

## The philosophy of herniology

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# R.E.P.A.I.R.-group (REsearch Projects for Abdominal surgical Innovation Rotterdam; Erasmus University Medical Center)









## Secret of teamwork: (unconditional) solidarity



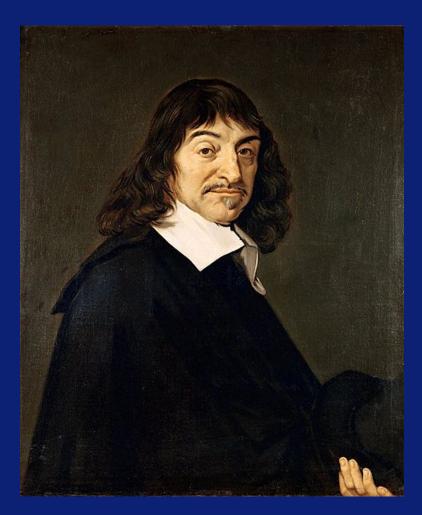
## 'Maître' Hans Jeekel, philosopher of the RCT





# What is herniology? The scientific method





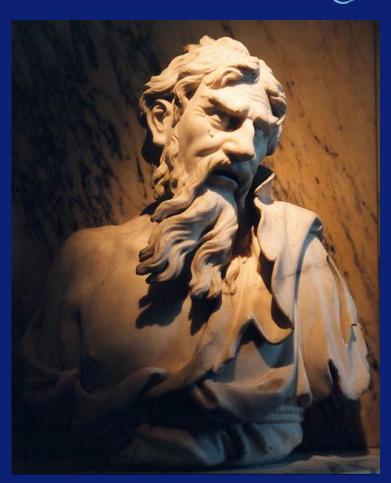
René Descartes 1506-1650



## Herniology in process

Erasmus MC zafuns

- New techniques
- New materials
- Position of Industry
- Concentration/centralisation
- Coordination of research
- Quality systems/ registration/ audits



Heraclitus: 'παντα ρει'

## **New techniques**

- TAR
- Milos
- TREPP
- Malmö
- Chen
- Botox
- Life style
- Prophylaxis
- Robot



## **New techniques Rotterdam**

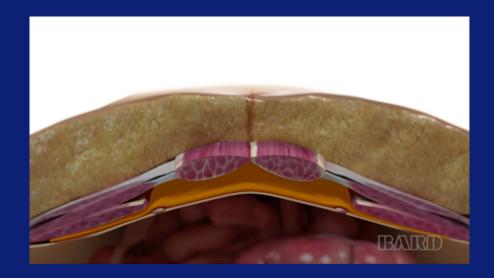


- Int J Surg. 2015 Jan;13:184-8
- Open incisional hernia repair with a self-gripping retromuscular Parietex mesh: a retrospective cohort study.
- Verhelst J<sup>1</sup>, de Goede B<sup>2</sup>, Kleinrensink GJ<sup>3</sup>, Jeekel J<sup>3</sup>, Lange JF<sup>4</sup>, van Eeghem KH<sup>5</sup>.
- INTRODUCTION:
- The Rives-Stoppa and component separation technique are considered to be favourable techniques in the treatment of complex incisional hernias. However, mesh-related complications like chronic pain are still a common problem after mesh repair. As a result, a new self-gripping mesh to omit suture fixation has been developed. This study aimed to evaluate the safety and feasibility of the Parietex™ Progrip self-gripping mesh in retromuscular position for the treatment of incisional hernias.
- METHODS:
- Patients with incisional hernia who underwent repair between June 2012 and June 2014, using a self-gripping mesh in retromuscular position, were included in the study. All patients visited the outpatient clinic to identify postoperative complications and early recurrence.
- RESULTS:
- A total of 28 consecutive patients with a median age of 48 years were included in the study. Twenty-two patients (79%) were diagnosed with an incisional hernia, of whom nine (32%) had a recurrence. Six patients (21%) had an incisional hernia combined with another abdominal wall hernia. The median follow-up was 12 weeks (IQR: 8-20 weeks). Twenty-three patients (82%) did not report any pain at their final outpatient clinic visit; two patients (7%) reported mild abdominal pain, and three patients (11%) had moderate abdominal pain. None of the 28 patients developed a recurrence during follow-up.
- CONCLUSION:
- This is the first study concerning the use of a Parietex™ Progrip mesh placed in retromuscular position. The study shows that it is a safe and feasible prosthesis in incisional hernias repair, as short-term recurrence did not occur and adverse events were limited.

## **New techniques Rotterdam**



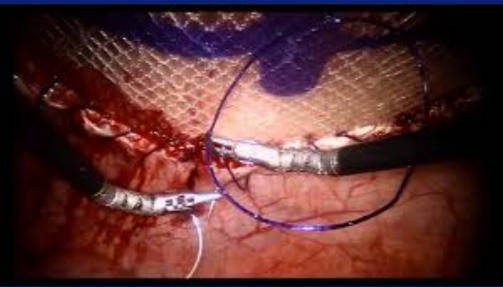
- TAR-ACST
- Small bites



## **New techniques: robotics?**







## **New materials**

- Synthetic slowly resorbable mesh
- Glue

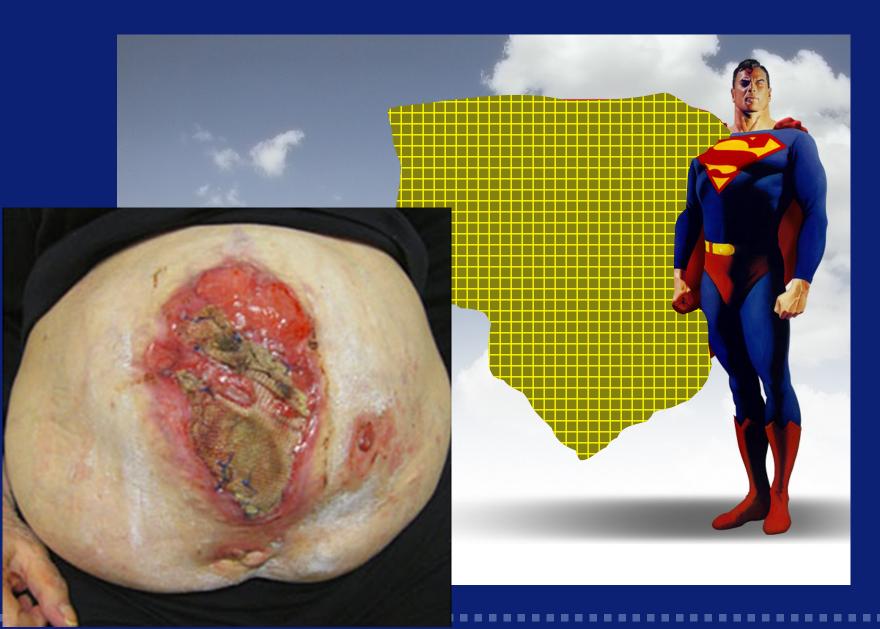






## Supermesh?





### **Customized hernia care**



Biores Open Access. 2016 Jan 1;5(1):6-14

## The Effect of Biomaterials Used for Tissue Regeneration Purposes on Polarization of Macrophages.

Boersema GS1, Grotenhuis N2, Bayon Y3, Lange JF4, Bastiaansen-Jenniskens YM5.

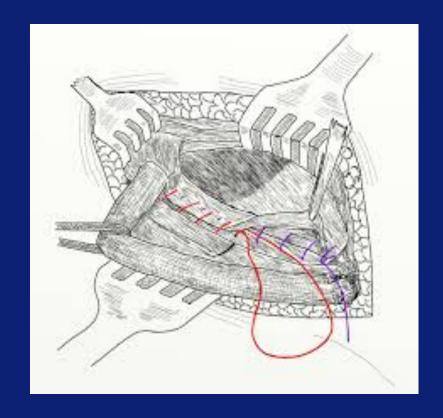
#### Abstract

Activation of macrophages is critical in the acute phase of wound healing after implantation of surgical biomaterials. To understand the response of macrophages, they are often cultured in vitro on biomaterials. Since a wide range of biomaterials is currently used in the clinics, we undertook a systematic review of the macrophage polarization in response to these different surgical biomaterials in vitro. Beside the chemistry, material characteristics such as dimension. pore size, and surface topography are of great influence on the response of macrophages. The macrophage response also appears to depend on the differences in sterilization techniques that induce lasting biochemical changes or residues of chemicals and their byproducts used for sterilization. Regarding tissue-based biomaterials, macrophages on human or porcine dermis, strongly cross-linked by chemicals elicit in general a proinflammatory response with higher amounts of proinflammatory cytokines. Synthetic biomaterials such as polyethylene, polyethylene terephthalate (PET) + polyacrylamide (PAAm), PET + sodium salt of poly(acrylic acid) (PAANa), perfluoropolyether (PFPE) with large posts, PEG-g-PA, and polydioxanone (PDO) always appear to elicit an anti-inflammatory response in macrophages, irrespective of origin of the macrophages, for example, buffy coats or full blood. In conclusion, in general in vitro models contribute to evaluate the foreign body reaction on surgical biomaterials. Although it is difficult to simulate complexity of host response elicited by biomaterials, after their surgical implantation, an in vitro model gives indications of the initial foreign body response and allows the comparison of this response between biomaterials

## **New materials**



• 75% of patients with abdominal wall hernia do not need a mesh, but who are they?!





- Hernia. 2009 Aug;13(4):421-6.
- Low recurrence rate of a two-layered closure repair for primary and recurrent midline incisional hernia without mesh.
- Dur AH<sup>1</sup>, den Hartog D, Tuinebreijer WE, Kreis RW, Lange JF.
- Abstract
- BACKGROUND:
- Incisional hernia is a serious complication after abdominal surgery and occurs in 11-23% of laparotomies. Repair can be done, for instance, with a direct suture technique, but recurrence rates are high. Recent literature advises the use of mesh repair. In contrast to this development, we studied the use of a direct suture repair in a separate layer technique. The objective of this retrospective observational study is to assess the outcomes (recurrences and complications) of a two-layered open closure repair for primary and recurrent midline incisional hernia without the use of mesh.

#### METHODS:

• In an observational retrospective cohort study, we analysed the hospital and outpatient records of 77 consecutive patients who underwent surgery for a primary or recurrent incisional hernia between 1st May 2002 and 8th November 2006. The repair consisted of separate continuous suturing of the anterior and posterior fascia, including the rectus muscle, after extensive intraabdominal adhesiolysis.

#### RESULTS:

• Forty-one men (53.2%) and 36 women (46.8%) underwent surgery. Sixty-three operations (81.8%) were primary repairs and 14 (18.2%) were repairs for a recurrent incisional hernia. Of the 66 patients, on physical examination, three had a recurrence (4.5%) after an average follow-up of 2.6 years. The 30-day postoperative mortality was 1.1%. Wound infection was seen in five patients (6.5%).

#### CONCLUSIONS:

• A two-layered suture repair for primary and recurrent incisional hernia repair without mesh with extensive adhesiolysis was associated with a recurrence rate comparable to mesh repair and had an acceptable complication rate

## **New materials Rotterdam**



Ultimate RCT on incisional hernia surgery:
 Meshless/small bites vs synthetic vs synthetic slowly resorbable



## **Industry**



Integrity vs profit





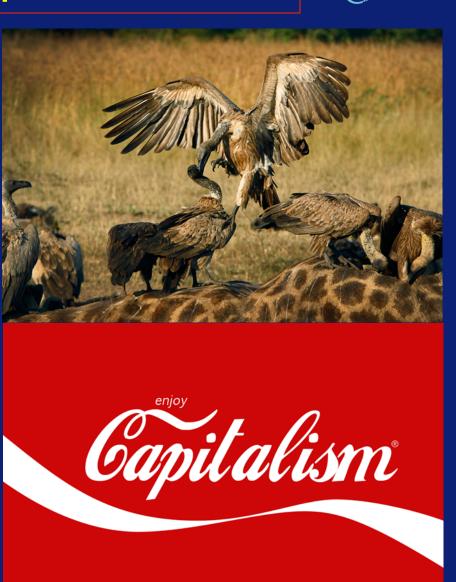
## >150 meshes in Europe!



## Concurring companies: risks?



- Safety?
- Transparance?
- Synergy?
- Long term-perspective?
- RCT's (versus seeding trials)?
- Industry driven courses?





Sunday Mail April 24, 2016 il.co.uk

## GRAND JURY IN STATES PROBE HEALTH SCANDAL

## **It was always** scandalous. A multinational medical equipment firm are facing a criminal investigation in America over claims they. Was it criminal 2

#### ■ Marion Scott

used unapproved and possibly defective resin to make mesh implants sold in Scotland.

Prosecutors have issued subpoenas for documents and witnesses to testify to a grand jury in West Virginia to decide if there are grounds to prosecute.

They have not accused Boston Scientific of wrongdoing and the company deny ordering counterfeit polypropylene resin.

It has been claimed the resin was delivered to America from China via Ireland and Belgium, with small consignments to avoid federal investigation.

The firm say they are co-operating with prosecutors and US medical watchdog the Food and Drug Administration and stand by their mesh products.

The counterfeit resin claims emerged in January when lawyers in Texas filed a suit accusing Boston Scientific of an "international conspiracy" to sell defective mesh.

They also accused the firm of "acting like a drug dealer" to hide shipments of about 33,000lbs of counterfeit plastic resin from US customs.

Amber Mostyn, a US attorney

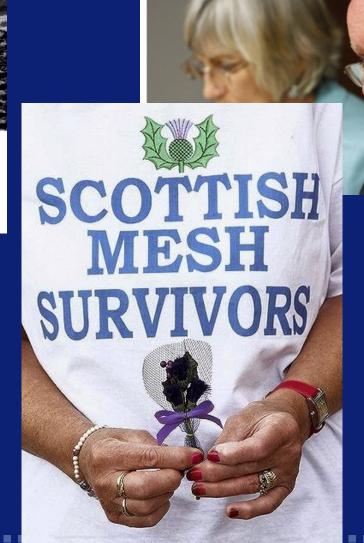
Multinational accused of making mesh with resin secretly smuggled from China



# Mesh Fact: Injuries minimized for shareholder profit.



A vehicle for doctor profit. Mesh disables and Kills! Scottish Health Secretary Alex Neil requests mesh implant suspension



## Intransparance



# NON-DISCLOSURE AGREEMENT

This Agreement is made on DD/MM/YYYY

#### BETWEEN

[The Disclosing Party]

#### AND

[The Receiving Party]

Reference: Information related, but not limited to, development projects and assignments to be performed by the Recipient for the Company.

The Company possesse competitively valuable Confidential Information (as hereinafter defined) regarding its current products, future products, research and development, and general business operations. Recipient may enter or has entered into a business relationship with the Company and in connection therewith may need to review or use the Company's Confidential Information and Materials or to create new Confidential Information and Materials or to create new Confidential Information and Materials for the Company. In consideration of the promises and coverants contained in this Agreement and the disclosure of Confidential Information and Materials from the Company to the Recipient, the parties hereto agree as follows:

#### 1. Confidential Information and Materials

(a) "Confidential Information" shall be written in different parts. Continue writing confidential information and relevant materials of this non disclosure agreement template. "Confidential Information" shall be written in different parts. Continue writing confidential information and relevant materials of this non disclosure agreement template. "Confidential Information" shall be written in different parts. Continue writing confidential information and relevant materials of this non disclosure agreement template.

## **Disclosures?**



60% of hernia surgeons have a financial relation with the industry (Robert Bendavid Can J Surg. 2015 Dec; 58(6): E7–E8)



## The American Hernia Society Corporate Alliance



Corporate Alliance
The American Hernia Society Corporate
Alliance is a group of manufacturers who
provide service and/ or materials to assist
professionals in the diagnosis or treatment
of disorders of the abdominal wall. The
Corporate Alliance is committed to support
scientific programs of the organization.
There are a number of benefits afforded to
Corporate Alliance members. Click here to
download more information.

Maquet Bard Davol Cook Medical Medtronic Ethicon General Surgery News

Gore LifeCell RTI Biologics

Insightra



## **Surgery-Industry**



- Registries
- R&D
- Trust of the scientific societies, funded by the industry, supporting investigator driven research
- Quality label EHS/AHS for meshes





## Concentration/Hernia surgeons/ Hernia centers



- Stimulated by scientific societies (audits)
- Training/certification

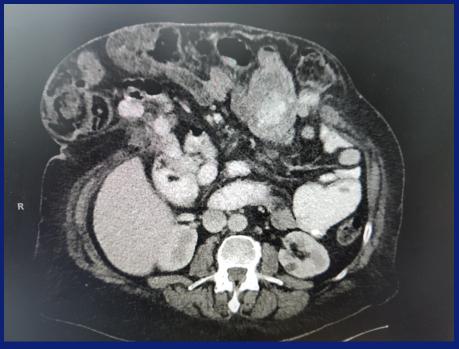




# Concentration of complex abdominal wall surgery







## Coordination



- Leuven-Maastricht-Rotterdam
- Consensus on experimental (animal, histological, mechanical) models



## Registries



■ Is it really science?



- World J Surg. 2013 Nov;37(11):2548-52. doi: 10.1007/s00268-013-2160-0.
- Lower reoperation rate for recurrence after mesh versus sutured elective repair in small umbilical and epigastric hernias.
   A nationwide register study.
- Christoffersen MW<sup>1</sup>, Helgstrand F, Rosenberg J, Kehlet H, Bisgaard T.
- Author information
- Abstract
- BACKGROUND:
- Repair for a small (≤ 2 cm) umbilical and epigastric hernia is a minor surgical procedure. The most common surgical repair techniques are a sutured repair or a repair with mesh reinforcement. However, the optimal repair technique with regard to risk of reoperation for recurrence is not well documented. The aim of the present study was in a nationwide setup to investigate the reoperation rate for recurrence after small open umbilical and epigastric hernia repairs using either sutured or mesh repair.

#### MATERIALS AND METHODS:

This was a prospective cohort study based on intraoperative registrations from the Danish Ventral Hernia Database (DVHD) of patients undergoing elective open mesh and sutured repair for small (≤ 2 cm) umbilical and epigastric hernias. Patients were included during a 4-year study period. A complete follow-up was obtained by combining intraoperative data from the DVHD with data from the Danish National Patient Register. The cumulative reoperation rates were obtained using cumulative incidence plot and compared with the log rank test.

#### RESULTS AND CONCLUSIONS:

In total, 4,786 small (≤ 2 cm) elective open umbilical and epigastric hernia repairs were included. Age was median 48 years (range 18-95 years). Follow-up was 21 months (range 0-47 months). The cumulated reoperation rates for recurrence were 2.2 % for mesh reinforcement and 5.6 % for sutured repair (P = 0.001). The overall cumulated reoperation rate for sutured and mesh repairs was 4.8 %. In conclusion, reoperation rate for recurrence for small umbilical and epigastric hernias was significantly lower after mesh repair compared with sutured repair. Mesh reinforcement should be routine in even small umbilical or epigastric hernias to lower the risk of reoperation for recurrence avoid recurrence.

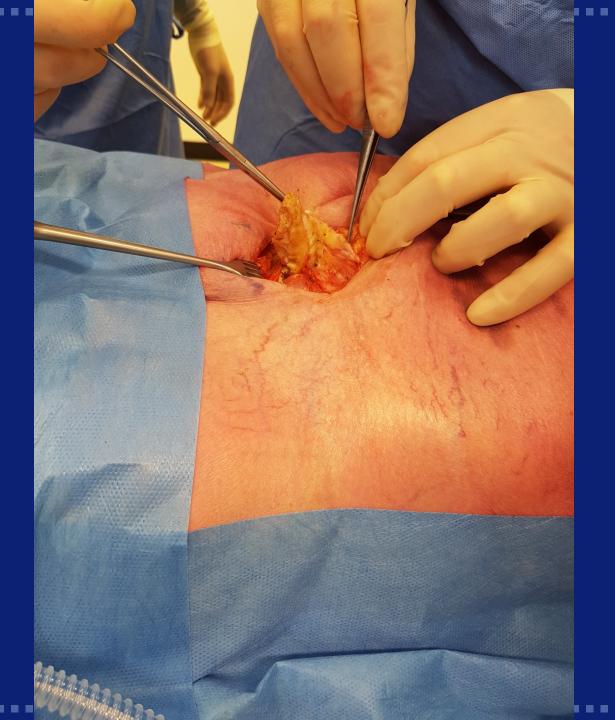
#### TRIAL REGISTRATION:

ClinicalTrials.gov NCT01607801





Erasmus MC 2 afuns



Erasmus MC 2 afung

## **Henri Bergson: intuition>reason**





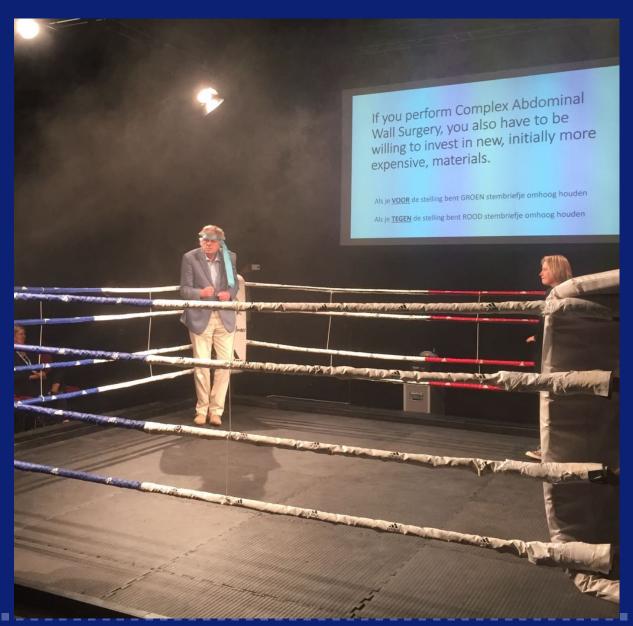
## Registries



# DUTCH SURGICAL COLORECTAL AUDIT



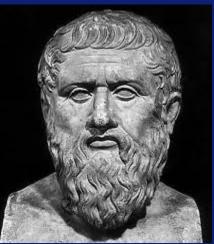


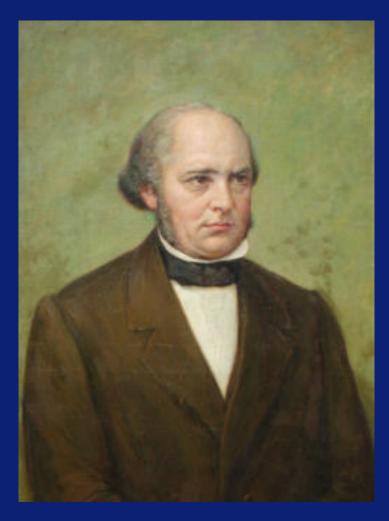


## Plato: let us get liberated from our framing!









Friedrich Albert Lange (1828-1875): 'Science is progressing via spontaneous creative moments like the Mesh congress'



## Without peanut butter we cannot make it!



