

Experiences with PMMA cement as a stand-alone intervertebral spacer

Percutaneous cement discoplasty in the case of vacuum phenomenon within lumbar intervertebral discs. English Version

Introduction

Interbody fusion facilitated by cages (or spacers) and transpedicular stabilization is a widely accepted surgical procedure for the treatment of certain forms of lumbar degenerative disc disease [7].

Interbody spacers (IBS) provide ventral mechanical support in the construction maintaining disc height and proper craniocaudal diameter of the intervertebral foramen [4]. Besides the instrumented cage application, different designs could be used as a “stand alone” implant if there is no need for additional segmental transpedicular stabilization [1].

In addition to appropriate implant positioning, vertebral endplate strength and integrity are the key factors to obtaining immediate stability and preventing later subsidence of the IBS with time. The load bearing capability of the endplate is highly dependent on the quality of the subchondral bone. In the “aging spine” population where, in addition to disc degeneration, osteoporosis is the leading pathology, the vertebral endplate frequently loses its integrity and shows different forms of fragmentation depending on the stage of disc degeneration [5]. Using industrially pre-shaped IBS in these discs produces a higher risk of cage subsidence and symptomatic postoperative segmental collapse as a late complication of the procedure [6]. To achieve immediate stability and reach a wide contact surface between the end-

plate and the interbody implant in these patients, the authors started using polymethylmethacrylate (PMMA) to create individually shaped “in-site” intervertebral spacers back in 1995 instead of IBS made of titanium or PEEK [13]. The primary advantage of using PMMA is that it can be individually shaped, thereby adapting the load-bearing surface of the implant fully to the shape of the endplates (particularly at endplates with high vault). A further advantage of using bone cement was observed during the filling stage when the liquid PMMA occupied the space between the broken endplate fragments, providing an immediate inter-fragmental stabilizing effect.

During the first years of using PMMA as an individually shaped intervertebral spacer, the authors applied transpedicular devices in all cases [13], but the “stand alone” method was later also considered in carefully selected patients and applied by means of open surgery using the standard TLIF approach. Between 2008 and 2011, the percutaneous application of PMMA was introduced in elderly patients (in whom severe comorbidities represented a higher risk for open spinal surgery) under local anesthesia, with a posterolaterally positioned needle according to the conventional technique of discography. In recent years, it has become the routine standard procedure of choice in elderly patients meeting the appropriate surgical

indication; nevertheless, the risk of peri-operative complications is high.

Much like the terms “vertebroplasty” and “kyphoplasty,” the authors call the procedure “cement discoplasty” (■ Fig. 1). The aim of this article is to introduce the indication, method, and clinical results of percutaneous cement discoplasty (PCD).

The German translation of this article can be found under [dx.doi.org/10.1007/s00132-015-3092-1](https://doi.org/10.1007/s00132-015-3092-1)

Table 1 Demographic and clinical variables

Variables	n = 47
Age; mean (range)	69.2 (44–84)
Gender (male/female)	12/35
Leg pain	32
Back pain	36
Walking distance < 100m	12
Cane usage	10
BMI; mean (range)	30 (16–39)
Comorbidities; mean (range)	4 (1–9)
PCD levels	
1	10
2	21
3	9
4	8
5	2
6	1
OR time (min)	40 (18–85)
<i>BMI</i> body mass index, <i>PCD</i> percutaneous cement discoplasty, <i>OR</i> operating	

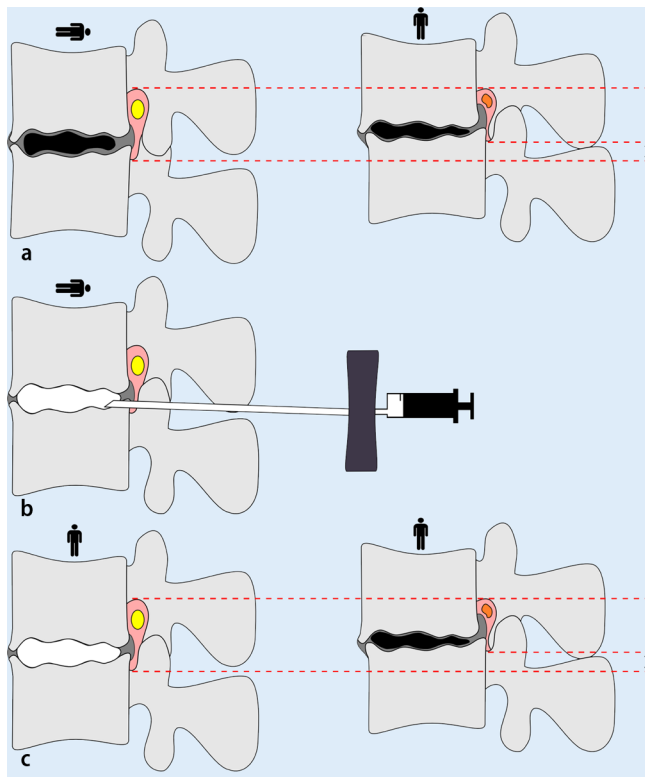


Fig. 1 ◀ The concept of vertical instability and cement discoplasty. **a** In standing position, under loading, the craniocaudal extension of the neuroforamen is smaller than in the prone position (without loading). While standing, the segmental nerve roots are compressed, leading to leg pain. **b** Percutaneous cement discoplasty: in a prone position, the “vacuum” disc is filled with PMMA. **c** After discoplasty in a standing position, the height of the intervertebral disc is maintained and the cross section of the neuroforamen is larger compared with preoperative dimensions

Methods

Patient eligibility criteria

Elderly patients who had lower back and leg pain due to degenerative disc disease, had one or more levels of vacuum phenomenon on their CT examination, showed foraminal stenosis at the same level(s) on MRI, and were not suitable for open procedures were selected for PCD. The procedure was discussed with the patient and the potential benefits and risks outlined. The potential complications specified were bleeding at the puncture site, bone infection or fracture, damage to the nerve roots or cord, extravasation of material into the surrounding epidural or paravertebral spaces, and passage of material into the venous system with embolization to the pulmonary vasculature or compression of neural tissue. The likelihood and risks of an open surgical procedure in the event that technical complications required an immediate surgical intervention were also discussed and included in the consent form.

Operative procedure

The surgical technique described below is the one used by the authors over the last 6 years. Patients are placed in a prone position on a radiolucent operating table. The patients are operated optimally under local anesthesia or, in selected cases, under general anesthesia. The intervertebral disc to be treated is localized under fluoroscopic control and a skin stab incision is then made and a Jamshidi needle inserted into the disc space (◻ Fig. 2a, b). Under lateral projection control, the needle is adjusted to the appropriate depth. A 2.0-mm K-wire is guided through the needle into the disc space (◻ Fig. 2c, d). Vertebroplasty trocars (KyphX® Osteo Introducer® and KyphX® Bone Filler Device) are guided over the K-wires, which are then removed (◻ Fig. 2e, f). This procedure is repeated in the case of multiple disc augmentations. In our experience, Kyphon high-viscosity radiopaque bone cement (KyphX® HV-R™) is the most suitable for discoplasty. The contents consist of a powder PMMA component and a liquid PMMA component. After the liquid agent is added to the powder, the slurry is mixed until a thin tooth-

paste-like consistency is achieved. The material is then suctioned into 3-ml syringes from where 1.5 ml is pushed into the vertebroplasty trocars. Once the desired consistency is achieved (usually 5–6 min), filling of the intervertebral discs is commenced under continuous fluoroscopic control in lateral (◻ Fig. 2g) and AP views (◻ Fig. 2h). The cement remains injectable for the following 10 min. Simultaneous filling of two disc spaces is possible. The flow of the cement must be monitored very carefully. The avoidance of cement leaks posteriorly into the spinal canal and laterally into the extraforaminal space is essential. The maximum amount of cement to be injected is determined during the procedure (3–5 ml), since filling is stopped in the event of cement extrusion. Prior to withdrawal of the needles, the material should be allowed to fully cure to avoid dragging of cement into the soft tissues (◻ Fig. 2i, j).

Data collection

A total of 81 patients were treated with PCD in a tertiary care referral center between 1 January 2009 and 31 December 2013. The current study included the 47 patients who had completed a pre- and postoperative questionnaire booklet, containing two visual analog scales VAS (0–100) on leg and back pain, and the ODI questionnaire. The questionnaire booklet was completed at baseline and at 6 months follow-up. Furthermore, pre- and postoperative inpatient and outpatient clinical records and the results of imaging studies (CT, MRI, and standing and prone X-rays) were recorded.

All statistical analyses were performed with SPSS 20.0 software; *p* values of less than 0.05 were considered significant.

Results

◻ **Table 1** shows the demographic and clinical characteristics of 47 patients. The male/female ratio was 12/35 with a mean age of 69.2 years (range 44–84) in our cohort. The majority of patients had lower back pain (92%) and leg pain (82%) before surgery with a mean VAS of 68 (range 0–100) and 60.6 (range 0–100), respectively. No patient had motor deficits.

P.P. Varga · G. Jakab · I. Bors · A. Lazary · Z. Szövérfi

Experiences with PMMA cement as a stand-alone intervertebral spacer. Percutaneous cement discolasty in the case of vacuum phenomenon within lumbar intervertebral discs. English Version**Abstract**

Background. The treatment of symptomatic degenerative disc disease of the lumbar spine in elderly patients by standard surgical methods is often limited due to severe comorbidities (e.g., cardiopulmonary disease, hypertension, diabetes). Minimally invasive procedures are more acceptable in this population, since they reduce surgical morbidity and the risk of complications. The percutaneous cement discolasty (PCD) technique was introduced by the authors to treat dynamic (and angular) instability of the symptomatic lumbar segment by injecting bone cement (polymethylmethacrylate, PMMA) into the disc spaces showing vacuum phenomena via a postero-

laterally positioned Jamshidi needle. The aim of this article is to describe the indication, method, and clinical results of PCD.

Method. A total of 81 patients were treated with PCD in a tertiary care referral center over a 6-year period. The current study includes the first group of 47 consecutive patients to complete a pre- and postoperative questionnaire booklet regarding leg and back pain using the visual analog scale (VAS) and the Oswestry disability index (ODI) questionnaire.

Results. A total of 130 discs in these 47 patients were treated with PCD. The majority of patients reported a reduction in their lower back and leg pain (69% and 66%, respec-

tively; $p < 0.02$) postoperatively. At 6-month follow-up, 61% of patients had a minimum 10-point reduction in their ODI scores ($p < 0.01$).

Conclusion. Elderly patients with symptomatic dynamic foraminal stenosis and vacuum phenomenon in the intervertebral disc are suitable candidates for PCD, particularly if they represent high-risk patients for open surgery.

Keywords

Chronic pain · Bone cement · Dynamic foraminal stenosis · Aging spine · Percutaneous cement discolasty

Erfahrungen mit PMMA-Zement als intervertebraler Stand-alone-Platzhalter. Perkutane Zement-Diskoplastie bei Vakuumphänomen der lumbalen Bandscheiben**Zusammenfassung**

Hintergrund. Die operative Behandlung einer symptomatischen degenerativen lumbalen Bandscheibenerkrankung bei älteren Patienten ist limitiert, da häufig schwere Komorbiditäten bestehen (z. B. kardiopulmonale Erkrankungen, Hypertonie, Diabetes). In dieser Population sind minimal-invasive Verfahren besser geeignet, da hierdurch die operative Morbidität und das Komplikationsrisiko gesenkt werden. Die Technik der perkutanen Zement-Diskoplastie („percutaneous cement discolasty“, PCD) wurde von den Autoren eingeführt, um dynamische (und anguläre) Instabilitäten des symptomatischen Lendenwirbelsegments zu behandeln, indem Knochenzement (PMMA) mittels einer posterolateral positionierten Jamshidi-Nadel in die Bandscheibenzwischenräume, welche ein Va-

kuumphänomen aufweisen, injiziert wird. Ziel dieses Beitrags ist es, Indikation, Methode und klinische Ergebnisse der PCD zu beschreiben.

Methoden. Während eines 6-Jahres-Zeitraums wurden 81 Patienten in einem tertiären Behandlungszentrum mittels PCD behandelt. In der aktuellen Studie wurde die erste Gruppe mit 47 konsekutiven Patienten eingeschlossen, die unter Verwendung der visuellen Analogskala (VAS) und des Oswestry-Disability-Index (ODI) einen prä- und postoperativen Fragebogen bezüglich Bein- und Rückenschmerzen ausgefüllt hatten.

Ergebnisse. Bei diesen 47 Patienten wurden insgesamt 130 Bandscheiben mittels PCD behandelt. Die Mehrzahl der Patienten (69% und 66%) berichtete postoperativ über ei-

ne Reduzierung ihrer Schmerzen im unteren Rückenbereich und in den Beinen ($p < 0,02$). Beim 6-Monats-Follow-up wiesen 61% der Patienten eine Reduzierung des ODI-Scores von mindestens 10 Punkten auf ($p < 0,01$).

Schlussfolgerung. Ältere Patienten mit symptomatischer dynamischer Foramenstenose und Vakuumphänomen der Bandscheiben sind geeignete Kandidaten für eine PCD, insbesondere wenn bei einem offenen Eingriff für diese Patienten ein hohes Risiko besteht.

Schlüsselwörter

Chronischer Schmerz · Knochenzement · Dynamische Foramenstenose · Alterungsprozess · Wirbelsäule

The mean baseline ODI score of the patient's was 50.34 (range 12–80). The majority of patients were overweight with a mean BMI of 30 (range 16–39).

All patients had at least one comorbidity (range 1–9) that contraindicated major surgery like the TLIF procedure (e.g., diabetes, rheumatoid arthritis treated with Leflunomide, hypertension, congestive heart failure, myocardial infarction, renal failure, liver disease, etc.).

A total of 130 discs in 47 patients were treated by PCD. Of these patients, 10 re-

ceived one-level, 21 two-level, 9 three-level, 8 four-level, 2 five-level, and 1 patient six-level surgery. Surgical time increased with the number of augmented levels. In the case of one-level PCD, the mean surgical time was 25.7 min, while in the case of two-, three-, four-, five-, and six-level surgical procedures, the duration was 31.3, 46.2, 62.5, 57.5, and 85 min, respectively.

Both ODI and VAS lower back and leg pain scores improved significantly ($p < 0.02$) postoperatively (■ Fig. 3). At 6 months follow-up postoperatively, the

majority of patients (69% and 66%) reported a decrease in their lower back and leg pain. The average VAS score was 43 for LBP and 47 for LP. Similarly, there was a decrease in postoperative disability. Altogether, 61% of patients had a minimum 10-point decrease in their ODI score ($p < 0.01$).

Case presentation

A 79-year-old woman presented to our outpatient clinic with lower back and leg

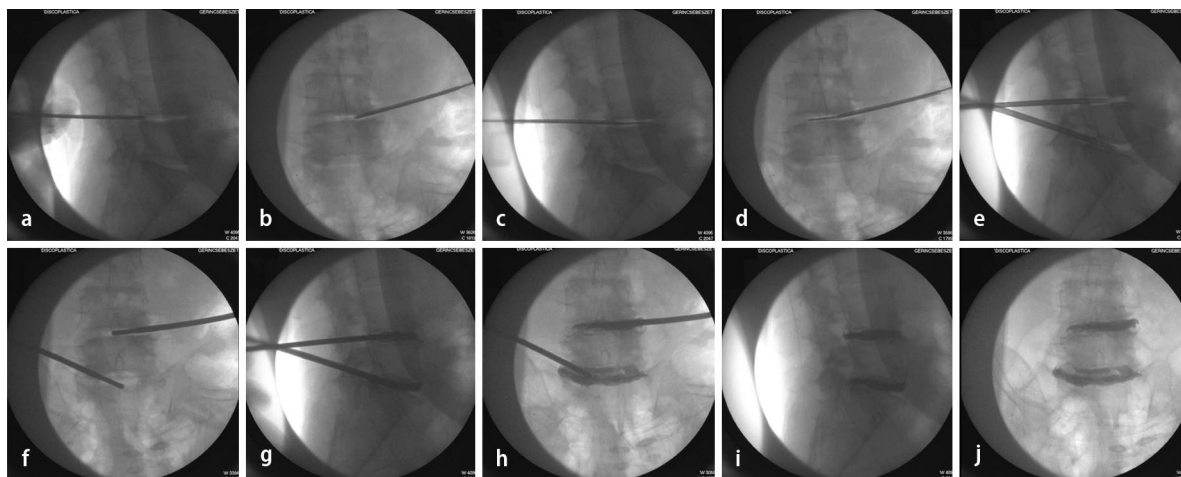


Fig. 2 ▲ Intraoperative C-arm images of the PCD procedure. **a** Insertion of the Jamshidi needle in the intervertebral disc space on lateral view. **b** Needle position on AP view. **c, d** Insertion of the K-wire through the Jamshidi needle. **e, f** Insertion of the vertebroplasty trocars. **g, h** Filling of the disc space with PMMA. **i, j** Postoperative status on lateral and AP X-rays

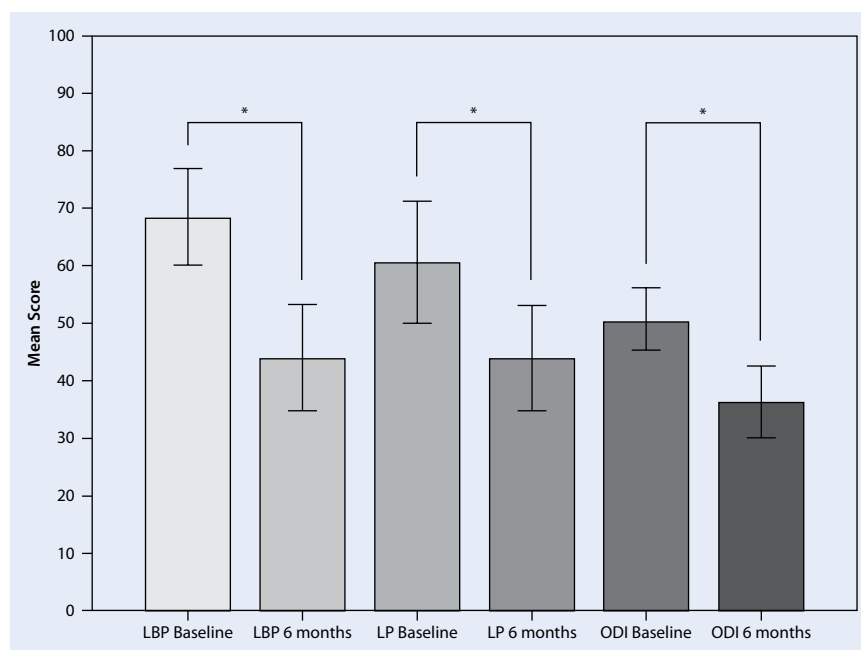


Fig. 3 ▲ Comparison of preoperative (baseline) lower back (LBP) and leg pain (LP), visual analog scale (VAS) and Oswestry disability index (ODI) scores with the scores registered on 6-month follow-up. Asterisks (*) indicate significant differences

pain. She had been treated for pain conservatively with physiotherapy and pain medication for several years. The pain was exacerbated when in an upright position and walking. The lower back pain irradiated to the L5 dermatome in both legs. The VAS score for the LBP and LP was 85 and she had an ODI score of 70. She had bilateral foot paresthesia. Walking range was below 100 m. On examination, we found multilevel disc degeneration in the lumbar spine. Functional X-ray suggested

instability in the L4–L5 motion segment. On standing X-ray (■ Fig. 4a), the area of the projected area of intervertebral foramen was smaller compared with the supine X-ray (■ Fig. 4b). On CT examination in the same segment, bilateral foraminal stenosis and a vacuum phenomenon were identified (■ Fig. 4e, f). Although we wanted to perform an L4–L5 TLIF procedure, the anesthesiologist contraindicated the surgery due to the high age of the patient and concurrent comorbidities (hy-

per-tension, cardiac failure, heart attack in the past, NIDDM). He only approved a small procedure like decompression. We decided to perform PCD since the patient required some form of stabilization. The patient was informed about the decision and she consented to the procedure. During surgery, 4 ml of PMMA was injected in the intervertebral disc (■ Fig. 4g, i). The duration of surgery was only 35 min and the patient was discharged on the third postoperative day. Both LBP and LP decreased significantly. At 6 months follow-up, the patient had a VAS score of 10 for LBP and 27 for LP. The patient's ODI decreased from 70 to 10. She stated in the questionnaire booklet that surgery had helped significantly and that she was satisfied with the surgical procedure.

Discussion

The current paper introduces a novel minimally invasive technique for the treatment of “vertical instability” (dynamic foraminal stenosis) in patients who are not suitable for a more invasive surgical procedure, such as the gold standard treatment of degenerative disc disease, 360° fusion.

The incidence of degenerative disc disease in the aging population is increasing steadily [8]. Foraminal stenosis due to vertical instability and consequent back and leg pain can dramatically affect patient quality of life [9]. Although non-operative treatment of this condition can ob-

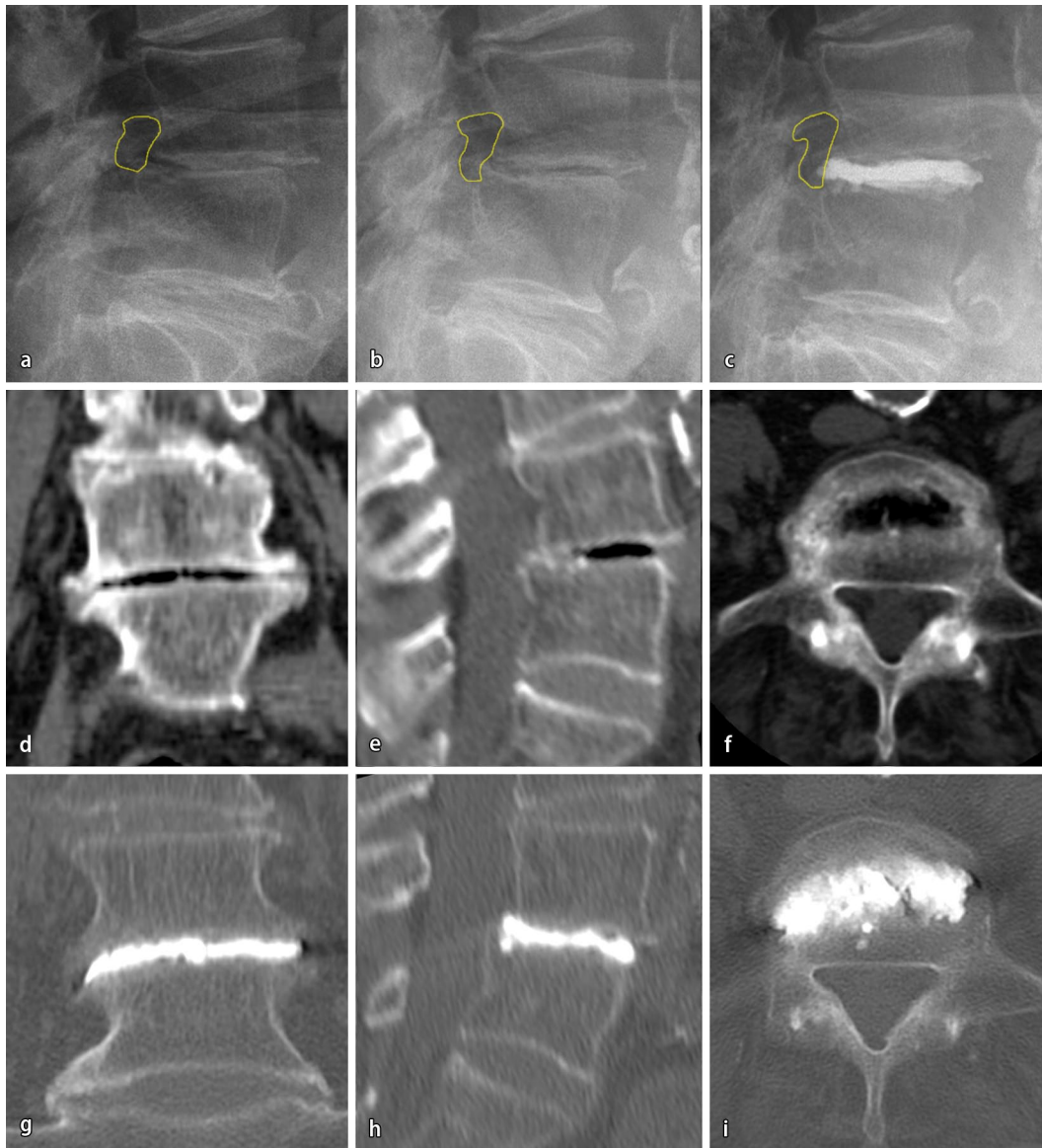


Fig. 4 ◀ One-level PCD. **a** Preoperative standing lateral X-ray. **b** Preoperative supine position lateral X-ray. Note: the cross section of the neuroforamen is larger. **c** Postoperative standing lateral X-ray (the cross section maintained). **d** Preoperative CT, coronal reconstruction of the affected segment, vacuum phenomenon in the disc space. **e** Same segment with sagittal reconstruction. **f** Same axial section showing the extension of the vacuum in the disc. **g** Postoperative CT, coronal reconstruction showing the cement position. **h** Same segment in sagittal reconstruction. **i** Same segment in axial section

tain good results, a significant number of patients require surgical intervention. The surgical treatment of elderly patients with spinal conditions can be challenging due to the high risk of general complications as a result of patient comorbidities, while more invasive surgical procedures, such as the gold standard treatment of degenerative lumbar disc disease, 360° instrumented fusion, has a higher risk of deep wound infection and thromboembolism [2]. Sobottke et al. [11] in their publication about the Spine Tango Registry, found that age, ASA status, and blood loss were significant co-factors for the occurrence of general complications. The influence of operative technique on complication rates was pointed out by Deyo et al.

[3], who showed that complication rates after fusion were almost twice as high as after open decompression alone. Similarly, Thomè et al. [12], in their randomized study ($n=120$) performed on elderly patients (average patient age, 70 years), showed that more invasive surgery has a higher complication rate.

The greater risk of morbidity in the elderly population was one of the factors giving rise to the spread of minimally invasive spinal surgery techniques [10]. Minimally invasive surgery can shorten operative times, minimize blood loss, and reduce tissue damage, resulting in a low surgical complication rate. PCD represents a minimally invasive procedure of this kind.

During a vertebroplasty procedure, the authors observed that the adjacent disc with vacuum phenomenon filled with PMMA, and signs of instability had disappeared on postoperative X-ray. This led to the development of the PCD procedure: PMMA augmentation of the intervertebral disc with vacuum phenomenon in patients otherwise not suitable for more invasive surgery. The hypothesis of the authors is that, by filling disc space with PMMA, instability is decreased, thus reducing in turn pain and disability.

As always, strict adherence to the indication criteria is key to clinical success. The surgical procedure is safe and single or multiple levels can be performed under local anaesthesia (■ Fig. 5). The stan-

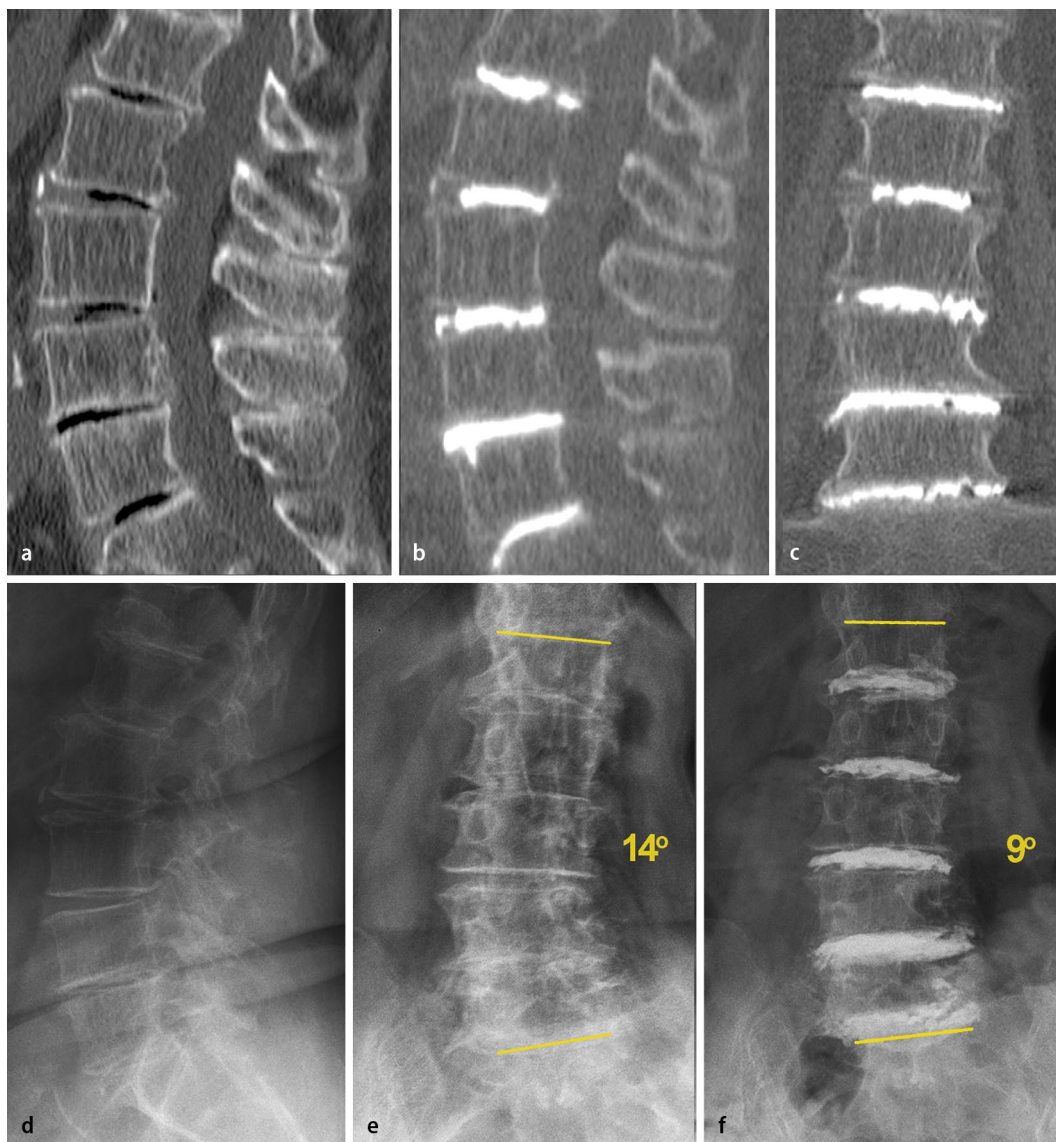


Fig. 5 ◀ Five-level PCD. **a** Preoperative CT, sagittal reconstruction of the lumbar spine. Multilevel disc degeneration with vacuum signs in all intervertebral spaces. **b** Position of the cement after five-level PCD. Postoperative CT, sagittal reconstruction. **c** Same in coronal reconstruction. **d, e** Preoperative X-ray in a standing position, lateral and AP view. **f** Postoperative standing AP X-ray, a moderate correction of the degenerative scoliosis can be observed due to PCD

standard percutaneous posterolateral route to the disc is the same, the one generally used in discography, and the process of filling the disc with high-viscosity PMMAs is well controlled by the routine C-arm control. The effect was immediate and, after consolidation of the bone cement, the patient was able to stand-up and ambulate while experiencing the benefits of painless movement under loading.

Elderly patients with relevant signs and symptoms of foraminal stenosis, a vacuum sign in the same segment, and positive dynamic radiological studies are suitable candidates for PCD, particularly in the presence of severe comorbidities that put them at high risk for open surgery. The intra- and postoperative local and general complication rate is low, and

surgery can be performed as a same-day or as an outpatient procedure.

The increasing number of PCD patients with comprehensive data collection during follow-up gives us a reliable understanding of the benefits of this intervention in this distinct patient population.

Conclusion

- Symptoms related to aging spine pathologies are common.
- Treating symptomatic degenerative disc disease of the lumbar spine in the elderly population using the standard surgical methods is often limited due to severe comorbidities (cardio-pulmonary diseases, hypertonia, diabetes, etc.). Minimally invasive pro-

cedures are more acceptable in this population, since they reduce surgical morbidity and the risk of complications.

- Elderly patients who had lower back and leg pain due to degenerative disc disease, one or more levels of vacuum phenomenon on their CT examination, foraminal stenosis at the same level(s) on MRI, and were not suitable for open procedures were selected for PCD.
- PCD is a safe and reliable method to maintain the craniocaudal diameter of the intervertebral foramen.
- The clinical results of PCD are immediate, and long hospitalization or rehabilitation periods are not required after the procedure.

Corresponding address



P.P. Varga
National Center for Spinal
Disorders, Kiralyhago u. 1–3
1126 Budapest
vpp@bhc.hu

Compliance with ethical guidelines

Conflict of interest. P.P. Varga, G. Jakab, I.B. Bors, A. Lazary, and Z. Szövérfi state that there are no conflicts of interest. All studies on humans described in the present manuscript were carried out with the approval of the responsible ethics committee and in accordance with national law and the Helsinki Declaration of 1975 (in its current, revised form). Informed consent was obtained from all patients included in studies,

References

1. Cain CM, Schleicher P, Gerlach R et al (2005) A new stand-alone anterior lumbar interbody fusion device: biomechanical comparison with established fixation techniques. *Spine* 30:2631–2636
2. Cloyd JM, Acosta FL Jr, Ames CP (2008) Complications and outcomes of lumbar spine surgery in elderly people: a review of the literature. *J Am Geriatr Soc* 56:1318–1327
3. Deyo RA, Mirza SK, Martin BI et al (2010) Trends, major medical complications, and charges associated with surgery for lumbar spinal stenosis in older adults. *JAMA* 303:1259–1265
4. Dipaola CP, Molinari RW (2008) Posterior lumbar interbody fusion. *J Am Acad Orthop Surg* 16:130–139
5. Dolan P, Luo J, Pollintine P et al (2013) Intervertebral disc decompression following endplate damage: implications for disc degeneration depend on spinal level and age. *Spine* 38:1473–1481
6. Hou Y, Luo Z (2009) A study on the structural properties of the lumbar endplate: histological structure, the effect of bone density, and spinal level. *Spine* 34:E427–E433
7. Keiler A, Schmoelz W, Erhart S et al (2014) Primary stiffness of a modified transforaminal lumbar interbody fusion cage with integrated screw fixation: cadaveric biomechanical study. *Spine* 39:E994–E1000
8. Mydlarz D (2012) Degenerative disc disease, active component, U.S. Armed Forces, 2001–2011. *MSMR* 19:6–9
9. Perez-Cruet MJ, Hussain NS, White GZ et al (2014) Quality-of-life outcomes with minimally invasive transforaminal lumbar interbody fusion based on long-term analysis of 304 consecutive patients. *Spine* 39:E191–E198
10. Rosen DS, O'toole JE, Eichholz KM et al (2007) Minimally invasive lumbar spinal decompression in the elderly: outcomes of 50 patients aged 75 years and older. *Neurosurgery* 60:503–509; discussion 509–510
11. Sobottke R, Aghayev E, Roder C et al (2012) Predictors of surgical, general and follow-up complications in lumbar spinal stenosis relative to patient age as emerged from the Spine Tango Registry. *Eur Spine J* 21:411–417
12. Thome C, Zevgaridis D, Leheta O et al (2005) Outcome after less-invasive decompression of lumbar spinal stenosis: a randomized comparison of unilateral laminotomy, bilateral laminotomy, and laminectomy. *J Neurosurg Spine* 3:129–141
13. Varga P, Jakab G, Bank A et al (2007) Surgical treatment of symptomatic pathology of the ageing spine. In: European instructional course lectures. British Editorial Society of Bone and Joint Surgery, London, pp 185–191

