Eur Spine J (2003) 12 : 108–116
DOI 10.1007/s00586-002-0500-0

REVIEW

M. de Kleuver
F. C. Oner
W. C. H. Jacobs

Total disc replacement for chronic low back pain: background and a systematic review of the literature

Received: 10 April 2002
Revised: 29 August 2002
Accepted: 6 September 2002
Published online: 7 December 2002

M. de Kleuver (✉)
Department of Orthopedic Surgery,
Sint Maartenskliniek, Hengstdal 3,
6522 JV Nijmegen, The Netherlands
e-mail: m.dekleuver@maartenskliniek.nl,
Tel.: +31-24-3659300,
Fax: +31-24-3659317

F.C. Oner
Department of Orthopedic Surgery,
University Medical Centre,
Utrecht, The Netherlands

W.C.H. Jacobs
Orthopedic Research Department,
Sint Maartenskliniek,
Nijmegen, The Netherlands

Abstract In this paper the rationale for total disc replacement is discussed, and the authors suggest seven requirements that should be met before the implantation of these devices can be accepted as regular procedures. In an attempt to answer the questions raised, a systematic literature search was performed. The search yielded no controlled trials and nine case series with a total of 564 arthroplasties in 411 patients. The devices used were SB Charité in eight and Acroflex in one study. The percentage results classified as "good" or "excellent" in the studies varied from 50 to 81%. Complications were observed in 3–50% of the patients. Twenty-two of the operated levels were fused either spontaneously or after additional surgery. A meta-analysis to compare the results with other treatments could not be performed due to the lack of comparative studies. Despite the fact that these devices have been implanted for almost 15 years, on the basis of this literature survey there are currently insufficient data to assess the performance of total disc replacement adequately. There is no evidence that disc replacement reliably, reproducibly, and over longer periods of time fulfils the three primary aims of clinical efficacy, continued motion, and few adjacent segment degenerative problems. Total disc replacement seems to be associated with a high rate of re-operations, and the potential problems that may occur with longer follow-up have not been addressed. Therefore, total disc replacements should be considered experimental procedures and should only be used in strict clinical trials.

Keywords Lumbar vertebrae · Intervertebral disc · Prostheses and implants · Treatment outcome · Literature review

Introduction

In a search for a better operative treatment of chronic low back pain, total disc replacement has received increasing attention over the last years. There has been an increasing mention of these procedures, especially at conferences and in the non-peer-reviewed publications. In this paper we will try to present the rationale for disc replacement, to perform a systematic review of the literature and, if possible, to draw some conclusions on the current status of these devices.

Rationale for total disc replacement

Chronic low back pain is believed to have a multifactorial origin of somatic pain sources accompanied by psychogenic aspects. The intervertebral disc is frequently incriminated as the most important somatic pain source in the lumbar spine [11, 28, 32], and the facet joints have also frequently been noted as sources of pain [1, 8]. The only available conventional surgical treatment of this process is an arthrodesis of the motion segment. The clinical outcomes of this procedure are variable, leading to continuing controversy about the indications. However, a recent

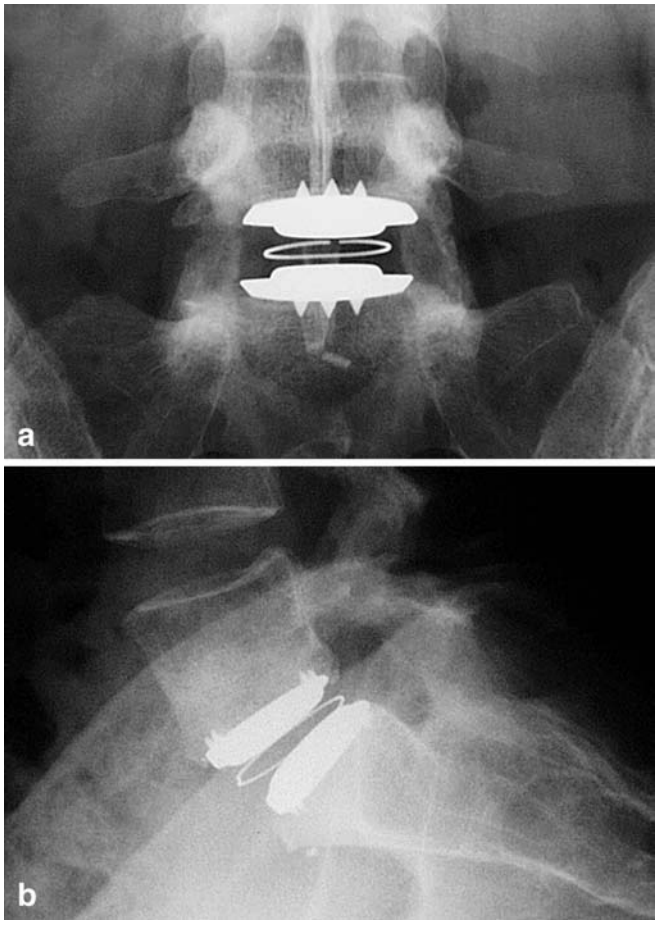

Fig. 1 **A** Antero-posterior and **B** lateral radiograph of an intervertebral disc arthroplasty with a clinically excellent result

prospective randomised trial showed significantly better clinical outcomes of arthrodesis in comparison to non-operative treatment [20]. Furthermore, a large literature survey comprising 5600 patients [4] reported a "satisfactory outcome" in 65–87% of the patients after an arthrodesis, with monosegmental fusions having better results than bi- or tri-segmental fusions. However, as in other fields of orthopaedics, arthrodesis of a joint is generally not considered an optimal solution, due to the increased stresses and subsequent degeneration at the adjacent joints. Development of arthroplasties has obviated the need for an arthrodesis for all major peripheral joints. In the lumbosacral spine, research has also concentrated on development of mobile intervertebral endoprostheses to retain motion and thereby possibly to avoid the disadvantages of an arthrodesis. Arthroplasty of the facet joints is considered technically unfeasible and, to our knowledge, has not yet been described. The efforts have been concentrated on the development of an intervertebral disc replacement. Replacement of disc nucleus has been described, but theoretically this leaves the degenerative and possibly painful annulus intact. Therefore, there has been an increasing interest in total disc replacement in the last two decades. This paper will concentrate on replacement of the disc by an artificial joint. There are currently two devices on the European market, the Link SB (Schelnack and Büttner-Janz) Charité III (Waldemar-Link GmbH, Hamburg, Germany, available since 1987) (Fig. 1), and the Prodisc (Spine Solution Inc, N.Y., USA, since 2000 in its current design).

Both devices are implanted through an anterior approach, at L5-S1 under the bifurcation and at L3-L4 and L4-L5 above the bifurcation by temporary retraction of the large vessels.

Both devices have low-friction sliding surfaces somewhat like a ball and socket joint, consisting of metal endplates with a polyethylene spacer. They are marketed as being developed from the successful total hip and knee arthroplasty materials. The metal endplates are meant to fuse to the vertebral endplates, much as an uncemented acetabular component attaches to the acetabulum in total hip arthroplasty. Supplementary primary fixation is provided on the SB Charité III by six teeth on each endplate, and on the Prodisc by a fin on each endplate, which is sunk into the adjacent vertebral bodies. Mechanically, the two devices differ considerably. The Prodisc has one articulating surface between the polyethylene and the upper plate, and is relatively more constrained by the spherical artificial joint surface. There are three degrees of freedom for rotation around a single fixed point that lies in the underlying vertebra. The SB Charité III has two articulating surfaces, between the polyethylene sliding core and the lower and upper plates, which allows rotation and, in contrast to the Prodisc, also allows some translation.

Replacing a painful intervertebral disc by a disc arthroplasty raises the following questions, which need to be answered before large-scale implementation can be accepted.

1. How do the clinical results compare to arthrodesis, the only surgical "gold standard" available?
2. What are radiologic results in terms of (i) loosening (in total hip arthroplasty radiologic loosening is recognised as a precursor of clinical loosening), (ii) subsidence of the implant into the vertebral bodies, and (iii) polyethylene wear?
3. Does the motion segment retain its mobility? And if it does, do these motions resemble a normal motion segment?
4. Can the arthroplasty reduce the incidence of adjacent segment degeneration compared to arthrodesis? What is the incidence of facet joint degeneration at the operated level?
5. How does the perioperative complication rate compare to fusion operations?
6. Is there an acceptable and safe salvage procedure in case of failure? Can the device, if necessary, be removed without major complications?

7. What could be considered the indication for arthroplasty of a vertebral motion segment?

In an attempt to answer these questions, a systematic literature search was performed. Question 1 was considered primary outcome and the other questions were of secondary interest.

Materials and methods

The methodology used is aimed at facilitating a "best evidence synthesis", because the number of studies on total disc replacement was expected to be limited. This means that the search was aimed at finding not only category 1 evidence [34], but also non-randomised (category 2) and non-experimental studies (category 3), to gather all possible evidence on the performance of this relatively new treatment.

Search strategy

Relevant literature was searched in the most common databases of medical literature:

- The Cochrane database of randomised controlled trials (issue 2001–4)
- Current Contents (1997 to January 2002)
- Medline (Through Pubmed; 1966 to January 2002)
- Cinahl (1982 to December 2001)

Search strings and number of hits are given in Table 1. Search strings were adapted for the different databases. A sensitive search was performed because terminology in the field of disc replacement is not yet standardised. During the search, no restriction was made with regard to language or date. References of selected articles were included in the search. One reviewer performed the search.

Selection

Two independent reviewers selected the articles from the obtained list. Consensus was strived for, but when no consensus could be reached a third reviewer was consulted. Articles were excluded on the basis of title and abstract when it was evident that:

- (One of) the intervention(s) used was not an intervertebral disc prosthesis
- The indication on which patients received this treatment was not degenerative disc disease at a lumbar level
- The outcome parameter was not a clinical measure
- The article had not been published in a peer-reviewed journal

If relevance could not be ascertained on the basis of the abstract, the complete article was retrieved.

Methodological evaluation

The two independent reviewers assessed the methodological quality of the selected articles and again consensus was strived for; but, if necessary, a third reviewer was consulted. Methodological quality was assessed with the aid of a checklist recommended for use in systematic literature reviews by van Tulder [36]. Items of the checklist are given in Table 2. The items are (re-) grouped in the categories: internal validity, external validity, data presentation and statistical analysis. The items are scored with "yes", "no", "unclear", or "not applicable". Because we expected a low number of controlled trials, five more questions were added. One question was added to differentiate between controlled and non-controlled trials, two questions were added to evaluate whether the (sub) groups were homogeneous and two questions were added on the description and validity of statistical analysis. Item C of the van Tulder list (Table 2) was regarded under internal validity rather than under descriptive.

Best evidence synthesis

Evidence on effectiveness of the treatment was first stratified for study type. The hierarchy of studies categorised study types from strong to weak according to Shekelle [34], in the following order: randomised controlled trials (category 1b), other controlled trials (category 2a and 2b), and non-experimental studies (cohort studies, cross-sectional studies; category 3). Within study categories, studies with higher methodological quality as measured with the checklist were regarded as providing stronger evidence. Internal

Table 1 Search strings and number of hits (*mh* mesh heading, *tiab* title/abstract, *PT* publication type)

Search strings	Medline	Current contents	Cochrane	Cinahl
"Lumbar vertebrae"[mh] OR "intervertebral disk"[mh] OR "disc degeneration"[tiab] OR (degenerative[tiab] AND (disk[tiab] OR disc[tiab]))	22.148	882	612	1.188
Artificial[tiab] OR flexible[tiab] OR mobile[tiab] OR kinematic[tiab] OR replacement[tiab] OR "implants, experimental"[mh] OR "prosthesis implantation"[mh] OR "prostheses and implants"[mh]	323.848	113.618	10.183	4.843
"Treatment outcome"[mh] OR "survival"[mh] OR survival[text word] OR clinical OR "reoperation"[mh] OR reoperation[tiab] OR evaluation[tiab]	1.663.532	642.317	262.473	*
Randomized controlled trial[PT] OR controlled clinical trial[PT] OR randomized controlled trial OR "random allocation"[mh] OR "double blind method"[mh] OR "single blind method"[mh] OR clinical trial [PT] OR comparative study[tiab] OR evaluation study[tiab] OR "follow-up studies"[mh] OR follow-up [tiab] OR followup[tiab] OR "prospective studies" [mh] OR case series [tiab] OR "retrospective studies"[mh] OR "cohort studies"[mh]	934.731	*	98.212	*
Combination	378	12	24	16
Total				430

* Not included in the search

Table 2 Criteria list as recommended by van Tulder [36] with added items (*RCT* randomised controlled trial, *CCT* controlled concurrent trial, *CT* controlled trial, *Pcoh* prospective cohort, *CS* cross-sectional study, *Hcoh* historical cohort)

Group	Item	van Tulder item	Criteria
Study type	T1	*	What is the study type (RCT, CCT, CT, Pcoh, CS, Hcoh)?
Internal	I1a	*	Is a control group used? If yes:
	I1b	B1	Was a method of randomisation performed?
	I1c	E	Was the care provider blinded to the intervention?
	I1d	H	Was the patient blinded to the intervention?
	I1e	I	Was the outcome assessor blinded to the intervention?
	I1f	C	Were the groups similar at baseline regarding the most common prognostic indicators?
	I2a	*	Were the groups homogeneous with regard to prognostic variables?
	I2b	*	If not, are there subgroups identifiable which are homogeneous?
	I3	F	Were co-interventions avoided or comparable?
	I4	N	Was the timing of the outcome assessment in all groups comparable?
	I5	L	Was the withdrawal/drop-out rate described and acceptable?
	I6	G	Was the compliance acceptable in all groups?
	I7	P	Did the analysis include an intention to treat analysis?
	I8	J	Were the outcome measures relevant?
External	E1	A	Were the eligibility criteria specified?
	E2	D	Were the index (and control) interventions explicitly specified?
	E3	K	Were adverse effects described?
	E4	M1	Was a short-term follow-up measurement performed?
	E5	M2	Was a long-term follow-up measurement performed?
Statistical	S1	O	Was the sample size for each group described?
	S2	Q	Were point estimates presented for the primary outcome measures?
	S3	Q	Were measures of variability presented or are individual patient data given?
	S4	*	Are the statistical methods used described?
	S5	*	Are the statistical methods used valid?

* Additional items

validity was the primary criterion in ordering the studies. Management of control groups was the most important item, followed by homogeneity of (sub) groups, dropout rate, and finally the remaining items.

Results

The search resulted in 430 references. Of these, 418 could be regarded as not relevant on basis of the title and abstract. After preview of the remaining 12 articles retrieved, five were excluded. Two were review articles [3, 14], two were not relevant [9, 30], and one was a letter to the editor [18].

Scanning of the references of the relevant articles added 13 references. After preview of these articles, five were excluded. Three were non-clinical studies [7, 26, 27], one was a review [25], and one reference concerned a steel ball-bearing implanted into the intervertebral disc space. As this is an old report, and it is unrelated to the current implants, this study was excluded [19]. Five articles [12, 21, 24, 31, 38] were not available in any library in the Netherlands.

There was one duplicate study base: the second article by Buttner-Janz [6] contains the patients from the first article [5]. Although not stated, we could infer this from the text, because all patients treated at the time were included in the second series. Therefore, the first article was excluded. It is further unclear whether the multicentre study of Griffith et al. [23] included patients from other studies. Although authorship suggests this, we could not conclude this from the text, and therefore they were kept in the review.

The remaining nine articles were evaluated with the criteria list. The results of this evaluation are given in Table 3. The table does not list the score for the control group, as this was ‘no’ for all studies, and consequently questions 1b–1f (Table 2) are not applicable. Compliance (I6) is not listed, because this is “not applicable” in all studies, because a patient cannot withdraw from therapy.

We did not find controlled trials comparing intervertebral disc prosthesis with the presumed gold-standard fusion or other operative techniques. Eventually, we found six retrospective cohort studies, one cross-sectional study and two prospective cohort studies.

Table 3 Methodological score of selected articles (*NA* not applicable, *?* unclear)

Group	Item	Buttner-Janz et al. [6]	Wittig et al. [39]	David [13]	Enker et al. [17]	Griffith et al. [23]	Cinotti et al. [10]	Lemaire et al. [29]	Zeegers et al. [40]	Sott and Harrison [35]
Study type	T1	Hcoh	Hcoh	Hcoh	Hcoh	Hcoh	Hcoh	CS	Pcoh	Pcoh
	I2a	–	–	–	–	–	–	–	–	–
	I2b	–	–	–	+	–	+	–	–	–
	I3	–	–	?	+	?	?	?	+	–
	I4	–	–	–	+	–	–	?	+	–
	I5	+	+	+	?	+	?	?	+	+
	I7	+	?	–	+	?	?	?	+	+
	I8	–	–	+	+	+	+	+	+	+
External	E1	+	+	+	+	–	–	–	–	–
	E2	+	+	+	+	+	+	+	+	+
	E3	+	+	+	+	+	+	+	+	+
	E4	+	+	+	+	+	+	+	+	+
	E5	–	–	–	–	–	–	–	–	–
Statistical	S1	–	+	+	+	–	+	+	+	+
	S2	–	–	–	–	+	–	–	–	–
	S3	–	–	–	+	NA	NA	–	NA	–
	S4	–	–	–	NA	+	+	–	+	NA
	S5	NA	NA	NA	NA	+	+	?	+	NA

Table 4 Clinical details of the selected studies (*SB* SB Charité prosthesis)

	Buttner-Janz et al. [6]	Wittig et al. [39]	David [13]	Enker et al. [17]	Griffith et al. [23]	Cinotti et al. [10]	Lemaire et al. [29]	Zeegers et al. [40]	Sott and Harrison [35]
Type of prosthesis	SB I, II, III	SB III	SB III	Acroflex	SB I, II, III	SB III	SB III	SB III	SB III
Average age	43		37	55	43	36	39	43	48
Range	26–59	30–54	27–50	33–75	25–59	27–44	24–50	24–59	31–61
No. of patients	62	13	22	6	93	46	105	50	14
No. of arthroplasties	76	14	29	6	139	56	154	75	15
Follow-up in months	15	9	19	41	11.9	38	51	24	48
Range	?-36	3–18	12–37	36–48	1–37	24–60	?		18–68
Good or excellent	81%	NA	15/22	3/6	?	63%	79%	70%	10/14
Secondary surgery		6/13						17/50	1/14
Arthrodesis or spontaneous fusion		2/15	3/30						
Complications	29/76	1?	1?	3/6	55/139	8/46	10	3/50	2/15
Motion on flexion extension radiographs in degrees (range)									
Average	5	–	7.1[a]	8 (2–16)	?	12.2	11.2	9 (2–17)	?
L3/L4			2			–	–		
L4/L5			9.4			16	13		
L5/S1			6.4			9	9.5		

[a] Average mobility is calculated from data provided

The methodological analysis of the articles is presented in Table 3, and the clinical details are presented in Table 4. Remarkable are the short periods of follow-up, and, in some series, the high rate of secondary arthrodesis due to spontaneous bony bridging or secondary surgical arthrodesis (Wittig et al. [39] 2 of 15, David [13] 3 of 30, Cinotti et al. [10] 12 of 46, Lemaire et al. [29] 1 of 105, Zeegers et al. [40] 4 of 46).

Discussion

A good surgical solution to low back pain is yet to be found. Arthrodesis of a painful motion segment in the lumbar spine has been shown to be an effective treatment [4, 20], but perceived disadvantages of arthrodesis are that adjacent segment degeneration may occur and that excellent long-term results are rarely achieved. For this reason, total disc replacement appears to be an attractive alternative to arthrodesis. Our review of the literature has revealed only a very limited number of articles concerning total disc replacement, and all are non-controlled case series with many methodological flaws.

Limitations of the study

Our study might be limited by the sensitivity of the search. We did not use EMBASE, as is advised for systematic reviews in the medical field [2, 36]. However, EMBASE primarily has a focus on pharmacological publications [22]; therefore, we did not expect to find additional studies for our review. Further, the present search was aimed solely at identifying published peer-reviewed literature, so that a publication bias cannot be entirely ruled out. These factors may explain the relatively large number of studies found with the reference scan.

Despite these serious limitations, we have attempted to answer the questions raised in the Introduction.

How do the clinical results compare to arthrodesis?

The short-term results (1–68 months) appear to be comparable to results of arthrodesis, but the studies are of such a limited quality that it is hard to justify such a conclusion. Potential long-term problems of an artificial joint as experienced in total hip and knee replacement are not addressed anywhere in the literature, despite the fact that the SB Charité III has been on the market for more than 10 years. Disc arthroplasties are performed generally in patients aged 30–50 years old. In this patient age category, the results of the "successful" total hip arthroplasty appear to be disappointing, with a 30% revision rate within a 10-year follow-up [33].

What are the radiologic results?

Loosening

In total hip arthroplasty, radiologic loosening is recognised as a precursor of clinical loosening, but none of the studied papers address this problem. Whether true fixation and ingrowth of these devices to the vertebral endplate occurs is not known.

Subsidence

Subsidence of fusion cages into vertebral bodies (Fig. 2) is recognised as a possible source of problems such as loss of lordosis and non-union. None of the arthroplasty arti-

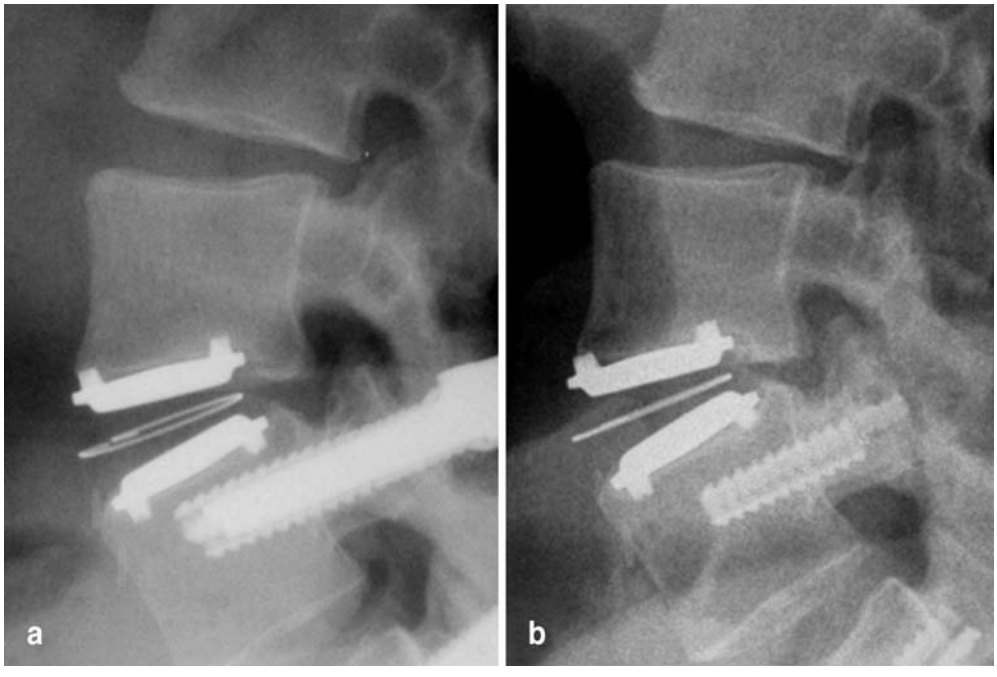

Fig. 2 **A** Lateral radiograph of total disc replacement placed for adjacent segment degeneration after a postero-lateral instrumented arthrodesis. **B** Subsidence of total disc replacement into the vertebral endplates; progressive anterior displacement of the superior arthroplasty endplate with the fixation teeth beginning to protrude anteriorly; and progressive osteolysis at the posterior margin of the superior arthroplasty endplate. Progressive disc space narrowing and retrolisthesis above the arthroplasty

cles discusses this item systematically, but subsidence is incidentally reported. If an arthroplasty moves as designed, stresses will continue to be transferred from the implant to the vertebral endplate, so that subsidence, once initiated, will probably progress.

Polyethylene wear

Polyethylene wear is known to be involved in at least one of the failure mechanisms of total hip arthroplasty due to foreign body reactions to wear particles [16]. Although the loads on polyethylene in disc prosthesis are thought to differ considerably from hip or knee arthroplasties, wear should be recognised as a potential problem, although this has not been reported (or accurately measured) to date. If polyethylene wear does take place, foreign body reactions leading to granulomas, as is seen in total hip arthroplasty, can develop with longer follow-up. This may cause a serious surgical problem with major blood vessels in the vicinity.

Does the motion segment retain its mobility?

Not all papers address this aspect, and the methods used to measure motion are not described. The operated segment does appear to move with a reported average range of motion of 5°–12°. However, the mobility of the motion segment is frequently lost, as in several of the studied series a substantial number of arthroplasties (in one series 26% [10]) eventually resulted in a fusion of the two vertebrae (surgical arthrodesis usually because of clinical failure or spontaneous fusion with a bone bridge around the prosthesis). Thereby, one of the primary aims of the arthroplasty is frequently not achieved.

Does adjacent segment degeneration occur?

Adjacent segment degeneration (Fig. 2) is a recognised problem in arthrodesis, and one of the main arguments for the use of an arthroplasty. However, even in arthrodesis the cause is unclear. It may be an expression of the natural history at another level of the underlying "disc disease" that originally caused the clinical problem at the operated level. In this case it will also occur after arthroplasty, even if this manages to maintain normal motion. Adjacent segment degeneration may also be due to increased stresses at the adjacent segment due to the arthrodesis, in which case an arthroplasty might result in less adjacent segment degeneration than an arthrodesis. Whatever the cause, the clinical consequences of this problem are not clear. The studied literature does not support the hypothesis that continued motion with arthroplasty leads to less adjacent segment degeneration than an arthrodesis, because all the follow-up is simply too short. In one series [40], re-operation was performed at the adjacent segment in 11 of 50 patients (22%) within 2 years. This high rate might even point to accelerated adjacent segment degeneration. Furthermore, in this same series, 13 re-operations were performed for various reasons at the arthroplasty level within 2 years, totalling 24 re-operations in 50 patients within 2 years.

One possible problem unique to the arthroplasty is that, due to the continued motion, the facet joints remain clinically relevant. Due to the distractive effect, when the total disc replacement is placed, the facets may be unloaded. However, the normal motion segment has a varied axis of rotation for different motions [37]. Arthroplasty probably cannot imitate these degrees of motion, and the more constrained the arthroplasty, the more stresses will occur either at the facet joints (possibly leading to degenerative changes), or at the polyethylene-endplate interface (leading to polyethylene wear), or at the implant-vertebral endplate interface (possibly leading to loosening or subsidence, Fig. 2). In a recent finite element model of an L3-L4 motion segment, 2.5 times increased loads were calculated at the facet joints if one experimental type of arthroplasty was implanted anteriorly in the intervertebral space [15], and similar results were obtained in a cadaver study [29]. Longer follow-up studies will have to address this aspect.

What is the complication rate?

The complication rate is highly variable, and is described in various ways, related to the approach, to the implant or to persistent pain. For the 411 patients, no infections are reported and the reported rate of vascular complications appears low: a total of six venous injuries, two arterial injuries (one at implantation, one at removal of an implant) and six thrombotic complications. Two series [6, 17] describe a prosthesis that is no longer available, and provide important information on implant failures such as fracture of metal implant endplates and subsidence into vertebral bodies. These two studies emphasise the technical difficulties of prosthetic design in this anatomic location, and should be seen as a warning for future developments.

Is there an acceptable and safe salvage procedure in case of failure?

In cases of failure of the implant, a postero-lateral arthrodesis may be considered as a salvage procedure, and was performed and discussed in several articles. However, removal of the implant may be necessary in some cases (e.g. dislocation, infection, polyethylene wear, polyethylene granulomas), and this may be difficult due to the fibrosis of the vena cava adjacent to the vertebral bodies. The

Prodisc has the potential extra disadvantage of the fins attached to the implant endplates, which require a direct anterior approach for removal. This may be a problem at L4-L5, and may necessitate a partial corpectomy.

What could be considered the indication for disc arthroplasty?

Most articles give a limited description of the patient population, and this makes identification of the ideal candidate from these studies impossible. The presence of a scoliosis or "topping off" of an arthrodesis are mentioned as poor indications [17].

Despite the fact that these devices have been implanted for more than 10 years, on the basis of this literature survey, there is no evidence that disc arthroplasty reliably, reproducibly, and over longer periods of time fulfils the three primary aims of clinical efficacy, continued motion, and few adjacent segment degenerative problems. The potential problems that may occur have not been addressed. From our study of the literature, it is not clear how the results relate to other treatment options, but based on the available data they do not appear to be better than an arthrodesis.

Conclusion

Although theoretically appealing, there are currently insufficient data to assess the performance of total disc replacement adequately. Introduction of this new technology has not followed the principles of scientific prudence, and despite almost 15 years of clinical application, there are insufficient data on the safety and efficacy of the procedure. Total disc replacement should therefore still be considered an experimental procedure, and in our opinion, should remain so until long-term results of adequate studies (which are now underway) are available. Arthroplasties should only be performed in strictly controlled studies with adequate informed consent of the patient. In our quest to find surgical solutions for the multifactorial problem of low back pain, patient selection remains the most important factor in achieving success, and a new experimental device, however appealing at first sight, will not change this.

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