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Vertebral Augmentation With a Novel Vessel-X Bone Void Filling Container System and Bioactive Bone Cement

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Study Design. Evaluation of a novel, leakage-free vertebroplastic instrumentation by fresh cadaveric studies.

Objectives. To compare Vessel-X, a novel percutaneous bone void filling container system, with conventional kyphoplasty in restoring strength, stiffness, and height in experimentally induced vertebral compressive fractures and morphologically determine the cement distribution.

Summary of Background Data. Clinically, both vertebroplasty and kyphoplasty perform well in reinforcement and pain relief. One of the shortcomings, however, is the risk of cement leakage. Vessel-X is a novel bone expander and bone void filler combined instrumentation for vertebral augmentation requiring evaluation.

Methods. A total of 28 fresh-frozen vertebral specimens were randomly assigned to 4 groups for testing: unipedicular kyphoplsty, bipedicular kyphoplsty, unipedicular Vessel-X, and bipedicular Vessel-X. Compressive fractures were experimentally created on each vertebra after determining the bone mineral density. Kyphoplasty and Vessel-X were performed using bioactive bone cement (SrHAC) under C-arm fluoroscopy and compared by compression testing to measure the effects of augmentation. Morphologic observations were also performed to determine the cement distribution and vertebral height restoration.

Results. There was no significant difference in bone mineral density, initial strength, and stiffness in any of the groups. Furthermore, no significant difference was observed in total cement volume in intragroup comparison within the unipedicular or bipedicular groups. Vessel-X bone filler container could expand well and contain most of the cement. The height restoration ranged from 88.5% to 96.4% in all groups. The augmented strength with unipedicular and bipedicular injections reached 3651.57 N and 4833.73 N, respectively. Stiffness with bipedicular injection was significantly higher than that of unipedicular injection.

Conclusion. Vessel-X was comparable to kyphoplasty in restoring the mechanical properties and height of the fractured vertebrae. Interestingly, Vessel-X instrumentation showed considerably less cement leakage and better cement placement in the vertebral body. Therefore, it could be a leakage controllable technique in percutaneous vertebral augmentation.

Key words: biomechanics, cement leakage, compressive fracture, kyphoplasty, vertebroplasty, Vessel-X system. **Spine 2007;32:2076–2082**

Minimally invasive vertebral cement augmentation procedures have been widely used to treat vertebral body compression fractures caused by either osteoporosis or spinal osteolytic tumors. Percutaneous vertebroplasty (PVP), first reported in 1984 by Galibert *et al*,[1] and balloon percutaneous kyphoplasty (PKP), developed in the 1990s,[2] are encouraging techniques regarding back pain relief, increased mobility, and safety with low morbidity.[3–8] Both procedures increased the strength and restored the stiffness of the fractured vertebrae to various degrees.

Although these achieved results were encouraging, a major problem with PVP and PKP is cement leakage. Investigations on cement leakage in PVP reported a rate of 11% to 76% with average of 29%.[1,3,4,7,9] PKP was thought to be safer than PVP for the low pressure injection of bone cement into a void of vertebrae; however, investigations on PKP still showed the leakage rate to range from 4.8% to 39%,[2–6,8,9] depending on surgical experiences. Although complications resulting from cement leakage occurred infrequently,[3,9] they may become more common as PVP and PKP are more widely used among the ageing population. Suggested safeguards and modifications to the procedure include venography to confirm needle position,[10] allowing partial curing of the cement before injection, use of high-quality fluoroscopy during cement injection,[11] and developing new injection system to minimize cement leakage.

The Vessel-X (A-Spine Corp., Taiwan) bone void filling container system has been recently developed for reducing leakage as an alternative to the PVP technique. Vessel-X, the essential component of this system, serves as a vertebral body expander and the bone void filling container (Figure 1). It can be introduced into the vertebra in a reduced configuration, followed by expansion to its predetermined configuration. It can raise the endplates and create a void along with the introduced bone filler material. The cement injected by this system is confined within the container; therefore, it can almost reach leakage-free during clinical application.

Strontium-containing hydroxyapatite cement (SrHAC) is a newly developed bone cement. After injection into the vertebrae, strontium can be delivered locally and promote

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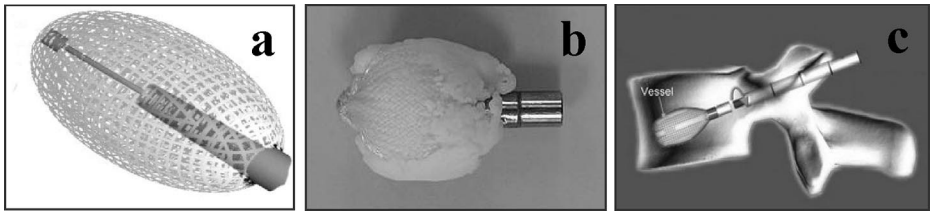

Figure 1. (**a**) The Vessel-X bone void filling container (**b**) expanded by SrHAC filling *in vitro* and (**c**) the schematic diagram of expansion of Vessel-X bone void filling container in the vertebrae.

bony ingrowth and bone bonding with cement.[12,13] Reports had shown that it is superior to PMMA in bioactivity, biocompatibility, and osseointegration. It also has shown sufficient mechanical strength properties in fresh porcine spine specimens.[14–16]

In this study, bioactive SrHAC and a new cement injection system were applied to control the cement leakage within the vertebrae. The purpose of this cadaveric study was to evaluate cement leakage, biomechanical and morphologic behavior of the Vessel-X system with SrHAC injection. The characteristics of the Vessel-X system were compared with those of the Kyphon balloon system (Kyphon Inc., Sunnyvale, CA).

■ Materials and Methods

Specimen Preparation. Human vertebrae specimens were harvested from 6 fresh-frozen cadaver spines (T8–L5) of mean age 87.5 years (range, 75–91 years; 1 male and 5 female). The specimens were disarticulated, excised of soft tissue, and cleaned of posterior elements to facilitate mechanical testing. Fractured vertebrae were excluded and 28 intact vertebrae were eventually selected for the experiment. Bone mineral density (BMD) was determined by dual-energy radiograph absorptiometry (DEXA, Hologic QDR 4500, Hologic Inc., Waltham, MA). Specimens were randomly divided into 4 groups (7 specimens per group): unipedicular Vessel-X (UVS), bipedicular Vessel-X (BVS), unipedicular kyphoplasty (UKS), and bipedicular kyphoplasty (BKS). The vertebrae heights of all specimens were recorded at the anterior, posterior, and midline planes of the vertebral bodies. Axial and lateral views of plane radiographs were taken in each vertebra before storing at −30°C until use.

Initial Mechanical Compression Test. Compression test was performed using a servo-hydraulic materials testing machine (MTS 858 Bionix Machine, MTS System Inc., Minneapolis, MN) to record the initial strength and stiffness of each vertebra. Each vertebra was held between a set of testing jig through its endplate, which had been filled with a fast dry epoxy. The loading axis was vertically aligned to the anterior one third of the vertebral body. Specimens were first ramp-loaded from 0 to 500 N for 5 cycles at a loading speed of 2 N/sec. Initial stiffness was defined as the average slope of the first 5 cycles based on the load/displacement curve. A displacement-controlled compression was then applied until the anterior height of the vertebrae was decreased by 25% (Figure 2). Failure load was defined when the vertebra height was reduced by 25%. The stiffness of the fractured vertebrae was measured similar to intact condition above by 5 additional cycles of compression using a ramped-load from 0 to 500 N.

Plane radiographs of each fractured vertebrae were taken in both the axial and lateral views and the vertebrae height determined from the image.

Surgical Procedures. The Vessel-X bone void filling container system and the Kyphon balloon system were used in this study. The main components of the Vessel-X system included: bone access needle, drill bit, flexible expansion tube, the volume control meter, and the cement container. The 3.0-mL cement container was a 30-mm-long double layer mesh made of polyethylene terephthalates (Figure 1) and had the inner and outer pore size of 60 to 90 μm and 100 to 180 μm, respectively.

Vessel-X cement injection and kyphoplasty were performed under C-arm fluoroscopy monitoring with the same experimental conditions. Briefly, in Vessel-X groups, the Jamshidi needle was inserted through the pedicle and advanced until its tip just crossed the posterior wall by about 2 to 3 mm. The stylet was then replaced by a drill bit, which drilled through the lumen into the vertebral body until the tip reached just 2 to 3 mm from the anterior cortex. The Vessel-X bone void filling container was inserted with its introducer through the needle canal in its initial contacted configuration after the drill bit was removed. On confirmation of the site by fluoroscopy, the metal core of the container was replaced by the Vessel-X meshed layer and the prepared SrHAC was injected into the filling container. A cement delivery system was used in controlling the flow and volume of the injected bone cement. As the maximum volume of the Vessel-X container was designed to be 3.0 mL, the maximum volume of cement injected on each side was controlled to less than 3.5 mL so that the container can be fully filled and expanded. For bipedicular groups, a second Vessel-X

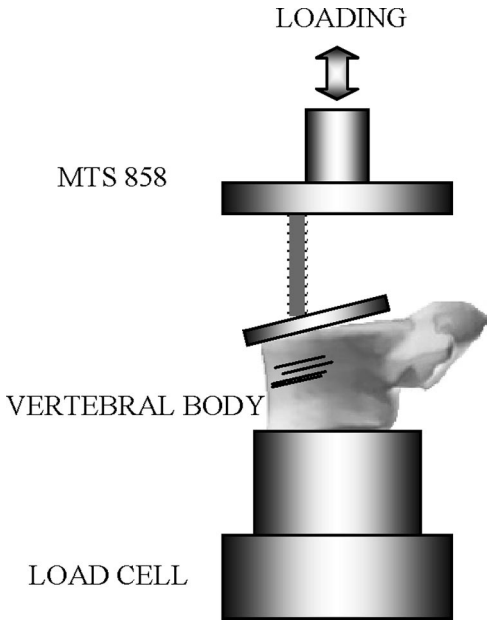

Figure 2. Simulated vertebral compressive fracture performed by compressing the anterior body up to height lose of 25%.

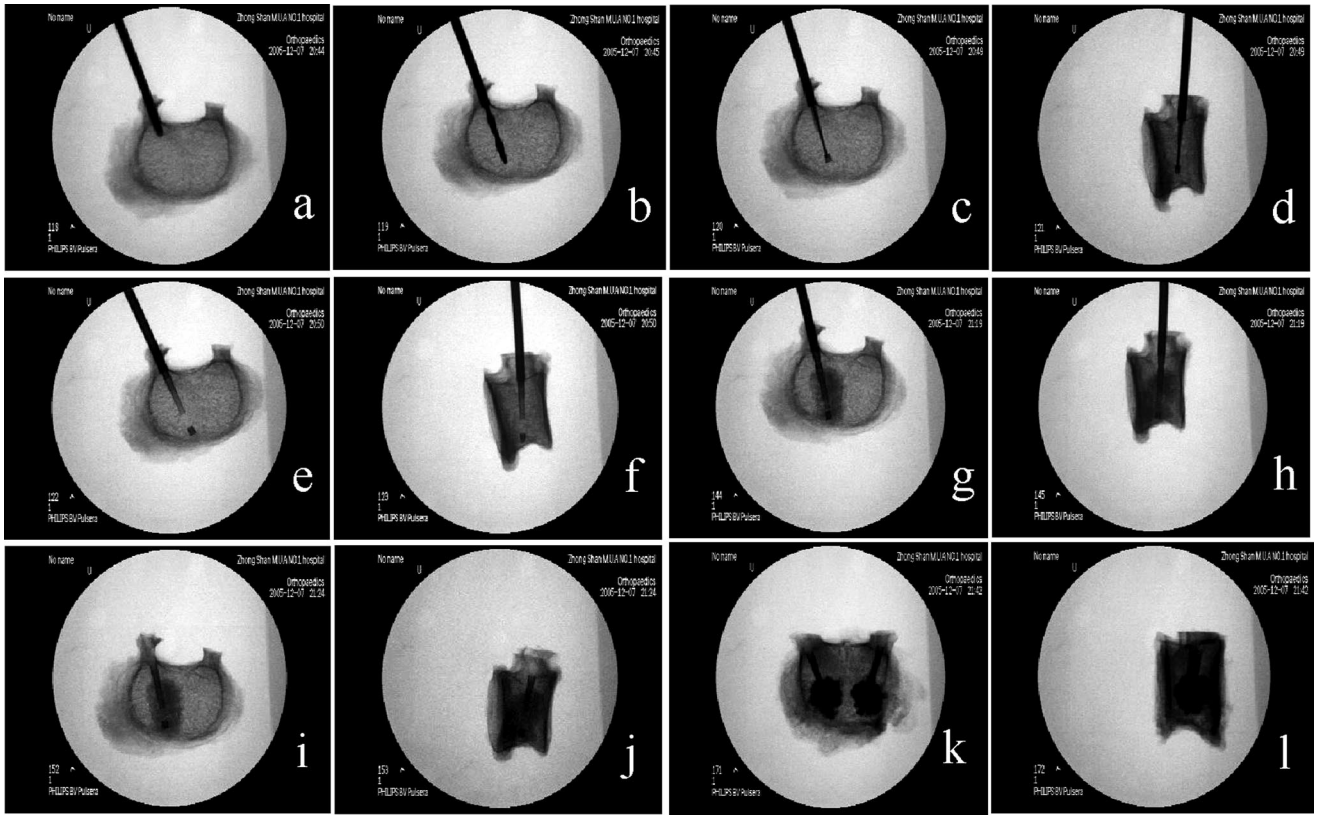

Figure 3. The procedure of Vessel-X augmentation under C-arm fluoroscopy monitoring. **a**, Insert Jamshidi needle. **b**, Insert driller. **c** and **d**, Insert Vessel-X bone void filling container system, **e** and **f**, Remove the metal core of Vessel-X. **g** and **h**, Inject SrHAC into Vessel-X unipedicularly. **i** and **j**, Remove the canula and complete SrHAC injection. **k** and **l**, Complete SrHAC injection bipedicularly.

container was introduced in the same way to the opposite pedicle (Figure 3).

In the kyphoplasty groups, a balloon bone tamp was inserted following the standard clinical procedure as reported previously.[17,18] Briefly, drill channels were created for placement of the balloon by passing a 3.2-mm-diameter bit (Kyphon Inc.) through the pedicle. The balloon (size 15/3, Kyphon Inc.) was then introduced into the vertebral body in its contracted configuration and inflated by consistent injection with 3 mL of radiopaque contrast medium, which corresponds to the maximum volume of the Vessel-X container. The vertebra was cemented with SrHAC using controlled cement volume (<3.5 mL) in each side after the balloon was retracted (Figure 4).

Axial and lateral radiographs of the vertebrae were then taken, and the vertebral heights were defined from the plane radiographs.

Mechanical Compressive Test and Morphology Observation. Mechanical compressive tests were performed on all cemented vertebrae to record the failure strength and stiffness as previously described. Cross sections of each vertebra in either transverse or sagittal plane were obtained for morphologic observations after the compressive test. The outcome measure of cement distribution and leakage was assessed from the cross-sectioned morphology and also from radiographs.

Statistical Analysis. One-way analysis of variance (ANOVA) was used to compare the BMD, initial strength, and stiffness of all vertebrae between groups. The data from all the groups were compared, and the Student-Newman-Keuls-q test was used to define the significant difference between groups. Paired-samples *t* test was used to compare the height restoration and

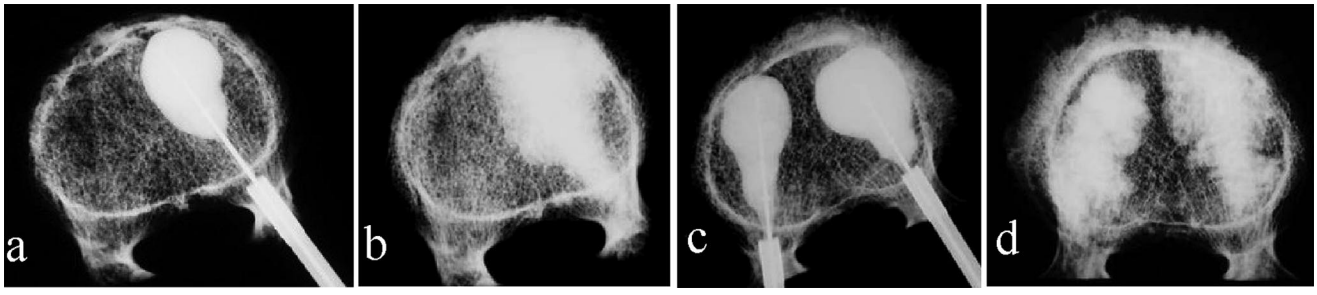

Figure 4. Radiographies of vertebrae in the kyphoplasty groups. The balloons were inflated by contrast medium (**a** and **c**) and the vertebrae were unipedicularly (**b**) or bipedicularly (**d**) augmented with SrHAC.

Table 1. The Bone Mineral Density (BMD), Initial Strength, and Initial Stiffness in Each Group

Group	BMD (g/cm^2) (mean ± SD)	Initial Strength (N) (mean ± SD)	Initial Stiffness (N/mm) (mean ± SD)
UVS	0.31 ± 0.07	2506.46 ± 580.93	1485.11 ± 432.70
BVS	0.39 ± 0.09	3323.71 ± 1153.56	1872.64 ± 655.83
UKS	0.38 ± 0.07	3277.54 ± 1223.84	1635.04 ± 572.47
BKS	0.34 ± 0.10	2626.16 ± 982.71	1765.60 ± 477.59

No significant difference was observed in the BMD, initial strength, and stiffness of vertebral body between the groups.

the biomechanical properties changes before and after surgery within each group. Significance level was set at $P < 0.05$.

■ Results

Vertebrae Sample

There was no significant difference in the BMD, initial strength, and stiffness of vertebral body between the groups, and details are listed in Table 1.

Bone Cement Volume

The volume of bone cement injected to each group is shown in Table 2. Cement volumes for Vessel-X and kyphoplasty groups were 3.26 ± 0.06 and 3.07 ± 0.05 mL for unipedicular injections and 5.97 ± 0.07 and 5.81 ± 0.36 mL for bipedicular injections, respectively. The cement volume in each injection side within the 4 groups was comparable, and there was no significant difference observed ($P = 0.11$). In addition, no significant difference in total cement volume was observed for intergroup comparison within unipedicular or bipedicular groups ($P = 0.29$ and 0.77, respectively).

Vertebral Height Restoration

Table 3 and 4 show the heights of intact, fractured, and the augmented vertebral body for each of the groups. Vertebral anterior heights were significantly decreased from 15.8% to 19.5% after fracture. After augmentation with unipedicular injection, the mean anterior height had restored by 47% with demonstrable statistical significance ($P < 0.05$). The midline height in the noninjected side was also significantly restored by 95.3%. There was no significant difference when comparing the absolute value of the midline height between the injected and noninjected sides of each vertebra. However, all the heights after augmentation did not reach the initial levels (Tables 3, 4).

No statistical difference between the Vessel-X and kyphoplasty groups was observed, suggesting that both techniques are able to restore the heights of the fractured vertebrae.

Similar results were seen in the 2 bipedicular groups, the heights of vertebrae were significantly restored ($P < 0.05$) from 88.5% to 96.4%; however, the body heights did not reach the initial levels. Similarly, when comparing the anterior, posterior, and midline heights between Vessel-X and kyphoplasty groups after augmentation, no significant difference was observed ($P = 0.34$).

Table 2. Bone Cement Volume Injected in Each Group

	Cement Volume in Each Side (mL) (mean ± SD)	Total Volume (mL) (mean ± SD)
Unipedicular groups		
UVS	3.26 ± 0.06	3.26 ± 0.06
UKS	3.07 ± 0.05	3.07 ± 0.05
Bipedicular groups		
BVS	2.93 ± 0.19 (left), 3.04 ± 0.11 (right)	5.97 ± 0.07
BKS	2.90 ± 0.22 (left), 2.91 ± 0.16 (right)	5.81 ± 0.36

The cement volume was comparable in each injection side within the four groups. No significant difference in total cement volume was observed for intergroup comparison within unipedicular or bipedicular groups.

Cement Distribution and Expansion of Vessel-X in Vertebrae

The axial radiographs showed that Vessel-X had its cement distributed mainly within the container with the appearance of a long ellipse. The bipedicular Vessel-X groups showed more symmetric cement distribution in the vertebral body than the unipedicular injection (Figure 3).

SrHAC used in balloon kyphoplasty was also mainly within the injected side of the vertebrae assuming an irregular configuration. Most of the cement was located in the anterior/middle part of the vertebral body in bipedicular groups (Figure 4).

Biomechanical Properties Change

Figure 5 shows the initial and augmented compressive strength results for all the groups. The augmented strength increased significantly (from 11.8% to 65.6%) in all 4 groups when compared with the initial data. Although the augmented strength in vertebrae with bipedicular injection (BVS, 4833.73 ± 1189.03 N; BKS, 4350.37 ± 1207.04 N) was greater than those with unipedicular injection (UVS, 3651.57 ± 436.35 N; UKS, 3664.66 ± 529.55 N), the differences were, however, not significant ($P = 0.19$).

Figure 6 shows the stiffness of initial, fractured, and augmented vertebrae of all the groups. Simulated compressive fracture decreased the stiffness of the vertebrae significantly in each group ($P < 0.05$). The augmentation either with unipedicular or bipedicular injection restored the stiffness significantly from 44.3% to 85.9%. However, the augmented stiffness was less than the initial stiffness in all groups. When comparing the augmented stiffness, no significant difference was observed between Vessel-X and kyphoplasty groups either in the unipedicular (UVS, 657.74 ± 36.43 N/mm; UKS, 758.28 ± 177.41 N/mm; $P = 17$) or bipedicular (BVS, 1608.62 ± 292.53 N/mm; BKS, 1422.81 ± 447.83 N/mm; $P = 0.38$) group. Nevertheless, bipedicular augmentation increased the stiffness significantly when compared with unipedicular augmentation ($P < 0.01$).

■ Discussion

The major purpose of current study was to provide more scientific information regarding a novel bone cement in-

Table 3. The Height Restoration of Unipedicular Groups

	Anterior Height (mm)			Posterior Height (mm)		
Group	Initial	Fractured	Augmented	Initial	Fractured	Augmented
UVS	25.65 ± 3.97	20.64 ± 2.37*	22.14 ± 2.72*†	24.40 ± 3.61	23.27 ± 3.72*	23.90 ± 4.01*
UKS	23.64 ± 3.31	19.90 ± 2.29*	22.29 ± 3.30*†	24.04 ± 3.12	22.64 ± 3.33*	24.03 ± 3.88*
	Midline Height (mm)					
	Injected Side			Noninjected Side		
	Initial	Fractured	Augmented	Initial	Fractured	Augmented
UVS	25.19 ± 3.97	22.63 ± 3.10*	23.63 ± 4.22*†	25.69 ± 3.97	23.24 ± 3.79*	24.39 ± 3.25*†
UKS	24.43 ± 4.03	21.46 ± 3.24*	23.15 ± 3.95*†	23.90 ± 4.07	21.17 ± 3.50*	22.79 ± 4.30†

Paired-samples *t* test; significance was set at $P < 0.05$. Compressive fracture decreased all the heights significantly. The anterior and midline heights were significantly restored after augmentation, but the heights did not reach the initial levels. No statistical difference between the Vessel-X and kyphoplasty groups was observed.
*Significant difference *versus* initial height.
†Significant difference *versus* fractured height.

jection system that was able to control cement leakage during kyphoplasty. Our current study with the injection of SrHAC into mesh found that Vessel-X was able to control the cement leakage. Furthermore, Vessel-X was able to expand in the vertebral body and consequently served as a bone expander restoring the vertebral height. In addition, comparing to Kyphon balloon system where a predistension procedure is required before cement injection, Vessel-X bone filler system achieved restoration of vertebral height and cement injection simultaneously. In this manner, vertebral augmentation surgical time and procedure with Vessel-X bone void filler system should be improved. Overall, the introduced Vessel-X system was not only aiming at controlling cement leakage but also at restoring vertebral biomechanical properties.

In this study, a bioactive cement, SrHAC, was used, and the main reason was to explore whether this novel instrument was able to contain and control a better cement well within the vertebral body as well as to evaluate whether Vessel-X with SrHAC was comparable to a common kyphoplasty technique in vertebral biomechanical restoration. Overall, the results from this current study were consistent with a number of previously reported studies.[15,16]

The height restoration results in this study could have been affected by the simulated fracture model configuration and the position of the bone expander in the vertebral body. The height loss in the fractured model was mainly in anterior and midline part of vertebral body, and the bone expander were placed in the anterior two thirds of the vertebral body. Therefore, as shown in Results, the anterior and midline height restoration were significantly restored when compared with the posterior position.

Since the balloon expansion and cement injection of kyphoplasty were not synchronous, as explained previously,[4,8] the vertebral void may reduce when the balloon was withdraw after expansion, which would have negative effects on height restoration. The Vessel-X container can retain the void size after expanding and did not cause additional reduction in height restoration. The difference be-

Table 4. The Height Restoration of Bipedicular Groups

	Anterior Height (mm)			Posterior Height (mm)		
Group	Initial	Fractured	Augmented	Initial	Fractured	Augmented
BVS	24.63 ± 2.89	19.68 ± 1.50*	19.68 ± 1.50*	26.03 ± 2.17	22.85 ± 2.66*	23.55 ± 3.02*
BKS	22.94 ± 3.18	17.86 ± 1.72*	17.86 ± 1.72*	24.48 ± 3.46	22.26 ± 3.45*	22.57 ± 3.57*
	Midline Height (mm)					
	Left Side			Right Side		
	Initial	Fractured	Augmented	Initial	Fractured	Augmented
BVS	24.81 ± 1.73	21.22 ± 1.58*	23.70 ± 1.95*†	24.77 ± 1.88	22.48 ± 2.30*	23.88 ± 1.93*†
BKS	23.53 ± 3.07	20.08 ± 2.28*	20.82 ± 2.58*†	23.27 ± 3.11	19.92 ± 2.28*	21.49 ± 2.42†

Paired-samples *t* test; significance was set at $P < 0.05$. Compressive fracture decreased all the heights significantly. The midline height was significantly restored after augmentation, but the heights did not reach the initial level. No statistical difference between the Vessel-X and kyphoplasty groups was observed.
*Significant difference *versus* initial height.
†Significant difference *versus* fractured height.

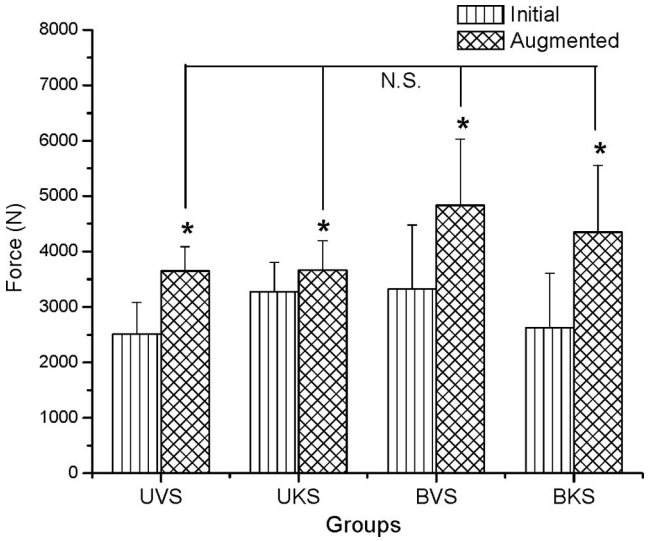

Figure 5. The change of strength in each group. *Significant difference between initial and augmented strength (paired-samples *t* test, $P < 0.05$). N.S., no significant difference between each group in augmented strength (ANOVA, $P > 0.05$).

tween these 2 techniques may be minor when performing cadaveric studies, but it might be significant clinically.

The results of mechanical test showed that unipedicular injection of about 3 mL SrHAC, using either Vessel-X or kyphoplasty, provided similar strength restoration effects to that of bipedicular injection with double volume cement. In stiffness restoration, either with unipedicular or bipedicular injection, Vessel-X was comparable in stiffness restoration to kyphoplasty. However, bipedicular injection provided better results of stiffness restoration than unipedicular injection. A few recent studies regarding the strength and stiffness restoration with the cement volume injected had indicated that only 2 mL PMMA cement should be able to restore strength of vertebrae,[19] but stiffness restoration needed up to 4 to 8 mL PMMA depending on different levels.[20,21] In addition, studies have shown that the cross midline or symmetric cement distribution in vertebral body can obtain better stiffness restoration than that of cement limited within one side.[22] In our study, we found that the strength restoration was not significantly different between unipedicular (with 3-mL cement injection) and bipedicular groups (with 6-mL cement injection), but the stiffness restoration was higher in bipedicular groups. This may be due to the doubled cement volume and the more symmetric cement distribution.

Radiographs of Vessel-X showed that the distribution of SrHAC in UVS and BVS groups was completely intact within the vertebral body. The expanded configuration of the Vessel-X container was relatively homogeneous with a balloon or long ellipse shapers. After cross section (Figure 7), we found that the Vessel-X container expanded well in the vertebral body and the mesh layer enwrapped the bone cement really well with almost no cement leakage. However, a layer of SrHAC was observed outside of the vessel mesh container, indicating that small size cement particles (<50 μm) or ions could be released from the container. Based on previous studies, such layer of bioactive bone cement could bond with the bone tissue[12,13] and should lead to a stronger restoration of the fractured vertebrae body. Our study was only based on human spine specimen; further *in vivo* investigations should be conducted regarding the long-term effects of the cement and bone bonding behaviors with none bioactive and bioactive bone cement. Nevertheless, the results from current observation suggest that the novel Vessel-X bone filler container would be able to limit the cement within certain positions in vertebrae body and control cement leakage.

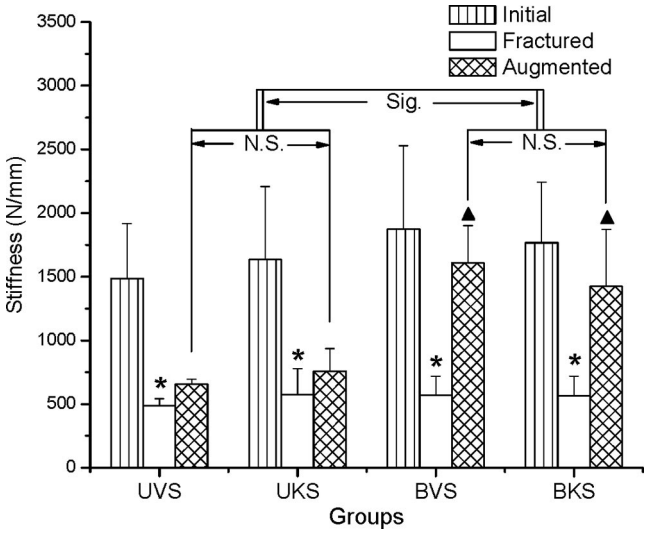

Figure 6. The change of stiffness in each group. *Significant difference between initial and fractured stiffness or between initial and augmented stiffness (paired-samples *t* test, $P < 0.05$). ▲ Significant difference between fractured and augmented stiffness (paired-samples *t* test, $P < 0.05$). N.S., no significant difference between each group in augmented stiffness (ANOVA, $P > 0.05$). Sig., Significant difference in augmented stiffness between any unipedicular group and any bipedicular group, respectively (ANOVA, $P < 0.05$, Student-Newman-Keuls-q test).

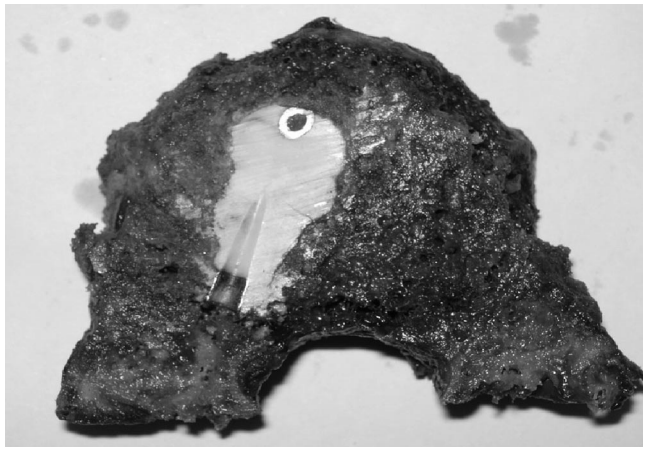

Figure 7. The cross section of vertebra augmented by Vessel-X with SrHAC. The Vessel-X container expanded well in the vertebral body, and the mesh layer enwrapped the bone cement well with almost no cement leakage.

■ Conclusion

The augmented strength after unipedicular or bipedicular injection with SrHAC was significantly greater than the initial strength with either Vessel-X or kyphoplasty. However, it was difficult to restore stiffness when performing Vessel-X and kyphoplasty with either unipedicular or bipedicular augmentation. But the stiffness of bipedicular injection was significantly greater than that with unipedicular injection. Furthermore, no significant difference was observed between the strength, stiffness, and height restoration of Vessel-X to that of kyphoplasty either with unipedicular or bipedicular injection. Vessel-X bone cement container expanded well in the vertebral body, and cement leakage was controllable within the vertebrae. The results may indicate that Vessel-X was comparable to kyphoplasty biomechanically with superior cement leakage control.

■ Key Points

- With injection of SrHAC, Vessel-X bone cement container expanded in the vertebral body well and showed effective cement leakage control.
- Unipedicular injection was comparable to bipedicular injection in restoring vertebral body strength, while bipedicular injection had better effects on restoring stiffness of the vertebrae.
- Vessel-X can restore the height to a certain degree and restore biomechanical properties of the fractured vertebrae comparably to that of kyphoplasty.

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