Assessment Group Addendum

Project Title

11/118/01 Total hip replacement and surface replacement for the treatment of pain and disability resulting from end stage arthritis of the hip (Review of technology appraisal guidance 2 and 44).

1. Assessment excluding DePuy ASR Resurfacing Arthroplasty

The scope for the report was to compare RS (i.e. a generic intervention) with different types of THR. The RS population included recipients of the De Puy ASR device which has now been withdrawn.

When RS devices are classified according the manufacturer of the head 17 different categories of device can be identified. Head and cup combinations are not always from a single manufacturer, and some manufacturers produce multiple brands of head, some heads are cemented and some are not and different cements are used for fixation, so there are many more than 17 distinct types of RS device used for NJR patients. A further increase in distinct types would be reached if RS head sizes should also be used to sub-classify the devices. Amongst the NJR recipients of RS ~8.8% received the De Puy ASR device. This device was associated with a high requirement for revision, so that when the De Puy ASR is omitted from the analysis a reduced requirement for revision is seen for the remaining RS recipients (Figure 1). This requirement is still substantially greater than that for recipients of THR prostheses categories A to E either considered singly or collectively (Figure 1 and 2). This held when comparisons were limited to patients aged less than 65 years, less than 55 years and less than 50 years, although the difference (RS versus THR) was less pronounced for younger patients.

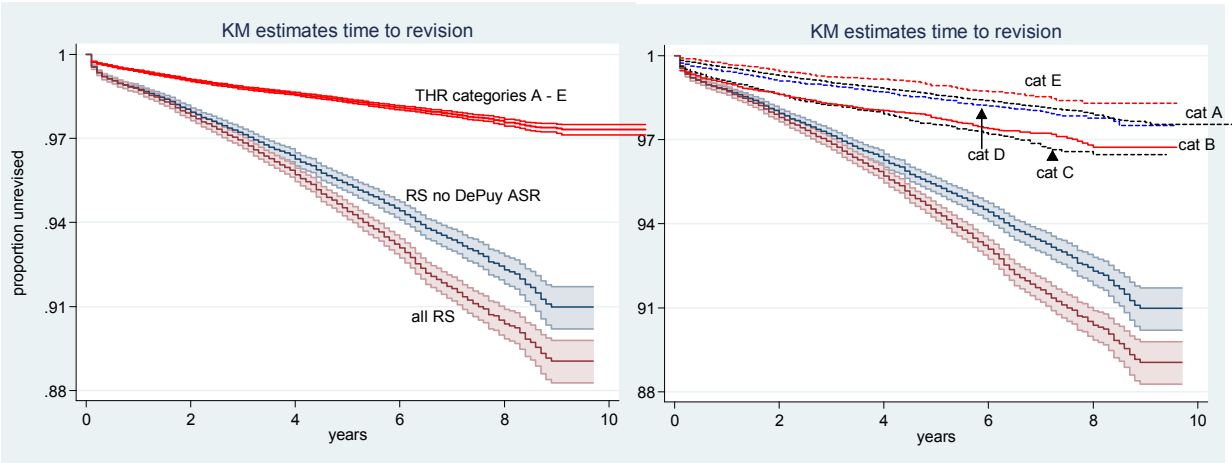

Figure 1. KM estimates time to revision De Puy ASR omitted from the analysis (left) categories A to E displayed separately (right)

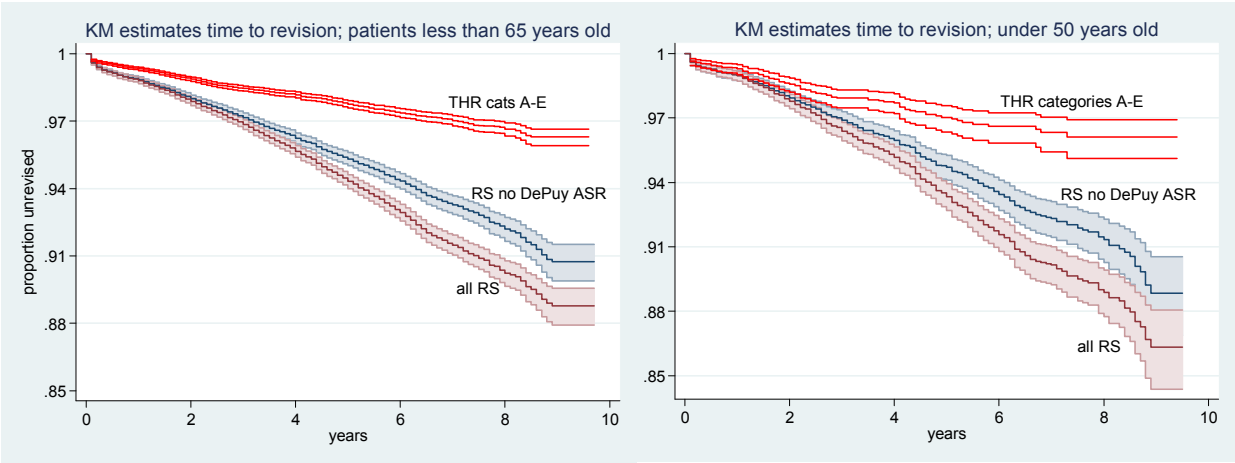

Figure 2. KM estimates time to revision patients less than 65 years old (left) under 50 years old (right)

Bathtub parametric models were superior to alternatives fits to RS (no De Puy) and THR categories A-E data (Figure 3). When bathtub models (for all THR patients and for all RS patients minus De Puy ASR) were controlled for age and gender and were used to predict revision requirement for populations aged 50 years at intervention and made up of equal numbers of male and female recipients the RS population required substantially more revision than the THR population (left). Results for population aged 55 years (50% male) according to THR category is shown (right).

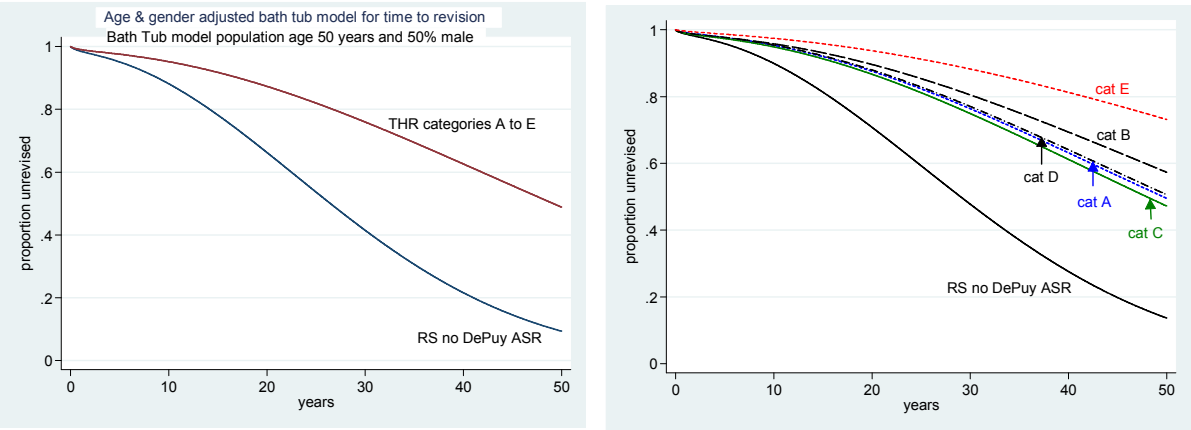

Figure 3. Age and gender adjusted bath tub model for time to revision

Amongst the many different types of RS implant there are some for whom NJR recipients show lower revision requirements than others. These differences were beyond the remit of the report scope and may be related to any of many variables (e.g. activity levels, surgeon, approach to surgery etc), as also may the differences between revision requirements observed for NJR recipients of different types of THR (of which many exist within the NJR database).

2. Wright RS device revision rates

The response from Wright Medical Technology, Inc. provides a table of revision rates for their RS device derived from several small RCTs (less than 100 patients). According to these the requirement for revision is quite low; the highest revision requirement tabulated being 6.6% at 8 years and 5.7% at 10 years depending on population. We compared this with the experience of NJR recipients of the Wright RS (Figure 4). The experience of the ~2,500 NJR patients with the Wright RS device does not

appear to be as good as that observed in the small RCTs, with about 10% of the NJR Wright recipients requiring revision by 7 to 8 years.

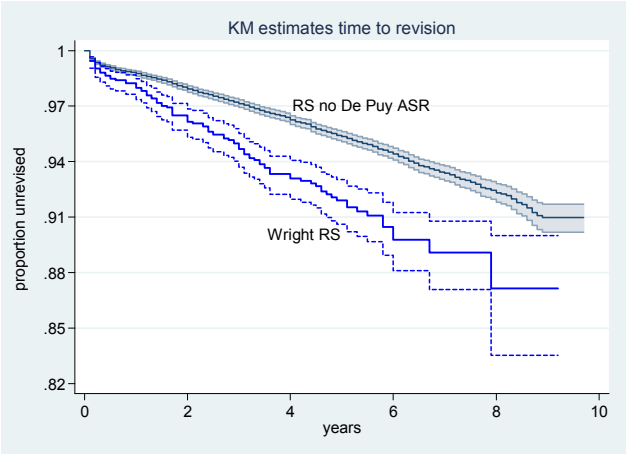

Figure 4. KM estimates time to revision Wright Medical Technology for their RS device

Economic models of hip replacement interventions have adopted a life time horizon and have assumed that from one year on after primary surgery mortality is the same irrespective of the type of prosthesis received. Differences in mortality observed between recipients of different prostheses have been attributed to age and gender differences between compared populations.

Recently McMinn et al presented analyses of mortality rates adjusted for differences in several baseline characteristics including age and gender and concluded that recipients of resurfacing (in particular the Birmingham Hip) have significantly superior life expectancy compared to both cemented or cement-less THR recipients. The authors argue that despite higher revision rates for resurfacing with the Birmingham Hip this intervention should be considered for active men less than 55 years of age since mortality is favourable compared to alternatives. We were interested to see if the data presented by McMinn would be useful for estimating the cost effectiveness of RS versus to THR.

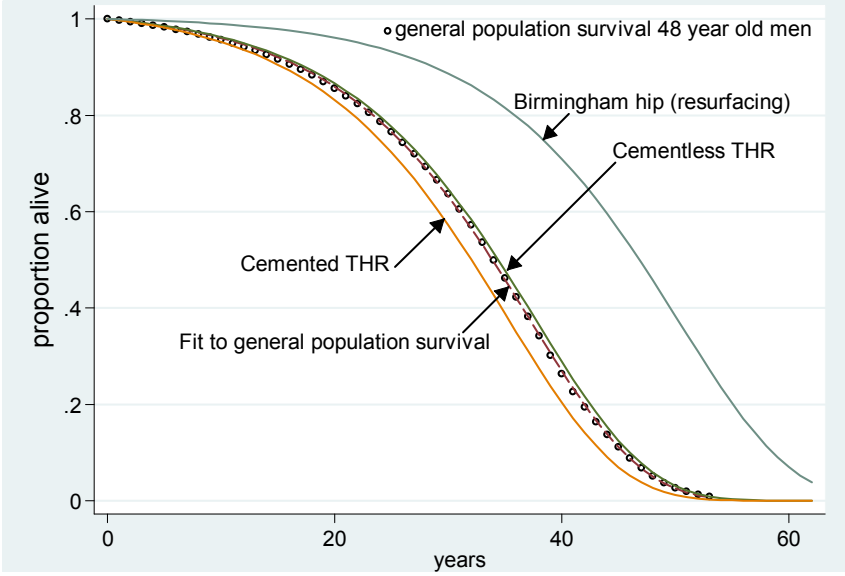

Figure 5. Survival curve Wright Medical Technology RS device analysed separately

McMinn's estimated survival at six years for male Birmingham Hip patients less than 55 years old to be 0.995 and that for similar men receiving a cemented THR was 0.018 worse at six years and those

with cement-less THR 0.013 worse. The mean age of National Joint Registry male patients aged less than 55 years receiving RS is 48 years and also for men under 55 receiving the Birmingham hip according to McMinn. The survival of UK men aged 48 years taken from the Office of National Statistics is shown in the figure above (circles). The general population survival is well described with a Gompertz distribution. Keeping the shape parameter for this distribution constant (as is consistent with the proportional hazards assumption adopted by McMinn) and using the data presented by McMinn it is possible to obtain a predicted lifetime survival for Birmingham Hip, cemented THR and cement-less THR recipients that might be useful for an economic model. These modelled survival curves are shown in the figure. According to these models survival for cement-less THR recipients is very slightly superior to that of the general population, and that for cemented THR recipients is slightly less favourable than the general population, while survival for Birmingham Hip recipients is remarkably good with about one third predicted to become centenarians. The survival for Birmingham Hip recipients appears unrealistic; this probably stems from an over optimistic estimated survival at 6 years. As McMinn acknowledge there is evidence of strong selection biases in the allocation of devices for particular patients and a limitation of the authors' survival estimates is inability to adjust for hidden confounders. These mortality estimates do not appear useful for economic models. It has been suggested by others that " *the findings of this paper reflect case mix selection for surface replacement rather than an excess mortality for other forms of arthroplasty*" .