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Non-fusion technology in degenerative lumbar spinal disorders: facts, questions, challenges

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Abstract Although surgical fusion of the painful degenerating functional spinal unit (FSU) of the lumbar spine has always been a matter of debate, it has become a gold-standard procedure for all cases that lack an alternative treatment. However, a detailed and honest review of the clinical data reveals a considerable number of undesired side effects, complications and poor outcomes. The continuous search for alternative surgical treatment modalities has led to the development of numerous ideas for surgical reconstruction of the anterior and/or posterior column.

The term “spine arthroplasty” summarises all procedures that have the goal of restoring function. This article describes the principles of the most current surgical techniques and implants, it points out potential challenges and poses a number of questions that need evidence-based answers before the incorporation of these innovations into surgical routine can be justified.

Keywords Spinal fusion · Spine arthroplasty · Artificial disc · Lumbar spine

Introduction

Surgical treatment of the painful degenerating spine has been continuously debated throughout the last 50 years. Although there is little evidence from the scientific literature that surgery can positively influence the course of degenerative spinal disorders, the number of surgical procedures is increasing continuously [5, 7, 39]. On the other hand, the same observations can be made about non-surgical therapeutic options, whose justification mainly stems from empirical results, and where an evidence base is also lacking. Whereas the acceptance of conservative measures is higher, especially in countries with medical and social security networks that allow long therapy periods with only minor negative socio-economic consequences, it is hard to convince patients to take “the long way” if there seems to be a surgical “short way” to get rid of the pain. The pressure “from the street” to resolve patients’ pain or improve their symptoms as quickly as possible has triggered the use of a variety of so-called “semi-invasive” procedures such as peridural injections, catheters, in-

tradiscal electrothermal therapy (IDET) and laser therapy to achieve these goals [17, 22, 32, 33].

However, a considerable number of patients with painful degenerative disc disease end up as candidates for spinal fusion, either primarily or after various unsuccessful semi- and/or minimally invasive procedures. This article will discuss the role of spinal fusion in the light of upcoming potential alternative treatments.

Spinal fusion in degenerative lumbar disc disorders

There is no doubt about the place of spinal fusion in deformities or unstable conditions of the lumbar motion segment. However, spinal fusion in degenerative disc disease without signs of instability or disturbed curvature, though performed quite frequently, is not generally accepted [13, 14, 19, 24]. In most cases, the indication is based on unsuccessful conservative therapy, and the lack of reasonable therapeutic alternatives. This lack of alternatives often leads surgeons to accept potential risks, side-effects and complications to help patients get rid of their symp-

toms [10, 20, 36]. However, the results seem to not always justify these decisions.

Own data

Between April 1998 and January 2000, a total of 134 patients (84 female; 50 male, age range: 20.4–87.2 years, mean age: 56.2 years) were treated with fusion for degenerative disorders of the lumbar spine. The diagnoses are listed in Table 1. Spinal fusion was performed in all patients; in 91 cases it was combined with segmental decompression. Posterior-anterior 360° fusion was performed in 94.8%, posterior lumbar interbody fusion (PLIF) in 3%

Table 1 Diagnosis for spinal fusion ($n=134$)

Diagnosis ^a	<i>n</i>
Degenerative disc disease	82
Degenerative spondylolisthesis	29
Failed back (following discectomy)	23
Total	134

^aSpinal stenosis was an additional diagnosis in 91 of the patients

and posterolateral fusion in 2.2%. In all patients, fusion was performed using autologous bone graft from the iliac crest, which was augmented by a titanium cage in only 4.5% of the patients. All operations were performed by an experienced team of surgeons, each of them having performed a minimum of 300 spinal fusions. After a minimum follow-up time of 24 months, the overall fusion rate was 97.0%. The clinical results were analysed according to the economic/functional rating (EFR) score published by Prolo et al. in 1986 [28]. They are shown in Fig. 1 and Fig. 2, and are comparable with the results published in the literature [13, 19, 23]. A meticulous analysis of negative side-effects and complications was performed retrospectively. There were a total of 74 complications or adverse side-effects in 44 of the 134 operated patients (33%) (Table 2). While there were ten general complications, the majority related to the surgery (Table 3). Detailed analysis of these surgery-related complications showed an implant failure rate of 4.5%, 3% non-union and a rate of superficial wound-healing disturbances of 4.5% (Table 4). There was no deep wound infection. Revision surgery had to be performed in ten patients (7.5%). Approach-related complications occurred in 7.5% of the posterior and 5.2% of the anterior approaches (Table 5, Table 6). These compli-

Fig. 1 Results of spinal fusion at the lumbosacral junction

Fig. 2 Results of spinal fusion at levels L2/3, L3/4, L4/5

Table 2 Complications following lumbar spinal fusion ($n=134$)

No. (%) of patients without complications	99 (67%)
No. (%) of patients with complications	44 (33%)
No. of complications	74
General: n (%)	10 (7.5%)
Surgery-related: n (%)	64 (47.6%)
Independent from approach: n (%)	10 (7.5%)
Approach/Fusion-related: n (%)	48 (35.9%)

Table 3 General complications following lumbar spinal fusion ($n=134$) (*GIT* gastro-intestinal tract, *DVT* deep vein thrombosis, *UT* urinary tract)

Total	10 (7.5%)
Cardiac (arrhythmia, infarction)	4
Pulmonary (pneumonia)	1
GIT (GI bleeding)	2
Vascular (DVT)	1
Urinary (UT infection)	1
Neural arm plexus	1

Table 4 Surgery-related complications (independent from approach) following lumbar spinal fusion ($n=134$)

Total	10 (7.5%)
Non-union	4 (3.0%)
Wound healing disturbance	6 (4.5%)

Table 5 Posterior approach-related complications following lumbar spinal fusion ($n=134$)

Total	10 (7.5%)
Sensory deficit	4
Motor deficit	5
CSF fistula (1/91 decompressions)	1

Table 6 Anterior approach-related complications following lumbar spinal fusion ($n=134$)

Total	7 (5.2%)
Irritation n. genitofemoralis	6
Sexual dysfunction	1

Table 7 Fusion technique-related complications ($n=134$)

Total	37 (27.6%)
Implant failure	6
Loosening	4
Screw breakage	2
Pain at iliac crest at discharge	11
Meralgia paraesthesia	8
Numbness iliac crest	7
Fracture spina il. ant. sup.	5

cation rates are well below those published in the literature [10, 36]. The vast majority of complications were specific to the fusion-technique, being associated with the harvesting of the autologous bone graft from the iliac crest (Table 7).

The following conclusions can be drawn from these data. The surgical goal (spinal fusion) was achieved in 97% of the patients with the fusion technique described (pedicle screw fixation and interbody fusion with iliac crest bone) (excellent radiological result). The clinical results according to the EFR-score were acceptable, and compare well to the results published in the literature (acceptable clinical result). However, whereas the rate of general complications was acceptable as well, the price for the clinical and radiological result seems to be high in the light of the complications produced by the surgical procedure(s). Looking at other surgical specialties, it is rare to find procedures in which an "acceptable" clinical result can be justified in the presence of such a high rate of complications and adverse side-effects in the first 2 years postoperatively. We have not analysed late effects of segmental fusion, such as accelerated degeneration of the adjacent level. However, the problem is obvious: it is neither the surgical approach nor the general complications that produce the complication and co-morbidity level, it is the fusion procedure itself that obliges us to search for alternative procedures.

Reconstruction versus fusion

The historical aspects of reconstructive procedures have been described extensively in the article by Szapalski et al. in this issue [38]. A variety of experimental and clinical applications will be presented in the following papers, which all have one thing in common: they represent partial solutions for the multi-factorial problem of degeneration of the functional spinal unit (FSU) and they can only be considered as part of a step-by-step treatment philosophy, which has as its goal avoiding any use of spinal fusion at all for this condition.

Nucleus pulposus reconstruction (biological concept)

Principle: The experience with autologous chondrocyte transplantation (ACT) in peripheral joints has recently been applied to the lumbar spine (autologous disc chondrocyte transplantation; ADCT) (Meisel, personal communication, and [2, 11, 27]). Nucleus pulposus tissue is harvested during lumbar disc operations, the cells are cultured and re-implanted through a minimal-invasive percutaneous route several weeks following discectomy, with the goal of a biological reconstruction of the nucleus pulposus.

Facts and Questions: Although animal experiments suggest a potential regeneration of the nucleus pulposus

as compared to the non-transplanted control groups, results of an ongoing clinical pilot study are not yet available. Though a fascinating idea, ADCT poses many questions such as: Does the nucleus re-grow? and if it does: How does it re-grow? Which qualities does the new nucleus have? Does it even make sense to re-grow the nucleus in a lumbar disc with a weakened or destroyed posterior annulus? Does ADCT influence the reintegration of the annulus fibrosis? All these questions need to be answered in the ongoing clinical and experimental studies. The idea of revitalising the nucleus pulposus at an earlier stage of the degenerative process with cell culture techniques or with genetic engineering techniques should draw our scientific attention. Looking even more into the future, the pre-implantation diagnosis will make corrective actions possible at a very early stage of life.

Nucleus pulposus replacement

Principle: Replacement of the degenerated or excised nucleus pulposus has been performed in experimental and clinical studies using different materials such as hydrogel cushions (Prosthetic Disc Nucleus, PDN RayMedica Inc., Fig. 3; Aquarelle, Stryker Spine); or polyurethane spirals (Sulzer Medica Inc.; Fig. 4) [1, 16, 29]. Empirical data are now accumulating very rapidly from the first clinical applications. Only two nucleus implants are currently used, with different indication criteria: the Nucleoplasty Spiral (Sulzer Medica) is indicated after simple microdiscectomy for lumbar disc herniation. It serves as a space-holder and is supposed to prevent early disc height loss following discectomy [16, 18]. The indication for implantation of the Prosthetic Disc Nucleus (PDN) is different. It is used in patients with discogenic low-back pain without previous operations. It can be implanted through a traditional PLIF approach [31]. However, due to the higher risk of extrusions into the spinal canal, the minimally in-

Fig. 3 PDN prosthetic disc nucleus (RayMedica Inc.)

Fig. 4 Spiral implant for nucleoplasty (Sulzer Medica)

vasive anterior retroperitoneal route is preferred by the protagonists of this implant [1].

Facts and Questions: The PDN and Aquarelle are “hydro-active” implants, which are able to behave in a manner similar to the natural nucleus pulposus by increasing their water content when unloaded and decreasing it under load [9]. Although there have been extrusions of the PDN device after implantation through a posterior surgical approach, the initial results of the anterior implantation technique seem to be acceptable [1, 30, 31, 34]. There are still only few data on the long-term effects and behaviour of the implants in the intervertebral disc space. Implantation through a posterior route seems to be associated with a high extrusion rate.

In discogenic low-back pain, the pain is generated by nociceptors in the tears of the outer annulus fibrosus or in the cartilaginous endplates (often associated with Modic type I changes) [26]. This means that, at the time the patient becomes symptomatic, the nucleus is no longer the primary morphologic problem. This leads to fundamental questions: Does it make sense to replace the nucleus pulposus if its “container” (annulus fibrosus; cartilaginous endplates) is insufficient? Can replacement of the nucleus pulposus by a hydro-active implant restore disc height and thus (temporarily) protect the annulus from further degeneration? How will the cartilaginous endplates of the lumbar vertebrae tolerate the new load distribution initiated by artificial nucleus? No standards have been elaborated with regard to the degree of annulus degeneration or disc height loss up to which a nucleus replacement can still be accepted.

Total disc replacement (TDR)

Principle: The easiest reconstructive philosophy is total disc replacement. The implant model currently in use re-

sembles the principles of total joint replacement of the hip or knee joint. This also means that, from a biomechanical point of view, preservation of motion is considered to be superior to load distribution and damping effect. Both implants that are on the world market today are characterized by a three-component modular design, which includes two metallic endplates and a nucleus pulposus made out of polyethylene (PE). In the ProDisc II implant (ProDisc II, Spine Solutions Inc.), the PE inlay is fixed in the lower endplate by a snap-lock mechanism. In the SB III Charité Disc (SB III Charité, Link Inc.), the nucleus moves freely between the endplates (Fig. 5, Fig. 6) [6, 21, 25]. With both implants, distraction of the intervertebral space is one of the main surgical goals. Disc height and foraminal height as well as segmental lordosis can be restored even in “collapsed” segments, and segmental motion is preserved. The latest disc generation (ProDisc) can be implanted through a minimal invasive anterior approach [24, 25].

Facts and Questions: TDR is the most advanced reconstructive concept of the anterior column of the lumbar spine. More than 3000 implantations have been performed with the two systems described above [6, 15, 21, 25]. The clinical results seem to be promising, although there has been no prospective randomised study comparing this procedure with the “gold standard” of lumbar fusion. The advantage of the latest implant generation (ProDiscs II) is that it can be implanted through less invasive anterior approaches [25], and that peri- and post-operative morbidity seem to be dramatically reduced as compared to lumbar fusion procedures. Many questions remain to be answered, and provide the motivation for further scientific work: Which morphological factors influence the indica-

Fig. 6 Link SB III Charité total disc prosthesis (Link Inc.)

tion and outcome? Special attention has to be focussed on the posterior column, especially on the degenerative status of the facet joints. How do the implants behave in the long term? How do the adjacent segments behave and react after disc replacement? Can total disc replacement relieve the load on the facet joints, and can a slightly degenerated facet joint recover? How does the implant design and the surgical approach influence post-operative mobility, clinical result and long-term behaviour? How does the position of the implant in the intervertebral space (centred, anterior or posterior deviation) influence the range of motion, implant behaviour and clinical result? etc.

Reconstruction of the posterior column

Principles: Compared to disc replacement techniques, attempts to reconstruct the posterior elements (ligaments, facet joints) have been rare. The most advanced technology is the so-called “dynamic neutralization” concept, with the Dynesys Implant (Dynesys, Sulzer Medica Inc.) [8, 37], which is a combination of a pedicle screw system with dynamic posterior stabilisation. The combination of slight distraction and posterior tension-banding allows segmental mobility, but obviously restricts it towards the physiological “neutral zone”. It thus represents an improvement over the initial “Graf” ligamentoplasty concept [12].

The distraction effect to ameliorate mild forms of spinal stenosis is the main rationale behind other concepts such as the Wallis system [35] or the posterior shock absorber [3]. These H-shaped implants are placed between the spinous processes with a minimal invasive approach. They do not provide rotational stability and are merely segmental distractors, which provide a positive stop in extension and keep the segment in a slightly kyphotic posi-

Fig. 5 ProDisc modular total disc (Spine Solutions Inc.)

tion. The latter effect accounts for the expected relief of symptoms in spinal stenosis cases.

Facts and Questions: These implant systems are promoted for different indications. The Dynesys concept is mainly indicated for dynamic stabilisation in cases where lumbar fusion procedures might be associated with a high surgical risk and/or bad results. It is, however, again a partial solution for a multi-factorial problem. Its efficacy strongly depends on the behaviour and integrity of the anterior column.

Interspinous space-holders are distractive devices proposed for the treatment of slight forms of spinal stenosis. There are no controlled studies available nor have any reliable clinical results been published to date. Looking at the pathology of degenerative lumbar spinal stenosis (hypertrophic facet osteoarthritis, yellow ligament hypertrophy, annular protrusion, kyphotic deformity), doubts can be raised as to whether these concepts can lead to acceptable clinical outcomes. However, they represent current developments that need to be discussed and evaluated using scientific criteria.

Conclusions

This survey describes the main developments in the field of lumbar spinal arthroplasty. It is probably not complete (since a considerable number of new devices are currently being developed), nor does it allow any final conclusions to be drawn. However, we are facing a change of paradigms in the surgical treatment of degenerative disorders of the lumbar spine. The progress in implant development, the acceptance of, and clinical routine in, less invasive surgical approaches, as well as the results of lumbar spinal fusion procedures have triggered a willingness for scientific discussion and clinical acceptance of ideas that are, in fact, not so new [29, 38]. We are at the beginning of another period of fundamental progress in the field of spine surgery, which can be compared to the "Charnley era" in the development of the total hip joint replacement more than 50 years ago [4]. We are looking at a variety of new concepts, some of which will disappear, but some of which will stay and will definitely be accepted as basic new therapeutic concepts. The more we learn about these new techniques, the more we realise how little we know. It is our responsibility to our patients and our scientific duty to critically elaborate the solutions to all these open questions.

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