ORIGINAL ARTICLE

Fresh-frozen femoral head allograft as lumbar interbody graft material allows high fusion rate without subsidence

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KEYWORDS
Lumbar circumferential fusion; Fresh-frozen allograft; Fusion rate; Interbody graft material; Femoral head allograft; PLIF

Summary
Background: Circumferential lumbar spinal fusion is widely used to increase fusion rate, but little data is available using fresh-frozen femoral head allograft (FFFHA) as a structural interbody graft alternative.

Hypothesis: Circumferential lumbar arthrodesis using FFFHA as interbody graft material could be an alternative to achieve interbody fusion without graft subsidence.

Methods: A retrospective review of 47 patients (56 levels) treated with lumbar circumferential fusion using FFFHA as interbody material. Consolidation was independently assessed by the two authors using a 3-type scale; interbody bone graft subsidence was also evaluated.

Results: Forty-four of the 47 patients (93.6%), and 53 of the 56 levels (94.6%) obtained consolidation, without differences between smokers and nonsmokers. Three levels (in three patients) did not fuse; one of them (2.1%) required revision. No patient presented graft dislodgment, signs of infection or graft subsidence at the last follow-up.

Discussion: FFFHA use as lumbar interbody graft in circumferential arthrodesis exhibited a 94% fusion rate, without graft subsidence. FFFHA may be considered a valid alternative to achieve interbody fusion.

Level of evidence: Level IV. Retrospective study.

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Introduction
Spinal fusion is performed to treat many spinal conditions, related to degenerative disorders, tumors, infections, trauma and deformities of the spine. The clinical and radiographic success rate of a lumbar spinal fusion depends on several factors, such as the primary diagnosis, the presence of instrumentation, the procedure performed and the graft material used [1-3].

Circumferential lumbar spinal fusion is widely used to achieve a solid union, both in primary procedures and in revision surgeries [4,5]. This method allows nearly complete discectomy for discogenic pain, provides structural support
along with restoration of normal sagittal contour, and is associated with a high fusion rate and a high degree of patient satisfaction [5–7]. Recent studies have reported improved functional outcomes [8], higher fusion rates [9], fewer reoperations and a better cost-effectiveness [10] in patients undergoing a circumferential fusion compared to patients undergoing posterolateral fusion (PLF) only.

Several graft alternatives have been used for interbody procedures, including autograft, allograft and ceramic blocks, and cages filled with bone graft, BMP-2 or other bone graft substitutes. Autograft material, harvested from the iliac crest, is a consistent bone grafting alternative, but it is associated with donor-site morbidity and limited supply [11,12]. BMP-2 is a successful bone substitute for interbody fusion, and is associated with high fusion rates [13,14]; however, its use is associated with a high cost and can result in significant complications [15–17]. Allograft bone is commonly used in lumbar interbody fusion [18–20]; it has good osteoconductive properties and a relatively low cost. However, despite the widespread use of allograft materials for interbody fusion, only two studies have evaluated the use of fresh-frozen femoral head allograft (FFHHA) as a structural interbody graft alternative [21,22].

The aim of this study was to evaluate the fusion rates of circumferential lumbar arthrodesis using FFHHA as an interbody graft material.

Materials and methods

Institutional review board approval was obtained to perform this study.

We performed a retrospective review of medical and imaging records of patients who received a lumbar circumferential fusion with pedicle-screw instrumentation and interbody graft with FFHHA in our institution. Inclusion period was from January 2004 to May 2010. Fifty-one patients underwent the procedure, but in four patients lost to follow-up, we could not assess their fusion status; therefore, 47 patients (36 females) were involved in the study, with a total of 56 levels undergoing circumferential fusion. This cohort represents 12.5% of all patients that underwent a lumbar spinal fusion in our institution during that period.

The mean age at the time of surgery was 46.5 ± 15.4 years; nine patients were smokers, and the mean follow-up period was 50.1 ± 19.4 months.

Techniques: all patients had a PLF either with autologus local bone graft alone (28 cases) or with iliac crest bone graft in the remaining cases. Interbody fusion was added to PLF to treat degenerative disc disease in 17 patients, to improve fusion in revision surgery in patients with non-union (nine patients), in case of spondylolisthesis (six patients) and in adult rigid deformities requiring long lumbar fusions (15 patients). The interbody procedure was an anterior lumbar interbody fusion (ALIF) at 35 levels, a posterior lumbar interbody fusion (PLIF) at four levels or a transforaminal lumbar interbody fusion (TLIF) at 17 levels. PLIF or TLIF were preferred in males to avoid the risk of retrograde ejaculation.

The interbody fusion was performed at one level in 39 patients, at two levels in eight patients, and at more than two levels in two patients. All levels with circumferential fusion were instrumented with pedicle screws, independently of the interbody fusion approach; no other instrumentation was used in any patient.

FFHHA were obtained from live donors who had undergone hip surgery as treatment for femoral neck fractures or hip osteoarthritis at our institution, excluding patients with a known history of malignancy, pathological fractures, infections and connective tissue diseases. Femoral heads were processed at our institution bone bank; regular donor screening was conducted as suggested by the National Society of Transplantation Clinical Guidance. Femoral heads were stored in freezers at —80°C, and thawed in saline solution for 10 to 15 minutes before the cartilage was removed with a rongeur. Next, an appropriately sized and contoured graft was obtained from the femoral head or head-neck region. For ALIF, a strut wedge allograft was contoured to the dimensions of the disc space as measured intraoperatively. The allograft was subsequently tapped into the disc space, which had been previously prepared by removing as much disc material as possible between the vertebral bodies; the endplates were also prepared using curettes to create an adequate space for the graft. A similar endplate preparation was performed for patients who underwent a PLIF. For TLIF, after preparing the disc space with the Travios® (Synthes GmbH, Switzerland) instrumentation, a strut allograft was contoured and sized using trail of the cage implant as a model, and the allograft was inserted using the Travios® instrumentation; the strut allograft was inserted without a cage.

The radiographic fusion rate was assessed independently by the two authors with anteroposterior and lateral radiographs of the lumbosacral region requested at 3, 6 and 9 months in all cases. A multi-slice computed tomography (CT) scan with reformatted images in the sagittal and coronal planes was also obtained at the one-year visit. Fusion assessment was performed using both plain radiographs and CT scan reformatted images; consolidation was defined by the presence of contiguous trabeculae between the graft and the vertebrae, either in radiographs or CT images. The fusion status was classified according to a 3-type scale as described by Fritzell et al. [1]: 1 (definite fusion), 2 (uncertain fusion) or 3 (definite pseudoarthrosis). PLF consolidation was defined as trabeculae crossing the graft—transverse process interface, with evidence of cortication of the graft. For interbody fusion, consolidation was defined as trabeculae crossing the graft—vertebral body interface on both sides of the graft either in plain radiographs (Fig. 1) or in CT scan images (Fig. 2). If there was a disagreement between the two authors evaluation, then the fusion status was graded according to the CT scan images (Fig. 2). Whenever there was a persistent disagreement, the case was classified with the worst score on the 3-type scale.

Interbody bone graft subsidence was evaluated with lateral radiographs; segmental intervertebral height at the last follow-up was compared to that measured in the immediate postoperative period. Intervertebral height at the front of the vertebral bodies was measured as percentage of body height; a loss of 20% or more in intervertebral height was considered a graft subsidence. An analysis of the fusion status and subsidence for each level was performed in patients who received an interbody fusion at two or more levels.
The statistical analysis was performed using the Fisher exact test to evaluate differences in proportions between two groups; when more than two groups were analyzed, we used the Pearson Chi² test. A $P < 0.05$ was considered to be statistically significant.

Results

We observed that 44 out of the 47 patients (93.6%) obtained a solid (type 1) fusion. A level-by-level evaluation showed that 53 of the 56 levels that underwent a circumferential fusion achieved consolidation (94.6% fusion rate). Three levels that underwent a circumferential fusion (in three patients) did not achieve a solid fusion (Fig. 3); nonetheless, only one of those patients (2.1%) was symptomatic and required revision surgery. In that case, rhBMP-2 was used for the revision procedure. No other patient required revision surgery. Furthermore, no patient presented signs of infection or graft dislodgment.

Comparing the patients based on the type of interbody procedure associated with circumferential fusion, we observed that 32 of 35 levels that underwent an ALIF obtained a solid fusion (91.4%), compared to four of four levels with a PLIF (100%) and to 17 of 17 levels that underwent a TLIF (100%), $P = 0.386$.

Nine smokers underwent circumferential fusion in 12 levels, and 11 of them achieved fusion (91.7%). Meanwhile, 38 nonsmokers had circumferential fusion at 44 levels, and 40 obtained healing (90.9%), $P = 1$.

No patient exhibited graft subsidence at any of the levels that underwent a circumferential fusion.

Discussion

Circumferential fusion, first performed by O’Brien [7], is associated with an increased fusion rate and fewer reoperations than PLF [3]; in addition, it has been reported that circumferential fusion is more cost-effective than instrumented PLF from a long-term, societal perspective [10]. In our study, we observed a 94% fusion rate using FFFHA as the
interbody graft material in patients undergoing a circumferential fusion. Circumferential fusion provides many advantages; however, a potential problem could be the increased costs associated with adding an interbody graft or graft substitute. At our institution, the cost of using one FFFHA is equivalent to US$ 600 (including the time required to process the femoral head and to shape it in the operating room), which compares favorably to freeze-dried allografts or cages filled with autograft or BMP-2, as FFFHA has a lower cost. Despite being easily available, only two studies support the use of FFFHA as interbody graft material [21,22].

Although allograft bone is commonly used for interbody fusion, most of the literature focuses on the use of fibular or iliac crest struts, or femoral-rings allograft (FRA) as interbody graft materials [18–20,23]. The use of FRA allows fusion rates from 40% to 100%, with lower fusion rates observed when more levels are fused [24], or when fusion is performed without associated instrumentation [25]. Despite femoral head allograft is mechanically weaker than FRA, femoral head allograft has the theoretical advantage of more rapid and complete incorporation than cortical grafts due to its corticocancellous structure, which allows for easier revascularization and consolidation; in addition, femoral head allografts are widely available from patients that undergo hip surgery. However, as the literature on the use of femoral head allograft as an interbody graft material is scarce, its use has not been well established. In this series, we added an interbody fusion to PLF as treatment of degenerative disc disease or to increase the fusion rate in patients with challenging fusion situations. Only two publications have previously evaluated the use of FFFHA as part of a circumferential fusion, reporting high fusion rates, even in heavy smokers [21,22].

Smoking has been widely described as the main risk factor for non-union in the lumbar spine [26–28]. In this study, 19.1% of the participants were smokers; we did not observe differences in fusion rates between smokers and nonsmokers in a level-by-level analysis of the segments that underwent a circumferential arthrodesis. Our results support the use of FFFHA both for smokers and nonsmokers, in agreement with previous data [22].

Our series also included several cases presenting other poor bone healing conditions, such as patients with a previous non-union or cases undergoing long fusions reaching the sacrum; however, a fusion rate of 94.6% was observed for the levels that underwent a circumferential arthrodesis. Different studies in the recent literature have reported similar results using other interbody graft materials, like autologous bone [23,29,30], femoral-ring allograft [19,24,31] and even cages with graft substitutes [13,23,32]. However, our study adds information on the use of FFFHA as a structural interbody graft alternative, a graft option for which very little data is available [21,22].

Bone allograft material can be preserved by freeze-drying or freezing. Frozen allograft material has demonstrated greater fusion rates than freeze-dried allograft material in lumbar PLF [33]. It has also been reported that interbody fresh-frozen FRA is associated with fewer revision procedures for non-union than freeze-dried allografts [18]; in our series we used only FFFHA, and only one patient (who was smoker) required a revision surgery for non-union. In addition, no patient experienced graft subsidence; this finding is important because a concern regarding the use of corticocancellous interbody graft material is its potential for intervertebral height loss. The absence of graft subsidence is comparable to results obtained using autologous tricortical bone blocks as interbody graft material [1], but without the morbidity associated with autograft harvesting. This absence of graft subsidence in our series may be explained by the addition of a rigid posterior instrumentation with pedicle screws in all of our cases. It has been described that an optimal preparation of corticocancellous FFFHA for anterior lumbar interbody fusion allows adequate graft strength [34]; moreover, it could be hypothesized that the absence of graft subsidence could be explained by more similar mechanical properties of FFFHA to vertebral bodies than other implants as metallic cages or cortical bone from FRA, considering their corticocancellous structure.

Several alternatives are used as interbody graft material to achieve lumbar fusion. Considering the well-documented morbidity associated with autograft bone harvesting procedures [11,12], the increased costs related to cages filled with bone graft or bone graft substitutes [20], and the evidence of significant problems associated with the use of cages filled with rhBMP-2 for interbody fusion [16], the best grafting alternative has not been established. FFFHA, which is widely available and allows a 94% fusion rate with an adequate cost-effectiveness ratio, should be considered to be a valid lumbar interbody graft material alternative to other options as autograft, FRA or cages filled with bone graft or bone grafts substitutes. Despite autograft could be considered the gold standard graft alternative, it is associated with significant morbidity [11,12]; FRA is associated to
significant subsidence [35] and osseointegration is slow as in any cortical bone graft. Cages (made of different materials as titanium, polyetheretherketone or carbon-fiber) act as containers for bone graft to obtain bone fusion; however, fusion assessment can be difficult, especially using metallic cages, and they are associated to a significant cost increase. Nonetheless, the potential risk of disease transmission associated to bone allograft, including FFFHA, should be discussed with every patient, despite recent studies have reported a low risk under current bone banking standards [36,37].

Our study only evaluated the healing properties of FFFHA as an interbody graft option for lumbar fusion. As it has been widely described that obtaining a successful fusion frequently does not correlate with clinical success, future prospective studies should help to determine how the fusion rate and lack of subsidence observed correlate with clinical outcomes using this graft alternative.

Disclosure of interest
The authors declare that they have no conflicts of interest concerning this article.

References


