



Statement for patients about hip and knee replacement implants from the British Orthopaedic Association (BOA), British Hip Society (BHS) and British Association for Surgery of the Knee (BASK)

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The BOA, BHS and BASK are aware of Daily Mail coverage regarding implants used for hip and knee replacement surgery. We are aware that orthopaedic patients (past, present and future) may see this article and have concerns or questions. This statement is intended to provide general background and information for those patients.¹

Introduction

The Daily Mail is reporting on two research papers published this week in the *BMJ Open*, which is a peer reviewed medical journal. The research has used data from the National Joint Registry, which is a dataset about joint replacements in England and Wales that began in 2003. Research like this is really important to help surgeons know more about the results of different implants, and for patients who are considering having this surgery it can help them to discuss with their surgeon the implants they intend to use.

The UK is a world leader in joint replacement research, because we have such a well-established and high-quality registry providing data about this kind of surgery.

What does the research say?

- This research compared the different brands of implant used for these procedures. It focused on the number of procedures requiring a second surgery in the ten years following the initial operation in order to produce a 'failure rate', and compared this to a benchmark or standard.
- The majority of implants used in the UK perform well.
- The research found some examples of implants that performed significantly worse than the standard, as follows:
 - In terms of implants that had double the failure rate of the benchmark implant (i.e. were over 100% worse), there was one hip implant and two knee implants performing at this level. (This was out of 26 hip implant combinations that had enough data to review them and 27 knee implants that had enough data.)

¹ Please note: Patients with specific concerns or queries should discuss these with their GP or orthopaedic surgeon. The BOA is not able to provide individual advice or support.

- When analysing for implants that were worse than the benchmark by at least 20 per cent there were a further 11 hip implants and 16 for knee implants that performed at this level.

We would like to highlight to patients that:

- Around 160,000 hip and knee replacements are carried out in England and Wales every year. These are two of the most common surgical procedures performed in the NHS.
- The overall likelihood of needing revision surgery following hip and knee surgery is low. The most recent NJR annual report² shows that: for hip replacement the failure rate after 10 years is 4.99%; for knee replacement the failure rate after 10 years is 4.36%. Therefore, in both cases, for every 100 people having surgery 5 or fewer would have a further operation within 10 years.
- There is no single implant or implant combination in this study (or in others previously) that outperforms all others. Different implants are typically used by surgeons in different types of patient, for example depending on their age. The surgeons will have knowledge and experience of which implants are expected to perform better in which types of patients. You could ask your surgeon about this if you are currently considering surgery.
- For knees in particular there are different implants for a different type of knee replacement - called a 'partial knee replacement' or 'unicondylar knee replacement'. The three knee replacement implants that have the highest failure rates in this research are all unicondylar implants, with rates between 10 and 15% at 10 years. The failure rate of unicondylar implants is improved in the hands of surgeons undertaking the procedure regularly and there are some advantages to this treatment option, such as a reduced infection rate. The decision to undertake unicondylar or total knee replacement should be a shared decision between patient and surgeon based on the relative advantages and disadvantages of each approach.
- When an implant performance is not as anticipated, it is important to note this can occur for a number of reasons and it remains important to investigate these to understand any underlying reasons.
- The function of the NJR is to identify implants that have not performed well, and this has led to discontinuation of several brands over the course of its operation. The data in this latest study spans 14 years and some of the brands identified are no longer in use.

Supplementary information

Medical devices and data – the situation in the UK

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

² <http://www.njrreports.org.uk/Portals/0/PDFdownloads/NJR%2015th%20Annual%20Report%202018.pdf>

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 problems with metal-on-metal hip replacements.

2. Beyond Compliance and the Orthopaedic Data Evaluation Panel

These are two further initiatives 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>.

What is the view of the BOA?

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

- We support high standards of device regulation.
- 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 orthopaedic specialist societies, has had significant involvement.
- The UK already has a highly successful National Joint Registry (<http://www.njrcentre.org.uk/>), and 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.