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Clinical Outcomes and FEM Results of ACDF Performed Using H-Beam-Shaped Allospacer Versus Rim-Shaped Allospacer (A Comparative Study)

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이 논문을 의과학 석사학위 논문으로 제출함.

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Abstract

Objective

The study's aim was to evaluate radiological outcomes and finite element method (FEM) results of anterior cervical discectomy and fusion (ACDF) performed using H-beam-shaped allospacer and compare these with the corresponding findings of ACDF with rim-shaped allospacer.

Methods

From March 2011 to February 2014, 95 patients underwent anterior cervical discectomy and fusion (ACDF) with allospacers (H-beam shaped and rim shaped). Thirty-three patients diagnosed with trauma, Ossification of the posterior longitudinal ligament (OPLL), or combined posterior fusion were excluded from the study. Sixty-two eligible patients were divided into two groups: Group A comprised patients treated with H-beam-shaped allospacer (n=31) and Group B comprised those treated with rim-shaped allospacer (n=31). Clinical outcomes such as neck and arm pain, radiographical fusion rate, and adverse effects were evaluated. In the FEM study, the performance of three types of allospacers varying in shape—H-beam shaped, H-hole shaped, and rim shaped—was assessed; the effectiveness of stress distribution from these allospacers was compared by using the evaluation criteria of (a) compression, (b) shear and (c) torsion, under the same load.

Results

Neck and arm pain were reduced by 63% to 73% in both the groups. Fusion rates after one year were 100% and 98% in Groups A and B, respectively. Regarding complications, the rates of breakage and displacement in Group B were 16% and 3%, respectively. Group A showed no adverse effects. The FEM study revealed that H-beam-shaped allospacer showed more effective stress distribution and diversification with respect to compression, shear, and torsion when compared with the rim-shaped allospacer.

Conclusion

In ACDF with allospacer, the H-beam-shaped allospacer offered higher stable fusion rates along with lower incidence of complications when compared with the rim-shaped allospacer.

Keywords: anterior cervical discectomy and fusion, finite element method (FEM) study, H-beam-shaped allospacer, rim-shaped allospacer

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1. Introduction

Anterior cervical discectomy and fusion (ACDF) is a standard neurosurgical procedure used in the treatment of cervical spondylotic radiculopathy.[2, 4, 9, 11, 14, 16-18] To supplement bone grafts, various methods of anterior cervical interbody fusion, such as stand alone,[11] autograft and plate-screw fixation,[15] cage and plate-screw fixation,[7] allograft and plate-screw fixation,[19] have been developed over the past four decades.

The use of autograft bone or other alternatives is associated with complications such as breakage, displacement, fusion failure, implant failure, and donor site complication (from the anterior iliac crest).[5, 8, 10, 12] In particular, with iliac crest autograft bone, donor site complication was associated with significant short- and long-term morbidity such as infection, pelvic fracture, meralgia paresthetica, wound hematoma, loss of sensation, and especially postoperative pain, which occurs in about 20% patients.[3]

Various ACDF methods have been reported. Although allobone graft and plate-screw fixation is an effective surgical treatment with higher bone fusion rate, it is associated with a higher incidence of graft stability-displacement, subcidence, and implant failure when compared with other methods that use cages and bone graft.[5, 12, 15, 19]

However, the incidence of graft-related complications with an allobone spacer has not been reported with respect to the spacer design and biomechanical stability. Therefore, in this study, we evaluated clinical outcomes and biomechanical stability across different types of allobone spacers by using radiological and finite element method (FEM) assessments.

2. Materials and Methods

Between March 2011 and February 2014, 95 patients who underwent multi-level ACDF were enrolled and reviewed retrospectively. Forty-eight patients underwent ACDF with H-beam-shaped cervical allobone spacer, and 47 patients underwent ACDF with rim-shaped cervical allobone spacer.

In our study, patients were included who had disc herniation, stenosis, spondylolisthesis, segmental instability, and no improvement either after conservative treatment for at least 6 weeks or more than 12 months after surgery. Patients who had infection, neoplastic disease, hemorrhagic disease, metabolic bone disease, ossification of posterior longitudinal ligament (OPLL), trauma, combined anterior with posterior cervical fusion, and operation in the past 12 months were excluded. Finally, 62 patients who met our inclusion criteria were divided into two groups: Group A comprised patients treated with the H-beam-shaped allobone spacer (n=31) and Group B comprised those treated with the rim-shaped allobone spacer (n=31).

Cervical plain radiographs (anteroposterior, lateral, flexion, and extension views) were obtained for all patients, and clinical outcomes were evaluated 3, 6, and 12 months after surgery.

Follow-up assessment of serial cervical plain radiographs (serial anteroposterior and lateral image) and observation of clinical outcomes were performed 3, 6, and 12 months postoperatively. To evaluate bone fusion, lateral flexion–extension radiography and computed tomographic (CT) scan assessments were done for all patients 12 months postoperatively. Solid bone fusion was defined as visualization of trabecular bridging across the bone-graft interface, absence of radiolucent gaps between the endplate and graft, and restriction of motion (up to 0-2 mm) of the fused-level spinous process on flexion–extension.

The assessed clinical outcomes included neck pain and arm pain (measured using visual analog scale [VAS] score), radiographical fusion rate, and breakage and displacement of spacers. Fisher's exact test was used for statistical analysis.

In the FEM study, we compared the implant stability across three allobone cervical spacers varying in shape: H-beam shaped, H-hole shaped, and rim-shaped (Fig.1). We tested the effectiveness of stress distribution from these allospacers by using the evaluation criteria of (a) compression, (b) shear, and (c) torsion, under the same load. The FEM study environment complied with the standards of ASTM F-2077 (American Society for Testing and Materials).

In the FEM study, compression, shear, and torsion were set to load conditions of 2000 N, 3 Nm,

and 2000 N, respectively. Under the same load, simulation was conducted using a stainless steel jig in the upper and lower parts of the implant.

3. Results

In total, 95 patients underwent allograft and cervical interbody fusion with an allobone cervical spacer (H-beam shaped, n=48; rim shaped, n=47). Sixty-two patients who met the inclusion criteria were enrolled and divided into two groups: Group A included 31 patients who underwent ACDF with the H-beam-shaped allobone spacer, and Group B included 31 patients who underwent ACDF with rim-shaped allobone spacer (Table 1).

In Group A, 10 patients had one-level fusion; 19 patients, two-level fusion; and 2 patients, three-level fusion. The corresponding values in Group B were 18 patients, 7 patients, and 6 patients (Table 2).

The fusion rates within 12 months postoperatively were 100% in Group A and 98% in Group B (Fig. 2). There was no significant difference in fusion rates between Group A and B (Fisher's exact test; $p > 0.05$; Table 3).

We compared the complications such as breakage and displacement between Group A and Group B. The overall breakage rates in Group A and Group B were 0% (0/31) and 16% (5/31), respectively. The breakage rate among patients who experienced in H-beam shaped spacer was significantly less likely than that using rim-shaped spacer (Fisher's exact test; $p < 0.05$). The overall displacement rates in Group A and Group B were 0% (0/31) and 3% (1/31), respectively, but the between-group difference was not statistically significant (Fisher's exact test; $p > 0.05$; Table 4).

We used the VAS scores to evaluate pre-operation and post-operation neck pain and arm pain. Neck pain was reduced in Group A and Group B by 68% and 73%, respectively, and arm pain was reduced by 63% and 72%, respectively. Based on the VAS score, Group B showed a slightly better result than Group A (Fig. 2).

In the FEM study, compression was set to a load condition of 2000 N in the simulation. Under the same load, peak von mises stress (PVMS) values were checked for 90.8 MPa, 126.3 MPa, and 365.1 MPa in the H-beam-, H-hole-, and rim-shaped allobone spacers. In the shear condition setting of 3 Nm, the PVMS values were 61.2 MPa, 85.0 MPa, and 621.2 MPa, respectively. In the torsion condition setting of 2000 N, the PVMS values were 244.7 MPa, 261.9 MPa, and 863.7 MPa, respectively (Fig. 3).

4. Discussion

Many studies have reported that ACDF with allografts offers clinically satisfactory results in patients with cervical radiculopathy and myelopathy,[1, 6] along with high radiologically stable fusion rate and low incidence of complication.[5, 12, 13, 15, 19] However, cervical allobone spacers are also occasionally associated with complications such as breakage and displacement. The H-beam-shaped cervical allobone spacer was created to reduce the incidence of these complications.

In this study, we compared the clinical outcomes between allobone spacers varying in shape (H-beam shaped or rim shaped). Postoperative VAS scores suggest that ACDF with H-beam-shaped allograft affords substantial pain relief and improvements in quality of life, similar to ACDF with rim-shaped allograft (Table 5).

The fusion rates at the 12-month follow-up were not significantly different between the H-beam-shaped and rim-shaped allograft groups (Fisher's exact test; $p > 0.05$). The large central hole accommodates packing of osteoconductive bone substitute and promotes fusion through the implant. The threaded surface of the H-beam spacer can minimize the risk of migration, which is caused by the force of gravity. The two holes in the middle plate of the spacer promote fusion through the implant and help blood circulation.

The displacement rate in the H-beam-shaped spacer group was not significantly lower than that in the rim-shaped spacer group (Fisher's exact test; $p > 0.05$). This could be because of the textured grooves on the surface of the H-beam spacer. These grooves can minimize the risk of migration and displacement in the anterior–posterior direction. The convex superior surface also enhances the anatomical interface with the vertebral endplate; that is, the anatomical shape matches that of the vertebral endplate. This shape secures the anchorage between the allobone spacer and the cervical vertebral body and minimizes tissue deformation and damage.

The breakage rate among patients who received the H-shaped spacer was significantly less than that in patients who received the rim-shaped spacer (Fisher's exact test; $p < 0.05$). The H-beam-shaped spacer thus showed better results than the rim-shaped spacer with regard to breakage. We conducted the FEM study to determine the systemic and biomechanical reasons underlying our observations. We designed three spacer models varying in shape: H-beam shaped, H-hole shaped, and rim shaped which are same with shapes of currently used allograft in our clinic. In the FEM study, the H-beam-shaped allobone spacer showed the most effective stress distribution. Under compression and shear force load, the PVMS values coincided with the thread value. On the other hand, under the torsion load, H-beam-shaped allobone spacer showed PVMS value corresponding to 28.3% relative to other allobone spacers. This implies that the stress distribution is effective with the torsion load than with the other loads.

Unlike the case with conventional products (rim-shaped allobone spacer), the application of a support structure (H-beam) plays a great role in the central part. The rim-shaped allobone spacer showed a large PVMS value under the shear and torsion loads, probably because of thin thickness of rim shaped allobone spacer. In conclusion, because of the rotary motions of the cervical spine, applying a structure in the middle of the spacer is likely to provide high stability.

There are no previous studies comparing the clinical outcomes and FEM findings between allobone cervical spacers of different shapes. To the best of our knowledge, this retrospective study is the first to compare the clinical outcomes and complications across cervical spacers of various shapes. As mentioned above, if clinical outcomes and FEM study results differ depending on the cervical spacer shape, then the shape of spacer should be considered when selecting a spacer.

This study also has certain limitations. First, the two groups were not randomly selected for treatment, and, thus, the groups are not strictly comparable. The second limitation is the small number of patients in each group. Finally, this study has the limitation with respect to the study design: this was an FEM study, not clinical trial.

5. Conclusions

The use of cervical allobone spacer and plate-screw fixation affords stable fusion with low incidence of complications when compared with other cervical implants. This study showed that ACDF with H-beam-shaped allobone spacer shows better stable fusion rate with lower incidence of complications when compared with ACDF with other types of allobone spacers.

Fig.1 FEM analysis: schematic pictures of three allobone cervical spacers of different shapes: H-beam-shaped, H-hole-shaped, and rim-shaped

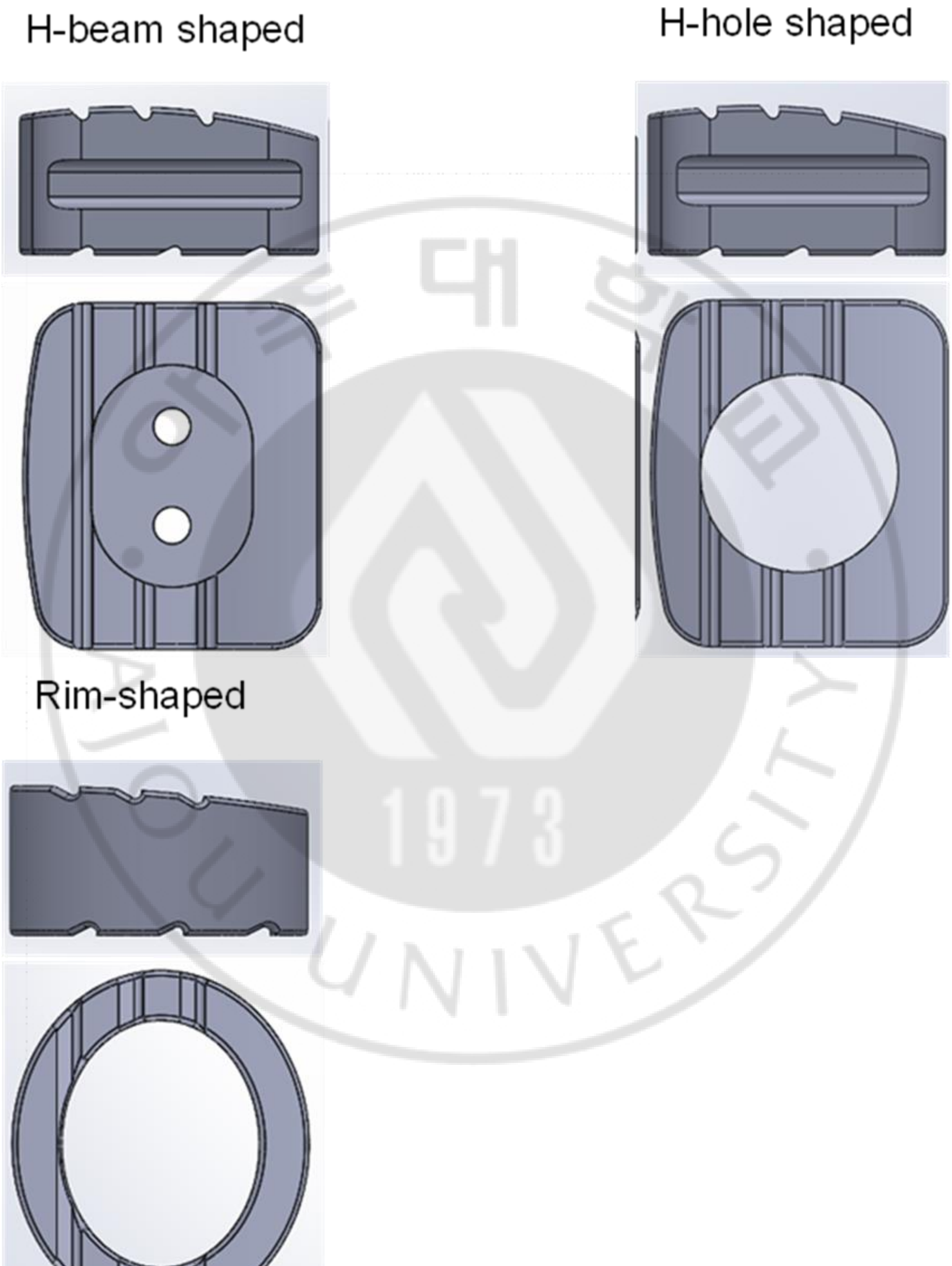

Fig. 2 Median absolute and improvement in neck and arm pain after treatment with H-beam-shaped or rim-shaped allospacer

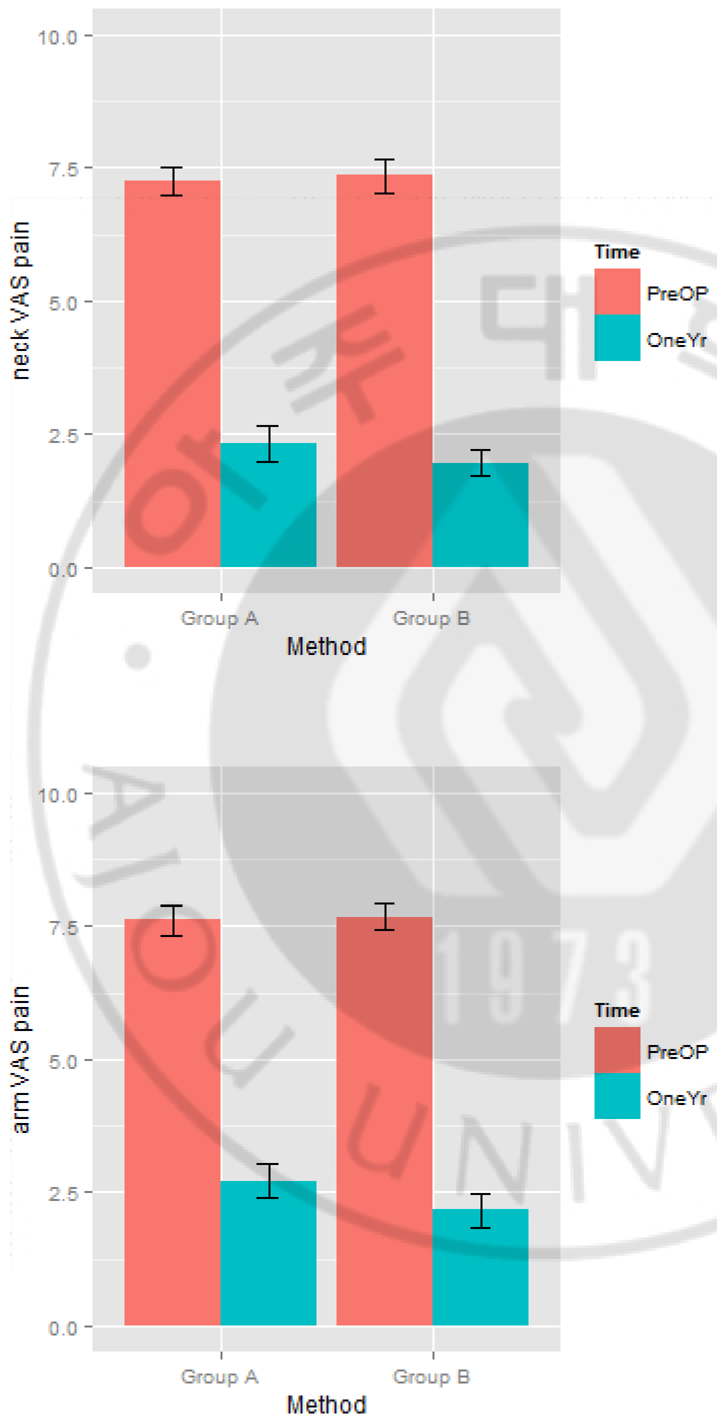

Fig. 3 FEM results of peak von mises stress (MPa) of compression, shear, and torsion, under the same load

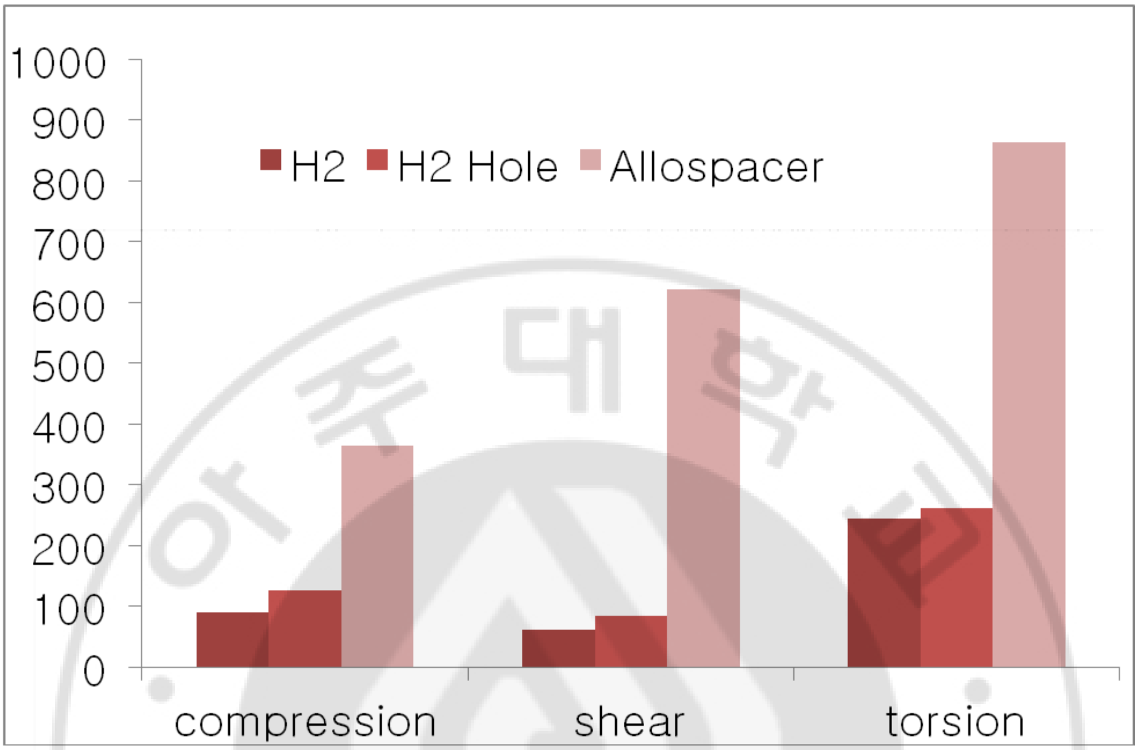

Table 1. Pathogenesis of the 95 patients with multilevel anterior segmental cervical fusion

Etiology	Allospacer type	
	H-beam shaped (n=48)	Rim shaped (n=47)
Trauma, etc., *n*	17	16
Degenerative, *n*	**31**	**31**

Table 2. Levels of anterior segmental cervical fusion

Fusion levels	Allospacer type	
	H-beam shaped (n=31)	Rim shaped (n=31)
One level, *n*	10	18
Two level, *n*	19	7
Three level, *n*	2	6

Table 3. Fusion rate of anterior cervical discectomy and fusion

Time point	H-beam-shaped allospacer*	Rim-shaped allospacer*	Fisher's exact test *p* value
12 months postoperation	100% (31/31)	98% (30/31)	0.5

Note: *Values in parentheses are expressed as level fused/the level at which discectomy was performed.

Table 4. Complications in the 62 patients who underwent anterior segmental cervical fusion

Complication type	H-beam-shaped allospacer (n=31)				Rim-shaped allospacer (n=31)				Fisher's exact test *p* value
	One level n=10	Two levels n=9	Three levels n=2	Total n=31	One level n=18	Two levels n=7	Three levels n=6	Total n=31	
Breakage	0	0	0	0/31 (0%)	2	1	2	5/31 (16%)	0.026
Displacement	0	0	0	0/31 (0%)	1	0	0	1/31 (3%)	0.5

Table 5. Median absolute (standard deviation) improvement in neck and arm pain after treatment with H-beam-shaped or rim-shaped allospacer

VAS score (pre and post)		H-beam-shaped allospacer (n=31)			Rim-shaped allospacer (n=31)		
		one level	two level	three level	one level	two level	three level
Neck pain	*M*	4.90	5.00	4.50	5.11	5.71	5.83
	(*SD*)	(1.20)	(1.15)	(0.71)	(0.76)	(0.76)	(0.98)
Arm pain	*M*	5.10	4.79	5.00	5.56	5.71	5.17
	(*SD*)	(1.37)	(0.54)	(0.00)	(0.86)	(0.76)	(0.41)

Note. *M* = mean, *SD* = Standard deviation

References

1. Albert TJ, Murrell SE: Surgical management of cervical radiculopathy. **Journal of the American Academy of Orthopaedic Surgeons** 7: 368-376, 1999.
2. An HS, Simpson JM, Glover JM, Stephany J: Comparison between allograft plus d emineralized bone matrix versus autograft in anterior cervical fusion| a prospective multicenter study. **Spine** 20: 2211-2216, 1995.
3. Aronson N, Filtzer DL, Bagan M: Anterior cervical fusion by the Smith-Robinson Approach*. **Journal of Neurosurgery** 29: 397-404, 1968.
4. Baba H, Furusawa N, Imura S, Kawahara N, Tsuchiya H, Tomita K: Late radiogra phic findings after anterior cervical fusion for spondylotic myeloradiculopathy. **Spin e** 18: 2167-2173, 1993.
5. Buttermann GR: Prospective nonrandomized comparison of an allograft with bone morphogenic protein versus an iliac-crest autograft in anterior cervical discectomy a nd fusion. **The Spine Journal** 8: 426-435, 2008.
6. Chesnut R, Abitbol J, Garfin S: Surgical management of cervical radiculopathy. Ind ication, techniques, and results. **The Orthopedic Clinics of North America** 23: 46 1-474, 1992.
7. Cho D-Y, Lee W-Y, Sheu P-C: Treatment of multilevel cervical fusion with cages. **Surgical Neurology** 62: 378-385, 2004.
8. Chou Y-C, Chen D-C, Hsieh WA, Chen W-F, Yen P-S, Harnod T, et al.: Efficacy of anterior cervical fusion: comparison of titanium cages, polyetheretherketone (PEE K) cages and autogenous bone grafts. **Journal of Clinical Neuroscience** 15: 1240-1245, 2008.
9. Cloward RB: The anterior approach for removal of ruptured cervical disks*. **Journ al of neurosurgery** 15: 602-617, 1958.

10. Floyd T: A meta-analysis of autograft versus allograft in anterior cervical fusion. **E uropean Spine Journal** 9: 398-403, 2000.

11. Gercek E, Arlet V, Delisle J, Marchesi D: Subsidence of stand-alone cervical cages in anterior interbody fusion: warning. **European Spine Journal** 12: 513-516, 2003.

12. Miller LE, Block JE: Safety and effectiveness of bone allografts in anterior cervica l discectomy and fusion surgery. **Spine** 36: 2045-2050, 2011.

13. Moreland DB, Asch HL, Clabeaux DE, Castiglia GJ, Czajka GA, Lewis PJ, et al.: Anterior cervical discectomy and fusion with implantable titanium cage: initial imp ressions, patient outcomes and comparison to fusion with allograft. **The Spine Jou rnal** 4: 184-191, 2004.

14. Pintar FA, Maiman DJ, Hollowell JP, Yoganandan N, Droese KW, Reinartz JM, et al.: Fusion rate and biomechanical stiffness of hydroxylapatite versus autogenous bo ne grafts for anterior discectomy: an in vivo animal study. **Spine** 19: 2524-2528, 1 994.

15. Samartzis D, Shen FH, Matthews DK, Yoon ST, Goldberg EJ, An HS: Comparison of allograft to autograft in multilevelanterior cervical discectomy and fusion with r igid plate fixation. **The Spine Journal** 3: 451-459, 2003.

16. Autho: Anterior cervical fusion using preserved bone allografts. **Transplantation Pr oceedings** 73-76, 1976.

17. Senter HJ, Kortyna R, Kemp WR: Anterior cervical discectomy with hydroxylapatit e fusion. **Neurosurgery** 25: 39-43, 1989.

18. Smith GW, Robinson RA: The treatment of certain cervical-spine disorders by anter ior removal of the intervertebral disc and interbody fusion. **The Journal of Bone and Joint Surgery American Volume** 40: 607-624, 1958.

19. Yue W-M, Brodner W, Highland TR: Long-term results after anterior cervical discectomy and fusion with allograft and plating: a 5-to 11-year radiologic and clinical follow-up study. **Spine** 30: 2138-2144, 2005.