BRITISH SOCIETY OF UROGYNAECOLOGY (BSUG)

MESH COMPLICATIONS SURGERY IN THE UK 2020 TO 2021

2ND NATIONAL REPORT

BSUG AUDIT AND DATABASE COMMITTEE 2024

BSUG Audit Database 2024
Registered charity No 1143157

Contents

Abbreviations

- British Society of Urogynaecology (BSUG)
- International Continence Society (ICS)
- International Urogynaecological Association (IUGA)
- Medicines and Healthcare Products Regulatory Agency (MHRA)
- Mid-urethral tape (MUT)
- Multi-disciplinary team (MDT)
- National Health Service (NHS)
- National Institute for Health and Care Excellence (NICE)
- Patient-reported global impression of improvement (PGI-I)
- Pelvic organ prolapse (POP)
- Patient-reported outcome measures (PROMs)
- Royal College of Obstetricians and Gynaecologists (RCOG)
- Stress Urinary Incontinence (SUI)
- Urinary incontinence (UI)

Preface

The British Society of Urogynaecology (BSUG) database has been available online since 2007. Its users can record details and outcomes of procedures for urinary incontinence, pelvic organ prolapse and mesh complications.

Thanks to the commitment of BSUG members - and the patients who kindly allowed their data to be recorded - the database has been utilised widely. Its use is supported by the National Institute for Health and Care Excellence (NICE) and is a prerequisite for BSUG accreditation of urogynaecology units in the UK. The database currently holds information on more than 170000 individual surgical episodes from across the UK. This wealth of information has generated national audits on operations for stress urinary incontinence and pelvic organ prolapse along with many publications which are listed on the BSUG website. At an individual level, consultants find the database useful for evaluating their own practice and for the purposes of annual appraisal and revalidation.

Continual improvements to the relevance and functionality of the database are being made, thanks to many consultants who have volunteered their time and expertise. Since November 2017, the database has been updated to capture more detailed information on surgery performed to treat mesh complications.

This is the second national report on Surgery for Mesh Complications from the BSUG Audit and Database Committee and covers the years 2020 and 2021. Since April 2021, all mesh complications are referred to designated specialist mesh centres for treatment. Currently there are 9 such centres in England.

Mesh surgery has never been under more scrutiny and publication of this report comes at an opportune time. In writing the report a conscious decision was taken to not interpret or comment on the results apart from where an explanation was necessary.

BSUG Audit and Database Committee 2024

CHAPTER 1: Introduction

1.1 BSUG DATABASE

The British Society of Urogynaecology (BSUG) database was established in 2004 and launched online in 2007. It collects data on operations for urinary incontinence (UI), pelvic organ prolapse (POP) and mesh complications. The database is held within the secure NHS N3 network and access to it is password protected. Patient consent is necessary for data entry. The database is accessible to BSUG members only and its use is voluntary.

1.2 AUDIT TIMEFRAME

The timeframe of the audit was from the start of 2020 to the end of 2021.

1.3 DATABASE USAGE

Data on mesh complication surgery was uploaded by 78 UK centres.

1.4 LIMITATIONS

The BSUG database is a voluntary database used by individual surgeons to record outcomes of their surgical procedures. Mesh complication operations are also undertaken by urologists, colorectal surgeons and consultants who have chosen not to be BSUG members. Therefore, not every operation performed for the treatment of mesh-related problems during the timeframe of the audit will be included in this analysis.

In addition, caution must be applied to the use and interpretation of this report because of missing data and the limited recording of long-term outcomes – both positive and negative. This is particularly the case for long-term complications which may arise after the initial period of follow-up, some of which will be treated in other units.

1.5 OPERATIONS INCLUDED

The database allows users to record prespecified mesh complication procedures. The current options for mesh complication operations are:

1. Abdominal removal of sacrocolpopexy mesh (Open/laparoscopic/robotic)
2. Burial of mesh/graft exposure vaginally (No mesh removed)
3. Excision vaginal part of MUT (Not exposed/eroded)
4. Localised excision and closure of transvaginal mesh exposure
5. Excision of mesh erosion (Bladder)
6. Excision of mesh erosion (Bowel)
7. Excision of mesh erosion (Urethra)
8. Partial removal of retropubic tape (Open/laparoscopic/robotic)
9. Suburethral tape - divided
10. Suburethral tape - stretched
11. Total excision of vaginal mesh for pelvic organ prolapse
12. Total removal of retropubic tape (Open/laparoscopic/robotic)
13. Total removal of transobturator tape
14. Excise mesh erosion

CHAPTER 2: Numbers and trends

2.1 NUMBER OF SURGICAL PROCEDURES TO TREAT MESH COMPLICATIONS AND TRENDS

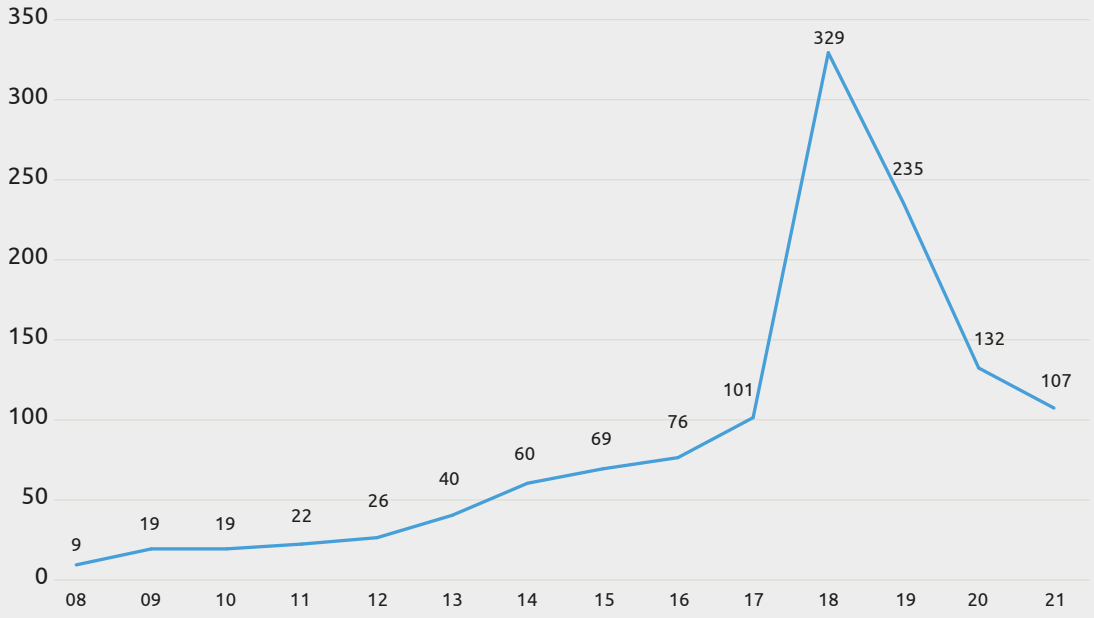
At the end of 2021, there were 1244 operations for mesh complications reported on the database.

Centres entering data included all NHS hospitals and private hospitals conducting these procedures as well as operations carried out by trainees on patients under the care of consultants. These cases are included in the audit as they cannot be easily separated.

Table 1: *Number of mesh complication surgical episodes 2008-2021*

Year	Mesh complication operations, n
2008	9
2009	19
2010	19
2011	22
2012	26
2013	40
2014	60
2015	69
2016	76
2017	101
2018	329
2019	235
2020	132
2021	107
Total	**1244**

Figure 1: *Number of mesh complication surgical episodes 2008-2021*



2.2 COMPARISON WITH MHRA DATA

Mesh-related adverse incidents reported to the MHRA [2] were compared to figures for the corresponding years from the BSUG database *(Table 2)*. MHRA incidents consist of mesh-related problems resulting from mesh operations for both POP and SUI and includes cases that may not have undergone surgery along with incidents of device malfunction. Whilst users of the BSUG database are healthcare professionals, MHRA incidents may be reported by both professionals and members of the public so each case is more likely to have been reported more than once. BSUG data is likely to underestimate the actual number of mesh-related problems in the UK.

Table 2: *Comparison of MHRA and BSUG data 2014-2021*

Year	MHRA incidents	BSUG episodes
2014	160	60
2015	271	69
2016	176	76
2017	689	101
2018	1066	329
2019	674	235
2020	401	132
2021	316	107

CHAPTER 3: Preoperative preparation

3.1 USE OF THE ICS/IUGA CLASSIFICATION FOR MESH COMPLICATIONS

The BSUG database allows the ICS/IUGA code for mesh complications to be recorded. A link in the database directs the user to an online code calculator. The code provides information regarding the category, timing, site and pain characteristics of the complication. This function was introduced in February 2012.

Since the introduction of this function, the ICS/IUGA mesh complication code was recorded in 233 (19.5%). The complication code was reported in 50 % (66/132) and 40% (43/107) of episodes in 2020 and 2021 respectively.

3.2 REPORTING MESH COMPLICATIONS TO THE MHRA

The database records whether a mesh complication episode has been reported to the MHRA through the Yellow Card Scheme. A link in the database directs the user to the MHRA website. This function was introduced in July 2017.

Since the introduction of this function, 366 (41.2%) episodes were recorded as having been reported to the MHRA. 83% (109/132) and 78% (83/107) of episodes from 2020 and 2021 were reported to the MHRA respectively.

3.3 MULTIDISCIPLINARY TEAM DISCUSSION

The database allows the user to record whether preoperative MDT review occurred. The section on surgery for mesh complications was added to the database in November 2017 and since then, a majority have had an MDT review. In 2020 and 2021, 88.7% of cases had been discussed at MDT *(Table 3)*.

Table 3: *Preoperative MDT review*

	n (%)
Unrecorded	25 (10.4)
No	2 (0.9)
Yes	212 (88.7)
Total	**239**

3.4 PROVISION OF PROCEDURE-SPECIFIC INFORMATION

The database allows the user to record whether procedure-specific information was provided to patients. In 2020 and 2021, procedure-specific information was provided prior to mesh complication surgery in 132 (55.2%) episodes *(Table 4)*.

Table 4: *Provision of procedure-specific information*

	n (%)
Unrecorded	64 (26.8)
No	43 (18)
Yes	132 (55.2)
Total	**239**

CHAPTER 4: Surgical data

4.1 INDICATIONS FOR MESH COMPLICATION SURGERY

Prespecified indications for surgery can be entered into the database. These options were added to the database in November 2017 and were available throughout the timeframe of the audit. They are:

1. Pain
2. Dyspareunia
3. Mesh erosion
4. Voiding dysfunction
5. Urgency
6. Urinary incontinence
7. Infection
8. Patient choice

In 2020 and 2021, 41.8% (249) of episodes had one indication for surgery *(Table 5)*. 58.2% (347) of episodes had more than one indication. Where multiple indications were present, it was not possible to determine the main indication.

Table 5: *Indications for surgery*

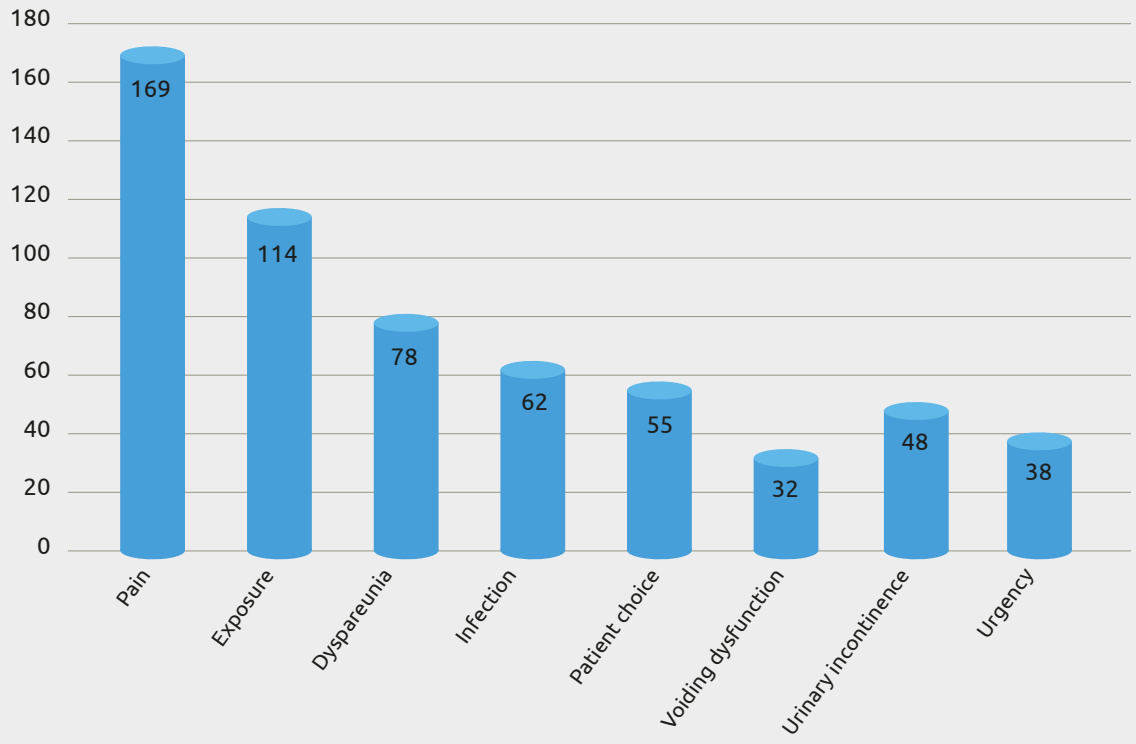
	n (%)
Unrecorded	6 (2.5)
1 indication	31 (13)
More than 1 indication	202 (84.5)
Total	**239**

The most common indications for surgery were pain (28.2%) followed by mesh erosion (23.4%) and dyspareunia (16.6%). It is not possible to ascertain the incidence of these mesh problems as the actual number of mesh complications and mesh implant operations during this timeframe is unknown. Patient choice comprised 7.6% of all indications for surgery *(Table 6, Figure 2)*.

Table 6: *Individual indications for mesh complication surgery*

	n (%)
Pain	169 (28.4)
Mesh erosion	114 (19.1)
Dyspareunia	78 (13.1)
Infection	62 (10.4)
Patient choice	55 (9.2)
Voiding dysfunction	32 (5.4)
Urinary incontinence	48 (8.1)
Urgency	38 (6.3)
Total	**596**

Figure 2: *Individual indications for mesh complication surgery*



4.2 PREVIOUS MESH OPERATIONS FOR UI AND POP

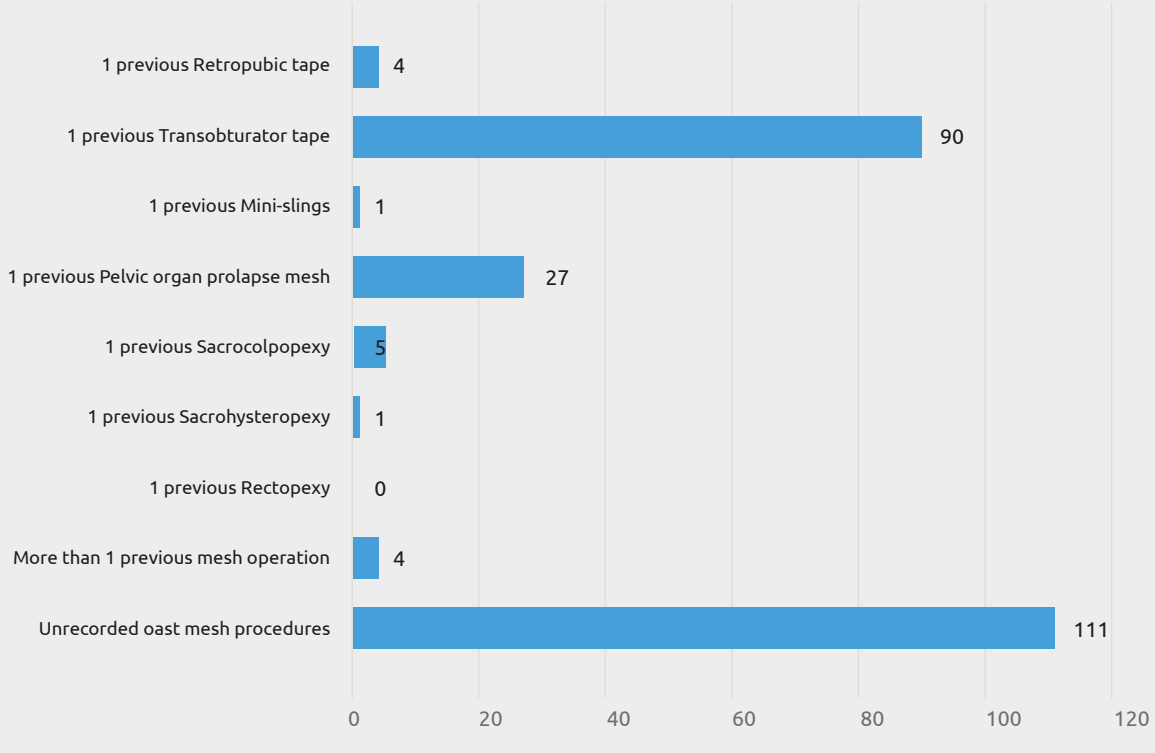
88.2 % (794) of episodes had 1 previous mesh operation for POP or UI. In this group, the commonest operations were retropubic tapes (45.2%) followed by transobturator tapes (19.5%) and transvaginal mesh operations for POP (16.3%) *(Table 7, Figure 3)*. It was not possible to calculate the incidence of mesh complications of these procedures as the actual number of mesh complications and mesh implant operations during this timeframe is unknown.

11.2% (100) of episodes had more than 1 previous mesh operation for POP or UI *(Table 7)*. In this group, it was not possible ascertain which operation caused the mesh complication.

Table 7: *Previous mesh procedures*

	n (%)
Unrecorded	110 (45.7)
More than 1 previous mesh operation	4 (1.6)
1 previous retropubic tape	4 (1.7)
1 previous transobturator tape	90 (37)
1 previous vaginal mesh for POP	27 (11.1)
1 previous sacrocolpopexy	5 (2.1)
1 previous mini sling	1 (0.4)
1 previous sacrohysteropexy	1 (0.4)
1 previous rectopexy	0
Total	**243**

Figure 3: *Previous mesh procedures*



4.3 TYPES OF MESH COMPLICATION OPERATIONS

The commonest operations for mesh complications were 'Localised excision and closure of vaginal mesh exposure' (23.5%) followed by 'Total removal of retropubic tape' (21.3%) and 'Excise mesh erosion' (19.1%) *(Table 8)*.

8.4% of operations involved the excision of mesh from the bladder, bowel or urethra. In this group, 73.5% were for presence of mesh in the urethra.

Table 8: *Operations for mesh complications*

PGII	n (%)
Localised excision and closure of transvaginal mesh exposure	191 (23.5)
Total removal of retropubic tape (open/laparoscopic/robotic)	173 (21.3)
Excise mesh erosion	192 (19.1)
Excision vaginal part of MUT (not exposed/eroded)	133 (16.4)
Total removal of transobturator tape	71 (8.7)
Total excision of vaginal mesh for pelvic organ prolapse	59 (7.3)
Partial removal of retropubic tape (open/laparoscopic/robotic)	52 (6.4)
Unanswered	292
Excision of mesh erosion (urethral)	50 (6.2)
Burial of mesh/graft exposure vaginally (no mesh removed)	36 (4.4)
Suburethral tape - divided	18 (2.2)
Excision of mesh erosion (bladder)	16 (2.0)
Suburethral tape - stretched	6 (0.7)
Abdominal removal of sacrocolpopexy mesh (open/laparoscopic/robotic)	6 (0.7)
Excision of mesh erosion (bowel)	2 (0.2)
Total	**1005**

4.4 PRIMARY AND REPEAT OPERATIONS

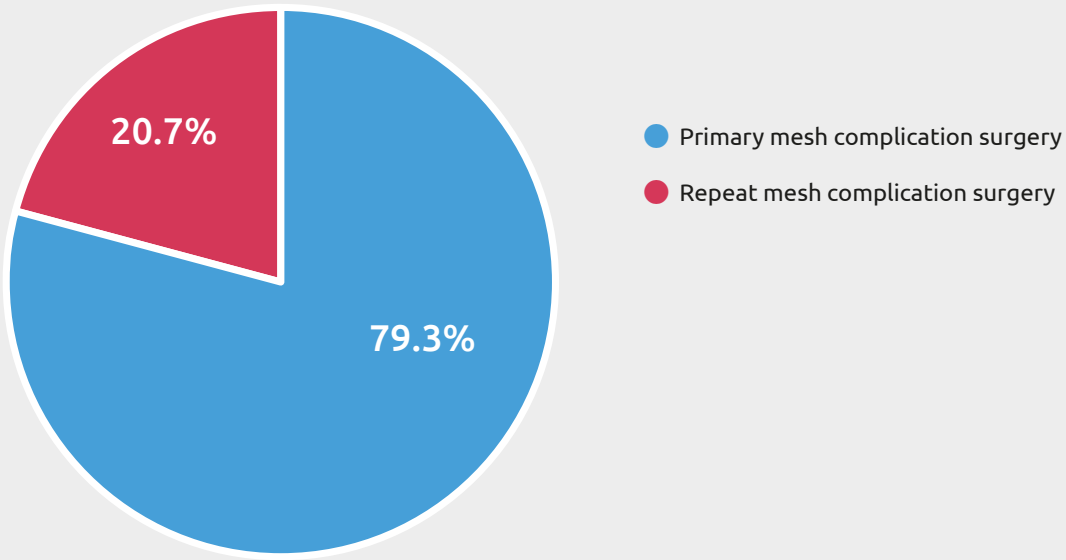
The database allows users to record whether an operation is for a patient's first mesh complication or for a recurrent problem.

79.3% (591) of episodes had first time surgery for mesh complications. 20.7% (154) were repeat operations *(Table 9, Figure 4)*.

Table 9: *Primary and repeat mesh complication operations*

	n (%)
Primary mesh complication surgery	591 (79.3)
Repeat mesh complication surgery	154 (20.7)
Unrecorded	260
Total	**1005**

Figure 4: *Primary and repeat mesh complication operations*



4.5 SOLE PROCEDURES AND THOSE WITH CONCOMITANT OPERATIONS

12.5% (125) of mesh complication operations had concomitant operations for POP or UI. In this group, 68.0% (85) of these concomitant procedures were for UI and 32.0% (40) for POP *(Table 10, Figure 5)*.

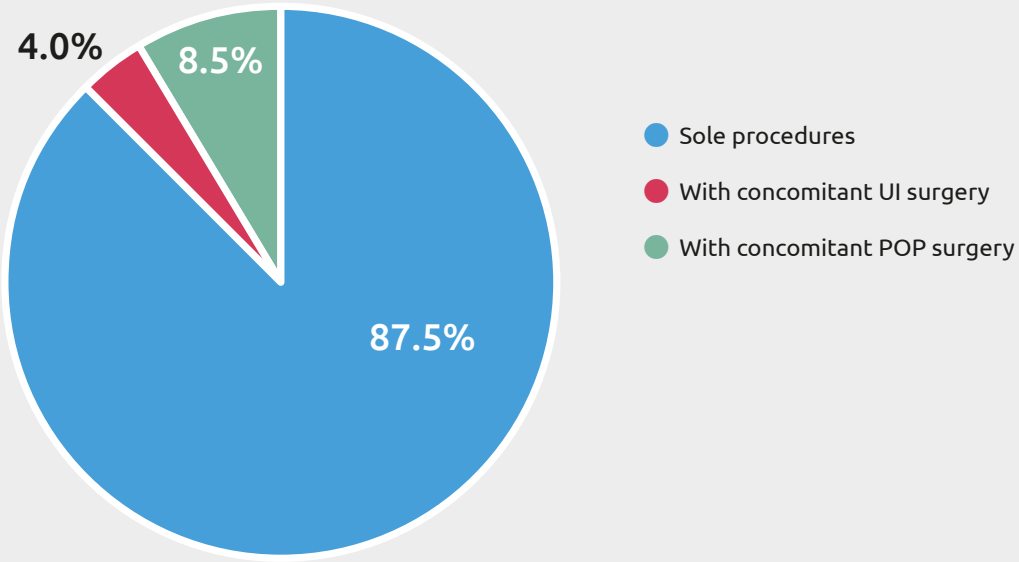
Concomitant procedures for POP were transvaginal repairs (64.8%, 81) and transabdominal repairs (3.2%, 4).

Concomitant procedures for UI were autologous fascial slings (18.4%, 23) and colposuspensions (13.6%, 17).

Table 10: *Sole procedures and procedures with concomitant operations*

	n (%)
Sole procedures	880 (87.5)
With concomitant UI surgery	40 (4.0)
With concomitant POP surgery	85 (8.5)
Total	**1005**

Figure 5: *Sole procedures and procedures with concomitant operations*



CHAPTER 5: Complications

5.1 COMPLICATIONS RECORDED

The database records prespecified intraoperative and postoperative complications. They are:

1. Ureteric injury
2. Bladder injury
3. Vaginal buttonhole
4. Urethral injury
5. Bowel injury
6. Vascular injury
7. Neurological injury
8. Estimated blood loss >500 ml
9. Perioperative blood transfusion
10. Thromboembolism
11. Return to theatre within 72 hours of the procedure
12. Catheterisation >10 days
13. Readmission within 30 days of the procedure
14. Death

5.2 ASSIGNMENT OF RISK FOR COMPLICATIONS

The incidence of each intraoperative and postoperative complication was assigned a level of risk based on guidance by the Royal College of Obstetricians and Gynaecologists [3] *(Table 11)*.

Table 11: *RCOG assignment of risk*

Term	Equivalent numerical ratio	Colloquial equivalent
Very common	1/1 to 1/10	A person in a family
Common	1/10 to 1/100	A person in a street
Uncommon	1/100 to 1/1000	A person in a village
Rare	1/1000 to 1/10 000	A person in a small town
Very rare	Less than 1/10 000	A person in a large town

5.3 INCIDENCE OF COMPLICATIONS

The most common intraoperative complications were blood loss >500 ml (1.4%) followed by urethral injury (1.2%) and bladder injury (0.8%) *(Table 12)*.

The most common postoperative complications were catheterisation >10 days (3.2%) followed by reoperation within 72 hours (0.6%) and readmission within 30 days (0.6%) *(Table 12)*.

Table 12: *Intraoperative and postoperative complications*

Complication (recorded outcomes)	Incidence, n (%)	Risk
Ureteric injury (966)	1 (0.1)	1 in 1000 Uncommon
Bladder injury (968)	8 (0.8)	1 in 125 Uncommon
Vaginal buttonhole (916)	3 (0.3)	1 in 333 Uncommon
Urethral injury (916)	11 (1.2)	1 in 83 Common
Bowel injury (967)	5 (0.5)	1 in 200 Uncommon
Vascular injury (966)	0	Very Rare
Neurological injury (966)	0	Very Rare
Estimated blood loss >500 ml (967)	14 (1.4)	1 in 71 Common
Perioperative blood transfusion (964)	3 (0.3)	1 in 333 Uncommon
Thromboembolism (956)	0	Very Rare
Death (956)	1 (0.1)	1 in 1000 Rare
Return to theatre within 72 hours (484)	3 (0.6)	1 in 167 Uncommon
Catheterisation >10 days (466)	15 (3.2)	1 in 31 Common
Readmission within 30 days (467)	3 (0.6)	1 in 167 Uncommon

CHAPTER 6: Follow-up

6.1 FOLLOW-UP METHOD AFTER SURGERY

Prespecified methods of follow-up can be recorded in the database.

The follow-up method was recorded in 43% (442) of episodes. 97.5% (431) were followed-up in clinic *(Table 13)*.

Table 13: *Follow-up method*

	n (%)
Unrecorded	563
Outpatient visit	431 (97.5)
Postal questionnaire	1 (0.2)
Telephone response	10 (2.3)
Total	**1005**

6.2 FOLLOW-UP INTERVAL AFTER SURGERY

The database records the interval to the 1st follow-up after surgery at 4 prespecified intervals: 6 weeks, 3 months, 6 months and 1 year.

438 (44%) episodes had the 1st follow-up interval recorded. The 1st follow-up occurred most frequently at 3 months (64.6%) *(Table 14)*.

Table 14: *Follow-up interval after surgery*

	n (%)
Unrecorded	567
6 Weeks	88 (20.1)
3 Months	283 (64.6)
6 Months	59 (13.5)
12 Months	8 (1.8)
Total	**1005**

6.3 PATIENT-REPORTED OUTCOME MEASURES

The database allows the recording of PGI-I for urinary incontinence and pelvic organ prolapse after surgery *(Table 15)*. Although they are relevant secondary outcome measures, they do not tell us whether the main mesh-related problems, such as pain and mesh erosion/exposure, have resolved. Improvement in incontinence was reported in 40% of episodes but it was not possible to determine if this was due to an improvement in urge leakage or concomitant continence procedures. A deterioration in UI was reported in 34%, possibly resulting from the loss of suburethral support after mesh excision.

The option of recording pre and postoperative pain on a visual analogue scale was introduced to the database at the end of 2019 to improve the capture of PROMs.

Table 15: *PGI-I for incontinence and prolapse*

	PGI-I UI, n (%)	PGI-I POP, n (%)
Unrecorded	755	879
Very much better	29 (11.6)	44 (34.9)
Much better	48 (19.2)	18 (14.3)
A little better	23 (9.2)	2 (1.6)
No change	65 (26.0)	56 (44.4)
A little worse	39 (15.6)	3 (2.3)
Much worse	30 (12.0)	2 (1.6)
Very much worse	16 (6.4)	1 (0.8)
Total	**1005**	**1005**

APPENDIX A: MHRA DATA

Table 16: *Mesh-related incidents reported to the MHRA from 2020-2021*

	For POP			For SUI			Unknown indication		
Year	Reported by professional users	Reported by MOP	Other	Reported by professional users	Reported by MOP	Other	Reported by professional users	Reported by MOP	Other
2020	58	13	12	186	30	16	49	15	22
2021	33	6	20	124	31	37	28	14	23

MOP - members of public
Other - this includes reports where the captured reporter origin includes the manufacturer, submitter, devolved administration, authorised representative, other, or where the field has been left empty.

Please also note the following considerations in relation to the data provided in the tables above:

- This information is accurate at the time we conduct the search on our database, changes in the number of adverse events can occur following receipt of additional information.
- Use of our Yellow Card scheme by the healthcare sector and members of the public is voluntary and it does not provide absolute adverse incident figures.
- The adverse incident figure is for all reports received within the time period specified.
- Individuals may report an incident at any time after the event and people can make multiple reports at any time after the mesh has been implanted and on the same issue. Where possible, multiple reports for the same event are linked, however as reporters are not required to complete all fields, we cannot always be sure enough to link every duplicate.
- Some reports do not include the necessary information to determine the indication of use of the surgical mesh, but we have included them to give you the data we hold on these devices since 2020 to 2022. These are identified as 'unknown indication'.
- It should be noted that this information may include a range of recognised complications related to this type of surgical procedure and do not necessarily indicate a fault with any particular device.
- Adverse incident data includes surgical mesh for surgical mesh-slings, pelvic organ prolapse surgical meshes or extra-gynaecological surgical meshes by different surgical approaches (e.g. transvaginal, retropubic and abdominal). We are unable to break this down as this is not a mandatory field in Yellow Card and may be unknown to the reporter.
- The number of reports received should not be used as a basis for determining the incidence of a health/clinical effect as neither the total number of effects occurring, nor the number of patients using the device is known.
- The inclusion of a report on the MHRA adverse incident database does not necessarily mean that the events described were caused by the device.

REFERENCES

1) Letter from NHS England and NHS Improvement to trust medical directors regarding 'high vigilance restriction' procedures. NHS England & NHS Improvement. July 2018. https://i.emlfiles4.com/cmpdoc/9/7/2/8/1/1/files/47633_mesh-letter-to-acute-ceosand-mds.pdf

2) MHRA email communication MHRA. July 2023.

3) Understanding how risk is discussed in healthcare. Royal College of Obstetricians and Gynaecologists. 2015. https://www.rcog.org.uk/globalassets/documents/patients/patient-information-leaflets/pi-understanding-risk.pdf