During the last five years, surgeons around the world have inserted more than 80,000 lumbar interbody fusion cages; in the United States alone, an estimated 5000 such devices are implanted each month. The recent interest in performing lumbar interbody arthrodesis with use of cages is attributable to three factors: the high rate of failure associated with use of bone graft alone[3,22,26,45,46,71,82,84,94,96,106,107]; the high rate of failure associated with use of posterior pedicle-screw instrumentation[39,97,102]; and the high rate of success associated with use of so-called stand-alone anterior fusion cages and autogenous bone graft, obviating the need to perform a 360-degree (combined anterior and posterior) lumbar arthrodesis with use of posterior instrumentation[77].

The purpose of the current review is to summarize the information in the literature with regard to the background, rationale, indications, techniques, results, and possible future developments of interbody arthrodesis for reconstruction of the spine.

Background

Early techniques of arthrodesis with use of allograft or autogenous graft and without instrumentation were associated with a high rate of failure. In a classic study, Stauffer and Coventry[96] reported on eighty-three patients who had had an anterior interbody arthrodesis between 1959 and 1967. Of seventy-seven patients who were followed clinically for an average of 3.75 years after the procedure, twenty-eight (36 percent) had good (76 to 100 percent) relief of pain, fifteen (19 percent) had fair (26 to 75 percent) relief, and thirty-four (44 percent) had poor (0 to 25 percent) relief. Thirty (44 percent) of sixty-eight patients who were evaluated radiographically at a minimum of eighteen months postoperatively had a pseudarthrosis. Stauffer and Coventry defined radiographic fusion as "a pattern of continuous trabeculae traversing the grafted region and the adjacent vertebral bodies, with no evidence of motion when the patient was bending." These results, and the equally unfavorable results reported by other investigators[20,26,33,45,56,57,82], prompted investigation into and development of various augmentation devices to improve the long-term outcome of spinal arthrodesis.

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Technology of Interbody Fusion Cages

History

Bagby[2] was responsible for the early development of the lumbar interbody fusion cage. Working with a veterinarian, Grant, and a series of thoroughbred horses that had wobbler syndrome (a form of spondylitic myelopathy that leads to ataxia), he found that the Cloward technique[20], which requires obtaining bone from the iliac crest, resulted in unacceptable morbidity. Bagby then developed a novel device, the first interbody stainless-steel basket (the Bagby basket), which was a thirty-millimeter-long, twenty-five-millimeter-diameter cylinder that had two-millimeter fenestrations in its walls to allow bone ingrowth. During a standard anterior cervical decompression and reaming procedure, cancellous-bone chips were removed from the posterior aspects of the cervical vertebrae. These chips then were packed inside the basket to promote anterior interbody cervical fusion.

Subsequent studies revealed that horses treated with the Bagby technique had improved neurological function; some not only survived for many years but also won races[38]. Other investigators began making modifications of this technique, including threads in the basket[72,108], adaptation of the cage for use in posterior lumbar interbody arthrodesis, and increases in the pull-out and compressive strength[72]; a two-cage technique also was developed, in 1988[25]. In another study of horses, DeBowes et al.[30] compared the results of arthrodesis with use of bovine xenograft with those of arthrodesis with use of autogenous graft inside a Bagby basket; they found that the rate of fusion was better when the Bagby basket had been used and that this device did not collapse. After the arthrodesis, the gross appearance of the bovine xenograft was usually pale, and seven of eight sites that were investigated were composed of fibrous tissue. The autogenous graft and the Bagby basket contained little or no fibrous tissue. Maceration studies, with use of maggots to decompose the soft-tissue component, indicated that only two of eight bovine xenografts contained enough ossified tissue in the intervertebral space in order to hold the vertebrae to-

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FIG. 1-A

Photograph showing some of the devices studied by Kanayama et al.[47], who used silicone elastomer gel inside cages to measure intracage pressures under *in vitro* loading conditions in an investigation of the forces acting on bone graft within different cage geometries. Bottom left, Brantigan cage; top left, Harms vertical cage; center, elastomer gel; top right, threaded femoral bone dowel; and bottom right, BAK cage.

gether, whereas seven of eight autogenous grafts in the Bagby baskets contained enough tissue.

Current Types of Fusion Cages

A variety of cages are currently available, each with its own indications, advantages, and disadvantages. This review will focus on five devices: the Bagby-and-Kuslich device[51] (BAK; Sulzer Spine-Tech, Minneapolis, Minnesota), the threaded interbody fusion device (TIBFD; Medtronic Sofamor-Danek Group, Memphis, Tennessee), the Ray cage (U.S. Surgical, Norwalk, Connecticut), the Harms titanium-mesh cage (DePuy-AcroMed, Cleveland, Ohio), and the Brantigan rectangular and rounded cages (DePuy-AcroMed). Most of these devices have been approved only for limited, investigational applications in humans because the long-term effects are not yet known. Thus, the BAK device may be used only for posterior, anterior, or lateral laparoscopic procedures; the TIBFD device, only in Food and Drug Administration-Investigational Device Exemption studies; the Ray cage, only as a posterior device; and the Brantigan cages, only as posterior devices and only in conjunction with posterior pedicle-screw instrumentation. Only the Harms cage has been approved for widespread, unrestricted use to date.

Mechanical, Biological, and Physiological Roles of Fusion Cages

In an effort to establish a baseline for the comparison of investigations of the role of fusion cages, Dennis et al.[31] studied thirty-one patients who had had an anterior interbody arthrodesis at a total of forty levels with use of autogenous graft or allograft but not metal cages. The height of the disc space was measured in each patient preoperatively, early postoperatively, and at an average of twenty-nine months postoperatively. Although immediate postoperative radiographs showed an average increase in the disc-space height of 9.5 millimeters (89 percent), use of graft alone did not provide long-term distraction of the disc space or increased neuroforaminal height. At the time of the latest follow-up examination, the disc-space height had decreased in every patient; at nineteen of the forty vertebral levels, the height at the most recent examination was less than the preoperative height. That study demonstrated that autogenous graft or allograft alone cannot maintain neuroforaminal distraction. Maintaining this distraction is important because it promotes anterior load-sharing, increases the amount of space for the nerve roots, and prevents flatback syndrome.

Mechanical Role

Rapoff et al.[76] compared the mechanical effects of the TIBFD and BAK cages in six fresh-frozen, thawed spines from human cadavera and found that the insertional torque and maximum pushout loads were similar for the two cages. Other authors have determined that the amount of interspace distraction is as important to the overall stability of the construct as the individual characteristics of the fusion cage[15,36,37,87,99].

Kanayama et al.[47] used bench-top mechanical tests to assess different types of fusion cages in sixty functional calf-spine units, each consisting of one vertebral disc space and the adjacent vertebrae (Fig. 1-A). There were six specimens in each treatment group. The methods of preparation of the cage, anterior discectomy, and annular distraction with use of sized distraction plugs before insertion of the cage were similar for all ten constructs. The devices that were tested included two BAK cages, two BAK proximity cages, two Ray cages,

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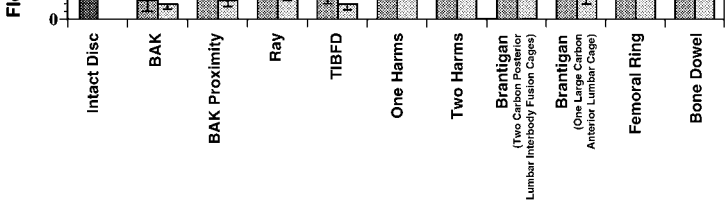

FIG. 1-B

Bar graph showing the intracage pressure measurements for the ten cage constructs. The four threaded titanium designs (BAK [Bagby and Kuslich], BAK proximity, Ray, and TIBFD [threaded interbody fusion device]) had significantly lower (more favorable) intracage pressures than did the other implants ($p < 0.05$, one-way analysis of variance). * = cage alone was significantly different from Group-A devices, ^ = cage alone was significantly different from BAK and TIBFD devices ($F = 8.15$, $p < 0.001$), and ^^ = cage alone was significantly different from cage with pedicle screws ($p < 0.05$). One pound per square inch = 6.89 kilopascals.

two TIBFD cages, one Harms titanium-mesh cage, two Harms vertical titanium-mesh cages, two Brantigan rectangular carbon-fiber cages, a larger rounded Brantigan anterior lumbar interbody fusion cage shaped to fit within the interbody disc space, one femoral ring allograft, and two bone-dowel allografts. The modes of testing included axial compression (500 newtons), torsion (three newton-meters), flexion (five newton-meters), and lateral bending (five newton-meters). Intracage pressures were measured with pressure-needle transducers throughout the various loading conditions after a silicone elastomer gel had been injected into the cages and allowed to polymerize. The purpose of the gel was to provide a homogeneous material, simulating bone graft, inside each cage for measurement of strain. Pilot studies had shown that it was not useful to measure the strain on actual bone graft as such strain proved to be extremely variable and depended on the amount of force used to pack the bone graft inside the cage. With the numbers available for study, no significant differences were detected among the ten cage constructs with regard to functional stability ($p > 0.05$, one-way analysis of variance). Intracage pressure was not found to be significantly different among the Harms titanium-mesh vertical cages, the Brantigan cages, the femoral ring allograft, or the bone-dowel allografts; however, the four threaded cages (the BAK, BAK proximity, Ray, and TIBFD devices) had significantly lower intracage pressures than did the other implants ($p < 0.05$, one-way analysis of variance) (Fig. 1-B). These findings were supported by those of Oxland et al.[73], who found no difference in bench-top mechanical loading between two porous bilateral BAK implants and a central contoured SynCage implant with end-plate fit.

Biological Role

To date, to the best of my knowledge, the only study of long-term results with use of fusion cages was reported by Cunningham et al.[27]. After an average of fourteen years (range, eight to fifteen years), histological analysis of six vertebral specimens from horses that had had an anterior interbody arthrodesis with insertion of a stainless-steel Bagby basket revealed successful fusion with mature trabecular bone spanning the sites of the arthrodesis. There was a significant decrease in bone-mineral density ($p < 0.05$) at the fusion site compared with that of the adjacent vertebral bodies, but this stress-shielding had no adverse clinical consequences. Sagittal microradiographs showed complete remodeling of the entire disc space, including the end plate and residual posterior remnants of the interbody disc posterior to the basket (Figs. 2-A and 2-B). Whether this equine model can be equated with the human situation remains to be determined.

Physiological Role

In a study of nine fresh-frozen lumbar spines from the cadavera of individuals who had had neuroforaminal stenosis, Chen et al.[18] found that placement of silicone molds in the neuroforamina after the application of a fusion cage significantly increased the neuroforaminal volume (by 23 percent at the fourth and fifth lumbar

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FIG. 2-A

FIG. 2-B

Microradiographs showing the extent of trabecular remodeling fourteen years after treatment with a Bagby basket (Fig. 2-A) and a bone-dowel allograft (Fig. 2-B, arrows) from the study by Cunningham et al.[27], who examined six equine specimens at an average of fourteen years after a successful anterior interbody arthrodesis and insertion of a Bagby stainless-steel basket.

level and by 22 percent at the fifth lumbar and first sacral level) and the posterior disc height (by 37 percent at the fourth and fifth lumbar level and by 45 percent at the fifth lumbar and first sacral level) ($p < 0.001$ for both).

Selection of Patients for Arthrodesis with Use of an Interbody Fusion Cage

Ray[78], in a Food and Drug Administration-approved Investigational Device Exemption study, selected patients for insertion of a lumbar interbody fusion cage with use of six criteria: severe, disabling, intractable back pain; degenerated disc spaces with resultant pain; an absence of disc-space or systemic infection; no previous interbody arthrodesis at the target levels; an absence of degeneration at adjacent, neighboring disc spaces, whether or not they were painful; and no or Meyerding[69] grade-I spondylolisthesis. In addition, the disabling back pain had to have been present for at least one year and refractory to extensive nonoperative care and there had to be substantial loss of both disc height and mobility. Patients who had a disc-space height of more than twelve millimeters were excluded.

I believe that most of these criteria are not selective enough; cages have been used for patients who have general disc pain or disc spaces that appear dark on magnetic resonance imaging studies (so-called black-disc disease — that is, the earliest changes, on magnetic resonance images, caused by degenerative disc disease that is due to loss of hydration signal within the nucleus pulposus). I prefer a more conservative selection process, with use of cages limited to patients who have postlaminectomy syndrome or disc-space collapse with neuroforaminal narrowing. I do not use cages for patients who have black-disc disease or simply a positive discogram. Most patients whom I manage with a cage have disease involving only one disc level, and I do not use the device for those with involvement of more than two levels. If a patient has instability at more than two levels, it should be treated with a posterior approach and pedicle-screw instrumentation.

Definition of Fusion

As stated in one review article[33], the rate of fusion "depends to a great extent on the investigator's interpretation." Because there is no single definition of what constitutes fusion, it is difficult if not impossible to compare the results of different studies. Moreover, it is difficult to determine radiographically if fusion has occurred. In addition, findings of biomechanical tests of stability do not always directly correspond to radio-

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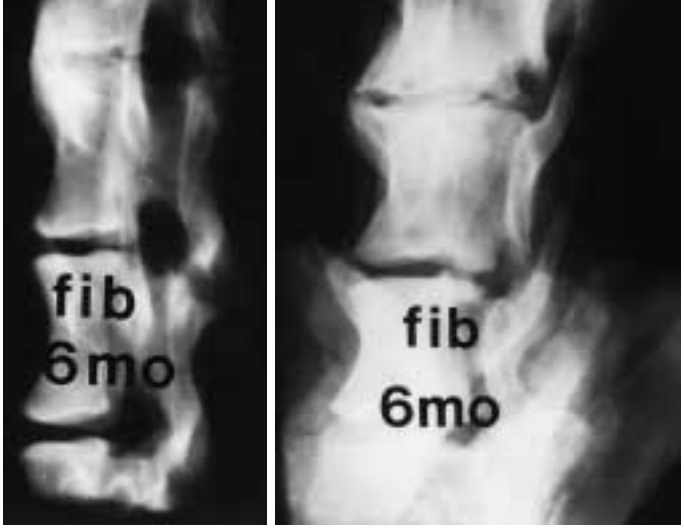

FIG. 3-A FIG. 3-B

Radiographs demonstrating the paradox regarding a solid fusion compared with a so-called functional arthrodesis. Most investigators would agree that Fig. 3-A shows a fusion (as indicated by solid, continuous trabecular bone-bridging between the vertebrae) and that Fig. 3-B shows a pseudarthrosis according to the criteria of Stauffer and Coventry[96] (a two-to-three-millimeter fibrous interface between the vertebral bodies). In laboratory testing, however, the flexural, torsional, and axial compressive stiffnesses were greater for the specimen shown in Fig. 3-B than for that shown in Fig. 3-A[59]; this was because the cross-sectional area of the hypertrophic pseudarthrosis callus in the specimen shown in Fig. 3-B was much greater than the cross-sectional area of the specimen shown in Fig. 3-A. (Reprinted, with permission, from: McAfee, P. C.; Regan, J. J.; Farey, I. D.; Gurr, K. R.; and Warden, K. E.: The biomechanical and histomorphometric properties of anterior lumbar fusions: a canine model. J. Spinal Disord., 1: 105, 1988.)

graphic evidence of fusion. For example, a radiographically solid fusion with continuously bridging trabecular bone in a canine specimen (Fig. 3-A) had less mechanical stiffness than did a specimen that contained a two-to-three-millimeter-wide fibrous interface between the vertebral bodies (Fig. 3-B).

The rates of fusion are approximately 20 percent higher when the sole criterion is loss of motion (determined by comparing lateral flexion and extension radiographs) rather than continuous trabeculae across the graft-vertebrae interfaces[4,16,20,23,54-56,59,67,83,85,90,101,104]. One study of 100 patients included eleven who had "a fibrous fusion . . . with absorption of the grafts"; this inclusion resulted in a rate of fusion of 94 percent[21].

My criterion for fusion is the presence of bridging trabecular bone between the vertebral bodies. The most reliable radiographic indication of fusion postoperatively is the sentinel sign, or the presence of bridging bone anterior to the fusion cage (Figs. 4-A, 4-B, and 4-C). Similar to the late-maturation phases of callus formation in a fracture of the femur, the cross-sectional area of an exuberant fracture callus can restore normal stability before mature haversian bone is seen in radiographic continuity. One drawback of a fusion cage inserted after a so-called reamed-channel discectomy is that the reparative process is confined to a smaller cross-sectional area (the fenestrations in the cage) in contrast to uninhibited hypertrophy.

To add to the confusion, the criteria for a successful fusion in patients who are managed with a cage are often different from those used in previous reports. Kumar et al.[50], in a retrospective review of the results for thirty-two patients who had had an anterior lumbar interbody arthrodesis, found that twenty-one patients (66 percent) had radiographic union and stability on flexion and extension, whereas four (13 percent) had nonunion and instability. The radiographic results for the remaining seven patients (22 percent) were ambiguous. Those authors coined the phrase "functional arthrodesis" to describe such patients, with the term

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