Observational Registry Study of Symbotex™ Composite Mesh in Ventral Hernia Repair

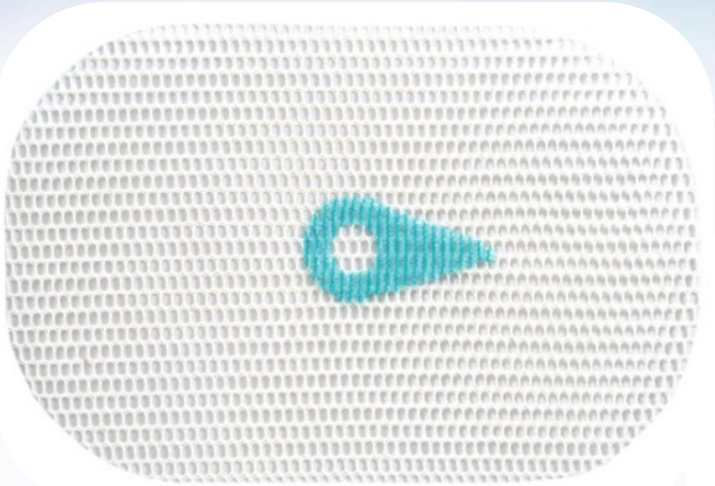
Constantin Zaranis[1] on behalf of the Club Hernie

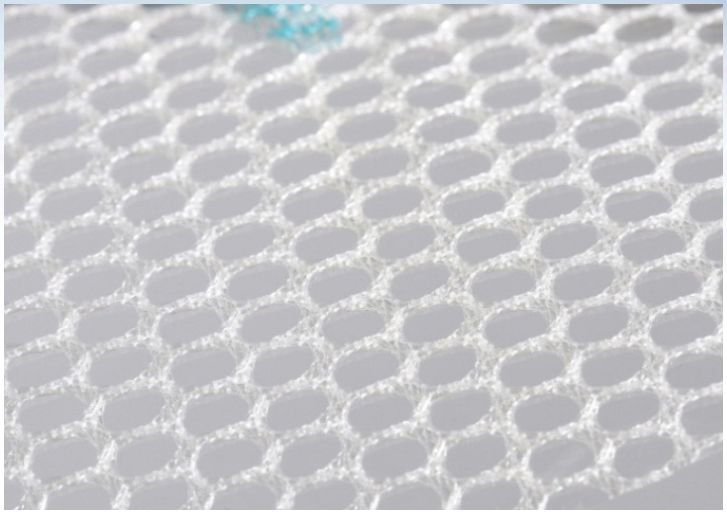
[1]Clinique du Mail, La Rochelle, France

Disclosures – Constantin Zaranis

- SymCHro study sponsorship, funding, and data analysis provided by Medtronic.

Symbotex™ Composite Mesh

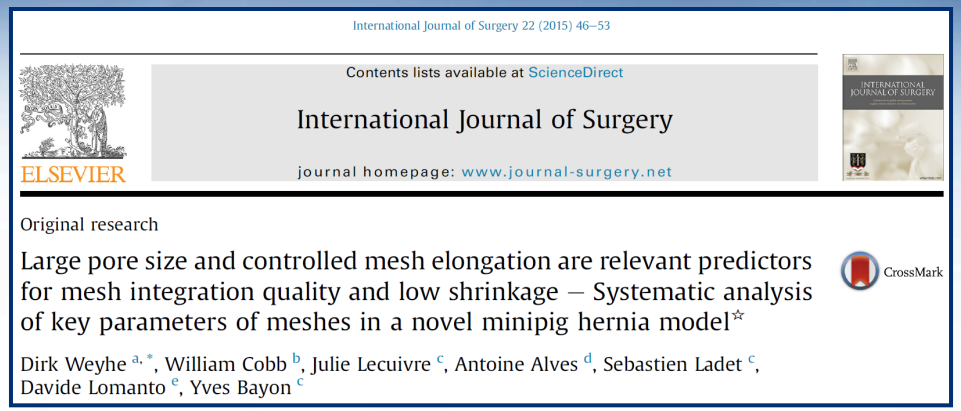




- Mesh transparency for increased visibility during placement[1]
- Green orientation marking for accurate positioning[1,2]
- Abdominal wall side: monofilament 3D polyester textile
- Visceral side: hydrophilic collagen bioabsorbable film
- Large pore size: 3.3 mm × 2.3 mm

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

Mesh Porosity Matters



International Journal of Surgery 22 (2015) 46–53

Contents lists available at ScienceDirect

International Journal of Surgery

journal homepage: www.journal-surgery.net

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

International Journal of Surgery 22 (2015) 46–53

SymCHro Study Design

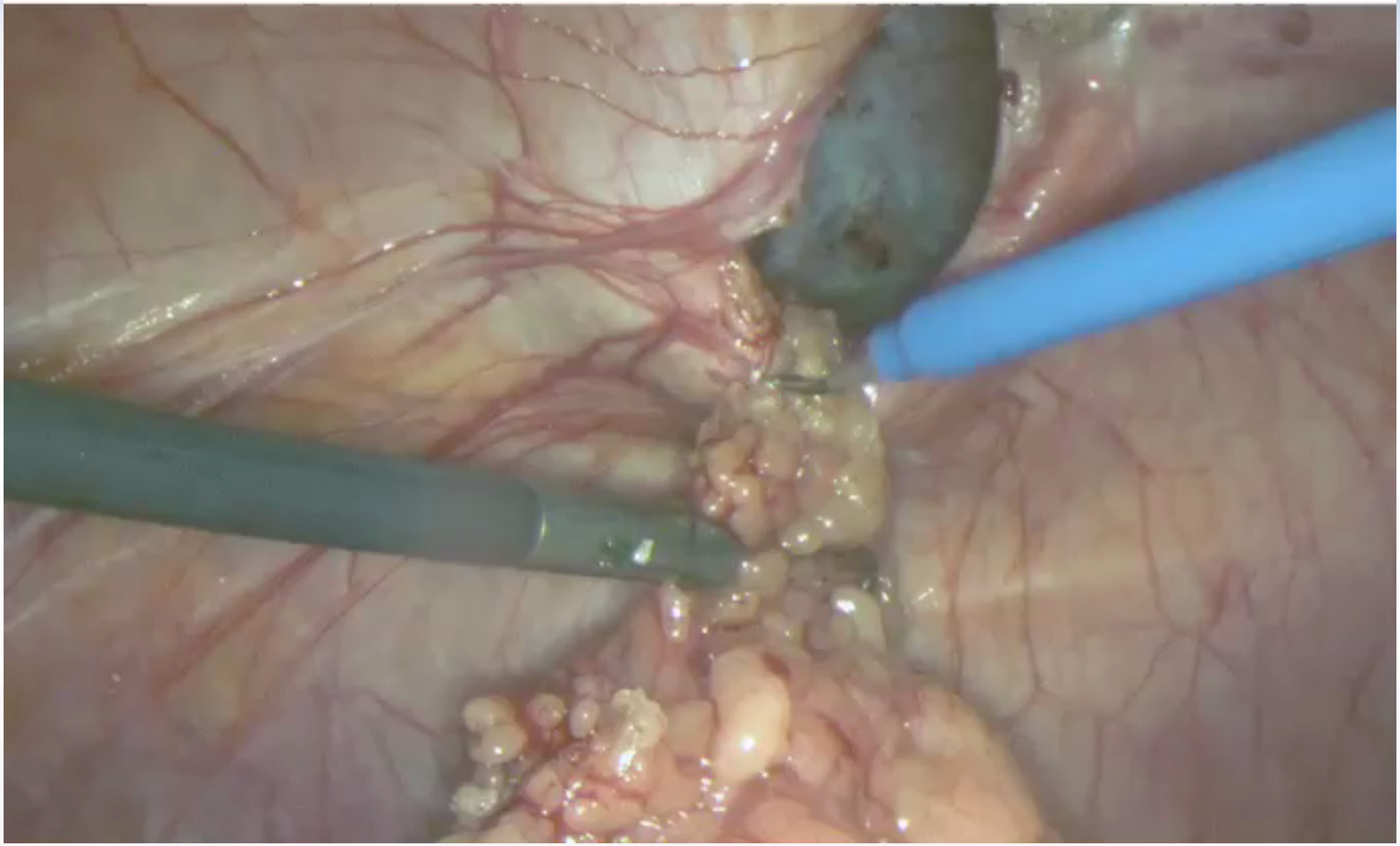
Observational registry study: the short- and long-term clinical outcomes following the use of Symbotex™ composite mesh.

- 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

Ventral hernia laparoscopic repair: Symbotex™ Composite Mesh after external defect raphy

Marc LEPERE / France - 2015



SymCHro Study Endpoints

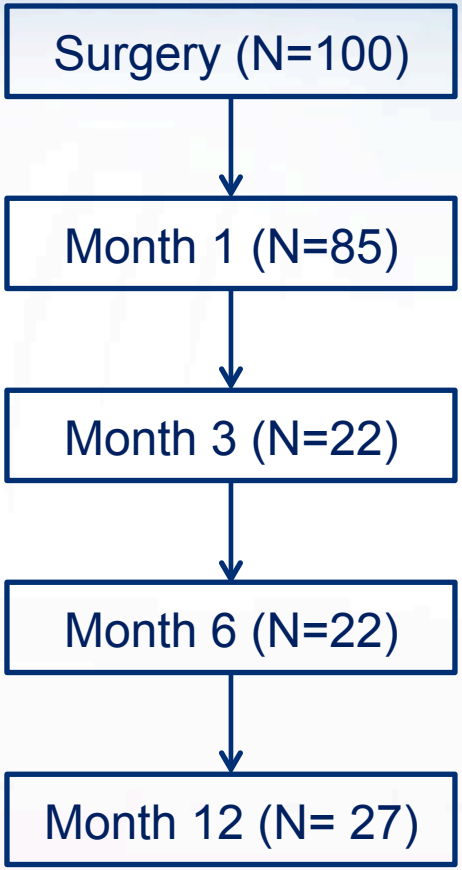
Primary Endpoints:

- 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

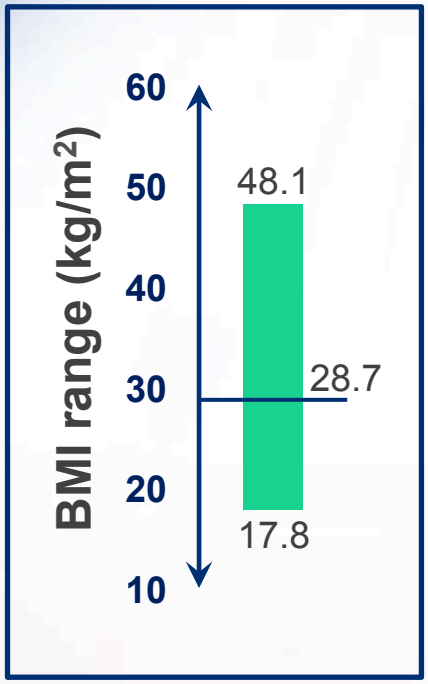
SymCHro Patient Follow-Up
(as of January 2016)

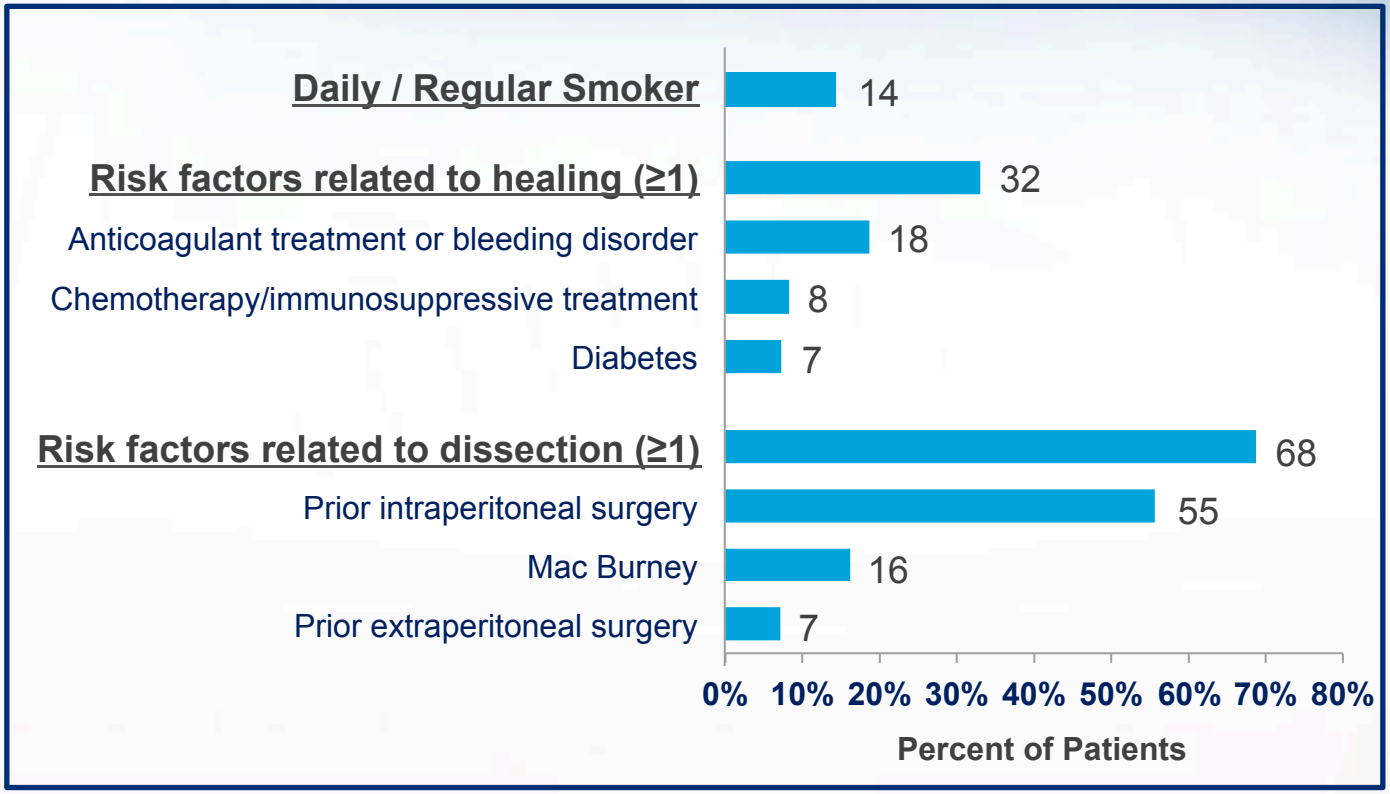


Completed Follow-Up:
46.5 (0 – 425) days

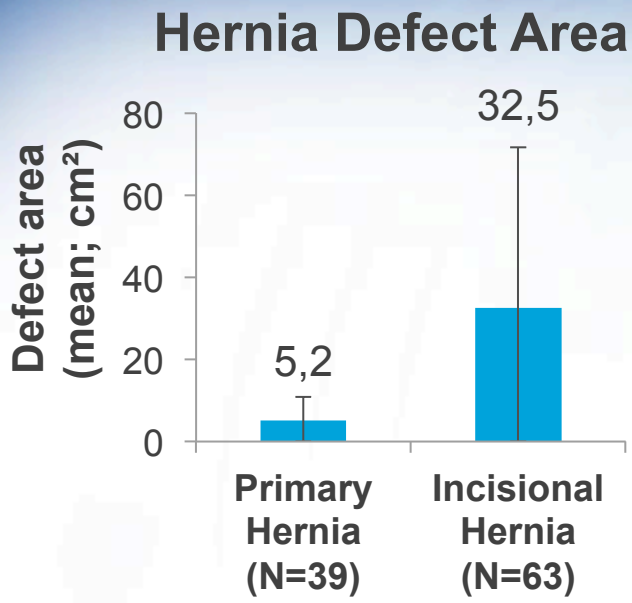
Theoretical Follow-Up:
360.5 (238 – 551) days

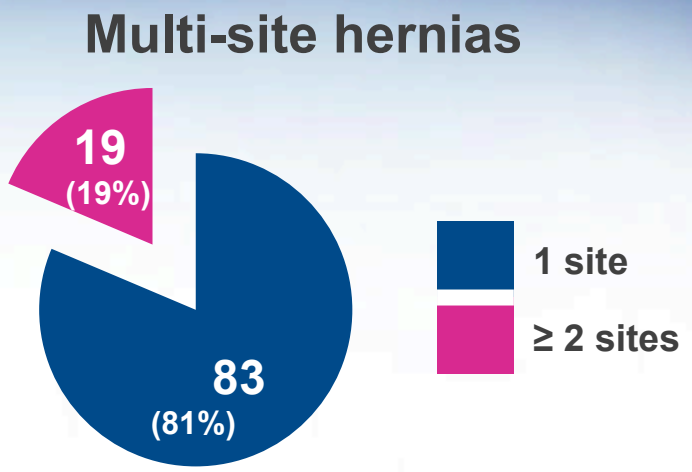
Patient Demographics & Risk Factors

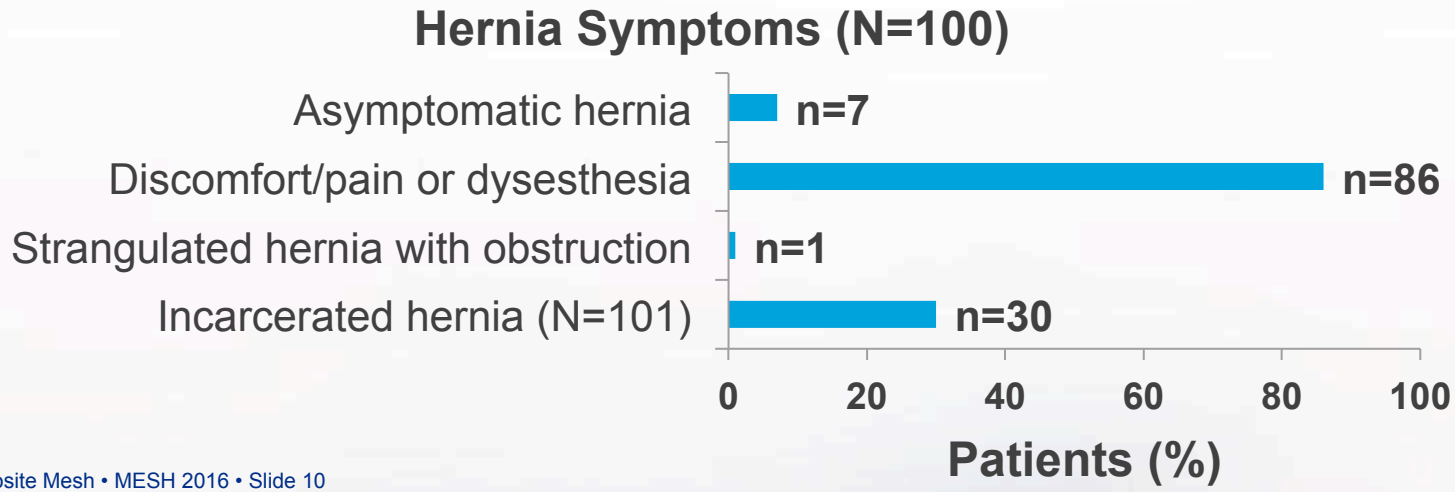




Hernia Characteristics

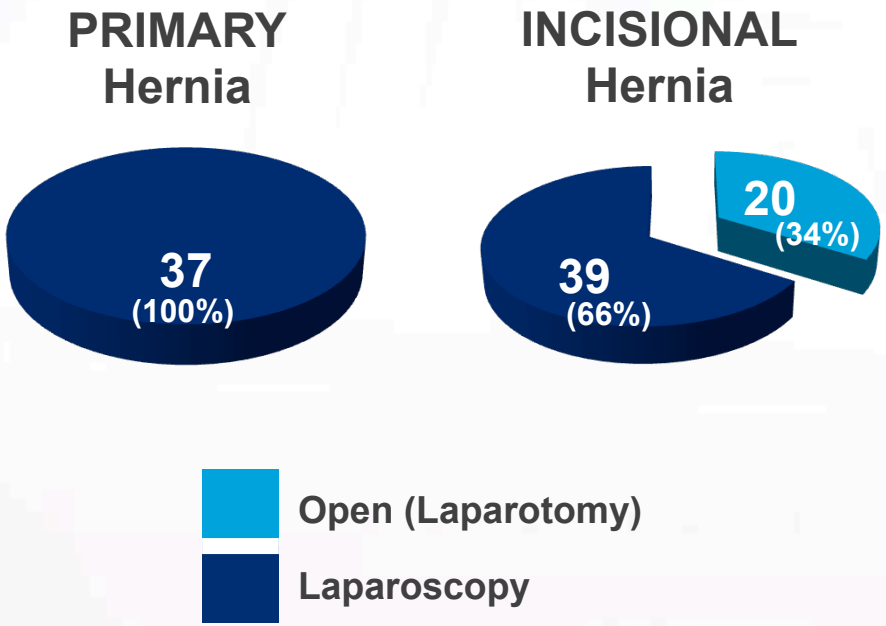




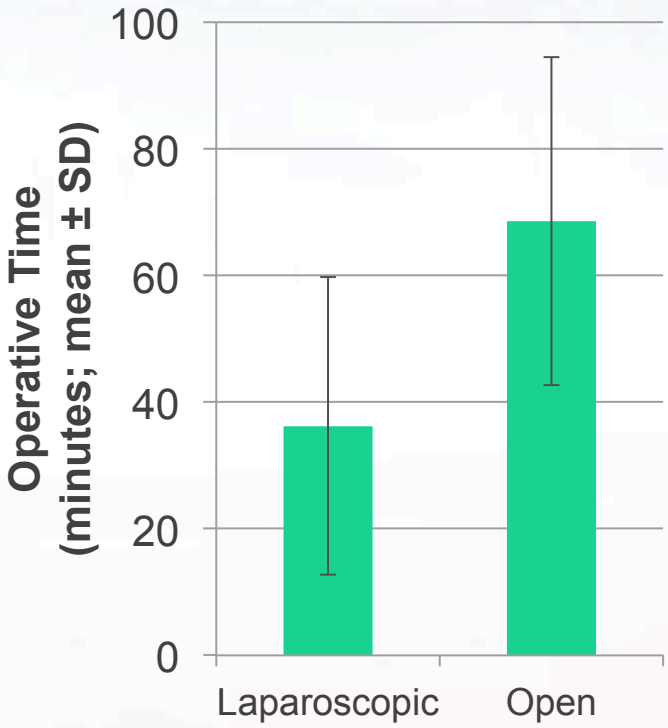


Operative Data

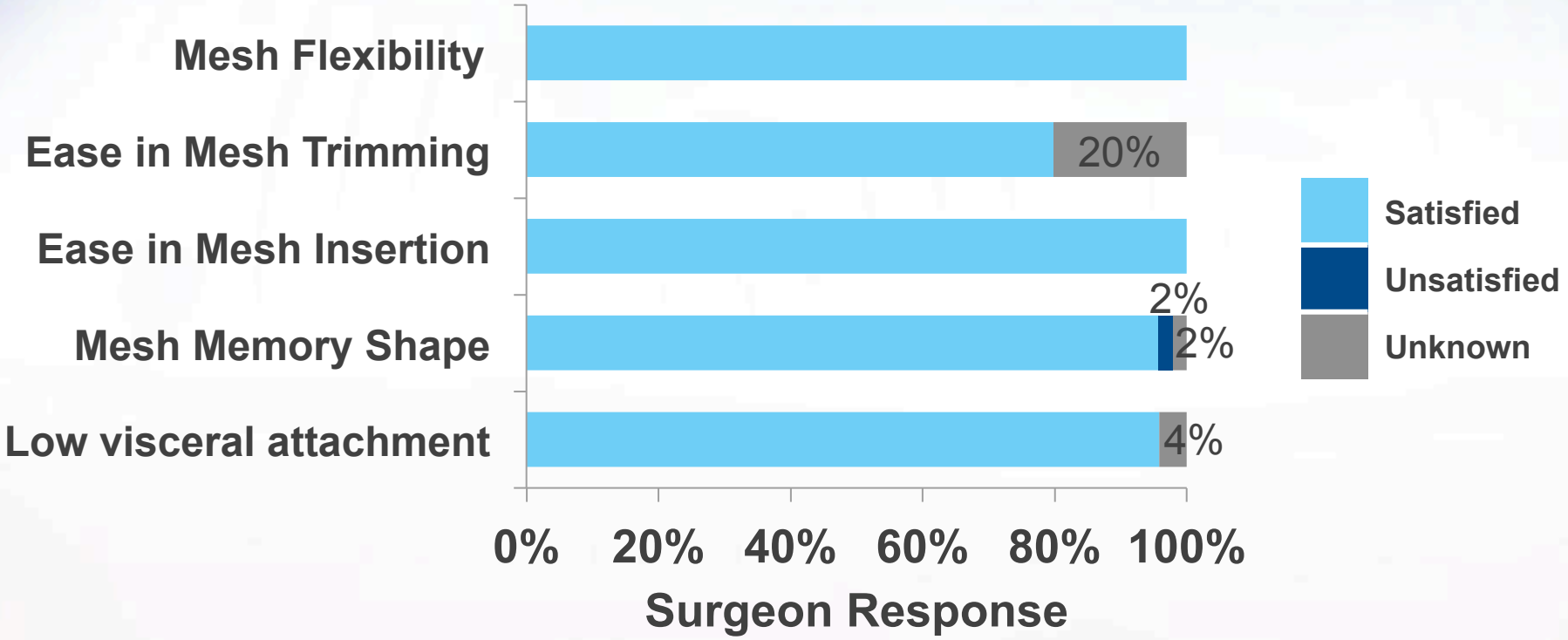
Surgical Approach



Operative time



Surgeon Satisfaction



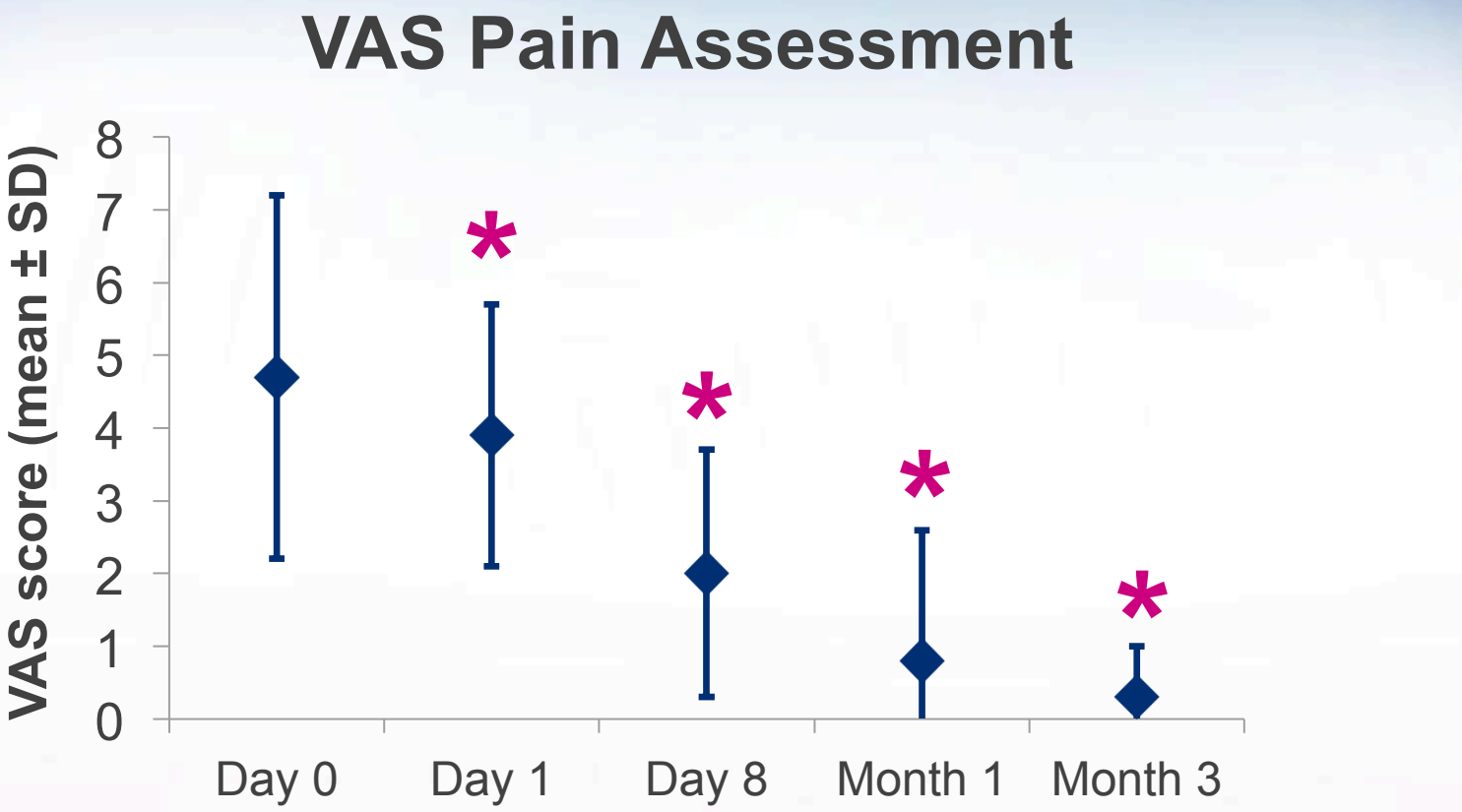
Patient Complications

- Few complications occurred; none required reoperation
- No recurrence, sepsis, nor serious adverse events were reported within 12 months

Complication	Symbotex™ composite mesh (N=100)	Time of occurrence
Seroma[1]	6/100 (6.0%)	1 perioperatively 4 within 1 month 1 within 2 months[2]
Transitory ileus[3] (Clavien 1 or 2)[4]	3/100 (3.0%)	2 perioperatively 1 within 1 month

[1] All seroma were minor/required no medical treatment; none were mesh-related
[2] Already identified at 1 month, but asymptomatic and punctured at 2 months
[3] Relation to mesh or procedure is unknown at this time
[4] Dindo D, et al., Ann Surg. 2004, 240(2):205-13

Post-Operative Pain



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

Conclusions

→ Only non-serious adverse events were reported

→ Post-operative pain decreased significantly

→ High rate of surgeon satisfaction regarding mesh handling

Intermediate results of this registry study support the use of Symbotex™ composite mesh in primary and incisional hernia repair. Two year patient follow-up is ongoing.