National Institute for Health and Clinical Excellence

265/2– Prosthetic intervertebral disc replacement in the cervical spine

Consultation Comments table

IPAC date: Thursday 17th December 2009

Com. no.	Consultee name and org.	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 NHS Professional	**1**	I beleive that statement 1.1 is not necessarily accurate. The evidence from the Â Prestige IDE study (Mummaneni 2007) is of a statistically significant benefit from the use of Â this arthroplasty technique over controls. This study represents the largest study of a spinal implant carried out to date and as such the findings carry considerable weight. It is not unreasonable to view this trial as showing a superior outcome of arthroplasty over fusion. This study also demonstrates that a statistically significant decrease in the number of secondary surgeries for arthroplasty patients when compared with fusion controls. This is good evidence for suggesting that arthroplasty is in fact safer than fusion surgery. Burkus et al in 2009 demonstrated preservation of motion at 5 year follow up in a large series of patients who had undergone cervical arthroplasty. There is therefore good evidence that segmental mobility is preserved.This is not reflected in the summary of current evidence.	Thank you for your comment. Revised consultation document issued.

Com. no.	Consultee name and org.	Sec. no.	Comments	Response Please respond to all comments
2	Consultee 2 NHS Professional	**1**	Studies in our hospital currently being prepared for publication show that in cases with up to 36 month follow-up we are acheiving significant movement in single as well as multi-level cases. we have also demonstrated that in comparison with fusion, disc replacements have a lower incidence of subsidence thus having a lower incidence of segmental kyphosis. Without wider use of what appears as a safe option of treatment we will never be able to promote further innovation! Regular audit should be done on any procedure. why after 4 years of safe use and relative to fusion few adverse effects should "special arrangements" be needed.	Thank you for your comment. Revised consultation document issued.
3	Consultant 3 Specialist adviser	**1**	The use of cervical arthroplasty is far more widespread due to the growing belief that preservation of motion (especially in multiple levels) Fusion without any cage leads to kyphosis and any studies under 5 years are inadequate to assess this as a reference. Complications such as neck pain, non fusion and subsidence do occur with traditional treatments. However, patients undergoing arthroplasty should be followed up for the same period.	Thank you for your comment. Revised consultation document issued.

Com. no.	Consultee name and org.	Sec. no.	Comments	Response Please respond to all comments
4	Consultee 4 Manufacturer	**1**	Overview Document 265a states ‘A fundamental aim of the procedure is to preserve segmental mobility in the neck, unlike spinal fusion, but there is inadequate evidence that this is achieved in the long term. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research’ The major concern with this proposed change to the recommendation from Â ‘normal’ to ‘special’ arrangements, relates to the impact Â the term ‘special arrangement’ is likely to have on PCT commissioners namely Â the opportunity to refuse NHS trusts future funding for this procedure. The commentary from the overview document 265a has cited the need for superiority and longer term evidence; focusing on the following key efficacy outcomes: NDI score, arm and neck pain score measured by visual analogue scale, Short Form-36 score, technical success and revision rate, range of movement and reduction in rate of adjacent level disease after 5 to 10 years. Cervical disc arthroplasty Â (C-ADR) has the potential for preserving motion at the operated level while providing biomechanical stability and global neck mobility and shows a positive trend at 60 months Â in reduction in adjacent segment degeneration. It also eliminates the complications associated with bone grafting techniques. C-ADR Â may provide the benefits of neural decompression without placing adjacent motion segments at risk for accelerated degeneration. C-ADR and anterior cervical discectomy & fusion (ACDF) are both safe procedures with a low incidence of significant adverse events related to the procedure, more additional surgeries has been shown for fusion in clinical RCT studies. **[The consultee’s full report is included in the Committee’s papers for consideration.]**	Thank you for your comment. Revised consultation document issued.

Com. no.	Consultee name and org.	Sec. no.	Comments	Response Please respond to all comments
5	Consultant 3 Specialist adviser	**2.1**	Multiple level cervical surgery in my opinion are the patients who are more likely to have adjacent level disease and should be offered arthroplasty.	Thank you for your comment. Revised consultation document issued.
6	Consultee 4 Manufacturer	**2.1**	Indications: In 2004 some insight was given about the indications for cervical disc replacement. According to survival modeling from 372 patients followed for 21 years Â , 1 out of 4 patients (95% CI, 20 to 30%) would have new disease at an adjacent level within 10 years after the anterior cervical arthrodesis. “In light of this compelling evidence”, the role of Cervical Disc Replacement would be adjacent to already established cervical fusions with adjacent segment spinal compression—herniated nucleus pulposis, cervical spondylosis and focal cervical spinal stenosis. Â(McAfee et al 2004 -The Spine Journal 4 (2004) 177S–181S ÂAuerbach (2008) conducted a retrospective study of 167 patients who underwent cervical spine surgery. Based on assessment of the patients’ history in terms of the indications and contraindications for C-ADR, 43% would have been candidates or 47% if indications were expanded to include treatment for adjacent segment disease, according to evidence-based criteria.Â	Thank you for your comment. Revised consultation document issued.

Com. no.	Consultee name and org.	Sec. no.	Comments	Response Please respond to all comments
7	Consultee 5 Consultant Neurosurgeon	**2.1**	It is of note that anterior cervical decompression without fusion is not currently accepted practice by the vast majority of spinal surgeons because of the increased risk of kyphotic collapse and poor outcome. This is underlined in a recent study (Haden N, Latimer M, Seeley M & Laing RH: Loss of intervertebral disc height after anterior cervical discectomy. British Journal of Neurosurgery, Dec 2005 19(6):469-474). Â In this series of 140 patients reviewed at 1 year, the mean improvement in neck disability index after surgery was 12 points and 49% showed kyphotic angulation in their follow up x-rays. By contrast in the FDA IND Study for Prestige, the control/fusion group showed a mean improvement in NDI of 33 points at one year and without angulation. Improvements in NDI of less than 15 points are considered by the FDA as a failed procedure.	Thank you for your comment. Revised consultation document issued.
8	Consultee 1 NHS Professional	**2.3**	I beleive the evidence from the Â Prestige IDE study (Mummaneni 2007)is of a statistically significant benefit from the use of Â this arthroplasty technique over fusion controls.	Thank you for your comment. Revised consultation document issued.
9	Consultee 2 NHS Professional	**2.3**	RCTs are extremely expensive to run and do not normally get funded for more than 2 years. At present all the studies show at least! equivalency to fusion. How does that result in the need for more time to approve? It looks more like a whitch hunt against innovation. If 5-10 year follow-up asked for, is NICE going to fund this? Current evidence shows that disc replacement is at least as good and in certain cases better than fusion there is no evidence of adverse effects of disc replacements being more prevalent than those of fusion. Therefore the question should be Why Not disc replacement? It certainly has a theoretical as well as a biomechancal advantage as demontrated in a number of biomechanics papers	Thank you for your comment. Revised consultation document issued.
10	Consultant 3 Specialist adviser	**2.3**	Only one study in multiple levels - Superiority of Multilevel Cervical Arthroplasty Outcomes Versus Single-Level Outcomes 229 Consecutive PCM Prostheses Luiz Pimenta, MD,†et al).	Thank you for your comment. Revised consultation document issued.

Com. no.	Consultee name and org.	Sec. no.	Comments	Response Please respond to all comments
11	Consultee 4 Manufacturer	**2.3**	Please find attached a clinical review of published data which illustrates that superiority and long term (between 4 – 10 year) data has been published for C-ADR versus ACDF and to inform the NICE consultation process accordingly. Although it is clear that IPAC's remit is to develop and review procedural rather than device-focused guidance, on behalf of NICE, Â the specialist advisors have pointed out that not all cervical arthroplasty devices are equal and their use should be governed by clinical studies, not just by CE marking. There are fundamental differences in arthroplasty design which significantly impact on both their short and long-term outcomes. Therefore, the outcomes from arthroplasty and subsequent approval by NICE should be judged on the information available for individual devices. There are certain devices with published evidence to demonstrate significant superiority and or Â 5 year oucome results in favour of C-ADR versus ACDF. It is important to note that stand alone cervical discectomy is not standard practice in the NHS as published evidence illustrates a poor NDI result (12 points) with evidence on cervical kyphotic deformity (Haden et al 2005)	Thank you for your comment. Revised consultation document issued.
12	Consultee 6 Healthcare Company	**2.3**	No comment, except to agree that long term outcomes are important	Thank you for your comment. Revised consultation document issued.

Com. no.	Consultee name and org.	Sec. no.	Comments	Response Please respond to all comments
13	Consultee 5 Consultant Neurosurgeon	**2.3**	The Prestige IDE level 1 study (Mummaneni et al 2007)(n541)shows that the Prestige cervical disc was not only statistically non-inferior at 12 and 24 months, but also statistically superior to the control at these intervals in overall success of the procedure.In addition, the following individual safety and efficacy outcomes are also significantly different and favoured the Prestige: 1.Better neck pain scores at 6 weeks,3 months and 12 months. 2.Greater mean improvement in NDI at 6 weeks and 3 months with trends in favour of Prestige at 12 and 24 months. 3.Higher rate of neurological success at 12 and 24 months. 4.Shorter median return to work time by 16 days. Â 5.Lower rate of secondary surgery at the same level (Prestige 1.8% v fusion/control 8.7%). 6.Lower rate of re-operation for adjacent segment disease within 2 years(3v12 levels), 1% Prestige, 3.4% Fusion. Angular motion maintained in all at 24 months. Robertson J et al 2004 presented 4 year outcome in 15 patients with maintained clinical benefits and mobility in 14. Patel et al 2007 have presented 5-9 year follow up in 31 patients with maintained motion and clinical improvements in 30.	Thank you for your comment. Revised consultation document issued.
14	Consultee 1 NHS Professional	**2.4**	Mummaneni 2007 demonstrated Â a statistically significant decrease in the number of secondary surgeries for arthroplasty patients when compared with fusion controls. This is good evidence for suggesting that arthroplasty is in fact safer than fusion surgery.	Thank you for your comment. Revised consultation document issued.

Com. no.	Consultee name and org.	Sec. no.	Comments	Response Please respond to all comments
15	Consultee 2 NHS Professional	**2.4**	section 2.4.1 is an implant specific complication and should be mentioned in that context. It should also be noted that most of these complications are the result of the decompression and not of the disc replacement. Almost all the adverse events noted by the specialist advisors are the same as those of an instrumented fusion. Some are completely theoretical, such as wear debris causing an inflammatory response(no clinical evidence). Some are not necessarily adverse, such as fusion of the prothesis, this means there is no added benefit of motion, however it is still a safe fusion allowing the spine to find its own balance.	Thank you for your comment. Revised consultation document issued.
16	Consultee 4 Manufacturer	**2.4**	Please see attached report to illustrate there are fundamental differences in arthroplasty design which significantly impact on the Â short and long-term safety outcomes reported for individual devices. As above, Â it is therefore reasonable to assess outcomes for cervical arthroplasty on an individual device basis and subsequent approval by NICE should be judged on this information.	Thank you for your comment. Revised consultation document issued.

Com. no.	Consultee name and org.	Sec. no.	Comments	Response Please respond to all comments
17	Consultee 5 Consultant Neurosurgeon	**2.4**	The Prestige IDE study (Mummaneni et al 2007) provides level I evidence that at 24 months the Prestige cervical arthroplasty technique is safer than cervical fusion.Although there was no significant difference in the immediate outcome from the primary procedure between the fusion and the arthroplasty group there were significant differences in the number of secondary surgeries required at the treatment level with 8.7% of the fusion group requiring secondary surgery within two years in contrast to 1.8% in the Prestige group.As there are approximately 10,000 anterior discectomies and fusions carried out in the United Kingdom per annum one would predict from this data that if current UK practice changed from fusion to arthroplasty that approximately 690 of the 10,000 patients undergoing surgery per annum would be spared from having to undergo repeated surgery at the index level and with it the prolonged suffering and of course increased cost to the individual and society.It is of note that revisional surgery carries significantly higher risks than the primary procedure. The Prestige study showed no device failures or migration at 24 months.	Thank you for your comment. Revised consultation document issued.
18	Consultee 4 Manufacturer	**Gen.**	Safety: **Anderson et al 2008; SPINE Volume 33, Number 12, pp 1305–1312** The 2 year safety assessment on the FDA IDE study for Bryan® Cervical Disc (Heller et al., 2009) reported overall, cervical spine reoperations as significantly different between groups. **This was true for both the treated and for the adjacent levels (5,4% investigational vs 7,7% control, p=0,045). The overall reoperation rate at adjacent levels at 2 years in the control group was similar to that reported by Hilibrand** J Bone Joint Surg 1999;81A(4):519–28	Thank you for your comment. Revised consultation document issued.

Com. no.	Consultee name and org.	Sec. no.	Comments	Response Please respond to all comments
19	Consultee 5 Consultant Neurosurgeon	**Gen.**	I was very concerned to read of the provisional recommendations proposed by NICE regarding the use of cervical arthroplasty. The re-categorising of this surgery so that it can only be carried out under “special arrangements” will affectively stop the use of cervical arthroplasty in this country because this gives PCT commissioners and private insurance companies the opportunity to refuse funding for this procedure. This will result in patients receiving second rate treatment with significantly worse outcomes.	Thank you for your comment. Revised consultation document issued.

Com. no.	Consultee name and org.	Sec. no.	Comments	Response Please respond to all comments
20	Consultee 5 Consultant Neurosurgeon	**Gen**	I think it would be fair to say that I have the greatest international expertise of cervical arthroplasty dating back to 1993 when I began to implant an in-house cervical joint developed by Mr Brian Cummins and the medical engineering department at Frenchay Hospital in Bristol (Cummins et al 1998). In 1998 I re-designed the Cummins device, turning it from a constrained ball and socket to a semi-constrained ball and trough with articulation in the posterior third of the body. This allows the articulation to match the physiological movement of the patient's vertebral motion segment. This device was taken on by Sofamor Danek/Medtronic and underwent rigorous pre-clinical and clinical testing over a 10-year period before it became FDA approved as the first cervical arthroplasty in clinical use in the USA. I have published widely in the field and both lecture and train surgeons internationally in cervical arthroplasty techniques. Frenchay Hospital receives a royalty from the sale of Prestige devices, from which I receive a portion. I feel that the clinical outcome from arthroplasty and subsequent approval by NICE should be judged on the information available for individual devices rather than the procedure as a whole because there are fundamental differences in arthroplasty design which greatly impact upon performance. I appreciate, however, that this may present an issue for IPAC in view of the fact that the IPG remit is to focus on procedural rather than device-specific recommendations, but this does highlight a major limitation with respect to such guidance.	Thank you for your comment. Revised consultation document issued.

Com. no.	Consultee name and org.	Sec. no.	Comments	Response Please respond to all comments
21	Consultee 5 Consultant Neurosurgeon	**Gen**	The centre of rotation of each motion segment in the neck is different, but is typically located in the posterior third of the inferior vertebral body (Bogduk & Mercer 2000). As one descends from the C2/3 level to C7/T1 the centre of rotation moves towards the middle of the inferior body. Cervical movements are also coupled and there is as much as 2½mm of true translation that accompanies cervical AP rotation. Unless the arthroplasty design accommodates these movements (as with Prestige), then the motion will be constrained, which may lead ultimately to fusion at the level, or device migration. The latter have been shown with the Prodisc C (Mehren C et al 2006) and the PCM devices , both of which are of a constrained ball and socket design. In view of the above I shall respond to the comments made in the provisional recommendation report by NICE with reference to known outcome data from clinical studies using the Prestige device with which I am most familiar.	Thank you for your comment. Revised consultation document issued.

Com. no.	Consultee name and org.	Sec. no.	Comments	Response Please respond to all comments
22	Consultee 5 Consultant Neurosurgeon	**Gen**	<u>Efficacy</u> Referring to the recent statement from NICE "*Current evidence on the efficacy of prosthetic intervertebral disc replacement in the cervical spine shows that this procedure is* ***as effective as fusion*** *in the short-term".* I believe that this statement is not supported by the outcome data from the Prestige IDE study (Mummaneni et al 2007). This remains the largest randomised controlled multi-centre trial ever carried out for a spinal implant (n = 541) and shows that the **Prestige cervical disc was not only statistically non-inferior at 12 and 24 months, but also statistically superior to the control at these intervals.** As the panel are aware the FDA device exemption studies use as their primary outcome measure a composite overall success outcome in which the patients are deemed as having a successful procedure if they fulfil the following criteria at the time of follow-up assessment. 1. At least a 15 point improvement in neck disability index. 2. Maintenance or improvement in neurological status. 3. No serious adverse events associated with the device. 4. No second surgeries at the treated level.	Thank you for your comment. Revised consultation document issued.

Com. no.	Consultee name and org.	Sec. no.	Comments	Response Please respond to all comments
23	Consultee 5 Consultant Neurosurgeon	**Gen**	***Efficacy:*** This is a well validated outcome that encompasses both efficacy and safety parameters which is a more robust evaluation than looking at individual outcome measures for the following reason. If two patients show equal improvement in neck disability index and neurological status at the end of one year and yet one of them had complications, such as a recurrent laryngeal nerve palsy or required a second surgical procedure because of the failure of the first operation then it is clear that they cannot both be judged as having a successful outcome. My impression, reading the NICE report was that the power of this evaluation tool was undervalued and that individual measures of efficacy and safety were deemed more important, but I would argue that this does not give the whole picture for the reasons given above.	Thank you for your comment. Revised consultation document issued.

Com. no.	Consultee name and org.	Sec. no.	Comments	Response Please respond to all comments
24	Consultee 5 Consultant Neurosurgeon	**Gen**	***Efficacy:*** In addition to the statistically significant differences between the groups in overall success that favoured Prestige the following individual safety and efficacy outcomes are also significantly different and favoured the Prestige: 1. Better neck pain scores at six weeks, three months and 12 months. 2. Greater mean improvement in NDI at six weeks and three months with trends in favour of Prestige at 12 and 24 months. 3. Higher rate of neurological success at 12 and 24 months. 4. Shorter median return to work time by 16 days. 5. Lower rate of secondary surgery at the same level (including revision, supplemental fixation and device removal). Prestige 1.8% v fusion/control 8.7%. 6. Lower rate of re-operation for adjacent segment disease within two years. (3 v 12 levels), 1% Prestige, 4% fusion/controlled group. Angular motion was maintained in all at 24 months with a mean angular motion of 7.59^{o} (pre-operatively the mean angular motion was 7.55^{o}).	Thank you for your comment. Revised consultation document issued.

Com. no.	Consultee name and org.	Sec. no.	Comments	Response Please respond to all comments
25	Consultee 5 Consultant Neurosurgeon	**Gen**	**Efficacy:** It must be appreciated that 30 centres in the US were involved in enrolling patients into this study and the outcome data for the Prestige will necessarily include their learning curves, whereas this is not the case for the well established fusion techniques. The outcome from the control group was exceptionally good and set a very high bar against which to judge the Prestige group which nevertheless showed superior outcomes. To put this into context, one of the larger British studies of anterior cervical decompression (Haden N. et al, 2005) reported the outcome of 140 patients followed up for one year and showed a mean improvement in neck disability index after surgery of 12 points, i.e. they would not on average have met the FDA minimum 15 point improvement in NDI to have been considered successful. By contrast the fusion/control group in the Prestige IDE study showed on average a 33 point improvement in NDI scores at one year which was still less than the improvement shown in the Prestige group. The two-year outcome data of the Prestige LP IDE study (n = 545) have been presented and show highly significant improvements in neck disability index, neck pain and neurological status at all follow-up time points to two years in favour of Prestige LP over fusion. (See enclosed presentation.) One year pooled site data from six sites on 180 patients from the two-level Prestige LP IDE study (n= 396) have been presented and show significant improvement in neck disability index, neck pain score, arm pain score and SF 36 PCS health score as well as neurological success rate at one year in favour of the Prestige LP group (see enclosed presentation).	Thank you for your comment. Revised consultation document issued.

Com. no.	Consultee name and org.	Sec. no.	Comments	Response Please respond to all comments
26	Consultee 5 Consultant Neurosurgeon	**Gen**	<u>Safety</u> In the provisional recommendations by NICE there is a statement that "*The evidence raises no particular safety issues not already known in relation to fusion procedures".* I contend that there are in fact safety issues which should be raised in relation to cervical arthroplasty and in particular that the Prestige IDE study (Mummaneni et al 2007) provides level I evidence that at 24 months the Prestige cervical arthroplasty technique is safer than cervical fusion. Although there was no significant difference in the immediate outcome from the primary procedure between the fusion and the arthroplasty group there were significant differences in the number of secondary surgeries required at the treatment level with 8.7% of the fusion group requiring secondary surgery within two years in contrast to 1.8% in the Prestige group. As there are approximately 10,000 anterior discectomies and fusions carried out in the United Kingdom per annum one would predict from this data that if current UK practice changed from fusion to arthroplasty that approximately 690 of the 10,000 patients undergoing surgery per annum would be spared from having to undergo repeated surgery at the index level and with it the prolonged suffering and of course increased cost to the individual and society. It is of note that revisional surgery carries significantly higher risks than the primary procedure. In this IDE study there were no Prestige device failures and there was no radiographic evidence of migration or subsidence of the devices at 24 months. Four Prestige cervical discs were removed during the study, but this was for persistent post-operative radiculopathy because of failure of adequate decompression at the time of primary surgery.	Thank you for your comment. Revised consultation document issued.

Com. no.	Consultee name and org.	Sec. no.	Comments	Response Please respond to all comments
27	Consultee 5 Consultant Neurosurgeon	**Gen**	Theoretical long-term safety issues regarding cervical arthroplasty include device failure due to wear, hyper reactivity due to metal ions and debris causing an inflammatory response and osteolysis. The Prestige LP device is constructed from titanium/titanium carbide ceramic, this ceramic composite has excellent wear characteristics with insignificant material loss after being tested to both ISO and ASTM standards for cervical discs. During this testing, devices were subjected to 10 million cycles of coupled lateral bending and axial rotation motions at 100N load then exposed to 10 million more cycles in flexion/extension motions under 100N load. (10 million cycles are considered as being equivalent to 100 years of typical neck movement). By comparison a metal on metal arthroplasty has four times the wear and a polymer on metal arthroplasty has 40 times the wear. The material has passed all biocompatibility testing including particulate injection studies and has fully complied with ISO10993.	Thank you for your comment. Revised consultation document issued.

Com. no.	Consultee name and org.	Sec. no.	Comments	Response Please respond to all comments
28	Consultee 5 Consultant Neurosurgeon	**Gen**	<u>Long term data on cervical motion preservation and protection against accelerated degeneration at associated levels.</u> Following single level anterior fusion approximately 2.9% of patients per annum require surgery at an adjacent level for the treatment of new symptomatic degenerative disc disease (Hilibrand AS et al 1999). There is now increasing evidence that this accelerated degeneration is directly attributable to the fusion which results in an increased range of motion and sheer forces at adjacent discs (Wigfield CC et al 2002/2003). Increased sheer forces are known to result in the laying down of type I collagen which is associated with degenerative disc disease. Hilibrand et al predict that 25% of patients will require adjacent level surgery within 10 years of their primary procedure. It is estimated that approximately 500,000 individuals undergo anterior cervical fusion per annum in the west and as many are in their forties and fifties it is likely that over half of them will require secondary surgery in their lifetime. This does not take into account however the number who will have recurrent neck pain and brachialgia as a consequence of new associated level degenerative disc disease that do not undergo surgery. Clearly if one can reduce the incidence of adjacent level disease and the need for secondary surgery by maintaining cervical mobility then this will have a significant impact on the burden of disease and cost to society. **From the Prestige IDE study there are early indications, even at two years, that maintaining mobility at the treatment level may be protective against symptomatic degeneration at adjoining levels**. In the fusion/control group 12 adjacent levels were treated in 9 patients (3.4% of patients), which was significantly greater than in the Prestige group where 3 adjoining levels were treated in 3 patients (1.1%).	Thank you for your comment. Revised consultation document issued.

Com. no.	Consultee name and org.	Sec. no.	Comments	Response Please respond to all comments
29	Consultee 5 Consultant Neurosurgeon	**Gen**	<u>Long term data on cervical motion preservation and protection against accelerated degeneration at associated levels.</u> **Long-term outcome of 15 patients treated with Prestige have been published (Robinson et al 2004).** At four years one patient had required removal of the device and the outcomes on the remaining 14 patients showed sustained clinical improvements In 12 patients where radiological results were available continued motion of the arthroplasty was present and there was no evidence of new adjacent disease. **Patel et al 2007 have presented a five to nine year follow-up of 31 patients treated with a Prestige cervical disc**. All but one patient maintained motion of the disc and improvements in neck disability index, neck pain and arm pain were sustained. There were no instances of device failure or adverse events associated with the implant.	Thank you for your comment. Revised consultation document issued.

Com. no.	Consultee name and org.	Sec. no.	Comments	Response Please respond to all comments
30	Consultee 5 Consultant Neurosurgeon	**Gen**	Long term data on cervical motion preservation and protection against accelerated degeneration at associated levels. Continued. **Burkus et al 2009 have reviewed the 5 year outcome of approximately half of the patients in the Prestige IDE study (Mummaneni et al J Neurosurg Spine 6: 198-209, 2007) ; 271 patients including 144 investigational and 127 controls.** Significant improvements in Neck Disability Index (NDI) scores, Physical Component Summary scores of the SF-36 Health Survey, and neck and arm pain scores were achieved by 1.5 months in both groups that were sustained at 5 years. The mean NDI improvements from preoperative scores were 35.4, 36.3, and 38.4 at 24, 36, and 60 months, respectively, in the investigational group. The corresponding means were 33.9, 31.3, and 34.1 in the control group. **The differences in NDI at both 36-month and 60-month periods were significant between the 2 treatment groups (p = 0.008 and 0.022, respectively). The overall rates of maintenance or improvement in neurological status in the investigational group were 91.6%, 92.8%, and 95.0%, respectively, at 24, 36, and 60 months compared with 83.6%, 83.2%, and 88.9% in the control group (p = 0.006, 0.004, and 0.051, respectively). The implant effectively maintained angular motion averaging more than 7.3° at 36 months and 6.5° at 60 months after surgery. This study also shows a positive trend at 5 years in reduction of adjacent segment degeneration requiring surgery.**	Thank you for your comment. Revised consultation document issued.