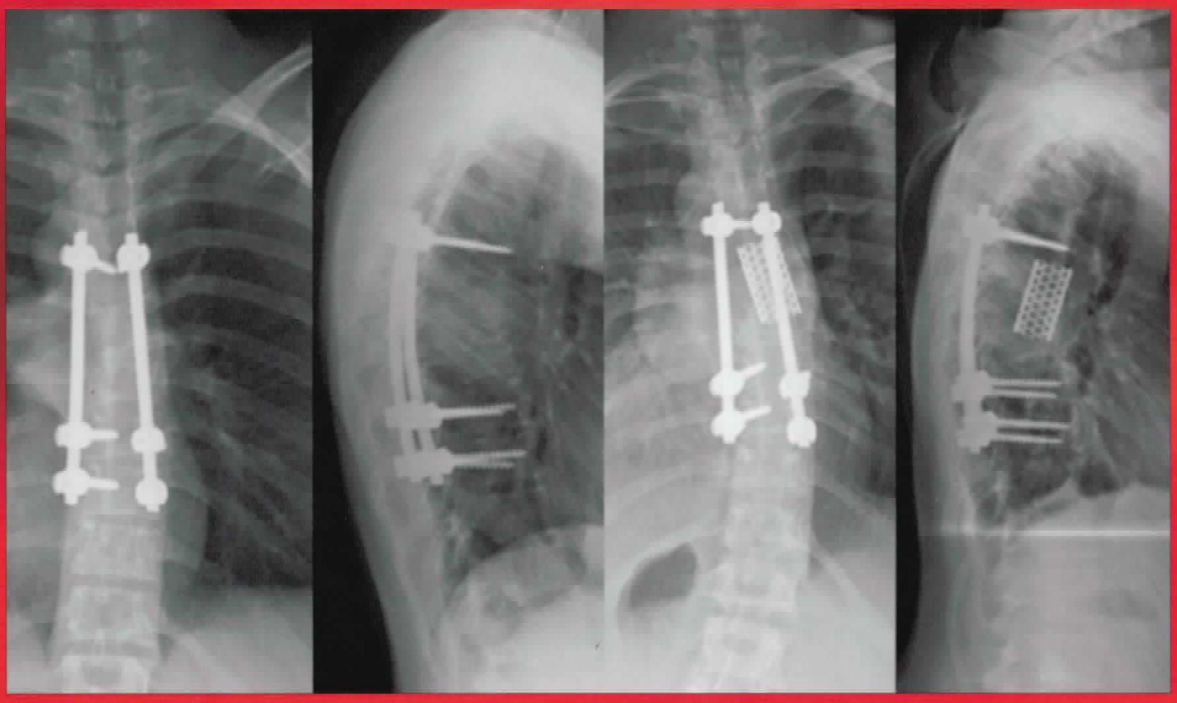
2084 3747

Indexed in:
Ministerstwo Nauki i Szkolnictwa Wyższego
MNiSW **2**

# the journal of spine surgery



1 (5) 2013

periodical / year III / january-june
price 16,00 € / 25,00 zł
www.medicalproject.com.pl
ISSN 2084-3747

This Journal is recommended by:
Polish Society of Spine Surgery

POLISH SOCIETY OF SPINAL SURGERY

# THE JOURNAL OF SPINE SURGERY

Periodical/Półrocznik • 1 (5) 2013 ISSN 2084-3747
january-june/styczeń-czerwiec



## Contents

**The translation and correction of the text / Tłumaczenie i korekta tekstu**
Biuro Tłumaczeń Specjalistycznych ORSA
oraz autorzy artykułów

Wydawca nie ponosi odpowiedzialności za błędy powstałe w wyniku tłumaczenia tekstów na język angielski

The circulation does not esceed 15,000 copies / Nakład nie przekracza 15 tys. egzemplarzy



# Spis treści

the journal of spine surgery

# Clinical evaluation of Elastoplasty, a percutaneous Augmentation of Vertebral Compression Fractures with an elastic Silicon-based Polymer

Original article/Artykuł oryginalny © J SPINE SURG 1 (5) 2013

Michael K. Eichler[1], Volkan Göktas[1], Bernd M. Hölper[1], Peer Joechel[2]

[1] Spine Center Fulda-Main-Kinzig, Germany
[2] Asklepios Paulinen Klinik, Wiesbaden

Address for correspondence/
Adres do korespondencji:
Spine Center Fulda-Main Kinzing
Flemingstr. 5, 36041 Fulda Germany
tel. +49 (0) 661 5801-0
fax +49 (0) 6615801159
e-mail: info@neuro-spine-center.com

Received: 16.10.2012
Accepted: 11.12.2012
Published: 17.06.2013

| STATISTIC STATYSTYKA | |
|---|---|
| Word count Liczba stów | 1516 |
| Tables Tabele | 4 |
| Figures Ryciny | 4 |
| References Piśmiennictwo | 20 |

**Summary**

*Introduction.* Percutaneous Vertebroplasty (pVP) and percutaneous Kyphoplasty (pKP) have been established as the Golden Standard in treatment of painful vertebral compression fractures. The vast majority of the Vertebroplasty and Kyphoplasty cases are performed by using PMMA (Polymethyl Methylacrylate) Cement.

Clinical studies show the good outcome of the procedures in terms of pain relief and patient satisfaction, although PMMA has serious limitations and safety concerns. The high stiffness of the PMMA seems to raise the risk of adjacent vertebral body fractures. The exothermic polymerization process releases a toxic monomer. Some authors report about this monomer to be causative for a pseudomembraneous reaction at the cement – bone interface. Furthermore we observed in our own patients treated with PMMA-Kyphoplasty a short to midterm loss of correction, probably caused by sintering of the bone around the stiff PMMA.

We evaluate a new filling substance, VK100™, an elastic polysiloxane polymer (Silicone). The VK100 silicon Elastomer is known to be absolute biocompatible, initial tests show an excellent interdigitation with the surrounding trabecular bone and in the mid- to long term aspect, due to its elastic properties (modulus of elasticity), it is supposed to accomplish a reduction of adjacent level fractures.

*Material and methods.* From April 2011 to June 2012 our group treated a total of 210 vertebral bodies in 172 patients. 120 patients (145 levels) were integrated in this report due to complete documentation. Pain relief and patient satisfaction was documented with VAS and ODI, Leakage rates were determined with intraoperative fluoroscopy and post-procedural CT Scans in cases, where leakage was seen or suspected intraoperatively.

*Results.* Mean VAS decreased from 8 (5-9) to 2(1-5), ODI decreased from 70% (52-91%) to 22% (8-42%). We observed leakages in 17 patients (14%) into paravertebral vein plexus, cranial and caudal disc space and through anterior wall or into the spinal canal. All of these leakages were asymptomatic. Especially in the cases of penetration into the spinal canal - in contrast to published experiences with PMMA - the new elastoplastic material had no space occupying effect and dispensed under the posterior longitudinal ligament. We did not observe embolisations with clinical relevance. 80 patients were evaluated in the 3-months observation interval, 25 patients in the one-year interval. Until now we have not seen any adjacent level fracture in the follow up interval.

*Conclusions.* Elastoplasty appears to be a safe treatment with equivalent pain relief compared to PMMA-Kyphoplasty procedures. The leakage rate of elastic polysiloxane polymer gives the impression to be comparable to other materials. One big advantage of the new material seems to be the superior safety of leakage into the spinal canal, not exerting any exothermic reaction and avoiding the typical local space occupying effect of PMMA. To further asses the biomechanical properties of elastoplasty, studies with a higher number of patients and a longer examination period are necessary.

**Key words:** Elastoplasty, Kyphoplasty, Vertebroplasty, Silicone, vertebral compression fracture, vertebral augmentation, leakage

**Streszczenie**

*Wprowadzenie*. Przezskórna wertebroplastyka (pVP) i przezskórna kifoplastyka (pKP) są uznawane jako Złoty Standard w leczeniu bolesnych złamań kompresyjnych kręgów. W większości przypadków wertebroplastyki i kifoplastyki wykorzystuje się cement PMMA (*Polymethyl Methylacrylate*).

Badania kliniczne wykazują dobre wyniki tych procedur pod względem ulgi w bólu i satysfakcji pacjenta, chociaż PMMA ma poważne ograniczenia i rozważa się jego bezpieczeństwo. Wysoka sztywność PMMA wydaje się zwiększać ryzyko złamań sąsiednich trzonów kręgów. Proces egzotermicznej polimeryzacji uwalnia toksyczny monomer. Niektórzy autorzy donoszą, że ten monomer powoduje rzekomobłoniastą reakcję na styku cement-kość. Ponadto, zaobserwowaliśmy u naszych pacjentów leczonych za pomocą kifoplastyki z PMMA krótko- do średniotrwałą utratę korekcji, prawdopodobnie spowodowaną martwicą kości wokół sztywnego PMMA.

Badaliśmy nową substancję wypełniającą, $VK_{100}$™, elastyczny polimer siloksanowy (Silikon). Elastomer silikonu $VK_{100}$ jest znany jako całkowicie biokompatybilny, wstępne badania wykazują doskonałe przenikanie z otaczającą kością beleczkową i w średnio-długoterminowym

aspekcie, dzięki swoim właściwościom elastycznym (moduł elastyczności), jest w stanie zmniejszyć złamania na sąsiednich poziomach.
*Materiał i metody.* Od kwietnia 2011 do czerwca 2012 nasza grupa badała 210 trzonów kręgowych u 172 pacjentów. 120 pacjentów (145 poziomów) zostało włączonych w tym raporcie. Ulga w bólu i satysfakcja pacjenta była dokumentowana za pomocą skal VAS i ODI, stopnie wycieku były określone za pomocą śródoperacyjnej fluoroskopii i pooperacyjnych skanów CT w przypadkach, gdy wyciek wystąpił, lub był spodziewany śródoperacyjnie.
*Wyniki.* Średni VAS zmniejszył się z 8 (5-9) do 2 (1-5), ODI zmniejszyło się z 70% (52-91%) do 22% (8-42%). Zaobserwowaliśmy wycieki u 17 pacjentów (14%) do przykręgowego splotu żylnego, wyższej i niższej przestrzeni dyskowej i przez przednią ścianę do kanału kręgowego. Wszystkie te wycieki były bezobjawowe. Szczególnie w przypadkach przebicia do kanału kręgowego – w przeciwieństwie do publikowanych doświadczeń z PMMA – nowy elastoplastyczny materiał nie miał żadnego wpływu na zajmowaną przestrzeń. Nie zaobserwowaliśmy embolizacji o znaczeniu klinicznym. 80 pacjentów zbadano w 3-miesięcznych odstępach czasu, 25 pacjentach w rocznych odstępach czasu. Do dziś nie zauważono żadnych złamań na sąsiednim poziomie podczas follow-up.
*Wnioski.* Elastoplastyka wydaje się być bezpiecznym leczeniem z jednakowym stopniem ustąpienia bólu w porównaniu do procedur kifoplastyki z PMMA. Stopień wycieku elastycznego polimeru siloksanowego daje wrażenie porównywalne do innych materiałów. Jedną z wielkich zalet nowego materiału jest większe bezpieczeństwo wycieku do kanału kręgowego, brak wpływu reakcji egzotermicznej i uniknięcie typowego zajmowania miejsca przez PMMA. W celu oceny biomechanicznych właściwości elastoplastyki, badania większej liczby pacjentów i dłuższy czas badania pacjentów jest konieczny.
**Słowa kluczowe:** Elastoplastyka, Kifoplastyka, Wertebroplastyka, Silikon, złamanie kompresyjne kręgu, wzmocnienie kręgu, wyciek

## INTRODUCTION

Percutaneous vertebroplasty and kyphoplasty with PMMA are the golden standard in treatment of painful vertebral compression fractures. Although success rate of these procedures are high, PMMA has serious limitations and safety concerns.

PMMA does not interdigitate with bone [1]. Several publications show the appearance of pseudo-membranous structures at the PMMA - bone interface with macrophages, giant cells and consecutive osteoclastic activity leading to a gap between PMMA and bone [1,2]. In our opinion this is one of the factors leading to sintering of the osteoporotic bone around the stiff PMMA bolus with loss of vertebral height. Recently, Shin et al. reported 3 cases of a progressive collapse of the vertebral body after percutaneous Vertebroplasty, he concluded that the reason for the collapse seems to be the missing adherence of PMMA with bone [3]

PMMA shows local tissue toxicity [4]. Furthermore, the exothermic reaction can harm local bone and nerve tissue. Laboratory investigations have shown that a local necrosis can be seen in bone tissue when temperatures higher than 50° C over a time period of 1 minute impacts the cancellous bone [5]. This may also be a factor of reduced adherence of PMMA to bone.

Adjacent Level Fractures: a potential complication of Vertebroplasty and Kyphoplasty is subsequent fractures occurring in adjacent vertebrae. Vertebrae treated with PMMA cement are stiffer than fractured vertebrae, and this may transmit increased force to adjacent levels. Injected PMMA forms a bolus with minimal interdigitation in the trabecular spaces. This lack of interdigitation may be a contributing factor in adjacent level fractures. Finite element analyses show that an interdigitated fill pattern may better distribute stresses over the entire vertebra and result in more physiological load transfer [6,7,8,9,10,11,12,13].

Elastoplasty is a new procedure of augmentation of fractured vertebral bodies. Based on percutaneous vertebroplasty and kyphoplasty a new elastic silicone-based filling substance, VK100, is used for vertebral augmentation.

Elastoplasty has the potential to overcome some of the above mentioned safety concerns and limitations of PMMA. Laboratory investigations and long term experience with this particular silicon formulation shows excellent biocompatibility and absence of local toxicity [14,15,16,17].

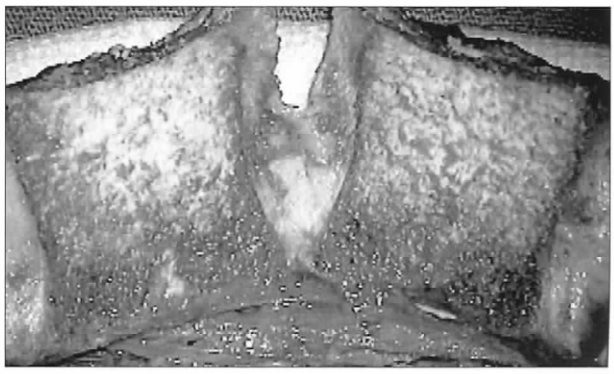


**Fig. 1.** Macro-histological cross-section of a cadaveric vertebra augmented with VK100

Investigations of the manufacturer suggest that VK100 shows a very good Interdigitation with bone (Figure 1). Our own investigations in a cadaveric thoracic vertebra show excellent immediate interdigitation (Figure 2).

VK 100 has a stiffness close to cancellous bone [18]. In our opinion, this can lead to less changes in load transmission over the augmented vertebral segment and to a lower rate of adjacent segment fractures after vertebral body augmentation using VK100. Furthermore we hope that the better adherence of the silicon filling substance will lead to a reduced rate of sintering of the augmented body.

As a first step in evaluating the clinical properties of Elastoplasty we focused in this investigation on evaluating pain relief, substance distribution, and periprocedural complications like leakages.

## MATERIALS AND METHODS

From April 2011 to June 2012 a total of 201 vertebral bodies in 172 patients have been treated with Elastoplasty in two Spine Centers. Out of these 172 patients we included 120 patients (145 treated levels) with complete documentation in this evaluation.

All patients have been treated with balloon Kyphoplasty with VK100 as filling substance.

Mean age of 120 treated patients was 74ys. (45-90), 71 patients (59%) were female.

*Indications*: In 101 patients (84%) inadequate fractures of osteoporotic origin were treated, in 19 patients the augmented fracture had an adequate traumatic genesis *(Table 1)*.

Out of the 120 evaluated patients 80 were examined at the 3-months follow up and 25 at the one year follow-up.

### ELASTOPLASTY

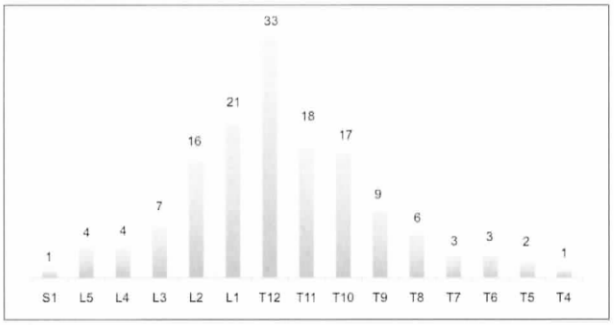
The VK100 Percutaneous Vertebroplasty and Kyphoplasty System (Bonwrx, Phoenix, AZ, USA) contains the VK100 elastomer. VK100 is an injectable cure-in-place silicone rubber elastomer indicated for use in performing percutaneous vertebroplasty. VK100 is comprised of two highly viscous liquid components, reinforced dimethyl methylvinyl siloxanes and reinforced dimethyl methylhydrogen siloxanes, supplied in equal parts (1:1 ratio). USP Grade Barium sulfate (BaSO4) 15% is added to both components to provide radiopacity:

VK100 - Component A:

- Vinyldimethyl terminated dimethyl polysiloxane / trimethylsiloxy terminated polydimethyl siloxane, 64 %
- Silica, amorphous, 21 %
- Barium Sulfate powder, USP, 15%
- Pt Catalyst, >.001%

VK100 - Component B:

1. Vinyldimethyl terminated dimethyl polysiloxane / trimethylsiloxy terminated
2. polydimethyl siloxane, 63 %




**Tab. 1.** Height distribution of augmented vertebral bodies (n=145)

**Tab. 2.** Timetable of performed scores

| | Pre-OP | Discharge | 3 Months | 12 Months |
|---|---|---|---|---|
| VAS | X | X | X | X |
| ODI | X | | X | X |

**Fig. 2.** Industrial high resolution CT-Scan of VK100 augmented vertebral bodies shows the distribution of VK 100 (green) after Kyphoplasty (upper vertebral body) and after vertebroplasty (lower VB) in a cadaveric specimen. In the upper level the trocar has been removed too early leading to a leakage in the trocar canal. This might be influenced by the very low body temperature of the cadaveric specimen with a decelerated and retarded cross linking of the silicone polymers

**Fig. 3.** Dispenser handle with 2-component cartridge and mixing element at the tip

3. Silica (amorphous), 21%
4. Barium Sulfate powder, USP, 15%
5. Trimethyl methyl-hydro dimethyl siloxane (crosslinker), 1%

Due to inherent low toxicity, pure silicones present a low risk for unfavorable biological reactions and have gained wide recognition and acceptance for medical applications. The addition of USP Grade BaSO4 (15 %) to the components results in the desired radiopacity necessary for the intended use.

The VK100 Percutaneous Vertebroplasty System supplies the two VK100 components in a two-part mixing and dispensing cartridge. *(Figure 3)*

Kyphoplasty procedure was performed with the Guardian® Kyphoplasty System (BM Korea, Gunpo-Si, South Korea).

## DOCUMENTATION

Pain relief and patient satisfaction was documented with Visual Analogue Scale (VAS) [19] and Oswestry Disability Index (ODI) [17]. VAS was determined preoperatively, at discharge, after 3 months and after the 12-months interval, whereas the ODI was measured preoperatively, at 3- and 12-months follow up.

Leakage rates were determined with intraoperative fluoroscopy and post-procedural CT Scans in 2 cases, where leakage into the spinal canal was seen or suspected intraoperatively.

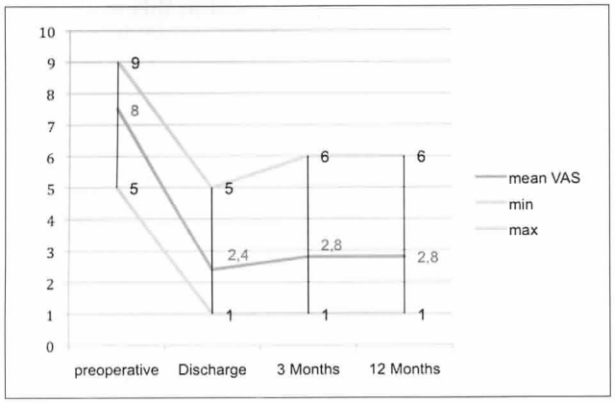
In the 3-months and 12-months follow-up examination, x-ray control is only performed in suspect cases with new or worsened pain.

## RESULTS

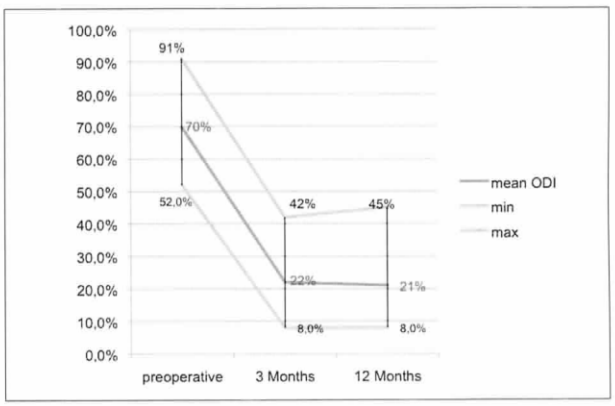
Mean age of 120 treated patients was 74ys. (45-90). 71 patients (59%) were female.

*Indications*: fractures in 101 patients (84%) were caused by osteoporosis, fractures in 19 patients had a traumatic genesis.

Out of the 120 evaluated patients 80 were examined at the 3-months follow up and 25 at the one-year follow up.




**Tab. 3.** VAS Score before treatment, at discharge and at 3 and 12 month follow-up examination




**Tab. 4.** ODI Score before treatment and at 3 and 12 month follow-up examination

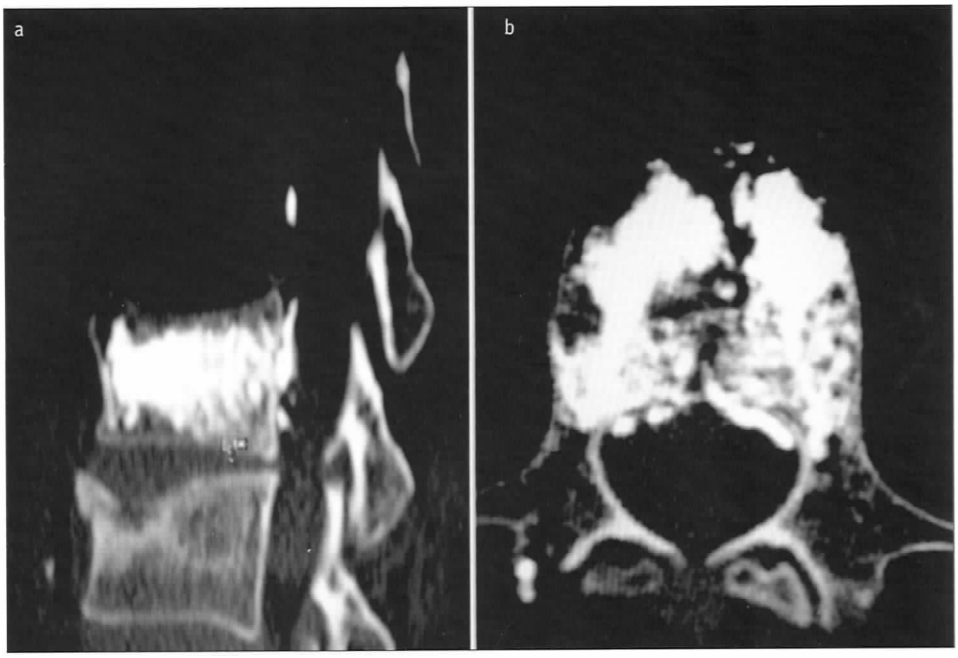



**Fig. 4a-b.** Lateral X-ray and CT (axial) of leakage of $VK_{100}$ in spinal canal

*Pain relief*: Mean **VAS** improved from 8 (5-9) to 2,4 (1-5) at discharge, whereas at 3 month- and 12 month control the Max.-VAS values slightly worsened from 5 to 6. Mean VAS at 3 and 12 Months: 2,8 (1-6). (Table 3)

*ODI:* Mean Oswestry Disability Score improved from 70% (52%-91%) to 23% (8%-42%) at 3-month interval with no significant changes at the 12-month interval: 21% (8%-45%) (Table 4).

*Leakages:* We observed leakages in 17 of the 120 patients (14%). Most frequently the leakage was seen in the perivertebral venous plexus (n=11) furthermore in the cranial (n=2) and caudal (n=2) disc space, through the anterior wall (n=3) and in 2 levels VK100 leaked into the spinal canal (figure 4a and 4b). In no case the leakage was symptomatic or led to the necessity of an intervention. We have not seen any embolisms with clinical relevance. Around 70% of all leakages happened in the first 30 patients.

Until today we have not detected any adjacent vertebral body fracture in 80 patients after 3 months and 25 patients in the 12 month follow-up examination.

## DISCUSSION

The results of this retrospective analysis show that Elastoplasty appears to be a save treatment of vertebral compression fractures.

Pain relief seems to be comparable to augmentation with PMMA, although we had the impression that the amount of filling substance, necessary for equivalent pain reduction, seems to be slightly higher compared to Standard PMMA cement.

The leakage rate also seems to be comparable to PMMA augmentation. In our opinion, the big advantage of the VK100 elastic silicone based filling substance, when leaking into the spinal canal, is the missing exothermic reaction. In both leakages we observed, in contrast to published experiences with PMMA, the elastoplasty substance didn't show any space occupying effect, it dispenses under the posterior longitudinal ligament.

Our experience shows that, similar to PMMA, the leakage rate of VK100 is directly depending on injection pressure and viscosity of the substance. In the first 30 patients we had much higher leakage rates (n=9) compared to the last 30 patients (n=2). Mainly the adaption of the waiting time during cross-linking process for proper viscosity before inserting the filling substance could reduce the leakage rate significantly.

In our opinion the handling of VK100 is superior to PMMA. The initiation of the cross-linking process through a dispenser handle avoids manual mixing with exothermic reaction and release of toxic monomer. A wider time window of processing the mixed substance and the possibility to adapt the amount of filling substance to the needs is a further advantage.

The influence of the biomechanical properties of Elastoplasty, e.g. enhanced bone adherence and reduced stiffness on long term reduction of adjacent level fractures and reduced rate of collapsed vertebrae, compared to PMMA, could not be investigated in this evaluation.

## CONCLUSION

Elastoplasty is a procedure promising to resolve several drawbacks of PMMA in augmentation of fractured vertebral bodies. In our opinion this evaluation shows that in terms of pain relief elastoplasty seems to be equal to PMMA. The rate of leakages also appears to be comparable to PMMA augmentation. We conclude that the absence of an exothermic reaction and the missing space occupying effect when leaking into the spinal canal is a big advantage. Furthermore VK100 has clear advantages over PMMA In terms of handling.

Further studies have to be performed to investigate if, and to which extent, the biomechanical properties of VK100 will have an influence on biomechanical load transmission and the rate of adjacent level fractures.

References/Piśmiennictwo:


1. *MA Freeman, GW Bradley, and PA Revell: Observations upon the interface between bone and polymethylmethacrylate cement. J Bone Joint Surg Br August 1982 64-B:489-493.*
2. *Togawa D, Bauer TW, Liebermann ICH et al.: Histologic evaluation of human vertebral bodies after vertebral augmentation with polymethylmethacrylate. Spine 28 (2003):1521-1527*
3. *Shin DA, Kim KN, Shin HC, Kim SH, Yoon DH: Progressive collapse of PMMA-augmented vertebra: a report of three cases. Zentralbl Neurochir. 2008 Feb;69(1):43-6.*
4. *T. Kalteis, C. Lüring, G. Gugler, S. Zysk, W. Caro, M. Handel, J. Grifka: Akute Gewebetoxizität von PMMA-Knochenzementen. Z Orthop Ihre Grenzgeb 2004; 142(6): 666-672*
5. *R. A. Eriksson, T. Albrektsson, and B. Magnusson: Assessment of Bone Viability After Heat Trauma: A Histological, Histochemical and Vital Microscopic Study in the Rabbit. Scandinavian Journal of Plastic and Reconstructive Surgery and Hand Surgery, 1984, Vol. 18, No. 3 : Pages 261-268*
6. *Polikeit A, Nolte LP, Ferguson SJ.: The effect of cement augmentation on the load transfer in an osteoporotic functional spinal unit: finite-element analysis. Spine 2003 May 15; 28(10):991-6.*
7. *Friebourgh D, Tang C, Sra P et al.: Incidence of subsequent vertebral fracture after Kyphoplasty. Spine 2004, 29:2270-6*
8. *Uppin AA, Hirsch JA, Centenera LV et al.: Occurrence of new vertebral body fracture after percutaneous vertebroplasty in patients with osteoporosis. Radiology 2003, 226: 119-24*
9. *Grados F, Depriester C, Cayrolle G et al.: Long term observations of vertebral osteoporotic fractures treated by percutaneous vertebroplasty. Rheumatology (Oxford), 2000 39: 1410-4.*
10. *Heini PF, Berlemann U.: Bone Substitutes in vertebroplasty, Eur Spine J, 2001, 10:S205-S213.*
11. *Jasper LE, Deramond H, Mathis JM, et al.: Material properties of various cements for use with vertebroplasty, J Materials Science Materials in Medicine, 2002, 14:1-5.*
12. *San Millan Ruiz D, Burkhardt K, Jean B, et al. Pathology findings with acrylic implants. Bone, 1999, 25 (Suppl 2):85S-90S.*
13. *Liebschner MAK. Biomechanics of vertebroplasty may be sensitive to intervertebral disc quality. ORS Abstract, 2006*
14. *Sinclair Research Center, Inc. Study Number 06505: Local tolerance of flexible implant polymer implanted into the paraverebral muscle of the rabbit. Pathology report. Literature available from the author.*
15. *VK100 Percutaneous Vertebroplasty System. Section 6: Biocompatibility. VK100-Clinical Safety Profile. Literature available from the author*
16. *Brandon HJ, Jerina KL, Wolf CJ, Young VL: Biodurability of retrieved silicone gel breast implants. Plast Reconstr Surg. 2003; 111(7): 2295-306*
17. *Charles Heide: Silicone Rubber for Medical Device Applications, Medical Device and Diagnostic Industry Magazine. November 1999.*
18. *VK100 Percutaneous Vertebroplasty System. Section 5.2: Mechanical and Cadaver Testing. VK100-Clinical Safety Profile. Literature available from the author.*
19. *Price DD, McGrath PA, Rafii A, Buckingham B: The validation of visual analogue scales as ratio scale measures for chronic and experimental pain. Pain 1983;17: 45-56*
20. *Fairbank JCT, Pynsent, PB: The Oswestry Disability Index. Spine 2000;25: 2940–2953*