Επαναξιολόγηση της Κυφοπλαστικής

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Why are we discussing that?

•750,000 new fractures occur each year in the US

•The incidence of vertebral fractures in people aged 75–79 years is twice as high in women than in men (29.3 vs 13.6 / 1000person / year).

•The incidence of OVCFs in individuals 50 years or older may be 307 per 100,000 person years, and the direct expenses concomitant with new-onset OVCFs in the first year approximately 6490 Euros

•Osteoporotic fractures are strongly related to disability, quality of life decrease and higher risk of mortality due to cardiopulmonary complications

•This surely represents a heavy social and medical care burden,
since cost for hospitalization, consequent rehabilitation

Why are we discussing that?

•In a systematic review that included 622,675 hospitalized patients with VCFs, the median length of admission was 10 days

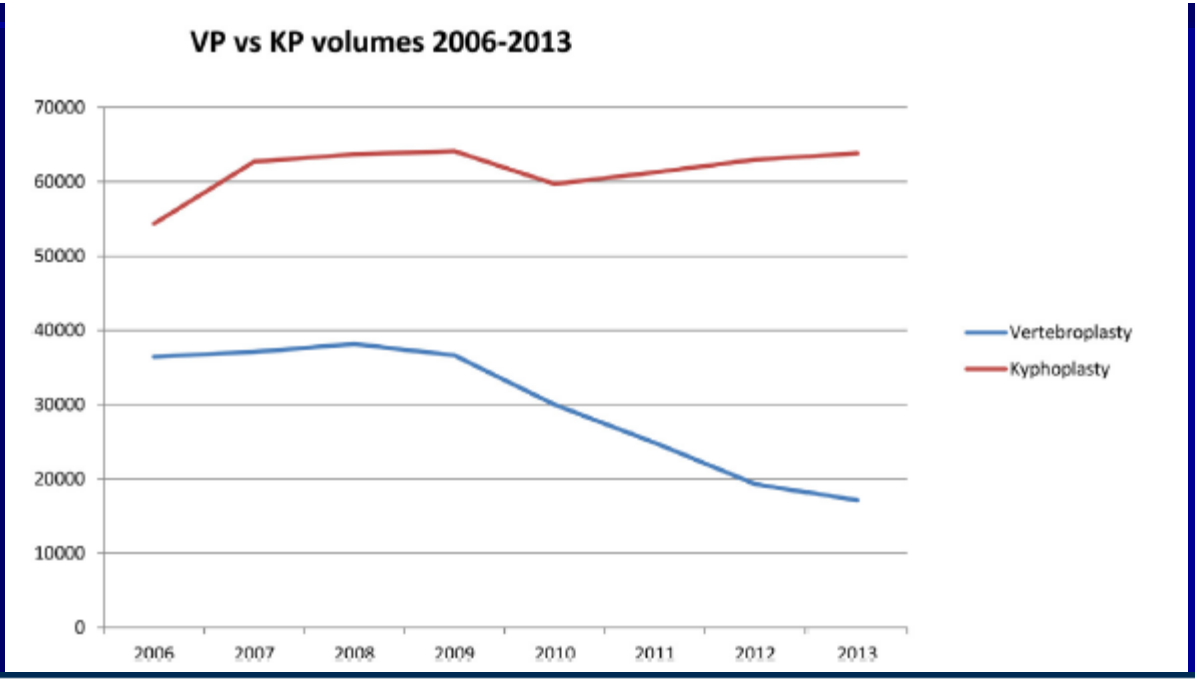
•1 in 4 patients stayed 2 weeks

•Hospital mortality ranged from 0.9% to 3.5%; up to 50% were discharged into a care facility. Moreover, 1 in 5 patients were re-admitted within 30 days.

Why are we discussing that?

TODAY…

Although over 300 articles have been published annually on vertebral augmentation in the last 5 years, there remains much debate about a fundamental question — is vertebral augmentation a safe and effective treatment to achieve analgesia, reduce disability, and improve quality of life



Specialty	2006	2007	2008	2009	2010	2011	2012	2013
Radiology	40,869	43,756	44,374	43,435	37,803	36,520	34,576	33,618
Orthopedic surgery	28,231	29,518	29,743	28,037	24,747	22,382	21,246	19,886
Neurosurgery	15,195	16,940	16,993	17,260	15,812	15,784	15,201	15,232
Anesthesia	2,706	2,866	2,874	2,957	2,262	2,064	2,342	2,518
Physical medicine and rehabilitation	263	359	497	715	918	1,109	1,002	1,142
Other	3,508	6,349	7,326	8,337	8,144	8,309	7,891	8,544
Total	90,772	99,788	101,807	100,741	89,686	86,168	82,258	80,940

Vertebral Augmentation After Recent Randomized Controlled Trials: A New Rise in Kyphoplasty Volumes

J Am Coll Radiol 2016;13:28-32.

Structure of the Presentation

- Basic Knowledge…*30 year story*
- Trends of the Literature and News Feed…*5 year story*
- Meta-Analysis…*focus on 2018/2019*
- Conclusion…Critique…Take Home Message

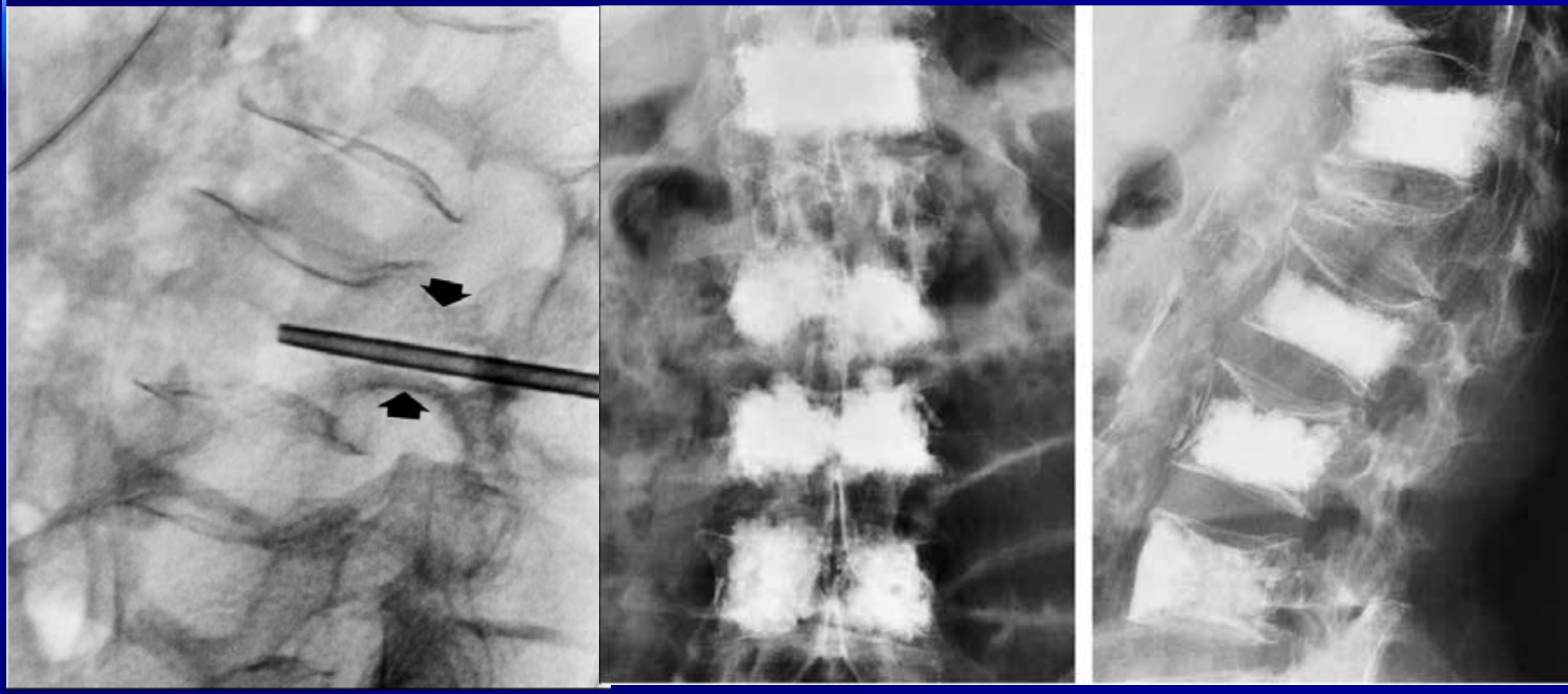
Structure of the Presentation

- Basic Knowledge…*30year story*
- Trends of the Literature and News Feed…*5year story*
- Robust Reviews + Meta-Analysis…*focus on 2018/19*
- Conclusion…Critique…Take Home Message

Historical review of the method

- The method of percutaneous vertebroplasty was pioneered/ firsty described by Deramond and Galibert in 1984/1987 for the treatment of haemangiomas.
- In 1989 1st publication for metastatic bone disease
- In 1997 were published by Jensen the first results for osteoporotic vertebral fractures
- In 1998 was the 1st publication for kyphopasty

Galibert P, Deramond H, Rosat P, et al. [Preliminary note on the treatment of vertebral angioma by percutaneous acrylic vertebroplasty]. Neurochirurgie 1987;33:166-8.
Jensen ME, Evans AJ, Mathis JM, et al. Percutaneous polymethylmethacrylate vertebroplasty in the treatment of osteoporotic vertebral body compression fractures: technical aspects. AJNR Am J Neuroradiol 1997;18:1897-904.
Kaemmerlen P, Thiesse P, Bouvard H, Biron P, Mornex F. Jonas P.Verte´broplastie percutane´e dans le traitement des me´tastases:technique et re´ sultats. *J Radiol* 1989;70:557–562



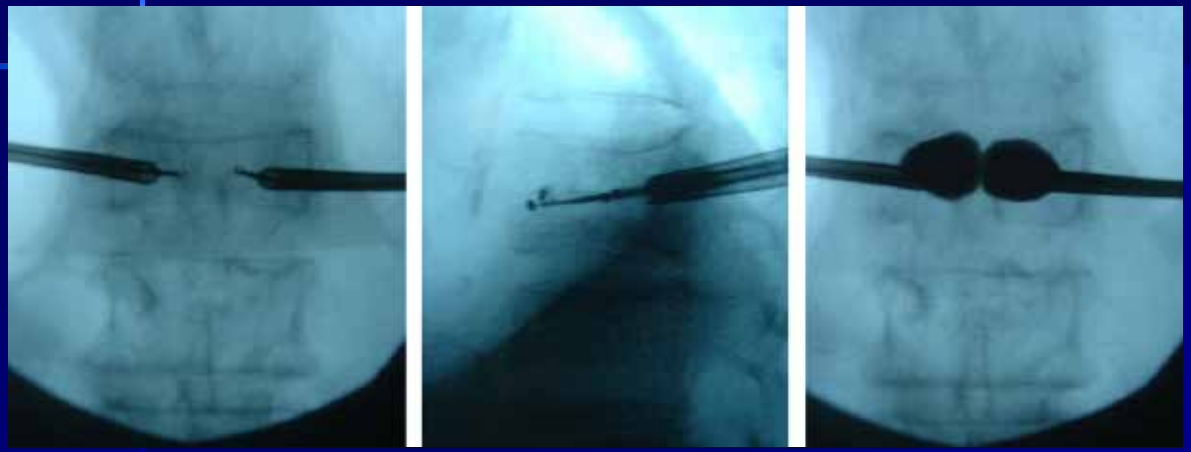
Jensen ME, Evans AJ, Mathis JM, et al. Percutaneous polymethylmethacrylate vertebroplasty in the treatment of osteoporotic vertebral body compression fractures: technical aspects. AJNR Am J Neuroradiol 1997;18:1897-904.

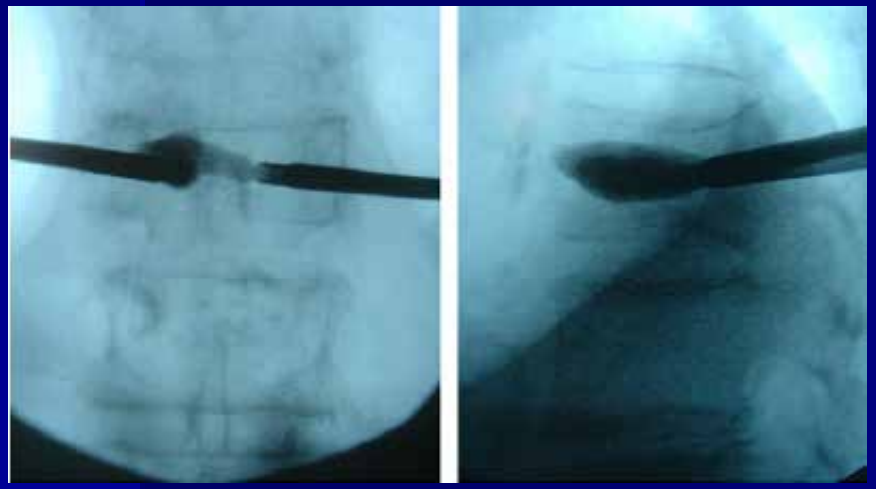
Surgical Technique

- The method is performed under local or general anesthesia
- Prone position
- Under flyoroscopic guidance
- Transpedicular / or extrapedicular is inserted a balloon into the fx vertebra – the balloon is inflated / reducing the fx by elevating the endplates - void with cement
- Time per segment 30 min
- Hospitalization 2-3 days
- Unipedicular or Bi…(Cost)

From 2001 à 2005 ….. 45 à 86.8 / 100.000

Surgical Technique





Vertebroplasty and kyphoplasty for the management of osteoporotic vertebral compression fractures.Orth Clin North Am 2007Jul;38(3):409-18

Aphorism

"Decisions are more important than Incisions"

Robert Bruce Salter, C.C., MD, FRCSC. Dec 15, 1924 – May 10, 2010

Indications

- Recent symptomatic vertebral osteoporotic fx with height loss more than 1/3. (3-… weeks)
- Kyphotic deformity of vertebra more 10 o
- vertebral body fractures that involve posterior cortical compromise/ posterior distortion… (modified Egg cell technique)
- Hemangiomas
- Kummel's disease
- Multiple myeloma
- Metastatic disease

Vertebroplasty and kyphoplasty for the management of osteoporotic vertebral compression fractures.Orth Clin North Am 2007Jul;38(3):409-18

Clinical Indication - Pain

Mechanisms of pain relief

- Destruction nerve endings from the exothermal reaction of PMMA.
- Internal cast fx vertebra – stabilizes micromotion
- Correction of kyphotic deformity.

Complications

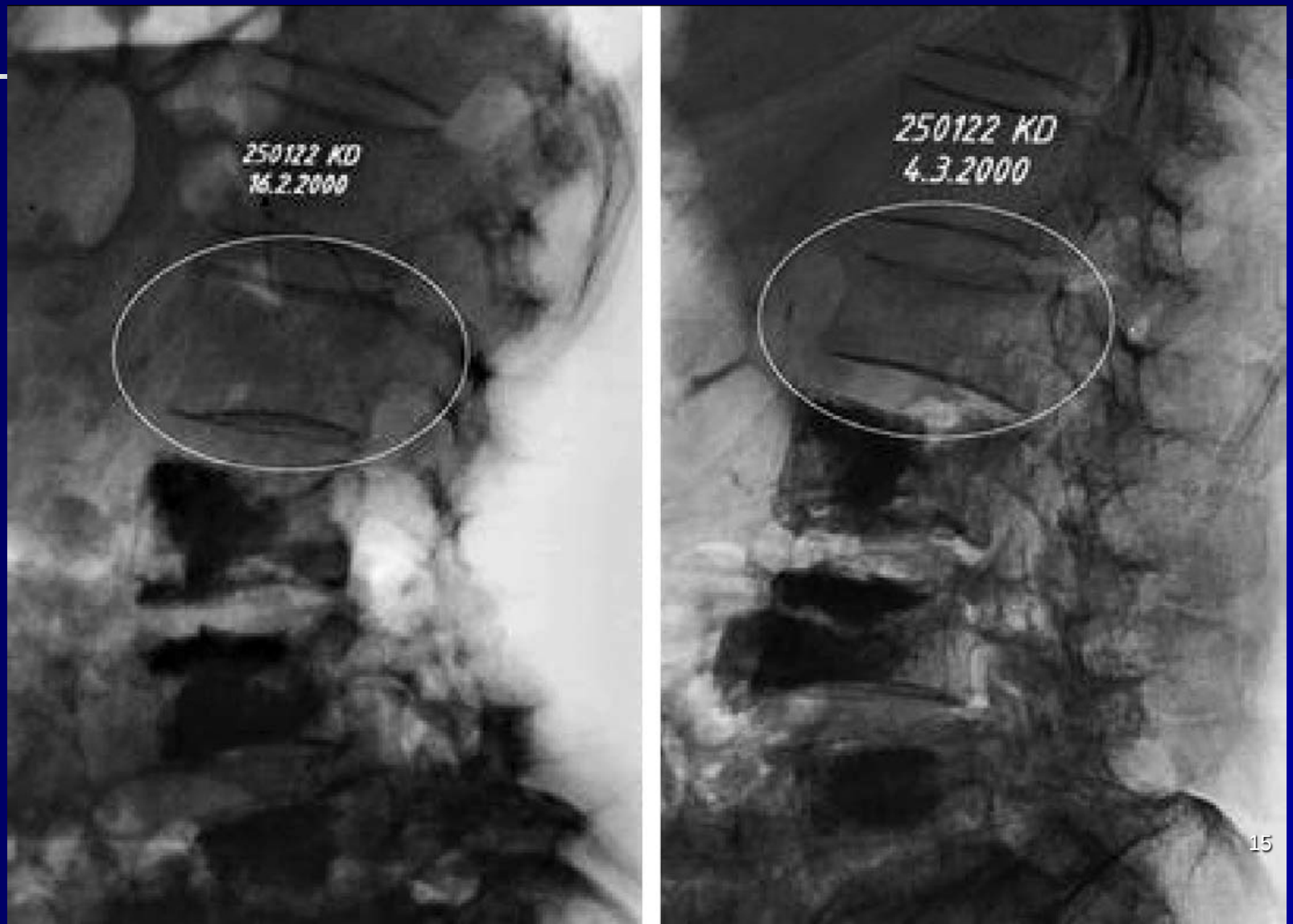
- Cement leak (7-9%....18%)
  1)vertebral canal(11%)
  2)paravertebral (48%)
  3)intradiscal (38%)
  (symptomatic extravasation <2%)

- Cement embolism(>1%)
- Subsequent vertebral fx
  (3-29%,21%)
  (66% in the adjacent vertebra
  (upper endplate of upper vertebra))

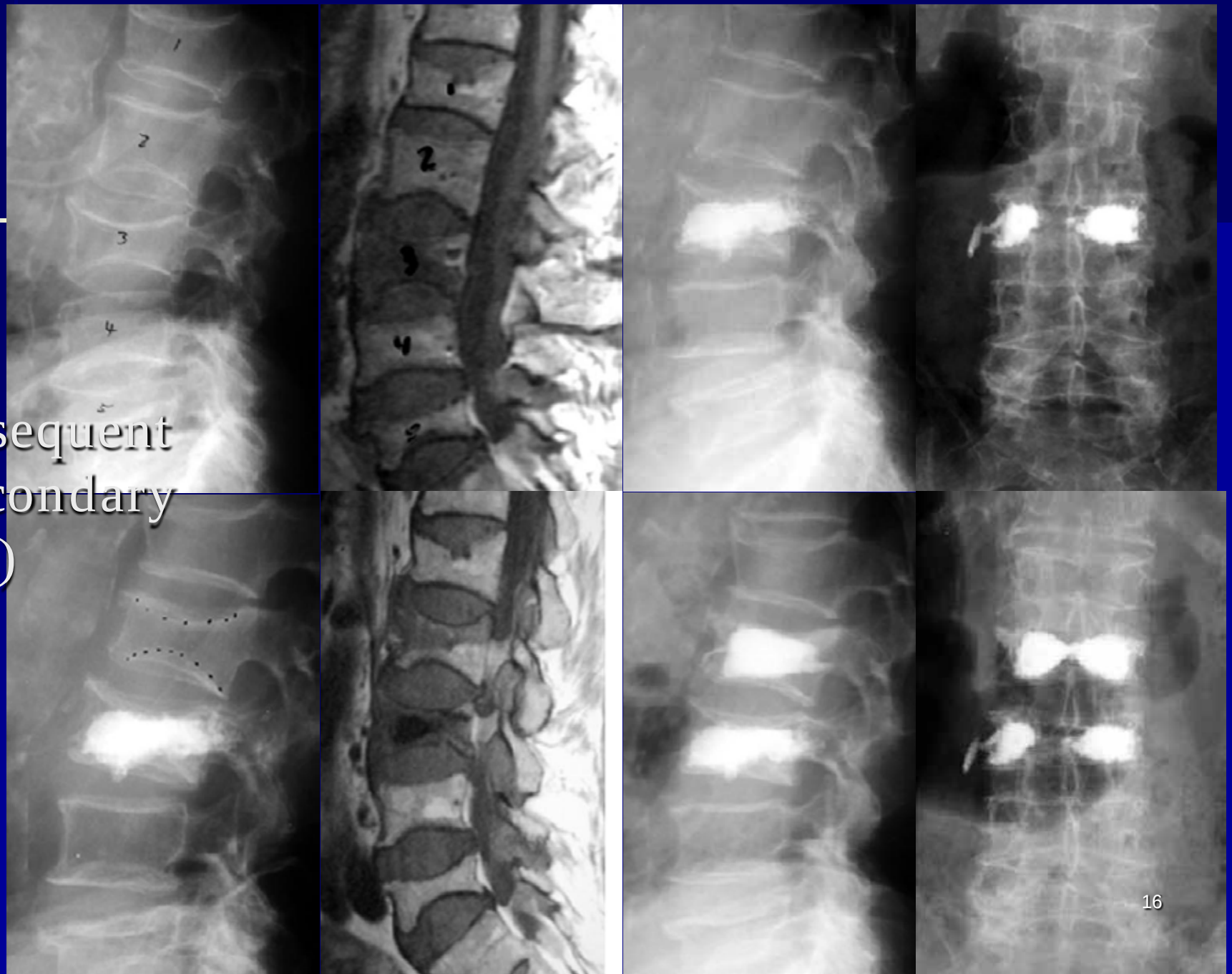
Vertebroplasty and Kyphoplasty: A Systematic Review of 69 Clinical Studies:Hulme PA, Krebs J, Ferguson SJ, Berlemann U. Spine. 2006 Aug 1;31(17):1983-2001.

Comparison of vertebroplasty and balloon kyphoplasty for treatment of vertebral compression fractures. A meta-analysis of the literature. Eck J.A, Nachtigall Dean .The spine journal 2007

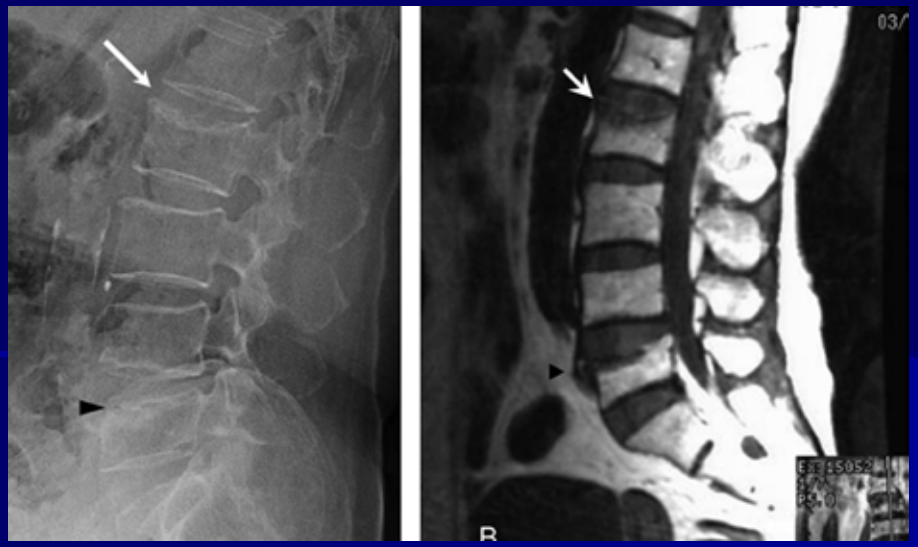
Subsequent/ Secondary fx



Subsequent / Secondary Fx(2)



Cement leak and subsequent fx



Combined extraforaminal and intradiscal cement leakage following percutaneous vertebroplasty Spine. 2007 May 20;32(12):1358-62

Background data

Lindsay et al, the incidence of another new compression fracture within 12 months of the initial fracture was 19.2% among patients with a history of spinal compression fracture and 24% among patients with a history involving more than two vertebrae

THE LANCET

vs

The NEW ENGLAND JOURNAL of MEDICINE

Efficacy and safety of balloon kyphoplasty compared with non-surgical care for vertebral compression fracture (FREE) a randomised controlled trial

Lancet 2009; 373: 1016–24

Compared the efficacy and safety of kyphoplasty with non-surgical
Hypothesis that kyphoplasty would result in increased improvement in quality of life

Materials and Methods:
300 Pts with up to 3 fx randomised in 2 groups 1)kypho (149) 2) conservative (151)
SF-36 , EQ-5D , Roland-Morris scale, pain , drug use
complications
f/u in 1, 3, 6, 12 months

Results
Stat significant difference à SF-36+Roland-Morris+pain+drug use
non stat signicicant diffence à subsequent fx at the end of the study(7.7%(25/33)---14%)

Conclusion
balloon kyphoplasty resulted in improvements in quality of life and disability measures and reduction of back pain FASTER
, differences in improvement between kyphoplasty and non-surgical control groups diminished by 1 year

A Randomized Trial of Vertebroplasty for Painful Osteoporotic Vertebral Fractures

N Engl J Med 2009;361:557-68.

Objective:

to determine the short-term efficacy and safety of vertebroplasty for alleviating pain and improving physical functioning

Materials and Methods:

78 Pts up to 2 vertebral fx randomized in 2 groups 1)vertebroplast 2)placebo

EQ-5D , Quality of life, Roland-Morris scale, pain , f/ u : week , 1, 3, 6 μήνες

Results:

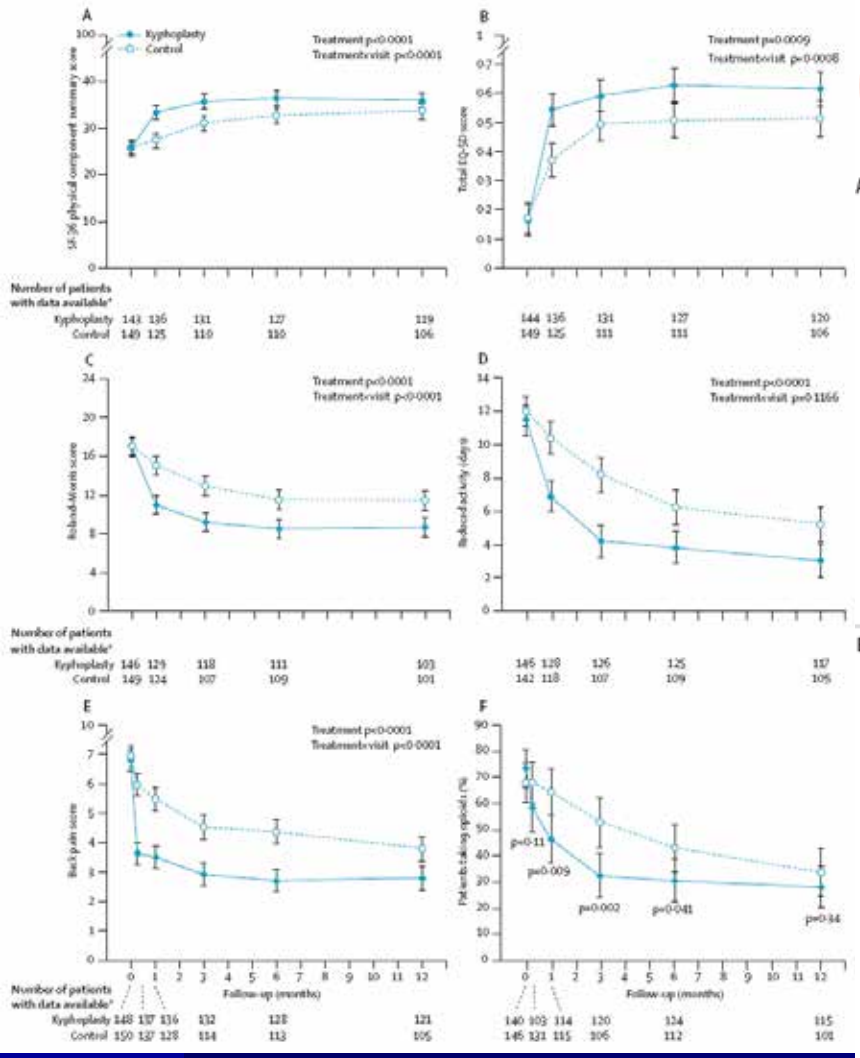
No significant differences between groups were seen in the primary outcome of overall pain

3 new # after VP , 4 after placebo treatment

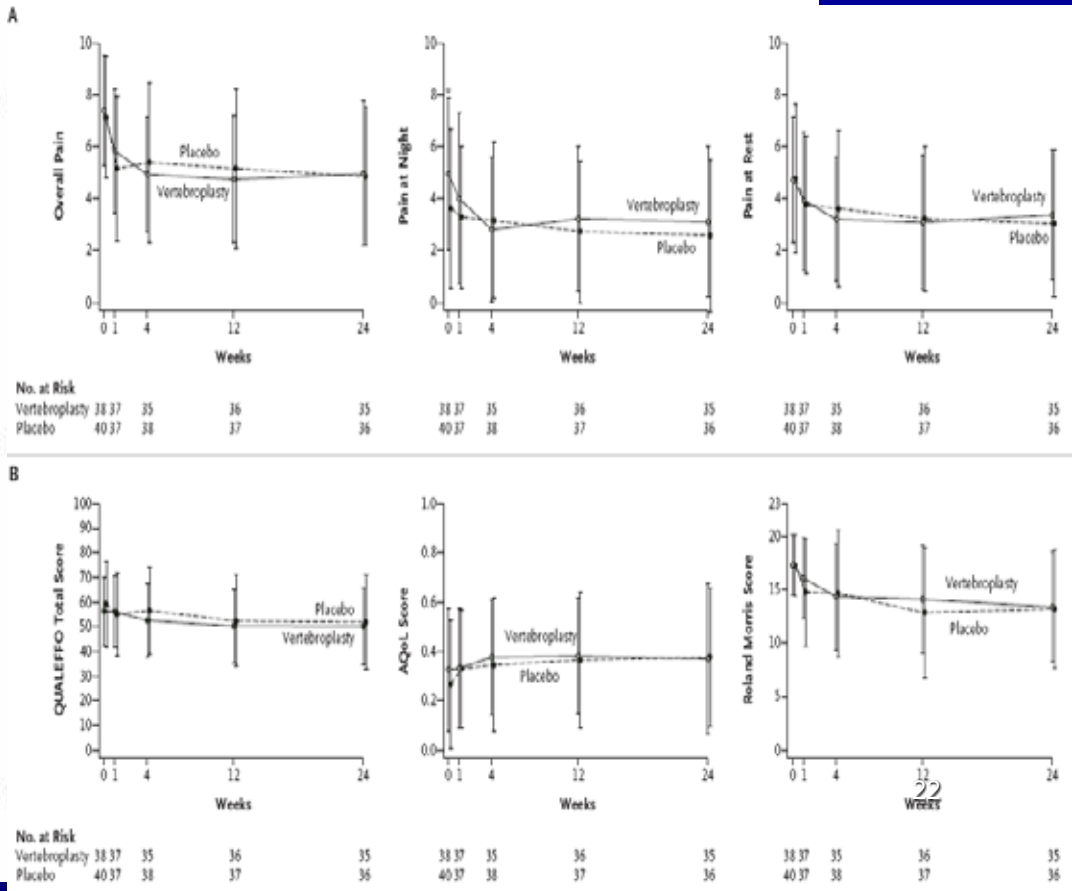
Conclusion:

No beneficial effect of vertebroplasty as compared with a sham procedure in patients with painful osteoporotic vertebral fractures

THE LANCET



The NEW ENGLAND JOURNAL of MEDICINE



Technique Analysis

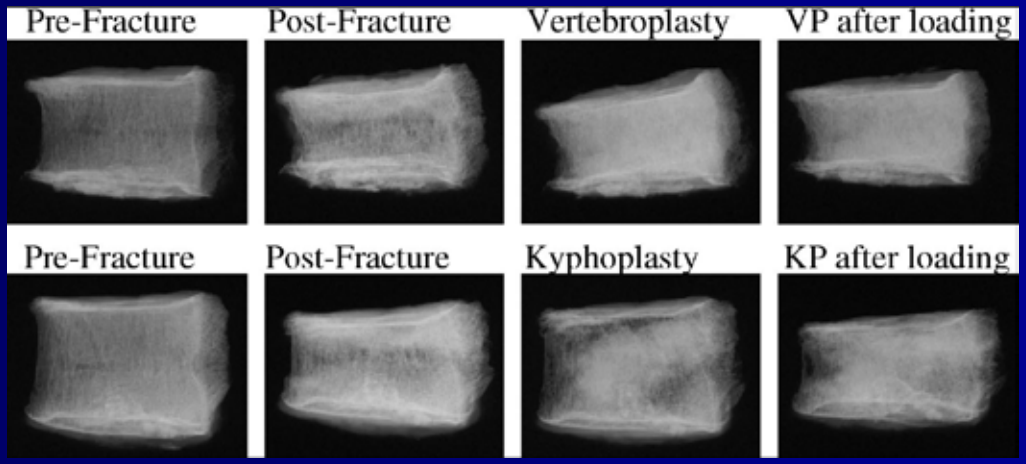
Sagittal Alignment

Local Kyphosis vs. Sagittal Alignment

- Kyphoplasty vs. Vertebroplasty

  1 vertebral thoracic compression fracture causes 9% loss of forced vital capacity

Vertebroplasty "freezes" the deformity without correcting the compression



Reduction of local kyphosis leads to an improved overall sagittal alignment?

Local Kyphosis vs. Sagittal Alignment (2)

- 65 patients (43 f ,22 m)

Height Restoration at VCF

	Preoperative	Postoperative	Regained
Average anterior height (mm)	20.5	23.6	15%
Average middle height (mm)	16.5	22.9	39%
Average posterior height (mm)	27.1	27.5	2%

Angular Restoration

	Average Angular Restoration
Sagittal Angle	
At VCF (fx site)	7.3° (from 11.7° to 4.3° postoperatively)
Spanning VCF by 1 vertebra	2.4°*
Spanning VCF by 2 vertebrae	1.4°*
Spanning VCF by 3 vertebrae	1.0°*

Spine 2006 31,4 435-441

Local Kyphosis vs. Sagittal Alignment

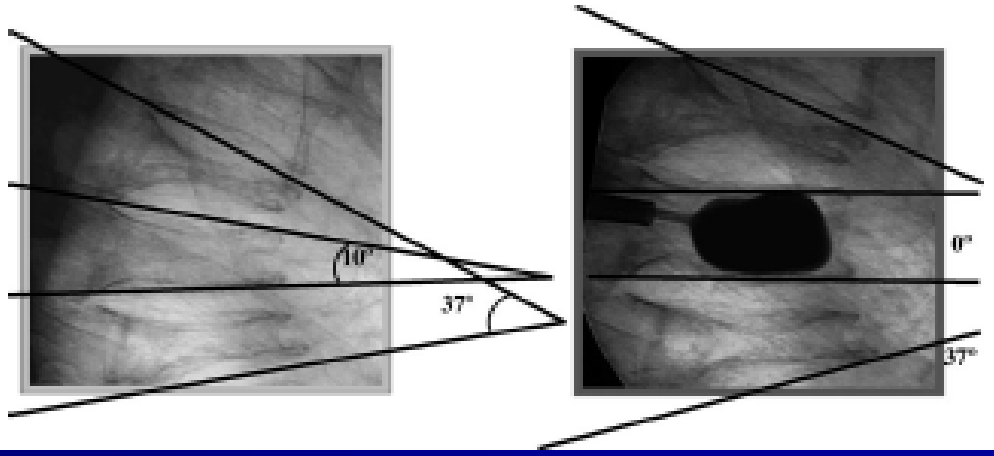
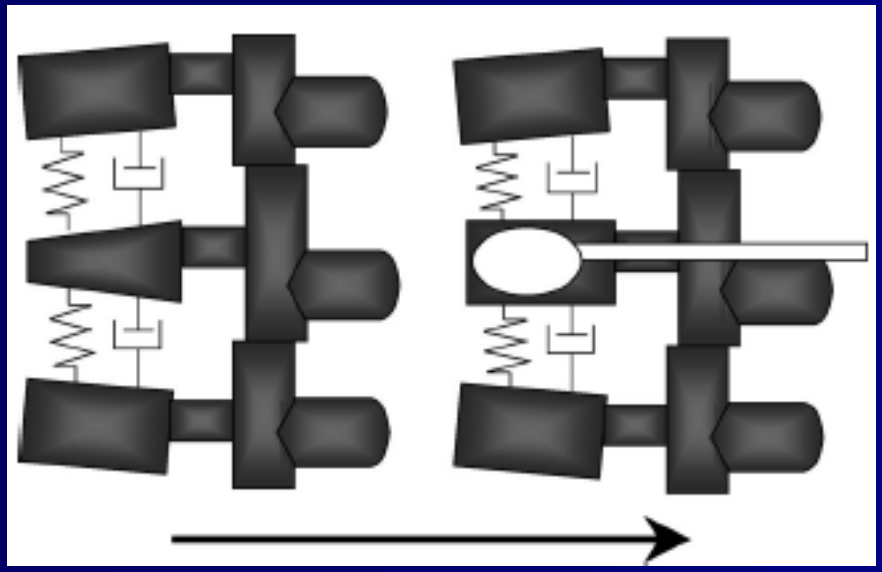


Table 5. Angular and Height Correction at VCF in Thoracic *Versus* Lumbar Spine

	Average Angular Restoration		
	Thoracic Spine (n = 21)	Lumbar Spine (n = 25)	*P*
Sagittal angle			
At VCF (fx site)	8.5°	6.4°	<0.01
Spanning VCF by 1 vertebra	3.7°	1.3°	<0.01
Spanning VCF by 2 vertebrae	2.5°	0.6°	<0.01
Spanning VCF by 3 vertebrae	1.4°	0.6°	<0.01
	Height Regained		
	Thoracic Spine (n = 21)	Lumbar Spine (n = 25)	
Height measured at			
Anterior height	27%	11%	<0.01
Middle height	52%	34%	<0.01
Posterior height	3%	1%	<0.01

Local Kyphosis vs. Sagittal Alignment

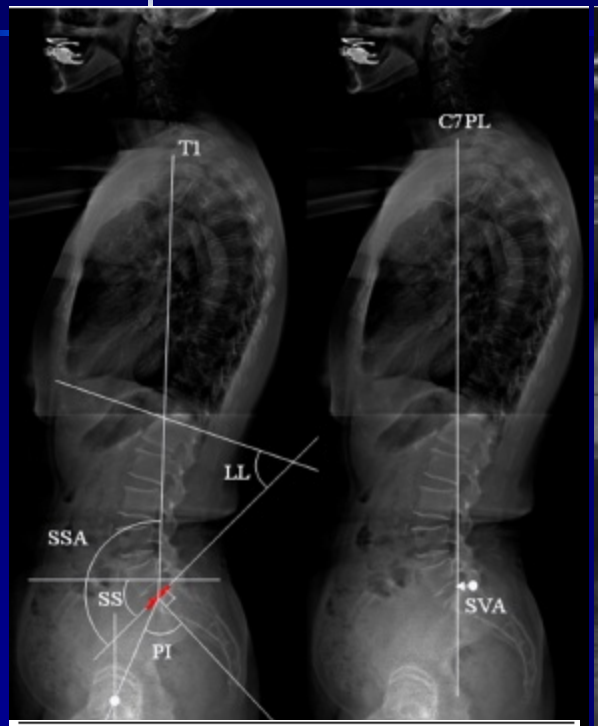
Local angular and height restoration falls within the “neutral zone”- disc – soft tissues of the spine motion segment.



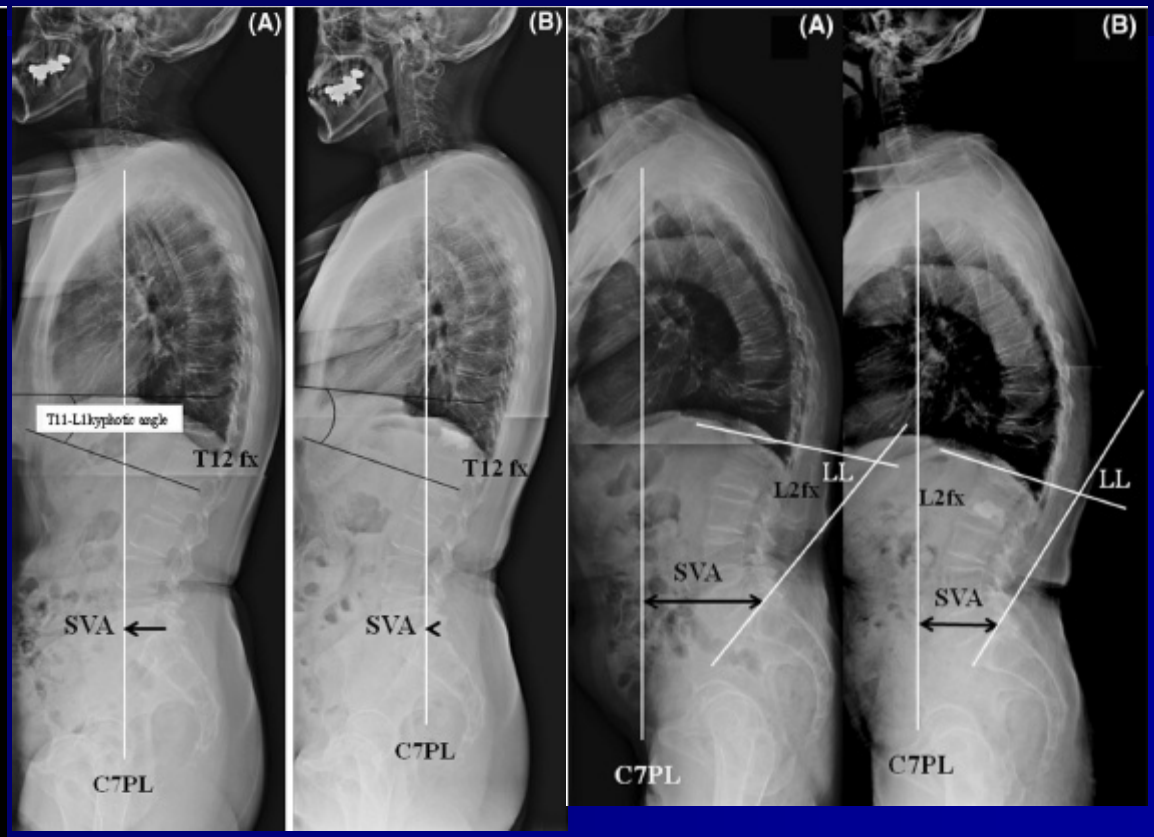
Eur Spine J (2015) 24:744–749
DOI 10.1007/s00586-014-3678-z

ORIGINAL ARTICLE

Postoperative change in sagittal balance after Kyphoplasty for the treatment of osteoporotic vertebral compression fracture



	Before surgery	1 month after surgery	*P* value
Visual analog scale	7.98 ± 1.8	2.38 ± 2.3	<0.0001
Pelvic incidence(°)	54.6 ± 14.1	54.9 ± 13.5	0.702
Sacral slope (°)	28.8 ± 16.0	27.2 ± 13.2	0.213
Pelvic tilt (°)	25.3 ± 7.51	26.0 ± 7.68	0.553
Lumbar lordosis (°)	41.8 ± 18.9	44.7 ± 18.5	0.028
Sagittal vertical axis (cm)	7.00 ± 3.92	5.02 ± 2.91	0.0007
Spinosacral angle (°)	106.2 ± 13.6	111.5 ± 14.3	0.0031
Kyphotic angle of vertebra(°)	9.96 ± 3.9	5.52 ± 2.4	<0.0001



Pain relief obtained by Kyphoplasty also appears to contribute to improving the sagittal imbalance.

Factors Affecting Kyphotic Angle Reduction in Osteoporotic Vertebral Compression Fractures with Kyphoplasty

APRIL 2013

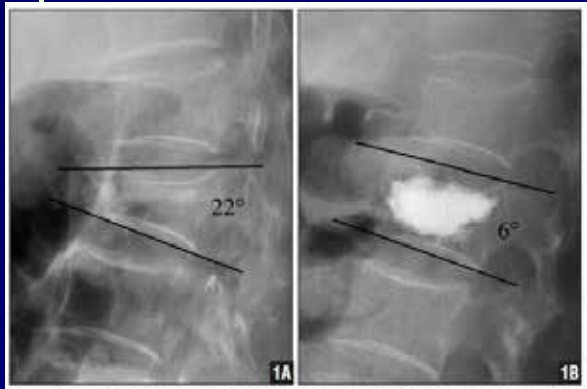


Figure 1: Pre- (A) and postoperative (B) lateral radiographs of a 71-year-old woman with an L1 vertebral compression fracture who was treated with kyphoplasty 2 weeks after acute and debilitating pain showing that the kyphotic angle improved from 22° to 6°, respectively. T-score was −3.8 SD.

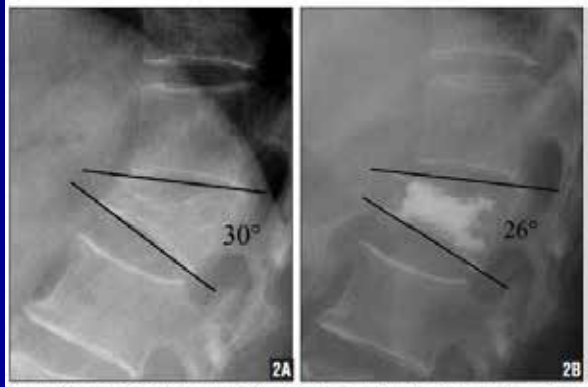


Figure 2: Pre- (A) and postoperative (B) lateral radiographs of a 66-year-old woman with an L1 vertebral compression fracture who was treated with kyphoplasty 3 months after onset of severe back pain showing that the kyphotic angle was corrected from 30° to 26°, respectively. T-score was −2.0 SD.

Table 2

Mean Improvement of Radiographic and Clinical Data

	Mean±SD		
Data	**Preoperative**	**Postoperative**	**Last Follow-up**
Anterior vertebral height variation (100%)	62.3±15.4	76.1±17.0[a]	75.2±16.7[a]
Middle vertebral height variation (100%)	67.0±15.1	81.6±13.0[a]	80.3±2.6[a]
Kyphotic angle, deg	17.4±6.6	12.7±7.1[a]	12.5±6.2[a]
Visual Analogue Scale	7.9±1.5	3.1±1.9[a]	3.4±1.8[a]
Oswestry Disability Index	67.2±13.7	35.2±14.7[a]	37.6±14.2[a]

Abbreviation: deg, degrees.
[a]$P<.05$ *compared with preoperative value.*

CONCLUSION

Kyphoplasty is a safe and effective treatment for osteoporotic compression fractures. The degree of kyphotic angle reduction achieved with kyphoplasty can be predicted by the preoperative kyphotic angle, BMD, and fracture age. The preoperative kyphotic angle is the most important factor for explaining kyphotic angle reduction. Low BMD and young fractures are also important factors for predicting better kyphotic angle reduction postoperatively.

Local Kyphosis vs. Sagittal Alignment

- Mechanical quality of the bone (density)
- Nature of fracture
- Mechanical quality of the disc
- Size of the disc
- Number and placement of balloon tamps
- Age of fracture

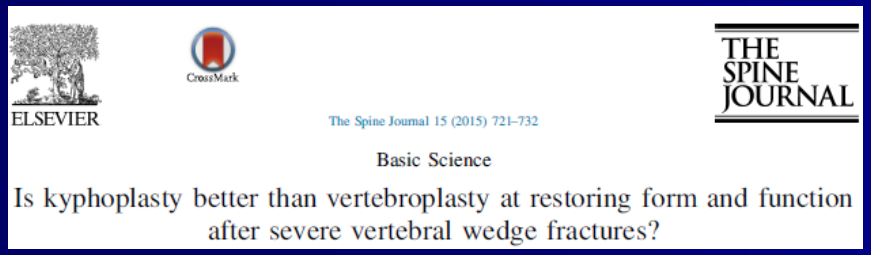
bias measurements . a

Local Kyphosis vs. Sagittal Alignment

Height Restoration 0-90%

Angular Correction 0-18^0 (10^0)

Kyphoplasty's advantage vs. Vertebroplasty


ELSEVIER

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THE SPINE JOURNAL

The Spine Journal 15 (2015) 721–732

Basic Science

Is kyphoplasty better than vertebroplasty at restoring form and function after severe vertebral wedge fractures?

Thoracic spine …> Lumbar spine

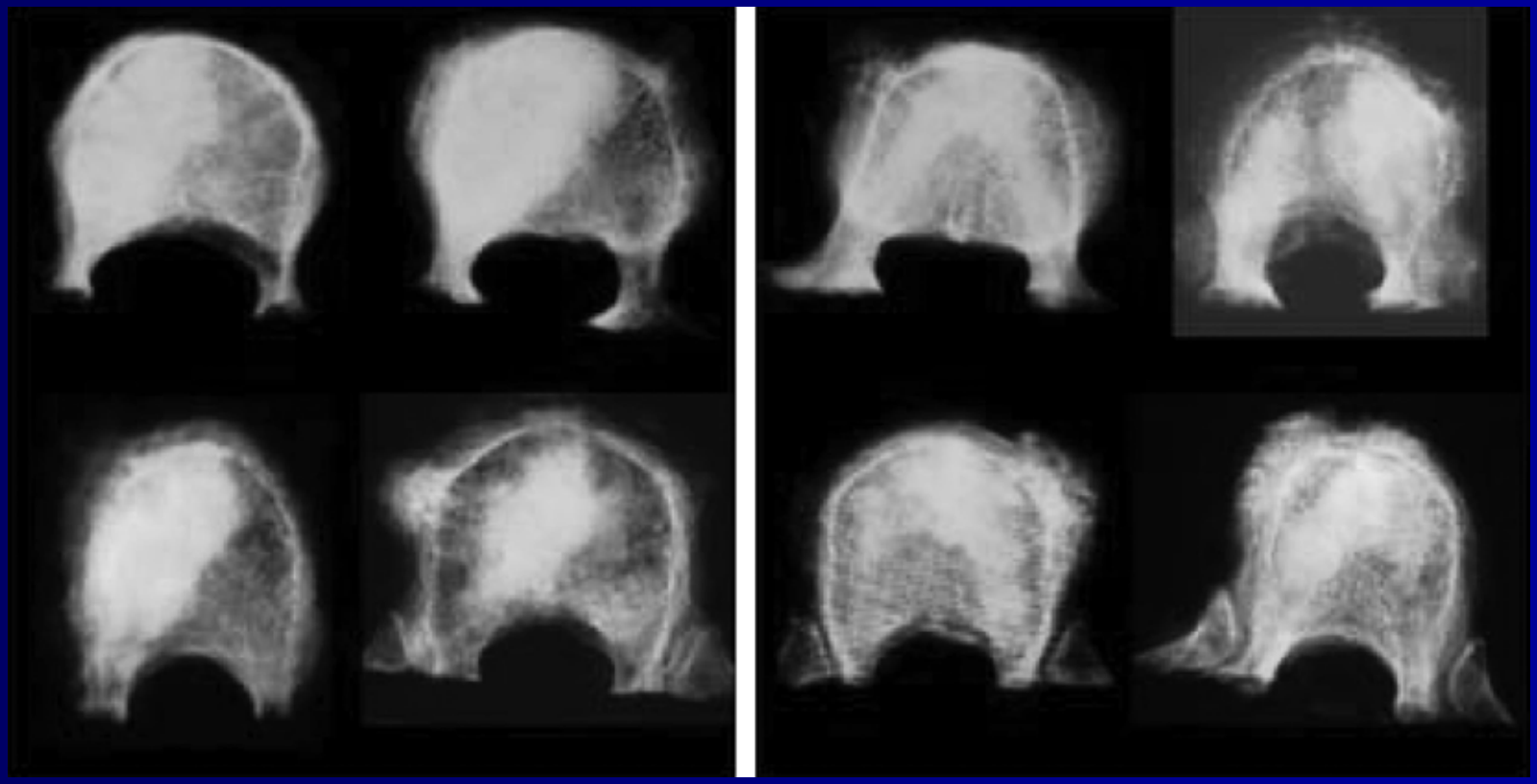
(smaller endplates and narrower discs,

smaller dimensions)

Technique Analysis

Unipedicular / Bipedicular

Biomechanical Comparison of Unipedicular *Versus* Bipedicular Kyphoplasty



Biomechanical Comparison of Unipedicular *Versus* Bipedicular Kyphoplasty

Conclusion

No statistical significant difference between unipedicular and bipedicular kyphoplasty

Unilateral Versus Bilateral Percutaneous Kyphoplasty for Osteoporotic Vertebral Compression Fractures: A Systematic Review and Meta-analysis of RCTs

Hui Feng, Peng Huang, Xuesong Zhang, Guoquan Zheng, Yan Wang

JOURNAL OF ORTHOPAEDIC RESEARCH NOVEMBER 2015

Pain relief

Surgery Time and Cement Dosage

Restoration of Vertebral Height… only in anterior height differs

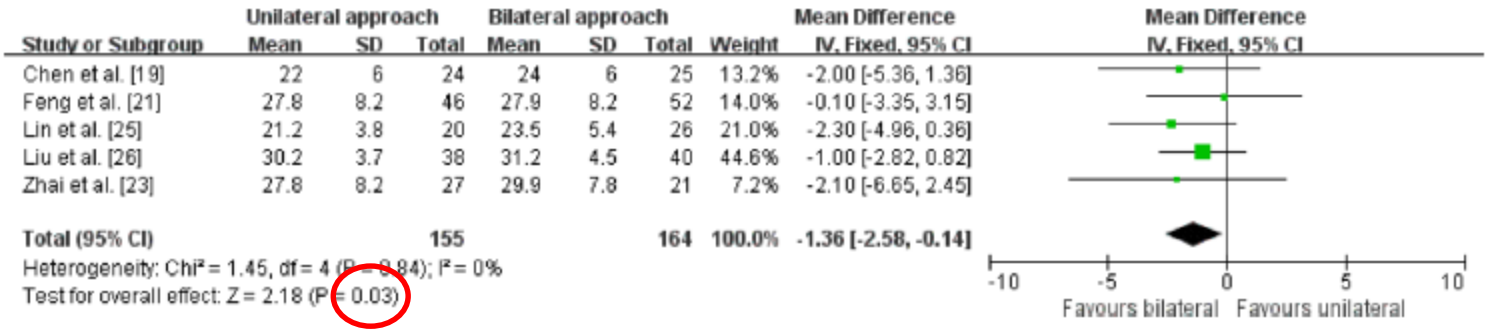


Figure 13. Forest plot of anterior vertebral height restoration with short-term follow-up after operation.

Complications

Quality of Life

Conclusion

UNILATERAL IS ADVANTAGEOUS

Technique Analysis

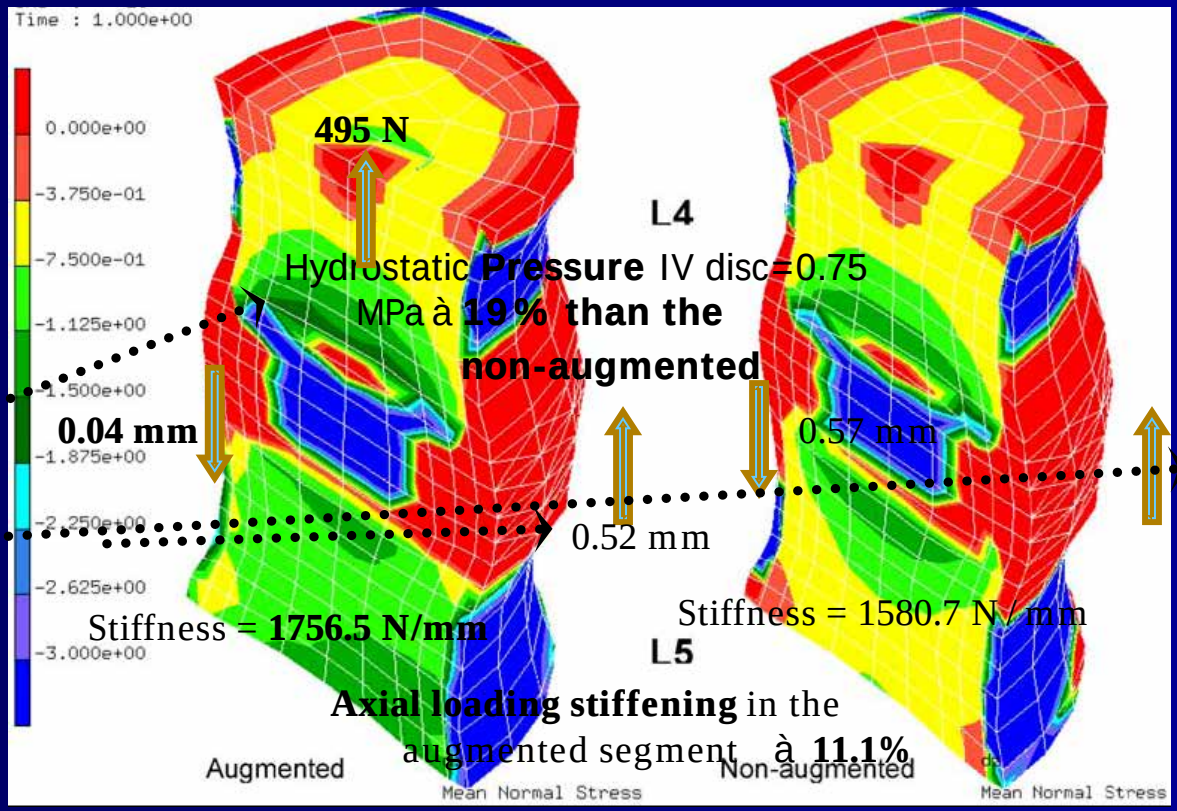
Subsequent Fx / Cement Leakage

The role of the disc in a non-osteoporotic spine + augmentation (non-degenerated disc)

Pillar theory

% of compression=% à **19.5%** IV disc
Axial compliance

% of compression=64.7% à IV disc
Axial compliance 35.3% à endplates L4-L5

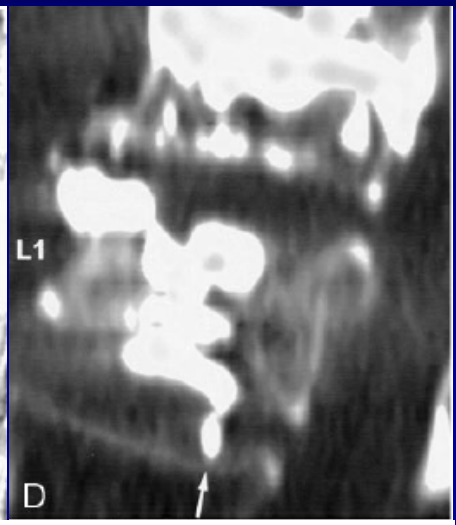


17% increase of the compressive stress - deflection

Colors à Mean stresses (MPa)

Eur.Spine(2003) 12 : 421–426

The role of the disc / clinical data



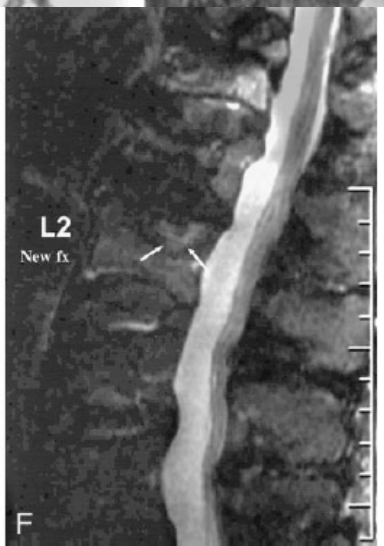


TABLE 2: Incidence of new fractures in relationship to cement leakage into the disk (n = 38 patients)

Fracture during Follow-up Period	Cement Leakage into Disk	No Cement Leakage into Disk	Total
No new fracture	8	16	24
New fracture	10	4	14
Total (P = .018)	18	20	38

AJNR Am J Neuroradiol 25:175–180, February 2004

The role of the disc / clinical data

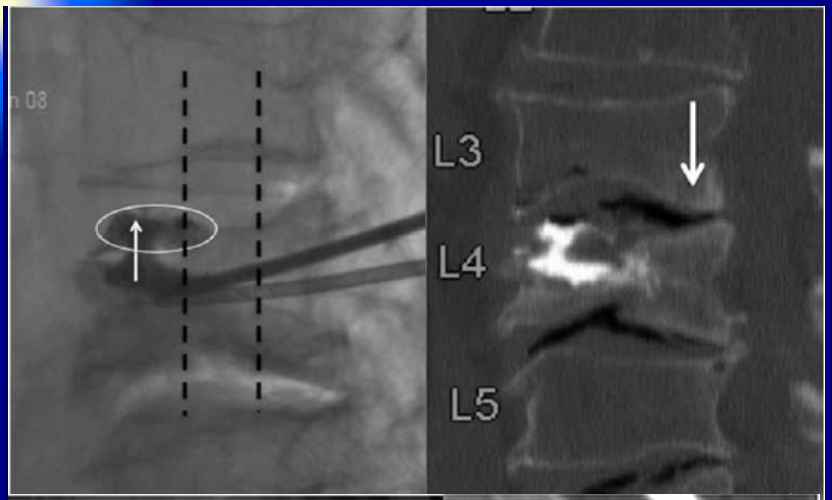
Conclusion:

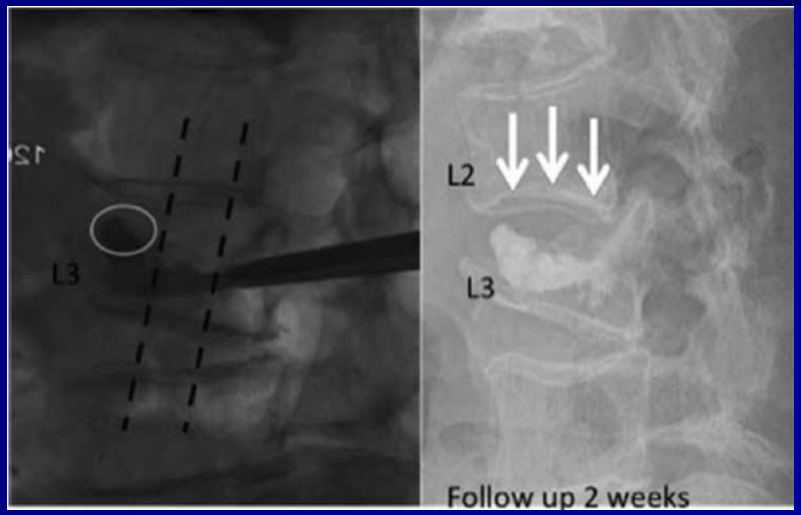
Cement leakage into the disk was a significant predictor of new vertebral body fracture after kyphoplasty/vertebroplasty (odds ratio = 4.6 – 5.9).

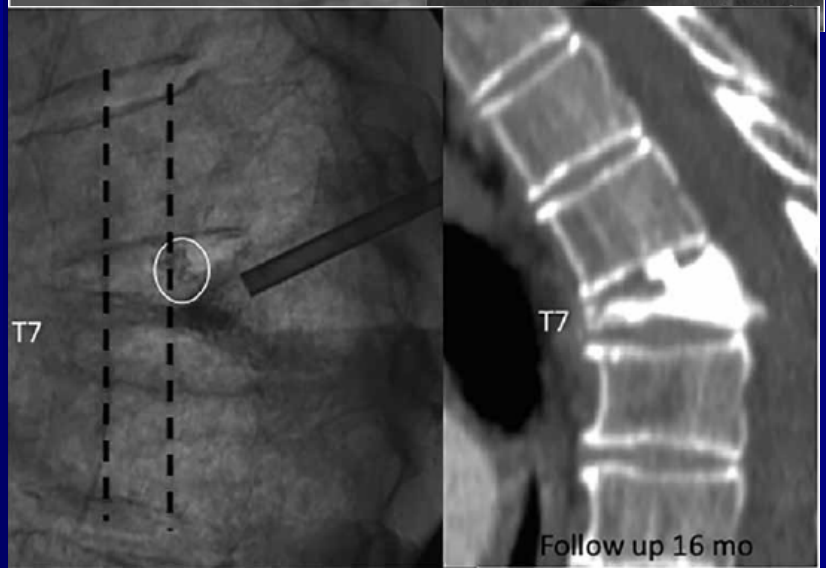
n Percutaneous vertebroplasty for osteoporotic compression fracture: multivariate study of predictors of new vertebral body fracture Cardiovasc Intervent Radiol. 2006 Jul-Aug;29(4):580-5.

Effect of the Location of Endplate Cement Extravasation on Adjacent Level Fracture in Osteoporotic Patients Undergoing Vertebroplasty and Kyphoplasty

Pain Physician 2015; 18:E805-E814 • ISSN 2150-1149







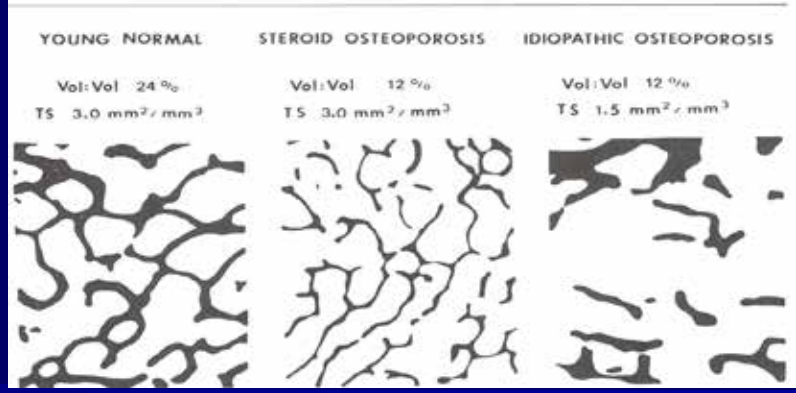
Increased impaction forces…

The odds of ALF were 22.6 times higher (95% CI: 3.0 to 170.9, $P = 0.003$) in a patient with anterior extravasation compared to the same patient with no leakage. Leakage in the middle or posterior third did not impact the odds of fracture (OR = 2.4, 95% CI: 0.45

Technique Analysis

Bone Metabolism / Special Patient Categories

The Bone quality - Corticosteroid use



Materials / Methods: 115 patients-225 kyphoplasties

80 patients primary OS,

35 patients secondary OS

Results: 22.6 % -15.1% (26 / 115 patients,34 / 225 kyphoplasties)

9 / 80 primary OS 11.25%

17 / 35 secondary OS 48,6 %

The period of follow-up 9.8 months in secondary OS *versus* the primary OS at 13.1

The corticosteroid patients were younger, having a mean age of 71.4 years *versus* 74.4

Conclusion: The subset of patients with secondary osteoporosis has an increased incidence of subsequent vertebral compression fractures compared with the primary osteoporosis population.

Primary and Secondary Osteoporosis' Incidence of Subsequent Vertebral Compression Fractures After Kyphoplasty Spine 2004

ELSEVIER

The Spine Journal ■ (2012) ■

THE SPINE JOURNAL

Clinical Study

Hypovitaminosis D as a risk factor of subsequent vertebral fractures after kyphoplasty

Hypovitaminosis D Osteopathy - Osteomalacia

Clinical

40 postmenopausal women with symptomatic vertebral fracture/s (primary OS)

Malignant fractures are excluded from this study

Male patients ,patients with secondary OS are also excluded in this S A.

Association of Vit D levels and subsequent fractures…

Conclusion: vit D levels… a prognostic factor of subsequent fractures

Structure of the Presentation

- Basic Knowledge…*30 year story*
- Trends of the Literature and News Feed…*5 year story*
- Robust Reviews + Meta-Analysis…*focus on 2018/2019*
- Conclusion…Critique…Take Home Message

Old stories…
Types of cement

(clinical or experimental use)

- Biopex (calcium-phosphate ionic cement) (slow release of heat)-low radiodensity
- Norian SRS (calcium-phosphate ionic cement) (slow release of heat))-low radiodensity
- Cranioplastic (high release of heat)
- Simplex / Simplex P (+barium sulfate) (high release of heat)
- Orthocomp (glass-ceramic-reinforced composite)
- Vertebroplastic

- KyphX HV-R (high viscosity radiopaque polymethylmethacrylate (PMMA) Bone Cement (+barium sulfate))

Joint Bone Spine 73 (2006)144-50
Spine 2001 26,14 1537-41

Elastoplasty…

Contents lists available at ScienceDirect

Acta Orthopaedica et Traumatologica Turcica

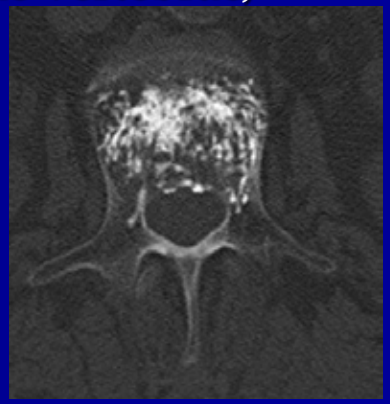
journal homepage: https://www.elsevier.com/locate/aott

Elastoplasty as a promising novel technique: Vertebral augmentation with an elastic silicone-based polymer

Alessandro Gasbarrini [a], Riccardo Ghermandi [a], Yunus Emre Akman [b, *], Marco Girolami [a], Stefano Boriani [a]

[a] Istituto Ortopedico Rizzoli, Bologna, Italy
[b] Metin Sabanci Baltalimani Bone Diseases Training and Research Hospital, Istanbul, Turkey

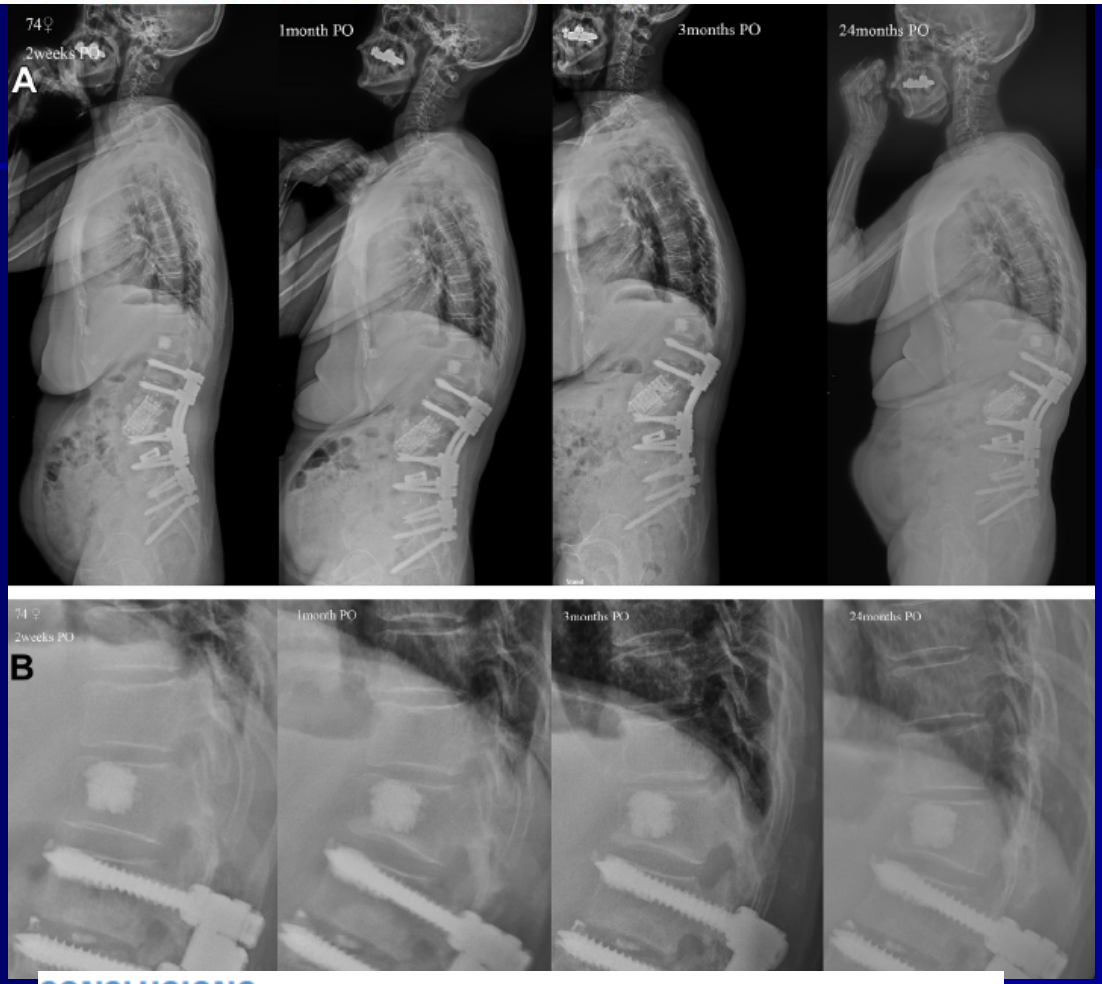
- 13 studies
- VK100 (BONWRX, Phoenix, AZ, USA), an elastic polysiloxane polymer (silicone) which is reported to show stiffness close to intact vertebrae
- The working time for VK100 is dependent on room or body temperature and is approximately 15 min from the beginning of the procedure to the end of the injection process in normal operating room and body Temperature.
- Mechanical properties to those of the trabecular bone of the vertebrae, VK100 may reduce the risk of subsequent fractures
- less additional fractures??????
- A leakage rate of 13%
- Worse height restoration



- Conclusion… elastoplasty is a safe and promising technique to overcome some certain drawbacks of PMMA

Effect of Vertebroplasty at the Upper Instrumented Vertebra and Upper Instrumented Vertebra +1 for Prevention of Proximal Junctional Failure in Adult Spinal Deformity Surgery: A Comparative Matched-Cohort Study

Effect of Vertebroplasty at the Upper Instrumented Vertebra and Upper Instrumented Vertebra +1 for Prevention of Proximal Junctional Failure in Adult Spinal Deformity Surgery: A Comparative Matched-Cohort Study



CONCLUSIONS

Cement augmentation at UIV and UIV+1 cannot prevent PJK, PJF, and PJFX; however, it plays a positive role by delaying their progression. Furthermore, PVP tends to decrease the reoperation rate after PJF in ASD surgery.

Instability of the Vertebrae Remains following Balloon Kyphoplasty

Global Spine J 2014;4:89–92.

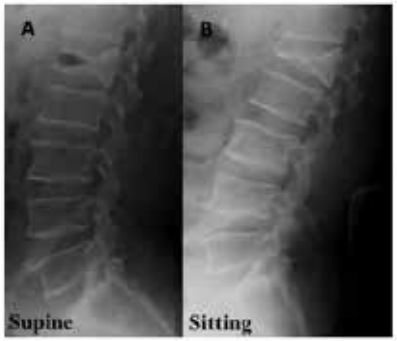


Fig. 2 (A) Lateral X-ray taken in the supine position before balloon kyphoplasty (BKP). The intravertebral cleft can be observed. (B) Lateral X-ray taken in the sitting position before BKP. The intravertebral cleft has disappeared.

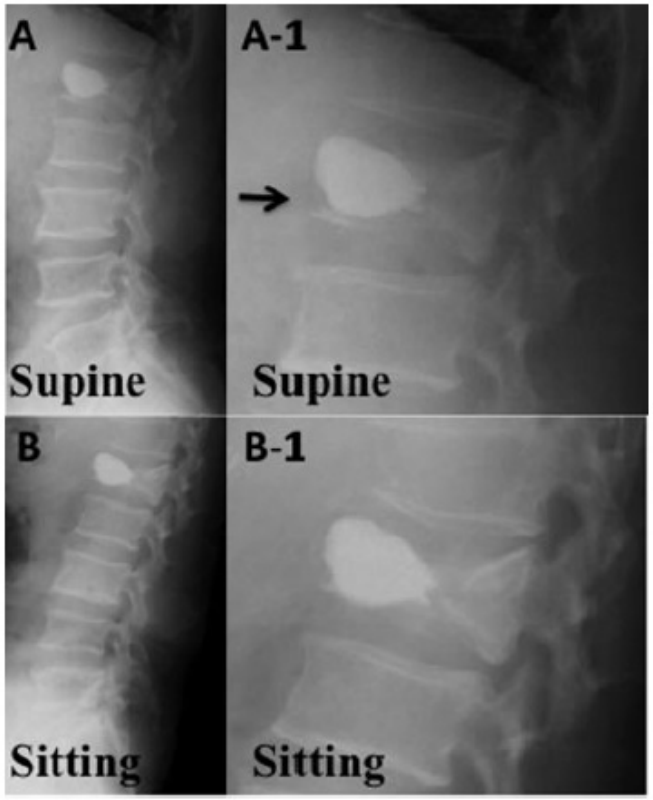


Fig. 3 (A) Lateral X-ray taken in the supine position after balloon kyphoplasty (BKP). (A-1) Magnified X-ray that focuses on the treated vertebra. The black arrow indicates the presence of a cleft between the cement and the end plate. (B) Lateral X-ray taken in the sitting position after BKP. (B-1) Magnified X-ray that focuses on the treated vertebra. The cleft between the cement and end plate previously observed in the supine position has now disappeared.

BKP. BKP may not be able to achieve strong fixation immediately.

Conclusions

BKP might not be able to gain strong fixation immediately. The mechanism of rapid pain relief following BKP was not achieved by strong fixation but by some degree of stabilization or other factors. We suggest that more research is needed to elucidate the mechanism of pain relief following BKP in the future.

Severe Rebound-Associated Vertebral Fractures After Denosumab Discontinuation: 9 Clinical Cases Report

Olivier Lamy, Elena Gonzalez-Rodriguez, Delphine Stoll, Didier Hans, and Bérengère Aubry-Rozier

Bone Unit, Lausanne University Hospital, 1011 Lausanne, Switzerland

Cases Description: We report 9 women who presented 50 rebound-associated vertebral fractures (RAVFs) after denosumab discontinuation. A broad biological and radiological assessment excluded other causes than osteoporosis. These 9 cases are unusual and disturbing for several reasons. First, all vertebral fractures (VFs) were spontaneous, and most patients had a high number of VFs (mean = 5.5) in a short period of time. Second, the fracture risk was low for most of these women. Third, their VFs occurred rapidly after last denosumab injection (9–16 months). Fourth, vertebroplasty was associated with a high number of new VFs. All the observed VFs seem to be related to denosumab discontinuation and unlikely to the underlying osteoporosis or osteopenia. We hypothesize that the severe BTR is involved in microdamage accumulation in trabecular bone and thus promotes VFs.

Conclusion: Studies are urgently needed to determine 1) the pathophysiological processes involved, 2) the clinical profile of patients at risk for RAVFs, and 3) the management and/or treatment regimens after denosumab discontinuation. Health authorities, physicians, and patients must be aware of this RAVF risk. Denosumab injections must be scrupulously done every 6 months but not indefinitely. (*J Clin Endocrinol Metab* 102: 354–358, 2017)

The 3 women treated with vertebroplasty sustained 10 new vertebral fractures in the following month.

Case No.	Age[a]	BMI[a]	FRAX MOF,[a] %	Prevalent OP Fx, Vertebral/ Nonvertebral, No.	Dmab Doses, No.	Time since Last Dmab, No.	Incidence of Vertebral Fx, No.	Reason for Dmab Discontinuation
1	52	21.5	11	0/0	5	9	5	No more OP
2	52	23.6	11	0/0	8	10	7 (+2[b])	Tx duration
3	55	22.1	11	0/0	7	10	2	No more OP
4	56	23.0	12	2/0	2	11	8	Patient's wish
5	61	20.0	15	0/0	2	12	1	Tx omission
6	61	23.1	16	1/0	8	10	6	Tx duration
7	71	22.7	27	1/1	2	11	5	Patient's wish
8	77	20.7	20	0/0	6	15	3 (+2[b])	End of AI
9	77	18.8	34	0/0	5	16	3 (+6[b])	Patient's wish

Abbreviations: AI, aromatase inhibitors; BMI, body mass index; Dmab, denosumab; Fx, fracture; MOF, major osteoporotic fracture; OP, osteoporosis; Tx, treatment.

[a]At the beginning of the denosumab treatment.

[b]One month after vertebroplasty.

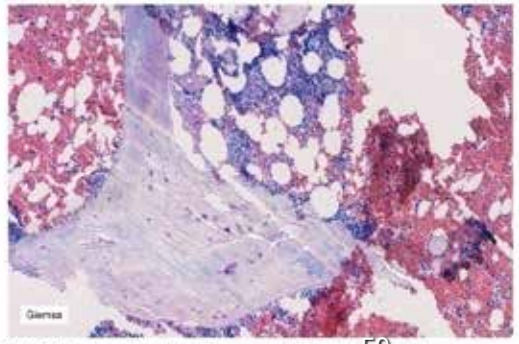


Figure 2. Giemsa coloration of aspiration biopsy vertebra L5 at the site of the vertebroplasty (case 9). Biopsy specimen shows no focal lesions or abnormal architecture. The hematopoietic marrow is trilinear and histologically normal. The immunohistological examination of the κ/λ ratio was 1. Analysis of the bone tissue does not show any malignant disease.

J Clin Endocrinol Metab, February 2017, 102(2):354–358

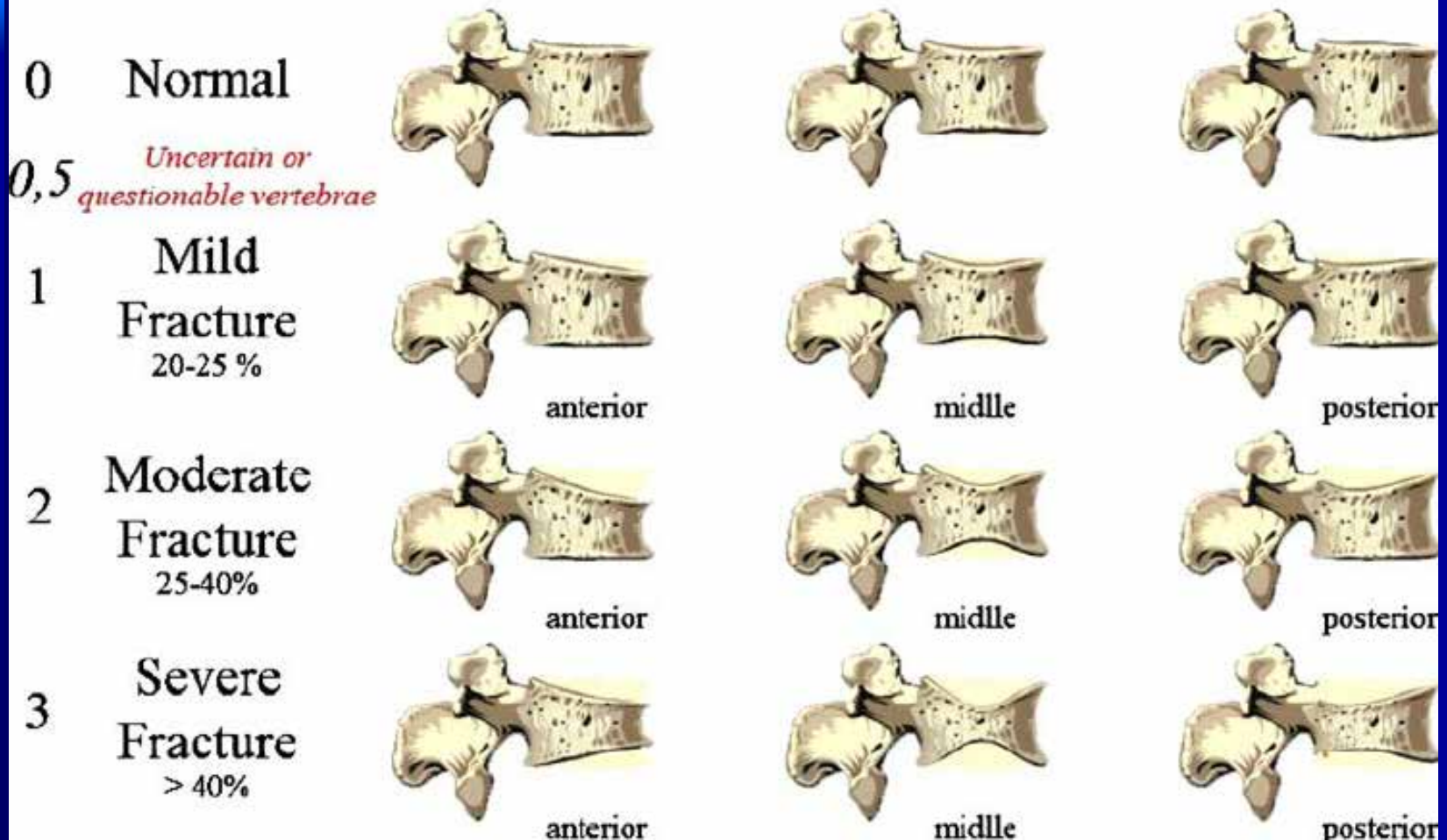
Vertebral collapse

JOURNAL OF BONE AND MINERAL RESEARCH
Volume 11, Number 7, 1996
Blackwell Science, Inc.

Comparison of Semiquantitative Visual and Quantitative Morphometric Assessment of Prevalent and Incident Vertebral Fractures in Osteoporosis

HARRY K. GENANT,[1] MICHAEL JERGAS,[2] LISA PALERMO,[3] MICHAEL NEVITT,[3] RIA SAN VALENTIN,[3] DENNIS BLACK,[3] and STEVEN R. CUMMINGS[3,4] FOR THE STUDY OF OSTEOPOROTIC FRACTURES RESEARCH GROUP

Semiquantitative (SQ) Grading for Vertebral Fractures



Classification of Vertebral Compression Fractures in the Osteoporotic Spine

Makoto Sugita, MD, Nobuyoshi Watanabe, MD, Yasuo Mikami, MD, Hitoshi Hase, MD, and Toshikazu Kubo, MD

- Sugita et al.

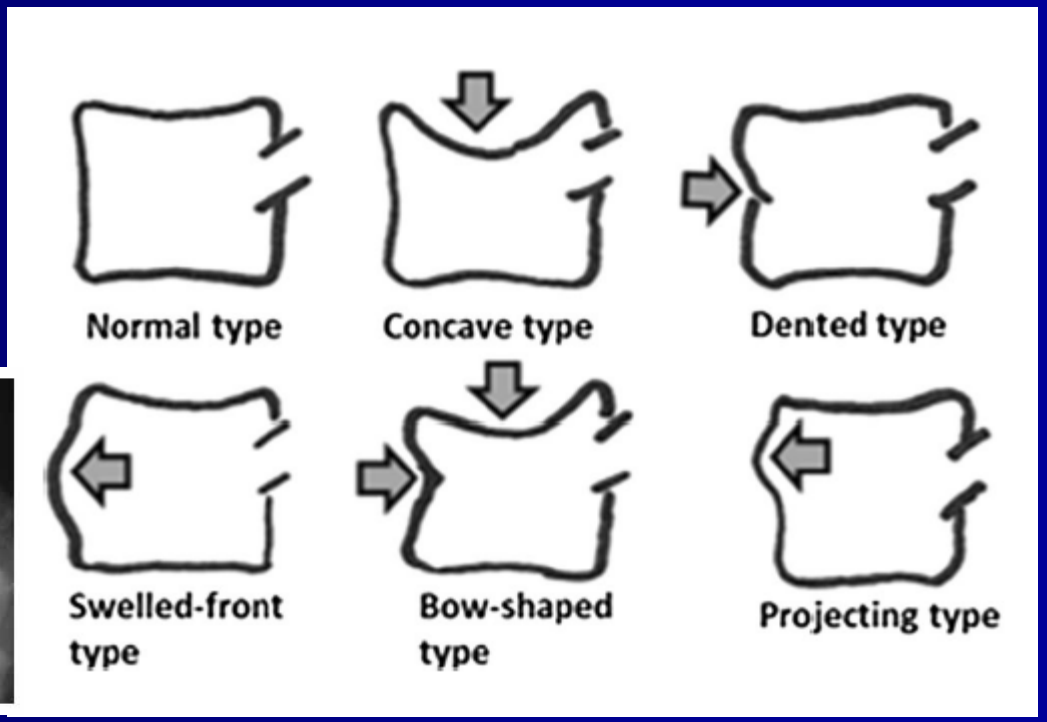


FIGURE 2. Dented-type fracture in a 76-year-old woman. A, Radiograph at injury. The center of the L1 body was dented, and the endplate was intact. B, Bone remodeling was completed 2 years after injury.

Good prognosis group:
- concave
- dented type

Poor prognosis group:
- swelled-front
- bow-shaped
- projecting type - cleft

FIGURE 2. Dented-type fracture in a 76-year-old woman. A, Radiograph at injury. The center of the L1 body was dented, and the endplate was intact. B, Bone remodeling was completed 2 years after injury.

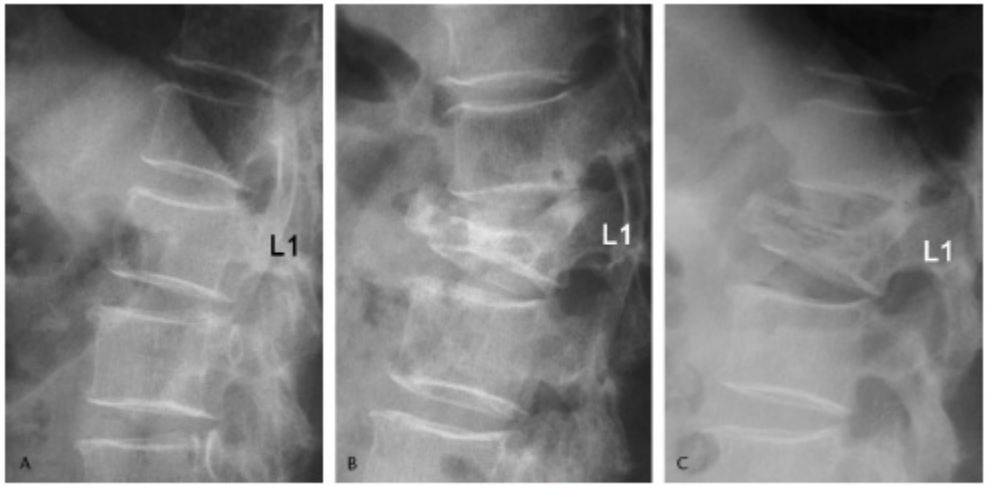


FIGURE 3. Swelled-front-type fracture in a 73-year-old woman. A, Radiograph at injury. The anterior wall of the L1 body was swollen. B and C, Dynamic imaging showed intravertebral mobility 1 year after injury.

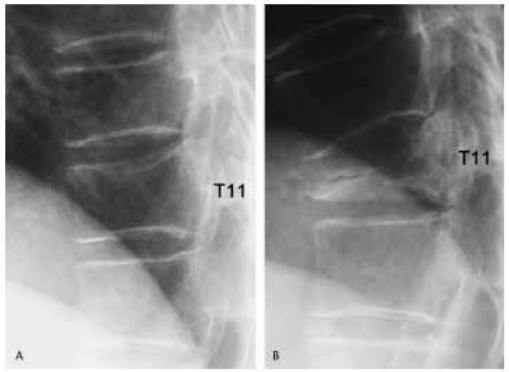
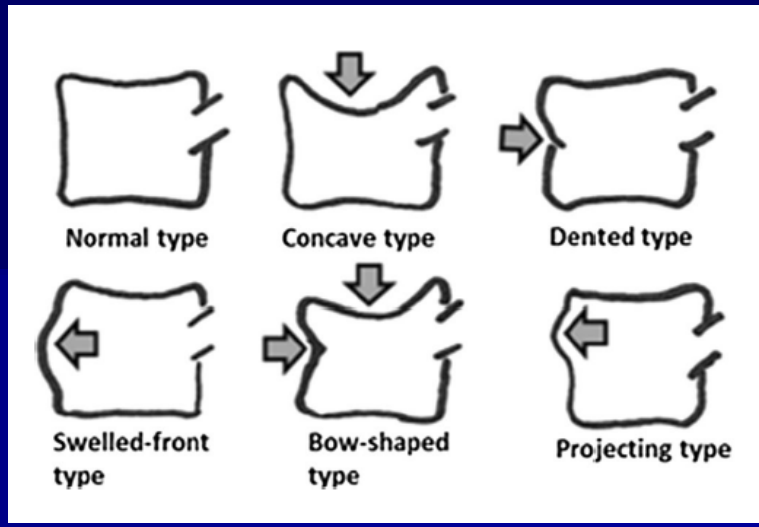


FIGURE 4. Bow-shaped-type fracture in an 80-year-old woman. A, Radiograph at injury. The endplate of the T11 body was falling in, and the anterior wall was pinched in. B, T11 body had collapsed 6 months after injury.



Vacuum cleft, which suggests nonunion, was more likely to appear in thoracolumbar fractures and in swelled-front, bow-shaped and projecting types

ORIGINAL RESEARCH

Vertebral Osteonecrosis: MR Imaging Findings and Related Changes on Adjacent Levels

- Yu et al. cohort of patients with vertebral osteonecrosis with collections of **intravertebral fluid, air or both**
- The purpose of this study was to investigate MR images of osteonecrotic vertebral bodies and adjacent intervertebral disks and vertebral bodies
- The authors found that loss of more than 50% of vertebral height was more frequent in patients with intravertebral air only or mixed with fluid, rather than those with intravertebral fluid only

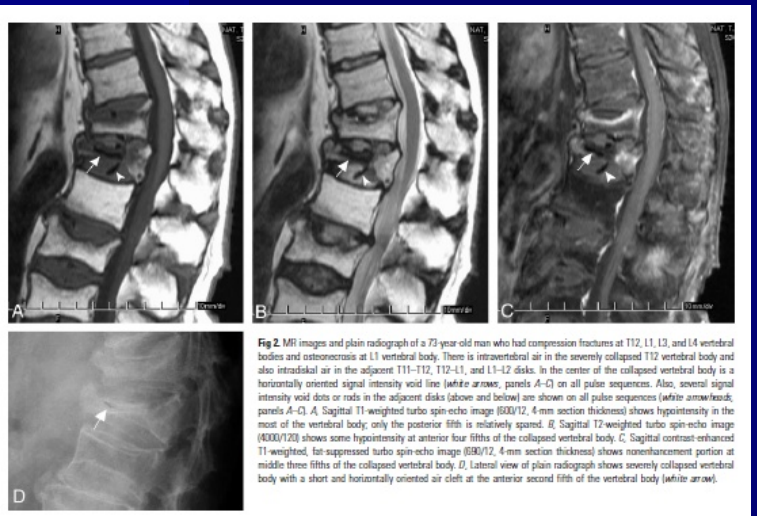


Fig 2. MR images and plain radiograph of a 73-year-old man who had compression fractures at T12, L1, L3, and L4 vertebral bodies and osteonecrosis at L1 vertebral body. There is intravertebral air in the severely collapsed T12 vertebral body and also intradiskal air in the adjacent T11–T12, T12–L1, and L1–L2 disks. In the center of the collapsed vertebral body is a horizontally oriented signal intensity void line (*white arrows*, panels *A–C*) on all pulse sequences. Also, several signal intensity void dots or rods in the adjacent disks (above and below) are shown on all pulse sequences (*white arrowheads*; panels *A–C*). *A*, Sagittal T1-weighted turbo spin-echo image (600/12, 4-mm section thickness) shows hypointensity in the most of the vertebral body; only the posterior fifth is relatively spared. *B*, Sagittal T2-weighted turbo spin-echo image (4000/120) shows some hypointensity at anterior four fifths of the collapsed vertebral body. *C*, Sagittal contrast-enhanced T1-weighted, fat-suppressed turbo spin-echo image (690/12, 4-mm section thickness) shows nonenhancement portion at middle three fifths of the collapsed vertebral body. *D*, Lateral view of plain radiograph shows severely collapsed vertebral body with a short and horizontally oriented air cleft at the anterior second fifth of the vertebral body (*white arrow*).

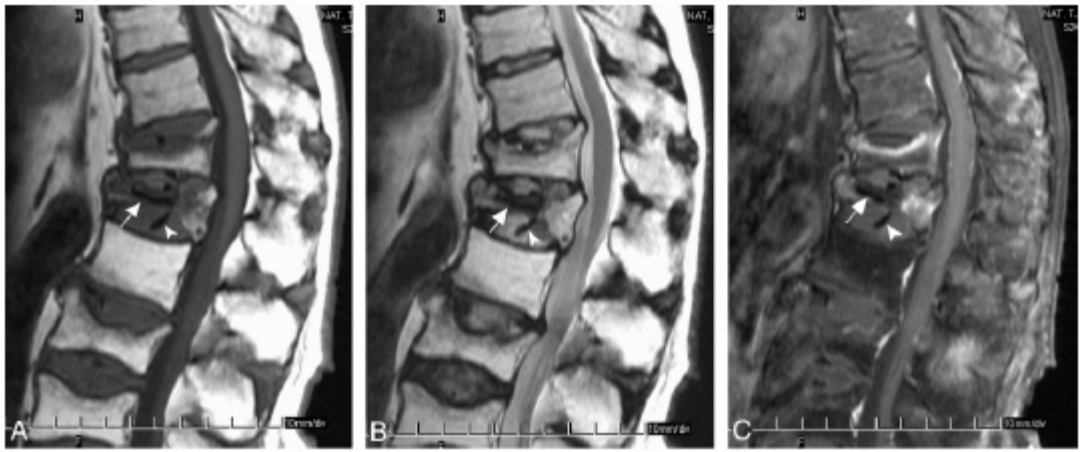


Fig 2. MR images and plain radiograph of a 73-year-old man who had compression fractures at T12, L1, L3, and L4 vertebral bodies and osteonecrosis at L1 vertebral body. There is intravertebral air in the severely collapsed T12 vertebral body and also intradiskal air in the adjacent T11–T12, T12–L1, and L1–L2 disks. In the center of the collapsed vertebral body is a horizontally oriented signal intensity void line (*white arrows*, panels *A–C*) on all pulse sequences. Also, several signal intensity void dots or rods in the adjacent disks (above and below) are shown on all pulse sequences (*white arrowheads*, panels *A–C*). *A*, Sagittal T1-weighted turbo spin-echo image (600/12, 4-mm section thickness) shows hypointensity in the most of the vertebral body; only the posterior fifth is relatively spared. *B*, Sagittal T2-weighted turbo spin-echo image (4000/120) shows some hypointensity at anterior four fifths of the collapsed vertebral body. *C*, Sagittal contrast-enhanced T1-weighted, fat-suppressed turbo spin-echo image (690/12, 4-mm section thickness) shows nonenhancement portion at middle three fifths of the collapsed vertebral body. *D*, Lateral view of plain radiograph shows severely collapsed vertebral body with a short and horizontally oriented air cleft at the anterior second fifth of the vertebral body (*white arrow*).

Fig 3. MR images and plain radiograph of an 82-year-old woman who had compression fractures and osteonecrosis at the L3 vertebral body. There is only intravertebral fluid in the mildly collapsed vertebral body. *A*, Sagittal T1-weighted turbo spin-echo image (600/12, 4-mm section thickness) shows complete bone marrow replacement by low signal intensity (*arrow*). *B*, Sagittal T2-weighted turbo spin-echo image (4000/128) shows homogeneous hyperintensity at the anterior superior portion of the vertebral body (*arrow*). The margin of the hyperintense area is well demarcated. *C*, Sagittal contrast-enhanced T1-weighted fat-suppressed turbo spin-echo image (700/12, 4-mm section thickness) shows nonenhancement of the anterior and superior portions of the vertebral body (*arrow*). The nonenhancing area corresponds to the hyperintense area of the T2WI in panel *B*. The remaining portion of this vertebral body had faint enhancement. *D*, Lateral view of plain radiograph shows faint radiolucent area at anterior superior portion of the vertebral body (*arrow*). The radiolucent area corresponds to the T2 hyperintnese area in the panel *B*.

Fig 4. *A–D*, MR images of an 83-year-old man who was diagnosed with osteonecrosis at the L1 vertebral body. There coexists both intravertebral fluid and air in the affected vertebral body. *A*, Sagittal T2-weighted turbo spin-echo image (4,000/110) shows hyperintensity at middle third (*arrowhead*) and signal intensity void at anterior third (*arrow*) of the vertebral body. *B*, Sagittal contrast-enhanced T1-weighted, fat-suppressed turbo spin-echo image (560/12, 4-mm section thickness) shows nonenhancement of the anterior two thirds of the vertebral body (*arrow* and *arrowhead*). Only the posterior one third of vertebra had enhancement. *C*, Transverse T2-weighted turbo spin-echo image (4000/110) shows an ellipsoidal signal intensity void area (*arrow*) anterior to the hyperintensity within the vertebral body. The interface between these 2 components revealed an air–fluid level (*small black arrowheads*). *D*, Sagittal T2-weighted turbo spin-echo MR image of another 76-year-old man who was diagnosed with osteonecrosis at T12 vertebral body. There coexists both intravertebral fluid (most, *arrowhead*) and air (minority, *arrow*) in the affected vertebral body.

collapsed lower adjacent vertebrae. Collapses were more frequent in patients with only intravertebral air than in those with only intravertebral fluid (air only versus fluid only, 25.0% vs 8.5%, $P < .05$). Collapse was more common when intravertebral air was present (air only and fluid with air versus fluid only, 12.3% vs 25.0%; $P < .05$) than when intravertebral fluid was present (fluid only and fluid with air versus air only, 23.0% vs 8.5%; $P < .05$). Collapses in vertebrae next to the adjacent upper and lower vertebrae did not differ significantly in groups (data not shown).

- Kanchiku et al. MRI bone marrow blood perfusion in fractured vertebrae
- The progression of vertebral collapse was calculated by subtracting the collapse on initial examination from the follow-up examination
- statistically significant association between the percentage of MR non-contrast area and the degree of vertebral collapse progression
- fractures with posterior wall involved showed higher noncontrast area percentage and vertebral collapse progression

Eur Spine J (2014) 23:2705–2710
DOI 10.1007/s00586-014-3490-9

ORIGINAL ARTICLE

Can MRI predict subsequent pseudarthrosis resulting from osteoporotic thoracolumbar vertebral fractures?

Hirotsugu Omi · Toru Yokoyama · Atsushi Ono · Takuya Numasawa · Kanichiro Wada · Yoichi Fujisawa

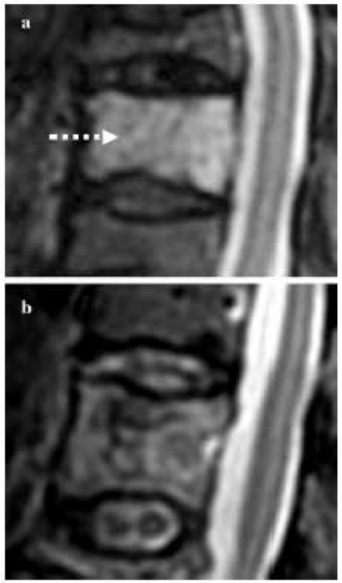


Fig. 1 Typical STIR image of **a** homogenous high signal change (*dashed white arrow*) and **b** non-homogenous high signal change

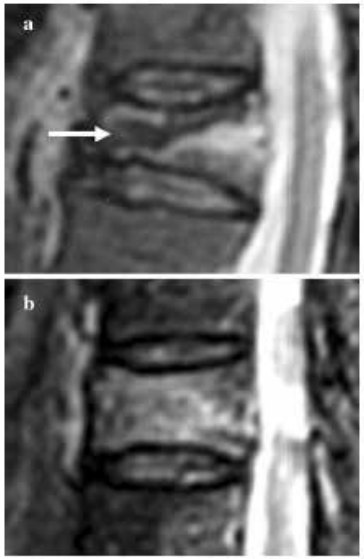


Fig. 2 Typical STIR image of **a** linear *black signal area* (*white arrow*) and **b** non-linear *black signal area*

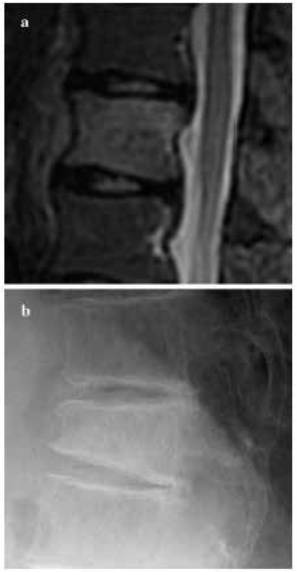


Fig. 4 **a** A Th11 fresh compression fracture showing the homogenous high signal change on STIR in a 78-year-old woman. **b** Bone union of Th11 was achieved by the 6-month follow-up examination

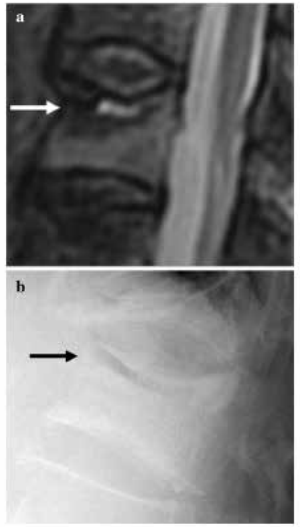


Fig. 5 **a** An L1 fresh compression fracture showing the linear *black signal area* on STIR in an 82-year-old woman. **b** Non-union of L1, which showed a cleft at the 6-month follow-up examination

Table 2 Kyphosis progression rate in each group

- STIR in MRI to predict the progression of vertebral collapse in osteoporotic vertebral fractures
- **Linear black signal area** is considered to be compressed cancellous bone that results from more extensive trabecular damage; it causes prolonged instability, which prevents new bone formation and results in early osteonecrosis

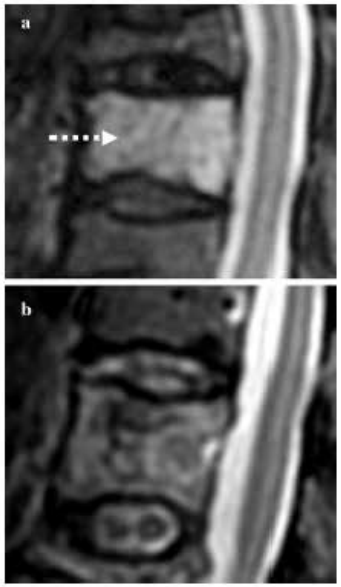


Fig. 1 Typical STIR image of **a** homogenous high signal chang (*dashed white arrow*) and **b** non-homogenous high signal change

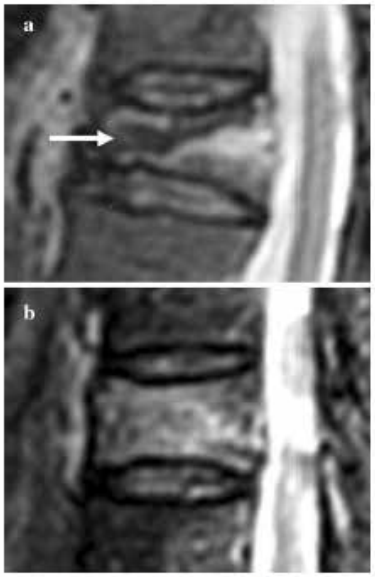


Fig. 2 Typical STIR image of **a** linear *black signal area* (*white arrow*) and **b** non-linear *black signal area*

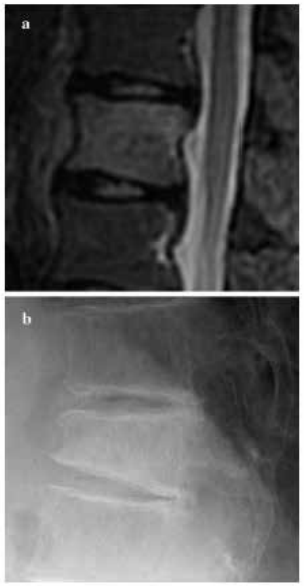


Fig. 4 **a** A Th11 fresh compression fracture showing the homogenous high signal change on STIR in a 78-year-old woman. **b** Bone union of Th11 was achieved by the 6-month follow-up examination

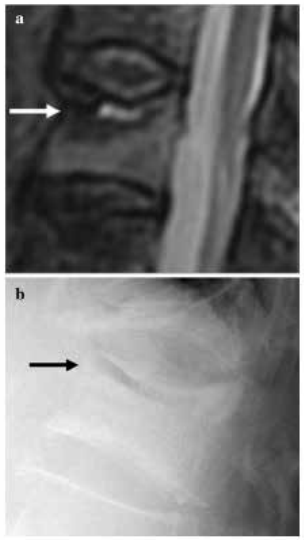


Fig. 5 **a** An L1 fresh compression fracture showing the linear *black signal area* on STIR in an 82-year-old woman. **b** Non-union of L1, which showed a cleft at the 6-month follow-up examination

Table 2 Kyphosis progression rate in each group

•They found a significant difference in affected vertebrae with linear black signal area—which was a linear black signal occupying more than half the length of the vertebral body—that showed higher vertebral collapse progression, when compared to those with nonlinear black signal area.

•Non-homogenous high signal change was a strong risk factor for nonunion, compared to homogenous high signal change obtained by STIR in MRI

In contrast, 24 OVFs with linear black signal area and 39 vertebrae with non-linear black signal area resulted in 10 (42 %) and 4 non-unions (10 %), respectively; a significant difference ($p = 0.005$, Fisher's exact test). The sensitivity and specificity of non-union by linear black signal area were 42 % (10 non-unions/24 linear black signal areas) and 90 % (35 bone union/39 non-linear black signal change), respectively (Table 1). Representative cases are shown in Figs. 4 and 5.

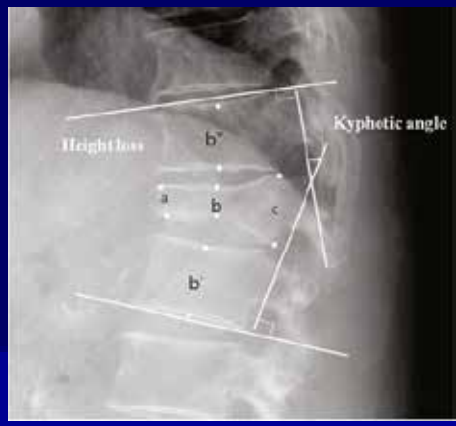
The mean kyphosis progression rates of the linear black signal area and non-linear black signal area groups were 35 ± 22 % and 23 ± 22 %, respectively; a significant difference ($p = 0.003$, t test) (Table 2).

Osteoporos Int (2013) 24:1207–1213
DOI 10.1007/s00198-012-2065-z

ORIGINAL ARTICLE

Risk factors affecting progressive collapse of acute osteoporotic spinal fractures

K. Y. Ha · Y. H. Kim



Ha and Kim proposed three criteria to define progressive vertebral collapse, which were **height loss > 15%, kyphotic angle > 10°, and presence of intravertebral cleft sign** during the follow-up

Thoracolumbar fracture, mid-column damage and posterior wall damage were important risk factors for progressive collapse.

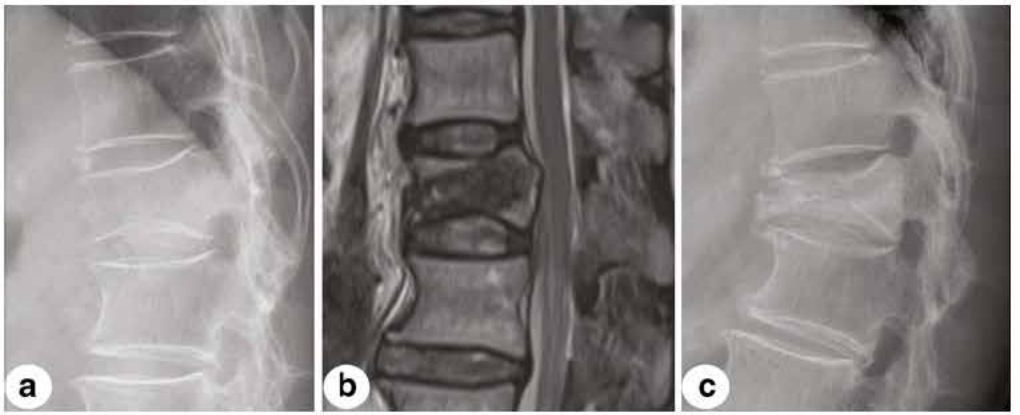
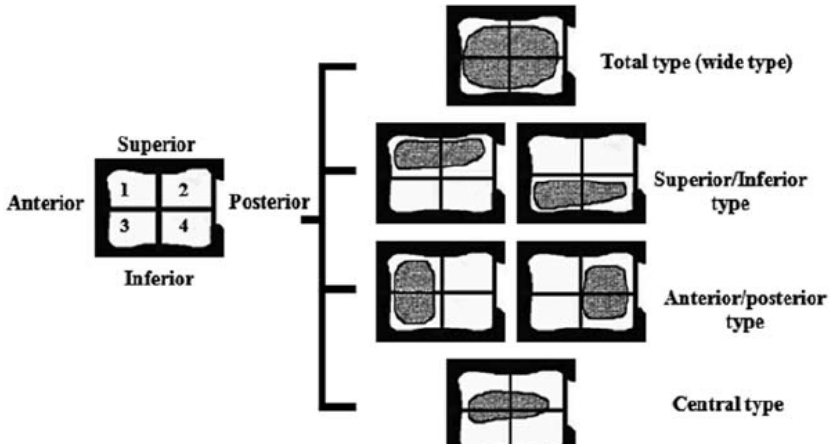


Fig. 4 Mid-portion type fracture in a 68-year-old woman. **a** Cortical disruption was noted at the mid-portion of the vertebral body (classified as dented type in Sugita's classification). **b** Diffuse signal change was noted around the mid-portion. **c** Increase in ≥15 % collapse of height and 10° kyphotic angle was noted on the post-injury 7-month radiograph

Usefulness of an Early MRI-based Classification System for Predicting Vertebral Collapse and Pseudoarthrosis After Osteoporotic Vertebral Fractures

Tsukasa Kanchiku, PhD, MD, Yasuaki Imajo, PhD, MD, Hidenori Suzuki, PhD, MD, Yuichiro Yoshida, MD, and Toshihiko Taguchi, PhD, MD



According to their findings, the frequency of vertebral collapse was greater for hypointense wide-type fractures than for hyperintense wide-type

On applying the T2WI classification to T1WI total-type fractures, which showed poor radiologic prognosis, they found that it was possible to narrow down types that had a higher chance of pseudoarthrosis conversion

TABLE 1. Vertebral Collapse and Pseudoarthrosis Onset Rates for Different Fracture Types According to the T1WI Classification

	Total Type	Superior Type	Inferior Type	Anterior Type	Central Type
No. vertebrae (%)	74 (57)	36 (28)	7 (5.5)	7 (5.5)	5 (4)
Vertebral collapse rate (%)	45 ± 21*	30 ± 15	30 ± 5	30 ± 10	37 ± 10
Pseudoarthrosis conversion rate (%)	20** (18.3)	0 (0)	0 (0)	0 (0)	0 (0)

In the T1WI classification, the total type accounts for approximately 60% of the total number of types. The vertebral collapse rate was significantly higher in the total type, and all cases that developed pseudoarthrosis were total-type fractures.
T1WI classification indicates T1-weighted image-based classification.
*$P < 0.01$ (Mann-Whitney).
**$P < 0.01$ (the Fisher test).

TABLE 2. Vertebral Collapse and Pseudoarthrosis Onset Rates for Different Facture Types According to the T2WI Classification

	Hyperintense Wide Type	Hyperintense Limited Type	Hypointense Wide Type	Hypointense Limited Type
No. vertebrae (%)	69 (53)	20 (16)	16 (12)	24 (19)
Vertebral collapse rate (%)	31 ± 12*	44 ± 27	63 ± 14**	44 ± 15
Pseudoarthrosis conversion rate (%)	0 (0)	6 (5.5)	7*** (10.1)	3 (2.7)

In the T2WI classification, the hyperintense wide-type was most common, accounting for approximately 50% of the total number of types, with a significantly lower vertebral collapse rate than others. The hypointense wide-type had significantly higher vertebral collapse and pseudoarthrosis onset rates than others.
T1WI classification indicates T1-weighted image-based classification, T2W1, T2-weighted image-based classification.
*$P < 0.01$ (Mann-Whitney).
**$P < 0.01$ (Mann-Whitney).
***$P < 0.01$ (the Fisher test).

Kyphotic deformity

Eur Spine J (2014) 23:2737–2742
DOI 10.1007/s00586-014-3457-x

ORIGINAL ARTICLE

Predictors of kyphotic deformity in osteoporotic vertebral compression fractures: a radiological study

Sanganagouda Patil · Abhay M. Nene

The radiological predictors for development of significant segmental kyphotic deformity that we analyzed included:

1. Location of the fracture
2. Endplate fracture (Fig. 1)
3. Anterior cortical wall fracture (Fig. 2)
4. Adjacent level fractures (Fig. 3)

Of the 64, 33 patients out of 40 (82.5 %) with fracture at TL junction 5 patients out of 15 (33.3 %) with fracture at L spine and 7 patients out of 9 (77.7 %) with fracture at T spine developed significant segmental kyphotic deformity at final follow-up.

Forty-one (75.9 %) of 54 patients with superior endplate fractures developed significant segmental kyphotic deformity at final follow-up. These included 33 (80.5 %) of 37 patients with fracture at TL junction, 4 (33.33 %) of 12 patients with fracture at lumbar spine and 4 (80 %) of 5 patients with fracture at thoracic spine. None of the three patients with inferior endplate fracture had significant segmental kyphotic deformity at final follow-up.

Forty of 46 (71.87 %) patients with fracture in the anterior cortical wall of the vertebra developed significant segmental kyphotic deformity. These included 28 (70 %) of 32 patients with fracture at TL junction, 6 (15 %) of 8 patients with fracture at lumbar spine and all patients with fracture at thoracic spine.

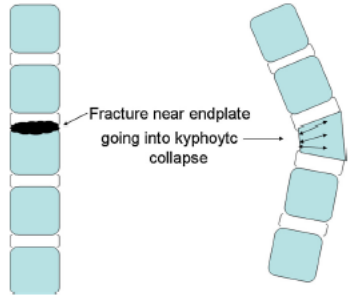


Fig. 1 Osteoporotic vertebral superior endplate fracture leading to segmental kyphotic collapse

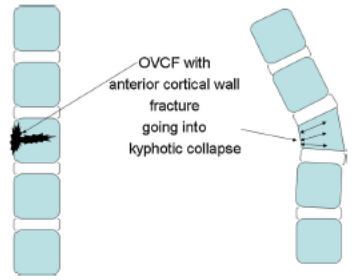


Fig. 2 OVCF with fracture of the anterior cortical wall leading to segmental kyphotic collapse

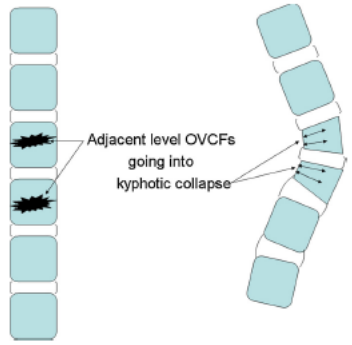


Fig. 3 More than one adjacent level OVCF and subsequent segmental collapse leading to kyphotic deformity

Structure of the Presentation

- Basic Knowledge…*30 year story*
- Trends of the Literature and News Feed…*5 year story*
- Robust Reviews + Meta-Analysis…*focus on 2018/2019*
- Conclusion…Critique…Take Home Message

Osteoporos Int (2015) 26:1239–1249
DOI 10.1007/s00198-014-2953-5

REVIEW

Health economic aspects of vertebral augmentation procedures

Conclusions

The number of published cost-effectiveness studies is limited and their scope restricted. Although associated with a fair bit of uncertainty, the available analyses indicate that VAPs are cost effective compared to NSM, especially when accounting for a mortality benefit. For further health economic research in this area, it is not primarily new assessments of cost effectiveness that are needed, but rather studies that can reduce the uncertainty in the underlying data.

Percutaneous vertebroplasty and percutaneous balloon kyphoplasty for the treatment of osteoporotic vertebral fractures: a systematic review and cost-effectiveness analysis

Matt Stevenson, Tim Gomersall, Myfanwy Lloyd Jones, Andrew Rawdin, Monica Hernández, Sofia Dias, David Wilson and Angie Rees

NHS
National Institute for Health Research

- *For people with painful osteoporotic VCFs refractory to analgesic treatment, PVP and BKP perform significantly better in unblinded trials than OPM in terms of improving quality of life and reducing pain and disability. However, there is as yet no convincing evidence that either procedure performs better than OPLA. The uncertainty in the evidence base means that no definitive conclusion on the cost-effectiveness of PVP or BKP can be provided.*

RESEARCH ARTICLE

A Systematic Review of the Level of Evidence in Economic Evaluations of Medical Devices: The Example of Vertebroplasty and Kyphoplasty

ORIGINAL ARTICLE

Journal of Bone and Mineral Research, Vol. 34, No. 1, January 2019, pp 3–21

JBMR®

The Efficacy and Safety of Vertebral Augmentation: A Second ASBMR Task Force Report

VS

Osteoporosis International
https://doi.org/10.1007/s00198-018-4804-2

ORIGINAL ARTICLE

CrossMark

Which is the best treatment of osteoporotic vertebral compression fractures: balloon kyphoplasty, percutaneous vertebroplasty, or non-surgical treatment? A Bayesian network meta-analysis

Key question addressed	Task Force recommendation/finding	Quality of evidence	Strength of findings	Strength of recommendation
1. Efficacy of percutaneous vertebroplasty on outcomes of pain, physical function, and quality of life	Percutaneous vertebroplasty provides no demonstrable clinically significant benefit over placebo or sham procedure. Results did not differ according to duration of pain.	High to moderate	High—5 randomized trials that compared vertebroplasty with placebo ($n = 535$). Follow-up period 2 years.	High to moderate
2. Efficacy of balloon kyphoplasty on outcomes of pain, physical function, and quality of life	Balloon kyphoplasty provides a small clinical benefit over nonsurgical management, percutaneous vertebroplasty, vertebral body stenting, or KIVA. There is also insufficient evidence versus placebo for KIVA.	Low	Low—1 randomized trial versus nonsurgical management. No placebo ($n = 300$). Follow-up period 2 years.	Weak
3. Harms of percutaneous vertebroplasty, including possible risk of new vertebral fractures	It is uncertain whether percutaneous vertebroplasty increases risk of incident or radiographic vertebral fractures or related serious AEs.	Moderate	Moderate—8 randomized trials (placebo control in 4 trials and usual care in 4 trials) ($n = 804$). Low number of events ($n = 203$ fractures; 57 SAEs). Follow up period 1–2 years.	Moderate
4. Harms of balloon kyphoplasty, including possible risk of new vertebral fractures	It is uncertain whether kyphoplasty increases risk of incident or radiographic vertebral fractures or serious AE related to kyphoplasty.	Low	Low—1 randomized trial versus nonsurgical management ($n = 223$) and case reports. Low number of events ($n = 101$ fractures; 157 SAEs). Follow-up period 2 years.	Weak
5. Efficacy and harms of spinal bracing after vertebral fracture	Spinal bracing may improve pain, spinal strength, kyphosis, pulmonary volume and quality of life at 6 months. Bracing may improve physical function, disability, or quality of life.	Low	Low—4 randomized trials comparing orthoses ($n = 281$). High risk of bias due to absent blinding of subjects and investigators. Low numbers of fractures and AEs. Follow-up period 3 weeks to 6 months.	Weak
6. Efficacy and harms of exercise interventions after vertebral fracture	Exercise may improve mobility and reduce pain and fear of falling. It is uncertain whether exercise improves balance, back extensor strength, reduces falls, and was safe.	Moderate	Moderate—9 randomized trials comparing exercise with usual care ($n = 749$). Low to high risk of bias due to absent blinding of subjects and investigators. Low numbers of events ($n = 15$ fractures; 5 SAEs). Follow-up period 4 weeks to 2 years.	Moderate

Key question addressed	Task Force recommendation/finding	Quality of evidence	Strength of findings	Strength of recommendation
1. Efficacy of percutaneous vertebroplasty on outcomes of pain, physical function, and quality of life	Percutaneous vertebroplasty provides no demonstrable clinically significant benefit over placebo or sham procedure. Results did not differ according to duration of pain.	High to moderate	High—5 randomized trials that compared vertebroplasty with placebo ($n = 535$). Follow-up period 2 years.	High to moderate
2. Efficacy of balloon kyphoplasty on outcomes of pain, physical function, and quality of life	Balloon kyphoplasty provides a small clinical benefit over nonsurgical management, percutaneous vertebroplasty, vertebral body stenting, or KIVA. There is also insufficient evidence versus placebo for KIVA.	Low	Low—1 randomized trial versus nonsurgical management. No placebo ($n = 300$). Follow-up period 2 years.	Weak
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5. Efficacy and harms of spinal bracing after vertebral fracture	Spinal bracing may improve pain, spinal strength, kyphosis, pulmonary volume and quality of life at 6 months. Bracing may improve physical function, disability, or quality of life.			
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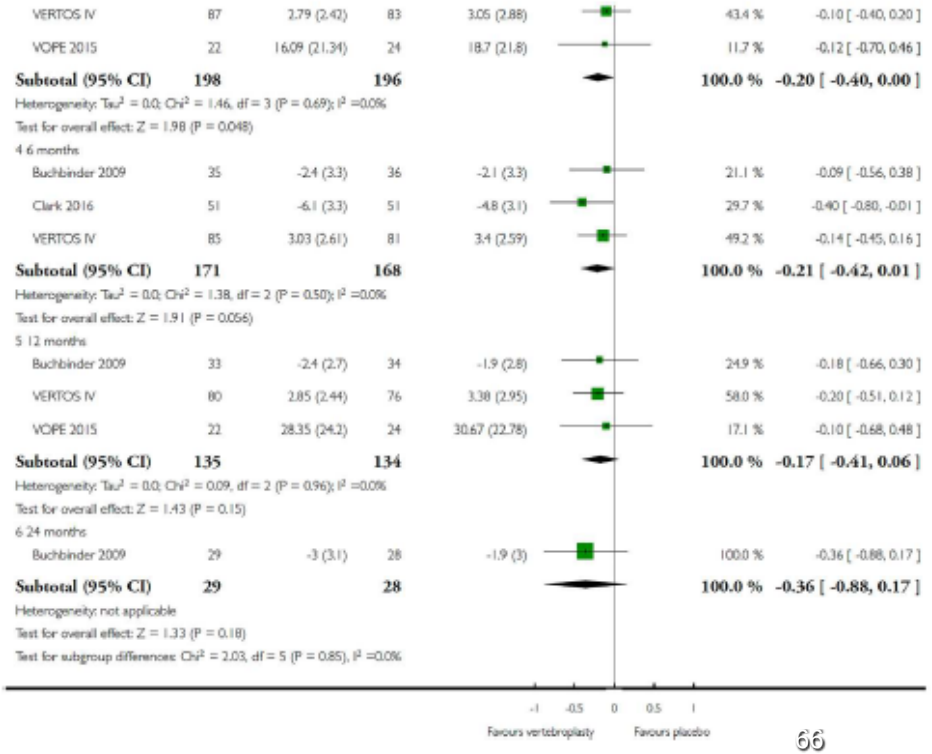

Fig. 3. Forest plot of the efficacy outcome: vertebroplasty versus placebo (sham), pain (0 to 10 point scale)[5].

a) Percutaneous vertebroplasty versus placebo

Efficacy findings are as follows:

Pain: At 1 month, there was a small and clinically unimportant difference in pain favoring the vertebroplasty group (mean difference [MD] −0.62 (95% CI −10.1 to −0.23) on a scale of 0 to 10, no statistical heterogeneity) (five trials, 535 participants). Mean pain was five points in the placebo group and 0.6 points better (0.2 to 1 better) in the vertebroplasty group. There were also no between-group differences in the proportion of participants who improved from baseline by 2.5 units or more or by 30% or more at 1 month based upon pooled data from 3 trials (89/166 in the percutaneous vertebroplasty group versus 56/160 in the placebo group, risk ratio [RR] 1.53 [95% CI 0.99 to 2.36]), but there was substantial statistical heterogeneity ($I^2 = 61\%$). Based upon data from up to five trials (539 participants), no between-group differences in mean pain or proportion who improved from baseline according to the above parameters were observed at 1 to 2 weeks or other endpoints up to 2 years (Fig. 3).

b) Percutaneous vertebroplasty versus standard medical (nonsurgical) care

Pain: Based upon data from up to six trials, the analysis favored the percutaneous vertebroplasty group, who had greater improvement in mean pain compared with the usual care group at 1 month (three trials, 384 participants, mean difference −3.30 (95% CI −5.36 to −1.22). Similar results were observed at 1 to 2 weeks and at other time points up to 1 year, but there was considerable statistical heterogeneity across all pooled pain analyses with the I^2 varying between 94% and 96%. At 24 months, there was no between-group difference in mean pain based upon one trial.

a) Balloon kyphoplasty versus nonsurgical management

Pain: Kyphoplasty was associated with significantly more reduction in pain than nonsurgical management at all time points, though the relative difference between groups in improvement in VAS appeared to diminish over time: mean difference at 1 month = −1.82 [−2.37, −1.27; $n = 264$]; at 3 months = −1.45 [−2.01, −0.89; $n = 246$]; at 6 months = −1.48 [−2.05, −0.91; $n = 241$]; at 12 months = −0.84 [−1.42, −0.26; $n = 226$]; and at 24 months = −0.69 [−1.27, −0.11; $n = 200$].

a) Percutaneous vertebroplasty versus placebo

Efficacy findings are as follows:

Pain: At 1 month, there was a small and clinically unimportant difference in pain favoring the vertebroplasty group (mean difference [MD] −0.62 (95% CI −10.1 to −0.23) on a scale of 0 to 10, no statistical heterogeneity) (five trials, 535 participants). Mean pain was five points in the placebo group and 0.6 points better (0.2 to 1 better) in the vertebroplasty group. There were

b) Percutaneous vertebroplasty versus standard medical (nonsurgical) care

Pain: Based upon data from up to six trials, the analysis favored the percutaneous vertebroplasty group, who had greater improvement in mean pain compared with the usual care group at 1 month (three trials, 384 participants, mean difference

decrease over time, and, based on available data, it was not possible to determine whether these between-group differences were dinically meaningful or the extent to which they were accounted for by sham effects or study bias.

improvement in VAS appeared to diminish over time: mean difference at 1 month = −1.82 [−2.37, −1.27; $n = 264$]; at 3 months = −1.45 [−2.01, −0.89; $n = 246$]; at 6 months = −1.48 [−2.05, −0.91; $n = 241$]; at 12 months = −0.84 [−1.42, −0.26; $n = 226$]; and at 24 months = −0.69 [−1.27, −0.11; $n = 200$].

General recommendations for all future studies

- Future trials should identify other novel and potentially useful interventions for pain after vertebral fracture.
- Future trials should ensure adequate sample sizes to answer the research question.
- Future trials should have inclusion criteria that allow generalizable conclusions to be drawn.
- Include cost-effectiveness outcomes.
- Include anti-osteoporosis therapy as part of interventions.
- Patient registries may be helpful for widespread systematic data collection for safety after vertebral augmentation.
- More trials are needed exploring exercise or rehabilitation interventions in the acute/subacute stage after vertebral fracture.
- De-implementation of vertebroplasty to reduce any potential harms of the procedure should be considered by translating evidence into changes in practice and policy.
- All future studies should consider including outcomes important to people with osteoporotic spine fracture(s), health care providers, or health systems, such as quality of life, pain, falls, fractures, and disability.
- Future trials should include men.
- Future studies should consider the relative benefit of short-term versus long-term improvements. If short-term improvements are substantial, this might be sufficient to warrant the treatment even if long-term outcomes are similar. Impact of the intervention on disability also should be considered over the short term and long term.
- Registries should be established to systematically collect safety data on patients treated with vertebral augmentation.
- More trials are needed exploring exercise or rehabilitation interventions in the acute/subacute stage after vertebral fracture.

Percutaneous vertebroplasty

- No further trials of vertebroplasty should be performed, unless they are adequately powered to alter the conclusions of the current body of evidence that concludes that the procedure is no more effective than placebo and the benefits are unlikely to outweigh any harms of the procedure.
- Potential participants in any further trials of these procedures should be fully informed about the current body of evidence.
- Ethics committees should also be fully informed about the current body of evidence to inform their decision about the ethics of any further trials.
- All future trials should include strategies designed to minimize the potential for bias, including adequate allocation concealment, use of a realistic placebo intervention, and blinding of both participants and investigators to the intervention.
- Future trials should carefully characterize the timing and severity of vertebral fracture among study participants.

Balloon kyphoplasty

- Any further trials of kyphoplasty should have a placebo control group.
- Further studies are needed to resolve whether kyphoplasty increases the risk of future vertebral fractures or serious AE, which should be systematically collected.
- All future trials should include strategies designed to minimize the potential for bias, including adequate allocation concealment, use of a realistic placebo intervention, and blinding of both participants and investigators to the intervention.
- Future trials should carefully characterize the timing and severity of vertebral fracture among study participants.

Osteoporosis International
https://doi.org/10.1007/s00198-018-4804-2

ORIGINAL ARTICLE

Which is the best treatment of osteoporotic vertebral compression fractures: balloon kyphoplasty, percutaneous vertebroplasty, or non-surgical treatment? A Bayesian network meta-analysis

Statistical heterogeneity was evaluated based on the magnitude of the heterogeneity parameter (I^2 or τ^2) estimated from the network meta-analysis models [24]. The heterogeneity was investigated by fitting covariates (i.e., mean age, female ratio, sample size, the duration of symptoms and the duration of follow-up) in the network meta-regression [25]. Subgroup meta-analyses were further performed based on the duration of symptoms (acute (≤ 6 weeks), subacute (6–12 weeks), or long-standing (> 12 weeks)) and the duration of follow-up (short-term (< 1 year) or long-term (≥ 1 year)), if possible.

Osteoporosis International
https://doi.org/10.1007/s00198-018-4804-2

ORIGINAL ARTICLE

Which is the best treatment of osteoporotic vertebral compression fractures: balloon kyphoplasty, percutaneous vertebroplasty, or non-surgical treatment? A Bayesian network meta-analysis

Pain

With respect to the efficacy endpoint (Fig. 3), the use of PVP was the most effective treatment for pain on the VAS [27–30, 32–41], while use of NST presented the highest mean difference in pain. PVP emerged as the best intervention in treatment ranking (probability of 88.75%), followed by BK or PVP (Fig. 4), but the extent of pain reduction compared with BK was minor (MD = − 0.51, 95% CrI − 1.4 to 0.35)

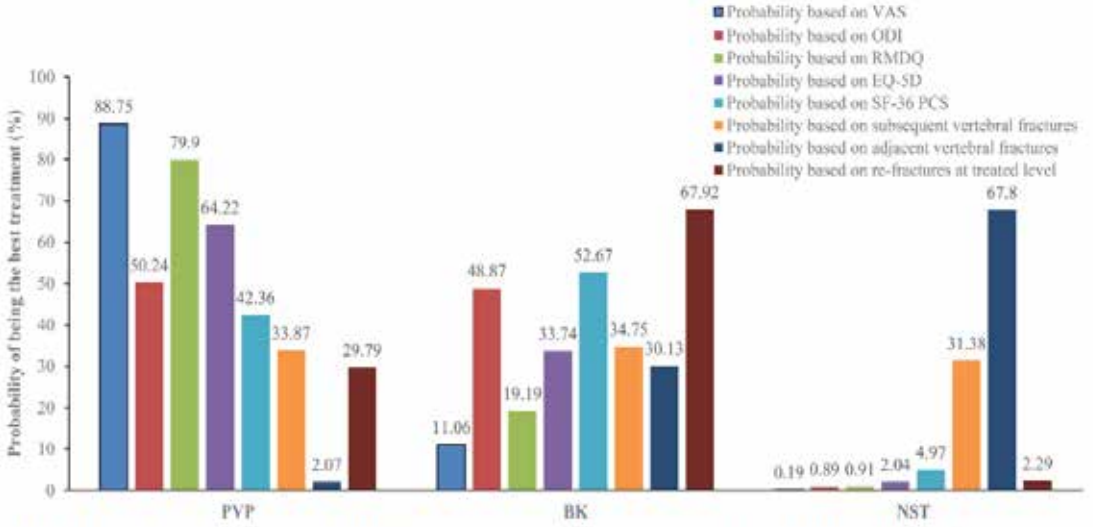

Fig. 4 Probability that each treatment is the most efficacious in the study network. BK, balloon kyphoplasty; PVP, percutaneous vertebroplasty; NST, non-surgical treatment; VAS, visual analogue scale; ODI, Oswestry Disability Index; RMDQ, Roland–Morris Disability Questionnaire; EQ-5D, European Quality of Life-5 Dimensions; SF-36 PCS, Physical Component Summary subscales of the Medical Outcomes Study 36-Item Short-Form General Health Survey

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ORIGINAL ARTICLE

Which is the best treatment of osteoporotic vertebral compression fractures: balloon kyphoplasty, percutaneous vertebroplasty, or non-surgical treatment? A Bayesian network meta-analysis

Conclusion

In conclusion, our network meta-analysis indicated that for pain and functional status, PVP was significantly better than NST, while the three treatments did not significantly differ in other outcomes. PVP was the most effective strategy in improving the pain, functional status, and quality of life (based on EQ-5D). BK emerged as the best intervention for improving the quality of life (based on SF-36 PCS) and for decreasing the risk of subsequent vertebral fractures and re-fractures at the treated level. NST could be ranked first in reducing adjacent vertebral fractures. The future direction of treatment of OVCFs will depend on the outcomes of additional and larger randomized trials that compare BK with PVP.

Structure of the Presentation

- Basic Knowledge…*30 year story*
- Trends of the Literature and News Feed…*5 year story*
- Meta-Analysis…*focus on 2018/2019*
- Conclusion…Critique…Take Home Message

Critique

RCTs

- VERTOS 2007 à Vert vs Medical Management…<50 year old, invalidating pain, subacute and chronic fx (6-24 weeks), 34 pts, 88% of MM pts crossed over, no f/u was possible
- FREE 2009 à Kypho vs MM, moderate pain 4/10, 300 pts, 21 year old and older, acute and subacute (> 3 mo). Improvement durable to 6 months. Pts gained 60 days unrestricted. Lack of blinding. Durable NRS scores – no difference in SF36
- Rousing 2009 à Vert vs MM, <65 year old, intractable pain, 49 pts, fx less than 8 weeks, VAS better in 24 hr – same in 3 months – shorter hospital stay
- INVEST 2009 (NEJM) à Vert vs Sham procedure (periosteum), 131 pts, 50 year old, moderate to severe back pain (>3/10), fx age <1 year. No differences in NRS at 1 month, only trend in Vert Group, by 3 months 43% cross over to Vert, No MRI requirement – only xray, only 131 pts during 4 years in 11 centers – very slow recruitment
- Buchbinder 2009 (NEJM) à Vert vs Sham. 78 pts, fx age 1 year, yes to MRI, 78 pts in 4 years at 4 centers, terminated the trial early – didn't reach the estimated sample size

Critique

RCTs

- VERTOS 2 à Vert vs MM, 50 year old, VAS>5, fracture age <6 week, MRI, Significant improvement in Vert durable at 1 year. No pain 3 months faster – 120 pain free days but… lack of blinding. 60% achieved sufficient (VAS<3) pain relief by 12 months. 40% who developed chronic pain. Idea for further trials: those who have chronic pain
- Farrokhi 2011 à Vert vs MM, severe pain, fx age 4weeks-1 year, 82 pts, significant difference in VAS score. All pts were ambulatory in 24 hr vs 2% of the MM group
- Blasco à Vert vs MM, VAS>4, fracture age <1 year, 25% of MM received intrathecal anaesthesia vs 5% in the Vert group, 11% crossover rate, Lack of blinding
- VAPOUR à Vert vs Sham (subcutaneous), 60 year old pts, severe pain (7), fracture age <6 weeks, significant treatment advantage durable to 6 months, 5,5 less inhospital days in Vert, different volumes in cement but well organized
- Placebo effect…Sham Effect…periosteal vs subcutaneous injection…focus on subgroups and fracture stages…admitted to hospital older pts is another subgroup

Take home message…

Pain Relief / Disability / QoL Improvement
Are VAPs Cost-Effective? Mortality Reduction
VAPs and Kyphotic Reduction / Vertebral Height Restoration
Cement leakage
Subsequent Fractures are not related probably to the intervention…osteoporosis related
Cement Types, Characteristics, and Optimal Filling
Unipedicular versus Bipedicular Approach
Significant role in MSK Oncology

Take home message…

Patient Selection & Early Detection of Complication









UNIVERSITY OF CALGARY SPINE PROGRAM

Thank you

#Free Samos