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Biological cages

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The PLIF Spacer and FRA Spacer are designed by and available through Synthes–Stratec Spine

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Abstract Restoring a stable anterior column is essential to achieve normal spinal biomechanics. A variety of mechanical spacers have been developed and advocated for both anterior and posterior approaches. The ability to radiographically assess the “biology” of bone incorporation in these mechanical (metal) spacers is an inherent limitation. The femoral ring allograft (FRA) and posterior lumbar interbody fusion (PLIF) spacers have been developed as biological cages that permit restoration of the anterior column with a machined allograft bone (biological cage). Test results demonstrate that the FRA and PLIF Spacers have a compressive strength 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 re-

construction with both the FRA and the PLIF biological cages are discussed. Clinical experience with the PLIF biological cage (10 patients) and the FRA biological cage (90 patients) has not revealed any graft migration, infection, or subsidence. Additional posterior instrumentation may increase the stability of the motion segment, but the degree of stability necessary to achieve a biological union remains unclear. The incorporation of these biological cages can be monitored by conventional radiographic techniques. The method of insertion preserves the vertebral end-plates and can be performed by a minimally invasive or standard open procedure.

Key words Biological cages · FRA spacer · PLIF spacer · Interbody lumbar fusion · Arthrodesis

Introduction

Pathological conditions such as trauma, infection, and tumor disrupt the integrity of the spine resulting in instability [20]. In many clinical situations, the optimal solution to restoring the spine's integrity is through surgical intervention. Posterior lumbar interbody fusion and anterior interbody fusion have been developed and employed to address these concerns. This paper aims to provide a detailed analysis of two newly developed biological cages, the FRA (femoral ring allograft) Spacer and the PLIF (posterior lumbar interbody fusion) Spacer (Fig. 1), that are used for anterior

lumbar interbody fusion and posterior lumbar interbody fusion, respectively. To aid in understanding the significance of these two biological cages, this paper will discuss the biomechanics of the spine, the development of the biological cages, the screening process for tissue donors, and the early clinical experience.

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,

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

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” [15]. Even among supporters of interbody fusion, enthusiasm toward the technique remained sedate until the 1940s. One of the primary supporters and leading figures in posterior lumbar interbody fusion was Ralph Cloward. Cloward’s innovative ideas contributed to the rectangular bone grafts and certain instruments used even today to insert bone grafts [5–7, 24]. Over the years, many variations of the posterior lumbar interbody fusion have been invented to facilitate the fusion process while maintaining stability to the spine. Capener first described anterior lumbar interbody fusions for spondylolisthesis in 1932 [4]. The year 1933 was pivotal for anterior interbody fusion, being the year when Burns inserted an autologous tibial peg anteriorly into the L5-S1 intervertebral space [3, 24]. 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, combined anterior and posterior column procedures which may include a posterior lumbar interbody fusion or anterior lumbar interbody fusion for anterior column support [24].

During the last decade, an increasing number of studies have looked toward the morphology, physiology, biomechanics, and immunology of the various components of the spine [18]. Today, there are several options available to spinal surgeons for correcting spinal instabilities to regain physiological anterior column support. Among these are autograft, allograft, synthetics, and metallic fusion cages. Fresh autologous cancellous bone is considered the best choice for osseous reconstruction because of its optimal biologic behavior and histocompatibility [10]. However, autologous bone has inadequate initial mechanical strength for interbody loading and may collapse and/or extrude [8, 11, 13, 19]. Significant morbidity is also associated with an-

terior structural graft harvesting of the ilium and may result in infection, chronic pain, incisional hernias, vascular injuries, neurologic injuries, and iliac wing fractures [23]. The use of allograft is a safe, simple, and inexpensive method of harvesting bone. Total operative time and blood loss can be reduced, and possible complications associated with the donor site can be avoided [22]. Through continued clinical research devices are being manufactured from cortical bone, similar to metal fusion cages, providing built-in lordosis and end-plate gripping “teeth” for additional stability. Two of these biological devices are the PLIF Spacer, for posterior lumbar interbody fusion, and the FRA Spacer, for anterior lumbar interbody fusion.

Anatomy and biomechanics

Even when subjected to an axial load of 8000 N, the spine is capable of moving in flexion, extension, and rotation. In order to maintain stability under demanding conditions, the spine is dependent upon the articulating processes of the intervertebral disc and the facet joints. Like the cervical spine, the lumbar spine has a lordotic curvature that is essential to its function. Because of its location and shape, the lumbar spine often fails under axial compression [21]. For these reasons, a successful biological cage needs both to address the lordosis of the lumbar spine and provide stability to the spine.

The anterior column of the spine absorbs 80% of an axial compressive force while the posterior structures absorb the remaining 20%. A study by Brown and colleagues 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 end-plates. These findings suggest that the vertebral body’s strength is dependent on intact end-plates [2].

The facet joints and the pars interarticularis control the movement of the posterior elements of the spine. According to Nachemson, the facets carry about 18% of the total compressive load of a motion segment [16]. When the body is in flexion, the facet serves to provide stability to the spine. Farfan and Sullivan established a correlation between facet joints asymmetry and the level of disc pathology [9]. An ideal implant must be capable of withstanding the axial compressive force 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 [14]. The quality of the bone graft both biologically and as a load-bearing device is crucial to achieving a solid fusion. Biological cages have been recently developed to address the criteria for both anterior and posterior interbody fusion.

Tests were conducted on the PLIF and FRA Spacers to ensure that they could withstand the loads in the lumbar spine. The ultimate compressive strength of a vertebral body is 8000 N [17]. Test results show that the PLIF and

Fig.2 Comparison of compressive strength of FRA Spacer and vertebral body

FRA Spacers have a compressive strength over 25,000 N (Fig. 2). 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 [1]. The goal for any spinal fusion 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 (see Fig. 1). 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 [21]. An axial preload (450 N) [21] 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) (Fig. 3). 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 to being expelled from the disc space was determined by pushout testing. A clinically relevant load (450 N) [21] and side load was applied to the implant to determine the pushout strength. Pyramid-shaped teeth are machined on the upper and lower surfaces of the implant to increase resistance to pushout. Test results show that the FRA Spacer has a pushout strength (1236 ± 132 N) three times the pushout strength of a comparable femoral wedge (405 ± 65 N).

Fig.3 Resistance to implant expulsion: results of pullout testing

Biology and screening process of allografts

In the past 40 years instrumentation and techniques for spine surgery have increased dramatically. Accompanying the rise is the demand for bone allograft. In many respects, bone autograft is more advantageous than allograft; however, the clinical demand for bone allograft in limb salvage, fractures, and joint replacements necessitates its use [12]. In order to understand how allografts are utilized, one must examine the biology and the screening process of allografts.

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 [12]. During the inflammatory stage the body's defenses elicit an immune response, causing inflammatory cells such as neutrophils and fibroblasts to invade the graft [12]. Rejection of the graft often occurs during revascularization where the host is highly sensitive to the graft's antigen [12]. 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 [10]. 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.

The PLIF and FRA Spacers are harvested and processed by the Musculoskeletal Transplant Foundation (MTF) which is a national consortium of medical schools, academic institutions, and recovery organizations involved in the aseptic recovery, processing and distribution of bone and related soft tissue for use in transplant surgery. Its quality and safety standards consistently meet or exceed the requirements of the American Association of Tissue Banks (AATB) and the guidelines for screening and testing of tissue donors set forth by the Food and Drug Administration.

MTF is AATB-accredited and uses the most complete and technically advanced testing available to assure the safety of its allografts. MTF was the first tissue bank to utilize HIV DNA by polymerase chain reaction (PCR) testing on every donor. In independent testing, PCR has been found to be 99.6% sensitive and 99.9% specific. MTF continues to require this testing in its routine screening of donors. Since its inception, MTF has recovered and processed tissues from over 15,000 donors. It has distributed more than 700,000 tissues without a confirmed disease transmission, including HIV.

To maintain biological integrity, MTF processes all tissue by using aseptic techniques in class 10 (certified) clean rooms. This eliminates the need for terminal sterilization by high-dose γ -irradiation or ethylene oxide gas, which have been shown to compromise the biological and biomechanical integrity of allograft tissue. All tissue undergoes a total of 27 separate quality assurance checks prior to release. All tissue is computer tracked from recovery through testing, processing, packaging, and distribution.

The age criteria for donors are 15–60 years for males and 15–55 years for females. This allows the selection of tissue with denser construction. All potential donors must pass through a comprehensive quality assurance process. Screening begins at the site of recovery, with a comprehensive medical and social history that includes the cause of death. Tissue and blood samples are tested for infectious diseases that include hepatitis, HIV, and syphilis. A team of medical/technical specialists from infectious disease and tissue banking fields evaluate all information, including test results.

The PLIF and FRA Spacers are preserved between -40°C and -90°C until time of shipping, and are shipped on dry ice. The grafts are stored at -40°C to -90°C until the time of surgery.

Surgical technique using PLIF Spacer

A successful posterior lumbar interbody fusion restores the disc height, opens the neural foramen, stabilizes the spinal segment, and provides anterior column support. Distractioning the segment in a posterior lumbar interbody fu-

Fig. 4a–f Surgical technique using the PLIF Spacer

sion is essential to the prosperity of the surgery. There are two major surgical techniques that may be used to distract, size, and insert the PLIF Spacer: distraction with the PLIF Distractor and distraction with the PLIF Trial Spacer (Fig. 4). The surgical technique used depends upon the patient's local anatomy, the pathology, and the surgeon's preference. The PLIF Distractor distracts the vertebrae to ensure maximum implant height and neural foraminal decompression (Fig. 4a,b). The PLIF Distractor distracts on one side while the PLIF Spacer is inserted on the contralateral side. The PLIF Trial Spacer ensures accurate sizing of the PLIF Spacer (Fig. 4c). There are five sizes ranging from 9 to 17 mm, in 2 mm increments, which correspond to implant geometry. The Quick Release T-Handle is an accessory designed for use with the PLIF Trial Spacer. The PLIF Trial Spacer distracts on one side while the PLIF Spacer is inserted on the contralateral side.

Once the site has been prepared for device insertion the PLIF Distractor blades are placed into the disc space lateral to the dura. The curve on the neck of the distractor should be oriented toward the midline (Fig. 4a). The distractor blades are inserted completely into the disc space so that the ridges at the end of the blades rest on the vertebral body. Fluoroscopy can assist in confirming that the distractor blades are parallel to the endplates. Correct placement will angle the handles of the distractor cranially, particularly at L5-S1. An appropriately sized PLIF Trial Spacer is connected to the Quick Release T-Handle and inserted into the contralateral disc space with gentle impaction. Fluoroscopy and tactile judgement can assist in confirming the fit of the trial spacer (Fig. 4c). If the Trial Spacer is too loose or too tight, the next larger or smaller size is used until a secure fit is achieved. The implant is selected according to the correct Trial Spacer. The Trial Spacer can then be removed. The PLIF Implant Holder is

used to hold the selected implant within the slots of the implant. The biological implant is introduced, in the correct orientation, into the contralateral disc space (Fig. 4d, e). Slight impaction is often necessary using the PLIF Impactor. The Implant Holder is removed once the desired position is achieved. Autogenous cancellous bone or a bone substitute is also placed in the anterior and medial aspect of the vertebral disc space prior to placement of the second implant (Fig. 4f). It is desirable to recess the implants 2–4 mm beyond the posterior rim of the vertebral body.

For surgical technique utilizing the PLIF Trial Spacer, it is necessary to begin with the Trial Spacer determined during preoperative planning. It should be inserted with the contoured sides facing inferior-superior into the disc space. It may also be inserted horizontally and turned vertically to size and distract the disc space. Slight impaction may be necessary. Fluoroscopy and tactile judgement can assist in confirming the fit of the Trial Spacer; if it is too loose or too tight, the next larger or smaller size is used until a secure fit is achieved. The implant corresponding to the correct Trial Spacer is chosen. The implant is then introduced, in the correct orientation, into the contralateral disc space. Slight impaction may be necessary. The Trial Spacer is removed and the second implant, of the same height, is inserted into the space using gentle impaction. Again, it is suggested to recess the implant 2–4 mm beyond the posterior rim of the vertebral body. Additional posterior instrumentation can be performed to enhance the fusion rate and decrease the risk of anterior column allograft migration.

Surgical technique using FRA Spacer

The FRA Spacer instruments are designed for use with this “biological cage” for a straight anterior or anterolateral approach (Fig. 5a, b). The preoperative planner is designed as an aid in determining the anterior height, posterior height, depth, and lordosis. This is performed by comparing the lateral view on the radiographic planner with the adjacent intervertebral discs on a lateral radiograph. The implant should be firmly seated with a tight fit between the end-plates where the segment is fully distracted.

Direct anterior approach

The midline of the intervertebral disc is exposed and the disc is evacuated with removal of the superficial layers of the cartilaginous end-plates to expose bleeding bone. Adequate preparation of the end-plates is essential to facilitate vascular supply to the biological cage (Fig. 5a).

Distraction is performed for the segment to restore disc height, open the neural foramen, and stabilize the biological cage (Fig. 6b). The distractor blades are inserted into the disc space. Once the desired distraction is achieved the implant size is determined utilizing a series of Trial Spac-

Fig. 5a, b Surgical technique using the FRA Spacer **a** Anterior approach, **b** anterolateral approach to the L5-S1 junction

Fig. 6a–d Details of use of the FRA Spacer in the anterior approach

ers. The implant corresponding to the correct Trial Spacer is then prepared. The biological cage is packed with bone graft material and inserted in an anterior posterior direction with contact of the adjacent end-plates and restoration of lordosis (Fig. 6c, d).

Anterolateral approach (30° offset)

For anterolateral insertion, the center of the implant and the distractor will sit 30° offset from the anterior vertebral midline (Fig. 5b). This approach is commonly used at the L2–L5 vertebral segments. The anterior longitudinal ligament need not be resected during the anterolateral approach. The disc is evacuated and the end-plates prepared as in the direct anterior approach. The trial size and biological cage are inserted at a 30° offset from the direct an-

terior approach, which requires less soft tissue dissection and less mobilization of the vascular midline structures. It is recommended that additional bone graft material be inserted into the hole of the biological implant and circumferentially in contact with the end-plates.

Clinical experience with biological cages

FRA Spacer

One hundred and twenty three biological cages were utilized for anterior reconstruction in 90 patients from March 1998 to July 1999. Forty-eight patients were male and 42 female; average age was 43 years (range 19–72 years).

The most common preoperative diagnoses were internal disc disruption with disc resorptive syndrome (51 patients), instability/spondylolisthesis (28 patients), recurrent disc herniation with instability (12 patients), degenerative scoliosis (7 patients), and vertebral osteomyelitis (2 patients).

The majority of patients (59) received 1 biological FRA Spacer, while 29 patients were given 2-level biological cages, and only 2 patients received 3-level implants. The majority of patients (35) were given additional posterior segmental pedicular screw fixation. Anterior “stand-alone” biological cages were utilized in 30 patients and additional posterior translaminar screw fixation was utilized in 25 patients. Additional posterior instrumentation (pedicle screw or translaminar screw fixation) increases the vertebral motion segment stability. However, the actual

Fig. 8 A 65-year-old woman with instability and neurogenic claudication. Treatment included posterior spinal fusion with anterior FRA reconstruction

degree of stability needed to achieve a solid fusion has not been precisely determined, and may be multifactorial.

This is an early clinical experience of utilizing this biological implant for anterior column reconstruction. The longest follow-up in this series of patients is 17 months (Fig. 7), with an average follow-up of 8 months (Fig. 8). Up to this time, there has been no evidence of graft migration, infection or subsidence. Two patients managed solely with an anterior approach have required additional posterior surgery for suspected pseudoarthrosis. Only one patient who had been managed with an anterior column reconstruction and posterior translaminar screw fixation required additional surgery. None of the 35 patients treated with additional posterior segmental instrumentation required further surgery. Fracture of the FRA Spacer was noted upon insertion in three patients, who required removal of the fractured biological cage and replacement at the time of the initial surgical procedure.

PLIF Spacer

The PLIF Spacer has been utilized for approximately 6 months (beginning January 1999). Ten patients have received implantation of this biological cage.

Twenty-four implants were utilized in three males and seven females. All patients were treated with additional posterior segmental instrumentation to include either translaminar screw fixation (three patients) or posterior segmental pedicular screw fixation (seven patients) (Fig. 9). The indications for surgical implantation of these ten patients included recurrent disc herniation (five patients), spondylolisthesis without foraminal stenosis, and instability (five patients).

Early clinical experience with this device is promising, without evidence of migration, dislodgment, infection, pseudoarthrosis, or iatrogenic instability.

Fig. 7 A 25-year-old man with isthmic spondylolisthesis and spinal stenosis. Treatment included posterior segmental fixation with an anterior column FRA Spacer

Fig.9 A 45-year-old woman with a third recurrent herniated nucleus pulposus. Treatment included re-exploration and PLIF with segmental fixation at L4-L5

Fig.10 A 50-year-old woman with two-level spondylosis. FRA Spacer inserted anteriorly at L4-S1 with posterior transaminar screw fixation

Summary

Bone, in various shapes and configurations, has been utilized for interbody arthrodesis for decades. More recently, preparation and machining of bone to function more like a mechanical device has become available, in the form of biological cages. Bone allograft is expected to function similarly to metallic fusion cages, and surgeons must look beyond the source of the material and consider the anticipated function, mechanical properties, and advantages of allograft bone over metallic structures.

The FRA Spacer is a wedge shaped femoral ring designed for both direct anterior and anterolateral insertion. The insertion can be performed with simultaneous distraction. Migration is decreased with pyramidal teeth on both surfaces. The PLIF Spacer is a contoured, wedge-shaped allograft that can be inserted with a minimally invasive foraminotomy. The five sizes permit preservation of the

Fig.11 A 40-year-old man with a 2-year history of axial back pain. Discography confirmed anterior column pain at L5-S1. Anterior FRA Spacer inserted for L5-S1 interbody arthrodesis. CT scan with reconstructions 6 months postoperatively

facets and minimal nerve root retraction. The design allows distraction and insertion with the saw-tooth pattern surface.

The FRA and PLIF biological cages have been designed along with a set of instruments that allow the surgeon to perform these surgeries with a minimally invasive approach. Both of these implants (for both an anterior and posterior approach) facilitate preservation of the vertebral end-plates and allow anatomical restoration of the sagittal alignment to provide the best "biologic" environment to obtain a stable intervertebral segment and a subsequent

arthrodesis (Fig. 10). This biological process of fusion can be monitored with conventional techniques, unlike common metallic anterior column implants. The FRA and PLIF instruments permit the spacers to be inserted via a laparoscopic, minimally invasive, or open approach to the thoracolumbar spine.

Our early clinical experience is promising, and these types of biological cages allow surgeons to visualize the biology of bony incorporation with standard radiographic techniques, which is one of the primary limiting factors with metallic implants (Fig. 11).

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