Australian TGA proposing up-classifying spinal implant devices based on European MDR rules.

I write in response to the Australian TGA proposing up-classifying spinal implant devices based on European MDR rules. It is unfortunate that the document has not been written by a spinal surgeon or that there was input from a spinal surgeon. This is clearly evident from the statements in the document which amounts to misinformation and a lack of knowledge and understanding. I speak from more than 45 years of experience in surgery of the spine and more recently a burgeoning medicolegal spinal practice. I am fully aware of the TGA and PLAC process having been involved in the spinal CAG and former PDC process including chairman of the PDC. My research specialty is fretting corrosion in spinal implants which is an expected curiosity but has not been shown to be a health (safety) issue.

Furthermore, the PLAC has a spinal implant classification little changed since my time and one wonders why subgroups were not specifically referred to and their proposed Classification (Class IIb or Class III) rather than the imprecise terminology used in the document. For example, what are spinal wedges? If they are intervertebral cages, then use the appropriate terminology. Furthermore, down-classifying locking screws and similar accessory devices which are not used in isolation but are part of a complex device will be false classification.

In response and critiquing the document the following comments are offered:

*However as with any implantable device, there are **HIGH**-risks of harm (my emphasis) and complications associated with the use of these products, especially if their design/performance is not fit for purpose.*

This is inappropriate use of the adjective “high”. No data has been provided in support of this statement. Firstly, intrinsic implant failure such as design faults or manufacture defects are very uncommon. There is a normal spread of complication rate for various complication which are usually not due to intrinsic device defects but to biological and technical factors. A good workman should never blame his tools! It is essential to differentiate defective devices from defective surgery.

Some types of device failure associated with spinal implants are: •

***Failure of spinal fusion:** The bone may not fuse as desired at the operated levels due to the move, slip or breakage of the implant used to secure the fusion during surgery. •*

Screws, plates rods and cages are used to temporarily immobilise the spine enabling the optimal circumstances for fusion to occur. If fusion does not occur, then eventually the instrumentation will break due to stress fatigue. These implants are designed to withstand a certain number of load bearing cycles before they fail. Therefore, if fusion fails, the implants will fail not the reverse. Even where implants break or move, fusion can occur. After all, before implants became available, fusion could be achieved. Implants have improved the fusion rate but does not guarantee that it will relieve spinal pain. Studies have shown that although spinal implants improve fusion rates, this has not correlated in improved patient outcomes. If the bone is soft (osteoporosis) then movement of the implant might be expected. This does not necessarily prevent fusion from occurring although the biological factor (osteoporosis) might lower the fusion rate.

***Implant or surgical instrument breakage, failure** or unexpected behaviour occurring during the operation: This can lead to serious injuries such as damage to blood vessels and nerves leading to paralysis or even death, and may be related to problems with the design of the instruments and the implant.*

What is the incident of surgical instrument breakage, failure or unexpected behaviour occurring during the operation? I cannot recall this ever being a problem. Sometimes patient anatomy might may operative procedures difficult but don't blame the tools. Serious injuries such as damage to blood vessels and nerves leading to paralysis or even death are usually due to surgical ineptitude not the implant. Misplacement of a spinal screw is a surgeon's/technical complication not an intrinsic implant complication.

Implant failure/fracture: *Spinal implants may erode, fracture/break, dislodge or have other problems after the surgery that result in recurrence of the initial health problem, pain, nerve impingement, and eventually in revision surgery.*

Fretting-corrosion will occur when there is movement between component parts. This is obvious in joint replacement where one surface is constantly moving large distances over another. This is tribiologically inevitable. For fusion implants (screws, rods and plates) which are only semi-rigid where micro-movement occurs between component parts and consequently corrosion can be inevitably found on all such implants after removal. The same occurs when plates and screws are used in long bone fractures. While systemic metal studies of spinal implants show inevitable local rises in metal concentrations and sometimes a rise in systemic metal concentrations, this does not translate or been shown to produce toxic systemic levels of metal from fusion implants of the spine. Fretting corrosion ceases when fusion is achieved and serum metal levels do not increase thereafter. Fusion devices may fail if fusion is not achieved within an appropriate time (say 12 months). Whether mobile bearing devices such as disc replacement produces a rise in local and systemic metal concentrations is unproven. Mobile devices (disc replacements) have to last decades. How long they last before failing and how they fail is unknown. This is what the joint registry has been established to determine. Because the range of motion of a disc replacement is small, fretting corrosion is less likely to be an issue when compared with hips, knees etc. Disc replacements do require at least two years of follow-up data to ensure function and safety just like any arthroplasty device. These are probably the only spinal implants that I believe require upgrading of the Class status.

Implant migration*: Sometimes after surgery, usually before the healing process has progressed to the point where the cage is firmly attached by scar tissue or bone growth, an intervertebral fusion cage might move out of place. If the cage moves too far, it may not be doing its job of stabilizing the two vertebrae. If it moves in a direction towards the spine or large vessels, it may damage those structures. A problem with implant migration may require a second operation to replace the cage that has moved.*

What is the incidence of spinal implant movement causing complications of nerve or vascular injury? If it is unknown, find out before making rash decisions. If the vertebra is osteoporotic then migration may be expected to occur. When there is some implant movement with osteoporosis then it is to be expected but in and of itself does not prevent fusion from occurring. It is sometimes an expected risk. In my experience lateral migration is usually a technical (surgeon) error due to malpositioning.

Transitional syndrome: *In a healthy spine vertebrae/discs work together to absorb and distribute the pressure or force placed on the spinal column. If one or two segments are not working properly, the*

neighbouring ones have to take on more. So if there is a spinal fusion anywhere in the spine, the segment next to fusion will begin to take on the extra load. Over time this can cause increased wear and tear to these neighbouring vertebrae/discs. New pain may be felt coming from the newly damaged segment. This is called a transitional syndrome.

Transitional syndrome is an inevitable biological response to spinal fusion. It should be part of the informed consent process. It may cause new pain since disc degeneration is a cause of spinal pain. From the surgeon's point of view, it is not an issue except if the adjacent disc not being fused is already degenerate. Transitional syndrome is then more likely to occur and at an earlier stage than a healthy disc. Sometimes less fusion is better.

Infection: *Spinal implant infection is not common but may be associated with implantation of any device and may result in local effects.*

Infection rates are greater when devices (a foreign body) is implanted in a patient. Don't blame the implant unless the manufactures sterilisation process is defective. Sometimes it is a surgeon issue which for the individual surgeon will only be identified by a spine surgery registry. The infection rate for spinal implants should be no greater than other implants inserted during clean surgery. One to two percent infection rate would be a reasonable threshold. Admittedly on rare occasions infected implants in proximity of the spine could cause neurological complications which in more than forty years of practice in spinal surgery I have never experienced.

Unlike large joint replacements, reoperation is not a good index of spinal implant safety, efficacy or durability. The vast majority of spine reoperation is due to poor decision making by the surgeon (indications and expectations), surgeon technical ineptitude, failure to achieve spinal fusion, patient biological factors (e.g. osteoporosis) and more often unmet and unrealistic patient expectations. Poor indications for spinal fusion more likely leads to an unsatisfactory outcome (at least according to the patient) and prompts further surgery with a diminishing chance of success.

You can't unbugger a buggered back by rebuggering it! Often surgeons don't know when not to operate or when to stop operating. When not to operate is the greatest test for a spinal surgeon.

I think that reclassification as proposed lacks insight into spinal surgery and implant purposes and what really constitutes an intrinsic implant failure. I think there is no merit in reclassifying fusion implants as there are few intrinsic failures =- most are biological or technical failure. There is merit in upgrading mobile devices (disc replacements) as they have to function safely for the duration of the patient's life with acceptable intrinsic (surgeon/technical or biological) complications.

Yours sincerely,

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