Traitement des éventrations et hernies ombilicales avec Symbotex™ Composite Mesh: Résultats à 1 an d'un registre prospectif

Presented by:

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Disclosures – Constantin Zaranis

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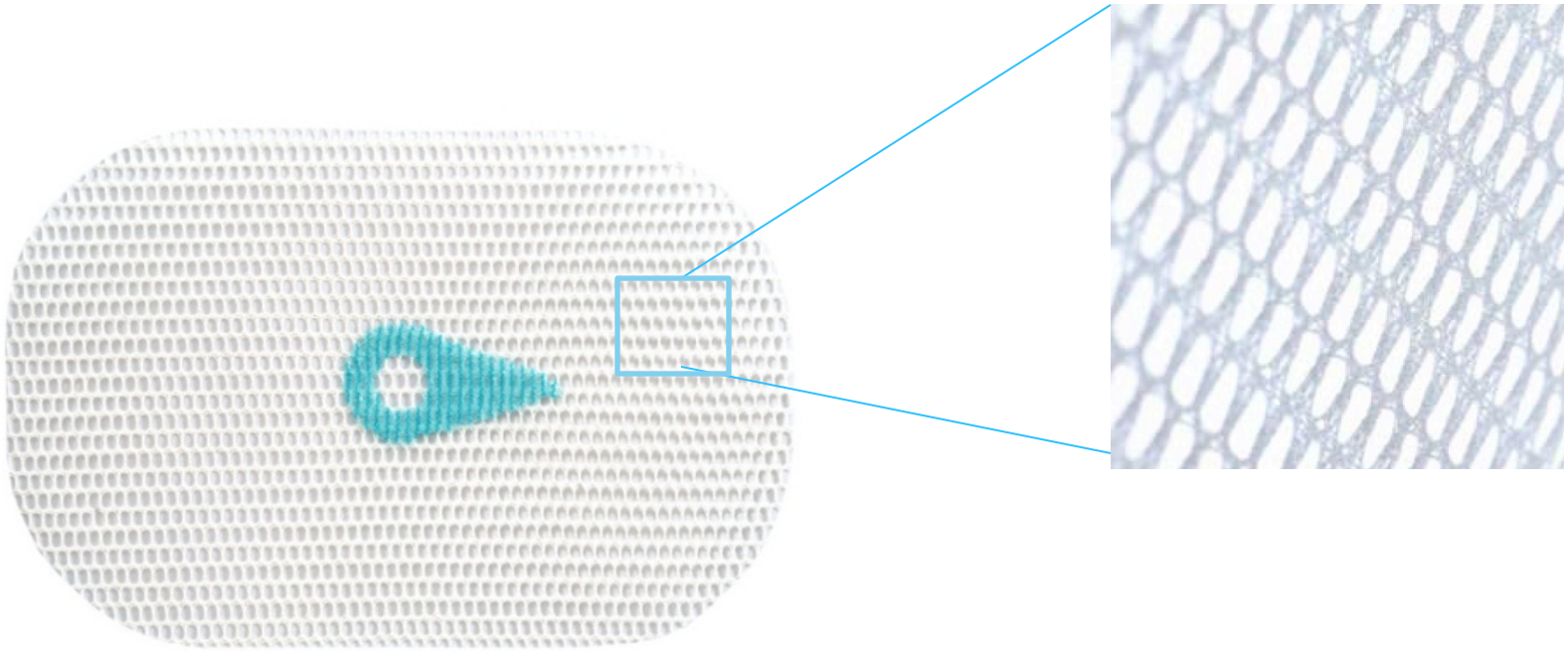
Medtronic

Symbotex™ Composite Mesh



- Mesh transparency for increased visibility during placement[1]
- Green orientation marking for accurate positioning[1,2]
- Abdominal wall side: monofilament 3D polyester textile
- Visceral side: hydrophilic collagen bioabsorbable film
- Large pore size: 3.3 mm × 2.3 mm

1. Covidien internal report 0901CR252a (June 2013)
2. Covidien design validation report 0901CR249a (June 2013)

Mesh Porosity Matters

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Original research

Large pore size and controlled mesh elongation are relevant predictors for mesh integration quality and low shrinkage – Systematic analysis of key parameters of meshes in a novel minipig hernia model☆

Dirk Weyhe [a,*], William Cobb [b], Julie Lecuivre [c], Antoine Alves [d], Sebastien Ladet [c], Davide Lomanto [e], Yves Bayon [c]

Methodology: Preclinical study of PET mesh integration and shrinkage comparing mesh weight (HW vs LW), pore size (SP vs LP) and weave (2D vs 3D)

- Large pore mesh showed better integration than small pore mesh
- Lightweight small pore mesh exhibited the most shrinkage
- 3D mesh supported the highest collagen count and exhibited the least shrinkage

→ **Mesh porosity is more important than mesh density for tissue integration**

1. Weyhe et al. International Journal of Surgery 22 (2015) 46-53

Study Design

Observational registry study: the short and long-term clinical outcomes following the use of Symbotex™ composite mesh.

- 100 consecutive patients reported in the Hernia Club database
- 2 Years Follow-up
- Inclusion Criteria:
  - ✓ ≥18 years of age
  - ✓ Ventral hernia: Primary or incisional
- Exclusion Criteria:
  - ✓ None

✓ Surgical technique is left to the surgeon's preference

Study Endpoints

Primary Endpoints:

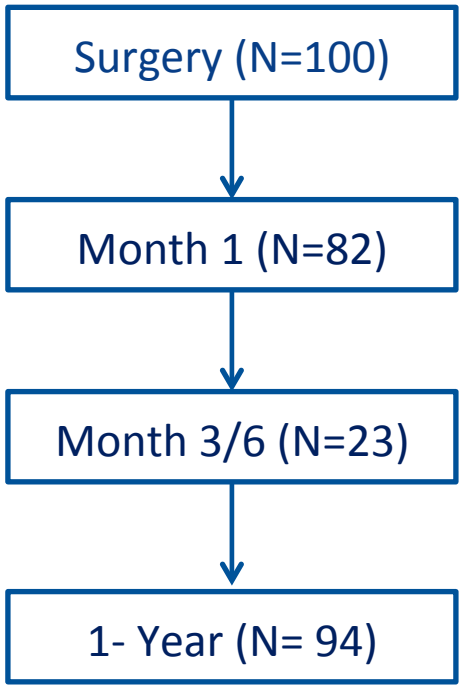
- Peri-operative complications
- Post-operative complications (up to 2 year follow-up)

Secondary Endpoints:

- Operative time and hospital stay
- Quality of life and patient satisfaction
- Ease of use / mesh manipulability assessment by surgeons

Patient Follow-Up (as of July 2016)

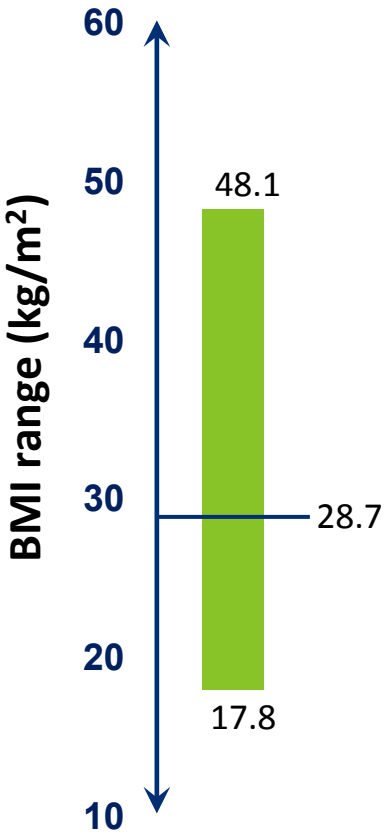
Study Flow Chart



Median Follow-Up:
349.5 (0 – 579) days

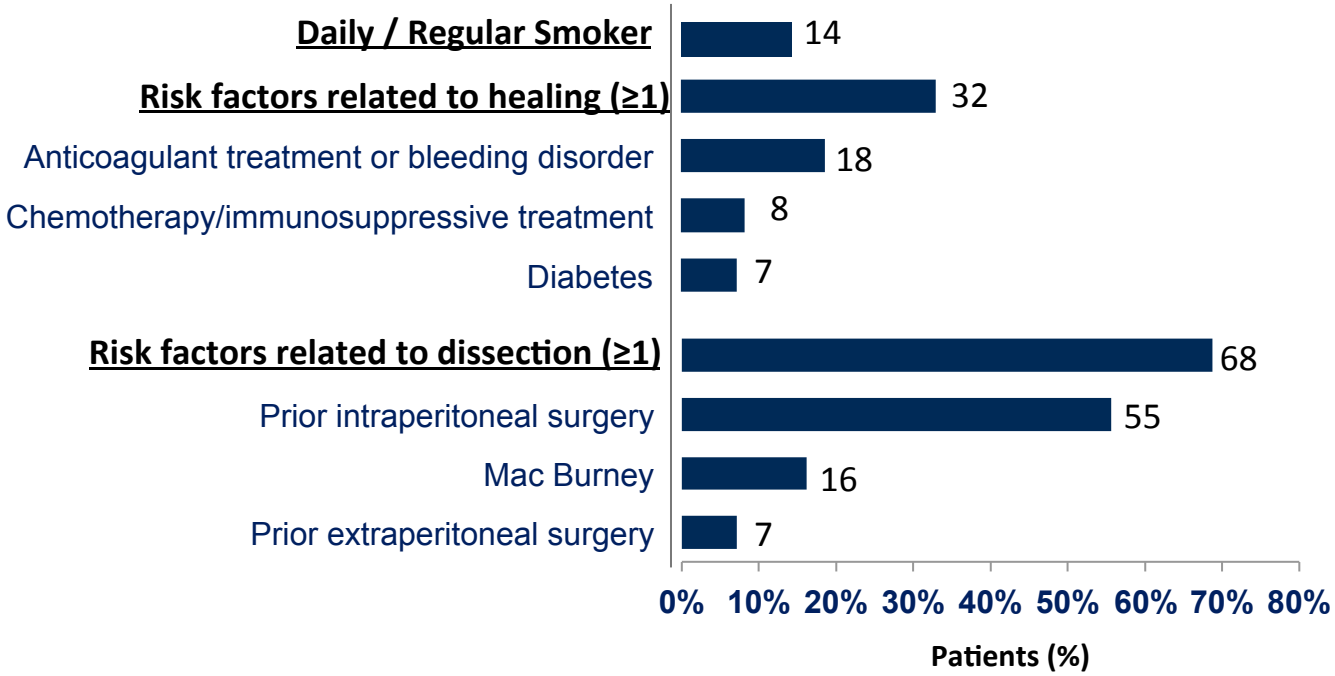
On-going study will assess 24 months follow- up

Patient Demographics & Risk Factors



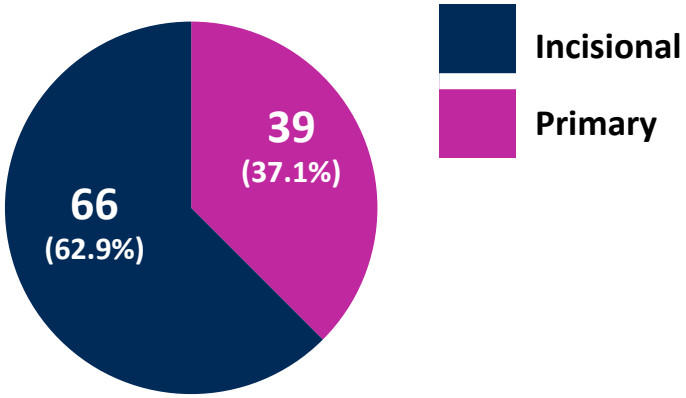
40.4% of patients had a BMI ≥30

Median Age (min – max)	
61.5 years (30-91)	
Gender (N= 100)	
Male	49
Female	51

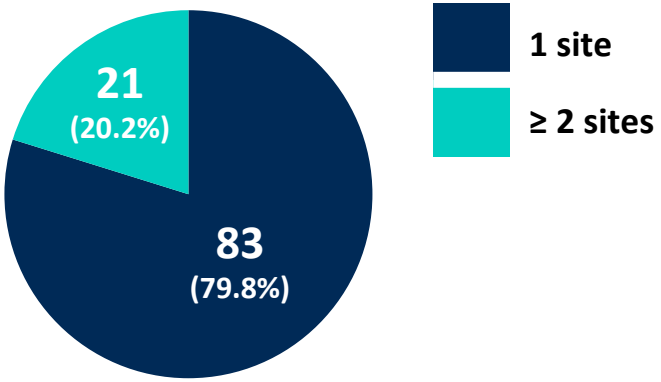


Hernia Characteristics

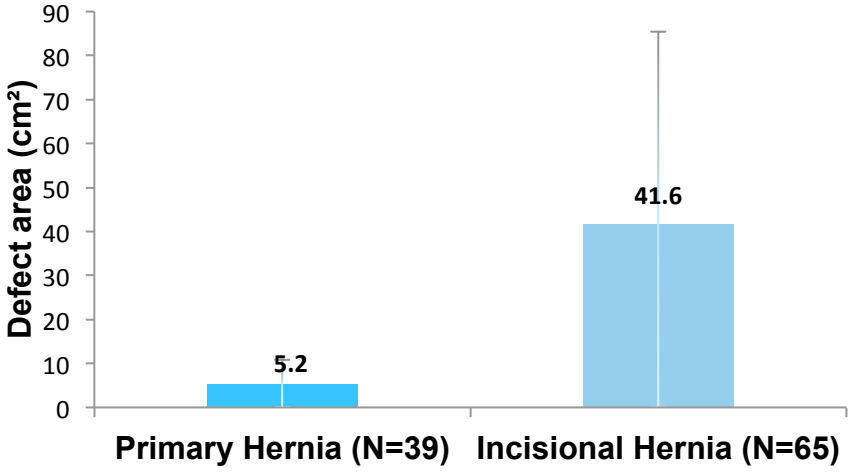
Hernia Type (N=105)



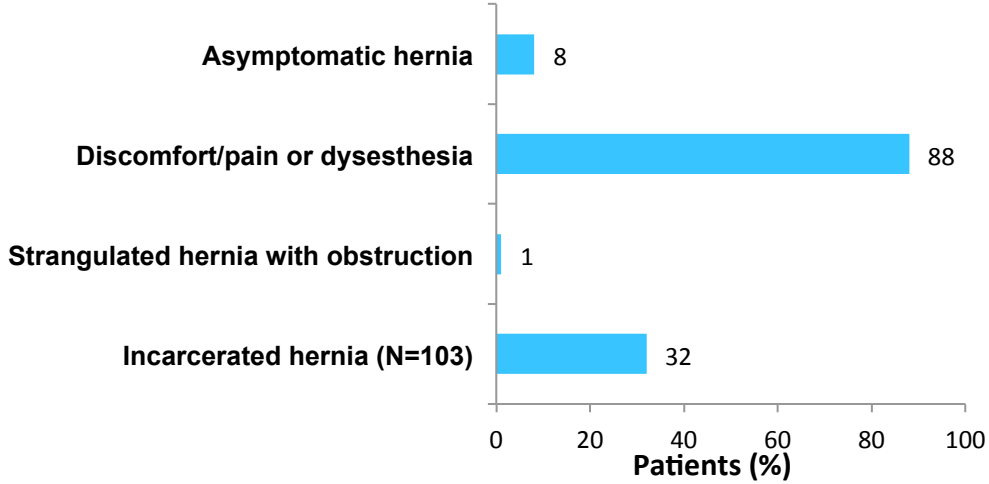
Multi-site hernias (N=104)



Hernia Defect Area (N=104)

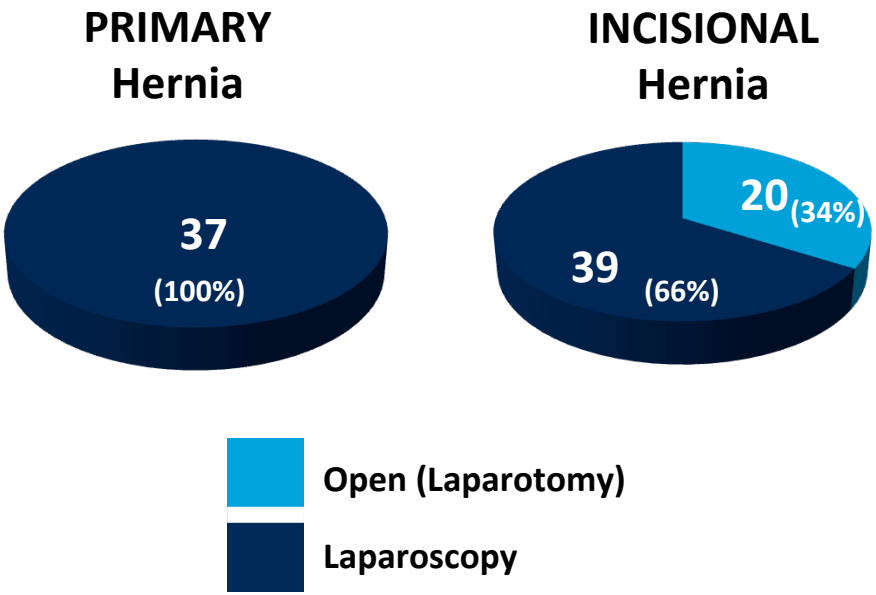


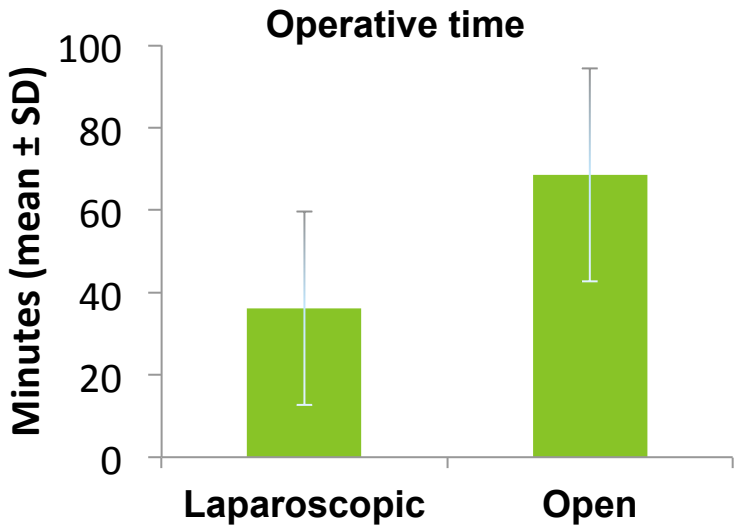
Hernia Symptoms (N=103)

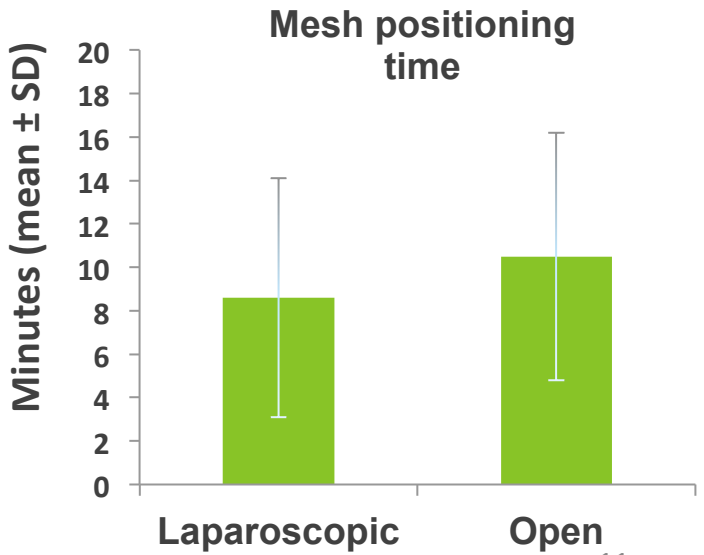


Operative Data

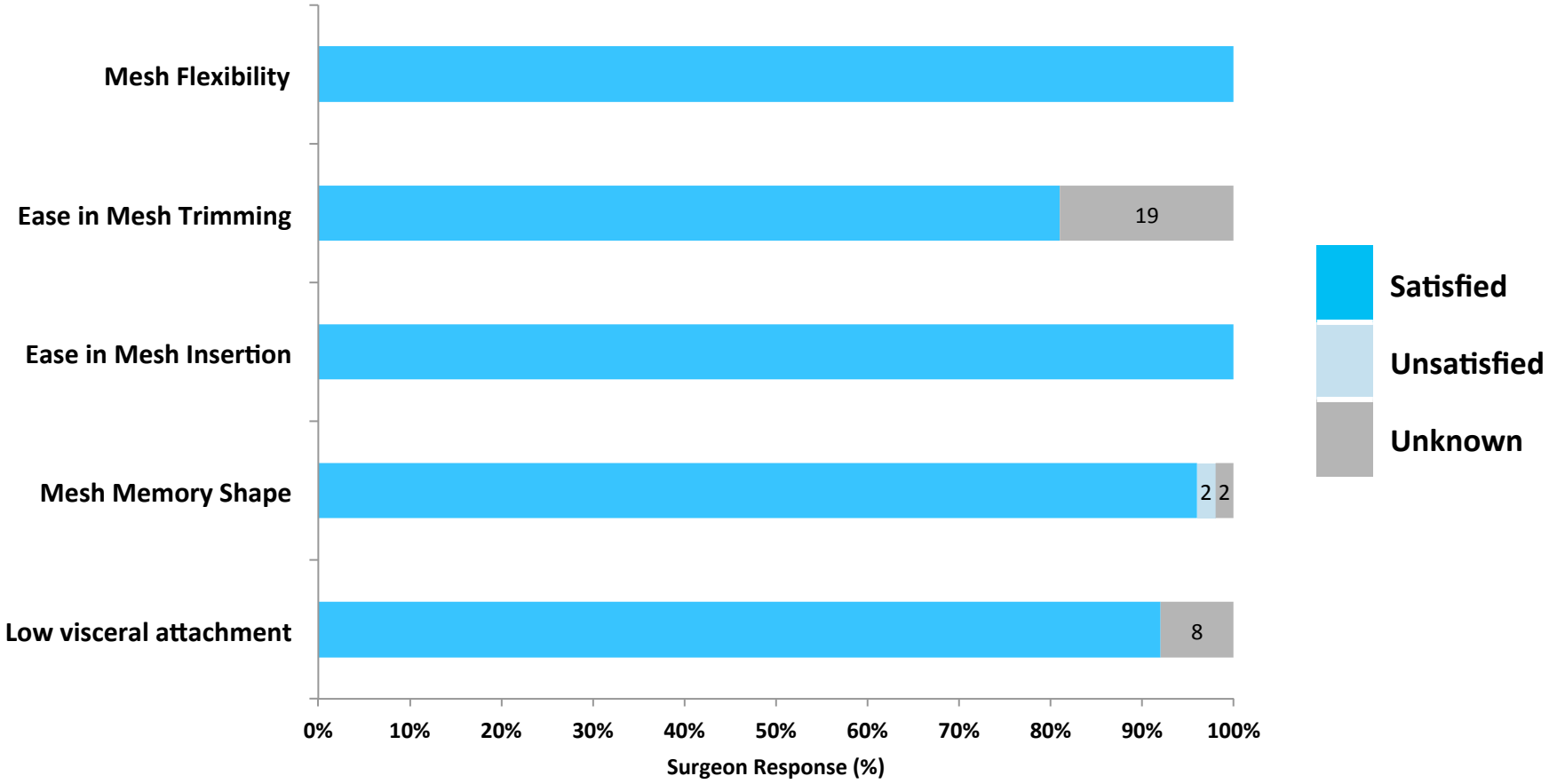
Surgical Approach







Surgeon Satisfaction



Patient Complications

- One recurrence occurred, patient was reoperated on
- Few complications occurred
- No sepsis or other serious adverse events were reported within 12 months

Patient Complications

Complication	Symbotex™ composite mesh (N=100)	Time of occurrence
Seroma[1]	1	Perioperative
	5	Post-operative (2-4 weeks)
	6 (6.0%)	**Total within one year**
Transitory ileus[2]	2	Perioperative
	1	Post-operative (2-4 weeks)
	3 (3.0%)	**Total within one year**
Recurrence[3]	**1 (1.0%)**	**Total within one year**

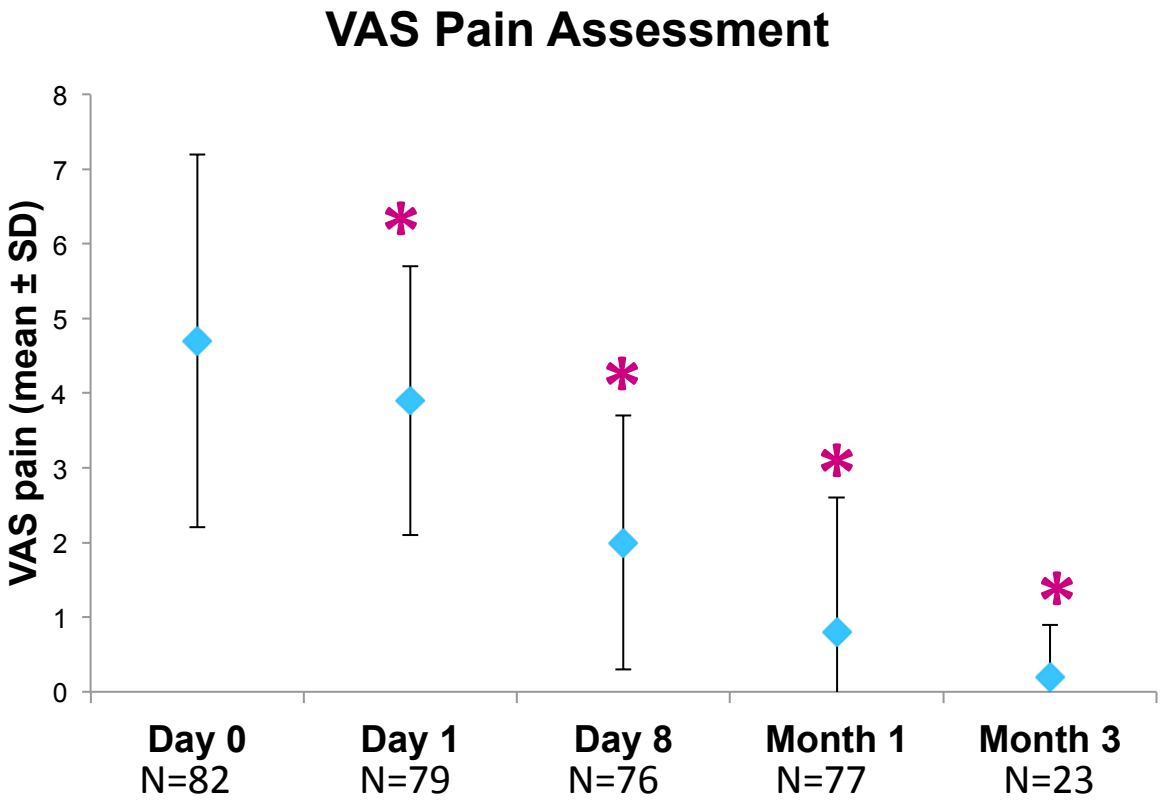
Data are represented as n (%)

[1] No seroma were mesh-related; five were minor, requiring no medical treatment; one diagnosed at 1 month was punctured at 2 months post-surgery

[2] All were low-grade (Clavien 1 or 2); relation to mesh or procedure is unknown at this time

[3] Asymptomatic occuring between 6 – 12 months, patient was reoperated on.

Post-Operative Pain



* P < 0.0001 for scores relative to baseline, based on Wilcoxon signed rank test (non-parametric) for paired data.

At 12 months, patients were given a questionnaire without VAS pain assessment

Patient Satisfaction

Patient Satisfaction Survey by Phone at One Year

Patient satisfaction rating	Responses (N=94)
Excellent	10 (10.6%)
Good	73 (77.7%)
Medium	7 (7.4%)
Bad	4 (4.3%)

Conclusions

- Primary and incisional ventral hernia repair with Symbotex™ composite mesh yielded minimal adverse events with only one recurrence
- High patient satisfaction at one year follow-up and high rate of surgeon satisfaction regarding mesh handling reported
- Post-operative pain decreased significantly
- These promising results support the use of Symbotex™ composite mesh in primary and incisional ventral hernia repair

Study results will be assessed again at two year follow-up