ACC Surgical Mesh Review

Analysis of Treatment Injury Claims

1 July 2005 to 30 June 2014

13/03/2015

Executive Summary

On 20 March 2014, a private petition was sent to the Health Committee, requesting that an independent inquiry be conducted regarding the safety of surgical mesh in New Zealand. ACC's mandate is to reduce or prevent injury; as such ACC undertook a retrospective audit review of treatment injury surgical mesh claims lodged and decided from 1 July 2005 to 30 June 2014.

The purpose of the retrospective audit review (hereafter referred to as "Surgical Mesh Review") was to identify any new information that could benefit the health sector, and to identify any potential risk factors relating to the use of surgical mesh.

Descriptive information about these claims is presented and covers:

- Overview of the claims by the financial year, surgery facility, geographical location, patient demographic, surgery type and mesh device.
- Characteristics analysis of the surgical procedures and the use of mesh devices for each type of surgery.

Key Findings

This is a retrospective review undertaken on 466 Treatment Injury claims received relating to the use of surgical mesh.

New information for the health sector

This review represents the first and the largest national surgical mesh analysis undertaken to date in New Zealand by ACC. While ACC already provides information to the health sector, this review has identified new information that is detailed further in the Report. The ACC datasheet developed in this review can be used as a template for surgeons, hospitals and the health sector to collect mesh-related information. This information may also assist providers in identifying 'at risk' patients when recommending, referring or undertaking treatment where surgical mesh is used.

Demographics

- The average age of clients was 56 years old; the age range was from 20 to 84 years.
- 40.1% of claims received for mesh-related events occurred in the Auckland region
- About 80% of claims received for mesh-related events occurred in the Auckland, Wellington, Canterbury and Waikato region. This is consistent with the population distribution in New Zealand, in that Auckland, Christchurch, Wellington, and Hamilton are the four largest cities.
- 86% of clients identified themselves as New Zealand European and 6% as New Zealand Maori.

Surgery procedures

- Two thirds of the claims received were for mesh-related events which occurred in private hospitals.
- 73% of hernia mesh repairs were open surgeries; while 20% used laparoscopic technique.
- 81% of the urogynaecological mesh surgeries were transvaginal repairs and 5% were abdominal repairs.
- Suture was the most common mesh securing method in all types of mesh implants.

Use of mesh device

- The denominator – for use of mesh surgeries overall – is not known.
- 56,508 mesh devices were sold in New Zealand between 1 January 2005 and 31 October 2014, 58% of mesh devices were sold for hernia repair, while 30% were for Pelvic organ prolapse (POP) repair and 11% were for Stress urinary incontinence (SUI) repair.

- 48% of the mesh was made of synthetic material, while less than 2% was biological mesh, and 21% was composite mesh. Twenty-nine percent of the device-related information was not documented.

Post surgery complications

- Treatment injury claims for mesh complications made up 0.7% of all treatment injury claims and 0.002% of all ACC claims.
- The claim rate is 5 times higher in using mesh for POP repair than SUI or hernia repair.
- The most common claims for urogynaecological procedures using mesh was mesh erosion also known as mesh exposure or extrusion (65%).
- The most common postoperative complication for hernia repair was infection or fistulae (51%).
- In the majority of cases where the surgical mesh failed, subsequent surgery was required.

More detailed tabulation can be found in Appendix 3.

Limitation of the review

- The review includes data collected on treatment injury claims that have been lodged with and decided by ACC. It is possible that other individuals have suffered complications, related to the use of surgical mesh, but have not lodged a claim with ACC.
- There is a possibility that claims related to post operative pain that was not associated with infection or a clear personal injury, may be under-represented as they would not have lodged a claim with ACC.
- ACC is mandated to collect relevant and sufficient clinical information to reach a treatment injury cover decision in a timely manner for our clients. This often means that technical details (e.g. medical device batch numbers) are not required for ACC to issue a decision. As a consequence the review was limited by the technical detail available, which differed from claim to claim.
- There is no single electronic data field in ACC's record that identifies claims relating to the use of surgical mesh. The claim identification method may miss some cases that did not include the key word "Mesh" and/or "Mesh erosion" in the Primary/Secondary/Tertiary Injury fields.
- The available data does not allow any comparison of injury rate for surgery with mesh to be compared to surgery without mesh.
- The review is limited as the dataset does not allow an estimation of the association between the potential risk factors and the surgical mesh-related complication. The descriptive analysis used in this review may help to identify a potential risk factor for

the surgical mesh-related complications/injuries, but it is not able to give the results statistical power to determine the association.

Topics of discussion for ACC

- To reduce the limitations on surgical mesh data and mitigate the risks relating to free text searches, ACC will explore and include more specific data fields in relation to surgical mesh claims.
- In addition to the current adverse event notifications (where serious and sentinel events are reported to Medsafe), in future ACC will now send all surgical mesh data (which can include minor or major injuries relating to mesh) to Medsafe for increased awareness of claims received.

Topics of discussion for the Health Sector

The health sector could discuss the possibilities of whether:

- a postmarket surveillance study would provide information regarding the surgical mesh complications for each specific mesh product already marketed in New Zealand.
- a multi-agency registry would provide a better means of tracking surgical mesh used and the associated complications to address mesh-related public health concerns.
- a full evidence-based review could identify or evaluate the effectiveness and safety of using surgical mesh in urogynaecologic surgeries and general surgeries. It could also possibly determine whether the evidence is directly applicable or generalisable to the New Zealand health sector.

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Abbreviations

ACC	Accident Compensation Corporation
FDA	Food and Drug Administration
UGSA	Urogynaecological Society of Australasia
RANZCOG	Royal Australian and New Zealand College of Obstetricians and Gynaecologists
POP-Q	The Pelvic Organ Prolapse Quantification System
POP	Pelvic organ prolapse
SUI	Stress urinary incontinence
TVT	Tension-free vaginal tape
TVT-O	Tension-free vaginal tape obturator

1 Background

1.1 Surgical Mesh

Surgical mesh is a medical device that is used to repair weakened or damaged tissue. Surgical mesh is composed of a synthetic or biologic material, or a combination of both. Synthetic materials can be found in knitted mesh or non-knitted sheet forms. Biological meshes come from human, porcine, or bovine sources. These devices are marketed as either stand-alone mesh products or mesh kits, which includes mesh and instrumentation specifically designed to aid in insertion, placement, fixation, and anchoring of the mesh in the body.

The first mesh was introduced in 1958 to repair abdominal herniaes. It was a milestone in hernia repair and led to the development of other mesh products of various densities, porosity, and weave, with the goal of minimizing the amount of permanent mesh implanted while providing sufficient tissue support (Bringman et al., 2010). In the 1970s, biologic grafts and synthetic mesh prostheses have been utilized in abdominal repairs for pelvic organ prolapse (POP). Since the 1990s, vaginal mesh has been used for gynaecologic surgery, such as surgical treatment of stress urinary incontinence (SUI) and transvaginal repair of POP (FDA, 2011).

The use of surgical mesh for SUI and/or POP has substantially increased over the last decade. The increased use of vaginal synthetic mesh has seen an increase in adverse event reporting. Between 2005 and 2007, the U.S. Food and Drug Administration (FDA) were notified of more than 1,000 adverse events related to use of surgical mesh for both POP and SUI repairs. In 2008, the FDA released a public health notification to inform patients of adverse events related to placement of surgical mesh in the urogynaecology setting. In 2011, it issued an updated Safety Communication specifically regarding the frequency of complications associated with the use of transvaginal mesh for POP repair. A number of international gynaecological and urological organisations, including the Urogynaecological Society of Australasia (UGSA), and The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), released response statements regarding transvaginal mesh and POP, and reported general agreement with the FDA's 2011 publication. In addition, the FDA is proposing to reclassify surgical mesh for POP repair from class II to class III[1]. The FDA proposed order does not include surgical mesh indicated for surgical treatment of SUI, abdominal POP repair, hernia repair, and other non-urogynaecologic indications.

In New Zealand surgical mesh has been employed in the treatment of hernia repair, urogynaecology and other surgeries (i.e. breast reconstruction). As Class II B devices, there is no

[1] The FDA requires products that will be classified as medical devices meet certain regulatory requirements based on the risk associated with their intended use. They are then stratified into classes I, II, or III, with class I having the lowest risk to public safety and class III having the highest.

requirement for surgical mesh devices to be approved by any overseas medical device regulator before they can be marketed in New Zealand. As the worldwide use of these devices increased during this period so did adverse event reporting in overseas and New Zealand. Between 2004 and 2014, Medsafe received a total of 68 adverse event reports following urogynaecological surgical mesh implants and seven adverse events following hernia mesh repair. However, the actual number of injuries may be much higher, as ACC received more than 400 mesh-related treatment injury claims during the same period.

1.2 ACC's legislation framework

ACC assesses all lodged Surgical Mesh claims under the legislative criteria of Treatment Injury (formerly Medical Misadventure) defined in the Accident Compensation Act 2001 ('the Act')[2]. On 1 July 2005, Treatment Injury amendments were made to the Act. This amendment moved the scheme away from the previous fault-based approach under the medical misadventure provisions which focused on the conduct of registered health professionals to a focus on the treatment outcome, which was more in line with the broader scope and intent of the ACC scheme. The legislative change also significantly moved ACC's role away from mandatory reporting to the Health Disability Commissioner (from being an agency that identified and assessed the actions of individual healthcare practitioners)to one that supports regulators by providing information if it believes there is a risk of harm.

Section 32 of the Act provides for ACC cover for people who have an injury that has occurred during treatment. For surgical mesh claims to be accepted, there must be a direct causal link between the medical treatment and the mesh-related injuries claimed.

1.3 Objective of this report

On 20 March 2014, a private petition was sent to the Health Select Committee, requesting an independent inquiry be conducted regarding the safety of surgical mesh in New Zealand. The private petition provided detailed information and evidence about post-operative problems associated with surgical mesh. ACC's mandate is to reduce or prevent injury; as such ACC undertook a retrospective review of surgical mesh claims lodged and decided from 1 July 2005 to 30 June 2014.

The review aimed to:

1. Identify any potential risk factors relating to the use of surgical mesh
2. Identify any new information that would benefit the health sector.

[2] Accident Compensation Act 2001
http://www.legislation.govt.nz/act/public/2001/0049/latest/DLM100942.html

2 Methods

2.1 Claim Selection and Review

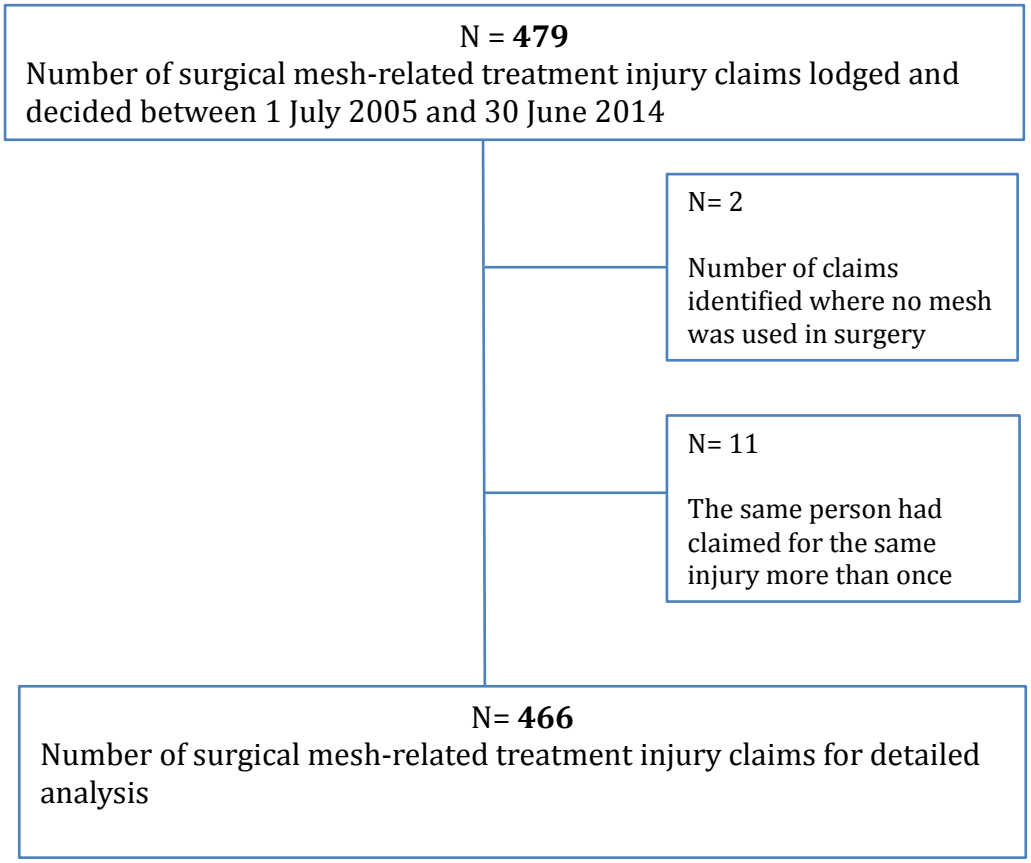
ACC undertook a retrospective review of all Treatment Injury claims lodged and decided between 1 July 2005 and 30 June 2014, regardless of the treatment injury cover decision (both accepted and declined decisions are included).

ACC claim database was searched using three search criteria:

- Fund Code "*Treatment Injury",* and
- Primary or Secondary Injury fields where Clinical Advisors had entered the words "*Mesh*" and/or "*Mesh erosion*", and
- Claims lodged and decided from the 1 July 2005 through to 30 June 2014

The search identified a total of 479 treatment injury claims relating to surgical mesh. After removal of duplicate claims, 466 claims were suitable for detailed analysis (see Figure 1).

Figure 1 Flow Diagram of Claims Used for Analysis



2.2 Data collection

2.2.1 Establishment of the Steering Committee and Working Group

The responsibility of the Steering Committee was to guide the Working Group through the review and ensure key stakeholders were notified (i.e. the ACC Board, Health Select Committee, Petitioners, Medsafe and Ministry of Health).

The Working Group was responsible for ensuring that a complete, quality and timely review be produced by identifying any gaps, weaknesses or opportunities to be included in the review, make recommendations as appropriate, and seek guidance from the Steering Committee.

2.2.2 Development of data collection criteria

- A list of suggested criteria was initially developed.
- The Working Group worked through the suggested criteria in detail with the Steering Committee's oversight.
- ACC sought input from two gynaecologists, a general surgeon and an urologist
- ACC sought input from the Petitioners and Medsafe.
- A further iteration of the criteria was reviewed by the Working Group with the Steering Committee's final oversight (see Appendix 1 for final iteration of data extraction template).
- A template was developed in MS Excel. This template was specifically tailored to the requirements of this review.
- It is important to note the level of data collected during this review does not form the base of what ACC currently collects when making a treatment injury cover decision.

2.2.3 Data extraction process

Two research advisors with health-related qualifications and experience were contracted through an external Recruitment Agency to conduct the data collection and analysis. Induction was provided to the two research advisors by the technical claims manager in the Treatment Injury Centre.

Following training 10 claims were selected at random for review by the research advisors and the technical claims manager. The results were compared and discussed. The parallel check was completed to achieve a level of consistency, accuracy and establish rules around the data collection process. A further 25 claims were then reviewed in the same manner and further rule refinement occurred to clarify the definitions and ensure consistent and comprehensive data collection.

The claim data was collected using a template. Claimant date of birth, gender, ethnicity, surgery context and location of surgery was collected from ACC's electronic database and matched to data collected during claim file analysis.

During the review process the two research advisors received support (when required) from the technical claims manager.

2.3 Data analysis

All extracted data was entered in an Excel spreadsheet by the research advisors and quantitatively analyzed using descriptive statistics. The data was analysed according to five surgical types: SUI repair, POP repair, Combined SUI and POP, hernia repair and other surgery. The detailed results about the claim characteristics were provided for each surgical type. General claim information about the financial year, surgery facility, geographical location, patient demographic, surgery type and mesh device information was recorded. In order to prevent the possibility of identifying a person, any result that includes claim counts fewer than four (n=1,2 or 3) will be presented as "<4".

2.4 Peer review of this report

This report has been internally reviewed by members of the Steering Committee, and externally peer-reviwed by an expert in Surgery.

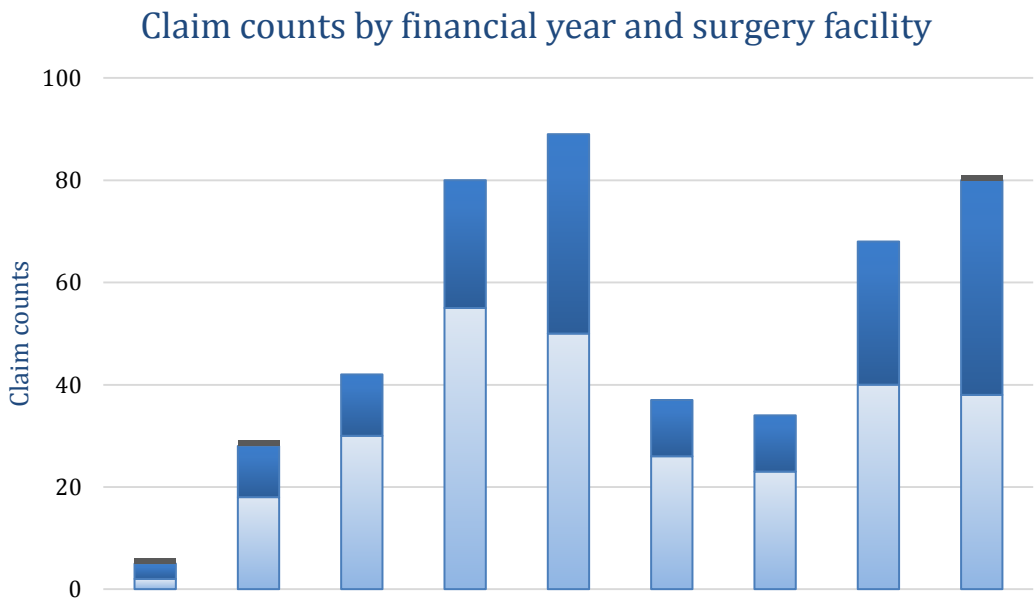
3 Overview of ACC surgical mesh-related claims

3.1 ACC surgical mesh-related claims 2005 to 2014

Between July 2005 and June 2014, ACC assessed and made decisions on 466 treatment injury claims for mesh-related injuries, which made up 0.7% of all treatment injury claims and 0.002% of all ACC claims.

Figure 2 shows the public and private hospital breakdown of ACC surgical mesh claims.. The results show that about 61% (n=284) of mesh-related claims occurred in private hospitals and 39% (n=182) occurred in public hospitals. In 2013-2014, slightly more claims occurred in public hospitals than private hospitals. Overall there were increases observed during 2008-2009, 2009-2010 and 2012-2014. This growth may be from an increased awareness in lodging treatment injury claims. Other reasons could include an increase in the number of injuries associated with mesh, or more awareness of the potential risks associated with mesh after two U.S FDA communications in 2008 and 2011, respectively. It is unable to be identified why there was a drop in claim counts 2010-2011.

Figure 2 Claim counts by financial year and surgery facility



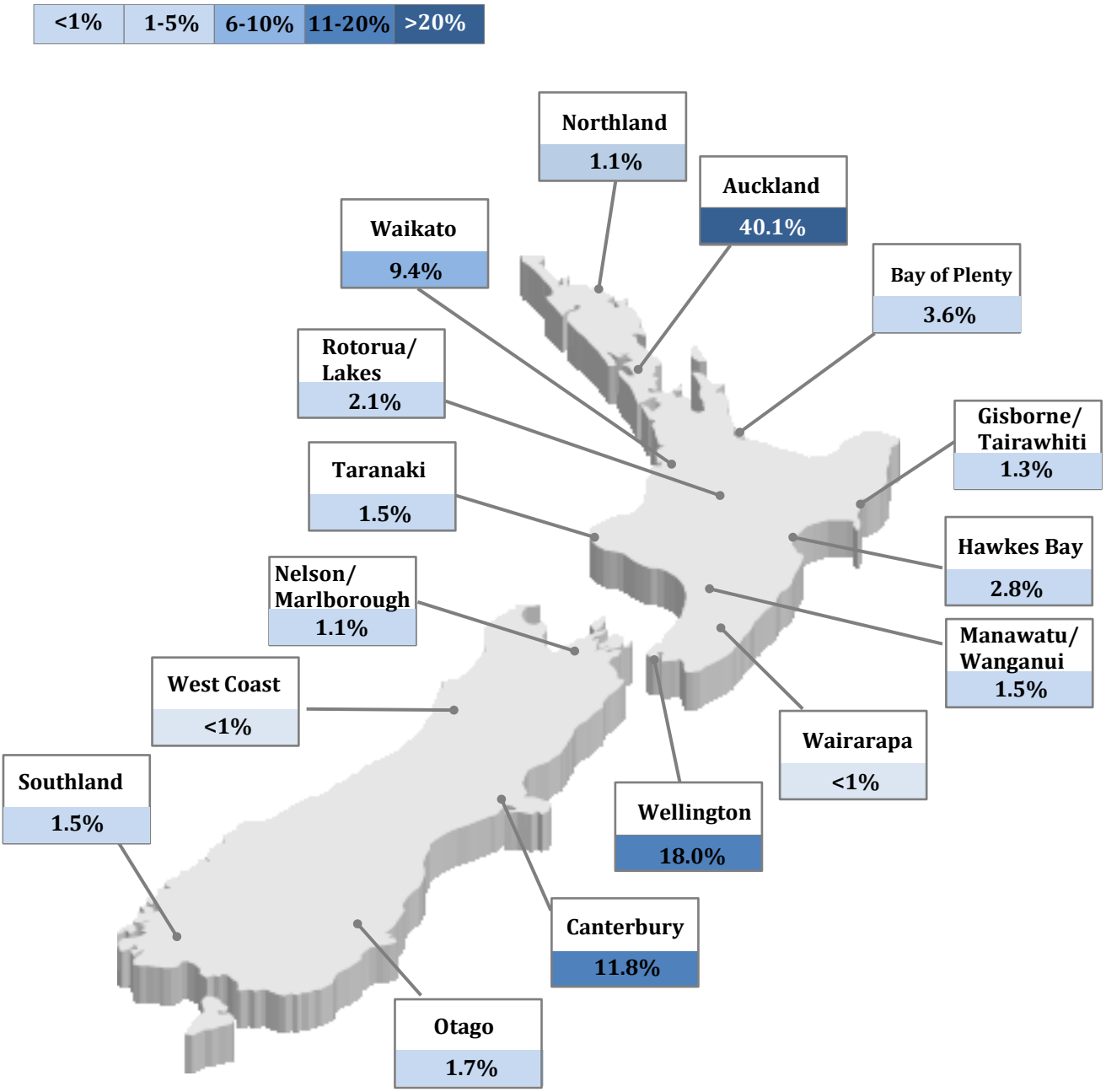
	2005-2006	2006-2007	2007-2008	2008-2009	2009-2010	2010-2011	2011-2012	2012-2013	2013-2014	Total
Public hospital	<4	10	12	25	39	11	11	28	42	**181**
Private hospital	<4	18	30	55	50	26	23	40	38	**282**
Unknown	<4	<4	0	0	0	0	0	0	<4	**<4**
Total	**6**	**29**	**42**	**80**	**89**	**37**	**34**	**68**	**81**	**466**

Note: Claim counts less than four (n=1,2 or 3) are all presented as "<4".

3.2 Location of the surgeries

Figure 3 and Table 3-1 shows the geographical distribution of mesh-related claims in New Zealand. The location recorded is where the patients had surgery and may differ from where they lived. Between 2005 and 2014, there were 187 claims recorded in the Auckland region. About 80% of the total claims were lodged from Auckland, Wellington, Canterbury and Waikato region. The distribution of claim counts is consistent with the population distribution in New Zealand, in that Auckland, Christchurch, Wellington, and Hamilton are the four largest cities[3].

Figure 3 ACC surgical mesh claims distribution in New Zealand



[3] "Subnational Population Estimates: At 30 June 2014 (provisional)". Statistics New Zealand. 22 October 2014. Retrieved 2 February 2015

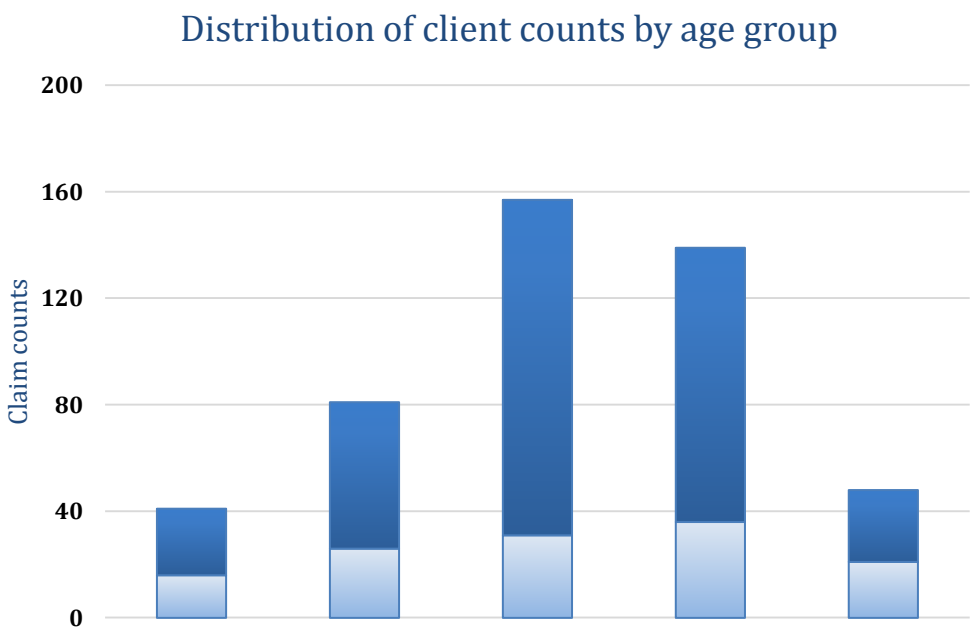
Table 3-1 Claim counts by location

Region	Claim counts	Percentage	Cumulative
Auckland	187	40.1 %	40.1 %
Wellington	84	18.0 %	58.2 %
Canterbury	55	11.8 %	70.0 %
Waikato	44	9.4 %	79.4 %
Bay of Plenty	17	3.6 %	83.0 %
Hawkes Bay	13	2.8 %	85.8 %
Manawatu/ Wanganui	12	2.6 %	88.4 %
Rotorua/Lakes	10	2.1 %	90.6 %
Otago	8	1.7 %	92.3 %
Taranaki	7	1.5 %	93.8 %
Southland	7	1.5 %	95.3 %
Gisborne/Tairawhiti	6	1.3 %	96.6 %
Northland	5	1.1 %	97.6 %
Nelson Marlborough	5	1.1 %	98.7 %
Wairarapa	<4	<1 %	>97.6 %
West Coast	<4	<1 %	>97.6 %
Unknown	<4	<1 %	100.0 %
Total	**466**	100.0 %	

3.3 Client demographics

Figure 4 shows the gender and age group distribution of all claims for surgical mesh injuries. The cohort comprised 336 (72%) female clients and 130 (28%) male clients. Out of the 466 clients, the highest proportion of clients were aged 50–59 years old (n=157, 34%), and 139 (30%) clients were aged between 60-69 years old.

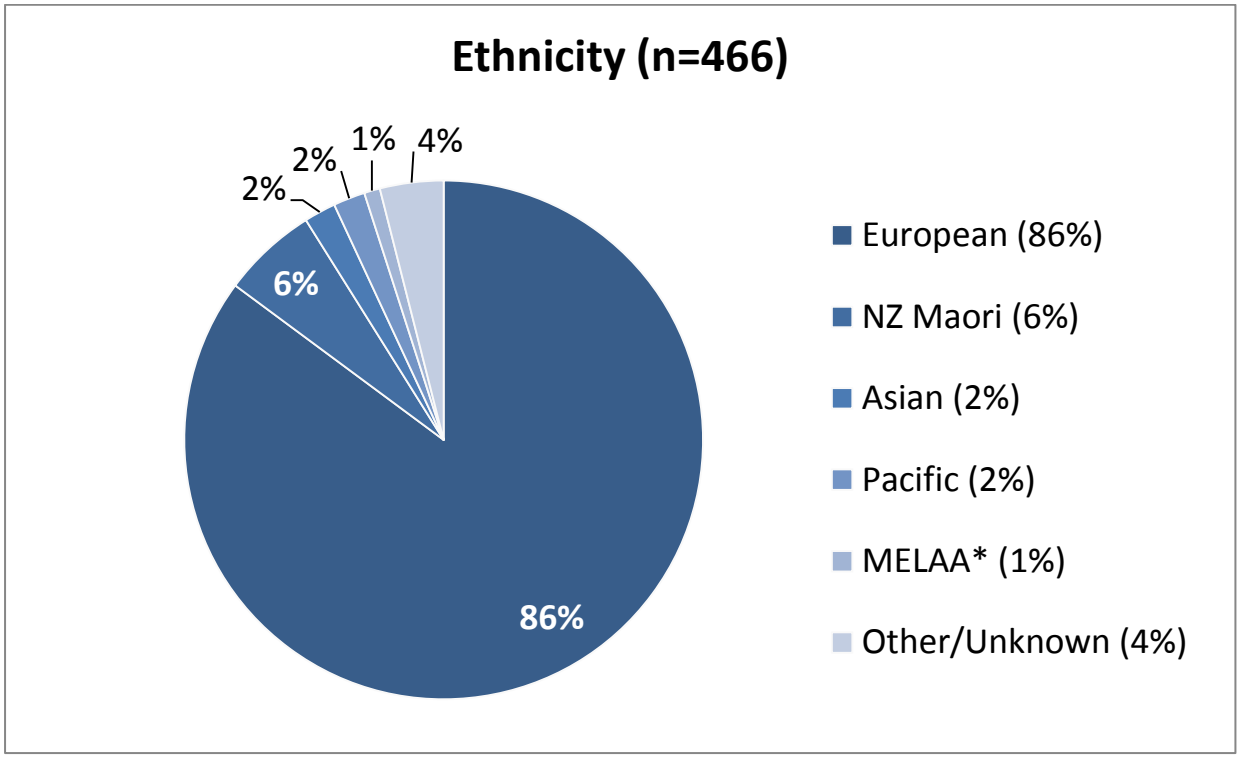
Figure 4 Patient by age group



	<40	40-49	50-59	60-69	≥ 70	Total
Female	25	55	126	103	27	**336**
Male	16	26	31	36	21	**130**
Total	**41**	**81**	**157**	**139**	**48**	**466**

Figure 5 reflects the population in general; 86% (n=401) of clients identified themselves as New Zealand European and 6% (n=28) as New Zealand Maori. 2% of clients were of Pacific (n=7) and Asian ethnicity (n=9). Less than one percent (n<4) of clients' ethnicity was Middle Eastern, Latin American or African. 4% (n=18) of clients either identified themselves as 'other' or did not identify their ethnicity.

Figure 5 Patients by ethnicity

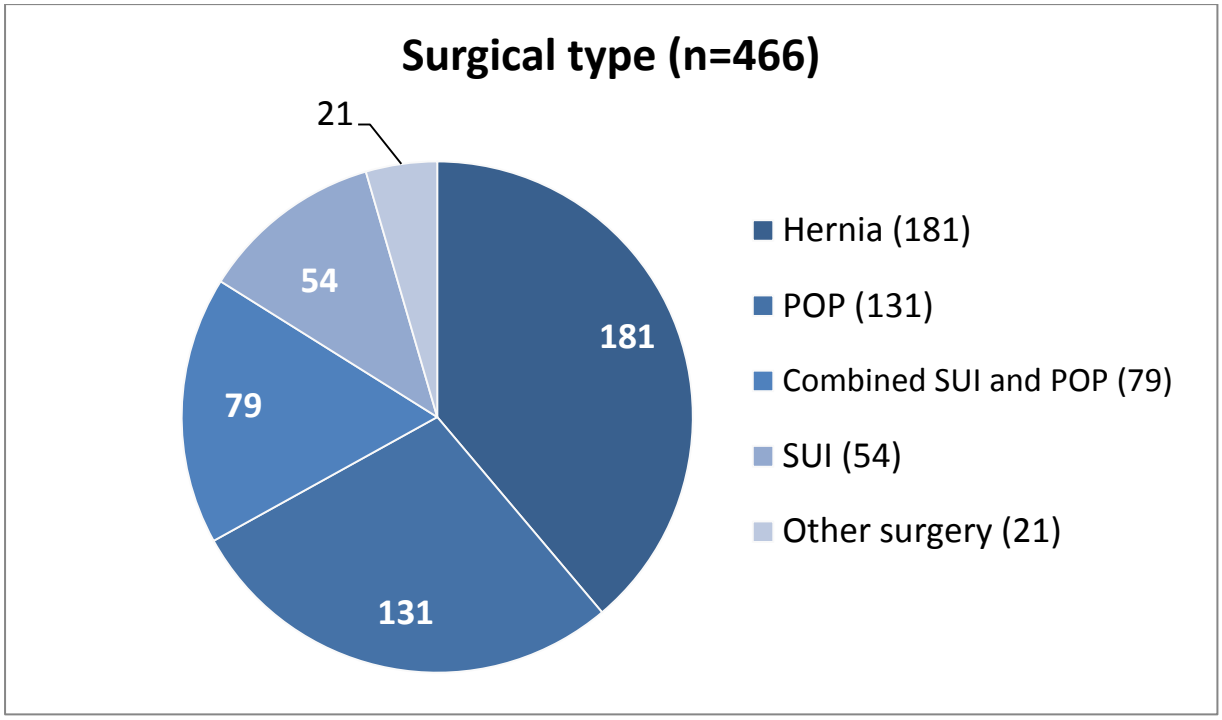


*MELAA = Middle Eastern, Latin American or African

3.4 Surgical type

Figure 6 shows the five types of surgery identified: "POP repair", "SUI repair", "Combined POP/SUI", "Hernia repair" and "Other surgery" (Figure 6). The majority of procedures were in obstetrics and gynaecology, including 54 (11%) SUI repair, 131 (28%) POP repair and 79 (20%) combined procedures for both SUI and POP repair. This explains the larger proportion of female patients in this cohort. The rest of procedures were general surgeries for 181 (39%) hernia repair and 21 (4%) other surgeries (surgery other than urogynaecological surgery and hernia repair).

Figure 6 Claims by surgical type



Actual incidence of surgical mesh-related injuries in New Zealand is unknown as data on total number of surgeries where mesh was used is not available. However, with the help of Medsafe, ACC have calculated the ratio between the number of mesh devices involved in this review (ACC claim data) and the total number of mesh devices sold in New Zealand during the same time period (Medsafe-supplied data).

Table 3-2 shows that, of 56,508 devices sold in New Zealand between 1 January 2005 and 31 October 2014), hernia repairs consumed the largest number of mesh devices (n=32,896, 58%) in New Zealand. POP repair has the highest claim rate of 3.3%, which is much higher than SUI repair (0.7%) and hernia repair (0.6%). A 2011 meta-analysis reported a 10.3% mesh erosion rate following transvaginal mesh repair of POP (Abed et al., 2011), and a 2014 meta-analysis revealed the rate of surgical site infection was about 7.3% following ventral hernia repair with mesh (Nguyen et al., 2014). The comparision of claims against the volumes of mesh supplied in NZ shows a much lower rate of complications. However, the true incidence of mesh complication is likely to be higher, because not all mesh complications result in claims to ACC. The available claim data shows a higher rate of mesh-related events associated with POP repairs than with SUI repair or hernia repair.

Table 3-2 Mesh Devices identified in ACC Surgical Mesh Review/Number of mesh devices sold in New Zealand

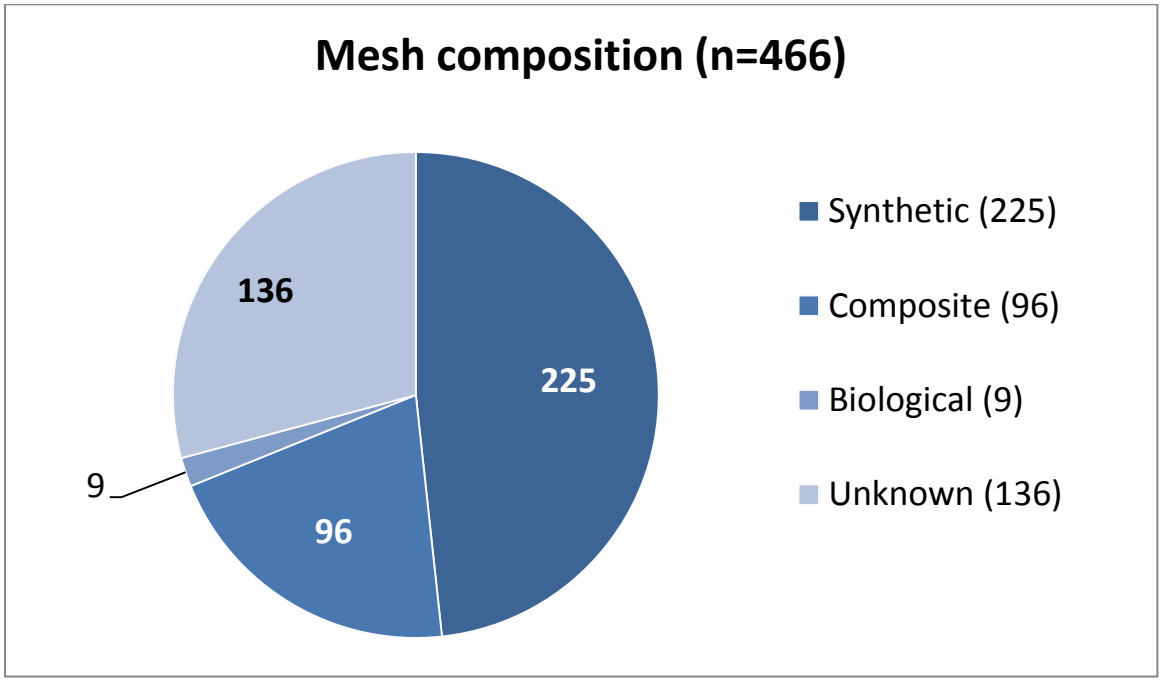
Product grouping	Mesh devices involved in Review	Devices sold in New Zealand (1 January 2005 - 31 October 2014)#	Percentage of Total Devices Sold
SUI (male)	<4	321	<0.1%
SUI (female)	133*	17,094	0.7%
POP	209*	6,197	3.3%
Hernia	201[T]	32,896	0.6%
Total	545	56,508	0.9%

Note: #Medsafe-supplied data, covering the period 1 January 2005 to 31 October 2014
*There were 79 combined procedures for POP and SUI where 2 types of mesh were used.
[T]Hernia includes 20 procedures for non-hernia surgeries where mesh used to treat defect in abdominal wall

3.5 Mesh devices

Figure 7 shows that of the 466 claims, 71% (n=330) of mesh devices used had brand name and composition indicated on medical records. Forty-eight percent (n=225) of mesh was made of synthetic material, 21% (n=96) was composite mesh, and less than 2% (n=9) was biological mesh.

Figure 7 Claims by mesh composition



The data identified a variety of mesh materials were used in New Zealand. TVT™/TVT-O™ (Ethicon, Somerville, NJ, USA), Monarc™ and SPARC™ (American Medical Systems, Minnetonka, MN, USA) were the most used mesh material for SUI repair. Apogee™, Perigee™ (American Medical Systems, Minnetonka, MN, USA) Gynaecare Prolift™ (Ethicon, Somerville, NJ, USA) were frequently used during POP repair procedures. Leading mesh devices for hernia repair were Prolene™ (Ethicon, Somerville, NJ, USA), Parietex™, Surgipro™ (Covidien, Mansfield, MA, USA), C-QUR™(Atrium Medical Corporation, Hudson, NH, USA), Proceed™ (Ethicon, Somerville, NJ, USA). A detailed device brand and a full list of devices used can be found in the Appendix 3 (Table 8-6).

About 29% (n=136) of the specific device-related information was not in the medical records provided to ACC. There is also a lack of information about the number of devices used/sold for each device in New Zealand. Therefore, the data is not sufficient to link the injuries associated with the use of surgical mesh to one particular brand of mesh in this report.

4 Data analysis of claims by surgical type

4.1 Urogynaecology

4.1.1 Pre-operative characteristics of clients

Table 4-1 below summarises client characteristics before the mesh surgery. The average age of the women who lodged a claim for mesh-related injury after urogynaecological mesh surgery is 56 years old. The SUI group is about 5 years younger than the POP or combined group. The results also provided information about the preoperative health status and known symptoms of the clients. Compared with the SUI group, the clients who underwent POP repair and combined POP and SUI repair had more identifiable symptoms aside from urinary incontinence,which is the main symptom of SUI.

Out of 264 women who underwent urogynaecological mesh surgery, 62% (n=163) had previous surgeries in the same area, 44% (n=116) had hysterectomy and 37% (n=98) had previous prolapse repair.

The Pelvic Organ Prolapse Quantification (POP-Q) system is objective, site–specific system commonly used to describe the degree of prolapse in women (Bump et al., 1996). A large proportion (73%) of missing POP-Q data was observed in the result as this information was not in the medical records provided to ACC and/or ACC did not require this information to make a decision. Out of 72 claims with POP-Q grade, 93% (n=67) women had Stage 2-4 prolapse.

Table 4-1 Preoperative characteristics of clients

	Total n =264	SUI n=54	POP n=131	Combined (POP/SUI) N=79
Age (years)	56±10	52±9	57±9	58±10
Health status				
Smoking	17(6%)	4(7%)	5(4%)	8(10%)
Respiratory	30(11%)	<4(<7%)	13(10%)	15(19%)
Vascular	30(11%)	<4(<7%)	15(11%)	12(15%)
Diabetes	13(5%)	<4(<7%)	9(7%)	<4(<5%)
Chronic constipation	43(16%)	6(11%)	26(20%)	11(14%)
Overweight	28(11%)	7(13%)	10(8%)	11(14%)
Immune/Inflammatory disease	20(8%)	<4(<7%)	9(7%)	9(11%)
Known symptoms				
Menopausal (pre and post)	188(71%)	27(50%)	98(75%)	63(80%)
Chronic pain	47(18%)	<4(<7%)	29(22%)	16(20%)
Pelvic pain	33(13%)	4(7%)	20(15%)	9(11%)

Bowel (faecal) incontinence	27(10%)	<4(<7%)	19(15%)	7(9%)
Urine (bladder) incontinence	156(59%)	53(98%)	42(32%)	61(77%)
Dyspareunia	23(9%)	<4(<7%)	14(11%)	7(9%)
Previous surgeries				
Hysterectomy	116(44%)	16(30%)	63(48%)	37(47%)
Prolapse	98(37%)	12(22%)	60(46%)	26(33%)
In same area	163(62%)	24(44%)	91(69%)	48(61%)
POP-Q Stage before surgery				
Stage 1	5(2%)	<4(<7%)	<4(<3%)	0(0%)
Stage 2	22(8%)	4(7%)	13(10%)	5(6%)
Stage 3	30(11%)	0(0%)	20(15%)	10(13%)
Stage 4	15(6%)	0(0%)	6(5%)	9(11%)

4.1.2 Characteristics of urogynaecological surgery involving mesh

Characteristics of mesh urogynaecologic surgery are presented in Table 4-2. In transvaginal POP repair surgery, mesh can be placed in the anterior vaginal wall to aid in the correction of cystocele, in the posterior vaginal wall to aid in correction of rectocele, and attached to the vaginal vault, uterine or rectal pelvic floor ligaments to correct prolapse.

Table 4-2 shows that most POP repair were anterior repairs (n=136, 65%) and/or posterior repairs (n=129, 61%). The laparoscopic approach was used in 36 POP/Combined procedures and less than four SUI repairs. There are 13 (5%) POP/Combined procedures involving the use of hysteroscope.

The urethral sling can be placed retropubically (multi-incision slings), transobturatory (multi-incision slings). Out of a total of 133 SUI repairs, 55% (n=73) were retropubic urethral slingplasties, and 45% (n=60) were transobturator urethral slingplasties. The two techniques were not significantly different in effectiveness, but their complications may differ. Published literature suggests retropubic urethral slingplasties are associated with a higher risk of bladder perforation and voiding dysfunction, while transobturator urethral slingplasties have a significantly higher risk of chronic thigh/leg pain (Barboglio & Gormley, 2013).

Table 4-2 Characteristics of urogynaecological surgery involving mesh

	Total n =264	SUI n=54	POP n=131	Combined (POP/SUI) N=79
Site of POP repair*				
Anterior vaginal wall	136(65%)	-	82(63%)	54(68%)
Posterior vaginal wall	129(61%)	-	83(63%)	46(58%)
Vaginal vault	44(21%)	-	23(18%)	21(27%)
Uterine	<4(<2%)	-	0(0%)	<4(<5%)
Rectal	7(3%)	-	7(5%)	0(0%)
Mesh insertion approach for SUI repair				
Retropubic urethral slingplasty	73(55%)	42(78%)	-	31(39%)
Transobturator urethral slingplasty	60(45%)	12(22%)	-	48(61%)
Surgical technique				
Transvaginal	213(81%)	49(91%)	100(76%)	64(81%)
Abdominal	14(5%)	<4(<7%)	10(8%)	<4(<5%)
Unknown	37(14%)	<4(<7%)	21(16%)	13(16%)
Use of laparoscope	37(14%)	<4(<7%)	19(15%)	17(22%)
Use of hysteroscope	13(5%)	0(0%)	9(7%)	4(5%)

*Some patients had more than one site of POP repair

Overall 81% (n=213) of the urogynaecological mesh surgeries were transvaginal repairs and only 5% (n=14) were abdominal repairs. This result indicates that abdominal mesh repair (sacrocolpopexy) of POP or/and SUI resulted in lower claim rates of mesh-related complications compared to transvaginal repair with mesh. These findings are similar to the findings found in published literature. A systematic review that included 54 studies and 7,054 women, reported the median mesh erosion rate to be 4% within 23 months following sacrocolpopexy (Jia et al., 2010), while a 2011 meta-analysis reported that the incidence of mesh erosion rate was 10.3% (95%CI 9.7-10.9%) following transvaginal mesh repair of POP (Abed et al., 2011).

4.1.3 Characteristics of mesh device used in urogynaecologic surgery

Table 4-3 shows that, in total, about 19% (n=51) mesh devices were modified and 44% (n=115) were secured. Suture was the most common mesh securing method and used in 42% (n=112) of the surgeries.

Table 4-3 Characteristics of mesh device used in urogynaecological surgery

	Total n =264	SUI n=54	POP n=131	Combined (POP/SUI) N=79
Mesh modification				
Yes	51(19%)	<4(<7%)	36(27%)	13(16%)
No	146(55%)	34(63%)	61(47%)	51(65%)
Unknown	67(25%)	18(33%)	34(26%)	15(19%)
Mesh secured status				
Yes	116 (44%)	5(9%)	80(61%)	31(39%)
No	75(28%)	28(52%)	20(15%)	27(34%)
Unknown	73(28%)	21(39%)	31(24%)	21(27%)
Mesh secured methods*				
Clips	<4(<2%)	0(0%)	<4(<3%)	0(0%)
Suture	112(42%)	5(9%)	78(60%)	29(37%)
Staple	<4(<2%)	0(0%)	<4(<3%)	0(0%)
Tack	7(3%)	0(0%)	5(4%)	<4(<5%)
Glue	54(20%)	13(24%)	27(21%)	14(18%)

Note: *One mesh surgery might use more than one securing methods.

In general, mesh products for vaginal POP repair are configured to match the anatomical defect they are designed to correct. FDA considered mesh size and shape as a contributor towards an increased risk of complications following surgery (FDA, 2011). However, the ACC data recorded whether the mesh was modified during the surgery, so it cannot be identified if an association between the mesh modification and injuries existed.

4.1.4 *Presenting mesh-related injuries per type of surgery*

Table 4-4 lists each type of injury received in the claim data. The injuries are ranked by the total number received and proportion. The proportion was calculated by dividing the number of claims for each injury by the total number of claims received for each type of surgery.

Many of these injuries are not unique to urogynaecological repair with mesh and are known to occur with non-mesh procedures as well. Like all general surgeries, postoperative complications after urogynaecological surgical mesh implants may be caused by a combination of mesh and non-mesh factors (i.e., surgical technique, patient anatomy etc.).

Table 4-4 Mesh-related injuries/complications per type of surgery

	Total n =264	SUI n=54	POP n=131	Combined (POP/SUI) N=79
Type of injury/complication*				
Mesh erosion/exposure/extrusion	187(71%)	46(85%)	83(63%)	58(73%)
Dyspareunia	63(24%)	13(24%)	34(26%)	16(20%)
Voiding symptoms	48(18%)	19(35%)	12(9%)	17(22%)
Pain	37(14%)	9(17%)	19(15%)	9(11%)
Infection/Fistula	36(14%)	9(17%)	12(9%)	15(19%)
Bleeding/haematoma	17(6%)	0(0%)	11(8%)	6(8%)
No injury related to mesh#	16(6%)	<4(<7%)	11(8%)	<4(<5%)
Mesh Shrinkage/Contraction/Migration	14(5%)	0(0%)	10(8%)	4(5%)
Organ perforation	12(5%)	<4(<7%)	4(3%)	6(8%)
Nerve injury	11(4%)	0(0%)	11(8%)	0(0%)
Scarring/adhesions	6(2%)	<4(<7%)	4(3%)	<4(<5%)
Incontinence Bowel	5(2%)	0(0%)	5(4%)	0(0%)
Other	<4(<2%)	0(0%)	<4(<3%)	0(0%)
Re-surgery				
Yes	242(92%)	52(96%)	116(89%)	74(94%)
No	20(8%)	<4(<7%)	14(11%)	4(5%)
Unknown	<4(<2%)	0(0%)	<4(<3%)	<4(<5%)

Note: # See detail about "No injury related to mesh" in Table 6-12 (Appendix 3)

The most common claims received for mesh-related injuries/complications were mesh erosion/exposure/extrusion (n=181, 71%), followed by dyspareunia (n=14, 5%), voiding symptoms (n=48, 18%), pain (n=37, 14%) and infection/fistula (n=36, 14%). The other claims were for bleeding/haematoma (n=12, 6%), mesh shrinkage/contraction/migration (n=10, 5%),

organ perforation (n=12, 5%), nerve injury (n=11, 4%), scarring/adhesions (n=6, 2%) and bowel incontinence (n<4, <2%).

This review found a large number of urogynaecology procedures where surgical mesh was used required additional surgery. This may be explained by a high proportion of Mesh erosion/exposure/extrusion, which are serious complications that are not experienced by patients who undergo traditional repairs. To manage these complications, partial or complete mesh removal or excision sometimes is unavoidable (Marcus-Braun and Theobald, 2010).

4.2 Hernia repair and other general surgery

4.2.1 Client demographics and preoperative characteristics

Table 4-5 shows that there are 130 (64%) male and 72 (36%) female in this cohort, with an average age of 55 years old. Published epidemiological data show males generally have a significantly higher number of hernia repairs compared with females (Burcharth, Pedersen, Bisgaard, Pedersen, & Rosenberg, 2013; Dabbas, Adams, Pearson, & Royle, 2011). Compared with the clients who underwent urogynaecological surgery, a higher percentage of preoperative health conditions and symptoms were reported in the hernia group with an exception of chronic constipation (9% vs. 11%). Similarly to the urogynaelogic surgery results , a high proportion of previous surgeries in same area was reported.

Table 4-5 Client demographics and preoperative characteristics

	Total n =202	Hernia n=181	Other surgery n=21
Gender			
Male	130(64%)	125(69%)	5(24%)
Female	72(36%)	56(31%)	16(76%)
Age (years)	55±13	56±13	51±14
Health status			
Smoking	45(22%)	41(23%)	4(19%)
Respiratory	55(27%)	51(28%)	4(19%)
Vascular	44(22%)	39(22%)	5(24%)
Diabetes	39(19%)	38(21%)	<4(<19%)
Chronic constipation	17(8%)	16(9%)	1(5%)
Overweight	61(30%)	58(32%)	<4(<19%)
Immune/Inflammatory disease	27(13%)	26(14%)	1(5%)
Symptoms			
Chronic pain	55(27%)	52(29%)	<4(<19%)
Pelvic pain	57(28%)	55(30%)	<4(<19%)
Previous surgeries in same area	123(61%)	110(61%)	13(62%)

4.2.2 Characteristics of general surgery involving mesh

Table 4-6 shows that the majority of the surgeries are elective hernia repairs or other general surgeries. Of the 181 hernia repair surgeries, 64 (35%) occurred in the groin and 117 (65%) occurred in the general abdominal/ventral wall. 153 (76%) surgeries were open repair with surgical mesh, while 41(20%) used laparoscope.

Table 4-6 Characteristics of general surgery involving mesh

	Total n =202	Hernia n=181	Other surgery n=21
Site of Hernia repair			
Groin	64(32%)	64(35%)	-
Ventral	117(58%)	117(65%)	-
Approach			
Open	153(76%)	132(73%)	21(100%)
Laparoscope	41(20%)	41(23%)	0(0%)
Unknown	8(4%)	8(4%)	0(0%)
Type			
Elective	175(87%)	160(88%)	15(71%)
Acute	27(13%)	21(12%)	6(29%)

4.2.3 Characteristics of mesh device used in general surgery

Table 4-7 shows that in total, about 34% (n=68) of mesh devices were modified and 64% (n=129) were secured. Suture was the most common mesh securing method and was used in 54% (n=110) of the surgeries.

Table 4-7 Use of mesh device in general surgery

	Total n =202	Hernia n=181	Other surgery n=21
Mesh modification			
Yes	68(34%)	65(36%)	<4(<19%)
No	50(25%)	45(25%)	<4(<19%)
Unknown	84(42%)	71(39%)	13(62%)
Mesh secured status			
Yes	135(67%)	126(70%)	9(43%)
No	<4(<2%)	<4(<3%)	<4(<19%)
Unknown	64(32%)	53(29%)	11(52%)
Mesh securing methods*			
Clips	0(0%)	0(0%)	0(0%)
Suture	110(54%)	102(56%)	8(38%)
Staple	13(6%)	12(7%)	<4(<19%)
Tack	24(12%)	24(13%)	0(0%)
Glue	0(0%)	0(0%)	0(0%)

Note: *One mesh surgery might use more than one securing methods.

4.2.4 *Injury/complication type and prevalence following general surgery*

Table 4-8 shows that the most common claims received for mesh-related injuries/complications were infection/fistula (n=117, 58%), followed by 22 (11%) dehiscence, mesh shrinkage/contraction/migration (n=21, 10%) and pain (n=18, 9%). Fistula is recognised as the most severe surgical complication. The other claims were for mesh erosion/expose/extrusion (n=12, 6%), nerve injury (n=10, 5%), organ perforation (n=9, 4%), bleeding/haematoma (n=7, 3%), Scarring/adhesions and dyspareunia (n<4, <2%). 75% of clients required further-surgery due to these injuries.

Table 4-8 Injuries/complications following general surgery

	Total n =202	Hernia n=181	Other surgery n=21
Type of injury/complications*			
Infection/Fistula	117(58%)	105(58%)	12(57%)
No injury related to mesh#	32(16%)	30(17%)	<4(<19%)
Dehiscence	22(11%)	17(9%)	5(24%)
Mesh Shrinkage/Contraction/Migration	21(10%)	20(11%)	<4(<19%)
Pain	18(9%)	16(9%)	<4(<19%)
Other	13(6%)	11(6%)	<4(<19%))
Mesh erosion/exposure/extrusion	12(6%)	12(7%)	0(0%)
Nerve injury	10(5%)	9(5%)	<4(<19%)
Organ perforation	9(4%)	8(4%)	<4(<19%)
Bleeding/haematoma	7(3%)	5(3%)	<4(<19%)
Scarring/adhesions	<4(<2%)	<4(<3%)	0(0%)
Dyspareunia	<4(<2%)	<4(<3%))	0(0%)
Re-surgery			
Yes	151(75%)	133(73%)	18(86%)
No	41(20%)	38(21%)	<4(<19%)
Unknown	10(5%)	10(6%)	0(0%)

Note: # See detail about "No injury related to mesh" in Table 6-12 (Appendix 3)

Many of these injuries are not unique to hernia repair with mesh and are known to occur with non-mesh procedures as well. Like all general surgery, postoperative complications can occur irrespective of the medical device used. To demonstrate this point a 2014 systematic review evaluated surgical site infection after primary ventral hernia repair using mesh or suture. The overall infection rate was similar between mesh repair 7.3% and suture repair 6.6%. However,

a further multivariate meta-analysis as part of the 2014 system review also identified a contradiction that infection occurrence was significantly associated with mesh repair (Odd Ratio: 0.65, 95% CI 0.12-1.18; P = .02). This suggests that mesh may increase the risk of surgical site infection (Nguyen et al., 2014).

5 References

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6 Appendices

6.1 Appendix 1: Data collection template

Criteria for ACC Surgical Mesh Review				
Category Label	**Criteria**	**Sub-criteria**	**Data fields**	**Notes**
Demographics	Date of birth		xx/xx/xxxx	This information is already available on ACC claims system
	Gender		M/F	This information is already available on ACC claims system
	Ethnicity		Ethnicity type	This information is already available on ACC claims system
Injury/Complication directly related to the surgical mesh	Nerve injury		Checkbox	
	Dehiscence		Checkbox	
	Bladder voiding symptoms (select all that apply)	Retention	Checkbox	
		Obstruction	Checkbox	
		Incontinence	Checkbox	
	Mesh adherence		Checkbox	i.e. to bone, bowel
	Mesh curling		Checkbox	
	Mesh migration		Checkbox	
	Mesh shrinkage/contraction		Checkbox	
	Mesh tearing		Checkbox	
	Mesh erosion/exposure/extrusion		Checkbox	
	Infection/Fistula		Checkbox	
	Bowel perforation		Checkbox	
	Bladder perforation		Checkbox	
	Rectum perforation		Checkbox	
	Vagina perforation		Checkbox	
	Other perforation: please specify		Free text	
	Bleeding/haematoma		Checkbox	
	Pain		Checkbox	In absence of any injury/complication giving rise to pain
	Scarring/adhesions		Checkbox	
	Incontinence bowel		Checkbox	
	No injury related to mesh		Checkbox	There may have been a complication/injury but it was not directly related to mesh
	Date of the injury/complication		xx/xx/xxxx	On what date does the injury/complication first appear in the clinical records
	Did the complication/injury result in a need for further surgery?		Y/N/U	

Surgery Involving Mesh	Context	Gynaecology		This information is already available in ACC claims system
		Urology		This information is already available in ACC claims system
		General Surgery		This information is already available in ACC claims system
	Date of surgery		xx/xx/xxxx	From operation report or similar
	Stress urinary incontinence	Retropubic urethral slingplasty	Checkbox	e.g. TVT, SPARC, IVS
		Transobturator urethral slingplasty	Checkbox	e.g. TVT-O, MONARC
		Single incision system	Checkbox	e.g. TVT-Secur
		Advance sling	Checkbox	Male
		Invance sling	Checkbox	Male
	Pelvic organ prolapse (select one or more as appropriate)	Anterior	Checkbox	e.g. anterior colporrhaphy, cystocele repair
		Posterior	Checkbox	e.g. posterior colporrhaphy, rectocele repair
		Uterine	Checkbox	e.g. sacrohysteropexy
		Vaginal vault	Checkbox	e.g. sacrocolpopexy after hysterectomy
		Rectal	Checkbox	e.g. external rectal prolapse, intussusception
	Hernia (select one or more as appropriate)	Groin	Checkbox	e.g. inguinal/femoral
		Ventral	Checkbox	e.g. incisional
	Surgery Route (select all that apply)	Open	Checkbox	
		Transvaginal	Checkbox	
		Laparoscopic	Checkbox	Direct indication that procedure performed laparoscopically
	Concomitant hysterectomy		Checkbox	
	Facility			Available on ACC claims system
Mesh Device & Use	Device name		Free text	e.g. Monarc, TVT, Apogee
	Brand name		Free text	e.g. American Medical Systems
	Model number		Free text	e.g. 810081
	Batch		Free text	e.g. 1307149
	Composition of mesh	Synthetic	Checkbox	
		Biological	Checkbox	
		Composite	Checkbox	
		Unknown	Checkbox	
	Mesh Design	Absorbable	Checkbox	
		Non-absorbable	Checkbox	
		Composite	Checkbox	
		Unknown	Checkbox	
	Was the mesh modified?		Y/N/U	e.g. fashioned/tailored/trimmed/cut to size
	How was the mesh secured (select all that apply)	Suture	Checkbox	e.g. PDS
		Staple	Checkbox	

		Tack	Checkbox	e.g. ProTack
		Glue	Checkbox	
		It wasn't	Checkbox	
		Unknown	Checkbox	
Health status at the time of mesh surgery	Smoker		Y/N/U	Defined as reference to being a smoker within the 2 years prior to surgery in which mesh was used.
	Autoimmune/Systemic inflammatory disease		Checkbox	e.g. diagnosed with systemic sclerosis (SSc), dermatomyositis, polymiositis, psoriatic arthritis, scleroderma, rheumatoid arthritis, systemic lupus erythematosus (SLE)
	Chronic Lung Disease		Checkbox	e.g. COPD, CORD, emphysema, chronic bronchitis, asthma
	Vascular disease		Checkbox	e.g. stroke (CVA), heart attack (MI), peripheral vascular disease, angina, transient ischaemic attack
	Diabetes		Checkbox	e.g. diagnosed with Type 1 or 2 diabetes
	Chronic constipation		Checkbox	e.g. use of Laxatives (constipation medication): Laevolac, Laxofast, Movicol, Laxsol, Senokot, Dulcolax
	Overweight/Obese		Y/N/U	BMI >30 or referred to as obese/overweight in clinical records.
	Grade of POP-Q (select one that apply)	Grade 1	Checkbox	
		Grade 2	Checkbox	
		Grade 3	Checkbox	
		Grade 4	Checkbox	
		Unknown	Checkbox	
	Previous surgery	For prolapse	Checkbox	
		Hysterectomy	Checkbox	
		In same area	Checkbox	
	Menopausal		Checkbox	e.g. treated with oestrogen cream, reference to vaginal atrophy, 65 years or older
Symptoms at the time of mesh surgery	Chronic pain		Y/N/U	e.g. chronic back or neck pain.
	Pelvic pain		Y/N/U	e.g. longstanding (greater than 1 week) pain/discomfort in the pelvis.
	Incontinence (select all that apply)	Bowel	Checkbox	
		Urine	Checkbox	
	Dyspareunia		Y/N/U	i.e. discomfort with sexual intercourse.

6.2 Appendix 2: Definition of indicators

Injury/Complication

'Primary Injury/Complication' – This was identified by reviewing the ACC 45 claim form, ACC 2152 Treatment Injury Claim form (where available) and medical information on file (i.e. contemporaneous medical records, reports from treating provider(s), external clinical advisor(s), internal medical advisor(s)). The Primary injury/complication was determined to be the main injury/complication and may have lead on to subsequent (secondary/tertiary) injuries (see template drop down list for the full list of injury/complications and definitions).

'Secondary/Tertiary Injury/Complication' – These were usually caused by or followed on from the primary injury (e.g. dehiscence caused the by the primary injury of infection) but may also have been unrelated (e.g. incontinence as a secondary injury unrelated to erosion as the primary injury).

'Date of Injury/Complication' – Was determined as a date the client first reported signs or symptoms related to the mesh injury/complication.

'Was further surgery required as a result of the injury/complication' – Where the available information indicated that further surgery was required to treat the injury/complication, this was noted. This was also the case if a need for further surgery had been indicated but the surgery had not yet taken place. "Surgery" also included minor procedures done under local anaesthetic.

'Date of surgery' – This was identified from either the operation report or other medical notes. If the day and/or month were not recorded then the 15th day of the month and/or June of the stated year was recorded. This was usually only the case when the surgery had taken place a considerable amount of time ago.

Surgery Involving Mesh

'Type of Surgery' – This involved four broad categories (stress urinary incontinence, pelvic organ prolapse, hernia, other). These were broken down into more detailed procedures for each category (see template for full list).

'Emergency/Elective Surgery' – This was identified from operation reports or other medical records for hernia only procedures (groin or incisional), using key words such as emergency, elective, acute, incarcerated hernia.

'Surgery Route' – There were several options for surgery route on the template: open, transvaginal or laparoscopic. All surgery routes that were used could be selected. For example: laparoscopic and transvaginal for prolapse repair surgeries.

'Concomitant Hysterectomy' – Where the uterus was removed at the same surgery as mesh was placed.

Mesh Device Details

'Brand name' – The brand names of mesh was usually indicated in the operation record and was recorded verbatim. Brand name of mesh was determined and entered post claim review using a master list of mesh brands classification. Model and batch number were recorded when present.

'Mesh Modification' – If operation record noted that the mesh was modified (i.e. - "trimmed", "cut to size", "fashioned") then it was noted that the mesh had been modified. If part of the mesh device was pulled through skin incision and cut, this was not considered a modification as this is a standard procedure.

'How was mesh secured' – If the operation records indicated the use of suture, staple, tack, or glue then it was recorded. If the mesh was "pulled through" then this was recorded as "it wasn't" secured.

Health status at the time of mesh surgery

The health status of the client at the time of mesh surgery was sourced from the medical records and reports on file. It should be noted that there were varying amounts of information on file which a client's health status could be determined. If there was a reasonable amount of clinical information on the file and there was no mention of a particular condition then -"No"- was recorded. It was felt that in these cases if a client did have a particular condition then it was reasonable to assume that it would be recorded in the available information and if it was not it was likely they did not have that condition. Alternatively if the medical information on file was sparse and a condition wasn't mentioned then "Unknown" was recorded.

'Smoker' – A smoker was defined as someone who was a current smoker at the time of surgery or who had given up smoking in the two years prior to surgery.

'Immune/systemic inflammatory disease' – Diagnosed with an autoimmune or systemic inflammatory disease i.e. rheumatoid arthritis, lupus, psoriatic arthritis, scleroderma.

'Chronic Lung Disease' – i.e. COPD, CORD, emphysema, chronic bronchitis, asthma.

'Vascular Disease' – i.e. history of CVA/TIA or MI, peripheral vascular disease, angina.

'Diabetes' – a diagnosis of type I or II diabetes.

'Chronic constipation' – Indicated either by diagnosis or the prescription of medication to treat constipation over a long period of time.

'Overweight/Obese' – Any mention of elevated BMI, excessive weight, "obesity", "overweight".

'Grade of Prolapse' – Where mentioned the grade of prolapse being surgically treated was noted. If several organs were prolapsed then the highest score was recorded.

'Previous Surgery (Prolapse, Hysterectomy, Same Area)' – Where mentioned in the available records, it was noted if the client had previous surgery to treat pelvic organ prolapse, a hysterectomy and/or surgery in the same area.

'Menopausal' – Clients were noted as being menopausal if they were prescript "Ovestin" cream prior to, or following surgery. If women were 65 years or older, if there was mention of vaginal atrophy or who previously had oophorectomies. Men were automatically recorded as "No".

'Chronic Pain' – This was noted if the records indicated that the client had suffered from chronic pain in any part of the body (i.e. back, neck, abdominal) for a period of six months or longer prior to mesh surgery.

'Pelvic Pain' – Was defined as a greater than one week history of pain/discomfort in the pelvic region before mesh surgery. This included groin pain associated with hernia, or pelvic pain associated with prolapse.

'Incontinence Bladder' – This included urge/stress incontinence.

'Incontinence Bowel' – This included any difficulty with bowel control, including involuntary passing of a stool.

'Dyspareunia' - Discomfort experienced during sexual intercourse.

6.3 Appendix 3: Detailed tabulations

Table 6-1 Demographic characteristics of clients by surgery type

	Total N=466	SUI N=54	POP N=131	Combined (POP/SUI) N=79	Hernia repair N=181	Other surgery N=21
Gender						
Female	72%	100%	100%	100%	31%	76%
Male	28%	0%	0%	0%	69%	24%
Total	100%	100%	100%	100%	100%	100%
Age at surgery						
Under 40	9%	11%	5%	<5%	12%	19%
40-49	17%	26%	11%	20%	19%	<19%
50-59	34%	44%	38%	33%	26%	48%
60-69	30%	15%	39%	34%	28%	<19%
Over 70	10%	<7%	6%	10%	15%	<19%
Total	100%	100%	100%	100%	100%	100%
Ethnicity						
European	86%	94%	94%	92%	76%	76%
NZ Maori	6%	<7%	<3%	<5%	12%	<19%
Asian	2%	0%	0%	0%	4%	<19%
Pacific	2%	0%	<3%	0%	3%	<19%
MELAA*	<1%	0%	<3%	0%	<2%	0%
Other/unknown	4%	<7%	3%	5%	4%	0%
Total	100%	100%	100%	100%	100%	100%

Total may not sum to 100% exactly due to rounding
*Middle Eastern, Latin American, African

Table 6-2 Heath status of clients at the time of mesh surgery by surgery type

Health status	Total N=466	SUI N=54	POP N=131	Combined (POP/SUI) N=79	Hernia repair N=181	Other surgery N=21
Smoking						
No	61%	52%	66%	63%	57%	67%
Unknown	26%	41%	30%	27%	20%	<19%
Yes	13%	7%	4%	10%	23%	19%
Total	100%	100%	100%	100%	100%	100%

Respiratory						
No	58%	59%	61%	58%	55%	67%
Unknown	24%	37%	29%	23%	17%	<19%
Yes	18%	<7%	10%	19%	28%	19%
Total	100%	100%	100%	100%	100%	100%
Vascular						
No	60%	57%	60%	63%	60%	62%
Unknown	24%	37%	29%	22%	18%	<19%
Yes	16%	<7%	11%	15%	22%	24%
Total	100%	100%	100%	100%	100%	100%
Diabetes						
No	65%	61%	64%	73%	61%	81%
Unknown	24%	37%	28%	23%	18%	<19%
Yes	11%	<7%	7%	<5%	21%	<19%
Total	100%	100%	100%	100%	100%	100%
Chronic constipation						
No	62%	52%	51%	66%	69%	76%
Unknown	25%	37%	29%	20%	22%	<19%
Yes	13%	11%	20%	14%	9%	<19%
Total	100%	100%	100%	100%	100%	100%
Overweight						
No	55%	48%	64%	62%	48%	52%
Unknown	26%	39%	28%	24%	20%	33%
Yes	19%	13%	8%	14%	32%	<19%
Total	100%	100%	100%	100%	100%	100%
Immune/inflammatory disease						
No	66%	59%	63%	66%	68%	81%
Unknown	24%	37%	28%	23%	18%	<19%
Yes	10%	<7%	7%	11%	14%	<19%
Total	100%	100%	100%	100%	100%	100%

Total may not sum to 100% exactly due to rounding

Table 6-3 Primary injury/complications of claims by surgery type

Primary injury/complication	Total N=466	SUI N=54	POP N=131	Combined (POP/SUI) N=79	Hernia repair N=181	Other surgery N=21
Mesh erosion/exposure/extrusion	38%	80%	60%	65%	4%	0%

Infection/Fistula	25%	<7%	<3%	10%	51%	52%
No injury related to mesh	10%	<7%	8%	<5%	17%	<19%
Mesh Shrinkage/Contraction/Migration	6%	0%	7%	<5%	9%	0%
Pain	5%	<7%	5%	<5%	6%	<19%
Nerve injury	4%	0%	8%	0%	4%	<19%
Voiding symptoms	3%	9%	<3%	8%	0%	0%
Other	2%	0%	<3%	0%	5%	<19%
Dyspareunia	2%	0%	4%	5%	0%	0%
Scarring/adhesions	2%	<7%	<3%	<5%	<2%	0%
Bleeding/haematoma	1%	0%	<3%	0%	<2%	<19%
Organ perforation	1%	<7%	<3%	0%	<2%	<19%
Dehiscence	<1%	0%	0%	0%	0%	<19%
Incontinence Bowel	<1%	0%	<3%	0%	0%	0%
Total	100%	100%	100%	100%	100%	100%

Total may not sum to 100% exactly due to rounding

Table 6-4 Secondary injury/complication of claims by surgery type

Secondary injury/complication	Total N=466	SUI N=54	POP N=131	Combined (POP/SUI) N=79	Hernia repair N=181	Other surgery N=21
No secondary injury/complication	57%	31%	53%	42%	73%	67%
Dyspareunia	15%	13%	13%	13%	<2%	0%
Infection/Fistula	15%	5%	9%	9%	7%	5%
Voiding symptoms	6%	24%	5%	8%	0%	0%
Pain	5%	7%	7%	6%	3%	0%
Dehiscence	4%	0%	0%	0%	9%	<19%
Mesh erosion/exposure/extrusion	4%	<7%	4%	9%	2%	0%
Bleeding/haematoma	3%	0%	6%	5%	<2%	<19%
Organ perforation	3%	<7%	<3%	8%	<2%	0%
Mesh Shrinkage/Contraction/Migration	1%	0%	<3%	<5%	<2%	<19%
Other	<1%	0%	<3%	0%	<2%	<19%
Incontinence Bowel	<1%	0%	<3%	0%	0%	0%
Nerve injury	<1%	0%	<3%	0%	<2%	0%
Scarring/adhesions	<1%	0%	<3%	0%	<2%	0%
Total	100%	100%	100%	100%	100%	100%

Total may not sum to 100% exactly due to rounding

Table 6-5 Tertiary injury/complication of claims by surgery type

Tertiary injury/complication	Total N=466	SUI N=54	POP N=131	Combined (POP/SUI) N=79	Hernia repair N=181	Other surgery N=21
No tertiary injury/complication	89%	81%	82%	87%	96%	100%
Dyspareunia	4%	9%	9%	<5%	0%	0%
Pain	2%	9%	9%	<5%	<2%	0%
Voiding symptoms	2%	<7%	3%	6%	0%	0%
Bleeding/haematoma	1%	0%	<3%	3%	0%	0%
Organ perforation	1%	0%	0%	0%	2%	0%
Incontinence Bowel	<1%	0%	<3%	0%	0%	0%
Mesh erosion/exposure/extrusion	<1%	0%	0%	0%	<2%	0%
Infection/Fistula	<1%	0%	<3%	0%	0%	0%
Mesh Shrinkage/Contraction/Migration	<1%	0%	0%	0%	<2%	0%
Total	100%	100%	100%	100%	100%	100%

Total may not sum to 100% exactly due to rounding

Table 6-6 Mesh device name of claims by surgery type

Device name	Total N=466	SUI N=54	POP N=131	Combined (POP/SUI) N=79	Hernia repair N=181	Other surgery N=21
Prolene	10%	0%	<3%	<5%	22%	19%
TVT/TVT-O	7%	32%	0%	22%	0%	0%
Gynaecare Prolift	7%	0%	11%	20%	0%	0%
Monarc	6%	28%	<3%	15%	0%	0%
Gynaecare	6%	0%	11%	14%	0%	0%
Apogee	5%	0%	16%	<5%	0%	0%
Perigee	4%	0%	12%	<5%	0%	0%
Parietex	3%	0%	0%	0%	6%	<19%
Marlex	2%	0%	<3%	0%	4%	<19%
SurgiPro	2%	0%	<3%	<5%	3%	<19%
C-Qur	2%	0%	0%	0%	4%	0%
IVS	2%	<7%	<3%	<5%	0%	0%
Caldera Ascend AC	1%	0%	<3%	<5%	0%	0%
Cysto Swing	1%	<7%	<3%	<5%	0%	0%
SPARC	1%	11%	0%	0%	0%	0%
Proceed*	1%	0%	0%	0%	3%	0%
ProlIte	1%	0%	<3%	0%	<2%	0%

Gynaecare Elevate	1%	0%	<3%	0%	0%	0%
Recto-Swing	1%	0%	<3%	<5%	0%	0%
Ultrapro	1%	0%	<3%	0%	<2%	0%
Uphold	1%	0%	<3%	0%	0%	0%
Atrium	1%	0%	0%	0%	<2%	0%
Permacol	1%	0%	0%	0%	<2%	<19%
Surgisis	1%	0%	<3%	0%	<2%	0%
Dualmesh	<1%	0%	0%	0%	<2%	0%
GoreTex	<1%	0%	0%	0%	<2%	<19%
Kugel	<1%	0%	0%	0%	<2%	0%
Pelvicol	<1%	<7%	<3%	0%	0%	0%
Sepra Mesh	<1%	0%	0%	0%	<2%	0%
Y mesh	<1%	0%	<3%	0%	0%	0%
3D Bard	<1%	0%	0%	0%	<2%	0%
A30ProLite	<1%	0%	0%	0%	0%	<19%
AdVance	<1%	0%	0%	0%	0%	<19%
Physio mesh	<1%	0%	0%	0%	<2%	0%
Prosimar	<1%	0%	<3%	0%	0%	0%
Surgilene	<1%	<7%	0%	0%	0%	0%
Teflon	<1%	0%	<3%	0%	0%	0%
Titanium mesh	<1%	0%	0%	0%	0%	<19%
Vipro	<1%	0%	0%	0%	<2%	0%
Unknown	30%	20%	20%	14%	46%	38%
Total	100%	100%	100%	100%	100%	100%

Total may not sum to 100% exactly due to rounding

Table 6-7 Mesh modified status of claims by surgery type

Mesh modified	Total N=466	SUI N=54	POP N=131	Combined (POP/SUI) N=79	Hernia repair N=181	Other surgery N=21
No	42%	63%	47%	65%	25%	24%
Unknown	32%	33%	26%	19%	39%	62%
Yes	26%	<7%	27%	16%	36%	<19%
Total	100%	100%	100%	100%	100%	100%

Total may not sum to 100% exactly due to rounding

Table 6-8 Mesh secured status of claims by surgery type

Mesh secured	Total N=466	SUI N=55	POP N=131	Combined (POP/SUI)	Hernia repair N=181	Other surgery N=20

				N=79		
No	17%	52%	15%	34%	<2%	<19%
Unknown	29%	39%	24%	27%	29%	52%
Yes	54%	9%	60%	39%	70%	43%
Total	100%	100%	100%	100%	100%	100%

Total may not sum to 100% exactly due to rounding

Table 6-9 Detailed mesh secured status by surgery type

	Total N=466	SUI N=54	POP N=131	Combined (POP/SUI) N=79	Hernia repair N=181	Other surgery N=21
Clips						
No	18%	24%	20%	18%	14%	24%
Unknown	82%	76%	79%	82%	86%	76%
Yes	0%	0%	<3%	0%	0%	0%
Total	100%	100%	100%	100%	100%	100%
Suture						
No	9%	18%	9%	14%	5%	<19%
Unknown	43%	73%	31%	49%	39%	52%
Yes	48%	9%	60%	37%	56%	38%
Total	100%	100%	100%	100%	100%	100%
Staple						
No	19%	24%	21%	19%	15%	24%
Unknown	78%	76%	78%	81%	78%	71%
Yes	3%	0%	<3%	0%	7%	<19%
Total	100%	100%	100%	100%	100%	100%
Tack						
No	18%	24%	20%	18%	14%	24%
Unknown	75%	76%	76%	80%	72%	76%
Yes	7%	0%	4%	<5%	13%	0%
Total	100%	100%	100%	100%	100%	100%
Glue	**466**	**55**	**131**	**79**	**181**	**20**
No	18%	24%	21%	18%	14%	24%
Unknown	82%	76%	79%	82%	86%	76%
Yes	0%	0%	0%	0%	0%	0%
Total	100%	100%	100%	100%	100%	100%

Total may not sum to 100% exactly due to rounding
One claim may have multiple mesh secured types

Table 6-10 Previous surgery of clients by surgery type

	Total N=466	SUI N=54	POP N=131	Combined (POP/SUI) N=79	Hernia repair N=181	Other surgery N=21
For hysterectomy						
No	58%	37%	37%	39%	86%	57%
Unknown	13%	34%	15%	14%	5%	<19%
Yes	30%	30%	48%	47%	9%	29%
Total	100%	100%	100%	100%	100%	100%
For prolapse						
No	65%	41%	39%	54%	94%	81%
Unknown	13%	37%	15%	13%	4%	<19%
Yes	22%	22%	46%	33%	<2%	<19%
Total	100%	100%	100%	100%	100%	100%
In same area						
No	23%	22%	14%	25%	29%	33%
Unknown	15%	36%	17%	14%	10%	0%
Yes	61%	45%	69%	61%	61%	62%
Total	100%	100%	100%	100%	100%	100%

Total may not sum to 100% exactly due to rounding
One client may have multiple previous surgeries

Table 6-11 Symptoms of clients at the time of surgery by surgery type

	Total N=466	SUI N=54	POP N=131	Combined (POP/SUI) N=79	Hernia repair N=181	Other surgery N=21
Menopausal						
No	40%	34%	11%	9%	77%	43%
Unknown	12%	16%	14%	11%	7%	29%
Yes	48%	50%	75%	80%	17%	29%
Total	100%	100%	100%	100%	100%	100%
Chronic pain						
No	56%	72%	50%	59%	53%	71%
Unknown	22%	24%	27%	20%	18%	<19%
Yes	22%	<7%	22%	20%	29%	<19%
Total	100%	100%	100%	100%	100%	100%
Pelvic pain						
No	57%	68%	51%	65%	52%	76%

Unknown	24%	24%	34%	24%	17%	<19%
Yes	19%	<7%	15%	11%	30%	<19%
Total	100%	100%	100%	100%	100%	100%

Total may not sum to 100% exactly due to rounding

Table 6-12 Injuries/complications not related to mesh

Reason	Number of claims	%
Recurrence/unmasking of pre-existing condition (e.g. recurrent hernia, recurrent prolapse, incontinence)	23	51%
Surgical injury not related to mesh (e.g. hematoma not in area of mesh, sutures other than those used to secure mesh)	15	33%
Symptoms caused by factors other than mesh (i.e. compartment syndrome, scar tissue formation, infection not related to mesh, pre-existing pain from previous non-mesh surgery, physiological processes)	7	16%
Total	45	100%

Table 6-13 Mesh composition characteristics by surgery type

Compositions	Total N=466	SUI N=54	POP N=131	Combined (POP/SUI) N=79	Hernia repair N=181	Other surgery N=21
Biological	2%	<7%	<3%	0%	<2%	<19%
Composite	21%	0%	41%	25%	11%	<19%
Polypropylene	48%	78%	37%	61%	42%	48%
Unknown	30%	20%	20%	14%	45%	38%
Total	100%	100%	100%	100%	100%	100%

Total may not sum to 100% exactly due to rounding

Table 6-14 Facility category of claims by surgery type

Facility category	Total N=466	SUI N=54	POP N=131	Combined (POP/SUI) N=79	Hernia repair N=181	Other surgery N=21
Private	61%	64%	76%	80%	41%	43%
Public	39%	36%	21%	20%	59%	57%
Unknown	1%	0%	<3%	0%	0%	0%
Total	100%	100%	100%	100%	100%	100%

Total may not sum to 100% exactly due to rounding

Table 6-15 Mesh claims compared with TI claims and ACC claims

Cover decision fiscal year	Number of Claims	% of TI claims decided	% of ACC claims decided
2005-2006	6	0.17%	0.0003%
2006-2007	29	0.52%	0.0005%
2007-2008	42	0.60%	0.0022%

2008-2009	80	0.97%	0.0043%
2009-2010	89	1.09%	0.0050%
2010-2011	37	0.45%	0.0021%
2011-2012	34	0.41%	0.0019%
2012-2013	68	0.70%	0.0037%
2013-2014	81	0.81%	0.0043%
Total	466	0.68%	0.0023%