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Applications of memory alloy stent in vertebral fractures

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Study Design A
Data Collection B
Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
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Background: The aim of this study was to evaluate the feasibility of treating vertebral compression fractures using an autonomously developed nitinol memory alloy vertebral stent.

Material/Methods: Thoracolumbar vertebral specimens from adult human cadavers were made into models of compression fractures. The models were divided into group A, which received percutaneous kyphoplasty (PKP), balloon dilation, and nitinol memory alloy vertebral stent implantation (PKP + nitinol stent group); group B, which received percutaneous vertebroplasty (PVP) and direct implantation of a nitinol memory alloy vertebral stent (PVP + nitinol stent group); and group C, which received PKP, balloon dilation, and bone cement vertebroplasty (PKP + polymethylmethacrylate (PMMA) group). Vertebral heights were measured before and after the surgery and the water bath incubation to compare the impact of the 3 different surgical approaches on reducing vertebral compression.

Results: The 3 surgical groups could all significantly restore the heights of compressed vertebral bodies. The vertebral heights of the PKP + nitinol stent group, PVP + nitinol stent group, and PKP + PMMA group were changed from the preoperative levels of (1.59±0.08) cm, (1.68±0.08) cm, and (1.66±0.11) cm to the postoperative levels of (2.00±0.09) cm, (1.87±0.04) cm, and (1.99±0.09) cm, respectively. After the water bath, the vertebral heights of each group were changed to (2.10±0.07) cm, (1.98±0.09) cm, and (2.00±0.10) cm, respectively. Pairwise comparison of the differences between the preoperative and postoperative vertebral heights showed that group A and group B differed significantly (P=0.000); group B and group C differed significantly (P=0.003); and group A and group C had no significant difference (P=0.172). Pairwise comparison of the differences in the vertebral heights before and after the water bath showed that group A and group C differed significantly (P=0.000); group B and group C differed significantly (P=0.000); and group A and group B had no significant difference (P=0.157).

Conclusions: The nitinol memory alloy stents can effectively support and reduce the compression of vertebral endplates and can be used to treat vertebral compression fractures without neurological symptoms.

MeSH Keywords: Alloys • Spine • Kyphoplasty

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Background

Percutaneous vertebroplasty (PVP) and percutaneous kyphoplasty (PKP) are effective treatment methods for osteoporotic vertebral compression fractures in the elderly, have small trauma and a reliable analgesic effect, and have now been accepted by the majority of orthopedic surgeons and patients [1–4]. However, the commonly used filler in current practice – polymethylmethacrylate (PMMA) – has the inherent shortcomings of toxicity in monomer form, heat generation, leakage, and incompatibility for application in young people [5–7]. The identification of an alternative material with low invasiveness and better tissue compatibility has been an important research topic in spine surgery in recent years. In this study, we implanted a type of autonomously developed memory nickel-titanium alloy vertebral stent (patent number: 200920144311) into vertebral specimens with compression fractures via passages and then observed the expansion of the stents and reduction of vertebral height compression and explored new minimally invasive treatment methods for vertebral compression fractures.

Material and Methods

Material

Nickel-titanium memory alloy stents and the ancillary equipment were provided by the Shaanxi Fulltai Medical Technology Co., Ltd. A total of 6 thoracolumbar vertebral specimens from adult human cadavers were provided by the Department of Anatomy at the School of Medicine of Xi'an Jiaotong University. Bone cement was provided by the Tianjin Synthetic Material Research Institute (polymethylmethacrylate resin cement III). The PKP puncture equipment and the balloon were from the Shanghai Kinetic Medical Co., Ltd.

Methods

The muscles around the cadaveric vertebral bodies were cleaned, and only the anterior and posterior ligaments and lumbar facet joint were retained. The T_9–L_5 vertebrae were selected with 3 vertebral bodies in each experimental segment, and each sample was made into 3 segments, for a total of 18 experimental segments. The upper and lower vertebral bodies of each segment were filled with bone cement via transpedicular puncture and solidified. The middle vertebrae were reserved for experiments, and the central vertebral heights were measured and recorded under fluoroscopy. First, the test segment was fixed on the electronic universal testing machine, pressure was applied at a rate of 5 mm/min, and the external force was terminated when the vertebral height was compressed by 1.5 cm to create a model of compression fractures. The 3 segments from the same specimen were given different interventions. Group A had the passage established by transpedicular puncture, followed by balloon dilation and memory alloy stent implantation (PKP + nitinol stent group); group B had the passage established by transpedicular puncture, followed by the direct implantation of a memory alloy stent (PVP + nitinol stent group); and group C had the passage established by transpedicular puncture, followed by balloon dilation and bone cement implantation (PKP + PMMA group). The balloon length was 20 mm, the volume expansion was 3 ml, and the volume of bone cement filling was 3 ml. The central vertebral height, diameter of stent expansion, bone cement leakage, and vertebral bone displacement were recorded under fluoroscopy. All specimens were placed in the water bath at 37°C and removed a week later. The anterior vertebral height and the diameter of stent expansion were again recorded under fluoroscopy.

Observation indicators

We measured the central vertebral heights of each group before and after the surgery and before and after the water bath, and calculated the differences. SPSS 17.0 software was used for the analysis, and the data are expressed as $\bar{x}\pm s$. The paired t-test was used to examine the difference in the changes of the vertebral body height of each group before and after surgery and before and after the water bath. The least significant difference (LSD) test was used for pairwise comparison, and the test level was $\alpha=0.05$.

Results

Each group successfully underwent the surgical procedures. No bone blocks were observed to shift to the spinal canal under fluoroscopy or under direct vision. There were 2 cases of bone cement leakage, which affected the intervertebral disc and vertebral anterior edge. Under fluoroscopy, it was observed that the 3 groups all showed varying degrees of vertebral height restoration, based on comparing the conditions before and after the experiment (Figure 1). We measured the preoperative and postoperative mean vertebral heights of each group (Table 1) and conducted respective paired t-tests. The results showed that the vertebral heights of the 3 groups of A, B, and C were increased from the preoperative levels of (1.59±0.08) cm, (1.68±0.08) cm, and (1.66±0.11) cm to the postoperative levels of (2.00±0.09) cm, (1.87±0.04) cm, and (1.99±0.09) cm, respectively. The postoperative vertebral height in each group was significantly increased compared with the preoperative level ($P<0.01$).

The mean increases in the vertebral height of each group after the surgical procedures were analyzed using single-factor analysis of variance (ANOVA). The homogeneity of variance

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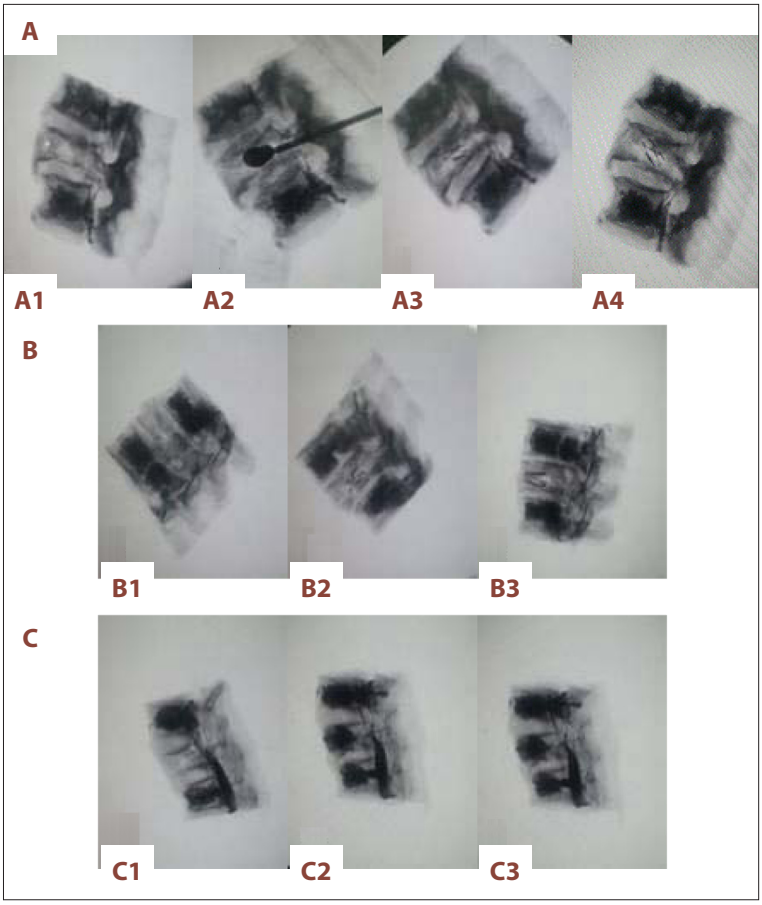

Figure 1. X-ray images of each group before, during, and after surgery, and after the water bath. Group **A**: PKP + nitinol stent group (**A1** – before the surgery, **A2** – during the surgery, **A3** – after the surgery, **A4** – after the water bath). Group **B**: PVP + nitinol stent group (**B1** – before the surgery, **B2** – during the surgery, **B3** – after the water bath). Group **C**: PKP + PMMA group (**C1** – before the surgery, **C2** – during the surgery, **C3** – after the water bath).

Table 1. Comparison of preoperative and postoperative mean vertebral heights in each group (unit: cm).

	Group A	Group B	Group C
Before surgery	1.59±0.08	1.68±0.08	1.66±0.11
After surgery	2.00±0.09	1.87±0.04	1.99±0.09
T and P values	–9.781, 0.000	–7.952, 0.001	–18.213, 0.000

Table 2. Comparison of the differences between the preoperative and postoperative vertebral heights of each group (n=6).

	Group A	Group B	Group C
Difference between preoperative and postoperative vertebral heights (cm)	0.39±0.09	0.19±0.06	0.33±0.04
P value	0.000 (A&B)	0.003 (B&C)	0.172 (A&C)

test revealed a Levene statistic of 1.737 and P=0.210, indicating homogeneity of variance. ANOVA showed an F value=13.386 and P=0.000, indicating that the mean increases in the vertebral height of the 3 groups were statistically significant. We further used the LSD test for pairwise comparison. The results (Table 2) showed that group A and group B differed significantly in the mean height difference before and after surgery (P=0.000), and group B and group C differed significantly in the mean height difference before and after surgery (P=0.003); however, there was no significant difference (P=0.172) between group A and group C.

We statistically analyzed the mean vertebral heights before and after the water bath for each group (Table 3) and performed

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Table 3. Comparison of the mean vertebral heights before and after the water bath in each group (unit: cm).

	Group A	Group B	Group C
Before water bath	2.00±0.09	1.87±0.04	1.99±0.09
After water bath	2.10±0.07	1.98±0.09	2.00±0.10
T and P values	–6.371, 0.001	–4.445, 0.007	–2.000, 0.102

Table 4. Comparison of the differences between the preoperative and postoperative vertebral heights of each group (n=6).

	Group A	Group B	Group C
Difference in vertebral heights before and after water bath (cm)	0.08±0.03	0.07±0.02	0.01±0.01
P value	0.157 (A&B)	0.000 (B&C)	0.000 (A&C)

respective paired t-tests. The results showed that the vertebral heights of group A and group B were increased from the pre-water bath levels of (2.00±0.09) cm and (1.87±0.04) cm to the post-water bath levels of (2.10±0.07) cm and (1.98±0.09) cm, respectively, and the changes in height were significant ($P<0.01$). In contrast, group C did not show a significant difference in the vertebral height before and after the water bath ($P=0.102$).

The mean vertebral height increases of each group after the water bath were compared using single-factor ANOVA, and the homogeneity of variance test showed that the Levene statistic was 2.669 and $P=0.102$, indicating homogeneity of variance. ANOVA showed the F value=21.161 and $P=0.000$, indicating that the mean height increases of the 3 groups were all statistically significant. We further applied LSD for pairwise comparison, and the results are shown in Table 4. There were significant differences ($P=0.000$) in the mean height difference before and after the water bath between group A and group C and between group B and group C; however, there was no significant difference ($P=0.157$) between group A and group B.

Discussion

As the population ages, the incidence of osteoporotic vertebral compression fractures will gradually increase; the associated low back pain can seriously affect the quality of life of patients. Conservative treatment requires long bed rest, which can easily lead to frequent complications, such as hypostatic pneumonia and bedsores. Due to the risks, such as severe trauma and osteoporosis, the procedure of open reduction and internal fixation is now less commonly used. Vertebroplasty and kyphoplasty have advantages, such as minimal invasiveness, reliable analgesic effect, and quick recovery, and have been widely used in the treatment of this type of fracture. Currently, the most commonly used vertebral filler is PMMA, which has the advantages of good fluidity and short solidification time and the shortcomings of easy leakage, heat generation, toxic monomers, excessive hardness, inability of tissue-creeping substitution, and incompatibility of applications in younger patients. Various types of new resorbable bone cement fillers have not yet been applied in clinical practice due to the limitations of their mechanical properties. With the improvement of operating technologies, the cement leakage rate has been significantly reduced, but leakage is still one of the most common complications of PVP and PKP [8–10].

Instead of finding a new material, we tried to find a new technique to replace the PVP and PKP. It can be minimally manipulated, restores the height of the vertebral body, and avoids the complication of PMMA. Though our study, we want to demonstrate that memory alloy may have the same expanding effect as with balloon expansion. Considering the biocompatible character of the alloy, which would be tested in future experiments, the success of developing memory alloy in use of osteoporotic VCF will greatly simplify the procedure and may change our current practice of treating spine compression fracture.

When memory alloy materials are cooled from a high temperature to the critical temperature, the crystal structure switches from cube to diamond; when the temperature rises from a low temperature to the critical temperature, the crystal structure recovers from diamond to cube. During the recovery process, the alloy can produce displacement and force as a function of the temperature, and the energy is derived from the phase transformation driving force. The phenomenon of the disappearance of alloy deformation and shape recovery of the alloy after the temperature increase is known as the shape memory effect [11–13]. Ti-Ni shape memory alloy materials are in wide use in the medical field [14–16] in applications such as thrombosis filters, bone plates, orthodontics wire, and

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cardiac and biliary stents, with the functions activated by the body temperature after implantation. They have good performance and high reliability as well as good biocompatibility with the human body. Their elastic modulus is similar to that of human bone. We utilized the characteristic that its shape changes at different temperatures and implanted the stents into the vertebral body via minimally invasive passages under low temperatures, which then expanded under the effect of the body temperature and thus achieved the sustained support of vertebral bodies.

The stents designed in this study were manufactured by laser-mediated carving of titanium-nickel memory alloy pipes. The stents contract into a rod shape with an outer diameter of 6 mm at 0–5°C and revert to the memorized shape and size with an outer diameter of 18 mm at 37°C, thus generating a superelastic supporting force and restoring the compressed vertebral bodies to a certain height. Previous studies [17,18] have reported similar lantern-shaped stents, which are formed by cutting sheet-shaped materials; however, after shaping, the peripheral wall still has gaps, inevitably affecting its support force when under pressure. In contrast, the stent that we designed was carved from materials in the shape of cylindrical pipes. After expansion, the peripheral wall is in a closed state, with the purpose of providing as large a supporting force as possible. The results showed that the vertebral heights of the 3 groups all had different levels of recovery after the experiments; the height restoration was superior in the balloon-using groups to the groups that did not use balloons, and the vertebral height restoration effect of balloon dilatation and the placement of the memory alloy stent was comparable with the effect of PMMA bone cement. The group with bone cement injection had 2 cases of leakage (an incidence rate of 30%), which is higher than the rate reported in the literature [19,20]. This result might be related to the small sample size and increased leakage diagnosis rate as observed by the naked eye. After 1 week of a water bath at 37°C to simulate body temperature, the vertebral height in the memory alloy stent group was further recovered and showed significant differences compared with the level before the water bath and with the PMMA group. This result confirmed the memory expansion capabilities of the stents.

Conclusions

Through this study, we confirmed the feasibility of memory alloy stent implantation via minimally invasive passages. The experimental results showed that the memory alloy stent could revert and expand within the vertebral body, thus playing supporting and reducing roles in diseased vertebral bodies. This application explores a new opportunity for the treatment of vertebral fractures without neurological symptoms. In subsequent experiments, we will further test the biomechanical properties and bone ingrowth conditions of the memory alloy stents after implantation into vertebral bodies.

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