Artificial Discs and Spinal Motion – Use of activ C™

a report by

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Promising experiences with lumbar disc functional replacement have led investigators to develop mobile disc prostheses for the cervical spine. The search for dynamic devices was initiated following reports by Hilibrand and Goffin,[1,2] who described adjacent segment overload after cervical fusion procedures during a long-term follow-up (see *Figure 1*). These findings were also supported by biomechanical studies demonstrating increased motion and/or intradiscal pressure at levels adjacent to fusion in the cervical spine.[3,4] On the other hand, the overall results of anterior cervical discectomy and fusion (ACDF) are very positive,[5–7] while the theoretical role of the natural course of cervical disc degeneration to 'adjacent segment disease' remains unclear.[2] Despite such arguments supporting the advocates of 'gold standard' fusion techniques, the evolution of motion preservation in spinal care cannot be stopped. The strongest motivator for the development of mobile implants for cervical total disc replacement (CTDR) is the natural desire of surgeons to preserve – at least in part – spine segment motion, thus simply adapting our surgical efforts to the normal behaviour of the human spine.

The indications for CTDR in cervical degenerative disc disease (cDDD) have changed since the initial clinical success of the first generation of CTDR implants. A simplified introduction technique and advanced design of the second generation of cervical prostheses resulted in increased frequency of implantations, with thousands of CTDRs being implanted worldwide. An increasing number of publications are reporting very good clinical and morphological results.[8–10] Complications after CTDR are also being described in the literature; these include dislocation of implants, neck pain, heterotopic ossification or fusion at the operated level during follow-up.[11–13] Despite a low rate of complications, such reports remind us that the development of CTDR technology is not yet at its peak. The indications for CTDR and implant design are crucial for success. Motion-preserving techniques in the cervical spine are currently limited to symptomatic disc spaces that remain high enough, are moving sufficiently and lack significant bony degenerative changes or markedly arthritic joints. The best results are usually achieved in middle-aged patients with acute soft disc herniation at a single level.

Current CTDR device development is focused on improvements in prosthesis design. One of the main evolutional tasks is to develop the ideal shape of the implant surface in order to avoid excessive bone drilling, as well as to allow adaptation of the implant–bone contact zones to the natural ones (see *Figure 2*).

The emphasis of most manufacturers is on the primary stability of mobile implants. The profile of usual fixating keels or pins has decreased over the years in such a manner that the devices are fixed in place without significant damage to contact surfaces during implantation. When devices with keel are used, the groove should not be chiselled but rather gently drilled using special tools.

In nearly all of the current types of prosthesis, the contact surfaces are covered by various osteo-conductive materials.[8,9,12] Among these, titanium plasmapore appears to have the best historical track record, in particular when used in non-cemented total hip prostheses. Solid, long-term implant stability is dependent on bony ingrowth through contact surfaces.

Another important biomechanical property of CTDR devices is their ability to mimic natural characteristics and range of motion.[14] So far, no mechanical device has come close to the complicated coupled motion of a cervical spine segment. Most of the existing implants are constrained or semi-constrained.[8,9] The natural axis of rotation is often not respected. The third generation of prosthesis is constructed with a dorsally located centre of rotation to imitate its physiological position (see *Figure 3*), at least as far as flexion–extension is concerned.

Despite these improvements, an ongoing critical appraisal of our results is absolutely essential. The technique is in its infancy and uncritical enthusiasm could hinder further development of promising CTDR technology.

The third generation of cervical disc replacement devices, such as activ C™ (Aesculap, Germany), is widely used in clinical practice today, with more than 1,000 implantations being registered worldwide. Ten selected spine centres in Europe have been continuously monitoring the results since the market launch of activ C in order to critically appraise the product and surgical outcome. We present here our preliminary 10-centre experience with the first 89 patients treated with the activ C prosthesis, including a detailed analysis of clinical data during a six-month follow-up in 31 patients.

Material and Methods

Between January 2007 and April 2008, we performed anterior cervical discectomy and CTDR implantation in 89 patients (21–60 years of age) with cDDD. All of the included surgeries were single-level: C3/4 (n=3), C4/5 (n=6), C5/6 (n=52) and C6/7 (n=28). Eighty-nine activ C mobile disc prostheses were implanted.

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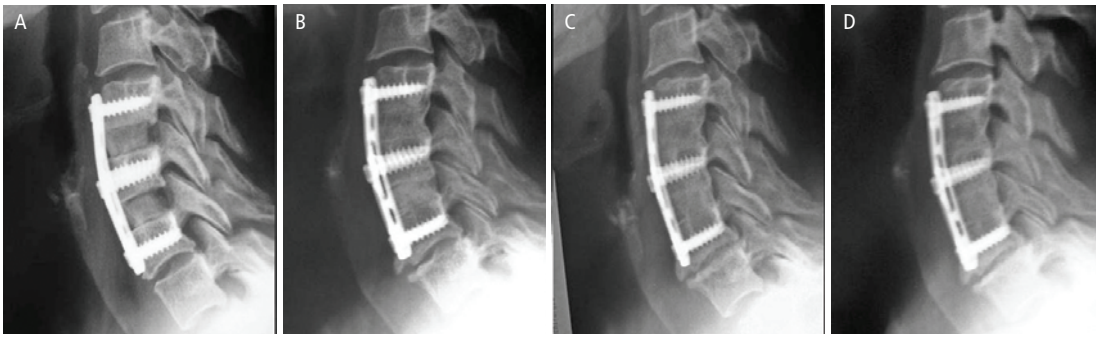
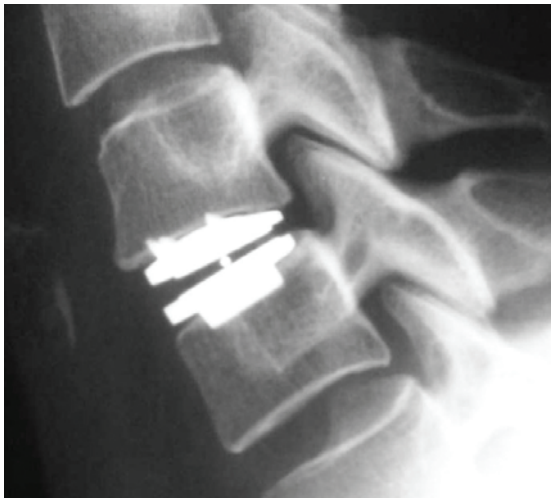
Figure 1: Development of Radiographic Marks of Adjacent Segment Degeneration



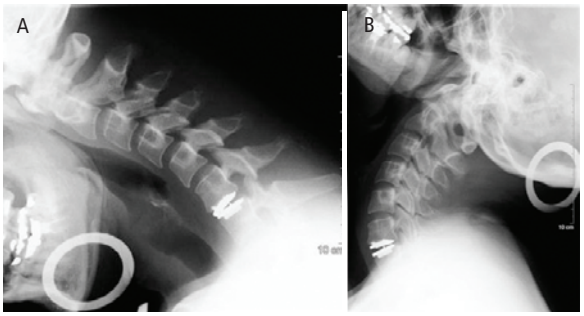
A. Immediately after surgery; B. Three years after surgery with caudal adjacent segment degeneration; C: Progression in both adjacent levels after five years; D: Lateral radiograph after seven years with evident degeneration in both adjacent segments.

Figure 2: Design of activ C Implant and Radiograph of Position in C5/6 Space Showing the Exact Adaptation of Contact Surfaces to the Natural Endplates



The implant is stabilised by self-cutting spikes on the superior prosthesis plate and a keel on the inferior one.

Figure 3: Lateral Radiograph of activ C in Flexion and Extension Showing Posterior 'Physiological' Location of Centre of Rotation



The indication for surgery was based on compatible clinical and radiographic findings. Most of our patients suffered from radiculopathy and/or myelopathy. Purely axial pain was an indication in one case only. Soft disc herniation with or without spondylosis was the main reason for total disc replacement in our series. Well-preserved motion in the target segment on dynamic radiographs and a disc height greater than 3mm were the main pre-operative indication criteria in the decision-making process. Conversely, contraindications to the procedure included mechanical segmental instability and patient age below 20 or above 65 years. Other contraindications were similar to those for cage implants (osteoporosis, allergy, etc.).

At the time of writing, 31 patients (31 implants) were available for six-month follow-up, and the clinical results of this group have been analysed further in detail. The average age of these patients was 45 years (range 21–60 years) and 56% were female. All patients, except those with rapidly progressing neurological deficits, were treated conservatively for at least eight weeks prior to operative intervention.

Surgery

A standard anterolateral approach was used in all cases. After a total anterior discectomy, posterior osteophytes were removed when necessary. The posterior longitudinal ligament was at least partially resected in the majority of cases. A trial implant was used to determine the proper height and size of the implant. Primary stability of the activ C implant is achieved by means of three anchoring, self-cutting spikes superiorly and a small central keel inferiorly in the bone of the neighbouring endplates (see *Figure 2*). The keel groove was cut with a specialised drill guided by the trial implant. Finally, the implant was simply introduced into the disc space using an implant holder, similar to any other interbody device placement. All steps of the disc implantation were monitored with the aid of lateral fluoroscopy. An external semi-rigid collar was used only for the duration of the recovery from general anaesthesia. All patients were mobilised immediately thereafter.

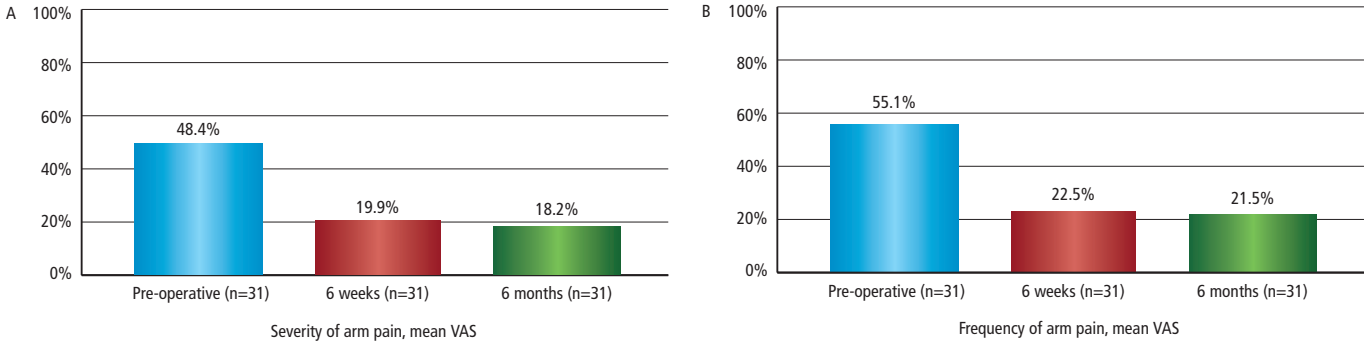
Outcome Measurements

Clinical, neck disability index (NDI) and visual analogue score (VAS) data were collected immediately after surgery, at discharge and six weeks and six months after the operation. Neurological status and VAS scores were assessed by an independent neurologist. All patients included in this prospective long-term study signed an informed consent.

Results

activ C implants are available in three heights (5–7mm). However, in this series only 5 or 6mm disc prostheses were used, with the majority of them (90%) being 5mm high. Excessive peri-operative bleeding occurred in one case. Other procedures were uneventful. Patients were discharged from hospital on post-operative day four on average (range one to seven days), and collars were not used. There were no infections, recurrent laryngeal nerve palsies or re-operations due to implant failure in this series. The mean VAS value for neck pain intensity improved from 48.7 to 20.3% and the VAS for neck pain frequency from 54.8 to 19.5%. VAS for arm pain intensity decreased from 48.4 to 18.2% and VAS for arm pain frequency from 55.1 to

Figure 4: Six-month Trend Evaluation of Visual Analogue Scale for Severity and Frequency of Arm Pain



21.5% (see *Figure 4*). The mean pre-operative value of NDI (39.5) was reduced to 21.6 at six-month follow-up (see *Figure 5*).

Preliminary Conclusions

Despite the preliminary nature of these results, activ C seems to be a suitable disc prosthesis with a simplified implantation technique. No significant complications occurred in this series. Longer follow-up and morphological evaluation of the results are necessary to evaluate long-term implant mobility and clinical outcome. ■

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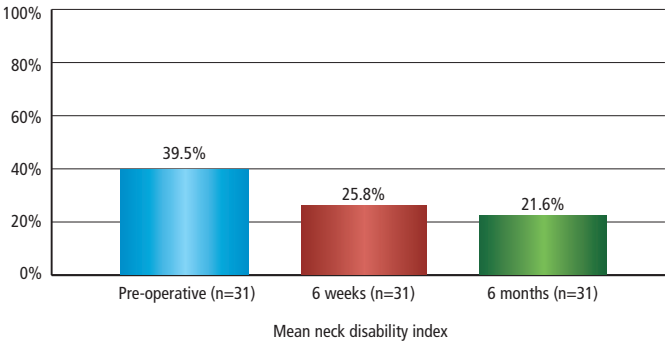
Figure 5: Neck Disability Index Improvement in Six Months



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