A Two-Year Follow-up, Post Implantation, Multi-Center, International Hernia Mesh Registry

Published: 25-09-2012
Last updated: 26-04-2024

The objective of the International Hernia Mesh Registry is to observe a minimum of 3,500 patients for up to 2 years post implantation, in a post-market setting, following the use of either ETHICON Mesh Products or other marketed mesh products to...

Ethical review	Approved WMO
Status	Pending
Health condition type	Soft tissue therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON36942

Source
ToetsingOnline

Brief title
IHMR

Condition

- Soft tissue therapeutic procedures

Synonym
hernia repair or herniorrhaphy

Research involving
Human

Sponsors and support

Primary sponsor: Johnson & Johnson
Source(s) of monetary or material Support: Ethicon and Johnson & Johnson Medical Ltd

Intervention

Keyword: Hernia, Mesh, Registry

Outcome measures

Primary outcome

The co-primary effectiveness variables are to evaluate the outcomes of the

hernia procedure defined as:

• Recurrence of the hernia

• Pain assessment scores provided by patients for the duration of the registry:

o Acute Pain

o Chronic Pain

Secondary outcome

The secondary effectiveness variables include post-operative evaluations

reported by the patients over the two year follow-up, utilizing web-based,

telephoned-based and/or mail systems. These variables will be used to collect

and assess data on each Mesh Product Group.

There will also be information supplied by each surgeon on ETHICON light weight

products handling and duration of operation.

The secondary effectiveness variables will include:

• Assessments of intra-operative handling characteristics for each light weight

ETHICON mesh product.

• Post-operative complications:

o Surgical Site Infection;

- Superficial SSI

- Deep SSI

o Seroma formation

o Hematoma

o Inflammation

o Fistula formation

o Extrusion

o Other device and implantation related adverse events

• Device and implantation procedure related adverse events after the scheduled

the Day of Implantation.

• Operating room time (defined as the time elapsed from first incision to

closure (suture, staples, etc.)

Study description

Background summary

Prosthetic mesh has been used for more than 25 years in the repair of hernia defects (2). A variety of prosthetic materials have been used for abdominal wall replacement with varying results. Complications of synthetic materials have been largely related to the intrinsic tendency of the materials to promote inflammation or serve as a nidus for infection (3).
Despite the advantages and the importance of alloplastic materials, there are a number of theoretical disadvantages arising from mesh use:
• The incorporation of a mass of biomaterial may promote the development of seromas
• The physiological wound healing process induces mesh contraction to some degree, depending on the mesh structure and the corresponding inflammation
• Concomitant scar plates can reduce abdominal wall mobility
• Meshes can migrate and produce persistent inflammation, while explanted meshes can appear bunched, shrunken and folded
• Mesh products have been associated with potentiation of infection, adhesion formation, fistula formation, extrusion and foreign body reaction.
Heavier weight meshes tend to have greater site response due to foreign body reaction. Studies in various animals have shown that the foreign body reaction is lower with lightweight meshes. The biocompatibility of the mesh is improved by a larger pore construction (4).

When operating in contaminated or potentially contaminated fields, such as incarcerated hernias, colorectal surgeries, or incisional hernias in high risk, i.e., highly obese, diabetic or immune-compromised patients, surgeons are reluctant to use permanent materials. This is due to a higher risk for deep mesh infection with the potential of possible bacterial biofilm formation that can occur on permanent material. The literature suggests biologic implants, consisting of animal (small intestine submucosa (SIS) of pigs) or human derived collagen, are frequently used in these situations since they may have less affinity to bacterial attachment, allow for better tissue in-growth and vascularization and induce less postoperative complications because no permanent material remains. Biologic materials show some promising short-term results but they can also lead to complications like seroma formation, high recurrence rates and even infection. Since these meshes fail to provide permanent support, their long-term efficacy is still unknown (5).

(2) Usher FC: *New technique for repairing incisional hernias with Marlex mesh* Am J Surg. 1979; 138; 740-41.
(3) Bauer JJ, Salky BA, Gelernt IM, Kreel I. Repair of Large Abdominal wall defects with expanded polytetrafluorethylene (PFTE). Annals of Surgery 1987; 206:6 765-769.
(4) Cobb WS, Kercher KW, Heniford, BT The Argument for Lightweight Polypropylene Mesh in Hernia Repair. Surg Innovations 2005, 12:1. T1-T7.
(5) Mesh for Contaminate Area (MCA) The treatment of hernias in challenging surgical situations - literature review-Internal ETHICON, Inc. document 2007-2009.

Study objective

The objective of the International Hernia Mesh Registry is to observe a minimum of 3,500 patients for up to 2 years post implantation, in a post-market setting, following the use of either ETHICON Mesh Products or other marketed mesh products to help identify best practices leading to lower recurrence rates and decreases in chronic pain, associated with the hernia repair procedure.

Study design

This is an open-label, multi-center, long-term, prospective hernia mesh registry. A minimum of 3,500 hernia patients will be enrolled at approximately 30-60 sites globally.
Prior to implantation, investigators will seek participation from patients interested in providing long-term, post-surgical, outcomes data for the International Hernia Mesh Registry. Investigators will sequentially enroll patients using any mesh product for hernia repair.

Patients will be enrolled into the registry into one of four Mesh Product Groups:

o Flat Mesh Group
- ULTRAPRO Mesh or other flat mesh for the same type of hernia procedure
o Tissue Separating Flat Mesh Group
- PROCEED Surgical Mesh or a comparable tissue separating mesh for the same type of hernia procedure.
- ETHICON PHYSIOMESHTM or a comparable tissue separating mesh for the same type of hernia procedure
* Tissue Separating Device Group
- PROCEED Ventral Patch or other tissue separating mesh devices for the same type of hernia procedure.
* Non-Tissue Separating Device Group
- ULTRAPRO Hernia System or other mesh device for the same type of hernia procedure.
- ULTRAPRO Plug or other mesh plug device for the same type of hernia procedure.

For each of the selected light weight ETHICON meshes a separate handling characteristic assessment will be completed by each surgeon for their first 5 operations using that mesh.
Patients will be asked to provide internet, mail, or telephone responses post-implantation at approximately Month 1, 6 and Years 1 and 2.. During each contact the patient will be asked to complete a follow up questionnaire, which encompasses any surgically-related issues and CCS which includes a pain assessment. Patients will be contacted by Outcome Sciences, utilizing the patient*s preferred method of contact if their responses have not been received. Outcome staff may complete the questionnaire during the telephone conversation with the patient.
If Outcome Sciences obtains questionnaire information by phone contact where a patient reports a recurrence of their hernia or disabling symptoms on the CCS, they will ask the patient to schedule a follow up visit for review of their symptoms with the original registry surgeon.
If a patient has a re-operation for a recurrence of the hernia for which he/she was entered into the registry, that patient should be discontinued by the surgeon.

Study burden and risks

Participants will receive standard of care for their hernia repair surgery.
The risks associated with participating in the Registry are the same as with any surgical procedure. The Registry does not deviate from normal standard of care at the investigator site.

As specified in the Patient Information Sheet:
"We do not anticipate there to be any side effects or risks linked to participation in the Registry. We will only collate information about how successful your operation was and how long you will be able to enjoy its

benefits. During the study you will be able to contact your surgeon at any time to discuss any concerns you may have.

As with any surgical procedure, there are a number of risks associated with the operation. Your surgeon will already have discussed these with you before you made your decision to undergo the operation, but you may ask him to explain these once again if you wish."

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

4.1. Inclusion Criteria
Patients must satisfy the following criteria before entering the registry:
1. Provide written informed consent;

2. Male or female patients that are > 18 years of age;
3. Be literate and able to understand a language available in the Registry Patient Questionnaires;
4. Be scheduled to receive a surgically implanted mesh product for repair of a hernia defect;
5. Agree to provide long-term, outcomes data to Outcome Sciences;
6. Agree to provide contact information.

Exclusion criteria

4.2. Exclusion Criteria
Patients who meet any of the following criteria will be excluded from participating in the registry:
1. Patients that are <18 years of age;
2. Patients who have been entered into the registry previously;
3. Employees of the investigator or registry center with direct involvement in the proposed registry or other studies under the direction of that investigator or registry center and employees of ETHICON;
4. Patients suffering from and currently receiving medication for chronic pain;
5. Patients known to be suffering from pre-existing chronic depression;
6. Patients currently known or suspected to abuse drugs or alcohol;
7. Patients suffering from a terminal illness (e.g. cancer);
8. Patients requiring multiple hernia repairs utilizing more than one mesh or device (except bilateral femoral, if operated on the same day). Two or more pieces of the same mesh product sewn together will be considered as one mesh, and is therefore allowed in this registry;
9. Patients requiring any other (concomitant) surgical procedure;
10. Patients suffering from an ongoing infection, sepsis, contaminated mesh or fistulas;
11. Patients who require inguinal hernia repair.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2012
Enrollment:	100
Type:	Anticipated

Medical products/devices used

Generic name:	Hernia Mesh
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	25-09-2012
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	15-11-2012
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	19-02-2014
Application type:	Amendment
Review commission:	METOPP: Medisch Ethische Toetsing Onderzoek bij Patienten en Proefpersonen (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT00622583
CCMO	NL41515.028.12