REtromuscular Keyhole vs SUgaRbaker Mesh for Open Parastomal Hernia Repair:

Long Term Outcomes of the REKUR Clinical Trial

Clayton Petro, MD
Assistant Professor of Surgery
Cleveland Clinic Lerner College of Medicine

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Long Term Outcomes of the SUKKER Clinical Trial

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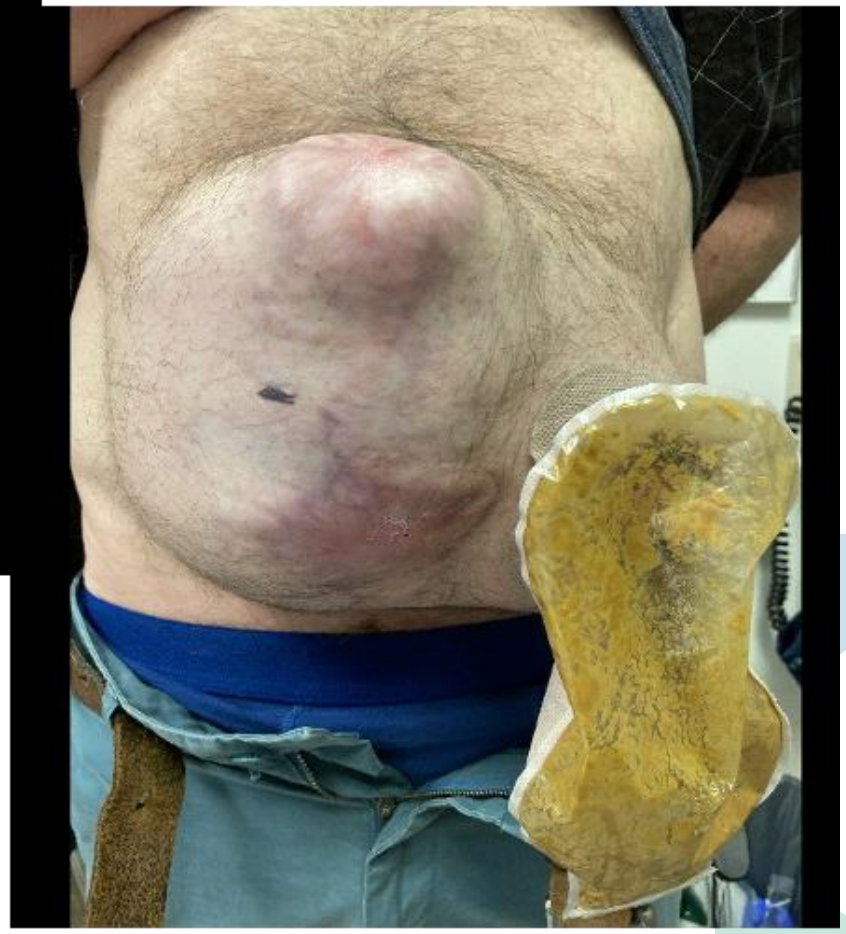
Disclosures

- Study Funding:
  - AHS Research Grant
  - Central Surgical Enrichment Grant

- Clayton Petro –
  - BD Consultant
  - Surgimatix Consultant
  - Advanced Medical Solutions Consultant

Background



Two Retromuscular Techniques

- Keyhole

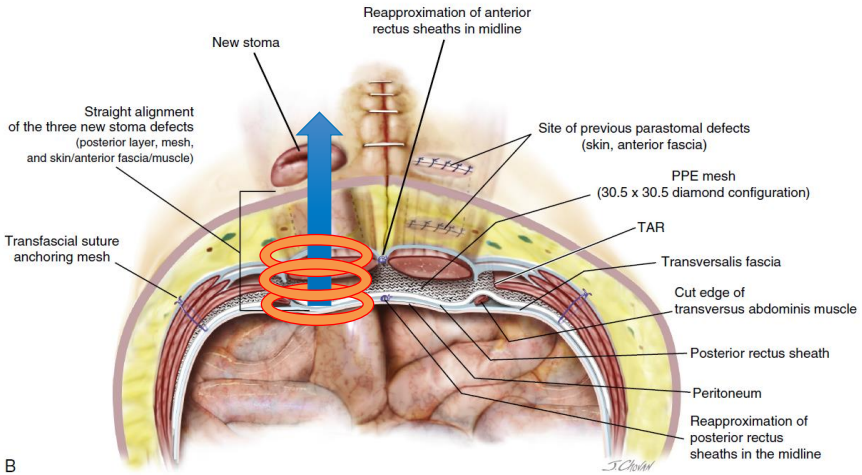


Fig. 7.10

- Sugarbaker

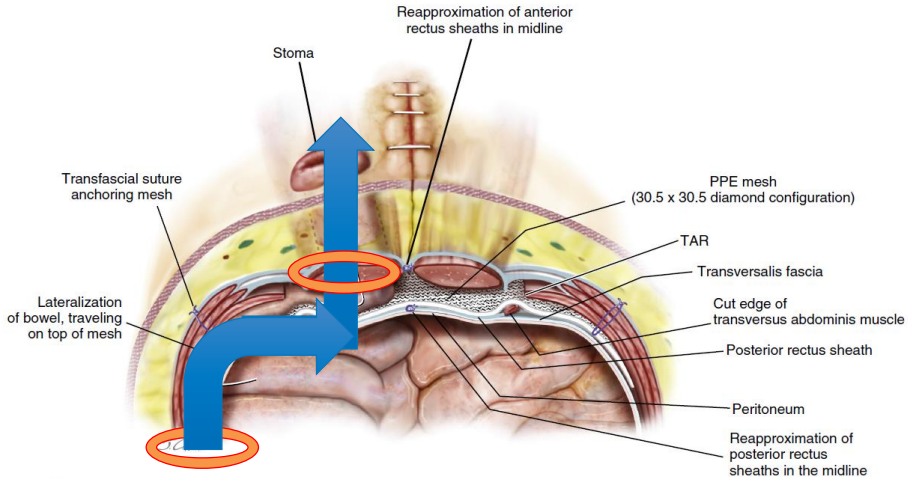


Fig. 7.18

- *Unknown Relative Rates of Parastomal Hernia Recurrence and Mesh Complications*

Biologic vs Synthetic Mesh for Parastomal Hernia Repair: Post Hoc Analysis of a Multicenter Randomized Controlled Trial

Benjamin T Miller, MD, David M Krpata, MD, FACS, Clayton C Petro, MD, FACS, Lucas R A Beffa, MD, FACS, Alfredo M Carbonell, DO, FACS, Jeremy A Warren, MD, FACS, Benjamin K Poulose, MD, MPH, FACS, Chao Tu, MS, Ajita S Prabhu, MD, FACS, Michael J Rosen, MD, FACS

2-year Parastomal Recurrence Rate

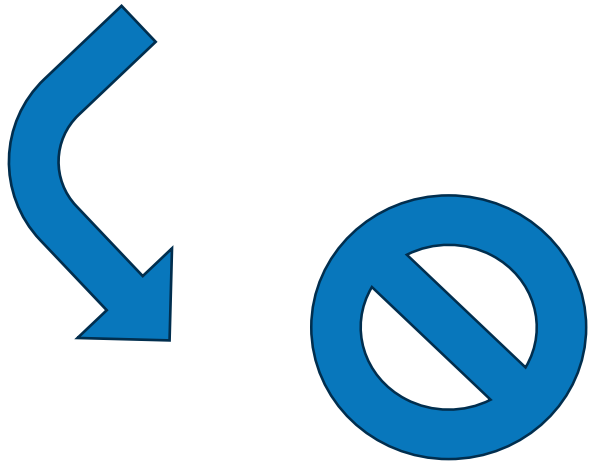
- RM Keyhole – 30.4%
- RM Sugarbaker– 10.7%
  - p = 0.07

Single center experience with the modified retromuscular Sugarbaker technique for parastomal hernia repair

L. Tastaldi[1] · I. N. Haskins[1] · A. J. Perez[1] · A. S. Prabhu[1] · S. Rosenblatt[1] · M. J. Rosen[1]

Mesh Erosion

- RM Sugarbaker – 8%



MESH FIXATION

Hypothesis

- Open retromuscular Sugarbaker repairs will have fewer parastomal hernia recurrences at 2 years compared to open retromuscular keyhole repairs

Secondary Outcomes

- Mesh Related Complications
- Wound Morbidity
- Reoperations
- Pain
- Abdominal Wall-Specific QOL
- Stoma-Specific QOL
- Decision Regret
  - 30-days, 1-year, 2-year

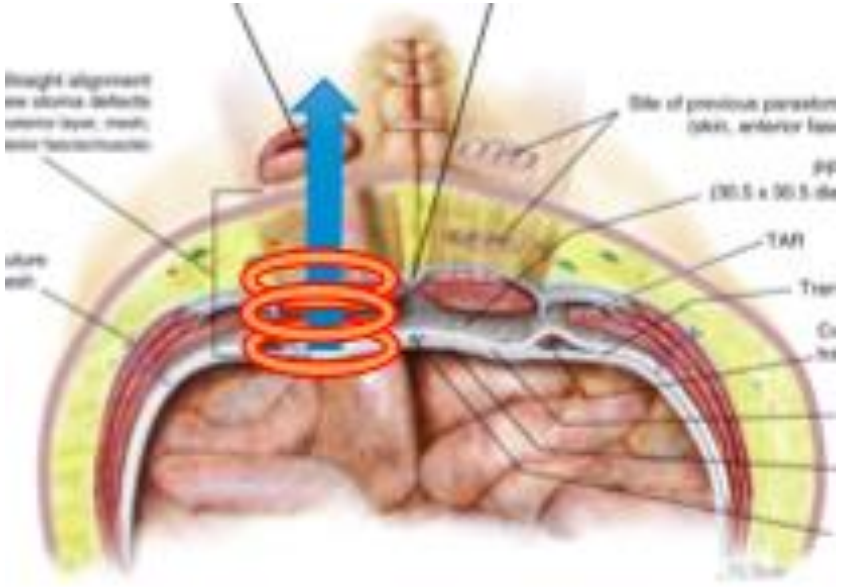
METHODS

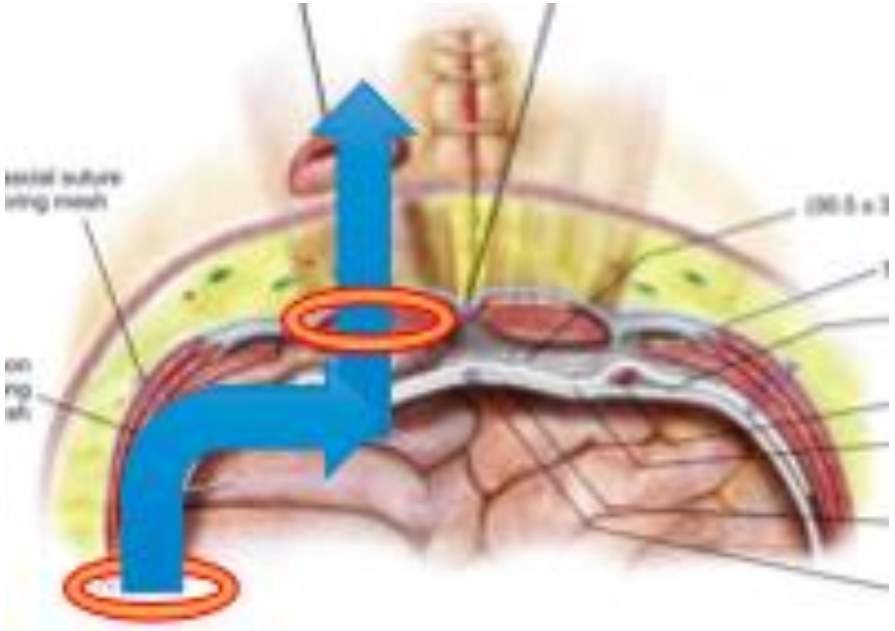
Inclusion/Exclusion Criteria

- Inclusion
  - ≥18yo Consenting
  - Open retromuscular hernia repair with concomitant stoma reinforcement
    - Existing stoma +/- parastomal hernia
    - New stoma

- Exclusion
  - Insufficient bowel length assessed intraoperatively
  - Emergent cases
  - >1 stoma
  - *Continent Urostomy*

Technique and Randomization





- **Keyhole**
  - Cruciate > lateral slit mesh incision
  - Minimal or no mesh fixation
- **Sugarbaker**
  - Lateralize as much as possible
  - Minimal or no peristomal mesh fixation

Outcome Timeline

	Baseline	POD#30/90	1-year	2-year
Promis 3a SF	x	x	x	x
Colostomy Impact Score	x	x	x	x
HerQLes	x	x	x	x
Decision Regret Scale		x	x	x
Hernia Recurrence Inventory		x	x	x
CT A/P			x	x
Wound morbidity (SSO, SSI, SSOPI)		x	x	x

- Primary Outcome –
  - 20% difference Parastomal Hernia Recurrence @ 2 years
  - α=0.05 β=80%
  - w/ 20% loss to follow-up n=142 -> n=150

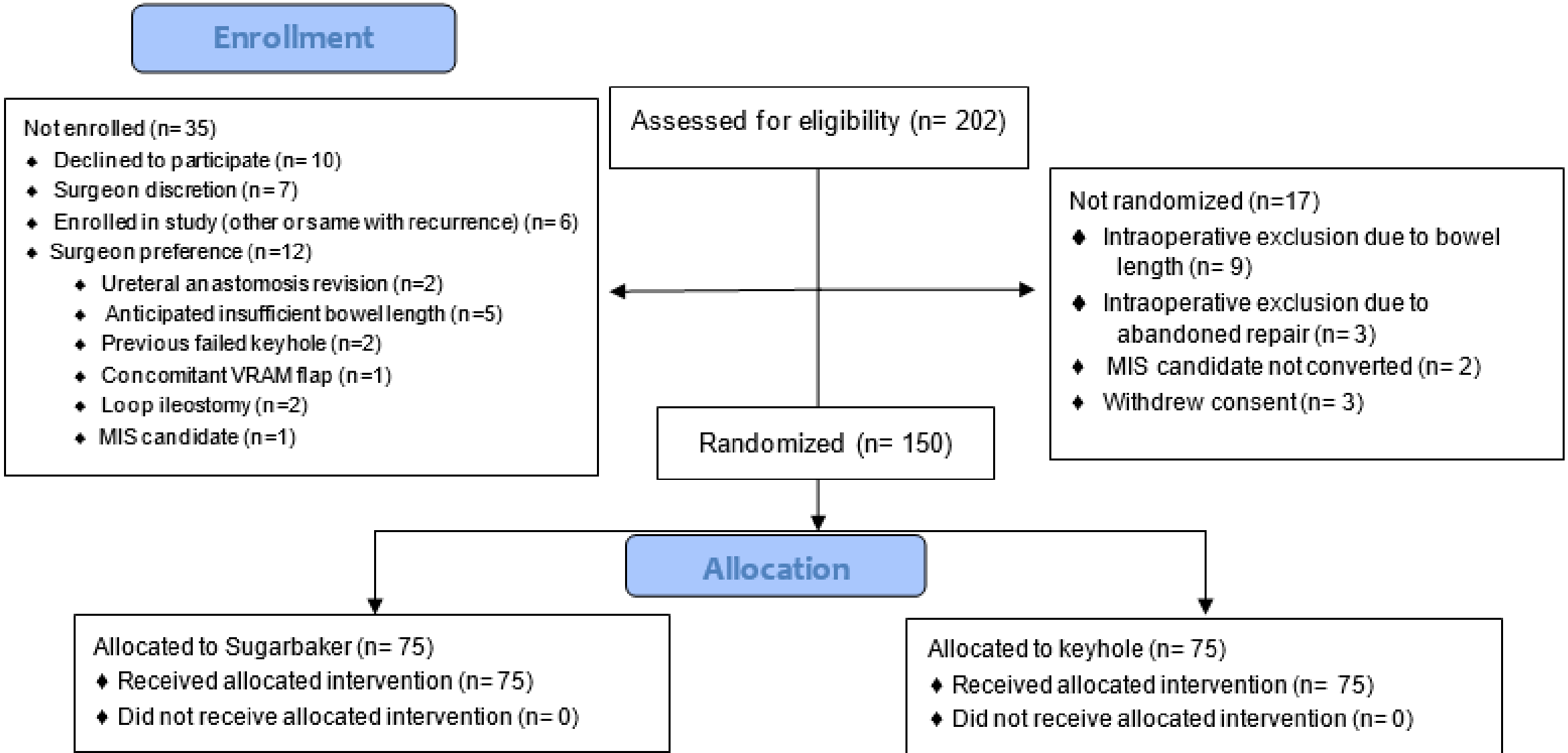
Outcome Measurements

Outcome	Measurement	Scale	Better
Recurrence	CT A/P – 2/3 Reviewer Consensus	Y/N	N
Pain	PROMIS 3a Pain Intensity	30.7-71.8	
Stoma-Specific QoL	Colostomy Impact Score	0-38	
Abdominal Core Health QoL	HerQLes	0-100	
Regret about pursuing surgery	Decision Regret Scale	0-100	

RESULTS

CONSORT
TRANSPARENT REPORTING of TRIALS

CONSORT 2010 Flow Diagram



Patient Demographics & Comorbidities

	Keyhole	Sugarbaker
N	75	75
Age (median)	64.0 [54.0, 73.5]	67.0 [54.0, 74.0]
Male %	50.7%	50.7%
BMI (median)	30.1 [27.3, 36.0]	31.1 [27.9, 35.0]
HTN %	64%	65%
DM %	25%	19%
COPD %	9.3%	13%
Active Smoker %	8%	7%
ASA %		
II	5%	4%
III	91%	91%
IV	2%	5%
Active Steroid Use %	15%	8%
Recurrent parastomal	41%	49%
Previous Mesh	34%	31%

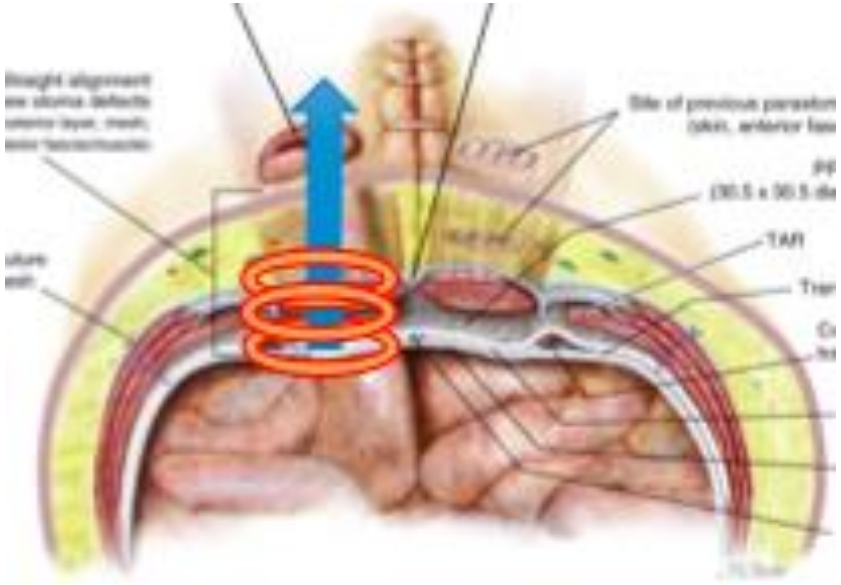
Operative Details

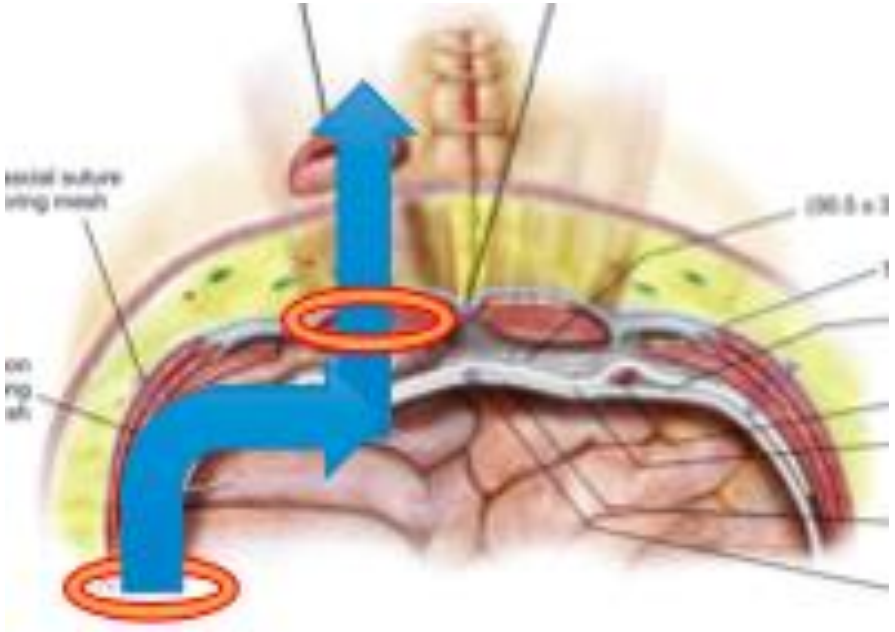
	Keyhole	Sugarbaker	p
#Non-elective (acute admission, non-emergent)	1	2	0.61
Hernia Width (median, cm)	16	15	0.29
Hernia Length (median, cm)	23	23	0.49
Mesh Area (median, cm^2)	1517	1391	0.22
Mesh Fixation %	17%	31%	0.09
Subcutaneous Drain %	17%	24%	0.33
Concomitant Procedure	32%	32%	0.82
Intraoperative Complications	8%	8%	1
OR Time			0.55
1-2 hr	0	2.7%	
2-3 hr	15%	20%	
3-4 hr	27%	28%	
>4 hr	59%	49%	

Operative Details

	Keyhole	Sugarbaker	p
Ostomy Disposition			<0.001
Left in situ	15%	51%	
Re-matured, same location	23%	17%	
Moved to new site	63%	32%	
CDC			<0.001
II	9%	41%	
III	91%	59%	
EHS Classification for Parastomal Hernias			NS
I	9%	8%	
II	31%	31%	
III	7%	9%	
IV	48%	51%	
Stoma type			NS
Ileostomy	52%	51%	
Colostomy	29%	35%	
Urostomy	19%	15%	

Intraoperative Decision Making





- **Keyhole**
  - Prefer Cruciate ->
  - More likely to mobilize and move to new site
- **Sugarbaker**
  - Prefer NOT to mobilize

Operative Details

	Keyhole	Sugarbaker	p
Ostomy Disposition			<0.001
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Open retromuscular keyhole compared with Sugarbaker mesh for parastomal hernia repair: Early results of a randomized clinical trial

Sara M. Maskal, MD[a], Jonah D. Thomas, MD[b], Benjamin T. Miller, MD[a], Aldo Fafaj, MD[a], Samuel J. Zolin, MD[a], Katie Montelione, MD[a], Ryan C. Ellis, MD[a], Ajita S. Prabhu, MD[a], David M. Krpata, MD[a], Lucas R.A. Beffa, MD[a], Adele Costanzo, RN[a], Xinyan Zheng, MS[c], Steven Rosenblatt, MD[a], Michael J. Rosen, MD[a], Clayton C. Petro, MD[a],*

	Keyhole	Sugarbaker	p
Length of Stay (median, d)	8	7	0.41
Ileus (NG Tube)	27%	29%	0.98
Transfusion	10%	8%	0.86
VTE	3%	3%	1
MI	0	1%	0.49
Prolonged Ventilation	3%	1%	1
UTI	4%	1%	0.62
PNA	4%	0%	0.25
Readmission	10%	15%	0.54

Short-Term Clinical Outcomes

	Keyhole	Sugarbaker	p
SSO	9%	11%	0.91
SSI	10%	15%	0.30
Superficial	7%	10%	0.69
Deep	4%	6%	0.51
SSOPI	13%	14%	1
Reoperation	5%	8%	0.53
Wound complication	5%	4%	1
Mesh Excision	1%	3%	1
Stoma Complications	0	(4) 6%	0.12

Sugarbaker Stoma Complications

- Stoma necrosis requiring revision
- Stoma obstruction requiring revision
- Early postoperative recurrence requiring reoperation
- Mucocutaneous separation requiring revision

30-Day Patient-Reported Outcomes

	Keyhole	Sugarbaker	p
PROMIS 3a			
Baseline (median)	52	49	0.65
30-day (median)	52	52	0.59
Colostomy Impact Score			
Baseline (median)	19	18	0.39
30-day (median)	11	12	0.63
HerQLes			
Baseline (median)	30	33	0.52
30-day (median)	48	45	0.64
Decision Regret 30-day	9	13	0.18

2-YEAR RESULTS

Follow-up

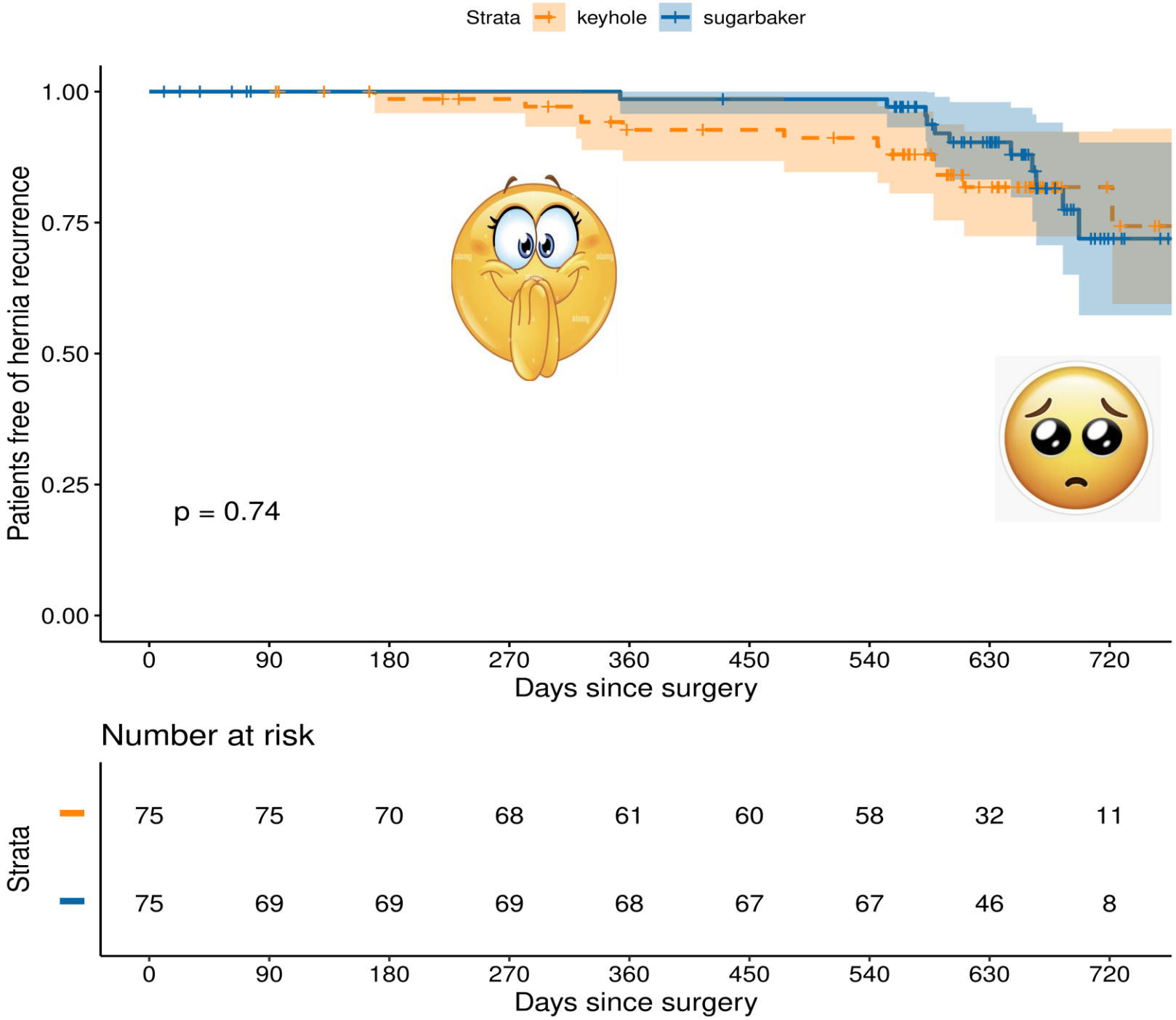
	Keyhole (75)	Sugarbaker (75)
Lost	1	2
Died	4	4
Reoperation for Recurrence (2.6%)	3	1
Reoperation with Stoma Revised	0	4
Recurred Before 2-y (12%)	13	5
Clinical Follow-up at 2-y (68%)	47	55
PRO Only at 2-y (7.3%)	3	8

Recurrence

Recurrence

	Keyhole	Sugarbaker	p
1-Year	21%	8%	0.04
2-Year	24%	17%	0.42
Adjusted RR 0.87 (0.42-1.69)			

Recurrence


Strata
keyhole
sugarbaker
1.00
0.75
0.50
0.25
0.00
Patients free of hernia recurrence
p = 0.74
0
90
180
270
360
450
540
630
720
Days since surgery
Number at risk
Strata
75 75 70 68 61 60 58 32 11
75 69 69 69 68 67 67 46 8
0
90
180
270
360
450
540
630
720
Days since surgery

Cox Proportional Hazard Regression Analysis
Parastomal Hernia Recurrence

	HR	95% CI	p
Randomization (Sugarbaker)	0.98	0.44-2.2	>0.9
BMI	0.94	0.88-1.01	0.1
Hx Recurrent Hernia	0.67	0.31-1.45	0.3
Ostomy Relocated	1.98	0.76-5.17	0.2
Re-matured Same Location	0.96	0.29-3.21	>0.9
Ileostomy	0.95	0.42-2.17	>0.9
Urinary Conduit	0.77	0.29-2.94	0.7

Reoperations

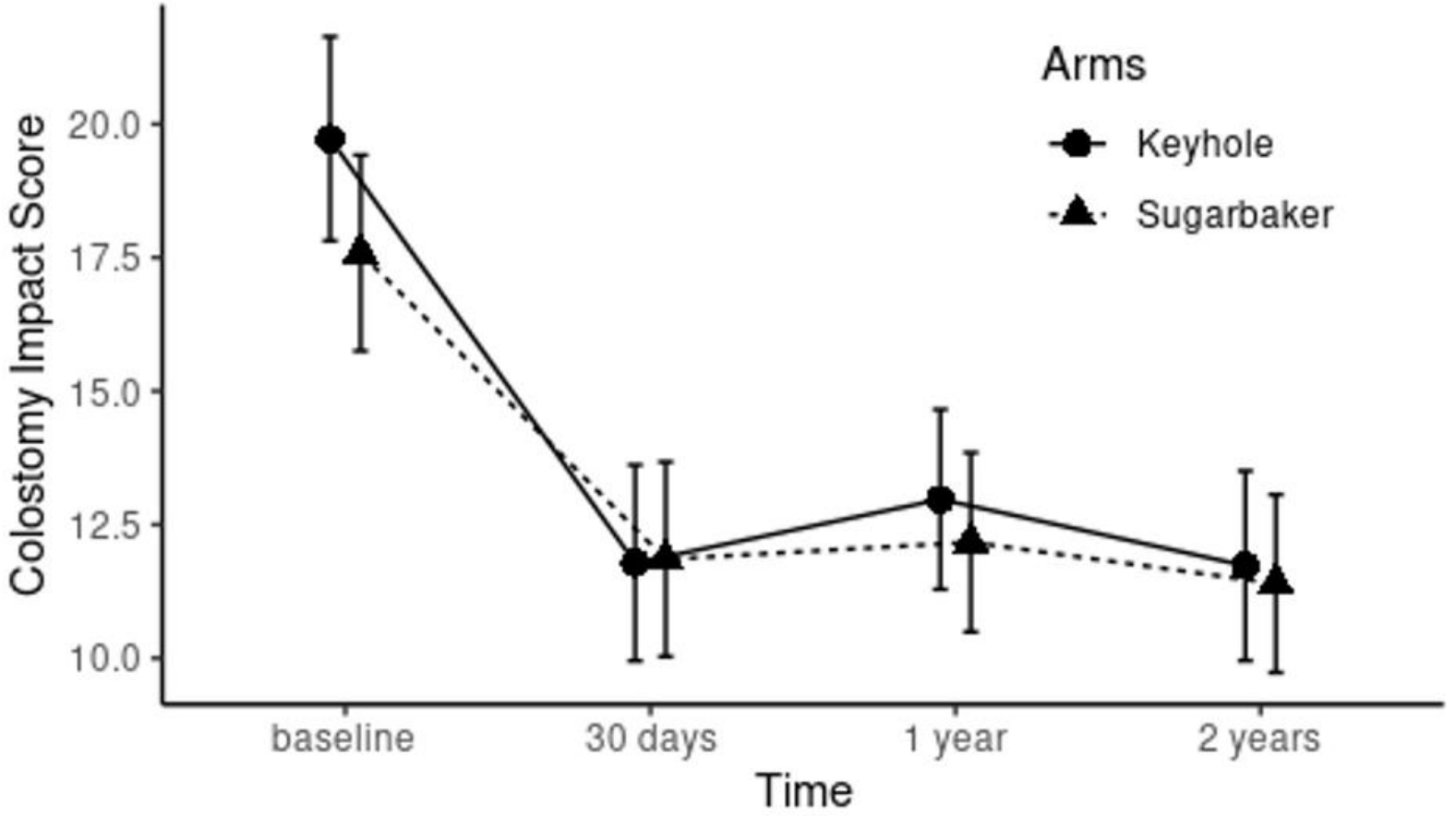
	Keyhole	Sugarbaker	p
For Recurrence	7	2	0.07
Mesh Complication	1	4	
Stoma Necrosis	0	1	
Other	10	4	
TOTAL	18	11	

Wound Morbidity

	Keyhole	Sugarbaker	p
1-Year			
SSO	3	3	>0.9
SSI	2	1	>0.9
SSOPI	3	2	>0.9
2-Year			
SSO/SSI/SSOPI	0	0	>0.9

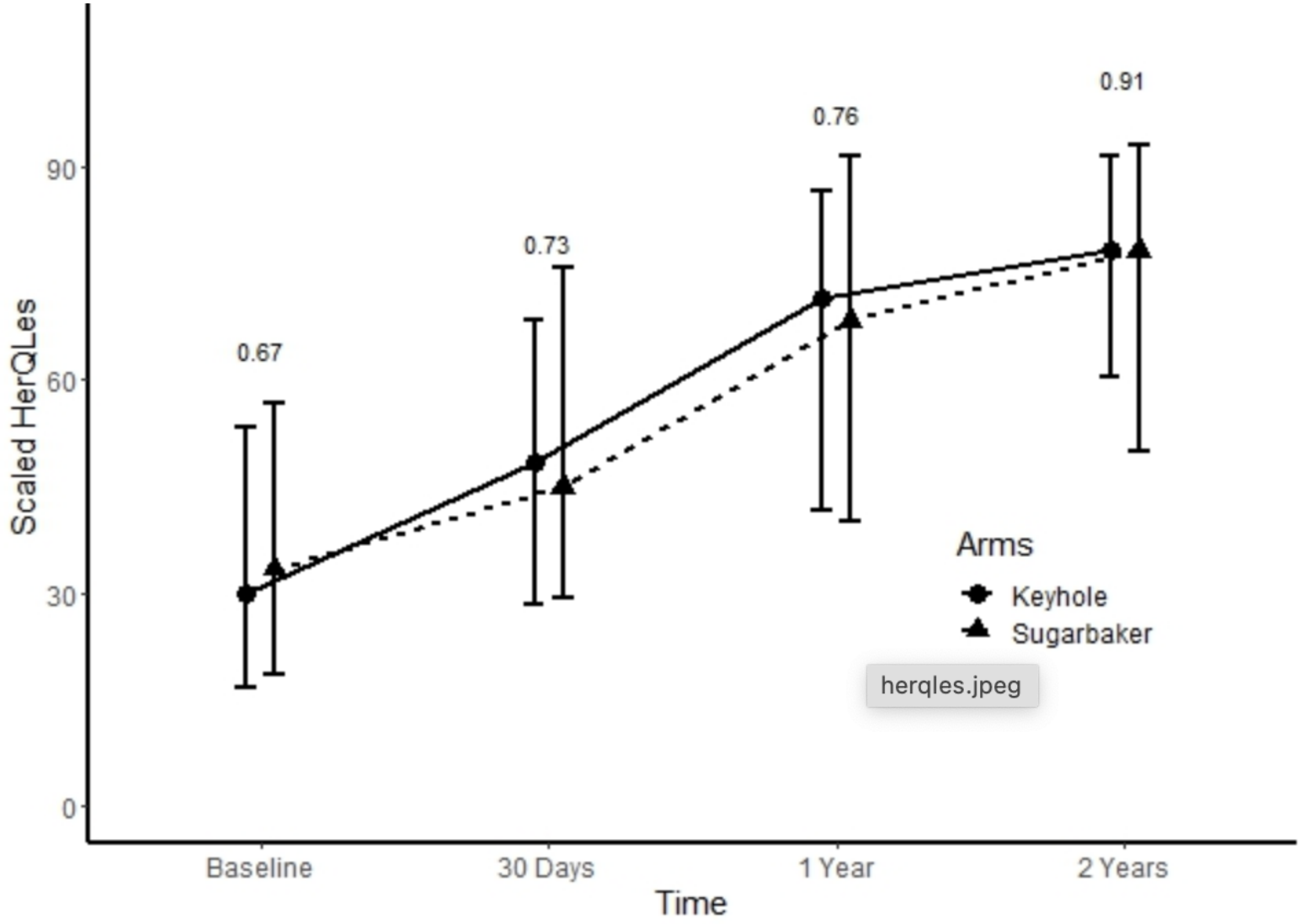
Patient Reported Outcomes

Colostomy Impact Score

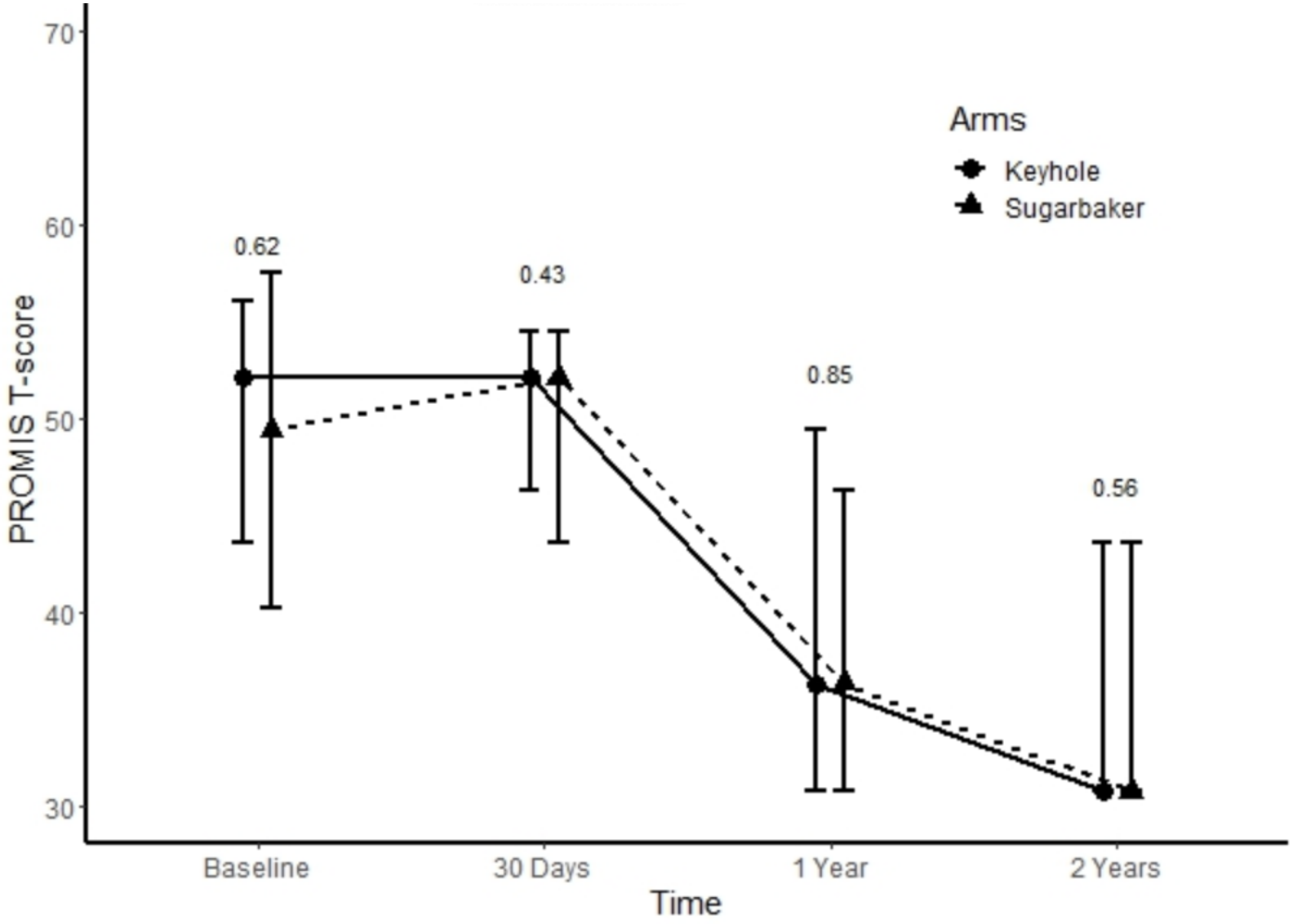


Keyhole	46	51	63	55
Sugarbaker	51	52	64	65

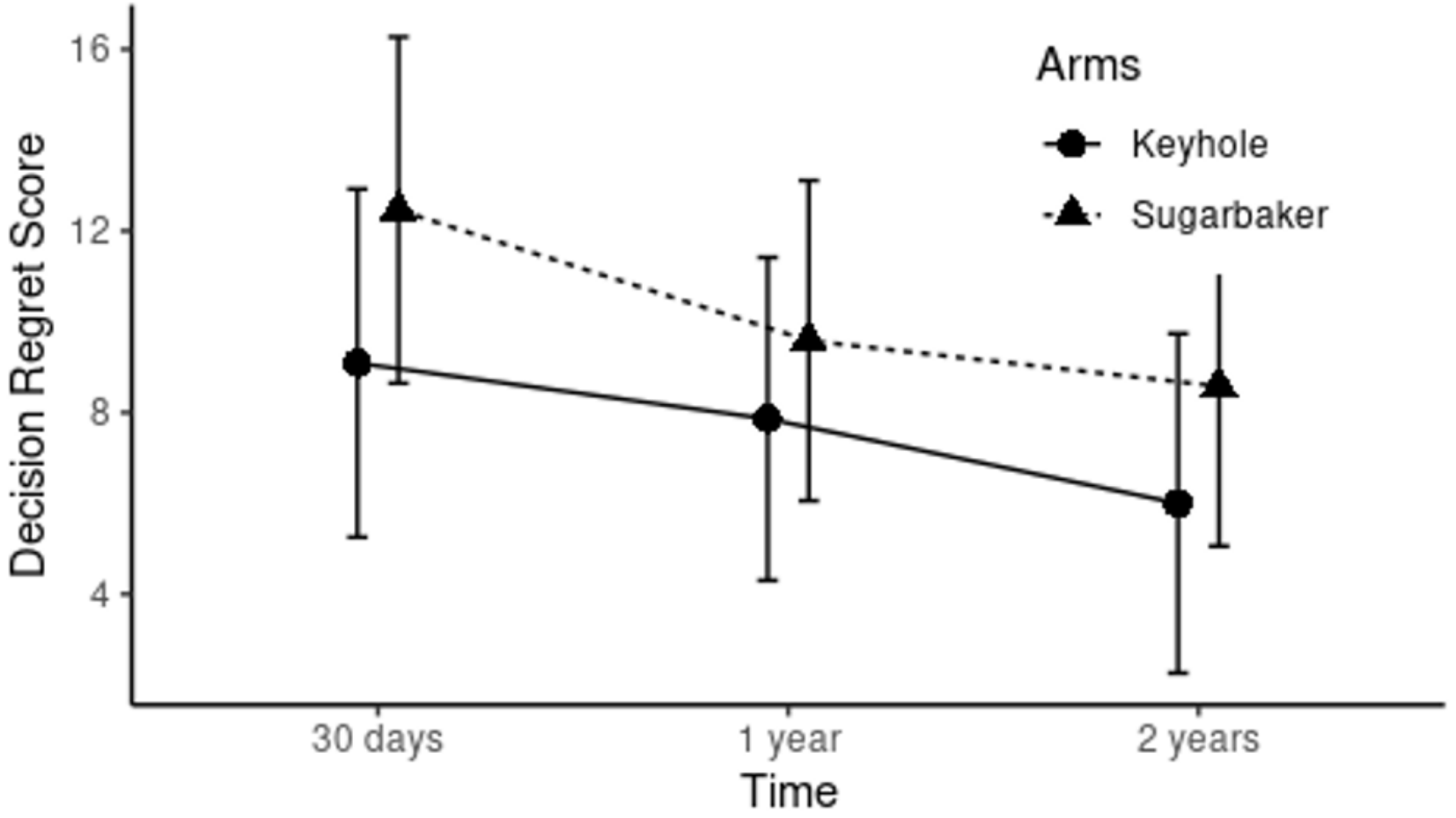
HerQLes


Scaled HerQLes
90
60
30
0
0.67
0.73
0.76
0.91
Baseline
30 Days
1 Year
2 Years
Time
Arms
Keyhole
Sugarbaker
herqles.jpeg

PROMIS 3a


70
60
50
40
30
PROMIS T-score
Arms
Keyhole
Sugarbaker
0.62
0.43
0.85
0.56
Baseline
30 Days
1 Year
2 Years
Time

Decision Regret



Keyhole	51	63	55
Sugarbaker	52	65	65

Summary – At 2 Years

- Open Retromuscular Sugarbaker Mesh Placement delays but does NOT reduce 2-year parastomal hernia recurrence compared to Keyhole Mesh
- No difference in PROs
- No difference in Wound Morbidity

Exploratory Questions

	Keyhole	Sugarbaker	p
Early Stoma Complications	0	6%	0.12
1-Year	21%	8%	0.04
2-Year	24%	17%	0.42
2-Year Reoperation	**18**	**11**	0.07
For recurrence	7	2	
Mesh complication	1	4	
Stoma necrosis	0	1	
Other re-op	10	4	

Ostomy Relocated	HR 1.98	95% CI 0.76-5.17	0.2

Conclusions

- In open retromuscular parastomal hernia repair, the keyhole mesh technique is still reasonable.
- The retromuscular Sugarbaker technique is:
  - technically challenging for the surgeon
  - often limited by patient anatomy
  - Delays recurrence at the cost of potentially more up-front stoma complications

- **No need to force a retromuscular Sugarbaker**