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Technical Notes & Surgical Techniques

Can the use of a novel bone graft delivery system significantly increase the volume of bone graft material in a lumbar in situ cage, beyond volumes normally achieved via standard cage filling methodology? Results from a cadaveric pilot study.

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ABSTRACT

Lateral lumbar interbody fusion (LLIF) is an interbody fusion technique which approaches the spine via the transpsoas route. Although such an approach eliminates many of the known complications associated with traditional fusion, it does not allow for the harvesting of local bone. Therefore, alternative strategies must be employed in order to ensure high rates of successful arthrodesis. One such strategy is to increase the volume of bone graft material (BGM) within the cage, thereby improving the environment for osteogenesis and subsequent fusion. In this study, we tested the hypothesis that the use of a novel bone graft delivery system would lead to significantly higher volumes of intra-cage BGM, compared to traditional cage filling methodology. The senior author performed a LLIF on a cadaveric spine in a traditional manner, which included hand-packing the cages with BGM and then inserting them into prepared disc spaces. A CT scan was performed and all BGM cage volumes were calculated. Next, attempts were made to inject additional quantities of BGM into the in situ cages, via the delivery system. A second CT was performed and new cage volumes of BGM were calculated. Results demonstrated significantly higher cage volumes of BGM after the use of the bone graft delivery system ($p = 0.014$), compared to those volumes achieved with standard cage packing methodology. This first-of-its-kind study suggests the use of a novel bone graft delivery system will significantly increase cage volumes of BGM which potentially may lead to increase rates of arthrodesis and improved clinical outcomes.

1. Introduction

Chronic low back pain (LBP), with or without associated lower extremity pain, is a major cause of world-wide morbidity [1,2], significantly affecting over 60% of all people at some point in their lives [3]. Most LBP can be successfully managed with conservative care; however, for those cases refractory to such care, lumbar arthrodesis (fusion) has become a standard surgical option [4].

Although there continues to be considerable controversy with regard to which fusion technique is best for what spinal disorder, it is generally accepted that the achievement of a solid interosseous fusion is the cornerstone for successful clinical outcomes [5].

Currently, there are four mainstream fusion techniques which include posterolateral fusion (PLF), posterior lumbar interbody fusion (PLIF), anterior lumbar interbody fusion (ALIF) and transforaminal lumbar interbody fusion (TLIF). Unfortunately, all of these techniques have been associated with well described complications. For example, TLIF and PLIF are associated with intraoperative nerve root injury and subsequent chronic radicular pain [6]; standalone posterolateral fusion is associated with a high rate of nonunion (pseudoarthrosis) [7]; and ALIF is associated with vascular injury [8], superior hypogastric plexus injury and retrograde ejaculation [9].

In hopes of avoiding such complications, alternate fusion techniques have been developed which include lateral lumbar interbody fusion (LLIF), also known as extreme lateral interbody fusion (XLIF Nuvasive®), XLIF, or direct lumbar interbody fusion (DLIF,

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Medtronic®).

Developed in the late 1990s by Pimenta [10], LLIF has been gaining popularity, particularly subsequent to the 2006 publication by Ozgur et al., which reported encouraging clinical outcomes, without the typical mainstream fusion complications [11].

Unlike the contemporary fusion techniques, LLIF employs a novel transpsoas approach to the spine which completely bypasses the great vessels, superior hypogastric plexus, traversing nerve roots, and exiting nerve roots, thereby eliminating the chance for intraoperative injury of those structures [9]. However, one disadvantage of this approach is that there is no local autogenous bone (autograft) to harvest and use as bone graft material (BGM). To compensate for this missing important source autograft, which is considered the gold standard BGM [12,13], the surgeon must either harvest autograft from the iliac crest or use bone graft alternatives, both of which have been associated with known complications. Specifically, the harvesting of iliac crest autograft (ICAG) has been associated with postoperative infection [14], the development of chronic harvest site pain [15], and injury to the lateral femoral cutaneous nerve [14]. In order to achieve similar rates of successful arthrodesis, many bone graft alternatives must be combined with biologics. Recombinant human bone morphogenetic protein-2 (rhBMP-2), has been particularly successful at increasing rates of successful fusion. However, it has also been associated with complications, such as pathological osteolysis, heterotopic bone formation, unexplained postoperative radiculopathy, and an increased risk for the development of cancer [16–21]. Therefore, researchers continue the search for novel BGMs and/or surgical techniques that could substitute for local bone, yet not have the aforementioned complications.

It is well-established that in order to achieve a successful interosseous fusion, a sufficient volume of BGM must be placed between the two bones being fused. Failure to do so has been shown to decrease the success of fusion and negatively affect clinical outcomes [22]. Therefore, it seems reasonable to assume that increasing the volume of BGM in and around the cage [cage volume] will lead to increased rates of successful fusion, which in turn will lead to improved clinical outcomes. Surprisingly, with regard to interbody fusion, it appears that this simple concept has not been tested in human or animal.

The objective of this pilot study was to test the hypothesis that the use of a novel in situ cage filling system will significantly increase the cage volume of BGM, as compared to traditional hand-packing cage filling procedures.

2. Materials and methods

2.1. Part 1

Using an adult cadaveric lumbar spine specimen which was stripped of paravertebral muscle the senior author performed an abbreviated LLIF on the top four lumbar discs (L1–L4) at a private cadaver laboratory.

From a standard transpsoas approach, a square-shaped annulotomy was made on the lateral aspect of each disc, followed by a standard nucleotomy and endplate decortication. A cage specifically designed for LLIF (InFill® V2 Lateral Interbody Fusion Device) was, in typical fashion, hand-packed with BGM made from a combination of demineralized bone matrix (DBM) and contrast material (OmniPaque®).

A specially designed insertion tool was next attached to the delivery port on the lateral margin of the cage, and then the cage was carefully inserted through the annular window and into the center portion of the prepared disc space [Fig. 1]. After the cage was in place, the insertion tool was removed and general observations were made with regard to the cage filling and insertion process. Subsequently, the same procedure and observations were repeated at the other three levels.

The specimen was transported to a local imaging facility where a comprehensive thin-sliced computed tomographic (CT) scan (0.6 mm cuts) with 3D reconstruction was completed. The subsequent images were assessed by a board-certified neuroradiologist who was instructed to calculate the pre-injection cage volume of BGM at each level by simply finding the product of its height, width, and length. Such measurements were easily made with the PACS imaging software. The senior author and DMG were also required to make qualitative observations with regard to the success of cage filling.

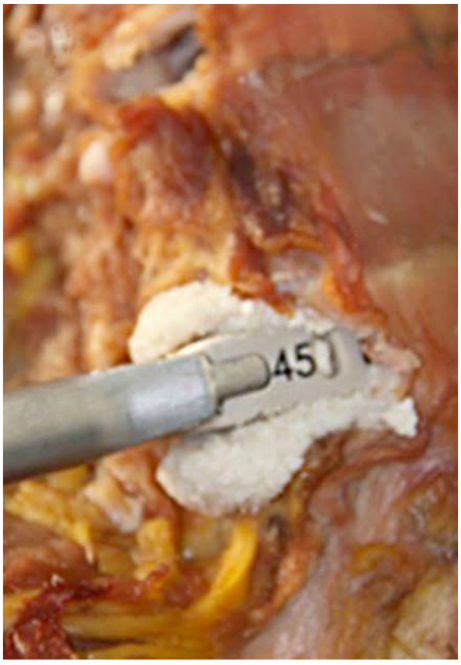

Fig. 1. Cage insertion process. As the interbody cage is being slid into the prepared disc space, any additional bone graft material above or below the margins of the cage is scraped off. Therefore, it is impossible to fill the cage endplate interval via traditional cage filling methodology.

2.2. Part 2

After pulling the specimen out of the CT scanner, a special BGM injection tool was carefully inserted through the annular window of the disc and connected to the delivery port of the in situ cage, which still contained the BGM from part I of the study.

Next, a specially designed syringe was hand loaded with the same BGM that was used in the first part of the study and then attached to the extra-spinal end of the injection tool. In attempts to inject more BGM into the cage, the metal plunger was slowly and steadily depressed until significant resistance was met. Next, the syringe was detached from the injection tool which in turn was removed from the disc space. General observations were made and recorded regarding the bone graft injection procedure. The same procedure and observations were repeated at the other three levels.

The specimen was once again returned to the imaging facility where another post-injection CT scan was performed using the same parameters as before. The new images were interpreted by the same board-certified neuroradiologist, and new post injection cage volumes of BGM were calculated at all levels using the previous described methodology. Again, the senior author and DMG make qualitative observations with regard to the success of cage filling.

2.3. Statistical analysis

The pre- and post-injection cage volume data were analyzed by a biostatistician who employed a two-sided paired *t*-test, at 95% level of confidence. A standard open-source statistical program platform, R, was used to perform this analysis.