Total disc replacement

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ABSTRACT

Total disc replacement (TDR) (partial disc replacement will not be described) has been used in the lumbar spine since the 1980s, and more recently in the cervical spine. Although the biomechanical concepts are the same and both are inserted through an anterior approach, lumbar TDR is conventionally indicated for chronic low back pain, whereas cervical TDR is used for soft discal hernia resulting in cervicobrachial neuralgia. The insertion technique must be rigorous, with precise centering in the disc space, taking account of vascular anatomy, which is more complex in the lumbar region, particularly proximally to L5–S1. All of the numerous studies, including prospective randomized comparative trials, have demonstrated non-inferiority to fusion, or even short-term superiority regarding speed of improvement. The main implant-related complication is bridging heterotopic ossification with resulting loss of range of motion and increased rates of adjacent segment degeneration, although with an incidence lower than after arthrodesis. A sufficiently long follow-up, which has not yet been reached, will be necessary to establish definitively an advantage for TDR, particularly in the cervical spine.

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The present article is restricted to total disc replacement (TDR) after complete intervertebral disc ablation at cervical (CTDR) or lumbar (LTDR) level. This involves mechanical prostheses for which we now have a certain follow-up, especially as regards LTDR, which has been regularly implemented since the 1980s. We shall not deal with nucleus replacement, which is less widely practiced and has a very limited literature.

The biomechanics of CTDR and LTDR is the same, but the indications differ. CTDR may be indicated after ablation of a hernia causing cervicobrachial neuralgia (CBN), while LTDR is indicated after ablation of a degenerative disc implicated in chronic low back pain.

Both procedures use an anterior approach, although the technical problems are specific, as the vascular obstacles to lumbar disc access, especially above L5–S1, have no equivalent at the cervical level.

Theoretically, the interest of TDR lies in implanting a mobile and, if possible, shock-absorbing component with sufficient height to replace the disc that has either been crossed so as to remove the cervical compressive disc hernia or totally removed in order to treat lumbar pain. The alternative, and inevitable comparator, is arthrodesis. The advantage of TDR is not immediately obvious, as CBN and low back pain are alleviated by both procedures if the indications were correct: the expected benefit of implantation is more long-term, with a lower rate of degeneration of adjacent segments, which cannot be properly assessed on less than 10 or even 15 years' follow-up.

As detailed below, most studies comparing arthrodesis and TDR demonstrated the non-inferiority of the latter in terms of immediate results; lack of sufficient follow-up, however, means that any long-term advantage remains to be proven.

1. History

1.1. LTDR

Historically, LTDR preceded CTDR.

The first LTDR, which had the form of a steel ball, was implanted by Fernstrom, using an anterior approach, in 1960. Initial results seemed encouraging, but proved disappointing in the long-term as the ball subsided into the subchondral bone.

In the early 1980s, Schellnack and Buttner implanted the SB Charité® prosthesis, which comprised two chromium-cobalt plates and a mobile polyethylene core. In France, David and Lemaire regularly used the three successive models [1–3] of this prosthesis.

In 1989, Marnay described the ProDisc-L®, which has plates with a central titanium stem.

Since then, many different LTDR designs have come onto the market (Fig. 1).

1.2. CTDR

In 1962, Fernstrom encountered the same problems in CTDR as in LTDR with his prosthesis.
The Prestige® prosthesis was not developed until 1989–1991. It was a metal-metal design, screwed into the vertebral bodies with a stabilization crest.

Only in 1995 did Bryan begin to use the CTDR named for him on a regular basis.

In Europe, the first implantation in 2000 was followed by numerous multicenter studies, mainly under the supervision of Goffin and Pointillart.

A large range of CTDR designs have subsequently been marketed (Fig. 2).

2. Biomechanics

TDRs are made up of bearing surfaces designed to accommodate load without breaking, to reduce friction and wear and to conserve range of motion as long as possible.

Assessment is in terms of wear and motion tests under varying loads and movements. Implementation of 30 to 50 million cycles is taken as equivalent to a lifetime of 30 to 50 years.

The materials used are the following:

- metals and alloys such as:
  - stainless steel alloys,
  - titanium and titanium alloys,
  - cobalt alloys;
- ceramics, more resistant to wear but more fragile due to their low ductility;
- high molecular weight polyethylene, such as UHMWPE (ultra-high molecular weight polyethylene), for the nucleus between the metal plates.

TDR models are classified by anchorage, surface and friction couple, constrained or unconstrained design, location of the center of movement and, finally, compatibility with MRI.

Anchorage (or contact between the implant and the vertebral plates (Fig. 2)) may be stem, screw or macro-texture. The surface coating facilitates osseointegration; it may be in hydroxyapatite, tricalcium phosphate, porous titanium or chromium-cobalt.

Constrained TDRs require stronger anchorage, as greater forces are transmitted to the vertebral plates. The plates of the Bryan CTDR are therefore highly mobile to protect them against the risks of mechanical stress.

2.1. Friction couples

The 4 types of friction couple are:

- metal/polyethylene;
- metal/metal;
- ceramic/polyethylene;
- ceramic/ceramic.

Metal/polyethylene is the oldest friction bearing used in arthroplasty, notably of the hip, and is a reference; the polyethylene debris particles generated are large sized.

Metal/metal and, even more so, ceramic/ceramic couples generate very little and smaller sized debris, thus reducing the risk of inflammation.

2.1.2. Constrained or non-constrained design

A normal disc has 6 degrees of freedom (df): 3 in translation and 3 in rotation. Three types of TDR can thus be distinguished:
3. Indications

Unlike hip implants, CTDRs and LTDRs may be indicated in young subjects, with a variety of clinical signs.

LTDRs are usually indicated for disabling low back pain; selection should be rigorous, as results in low back pain surgery are generally less than excellent.

CTDRs are associated to decompression surgery, usually for CBN or occasionally for incipient myelopathy.

Both cervical and lumbar procedures may be hybrid, associating TDR and fusion of adjacent levels, with the implant usually above the arthrodesis.

3.1. Lumbar indications

The essential indication for LTDR is chronic low back pain resistant to conservative management, with little or no associated radiculalgia.

Clinical assessment must be precise, comprising:

- VAS (visual analog scale) lumbar and radicular assessment;
- Oswestry score for lumbar radicular pathology and especially the Quebec score, for optimal assessment of the functional impairment induced by the low back pain;
- SF12 score to assess perceived physical and psychological health, associated, in some cases, to more strictly psychological scales such as the Hospital Anxiety and Depression scale (HAD), assessing emotional impact, or the Coping Strategy Questionnaire (CSQ), assessing coping as defense strategy.

Mannion et Elfering [1] reported the following factors of poor prognosis: prolonged symptom evolution, severity of the pathology being treated, poor health status and comorbidity, anxiety and depression, “familial reinforcement” of pain, smoking, occupational dissatisfaction, and prolonged sick leave and sickness benefit.

There are few physical signs specific to low back pain of discal origin that can be taken as indications for LTDR. Roughly, lumbar disc pain, increasing under flexion, may be contrasted with posterior joint pain, increasing in extension.

Paraclinically, plain and especially EOS whole-spine radiographs determine overall sagittal balance.

Standardized dynamic radiographs may reveal very exceptional hypermobility. CT is best suited to the posterior joints, which should be as normal as possible. In MRI, MC (modic change) 1 (inflammation) or mixed one-half MC enhanced on fat-sat sequences are major indications, validated by Blondel et al. [2] (Figs. 4–6). MRI also assesses the degree of fatty degeneration in the paravertebral muscles.

Vascular exploration on MRI or CT angiography is recommended, to locate the large vessels (Fig. 7). Discography by pain reproduction may help in case of discordant imaging findings, and is increasingly discussed in the literature.

Previous discal surgery is, surprisingly, a frequent indication in case of postoperative MC-1. Any malalignment such as scoliosis...
Fig. 3. Ceramic/ceramic TDR: non-artifacted control MRI.

Fig. 4. Indication for LTDR for inflammatory L5–S1 discopathy.
or spondylolisthesis and proven osteoporosis, on the other hand, contra-indicates LTDR.

3.2. Cervical indications

CTDR is mainly indicated for:

- soft hernia inducing CBN resistant to 6 weeks’ classical medical treatment or causing radicular motor deficit;
- stenosing soft hernia inducing myelopathy.

The patient is assessed by cervical VAS and especially upper-limb VAS, NDI (Neck Disability Index) and possibly a cervical myelopathy score such as the EMS (European Myelopathy Score). Soft hernia surgery may consist in simple discectomy, inducing kyphosis, or in arthrodesis, which was long the gold standard but involves risk of non-union and adjacent level syndrome (Fig. 8).

Osteophytic hard discal hernia is a more debatable indication, as the intervertebral segment is less mobile. CTDR is considered indicated in case of <4° range of motion in flexion-extension on preoperative dynamic X-ray. Broad uncal release may, however, be performed to restore range of motion after implantation in the stiffer segments.

Myelopathy caused by cervical osteoarthritis with local compression is an even more debatable indication: CTDR would enhance range of motion, but motion caused the circumferential stenosis compressing the spinal cord. Sekhon [3] reported 11 cases of CTDR for myelopathy, with good clinical results in all but 1 case where there was kyphosis after Bryan CTDR. These positive findings suggest that the risk of post-surgical soft tissue hypertrophy is low if all the compressive tissue is removed, and the implant prevents discal subsidence aggravating the medullary compression.

Contra-indications to CTDR are previous anterior cervical surgery, posterior joint osteoarthritis (which is always difficult to
assess, although CT is more effective than MRI, longitudinal dorsal ligament ossification, hyperostosis, myelopathy due to retrocorporal compression, traumatic discal and ligamentary instability, osteoporosis and infectious or neoplastic pathology.

4. Surgical techniques

LTDR and CTDR both use an anterior approach, but with differing techniques.

Cervicotomy is performed for any anterior cervical discal procedure, inclining the trachea-bronchial axis sideward.

In LTDR, the approach is complicated by the relations of the aorta and the vena cava and its bifurcation branches, especially at L4–L5 and L3–L4.

4.1. LTDR

The patient is usually positioned with the legs apart (“French position”), with a bladder catheter (Fig. 9).

The disc in question is located under AP and lateral radiography. An oximeter on the left hallux monitors blood pressure.
The surgical field is wide, from the xyphoid region to the pubis, with the iliac crests visible.

The approach is retroperitoneal, with a lower risk to the superior hypogastric plexus and thus of retrograde ejaculation in men or vaginal dryness in women than on a transperitoneal approach (0.8% versus 10%) (Fig. 10).

In L5–S1, the median sacral vessels should be controlled and the disc freed with a width of 4 cm, taking care on the side of the left iliac vein.

In L4–L5, the aorta and vena cava are inclined from right to left after, if necessary, ligating any ascending lumbar or iliolumbar vein (Fig. 11).

The disc is ablated completely up to the dorsal longitudinal ligament, which according to some authors should also be systematically resected, which incurs a risk of epidural bleeding. Stem or macro-texture anchorage is performed after thorough freshening of the vertebral plates, without going beyond the subchondral bone. Centering may be navigation-assisted (Le Huec [4]), and should be very strict, both frontally and sagittally, as it determines mechanical functioning.

LTDR height averages 11–13 mm, obviously varying with level and with the size of the patients (Fig. 12).

Some authors, such as Marnay, recommend oblique prostheses in L4–L5, to avoid undue vessel traction.

Vessel exposure can be complicated, with risk of vascular wounding, and the orthopedic surgeon needs to have skilled backup in vascular surgery (“access surgeon”) available, following the very clear recommendations of Brau et al. [5], especially in revision procedures.

A lateral transpoas approach avoids the need for vessel dissection, but has not been validated.

4.2. CTDR

The CTDR technique is much the same as for implanting an intersomatic cage, as is also the case for LTDR.

Preoperative planning should take account of the dimensions of the intervertebral disc and vertebral bodies, using tracing, as in the Bryan technique.

The patient is positioned in dorsal decubitus, slightly forward to reduce epidural bleeding, under fluoroscopy throughout (Fig. 13). It is essential to locate the level to be operated on; cervicotomy may be horizontal for 1-level CTDR or vertical for 2 or more levels (Fig. 10).

The two longus colli muscles are carefully pulled aside and disectomy is almost always completed by sectioning the dorsal longitudinal ligament, soft hernia very frequently being intraligamentary.

The intersomatic distractor, with its tips planted in the adjacent bodies, reveals the posterior part of the discal space. The tips are placed precisely in the middle of the vertebral bodies by ancillaries which locate the center of the disc by contacting the two unci (Fig. 14). This technique provides better centering than frontal fluoroscopy [6].

For soft hernia, resection uses disc forceps or, for hard hernia, a high speed burr and a rongeur. The transverse and anteroposterior dimensions are measured using a trial component.

The height of the CTDR is that of the neighboring discs in the case of soft hernia. If all the discs are damaged, the implant is placed not too high, to avoid postoperative neck pain by tension to the posterior joints, and not too low, to conserve range of motion and avoid the risk of early postoperative heterotopic ossification. Mean CTDR height is 5 mm.

Postoperative course is simple in both cases:

- after LTDR, the patient can leave bed the following day with a simple lumbar belt;
- after CTDR, no cervical collar is needed.

5. Results

Assessment is founded:

- clinically, on the evolution of CBN and neck pain or of low back pain;
- radiologically, on range of motion and sagittal balance.

Follow-up for assessment is:
5.1. LTDR results

In the short-term (2 years’ follow-up), Hellum et al. [7] reported better results in 154 LTDR recipients when the back pain had been of short evolution and the patients presented MC-1 or 2. Blondel et al. [2] reported better results in case of MC-1.

Over the medium-term (8.6 years’ follow-up), Huang et al. [8] reported better results when the implant remained mobile, whereas Ross et al. [9], at 78 months’ follow-up, found only a 14% improvement in Oswestry score and decided to abandon LTDR.

Over the long-term, Lemaire [10] reported 100 LTDRs at a mean 11.3 years’ follow-up, with only 10% bad clinical results (i.e., condition worsened). David [11], reporting 106 LTDRs at 13 years’ follow-up, found only 10% of implants that had ceased to show motion.

Finally, the results of these retrospective series, which are always open to criticism, appear to be discordant.

In the USA, there have been numerous prospective randomized studies comparing LTDR and fusion.

The SB Charité® LTDR was compared to anterior arthrodesis by Blumenthal et al. [12] and by MacAfee et al. [13]. Their clinical success criterion was ≥ 25% improvement in Oswestry score, found in 75% of LTDRs versus 57% of arthrodeses. The radiological success criterion was conserved range of motion, found in two-thirds of LTDRs at 2 years’ follow-up. The authors thus concluded that LTDR was not inferior to anterior arthrodesis.

Another series of randomized studies compared the ProDisc® to circumferential arthrodesis, with Ziegler et al. [14] treating 1-level and Delamarter et al. [15] 2 levels. Their clinical success criterion was 15% improvement in Oswestry score, found in 63% of LTDRs versus 45% of arthrodeses. The radiological success criterion was conserved implant motion, found in 94% of LTDRs at 2 years’ follow-up.

These randomized studies found little difference in terms of clinical results or complications between LTDR and arthrodesis.

A large number of publications have reported series, often designer series; the most interesting results come from randomized comparative studies, required in the USA for FDA marketing approval.

One issue in the comparative studies is the type of arthrodesis compared with TDR. In CTDR, it was mainly allograft associated to a screwed plate, which in Europe is not the gold standard for arthrodesis. In LTDR, arthrodesis was either purely anterior or else circumferential.

Finally, in both CTDR and LTDR, multilevel procedures gave better results and, above all, fewer cases of adjacent level syndrome; this is understandable, as adjacent levels liable to become symptomatic over time were replaced.

TDR range of motion diminished progressively over time, like a normal disc that stiffens with age.

Sagittal balance was slightly affected by TDR, which improved discal lordosis, whereas underlying discs lost lordosis.
(especially in case of anterior arthrodesis using bone morpho-
genetic protein, avoiding the harmful effects of graft harvesting). Follow-up, however was too short for assessment of possible impact on adjacent levels.

5.2. CTDR results

In the USA, numerous randomized studies have compared clinical efficacy in CTDR and anterior arthrodesis by allograft and screwed plate (Murray et al. [16], McAfee et al. [17]). At a mean 2 years’ follow-up, there was no difference in clinical results.

In Beaurain’s multicenter retrospective study [18] of the MOBI- C® implant, the VAS neck pain score fell from 46 preoperatively to 21 postoperatively, upper-limb VAS score from 64 to 23, and NDI score from 50% to 26%. 91% of the patients would agree to re-operation.

Recently, Grob et al. [19] stressed the difficulty of interpreting the results of randomized studies comparing implantation and fusion: the better results associated with the former may be due to more rigorous patient selection.
6. Complications

The most frequent complications are: adjacent segment degeneration (expected to be less than with arthrodesis) and heterotopic ossifications, reducing the implant’s range of motion in CTDR.

Complications related to the surgical approach, prosthesis subsidence into the plates (axial migration) or very occasional anteroposterior migration are less specific to CTDR.

Anteroposterior migration, by displacement of plates or nucleus, is exceptional but may have severe consequences: backward neurological compression (Fig. 15), forward oesophageal compression in CTDR, and forward vascular compression in LTDR (Figs. 16 and 17). Anterior revision surgery is complicated, especially in the lumbar region [5].

6.1. Axial subsidence of the implant into the plates, and kyphosis

In LTDR, subsidence is due to osteoporosis, and significantly impairs implant functioning (Fig. 18). In CTDR, there is a risk of kyphosis, notably with the Bryan model, due either to poor indication (excessive anterior disc narrowing) or to defective technique.

Metal ion release with inflammatory reaction was reported by Cavanaugh et al. [20], who discovered fibrous and inflammatory tissue following ProDisc-C® CTDR.

Fig. 13. Patient positioning for CTDR (horizontal incision after location of sternocleidomastoid, with fluoroscope).

Fig. 14. Transverse CTDR centering (a: AP view; b, c, d: superior views of 3 different ancillaries).
Anterior, posterior or circumferential heterotopic ossification (Figs. 19 and 20) induces fusion that is more rapid than the natural evolution. MacAfee et al. [21] provided a classification for the lumbar and Mehren et al. [22] for the cervical region.

Mehren et al. reported 42% class-11 heterotopic ossification (complete bone bridges but conserved motion) and 8% class IV (complete fusion, not systematically associated with poor results).

Goffin et al. [23] reported 12% fusion at 4 years after Bryan TDR. Quang and Pointillart [24], reporting a series of Bryan TDR at 8 years' follow-up, found 48% heterotopic ossification, with only 9 of the 27 patients (one-third) having a completely immobile CTDR. It is to be borne in mind that secondary fusion with kyphosis is associated with more severe risk of adjacent syndrome than is arthrodesis.

Prevention of heterotopic ossification is founded on:

- indication of soft hernia, with sufficient preoperative motion on a disc showing little degeneration;
- minimal longus colli dissection, with painstaking wax hemostasis of the bone;
- using an implant of sufficient but not excessive height, so as not to block the posterior joint system;
- iterative lavage with physiological saline, to eliminate bone powder caused by decompression using a high speed burr;
- for some authors, 2–3 weeks' postoperative anti-inflammatory drugs, as in hip replacement.

Chen et al. [25], in a recent meta-analysis, found ossification in 44.6% of cases at 1 year and in 58.2% at 2 years, without correlation with functional results or any clear effect of anti-inflammatory medication.

6.2. Impact on adjacent segments (adjacent syndrome)

The reduced rate of adjacent syndrome is the real theoretic advantage of TDR over fusion.

As in all spinal surgery, the distinction must be made between:

- radiologic adjacent syndrome (40–90%), with a frequency increasing over follow-up, approximating natural evolution; this
Fig. 17. Expulsion of L5–S1LTDR nucleus.

Fig. 18. Axial subsidence: a: of inferior plate of L3L4 LTDR; b: of superior plate of L5–S1 LTDR; c: of superior plate of L3L4 LTDR.

may consist of osteophytes, ante- or retro-listhesis or excessive motion on dynamic X-ray;
• clinical adjacent syndrome (20–30%), with spinal and/or radicular pain associated with one of the above images;
• surgical adjacent syndrome (5–15%), requiring revision in view of clinical severity.

Many retrospective studies reported rates of clinical and above all surgical adjacent syndrome that were lower (although non-zero) with TDR (Jawahar et al. [26]).

Roberston et al. [27], comparing 158 arthrodeses and 74 CTDRs, found 17.5% and 3.4% rates of adjacent syndrome, respectively.

Ahn et al. [28], comparing 18 ProDisc-C® implants and 20 cages, found impaired motion in the discs above and under the implant at 1 month post-surgery, followed by recovery of preoperative range of motion and increased previous and late range of motion of segments adjacent to cages, without difference between upper and lower discs. According to him, TDR provides more lordosis than cages.

In 2008, Harrop et al. [29] reported reduced incidence of adjacent syndrome with LTDR.

7. Costs and reimbursement

In a randomized study at 2 years’ follow-up, Fritzell [30] compared 3 types of LTDR versus posterior arthrodesis. Clinical results and costs were identical, but revision was more frequent with arthrodesis.

Following a decree dated December 2, 2001, the French governmental Journal Officiel included the Mobidisc®, Maverick® and
ProDisc-L® implants in the list of products and procedures reimbursed under the national health insurance scheme.

Regulations have been drawn up for them to be implanted in centers having expertise in spine pathology, with indications formulated by a multidisciplinary team meeting; Indication is for a single level and requires presence of a vascular surgeon in the center. The procedure is coded as LFKA900.

A French national registry of LTDR is intended to be the basis of a prospective multicenter observational study including 600 patients with 5 years' follow-up, assessing
revision rates and satisfaction. Nothing is as yet planned for CTDR.

8. Conclusion

TDR has demonstrated non-inferiority to fusion. Indications for LTR have diminished, as results are uncertain in low back pain surgery, except for very specific indications such as inflammatory lower lumbar single-discopathy.

CTDR is a reasonable option in cervical disc hernia with compression of a root or of the spinal cord in young patients.

The required preoperative range of motion of the operated intervertebral segment is conserved postoperatively, with clinical results identical to those of intersomatic arthrodesis. Implantation technique must be perfect, especially in terms of centering.

All comparative studies between TDR and arthrodesis, on the other hand, have demonstrated reduced involvement of adjacent segments with implantation.

The present limitation is lack of follow-up, currently less than the 10 to 15 years needed to confirm definitively the advantage of TDR over arthrodesis.

Disclosure of interest

LDR laboratory designer.

References