Orthopaedic Expert Working Group (OEWG)

OEWG 2011/2
25 May 2011

Item 4.1

ESKA Adaptor (cementless) Femoral Stem Prosthesis

Extract from 2010/3 OEWG Minutes

4.1 ESKA Adaptor (cementless) Femoral Stem Prosthesis

4.1.2 The revision rate for the Adapter (cementless) at 3 years is 5.4% compared to 2.7% for other total conventional hips. Members expressed concerns over the high revision rates and noted the poor quality response from the Company (for example the information provided by the sponsor does not relate directly to the Adaptor device).

4.1.3 The NJRR representative observed that the Adapter has exchangeable femoral necks which could be associated with an increased rate of revision.

4.1.4 A member noted that the metal bearings for this implant are made from a high carbon on low carbon cobalt chrome which is quite different to the materials used by similar implants made by other companies.

4.1.5 It was also noted that of the 567 implants there were 23 revisions and these were not common to one hospital or state indicating that the cause for revision is not surgical technique.

4.1.6 The NJRR representative added that, while only the cementless form of the implant was identified in 2010, the cemented form of the implant is also of concern and this indicates that the revision rates are likely to be related to implant design rather than surgical technique.

Advice: The Working Group advised that the use of the ESKA Adapter (cementless) Femoral Stem Prosthesis should be discontinued.

TGA Comment on Manufacturer's Response (Blue Section)

The OEWG considered the NJRR report and the Australian Sponsor's submission in relation the revision rates of the ESKA Adapter Femoral Stem prosthesis and the ESKA Bionic Resurfacing Femoral Head Prosthesis at the meeting in November 2010.

The Sponsor's response at the time was very poor, and the OEWG recommended that the TGA should consider removing these implants from the Australian Market. The TGA relayed the OEWG recommendation to the Sponsor and requested last arguments before making a final decision, upon which the Sponsor engaged the help from the German Manufacturer, Orthodynamics GMBH.

Orthodynamics advises that the previous response had not been verified or reviewed by them and have now provided what appear to be well structured, well reasoned and well referenced arguments in support of both implants.

In brief:

- The majority of the Adapter stems used in Australia (63%) have been with a large metal on metal bearing combination. The NJRR has noted in previous reports that this combination leads to higher revision rates. The MHRA and the FDA have issued device alerts warning of high revision rates of metal on metal implants, particularly when large diameter femoral heads are used[1]. Further the manufacturer notes that of the 23 Adapter revisions recorded by the NJRR 17 (74%) have been on implants where this combination was in use.

- The Adapter stem has been used with the Bionik femoral head. There were external geometry issues with the Bionik Femoral head which were rectified progressively in 2007 and 2008, and the revision rate has subsided since the implementation of the changes. (Note: the latest – 2010 - NJRR report contains analysis of data collected until December 2009. The effect of the design changes may not be evident in the NJRR data for some time to come).

- The performance of the Adapter Stem in Germany and other countries, where the use of metal on metal bearings is not as prevalent, is 0.73 revisions/100 component years. This compares well with the average revision rate for similar implants in Australia (0.78 revisions/100 component years. Many other references are provided which suggest that the Adapter stem has been performing well where the use in combination with large metal in metal bearings is not as prevalent.

The Manufacturer concludes that the Adapter Stem can perform well, and has provided plausible reasons as to why the implant has experienced high revision rates in Australia. The Manufacturer's argument that decreased use of large diameter metal on metal bearings and design changes to the Bionik femoral head should see improvements in revision rates in the future also seem reasonable.

Members are requested to read the full text of the company's submission and to consider whether previous OEWG advice regarding these implants needs to be modified in the light of the new arguments from the manufacturer.

[1] After considering advice from both the AOA and the OEWG on the matter, the TGA has decided against publishing a similar Alert.