Open versus Robotic REtrOmuscular Ventral Hernia Repair: ORREO trial

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Disclosure

Intuitive (JAW, AMC)

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Background

Does minimally invasive abdominal wall reconstruction improve clinical outcomes?

Background

Reducing Length of Stay Using a Robotic-assisted Approach for Retromuscular Ventral Hernia Repair

A Comparative Analysis From the Americas Hernia Society Quality Collaborative

222 open vs 111 roboticRM

4 vs 2% SSI (p=0.05)

LOS 3 vs 2 days (p<0.001)

Carbonell AM, Ann Surg 2018

Background

Transversus abdominis release (TAR) for ventral hernia repair: open or robotic? Short-term outcomes from a systematic review with meta-analysis

237 rTAR vs 594 oTAR from 6 studies

- No difference in SSI (3.6 vs 5.2%; p=0.44)
- Lower SSO for rTAR (5.3 vs 11.5%; p=0.02). No diff in SSOPI
- Lower systemic complications rTAR (6.3 vs 26.5%; p<0.001)
- Shorter LOS with rTAR

Bracale U, Hernia 2021

Methods

Prospective RCT

- Inclusion:
  - Hernia 7-15cm
  - At least one: DM, COPD, BMI >30, current smoker
- Exclusion:
  - Presence of stoma
  - Wound class 3 or 4

Methods

Primary endpoint:

- Composite outcome
  - SSO (excluding simple seroma)
  - SSOPI
  - SSI
  - Readmission
  - Recurrence

Methods

Power analysis:

- Based on retrospective review of open / robotic cases
- Composite outcome: Open - 52.2%, Robotic - 24.1%
- Calculated 46pts in each arm to detect difference
- Enrolled 100 total (50 each arm)

Intention to treat analysis: 5 patients converted to open included in robotic arm

Patients

Characteristic	Robotic	Open	p-value
Number of Patients	46	44	---
Age – Years			
Median (IQR)	59.5 (50, 67)	59.5 (47, 66)	0.686
Min, Max	28, 76	32, 75	
Gender: No. (%)			
Female	28 (60.9)	30 (68.2)	0.514
Male	18 (39.1)	14 (31.8)	
Body Mass Index (BMI)			
Median (IQR)	36.7 (30.6, 41.9)	36.7 (31.6, 40.2)	0.774
Min, Max	24.4, 57.6	21.6, 51.9	
Insurance Status: No. (%)			
Private/Commercial	14 (30.4)	18 (40.9)	0.393
Medicare	23 (50.0)	16 (36.4)	
Medicaid	6 (13.0)	4 (9.1)	
Other	3 (6.5)	6 (13.6)	
History of: No. (%)			
Hypertension	26 (56.5)	28 (63.6)	0.525
Diabetes	13 (28.3)	16 (36.4)	0.500
COPD	7 (15.2)	6 (13.6)	1.000
ASA Class: No. (%)			
2	13 (28.3)	12 (27.3)	1.000
3	32 (69.6)	32 (72.7)	
4	1 (2.2)	0 (0.0)	

Operative Details

Characteristic	Robotic	Open	p-value
Number of Patients	46	44	---
Hernia Type: No. (%)			
Incisional	44 (95.7)	41 (93.2)	0.421
Parastomal	2 (4.3)	1 (2.3)	
Primary Ventral	0	2 (4.5)	
Recurrent: No. (%)	16 (34.8)	23 (52.3)	0.136
Hernia Length			
Median (IQR)	15 (12, 20)	15 (10, 19)	0.363
Min, Max	7, 30	3, 28	
Hernia Width			
Median (IQR)	8 (6, 10)	10 (8, 12)	0.024*
Min, Max	5, 23	3, 20	
Mesh Length			
Median (IQR)	31 (27, 36)	30 (23, 38)	0.630
Min, Max	20, 42	11, 45	
Mesh Width			
Median (IQR)	20 (17, 25)	21 (16, 25)	0.952
Min, Max	12, 30	9, 42	

Characteristic	Robotic	Open	p-value
Number of Patients	46	44	---
Number of Prior Repairs: No. (%)			
None	30 (65.2)	21 (47.7)	0.066
1	10 (21.7)	20 (45.5)	
2	5 (10.9)	2 (4.5)	
3	1 (2.2)	1 (2.3)	
Prior mesh Present: No. (%)	7 (15.2)	16 (36.4)	0.030*
Myofascial Release: No. (%)			
None	0 (0.0)	3 (6.8)	0.205
Post Rectus Sheath Incision	32 (69.6)	31 (70.5)	
Transversus abdominis	14 (30.4)	10 (22.7)	
Operative Time (Minutes)			
60 – 119	3 (6.5)	6 (13.6)	0.003*
120 – 179	11 (23.9)	24 (54.5)	
180 – 239	25 (54.4)	9 (20.5)	
≥ 240	7 (15.2)	5 (11.9)	
Intra-op Complication: No. (%)	**6 (13.0)**	**4 (9.1)**	**0.740**
Robotic Converted to Open	5	n/a	

Results

Study Outcome	Robotic	Open	p-value
Number of Patients	46	44	---
Any postop 30-day comp: No. (%)	**22 (47.8)**	**13 (29.6)**	**0.087**
Any SSO or SSI	19 (41.3)	12 (27.3)	0.188
Any SSO	19 (41.3)	11 (25.0)	0.121
Any SSO requiring PI	3 (6.5)	1 (2.3)	0.617
Any SSI (both required PI)	0	2 (4.6)	0.236
Readmission	3 (6.5)	1 (2.3)	0.617
Reoperation	0	1 (2.3)	0.489
Reoccurrence	0	0	---
Other:			
Pain requiring intervention	0	1	
Renal failure	1	0	
Urinary retention req. catheter	2	0	

Results

Study Outcome	Robotic	Open	p-value
Number of Patients	46	44	---
Primary Composite: No. (%)	**9 (19.6)**	**9 (20.5)**	**1.000**
SSO (exc. untreated seromas)	8 (17.4)	7 (15.9)	1.000
SSI	2 (4.4)	3 (6.8)	0.673
Readmission w/in 30 days	3 (6.5)	1 (2.3)	0.617
Recurrence of hernia	1 (2.2)	0 (0.0)	1.000
Secondary Endpoints:			
All surgical site occurrences	22 (47.8)	13 (29.6)	1.000
SSOs requiring PI	6 (13.0)	3 (6.8)	0.486
Hospital LOS (Days):			
Median (IQR)	1 (0, 2)	2 (1,3)	<0.001*
Min, Max	0, 5	0, 5	

No difference in primary outcome

Shorter LOS

SSIPI - wound opening, perc drain x2 (open); wound opening (robotic)

All SSOPI were perc drains

Results

5 patients required conversion to open

0 SSI
3 SSO (2 seroma, 1 cellulitis)
0 SSOPI

Results: PRO

HerQLes: Median (IQR)

Time	Robotic	Open	p-value
No. with 30-day	41	41	---
Baseline	34 (16, 52)	28 (16, 64)	0.628
30-day	38 (18, 68)	50 (34, 58)	0.325
Difference	0 (-22, 32)	16 (-20, 30)	0.339
P-value	0.641	0.119	---
No. with 6 mo.-1 yr.	39	33	---
Baseline	26 (12, 40)	46 (34, 80)	<0.001*
6 mo. – 1 year	86 (64, 94)	90 (72, 96)	0.590
Difference	60 (22, 78)	20 (10, 54)	0.008*
P-value	<0.001*	<0.001*	---
No. with 2-year	32	30	---
Baseline	36 (21, 69)	32 (16, 50)	0.359
2 year	80 (42, 92)	91 (76, 94)	0.165
Difference	28 (-5, 56)	59 (14, 64)	0.016*
P-value	0.002*	<0.001*	---

Everyone improved at all time points.

Degree of improvement varied:

- Greater improvement robotic at 6-12mos
- Greater improvement open at 2 years

*MCID for HerQLes: 15.6

Results: PRO

Pain score: Median (IQR)

Time	Robotic	Open	p-value
Baseline	2 (1, 2)	3 (2, 3)	0.027*
30-day	3 (2, 3)	2 (2, 3)	0.020*
Difference	1 (0, 2)	0 (-1, 1)	0.006*
P-value	0.005*	0.404	---
Baseline	2 (2, 3)	2 (1, 3)	0.020*
6 mo. -1 year	1 (1, 2)	1 (1, 2)	0.805
Difference	-1 (-2, 0)	-1 (-1, 0)	0.170
P-value	<0.001*	0.078	---
Baseline	2 (2, 3)	2 (2, 3)	0.123
2 year	1 (1, 2)	1 (1, 1)	0.286
Difference	-1 (-1.5, 0)	-1 (-2, 0)	0.128
P-value	0.027*	<0.001*	---

Everyone improved at all time points.

Robotic repair reported more pain at 30 days, but similar across other time points.

Patient Reported Follow-up (months)			
Median (IQR)	**10.0 (3, 24)**	**10.5 (1, 20)**	**0.137**
Surgeon Follow-up (months)			
Median (IQR)	**12.2 (6, 25)**	**12.4 (6, 24)**	**0.851**

Results: PRO

Patient Reported Follow-up (months)			
Median (IQR)	**10.0 (3, 24)**	**10.5 (1, 20)**	**0.137**
Surgeon Follow-up (months)			
Median (IQR)	**12.2 (6, 25)**	**12.4 (6, 24)**	**0.851**
Reoccurrence of hernia w/in 2 yrs			
	11/32 =34.4%	4/30=13.3%	0.076

Results: Cost

Cost: Median (IQR)			
Total cost	11747 (9717, 13530)	9267 (8873, 11641)	0.092
Direct cost	6084 (4799, 6878)	4826 (4450, 5966)	0.137

Limitations

Small sample size

Recruitment and randomization

Follow-up

Technique (eTEP vs double-dock), no TAP blocks, no drains

Summary

First RCT comparing open v robotic VHR.

Robotic repair appears to shorten LOS compared to open, as seen with other studies.

No difference in composite outcome.

No differences in secondary outcomes or PRO.