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Donna D. Ohnmeiss and Richard D. Guyer

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## Twenty-four month follow-up for reporting results of spinal implant studies: Is this guideline supported by the literature?

Donna D. Ohnmeiss, Dr.Med \*, Richard D. Guyer, MD

*Texas Back Institute Research Foundation, Plano, Texas*

### Abstract

**Background:** Traditionally, spine societies and journals have set guidelines requiring a minimum 24-month follow-up for reporting results of surgical implant studies. However, the basis for this particular time period is not clear. The purpose of this study was to analyze prospective spinal implant studies reporting data at multiple specific follow-up periods to determine if there were significant changes in the clinical outcome throughout the 24-month follow-up period.

**Methods:** A comprehensive literature search was conducted using PubMed as well as searching the FDA web page. Studies were evaluated to identify those meeting the inclusion criteria: involved at least 100 patients receiving a spinal implant with data reported at multiple pre-defined time periods post-operatively for at least 24-months. Data recorded from each study included, number of patients, diagnoses, implant used, outcome measures used, and the results reported. The primary outcome data were analyzed in the current study to determine the amount of change in scores, with particular focus on the six and 24-month follow-up periods.

**Results:** Only 7 studies met the inclusion criteria. All seven studies were FDA-regulated trials published since 1997. Six addressed the treatment of symptomatic disc degeneration and 1 involved patients with neurogenic claudication due to stenosis. The outcome measures in the studies varied but pain and function were frequently assessed. In none of the studies was there a significant deterioration in results between the 6 and 24-month follow-up periods. In fact, the only changes during the follow-up periods were slight, not statistically significant, improvements, with the exception of 1 scale in 1 study where a slight, not statistically significant, decrease in the extent of improvement on a physical function assessment was noted between 6 and 24 months. These results suggest a great deal of stability in the mean scores for various outcome measures between the 6 and 24 months in patients receiving spinal implants.

**Conclusions:** Although long-term follow-up is certainly desirable for any clinical outcome study, there appears to be no significant change in outcome measures between the 6-month and 24-month follow-ups. These results support that earlier dissemination of results may be appropriate without producing overly-optimistic reports.

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*Keywords:* Clinical outcome; Spinal implants; Prospective studies

Traditionally, spine societies and journals have set guidelines requiring a minimum 24 months follow-up for evaluating results of surgical implants. However, the basis for this guideline is not clear, although it is sometimes attributed to mirror the frequently-employed guidelines set by the FDA (Food and Drug Administration) for clinical trials evaluating implants. No documentation could be found providing the rationale for the 24-month follow-up requirement. This requirement typically dictates that a device must have been introduced approxi-

mately 4.5 years (1 to 2 years to enroll an adequate number of patients, 2 years to follow them, and time to analyze results and complete the abstract/manuscript submission and review process) prior to the dissemination of data on the performance of a new device. With the rapidly increasing number of spinal treatments being evaluated and developed, there is a very high level of interest among clinicians and patients in receiving information in the outcomes from these emerging treatments as soon as possible.

The purpose of this study was to analyze prospective studies in the literature that have reported data at specific, multiple time periods following implantation of spinal devices to determine if there were significant changes in the results during 24-month follow-up.

\* Corresponding author: Donna D. Ohnmeiss, Dr Med, Texas Back Institute Research Foundation, 6020 West Parker Road, Suite 200, Plano, TX 75093; Tel: 972-608-5097; Fax: 972-608-5137.

E-mail address: [dohnmeiss@texasback.com](mailto:dohnmeiss@texasback.com)

Table 1  
Description of the studies included in the analysis

Author	Implant	Diagnosis	Control	N	Primary outcome measures used
Kuslich <sup>1</sup>	BAK cages	Symptomatic disc degeneration	None	947	Modified Prolo Scale
Ray <sup>2</sup>	Ray threaded fusion cages	Symptomatic disc degeneration	None	236	Prolo Scale
Brantigan <sup>3</sup>	Brantigan I/F cages	Symptomatic disc degeneration with failed discectomy	None	221	5 point Likert scale for pain
Burkus <sup>4</sup>	InFUSE bone graft in tapered cages	Symptomatic disc degeneration	Autogenous iliac crest bone graft in tapered cages	143 Infuse; 136 autograft	ODI, back pain, leg pain, patient satisfaction, work status
Blumenthal <sup>5</sup>	CHARITÉ Artificial Disc	Symptomatic disc degeneration	ALIF (BAK cages with iliac crest bone graft)	205 CHARITÉ; 99 fusion	VAS, ODI
Zigler <sup>6</sup> and Synthes Spine <sup>7</sup> (on FDA website)	ProDisc-L Total Disc Replacement	Symptomatic disc degeneration	Combined anterior/posterior instrumented fusion	162 ProDisc-L; 80 fusion	ODI, VAS, satisfaction
Zucherman <sup>8</sup>	X-STOP	Neurogenic intermittent claudication due to stenosis	Non-operative care	100 X-STOP; 91 control	Zurich Claudication Questionnaire

## Methods

A comprehensive literature search was conducted using PubMed and submissions of Investigational Device Exemption (IDE) clinical trial data to the U.S. Food and Drug Administration (FDA). Only studies meeting the following criteria were included in the analysis:

- Involved the use of a lumbar spinal implant
- Included at least 100 patients
- Had a minimum of 24-month follow-up
- Presented data collected at specific, defined time periods during the 24-month follow-up (studies reporting only pre- and 24-month postoperative values were excluded since there was no opportunity to evaluate the pattern of change in scores throughout the follow-up period).

Data recorded from each study included the number of patients, diagnoses, implant(s) used, outcome measures, and results. The data were reviewed with the primary focus being

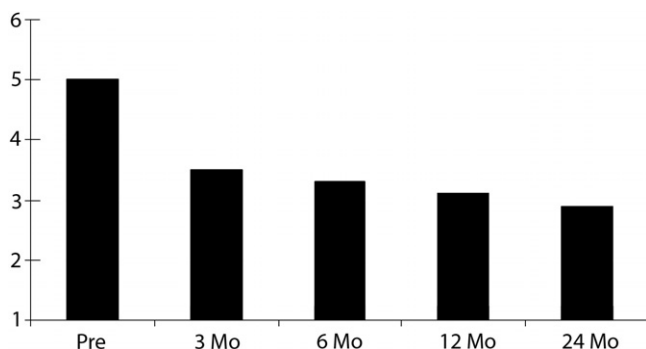


Fig. 1. Pain was measured on a 1–6 point Modified Prolo Scale. A slight improvement in pain scores was noted between 6- and 24-month follow-up periods. (Adapted with permission from Kuslich et al.<sup>4</sup>)

changes in the outcome measures over time, particularly the 6- and 24-month follow-up periods. In addition to clinical outcome, the other important factor in evaluating new technologies is safety. In this study, we reviewed the articles to determine if any change in the incidence of complications could be identified during the 24-month follow-up.

## Results

### Studies included in the review

Only 7 articles met the inclusion criteria for this study.<sup>1–7</sup> The implants investigated in the studies were the BAK cage (Sulzer Spine-Tech, Minneapolis, Minnesota), Ray Threaded Fusion Cage (Surgical Dynamics, Norwalk, Connecticut), Brantigan I/F Cage (DePuy–Acromed Corp., Raynham, MA), InFUSE Bone Graft (Medtronic Sofamor Danek, Memphis, Tennessee), CHARITÉ Artificial Disc

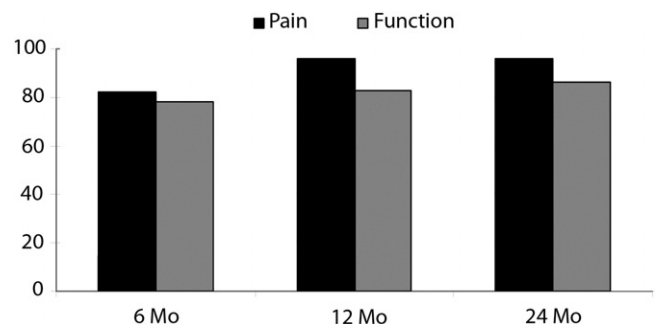


Fig. 2. Pain and function were assessed using Prolo scales and results reported as the percentage of patients classified as having excellent, good, or fair outcome. The percentage of patients increased 14% on the pain assessment and 8% on the functional assessment between 6 and 24 months. (Graph generated from data published by Ray.<sup>5</sup>)

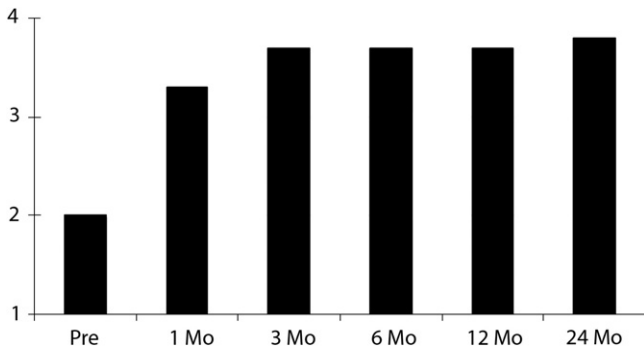


Fig. 3. Pain scores were assessed on 1–5 point Likert Scale. Greater scores indicate less pain. There was a slight improvement (2.7%) in mean pain scores between the 6- and 24-month follow-up visits. (Graph generated from data published by Brantigan et al.<sup>2</sup>)

(DePuy Spine, Rayham, Massachusetts), ProDisc-L Total Disc Replacement (Synthes Spine, West Chester, Pennsylvania), and the X-STOP (St. Francis Medical Technologies, Concord, California). All 7 studies were FDA-regulated multicenter clinical trials published since 1997.

Table 1 provides an overview of the studies included in this review. The number of patients enrolled ranged from 191 to 947. Symptomatic disc degeneration was the primary diagnosis in six of the studies.<sup>1–5,7</sup> In one study, patients were treated for neurogenic claudication due to stenosis.<sup>6</sup> Four studies were randomized.<sup>1,3,6,7</sup> The treatments used in the control groups included anterior fusion using cages packed with autograft,<sup>1,3</sup> circumferential fusion,<sup>7</sup> and non-operative management.<sup>6</sup>

#### Clinical outcome

The outcome measures varied in the seven studies, but pain and/or function were generally the parameters used to assess results. The outcome measures for this review study were the changes between the scores reported between the 6- and 24-month follow-up periods. In none of the seven studies was there significant deterioration in results between the 6- and 24-month follow-up periods. In fact, the only change between 6 months and 24 months was a slight improvement, though not statistically significant, with the exception of a physical function assessment where the percentage improvement decreased slightly between these two follow-up periods. Each study is reviewed in greater detail.

In the Kuslich et al. study, pain was measured on a 1 to 6 Modified Prolo Scale.<sup>4</sup> There was a 0.4 improvement in the mean scores between the 6- and 24-month follow-up visits (Fig. 1). In a later study of the same device, the 4-year results were presented on a subgroup of patients.<sup>8</sup> This longer follow-up data indicated that there was no significant change in scores between the 24- and 48-month mean scores.

In the Ray study, results were reported in terms of the percentage of patients with excellent, good, or fair results at various follow-up periods.<sup>5</sup> The percentage of patients classified as having a favorable outcome increased 14% on the

pain assessment and 8% on the functional assessment between 6 and 24 months (Fig. 2).

In the Brantigan et al. study, pain was assessed using a 1 to 5 point Likert scale, with greater scores indicating less pain.<sup>2</sup> The mean scores changed by only 2.7% (improvement) between the 6- and 24-month follow-up visits (Fig. 3).

In the study investigating the use of rhBMP-2 in tapered cages, back and leg pain were assessed separately, each on a 20 point scale evaluating pain intensity and duration.<sup>3</sup> Pain and Oswestry scores stabilized after six months (Fig. 4). The

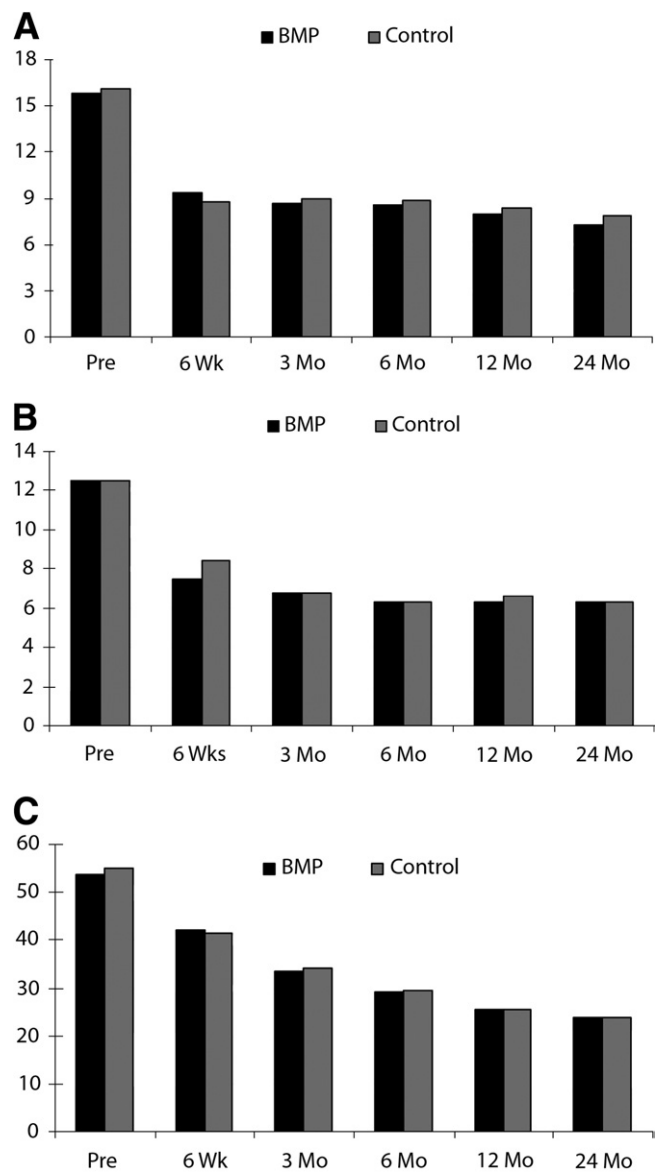


Fig. 4. (A) The only changes in the mean back pain scores between the 6- and 24-month follow-up were improvements of 1.3 (on a scale of 20) in the BMP group and 1.0 in the control group. (B) There were no changes in the mean leg pain scores when comparing the 6- and 24-month follow-up values in the investigational or control group. (C) Mean Oswestry scores stabilized in both groups 6 months after surgery. Scores improved 5.4 in the the BMP group and 5.6 in the control group between 6 months and 24 months. (Graphs generated from data published by Burkus et al.<sup>3</sup>)

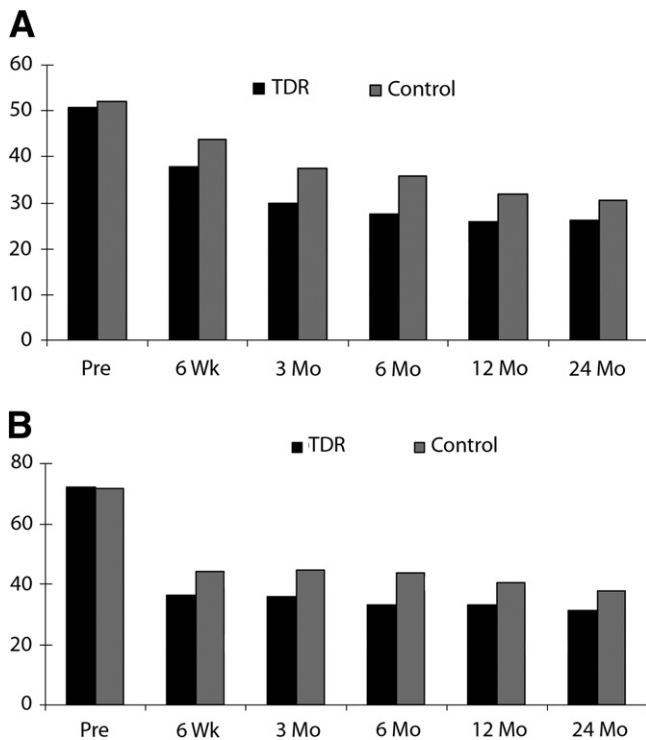


Fig. 5. (A) In the TDR group, there was a 1.2% change between the 6-month and 24-month Oswestry scores. In the fusion group, the scores improved 5.3% between these two time periods. (B) In the TDR group, there was a 1.9% change between the 6-month and 24-month VAS pain scores. In the fusion group, the scores showed an improvement of 6.4% between these follow-up periods. (Graphs generated from data published by Blumenthal et al.<sup>1</sup>)

mean back pain scores improved slightly (1.3 in the treatment group and 1.0 in the control group on a scale of 0 to 20) between 6- and 24-month follow-up. The leg pain scores did not change between these 2 follow-up periods. Oswestry scores changed only 5.4 (on a scale of 0 to 100). This study also reported the percentage of patients working at the various follow-up periods. At 6 months, 50.7% of the BMP group and 45.5% of the control group were working. At 24 months, these figures improved to 66.1% and 56.1%, respectively. A recent study reporting 6-year outcome in this group found that there were no significant changes in outcome scores between the 2-year and 6-year follow-up.<sup>9</sup> The authors stated that improvements in mean scores noted at 6 weeks were maintained at the 6-year follow-up. Data comparing specifically the 6-month to 6-year results were not available from the paper.

In the Blumenthal et al. study, visual analogue scale (VAS) and Oswestry (ODI) scores were stable between 6 and 24 months in both the total disc replacement (TDR) and fusion groups (Fig. 5).<sup>1</sup> In the TDR group, the mean VAS score improved only 1.9% and the Oswestry scores improved 1.2% between the 6- and 24-month follow-up periods. The fusion group had slightly greater improvements during this time frame with the VAS scores improving 6.4% and the mean Oswestry scores improving 5.3%. In a recent

report on the 5-year follow-up of patients enrolled in this study, no changes in outcome were found in the treatment or control group between the 24-month and 60-month follow-up scores on the Oswestry or VAS.<sup>10</sup>

In the FDA submission data for the other TDR trial, the mean Oswestry scores improved by approximately 4% in the TDR and fusion groups between 6 and 24 months postoperative (Fig. 6A).<sup>11</sup> The VAS and satisfaction scores appeared to remain stable (Fig. 6B), although the numerical data were not available to calculate the actual change in scores between 6- and 24-month follow-up for these two outcome measures.<sup>7</sup>

In the interspinous device study, the symptom severity scores remained relatively unchanged between 6 and 24 months in both the investigational and control groups (Fig. 7A).<sup>6</sup> A slight decrease in the percentage improvement in physical function scores was observed at 24 months in both treatment groups (Fig. 7B). These changes were not statistically significant.

#### Complications

Device safety is paramount in evaluating new technologies. Several postoperative device-related problems were reported in the studies reviewed, but their time frames were not reported.

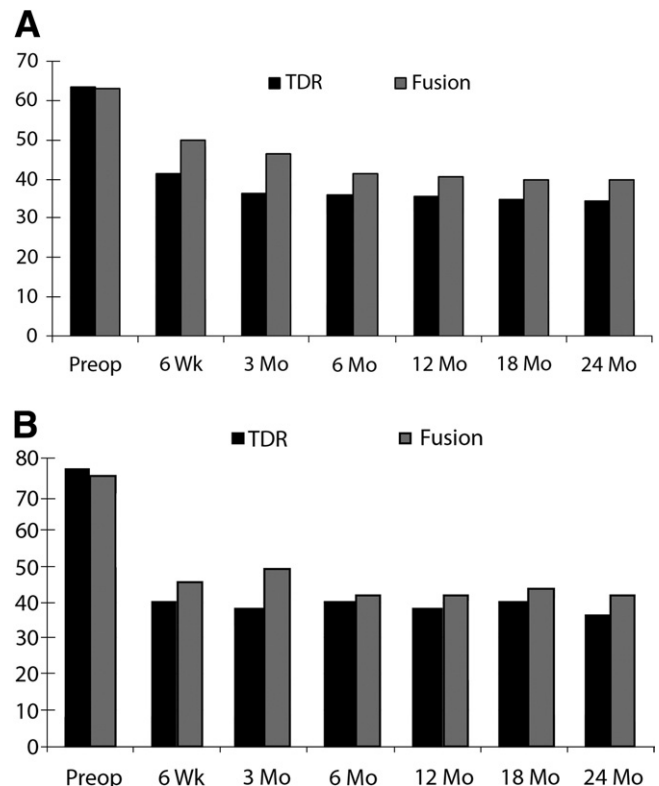


Fig. 6. (A) The mean Oswestry scores improved by approximately 4% between 6 and 24 months in both the TDR and fusion groups. (Created based on data from reference 11). (B) The mean VAS pain scores changed only slightly between 6 months to 24 months in both the ProDisc and fusion groups. (Adapted from Zigler et al.<sup>7</sup>)



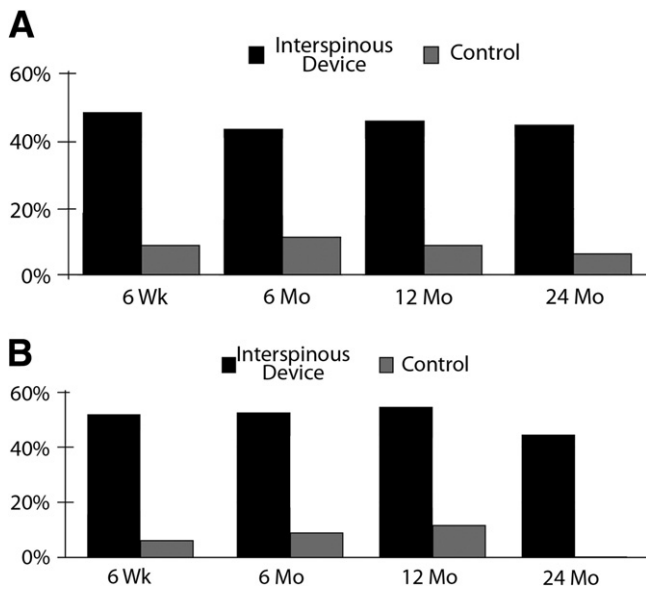


Fig. 7. (A) Outcome was reported as the percent change in the preoperative to postoperative scores at the various time periods on the symptom severity outcome assessment. There were no significant changes in scores between 6 and 24 months in either the interspinous device or control groups. (B) Based on the physical function scores, there were no significant differences between the 6 and 24 month time points for either the interspinous device or control groups, although some decrease in the percentage improvement was seen in both groups. (Adapted from Zucherman et al.<sup>6</sup>)

Results from a survival analysis of a TDR device based on data for almost 2,000 patients from 8 international sites were reported.<sup>12</sup> The analysis covered a span of 60 months. The survival rate was 93% with a rate of at least 90% at each of the individual centers. The authors also noted that the majority of reoperations occurred during the first 24 months. The rate between 6 and 24 months could not be compared based on the data in the abstract.

## Discussion

This study found that there were no significant differences in outcome measures between the 6 and 24-month follow-up evaluations in studies dealing with lumbar spinal implants. The outcome measures used in these studies included in the review varied. While this is typically a weakness in review and meta-analysis studies, it was actually a strength in the current study. Regardless of the outcome measure used, the scores were stable between the 6- and 24-month follow-up visits. This supports the generalizability of the finding. In most studies there was a slight, not statistically significant, improvement between the 6- and 24-month follow-up visits. In only the interspinous device study was there a diminution in the percentage improvement in the outcome measures; however, this change was not significant. These findings supports that there was no worsening of scores during the longer follow-up, suggesting that the 24-month results were at least as good as the 6-month values.

The reason for the stability in the scores could not be determined from the data presented in the studies reviewed. There are two possibilities. First, the data may be stable for each patient. That is, care providers could feel relatively comfortable that the patient's condition at 6 months after surgery will remain stable during future follow-up visits. The other possibility is that when analyzing a group of patients there are compensatory changes among patients. That is, some patients improve while others worsen. These compensatory changes could produce mean values similar to those that would be produced by individual patients stabilizing early in the study. Investigating which of these scenarios occurs in the studies would require analyzing changes in scores for each patient across time. Such data are not available from the literature. However, such work is currently underway at our center to determine if the stability over time is due to each patient's scores remaining relatively stable or if there tends to be compensatory improvement and worsening between patients that produces stable mean values.

The data analyzed for this study came from studies evaluating patients undergoing implantation of a spinal device for the treatment of symptomatic degenerative spinal conditions. The results of this study found that in prospective clinical trials evaluating lumbar spinal implants, there is little change in the mean outcome scores following the 6-month follow-up period. Dissemination of early results, positive or negative, could help guide decision making. It may also provide information earlier to those designing the next generation of implants to address any problems with those currently under evaluation.

One important factor that could not be addressed in this study was comparing the occurrence of device-related complications or reoperations between the 6-month and 24-month follow-up periods. While such events were reported in the reviewed studies, the timing of the events was not reported and thus temporal comparison, which is the focus of this paper, could not be made. Of note, follow-up of greater than 5 years available for some of the devices included in this study have not identified a significant increase in device failure beyond 2-year follow-up.<sup>8–10,12–15</sup>

Of course, long-term follow-up is desirable and important for ongoing assessment of implants. The results of this study, reviewing outcomes from a variety of devices and using a variety of outcome assessments, found no significant changes in outcome scores between the 6-month and 24-month follow-up periods. Longer follow-up for some of these devices has not identified significant problems with device failure in 5 to more than 10 years.<sup>8–10,12–15</sup> The results of this review study support that earlier dissemination of results of new implants may be acceptable without producing overly optimistic reports.

## Extended references

A prospective, randomized, multicenter Food and Drug Administration Investigational Device Exemption study of lumbar total disc replacement with the CHARITE Artificial Disc versus lumbar fusion:

**Part I: Evaluation of clinical outcomes.**

Blumenthal S, McAfee PC, Guyer RD, Hochschuler SH, Geisler FH, Holt RT, et al.

**STUDY DESIGN:** A prospective, randomized, multicenter, Food and Drug Administration-regulated Investigational Device Exemption clinical trial. **OBJECTIVES:** The purpose of this study was to compare the safety and effectiveness of lumbar total disc replacement, using the CHARITE artificial disc (DePuy Spine, Raynham, MA), with anterior lumbar interbody fusion, for the treatment of single-level degenerative disc disease from L4-S1 unresponsive to non-operative treatment. **SUMMARY OF BACKGROUND DATA:** Reported results of lumbar total disc replacement have been favorable, but studies have been limited to retrospective case series and/or small sample sizes. **METHODS:** Three hundred four (304) patients were enrolled in the study at 14 centers across the United States and randomized in a 2:1 ratio to treatment with the CHARITE artificial disc or the control group, instrumented anterior lumbar interbody fusion. Data were collected pre- and perioperatively at 6 weeks and at 3, 6, 12, and 24 months following surgery. The key clinical outcome measures were a Visual Analog Scale assessing back pain, the Oswestry Disability Index questionnaire, and the SF-36 Health Survey. **RESULTS:** Patients in both groups improved significantly following surgery. Patients in the CHARITE artificial disc group recovered faster than patients in the control group. Patients in the CHARITE artificial disc group had lower levels of disability at every time interval from 6 weeks to 24 months, compared with the control group, with statistically lower pain and disability scores at all but the 24 month follow-up ( $P < 0.05$ ). At the 24-month follow-up period, a significantly greater percentage of patients in the CHARITE artificial disc group expressed satisfaction with their treatment and would have the same treatment again, compared with the fusion group ( $P < 0.05$ ). The hospital stay was significantly shorter in the CHARITE artificial disc group ( $P < 0.05$ ). The complication rate was similar between both groups. **CONCLUSIONS:** This prospective, randomized, multicenter study demonstrated that quantitative clinical outcome measures following lumbar total disc replacement with the CHARITE artificial disc are at least equivalent to clinical outcomes with anterior lumbar interbody fusion. These results support earlier reports in the literature that total disc replacement with the CHARITE artificial disc is a safe and effective alternative to fusion for the surgical treatment of symptomatic disc degeneration in properly indicated patients. The CHARITE artificial disc group demonstrated statistically significant superiority in two major economic areas, a 1-day shorter hospitalization, and a lower rate of reoperations (5.4% compared with 9.1%). At 24 months, the investigational group had a significantly higher rate of satisfaction (73.7%) than the 53.1% rate of satisfaction in the control group ( $P = 0.0011$ ). This prospective randomized multicenter study also demon-

strated an increase in employment of 9.1% in the investigational group and 7.2% in the control group.

**Anterior lumbar interbody fusion using rhBMP-2 with tapered interbody cages.**

Burkus JK, Gornet MF, Dickman CA, Zdeblick TA.

In a multicenter, prospective, randomized, nonblinded, 2-year study, 279 patients with degenerative lumbar disc disease were randomly divided into two groups that underwent interbody fusion using two tapered threaded fusion cages. The investigational group (143 patients) received rhBMP-2 on an absorbable collagen sponge, and a control group (136 patients) received autogenous iliac crest bone graft. Plain radiographs and computed tomographic scans were used to evaluate fusion at 6, 12, and 24 months after surgery. Mean operative time (1.6 hours) and blood loss (109.8 mL) were less in the investigational rhBMP-2 group than in the autograft control group (2.0 hours and 153.1 mL). At 24 months the investigational group's fusion rate (94.5%) remained higher than that of the control group (88.7%). New bone formation occurred in all investigational patients. At all intervals, mean postoperative Oswestry, back pain, and leg pain scores and neurologic status improved in both treatment groups with similar outcomes. In the control group, eight adverse events related to the iliac crest graft harvest occurred (5.9%), and at 24 months 32% of patients reported graft site discomfort and 16% were bothered by its appearance. Lumbar fusion using rhBMP-2 and a tapered titanium fusion cage can yield a solid union and eliminate the need for harvesting iliac crest bone graft.

**Threaded titanium cages for lumbar interbody fusions.**

Ray CD.

**STUDY DESIGN:** This study evaluated safety, fusion success rate, and clinical outcome of a new lumbar interbody hollow, threaded titanium fusion cage in a multicenter, prospective 236-case program adhering to a United States Food and Drug Administration Investigational Device Exemption controlled protocol. **OBJECTIVES:** The results were evaluated to demonstrate the safety and effectiveness of this new method to achieve solid lumbar interbody fusions. **SUMMARY OF BACKGROUND DATA:** Interbody fusions have certain distinct mechanical advantages over lateral or posterolateral ones. Autologous, cancellous bone is the preferred graft material, but is too soft to maintain the space during fusion without mechanical support. Various methods have been used in the past to maintain the graft integrity during fusion development. **METHODS:** An initial pilot study began on 10 patients (followed for 84 months, average 80 months). Two years after that investigation started, the multicenter United States Food and Drug Administration Investigational Device Exemption study began, with cases followed for 28–46 months (average, 32). Ninety-six percent of the investigational Device Exemption study cases had severe, disabling back pain; in addition, 74% had major annular degeneration; 57% had herniations;

21% had osteophytes; and 43% had disc height reduced by greater than 10%. Forty-five percent of cases had previous spinal surgeries, and none were posterior lumbar interbody fusions. Titanium fusion cage pairs were screwed into bored and threaded, parallel intradiscal holes, and 3–8 ml autologous cancellous bone was packed inside each. Fusion success was judged by absence of motion on flexion-extension radiographs, absence of bone halo around the implants, and maintenance of visible bone inside the cages on Ferguson view radiographs. **RESULTS:** Segments fused rapidly; the pilot study cases fused at 10 (91%) of 11 levels, with a reported 80% average clinical improvement. Ninety-six percent of the 208 2-year follow-up Investigational Device Exemption cases had fusion, and the Prolo socioeconomic/functional improvement scale showed: 40% excellent, 25% good, 21% fair, and 14% poor results. Less than 1% of Investigational Device Exemption cases had complications that persisted beyond the average 5 days of hospitalization, and none were serious. **CONCLUSIONS:** The Ray titanium fusion cage (Surgical Dynamics, Norwalk, CT) implant method has been found to be an effective, rapid, safe procedure for lumbar spine fusions, demonstrating a high fusion rate and clinical success with rare, serious, or permanent complications.

**A multicenter, prospective, randomized trial evaluating the X STOP interspinous process decompression system for the treatment of neurogenic intermittent claudication: two-year follow-up results.**

Zucherman JF, Hsu KY, Hartjen CA, Mehalic TF, Implicito DA, Martin MJ, et al.

**STUDY DESIGN:** A randomized, controlled, prospective multicenter trial comparing the outcomes of neurogenic intermittent claudication (NIC) patients treated with the interspinous process decompression system (X STOP) with patients treated nonoperatively. **OBJECTIVE:** To determine the safety and efficacy of the X STOP interspinous implant. **SUMMARY OF BACKGROUND DATA:** Patients suffering from NIC secondary to lumbar spinal stenosis have been limited to a choice between nonoperative therapies and decompressive surgical procedures, with or without fusion. The X STOP was developed to provide an alternative therapeutic treatment. **METHODS:** 191 patients were treated, 100 in the X STOP group and 91 in the control group. The primary outcomes measure was the Zurich Claudication Questionnaire, a patient-completed, validated instrument for NIC. **RESULTS:** At every follow-up visit, X STOP patients had significantly better outcomes in each domain of the Zurich Claudication Questionnaire. At 2 years, the X STOP patients improved by 45.4% over the mean baseline Symptom Severity score compared with 7.4% in the control group; the mean improvement in the Physical Function domain was 44.3% in the X STOP group and -0.4% in the control group. In the X STOP group, 73.1% patients were satisfied with their treatment compared with 35.9% of control patients. **CONCLUSIONS:** The X STOP provides a conservative yet effective treatment for patients suffering

from lumbar spinal stenosis. In the continuum of treatment options, the X STOP offers an attractive alternative to both conservative care and decompressive surgery.

**Results of the prospective, randomized, multicenter Food and Drug Administration Investigational Device Exemption study of the ProDisc-L Total Disc Replacement versus circumferential fusion for the treatment of 1-level degenerative disc disease.**

Zigler J, Delamarter R, Spivak JM, Linovitz RJ, Danielson GO, 3rd, Haider TT, et al.

**STUDY DESIGN:** A prospective, randomized, multicenter, Food and Drug Administration-regulated Investigational Device Exemption clinical trial. **OBJECTIVE:** To evaluate the safety and effectiveness of the ProDisc-L (Synthes Spine, West Chester, PA) lumbar total disc replacement compared to circumferential spinal fusion for the treatment of discogenic pain at 1 vertebral level between L3 and S1. **SUMMARY OF BACKGROUND DATA:** As part of the Investigational Device Exemption clinical trial, favorable single center results of lumbar total disc replacement with the ProDisc-L have been reported previously. **METHODS:** Two hundred eighty-six (286) patients were treated on protocol. Patients were evaluated before and after surgery, at 6 weeks, 3, 6, 12, 18, and 24 months. Evaluation at each visit included patient self-assessments, physical and neurologic examinations, and radiographic evaluation. **RESULTS:** Safety of ProDisc-L implantation was demonstrated with 0% major complications. At 24 months, 91.8% of investigational and 84.5% of control patients reported improvement in the Oswestry Low Back Pain Disability Questionnaire (Oswestry Disability Index [ODI]) from preoperative levels, and 77.2% of investigational and 64.8% of control patients met the > or =15% Oswestry Disability Index improvement criteria. Overall neurologic success in the investigational group was superior to the control group (91.2% investigational and 81.4% control;  $P = 0.0341$ ). At 6 weeks and 3 months follow-up time points, the ProDisc-L patients recorded SF-36 Health Survey scores significantly higher than the control group ( $P = 0.018$ ,  $P = 0.0036$ , respectively). The visual analog scale pain assessment showed statistically significant improvement from preoperative levels regardless of treatment ( $P < 0.0001$ ). Visual analog scale patient satisfaction at 24 months showed a statistically significant difference favoring investigational patients over the control group ( $P = 0.015$ ). Radiographic range of motion was maintained within a normal functional range in 93.7% of investigational patients and averaged 7.7 degrees. **CONCLUSIONS:** ProDisc-L has been found to be safe and efficacious. In properly chosen patients, ProDisc-L has been shown to be superior to circumferential fusion by multiple clinical criteria.

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