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We encourage authors to submit their manuscripts to *WJO*. We will give priority to manuscripts that are supported by major national and international foundations and those that are of great basic and clinical significance.

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Retrospective Cohort Study

Soft tissue swelling incidence using demineralized bone matrix in the outpatient setting

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Data sharing statement: This dataset available from the corresponding author at Dryad repository, who will provide a permanent, citable and open-access home for the dataset.

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Abstract

AIM

To assess use of demineralized bone matrix (DBM) use in anterior cervical discectomy and fusion (ACDF) in outpatient setting.

METHODS

One hundred and forty-five patients with prospectively collected data undergoing single and two level ACDF with DBM packed within and anterior to polyetheretherketone (PEEK) cages. Two groups created, Group 1 (75) outpatients and control Group 2 (70) hospital patients. Prevertebral soft tissue swelling (PVSTS) was measured anterior to C2 and C6 on plain lateral cervical radiographs preoperatively and one week postoperatively and fusion assessed at two years.

RESULTS

There was no intergroup significance between preoperative and postoperative visual analogue scales (VAS)

and neck disability index (NDI) scores between Group 1 and 2. Mean preoperative PVSTS in Group 1 was 4.7 ± 0.2 mm at C2 level and 11.1 ± 0.5 at C6 level compared to Group 2 mean PVSTS of 4.5 ± 0.5 mm and 12.8 ± 0.5 , $P = 0.172$ and 0.127 respectively. There was no radiographic or clinical evidence of adverse reaction noted. In Group 1 mean postoperative PVSTS was 5.5 ± 0.4 mm at C2 and 14.9 ± 0.6 mm at C6 compared to Group 2 mean PVSTS was 4.9 ± 0.3 mm at C2 and 14.8 ± 0.5 mm at C6, $P = 0.212$ and 0.946 respectively. No significant increase in prevertebral soft tissue space at C2 and C6 level demonstrated.

CONCLUSION

ACDF with adjunct DBM packed PEEK cages showed a statistical significant intragroup improvement in VAS neck pain scores and NDI scores ($P = 0.001$). There were no reported serious patient complications; post-operative radiographs demonstrated no significant difference in prevertebral space. We conclude that ACDF with DBM-packed PEEK cages can be safely done in an ASC with satisfactory outcomes.

Key words: Ambulatory surgery center; Anterior cervical discectomy and fusion; Demineralized bone matrix; Less Exposure Surgery; Packed polyetheretherketone cages

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Core tip: This manuscript scientifically assesses prevertebral swelling with the use of demineralized bone matrix (DBM) anterior to cervical cage. The use of clinical and radiographic outcomes demonstrates the safety of DBM in the outpatient setting. There are no studies showing safety or outcomes of DBM anterior to the cage and directly exposed to the pre vertebral soft tissues therefore we wanted to document this study.

Chin KR, Pencle FJR, Seale JA, Valdivia JM. Soft tissue swelling incidence using demineralized bone matrix in the outpatient setting. *World J Orthop* 2017; 8(10): 770-776 Available from: URL: <http://www.wjgnet.com/2218-5836/full/v8/i10/770.htm> DOI: <http://dx.doi.org/10.5312/wjo.v8.i10.770>

INTRODUCTION

Instrumented anterior cervical discectomy and fusion (ACDF) introduced in 1952^[1] has remained the gold standard in the treatment of cervical spondylosis. Complications ranging from relatively minor and transient dysphagia, hoarseness, post-operative neck pain and wound infection to potentially catastrophic hematoma and airway compromise, vertebral artery and neurologic injury as well as esophageal perforation^[2] have reduced over the years. This can be attributed to better technology and less exposure surgery techniques.

The outcome of ACDF is based on adequate decompression and osseous radiographic fusion^[3,4]. Autogenous bone grafts have demonstrated high fusion rates however; the immediate and long-term morbidity associated with iliac crest harvest is well recognized^[5-7]. The use of demineralized bone matrix (DBM) to aid in fusion has been demonstrated to be safe and effective^[8-10]. A review conducted by Aghdashi *et al*^[9], DBM has similar outcome to autogenous bone graft^[11]. Studies also revealed good outcomes compared to recombinant bone morphogenic proteins (rh-BMP)^[12]. Rh-BMP has been shown to cause life threatening airway edema and compromise^[13-15].

Several studies over recent years have looked at the feasibility of ACDF being done on an outpatient basis with promising results and low complication rates^[2,16-18]. Additionally, there are studies which have found that it is clinically safe to use DBM during ACDF within cages in a hospital setting^[4,11,19]. A study by Suk *et al*^[20] demonstrated peak onset of prevertebral soft tissue swelling (PVSTS) at 3 d post op. There were no studies assessing prevertebral soft tissue swelling and DBM in the outpatient setting found. The authors aim to demonstrate the safety of DBM in the outpatient setting.

MATERIALS AND METHODS

This was a non-randomized, single-center, prospective study of a total of 145 patients. We reviewed the charts retrospectively of 75 consecutive patients who single and two-level instrumented ACDF in the ASC (Outpatient ACDF), in which polyetheretherketone (PEEK) cages (Arena-C®, SpineFrontier Inc. Malden, MA, United States) with DBM (DBM pure®, SpineFrontier Inc., Malden, MA, United States) packed within and anterior to the cage and assigned them to Group 1. Fusion was reinforced with an anterior cervical plate (Inset®, SpineFrontier Inc. Malden, MA, United States). Our control group, Group 2 included 70 patients who had single and two levels ACDF in the hospital setting (Inpatient ACDF), all implants and DBM was from the same company and design. IRB approval was granted for patients involved in study as part of a cohort of patients who had anterior cervical surgery.

Operations were performed by a single surgeon, who was experienced in performing procedures in academic and private hospitals, prior to commencing in an outpatient setting. Patients were only considered for surgery after failed conservative management for at least six weeks. Indications for surgery included but not limited to patients with cervical degenerative disc degeneration (DDD) and herniated nucleus pulposus. Decision on type of surgery was based on severity of pathology. Exclusion criteria for surgery included acute severe trauma, fractures, malignancy, infection, unstable chronic medical illnesses, prior anterior cervical fusions and BMI > 42^[21-23]. All patients were assessed preoperatively and narcotics were recommended to be discontinued

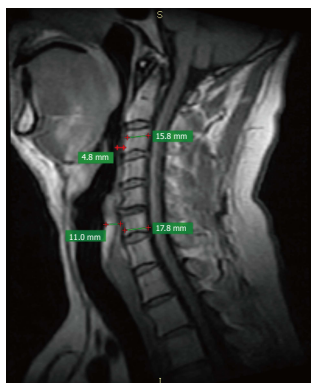


Figure 1 Preoperative radiograph showing retropharyngeal/prevertebral soft tissue at the level of C2 vertebral body and at the level of C6 vertebral body.

in patients with chronic use^[24]. Patients with chronic but stable medical conditions, including hypertension, diabetes mellitus, asthma, hypercholesterolemia and heart disease were medically cleared by their family practitioner and/or cardiologist where applicable. All preoperative radiographs were reviewed by the chief surgeon, as well as two additional researchers, to rule out pre-existing abnormal widening of the prevertebral soft tissue space. This was standardized by ensuring that the prevertebral soft tissue space (PVSTS) at the level of C2 was less than 50% of the C2 vertebral body and at the level of C6 measurements were approximately less than 22 mm or the prevertebral measurement should not be greater than the width of the vertebral body of C6^[25] (Figure 1). Post-operative radiographs were assessed at one week, 3 mo and at the end of follow up. Prevertebral soft tissue space (PVSTS) was compared between pre-op and 1 wk post-op films^[20,26,27].

Surgical technique

Signed consent was obtained for the procedure and under general anesthesia; patients were prepped and draped under sterile conditions. Surgical exposure of the desired vertebral level was achieved through a midline anterior cervical incision. Following discectomy, the posterior longitudinal ligament was retained *in situ*^[28] and the appropriately sized PEEK cage was inserted. DBM was packed within and anterior to the cage prior to an anterior cervical plate (ACP) being placed (Figure 2). The smallest sized ACP was placed, hemostasis confirmed and a Penrose drain was placed in all patients for wound drainage for 24 h to prevent postoperative hematoma development at home.

Discharge and follow up

Outpatients were discharged within hours of completing surgery after being deemed oriented and neurologically intact by the anesthesiologist and operating surgeon^[22,23]. Outpatient postoperative instructions were discussed with patients and caregivers with written copies provided. An assigned member of the outpatient team was responsible

for educating patients prior to consent on the risks and benefits of outpatient ACDF, as well as potential complications such as transient to persistent dysphagia, postoperative hematoma, infection and soft tissue edema with possible airway compromise. A team member called patients postoperatively on the night of surgery as well as the following morning to ensure a normal and comfortable postoperative recovery period, as well as to identify any evolving complications, which may require hospital admission. In the event of a complication, a prearranged agreement with a nearby local hospital was established before surgery. Patient reported outcomes included visual analogue scales (VAS) for neck pain, neck disability index (NDI) score and Nurick grade for those with myelopathy. Clinical outcomes were assessed based on the presence of soft tissue swelling and airway compromise. Postoperative potential DBM-related side effects were assessed clinically in all patients by palpating for soft tissue edema or swelling along the medial aspect of the sternocleidomastoid muscle. Postoperative radiological assessment was conducted with the use of anteroposterior (AP) and lateral plain radiographs looking for soft tissue emphysema, airway narrowing, tracheal deviation and PVSTS measurement in the first week postoperatively^[25-27]. Evidence of interbody fusion was assessed by radiographs at the patient's final follow up. Follow up visits occurred within the first week, one month, three months, six months, twelve months and at final two year follow up. Additional postoperative complications were also recorded.

Statistical analysis

Statistical analysis was performed using SPSS v22 (IBM corporation, New York, United States). An independent sample student *T*-test was used to compare groups for continuous data and χ^2 used for categorical data. Continuous data comparisons were expressed as means with standard error. Tests were considered significant if $P < 0.05$.

RESULTS

Comparing group 1 (75 patients outpatient ACDF) to group 2 (70 patients inpatient ACDF) no statistical differences in age, BMI and gender were found between groups, $P = 0.591$, 0.484 and 0.631 respectively. Demographics and initial diagnosis are illustrated in Table 1.

There was no significance between preoperative VAS and NDI scores between Group 1 and 2, $P = 0.75$, $P = 0.289$ respectively as shown in Table 2. After two years follow up intragroup significant improvement was demonstrated in both groups for VAS and NDI scores demonstrated in Table 2. Statistical comparison of postoperative outcomes between Group 1 and 2 shows no statistical difference in VAS and NDI scores $P = 0.62$, $P = 0.34$ respectively (Table 2). The surgical operative time in Group 1 was 92 ± 15 min as compared to Group 2 which was 140 ± 3 min. This difference of 48 min did



Figure 2 Photograph showing demineralized bone matrix packed within cage after insertion into disc space and anterior cervical discectomy and fusion plate.

Table 1 Cohort demographics with chief complaint

Variable	ACDF + DBM outpatient	ACDF + DBM inpatient	P value
Sample size (<i>n</i>)	75	70	
Age (yr)	53 ± 1.0	53.4 ± 1.6	0.591
BMI (kg/m ²)	27.9 ± 0.8	25.4 ± 1.0	0.484
Male	33	34	0.631
Female	42	36	
Diagnosis			
Herniated disc	28	23	
Degenerative disc disease	26	24	
Spondylosis (chronic pain)	7	12	
Myelopathy	3	4	
Radiculopathy	11	7	

ACDF: Anterior cervical discectomy and fusion; DBM: Demineralized bone matrix; BMI: Body mass index.

Table 2 Showing preoperative and postoperative visual analogue scales and neck disability index scores

	Preoperative VAS	Postoperative VAS	Intragroup P value	Preoperative NDI	Postoperative NDI	Intragroup P value
Group 1	7.4 ± 0.2	4.0 ± 0.2	0.001	46.9 ± 1.9	26.1 ± 1.2	0.001
Group 2	8.9 ± 1.5	5.3 ± 0.3	0.03	46.2 ± 2.6	33.4 ± 2.4	0.002
Intergroup P value	0.75	0.62		0.289	0.34	

VAS: Visual analogue scales; NDI: Neck disability index.

achieve statistical significance, $P = 0.001$. Estimated blood loss of 42 ± 6 mL in group 1 compared to 77 ± 9 mL in Group 2 showed no intergroup significance, $P = 0.131$.

Preoperative dimensions of airway diameter were all within normal limits^[29]. No intergroup significance demonstrated (Table 3) preoperatively at C2 and C6, $P = 0.172$ and 0.127 respectively. None of our patients complained of difficulty breathing within the first 24 h postoperatively. There was no radiographic^[30] or clinical evidence of adverse reaction in the patients who had ACDF to DBM (airway edema or neck swelling) within the first week postoperatively, Figure 3. Postoperative PVSTS dimension increased in both groups; however this was not a significant intragroup increase or intergroup difference as shown in Table 3. Additionally, all our patients achieved solid bony fusion^[31] as evidenced

by clinical and radiological (confirmed by report from independent radiologist) by the final follow up visit.

Three patients (4%) in Group 1 diagnosed with myelopathy without radiculopathy had a preoperative Nurick grade of 2, 1 and 1 respectively, which improved to 1 and 0 for the first two patients and remained unchanged for the third patient by the final follow up visit.

During the study period from 2011-2014, no major complications were reported in our series and there were no unplanned postoperative admissions for pain, nausea or any other complaints, all complaints are listed in Table 4. The main postoperative complaint of postoperative dysphagia was defined as any discomfort or difficulty with swallowing which was not historically present prior to surgery^[32]. The severity was assessed using the Bazaz-Yoo dysphagia severity scale

Table 3 Showing preoperative and postoperative prevertebral soft tissue swelling at C2 and C6 vertebrae

	C2 preop PVSTS (mm)	C2 postop PVSTS (mm)	C2 intragroup <i>P</i> value	C6 preop PVSTS (mm)	C6 postop PVSTS (mm)	C6 intragroup <i>P</i> value
Group 1	4.7 ± 0.2	5.5 ± 0.4	0.08	11.1 ± 0.5	14.9 ± 0.6	0.285
Group 2	4.5 ± 0.5	4.9 ± 0.3	0.107	12.8 ± 0.5	14.8 ± 0.5	0.873
Intergroup <i>P</i> value	0.172	0.212		0.127	0.946	

PVSTS: Prevertebral soft tissue swelling.

Table 4 Demonstrating complications after surgery in each group

Complication	Outpatient	Inpatient
Dysphagia	4	5
Visited ER (not admitted)	3	0
Pain not relieved by TTH medications	2	0
Dressing completely soaked	1	0
Intractable pain	0	1

TTH: To take home.

of mild, moderate and severe, over the initial 3 mo postoperative period^[33].

DISCUSSION

The authors aimed to demonstrate the safety of the use of DBM within and anterior to an ACDF PEEK cage in the outpatient setting. This study shows significant improvement in postoperative outcomes in both groups; however no intergroup significance was noted. Analysis of postoperative PVSTS demonstrated no clinical or statistically significant intragroup increase as well as no significant difference between groups.

The literature has copious studies endorsing ACDF as the gold standard treatment for failed conservative management of numerous cervical pathologies^[34-37]. More recently, patients and spine surgeons are turning their attention toward the potential benefits of ACDF in an ambulatory surgery center, based on promising results of preliminary reports^[2,16,17,38]. While the feasibility and safety of outpatient ACDF has been established for up to three cervical levels^[39], there is a lack of consensus regarding the safety of DBM in the anterior cervical spine as an adjunct to fusion. Studies have looked at the effectiveness, safety of its use in a hospital setting^[4,11,19] as well as normal prevertebral soft tissue swelling post ACDF^[30]; however, the paucity of data on the clinical outcomes of DBM use during ACDF in an ASC, prompted the authors to report the results of a single-center local experience.

In this series there were no adverse graft related complications noted. There was no clinical or radiologic evidence of edema one week post-operative and therefore no further evaluation for this finding performed beyond this point. The creation of DBM involves a process of allograft bone acid extraction^[40] which exposes type I collagen, growth factors and BMPs. Although lacking

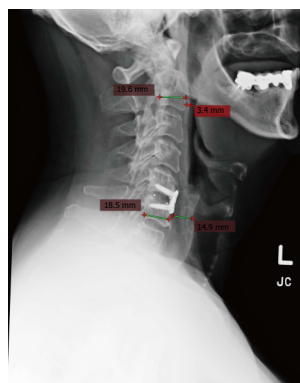


Figure 3 Plain lateral radiograph of the cervical spine, taken one week postoperatively, which shows the normal dimensions of the prevertebral space being less than 50% of the vertebral body at C2 and less than the body width of C6 respectively.

in structural integrity, DBM contains osteoconductive agents, which render it a viable alternative biologic agent for bony fusion. This study has demonstrated the effective use of DBM within and anterior to PEEK cages therefore, the authors conclude that the exposed BMPs within DBM is not significant in concentration to cause a clinical or radiographic response.

The adherence to our local, standardized outpatient criteria^[21-23], comprehensive patient education and postoperative protocol were instrumental in providing self-assurance to both patients and the surgeon when proceeding with this operation^[4,11,19]. Included in all preoperative counseling and consent sessions, were the potential risks for postoperative dysphagia, airway irritation and soft tissue swelling. Additional comfort was added by calling our patients the night of, and the morning after surgery in order to act in a timely manner should any complications occur, requiring immediate admission to hospital, which is always within 30 min of the patients' location.

As the literature expands on the safety and effectiveness of anterior cervical fusions in ambulatory surgery centers, this paper reinforces the conclusion that it is safe, with excellent patient satisfaction. The authors do acknowledge the limitations of this study: Its retrospective nature and the lack of CT scan to assess post-op soft tissue swelling. However, despite these limitations, we are confident that adherence to our strict patient selection criteria, preoperative education, consistent operating team, and systematic postoperative protocol can safely produce excellent outcomes. Our findings show that the

use of DBM within and anterior to cervical PEEK cages in the outpatient setting is safe with similar outcomes in the inpatient setting.

ACDF with adjunct DBM packed PEEK cages showed a statistical significant intragroup improvement in VAS neck pain scores and NDI scores. There were no reported serious patient complications; post-operative radiographs demonstrated no statistically significant difference in prevertebral space. We conclude that ACDF with DBM-packed PEEK cages can be safely done in an ASC with satisfactory outcomes.

COMMENTS

Background

Demineralized bone matrix (DBM) has been demonstrated to be safe in the hospital setting; however concerns may be heightened with use anterior to the cage in the outpatient setting. The authors hypothesize that clinical outcomes and safety should be similar or improved in the outpatient setting.

Research frontiers

Outpatient spine surgery continues to evolve with the introduction of minimally invasive and less exposure surgery. This study adds to the body of knowledge for outpatient surgery.

Innovations and breakthroughs

Based on literature no other study has assessed clinically DBM being placed anterior to the cage as well as within the cages looking specifically at soft tissue swelling.

Applications

This study demonstrates the safety of DBM being used anterior to polyetheretherketone interbody cage with no additional complications.

Terminology

Standard terminology used throughout text.

Peer-review

It is a well written paper.

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