ECHNIQUES for lumbar interbody fusion have evolved rapidly over the last decade because of recent advances in instrumentation. The development of interbody prosthesis began in veterinary medicine in the 1970s; the goal was to achieve cervical fusion in horses with cervical spondylosis,14 and the original device was a cortical bone dowel similar to that used in a Cloward-type fusion. This led to the development of threaded interbody metallic devices, which were investigated and cleared by the United States Food and Drug Administration on a limited basis. Subsequently, there has been a large resurgence of procedures in which interbody fusion is performed. A wide array of devices is available for interbody fusion at all levels of the spine. Although fusion rates and outcomes for procedures in which TCBDs are used in the cervical region are well documented, little has been reported regarding the application of TCBDs in the lumbar region. In this report we detail our 1-year follow-up results and review the literature regarding interbody devices.

Clinical Material and Methods
Between June 1997 and December 1998, ALIF or PLIF was performed in 35 patients by two surgeons (G.E.R. and R.W.H.) who used TCBDs (Regeneration Technologies, Alachua, FL) to treat mechanical low-back or discogenic
pain. The series was composed of 18 men and 17 women whose mean age was 46 years (range 17–76 years). There were nine active cigarette smokers. Data were collected by chart review and clinical follow-up examination. Immediate postoperative static radiographs and follow-up static and dynamic radiographs were reviewed to determine changes in lordosis as well as the success of fusion and spinal stability. In some cases, CT scanning was used for supplemental verification of plain radiographic findings. All patients presented with symptoms consistent with mechanical low-back pain or discogenic pain. Operative criteria for ALIF were intractable back pain that was unresponsive to nonoperative management; minimal or no radicular pain; magnetic resonance imaging—confirmed degenerative changes; disc collapse greater than 50% of one or two levels compared with the adjacent normal-appearing level(s); and concordant pain provocation as demonstrated on discography in some cases. Operative criteria for PLIF were the same as those for ALIF with the addition of significant posterior disease such as lateral recess or foraminal stenosis.

Twenty-three patients underwent PLIF and 12 underwent ALIF for the placement of the TCBD implants. In all patients except one in the PLIF group, pedicle screw and rod constructs were used without posterolateral fusion. In all ALIF procedures except one, TCBDs were used as stand-alone devices without posterior tension-band fixation. All TCBDs were packed with morselized cancellous autograft prior to implantation. Outcomes assessed using a modified Prolo Scale were rated as excellent, good, fair, or poor. Excellent and good outcomes were considered satisfactory; fair or poor outcomes were considered unsatisfactory.

The vertebral levels at which implants were inserted were as follows: L3–4 (one patient), L4–5 (11 patients), L5–S1 (eight patients), transitional (L6–S1, one case), L4–S1 (two-level implants: one ALIF and one PLIF patient). Fusion was determined at follow-up intervals and was defined as the following: the absence of luencies around TCBDs; an increase in subchondral endplate sclerosis; and the presence of bridging bone incorporating the anterior bone graft, as demonstrated on static lumbar radiographs (Figs. 1 and 2 left).

In some cases, noncontrast-enhanced CT scans were obtained to confirm plain radiographic findings. Spinal stability was also judged by an absence of movement on dynamic lumbar radiographs. The radiographic determination of fusion and stability was confirmed in all cases by both a senior author (R.W.H. and G.E.R.) and an attending radiologist.

Angulation was determined using a modified Cobb technique by measuring a line parallel to the superior endplate of the superior VB and a line parallel to the inferior endplate of the inferior VB. Angulation observed on immediate postoperative x-ray films was measured and compared with VB angulation on follow-up studies.

Outcomes were determined using a modified Prolo Scale (excellent, good, fair, or poor) based on the results of follow-up physical examination and interview. In cases of excellent outcome, the patient subjectively noted a significant improvement in pain status, was participating fully in premorbid activities and/or working full time, and required minimal or no narcotic/analgesic medications. In cases of good outcome, the patient noted a subjective improvement in pain, had returned to work on a part-time basis, and/or had partially returned to premorbid activities and required reduced doses of narcotic and/or analgesic substances. In cases of fair outcomes, patients reported a mild improvement in pain status, a diminished degree of participation in premorbid and/or work activities, and no change in analgesic/narcotic use. In cases of poor outcome, the patient’s pain status was unchanged or worse than preoperatively; there was no participation in work and/or premorbid activities, and there was no change or increased usage of narcotic/analgesic substances.

Results

In 28 patients adequate clinical and radiographic follow-up data were available for review (eight [67%] of 12 patients in the ALIF group and 20 [87%] of 23 patients in the PLIF group). The remaining seven patients did not keep follow-up appointments and could not be contacted at the last known address. There were no significant differences in age, sex, or smoking characteristics among the initial 35 patients and those included in the follow up (p < 0.05, analysis of variance). There were no significant differences in age, sex, or smoking characteristics between patients in the ALIF and PLIF groups (p < 0.05; Table 1). The overall mean duration of follow up was 12.3 months. The mean duration of follow up was 12.4 months in the PLIF group and 12.1 months in the ALIF group. Outcome study data comprised only those patients for whom minimum 12-month radiological and clinical follow-up data were available.

Overall outcome was 60% satisfactory: 70% satisfactory in patients who underwent PLIF and 38% in those who underwent ALIF.

The overall fusion rate was 70%. In patients who underwent ALIF the fusion rate was 13% (one of eight patients available for follow up). Osseous fusion was observed in 95% of the 20 patients who underwent PLIF. Of note, the
one patient in the PLIF group in whom fusion did not occur had undergone an L5–S1 procedure in which supplemental screw and tension-band fixation was not performed (Fig. 3).

The mean kyphotic change in modified Cobb angle between operation and follow up was 3.7˚ in the ALIF group and 3.2˚ in the PLIF group, representing a mean loss of lordosis of 12% and 10%, respectively.

There were four complications: one L-5 nerve root injury, which resolved with observation; two deep postoperative infections, which resolved with operative debridement, irrigation, and intravenously administered antibiotic medication; and lateral breakout of an implant, which was detected on a CT scan 8 months postoperatively (Fig. 2 upper right).

Discussion

Among lumbar interbody fusion devices, titanium cages have been determined to provide a reliably high fusion rate.5–7,9–12,16 There are numerous types of cages available including cylinders, vertical rings, and open boxes.15 Horizontal cylinders such as the BAK cage, Ray cage, and impacted carbon cages provide excellent segmental stability, as has been evidenced in both animal and human cadaver studies.4,6,8,13 Investigators in prospective multicenter studies of the BAK device found overall fusion rates of 85.6%, 90.6%, and 98.3% at 1, 2, and 3 years postoperatively, respectively, with significant improvement in pain and functional status among the patient population (unpublished data). In a different study there was a 96% fusion rate at 2-year follow up in patients in whom the Ray cage was implanted; 86% of these patients experienced satisfactory clinical relief of their back or radicular pain.10 Agazzi, et al.,1 have reported a 90% fusion rate in a mean 28-month follow-up period when using impacted carbon cages.

Compared with titanium cages, TCBDs may have the advantage of allowing easier radiographic assessment of fusion and may be more amenable to surgical revision. Moreover, TCBDs have a modulus of elasticity similar to that of native bone in the area of implantation as opposed to titanium and carbon fiber cages. Theoretically, this may increase the rate of fusion—over that provided by titanium cages—by minimizing stress shielding of the graft and decreasing the degree of subsidence.

There was a markedly higher incidence of fusion in patients who underwent PLIF in which TCBDs were placed in combination with supplemental pedicle screw and rod constructs compared with those who underwent ALIF in which TCBDs alone were implanted (95% and 13%, respectively). This difference in fusion rates correlated with improved clinical outcome in our series, as evidenced by a 32% higher satisfactory outcome rate for PLIF compared with ALIF-treated patients (70% and 38%, respectively). We believe that a 1-year follow-up period is a reasonable amount of time to conclude that TCBDs as stand-alone devices are associated with an unacceptably high rate of radiographically documented pseudarthrosis and poor clinical outcome; as such, we have abandoned the use of TCBDs as stand-alone anterior-approach devices for lumbar interbody fusion. Additional evidence underscoring the ineffectiveness of stand-alone bone dowels in ALIF was observed by a team from the University of Florida who studied 27 patients; at a mean follow up of 10.7 months, a 33% fusion rate was demonstrated in cases of stand-alone ALIF, whereas an 82.4% fusion rate was demonstrated in
We are more optimistic about the PLIF and pedicle screw/rod constructs, with which we have found a 95% fusion rate and 70% satisfactory outcome at 1 year. As noted previously, this construct provides a very rapid and reliably high rate of fusion (94% at 7.9 months) and is easy to evaluate radiographically. Our rate of fusion and 1-year outcomes compare favorably with those achieved using titanium interbody cages.

There were dramatic differences in fusion rates between PLIF and the stand-alone ALIF procedures; we believe this disparity is related to increasing the compression and therefore stress on the graft (the Wolff law), thereby promoting fusion, although we have no objective data to support this contention.

Because of the poor results observed at 12 months, we discontinued use of TCBDs as stand-alone implants in ALIF procedures. As a corollary, we are favorably influenced and encouraged by the fusion and satisfactory outcome rates demonstrated in our patients who underwent PLIF in which TCBD and pedicle screw/rod constructs were placed. We continue to follow this group of patients in an effort to provide longer-term data on the use of TCBDs for lumbar interbody fusion.

**Financial Disclaimer**

Both Drs. Haid and Rodts have significant financial interest in Sofamor Danek Corp., which manufactures and distributes the bone dowels and pedicle screws used in this series of patients.

**References**


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