Available online at www.sciencedirect.com

ScienceDirect

journal homepage: http://www.elsevier.com/locate/pjnns

Original research article

In vitro simulation of intraoperative vertebroplasty applied for pedicle screw augmentation. A biomechanical evaluation

Krzysztof Zapałowicz [a,*], *Agnieszka Kierzkowska* [b], *Lechosław F. Ciupik* [b]

[a] *Department of Neurosurgery, Independent Public Clinical Hospital No. 7 of the Medical University of Silesia in Katowice, Professor Leszek Giec Upper Silesian Medical Centre, Ziołowa 45/47 Street, 40-635 Katowice, Poland*

[b] *IBeMT Institute of Bioengineering and Medical Technologies/LfC Medical, 65-364 Kożuchowska 41, Zielona Góra, Poland*

ARTICLE INFO

Article history:
Received 26 August 2017
Accepted 4 December 2017
Available online 8 December 2017

Keywords:
Vertebroplasty
Transpedicular stabilization
Screw augmentation
Polymethylmethacrylate
Biomechanics

ABSTRACT

Background and purpose: The purpose of this study was to evaluate the effect of an in vitro simulation of intraoperative vertebroplasty on embedded pedicle screws resistance to pullout. This method involved an application of acrylic cement into the vertebral bodies only after pedicle screws implementation.

Materials and methods: For the purpose of conducting this research, the authors used the spines of fully-grown pigs. The procedure was as follows: firstly, the pedicle screws were bilaterally implemented in 10 vertebrae; secondly, cancellous bone was removed from vertebral bodies selected for screws augmentation and lastly it was replaced by polymethylmethacrylate (PMMA). Six vertebrae with implemented pedicle screws served as a control group. The pullout strength of thirty-two screws (20 augmented and 12 control) was tested. All screws were pulled out at a crosshead speed of 5 mm/min.

Results: The PMMA-augmented screws showed a 1.3 times higher average pullout force than the control group: respectively 1539.68 N and 1156.59 N. In essence, no significant discrepancy was determined between average pullout forces of screws which were pulled as first when compared with consecutive contralateral ones.

Conclusions: An in vitro simulation of intraoperative injection of PMMA in the vertebral body instrumented with screws (intraoperative vertebroplasty) resulted in enhancing its pullout strength by 33%. Pulling of one of the pedicular screws from the augmented vertebral body did not affect the pullout resistance of the contralateral one.

* *Corresponding author.*
E-mail address: krzysztofzapalowicz1@wp.pl (K. Zapałowicz).

https://doi.org/10.1016/j.pjnns.2017.12.001

1. Introduction

Elderly frequently suffer from osteoporotic vertebral fractures. In some cases, they require open surgery with transpedicular stabilization [1,2]. However, the low bone mineral density may contribute to loosening of the screws holding the spine stabilizing components. One technique preventing this occurrence is to enhance screws strength in osteoporotic vertebrae by applying bone cement into surrounding spongious bone [3]. Typically, the polymethylmethacrylate (PMMA) cement is injected into vertebral bodies prior to screw insertion or through inserted fenestrated screws [3–15]. Recently the reinforcement of pedicle screws fixation by means of an intraoperative injection of bone cement using an extrapedicular approach was also described [16]. The following paper is an attempt to determine the mechanical effect of the latter pedicle screws' augmentation technique.

2. Materials and methods

2.1. Specimen preparation

For the purpose of the following research the authors used 3 spinal segments of fully grown pigs deceased in the slaughterhouse: first comprised of vertebrae raging from Th7 to Th12 whereas second and third ranged from Th8 to Th12 (Table 1). Fresh spines were harvested, cleaned for soft tissues and stored frozen at temperature of −20 °C. Prior to the testing day spines were defrosted at room temperature for 24 h. Screw augmentation, cement injection and biomechanical testing were carried out at temperature of ca. 20 °C in IBeMT/LfC Medical laboratories (Zielona Góra, Poland). According to Magerl technique, in each pedicle convergent 40-mm pilot holes for transpedicular screws were made by means of a 3-mm drill [17]. Afterwards transpedicular solid fully threaded screws (5 mm in diameter and 40 mm in length, DERO-LfC, Poland) were inserted to penetrate up to 1/3 of the anterior vertebral body. The augmented group comprised of 10 vertebrae in which the anterior of the cortical bone was cut and through that opening the cancellous bone was removed using a bone curette in order to expose the threads. The void left in the vertebrae was filled with PMMA - its volume averaged 1.6 ml per vertebral body (Fig. 1). The control group comprised of 6 vertebrae with nonaugmented transpedicular screws. After hardening of PMMA, positioning of each of the screws (augmented and nonaugmented) was visualized using GE CT scanner equipped in a 16-bit image reconstruction algorithm with matrix consisting of 1024 × 1024 pixels and resolution in full CT Hounsfield scale. In the next step, vertebrae were separated by an incision

Table 1 – The values of the ultimate pullout force (F_{max}) and dislocation in PMMA-augmented and control vertebrae.

Spine vertebra	PMMA-augmented group				Control group			
	F_{max} (N)		Dislocation (mm)		F_{max} (N)		Dislocation (mm)	
	Screw I	Screw II	Screw I	Screw II	Screw I	Screw II	Screw I	Screw II
SPINE 1								
Th7					550.3	439.0	3.8	5.8
Th8	1003.0	999.0	10.7	4.4				
Th9					542.0	556.0	3.8	3.3
Th10	778.0	1000.0	2.7	4.8				
Th11					976.0	1114.0	6.7	5.5
Th12	1630.0	2022.0	5.1	12.4				
SPINE 2								
Th8	1548.4	1442.1	13.2	8.2				
Th9					1737.1	1004.5	11.1	6.4
Th10	2258.3	1682.0	12.6	13.7				
Th11					1139.5	2177.7	10.2	16.4
Th12	1639.4	2615.5	12.0	12.6				
SPINE 3								
Th8	1422.2	1680.1	9.13	9.1				
Th9	1271.0	1320.8	5.7	11.6				
Th10	1663.1	1259.4	5.0	11.4				
Th11	2055.9	1503.4	5.7	9.7				
Th12					2096.0	1547.0	5.9	10.7
Mean	1526.9	1552.4	8.2	9.8	1173.5	1139.7	6.9	8.0
MED	1589.2	1472.8	7.4	10.6	1057.8	1059.3	6.3	6.1
SD	443.3	488.7	3.8	3.2	631.8	647.1	3.1	
Minimum I + II	778.0		2.7		439.0		3.3	
Maximum I + II	2615.5		13.7		2177.7		16.4	
Mean I + II	1539.7		9.0		1156.6		7.5	
MED I + II	1525.9		9.4		1059.3		6.1	
SD I + II	454.3		3.5		610.0		3.9	

Abbreviations: F_{max} – maximum load/pullout force, MED – median, mm – millimeter, N – Newton, PMMA – polymethylmethacrylate, SD – standard deviation.

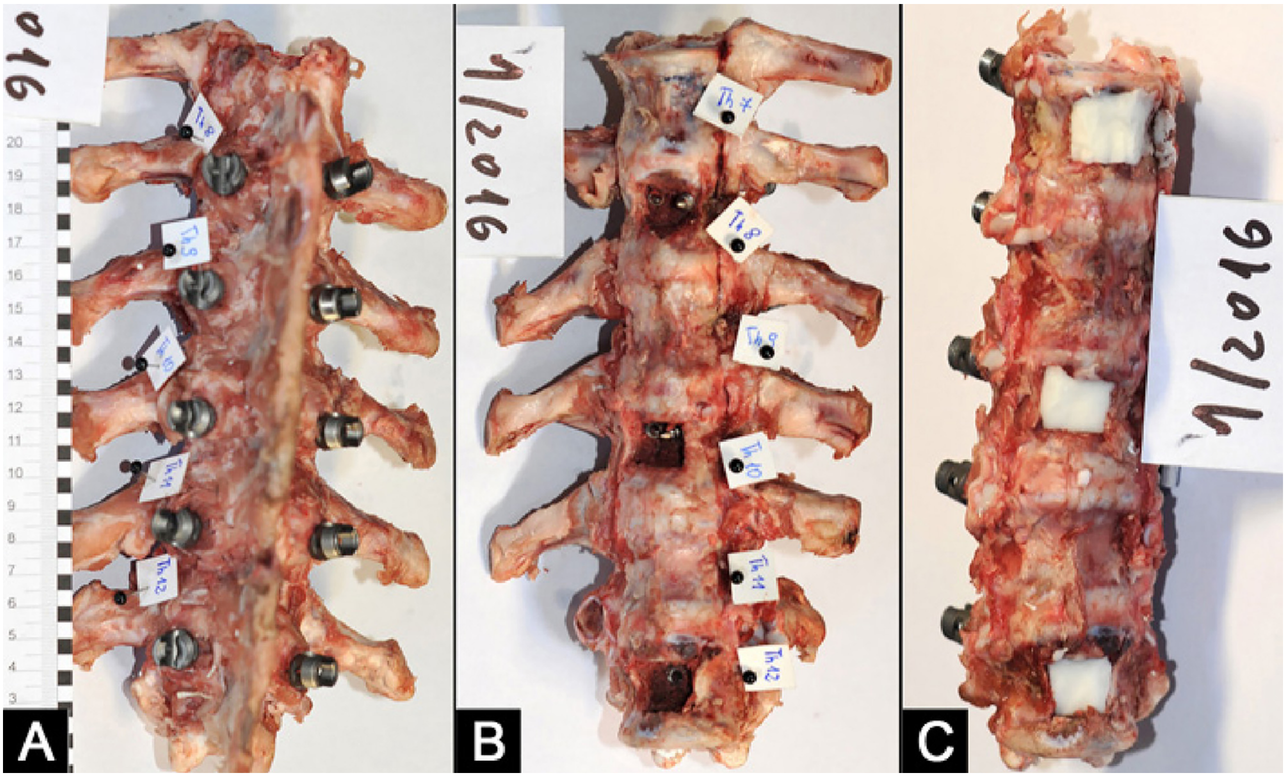

Fig. 1 – Spine 2 (Specimen 1/2016), spinal segment with vertebrae Th7–Th12. (A) Posterior view after insertion of transpedicular screws. (B) Anterior view, vertebral bodies Th8, Th10 and Th12 show removed anterior cortical bone as well as lack of cancellous bone (curetted) with denudated screws. (C) Anterior view, vertebral bodies Th8, Th10 and Th12 packed with PMMA.

made through the intervertebral disk, joints and ligaments (Fig. 2).

2.2. *Biomechanical testing*

The vertebra was rigidly clamped to the base of the testing machine MTS 858 MiniBionix II by means of fixture comprising the plate with a hole, which allowed protruding the pedicle harboring a screw (Fig. 3A). The head of the screw was fixed to the adapter with an outer thread that matched the inner thread of the screw head. The adapter was then attached to the testing machine and applied loads parallel to the long axis of the screw. After the vertebra was mounted, pullout force was applied at a constant crosshead rate of 5 mm/min. The force and dislocation (*D*) were recorded as well as the ultimate pullout force (F_{max}), defined as the maximum load sustained before screw failure (Fig. 3B and C). In the first specimen the screws from right pedicles were pulled first, conversely left screws were pulled first in two following specimens. Once the first screw was pulled out, the vertebra was repositioned so that the contralateral screw could be tested in the same manner.

2.3. *Data analysis*

The sets of F_{max} and *D* values obtained in PMMA group were compared with control one. In PMMA group F_{max} and *D* values characterizing the firstly pulled screws were compared with consecutive contralateral ones. The Kolmogorov–Smirnov test and Student's *t*-test were used. The level for statistical significance was set at $p < 0.05$.

3. Results

Recorded results are listed in Table 1. In the PMMA-augmented group the force F_{max} ranged between 778.0 and 2615.5 N (mean: 1539.7 N, SD: 454,3). Screws' dislocation peak before they were completely pulled out ranged between 2.65 and 13.7 mm (mean: 9.0 mm, SD: 3.5). In the control group, the F_{max} ranged between 439 and 2177.7 N (mean: 1156.6 N, SD: 610.0) and dislocation between 3,3 and 16,4 mm (mean: 7.5 mm, SD: 3.9). The average F_{max} values recorded in the augmented group were 383,1 N (33%) greater than the average values in the control one. This difference was statistically significant ($p < 0.05$) (Figs. 4 and 5). The average D in PMMA-augmented group 1 was 1.5 mm (20%) greater than in control one. Here the discrepancy between the two was statistically insignificant ($p = 0.2635$). No statistically significant discrepancy was recorded between the firstly pulled screws and consecutive contralateral ones in PMMA group when taking into account F_{max} and *D* values (respectively: $p = 0.9040$ and $p = 0.3190$). One can conclude that the removal of one of the screws embedded in PMMA did not affect the durability of the contralateral one. The analysis of force-dislocation curves allows one to distinguish 3 patterns: (1) 62.5% – twenty show a gradual

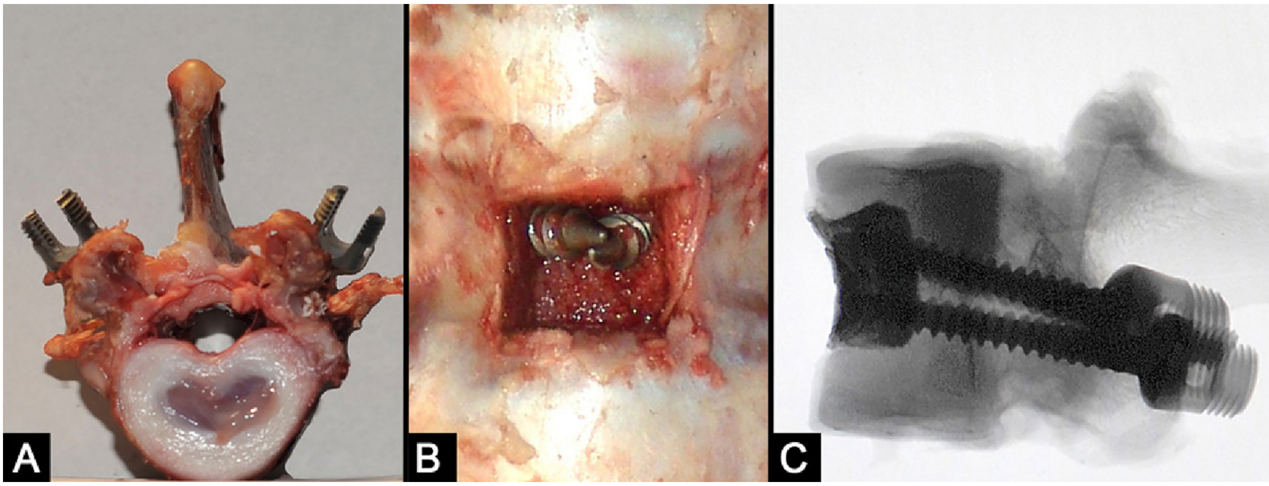

Fig. 2 – (A) Vertebra with inserted transpedicular screws. (B) Anterior view of vertebra, removed cortical and cancellous bone, denudated threaded tips of the screws. (C) Computed tomography reconstruction image showing anterior part of the vertebral body packed with PMMA, which surrounds threaded tips of transpedicular screws.

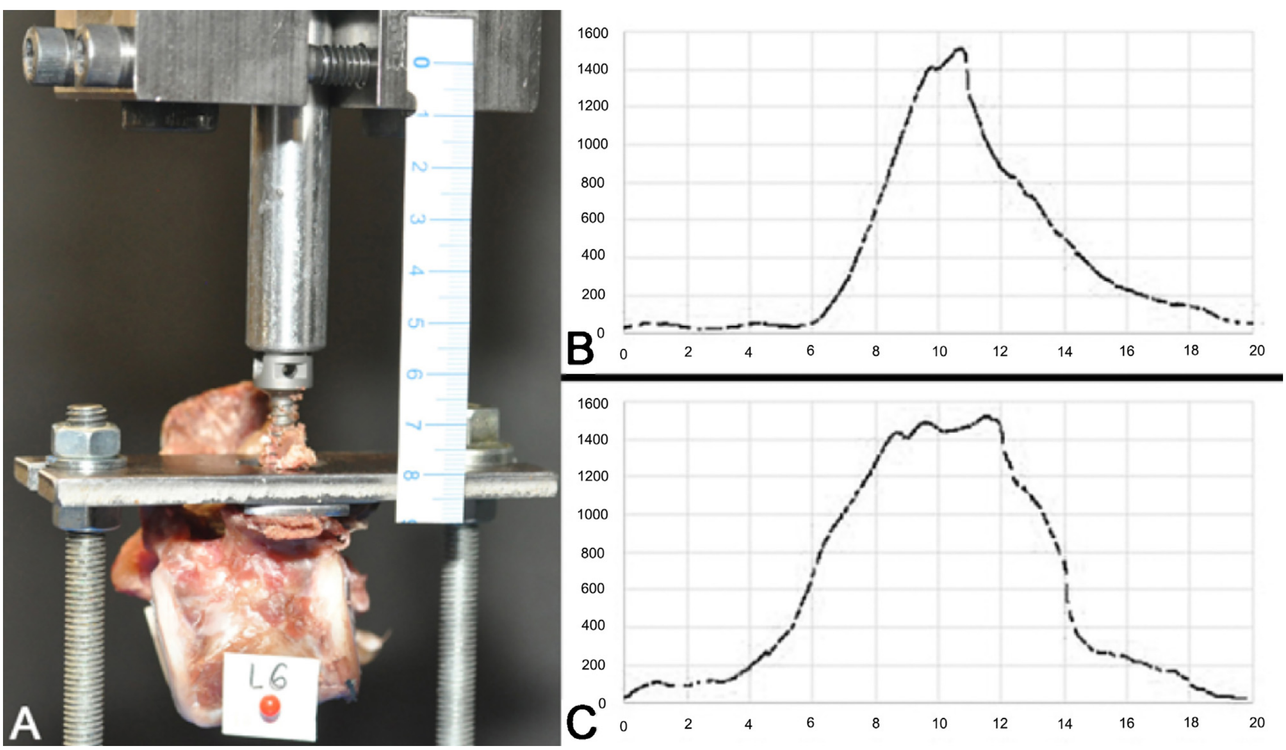

Fig. 3 – (A) The vertebra fixed in the testing machine. (B) Proportional ascending slope of the curve until F_{max} point followed by descending slope. (C) Proportional ascending slope of the curve and plateau (level close to F_{max} value) followed by descending slope.

force increase up to its peak (F_{max}) after which a gradual decrease occurred (Fig. 3B); (2) 31.35% – ten show a proportional force increase culminating in a flat segment, which implies a level close to F_{max} value despite the change in gauge length (Fig. 3C); (3) 6.25% – two records show a steady and slow increase up to F_{max} and a slow decrease once reaching the peak.

4. Discussion

One of the most common methods used for treating spinal instability is transpedicular stabilization. It enables correction and immediately fixation of any spinal deformity [2,18,19].

The thoracolumbar fixation systems used via the posterior approach are attached to vertebrae by means of screws, hooks

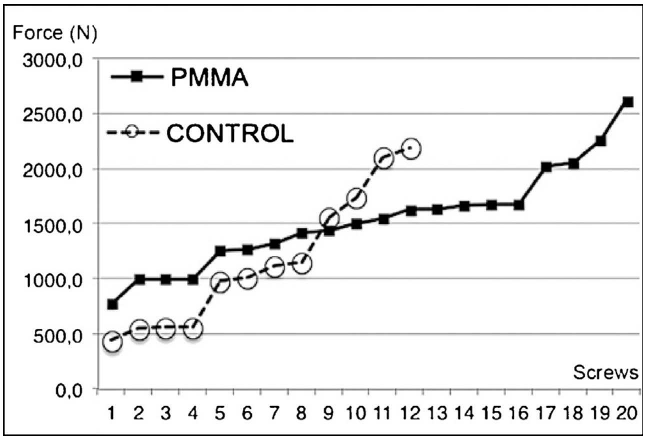

Fig. 4 – Values of pullout force (F_{max}) registered in both groups (PMMA-augmented and control), ranged in ascending order.

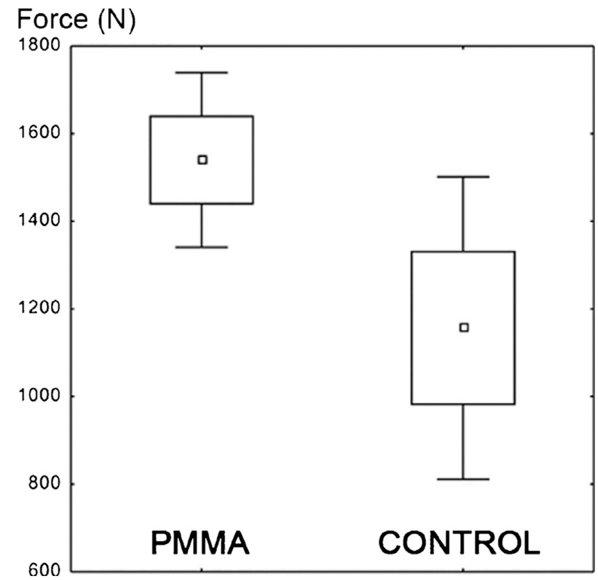

Fig. 5 – Boxplot of pullout force (F_{max}) registered in both groups. Large box: mean ± standard error. Small box: mean. Whiskers: mean ± 1.96 standard error.

or wires. Among the listed attachments, pedicle screws implemented through all three spinal columns present the highest pullout resistance when taking into account low bone density [2–21]. However, in cases such as patients suffering from osteoporosis, low bone density affects their biomechanical resistance to pullout [1–3]. Furthermore, attempts of transpedicular stabilization face a common problem of pedicle screw loosening [2–5,13–15,22]. To eliminate the risk of such an occurrence the reinforcement of screws purchase with bone cement (PMMA) is commonly used [1–10,13,14].

Majority of authors advocating this approach firstly filled the vertebral bodies with cement and afterwards inserted the screws [1,4,6,11,13,15]. The most common method comprised injection of the PMMA into the pilot holes taped in pedicles; consecutively transpedicular screws were inserted in holes before cement hardening. Consequently an increase in holding strength was observed. According to research conducted by Becker et al., the results were 1.5–1.8 times greater [4], Burval et al., noted a 90%-255% increase [6], and Sarzier et al., 181–213% [14]. Frankel et al. constructed a novel fenestrated bone tap by means of which PMMA was injected into the vertebral body, next having removed the tool a pedicle screw was inserted. They reported that F_{max} increased in primary and salvage procedures by 119% and 162% [8,9]. Yamana et al. invented the non-threaded ''pedicular nail'' designed to be inserted in transpedicular pilot holes previously filled with PMMA; its average pullout strength reached 760 N, while the control nonaugmented screws resisted 346 N [22]. Experimental results from different studies listed above differ depending on the technique and bone density. Approach that is set apart from others is injecting cement through cannulated pedicle screws into the cancellous bone [4,5,10,13]. In 2012, the first author of this paper described the method of cement application combining the advantages of vertebroplasty with the possibility of enforcing pedicle screws [16]. The procedure began with the insertion of the pedicle screws into the vertebrae. Later a vertebroplasty needle was unilaterally inserted in each instrumented vertebra using an extrapedicular way. The point of insertion was situated between the superior vertebral endplate and pedicle, in the line joining lateral margins of pedicles. Needles were inserted to reach the anterior third of each vertebral body. Then PMMA was injected consecutively through needles, which were removed afterwards. Once the cement hardened, corrections to the spinal kyphotic deformity were made and the spinal stabilization system was fixed [16]. The research made by Higgins et al. served as a point of reference for the authors when estimating the biomechanical value of the above-mentioned method [23]. Higgins at al. reported that unipedicular injection of an amount of cement equal to 20% of vertebral body volume resulted in a 36% strength increase as compared with non-augmented controls [23]. The main goal of this paper was to evaluate the resistance to pullout of pedicle screws inserted into the vertebral bodies and in vitro embedded in PMMA; the cancellous bone was curetted from vertebral bodies prior to PMMA application to eliminate the influence of bony trabeculae. Secondly, its aim was to determine whether removal of one of the pedicle screws embedded in PMMA would have influence on the durability of the contralateral one. The conducted research revealed that in case of pedicle screws embedded in PMMA the average pullout strength required was 1.3 (133%) times greater than in case of the ones without PMMA; which is comparable with Burval et al., and Frankel et al. results [6,8]. Pulling out one of the pedicle screws did not result in diminishing the durability of the contralateral one (mean F_{max} values statistically indifferent, $p = 9040$) although both were embedded in the same chunk of bone cement. All of the presented results provide ample evidence supporting the thesis that intraoperative PMMA augmentation may significantly increase pedicle screws holding strength.

Limitations to study are as follows: animal vertebrae not weakened by osteoporosis were used, no bone mineral density examination was performed on the specimens and a relatively low number of vertebrae were tested.

5. Conclusions

An in vitro simulation of intraoperative injection of PMMA in the vertebral body instrumented with screws (intraoperative vertebroplasty) resulted in enhancing its pullout strength by 33%.

Pulling of one of the pedicular screws from the augmented vertebral body did not affect the pullout resistance of the contralateral one.

Conflict of interest

None declared.

Acknowledgement and financial support

We thank Adam Dudziński, MA, for his linguistic review of the manuscript. This study was financially supported by The National Centre for Research and Development (NCBiR): Applied Research Program PBS/B9/45/2015-2018.

Experiments were realized in the Research Laboratories IBeMT Institute of Bioengineering and Medical Technologies/ LfC Medical, 65-364 Kożuchowska 41, Zielona Góra, Poland.

The authors used 3 spinal segments of fully-grown pigs deceased in the slaughterhouse, for this reason no agreement of the Bioethics Committee was necessary.

The authors confirm, that this paper has not been published previously.

REFERENCES

[1] Heini PH. The current treatment – a survey of osteoporotic fracture treatment. Osteoporotic spine fractures: the spine surgeon's perspective. Osteoporosis Int 2005;16(Suppl. 2): S85–92. http://dx.doi.org/10.1007/s00198-004-1723-1 [Epub 2004 September 09]

[2] Wang MY, Hoh DJ. Bone metabolism and osteoporosis and its effects on spinal disease and surgical treatment. In: Winn RH, editor. Youmans neurological surgery. 6th ed. Philadelphia: Elsevier Saunders; 2011. p. 2763–72.

[3] Shea TM, Laun J, Gonzalez-Blohm SA, Doulgeris JJ, Lee III WE, Aghayev K, et al. Designs and techniques that improve the pullout strength of pedicle screws in osteoporotic vertebrae: current status. Biomed Res Int 2014. http://dx.doi.org/10.1155/2014/748393 [Epub 2014 March 03]

[4] Becker S, Chavanne A, Spitaler R, Kropik K, Aigner N, Ogon M, et al. Assessment of different screw augmentation techniques and screw designs in osteoporotic spines. Eur Spine J 2008;17:1462–9.

[5] Blattert TR, Glasmacher S, Riesner HJ, Josten C. Revision characteristics of cement-augmented, cannulated-fenestrated pedicle screws in the osteoporotic vertebral body: a biomechanical in vivo investigation. Technical note. J Neurosurg Spine 2009;11:23–7.

[6] Burval DJ, McLain RF, Milks R, Inceoglu S. Primary pedicle screw augmentation in osteoporotic lumbar vertebrae: biomechanical analysis of pedicle fixation strength. Spine 2008;32:1077–83.

[7] Elder BD, Lo SFL, Holmes C, Goodwin CR, Kosztowski TA, Lina IA, et al. The biomechanics of pedicle screw augmentation with cement. Spine J 2015;15:1432–45.

[8] Frankel BM, D'Agostino S, Wang C. A biomechanical cadaveric analysis of polymethyl-methacrylate-augmented pedicle screw fixation. J Neurosurg Spine 2007;7:47–53.

[9] Frankel BM, Jones T, Wang C. Segmental polymethylmethacrylate-augmented pedicle screw fixation in patients with bone softening caused by osteoporosis and metastatic tumor involvement: a clinical evaluation. Neurosurgery 2007;61:531–8.

[10] Fransen P. Increasing pedicle screw anchoring in the osteoporotic spine by cement injection through the implant. J Neurosurg Spine 2007;7:366–9.

[11] Kim HS, Park SK, Joy H, Ryu JK, Kim SW, Ju CL. Bone cement augmentation of short segment fixation for unstable burst fracture in severe osteoporosis. J Korean Neurosurg Soc 2008;44:8–14.

[12] Kuhns CA, Reiter M, Pfeiffer F, Choma TJ. Surgical strategies to improve fixation in the osteoporotic spine: the effects of tapping, cement augmentation, and screw trajectory. Glob Spine J 2014;4:47–54.

[13] Moon BJ, Cho BY, Choi EY, Zhang HY. Polymethylmethacrylate-augmented screw fixation for stabilization of the osteoporotic spine: a three-year follow-up of 37 patients. J Korean Neurosurg Soc 2009;46:305–11.

[14] Sarzier JS, Evans AJ, Cahill DW. Increased pedicle screw pullout strength with vertebroplasty augmentation in osteoporotic spines. J Neurosurg (Spine 3) 2002;96:309–12.

[15] Wuisman PIJM, Van Dijk M, Staal H, Van Royen BJ. Augmentation of (pedicle) screws with calcium apatite cement in patients with severe progressive osteoporotic spinal deformities: an innovative technique. Eur Spine J 2000;9:528–33.

[16] Zapałowicz K, Godlewski B, Jekimov R, Grochal M. Augmentation of transpedicular screws by intraoperative vertebroplasty. Neurol Neurochir Pol 2012;46:560–8.

[17] Krag MH. Biomechanics of thoracolumbar spinal fixation. A review. Spine 1991;16(Suppl. 3):S84–99.

[18] Boos N, Webb JK. Pedicle screw fixation in spinal disorders: a European view. Eur Spine J 1997;6:2–18.

[19] Hatschmann D, Ferguson SJ. Spinal instrumentation. In: Boos N, Aebi M, editors. Spinal disorders. 1st ed. Berlin, Heidelberg/New York: Springer Verlag; 2008. p. 67–90.

[20] Hackenberg L, Link T, Lilienqvist U. Axial and tangential fixation strength of pedicle screws versus hooks in the thoracic spine in relation to bone mineral density. Spine 2002;27:937–42.

[21] Hitchon PW, Brenton MD, Black AG, From A, Harrod JS, Barry C, et al. In vitro biomechanical comparison of pedicle screws, sublaminar hooks, and sublaminar cables. J Neurosurg (Spine 1) 2003;99:104–9.

[22] Yamana K, Tanaka M, Sugimoto Y, Takigawa T, Ozaki T, Konisi H. Clinical application of a pedicle nail system with polymethylmethacrylate for osteoporotic vertebral fracture. Eur Spine J 2010;19:1643–50.

[23] Higgins KB, Harten RD, Langrana NA, Reiter MF. Biomechanical effects of unipedicular vertebroplasty on intact vertebrae. Spine 2003;28:1540–8.