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

de Kleuver M, Oner F C, Jacobs W C

CRD summary
This review assessed total disc replacement as a treatment for chronic lower-back pain. There was insufficient evidence on safety and efficacy to assess the performance of total disc replacement adequately. The authors' conclusions reflect the paucity of evidence found by the review.

Authors' objectives
The authors' objective appears to have been the evaluation of total disc replacement as a treatment for chronic lower-back pain.

Searching
MEDLINE (via PubMed; from 1966 to 2002), the Cochrane Controlled Trials Register (Issue 4, 2001), Current Contents (from 1997 to 2002) and CINAHL (from 1982 to 2001) were searched. The search terms were given and no language restrictions were applied. In addition, references of selected articles were included in the search. Studies not published in a peer-reviewed journal were excluded from the review.

Study selection
Study designs of evaluations included in the review
The inclusion criteria did not limit the study designs included in the review. Included in the review were prospective and retrospective cohort studies and cross-sectional studies.

Specific interventions included in the review
The inclusion criteria specified intervertebral disc prosthesis. The interventions included in the review were SB Charite I, II and III and Acroflex prostheses.

Participants included in the review
The inclusion criteria specified patients with degenerative disc disease at a lumbar level.

Outcomes assessed in the review
The inclusion criteria specified that a clinical outcome had to have been assessed. The outcomes included in the review were the clinical success rates, radiologic results, loosening and polyethylene wear, retention of mobility, adjacent segment deterioration and the complication rate.

How were decisions on the relevance of primary studies made?
Two independent reviewers made decisions about the relevance of each article on the basis of either the abstract, where possible, or the full paper where this was not possible. A third reviewer was consulted when any disagreements could not be resolved.

Assessment of study quality
Validity was assessed using a checklist recommended by the Cochrane Collaboration Back Review Group for Spinal Disorders (see Other Publications of Related Interest), with some adaptations and with the items regrouped into the following categories: internal validity, external validity, data presentation, and statistical analysis. Details of this checklist were provided. Importance was given to consideration of the management of the control groups, homogeneity of the groups and the drop-out rate. In addition, the studies were stratified on a hierarchy of evidence Two independent reviewers made judgements of validity. A third reviewer was consulted when consensus could not be reached.
Data extraction
The authors did not state how the data were extracted for the review, or how many reviewers performed the data extraction. The data extracted were: the age of the patients, the type of prosthesis, the length of follow-up, the occurrence of arthrodesis or spontaneous fusion, complications, whether secondary surgery was performed, and motion on flexion extension radiographs.

Methods of synthesis
How were the studies combined?
A narrative synthesis of the studies was undertaken. This was contained in the 'Discussion' section.

How were differences between studies investigated?
Differences between the studies were explored in a narrative synthesis and evidence tables.

Results of the review
Nine studies were included in the review: 2 prospective cohort studies, 6 retrospective cohort studies and 1 cross-sectional study. The total number of patients was 411.

The short-term clinical results appeared to be comparable to the alternative treatment of arthrodesis, but problems with study quality limited the conclusions that could be drawn.

None of the studies addressed radiologic loosening, a recognised precursor of clinical loosening or polyethylene wear. None of the studies systematically assessed the subsidence of fusion cages into vertebral bodies.

Operated segments appeared to move with an average range of 5 to 12 degrees (6 studies), but the mobility of the motion segment was frequently lost as a number of arthroplasties eventually resulted in a fusion of the two vertebrae. This was as high as 26% in one case series.

Adjacent segment deterioration was hard to assess because the duration of follow-up was too short. In one study, reoperation was performed at the adjacent segment in 11 of the 50 patients within 2 years and there was a further 13 reoperations at the arthroplasty level during the same period (a total of 24 reoperations in 50 patients).

The complication rate showed wide variation and was described in various ways. Complications were observed in 3 to 50% of the patients (9 studies). No infections were reported, but there were 6 venous injuries, 2 arterial injuries and 6 thrombotic complications. Two studies described a type of implant no longer used and gave information on implant failures.

Authors' conclusions
There were insufficient data on safety and efficacy to assess the performance of total disc replacement adequately.

CRD commentary
The review question was reasonably clear, as were the inclusion criteria. The search was adequate, although the authors suggested that the failure to search EMBASE may have limited the number of studies found. The authors acknowledged that the fact that the review was limited to studies published in peer-reviewed journals may have led to the introduction of publication bias, which was not assessed. The authors applied procedures to minimise bias and error when selecting studies for the review and in the validity assessment, which was thorough. However, they did not report using such methods when extracting data for the review.

Details of the primary studies were presented adequately in tabular format, with the results of the quality assessment tabulated separately. The decision to adopt a narrative synthesis of the results was appropriate given the heterogeneity between the studies' measurement of the outcomes. However, the synthesis was primarily contained in the 'Discussion' section of the study and was difficult to relate to the evidence table. The authors' conclusions reflect the paucity of evidence found by the review. The implications for practice which they draw from these conclusions were appropriate.
Implications of the review for practice and research

Practice: The authors stated that total disc replacements should be considered experimental procedures and should be used only in strict clinical trials.

Research: The authors stated that adequate studies are now in progress and that their long-term results should be awaited.

Bibliographic details


PubMedID
12709847

DOI
10.1007/s00586-002-0500-0

Other publications of related interest


Indexing Status

Subject indexing assigned by NLM

MeSH

Arthroplasty, Replacement /methods; Diskectomy; Humans; Intervertebral Disc /surgery; Joint Prosthesis; Low Back Pain /surgery; Lumbar Vertebrae /surgery; Spinal Fusion; Treatment Outcome

AccessionNumber
12003001191

Date bibliographic record published
30/09/2004

Date abstract record published
30/09/2004

Record Status

This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.