Lecture

Comparative biomechanical study of a new transpedicular vertebral device and vertebroplasty for the treatment or prevention of vertebral compression fractures

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A B S T R A C T

Background: A comparative study was performed between a novel transpedicular implant (V-STRUT©, Hyprevention, France) and vertebroplasty. This study aims to assess the biomechanical efficacy of this implant in resurrecting and fortifying the osteoporotic vertebra following a vertebral body fracture.
Methods: A total of 17 vertebrae from 3 human osteoporotic spine segments (T9-L5) were selected. Vertebral compression fractures were generated by eccentric compressive loading until a height reduction of 25%. Then the vertebrae were either fixed using vertebroplasty technique (control group; n = 8) or implanted with V-STRUT© implant combined with bone cement (device group; n = 9). A new compressive loading was performed in the same conditions. Maximal load and stiffness, as well as total energy to fracture were measured.
Findings: Fracture force and energy to fracture were both increased either after V-STRUT© implantation or vertebroplasty compared to when the initial fracture was generated. Mean increase percentage between the initial value and the post-treatment value for each parameter were +77% vs +39% regarding fracture load and +126% vs +99% for energy to fracture, for the device group vs vertebroplasty group respectively. No pedicle fractures were observed in both groups, nor implant breaking or bending in the device group.
Interpretation: These results show the ability of V-STRUT© combined with bone cement to reinforce the vertebral body strength, with an at least equivalent biomechanical performance as vertebroplasty. Further clinical investigation needs to be undertaken to demonstrate any clinical superiority of V-STRUT© over vertebroplasty.

1. Introduction

Worldwide, there are approximately 1.4 million new vertebral compression fractures (VCFs) reported each year, with approximately 750,000 annually in the US. Osteoporotic VCFs affect nearly 25% of individuals over 50 years old during their lifetime (Hazzard et al., 2014). In particular, 26% of women over 50 years old and 40% of women over 80 years old are reported to have sustained a VCF (Hsieh et al., 2013). Most osteoporotic VCFs are asymptomatic or result in minimal pain. It is estimated that only one third of vertebral fractures result in medical attention (Chandra et al., 2013). However, non-surgical management may lead to a doubled risk for future fractures (22%) compared to vertebral augmentation procedures (11%) (Papanastassiou et al., 2014). Moreover, prophylactic augmentation at adjacent levels can be used to reduce this risk (Papanastassiou et al., 2014).

The main current therapeutic options available on the market are vertebroplasty, and expandable implantable devices, including balloon kyphoplasty. Vertebroplasty consists of a polymethyl methacrylate (PMMA) bone cement injection into the vertebral body. It is the current gold standard for surgical treatment of VCFs despite higher cement leakage rates often associated with this technique (Papanastassiou et al., 2014). Kyphoplasty and expandable implants such as Kiva® (Benvenue Medical, USA) or SpineJack® (Vexim, France) are used to provide vertebral height restoration before cement injection. However their long-term efficacy to maintain this height restoration has not been proven, and their superiority against vertebroplasty is still under

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discussion in the literature (Filippiadis et al., 2017; Papanastassiou et al., 2014). Some authors reported no significant difference for subsequent fractures between kyphoplasty and vertebroplasty (Dohm et al., 2014). Both options employ a similar augmentation exclusively in the vertebral body, be it with PMMA or PMMA + an expandable device, and do not stabilize from further fracture progression.

A new device that anchors into the pedicles has been developed (V-STRUT©, Hyprevention, France). The transpedicular implantation aims to prevent progression of postoperative fractures and continued vertebral body compression. This is a goal that remains unmet with the currently available treatment options that mainly aim to restore the vertebral body height at the time of implantation (Dohm et al., 2014). Its design, a PEEK (PolyEtherEtherKetone) cylindrical cannulated implant with through holes, and purpose to anchor itself in the strong bone, should provide biomechanical reinforcement of the trabecular bone when combined with bone cement. This device is derived from the femoral implant Y-STRUT® (Hyprevention, France) (Cornelis et al., 2017b; Cornelis et al., 2017a; Szpalski et al., 2015; Szpalski et al., 2017). The purpose of this study was to assess the biomechanical performance of the V-STRUT© device in supporting an axial compression on the vertebral body and comparing it to the currently used vertebroplasty.

2. Methods

2.1. Device description

The implantable device (V-STRUT©, Hyprevention, France) was developed for fixation or prophylactic treatment of vertebral compression fractures (type A.1, some A.2 and rarely A.3 Magerl classification) due to osteoporosis or tumorous bone lesions in the thoracic and/or lumbar spine (T9 to L5). With its posterior support through the pedicles, the device aims to resist to axially applied loads on the vertebral endplate of fractured vertebral bodies or of vertebral bodies that are weakened by lytic lesions (Fig. 1).

The device is made of radiotransparent PEEK polymer (PEEK Optima®, Invibio, UK) and includes visualizing markers made of Tantalum. A range of implants (different diameters and lengths) has been developed to adapt to the different anatomies. It is inserted through a transpedicular approach by minimally invasive surgery. Prior to the implantation, the vertebral collapse can be reduced by placing

Fig. 1. Schematic view of V-STRUT© before cement injection.

the patient in hyperlordosis or in hyperkyphosis (depending on to the affected vertebral segment). It aims at restoring the initial vertebral height as much as possible, thanks to the extension of the ligaments (Ng et al., 2016). Two implants per vertebra (one through each pedicle) are inserted as close as possible under the endplate, up to the anterior vertebral wall, to stabilize and fix the vertebral endplate. Pedicles and posterior wall have to be intact to prevent a failure of the procedure. Furthermore, the cannulated design, bipedicular approach, and hole distribution are intended to allow a homogeneous cement diffusion and injection control. Indeed, the adjacent fractures and cement leakages frequently reported in the literature after the current treatments (Dohm et al., 2014; Wang et al., 2015) can be due to a non-homogeneous and uncontrolled distribution of the cement in the vertebral body.

2.2. Selection and preparation of the specimens

Three human osteoporotic spines (T9-L5) were selected. Spine specimens were purchased from Science Care (Long Beach, USA). The severe osteoporosis was confirmed for the 3 specimens by DXA measures, with T-scores inferior to −2.5: −2.8, −4.9, and −3.8, respectively.

All soft tissue, including ligaments, was initially removed from the entire thoracolumbar spines, and adjacent vertebrae were then separated. Superior and inferior endplates were cleaned of any remaining disc tissue and embedded in PMMA moulds to create a plate surface which would permit the endplate to be normal to the applied axial load. The vertebral body (VB) height was measured in the vertebra's sagittal plane between superior and inferior marginal rims with a caliper. Specimens were stored at around −20 °C and unthawed at 4 °C for 10 to 12 h prior to fracture generation, device implantation, and testing. A total of 17 vertebrae were selected and isolated.

2.3. Initial fracture generation

Compression fractures (Magerl classification type A.1 (Magerl et al., 1994)) were generated by axial compression in a testing machine (Zwick 1454, Ulm, Germany). The VB was placed within a parallel plate system connected to a load cell, which was mounted into the machine (Fig. 2A). The center of each vertebra specimen was placed at the same position and the compressive force acting on parallel plates was applied 60 mm anterior to the VB center (Kettler et al., 2006). Although the center of gravity will differ based on the lordosis curve and vertebral level, this moment arm was chosen as a reasonable compromise for the distance between the center of gravity and the center of the vertebra, as has been implemented in prior studies. In this way, the moment arm acting on each vertebra was kept constant for each treatment group and at every testing time point.

A pre-load of 20 N was applied (Belkoff et al., 2002). The wedge fracture was then generated by compressing the vertebral body at a rate of 5 mm/min until a 25% height reduction was achieved, measured from the anterior edge (Dalton et al., 2012; Belkoff et al., 2002; Ghofrani et al., 2010; Rodrigues et al., 2011; Upasani et al., 2010). Fracture progression was monitored with the help of mobile C-arm fluoroscopy (Exposcope CB7-D, Ziehm, Nuremberg, Germany) (Fig. 2B).

Vertebrae were evenly distributed into both test groups according to T-score and level of the spine, which was determined from pre-treatment force-deformation curves and fracture mode analysis (Section 2.6). During preparation, all vertebrae were assessed for pre-existing VB collapse or damage, or for any pedicle damage. The vertebroplasty was issued as a control (control group; n = 8). The other treatment group consisted of V-STRUT© implants (device group; n = 9) (Hyprevention, Pessac, France).
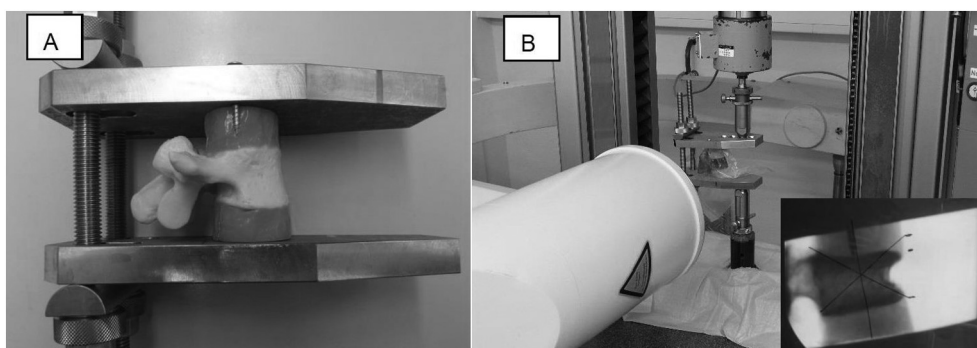
Fig. 2. (A) A model vertebra is placed inside the parallel plate load cell at the correct distance from the load application. (B) Wedge fracture was generated by reducing the anterior VB by 25% and monitored with the C-arm fluoroscope.
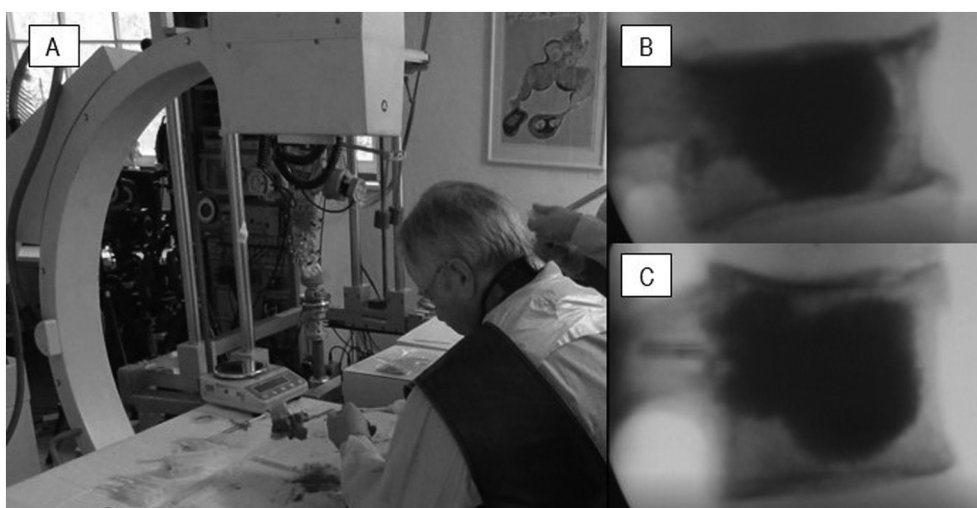

Fig. 3. (A) Procedures were performed by an experienced spine surgeon under fluoroscopy. (B) A sample vertebra after vertebroplasty. (C) A sample vertebra after V-STRUT© implantation together with 7 mL of cement. Cement distribution can be seen in dark.

2.4. Treatment

All procedures were performed by an experienced spine surgeon (Fig. 3A). For the control group, a vertebroplasty was performed with a bipedicular approach (Fig. 3B). A trocar was inserted in each pedicle to inject the PMMA bone cement (CORTOSS, Stryker, Kalamazoo, USA) into the VB (Fig. 3). The first cementoplasty was performed on the thoracic vertebra T9 (the smallest vertebra in the study) in order to define the minimal quantity of cement (i.e. $7 \, cm^3$). Then the same amount was injected as far as possible into all tested vertebrae. An amount of $7 \, cm^3$ corresponds to the average of filling grades currently reported in the literature (Schulte et al., 2013).

For the second group, device implantation combined with cementoplasty was performed. A single implant size was used for all vertebrae. The procedures were performed with a dedicated instrumentation kit. First, as for vertebroplasty, a trocar was used to determine the axis of implantation, followed by the insertion of a guide wire. Drilling was performed to prepare the implant bed and implants were then inserted through the pedicles into the VB. Lastly, the same amount of cement used for the vertebroplasty group – $7 \, cm^3$ of PMMA bone cement (CORTOSS, Stryker) – was injected through the implants into the VB. Location of the implants and cement distribution was controlled by mobile C-arm fluoroscopy (Fig. 3C).

2.5. Post-treatment fracture

Vertebrae were installed into the parallel plate system under the same stipulations as during fracture generation. VB height was measured for post-implantation resurrection by fluoroscopy prior to loading.

Load was applied and load-displacement curves were recorded. From this data, stiffness, absorbed energy, and Fmax were calculated. The final VB height was measured with a caliper and each specimen was stored once again in bags at around $-20 \,°C$.

2.6. Fracture mode analysis

A VB height reduction of 25% was defined as the end condition for the compressive loading. However, the load-deformation curves were also taken into account to determine if wedge fractures were indeed generated. VB wedge fractures were said to have occurred if a maximum peak load was reached, followed by continued displacement at a lesser load. Two other scenarios are also conceivable. It is possible for a specimen to reach the height reduction endpoint without having sustained enough micro fractures to render the entire VB fractured. This is evident if 25% reduction is achieved while the vertebra is still in the elastic phase of the load-displacement curve. Secondly, force-displacement curves can reach a yield point ($< Fmax$), thus there may be failure of internal trabecular structures that cause micro failure but not a complete VB fracture. Furthermore, videos of the compression test were analyzed to determine if the initial fracture modes corresponded to a collapse of the vertebral endplate. Following the post-treatment compression test, vertebrae were examined for pedicle fractures. Vertebrae treated with V-STRUT© were cut along the axis of the implants and bone was removed gently to assess whether implant breaking or bending occurred.

2.7. Measurements and statistical analysis

Load-displacement curves were recorded and stiffness, absorbed energy, and maximum peak load (Fmax) were calculated from this data. Sample frequency lay at 10 Hz. Since compression testing was performed twice, once during fracture generation and then again to test the efficacy of treatment, the above mentioned measurements were compared to each other as percentage deviations from the initial value of each vertebra (e.g. a larger final value would be described as positive, whereas a lower final value would be negative). These percentages were then averaged for each group. The statistical analysis was performed using XLSTAT (Addinsoft, NY, USA).

3. Results

3.1. Vertebrae selection and fracture generation

Three vertebrae did not sustain a VB collapse during the initial fracture generation stage and were therefore excluded from the study. Average pre-fracture height values were not significantly different between both groups ($P > 0.05$): 27 mm (SD 5) for the control group (n = 7) and 26 mm (SD 4) for the device group (n = 7). Vertebrae in the control group had a higher average Fmax of 1965 N (SD 572) during fracture generation, whereas vertebrae in the device group had values of 1396 N (SD 524), yet the difference between the 2 groups is not significant ($P > 0.05$).

Regardless of the treatment, average post-implantation height measurements were 25 mm (SD 5) for the control group and 24 mm (SD 4) for the device group (no difference, $P > 0.05$). Although a 25% reduction was applied during fracture, the vertebrae heights resurrected to approach their unfractured states similar to the way that height restoration is achieved through patient positioning in clinical practice. Complete VB fracture was less common in the final compression testing for both treatment options. The curves of the force-displacement plot are consistent between both groups and therefore it can be inferred that fractures were generated homogeneously (Fig. 4) (Eskander and Eck, 2012).

3.2. Post-treatment testing

The results show that both treatments are efficient to significantly increase the fracture load and energy to fracture, compared to before treatment. After post-treatment compression, both control and device groups had a final height average of 20 mm (SD 3 and 2 respectively, with a non-significant difference. Results are presented in the Table 1. After treatment, the fracture load increased by 53% for the control group and 68% for the device group. Energy to fracture also increased in both treatment groups, by 131% for the control group and 124%, for the device group. While both the Fmax and the stored energy increased, the stiffness of the vertebrae decreased after either of the treatments was administered – by 66% for the control group and 50% for the device group. However, it should be noted that the initial median stiffness (before treatment) of the control group was significantly higher compared to the device group.

A second analysis was performed on the results when excluding the most osteoporotic donor specimens (T-Score of −4.9, 3 specimens excluded) to homogenise the pre-treatment groups (Table 2). In these sub-groups, fracture load increased significantly with the implants (n = 5) as well as with vertebroplasty (n = 6) (39% for the control group and 77% for the device group). Again, device group samples were initially weaker (pre-treatment fracture load of 2047 N (SD 530) vs 1642 N (SD 262) respectively), but this difference was still not significant ($P > 0.05$). Energy to fracture increased by 99% for the control group and 126% for the device group. Results for the stiffness were similar to previous results (−66% and −50% respectively), where the initial stiffness was again significantly higher in the control group ($P < 0.05$).

3.3. Other outcomes

No pedicles were fractured in the post-treatment compression. In no case was the implant broken or bent (Fig. 5).

4. Discussion

This study showed an at least equivalent biomechanical performance of V-STRUT© combined with cement compared to vertebroplasty, by adding posterior reinforcement through the pedicles.

Thoracolumbar vertebrae (T9-L5) of three osteoporotic spines were distributed into two groups with the goal to synthesise a homogenous population within each treatment group with respect to T-score measurements, initial height, and vertebral level. These results show that any of the treatments is efficient to increase the fracture load and energy to fracture. V-STRUT© implants appeared at least as efficient as vertebroplasty in increasing the fracture load (+68% and +53% respectively). These results are even more evident when excluding the most osteoporotic donor (T-score − 4, 9) to homogenise the pre-treatment groups, with a fracture load increase of 77% for V-STRUT© implants and 39% for vertebroplasty group, respectively. It should be noted that the energy to fracture also appeared to be higher in these sub-groups with 126% for V-STRUT© implants and 99% for vertebroplasty. Nevertheless, the small sample size does not allow to conclude on the significance of this difference between the two groups. Although a trend for device superiority can be noted in this study, further clinical investigation needs to be undertaken to demonstrate any clinical superiority of V-STRUT© over vertebroplasty, thanks to the pedicle anchorage. The stiffness decreased in all cases, as currently assessed in the literature (Belkoff et al., 2002; Ghofrani et al., 2010; Rodrigues et al., 2011; Upasani et al., 2010). For Belkoff et al. (2002) who compared hydroxyapatite (HAP) and PMMA vertebral augmentation, the stiffness decrease only depended on the quantity injected, but not on the treatment material. Results of Rodrigues et al. (2011), who compared a modified two-solution bone cement and a cement currently used in kyphoplasty, were in accordance with those of Belkoff et al. However, the authors question the clinical interest of restoring the bone stiffness. In their study of a bilateral titanium mesh implant combined with bone cement, Ghofrani et al. (2010) went further in their reflection by alluding to the hypothesis that adjacent fractures could be attributed to high cement stiffness.

The data have not been normalised by percent cement per VB volume. Since the same amount of cement was injected into each vertebra, strength and stiffness of thoracic vertebra should naturally be expected to have recovered the most compared to larger lumbar vertebra where the cement would have to fill a larger VB cavity. Interestingly, stiffness of the control group decreased the most, even if the same amount of cement was injected in all vertebrae. However it should be noted that the median pre-treatment stiffness of the vertebroplasty group was significantly higher compared to the device group ($P < 0.05$).

The fact that no pedicle was fractured during the post-treatment compression, while no implant was broken or bent, confirms the potential of a pedicle anchorage. V-STRUT© relies on the posterior arch strength, similar to pedicle screws, for posterior fixation (such as during scoliosis or spondylolisthesis treatments). No pull-out was expected because the device is not subject to the stresses produced by rigid multilevel posterior fixation system. Osteoporosis can affect the whole vertebra but Jacobson et al. reported that pedicles are less weakened by osteoporosis than vertebral bodies (Jacobson et al., 2017). According to the authors, the pedicle robustness is given by its oval shape and its composition (only 65 to 75% of cancellous bone). The VCF type (according to Magerl classification) and the preliminary verification that pedicles are not damaged are the main criteria to prevent an implant failure. By the way, the studied device is made of polymer to limit the stiffness on the surrounding bone.

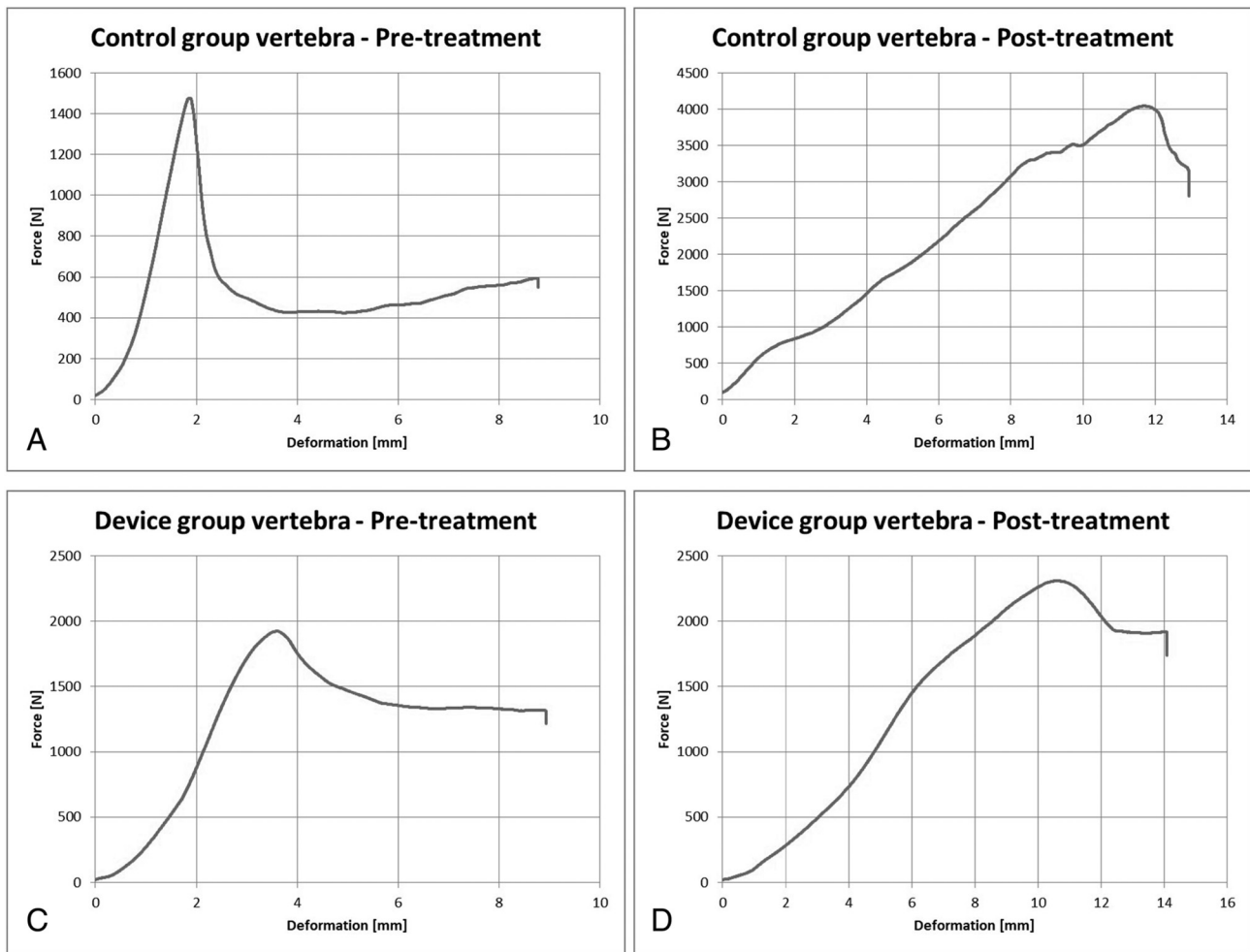A limitation that cannot be mitigated by means of normalisation is

Fig. 4. Examples of load-deformation curve before and after treatment of a vertebra of each group.

Table 1
Results after exclusion of the non-indicated initial fractures.

	Fmax (N)	Energy at fracture (N·mm)	Stiffness (N/mm)
Control group			
Initial – mean (SD)	1965 (530)	9015 (4187)	1166 (144)
Post-treatment – mean (SD)	3013 (782)	20,823 (6750)	402 (97)
Difference (%)	+53%	+131%	−66%
P-value	*P* < 0.05	*P* < 0.05	*P* < 0.05
Device group			
Initial – mean (SD)	1396 (485)	6924 (3912)	739 (15)
Post-treatment – mean (SD)	2341 (1565)	15,505 (7635)	368 (112)
Difference (%)	+68%	+124%	−50%
P-value	*P* < 0.05	*P* < 0.05	*P* < 0.05

Table 2
Results after exclusion of the non-indicated initial fractures and exclusion of the most osteoporotic specimen samples.

	Fmax (N)	Energy at fracture (N·mm)	Stiffness (N/mm)
Control group			
Initial – mean (SD)	2047 (530)	9729 (4110)	1164 (156)
Post-treatment – mean (SD)	2842 (712)	19,317 (6105)	400 (104)
Difference (%)	+39%	+99%	−66%
P-value	*P* < 0.05	*P* < 0.05	*P* < 0.05
Device group			
Initial – mean (SD)	1642 (262)	8535 (3464)	796 (133)
Post-treatment – mean (SD)	2906 (1521)	19,277 (5638)	400 (113)
Difference (%)	+77%	+126%	−50%
P-value	*P* < 0.05	*P* < 0.05	*P* < 0.05

the fact that only one size implant was used throughout the study. It is conceivable that the implant could have stabilizing effects in smaller vertebrae that become more negligible in larger vertebrae. Another limitation is the way in which loads were applied in this study with a constant moment arm as opposed to the physiological follower load mechanism by which loads are transferred through the spine. Not only are endplates of each vertebra not always oriented normally to the direction of the force vector, but intervertebral discs also distribute the load onto the endplate differently than the PMMA moulds would. Including discs would have increased the number of spines needed in the study (as adjacent vertebra would be disc-less) and would also have

confounded the results by increasing variation due to disc degeneration. Using PMMA moulds allowed for a reproducible method and has been applied in similar testing.

Finally, as previously explained, the set-up and testing protocol definition were based on the literature (Dalton et al., 2012; Belkoff et al., 2002; Ghofrani et al., 2010; Kettler et al., 2006; Rodrigues et al., 2011; Upasani et al., 2010). The vertebroplasty group results are consistent with data found in the literature, especially regarding the reference study of Belkoff et al. (2002), a comparative study between PMMA and HAP cements with a similar set-up. Therefore, we can affirm

Fig. 5. Section of a vertebra along the implant axis.

the study design validity.

5. Conclusion

Both treatments significantly increased the fracture force and energy to fracture. Vertebrae that were implanted with the V-STRUT© device were at least as much fortified as vertebrae treated solely with a vertebroplasty. This benefit became more evident in vertebrae that were not hyper osteoporotic (T-score of -4.9 vs -2.8) where the studied device seemed to produce a higher fracture force and energy to fracture increase compared to the vertebroplasty treatment, even though this difference is not significant. However, in order to show any device superior clinical efficacy compared to vertebroplasty, further clinical investigations should be conducted.

Authorship

All authors were fully involved in the conception and design of the study, acquisition, analysis and interpretation of data, drafting or revising the article. All authors have approved the final article.

Acknowledgments

Conflicts of interest

The study was sponsored by Hyprevention. MA: Cofounder, shareholder of Hyprevention. CM: Hyprevention employee. HW, TDPVT, HF: No conflict of interest.

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