Surgical Mesh for Uro-Genital Report Adverse Event Reports

November 2008

Medsafe has received a number of medical device adverse event reports relating to several brands of surgical mesh implants used for uro-genital repair. Medsafe seeks MDIRC's guidance on what would be the most appropriate response to these reports.

Background

Since 2006 Medsafe has received 14 adverse event reports relating to complications resulting from the use of surgical mesh implants for the continence and pelvic repairs. All of these events have been reported via the New Zealand Accident Compensation Corporation (ACC). The events have occurred at a mixture of public and private hospitals (11 in total) over a wide geographical area. Only one hospital is involved in more than one adverse event, with three (3) events reported.

Before the events were referred to Medsafe they were reviewed by the ACC Harm Panel. The panel advised that it viewed the events as "serious with a moderate likelihood of recurrence."

These events have not previously been reported to MDIRC as they have been subject of an on-going study by Medsafe.

Adverse Event Summary

The table below summarises the main details of the events reported.

Date of Event	Injury	Brand	Device	Model	Batch
30-Oct-2005	Rectal damage/tear	American Medical System	SPARC Sling	72403657	375289008
03-Mar-2006	Vaginal damage/tear	Unable to obtain information			
19-May-2006	Vaginal damage/tear	American Medical System	Apogee System with InterPro	72404025	447138028
5-Jul-2006	Vaginal damage/tear	Johnson & Johnson Medical	Gynaecare TVT	810041B	1319566
15-Jul-2006	Vaginal damage/tear	American Medical System	Perigee System with IntePro	72404046	424923013
19-Jul-2006	Vaginal damage/tear	Unable to identify patient at the reported hospital			
19-Jul-2006	Procedural complications	Johnson & Johnson	Gynaecare TVT	810081	2906367

		Medical			
14-Sep-2006	Vaginal damage/tear	Information not recorded			
Date of Event	**Injury**	**Brand**	**Device**	**Model**	**Batch**
11-Dec-2006	Vaginal damage/tear	Johnson & Johnson Medical	Gynaecare Gynaemesh PS	GPSL L02	XBE363
18-Jan-2007	Urinary retention	Johnson & Johnson Medical	Gynaecare Gynaemesh PS	GPSL	XAD746
25-Jan-2007	Vaginal damage/tear	Johnson & Johnson Medical	Gynaecare Gynaemesh PS	GPSL	XAD746
11-Oct-2007	Vaginal damage/tear	Labastide Rouairoux		THT81270	504904
13-Mar-2008	Vaginal damage/tear	Johnson & Johnson Medical	Gynaecare Gynaemesh PS	810081	1307149
4-Apr-2008	Vaginal damage/tear	TVT Prolene	Unable to obtain information		

Product Information

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists issued a statement entitled “The Use of Mesh in Gynaecological Surgery (Ref C-Gyn 20)” in July 2007. The statement noted that there was now a wide range of prosthetic materials available for the treatment of pelvic organ prolapse and that there are potential major complications in the use of mesh in the management of pelvic organ prolapse.

The instructions for use accompanying the AMS SPARC Sling System notes that erosion through the surrounding tissue and migration of the device from the desired location are known risks with the product. Johnson & Johnson Medical issued similar advice about the potential for adverse reactions of erosion and extrusion in their instructions for use for the Gynaecare Gynaemesh PS product.

Literature Review

The use of vaginal meshes has been in advance of surgical management of women with POP (pelvic organ prolapse) syndrome (Segev Y. et al, 2008). Although the use of vaginal meshes has become a new effective method of pelvic organ prolapse surgery clinicians should be aware of the various post-operative complications, including mesh-related infections. (Falagas M.E. et al, 2007).

The January 2002 issue of “OB/GYN News” published an article entitled “Tension-Free Vaginal Tape: Follow the Rules”. It stated that “Mesh protrusion is the most common TVT complication. It’s a technical error, often due to inadequate suturing, improper passage of the tape through the anterior vaginal wall, or premature resumption of sexual activity. Careful technique in needle passage and wound

closure should prevent most cases of this. Treatment includes antibiotics and a minor plastic surgery procedure to trim and cover the tape with healthy epithelium." The incidence of mesh-related complications, such as mesh-related infections and erosion varies substantially from 0 to 8% and 0 to 33%, respectively (Falagas M. E. et all, 2007; Stepanian A.A. et al, 2008). Surgical correction of the disorder can be performed through either the abdominal or transvaginal approaches.

Prospective randomized trials have compared these approaches demonstrating better anatomic success for the abdominal approaches as opposed to faster recovery and lower morbidity for the transvaginal approach.

Laparoscopic and other transvaginal minimal access techniques have recently been advocated utilizing synthetic or biological adjuvant grafts. These techniques have been associated with high success rates albeit substantial graft complications such as erosion, contraction and dyspareunia. (Segev Y. et al, 2008).

Risk factors for this condition include obesity, previous vaginal deliveries and hysterectomy, and genetic predisposition leading to reduce connective tissue and muscle strength (ibid).

Various factors influence the development of vaginal mesh-related complications such as the kind of biomedical materials (e.g. filament structure, pore size) of the mesh, the type of procedure, the preventive measures taken, and the age and underlying co-morbidity of the treated women (M. Falagas, et al).

At the same time, according to A. Stepanian (2008), "an estimated 975 to 17,000 patients were required to achieve statistically significant difference of mesh-related complications". He reported an erosion rate of 2.3% for the group of 402 patients that were studied. French researchers (Gadonneix P. et al, 2004) are reporting higher level of incidence of complications related to the use of two separate meshes with success rate for POP (pelvic organ prolapse) of 83 %.

Statistics

Medsafe requested information about complication rates relating to erosion from both Johnson & Johnson Medical and American Medical Systems.

Description	JJM	AMS
World wide sales since launch	101,532	138,000+
No. of reported complications	256	Not advised
No. of Erosion reports	9	3.2%
No. of Vaginal Exposure reports	34	Not advised

[The data provided in this publication is as requested and submitted to Medsafe as of 2008 only. This notation added January 2013.]

*** advise that approximately xxx units are supplied per annum in New Zealand.
*** advise that xxxx units were supplied in New Zealand between April 2003 and December 2007.

Conclusions

Taking into consideration the relatively small number of procedures performed in New Zealand, and lack of information about the surgical techniques and the level of co- morbidity of women undertaken the procedure, it is hard to make any judgment about the New Zealand numbers of mesh-related complications.

Medsafe Questions

Medsafe seeks MDIRC's guidance on the following points.

- Would MDIRC consider 12 reports of surgical mesh erosion into either the vagina or bowel over a period of 3 years to be consistent with known complication rates?

- What action would MDIRC recommend as a suitable response to this issue?

Bibliography

1. Falagas M. E., Velakoulis S., Iavazzo C., and Athanasiou S. Mesh-related infections after pelvic organ prolapse repair surgery. Eur. J. Obstet. Gynecol. Reprod. Biol., 2007, Oct; 134(2):147:56

2. FDA Public Health Notification: Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence. Issued October 20, 2008.

3. Gadonneix P., Ercoli A., Saalet-Lizee D., Cotelle O., Bolner B., Van Den Akkr M., and Villet R. Laporoscopic sacrocolpoplexy with two separate meshes along the anterior and posterior vaginal walls for multicompartment pelvic organ prolapse. J Am Assoc Gynecol Laporosc., 2004 Feb; 11(1):29:35

4. Segev Y., Auslander R., Lavie O., Lissak A., and Abramov Y. Post hysterectomy vaginal vault prolapse: diagnosis prevention and Treatment. Harefuah. 2008 May; 147(5):406-12

5. Stepanian A. A., Miklos J. R., Moor R. D., Mattox T. F. Risk of mesh extrusion and other mesh-related complications after laparoscopic sacral colpoplexy with or without concurrent laparoscopic- assisted vaginal hysterectomy: experience of 402 patients. J Minim Invasive Gynec. 2008 Mar-Apr; 15(2): 188 - 96