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Prospective Analysis of Fusion Rate with a New Demineralized Bone Matrix

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Abstract

Study background: Autologous Iliac Crest Bone Graft is considered the gold standard graft for use in instrumented spinal fusion procedures. Due to significant morbidity and complication rate, alternate graft materials have been investigated. This study seeks to determine the fusion rate of one such alternative, the K2M VESUVIUSTM Osteobiologic Fibers, a form of demineralized bone matrix.

Methods: Prospectively collected CT scans of 27 patients with 29 instrumented levels were taken 1 year post-operatively. These were reviewed blindly by 5 fellowship trained spine surgeons to evaluate for fusion. The fusion mass was graded as no fusion (grade 1), partial unilateral (grade 2), partial bilateral (grade 3), solid unilateral (grade 4), or solid bilateral (grade 5). The fusion mass was then further classified as solid (grade 4-5), probable fusion (grade 3), or non-union (grade 1-2). The Kappa method was used to assess interrater reliability. We calculated the proportion of successful subjects at both cut-off values of either Grade 3 or Grade 4/5.

Results: When using a cut-off grade of 3 or higher, 40% of subjects achieved fusion according to 4 of 5 graders and 50% achieved fusion according to 3 of the 5 graders. When using a cut-off grade of 4 or higher, 28% of subjects were found to achieve fusion by at least 4 graders and approximately 50% achieved fusion according to 3 of the graders. When analyzing correlation between the reviewers, 8 of 10 interrater reliabilities demonstrated moderate to good agreement. Correlation by grade showed that only grade 1 had significant agreement amongst the graders with a kappa value of 0.3394. Otherwise, the combined kappa value was 0.1092.

Conclusion: Compared to the literature control using iliac crest bone autograft of 70.6% fusion rate, the results with K2M VESUVIUSTM Osteobiologic Fibers DBM were disappointing regardless of the cut off used.

Keywords: Postero-lateral fusion • Bone graft • Demineralized bone matrix • Allograft • CT

Introduction

Posterolateral intertransverse spinal fusion in combination with decompression of the spinal canal and involved nerve roots is a common technique employed to address degenerative conditions of the lumbosacral spine. The overall success of this method is dependent on not only a thorough and complete decompression of the neural elements, but also on achieving a stable biomechanical environment via rigid fixation and by providing a favourable biologic environment for a fusion to occur. The use of bilateral pedicle screw fixation has become the standard of care to achieve immobilization of the segment and has replaced the use of other historical techniques which had inferior long-term results [1-5]. Historically, autologous iliac crest bone graft (ICBG) was considered the gold standard fusion graft due to its oestrogenic, osteoinductive, and osteoconductive properties. However, there is significant morbidity and a relatively high complication rate associated with the harvesting of the graft [6-8] which has driven the search for alternative graft materials.

Demineralized bone matrix (DBM) is commercially available, processed allograft tissue which has been investigated as a potential alternative graft material. The allograft bone tissue is demineralized in a process which leaves growth factors (BMP, TGF-b amongst others) as well as a collagen scaffold available. This leaves the material with both osteoinductive and osteoconductive properties. Despite this potential, there has been concern over the consistency in effectiveness of each type of DBM given the variability of both factors related to donor tissue as well as differing processing techniques [9].

In this report, prospectively collected data from a post-market clinical study evaluating one type of allogeneic demineralized bone matrix (DBM, K2M VESUVIUSTM Osteobiologic Fibers) was reviewed to determine the rate of fusion when used in conjunction with pedicle screw fixation via evaluation of 1-year postoperative CT scans.

Research Methodology

Data was collected from one site of a prospective, non-randomized multicenter post-market clinical study of K2M VESUVIUSTM Osteobiologic Fibers (processed by LifeNet, Virginia Beach, VA) when used with the K2M EVEREST® Pedicle Screw System. The use of an interbody device was allowed at the surgeon's discretion. Local autograft was collected and used in either a posterolateral fusion or an interlaminar fusion at the surgeon's discretion. Patients were older than 18 years old and required posterior stabilization for fusion to address spinal stenosis, spondylolisthesis and/or degenerative disc disease. There were 27 patient's total, with 29 instrumented levels. An interbody device was used in 6 levels total.

As part of the original study standard demographic data, Oswestry Disability Index (ODI), Vilsual Analog Scale (VAS), SF-12 v2 scores were collected. Operative measures including surgical time estimated blood

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loss, length of hospital stay and adverse events were recorded. Additionally, radiographic assessment including pre and postoperative AP, lateral, flexion / extension radiographs along with 1 year CT scan assessments were collected.

This report focused on the 1-year CT scan (obtained with 2 mm slices and both sagittal and coronal reconstructions) assessments to evaluate the presence of fusion. The CT scans were read by 5 fellowship trained spine surgeons who were blinded to the ID of the patients. One of the 5 reviewers was a participating surgeon and part of the original study. CT scans were graded using a scale previously used in the literature as demonstrating no fusion (grade 1), partial or limited unilateral fusion (grade 2), partial or limited bilateral fusion (grade 3), solid unilateral fusion (grade 4), or solid bilateral fusion (grade 5) [10]. The fusion mass was then further classified as solid fusion (grade 4-5), probable fusion (grade 3), or non-union (grade 1-2). The comparison group as part of the original industry study was quoted as the literature reported outcomes of adult patients with fusion using posterior stabilization and iliac crest autograft for treatment of spondylolisthesis and/or DDD. The fusion rate of the control group was determined to be 70.6% with a range from 40% to 100% fusion.

Analysis on the agreement among raters (inter-rater reliability, IRR) on these 29 subjects was performed using the Kappa method, the gold standard for IRR. We also calculated the proportion of successful subjects at both cut-off values of either Grade 3 or Grade 4/5.

Results

There were a total of 27 patients with 29 total instrumented levels from an original cohort of 35 patients who had 1 year CT scans available for review. The baseline characteristics of these patients are summarized in Table 1. There were 13 males and 14 female patients. The average age at time of surgery was 62.4. Out of the 27 patients 15 had a history positive for tobacco use, with 6 current smokers. Average BMI was 29.5. Surgical details are summarized in Table 2. Three of the 27 patients had a previous thoracolumbar spine surgery performed at a non-index level. None of the patients had any surgery performed at the index levels. Notably there were 4 patients who underwent interbody fusion via a Transforaminal Lumbar Interbody Fusion (TLIF) using a PEEK interbody spacer at 6 levels. There were 2 patients that underwent 2 level fusions and 25 that underwent single level fusions. Both patients who underwent 2 level fusions also received a TLIF.

Figure 1 is the graphical representation of the distribution of patients graded as successfully having a fusion when using either grade 3 or grade 4 as the minimum cut off for fusion. When looking strictly at patient's graded as achieving successful fusion by using a grade 3 or higher score, 40% of subjects were given a grade 3 or higher by at least 4 of the 5 graders and 55% of subjects were given a grade 3 or higher for 3 of the 5 graders. When using a more stringent threshold of fusion success using a grade 4 or higher score, successful fusion was found 28% of subjects with at least 4 graders and approximately 50% with at least 3 graders.

Correlation between raters was analysed using Kappa statistics. Overall, 8 out of 10 interrater reliabilities demonstrated moderate to good agreement. One instance of poor and fair interrater reliability was found between surgeons. When looking at correlation of raters by grade, only grade 1 showed significant agreement with a kappa value of 0.3394. Otherwise, the combined kappa value was 0.1092 for all grades.

Discussion

In this study, the posterolateral fusion rates of a particular type of DBM when used in conjunction with a modern pedicle screw fixation system were ascertained radiographically by evaluating 1-year postoperative CT scans. Correlations (R2 values) of ratings across the 29 subjects by each rater were analysed. Overall, it was found that there was moderate to good agreement amongst 4 of the 5 raters. One rater showed poor to moderate agreement when compared to all others. Correlation of raters by grade was also analysed

Table 1. Patient demographic information.

Patients (n)	**27**
Number of Levels addressed	29
Sex (M/F)	13/14
Age	62.4
Tobacco Use	15 (6 current smokers)
Average BMIt	29.5

Table 2. Surgical information.

Previous Spine Surgery	**3**
Level Fused	
-L4-L5	15
-L5-S1	7
-L3-L4	2
-L4-S1	1
-L3-L5	1
Interbody use	6 levels in 4 patients

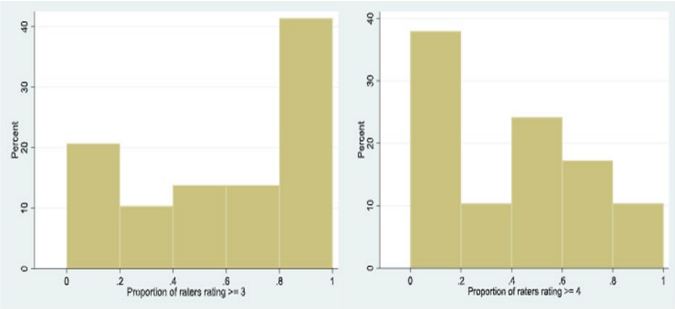

Figure 1. Distribution of patients graded "successful" using grade 3 versus grade 4 or higher.

using the kappa method. Grade 1 showed significant agreement with a kappa value of 0.3394. Otherwise, the combined kappa value was 0.1092 for all grades. Compared to the literature control using iliac crest bone autograft, which was cited to have a 70.6% fusion rate, the results with this DBM in our cohort were disappointing regardless of the cut off used.

Interestingly, the rate of fusion reported of all patients' at all clinical sites that were part of the clinical trial was calculated to be 78.8%. The total number of participants was 108 of which 80 went on to have the necessary radiographic follow up. 63 of the 80 were found to have fusion present on CT scan analysis. Furthermore, ODI<VAS and SF-12v2 scores all significantly improved at all-time points up to 24 months postoperatively [11].

Autograft bone, and in particular, Iliac crest bone autograft is most often cited as the gold standard for bone graft material to be used in spinal fusions. It provides both cancellous and cortical graft and is osteoinductive, osteoconductive and osteogenic. Additionally, it can provide structural support. However, there are some downsides to its use primarily due to the process of harvesting the graft. Increased blood loss has been observed, as well as chronic pain [12]. Kurz found a major complication rate of 10% while minor complications were 39% [13]. Autograft in the form of local laminectomy bone collection is another option for grafting which involves much less morbidity given no need for a separate surgical incision and harvesting of graft. One study found that it was equivalent to ICBG when combined with bone marrow aspirate (Niu) [14]. Additionally, a study by Kangkang [12] found that when combined with Ggrafton DBM and local bone it had equivalent fusion rates to ICGB, and in 1-2 level posterolateral fusions Park found it to be equivalent to ICBG [15]. However, another study found when used alone it led to a significantly lower fusion rate when compared with ICBG [16].

Allograft bone is another option which is especially attractive especially when there is no opportunity to obtain local autograft such as in the revision setting, or when local autograft is not sufficient. This is an attractive option as it carries no donor site morbidity. However, due the treatment this graft

type receives to ensure no host versus graft reaction occurs, it is purely osteoconductive and should be used with other graft materials which contain osteogenic and osteoinductive properties. When combined with bone marrow aspirate it was found to be useful in single level revision fusions and may be more cost effective than other substitutes such as BMP2 [17].

As previously mentioned, DBM is another allograft option which is reliably osteoconductive, but has highly variable osteoinductivity due to the manner in which it is processed. Allograft is typically treated in an acid extraction process which removes the minerals from the allograft bone and leaves a collagen matrix as well as a variety of proteins (BMPs, TGF-beta) which have osteoinductive potential. With demineralization, DBM will lose its mechanical properties and is therefore not suitable to be a standalone structural graft material. Furthermore, osteogenic properties are lost as mesenchymal precursor cells are no longer present in the formulation. The quantity of these remnant proteins is also highly variable on the technique of processing. Lastly, the concentration of protein such as BMPs is often quite smaller than what is found in commercially available come in recombinant human BMP formulations. For all of these reasons, DBM is rarely used as a stand-alone graft, but is normally used as a graft extender in conjunction with BMPs and/or autograft/allograft [18]. In various studies, DBM has been found to have good fusion rates when used as a graft extender both with iliac crest bone graft as well as local autograft or bone marrow aspirates [19,20]. Eleswarapu et al. retrospectively compared the use of rhBMP2 in instrumented lumbar fusion with DBM and found that both had good fusion rates which were not significantly different. However, they did note that the average cost was much lower for DBM.

The third type of graft material which has gained popularity is the synthetic graft materials such as calcium sulfate. This has been found to be a useful graft extender due to its osteoconductive properties [21], but when compared with autograft, it has been inferior in performance [14].

A final option for spinal fusion grafts is bone morphogenic protein or BMP. rhBMP2 is currently the only commercially available graft on the market. Although BMP-7 had previously been investigated in the literature, it is no longer available in the market and only BMP-2 has been approved in a limited manner to be used in spinal fusion as part of an anterior lumbar interbody fusion using a Medtronic device (LT-Cage Lumbar Tapered Fusion Device) [22]. Several studies found BMPs to be quite useful in the clinical setting with fusion rates approaching 100% [23-25] and at times even higher when compared to autograft [26]. There have however been concerns over adverse events and complications with use of BMP clinically. Specifically, bony overgrowth, cancer risk, systemic and local toxicity despite initial reports of a paucity of adverse events [27,28]. Most notably in 2011, Vaccarro et al. systematically reviewed available clinical published data on rhBMP -2 and found that with higher dose formulation there was a concern over increased risk of malignancy. They also found that wound complications, leg and back pain were increased in the BMP groups. Lastly, they noted that due to potentially biased methods clinical results may have been in favour of BMP without merit.

In this study, a 1-year postoperative CT scan with fine cuts was chosen as the assessment method for bony fusion. There is however no set standard or grading scale in the literature as to ideal methodology to rate fusion via imaging postoperatively. The gold standard used today is surgical exploration and direct visualization of the fusion mass. Static radiographs have been found to be inferior in the assessment of fusion compared to dynamic imaging as well as advanced CT scan assessments. There is also consensus that flexion-extension x-rays are inferior to fine cut CT scan assessments [29]. Brodsky et al. [30] reported only a 64% correlation between pre- operative plain radiographs and surgical exploration in a retrospective study of 214 lumbar fusion exploration procedures in patients who had undergone prior PLF. Plain radiography had 89% sensitivity and 60% specificity for predicting solid fusion. They noted that absence of motion on flexion-extension radiographs is highly suggestive of a solid fusion. The occurrence of some degree of motion at the treated levels, however, does not necessarily indicate a pseudarthrosis. Furthermore, when assessing a CT scan or XRs for fusion, there is data supporting that absence of facet fusion is a more powerful indicator than posterolateral fusion [31]. Lastly, there is a paucity of data in the literature regarding ideal timing for fusion assessment and many studies tend to grade fusions at either 12 months or 24 months postoperatively. Arnold et al. [32] found no difference in PLIF on flex- ex radiographs at 12 versus 24 months with 98% fusion rate in both groups. Whereas Lehr et al. [33] found a significantly increased rate of fusion at 2 years compared to 1 year postoperatively when using both a bone graft substitute as well as autograft.

This study has several notable limitations. This is a retrospective review of prospectively collected data which carries with it inherent limitations. One of the observers although blinded to the identity of the patients, also performed a large portion of the surgeries. The inter observer reliability was found to be relatively low when using this scale in this study. There was good interobserver reliability when assessing a film that was deemed to be a grade 1(no fusion), however all other grades had lower interobserver reliability than would have been preferred. Additionally, this study only evaluated 1 year CT scan assessments and did not include any patient reported outcomes for the cohort of patients.

Conclusion

In conclusion, when analysing 1 year CT scan examination is after use of this specific type of DBM for posterior spinal fusion we have found fusion rates to be disappointing. Although there are significant limitations to this study which have been acknowledged above, we still believe that the results show a relatively low rate of fusion when compared with to published rates for other formulations of DBM as well as other graft materials.

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