

Impact case study (REF3b)

<p>Institution: University of Bristol</p>
<p>Unit of Assessment: 4 – Psychology, Psychiatry and Neuroscience</p>
<p>Title of case study: Artificial cervical joint improves patient outcome, reduces healthcare costs worldwide and benefits business</p>
<p>1. Summary of the impact</p> <p>An artificial cervical joint, designed by Mr Steven Gill, honorary Chair in the University of Bristol and consultant in Neurosurgery at Frenchay Hospital, is widely used for the treatment of degenerative cervical disc disease. Patients who have received the device have retained neck mobility and have experienced less neck pain and better neurological function than patients who have undergone conventional treatment involving fusion of the vertebrae. The device has also yielded substantial long-term savings as far fewer patients require secondary surgery. Gill's device was the first artificial cervical joint approved by the US Food and Drug Administration (FDA), in 2007. In early 2008, the global medical technology company Medtronic launched the device commercially in the US. The device is now used in 60 countries and has so far generated more than \$137 million in sales.</p>
<p>2. Underpinning research</p> <p>Background</p> <p>The discs between the vertebrae act as natural shock absorbers and provide flexibility in the spine. When these discs degenerate – through natural wear and tear or as a result of impact or other injury – the result can be marked discomfort, reduced mobility of the head and neck and numbness and/or weakness in the extremities as a consequence of compressed or irritated nerves in the cervical region. It is estimated that 60% of people over the age of 40 have some degree of degenerative disc disease. Degeneration of these discs in the neck region is known as cervical degenerative disc disease (cDDD). Since the 1950s, the prevailing surgical treatment of cDDD was to remove the disc, partially or fully, and fuse the vertebrae together – a procedure known as anterior cervical decompression and fusion (ACDF). However, by the early 1990s it was recognised that fusion of the vertebrae accelerated the degeneration of adjacent discs: ACDF altered the biomechanics of the spine to the extent that 25% of patients were exhibiting symptoms of adjacent-level disease within ten years of their operation and having to undergo additional surgery. Devices were designed to replace intervertebral discs and to mimic natural vertebral movement but were largely unsuccessful. Most devices were directed at the lumbar spine rather than the cervical spine, and very few made it to clinical trials.</p> <p>The research</p> <p>In 1993, Mr Steven Gill was appointed Honorary Senior Lecturer in the University of Bristol and Consultant in Neurosurgery at Frenchay Hospital. Gill worked with Mr Brian Cummins, a Consultant Neurosurgeon at Frenchay Hospital, to place an artificial cervical joint (ACJ) – known as the Cummins joint – in 20 eligible patients. Though adjacent segment degeneration was not observed in any of the patients [1], there were complications with the device. Gill subsequently designed a new device which allowed more physiological motion, and made significant changes to the screw locking mechanism to address complications associated with the Cummins joint. This new ACJ became known as the Frenchay artificial cervical joint and a patent for the design was filed in October 1998, with Gill listed as one of the inventors and Sofamor Danek Holdings Inc (now Medtronic) holding the patent (US patent no. 6,113,637; published September 5, 2000).</p> <p>In 1998, Gill (by now Head of the Functional Neurosurgery Research Group in the University of Bristol) and his colleagues placed the new joint in 15 patients. In a two-year pilot study, Gill and his colleagues established the safety of their surgical technique, proved the stability of the implanted device and confirmed the ability of the joint to maintain natural intersegmental motion at the level of the ACJ without causing excessive motion at adjacent intervertebral levels, in contrast to the</p>

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effects of intervertebral fusion [2, 3].

In 2000, the first prospective, randomized trial to compare cervical arthroplasty (using the Frenchay ACJ) with ACDF was conducted in centres in Belgium, the UK, Switzerland and Australia. In 2004, Gill and his colleagues presented the data on 47 of the patients involved in the trial [4], which showed significantly greater improvement in the neck disability index six weeks after the operation in the arthroplasty group (as well as slightly shorter operating times and reduced intraoperative blood loss) [4].

This research, which provided evidence of the efficacy of Gill's ACJ design in the treatment of degenerative cervical disc disease, led to the Frenchay joint becoming the first FDA-approved ACJ, sold commercially by Medtronic as the PRESTIGE® Cervical Disc System. The commercial adoption of this device in 2007 and its widespread subsequent use has improved clinical outcome and quality of life for patients with cDDD.

3. References to the research

- [1] Cummins, B.H., Robertson, J.T. & Gill, S.S. (1998) 'Surgical experience with an implanted artificial cervical joint', *Journal of Neurosurgery*, 88 (6): 943-948. <<http://thejns.org/doi/abs/10.3171/jns.1998.88.6.0943?journalCode=jns>> Citations*=188.
- [2] Wigfield, C.C., Gill, S.S., Nelson, R.J., Metcalf, N.H. & Robertson, J.T. (2002) 'The new Frenchay artificial cervical joint: results from a two year pilot study', *Spine*, 27(22): 2446-2452. doi: 10.1097/01.BRS.0000032365.21711.5E. Citations=166.
- [3] Wigfield, C., Gill, S., Nelson, R., Langdon, I., Metcalf, N. & Robertson, J. (2002) 'Influence of an artificial cervical joint compared with fusion on adjacent-level motion in the treatment of degenerative cervical disc disease', *Journal of Neurosurgery: Spine*, 96 (1): 17-21. <<http://thejns.org/doi/abs/10.3171/spi.2002.96.1.0017>> Citations=201.
- [4] Brotchi, J., Gill, S., Kahler, R., Lubansu, A., Nelson, R., McCombe, P. & Porchet, F. (2004) 'A multicenter, prospective, randomized, study of an artificial cervical disc versus fusion for primary cervical disc surgery', *Journal of Bone & Joint Surgery, British Volume*, SUPP I: 85-86. <http://www.bjiprocs.boneandjoint.org.uk/content/86-B/SUPP_1/85.5.abstract>

*All citation values from Google Scholar as of September 6th, 2013.

4. Details of the impact

Patients benefit from improved clinical outcomes and improved quality of life

Several studies (cited in [a]), including a five-year randomised control trial comparing the outcomes of 541 patients across 32 investigational sites and showing improved outcomes for those patients who had received a PRESTIGE disc (276 patients) versus those who had the ACDF (265 patients) [b], confirmed the clinical benefit of the artificial joint and underpinned changes in NICE guidance. The following outcomes were reported:

- *Neurological function* as evaluated through tests of motor function, sensory function and deep tendon reflexes was consistently significantly higher for the ACJ group.
- *Neck disability index* improved for both patient groups, but those that had received the ACJ consistently had lower scores (i.e., less pain and disability) than those that had ACDF. At both three and five years after the operation, the differences between these two treatment groups were significant.
- *Neck pain* after the operation was consistently less among those that had received the ACJ (though the differences between groups were not significant after five years).
- *Mean angular motion* in the spine at the site of operation was maintained in the ACJ group five years after the operation, whereas it was greatly restricted in the ACDF group, as expected.
- *Reduced number of secondary surgeries and interventions at the original site of operation* among those that had received the ACJ. There were 11 secondary surgeries associated with the ACJ group and 32 associated with the ACDF group.

For people living with debilitating neck pain, replacement of the cervical disc with an ACJ is a viable treatment option that will not compromise future mobility. One patient reported that after having the PRESTIGE disc surgery, “the neck pain [she] had come to think of as normal was gone. [She] went back to work within a week and did a 25-mile bike ride within two weeks” [c, pg 16].

Changes to National Institute for Health and Clinical Excellence (NICE) guidance

The most recent (May 2010) guidance from NICE is that “current evidence on the efficacy of prosthetic intervertebral disc replacement in the cervical spine shows that this procedure is as least as efficacious as fusion in the short term and may result in a reduced need for revision surgery in the long term” [a]. This represents a shift from the NICE guidance issued in November 2004, which stated that there was sufficient evidence regarding the safety and efficacy of the prosthetic intervertebral disc replacement procedure to support its use, but that “there is little evidence on outcomes beyond 2-3 years” [d].

Economic benefits to society associated with ACJ

There are substantial cumulative long-term healthcare savings associated with the use of an ACJ rather than ACDF. Though in-patient cervical arthroplasty is initially more costly, there is a reduced need for subsequent surgeries, resulting in a mean net benefit of \$431 per patient [e]. When considering only outpatient single-level procedures, ACJ is 62% less costly than ACDF [f]. Patients who received an ACJ also had fewer days off work post-surgery (a mean of 38 work days) than patients who had fusion surgery [e]. Based on the occupations and wages of the study group participants, this resulted in a mean societal benefit of \$6,547 (2007 figures) per patient over two years post-surgery due to reduced wage loss [e]. The long-term reduction in healthcare costs associated with cervical arthroplasty will have an ongoing positive economic impact on society.

Medtronic benefits from the commercialisation of the ACJ developed in Bristol

Medtronic is the world’s largest medical technology company, reaching more than 120 countries. The ACJ developed by Medtronic in 1998, known as PRESTIGE I, used Gill’s design that improved upon Cummins’ original device to allow translational and rotational motion [Gause, Gill *et al.* (2006). United States patent No. 6,113,637, cites 1]. Medtronic subsequently invested in several more adaptations of the PRESTIGE ACJ and the final version, developed in 2002, was approved by the FDA in July 2007 [g]. This enabled Medtronic to launch the PRESTIGE ® Cervical Disc System in the US in the first quarter of 2008. The unit sold for \$4,450 USD (2010 pricing) [h]. Since its launch, 31,000 Prestige units have been sold in 60 countries (personal communication, Marc Dace, Director of Product Development at Medtronic Spine & Biologics). This amounts to more than \$137million in sales for Medtronic since 2008. Medtronic’s net sales of core spinal devices, including the PRESTIGE, in the 2008 fiscal year were \$1.869 billion USD – an increase of 9% over the prior fiscal year [i]. Medtronic attributed this increase to “continued acceptance of our products for the thoracolumbar and cervical sections of the spine” [i, pg 24]. Looking ahead in its 2008 annual report, Medtronic singled out the “continued growth and acceptance of our PRESTIGE ® Cervical Disc System” as an area of growth for future sales [i, pg 25].

The trend for increased growth in Medtronic’s core spinal sales has continued since 2008 [i-k]. In 2012, sales were \$2.467 billion USD [k], an increase of 32% from 2008, with much of the growth occurring in international markets [k]. Spinal restorative therapies constituted 20% of Medtronic’s annual revenue of \$16 billion in 2012 [k].

5. Sources to corroborate the impact

- [a] NICE (May 2010) *Prosthetic intervertebral disc replacement in the cervical spine*, Interventional procedure guidance 341. <http://www.nice.org.uk/nicemedia/live/11157/48666/48666.pdf>
- [b] Burkus, J.K., Haid, R.W., Traynelis, V.C. & Mummaneni, P.V. (2010) ‘Long-term clinical and radiographic outcomes of cervical disc replacement with the Prestige disc: results from a prospective randomized controlled clinical trial’, *Journal of Neurosurgery: Spine* 13:308-318. [cites 1-3]

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- [c] Medtronic (2010) *Innovating for life: 2010 Annual Report*.
<<http://www.medtronic.com/downloadablefiles/mdt-2010-annual-report.pdf>> Provides a quote from an ACJ patient that has experienced improved quality of life.
- [d] NICE (November 2004) *Prosthetic intervertebral disc replacement*, Interventional procedure guidance 100.
<http://www.spitjudms.ro/files/protocoale_terapeutice/neurochirurgie/ipg100guidance.pdf>
- [e] Menzin, J., Zhang, B., Neumann, P.J., Lines, L.M., Polly, D.W., Barnett-Myers, S., Fontes, R. & Traynelis, V.C. (2010) 'A health-economic assessment of cervical disc arthroplasty compared with allograft fusion', *Techniques in Orthopaedics*, 25 (2):133-137. Doi: 10.1097/BTO.0b013e3181de5769. Independent evidence of financial benefit of 'in-patient' cervical arthroplasty procedure over ACDF
- [f] Wohns, R. (2010) 'Safety and cost-effectiveness of outpatient cervical disc arthroplasty', *Surgical Neurology International*, 1:7. doi: 10.4103/2152-7806.73803. Independent evidence of financial benefit of 'out-patient' cervical arthroplasty procedure over ACDF.
- [g] U.S. Food and Drug Administration 'PRESTIGE® Cervical Disc System –P060018', *Medical Devices, Device Approvals and Clearances* [website], (7 Jan2013).
<<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm076928.htm>> accessed 9 May2013. Letter from FDA approving the PRESTIGE ACJ.
- [h] Mendenhall Associates Inc. (2010) 2010 Spinal Implant Price Comparisons. *Orthopedic Network News* 21 (4):11-14.
<<http://spine.orthopedicnetworknews.com/archives/onnn214s5.pdf>> 2010 pricing of the PRESTIGE Cervical Disc System.
- [i] Medtronic (2008) *Expanding Our Role: 2008 Annual Report*.
<<http://216.139.227.101/interactive/mdt2008/>> Gives annual sales figures for core spinal devices, including the PRESTIGE ACJ.
- [j] Medtronic (2009) *Better Healthcare: 2009 Annual Report*.
<<http://www.medtronic.com/temp/2009/annual-report/medtronic-2009-annual-report.pdf>> Evidence of continued growth in the sale of core spinal devices, including the PRESTIGE ACJ.
- [k] Medtronic (2012) *Transforming for Growth: 2012 Annual Report*.
<http://www.medtronic.com/wcm/groups/mdtcom_sg/@mdt/@corp/documents/documents/ar12_annual_report_final.pdf>. Further support for financial benefits and growth in the sale of core spinal devices, including the PRESTIGE ACJ.