■ REVIEW ARTICLE

Total lumbar disc replacement

H. M. Mayer

From Spine Centre,
Munich, Germany

Rationale for total lumbar disc replacement

In the early 20th century, surgical fusion of one or more 'functional spinal units' (FSU) was developed and primarily performed for the treatment of spinal infection.¹⁻⁴ In the second half of the century, the indication was broadened and soon included the treatment of deformities, fractures, and tumours.⁵⁻¹⁰ The main goal of this type of operation was to preserve or re-establish segmental stability *in situ* or after reduction manoeuvres aiming at the restoration of physiological curvature. The fact that a functional and mobile spinal unit was turned into a stiff non-functional part of the spine was accepted as unavoidable. With the development of spinal instrumentation in the late 1970s and early 1980s, spinal fusion became more popular because these implants facilitated intra-operative manipulation of the spine to restore disc height, foraminal height, and curvature.¹¹⁻¹³ Moreover, the instrumented spine was often given immediate post-operative stability so that patients could be mobilised quickly and post-operative complications because of long-term hospitalisation and periods of immobilisation could be decreased.

Spinal fusion had become a standard surgical procedure which was now more predictable and reproducible. Soon it was used for the treatment of degenerative or post-operative changes of the spine.¹⁴⁻²⁰ Although there is still controversy about its benefit,²¹⁻²⁷ lumbar spinal fusion became accepted worldwide as a treatment option for symptomatic degenerative disease, degenerative spondylolisthesis, degenerative lumbar scoliosis, post-discectomy-syndromes or segmental instability adjacent to a previous fusion.²⁸⁻³²

However, with improving surgical technique and increasing demands and expectations from patients, the disadvantages of iatrogenic collateral damage to the tissues surrounding the spine, the incidence of complications and adverse side effects, as well as the conse-

quences of the immobilisation of one or more mobile spinal segments seem to be less acceptable to the patient as well as the surgeon.^{21,23,24,32-37} There have been numerous attempts, dating back to the early 1950s to design and manufacture implants aimed at a functional reconstruction of a spinal segment. A complete survey of the patent situation was published recently by Szpalski, Gunzburg and Mayer.³⁸ In the last four years a variety of new techniques and implants have been developed which aim to avoid fusion of the degenerative lumbar spine. They can be summarised under the new term of arthroplasty of the spine.³⁹ Replacement of lumbar discs has been shown to be the most advanced spinal philosophy.^{38,40} However, there are other surgical methods which are to be considered. Table I surveys these techniques and their development to date. This review focuses on total lumbar disc replacement.

Presumed goals of total lumbar disc replacement

To be a true alternative to spinal fusion, the goals of disc replacement should at least include those of fusion, i.e. removal of the disc, assuming it to be the main source of pain and the restoration of disc height, segmental stability and lordosis curve. Preservation or improvement of segmental motion is the additional goal of total disc replacement (TDR).^{25,41-44} Increasing disc height should increase the foraminal diameter, relieve loads across the facet joints and improve the pattern of load bearing between vertebrae.⁴⁵⁻⁴⁹ Restoration of segmental lordosis should rebalance the spine and, together with the preservation of motion,^{41,50} protect the adjacent segment from accelerated degeneration. To achieve these goals, implant material, design and biomechanical function have to meet certain criteria.⁵¹ The materials must be biocompatible and endure *in vivo* for up to 40 years.^{52,53} The biomechanical properties should allow for a near-normal range of movement and function.⁵³ The design of the

■ H. M. Mayer, MD, PhD,
Orthopaedic Surgeon,
Neurosurgeon, Associate
Professor
Orthozentrum München,
Spine Center Munich,
Harlachinger Str. 51, D-81547
München, Germany.

Correspondence should be
sent to Dr H. M. Mayer;
e-mail: mmayer@schoen-
kliniken.de

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Table I. Spinal arthroplasty procedures (2004)

Region	Principle	Procedure/implant	Application	Status
Posterior column	Ligament reconstruction	Graf ligaments	Therapeutic	Clinical studies
	Ligament augmentation			
	Dynamic neutralisation	Dynesys	Therapeutic	Clinical studies
	Interspinous spacers	Wallis	Therapeutic	Clinical studies
		X-Stop	Therapeutic	Clinical studies
Anterior column	Nucleus pulposus	DIAM	Therapeutic	Clinical studies
		PDN	Therapeutic/preventive	Clinical studies
		Spiral nucleoplasty	Therapeutic/preventive	Pilot study
	Regeneration	Disc chondrocyte		
		Replantation	Therapeutic/preventive	Clinical study
		Growth factors	Therapeutic/preventive	Experimental
		Gene transfer	Therapeutic/preventive	Experimental
	Annulus fibrosus		Therapeutic/preventive	Experimental
Total disc	Repair/reinforcement			
	Replacement	SB Charité III	Therapeutic	Study/routine
		Prodisc L	Therapeutic	Study/routine
		Maverick	Therapeutic	Study
		Flexicore	Therapeutic	Study
		Mobidisc	Therapeutic	Study

Fig. 1

Photograph showing the SB Charité III disc.

prosthesis and instrumentation should facilitate safe implantation, preferably through a modest incision.⁵⁴ The implant must not preclude modern imaging techniques for periodic monitoring and regard must be given to the possible need for revision or salvage procedures.

Prostheses

There are currently five total disc implants designed for the lumbar spine but one has been only approved in the United States by the Food and Drug Administration (FDA) in 2004 (SB Charité III; Depuy Spine; Raynham, Massachusetts).

SB Charité III. The SB Charité III has been developed in the former East Germany (Fig. 1).⁵⁵ It consists of two metal endplates made from Cobalt Chromium Molybdenum (CoCrMo)-alloy.⁴³ The surfaces facing the vertebral end-

plate are covered with porous plasma-sprayed titanium and coated with calcium phosphate to promote ongrowth of bone from the vertebral body. The free-floating biconvex sliding core is made from ultra-high-molecular-weight polyethylene (UHMWPE), encased between the biconvex endplates and surrounded by a metal wire for radiological marking.^{43,56} Primary stability is achieved by press-fit implantation, through five teeth on the endplate surface which anchor into the subchondral bone. Secondary stability is achieved by osseous ingrowth and integration supported by the osteoconductive surface structure. The implant is unconstrained and the UHMWPE-core mimics the performance of the nucleus pulposus adapting to a variable centre of rotation.^{46,47,57,58} It is available in two different plate sizes, four different angles and five different heights.⁵⁶

Since the first clinical use of this prosthesis in the late 1980s, more than 10 000 implantations have been performed worldwide. The results have been reported mainly in uncontrolled clinical series. The success rates vary between 60% and more than 80% in medium-term follow-up.^{55,59-63} The indications in these series included degenerative disc disease, but also 'revision' cases, spondylolysis etc which might explain the heterogeneity of the results. In more tightly selective series with single level degenerative disc disease at L4/5 or L5-S1, evaluated in a randomised, controlled trial such as the FDA-controlled investigational device exemption study, the results seem to be more homogenous leading to a significant improvement in visual analogue (VAS) and Oswestry scores.⁶⁴ After 24 months the overall success was 63% for the TDR as compared with 53% for fusion. There was a successful outcome using the Oswestry score ($\geq 25\%$ improvement) in 70% (*vs* 58%); 74% (*vs* 62%) of the patients showed a significant improvement in the VAS. There were 7.3% device-related, adverse events and 4.9% of the patients required further

Fig. 2

Photograph showing the Prodisc L with semi-constrained design.

Fig. 3

Photograph showing the Maverick disc.

surgery. Empirical data however, showed that the complication rates can reach 18%.^{51,59,62,65} The majority of adverse events and complications were related to the surgical approach.

The Prodisc L. The Prodisc L (Synthes, Paoli, Pennsylvania) was developed in the late 1980s and its use described in the early 1990s in a single case series from France.⁶⁶ The second generation has been available since 1999 (Fig. 2). The implant consists of two flat CoCrMo-alloy endplates. The lordosis angle is determined by the design of the superior endplate (6°/11°). The UHMWPE inlay is snapped into the lower endplate during the operation⁵⁴ which allows for the

insertion of the endplates without distraction of the intervertebral space. Since the inlay does not move, the centre of rotation is fixed at the level of the endplate of the lower vertebra. This leads to constrained motion in flexion/extension and in lateral flexion. The implant does not allow pure translation movement. The superior vertebra rotates around this fixed centre of rotation.⁶⁷ Primary stability of the implant is achieved by two spikes on each side of the endplate and by two central keels orientated in a sagittal direction to avoid rotational instability and to promote bony ongrowth for secondary fixation. The surfaces of the keels and endplates are coated with plasma-sprayed porous titanium. The implant comes in two sizes, two lordosis angles and three heights. The implant was first used by Marnay⁶⁶ in the early 1990's. Since the release of the second generation in 1999 more than 7000 have been implanted. Marnay⁶⁶ reported good and excellent results with the first generation implant after follow-up of eight to ten years. Other authors reported success rates between 80% and more than 90% in uncontrolled clinical series.^{41,54,68} Complication rates of 10% have been reported. Major complications include vertebral body fracture, subsidence or malpositioning and radicular pain.⁶⁸ The re-operation rate was 6% in this series. Preliminary results from one centre which participated in an FDA-controlled randomised trial, comparing TDR with 360° fusion, show a significant difference in the Oswestry disability index⁶⁹ three months post-operatively favouring TDR in a series of 28 patients.⁷⁰ Hospital stay was significantly shorter and there was a trend towards higher rate of patient satisfaction after six months. Similar results were reported in 35 patients (which were part of the same multi-centre study) by Delamarter et al.⁷¹

The Maverick disc. The Maverick disc (Medtronic, Minneapolis, Minnesota) design resembles the Prodisc L (Fig. 3). It consists of two flat metal parts comprising of a ball-and-socket-joint. The centre of rotation is fixed in the posterior third of the disc space. It is a semi-constrained device which does not allow for pure translation. Rotation of the upper vertebra around the ball in the lower endplate is determined by the small radius of the ball. Primary fixation and stability are achieved by the large central keels which are driven into the adjacent vertebral bodies in a manner similar to the Prodisc. The heights of each keel may limit a bisegmental application in patients with smaller vertebral bodies. This implant is currently being evaluated in clinical studies in Europe and the United States. Preliminary results have been reported by Le Huec et al.⁴² in 2004. In a series of 30 patients with a follow-up of up to one year, they reported clinical success in 86%.⁴² There was only one non-device-related complication. Since 2003, a prospective FDA-controlled trial is in progress.

The Flexicore disc. The Flexicore disc (Stryker Corp, Kalamazoo, Michigan) is a metal-on-metal, captured ball-and-socket device. The endplates are dome-shaped and thus adapt to the concavity of the vertebral endplates. The sur-

Table II. Inclusion and exclusion criteria currently (2004) accepted for total lumbar disc replacement

Inclusion criteria	Exclusion criteria
Discogenic low back pain with single level DDD (L4/5 or L5-S1), proven by MRI or CT and/or discography	Deformities
Age: 18 to 60 yrs	Tumours
Minimum six months of unsuccessful conservative therapy	Infection
Back pain greater than leg pain (no signs of nerve root compression)	Post-traumatic segments
Referring to outcome measurements, the majority of the studies require a pre-operative Oswestry score ⁶⁴ of > 40% and a VAS value of > 40 mm	Post-operative segment(s) excluding post-discectomy
	Metabolic bone diseases (osteoporosis, osteopenia)
	Metal allergy
	Pregnancy
	Autoimmune disorders
	Morbid obesity (BMI > 40)

Table III. Associated pathologies without general acceptance for total lumbar disc replacement

Endplate irregularities
Spinal stenosis
Extruded disc herniations
Facet joint osteoarthritis
Translational instability (antero- and retro-listhesis)
Mild deformities (e.g. segmental tilt without rotation)
Bi- and multi-segmental pathology

face of the endplates is titanium plasma-sprayed to promote bone ingrowth. The endplates are linked by the ball-and-socket-joint. Because of the anatomically-shaped endplates, implantation is possible through either an anterior or anterolateral approach. The device is implanted as a single unit. There are no clinical data available at the present time but a randomised FDA-controlled investigation device exemption study has been started.⁶³

Mobidisc. The Mobidisc (LDR Médical; Troyes, France) consists of three pieces. Two flat metal endplates each with a porous-coated surface and a keel to provide stability. The polyethylene inlay contains a radiological marker and is inserted in the lower endplate. It is capable of a limited horizontal slide during movements of the segment, adapting to the instantaneous centre of rotation and mimicking the physiological movements of the nucleus. No clinical data are available at present.

There are many other patented devices for TDR³⁸ but regulatory and approval processes usually take four to five years from manufacture to approval for worldwide use. The five implants mentioned above will probably be the devices to provide outcome evidence in the foreseeable future.

Indications for TDR. There is no consensus on the spectrum of indications for TDR but some agreement exists about 'good' indications. For example there are the inclusion criteria of the FDA-controlled, randomised trials which only allow small differences in the study design between the different implants. The currently accepted inclusion and exclusion criteria are listed in Table II.

There is as yet no consensus as to whether patients with associated pathologies listed in Table III, can or should be

candidates for TDR. There are several papers describing reasonable success rates in patients with these associated pathologies but no controlled clinical studies.^{41,42,44,59}

Diagnostic tools. There is general consensus that plain radiographs, including flexion and extension views, and MRIs are necessary to prove the discogenic pathomorphology. Other semi-invasive diagnostic tests including discography are being evaluated, and, although they probably do not have predictive value for the result of surgery, facet blocks, sacroiliac joint-blocks or nerve root blocks might help to exclude non-discogenic sources of pain.⁷²⁻⁷⁸

The role of discography in identifying discogenic pain is contradictory. Whereas the specificity and sensitivity to diagnose disc degeneration is high,⁷⁹⁻⁸¹ it is low in identifying the site of pain.⁸²⁻⁸⁴ High rates of false positive results,^{83,85} failure of the patient to distinguish concordant from non-concordant pain,⁸² 100% 'memory pain' response in patients with abnormal psychometric testing,⁸² an infection rate of 0.5%^{82,86} and a lack of a predictive value in spinal fusion studies,^{26,87} question the value of this method. Even if discography is used as one of several pre-operative tests to select patients for TDR, the surgeon should be aware that a positive or negative discogram might not be predictive for the clinical outcome.

Detailed information about the individual topography of retroperitoneal blood vessels may be helpful for planning surgical access. It can be obtained by a three-dimensional, colour-coded CT angiogram (Fig. 4).

Facts and unanswered questions

Implant materials. The endplates of all implants described are made of ferromagnetic metals. Three of the five implants have metal-on-polyethylene interfaces (SB Charité, Prodisc L, Mobidisc prostheses). This raises the question of creep, cold flow and wear debris over time. Since polyethylene wear debris and the biological reactions to it, are known to cause osteolysis and aseptic loosening in both total hip and knee replacements, there is a concern that this might be a problem in the spine.⁸⁸⁻⁹⁰ There are *in vitro* data available from the SB Charité and the Prodisc L implants. Biomechanical testings of the SB Charité disc suggest that the creep rates were low *in vitro* and that under normal *in vivo* conditions, a permanent deformation of the

Fig. 4

Three-dimensional CT colour-coded angiogram showing localisation and topography of prevertebral arteries and veins in relation to the lumbar spine.

polyethylene core should not be expected.⁴³ After 10 million loading cycles the polyethylene wear was mild and the volume of polyethylene particles was negligible.^{43,91} However, Ross, Asker and Hughes⁹² described two cases of loss of disc height without signs of subsidence which they interpreted as creep of the polyethylene inlay after a mean follow-up of 9.7 years.

For the metal-on-metal Maverick disc, wear tests were performed with 10 million loading cycles (corresponding with clinical function for more than 30 years).⁴² It could be shown, that under comparable conditions, the metal wear debris was between 7.6% and 8.9% of what has been measured for metal-on-metal hips.^{42,90,93,94} Moreover, the amount of metal wear debris is 10% of the toxic threshold on cells.^{42,95}

In case series with longer follow-ups, aseptic loosening does not seem to be a significant problem,^{59-61,63,89,91} although one case was described in a series of post-operative complications.⁵³ There are no long-term results of metal-on-metal implants.

Implant design. The endplate surface of the SB Charité, Prodisc L, Maverick and Mobidisc are more or less flat. The

Flexicore disc has a convex surface which corresponds with the often concave form of the lower endplates. All endplates have more or less porous-coated surfaces to promote bony ingrowth. The SB Charité offers in addition a coating with calcium phosphate; the Maverick uses an hydroxyapatite coating. Primary stability is achieved by spikes and fins. The Flexicore and the Charité discs are implanted after predistracted of the disc space and anchored with the spikes on the endplate surfaces. The implantation direction may deviate from the midline but fine-correction of the implant position can be performed within the disc space. The 'fin-type' implants (Prodisc L, Maverick, Mobidisc) however must be inserted through a midline approach. This requires an exposure of the anterior disc circumference over a minimum of 4 cm which can be difficult at L4/5 and higher levels. It also requires a chiselled groove into the adjacent vertebral bodies. In the Maverick disc, the fin has a considerable height, so that bisegmental implantations could lead to a significant weakening or fracture of the vertebral body. Moreover, implantation of the 'fin-type' implants requires more x-ray exposure to control the technique. There is no possibility of minor corrections once the implant is in place.

Biomechanics. There is ongoing discussion about the advisability of a constrained or unconstrained design of total disc implants, as well as about a fixed or a mobile instantaneous axis of rotation.^{57,58,96,97} In a normal segment, the axis of rotation changes during motion. Semi-constrained disc implants such as Prodisc L, Maverick or Flexicore have a fixed centre of rotation. Although they are unconstrained for rotational movements, they only allow a guided range of motion around this fixed instantaneous axis of rotation. The kinematics of such discs are sensitive to the surgeon's placement of the disc and to the implant design (radius and position of the ball). Even slight malpositioning, too far anteriorly or posteriorly to the normal axis of rotation can result in a decreased range of movement or overloading of the posterior elements.^{98,99} Unconstrained implants such as the SB Charité and the Mobidisc seem to be more forgiving and can compensate for small errors in placement.⁶⁷ They also seem to allow a greater range of movement.^{59,61,63,99} The effect of a fixed or mobile axis of rotation and of translation of the implant, of the shear forces and load across the facet joints on the outcome, is not clear and should be evaluated in controlled clinical trials.⁹⁹⁻¹⁰⁴ In this respect, the role of an increased rotational instability due to a subtotal resection of the annulus fibrosus during the operation, is also not clear.^{105,106}

Every total disc implant is a simplification of the normal anatomy of the lumbar disc. The main goal is to preserve movement. Shock absorbing properties of the intervertebral disc do not play an important role.¹⁰⁷ However, the necessity of such properties has been mentioned by several authors.^{41,59,98,108} In *in vitro* tests comparing two different implants (metal-on-metal *vs* metal-on PE) Le Huec et al¹⁰⁹ demonstrated that these prostheses did not show effective

Fig. 5a

Fig. 5b

Radiographs showing pre- and post-operative loss of lordosis in the segments above L5-S1 after total disc replacement with 11° lordosis at L5-S1.

shock absorbing properties. They observed no difference between the behaviour of the metal-on-metal and the metal-on-polyethylene implants.¹⁰⁹

Post-operative imaging. Due to metallic artefacts, the use of post-operative MRI scans to evaluate the operated level is problematic. On the other hand, there are no data available from the manufacturers as to whether a post-operative MRI of the treated segment might cause adverse effects from heating or vibration of the components of the implant. It must be considered as a disadvantage of all total lumbar disc implants, that for post-operative evaluation of the implanted segment and its surroundings, the surgeon has to rely on second-choice diagnostic tools, such as CT or myelography. Three-dimensional, CT images can be a future option at least to evaluate the position of the implant.

Sagittal balance. To protect the adjacent segment from accelerated degeneration is another argument in favour of TDR.⁴² Preservation of movement, restoration of disc height and segmental lordosis are considered to be determinant factors. Hyperlordosis as well as hypolordosis have been identified as a cause of low back pain.¹¹⁰⁻¹¹³ Following spinal fusion, a loss of segmental lordosis can accelerate the degeneration of adjacent segments.^{24,114-118} In a recent study, Cakir et al¹¹⁹ demonstrated significant increases of segmental lordosis angles with only minor changes in the total lordosis. They concluded that the lumbar spine com-

pensates for segmental hyperlordosis with a hypolordosis in the adjacent segments.¹¹⁹ The increase of segmental lordosis after TDR leads to a decrease in lordosis of the adjacent segments as well as to changes in the pelvic parameters (sacral slope, pelvic incidence, pelvic tilt) (Fig. 5a). A lumbar flat back can be the consequence (Fig. 5b). These findings emphasise that the potential benefits of TDR are only valid if a pre-operatively balanced spine is not forced to compensate for a disc replacement-induced disturbance of sagittal balance.

Heterotopic ossification and spontaneous fusion following TDR. Heterotopic bone formation following total hip replacement is a well-known complication. Its incidence is reported to be between 2% and 53%.¹²⁰⁻¹²² It can significantly alter the range of movement of the hip. The paramount goal of TDR is to preserve movement over a substantial post-operative period. Heterotopic ossification, even spontaneous fusion, would question this concept. There are a few case reports published which describe spontaneous fusion following lumbar disc replacement^{53,121} (Fig. 6), but Putzier et al¹²³ reported a spontaneous fusion rate of more than 60% in a 17-year follow-up series of patients with a SB Charité total disc. The rate of heterotopic ossification ranges between 1.4% and 15.2% for the Prodisc and SB Charité disc.^{59,61,65,121,124} McAfee et al¹²¹ have recently proposed a classification system for heterotopic ossification.

Fig. 6

Radiograph showing spontaneous fusion following total disc replacement with SB Charité disc (first generation) 18 years post-operatively.

Operative access. TDR can be performed through a limited operative exposure.^{25,53} Retroperitoneal anterior approaches are used as standard access. Whereas the access to L5-S1 is relatively straightforward, the midline access to L4/5 and to higher levels requires a significant mobilisation of the major retroperitoneal blood vessels.¹²⁵ Vascular complications including arterial and venous injury or thrombosis, have been reported in 2.8% of patients operated upon by experienced surgeons.¹²⁵ Cadaver training is obligatory for spinal surgeons without experience in limited access anterior approaches. Because of regional and national differences in surgical education and interdisciplinary co-operation, personal responsibility of the spinal surgeon for individual risk management is required. Lack of experience and medicolegal considerations can make co-operation between the spinal surgeon and a vascular or abdominal surgeon, mandatory.

Outlook. The future looks bright for the manufacturers and the protagonists of total lumbar disc replacement. In 1992 Ray⁴⁰ stated that probably 50% or more patients suffering from low back pain might be candidates for TDR and that the market potential may reach \$500 million per year. These optimistic data are supported by the fact that within

the last two years the five market-leading manufacturers have together spent more than \$1.5 billion to acquire non-fusion technology companies.

In the next few years, spinal surgeons will face a massive pressure from the industry, as well as from patients to adopt disc replacement technology. The lack of evidence-based data and the rapidly accumulating experience-based data, challenge the responsibility of the spinal surgeon, as well as scientific and professional spinal organisations, to initiate studies, encourage scientific work and to control clinical outcomes. TDR has opened a new era in spinal surgery, which has to stand the test of time.

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