Developments in Spine Surgery – Non-fusion Technology

**a report by**

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Degenerative disc disease of the cervical and lumbar spine refractory to conservative therapy has been treated over decades by surgical fusion of the painful segments.

The clinical outcome is influenced by the indication – e.g. the success rate following anterior cervical discectomy and fusion for radiculopathy is significantly higher than that of lumbar fusion for low-back pain. Furthermore, long-term follow-up has shown an accelerated rate of disc degeneration on the adjacent discs. This entity has been defined as ‘transitional’ or ‘adjacent segment’ disease. Several biomechanical studies in human cadaveric models have shown that spinal fusion increases motion and intradiscal pressure in adjacent non-operated discs, which can accelerate the rate of disc degeneration.1 Last but not least, pseudoarthrosis is a non-negligible cause of failure in fusion surgery.

Non-fusion technology is driven by the philosophy to combine the goals achieved hitherto by conventional procedures with a still-functioning spinal unit, thereby improving the long-term results. Non-fusion techniques are intended to provide the benefits of neural decompression at the cervical level or the favourable redistribution of the axial load at the lumbar level along with motion preservation.

Non-fusion techniques include total disc replacement (TDR) for the cervical area, and nucleus pulposus replacement (NPR), TDR, dynamic stabilisation and interspinous devices.

**Cervical Total Disc Replacement**

Since cervical TDR is a relatively new treatment the patient selection is still open to discussion. A restrictive indication limited to radiculopathy or acute myelopathy caused by soft-disc herniation seems to yield the best results. A single-level disease with a preserved lordotic and non-degenerated C-spine is also a favourable prognostic factor. Patients without pre-existing motion cannot be expected to regain mobility by implanting a prosthesis.

The Bryan Cervical Disc (Medtronic Sofamor Danek, Memphis, Tennessee) is a non-constrained and closed prosthesis. The device consists of two titanium alloy shells with a polyurethane nucleus. It was implanted for the first time in 2000, and since then approximately 6,000 patients have been treated with the Bryan disc. The original cumbersome implantation technique has been simplified. Goffin et al.2 reported a clinical success rate ranging from 86 to 90%.

The Prodisc-C (Synthes Inc., US) features a ball and socket design. The modular implant consists of two cobalt-chrome-molybdenum end-plates and an ultra-high-molecular-weight polyethylene inlay. Two keels provide an immediate fixation of the prosthesis (see Figure 1).

The one-year results of a prospective multicentre clinical investigation showed a significant improvement in the visual analogue scale (VAS) score for neck and arm pain. The Neck Disability Index (NDI) improved from 40.5 pre-operatively to 18.3 one year after surgery. The complication rate was 6.6%, of which the majority were transient minor neurological deficits with complete recovery.3

During the last few years other prostheses have been designed and are under clinical evaluation. Generally speaking, they all compare favourably with cervical fusion. Heterotropic periprosthetic ossifications have been observed independently from the implant design and one year post-operatively account for 9.1% of spontaneous fusion of the treated segment.4-5 Non-steroidal anti-inflammatory drugs are given two weeks post-surgery to reduce the incidence of heterotropic ossification.6

**Nucleus Pulposus Replacement**

Degeneration of the lumbar disc means dehydration and shrinking with failing of transferring loads between vertebral bodies. The principal aim of NPR techniques is to restore the biomechanical function of the annulus by placing annular fibres in tension.

This goal can be achieved either by inserting intradiscal implants or by injecting in situ curable polymers. The indication is low-back pain without previous spine surgery. The differently designed implants share the hydrophilic property, i.e. they are inserted in a dehydrated state via a minimally invasive posterior or a transpsoatic approach and absorb up to 90% of their weight in water to restore disc height and improve compressive axial load resistance.

The Prosthetic Nucleus Device (Raymedica, Inc., Bloomington, Minnesota) is the most extensively studied implant. Although biocompatibility was studied according to the guidelines of the International Standards Organization, severe oedematous reactions of the vertebral end-plates led in 10% of cases to the explantation of the device (see Figure 2). The clinical success rate ranged between 79 and 91%. The most common elastomers injectable within the disc space are silicone and polyurethane.
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To date clinical studies include small number of patients so conclusions cannot be drawn. Moreover, preservation of motion in the discs and facets was documented on plain radiographs and computed tomography (CT) scans.

Lumbar Total Disc Replacement
The combination of load-dependent back pain, refractory to non-operative therapy, a single ‘black disc’ on magnetic resonance imaging (MRI) and intact facet joints in a highly motivated patient seem to be a reasonable indication for TDR. Selective indication still represents the key for clinical success of a debatable surgical option: up to now there is scarce evidence that fusion or TDR may influence the course of degenerative spinal disorders.

The implants on the market show a three-component modular design (SB III Charité Disc, Link Inc. and ProDisc II, Synthes Inc.), including two metallic end-plates and an inlay made of polyethylene. There is also a model featuring two metallic articulating components: Prestige (Medtronic Sofamor Danek, Memphis, Tennessee). A special design allows also for an oblique insertion, avoiding the dissection of the prevertebral vessels. The clinical results seem to be promising, with a lower success rate at the level L5/S1.

Dynamic Stabilisation
The dynamic neutralisation system for the spine (Dynesty, Sulzer Medica Inc.) is a pedicle screw system connected by an elastic synthetic compound for mobile stabilisation. The system is thought to be an alternative to rigid fusion. The combination of slight distraction and posterior tension-band allows for segmental mobility. However, a recent biomechanical study shows that the mechanical effects of a dynamic implant are similar to those of a rigid fixation device, except after distraction, when intradiscal pressure is considerably lower for rigid than for dynamic implants.9 The main indication is spinal canal stenosis associated with degenerative spondylolisthesis. A prospective, multicentre study evaluating 83 patients showed results comparing well with conventional procedures.8

Interspinous Devices
These devices are placed as a spacer between the spinous processes at the symptomatic level. They limit extension with no effect on flexion, axial rotation or lateral bending. Furthermore, these implants reduce intervertebral disc pressure and ‘off-load’ the facet joints.9 On the other hand, they do not influence the intradiscal pressure or the motion at adjacent segments.10

The current primary indication is for patients with symptomatic lumbar stenosis who improve clinically in a flexed position. An insertion at the level L5/S1 is not recommended for anatomical reasons. The success rate of 78% compares favourably with the conservative treatment of spinal canal stenosis but is not superior to that of the microsurgical decompression.10

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Conclusions
Non-fusion technology is bringing a bundle of novel techniques addressing degenerative spinal diseases that are conventionally treated by fusion. The simultaneous use of multiple new techniques makes it more difficult to compare them with conventional methods. Furthermore, the rapid proliferation of techniques impairs long-term analysis.

To date, it seems that the short-term results of non-fusion techniques are similar to those of fusion procedures, with the hope of a lesser rate of transitional disease. On the other hand, the pitfall rate of these new devices (see Figure 2), is unknown and the costs are considerable. The value of careful patient selection and of gathering further data in controlled prospective studies will not be of less importance in non-fusion technology. Despite some unavoidable drawbacks, non-fusion technology is going to become a part of spine surgery.