Statement for patients about orthopaedic implants based on recent media reporting

This statement has received input and support from the British Hip Society and British Scoliosis Society.

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Introduction

Yesterday, BBC One's Panorama aired a programme on medical device regulation, which is part of a large international investigation called 'Implant Files' carried out by the International Consortium of Investigative Journalists (ICIJ). There have also been news articles published by other UK partners in the investigation, including the BBC and The Guardian.

We are aware that orthopaedic patients (past, present and future) may see these programmes and articles, and have concerns or questions. This statement is intended to provide general help and support those patients.

As an organisation, our position in relation to devices and their regulation is as follows:

- We support high standards device regulation and the calls for urgent improvements in this area.
- We support high quality surveillance of implants once they have started to be used clinically and the need for registries to track the patients in whom they are used – this is an area where the BOA, supported by the specialist societies, has had significant involvement.
- The UK already has a highly successful National Joint Registry (http://www.njrcentre.org.uk/). Established in 2003, the NJR collects comprehensive details of hip and knee implants across England, Wales and Northern Ireland (with a separate system in Scotland).
- The BOA supports mandating similar programmes for all other orthopaedic implants as a priority.
- Each year tens of thousands of patients in the UK undergo an operation that involves an orthopaedic implant and the vast majority of these will have excellent outcomes from these procedures.
- We recognise that implants wear and fail, sometimes unexpectedly, and we understand the importance of investigating and explaining why this may have occurred.

The media coverage has particularly focused on three areas of orthopaedic surgery, which are covered in turn in this paper:

- Metal on metal hip replacement
- Hip and knee replacements more generally
- Regarding spine and other surgery involving implants

There is a final section at the end for general patient concerns.

We hope that this paper will support patients with concerns and questions, and will illustrate that the BOA and the orthopaedic profession as a whole in the UK has been very active on the issue of data and monitoring of implants.

Please note: The BOA is unable to provide individual advice to patients, and anyone with specific questions or concerns is advised to speak to their GP or surgeon to discuss these in the first instance.

Regarding metal-on-metal hip replacement

For past hip replacement patients

Most patients who have had a hip replacement have not had a 'metal on metal' bearing hip implant. The use of the metal on metal bearing was about one in six (15%) at its peak over 10 years ago, and has been less than 1% for the last 5 years. As such, only a small percentage of patients received that bearing and in fact the majority of patients with these devices have well-functioning hips. A fairly small proportion may develop soft tissue reactions related to their implant. Overall the evidence shows that the best outcomes are achieved if these problems are detected early, monitored and treated if necessary, and a follow-up programme for these patients has been in place for some time.

We highlight that there is guidance from the Medicines and Healthcare Regulatory Agency (MHRA) that provides a framework within which patients who have received a metal-on-metal implant must be assessed. The MHRA guidance was most recently updated in June 2017. The majority of patients at highest risk of problems from these implants were already under follow up and in surveillance programmes prior to 2017, and from June 2017, all patients with metal on metal hips were recommended to have follow up. Anyone with concerns or questions should contact the hospital where their operation took place, or their GP.

MHRA advice: https://www.gov.uk/drug-device-alerts/all-metal-on-metal-mom-hip-replacements-updated-advice-for-follow-up-of-patients

For current and future patients

The use of metal on metal hips has dramatically reduced and is now less that 1% of all hips; these are largely confined to very active males with larger hip sizes, having hip resurfacing. This surgery is now performed mainly in a few specialist centres and the results in this patient group continue to be good.

Regarding hip and knee replacements more generally

There are a range of different hip and knee implants in current usage in the UK, and many have been in use for a number of years and have strong evidence to support their safe use. If you are undergoing a joint replacement procedure, your surgeon will know about the implant options that are available to use in your case and should discuss them with you. If you are still concerned, ask about the implant they are planning to use, the evidence behind it and the reasons for using that one.

Also, as a patient you may like to be aware that hip and knee replacement data is an area where the UK is at the forefront of data usage worldwide:

1. *National Joint Registry*

The world-renowned National Joint Registry (NJR) has records of over 2.5 million joint replacements performed in the UK. From the outset it was designed to support the long-term surveillance of outcomes from different implants. It includes data for hip and knee replacements going back to 2003, and more recently for ankle, shoulder and elbow replacements. The NJR played a vital role in the initial identification of the problems with metal-on-metal hip replacements.

2. *Beyond Compliance and the Orthopaedic Data Evaluation Panel*

More recently, two further initiatives have been developed to support the evaluation of implants used for joint replacement. The Beyond Compliance Service was set up in the UK to support the safe and stepwise introduction of new or modified medical implants such as joint replacements. You can read more about this here: http://www.beyondcompliance.org.uk/WhatItMeans/ForPatients.aspx.

The Orthopaedic Data Evaluation Panel (ODEP) is a panel of experts that rate implants with a 'score' depending on the strength of the evidence about its safe usage. ODEP provides ratings for hip replacements and knee replacements, and recently began benchmarking shoulder replacements. You can read more about this at http://www.odep.org.uk/ODEPExplained/toPatients.aspx and look up the rating for specific implants here: http://www.odep.org.uk/Products.aspx. In addition, the NHS Choices website can be used to look up for either hip replacement or knee replacement the proportion of implants used that are of the highest ODEP rating at each hospital in England: https://www.nhs.uk/service-search.

Regarding spine and other surgery involving implants

Implant data for spinal use and other areas is not as well developed as is the case for joint replacement, and is an area in which the BOA calls for further investment. However, progress has recently been made:

- The British Spine Registry was established in May 2012 with the aim to improve patient safety and monitor the results of spinal surgery: www.britishspineregistry.com.
- Several more registries covering other orthopaedic operations are at varying stages of development.

For patients who are considering or having an orthopaedic procedure, you can always ask your surgeon about the implant they plan to use and the evidence for it.

MAGEC rods

Some of the media coverage has focused on MAGEC rods used in spinal surgery for children with a scoliosis (curvature of the spine). Parents of these children are being contacted with a letter from the British Scoliosis Society and the BOA to provide further information to them. We provide here some key points from that letter.

MAGEC rods have been available for 10 years in the UK, and have been used by spinal surgeons specialising in children's spinal deformity surgery. They are only used in children with progressive scoliosis who are too young to perform a full spinal fusion, and who need a "growing" system to help straighten the spine but still allowing growth. This group of patients present a unique challenge for surgeons.

The surgery option available before MAGEC was the surgically lengthened rods, which required operations to lengthen the rod every six months, often leading to 10 or more operations in each child. There is a significant complication rate with this form of surgery, as well as pain and time off school after every surgery and concerns around multiple anaesthetics. MAGEC rods allow lengthening as the child grows without the need for the child to have another operation (which is lengthened while awake in the clinic). The MAGEC rods also have their complications, and the surgeons using them are very aware of this and are following up potential problems closely. But overall, they have proven very useful and helpful in managing this specific group of patients.

The British Scoliosis Society (BSS) agreed to the use of MAGEC rods following the decision by NICE to make them the preferred choice in patients of this type. The BSS asked surgeons to submit the details of the operations to the British Spine Registry in order to monitor progress. Each year the outcomes have been discussed at the BSS national meeting, and the agreement has been that whilst there are occasional problems with the MAGEC rods, that they remain the best option in many children with severe, life threatening scoliosis. The BSS will continue to keep this under review.