ROYAL AUSTRALASIAN COLLEGE OF SURGEONS RACS

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Ms Adriana Platona
First Assistant Secretary
Medical Devices & Product Quality Division
Therapeutic Goods Administration
Department of Health
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Dear Adriana,

Surgical mesh consultation

Thank you for the opportunity to provide input to the Therapeutic Goods Administration's consultation on Alignment with European medical device regulatory framework: Up-classification of surgical mesh & patient implant cards.

The Royal Australasian College of Surgeons (RACS) is committed to optimal patient safety and the provision of high quality care to all people requiring surgery. We support the TGA's intention to up-classify surgical mesh and implement patient implant cards and product information for all implantable medical devices. We also encourage the TGA to consider the design of the procedures in which mesh is utilised.

The European regulatory changes involved extensive consultation, the consolidation of a large body of international evidence, and introduced a suite of improvements to address weaknesses in the legal system, improve the safety of medical devices, and allow continuous quality improvement to occur while protecting patient safety.

There is currently no post-operative surveillance system in place in Australia for patients or clinicians to monitor the outcomes of surgery involving mesh, and this is a major concern for several of our craft groups and consumer health groups. We acknowledge their contributions to our submission.

We believe an expert panel or working group is needed to improve transparency, surveillance and quality of surgical approaches involving mesh and would be happy to provide experts as needed.

We look forward to hearing more about how RACS can assist the Australian Government to introduce new regulatory requirements and better monitor post-operative outcomes.

Sincerely,

Mr Richard Perry, FRACS
Chair, Professional Development and Standards Board

cc Mr John Batten, President, RACS
Dr Lawrie Malisano, Chair, Professional Standards Committee, RACS
Mr John Biviano, Acting CEO, RACS
Ms Rebecca Clancy, Acting Director, Fellowship & Standards, RACS

ROYAL AUSTRALASIAN COLLEGE OF SURGEONS

SURGICAL MESH CONSULTATION

Therapeutic Goods Administration

September 2017

INTRODUCTION

Established in 1927, the Royal Australasian College of Surgeons (RACS) is the leading advocate for surgical standards, professionalism and surgical education in Australia and New Zealand. The College is a not-for-profit organisation representing more than 7,000 surgeons and 1,300 surgical trainees and international medical graduates.

RACS and the surgical specialty societies play an active role in training surgeons and setting high standards of surgical care. Their focus is on maintaining standards with an expectation that all Fellows will actively participate in continuing medical education throughout their lifetime of surgical practice.

With rapid increases in medical knowledge, technological advancements and the development of highly individualised packets of care available to meet specific patient requirements, being appropriately informed on these aspects of continuing education remains the responsibility of each individual surgeon.

The introduction of new technologies and treatments is dependent on the publishing of supportive peer-reviewed articles demonstrating efficacy without undue risk, and practitioners ensuring they have acquired the appropriate levels of knowledge and skill. This is most satisfactorily monitored through the robust credentialing of practitioners and their work environment, expected as part of each practitioner's employment or right to access surgical facilities.

KEY POINTS

- Patients should be well-informed of all risks associated with their surgery, including those related to implantable medical devices as part of the consent process so they can decide whether surgery is the best option for them.

- To do this they need access to appropriate and readily understandable information about treatment options, benefits, and possible adverse effects of investigations or treatment.

- Non-absorbable surgical meshes are widely used by surgeons and for the most part have resulted in good patient outcomes.

- Clinical quality registries and a robust method of tracking devices are needed, particularly for high risk products, to better monitor patient outcomes and allow continuous quality improvement to occur.

- No one procedure is appropriate for all patients therefore surgeons need to be able to offer a complete range of surgical and non-surgical options for consideration.

- RACS encourages regulatory and other government authorities to work together to ensure patients are adequately protected from high risk surgical devices. This requires a comprehensive approach of which up-classification is the first step.

- RACS seeks further clarification on the transitional arrangements, in particular, how clinicians will be informed of any regulatory changes, and other plans to improve transparency, surveillance and outcomes from operations involving surgical mesh.

EFFICACY OF SURGICAL MESH

Surgical mesh is a broad term encompassing a variety of surgical implants used in the repair of structural defects, usually occurring as a consequence of defective support fascial or fibrous tissue. While the mesh may be constructed from a range of absorbable or non-absorbable materials, most concern appears to be related to the use of non-absorbable meshes constructed of polypropylene, polyester or polytetrafluoroethylene.

The use of mesh devices to support organs and biological structures has been evolving over many years. As our understanding of plastics, aseptic technique and anaesthesia increased, it became a viable practical therapy.

As evidence of its efficacy emerged, non-absorbable surgical meshes became widely used by general surgeons, paediatric surgeons, urologists, and plastic and reconstructive surgeons. Its use in the repair of hernias involving the abdomen and chest has been associated with a lower risk of recurrence than where mesh has not been used, without an increase in other symptoms such as local discomfort.

Given the successful use of surgical mesh in the repair of cavity wall defects, the indications for its use have been extended to other areas of surgery such as complex breast reconstruction surgery, to address female stress urinary incontinence (SUI), and to correct vaginal or rectal prolapse.

In the case of some products such as the mid-urethral sling (MUS) there are extensive data to support product use. The MUS' efficacy has been reviewed in thousands of publications and been the subject of multiple, high quality randomised controlled trials making it the most extensively investigated incontinence procedure ever.

While the use of any artificial implant is associated with a slightly greater risk of infection, the overall benefits of using mesh have been confirmed through extensive use and observation of patient outcomes over many years. In most cases the use of mesh has allowed difficult conditions to be well managed, however there has been a higher incidence of local complications including discomfort and implant extrusion.

RACS is concerned by recent reports about adverse outcomes for urogynaecology patients who have undergone a procedure involving surgical mesh. This highlights issues in relation to mesh classification, surveillance and transparency and the need to improve existing systems to identify mesh-related problems.

A concern raised is that removal of the mesh used in these types of procedures cannot be undertaken in Australia and that those patients, sometimes at considerable expense, must travel overseas. RACS believes there are surgical units in every state and territory with the skills to safely remove problematic mesh and we stand ready to assist as required.

There are several key strategies to ensure continuous quality improvements in surgery and they are critical to ensuring patients receive the highest possible standard of care available. These include stricter pre-market scrutiny of high-risk devices, clinical quality registries and a robust method of tracking high risk devices in patients.

The current lack of post-operative surveillance capabilities for surgical mesh is a major issue.

SCOPE OF PRACTICE

The Urological Society of Australia and New Zealand (USANZ) reports that more urologists are involved in surgical management of female SUI than pelvic organ prolapse.[1] USANZ collaborates with the UroGynaecological Society of Australasia and holds the position that surgeons who regularly manage advanced and/or recurrent prolapse need to be able to offer patients a complete range of surgical and non-surgical options.[2]

No single surgical option is appropriate for all patients. Surgeons should tailor the therapy required to the patient's condition and need to be aware of their scope of practice and offer options within their appropriate scope.

Collaborative efforts between sub specialties should be encouraged to optimise patient outcomes, and when a surgeon cannot offer a given treatment the patient seeks or needs, referral to a suitably skilled colleague should be recommended.

INFORMED CONSENT

Apart from being a legal requirement, the College's Code of Conduct requires surgeons to fully inform the patient and obtain consent before employing a new intervention, technique or prosthesis.[3] It also requires surgeons to obtain consent from the patient (or guardian) before elective operations are undertaken and wherever possible in emergency situations.

Surgeons need to be able to counsel their patients about the range of options available and tailor treatment to the patient's needs, not their skill base as a surgeon.

Patients should be well-informed of all risks associated with their surgery, including those related to implantable medical devices as part of the consent process so they can decide whether surgery is the best option for them.[4]

There is an expectation that patients will be provided with a general overview of the benefits and the risks of the potential care available to them.

Surgeons should assist patients in their selection of the form of treatment most appropriate to their particular situation. Where any form of surgery is planned information should be provided which outlines the anticipated benefits of the intervention along with any potential risks. Discussion is expected to be more specific where the proposed procedure is more controversial or of higher risk.

CONSEQUENCES OF ALIGNMENT WITH EUROPEAN MEDICAL DEVICE REGULATORY FRAMEWORK

As in any area of medicine, clinicians have to try to balance the benefits of a treatment against the possibility of uncommon adverse events.

Given the variability of outcomes for some procedures involving the use of surgical mesh, RACS supports the reclassification of all implantable surgical mesh medical devices from Class IIb (medium to high risk) to Class III (high risk); however it is important that reclassification does not restrict access to good quality products when needed, or the continuous quality improvement process.

Aligning Australia with the European Medical Device Regulatory Framework is much broader than simply up-classifying all implantable surgical mesh medical devices to Class III.

The new European Union (EU) Regulations commit to a range of measures which are not covered in the TGA consultation document, specifically:

- Improved transparency through the establishment of a comprehensive EU database on medical devices and of a device traceability system based on Unique Device Identification.
- Reinforcement of the rules on clinical evidence, including an EU-wide coordinated procedure for authorisation of multi-centre clinical investigations.
- Strengthening of post-market surveillance requirements for manufacturers.
- Improved coordination mechanisms between EU countries in the fields of vigilance and market surveillance.[5]

If Australia does not plan to completely adopt the European Framework, points of difference need to be clarified.

Surgical audit and peer review are important strategies in maintaining standards in surgical care at the clinical level,[6] and clinical quality registries have been identified as a 2016-18 Australian medical research and innovation priority.[7]

RACS believes a comprehensive mesh tracking system is required so that patients can seek the opinion of their general practitioner, primary surgeon or another expert if their condition is deteriorating.

Currently patients who have deteriorating function or pain after surgery involving mesh have limited capacity to determine the precise nature of the surgery performed. Often there is a significant delay between surgery and the onset of any surgery-related problems and identifying the details of the mesh used can be very difficult.

For a general practitioner, surgeon or patient to easily identify the mesh product that has been used will be very helpful and would complement and ultimately make redundant patient implant cards.

General Surgeons Australia is investigating the feasibility of establishing a mesh audit, particularly for ventral hernias where the implanted mesh is >15cm^2. This would be a useful tool to ensure rigorous safeguards are in place for the use of mesh and would help identify ways of improving and maintaining quality of care for patients. It's estimated around nearly 100,000 Australians are hospitalised for hernia each year, so a registry represents good value for money.[8]

The Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) has demonstrated a continual decline in the number of individuals requiring revision hip and knee replacement procedures since its inception.[9] If a registry of all implantable devices including mesh were established, the AOANJRR would be a good model, as is the Australian Breast Device Registry to which plastic, cosmetic and breast surgeons contribute. Comprehensive data collection where reoperation is required should be captured.

Governments will also need to consider how to identify and where necessary remove stockpiles of medical devices from hospitals if they are subsequently reclassified. It is very important that practitioners are informed of any changes using a comprehensive variety of communication platforms.

PATIENT IMPLANT CARDS

RACS supports the proposal to introduce patient implant cards and product information directed at consumers for all implantable medical devices because it complements the process of obtaining informed consent.

Patients are entitled to make their own decisions about treatment and to do so they need access to appropriate and readily understandable information about treatment options, benefits, and possible adverse effects of investigations or treatment.

Patients also need to be fully aware of any significant long term physical, emotional or other outcomes which may be associated with interventions, and patient implant cards are a good way to ensure information about a device can be rapidly accessed and will assist in facilitating patient-doctor discussions.

Artificial Urinary sphincter patients are given a card for their wallet and a plasticized card on a key ring at the time of insertion. They contain information about the device including the serial number and cautionary advice in case of emergency. These return to the ward with the patient and are checked off as part of discharge. It is appropriate that these are required and supplied by the manufacturer. This has always been an opt-in system for the surgeon but appears to have worked.

The above system works well but advice on whether patients should also be encouraged to wear medical identification jewellery is needed, as this may assist medical staff should the patient be unconscious or unable to inform them.

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[2] UroGynaecological Society of Australasia. Submission to Senate Inquiry into transvaginal mesh implants. East Melbourne, Vic: UGSA; May 2017. Available from: http://www.ugsa.com.au/.

[3] Royal Australasian College of Surgeons. Code of Conduct. Melbourne, Vic: RACS; 2016. Available from: www.surgeons.org.

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[7] Australian Government Department of Health. Medical Research Future Fund Australian Medical Research and Innovation Priorities 2016-2018 [Internet]. Canberra, ACT: Australian Government; 24 August 2017 [cited 4 September 2017]. Available from: http://www.health.gov.au/internet/main/publishing.nsf/Content/mrff.

[8] Australian Institute of Health and Welfare. Australia's hospitals 2015-16 at a glance. Health services series no. 77. Cat. no. HSE 189. Canberra, ACT: AIHW; 2017.

[9] Australian Orthopaedic Association. National Joint Replacement Registry: Hip, Knee & Shoulder Arthroplasty Annual Report 2016. Adelaide, SA: AOA; 2016. Available from: https://aoanjrr.sahmri.com.