**British doctors highlight 'unacceptably high revision rate' for hip implant**

By [PRESS ASSOCIATION](http://www.dailymail.co.uk/home/search.html?s=&authornamef=Press+Association)

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British doctors have published evidence of an "unacceptably high revision rate" for a hip implant that has been the subject of a multi-million pound US lawsuit.

Almost 12,000 Britons have received the Pinnacle metal-on-metal hip implant made by DePuy, part of Johnson & Johnson, according to official joint registry data.

Now researchers say they have operated on patients with "black tissue" caused by "high levels of chromium and cobalt" and that patients have suffered pain.

DePuy was forced to recall a different implant (the ASR) in 2010 after the devices were linked to muscle and bone damage and neurological issues.

In March this year, Johnson & Johnson was ordered by a Texas federal jury to pay around 500 million US dollars (£343m) to five people who said they were injured by the Pinnacle metal-on-metal hip implants.

The jury decided the Pinnacle hips were defectively designed and that DePuy had failed to warn the public about their risks.

Johnson & Johnson has said the company will appeal against that verdict. Thousands more people have launched action against the company.

Dr David Langton, from the University Hospital of North Tees, who led the latest study, said his team had told DePuy in the UK, and the Medicines and Healthcare products Regulatory Agency (MHRA), of problems with the Pinnacle over several years.

He said: "These Pinnacle implants were advised for younger patients who were very active.

"We have found that they fail at a higher rate than conventional ones but they fail in a much nastier way.

"You get very high levels of chromium and cobalt around the hip and that can go into the bloodstream. There can be black metal-stained tissue.

"The Pinnacle was put into people in lot bigger numbers than the ASR - up to about 500,000 people worldwide.

"What we've found is that some of our patients have come back with lots of pain. The implants have then been taken out by us.

"In total myself, I've looked at between 150 and 200 Pinnacle implants."

He added: "We've reported this and had several meetings with DePuy and the MHRA.

"We physically handed the implants to DePuy and showed them how they were not the right size and how they were going to fail.

"In my opinion, they should never have left the factory.

"Hips should fail at no more 0.5% per year but we found the Pinnacle has been failing at a significantly higher rate than that."

Dr Langton said his team believed up to 20,000 people in the UK had received the implants.

The study, published in the journal BMJ Open, found in particular that Pinnacle metal on metal implants manufactured and implanted since 2006 were more prone to failure.

The team looked specifically at the long-term performance of the 36mm Pinnacle metal-on-metal hip.

Over the study period, 489 metal-on-metal Pinnacle hips were implanted into 434 patients.

Of these, 352 patients attended future clinics and 71 metal hips required surgical removal and replacement.

There was a revision rate of 16.4%, which researchers described as "unacceptably high".

The study found that before 2006, only five out of 43 hips (12%) failed to meet the manufacturer's product specification.

But after 2006 more than a third (36% or 43 out of 118) failed to comply.

Furthermore, in over 40% of cases, the taper surface - a key part of the implant - was defective.

The authors said this was significantly associated with the excessive release of metal particles.

Staining of bodily tissue had also occurred in around one in five (19%) cases.

In 2012, the MHRA said patients who had undergone large head metal-on-metal hip replacements should be monitored annually for life.

They should have blood tests to check for metal ions, and MRI scans if necessary, it said.

No comment was immediately available from Johnson & Johnson or the MHRA.

An MHRA spokeswoman said: "MHRA take allegations of device non-conformities seriously and will investigate these with manufacturers when sufficient evidence is presented to MHRA.

"We are, however, unable to comment on regulatory matters which may involve a manufacturer due to confidentiality restrictions within the medical device regulations.

"The majority of patients who receive hip implants have well-functioning hips and are at a low risk of developing any serious problems.

"MHRA continues to monitor the performance of all hip implants in the UK though its post market surveillance system.

"We also work closely with our expert orthopaedic advisory group which includes representatives from the British Orthopaedic Association, the British Hip Society and the National Joint Registry for England, Wales, Northern Ireland and Isle of Man to assess any new scientific evidence and we will take safety action if needed to ensure that patients are protected from unsafe hip implants."

Law firm Leigh Day said it was acting on behalf of 333 clients who were claiming compensation from DePuy for having to undergo early revision surgery following a Pinnacle implant.

A three-month trial in the High Court is due to begin in October 2017.

Spokeswoman Sarah Moore said: "We consider that this study is highly significant to the individuals whom we represent.

"The study reports that after analysing hundreds of explanted Pinnacle components, the doctors involved have found that a significant number of devices were found to be manufactured out of their specifications.

"This is a very serious allegation that we will continue to investigate with our expert team.

"If this allegation is proven, this may be a further factor in explaining why so many individuals have suffered severe injuries and early revision following their implantation with these products.

"The evidence of an 'unacceptably high revision rate' should put more pressure on DePuy to come to the negotiating table rather than our clients having to drag them through the courts."

Read more: <http://www.dailymail.co.uk/wires/pa/article-3564703/British-doctors-highlight-unacceptably-high-revision-rate-hip-implant.html#ixzz4ILB97NUr>   
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