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ORIGINAL ARTICLE

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Outcomes of allogenic cages in anterior and posterior lumbar interbody fusion

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Abstract Interbody lumbar fusions provide a proven logical solution to diseases of the intervertebral discs by eliminating motion of the segment. Historically, there are many techniques to achieve spinal fusion in the lumbar spine. These include anterior, posterior, and foramenal approaches, often in combination with various internal fixation devices. The surgeon's choice of the approach and mechanical or biological implant is dependent on the patient's specific pathology and anatomy, in addition to the experience and training of the surgeon in similar conditions. In the past decade, new mechanical spine implants/spacers have been designed to provide restoration of disc height and improve stabilization of the spine. The ability to radiographically assess the "biology" of bone incorporation in these mechanical (metal) spacers has become a significant limitation.

The femoral ring allograft (FRA) and the posterior lumbar interbody fusion (PLIF) spacers have been developed as "biological cages" that permit restoration of the anterior column with machined allograft bone biological cages. Test results demonstrate that the FRA and PLIF spacers have a compressive strength of over 25,000 N. The pyramid-shaped teeth on the surfaces and the geometry of the implant increase the resistance to expulsion at clinically relevant loads (1053 and 1236 N). The technique of anterior column reconstruction with both the FRA and the PLIF biological cages have been previously reported.

Clinical outcomes and experience with the FRA spacer (137 patients) and the PLIF spacer (13 patients) were reported on and did not reveal any evidence of bone cage resorption or infectious inflammatory process. There was clinical migration with one PLIF spacer, which was later revised with an anterior approach and a FRA spacer. The radiographic outcomes demonstrated that 94% arthrodesis was achieved with the biological spacer and additional posterior instrumentation. The clinical success of every spine fusion procedure is dependent on many factors such as the extent of the instability, the pathology, type of graft used, the patient's pathology/anatomy and lifestyle.

Keywords Biological cages · Femoral ring allograft spacer · Posterior lumbar interbody fusion spacer · Interbody lumbar fusion · Arthrodesis

Introduction

Spinal arthrodesis is a generally accepted procedure for the management of patients with a variety of spinal disorders. The primary goal for spinal fusion is to eliminate the instability of the spine, often caused by trauma, deformity, tumor, inflammation or infection, and common degenerative deterioration of the motion segments. In many clinical situations, the optimal solution in restoring the spine's integrity is through surgical intervention. There are many techniques of spinal fusion applicable to the lumbar spine. Posterior (PLIF) and anterior lumbar interbody fusion (ALIF) have been developed and employed to address these concerns alone or in combination with various internal fixation devices. The anterior column is often reconstructed with metallic intervertebral cages or biological implants (allograft or autograft bone) [16, 31].

The success of every spine fusion procedure depends on the phenomenon of bone healing. Whether the healing process occurs depends on many factors, including the type of biological graft, host factors, technique, and the rigidity of the particular surgical construct. Bone grafts serve two main functions: they provide for the synthesis of new bone originating from the host cells (osteogenesis), and they can serve as mechanical/structural support [31]. Graft bone cells have been shown to survive initial transplantation if properly handled to synthesize new bone.

Many studies have compared allografts with autografts in spinal arthrodesis for a variety of pathologic conditions. In adults, autografts are generally superior to allografts for achieving bone fusion. However, under certain circumstances, it may be advantageous to use an allograft. The usage of a structural allograft precludes the need for harvesting a graft from the patient and eliminates the morbidity associated with donor site complications [31]. These complications may include infection, pain, blood loss, secondary fracture, instability at the donor site, and possible neural damage. A recent retrospective study involving the Smith-Robinson technique compared the results of fibular allograft interbody fusions in 23 patients with tricortical iliac autograft fusions in 25 patients [5, 17]. The results indicate that there was no significant difference in the fusion rates in autogenic bone grafting compared with allogenic bone grafting.

Preservation techniques can maintain the graft's mechanical properties and its ability to stimulate osteogenesis while eliminating its antigenicity [14]. Frozen allografts are still somewhat immunogenic. Revascularization and remodeling are delayed compared with fresh autografts, but resorption and osteoconduction occur more rapidly and completely in these grafts. Freeze-drying reduces the immunogenicity of allografts even more, but alters their mechanical properties, resulting in a weaker structure. Although the initial inflammatory stage is diminished after transplantation of frozen or freeze-dried allografts, resorption and ultimately new bone formation will occur slowly.

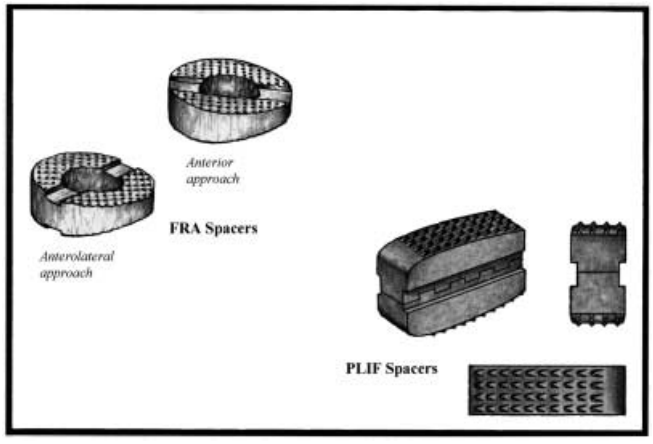

Fig. 1 Femoral ring allograft (*FRA*) and posterior lumbar interbody fusion (*PLIF*) spacers

This paper aims to provide a review of the two newly developed biological cages, the femoral ring allograft (FRA) spacer and the posterior lumbar interbody fusion (PLIF) spacer (Fig. 1). To aid in the understanding of the clinical outcome of these devices, this paper will review the biomechanics, development, and the screening process of these unique "biological cages."

History

As we reflect on past centuries and where science has led us in the study of the spine, we can begin to envision what is in store for the next century. Take, for example, Mercer, who in 1936 stated, "The ideal operation for fusing the spine would be an interbody fusion, but the surgical difficulties encountered in performing such a feat would make the operation technically impossible" [24]. Even among supporters of interbody fusion, enthusiasm for the technique remained sedate until the 1940s. Over the years, many variations of PLIF have been invented to facilitate the fusion process while maintaining stability of the spine. Capener first described ALIF for spondylolisthesis in 1932 [6]. Today, spinal fusion can be accomplished by various techniques such as posterior procedures with and without internal fixation, anterior procedures with and without internal fixation, and combined anterior and posterior column procedures, which may include PLIF or ALIF for anterior column support [31].

During the last decade, an increasing number of studies have looked at the morphology, physiology, biomechanics, and immunology of the various components of the spine [26]. Today, there are several options available to spine surgeons for correcting spinal instabilities and achieving physiological anterior column support, including autograft, allograft, synthetics, and metallic fusion cages. Fresh autologous cancellous bone is considered the

best choice for osseous reconstruction because of its optimal biological behavior and histocompatibility [12]. However, autologous bone has inadequate initial mechanical strength for interbody loading and may collapse and/or extrude [10, 13, 18]. Significant morbidity is also associated with anterior structural graft harvesting of the ilium and may result in infection, chronic pain, incisional hernias, vascular injuries, and iliac wing fractures [30]. The use of allograft is a safe, simple, and inexpensive method of harvesting bone. Through continued clinical research, devices are being manufactured from cortical bone similar to metal fusion cages, providing built-in lordosis and endplate gripping "teeth" for additional stability. Two of these biological devices are the PLIF spacer for PLIF and the FRA spacer for ALIF.

Various aspects of intervertebral disc disease have been proposed as definitive indications for PLIF. Collis' indications are lumbar pain with or without sciatica, a degenerative disc with or without a protrusion, a midline disc protrusion, post-lumbar laminectomy/disectomy syndrome, a recurrent soft tissue protrusion, spondylolisthesis (grade I or II), a reverse spondylolisthesis, or any combination of the preceding seven conditions [8]. The advantages of PLIF are (a) the large surface area for fusions provided by the vertebral bodies, (b) the fusion is in compression across the vertebral bodies, and (c) the potential for partial restoration of disc space height. In addition, because the patient is already exposed for decompression, it eliminates the need for another incision [1]. The disadvantages of PLIF include the high degree of technical demands and the possibility of extrusion of the graft. However, using internal fixation devices probably can decrease this risk. Dural tears are more likely when this extensive exposure is undertaken, and scarring of the anterior portion of the dural sac is more common.

Historically, the indications for and role of anterior spinal surgery of the lumbar spine have been controversial. At present, the specific indications for ALIF include symptomatic post-traumatic kyphosis with or without neurologic sequelae, iatrogenic lumbar kyphosis (flatback syndrome), and painful lumbar degenerative scoliosis with disc disease. In addition, relative indications for anterior internal fixation and fusion include repair of failed posterior fusion, instability secondary to wide laminectomy and posterior decompression, high-grade spondylolisthesis or spondyloptosis, and spinal osteotomy [27].

ALIF has the same potential benefits as PLIF. First, the graft will be in compression, and there is a large area for fusion. In addition, more bone can be placed between the vertebral bodies in ALIF than in PLIF, and the disc height appears to be only temporarily increased. Other advantages include a reduced operative time and blood loss, non-interference with the potentially painful posterior elements of the lumbar spine, and avoidance of scarring within the spinal canal [1]. However, ALIF does have several drawbacks. First, it requires a separate incision. With a transperitoneal approach, there is risk of abdominal adhesions and incisional hernias. Damage to the major vessels is a rare complication. In males, ALIF also carries the risk of impotence or retrograde ejaculation. Isolated ALIF has also been associated with a high pseudoarthrosis rate. For this reason, we routinely combine anterior fusion with posterior intertransverse fusion, often under the same anesthesia, and with internal fixation. This combination achieves the maximum biomechanical stability, neural element decompression, and recruitment of motion segment bone-grafting surface area.

Anatomy and biomechanics of interbody fusion

Interbody fusions provide a logical solution to diseases of the intervertebral disc. The definition of "success" in spine care is controversial and can vary from the perspectives of the patient, family, employer, insurance company, attorney, primary care physician, and the treating surgeon. A fusion is often considered "clinically" successful if (a) there is increased or maintained bone density within the cage implant due to the presence of mature bony trabeculae bridging the interbody space, (b) there is an absence of a "halo" around the implant (resorption), (c) there is a sclerotic line between the cage and vertebral endplate, due to bone remodeling and new bone formation, (d) resorption of anterior vertebral traction spurs or anterior progression of the graft within the disc space occurs, and (e) there is a lack of movement on flexion/extension views [16]. Pseudoarthrosis, or failure of fusion, is suggested by persistent pain, progression of deformity, loss of disc height, vertebral displacement, hardware failure, haloing,

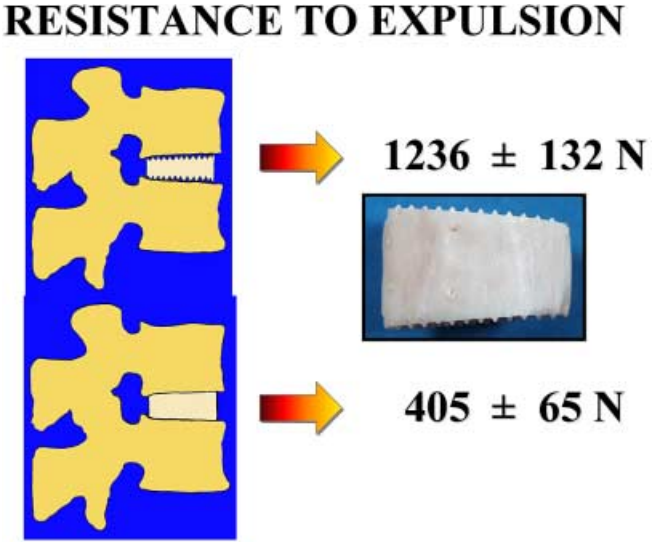

Fig. 2 The "teeth" on the femoral ring allograft (FRA) increase the resistance to implant pullout

migrations, or resorption of the bone graft with movement on flexion/extension views.

The FRA/PLIF biological cages are innovative lumbar interbody allografts, manufactured by the Musculoskeletal Transplant Foundation in conjunction with SYNTHES Spine. They come in a variety of sizes to precisely fit the disc space of each individual patient. Each FRA/PLIF spacer is machined from allograft into a wedge-shaped ring with "teeth." The teeth grip the adjacent vertebrae, thereby increasing the stability of the spacer (Fig. 2). The FRA spacer also has a hollow center that can be filled with autograft, allograft bone filler, a synthetic bone substitute, or bone morphogenic protein (BMP). This "bone void filler" may enhance or accelerate the biological fusion process of the spacer. An ideal implant must be capable of withstanding the axial compressive forces of the body. In addition, it must be able to displace the compressive force without inducing a great deal of motion in the adjacent segment while also promoting arthrodesis [20].

The anterior column of the spine absorbs 80% of axial compressive force, while the posterior structures absorb the remaining 20%. A study by Brown and colleagues [3] of motion segments of the lumbar region with static compressive loads indicated that the first component to fail was the vertebral body. This occurred as a result of the fractured endplates. These findings suggest that the vertebral body's strength is dependent on intact endplates.

Tests were conducted on the PLIF and FRA spacers to ensure that they could withstand the loads on the lumbar spine. The ultimate compressive strength of a vertebral body is 8000 N [25]. Test results show that the PLIF and FRA spacers have a compressive strength of over 25,000 N. A successful interbody fusion will restore every mechanical function of the functional spinal unit except motion. The bone graft must bear substantially all of the body's weight above the fusion level(s) while it is being incorporated [4]. The goal of any spinal fusion procedure is to maintain the correction, avoid hardware or graft failure, and obtain a solid fusion.

In addition to compressive strength, resistance to implant expulsion is a major factor in the design of intervertebral spacers. The PLIF spacer is designed with "saw teeth" to increase resistance to pullout. Pullout testing was conducted to ensure that the spacer was able to resist expulsion. The maximum shear force that a human disc can withstand is about 150 N [29]. An axial preload (450 N) [29] and a shear load were applied to the implant to determine the pullout strength. The results show that the PLIF spacer has a pullout strength of (1053±80 N), more than three times the pullout strength of a comparable design without teeth (234±38 N). Testing was conducted on the FRA spacer to ensure that it was capable of resisting expulsion at clinically relevant loads. The resistance of the implant being expelled from the disc space was determined by pushout testing. A clinically relevant load (450 N) [29] and side load was applied to the implant to increase resistance to pushout. Test results show that the FRA spacer has a pushout strength (1236±132 N) three times that of a comparable femoral wedge (405±65 N).

Biological fusion cages

Over the years, many variations of fusion cages have been invented to facilitate the fusion process while maintaining stability of the spine. Metal cages are widely utilized for anterior column reconstruction, with the goal of achieving spinal arthrodesis. The disadvantages of these metallic cages include subsidence and the inability to assess the "biology" of the intervertebral segment. Other potential problems include sizing of the implant, loosening, migrations, and theoretical metallic ion absorption [23]. In the last few years, several interbody cages of different designs have been developed for use through an anterior and posterior approach. The aim was to provide mechanical support to the segment being fused with biocompatible implant material and to allow the use of autogenous bone to promote fusion. Theoretically, these new biological implants give more lasting restoration of disc height and better stabilization to the spine.

There are five processes involved in the incorporation of the graft. The first stage of the graft is the inflammatory process, which occurs within hours after implantation. Inflammation is followed by revascularization, osteogenesis, remodeling, and finally mechanical stability [14]. During the inflammatory stage, the body's defenses elicit an immune response, causing inflammatory cells such as neutrophils and fibroblasts to invade the graft [14]. Rejection of the graft often occurs during revascularization where the host is highly sensitive to the graft's antigen [14]. During revascularization, possible complications may occur, including graft necrosis and occlusion of the host vessels. Osteogenesis, the synthesis of new bone by the host, begins shortly after the immediate postoperative period. This process involves the mesenchymal cells proliferating and eventually differentiating into chondrocytes and later into osteoblasts. "Osteoconduction" refers to the graft's ability to induce osteogenesis, which can persist for several months following surgery. Remodeling and mechanical stability follow, producing a functional and efficient graft [12]. Because allografts are capable of eliciting a more aggressive immune response, freeze-drying, cryopreservation, and other preservation techniques are used to delay the inflammatory and revascularization process.

Surgical technique and clinical outcomes

Femoral ring allograft spacer

The FRA spacer instruments are designed for use with this "biological cage" for a straight anterior or anterolat-

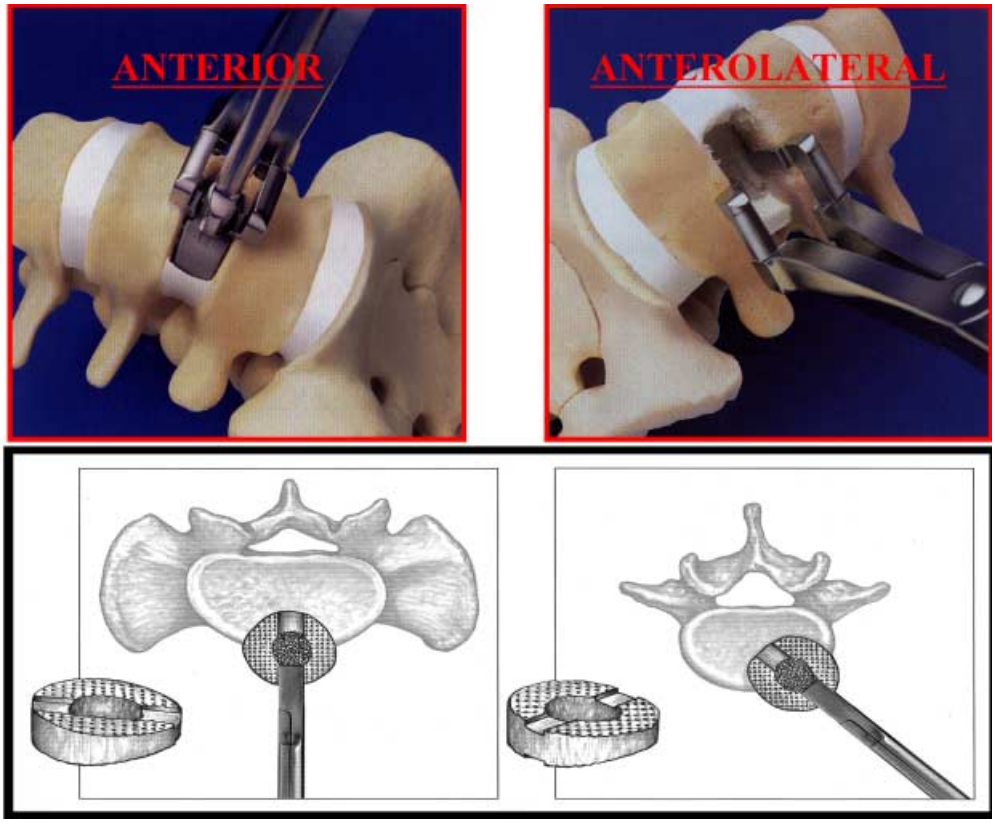

Fig. 3 Anterior and anterolateral approach using a femoral ring allograft (FRA) spacer

eral approach (Fig. 3). A preoperative planner can aid in determining the size of the adjacent intervertebral discs and allow the implant to be firmly seated with a secure fit between the endplates.

For a direct anterior insertion/approach, the midline of the intervertebral disc is exposed and evacuated with removal of the superficial layers of the cartilaginous endplates to expose the bleeding bone (Fig. 4a,b). Adequate preparation is essential to facilitate the vascular supply to the biological cage. Distractor blades are inserted into the disc space to restore the disc height, open the neural foramen, and stabilize the biological cage (Fig. 4a,b). The implant size is determined using the trial spacers. The implant corresponding to the correct trial spacer (Fig. 4c) is prepared, and bone graft material (either autograft, demineralized bone matrix, bone morphogenic protein, or allograft) can be inserted into and around the biological implant and in contact with the endplates (Fig. 4d) [19].

For an anterolateral insertion/approach, the center of the implant and the distractor sit 30° offset from the anterior vertebral midline. This approach is commonly used at the L2–L5 vertebral segments and requires less soft tissue dissection and mobilization of vascular midline structures. The anterior longitudinal ligament need not be sacrificed in this approach. The trial size and biological cage are inserted at a 30° offset from the midline (Fig. 3).

A total of 179 FRA cages were utilized for anterior column reconstruction in 137 patients from March 1998 to July 2000. There were 89 men and 48 women. The age range of the patients was from 19 to 73 years, with the average age being 45 years. Sixty-five patients from this group also exhibited co-morbidities including smoking (n=46), obesity (defined as >20% of the ideal body weight, n=12), and diabetes (n=7) (Table 1).

The most common preoperative diagnoses were internal disc disruption with disc resorptive syndrome, instability/spondylolisthesis, recurrent disc herniation with instability, degenerative scoliosis, vertebral osteomyelitis, and previous posterolateral arthrodesis that required additional anterior column support. Anterior “stand-alone” devices were used in about 25% (33/137) of the patients, while the majority of the patients (104/137) had additional posterior instrumentation. Additional posterior pedicle screw fixation was utilized in 49 patients, and translaminar screws (n=55) were more frequently used (Table 2). The additional posterior instrumentation in general is widely accepted by orthopedic surgeons to provide rigidity, improve fusion rates, reduce postoperative morbidity, and correct deformity [27]. Pedicle screws were used in patients who had spondylolisthesis, instability, or previous wide decompressive procedures. Patients with pedicle screws more often reported increased myofascial pain most likely secondary to greater soft tissue dissection and surgical exposure. Translaminar screws can be inserted with less dissection and tend to result in less postoperative morbidity. However, there was no difference in the fusion

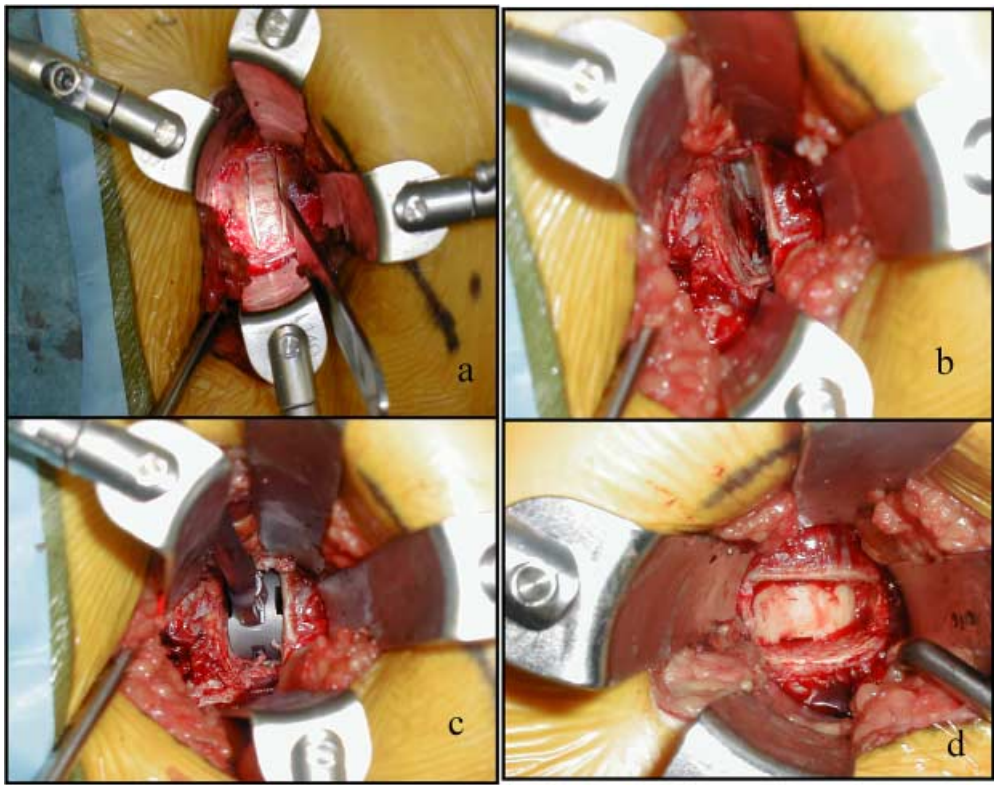

Fig. 4a–d Surgical technique using a femoral ring allograft (FRA) spacer

Table 1 Patient characteristics

	FRA spacer (*n*=137)	PLIF spacer (*n*=13)
Mean age (years)	45	54
Females (*n*)	48	8
Males (*n*)	89	5
Smokers (*n*)	46	4
Obese patients (*n*)	12	0
Diabetic patients (*n*)	7	0

FRA, femoral ring allograft; PLIF, posterior lumbar interbody fusion.

rate whether pedicle screws or translaminar screws were used in this series.

The majority of the patients (*n*=98) received one biological FRA spacer, while 39 required two-level biological cages, and only one patient received three-level implants (Table 2). The most common motion segment fused was L5–S1. Patients had either autograft (*n*=117) taken from the patient's iliac crest, demineralized bone matrix (*n*=13), or some other graft material (*n*=2) packed into and around the FRA spacer to promote a biological environment for arthrodesis. No differences in fusion rates were observed in patients that received autogenous bone versus patients with demineralized bone matrix. Additional postoperative orthosis was not indicated in any of the anterior column support patients. The radiographic outcomes were favorable for the majority (94%) of the patients and therefore demonstrate that arthrodesis was achieved with the biological bone spacer (Fig. 5a–c). These results support the theory that additional posterior column fixation predictably achieves a greater incidence of successful anterior interbody fusion. The longest follow-up in this series of patients was 36 months, with an

Table 2 Method of arthrodesis

	ALIF alone (*n*=33)	ALIF with posterior fusion (*n*=104)	PLIF with posterior fusion (*n*=13)
FRA spacers (*n*)	35	144	–
PLIF spacers (*n*)	–	–	30
Pedicle screw fixation (*n*)	0	49	12
Translaminar screw fixation (*n*)	0	55	1
One-level fusion (*n*)	27	71	11
Two-level fusion (*n*)	4	35	2
Three-level fusion (*n*)	0	1	0

ALIF, anterior lumbar interbody fusion; PLIF, posterior lumbar interbody fusion.

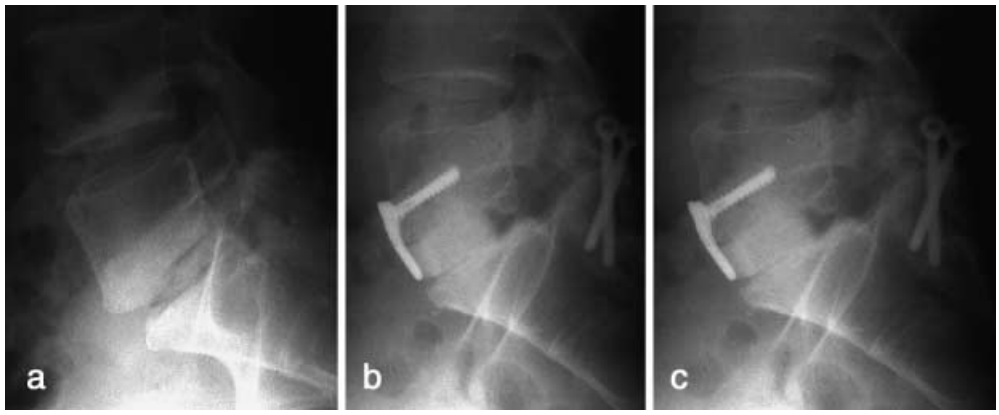

Fig. 5 **a** Preoperative X-ray of a 40-year-old man with degenerative disc disease and instability at L5–S1. **b** X-ray (1 month after surgery) of an anterior interbody fusion with femoral ring allograft (FRA) spacer insertion in addition to posterior fusion with translaminar screw fixation. **c** X-ray 6 months after surgery showing successful fusion with the FRA spacer in L5–S1

average follow-up of 18 months. At the time of review, there had been no evidence of bone graft rejection/resorption, migration, or infection (human immunodeficiency virus, HIV; hepatitis). Only one patient in this series had to be revised early, because of a postoperative radiculopathy that was felt to be secondary to over-distention resulting in neuropraxia to the right S1 nerve that resolved in about 6 months. One patient had radiographs that demonstrated a L4–L5 graft collapse and change in screw angulation, resulting in a segmental loss of lordosis and deformity.

Three patients requiring an anterior interbody fusion had clinical failure of the intradiscal electrothermal therapy (IDET) procedure, and in one patient pseudoarthrosis was suspected (on plain radiographs) but solid arthrodesis was confirmed on additional imaging techniques (CT scan) (Fig. 6). Five patients treated solely with the anterior approach required additional posterior fusions with instrumentation (5/33), secondary to either persistent pain, lucency of the implant, or motion with dynamic X-rays. Intra-operative fracture of the implant (the smallest size) occurred early in the series in five patients. These patients required removal of the fractured biological spacer and replacement at the time of the initial surgical procedure. This most commonly occurred when the trial spacer was not inserted completely prior to the implant or there was a geometrical mismatch of the endplates to the biological cage. No remaining patients demonstrated any radiographic evidence of motion or failure of consolidations.

Posterior lumbar interbody fusion spacer

The PLIF spacer is a contoured, wedge-shaped cortical allograft that comes in five anterior heights: 9–17 mm, in 2-mm increments. The surface of the spacer contains a saw-tooth pattern on the superior and inferior surfaces to minimize migration (Fig. 1). Two implants are inserted into the same disc height to ensure maximum stabilization.

There are two major techniques that may be used to distract, size, and insert the implants: distraction with the PLIF distractor or distraction with the PLIF trial spacer. The surgical technique used depends on the patient's local anatomy, the pathology, and the surgeon's preference [19]. The majority of the posterior elements, including the

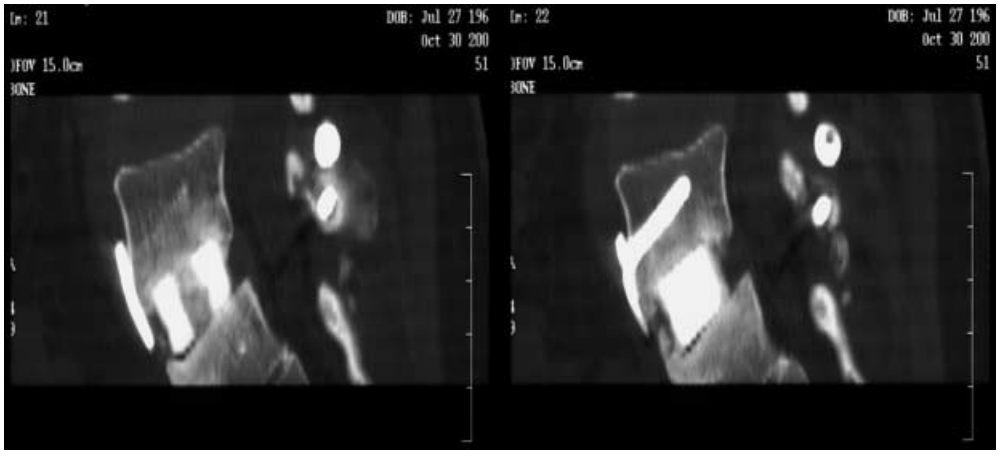

Fig. 6 A 35-year-old woman had a femoral ring allograft (FRA) spacer in which pseudoarthrosis was suspected on plain films. However, this computed tomography (CT) scan showed that the patient had a solid fusion at the level of surgery

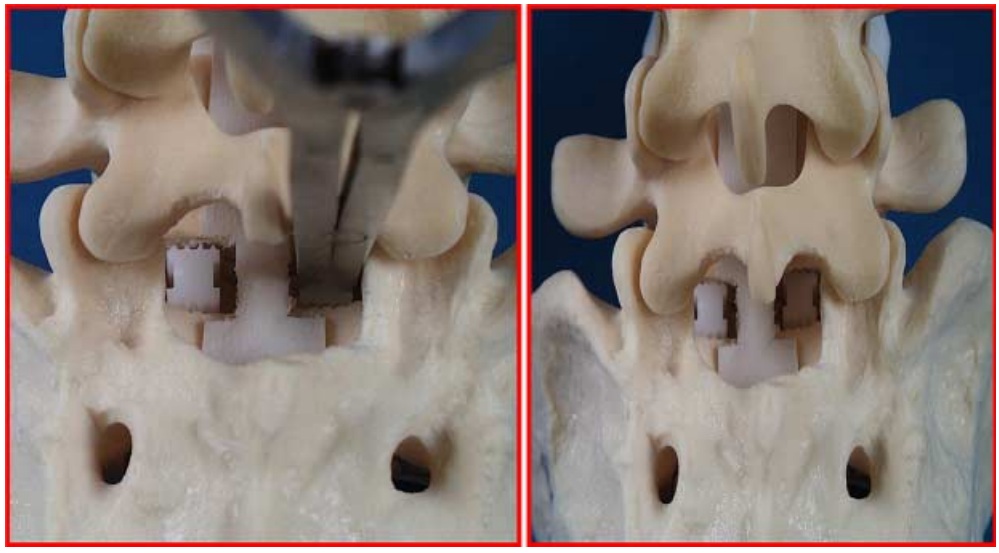

Fig. 7 Surgical technique using a posterior lumbar interbody fusion (PLIF) spacer

facets, do not have to be sacrificed for delivery of this geometry of biological implants (Fig. 7). The PLIF trial spacer ensures accurate sizing of the PLIF spacer. Once the site has been prepared for device insertion, the PLIF distractor blades are inserted completely into the disc space so that the ridges at the end of the blade rest on the vertebral body and are lateral to the dura. The PLIF distractor distracts the vertebrae to obtain maximum implant height, while the PLIF trial spacer is inserted into the contralateral disc space to ensure the accurate sizing of the PLIF spacer. Fluoroscopy and tactile judgment can assist in confirming the fit and placement of the trail spacer. If the trial spacer is either too loose or too tight, the next size is used to achieve the desired secure fit. Once the correct sizing is obtained, the trial spacer can be removed and the biological implant is introduced (using the implant holder) in the correct orientation into the contralateral disc space (Fig. 7). Autogenous cancellous bone or bone substitute (demineralized bone matrix, BMP, or allograft) is also placed in the anterior and medial aspect of the vertebral disc space *prior* to placement of the second implant.

For the surgical technique utilizing the PLIF trial spacer, it is necessary to begin with the trial spacer determined during preoperative planning. It is first inserted horizontally and then rotated vertically to size and distract the disc space. The implant corresponding to the correct trial spacer is chosen and introduced in the correct orientation into the contralateral disc space. The trial spacer is removed and the second implant is inserted. It is advisable to recess the implant 2–4 mm beyond the posterior rim of the vertebral body [19]. Additional posterior instrumentation may also be used to enhance the fusion rate and decrease the risk of anterior column allograft migration.

Thirty implants were inserted into 13 patients between January 1999 and July 2000. Five were men and eight were women, ranging in age from 32 to 70 years (average age, 54 years) (Table 1). The follow-up on these preliminary patients averaged 18 months (range, 6–24 months). The indications for surgical implantation included recurrent disc herniation, spondylolisthesis with foraminal stenosis, and instability. The most common levels fused were L4–L5 and L5–S1. All of the patients were treated

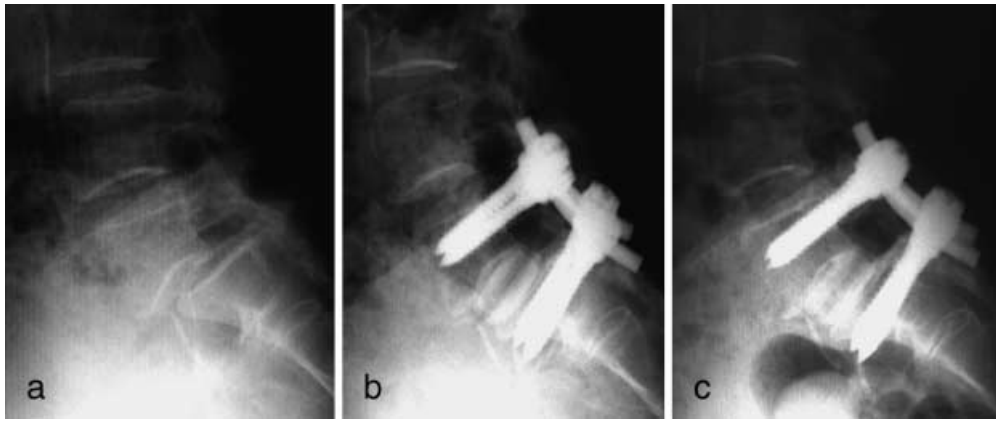

Fig. 8 **a** Preoperative X-ray of a 69-year-old woman with spondylolisthesis, instability, and bilateral pars fracture. **b** X-ray (1 month after surgery) of a posterior interbody fusion with posterior lumbar interbody fusion (PLIF) spacer insertion and pedicle screw fixation. **c** X-ray 6 months after surgery showing a successful fusion with the PLIF spacer in L5–S1

with additional posterior segmental instrumentation including pedicle screw fixation (n=12) or translaminar screw fixation (n=1) (Table 2). In this series of patients, there were four (33%) smokers, but results did not show any differences in the fusion rates of smokers versus nonsmokers. There were no additional co-morbidities observed in this selected patient population (Table 1). One patient developed anterior migration of a single PLIF spacer that required revision and an anterior approach and reconstruction, with a good clinical outcome. The clinical outcome of this posterior device is promising, with minimal incidence of migration, dislodgment, infection, pseudoarthrosis, or iatrogenic instability (Fig. 8a–c).

Discussion

The purpose of interbody fusions (either anterior or posterior) are to decrease motion and increase function in relation to the existing pathology. Unfortunately, these are difficult parameters to measure objectively because people have different ways of evaluating pain and their perceptions of realistic goals from a spine surgical procedure. The criteria we used to evaluate our results were therefore based on radiographic fusions because they offered the most objective evaluation. Mature fusion appears on X-rays films at a postoperative interval of 6–9 months (Fig. 9a–c).

The combined anterior and posterior column reconstruction used in this study seemed to produce better success rates than those obtained by "stand-alone" anterior interbody arthrodesis. Previous studies have shown that, in general, the technical success rate (indicated by obtaining fusion) is greater than the clinical success rate (indicated by decrease in pain) [7, 11, 28]. Although the radiographic fusion rates in the current study were higher than 90%, the clinical results were variable and often influenced by such factors as litigation, co-morbidities, disability, and secondary gain issues.

Our results were consistent with Brodke et al. [2] and Enker and Steffee [9] that concurrent use of instrumentation increases interbody fusion success by increasing rigidity at the fusion site. Pedicle screw fixation restores segmental stability and minimizes graft retropulsion. Lorenz and coworkers [22] reported 100% fusion for posterolateral fusion with segmental pedicle screw fixation, compared with 58.6% without instrumentation. Laminar-based systems have also been employed to enhance fusion rates. In comparing laminar- and pedicle-based instrumentation systems, Gurr et al. [15] demonstrated superior axial, torsional, and flexural rigidity with pedicle-based segmental instrumentation systems. Although pedicle

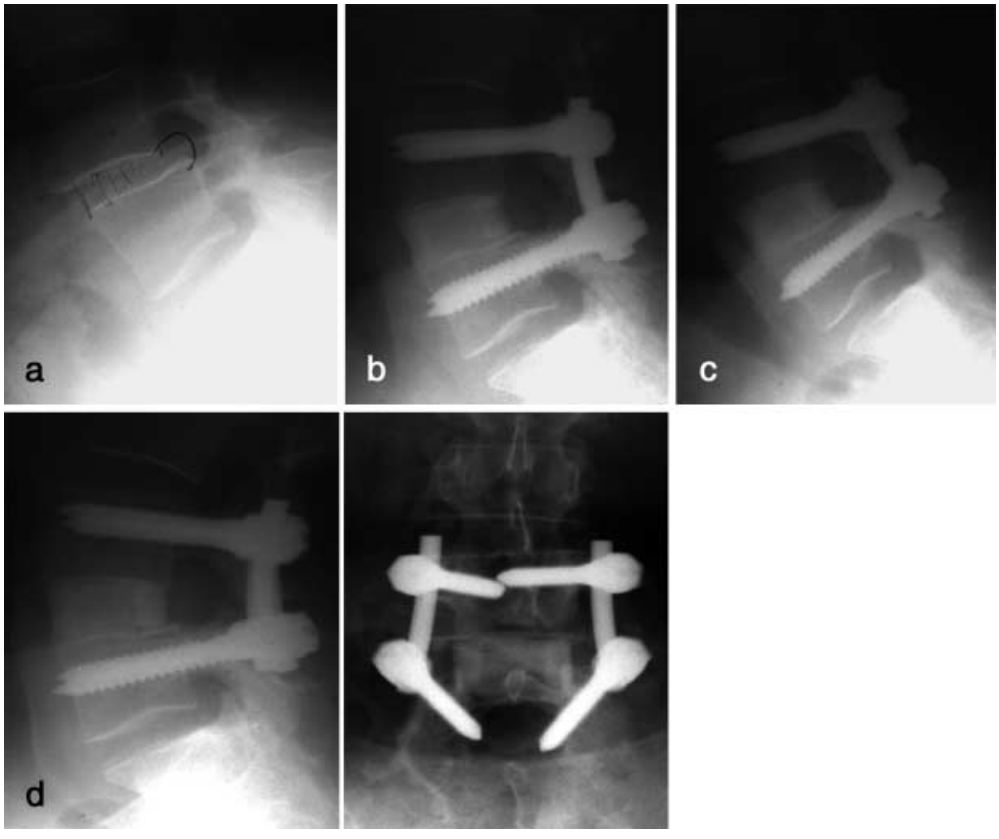

Fig. 9 **a** Preoperative X-ray of a 59-year-old woman with degenerative disk disease, L4–L5 facet arthropathy, and spondylolisthesis. **b** 24-month lateral view X-ray of a femoral ring allograft (FRA) spacer in L4–L5 with pedicle screw fixation. **c** 24-month flexion view. **d** 36-month extension and anteroposterior views

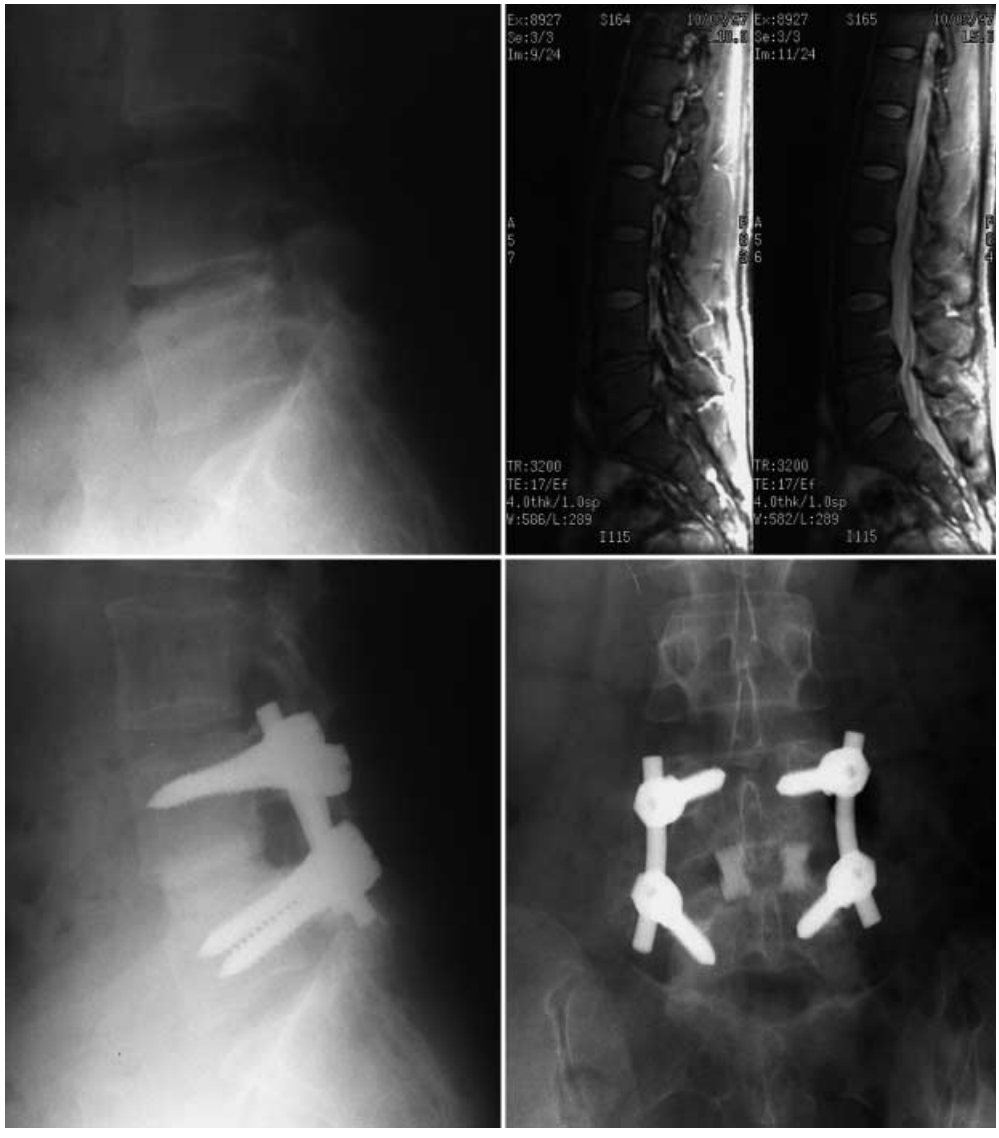

Fig. 10 Both of these implants facilitate preservation of the endplates and anatomic restoration of the sagittal alignment to provide the optimal "biological" environment to obtain arthrodesis

screws are proven to be more effective for stabilization in patients with degenerative disc disease or instability, our results do not show any differences in fusion rates between the pedicle and translaminar screws. However, for the treatment of spondylolisthesis or Par's defect, the pedicle screws were equally successful when used with FRA spacers or PLIF spacers (Fig. 10).

In a study carried out by Loguidice and colleagues [21], nonsmokers had a 14% incidence of pseudoarthrosis. Those smoking up to one pack per day had a 17% incidence of pseudoarthrosis, while those smoking more than one pack per day had a 36% incidence of pseudoarthrosis. However, the 50 smokers in our study who had either anterior or posterior interbody arthrodesis did not exhibit a greater incidence of pseudoarthrosis than the nonsmokers.

The success of every spine fusion procedure hinges on the biological phenomenon of bone healing. Whether this biological process occurs, however, is dependent on many factors. The extent of the instability problem being addressed, type of bone graft chosen, type of surgical construct created, and even the patient's own anatomy and lifestyle can affect the success of a fusion procedure. Although a number of studies have examined the outcome of interbody fusions, the results of many studies have been contradictory. It needs to be realized that there are many varieties of surgical techniques and healing processes, and expected outcomes may vary considerably regardless of recent research.

Conclusion

Bone has been used in a variety of shapes and configurations for interbody reconstruction for decades. More recently, the preparation and machining of allograft bone al-

lows it to be used and to function similarly to other metal mechanical spacers. FRA and PLIF biological cages are designed along with a set of instruments that allow the surgeon to perform these procedures using a minimally invasive approach. Both of these implants facilitate preservation of the endplates and anatomic restoration of the sagittal alignment to provide the optimal "biological" environment in order to obtain arthrodesis (Figs. 9a-c, 10).

This biological process of fusion can be monitored with conventional techniques, unlike common metallic anterior column implants. Our clinical experience in these 150 patients is encouraging. Future development of additional BMP may increase the arthrodesis rate, reduce the time to consolidation, and alter the need for rigid posterior instrumentation.

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