

# The Pain, Life Quality and Low Back Pain Disability of the Patients Who Received Endoscopic Lumbar Intervertebral Fusion With Cages Made of Metal Material Versus Calf Bone: a Real World Study

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## Research article

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# Abstract

**Background** Interbody fusion is a common operation in spinal surgery, which is often used for various causes such as vertebral instability caused by trauma or degeneration. At present, a new material of calf bone interbody fusion cage has been used in clinic, but the curative effect has not been reported yet. In this study, the traditional metal interbody fusion cage was used as the control to evaluate the curative effect of this new type of interbody fusion cage.

**Method** This retrospective non-blind case-control study included 96 patients with lumbar degeneration who underwent single segmental interbody fusion. Among them, 58 cases used calf bone material interbody fusion cage and used metal material (titanium) in 38 cases. The Visual Analogue Score (VAS) and Oswestry Disability Index (ODI) score were compared before, immediately after, 3 months after, 1 year after operation and the last follow-up. IBM SPSS is used to compare the collected data one by one, and the parameter samples are tested by independent-samples t-test.

**Result** There was no significant statistical difference between patients who received calf bone fusion cage and metal fusion cage in each follow-up time point.

**Conclusion** The curative effect of calf bone fusion cage was not inferior to that of traditional metal interbody fusion cage at each follow-up time.

**Level of Evidence** ⓧ

## Background

Lumbar degeneration mainly presents as lumbar disc herniation, stenosis, lumbar spondylolisthesis, spondylolysis and other diseases, which often occurs in middle-aged and senior patients. Due to the developing pace of life style and incorrect working postures the disease tends to affect younger population. Degenerative diseases often lead to severe low back and leg pain, seriously affecting the quality of life of patients. For patients not respond to conservative treatments, discectomy followed by fusion and internal fixation are often the treatment options. The main material used for interbody fusion could be classified to autogenous and allogeneic bone material. In order to provide sufficient support and bone regrowth conduction, a cage filled with bone material was developed and widely applied in the past decades. At present, interbody fusion cages mainly made of non-absorbable (e.g. titanium alloy and other metal materials, Polyetheretherketone (PEEK) composite materials), absorbable (e.g. polylactic acid and other organic) materials, and the non-absorbable materials are the mostly used (1). A new type of interbody fusion cage was developed in recent years and attracted much attention, and it was deproteinized (by 10–20%) calf tibia. Compared with traditional cages, this material has good strength, suitable elastic modulus, wide range of materials, low cost and other advantages. However, the clinical efficacy of this kind of fusion cage has not been reported. In this study, by comparing life quality, the pain and physical performance (evaluated by Oswestry Disability Index (ODI) scores) between the patients using either metal and calf bone interbody fusion cage, the efficacy of such a new cage will be discussed.

# Methods

**Study Design** This study is a retrospective, non-blind, case-control study. The evaluation criteria were the results of Visual Analogue Score (VAS) scale and ODI scale score at before operation, immediately after operation, 3 months after operation, 1 year after operation and the last time follow-up.

**Patients Characters** A total of 96 patients with lumbar degeneration were included in this study, including 34 males (35.42%) and 62 females. There were 58 patients in calf bone group, including lumbar disc herniation (n = 51), spinal stenosis (n = 3), lumbar spondylolisthesis (n = 4). The main segments are L4-L5 (n = 41), followed by L5-S1 (n = 15), L3-L4 (n = 2). In metal group (n = 38), lumbar disc herniation (n = 34), spinal canal stenosis (n = 2), lumbar spondylolisthesis (n = 2), for segments, L4-L5 (n = 23), L5-S1 (n = 15). The following are the specific criteria:

## Entry criteria

1. The first diagnosis was lumbar disc herniation, lumbar stenosis and lumbar spondylolisthesis.
2. Age between 35–75 years old.
3. There is no primary underlying chronic disease, or the primary disease is well controlled and does not produce definite symptoms of physical pain.
4. There was no surgery have been received in related sites before.
5. No definite complications were found before the last follow-up, such as infection, failure of fusion, fracture of internal fixation device, etc.

## Exclusion criteria

1. Patients who refuse to join the study.
2. Those who suffered from diseases of other related sites during the follow-up period cause physical discomfort or undergo surgical treatment again.
3. Those who miss follow-up and lack of data.

**Surgical Technique** The selected two groups of patients were operated by clinicians of the same qualification and level in our hospital, and all patients were treated with general anesthesia. All patients underwent Endo-Transforaminal Lumbar Interbody Fusion (TLIF) operation with standard procedure. Autogenous bone grafts were taken from diseased segments and placed into metal or PEEK fusion cages. After adequate spinal canal decompression, autografts were placed into the intervertebral space of diseased segments. Finally, internal fixation was used in related lamina or pedicles. All patients received standard lower limb muscle exercise, low back muscle exercise, and other rehabilitation treatment. As of the last follow-up, there were no clear complications.

**Statistics Analysis** All data use IBM SPSS statistical analysis software, parameter samples use independent-samples t-test.

# Results

**Grouping Results** There was no significant difference in average age ( $P = 0.2803$ ), operation time ( $P = 0.8740$ ), total hospital staying time, postoperative hospital staying time, preoperative VAS and preoperative ODI between calf bone fusion cage group and metal fusion cage group, the samples were comparable.

**Curative Effect Evaluation** There was no significant statistical difference between calf bone fusion cage and metal fusion cage group, the corresponding scores of VAS scale and ODI scale in waist and leg before operation, immediately after operation, 3 months after operation, 1 year after operation and the last follow-up.

## Discussion

Lumbar fusion cage is a commonly used surgical instrument to solve patients' lumbar instability and other problems, from the first generation of metal interbody fusion cage was invented, a variety of different materials of instruments are still in the process of innovation, but various materials of fusion cages have their shortcomings. Metal is the traditional material of interbody fusion cage, mainly titanium alloy, but also cobalt or magnesium alloy and other materials. The former is widely used, with sufficient strength, toughness, strong fracture resistance and good histocompatibility. However, the large elastic modulus of titanium causes the problem of stress shielding. At the same time, titanium cage has a high incidence of cage subsidence, and the cost is high. The magnesium metal fusion cage could also belongs to the absorbable material and has a suitable elastic modulus. The degraded magnesium can be excreted from the body through urine, but the biodegradation rate of magnesium alloy is too fast. It may not be able to provide sufficient support before the bone fusion fully reaches the load-bearing standard. Metal interbody fusion cage will also affect the imaging judgment, so it is difficult to evaluate the specific conditions after interbody fusion in detail.

The PEEK interbody fusion cage which was born at the turn of the century is also widely used at present. Compared with metal fusion cage, its biggest advantage is that it has good ability to pass through X-ray, good compatibility to MRI, biological inertia and elastic modulus are also more suitable. The clinical study of titanium alloy fusion cage shows that PEEK material has higher fusion rate and lower sedimentation rate. However, due to the halo effect caused by poor osseointegration, the practical application of PEEK is still limited in some cases<sup>(2)</sup>. Recently, in order to integrate the advantages of these two kinds of fusion cages, a titanium-coated PEEK interbody fusion cage has emerged, which not only does not curb the early osseointegration, but also facilitates imaging judgment. It also responds to the problem of surface inertia of metals or polymers. Recent clinical studies have found that this kind of fusion cage can significantly improve the rate of vertebral fusion in the short term <sup>(3)</sup> <sup>(4)</sup> <sup>(2)</sup>.

In addition to the two mainstream fusion cages, absorbable, degradable and biological interbody fusion cages are also developing rapidly, and some of them are used in practical clinical work. In addition to the

magnesium mentioned above, the absorbable fusion cage is mainly made by polylactic acid and polyglycolic acid, which can be degraded with metabolism in the body. The ideal absorbable fusion cage has good mechanical strength and suitable elastic modulus, and the degradation rate should match the bone fusion speed. However, after degradation, polylactic acid fusion cage is easy to appear local acidic environment in the surgical area, leading to inflammation or other problems. In addition, there are carbon fiber and other polymer materials, high hardness, light weight, not easy to cause vertebral body subsidence, but poor toughness, easy to fracture inside of the body. These material innovations of physical and chemical modification to improve bone bonding ability are still under continuous testing and development(4) (5).

The calf bone interbody fusion cage is a new type of fusion cage developed in the past few years, which is made of 10–20% of the total protein removed from calf bone. It has sufficient strength to support spinal pressure and has the structural characteristics of cancellous bone, which provides a good environment for bone fusion. The elastic modulus of deproteinized calf bone is close to that of human bone tissue, so it is not easy to have problems such as lumbar subsidence and stress shielding in theory. And the surface of calf bone material is not inert, so it has strong adhesion ability with surrounding bone tissue in vivo. The results of this study show that, from the point of view of postoperative patient orientation, calf bone interbody fusion cage has no worse therapeutic effect than metal fusion cage, which can effectively relieve pain and improve the quality of life of patients.

Inevitably, this study also has some limitations. This new type of calf bone interbody fusion cage has not been widely used, so the long-term effect of this device has not been verified. The longest follow-up time in this study is 2 years. Secondly, this study can only prove on the level of patients' self-perception that the new fusion cage can achieve the same therapeutic effect as the metal interbody fusion cage after lumbar degenerative diseases. As for the other theoretical advantages of this fusion cage, such as the incidence and degree of vertebral subsidence, stress shielding to new bone and other (long-term) problems, still need further follow-up, observation and control study to draw a conclusion. Considering that there are some differences in the structure and fineness of the operation area in different parts of spine, the shape, size and material of the most suitable interbody fusion cage in different parts are not the same. In addition, this study did not refer to the fusion rate, which is the key parameter to evaluate the nature of the interbody fusion cage, and did not collect the imaging data of the patients with calf bone fusion cage. It is difficult to objectively compare the advantages and disadvantages of the two kinds of fusion cages from the actual vertebral body stability, interbody fusion rate, sedimentation rate and other parameters.

## Conclusion

There was no significant difference in VAS and ODI scores between calf bone fusion cage group and metal fusion cage group at each follow-up time point. It can be concluded that the therapeutic effect of the new calf bone interbody fusion cage is not inferior to metal fusion cage during the follow-up period of 2 years.

# List Of Abbreviations

VAS: Visual Analogue Score

ODI: Oswestry Disability Index

PEEK: Polyetheretherketone

TLIF: Transforaminal Lumbar Interbody Fusion

## Declarations

### **Ethics approval and consent to participate**

This article deals with questionnaire data from real-world patients, all of which have obtained the informed consent of the patients themselves, including written and / or oral consent. In addition, personal data including the privacy of patients are not involved.

### **Consent for publication**

Not applicable

### **Availability of data and materials**

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

### **Competing interests**

The authors declare that they have no competing interests.

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### **Authors' contributions**

Li J finished follow-up processes of included patients and collected the original data. Niu SB analyzed the data using software, and finished main of this manuscript. All authors read and approved the final manuscript.

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Not applicable

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## Table

Table 1

Patients characters, follow-up data( the average) and analysis consequence.

		Calf bone	Metal	P value	Sig differ
Diagnosis	LDH	51	34		
	Stenosis	3	2		
	Spondylolisthesis	4	2		
Level	L3-L4	2	0		
	L4-L5	41	23		
	L5-S1	15	15		
Basic information	Male	23	11		
	Female	35	27		
	Age	53.17	51.35	0.2803	NO
	Surge time/min	197.07	188.61	0.1589	NO
	Total days	16.09	16.24	0.8740	NO
	Postoperation days	11.67	12.61	0.1446	NO
VAS Lumbar	Preoperation	7.10	7.13	0.6761	NO
	Immediately postoperation	4.10	4.16	0.5572	NO
	3months	1.98	1.92	0.4414	NO
	1year	1.93	1.90	0.6674	NO
	Last	1.55	1.50	0.6970	NO
VAS Leg	Preoperation	0.55	0.65	0.7782	NO
	Immediately postoperation	0.29	0.34	0.8094	NO
	3months	0.17	0.21	0.7641	NO
	1year	0.12	0.10	0.8347	NO
	Last	0.10	0.11	0.9776	NO
ODI Scores	Preoperation	39.00	39.18	0.7648	NO
	Immediately postoperation	8.31	8.15	0.1952	NO
	3months	8.31	8.15	0.1952	NO
	1year	4.18	4.07	0.4761	NO

	Calf bone	Metal	P value	Sig differ
Last	3.79	3.68	0.4749	NO

## Figures

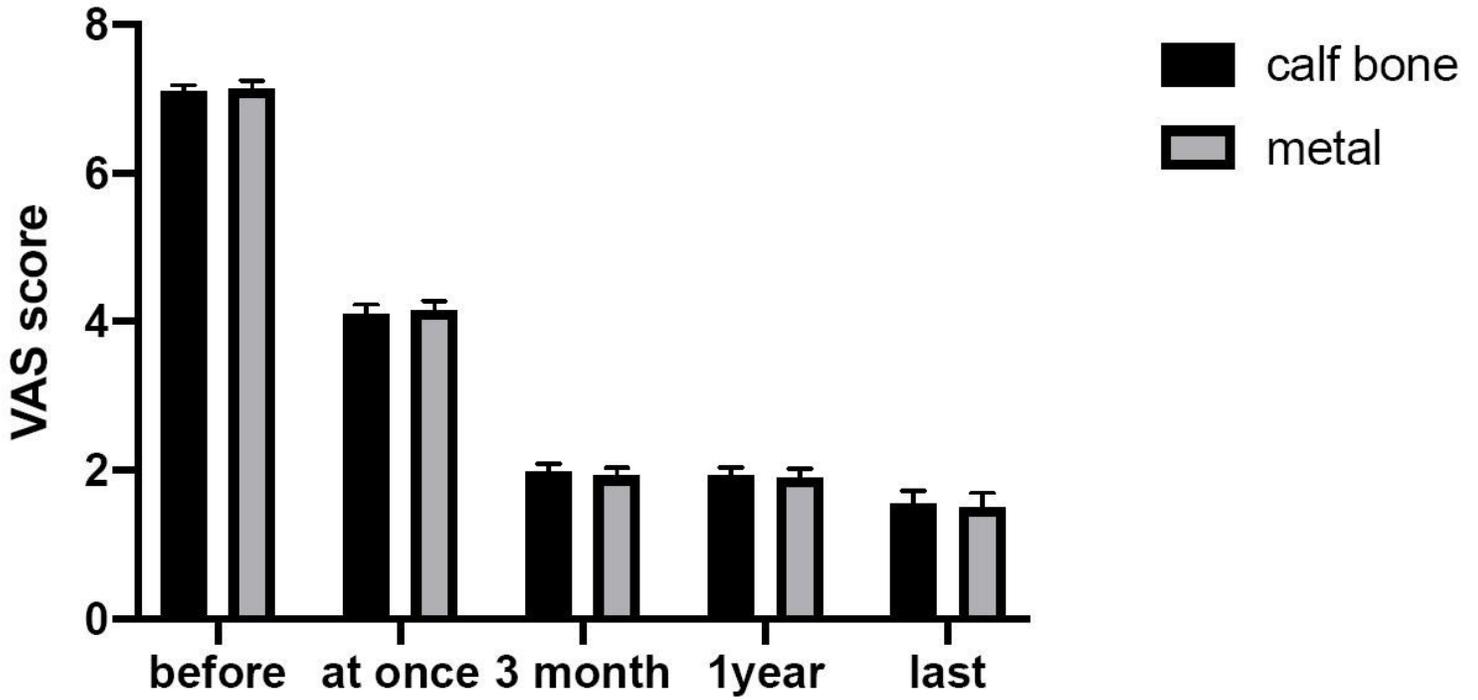


Figure 1

Comparison of lumbar VAS scores between the two groups at different follow-up time points (mean and standard deviation, 95% confidence interval)

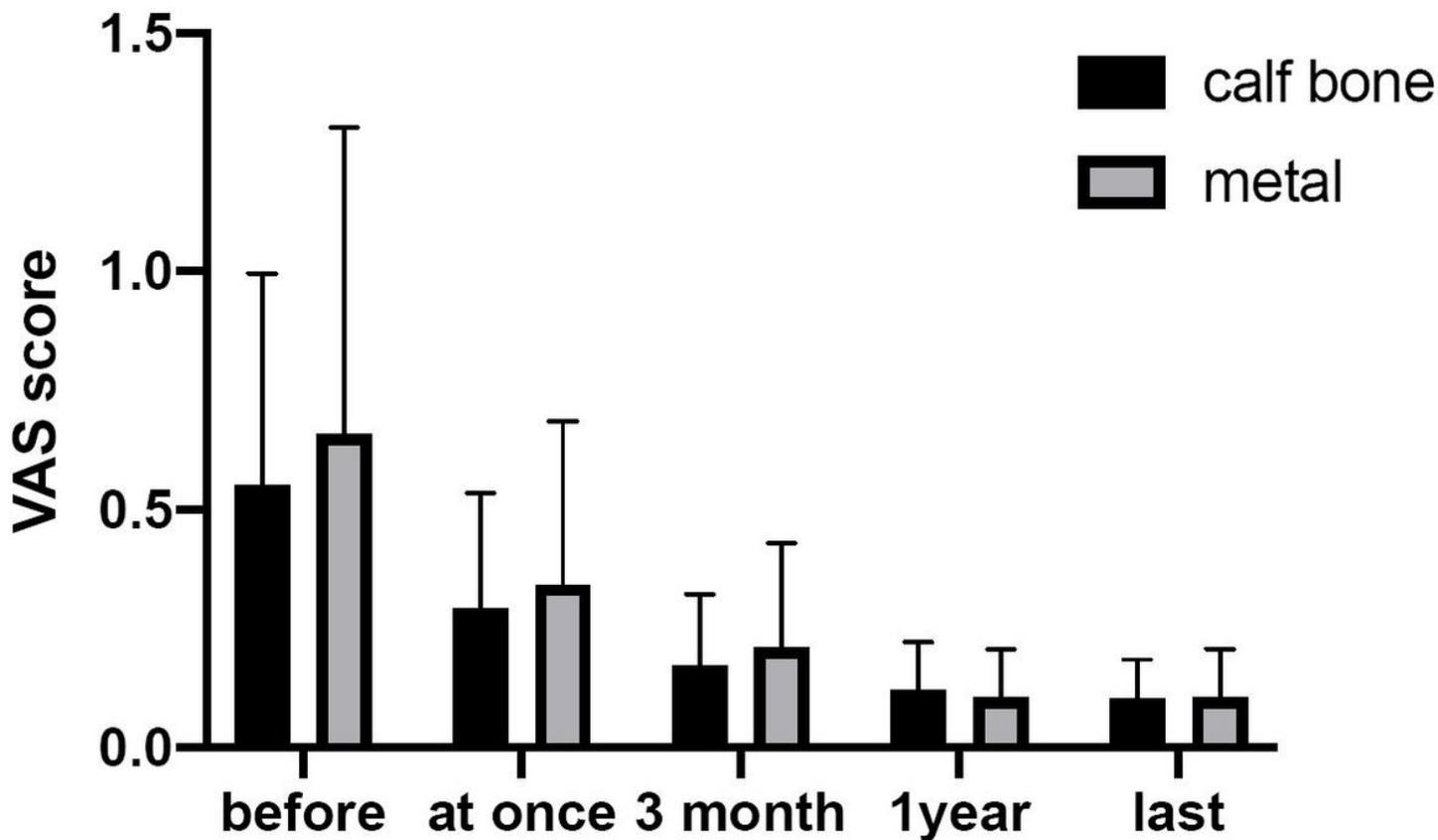


Figure 2

Comparison of leg VAS scores between the two groups at different follow-up time points (mean and standard deviation, 95% confidence interval)

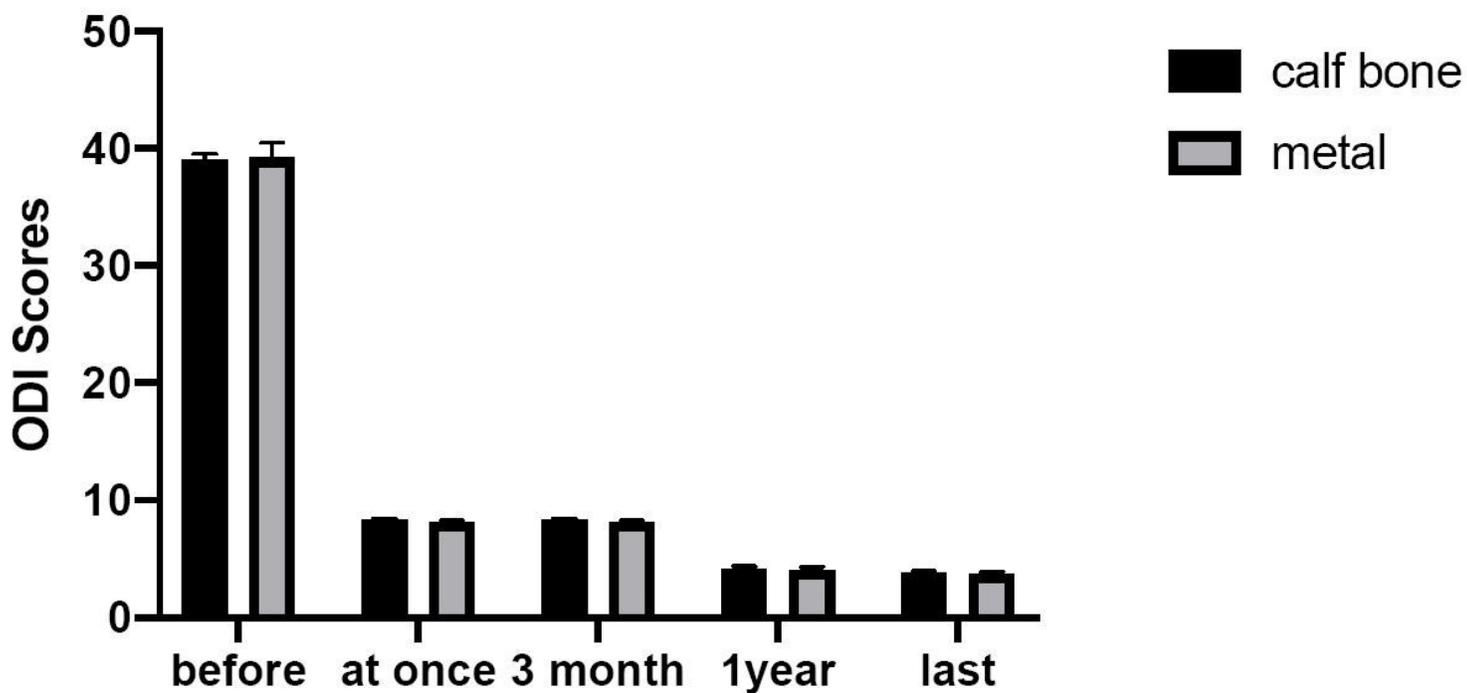


Figure 3

Comparison of ODI scores between the two groups at different follow-up time points (mean and standard deviation, 95% confidence interval)