 (24)	
II	7 (17)	12 (27)	25 (40)	
III	11 (27)	5 (11)	17 (27)	
Percent response to chemoradiation*				0.016†
100% response (pCR)	10 (26)	11 (27)	6 (10)	
86%–99% response	9 (23)	10 (24)	11 (18)	
<86% response	20 (51)	20 (49)	44 (72)	
T-category downstaging‡	27 (66)	29 (66)	30 (47)	
Histologic differentiation				0.003+
Well/moderate differentiated	38 (93)	42 (95)	45 (71)	
Poor/undifferentiated	3 (7)	2 (5)	18 (29)	
Circumferential resection margin ≤1 mm	0 (0)	2 (5)	8 (13)	
Distal resection margin ≤1 mm	0 (0)	2 (5)	0 (0)	
Crude recurrence rate	6 (15)	7 (16)	26 (41)	
Local	1 (2)	0 (0)	6 (9)	
Distant	5 (12)	7 (16)	22 (35)	
Recurrence-free survival (95% CI)	85% (74–96)	83% (71–94)	47% (31–62)	
Disease-specific survival (95% CI)	97% (92–99)	96% (87–99)	59% (42–76)	

*Of those in which percent response data was available (n = 141).
†*P* value comparing sphincter preservation (LAR) versus APR.
‡Pathologic T-category lower than pretherapy ERUS T-category.
Numbers in parenthesis are percentages unless stated otherwise.

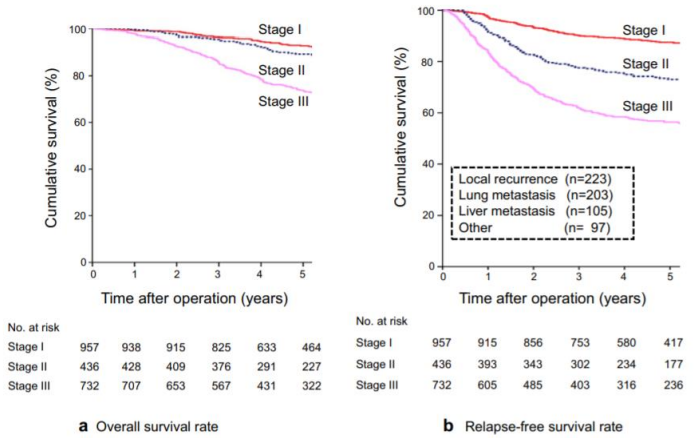


Fig. 2 Overall survival rates and relapse-free survival rates according to TNM stage for 2125 patients who underwent ISR

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Weiser, et al. *Ann Surg* 2009; 249:236-242

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Surgery Today (2019) 49:275–285
https://doi.org/10.1007/s00595-018-1754-4

REVIEW ARTICLE

Long-term results of intersphincteric resection for low rectal cancer in Japan

Kazutaka Yamada[1] · Yasumitsu Saiki[1] · Shota Takano[1] · Kazutsugu Iwamoto[1] · Masafumi Tanaka[1] · Mitsuko Fukunaga[1] · Tadaaki Noguchi[1] · Yasushi Nakamura[1] · Saburo Hisano[1] · Kensaku Fukami[1] · Daisaku Kuwahara[1] · Yoriyuki Tsuji[1] · Masahiro Takano[1] · Koichiro Usuku[2] · Tokunori Ikeda[2] · Kenichi Sugihara[3]

- 2125 patients underwent curative ISR 2005-2012 at 127 institutions
- Total (402) , subtotal (559) and partial (1164) ISR was performed
- Median follow up: 58 (1-129 months)
- 5 year overall survival was 92.8% (stage 1), 89.3 %(II) and 56.4% (III)
- 5 year cumulative local recurrence rate was 4.2%(T1), 8.5% (pT2), 18.1%(pT3), 36.6% (pT4)

Functional Outcomes with ISR Imperfect

Table 7 Defecatory function evaluated 12 months after intersphincteric resection in 168 patients who underwent diverting stoma closure

		Total ISR (n=18)	Subtotal ISR (n=43)	Partial ISR (n=90)	ISR (n=151)	Partial ESR (n=17)
Bowel frequency (per day)		4.0 ± 2.3	3.7 ± 1.9	3.9 ± 2.2	3.9 ± 2.1	4.0 ± 1.9
P value [a]		*0.129*	*0.163*			*0.129*
Continence						
Kirwan's [b]	Grade 1	2	5	20	27	3
	Grade 2	8	22	43	73	5
	Grade 3	5	14	23	42	8
	Grade 4	3 (44.4 %)	2 (37.2 %)	4 (30.0 %)	9 (33.8 %)	1 (52.9 %)
	Grade 5	0	0	0	0	0
Wexner's score						
Continent patients (Kirwan's Grade 1, 2)		3.5 ± 1.5	4.8 ± 3.1	4.2 ± 3.2		3.6 ± 2.8
Incontinent patients (Kirwan's Grade 3, 4)		12.4 ± 2.7	12.1 ± 2.0	12.1 ± 2.8		14.3 ± 2.4

ISR intersphincteric resection, *ESR* external sphincter resection

[a] Versus partial ISR, Tukey–Kramer's test

[b] Kirwan's classification [18]

Continence Not the Only Functional Outcome of Relevance

Low Anterior Resection Syndrome

Frequency | Urgency | Incontinence to liquids | Clustering | Incontinence to gas

"…disordered bowel function after rectal resection, leading to a detriment in quality of life…."[1]

[1]Bryant, Lunniss, Knowles et al. 2012

LARS Score Developed a Decade Ago

APPENDIX 2. LARS Score: Scoring Instructions

Add the scores from each 5 answers to one final score.

Do you ever have occasions when you cannot control your flatus (wind)?

☐ No, never	0
☐ Yes, less than once per week	4
☐ Yes, at least once per week	7

Do you ever have any accidental leakage of liquid stool?

☐ No, never	0
☐ Yes, less than once per week	3
☐ Yes, at least once per week	3

How often do you open your bowels?

☐ More than 7 times per day (24 hours)	4
☐ 4–7 times per day (24 hours)	2
☐ 1–3 times per day (24 hours)	0
☐ Less than once per day (24 hours)	5

Do you ever have to open your bowels again within one hour of the last bowel opening?

☐ No, never	0
☐ Yes, less than once per week	9
☐ Yes, at least once per week	11

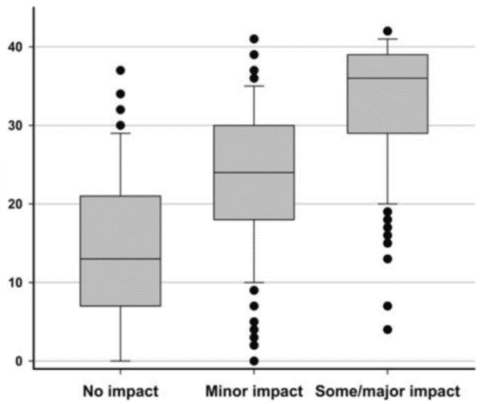
Do you ever have such a strong urge to open your bowels that you have to rush to the toilet?

☐ No, never	0
☐ Yes, less than once per week	11
☐ Yes, at least once per week	16

Total Score:

Interpretation:

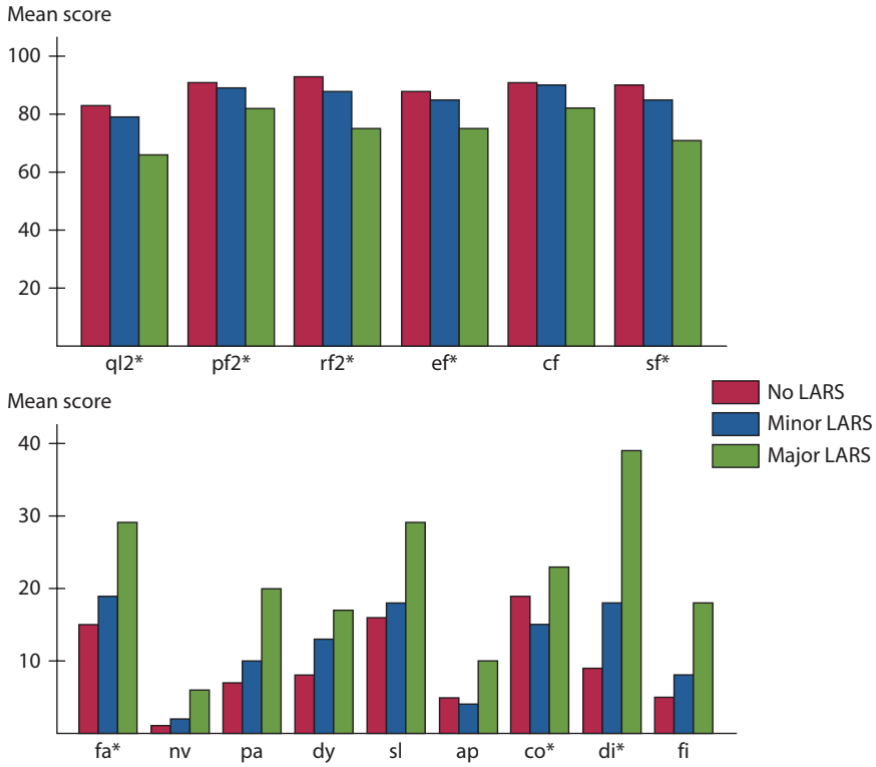
0–20:	**No LARS**
21–29:	**Minor LARS**
30–42:	**Major LARS**



Emmertsen, Laurberg. Ann Surg2012

QOL Impacted For Life When LARS Present

- Impact lasts for decades
- More prevalent in females
- Worse in the elderly but can affect all ages
- Major cause of long term disability and disaffection
- Associated with bladder and sexual dysfunction



Gaining the patient perspective on pelvic floor disorders' surgical adverse events

Gena C. Dunivan, MD; Andrew L. Sussman, PhD, MCRP; J. Eric Jelovsek, MD, MMEd; Vivian Sung, MD, MPH; Uduak U. Andy, MD; Alicia Ballard, MD; Sharon Jakus-Waldman, MD; Cindy L. Amundsen, MD; Christopher J. Chermansky, MD; Carla M. Bann, PhD; Donna Mazloomdoost, MD; Rebecca G. Rogers, MD, on behalf of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development Pelvic Floor Disorders Network

- 81 patients
- 12 focus groups: preoperative, short term and long term postoperative
- Incontinence, constipation, nocturia and sexual dysfunction after surgery was ranked by patients to be of the **same level of perceived severity as needing admission to intensive care**

Surgeons as Listeners, Advisors and Clinicians

First Step: Prognostication of LARS Risks Within the Context of the Patient

RADIATION

TUMOR HEIGHT

FEMALE

YOUNG AGE

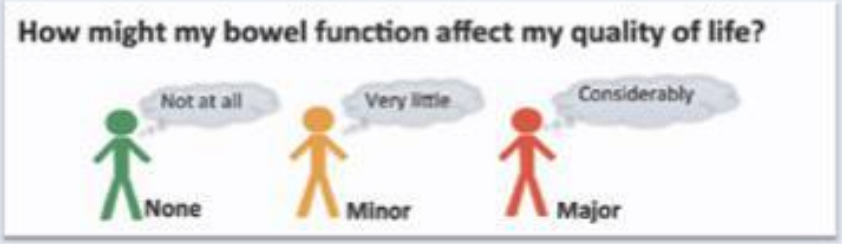
STOMA

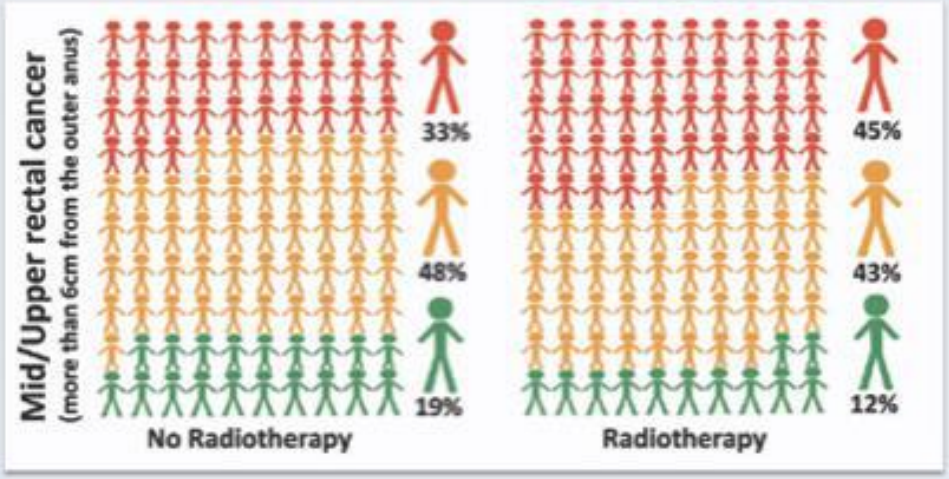
ANASTOMOTIC LEAK

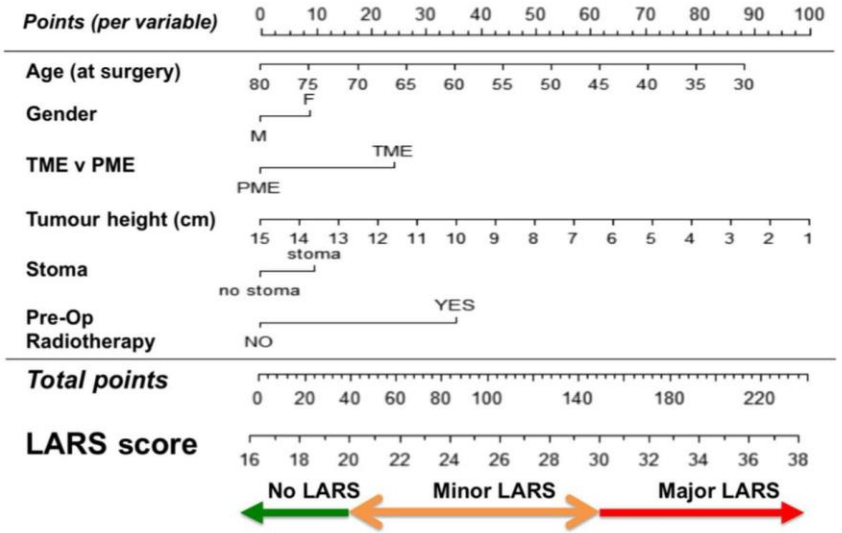
Hain et al. Surgery 2016; Battersby et al. Gut 2018

POLARS

Helps Predict LARS







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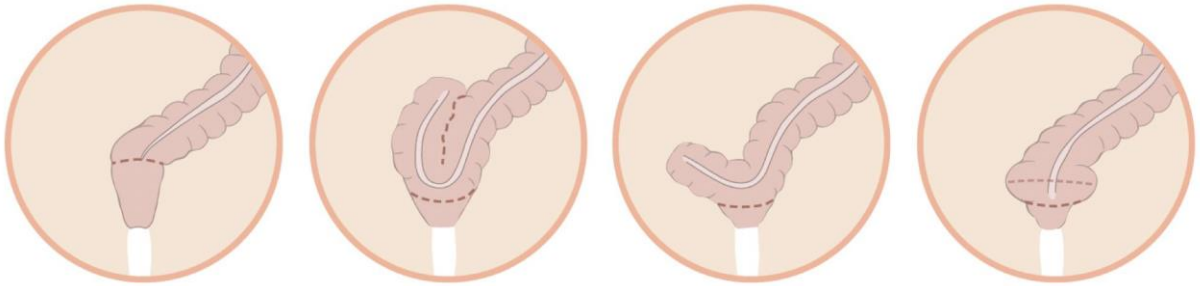
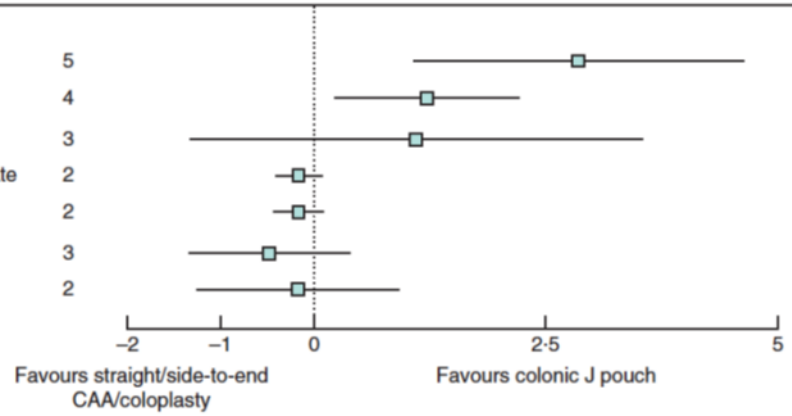
Next Step: Modification of LARS Risks Within the Context of the Surgical Technique



Straight anastomosis | Colonic J-pouch | Side-to-end anastomosis | Transverse coloplasty

Comparison	*n*	Mean difference	*P*	I^2 (%)
Stool frequency				
Straight CAA *versus* colonic J pouch, early	5	2·85 (1·09, 4·61)	0·001	93
Straight CAA *versus* colonic J pouch, intermediate	4	1·22 (0·25, 2·20)	0·014	78
Side-to-end CAA *versus* colonic J pouch, early	3	1·10 (–1·32, 3·53)	0·372	97
Side-to-end CAA *versus* colonic J pouch, intermediate	2	–0·15 (–0·39, 0·08)	0·198	0
Side-to-end CAA *versus* colonic J pouch, late	2	–0·16 (–0·41, 0·09)	0·206	0
Coloplasty *versus* colonic J pouch, early	3	–0·47 (–1·33, 0·38)	0·279	0
Coloplasty *versus* colonic J pouch, intermediate	2	–0·17 (–1·25, 0·91)	0·759	82

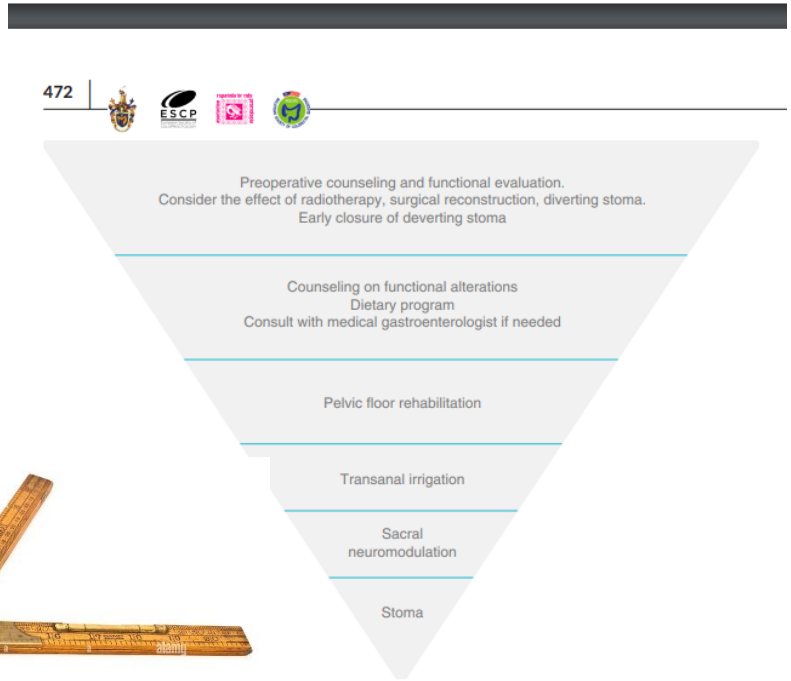


Massachusetts General Hospital
Founding Member, Mass General Brigham

Center for Pelvic Floor Disorders

Management guidelines for low anterior resection syndrome – the MANUEL project

Peter Christensen[1] | Coen IM Baeten[2] | Eloy Espín-Basany[3] | Jacopo Martellucci[4] | Karen P Nugent[5] | Frank Zerbib[6] | Gianluca Pellino[3,7] | Harald Rosen[8] | MANUEL Project Working Group*



- **Multiple treatments exist**

  - **LARS score <u>insensitive to change</u> despite patients telling us that they are improving with interventions**
  - **Domains are missed**
  - **Lack of measurement hinders research on effective treatments**

Christensen P, et al.Colorectal Dis. 2021;23:461–475

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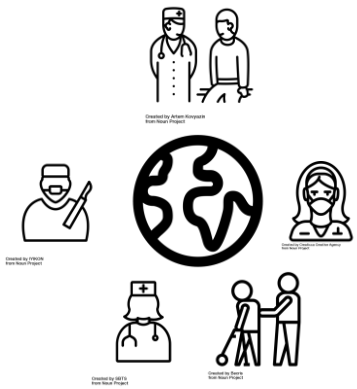
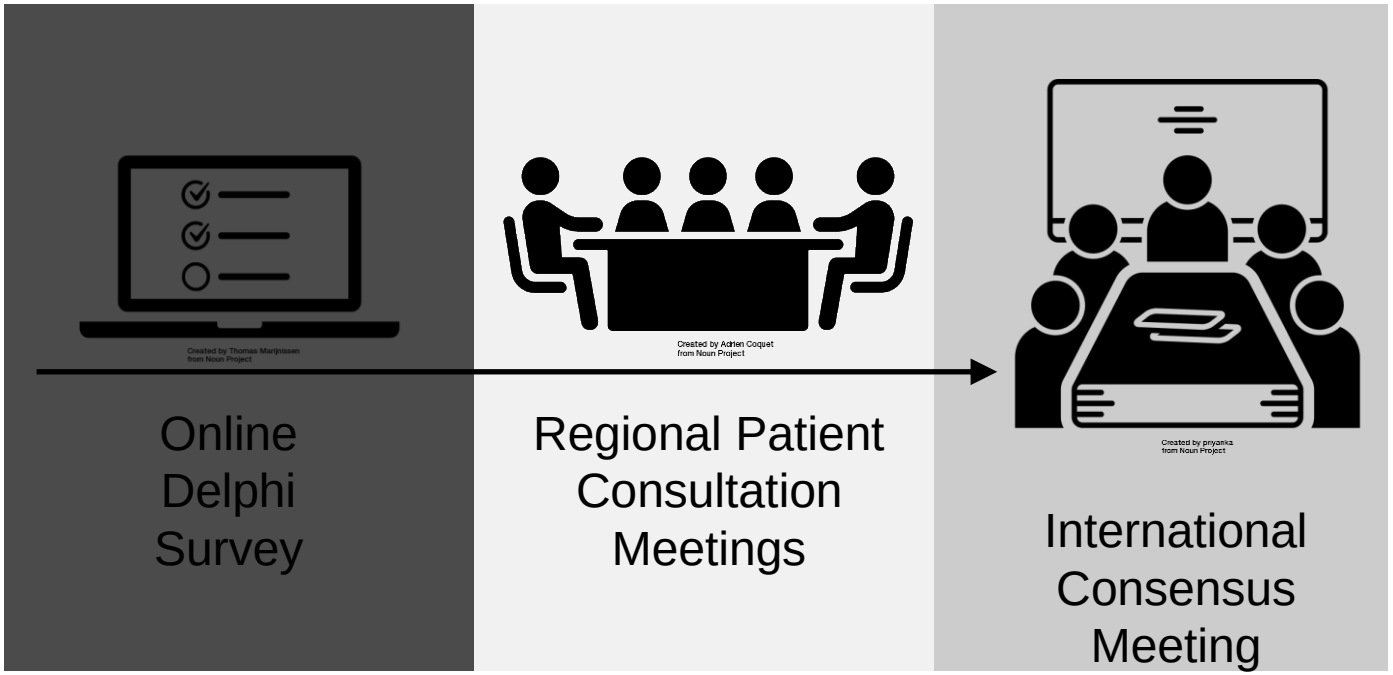
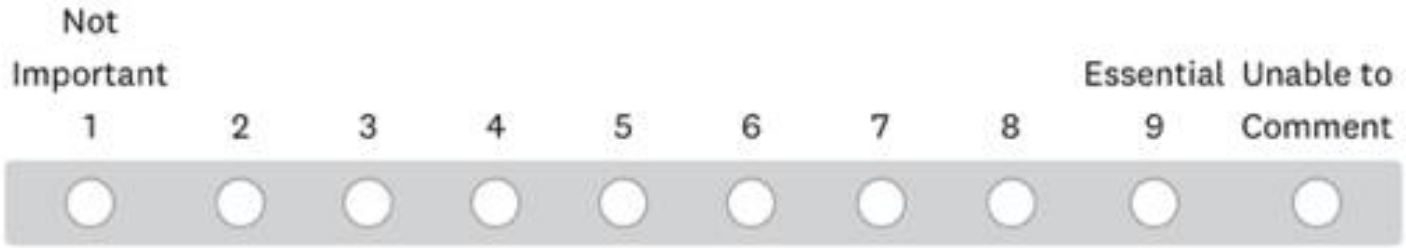
Can Measurement of LARS be Improved to Allow for More Sensitivity to Change? Time to Get Back to the Patients

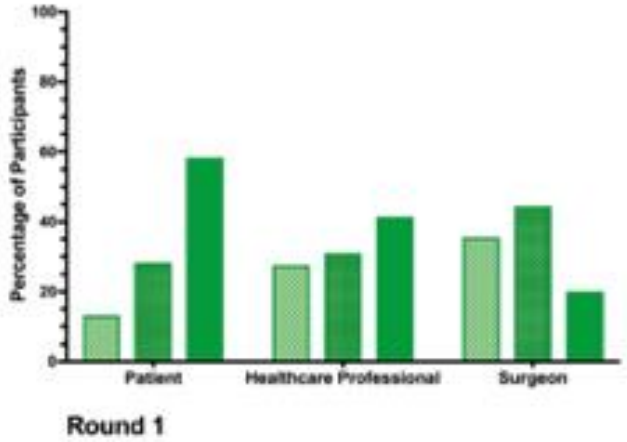


3 expert panels
5 regions
3 languages

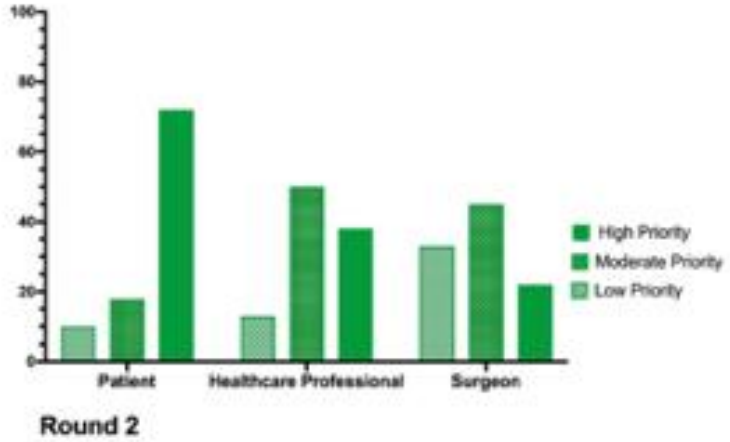


2. Change in stool consistency following surgery





Round 1



Round 2

1. Fecal Incontinence

Accidental leakage of liquid and/or solid stool, with inability to discriminate gas passage from stool passage; inability to pass gas without also passing stool and therefore requiring additional bathroom trips

"It's not just gas itself, but there's always stool when it comes to the gas. If you can't find a bathroom, and you're trying to hold the gas in, that's where accidents happen."

"My intestine is like a leaky pipe, and the feeling is that the pipe isn't shut tight. Sometimes I address it in time and then sometimes I am late…it's embarrassing."

"It gets better with time. Now I find that I can hold it for almost as long as I need to: it might be painful, but if I'm in a car ride and there's not an exit, I don't freak out. It might start to hurt, and I really might need to find somewhere to stop because it's painful, but…I can hold it if I need to… [after 2 years of practice]."

2. Soiling

Involuntary staining of sanitary items, pads, or underwear with fecal material

"It is as if my anus is open and will not close, it leaks even if there's no need to have a bowel movement."

"I stain my pants every time I try to pass gas, forget about white clothing."

"Cannot tell if its just staining or if my skin is just raw but there is always something there and I worry that it will leak though."

3. Urgency

Inability to defer BMs for a sufficient time thus needing to rush to the toilet to have a bowel movement

"I'm four years [since surgery] and I still have a lot of urgency, but now I'm very good at holding it in. I never have an accident, but it's very uncomfortable to the point that I'm chained to the bathroom. There are days that I do wish I still had my ostomy bag."

"The first year and a half was absolutely wretched, because you can't plan on car trips. I had a 2 hour car trip on a regular basis, and I'd have to stop sometimes 2 or 3 times just in that car trip because of the urgency. And I also didn't have the confidence to hold it in. Now I can do better."

A Teaching Affiliate of Harvard Medical School

MGH 1811 MASSACHUSETTS GENERAL HOSPITAL
DIGESTIVE HEALTHCARE CENTER

CONSENSUS STATEMENT

International Consensus Definition of Low Anterior Resection Syndrome

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Eloy Espin Basany, M.D.[5] • Søren Laurberg, M.D., D.M.Sc.[4]
Anders Mellgren, M.D., Ph.D.[6] • Craig Messick, M.B.Ch.B., M.D.[7]
Guy R. Orangio, M.D.[8] • Azmina Verjee, B.Sc.[9] • Kirsty Wing, B.Nurs.[10]
Ian Bissett, M.B.Ch.B., M.D.[1,11] on behalf of the LARS International Collaborative Group*

Symptoms

- Variable, unpredictable bowel function
- Altered stool consistency
- Increased stool frequency
- Repeated painful stools
- Emptying difficulties
- Urgency
- Incontinence
- Soiling

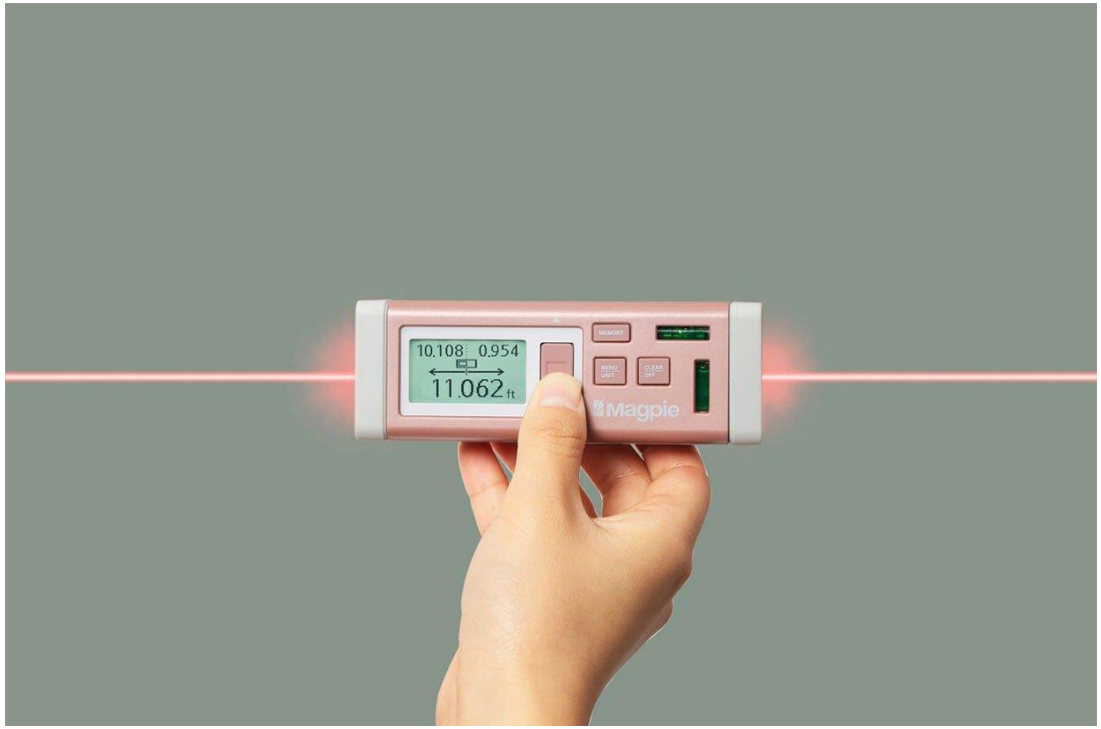
Consequences

- Toilet dependence
- Preoccupation with bowel function
- Dissatisfaction with bowels
- Strategies and compromises

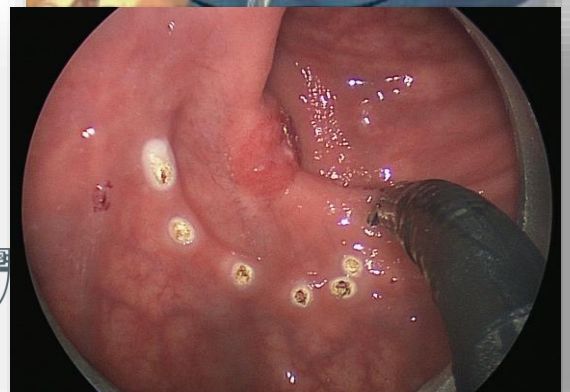
Impact on:

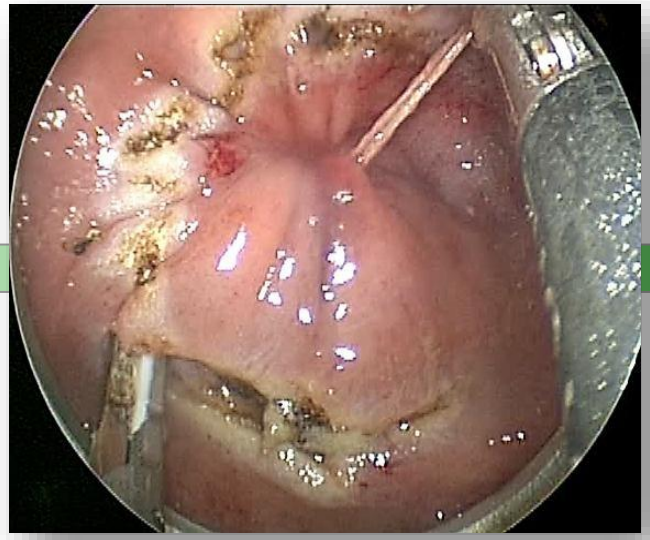
- Mental and emotional wellbeing
- Social and daily activities
- Relationships and intimacy
- Roles, commitments and responsibilities

From Ruler to Laser Ruler Through Patient Engagement



Does Nerve Sparing During Ultralow Dissection With Transanal Assistance Make a Difference?





taTME?

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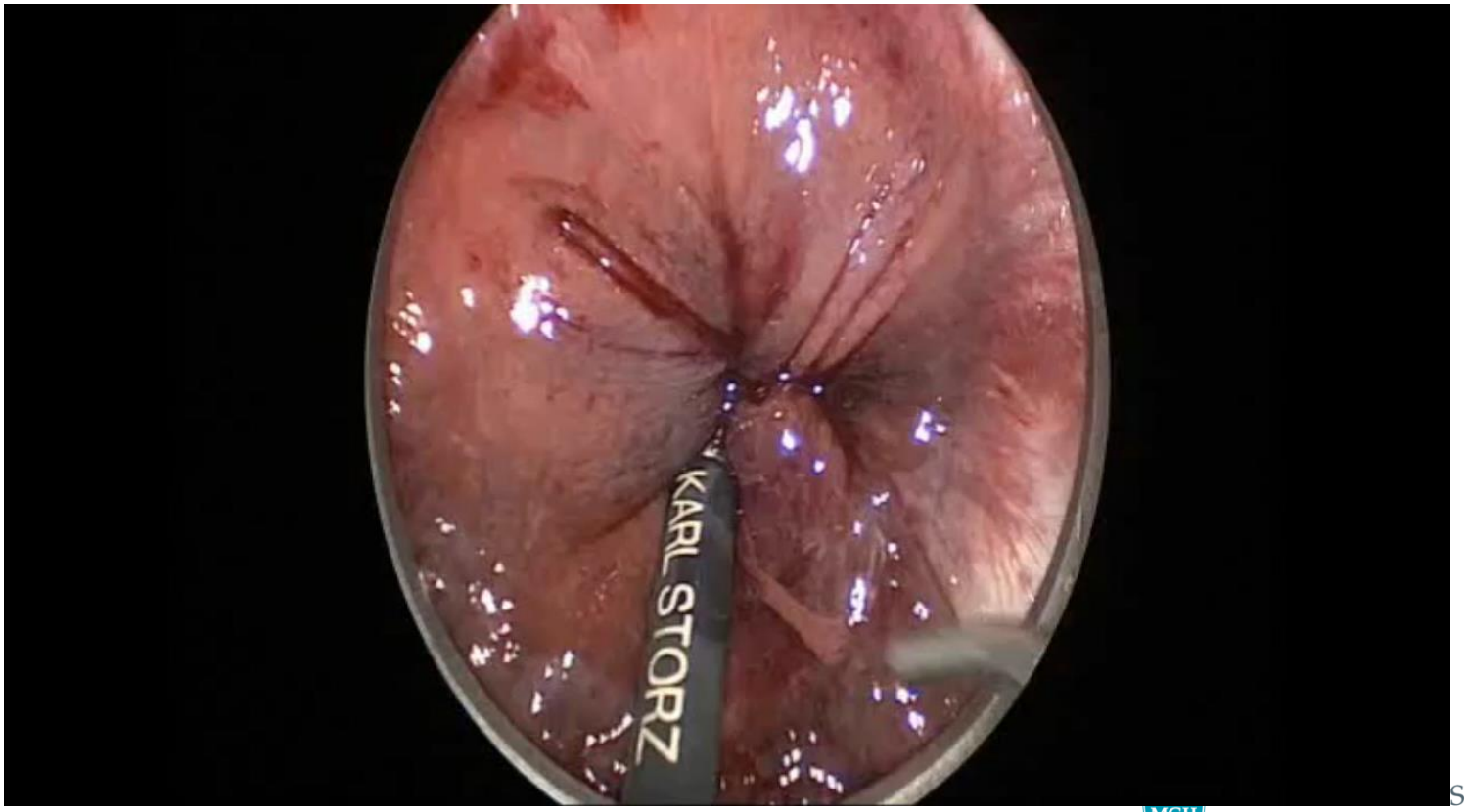
Surg Endosc (2013) 27:3396–3405
DOI 10.1007/s00464-013-2922-7

A pilot study of natural orifice transanal endoscopic total mesorectal excision with laparoscopic assistance for rectal cancer

Patricia Sylla · Liliana G. Bordeianou · David Berger · Kyung S. Han · Gregory Y. Lauwers · Dushyant V. Sahani · Mohammed A. Sbeih · Antonio M. Lacy · David W. Rattner

Patient	Final tumor stage (TNM)	Retrieved LN	TME quality	Tumor size (cm)	Distal margin (cm)	CRM (cm)	Adjuvant Treatment	Ileostomy closure
1F	ypT2N0M0	41	Complete	1.5	10	0.6	Y, Folfox	Y
2M	ypT2N0M0	16	Complete	5	1.5	1	Y, Capox	N
3M	pT1N0M0	53	Complete	5.5	2	1.1	N	N
4M	pT2N1M0	34	Complete	2.7	0.8	0.2	Y	N
5F	pT0N0M0	21	Complete	N/A	N/A	N/A	N	Y
Mean		33		3.6	3.5	0.73		



Does LARS Improve with Better Visualization and Surgeon Dexterity with Robotic Assistance?

Can We Use Artificial Intelligence to Guide Surgeons Around Critical Structures ? Research from the MGH Surgical AI and Innovation Laboratory

Surgical Artificial Intelligence & Innovation Laboratory

Oz Meireles,
Surgical Director of SAIL at MGH

Daniela Rus,
Head of IAI at MIT

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AI and Computer Vision Guided Surgery: Gallbladder Dissection : Surgical GPS

10.1097/SLA.0000000000004594

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Crowdsourcing of Surgical Videos: OR Blackbox

The SAGES Critical View of Safety Data Challenge

Donate your laparoscopic cholecystectomy videos through the

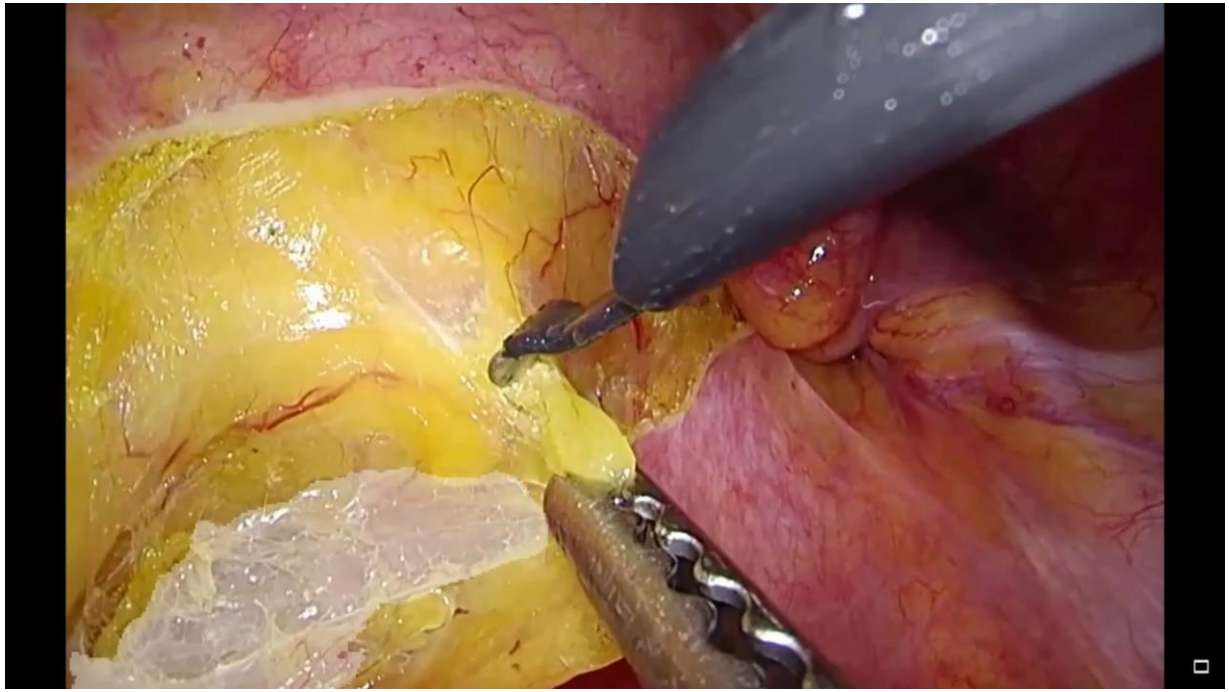
SAGES Video Acquisiton Portal

for easy and safe de-identification of PHI

more information & opportunities to participate:

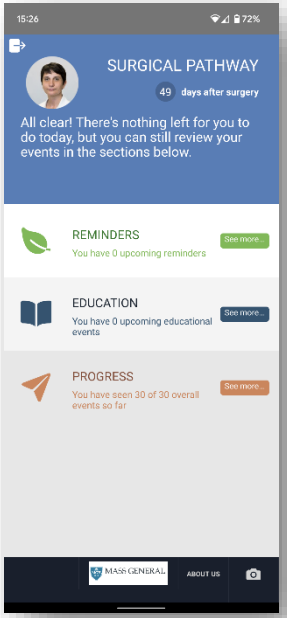
www.cvschallenge.org

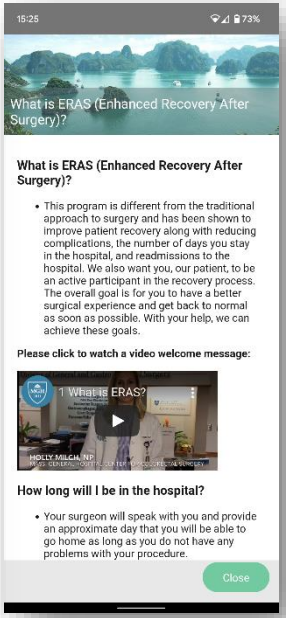
AI and Computer Vision Guided Surgery: Total Mesorectal Excision GPS

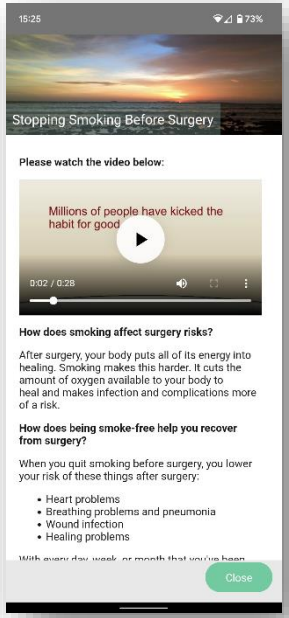


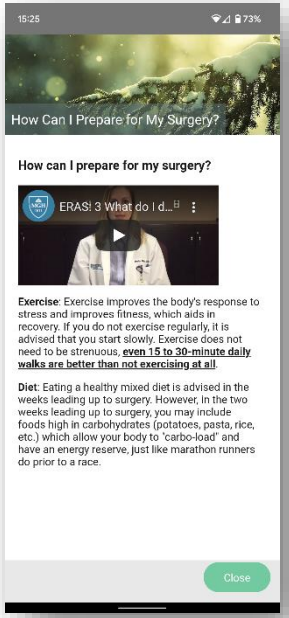
Crowdsourcing of Parallel Collection of Patient - Relevant Surgical Endpoints at 3,6,12 months and beyond

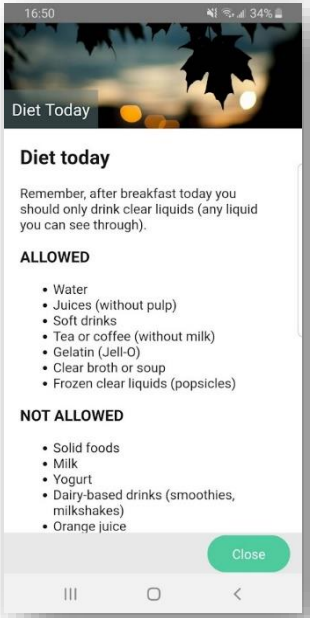
Cell Phone Apps for Patient Education and Data Collection



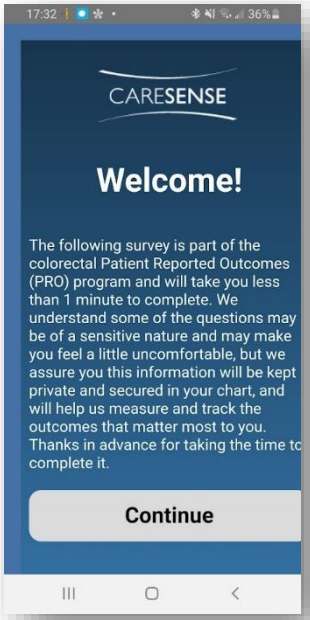


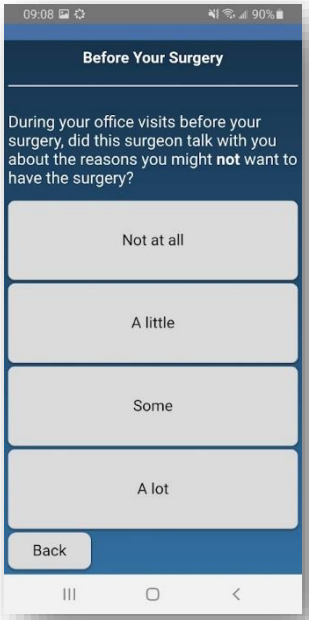


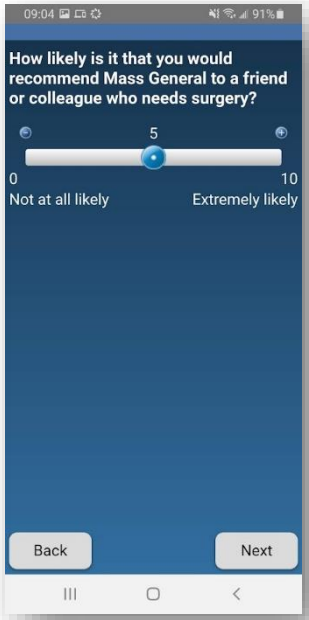




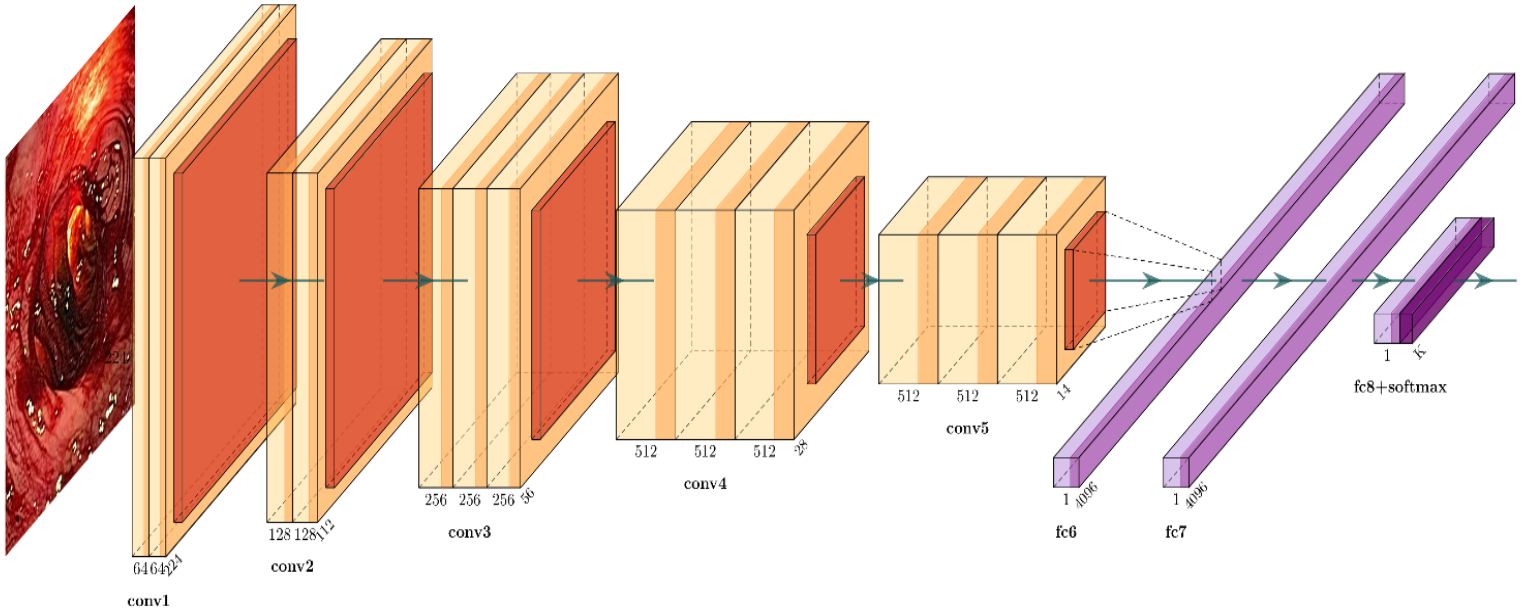
Patient Surveys







Measuring and Improving Patient Relevant Outcomes



Leak ?

Conclusions

- Continues innovation in rectal cancer care and rectal cancer surgery continues
- Similar innovation occurs in other surgical diseases
- We are not getting to the point where wish for sphincter preservation is fulfillable in the majority of rectal cancer patients
  - Independent of distance from anal verge
  - As long as external sphincter is spared or cleared of disease with chemo and radiation
  - With watch and wait entire organ is sometimes spared
- However, LARS after rectal cancer surgery in general and especially after ultra low sphincter sparing surgery is a major concern
  - Patient counselling to expect LARS clinic is critical, but not enough
  - High quality postoperative clinics to address LARS and other survivorship concerns are an important frontier in research, and a must
- Further innovation in surgery techniques is also possible
- Most of this research will require massive data crowdsourcing through selfless, generous, painstaking data collection :
  - PROMs collection
  - Surgical video collection in a HIPPA compliant repository

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