NHS Birmingham and Solihull CCG
NHS Sandwell and West Birmingham CCG

Policy for the use of Biological Mesh

Document Details:

Version:	1.0
Ratified by (name and date of Committee):	Treatment Policy Clinical Development Group 20.12.2019
Date issued for Public Consultation:	02.09.2019
Equality & Quality Impact Assessment	17.01.2020
Joint Health Overview and Scrutiny Committee	23.01.2020
Governing Board	04.02.2020

The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

65. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
66. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
67. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
68. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
69. CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
70. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
71. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
72. All policy decisions are considered within the wider constraints of the CCG's legally responsibility to remain fiscally responsible.

Category: Restricted

Surgical Mesh

Surgical mesh is a screen-like material that is used as a reinforcement for tissue or bone. It can be made of synthetic polymers or biopolymers.

Materials used for surgical mesh include:

- Non-absorbable synthetic polymers (polypropylene)
- Absorbable synthetic polymers (polyglycolic acid or polycaprolactone)
- Biologic (acellular collagen sourced from cows or pigs)
- Composite (a combination of any of the three previous materials e.g. Biosynthetic)

Mesh implants may be used in a number of surgical procedures to provide additional support when repairing weakened or damaged tissue.

Over recent years attention has increased on complications that can occur with the use of this mesh in urogynaecological procedures to treat pelvic organ prolapse (POP) and stress urinary incontinence (SUI). These complications may include persistent pain, sexual problems, mesh exposure through vaginal tissues and occasionally injury to nearby organs, such as the bladder or bowel. There has been an acknowledgement from the NHS England Mesh Working Group that there is a lack of comprehensive data on these complications. Work is ongoing to ensure that patients are encouraged to report complications and clinicians report adverse events.

Currently, the use of mesh in urogynaecological procedures to treat pelvic organ prolapse and stress urinary incontinence is not supported across the NHS and a wider NHS England review of the use of mesh in these clinical circumstances, means that at the current time in line with NHSE recommendation, the CCG does not support the use of mesh implants in these urogynaecological procedures.

However, surgical mesh implants (non-biological mesh) are routinely used across the NHS to address the clinical problem of hernia. A hernia may be inguinal, femoral; umbilical; para-umbilical or incisional. These implants typically restore structural domain to the abdominal/pelvic wall and prevent extrusion of visceral contents. Surgery takes place either as an open or laprascopic procedure.

Open surgery

The surgeon makes a single cut (incision) over the hernia. This incision is usually about 6 to 8cm long. The surgeon then places the lump of fatty tissue or loop of bowel back into your abdomen (tummy). A mesh is placed in the abdominal wall, at the weak spot where the hernia came through, to strengthen it. When the repair is complete, your skin will be sealed with stitches. These stitches usually dissolve on their own over the course of a few days after the operation.

If the hernia has become strangulated and part of the bowel is damaged, the affected segment may need to be removed and the 2 ends of healthy bowel rejoined. This is a bigger operation and you may need to stay in hospital for 4 to 5 days.

Laparoscopic (keyhole) surgery

During keyhole surgery, the surgeon usually makes 3 small incisions in your abdomen instead of a single larger incision. A thin tube containing a light source and a camera (laparoscope) is inserted through one of these incisions so the surgeon can see inside your abdomen. Special surgical instruments are inserted through the other incisions so the surgeon can pull the hernia back into place.

There are 2 types of keyhole surgery.

1. Transabdominal preperitoneal (TAPP)

Instruments are inserted through the muscle wall of your abdomen and through the lining covering your organs (the peritoneum).

A flap of the peritoneum is then peeled back over the hernia and a piece of mesh is stapled or glued to the weakened area in your abdomen wall to strengthen it.

2. Totally extraperitoneal (TEP)

This is the newest keyhole technique and involves repairing the hernia without entering the peritoneal cavity.

Once the repair is complete, the incisions in your skin are sealed with stitches or surgical glue.

Evidence Review

A review of the clinical evidence found mixed clinical review, with no strong basis for the use of biological mesh over standard mesh in standard or first line hernia repair operations (inguinal; umbilical; paraumbilical or incisional). The standard of the evidence reviewed comprised mainly of retrospective studies of low to moderate quality, but with hernia reoccurrence being slightly higher following the use of biological mesh, but no significant difference was determined in the occurrence of wound and mesh infection. It is possible due to the nature of the studies that the high rates of reoccurrence could be accounted for due to the more complex nature of the hernia repairs where biological mesh was utilised. Therefore, in light of the currently available low quality evidence, to support the use of biological mesh over standard mesh, in first line or standard hernia repair procedures, the use of biological or bio-synthetic mesh is not routinely commissioned.

However, the use of biological or biosynthetic mesh in hernia repair may be undertaken when first line hernia repair surgery with permanent synthetic mesh or conservative treatment has failed or is inappropriate to use synthetic mesh and the use of biological / biosynthetic mesh has been deemed the most clinically appropriate surgical intervention by a complex abdominal wall repair multidisciplinary team.

Eligibility Criteria: Restricted

The use of biological or biosynthetic mesh in standard hernia (inguinal; femoral; umbilical, para-umbilical and incisional) repair is Not Routinely Commissioned.

The use of biological or biosynthetic mesh in hernia repair is only to be undertaken when:

- first line hernia repair surgery with permanent synthetic mesh followed by conservative wound care management has failed

OR

- first line hernia repair surgery with permanent synthetic mesh followed by conservative wound care management is deemed inappropriate

In ALL surgical cases, where the use of biological / biosynthetic mesh is to be considered for use in hernia repair, the patient must be reviewed by a specialist complex abdominal wall repair MDT and the use of biological / biosynthetic mesh must be deemed the most clinically appropriate surgical intervention by a complex abdominal wall repair MDT.

Conservative wound care management is defined as follows:

- Wound care management plan developed for the individual patient by the specialist wound care management team has failed.

Investigations for suspected or proven malignancy are outside the scope of this policy and should be treated in line with the relevant cancer pathway.

This means **(for patients who DO NOT meet the above criteria)** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

Guidance

1. Barber, S. 2018. BRIEFING PAPER: Surgical mesh implants. Number CBP 8108, 15 January 2018. House of Commons Library. https://www.baus.org.uk/_userfiles/pages/files/Patients/CBP-8108.pdf

2. RCOG. (2019) https://www.rcog.org.uk/globalassets/documents/guidelines/safety-alerts/nhs-mesh-letter-extension-of-pause-on-the-use-of-vaginal-mesh-29-march-2019.pdf

3. F. Köckerling, N. N. Alam, S. A. Antoniou, I. R. Daniels, F. Famiglietti, R. H. Fortelny, M. M. Heiss, F. Kallinowski, I. Kyle-Leinhase, F. Mayer, M. Miserez, A. Montgomery, S. Morales-Conde, F. Muysoms, S. K. Narang, A. Petter-Puchner, W. Reinpold, H. Scheuerlein, M. Smietanski, B. Stechemesser, C. Strey, G. Woeste, N. J. Smart. What is the evidence for the use of biologic or biosynthetic meshes in abdominal wall reconstruction? Hernia. 2018; 22(2): 249–269. Published online 2018 Jan 31. doi: 10.1007/s10029-018-1735-y https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5978919/

4. James F. FitzGerald, Anjali S. Kumar. 2014. Biologic versus Synthetic Mesh Reinforcement: What are the Pros and Cons? Clin Colon Rectal Surg. 2014 Dec; 27(4): 140–148. doi: 10.1055/s-0034-1394155 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4477030/

5. Majumder A[1], Winder JS[2], Wen Y[1], Pauli EM[2], Belyansky I[3], Novitsky YW[4]. 2016. Comparative analysis of biologic versus synthetic mesh outcomes in contaminated hernia repairs. Surgery. 2016 Oct;160(4):828-838. doi: 10.1016/j.surg.2016.04.041. Epub 2016 Jul 21. https://www.ncbi.nlm.nih.gov/pubmed/27452954

6. Carver DA, Kirkpatrick AW, Eberle TL, *et al.* 2018. Performance of biological mesh materials in abdominal wall reconstruction: study protocol for a randomised controlled trial. BMJ Open 2019;9:e024091. doi: 10.1136/bmjopen-2018-024091 . https://bmjopen.bmj.com/content/9/2/e024091

7. C. S. Seefeldt; J. S. Meyer; J. Knievel; A. Rieger; R. Geißen,R. Lefering; M. M. Heiss (2019) BIOLAP: biological versus synthetic mesh in laparo-endoscopic inguinal hernia repair: study protocol for a randomized, multicenter, self-controlled clinical trial. *Trials*2019**20**:55. https://doi.org/10.1186/s13063-018-3122-5https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-018-3122-5

8. Loes Knaapen, Otmar Buyne, Harry van Goor, Nicholas J (2016) Synthetic vs biologic mesh for the repair and prevention of parastomal hernia. *World J Meta-Anal* 2017 December 26; 5(6): 150-166. DOI: 10.13105/wjma.v5.i6.150. https://f6publishing.blob.core.windows.net/66e60003-20b2-4ada-9595-26b5152dc122/WJMA-5-150.pdf

9. David A Carver, Andrew W Kirkpatrick, Tammy L Eberle, Chad G Ball (2019)Performance of biological mesh materials in abdominal wall reconstruction: study protocol for a randomised controlled trial BMJ Open. 2019; 9(2): e024091. Published online 2019 Feb 15. doi: 10.1136/bmjopen-2018-024091

10. Hubert Scheuerlein, Andreas Thiessen, Christine Schug-Pass, Ferdinand Köckerling. (2018)What Do We Know About Component Separation Techniques for Abdominal Wall Hernia Repair? Front Surg. 2018; 5: 24. Published online 2018 Mar 27. doi: 10.3389/fsurg.2018.00024