Threaded fusion cages for lumbar interbody fusions: an economic comparison with 360-degrees fusions

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Ray threaded fusion cage (TFC) method for lumbar interbody fusions at one and two lumbar levels in patients suffering from severe, disabling back pain with discal degeneration.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Patients suffering from severe, disabling back pain with discal degeneration.

Setting
Hospital. The economic study was carried out in the USA.

Dates to which data relate
Effectiveness and resource use data were related to the period 1991 to 1995. Some effectiveness data were reported from studies published between 1989 and 1995. The price year was 1995.

Source of effectiveness data
Effectiveness data were derived from a single study.

Link between effectiveness and cost data
Costing was retrospectively performed on the same patient sample as that used in the effectiveness analysis.

Study sample
Power calculations were not used to determine the sample size. The study sample consisted of 50 patients assigned to receive a 360 degree fusion technique between 1992 and 1995 (25 with a median age of 36 (range: 24-55) years) or a TFC fusion procedure between 1991 and 1993 (25 with a median age of 42 (range: 29-58) years). One surgeon (the author) performed all the surgical procedures using the same spine team.

Study design
This was a non-randomised prospective study carried out in a single centre. The mean follow-up period was 24 (range:
3 to 29) months. No loss to follow-up was reported. The assignment of the study patients to each study group was dictated by circumstances beyond the author's control (Food and Drug Administration (FDA) rules regarding the conduct of the TFC study).

Analysis of effectiveness
The analysis was based on intention-to-treat. The health outcome measures were the percentage of patients with solid fusions using established radiographic image criteria, blood loss, operating time, the percentage of patients developing a fusion transition syndrome requiring second fusion procedure, percentage of patients requiring removal of the implants due to instrumentation-associated pain. Patient selection criteria were reported to be similar between the two study groups.

Effectiveness results
Solid fusions were judged to be present in all patients.

The TFC group had a mean blood loss of 280 ml for one-level and 779 ml for two-level cases, while the 360 degree technique group had a mean blood loss of 729 ml for one-level and 1,076 ml for two-level cases.

The mean operating time was 159 min for one-level TFC and 253 min for two-level TFC, while the corresponding values for the 360 degree technique group were 289 min for one-level and 320 min for two-level cases.

The percentage of patients developing a fusion transition syndrome requiring a second fusion procedure was 0% in both study groups.

The percentage of patients requiring removal of the implants due to instrumentation-associated pain was 40% (10 out of 25 patients) in the 360-technique group versus 0% in the TFC group.

Clinical conclusions
The two procedures offer similar effectiveness but improvements in surgical time and blood losses are provided by the threaded fusion cage technique.

Measure of benefits used in the economic analysis
With the assumption of similar fusion success, clinical outcome, and complication rate between the two techniques, the author chose to focus on comparing the costs associated with the use of each technique. In this respect the economic analysis took the form of a cost-minimisation exercise.

Direct costs
Discounting was not applied but this may be justifiable as most of the costs were incurred over a short period. Some quantities were reported separately from the costs and cost items were reported separately. The cost analysis covered the direct medical costs of surgeon, hospital, anesthesiologist, and implants. The perspective adopted in the cost analysis was that of third parties, insurance carriers, Medicare, self-payers, and others. The sources of charge data were the hospital records, related departments and affiliated experts and groups. The charge data were inflated to the corresponding prices of the fiscal year. 1995 price data were used. The cost of prior non-surgical care was not included in the cost analysis.
Statistical analysis of costs
Not carried out.

Indirect Costs
Not considered.

Currency
US dollars ($).

Sensitivity analysis
Not conducted.

Estimated benefits used in the economic analysis
Not applicable due to the cost-minimisation analysis.

Cost results
The average costs of TFC 1-level were $25,171 and TFC 2-level were $33,113 versus $41,813 for the 1-level 360 degree fusion procedure and $47,320 for the 2-level 360 degree fusion procedure. Aggregating for 25 patients in each group led to a 35% savings due to the use of the TFC procedure.

Synthesis of costs and benefits
Not combined since, with the assumption of equal efficacy, the use of TFC resulted in a cost saving relative to the use of the 360 degree fusion procedure.

Authors' conclusions
In this limited study, the Ray TFC procedure was found to be more cost effective than the well established method of anterior composite interbody grafting with posterior pedicle screw fixation, even though the fusion and complication rates and clinical success rates are similar.

CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparator was its well-established track record. You, as a database user, should consider whether this is a widely used health technology in your own setting.

Validity of estimate of measure of benefit
The internal validity of the estimates of benefit can not be reasonably guaranteed given the nonrandomised nature of the study design and the relatively small sample size. The study was predominantly a cost-minimisation analysis.

Validity of estimate of costs
Some quantities were reported separately from the costs. Adequate details of methods of cost estimation were given. The cost results may not be generalisable to other settings or countries.

Other issues
The authors' conclusions may not to be fully justified given the limitations in the study design. Costs were not subjected to statistical or sensitivity analyses. The issue of generalisability to other settings or countries was not
addressed. Appropriate comparisons were made with other studies.

**Implications of the study**
The TFC procedure deserves further use and comparative study in the future.

**Source of funding**
None stated.

**Bibliographic details**

**PubMedID**
9089941

**Original Paper URL**
http://www.spinejournal.com/

**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
Cohort Studies; Health Care Costs; Humans; Lumbar Vertebrae /surgery; Prospective Studies; Prostheses and Implants; Reoperation; Spinal Fusion /economics; Treatment Outcome

**AccessionNumber**
21997000542

**Date bibliographic record published**
30/06/2000

**Date abstract record published**
30/06/2000