Orthopaedic Expert Working Group (OEWG)

OEWG 2011/2
25 May 2011

Item 4.2

Extract from 2010/3 OEWG Minutes

4.2 ESKA Bionik Resurfacing Femoral Head when used in conjunction with the Bionik Acetabular Component

4.2.1 Members noted that this implant it as a resurfacing device where only 175 were implanted. 6 out of the 9 revisions were for Femoral and Acetabular, and 3 revisions were for Acetabular only.

4.2.2 Members discussed the metal-on-metal bearing options and the expertise of surgeons using these prostheses. Members agreed that the Company's response was inadequate and requested that the TGA raise concerns about the data provided with the Company.

4.2.3 The TGA drew the members' attention to the summary of the Company's response. In its summary the Sponsor asserts that none of the revisions reported in the NJRR against the Bionik implant are related to the design of the implant. ESKA has also provided papers and citations as evidence of implant performance elsewhere in the world, but the revision rates reported in the literature provided appears to be higher – sometimes much higher than the revision rate reported by the NJRR for this implant.

4.2.4 The TGA asked the Working group to comment on the observation made in one of the papers supplied by the Company – neck shaft angles must be greater than 130° - Whether this affects all similar implants and whether this is commonly known in the orthopaedics field. A member confirmed the importance of the neck shaft angle and that this is commonly known. However, in this case the design of the femoral head does not lend itself to ease of use and the stem is noticeable smaller in diameter and therefore more difficult to seat with accurate alignment. This fact in combination with the implants being metal on metal is a cause for concern.

Advice: **For the reasons outlined above, the Working Group advised that the use of the ESKA Bionik Resurfacing Femoral Head when used in conjunction with the Bionik Acetabular Component is of concern. Consideration should be given to the discontinuation of this implant combination.**

TGA Comment on Manufacturer's Response (Blue Section)

The OEWG considered the NJRR report and the Australian Sponsor's submission in relation to 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.

In relation to the Bionik Resurfacing Femoral Head, the manufacturer highlights the following:

- The use of the Cera-Metal (similar to oxynium) material which has now been discontinued and experienced 11.11 revisions /100 component years – this extremely high revision rate has skewed the revision rate of all Bionik implants.

- The Bionik Resurfacing heads have also undergone a design change in 2008 which the manufacturer hopes to improve revision rates.

- That the revision rates in Tasmania have been very high and may also have skewed the revision rate of the implant.

- The clinical studies conducted abroad suggest very good performance.

- Further laboratory testing is being conducted on the effect of "Biosurf" on femoral component wear rates.

Again the manufacturer concludes that the experience with this implant abroad has been much better and that design changes are expected to improve revision rates into the future.

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.