AIDA Study:Primary Onlay Mesh Augmentation following AAA Repair Prevents Incisional Hernia– a Multicenter Randomized Trial

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Disclosures

- ❑ X I have the following potential conflicts of interest to report:
  - ❑ X Receipt of AIDA research support (BBraun)
  - ❑ Receipt of honoraria and travel support
  - ❑ Participation in a company sponsored speakers‘ bureau
  - ❑ Employment in industry
  - ❑ Shareholder in a healthcare company
  - ❑ Owner of a healthcare company

„endogenous fate?“

Incisional hernia after AAA repair 10-30%

Antoniou et al. Abdominal aortic aneurysm and abdominal wall hernia as manifestations of a connective tissue disorder. J Vasc Surg. 2011 Oct;54(4):1175-81. doi: 10.1016/j.jvs.2011.02.065. Epub 2011 Aug 6.

Metaanaylsis 757 Patients: postoperative midline incisional hernia

- AAA 10-37% } 2.9 fold increased risk

H. Takagi et al. Postoperative Incision Hernia in Patients with Abdominal Aortic Aneurysm and Aortoiliac Occlusive Disease: A Systematic Review. Eur J Vasc Endovasc Surg Vol 33, February 2007

Systematic Review: 1132 Patients (719 AAA)

- Incidence of postoperative incisional hernia AAA 21%
- Pooled analysis: 5,4 fold risk

Hypothesis: Preventive onlay mesh is superior to suture alone

Abdominal Incision Defect following AAA Surgery

- A prospective, multicenter (11), randomized, controlled clinical investigation
- Elective aortic aneurysm repair (OR)

Endpoints

Reduced herniation rate in the 24 months after mesh implantation (assumption: 30% incidence, Decrease to 10%)

- **Secondary objectives**
  - wound complications
  - safety / AE, SAE
  - Pain (VAS)
  - Quality of life (EQ-5D)
  - Non-inferiority of MonoMax suture material

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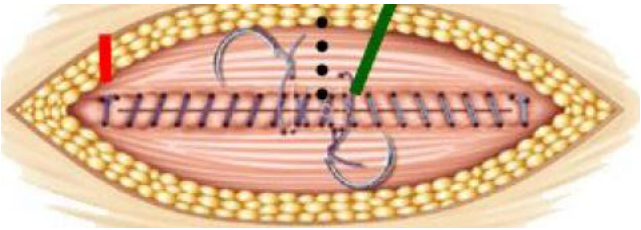
Study design

Group A

- monofile Polydioxanine
- runing suture Technique
- Large bite (2-2,5cm)



Group B

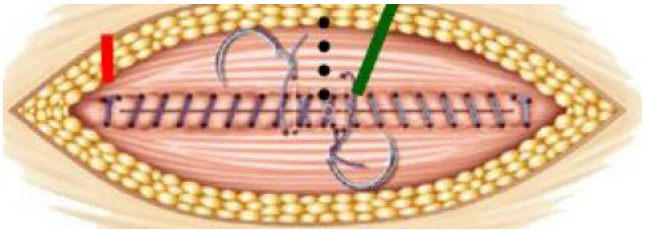
- Polydioxanine

  Plus

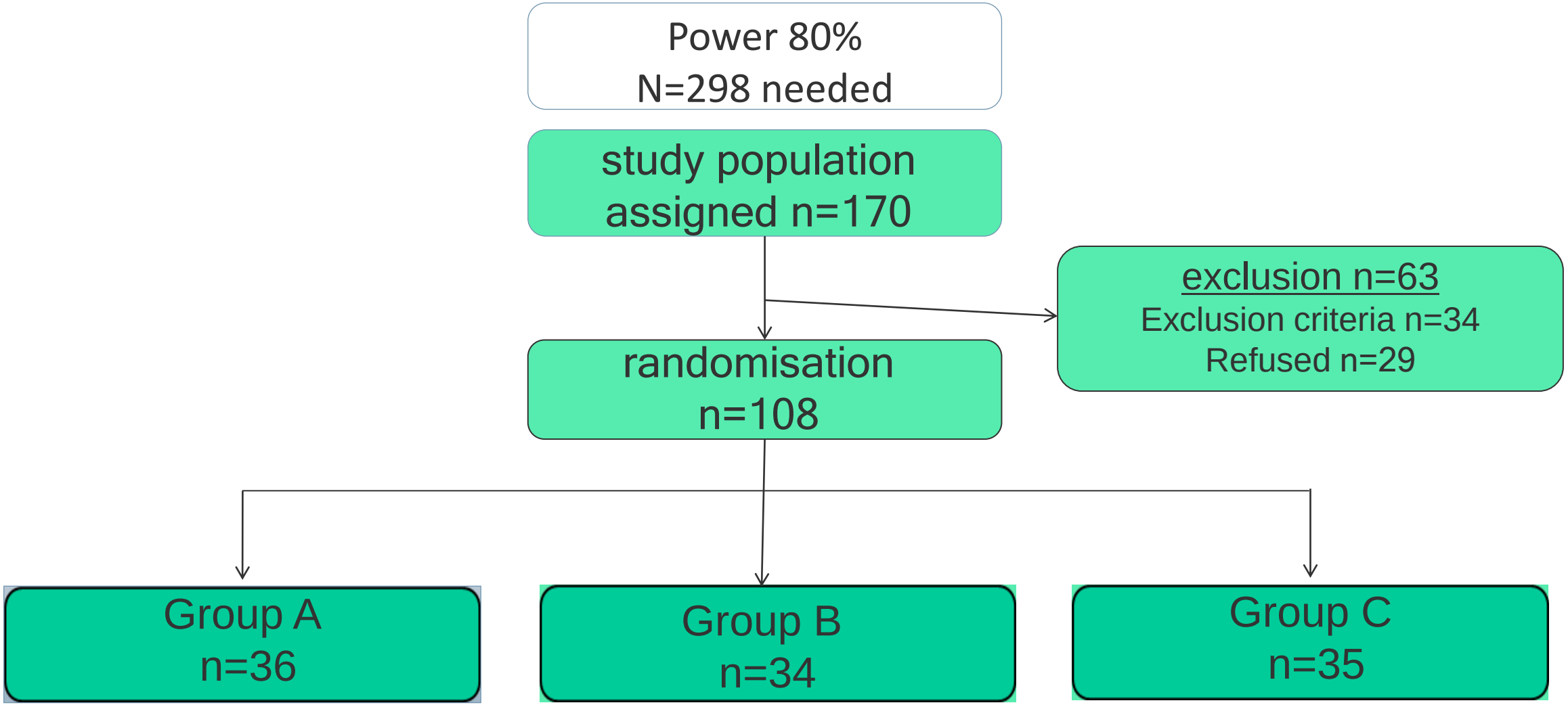
  Polypropylene Elastic Mesh
- Overlap 5cm

Group C

- Monofile Poly -4-Hydroxybutyrate (long lasting, absorbable & flexible)
- Running suture
- Large bite (2-2.5 cm)



Study enrollement 2011 - 2013



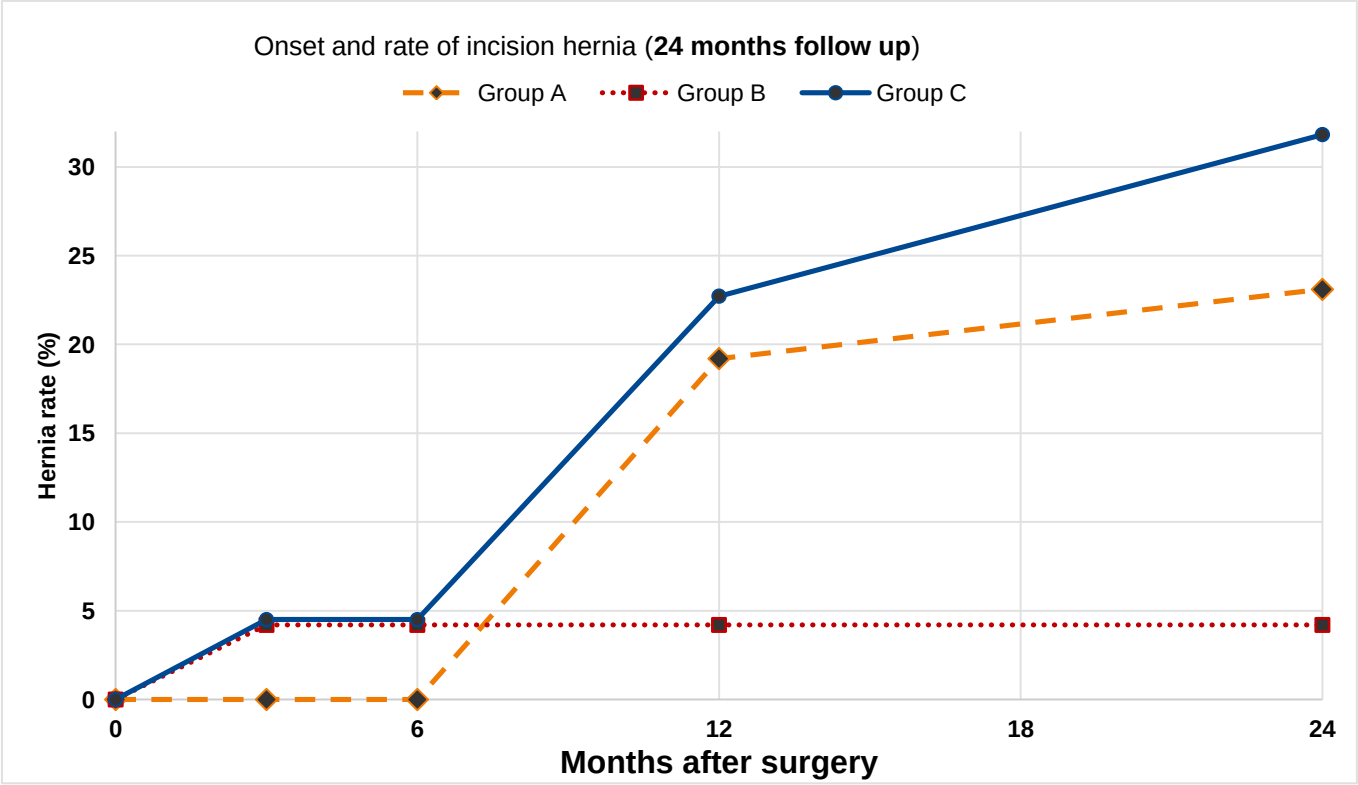
Patients characteristics & risk factors

	Group A	Group B	Group C	Total cohort	P-value*
Patients (male/female)	30 (28/2)	26 (25/1)	23 (19/4)	79 (72/7)	**0.280**
Age [years]	68.40 ±9.48	70.12 ±8.39	70.78 ±5.86	69.66 ±8.17	**0.547**
Abdominal girth [cm]	104.28 ±9.36	102.37 ±18.10	108.75 ±21.48	104.94 ±16.91	**0.456**
Weight [kg]	83.24 ±11.74	84.23 ±17.23	83.22 ±15.11	83.56 ±14.03	**0.960**
Height [cm]	176.87 ±7.82	176.81 ±6.26	173.78 ±7.36	175.95 ±7.25	**0.237**
BMI [kg m^{-2}]	26.56 ±2.90	27.97 ±6.59	27.58 ±4.98	26.93 ±4.07	**0.651**
Systolic RR [mmHg]	138.97 ±15.20	138.04 ±14.28	140.78 ±		**0.843**
Diastolic RR [mmHg]	80.83 ±9.00	82.50 ±			**0.508**
Smokers [%]					**0.145**
Adiposity [%]				20.25	**0.438**
Alcohol consump			73.91	68.35	**0.718**
Current renal dia		3.85	0.00	1.27	**0.382**
Chronic liver disea	3.33	0.00	0.00	1.27	**1.000**
Renal insufficiency [%]	10.00	15.38	13.04	12.66	**0.912**
Renal failure [%]	0.00	3.85	0.00	1.27	**0.620**
Myocardial infarction [%]	16.67	7.69	8.70	11.39	**0.670**
Arterial hypertonia [%]	90.00	69.23	91.30	83.54	**0.078**
Diabetes mellitus [%]	13.79	23.08	21.74	18.99	**0.748**
Insulin-dependent diabetes [%]	6.90	0.00	8.70	5.06	**0.452**
COPD [%]	20.00	8.00	8.70	12.66	**0.410**
ASA status	2.63 ±0.56	2.50 ±0.51	2.52 ±0.51	2.56 ±0.53	**0.599**

No significant differences

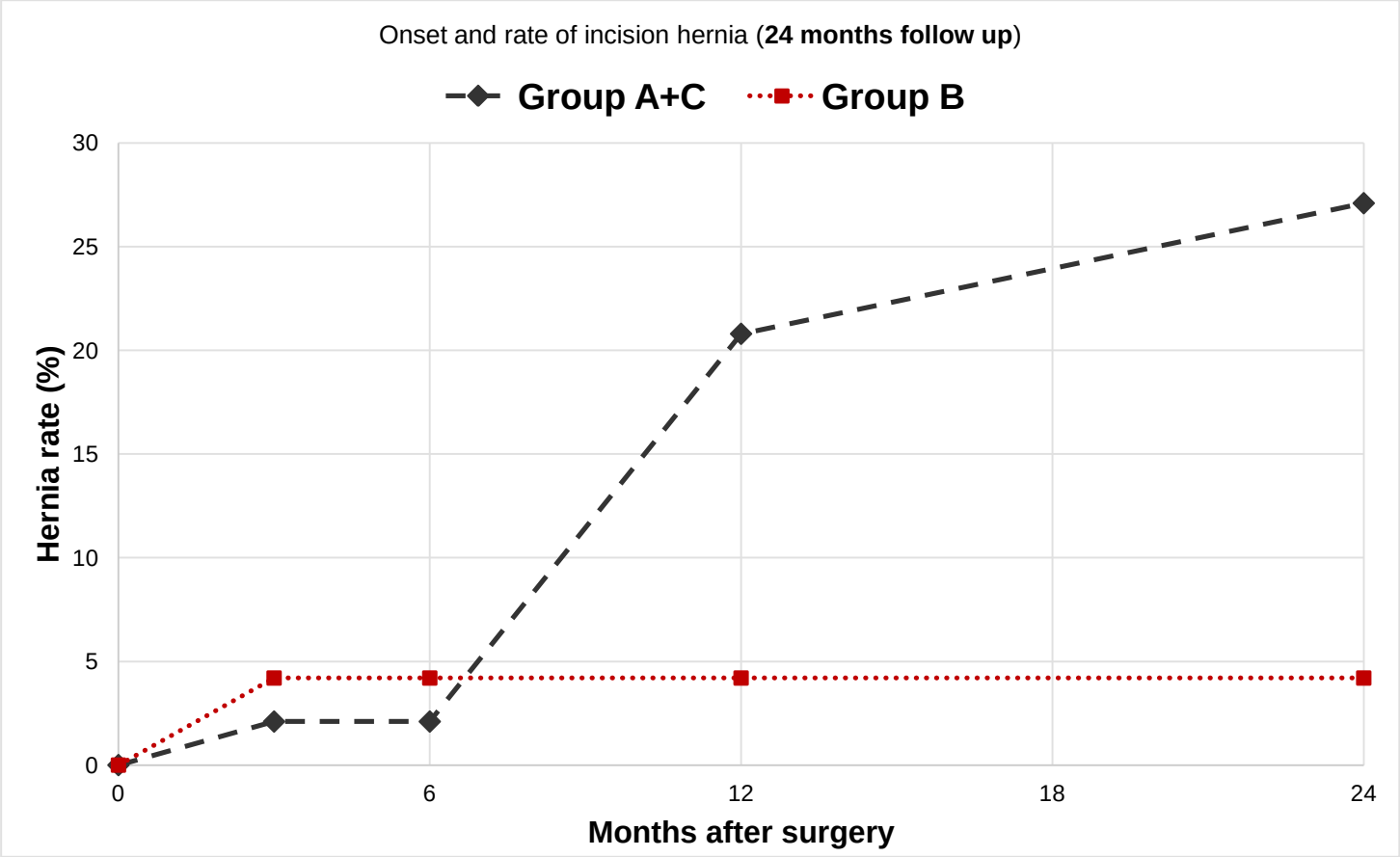
Incisional hernia

Incision hernia occurred 0-12 months after surgery				
	Group A *(PS)*	Group B *(Mesh)*	Group C *(PS)*	Total cohort
12 months	16.67 %	3,85%	17,39%	12,66 %
24 months	**23,1%**	**4,1%**	**31,8%**	**19,4%**



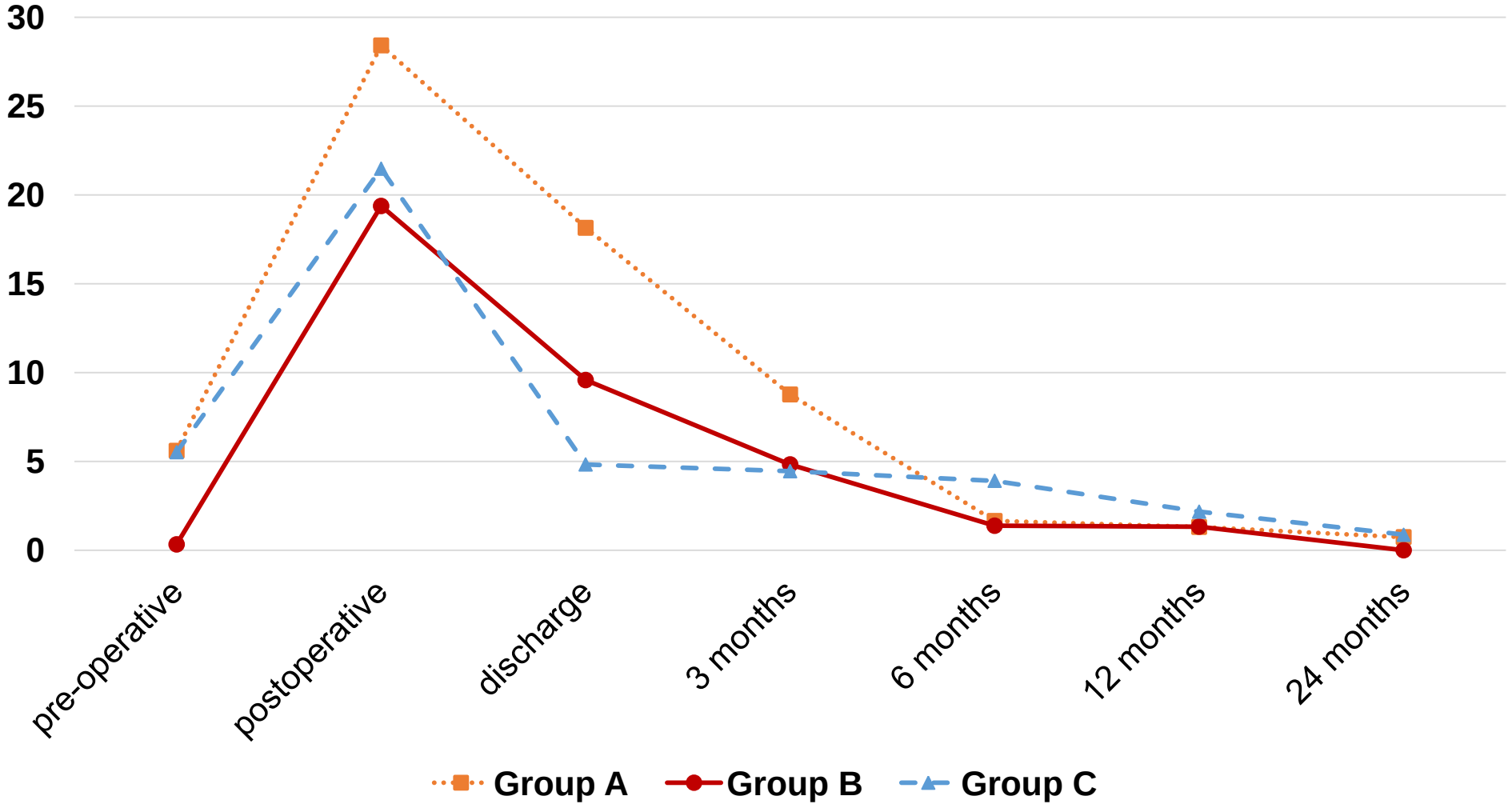
12 months	Deviation from 30% hernia rate (p-value)	Deviation from 20% hernia rate (p-value)
Group A	0.298	0.539
Group B	**0.002**	**0.027**
Group C	0.229	0.540
24 months	**Deviation from 30% hernia rate (p-value)**	**Deviation from 20% hernia rate (p-value)**
Group A	0.297	0.423
Group B	**0.002**	**0.033**
Group C	0.506	0.133

Suture vs mesh technique

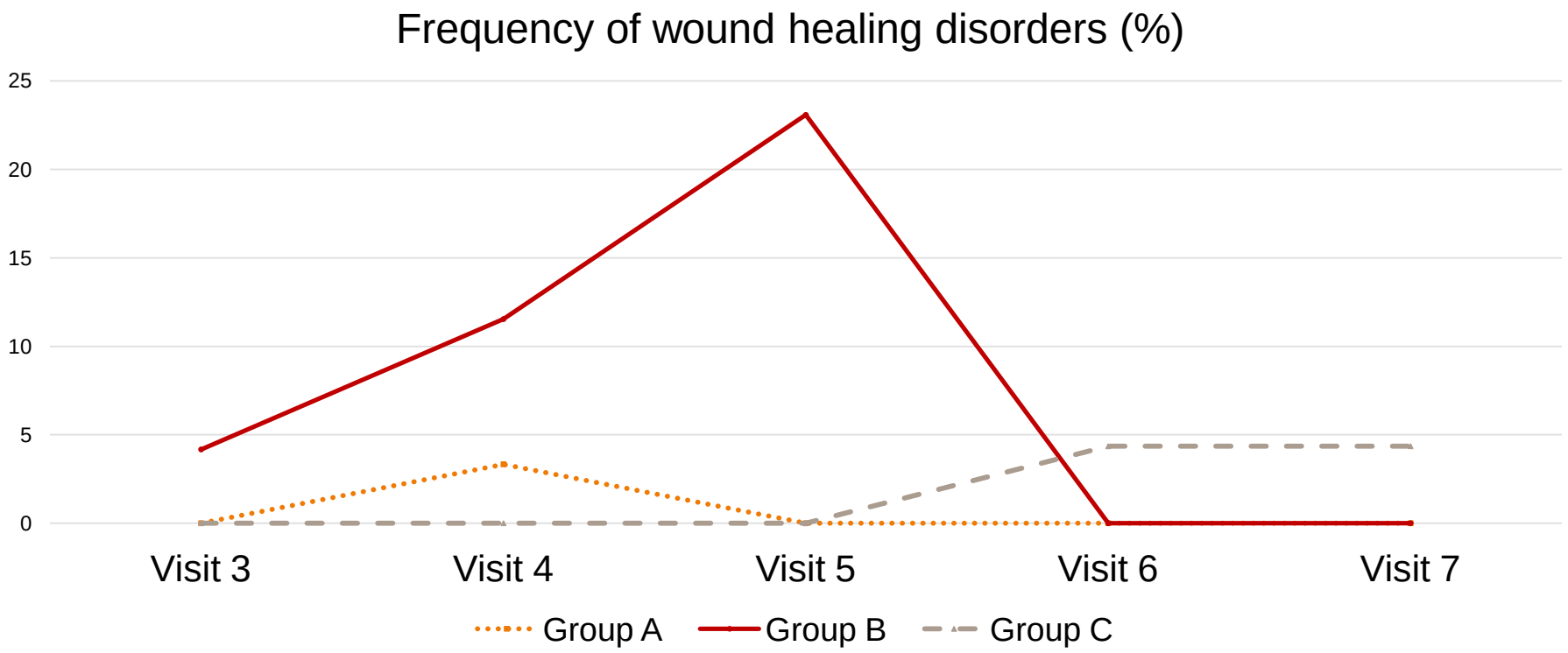


Groups	12 months p-value	24 months p-value
A and C vs. B	0.086	0.026

Postoperative pain VAS (mm)



Wound healing disorders



Overall: 12%

Formation of seromas :
Exclusively using a mesh 18% (6/34)

Serious Adverse Event

27 SAE

7 patients died (6,8%), 2 in Mesh Group

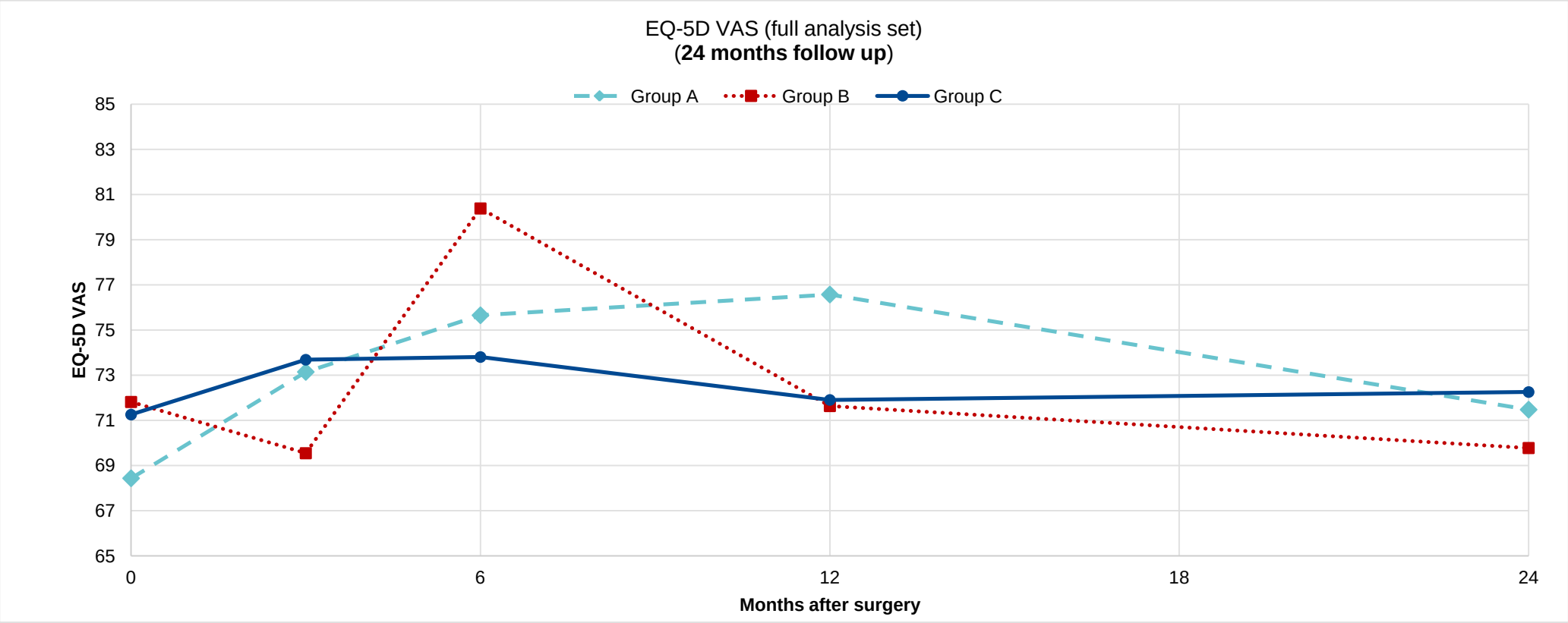
11(10,7%) reoperation

6 (5,8%) re-laparotomy

- 2x Ileus, 1x ischemic bowel,1x dehiscence of abdominal wall , 2x incisional hernias

- 2x Seromas, 1x post Op bleeding, 2 ischaemic leg

Quality of Life



No difference in mean patient health status

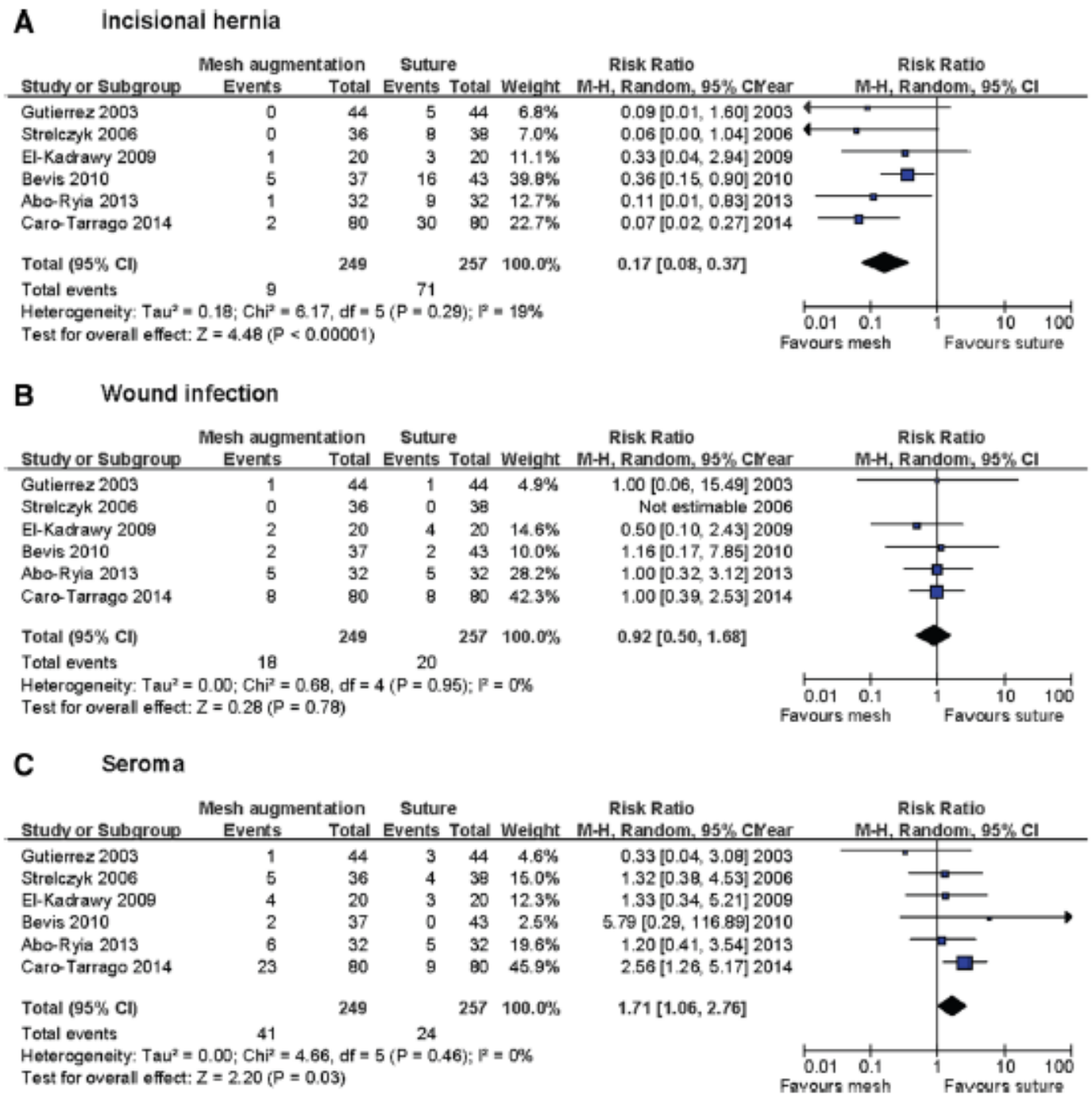
Hernia (2015) 19:1–24
DOI 10.1007/s10029-014-1342-5

REVIEW

European Hernia Society guidelines on the closure of abdominal wall incisions

F. E. Muysoms · S. A. Antoniou · K. Bury · G. Campanelli · J. Conze · D. Cuccurullo · A. C. de Beaux · E. B. Deerenberg · B. East · R. H. Fortelny · J.-F. Gillion · N. A. Henriksen · L. Israelsson · A. Jairam · A. Jänes · J. Jeekel · M. López-Cano · M. Miserez · S. Morales-Conde · D. L. Sanders · M. P. Simons · M. Śmietański · L. Venclauskas · F. Berrevoet

Statement	Prophylactic mesh augmentation for an ele laparotomy in a high-risk patient in order t incisional hernia is suggested.
Statement	No recommendation on the optimal mesh p prophylactic mesh augmentation can be giv
Statement	No recommendation on the optimal method prophylactic mesh augmentation can be giv
Statement	No recommendation on the type of mesh fo augmentation can be given due to lack of da



Surgery. 2017 Apr;161(4):1149-1163. doi: 10.1016/j.surg.2016.09.036. Epub 2016 Dec 28.

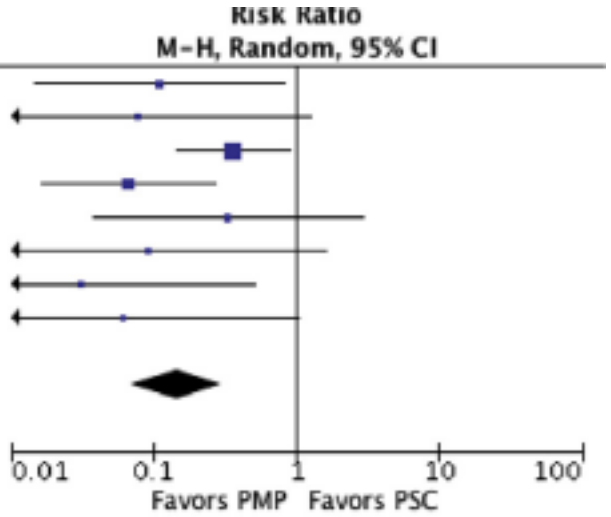
Does prophylactic mesh placement in elective, midline laparotomy reduce the incidence of incisional hernia? A systematic review and meta-analysis.

Borab ZM[1], Shakir S[2], Lanni MA[2], Tecce MG[2], MacDonald J[3], Hope WW[4], Fischer JP[5].

Conclusion. **Prophylactic mesh placement** is associated with an **85% postoperative incisional hernia risk reduction** when compared to primary suture closure in at-risk patients undergoing elective, midline laparotomy closure. This **technique appears to be safe** with comparable complication profiles, **baring an increased risk of seroma**, especially with the onlay technique

Study or Subgroup	PMP Events	PMP Total	PSC Events	PSC Total	Weight	Risk Ratio M-H, Random, 95% CI
Abo-Ryia 2013	1	32	9	32	11.2%	0.11 [0.01, 0.83]
Bali 2015	0	20	6	20	6.2%	0.08 [0.00, 1.28]
Bevis 2010	5	37	16	43	34.7%	0.36 [0.15, 0.90]
Caro-Tarrago 2014	2	80	30	80	19.9%	0.07 [0.02, 0.27]
El Khadrawy 2009	1	20	3	20	9.7%	0.33 [0.04, 2.94]
Gutierrez 2003	0	44	5	44	5.9%	0.09 [0.01, 1.60]
Muysoms 2016	0	56	16	58	6.2%	0.03 [0.00, 0.51]
Strzelczyk 2006	0	36	8	38	6.1%	0.06 [0.00, 1.04]
Total (95% CI)		**325**		**335**	**100.0%**	**0.15 [0.07, 0.30]**
Total events	9		93			

Heterogeneity: $Tau^2 = 0.19$; $Chi^2 = 8.42$, df = 7 (P = 0.30); $I^2 = 17\%$
Test for overall effect: Z = 5.19 (P < 0.00001)



Prevention of incisional hernia with prophylactic onlay and sublay mesh reinforcement versus primary suture only in midline laparotomies (PRIMA): 2-year follow-up of a multicentre, double-blind, randomised controlled trial

An P Jairam, Lucas Timmermans*, Hasan H Eker, Robert E G J M Pierik, David van Klaveren, Ewout W Steyerberg, Reinier Timman, Arie C van der Ham, Imro Dawson, Jan A Charbon, Christoph Schuhmacher, André Mihaljevic, Jakob R Izbicki, Panagiotis Fikatas, Philip Knebel, René H Fortelny, Gert-Jan Kleinrensink, Johan F Lange, Hans J Jeekel, for the PRIMA Trialist Group†*

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p715-820

	Incidence (%)	Odds ratio (95% CI)	p value
All patients with follow-up to 2 years (n=480)			
Primary mesh reinforcement *vs* primary suture*	59/373 (16%) *vs* 33/107 (30%)	0·45 (0·27–0·77)	0·003
Onlay mesh reinforcement *vs* primary suture*	25/188 (13%) *vs* 33/107 (30%)	0·37 (0·20–0·69)	0·0016
Sublay mesh reinforcement *vs* primary suture*	34/185(18%) *vs* 33/107 (30%)	0·55 (0·30–1·00)	0·05
Onlay mesh reinforcement *vs* sublay mesh reinforcement†	25/188 (13%) *vs* 34/185 (18%)	1·39 (0·73–2·65)	0·31
Abdominal aortic aneurysm (n=150)			
Primary mesh reinforcement *vs* primary suture*	20/113 (17%) *vs* 16/37 (43%)	0·29 (0·12–0·67)	0·004
Onlay mesh reinforcement *vs* primary suture*	10/61 (16%) *vs* 16/37 (43%)	0·27 (0·10–0·71)	0·008
Sublay mesh reinforcement *vs* primary suture*	10/52 (19%) *vs* 16/37 (43%)	0·36 (0·13–0·93)	0·03
Onlay mesh reinforcement *vs* sublay mesh reinforcement†	10/61 (16%) *vs* 10/52 (19%)	1·04 (0·32–3·39)	0·95

conclusion

Prophylactic Onlay Mesh....

significant reduction of hernia rate after 24 months

Easy to perform

Seroma more frequent with onlay mesh

No Differences in Wound Infections

Glue versus stitches for mesh fixture ?

Comparison small bite technique ?

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Thank you!

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