Check for updates

CASE REPORT

Case Report: Severe allergic reaction to Physiomes[®] after laparoscopic ventral hernia repair [version 1; peer review: 2 approved with reservations]

Laura Quitzau Mortensen¹ , Thue Bisgaard², Tine Plato Hansen³, Jacob Rosenberg¹

¹Center for Perioperative Optimization, Department of Surgery, Herlev Hospital, University of Copenhagen, Herlev, 2730, Denmark

²Department of Surgery, Hvidovre Hospital, University of Copenhagen, Hvidovre, 2650, Denmark

³Department of Pathology, Herlev Hospital, University of Copenhagen, Herlev, 2730, Denmark

V1 First published: 17 May 2017, 6:685
<https://doi.org/10.12688/f1000research.10798.1>

Latest published: 17 May 2017, 6:685
<https://doi.org/10.12688/f1000research.10798.1>

Abstract

Due to a relative high rate of recurrence compared with other meshes for laparoscopic ventral hernia repair, Physiomes[®] was recalled in 2016. This case report describes one of two reported cases of allergic reaction after insertion of Physiomes[®]. The patient was a 50-year-old male who had a laparoscopic operation for ventral hernia with insertion of Physiomes[®] as an intraperitoneal onlay procedure. Two months later, the patient was admitted with intense epigastric pain, and CT scan showed signs of ileus. Emergency surgery was performed revealing severe allergic signs in the abdomen and retroperitoneum. The mesh was removed. The postoperative course was complicated; the patient had multiple admissions with incomplete ileus, as well as recurrence of the ventral hernia. An open sublay hernia repair using a monofilament polyester mesh was subsequently performed with good effect. This case report illustrates a rare complication with mesh insertion. This adverse event adds to the risk of complications following implantation of mesh to reinforce a hernia repair. The allergic reaction was not suspected until during operation. Therefore, this report also illustrates the importance of surgeons' clinical assessment and ability to take relevant action, which in this case consisted of mesh removal and retrieving tissue samples for histology.

Keywords

Hypersensitivity, allergy, allergic reaction, physiomes, hernia mesh, case report

Open Peer Review

Approval Status

	1	2
version 1
17 May 2017	view	view

1. **Marc Miserez**, KU Leuven, Leuven, Belgium

2. **Ferdinand Köckerling**, Vivantes Hospital
Berlin-Spandau, Berlin, Germany

Any reports and responses or comments on the article can be found at the end of the article.

Corresponding author: Laura Quitzau Mortensen (lauraquitzau@outlook.com)

Competing interests: LQM, TB and TPH have nothing to disclose. JR reports grants from Johnson & Johnson, grants and personal fees from Bard, personal fees from Merck, outside the submitted work.

Grant information: The author(s) declared that no grants were involved in supporting this work.

Copyright: © 2017 Mortensen LQ *et al.* This is an open access article distributed under the terms of the [Creative Commons Attribution License](#), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

How to cite this article: Mortensen LQ, Bisgaard T, Hansen TP and Rosenberg J. **Case Report: Severe allergic reaction to Physiomes[®] after laparoscopic ventral hernia repair [version 1; peer review: 2 approved with reservations]** F1000Research 2017, 6:685 <https://doi.org/10.12688/f1000research.10798.1>

First published: 17 May 2017, 6:685 <https://doi.org/10.12688/f1000research.10798.1>

Introduction

Ventral hernia repair is a common surgical procedure¹. Physiomesh® Flexible Composite Mesh (Ethicon, Somerville, NJ, USA) was recalled in May 2016, due to a higher rate of recurrence and reoperations following laparoscopic ventral hernia repair compared with other meshes (<https://archive.org/details/EthiconPhysiomeshRecall>).

In this case report, we describe a rare complication of using Physiomesh®. Mesh-related allergic reaction following hernia repair has only been described in one previous case report². We present a patient with allergic reaction to Physiomesh® after laparoscopic ventral hernia repair.

Case report

The patient was a 50-year-old male. Ten years prior, the patient had a primary umbilical open non-mesh repair with good effect. The patient's father died of colon cancer. There were no other dispositions. In 2014, the patient had recurrence of the hernia and underwent a laparoscopic intraperitoneal onlay mesh (IPOM) reoperation with insertion of Physiomesh®. The hernia defect, measuring 2.5 cm, was sutured prior to application of a Physiomesh®, measuring 13x13 cm and placed with IPOM technique and fixated with ProTack® (Medtronic/Covidien, CT, USA) with double crown tacks. An emergency operation was performed later the same day due to severe abdominal pain reported by the patient. At the operation, no perforation, bleeding, or pathology was found. The surgeon removed three tacks at the point of maximum pain. The patient received intravenous (i.v) cefuroxime 1.5 g × 2 perioperatively and by oral administration ibuprofen (600 mg × 4) and paracetamol PRN. He was discharged two days later with regained bowel activity and no pain.

Two months later, the patient was readmitted with acute epigastric pain. Blood tests showed leucocytes $19 \times 10^9/l$ and CRP 140 mg/l, with no eosinophilia. An abdominal CT scan was performed, due to suspicion of perforated ulcer. The CT showed signs of ileus with no obvious obstruction or recurrence of the hernia. The patient underwent diagnostic laparoscopy with conversion to laparotomy, due to insufficient overview. The proximal half of the small intestine was dilated with no sign of obstruction or adhesions. The retroperitoneum was edematous, increasing towards the mesh. A thick layer of fibrin was observed in close proximity to the mesh, and the peritoneum was covered by a hard layer of connective tissue, which resembled granulation tissue. Mesh and tacks were removed, and tissue samples were sent for histology. Histology showed inflammation with an allergic foreign body reaction (Figure 1). The tissue samples consisted of soft tissue with chronic inflammation, many infiltrating eosinophils, fibrinoid degeneration, fibrosis, and areas resembling granulation tissue. Scattered birefringent foreign body material was present but there were no giant cells or granulomas. Postoperatively, the patient was treated with analgesics and a nasogastric tube due to pain and nausea, respectively. The patient was discharged 2.5 weeks after his reoperation with normalized bowel function and no pain.

Two weeks later, the patient was readmitted with incomplete ileus. CT showed the small bowel with a thickened wall and gathered in

Figure 1. Tissue sample with inflammation. H&E stained tissue sample taken from peritoneum in close proximity to the Physiomesh®. The histology showed inflammation with an allergic foreign body reaction. Arrow A indicates hyaline fibrosis; arrows B indicates eosinophils, some intact and some degranulated.

a conglomerate. Small bowel follow-through indicated normal passage. The patient was not operated on and was well and discharged four days later. Six months after the mesh was removed, the patient had CT-diagnosed recurrence of his umbilical hernia, as well as a new incisional hernia. The patient did not want another operation, and the hernias were therefore relieved with a truss. Eleven months after removing the mesh, the patient was again admitted with incomplete ileus and was treated non-operatively. Due to strong pain from the umbilical and incisional hernias, the patient had a final surgical procedure 18 months after removal of the Physiomesh®. The hernia defect now measured 10 cm craniocaudally and 8 cm transversely. The surgical procedure was performed as an open repair. The small intestines were adherent to the hernia sac and were only covered by skin. Complete adhesiolysis was performed, and the hernia was repaired with a modified Stoppa procedure with a ProGrip™ mesh (Medtronic/Covidien, CT, USA) in the sublay position. During admission, the patient received standard perioperative antibiotics and analgesics. No further treatment was given. Five days later, the patient was well and discharged. For follow-up, the patient was contacted once by telephone. One year after this final operation, there have been no further admissions to hospital.

Discussion

The focus on foreign body implantation to the abdominal cavity has increased. This is partly due to the recall of Physiomesh® Flexible Composite Mesh on the basis of high rates of recurrence, as well as a recently published study on mesh-related surgical complications³.

We have presented a rare case of allergic reaction to Physiomesh®. The clinical presentation was acute epigastric pain two months after a laparoscopic ventral hernia repair. CT showed ileus with no sign of obstruction or recurrent hernia. The diagnosis of allergic reaction to the mesh was finally confirmed by histological

examination of peritoneal tissue samples with chronic inflammation, many infiltrating eosinophils, fibrinoid degeneration, fibrosis, and areas resembling granulation tissue.

The strengths in the approach to this case were that the surgeons, based on the patient history and the perioperative findings, suspected an allergic reaction. They did so despite the rarity of allergic reaction and no indication from paraclinical tests. Furthermore, based on their assessment, they removed the mesh and took out tissue samples for histological verification. The limitation in the approach to this case was that the allergic reaction was not recognized at the first operation following mesh insertion and the patient had to wait for two months and develop incomplete ileus before the hypersensitivity reaction was diagnosed and the mesh removed.

Hypersensitivity reactions are immune responses that cause tissue injury⁴. Type IV hypersensitivity is the T cell-mediated response, which for instance is involved in contact sensitivity, chronic inflammation, and graft rejection⁴. There are few published reports on hypersensitivity reactions to meshes in general and only one regarding a mesh used for a hernia repair². There are, to the best of our knowledge, no previously published articles reporting hypersensitivity to Physiomesh®. However, an adverse event report has been filed at the U.S. Food and Drug Administration regarding a possible allergic reaction (<https://archive.org/details/MAUDEAdverseEventReportETHICONINC>). Physiomesh® is a polypropylene mesh encapsulated by polydioxanone and coated with a monocryl layer on both sides of the mesh⁵.

In the present case report, the indications that a component of the Physiomesh® was the cause of the allergic reaction were that the edema and the fibrin layer were most pronounced in close proximity to the mesh, that the patient experienced remission of

his symptoms after removal of the mesh, and that the patient experienced no hypersensitivity to the monofilament polyester mesh that was used for the final sublay repair.

Conclusion

We have presented a very rare case of severe allergic reaction to Physiomesh®. This adverse event adds to the risk of complications following implantation of mesh to reinforce a hernia repair. The allergic reaction was not suspected until during operation, since paraclinical tests were not indicative of allergy. Therefore, this case also highlights the importance of surgeons' clinical assessment and ability to take relevant action, which in this case consisted of mesh removal and retrieving tissue samples for histology.

Consent

Written informed consent for publication of the patient's clinical details and/or clinical images was obtained from the patient.

Author contributions

All authors contributed to the acquisition of the data. LQM interpreted the data and drafted the manuscript. TB, TPH and JR revised the manuscript critically. All authors have approved the final manuscript and are accountable for the work.

Competing interests

LQM, TB and TPH have nothing to disclose. JR reports grants from Johnson & Johnson, grants and personal fees from Bard, personal fees from Merck, outside the submitted work.

Grant information

The author(s) declared that no grants were involved in supporting this work.

References

1. Poulouse BK, Shelton J, Phillips S, *et al.*: **Epidemiology and cost of ventral hernia repair: making the case for hernia research.** *Hernia*. 2012; **16**(2): 179–183. [PubMed Abstract](#) | [Publisher Full Text](#)
2. Vedak P, St John J, Watson A, *et al.*: **Delayed type IV hypersensitivity reaction to porcine acellular dermal matrix masquerading as infection resulting in multiple debridements.** *Hernia*. 2015; 1–4. [PubMed Abstract](#) | [Publisher Full Text](#)
3. Kokotovic D, Bisgaard T, Helgstrand F: **Long-term Recurrence and Complications Associated With Elective Incisional Hernia Repair.** *JAMA*. 2016; **316**(15): 1575–1582. [PubMed Abstract](#) | [Publisher Full Text](#)
4. Kobayashi K, Kaneda K, Kasama T: **Immunopathogenesis of delayed-type hypersensitivity.** *Microsc Res Tech*. 2001; **53**(4): 241–245. [PubMed Abstract](#) | [Publisher Full Text](#)
5. Deeken CR, Faucher KM, Matthews BD: **A review of the composition, characteristics, and effectiveness of barrier mesh prostheses utilized for laparoscopic ventral hernia repair.** *Surg Endosc*. 2012; **26**(2): 566–575. [PubMed Abstract](#) | [Publisher Full Text](#)

Open Peer Review

Current Peer Review Status: ? ?

Version 1

Reviewer Report 02 October 2017

<https://doi.org/10.5256/f1000research.11644.r26035>

© 2017 Köckerling F. This is an open access peer review report distributed under the terms of the [Creative Commons Attribution License](#), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

Ferdinand Köckerling

Department of Surgery and Center for Minimally Invasive Surgery, Academic Teaching Hospital of Charite Medical School, Vivantes Hospital Berlin-Spandau, Berlin, Germany

In the presented case report the authors explain the complications after a laparoscopic ventral hernia repair leading to mesh removal with an allergic reaction to Physiomesh. A revisional reoperation due to severe abdominal pain on the same day as the primary operation and high levels of leucocytes and CRP at the time of the second reintervention deliver arguments pro chronic mesh infection. We know from experimental studies that the histological findings of the incorporation of Physiomesh into the abdominal wall show different pictures compared to other composite meshes induced by the absorbable membrane on both sides of Physiomesh (Köckerling et al. 2017¹). As an allergic reaction to synthetic hernia meshes is not reported until today, the authors should discuss other possible explanations for their findings.

References

1. Köckerling F, Simon T, Hukauf M, Hellinger A, et al.: The Importance of Registries in the Postmarketing Surveillance of Surgical Meshes. *Ann Surg*. 2017. [PubMed Abstract](#) | [Publisher Full Text](#)

Is the background of the case's history and progression described in sufficient detail?

Yes

Are enough details provided of any physical examination and diagnostic tests, treatment given and outcomes?

Yes

Is sufficient discussion included of the importance of the findings and their relevance to future understanding of disease processes, diagnosis or treatment?

Partly

Is the case presented with sufficient detail to be useful for other practitioners?

Yes

Competing Interests: Workshop honorarium by Bard and Tutogen

Reviewer Expertise: Mesh technology

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Reviewer Report 03 July 2017

<https://doi.org/10.5256/f1000research.11644.r22919>

© 2017 Miserez M. This is an open access peer review report distributed under the terms of the [Creative Commons Attribution License](#), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

Marc Miserez

University Hospitals, KU Leuven, Leuven, Belgium

Major comment

With the current data provided, I am not convinced we are dealing with an allergic reaction:

- No bacteriology results are provided: are we not dealing with chronic infection?
- Macroscopic picture of intraabdominal findings during reoperation after 2 months is missing
- I am not sure Fig 1 is sufficient to determine an “allergic foreign body reaction”; moreover the authors do not use the histological aspects in their argumentation for an allergic reaction (last paragraph of the discussion); do we have other lab results or patch testing available?
- How do we explain the retroperitoneal inflammation if the problem arises intraabdominally on the ventral abdominal wall?
- Is the patient allergic to prolene, monocryl, polydioxanone or other parts of the mesh? Was patch testing performed? The advice of an allergic/immunology specialist is needed

Minor comment

The authors should give (a) reference(s) on the higher rate of recurrences and reoperations with physiomesh after lap ventral hernia repair; are there any comparable findings described as in this case during reoperation?

Is the background of the case's history and progression described in sufficient detail?

Yes

Are enough details provided of any physical examination and diagnostic tests, treatment given and outcomes?

No

Is sufficient discussion included of the importance of the findings and their relevance to future understanding of disease processes, diagnosis or treatment?

Partly

Is the case presented with sufficient detail to be useful for other practitioners?

No

Competing Interests: Research Grant by Bard; Honorarium by Springer

Reviewer Expertise: Surgery

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

The benefits of publishing with F1000Research:

- Your article is published within days, with no editorial bias
- You can publish traditional articles, null/negative results, case reports, data notes and more
- The peer review process is transparent and collaborative
- Your article is indexed in PubMed after passing peer review
- Dedicated customer support at every stage

For pre-submission enquiries, contact research@f1000.com

F1000Research