Long term mesh-related outcomes: Biologic vs Synthetic Mesh for Single-stage Repair of Contaminated Ventral Hernias

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Principal Investigator:

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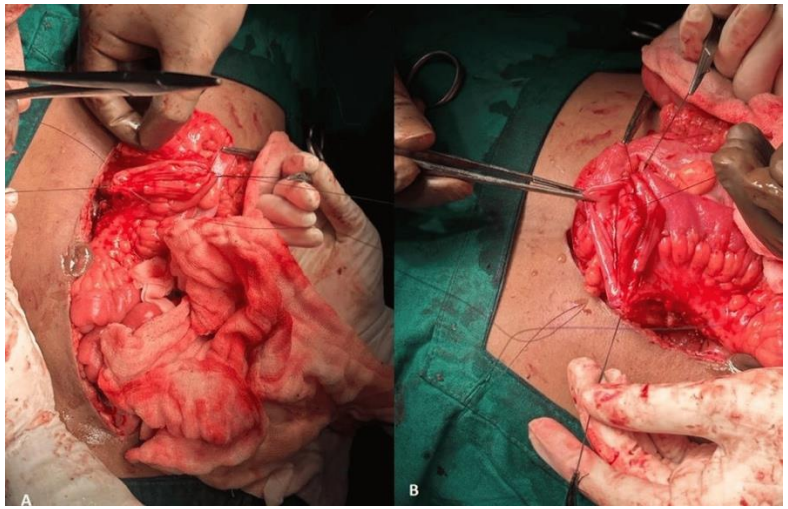
Disclosures

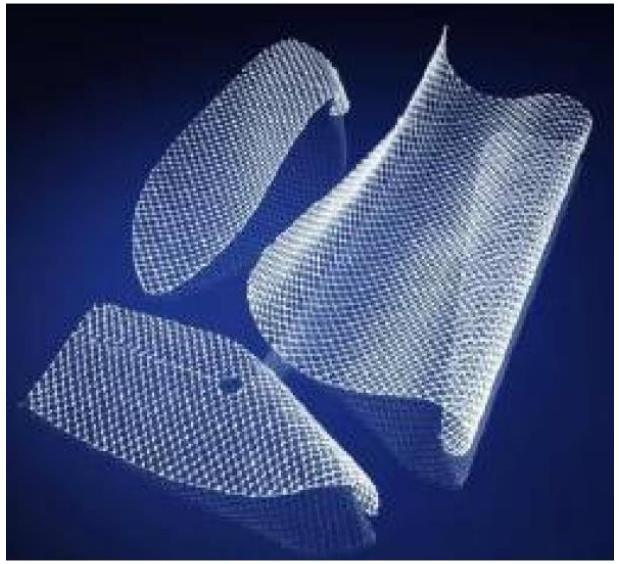
- Daphne Remulla, MD
  - None

Background



Contaminated

+



Synthetic

=

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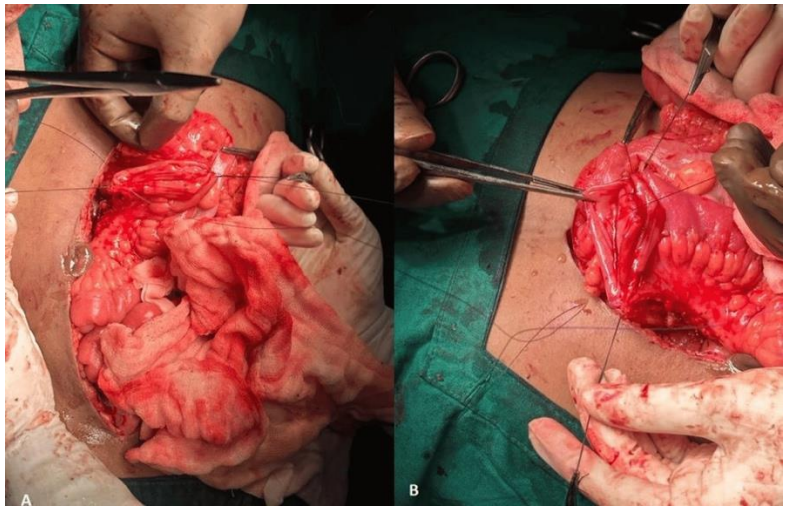
Background



Contaminated

Biologic Mesh

What is safe? What is effective?

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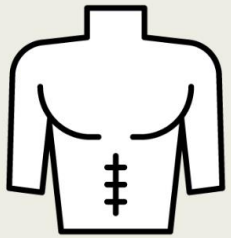
Biologic vs Synthetic Mesh for Single-stage Repair of Contaminated Ventral Hernias
A Randomized Clinical Trial

Michael J. Rosen, MD; David M. Krpata, MD; Clayton C. Petro, MD; Alfredo Carbonell, DO; Jeremy Warren, MD; Benjamin K. Poulose, MD, MPH; Adele Costanzo, RN; Chao Tu, MS; Jeffrey Blatnik, MD; Ajita S. Prabhu, MD

RCT: Biologic vs Synthetic Mesh for the Single-stage Repair of Contaminated Ventral Hernias

POPULATION

117 Men, 136 Women

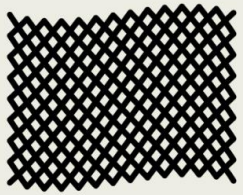


Adults with clean-contaminated and contaminated ventral hernias undergoing single-stage retromuscular hernia repair

Median (IQR), 64 (55-70) y

INTERVENTION

253 Patients randomized

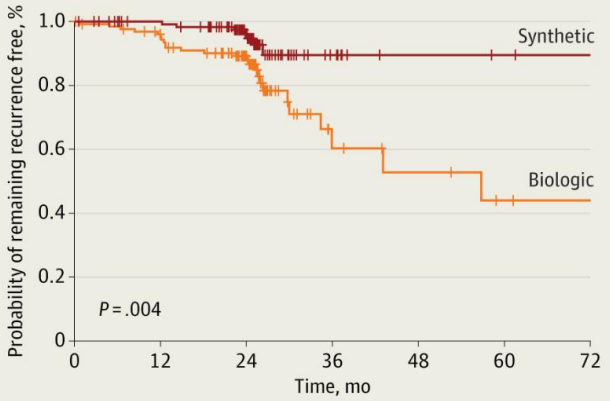


126 Synthetic mesh
Synthetic mesh placed in the retromuscular position

127 Biologic mesh
Biologic mesh placed in the retromuscular position

FINDINGS

Compared with biologic mesh, synthetic mesh significantly reduced the risk of hernia recurrence



Risk of hernia recurrence at 2 y:
5.6% vs 20.5% (HR, 0.31; 95% CI, 0.23-0.42, *P* < .001)

SETTINGS / LOCATIONS

5 Academic medical centers in the US

PRIMARY OUTCOME

Hernia recurrence at 2 y as evaluated by physical examination, radiographic assessment, and patient-reported outcomes

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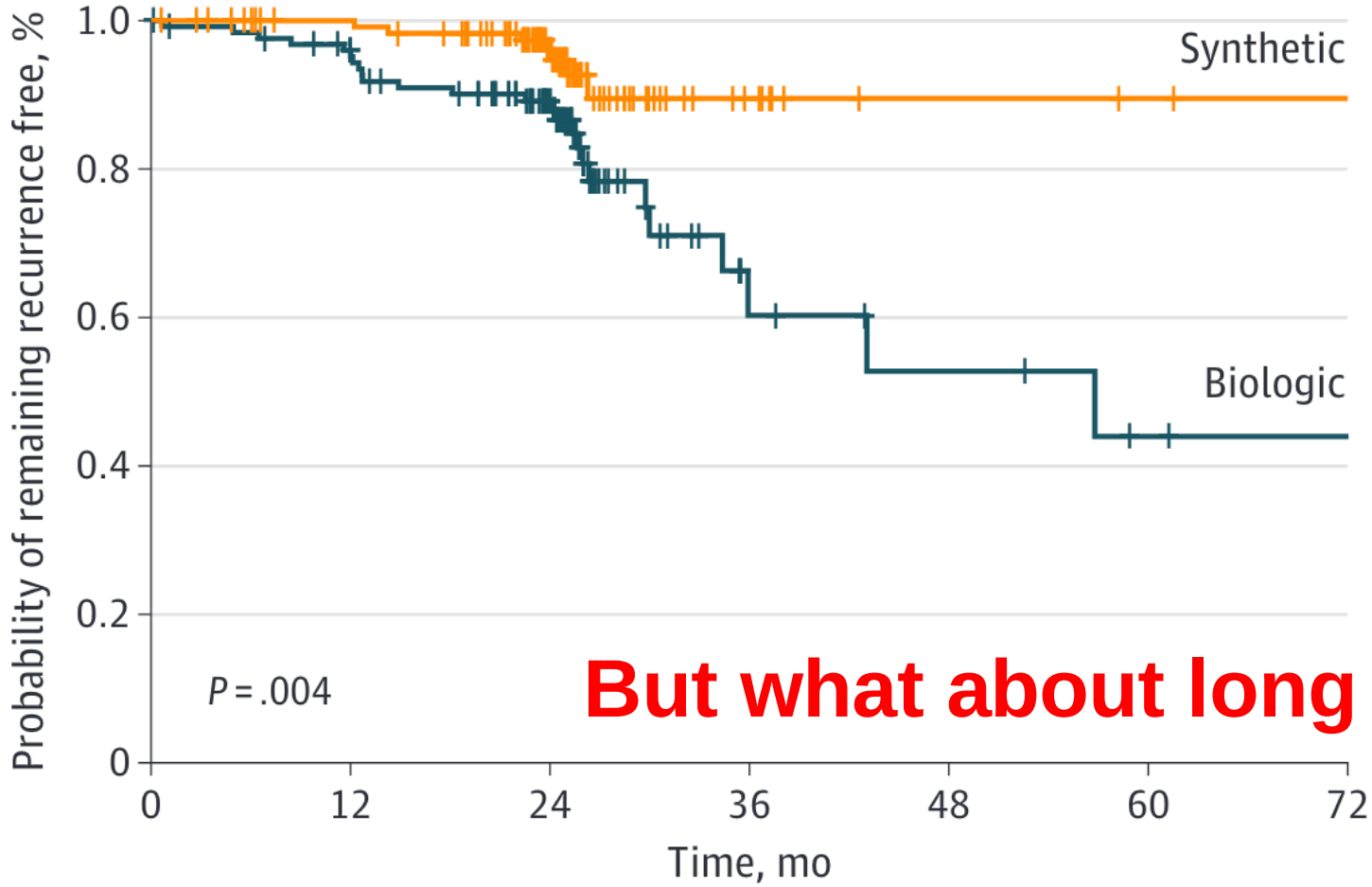
Figure 2. Kaplan-Meier Plot of Time to Hernia Recurrence



But what about long term??

No. at risk							
Biologic	127	114	74	10	7	4	3
Synthetic	126	117	69	9	3	2	1

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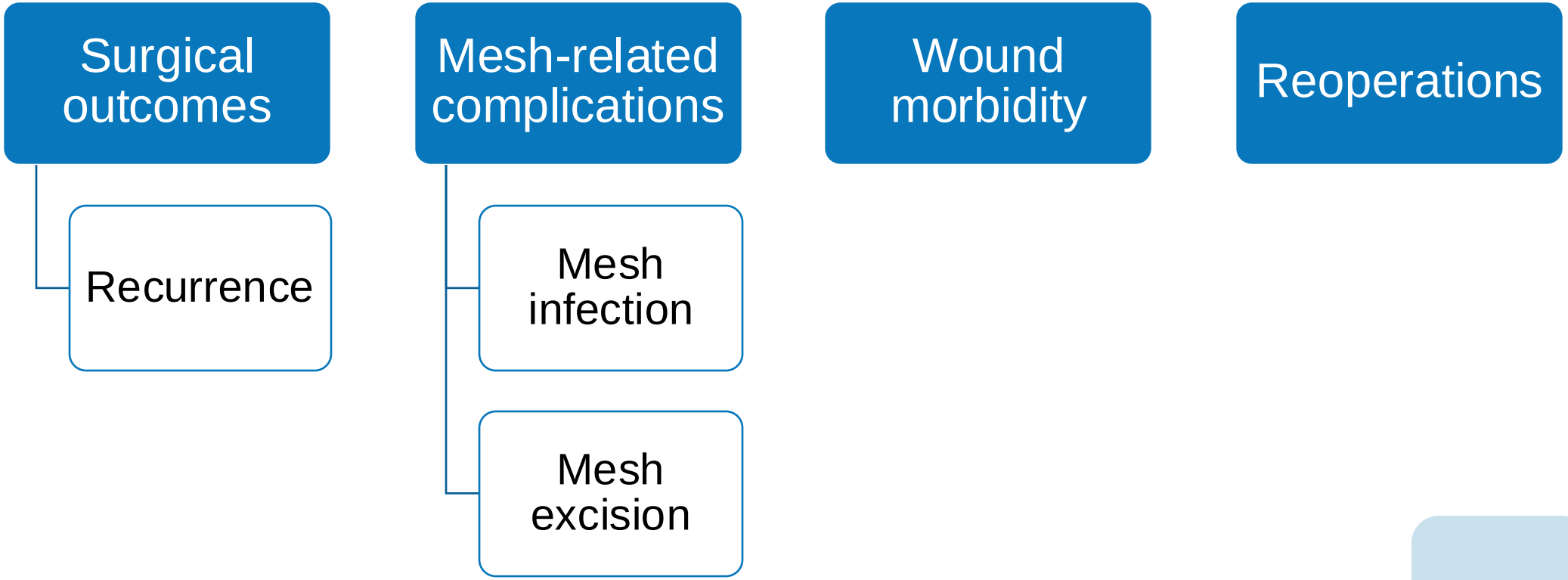
Aims



Minimum 5 year follow up

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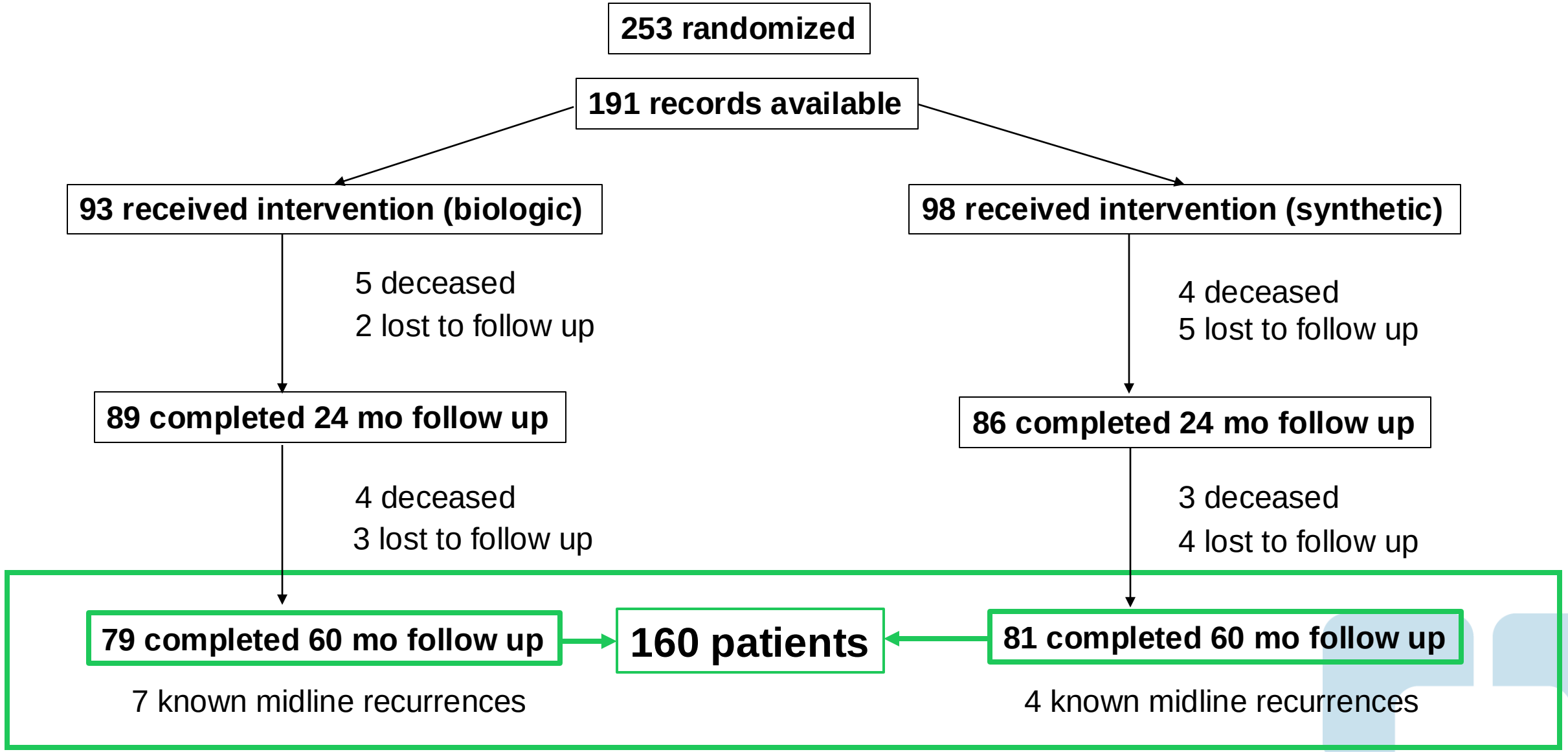
253 randomized
191 records available
93 received intervention (biologic)
98 received intervention (synthetic)
5 deceased
2 lost to follow up
4 deceased
5 lost to follow up
89 completed 24 mo follow up
86 completed 24 mo follow up
4 deceased
3 lost to follow up
3 deceased
4 lost to follow up
79 completed 60 mo follow up
160 patients
81 completed 60 mo follow up
7 known midline recurrences
4 known midline recurrences

Methods

Patients identified from original study

- Completed follow up at CCF

Clinic follow up + Chart review

- Imaging since end of original study
- Physical exam

Blinded imaging review and 3-surgeon consensus determination

- Presence of recurrence
- Date of recurrence

Patients contacted and validated surveys distributed

- Ventral Hernia Recurrence Inventory

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Demographics

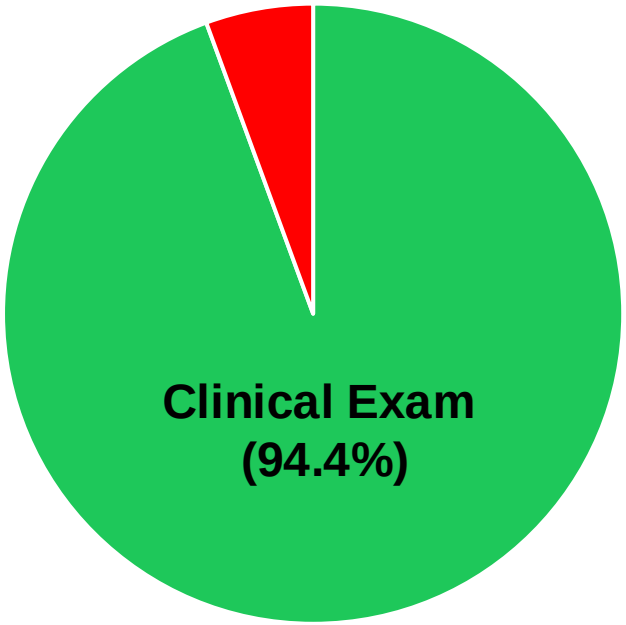
	Total (n=160)	Biologic (n=79)	Synthetic (n=81)	P value
Age, median [25th;75th]	63.2 [55.0;69.2]	63.0 [55.8;69.8]	63.3 [54.8;68.8]	0.643
Female sex (%)	86 (53.8%)	44 (55.7%)	42 (51.9%)	0.742
Obesity (%)	98 (61.3%)	51 (64.6%)	47 (58.0%)	0.493
Body Mass Index, Median [25th;75th]	33.1 [28.6;36.4]	33.5 [29.4;37.0]	32.3 [27.7;35.7]	0.182
Hypertension	99 (61.9%)	54 (68.4%)	45 (55.6%)	0.133
Smoker, N (%):	8 (5.00%)	2 (2.53%)	6 (7.41%)	0.277
Diabetes, N (%):	44 (27.5%)	27 (34.2%)	17 (21.0%)	0.091
Recurrent Ventral Incisional Hernia, N (%):	85 (53.1%)	45 (57.0%)	40 (49.4%)	0.423
Recurrent Parastomal Hernia, N (%):	39 (24.4%)	20 (25.3%)	19 (23.5%)	0.928
Stoma Present, N (%):	101 (63.1%)	53 (67.1%)	48 (59.3%)	0.388

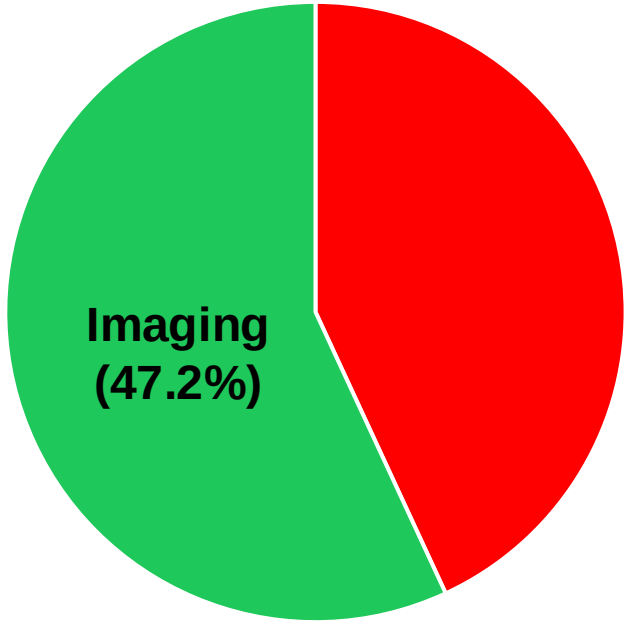
Operative Details

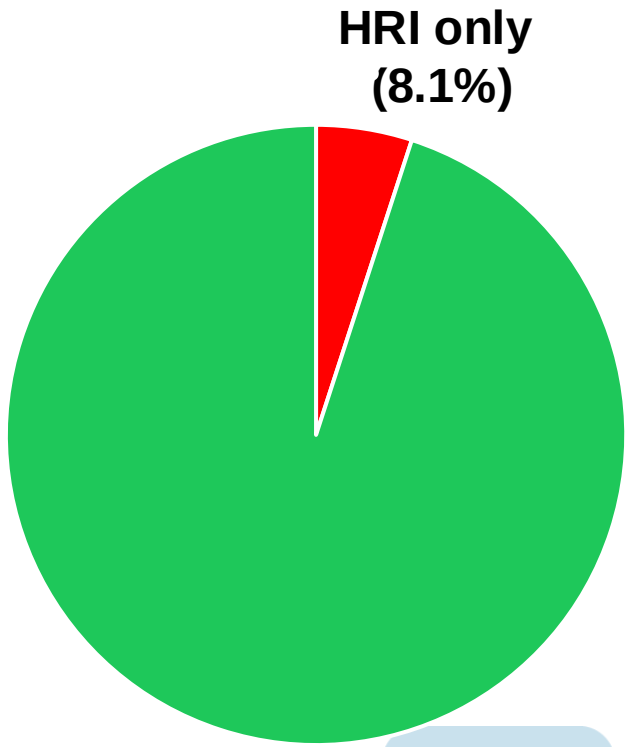
	Total (n=160)	Biologic (n=79)	Synthetic (n=81)	P value
OR Time, Median [25th;75th]	232 [178;311]	235 [176;307]	230 [179;315]	0.788
Hernia Type, N (%):				0.409
Incisional	71 (44.4%)	32 (40.5%)	39 (48.1%)	
Both	85 (53.1%)	44 (55.7%)	41 (50.6%)	
Parastomal	4 (2.50%)	3 (3.80%)	1 (1.23%)	
Wound Class, N (%):				0.885
Clean-contaminated	73 (45.6%)	37 (46.8%)	36 (44.4%)	
Contaminated	87 (54.4%)	42 (53.2%)	45 (55.6%)	
Hernia width, Median [25th;75th]	15.0 [12.0;17.0]	15.0 [12.0;18.0]	15.0 [12.0;16.0]	0.71
Hernia length, Median [25th;75th]	23.0 [20.0;26.0]	23.0 [19.5;26.0]	23.0 [20.0;25.0]	0.986

Median follow up:
6.1 years (5.43 – 7.58)

Follow Up



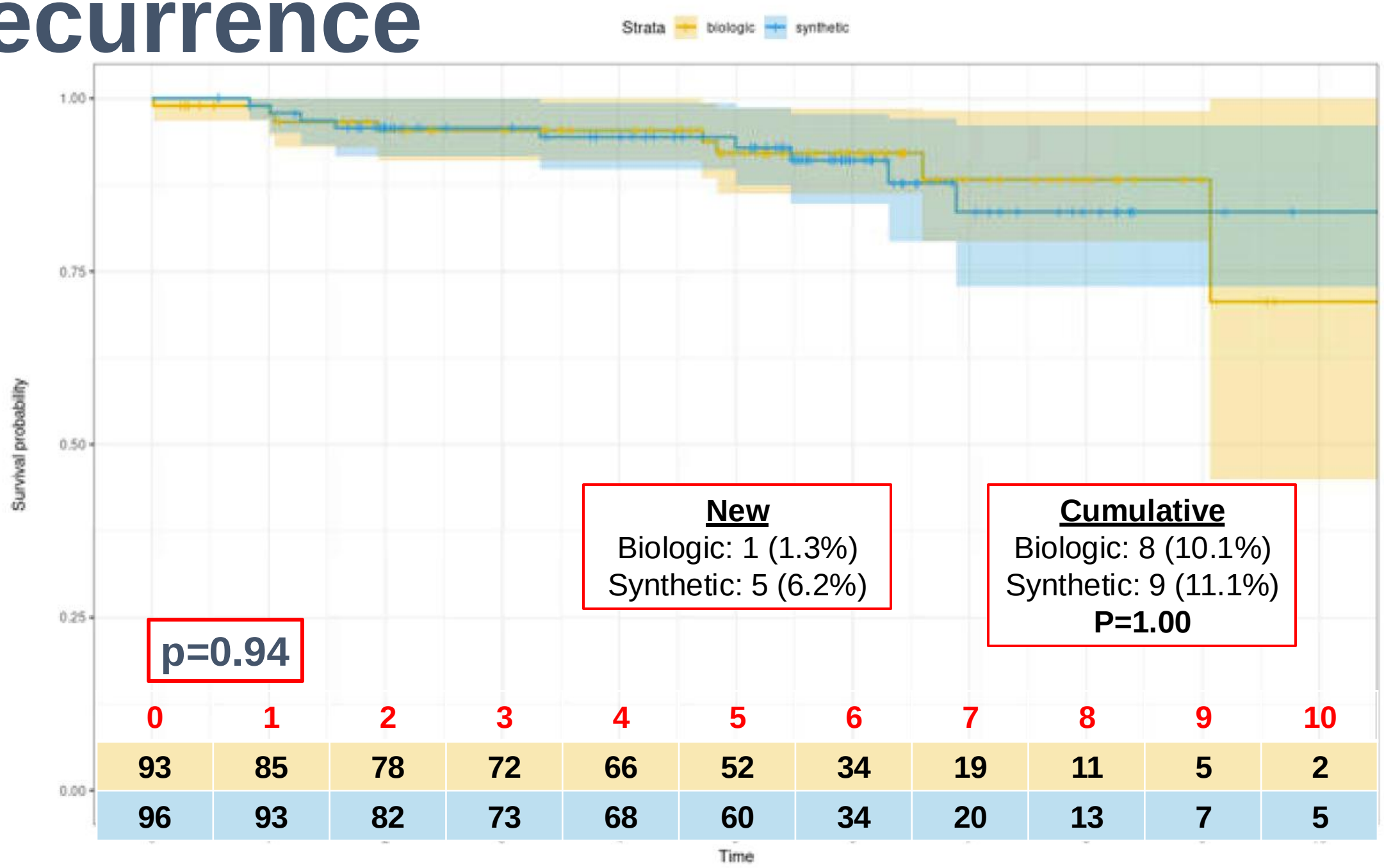




Biologic Group (n=79)
- Clinical exam: 76 (96.2%)
- Imaging: 47 (59.5%)
- HRI only: 3 (3.8%)

Synthetic Group (n=81)
- Clinical exam: 75 (96.2%)
- Imaging: 44 (54.3%)
- HRI only: 5 (6.2%)

Recurrence



New
Biologic: 1 (1.3%)
Synthetic: 5 (6.2%)

Cumulative
Biologic: 8 (10.1%)
Synthetic: 9 (11.1%)
P=1.00

p=0.94

0	1	2	3	4	5	6	7	8	9	10
93	85	78	72	66	52	34	19	11	5	2
96	93	82	73	68	60	34	20	13	7	5

Wound Morbidity

Within 2y

>2 yrs

Biologic

Chronic draining sinuses → OR for debridement (4y, 6y)

Seroma + Suture granuloma → OR for debridement (3y)

Synthetic

Suture abscess + excision → Repeat excision (5y)

Mesh-related Complications

Biologic

- 2 mesh infections
  - Managed with bedside excision

Synthetic

- 1 mesh infection
  - Reoperation

No new mesh-related complications

Reoperations

	Total (n=160)	Biologic (n=79)	Synthetic (n=81)	P value
Reoperations	**42 (26.3%)**	**20 (25.3%)**	**22 (27.2%)**	1
Hernia recurrence-related				
Parastomal Recurrence	**7 (4.4%)**	**5 (6.3%)**	**4 (4.9%)**	
Midline Recurrence	4 (2.5%)	3 (3.8%)	1 (1.3%)	
Wound morbidity	**8 (5.0%)**	**5 (6.3%)**	**3 (3.7%)**	
Other				
SBO	**7 (4.4%)**	**3 (3.8%)**	**4 (4.9%)**	
Cholecystitis	3 (1.9%)	2 (2.5%)	1 (1.3%)	
Perforated Bowel	2 (1.3%)	0 (0%)	2 (2.5%)	
Cancer	2 (1.3%)	0 (0%)	2 (2.5%)	
Stoma revision	1 (1.3%)	0 (0%)	1 (1.3%)	
Prostato-cutaneous fistula	1 (0.6%)	1 (1.3%)	0 (0%)	
PEG	2 (1.9%)	0 (0%)	2 (2.5%)	
RNYGB	1 (0.6%)	0 (0%)	1 (1.3%)	
Retained foreign body	1 (0.6%)	0 (0%)	1 (1.3%)	
Unrelated flank abscess	1 (0.6%)	1 (1.3%)	0 (0%)	

Session 9

Research & RCTs

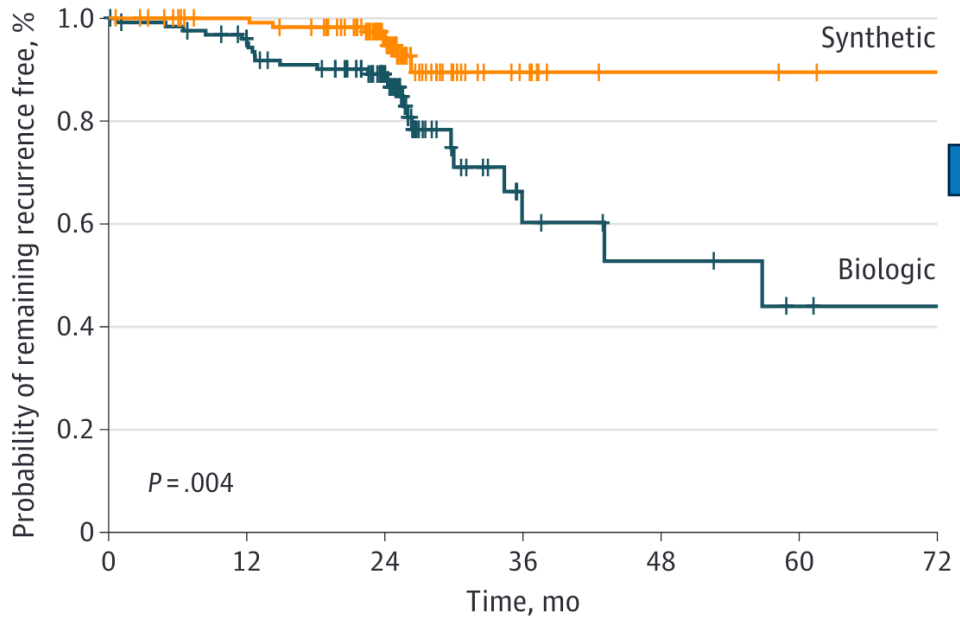
Session Moderators:

Clayton Petro, MD & Richard Pierce, MD, PhD

8:31 AM

Long-Term Follow Up of a Randomized Controlled Trial of Biologic Versus Synthetic Mesh

Daphne Remulla, MD



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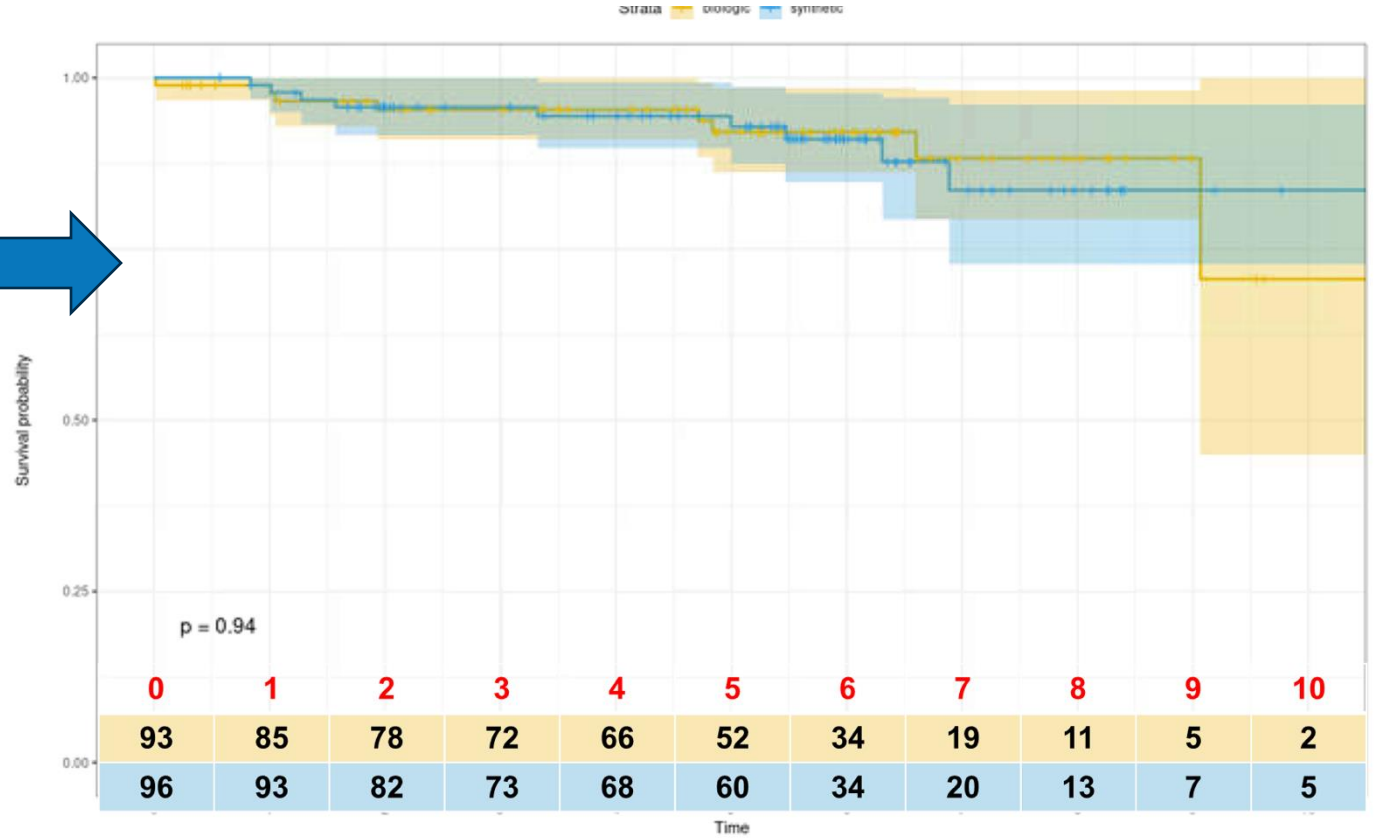

0	1	2	3	4	5	6	7	8	9	10
93	85	78	72	66	52	34	19	11	5	2
96	93	82	73	68	60	34	20	13	7	5

JUST DON'T DO IT

Summary

- Interesting trends from long-term data from single center
- Further long term follow up is needed
- Currently obtaining data from other sites

Conclusions

- At greater than 5-year follow-up, synthetic mesh demonstrated comparable long-term recurrence rates and complications to biologic mesh in contaminated ventral hernia repairs.
- Given the substantial cost difference, these findings further support the use of synthetic mesh in this setting.

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Every life deserves world class care.