

# Dynamic compared to rigid fixation in lumbar spine: a systematic review

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## SUMMARY

**Objective:** The objective of this review is to reveal the quality of published data and the effect size of DPFs compared to rigid fixation in lumbar spine. Summary of background data: since 2002, several dynamic pedicle fixation (DPF) systems have been developed with the aim to stabilize the spine without the undesirable effects of rigid lumbar spine fixation. Nearly ten years later, there are several studies on these dynamic systems.

**Methods:** A systematic review was done in MEDLINE/PubMED, Embase, Cochrane Central Register of Randomized Trials and Google Scholar to assess the quality of published literature and the available studied outcomes in randomized controlled trials of DPF.

**Results:** Only three papers described randomized trials studying DPF. One of them focused on protection of adjacent level disease provided by DPF.

**Conclusion:** It was not possible to reveal any evidence for benefits using DPF compared to rigid fixation in surgery for lumbar spine.

**Key words:** lumbar vertebrae, intervertebral disc degeneration, surgical fixation devices, internal fixators, bone screws, spinal fusion.

Study conducted at the post graduation program in health sciences- IAMSPE- São Paulo, SP, Brazil

**Conflict of interest:** none

**Article received:** 10/04/12

**Accepted for publication:** 07/01/13

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<http://dx.doi.org/10.1590/1806-9282.60.02.013>

**Conflict of interest:** none

## INTRODUCTION

Fusion using spine fixation is a surgical intervention used for the treatment of degenerating lumbar spine.<sup>1,2</sup> For patients with vertebral instability and those with painful conditions secondary to disc degeneration, the elimination of the vertebral joint movement could produce clinical improvement from the stabilization of the spine.<sup>3</sup> Although there can be favorable clinical outcomes for certain conditions, complications of fusion with rigid fixation have appeared, such as intervertebral disc degeneration adjacent to fusion.<sup>4,5</sup>

To reduce or eliminate the undesirable effects of rigid fixation, dynamic systems have been developed based on flexible screws and rods (DPF). These implements could protect the spine from mechanical overload imposed by the rigid fixation of the spine while retaining spine movement and preventing adjacent disc degenerative disease.<sup>6,7,8</sup>

A decade after the first description of the dynamic fixation devices, some authors claim that indications for these devices are not yet defined, although there are potential diseases that could benefit from their use.<sup>9,10</sup> The objective of this study is to evaluate the clinical outco-

mes of these procedures compared with rigid pedicle fixation systems.

## METHODS

A systematic literature review was performed for publications between January 2002 (the first DPF publication date<sup>6</sup>) and August 18, 2011, in the following electronic primary literature databases: MEDLINE/PubMed, the Cochrane Central Register of Controlled Trials (CENTRAL) and EMBASE. Google Scholar and electronic database search engines were used, and publications in all languages were included.

The research protocol was based on the method of questions structured by types of participants (study population), comparing the two types of intervention (rigid, and semirigid or dynamic fixation) and selecting the type of study as a prospective randomized trial (appendix 1).<sup>11</sup>

### Study population

Adult patients with symptoms of lumbar spine degenerative disease who were not previously submitted to sur-

gery. Patients with infection, trauma, surgical treatment of osteoporosis, and comorbidities that interfere with walking were excluded.

#### Intervention

Patients who underwent DPF.

#### Control

Patients who underwent rigid fixation.

#### Outcome

To reveal the effect on all outcomes studied, all reported outcomes were compared.

#### Type of selected studies

Randomized trials.

#### Study selection

Searches were performed by three independent reviewers. The papers were initially assessed by title, and those selected were subsequently re-analyzed by abstract. The references of selected articles were studied to find other relevant citations. Disagreements were solved among the authors through discussion. The search strategy is detailed in appendix 1.

#### Quality of papers selected for study

Because of the importance and prevalence of degenerative disease of the lumbar spine, only randomized controlled trials (RCTs) were included due to the more compelling evidence they provide. Assessments of methodological quality were made according to Cochrane collaboration's tool for assessing risk of bias (table 1).<sup>12</sup>

## RESULTS

The electronic search revealed a total of 321 articles. Of these, 302 studies were categorized as human clinical trials and published as journal articles or conference papers. Selection by title identified 27 articles that were subsequently reviewed by abstract, resulting in four articles. However, one of the papers (Putzier *et al.*) was not randomized and was excluded.<sup>13</sup>

#### Description of included studies and assessment of methodological quality

Evaluation of final three papers:

- **Korovesis *et al.***<sup>14</sup> The study population was composed of patients with lumbar canal stenosis. Patients were treated with rigid fixation and dynamic system (Twinflex). All patients were fused with autograft. Thirty patients were examined 3 months after surgery. There was no description

of the randomization method and no blinded allocation attempt. This study did not detail clinical outcomes. Lumbar lordosis, sacral inclination, intervertebral angle, and intervertebral disc index were evaluated. Comparisons were not made between the randomized groups, only within groups regarding pre- and postoperative outcomes.

- **Korovesis *et al.***<sup>15</sup> As in the first work by the same author, the study population was composed of patients with lumbar canal stenosis. Patients were treated with dynamic, semi-rigid and rigid fixation. All patients underwent bone fusion with bone grafts from the iliac crest. Forty-five patients were randomized, but the randomization method was not described and there was no attempt to conceal allocation. Radiological evaluation was done by independent evaluators. Clinical outcomes assessed were the visual analogic scale VAS for back pain and lower extremity. The quality of life questionnaire F-36 was also used. Degeneration and complication rate adjacent to the surgery site and failures of the systems were evaluated. Apparently there were no differences in VAS between the groups, and authors did not provide statistical analyses between groups. There were no differences in the final clinical or radiological evaluations. The complication rate evaluation revealed that it was too low to allow for comparisons. There was no degeneration in any of the adjacent groups. The analysis of provided radiological findings suggest that results were compared within each group, pre- and postoperatively, but not among the three randomized groups.

- **Putzier *et al.***<sup>16</sup> The authors studied patients with low back pain, presence of Modic signs, lumbar spine facet arthritis and spondylolisthesis. Sixty patients were studied comparing dynamic and rigid fixation. Randomization was performed by a specific software program, and there was no attempt to conceal allocation. The sample size of patients to be studied had been calculated previously and there was an adequate description of follow-up loss of patients. The final follow-up period was 6 years. Clinical outcomes were the rate of satisfaction with treatment, the ODI, and the VAS. Radiological evaluation consisted of changes in vertebral plateau sign (Modic sign) and the Fujiwara facet arthritis degeneration index, intervertebral disc height and presence of dynamic instability in plain radiographs. There were no differences between groups in any of these outcomes.

#### Risk of bias in included studies (Table 1)

There are few randomized trials studying the dynamic versus rigid fixation. Each of the identified studies had

some kind of methodological weakness. Due to the nature of surgical intervention, blinding of treatment execution and evaluation was not possible (double-blind). Only one of the three papers described the randomization method. In one study, there was no assessment of clinical outcome (Korovesis *et al.*) and in the others, only the VAS was used. Outcomes were determined by the staff that performed the procedures. Korovesis *et al.*, followed the outcomes for just three months, and Korovesis *et al.*, followed the outcomes for two years. The final pooled analysis consisted of only 135 patients, and the low methodological quality of the papers introduces considerable potential for bias.

## DISCUSSION

Lumbar spine Degenerative Disc Disease (DDD) causes social, economic and financial burden to patients affected. It is estimated that annual expenditures for treatment cost are higher than those for all types of cancer

combined. Current studies suggest that DDD has a strong genetic component and progressive evolution.<sup>17</sup> Due to complications of spinal fusion, semi-rigid and dynamic systems have been developed to protect the spine against adjacent disk degeneration disease and to eventually ameliorate the mechanical effects superimposed on normal spine by rigid spine fusion.<sup>9</sup> It has been suggested that these systems can return the degenerated intervertebral disc to a normal condition and eventually slow or reverse the degenerative process.<sup>7</sup> Here, randomized studies that compared the two types of systems were evaluated. Due to the economic and financial importance of these systems, only randomized trials were analyzed. Studies comparing effect sizes based on nonrandomized trials illustrate that lower quality manuscripts tend to increase effect size. Even among RCTs, distortion of the actual effects can occur when randomization and allocation concealment are not performed properly, or when there is a high degree of follow-up loss.<sup>18,19,20</sup>

**TABLE 1.** The Cochrane Collaboration's tool for assessing risk of bias

Author/Year	Korovesis <i>et al.</i> 2002	Korovesis <i>et al.</i> 2004	Putzier <i>et al.</i> 2010
Domain			
<b>Selection bias</b>			
Random sequence generation.	No	No	Randlist Software (DataInf GmbH, Tübingen, Germany).
Allocation concealment.	No	No	No
<b>Performance bias</b>			
Blinding of participants and personnel Assessments should be made for each main outcome (or class of outcomes).	No	Radiological criteria were analyzed by independent evaluators.	The blinded radiographs were evaluated independently by both a radiologist specializing in spinal imaging and an orthopedic surgeon. A second independent orthopedic surgeon was consulted to adjudicate conflicting fusion findings.
<b>Detection bias</b>			
Blinding of outcome assessment Assessments should be made for each main outcome (or class of outcomes).	No	Radiological criteria were analyzed by independent evaluators.	The blinded radiographs were evaluated independently by both a radiologist specializing in spinal imaging and an orthopedic surgeon. A second independent orthopedic surgeon was consulted to adjudicate conflicting fusion findings.
<b>Attrition bias</b>			
Incomplete outcome data Assessments should be made for each main outcome (or class of outcomes).	No (only three months of FU).	There were no follow-up losses.	The mean long-term follow-up was 76.4 months (60-91 months). Five patients (5/30) from the SLF group and eight patients (8/30) from the DFT group failed to attend every follow-up and were therefore excluded.
<b>Reporting bias</b>			
Selective reporting.	Only radiographic findings were studied.	No	

The first description of dynamic screw fixation was published in 2002. Although there is extensive literature related to biomechanical and case series studies,<sup>3,21,22,23,24,25</sup> only three randomized trials compared dynamic pedicle fixation with rigid fixation.<sup>14,15,16</sup> It is remarkable that the three RCTs used bone fusion in both rigid and dynamic fixation. Two of the three studies failed to make direct comparisons between rigid and dynamic techniques. Rather, they compared the outcomes within each group, between pre- and postoperative status.<sup>14,15</sup>

Among all lumbar degenerative diseases, lumbar spinal stenoses were the focus in two studies,<sup>14,15</sup> and the third study assessed a group of patients with heterogeneous degenerative disc disease, characterized by Modic type changes in the vertebral plateau, facet arthritis and spondylolisthesis.<sup>16</sup> In this study, which had the longest follow-up time and best design, the incidence of degeneration adjacent to the fusion site was directly and objectively appraised. Six years after surgery, there was no evidence of protection against adjacent degeneration with dynamic systems.

## CONCLUSION

### Implications for practice

Although dynamic systems have been designed to protect the spine from undesirable rigid fixation effects, ten years of clinical use have failed to show superiority of these systems in clinical or radiographic outcomes. There were no differences in the rate of degeneration in adjacent dynamical systems compared with rigid systems.

### Implications for research

There are few randomized trials comparing both systems, and the methodological quality still needs to be improved. Specific areas to address include the categories of independent randomization, blinding and follow-up duration.

**Disclosure of funding received for this work:** Rafael Bastianello Junior, Luciana Dini Gianini de Albuquerque received grants from the Institutional program of scientific initiation scholarships (PIBIC/CNPq).

## RESUMO

Fixação pedicular dinâmica comparada com a fixação rígida na coluna lombar: uma revisão sistemática

**Objetivo:** Desde 2002, vários sistemas de fixação dinâmica pedicular (FDP) foram desenvolvidos com o objetivo de estabilizar a coluna vertebral, sem os efeitos indesejáveis da fixação da coluna lombar rígida. Cerca de 10 anos

mais tarde, existe uma série de estudos sobre os sistemas dinâmicos. Revelar a qualidade dos dados publicados e o tamanho do efeito da FDP em comparação com a fixação rígida na coluna lombar.

**Métodos:** Uma revisão sistemática foi feita utilizando MEDLINE/ PubMed, Embase, a CENTRAL Cochrane de ensaios randomizados e Google Scholar para avaliar a qualidade da literatura publicada e os desfechos estudados disponíveis em ensaios clínicos randomizados.

**Resultados:** Apenas três estudos randomizados foram encontrados. Um deles estudou a proteção de degeneração no nível adjacente à fixação rígida proporcionada pela FDP.

**Conclusão:** Não foi possível revelar qualquer evidência de benefícios da FDP, em comparação com a fixação rígida em cirurgia para a coluna lombar.

**Unitermos:** doenças da coluna vertebral, dor lombar, instrumentação, fusão vertebral, degeneração do disco intervertebral.

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