



29th Annual Gabor Racz
Advanced Interventional
Pain Conference and Workshop
Budapest, Hungary August 24-26, 2026

Emerging Concepts of Vertebral Augmentation

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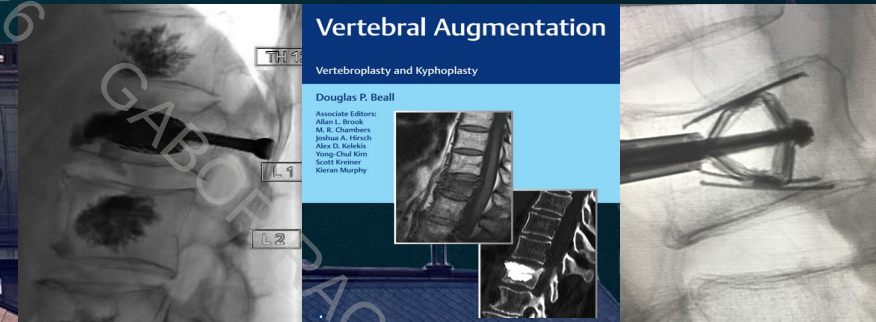
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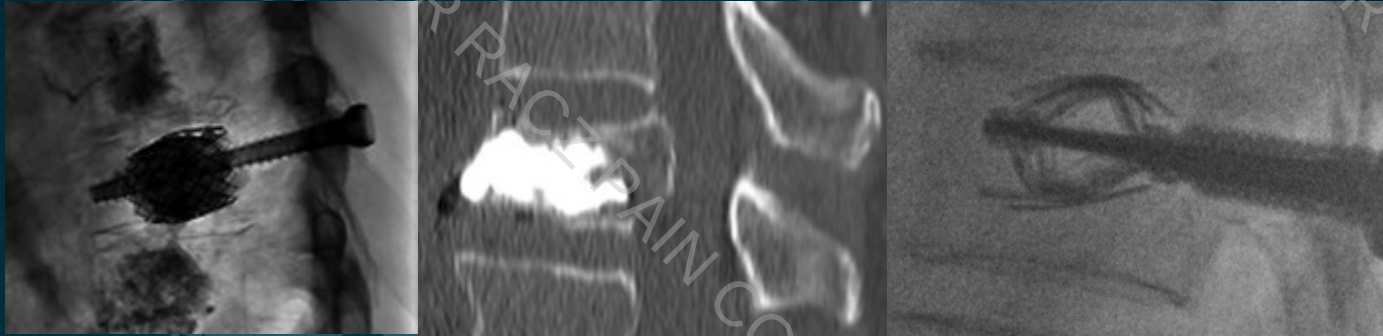
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Conflict of Interest



Type of affiliation/financial interest	Name of commercial company
Consultant/Receipt of grants/research supports:	Medtronic, Merit Medical, Johnson & Johnson, Stryker, IZI, SetBone Medical, Lenoss Medical, Amber Implants
Receipt of honoraria or consultation fees:	Medtronic, Merit Medical, Stryker, IZI, Lenoss Medical, Kahtnu Surgical, Amber Implants
Participation in company sponsored speakers bureau:	Avanos, Merit Medical, IZI, Medtronic, Stryker, Lenoss Medical

NSM vs NSM – RCTs bracing

- Bracing:

- No brace / soft brace / rigid brace for 12 weeks
→ No difference in pain reduction¹
- No brace or brace for 8 weeks for acute (<72 h) fractures → No difference in pain reduction²



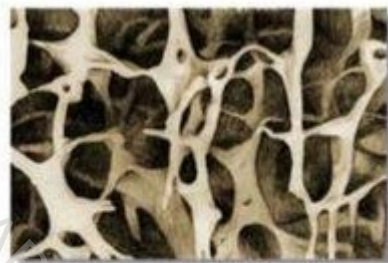
Efficacy of NSM – meta-analyses

- Non-surgical management¹:

- 5 studies
- **Low-quality evidence** on benefits of opioids, NSAIDs, or spinal orthoses
- Conclusion: **There is insufficient data to recommend the optimal conservative management for osteoporotic vertebral fractures.**



Normal Bone²



Osteoporotic Bone²

1. National Osteoporosis Foundation website. <http://norf.org/articles/235>. Accessed May 2016.
2. Dempster DW, et al. J Bone Miner Res. 1986;1:15-21.



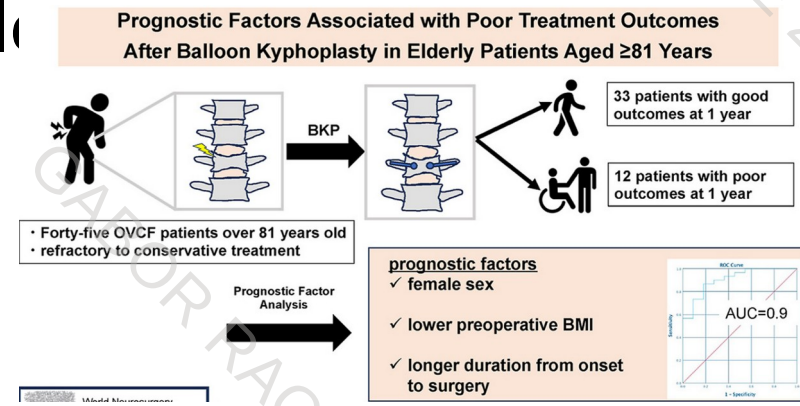
Risks of Vertebral Augmentation Comp to Risks of NSM

- Risks of NSM are significant
- Liu et. al.* (2019) eval'ed KP vs NSM
- Study Found:
 - KP sig better at improving symptoms & vertebral deformity
 - Found to have sig < complications at 1.72% comp to NSM w/ comp rate of 15.52%
- Complication Rate 9X Higher in NSM Comp to KP
- Otsuka et. al.** (2024): ↑ Poor Outcomes w/ Female Lower BMI & Delay in Tx



*Liu Q, Cao J Kong JJ. Clinical effect of balloon kyphoplasty in elderly patients with multiple osteoporotic vertebral fracture. *Niger J Clin Pract* 2019; 22:289-92.

**Otsuka R, Takahashi T, Inoue T, Saruta W, Shimauchi-Ohtaki H, Kanematsu R, Minami M, Hanakita J. Prognostic Factors Associated with Poor Treatment Outcomes After Balloon Kyphoplasty in Elderly Patients Aged ≥81 years. *World Neurosurg*. 2024 Sep;189:e38-e45. doi: 10.1016/j.wneu.2024.05.030. Epub 2024 May 14. PMID: 38750892.



Kyphoplasty vs Vertebroplasty: Meta-Analysis of Vertebral Aug vs NSM

- 27 prospective multi-arm studies* with ≥ 20

- VAS ↓: BKP 5.07, VP 4.55, NSM 2.17

- BKP sig better than VP in QOL improvement

- Hoyt et al. Level I & II studies (2020)

- BKP sig better pain reduction comp to PVP & NSM

Eur Spine J (2012) 21:1826–1843
DOI 10.1007/s00586-012-2314-z

REVIEW ARTICLE

Comparing effects of kyphoplasty, vertebroplasty, and non-surgical management in a systematic review of randomized and non-randomized controlled studies

Ioannis D. Papanastassiou · Frank M. Phillips · Jan Van Meirhaeghe · James R. Berenson · Gunnar B. J. Andersson · Gary Chung · Brent J. Small · Kamran Aghayev · Frank D. Vronis

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Abstract

Purpose To determine if differences in safety or efficacy exist between balloon kyphoplasty (BKP), vertebroplasty (VP) and non-surgical management (NSM) for the treatment of osteoporotic vertebral compression fractures (VCFs).

Methods As of February 1, 2011, a PubMed search (key words: kyphoplasty, vertebroplasty) resulted in 1,587 articles out of which 27 met basic selection criteria (prospective multiple-arm studies with cohorts of ≥ 20 patients).

This systematic review adheres to preferred reporting items for systematic reviews and meta-analyses (PRISMA) guidelines.

Results Pain reduction in both BKP ($-5.07/10$ points, $P < 0.01$) and VP ($-4.55/10$, $P < 0.01$) was superior to that for NSM ($-2.17/10$), while no difference was found between BKP/VP ($P = 0.35$). Subsequent fractures occurred more frequently in the NSM group (22 %) compared with VP (11 %, $P = 0.04$) and BKP (11 %, $P = 0.01$). BKP resulted in greater kyphosis reduction than VP (4.8° vs. 1.7° , $P < 0.01$). Quality of life (QOL) improvement showed superiority of BKP over VP ($P = 0.04$), along with a trend for disability improvement ($P = 0.08$). Cement extravasation was less frequent in the BKP ($P = 0.01$). Surgical intervention within the first 7 weeks yielded greater pain reduction than VCFs treated later.

Conclusions BKP/VP provided greater pain relief and fewer subsequent fractures than NSM in osteoporotic VCFs. BKP is marginally favored over VP in disability improvement, and significantly favored in QOL improvement. BKP had a lower risk of cement extravasation and resulted in greater kyphosis correction. Despite this analysis being restricted to Level I and II studies, significant heterogeneity suggests that the current literature is delivering inconsistent messages and further trials are needed to delineate confounding variables.

Keywords Vertebral compression fractures · Osteoporosis · Balloon kyphoplasty · Vertebroplasty · Non-surgical management

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*Papanastassiou ID, Phillips FM, Meirhaeghe JV, et al. Comparing effects of kyphoplasty, vertebroplasty, and nonsurgical management in a systematic review of randomized and non-randomized controlled studies.

**Hoyt D, Urits I, Orhuru V, et al. Current concepts in the management of vertebral compression fractures. Curr Pain Headache Rep. 2020; 20:24(5).

Pain Reduction & Height Restoration

International Journal of Spine Surgery Publish Ahead of Print, published on July 3, 2018 as doi:10.14444/5

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Review of Vertebral Augmentation: An Updated Meta-analysis of the Effectiveness

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ABSTRACT

Background: To update vertebral augmentation literature by comparing outcomes between vertebroplasty (VP), balloon kyphoplasty (BKP), vertebral augmentation with implant (VAI), and nonsurgical management (NSM) for treating vertebral compression fractures (VCFs).

Methods: A PubMed literature search was conducted with keywords *kyphoplasty*, *vertebroplasty*, *vertebral body stent*, and *vertebral augmentation AND implant* for English-language articles from February 1, 2011, to November 22, 2016. Among the results, 25 met the inclusion criteria for the meta-analysis. Inclusion criteria were prospective comparative studies for mid-/lower-thoracic and lumbar VCFs enrolling at least 20 patients. Exclusion criteria included studies that were single arm, systematic reviews and meta-analyses, traumatic nonosteoporotic or cancer-related fractures, lack of clinical outcomes, or non-Level I and non-Level II studies. Standardized mean difference between baseline and end point for each outcome was calculated, and treatment groups were pooled using random effects meta-analysis.

Results: Visual analog scale pain reduction for BKP and VP was -4.05 and -3.88 , respectively. VP was better than but not significantly different from NSM (-2.66), yet BKP showed significant improvement from both NSM and VAI (-2.77). The Oswestry Disability Index reduction for BKP showed a significant improvement over VAI ($P < .001$). There was no significant difference in changes between BKP and VP for anterior ($P = .226$) and posterior ($P = .293$) vertebral height restoration. There was no significant difference in subsequent fractures following BKP (32.7%; 95% confidence interval [CI]: 8.8%–56.6%) or VP (28.3%; 95% CI: 7.0%–49.7%) compared with NSM (15.9%; 95% CI: 5.2%–26.6%).

Conclusions/Level of Evidence: Based on Level I and II studies, BKP had significantly better and VP tended to have better pain reduction compared with NSM. BKP tended to have better height restoration than VP. Additionally, BKP had significant improvements in pain reduction and disability score as compared with VAI.

Clinical Relevance: This meta-analysis serves to further define and support the safety and efficacy of vertebral augmentation.

Other & Special Categories

Keywords: meta-analysis, vertebral augmentation, vertebral compression fractures, vertebroplasty, balloon kyphoplasty

INTRODUCTION

Vertebral compression fractures (VCFs) are costly and are becoming even more common as more than 10 000 Americans turn 65 years old each day. In the United States, there are 1.5 million VCFs annually, and worldwide a vertebral fracture occurs every 22 seconds.^{1–3} Symptomatic fractures usually present with sudden onset of back pain and functional debilitation in an elderly patient with osteoporosis, though many fractures may be asymptomatic. VCFs are expensive to treat, costing around \$17 billion per year.^{4,5} Morbidities associated with VCFs are substantial and can result in permanent loss of mobility and quality of life and

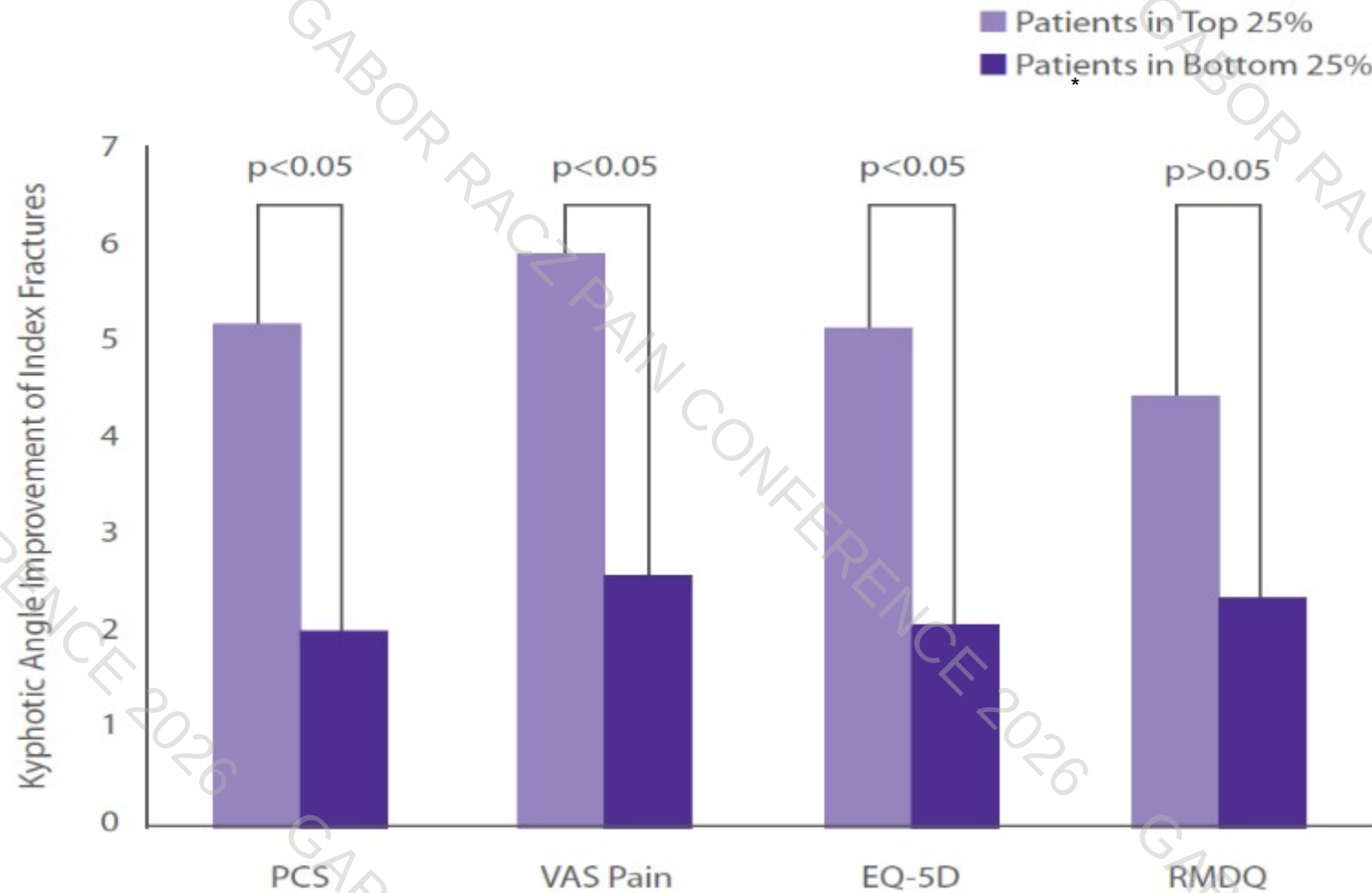
In addition, the deconditioning that affects patients with VCFs leads to mortality at a far higher rate than in age-matched controls.^{7,8} Increased mortality associated with VCFs has been well established for quite some time, but effects on mortality when patients undergo treatment with vertebral augmentation has only been described recently.^{9–12} Edidin et al¹³ reported significant reduction in morbidity and mortality in over a million patients with VCFs treated with vertebral augmentation as compared with patients treated with nonsurgical management (NSM).

Vertebral augmentation, including kyphoplasty and vertebroplasty (VP), have been accepted treat-

Conclusions:

- Based on Level I and II studies, BKP had significantly better pain reduction than NSM
- BKP tended to have better height restoration than VP

Patients with Higher Clinical Benefits Have Higher Kyphotic Restoration



*Data were subset into quartiles, comparing the top 25% against the bottom 25%

VCF treatment options

Vertebroplasty vs Sham Studies

Vertebroplasty vs sham	N-value	Follow-up	Key findings
Kallmes et al.* (NEJM 2009) ²⁸	131 VP (n=68) Control (n=63)	30 days	Improvements in pain and pain-related disability associated with osteoporotic VCFs in patients treated with vertebroplasty were similar to the improvements in a control group. VP = Sham
Buchbinder et al.* (NEJM 2009) ²⁹	78 VP (n=38) Control (n=40)	6 Months	No beneficial effect of vertebroplasty as compared with sham procedure in patient with painful osteoporotic vertebral fractures, at 1 week or at 1, 3, or 6 months after treatment. VP = Sham
Clark et al.* (Lancet 2016) ³⁰	120 VP (n=61) Control (n=59)	12 Months	Vertebroplasty is superior to placebo for pain reduction in <u>acute OVCFs</u> of less than 6 wks in duration VP > Sham
Hansen et al.* (Integrative J of Ortho and Traumatology 2016) ³¹	46 VP (n=22) Control (n=24)	3 Months	Vertebroplasty is statistically superior to sham for pain reduction in <u>acute OVCFs</u> VP > Sham
Lohle et al.* (12th Annual European Vertebral and Osteoarticular Interventional Therapeutics. Paris, France, 2020) ³²	80 VP (n=40) Control (n=49)	12 Months	Vertebroplasty is superior to sham in regard to pain reduction (VAS) and quality of life (Qualeffo) in <u>chronic VCFs of > 3 months in duration</u> VP > Sham

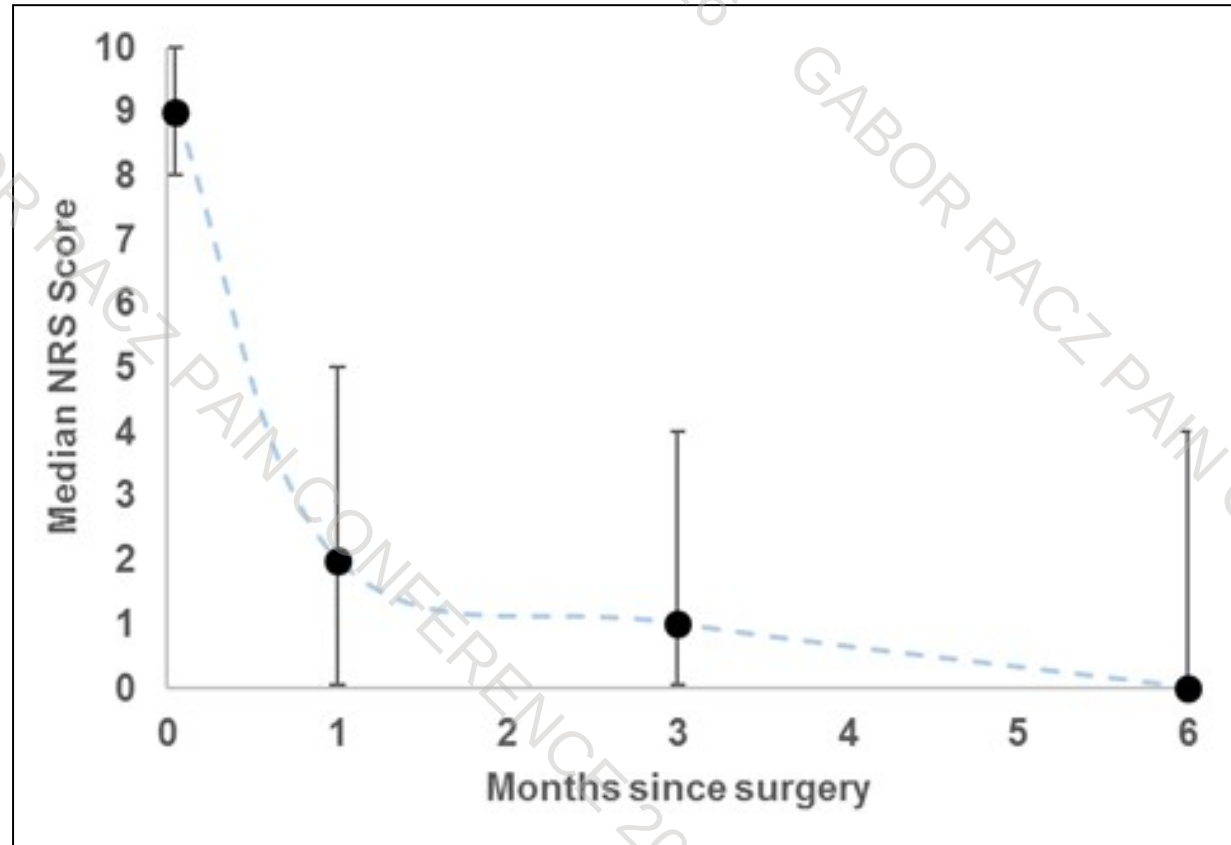
The US Vertebral Augmentation Registry: Findings from the World's Largest Registry of Vertebroplasty & Kyphoplasty

- Prospective enrollment @ 10 sites
- 1096 Total Pts
- 6 month data available for 732 pts
- Painful, acute/subacute, VCF's
- 1° Endpoints: NRS back pain, RMDQ
- 2° endpoints: AE's, cement extrav, hospital readmission

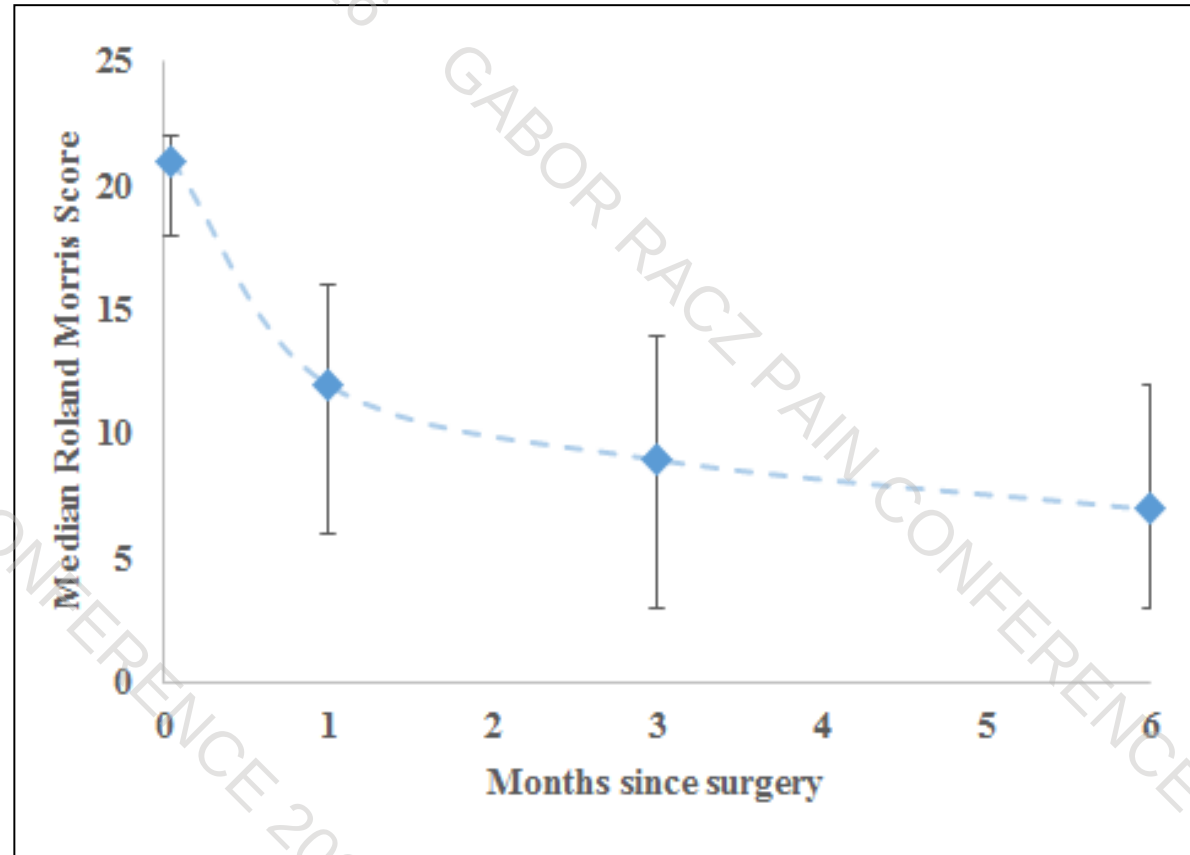
Patient Demographics and Baseline Characteristics

Characteristics		N (%)
N		732
Age, mean (SD)		78.1 (10.5)
Female		529 (72.3%)
Steroids use	No	275 (37.6%)
	Yes	91 (12.4%)
Smoking History	Current Smoker	45 (6.1%)
	Former Smoker	143 (19.5%)
Failure of conservative medical management for back pain	No	114 (15.6%)
	Yes	616 (84.2%)
Received non-operative treatment	No	23 (3.1%)
	Yes	530 (72.4%)
Procedure Technique	Balloon Kyphoplasty	419 (76.9%)
	Vertebroplasty	75 (13.8%)
	missing	187 (25.5%)

Finding of the US Vert Aug Registry: Results



Mean VAS Reduction from 8.7 to 2
Median VAS Reduction from 9 to 0 at 6
mos



Roland Morris decrease from 21 to 7
at 6 mos

Mean Pain Reduction Scores: Real World/Post Market Compared w/ RCTs

- Sacroplasty Registry – 6.9 pts
- Kyphoplasty: EVOLVE Trial – 6.0 pts
- US Vert Aug Registry – 6.7 pts

Vs

- INVEST – 3.5 pts
- Buchbinder – 2.6 pts
- FREE Trial – 3.5 pts



Impact on Healthcare Utilization

Prompt Care (1 Day)

• Cost \$6,420

• Only 3 imaging appointments

Positive impact on quality of life.

- Roland Morris: 20 (Baseline), 1 (3 Mos), 3 (6 Mos)
- NRS: 8 (Baseline), 1 (3 mos), 1 (6 mos)

Delayed Care (171 Days)

• Cost \$19,590

• 16 clinic visits, 8 imaging studies, 1 ER visit

Negative impact on quality of life.

- Roland Morris: 20 (Baseline), 5 (3 Mos), 9 (6 Mos)
- NRS: 8 (Baseline), 1 (3 mos), 3 (6 mos)

- Pts w/ acute/intermediate tx had greatest pain & fxn improvement & lowest HCU costs
- Pts w/ delayed tx had the least improvement and highest (3-fold) HCU costs
- Any TTT delay resulted in higher HCU costs and diminished benefits

PAIN
MEDICINE
CASE
REPORTS

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TIME TO TREATMENT VERSUS HEALTH CARE UTILIZATION IN COMPRESSION FRACTURES TREATED WITH VERTEBRAL AUGMENTATION: THE VERTEBRAL AUGMENTATION CARE PATHWAYS CASE SERIES

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Nell Shonnard, BS⁶, and Douglas P. Beall, MD⁶

Background: There is little data on the economics of the timing of percutaneous vertebral augmentation (PVA) for vertebral compression fractures (VCFs).

Case Report: The purpose of this case series is to compare health care utilization (HCU) costs vs the time to treatment (TTT) of the VCF. The BenchMarket Medical VCF Registry (now Talosia) was utilized. Patients receiving acute or intermediate treatment had the greatest pain and function improvement and the lowest HCU costs. Patients receiving delayed treatment had the least improvement and the highest (3-fold) HCU costs. Any TTT delay resulted in higher HCU costs and diminished benefits. The most beneficial PVA outcome and lowest HCU costs were recorded in patients whose PVA was expedited and performed within 3 months from injury.

Conclusions: This series suggests the best pain and function improvement and lowest HCU costs result from efficient, timely PVA.

Key words: Vertebroplasty, kyphoplasty, health care economics, registry, osteoporotic fracture, health care overutilization, case series

BACKGROUND

Due to the increase in osteoporosis, there are over 2 million osteoporotic fragility fractures in the United States, and the number is increasing each year (2). Studies (3,4) also suggest that 1 in 2 women and up to 1 in 4 men > 50 years will sustain an osteoporotic fragility fracture. Patients with vertebral compression fractures (VCFs) are known to require a primary care provider's

(PCP) services at a rate 14 times more than the general population (5). Moreover, the medical costs attributed to VCFs exceeded \$1 billion in 2005 and are predicted to reach \$1.6 billion by 2025 (6). Since the 2 original trials of percutaneous vertebral augmentation (PVA) were published in 2009 (7,8), there have been numerous randomized control trials (RCTs) and meta-analyses demonstrating the effectiveness of PVA for the treat-

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Conflict of interest: NHS has received compensation unrelated to this study, related to royalties (Globus), consulting, research, and teaching (Medtronic). DPH declares the following disclosures: Unrelated to this study, I received compensation from Medtronic related to consultancy, research, and teaching. DPH also declares grants from Biogen; grants and personal fees from Medtronic, Halyard, Vivex, and Vertiflex; consultancy fees from Dfine, Ossor; others from Lilly, Smith & Nephew, Biomet, Vertiflex, Synthes, and Integral Spine Solutions; and grants from Alphatech Spine, Medical Metrics, Liventa, Vestim, and Mesoblast. Remaining authors certify that he or she, or a member of his or her immediate family, has no commercial association (i.e., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted manuscript.

Patient consent for publication: Consent obtained directly from patients.

This case report adheres to CARE Guidelines and the CARE Checklist has been provided to the journal editor.
Accepted: 2024-08-08, Published: 2024-11-30

Several Studies of Pt w/ VCF's followed @ least 12 mos Concluded Mortality Rates Sig Higher for pts Treated w/ NSM vs VP or KP

- With VCF's followed @ least 12 mos
- Concluded Mortality Rates are Sig Higher for pts Treated w/ NSM vs VP or KP

SIGNIFICANTLY HIGHER MORTALITY RISK with NSM vs BKP/VP		n	Years follow up	Key Findings
Ong et al. * (Osteo Int 2017) ¹	✓	2,077,944 BKP (n=261,756)/ VP (n=117,232)/ NSM (n=1,698,956)	10*	NSM: 55% and 24% higher mortality risk at 1 year and 10 years than BKP (Propensity adjusted: 95% CI: 23-24%; p<0.001) NSM: 30% and 8% higher mortality risk at 1 year and 10 years than VP (Propensity adjusted: 95% CI: 8%-9%; p<0.001)
Lange et al. * (Spine 2014) ²	✓	3,607 BKP (n= 441)/ VP (n= 157)/ NSM (n= 3,009)	5**	VP/BKP: 43% lower mortality risk than NSM (AHR = 0.57; 95% CI: 0.48-0.70)
Edidin et al. * (Spine 2015) ³	✓	1,038,956 BKP (n= 141,343)/ VP (n= 75,364)/ NSM (n= 822,249)	4*	NSM: 55% higher mortality risk than BKP (AHR = 1.55; 95% CI: 1.53-1.56) and 25% higher mortality risk than VP. After propensity matching, the Kaplan-Meier risk of mortality at 4 years was still found to be greater for the nonoperated cohort. (AHR = 1.62; 95% CI: 1.60-1.64)
Edidin et al. * (JBMR 2011) ⁴	✓	858,978 BKP (n=119,253)/ VP (n=63,643)/ NSM (n=676,082)	4*	BKP: 44% lower mortality risk than NSM (AHR = 0.56, 95% CI 0.53-0.57) VP: 24% lower mortality risk than NSM
Chen et al. * (JBJS 2013) ⁵	✓	68,752 BKP (n= 22,817)/ VP (n= 7,886)/ NSM (n= 38,049)	3*	BKP: 32.3% lower mortality risk than NSM (AHR = 0.68, 95% CI 0.66-0.70) VP: 15.5% lower mortality risk than NSM
Hinde et al years Radiology 2020	✓	16 study meta-analysis 2 MM patients	Vert Aug pts 22% less likely to die at 10 than NSM pts	

Risk of Death: 2005-09 vs. 2010-14

- Est 59,389 to 75,452 pts at higher mortality risk due to change in treatment patterns
- Est 5,287 to 6,814 extra lives lost

$$\text{NNT} = 15^*$$

NNT to save 1 life at 1 yr

$$\text{NNT} = 12^*$$

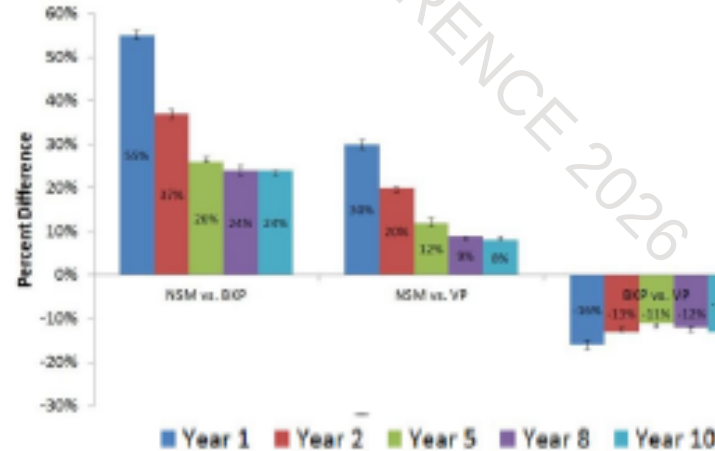
NNT to save 1 life at yr 5

This study reported statistically significant

HIGHER MORTALITY RISK with NSM compared to BKP/VP¹

- Higher mortality risk with NSM vs BKP: 24%, 10-yr propensity adjusted 95% CI: 23%-24%; p<0.001)

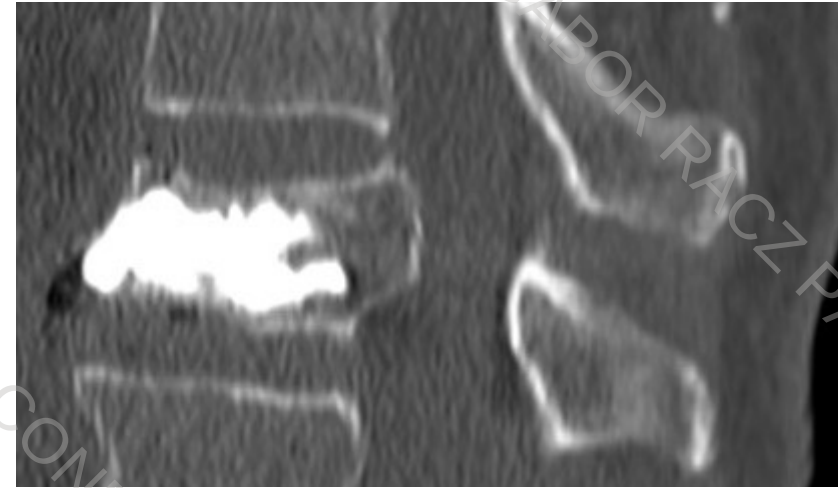
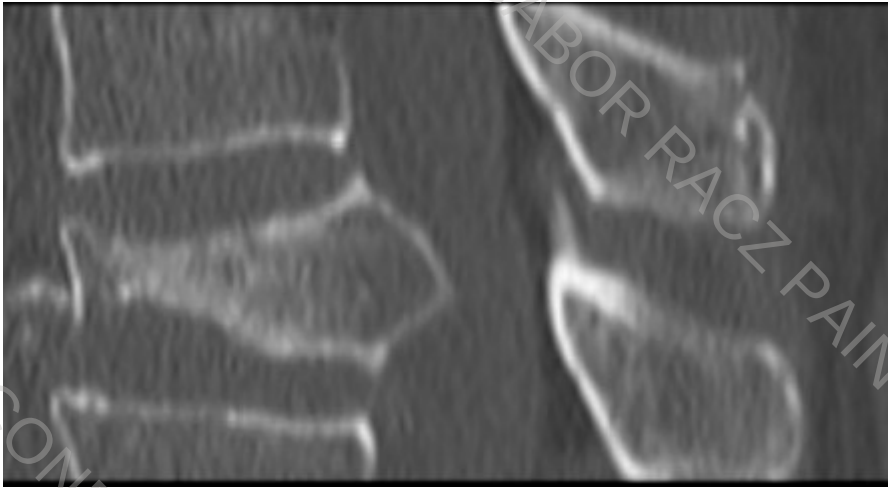
- Higher mortality risk with NSM vs VP: 8%, 10-yr propensity adjusted 95% CI: 8%-9%; p<0.001)



Mortality Risk		
Year	NSM vs BKP	NSM vs VP
1	55%	30%
2	33%	20%
5	26%	12%
8	24%	9%
10	24%	8%

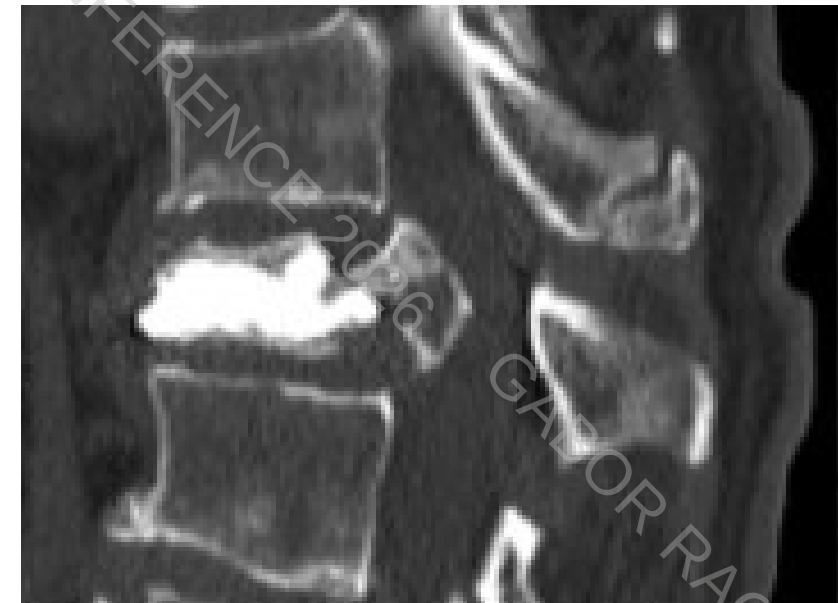
BKP had statistically significant lower mortality risk compared to VP at all time points (10-yr Propensity adjusted: 95% CI: 12%-13%; p<0.001)

Where Can We Improve at Treating VCFs?

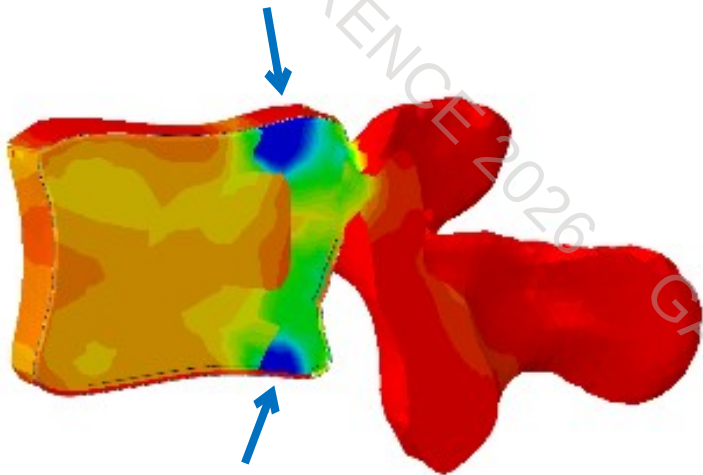


Mid column fx:

- *splitting*
- *post wall retropulsion*
- *kyphosis*

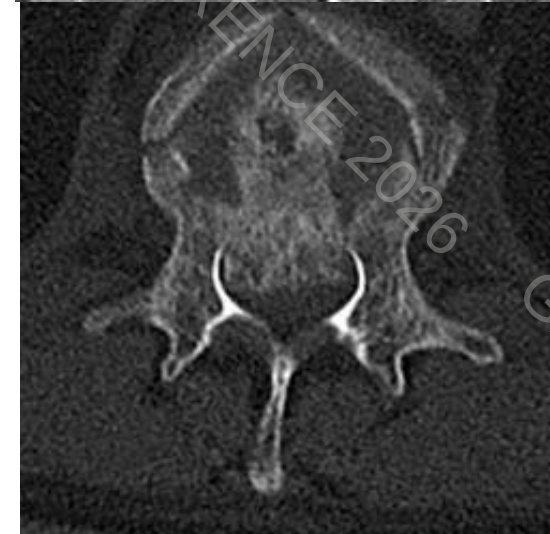
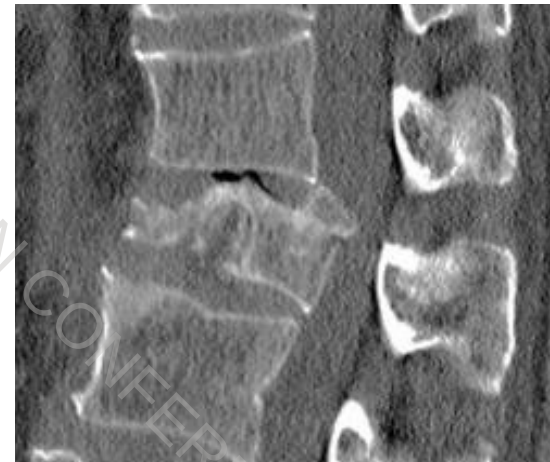


Collapse Can Happen at the Incident Level as well as Adjacent Levels



What Types of Fractures Should Have Treatment with VB Implants?

High degree of fragmentation



What Types of Fractures Should Have Treatment with VB Implants?



Past Approach to Treating Spine Fractures

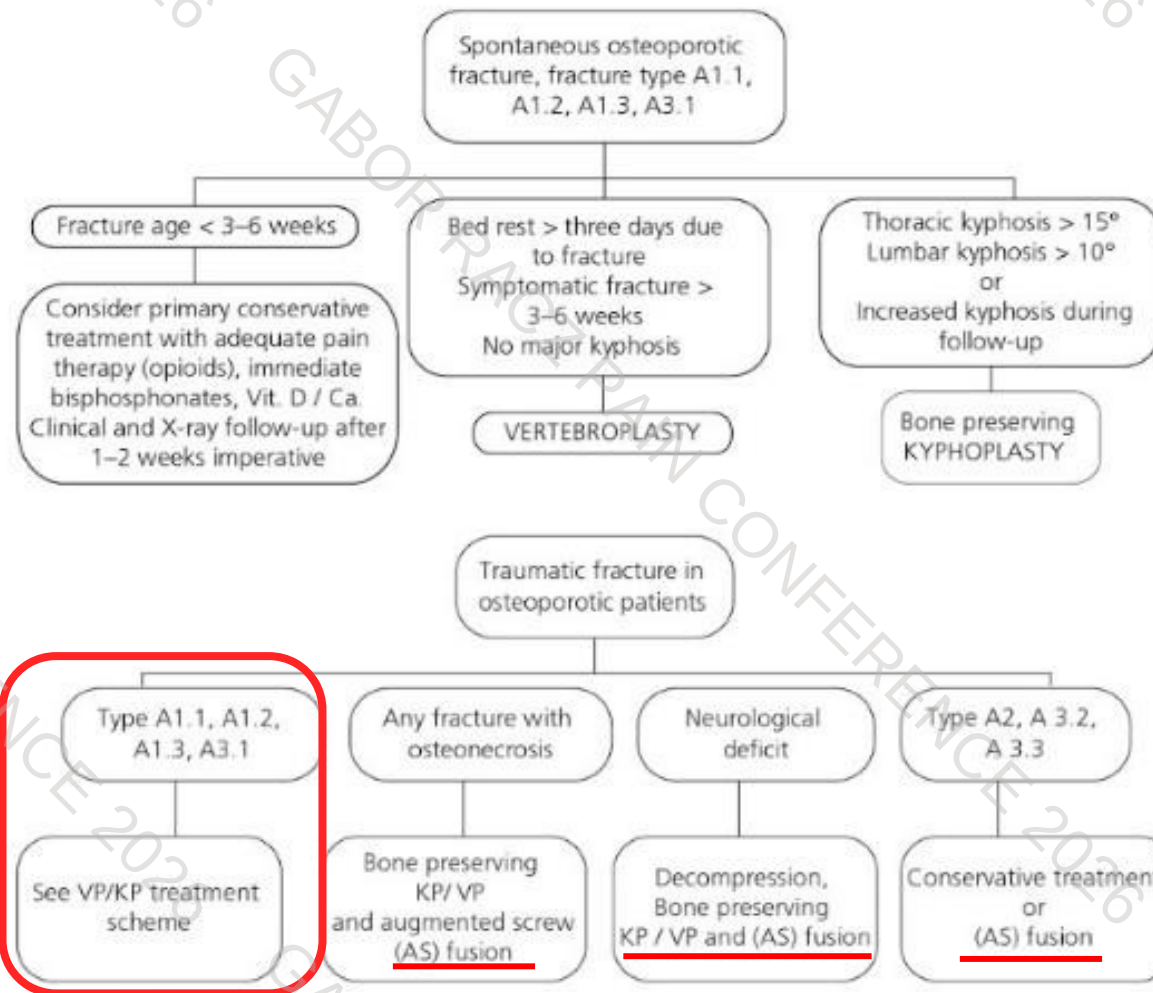


Figure 90.12 Treatment scheme after spontaneous osteoporotic vertebral fractures for fracture types A1.1, A1.2, A1.3, A3.1 (fracture classification after AO),⁴¹ all other fracture types see Figure 90.13.

Figure 90.13 Treatment scheme in trauma (fracture classification after AO).⁴¹

Mercer's Textbook of Orthopaedics and Trauma Tenth edition
 edited by Suresh Sivananthan, Eugene Sherry, Patrick Warnke,
 Mark D Miller

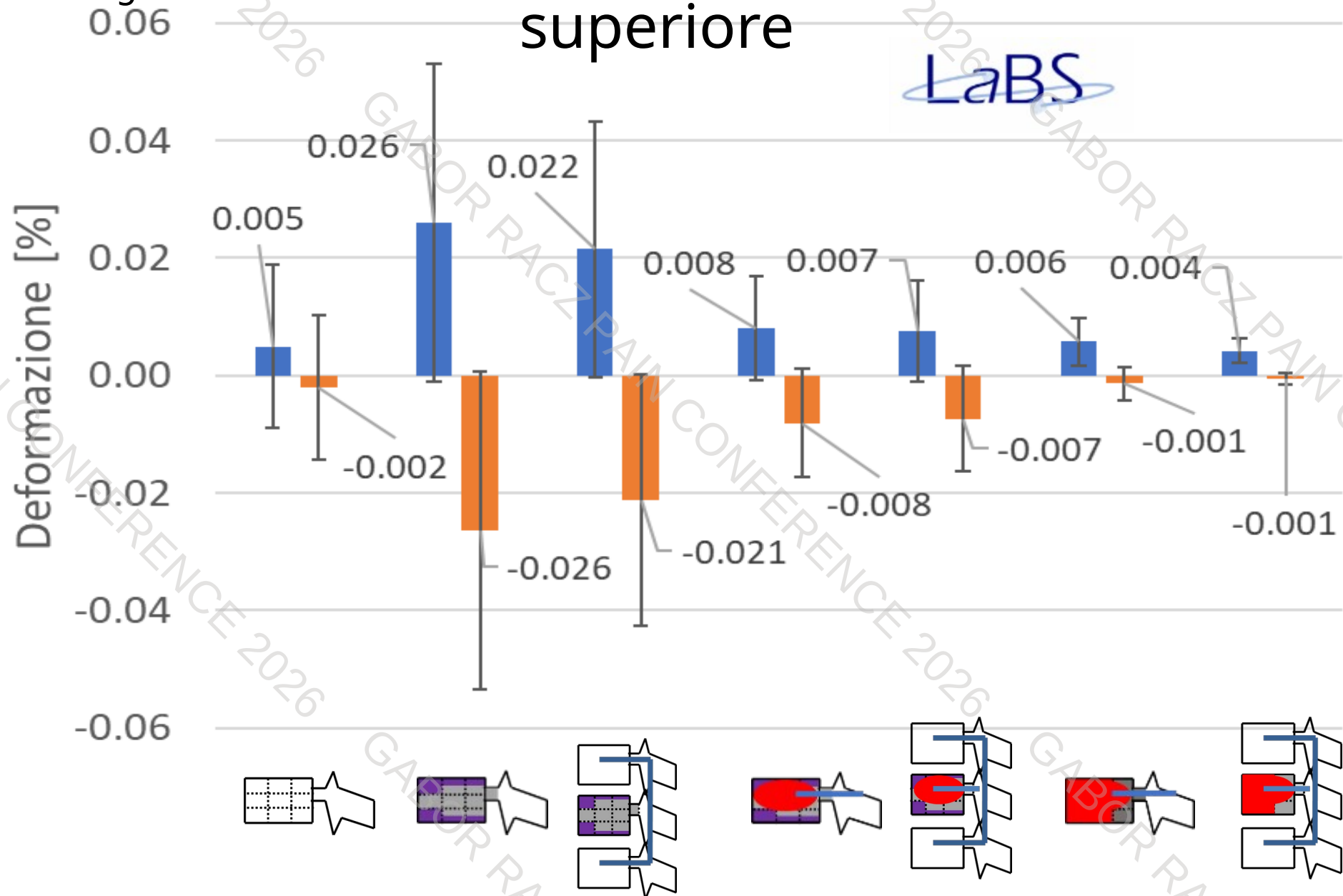
but....do we need to
instrument the posterior
column?



FEM: Deformation sup endplate on axial loading

Confronto tra i diversi approcci - endplate superiore

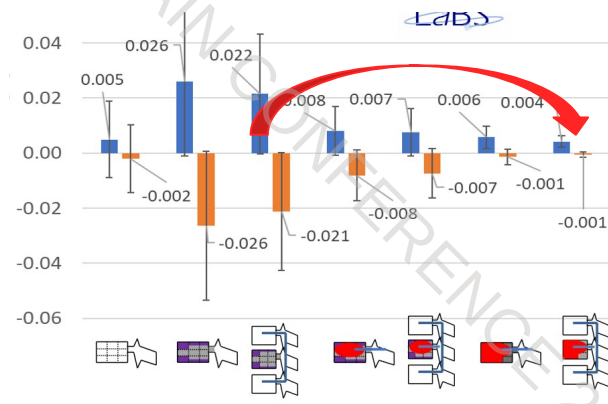
LaBS



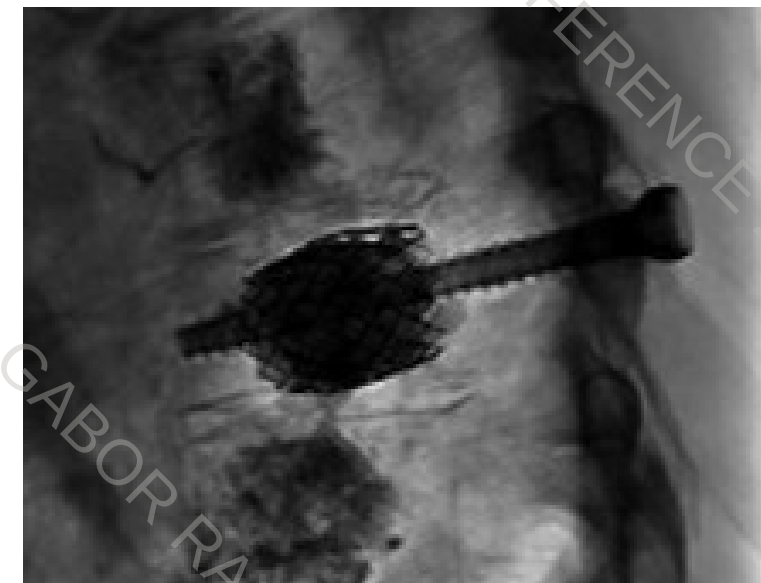
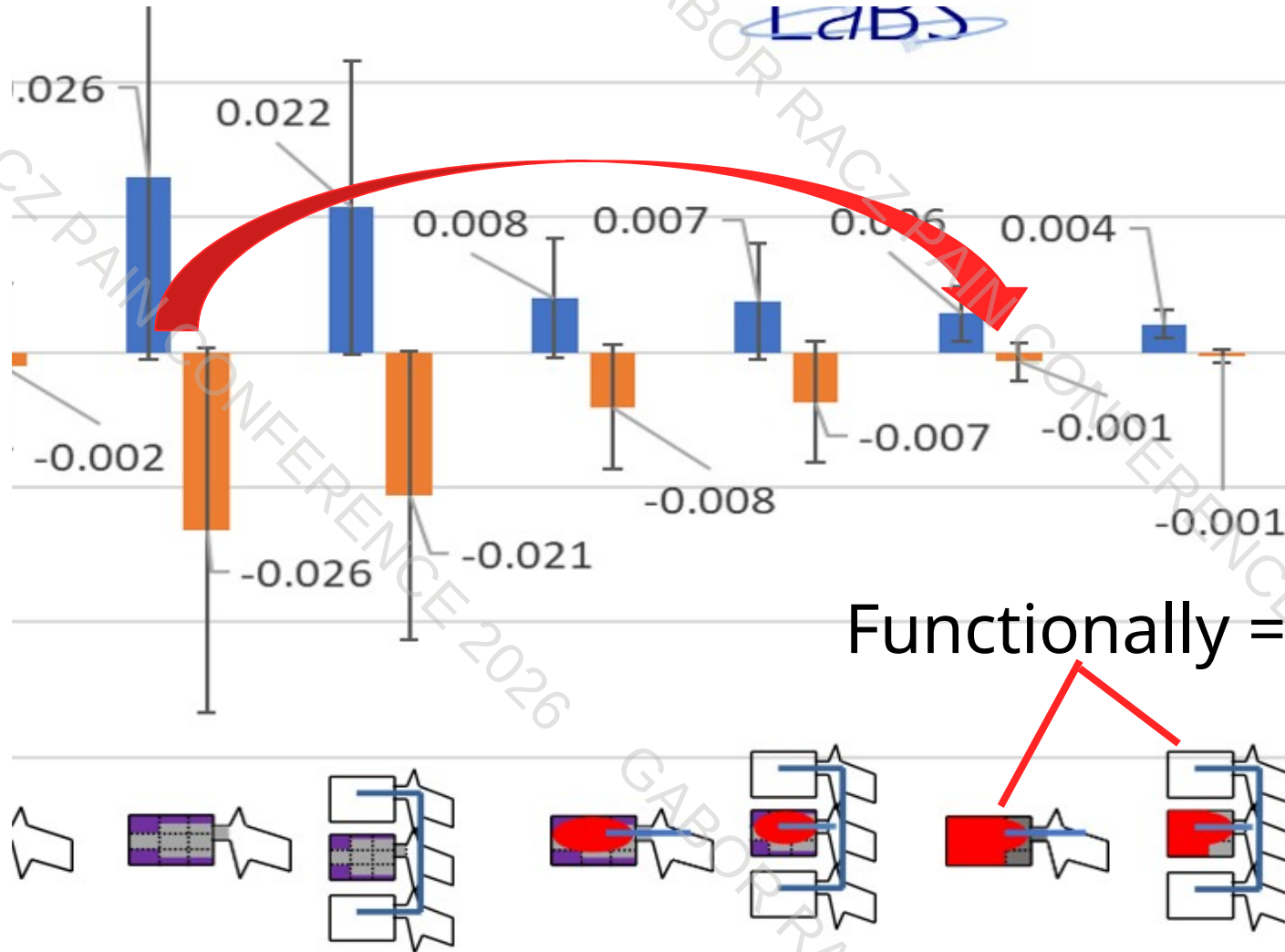
but..if instrumentation of the posterior column is insufficient to stabilize...

Go to the construct w/ the greatest support?

Should We

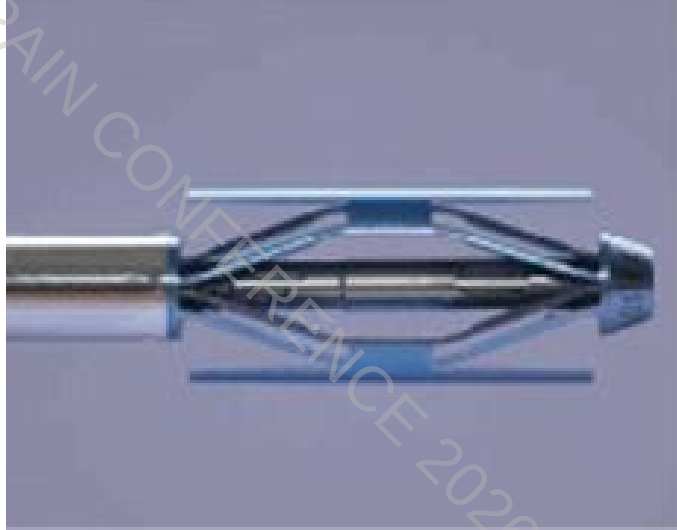


No. There is Negligible Difference in an Implant + Pedicle Screw/Rod Construct and Screw Assisted Internal Fixation (SAIF)



Expandable Titanium Reduction Device

- May be used OVF, Neoplastic VCFs, or traumatic fractures (A1.1, A1.2, A1.3, A3.1 and type B in selected cases, according to AO classification).



35 Miscellaneous Tips by the Masters of Vertebral Augmentation

35.1 If You Aim at Height Restoration, Mind the Access!

35.1 If You Aim at Height Restoration, Mind the Access!

35.2 Pearls of Vertebroplasty and Kyphoplasty

35.3 Excellence is a Habit

35.4 Osteonecrosis of the Spine (Kümmel–Verneuil disease)

35.5 Cement Augmentation

35.6 Tips and Techniques of Vertebral Augmentation

35.7 Radiofrequency Ablation and Vertebral Implant Augmentation in a Patient with Lytic Metastatic Disease

35.8 Vertebral Hemangioma Causing Congestive Myelopathy Despite Absence of Angiographically Evident Arteriovenous Shunting

35.9 Vertebral Augmentation Devices in the Treatment of Traumatic Vertebral Fractures

35.10 Vertebral Augmentation: Tips and Tricks

35.11 Dorsal Root Ganglion Stimulation to Treat Persistent Radicular Pain after Compression Fracture

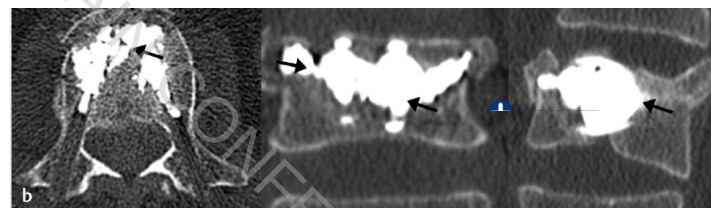
35.12 Vertebral Augmentation: Tips and Tricks

35.13 Treating Thoracic Vertebral Fractures with Vertebroplasty

35.14 Vertebral Augmentation through a Minimally Invasive Approach

35.15 Reversing Thoracic Kyphoplasty

35.16 Treating Thoracic Fractures



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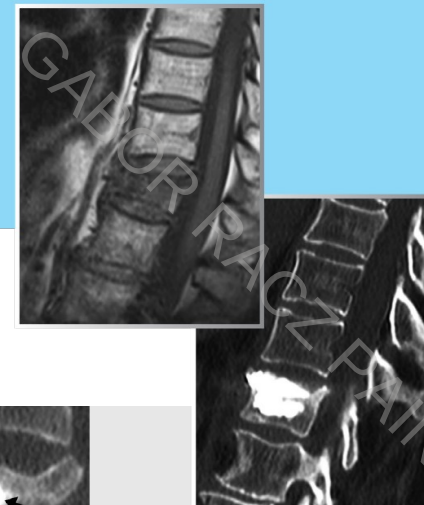
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Vertebral Augmentation

Vertebroplasty and Kyphoplasty

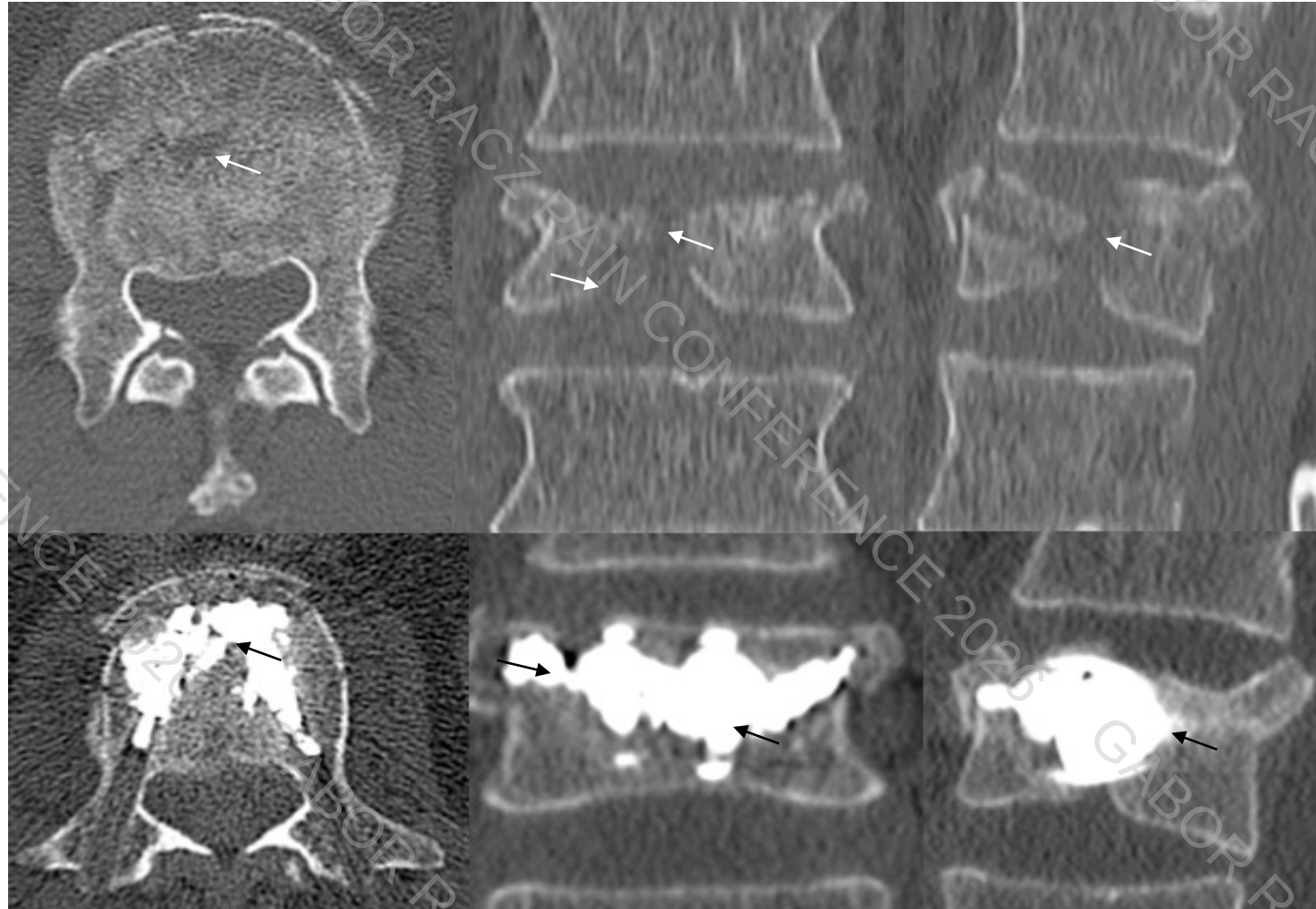
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Although most implants are effective, SpineJack seems best for tx traumatic VCFs (incl A2 & A3 fractures as a stand-alone) w/o add'l posterior instrumentation



Tx of Thoracolumbar A3 VCF's using Perc Intravert Expandable Ti Implant (PIETI): Long-term f/u

Noriega, Beall, et. al.

- **Purpose:** Assess long-term o/comes of PIETI.
- **Material and Methods:** Prosp single ctr study of 44 consec pts w/ acute (< 2 wks) Type 3 T-L VCFs w/ avg f/u of 5.6 yrs. Clin and Radiographic outcomes assessed.
- **Results:**
 - Sig improvements in VAS & ODI seen @ 1 month. Sig incr VB height restoration seen. Sig correction of sag kyphotic angle seen
 - All improvements maintained throughout f/u period; only 1 cement extrav
- **Conclusions:** PIETI is safe & effective in tx of AO A3 VCFs & grt sig clin improvement & anatomic VB restoration w/ results maintained > 5 yrs.

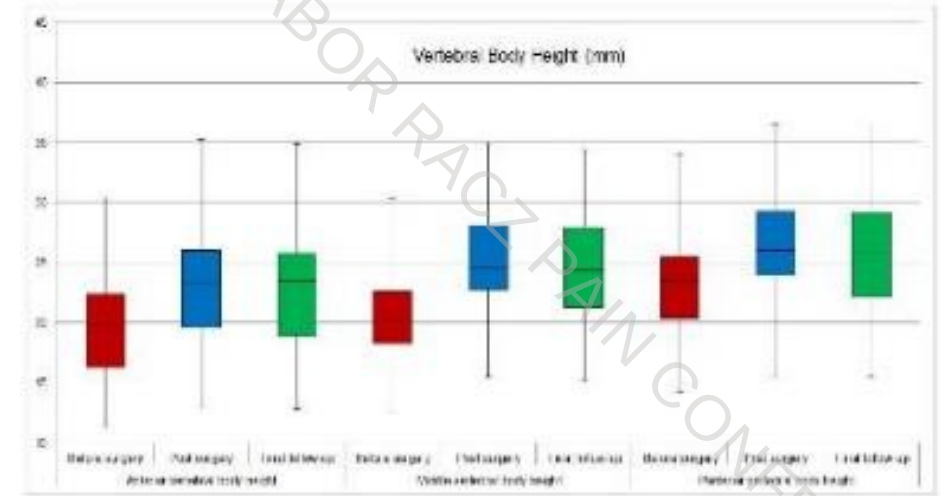
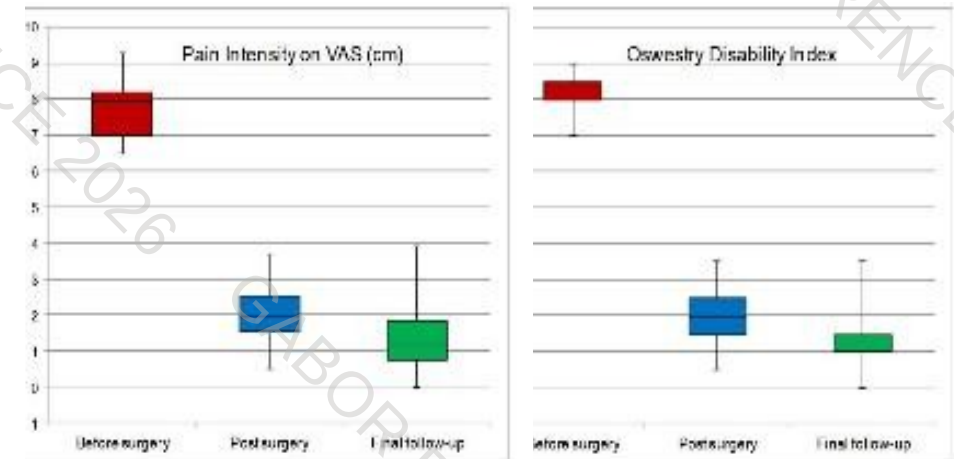
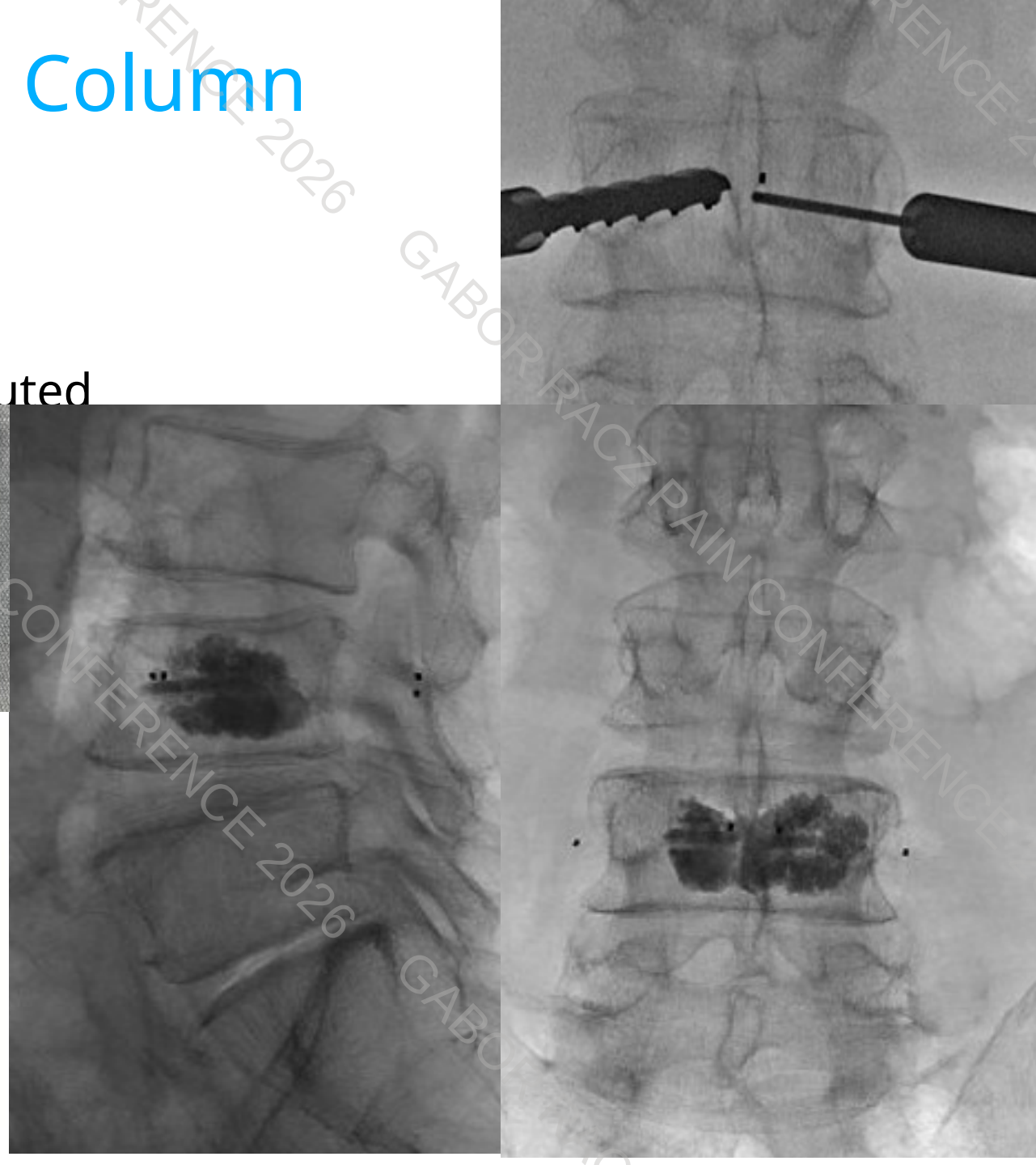
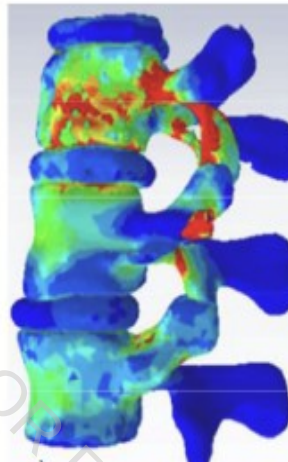
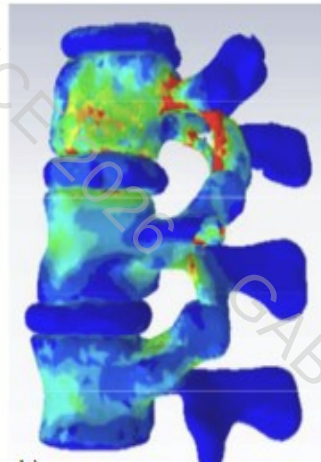
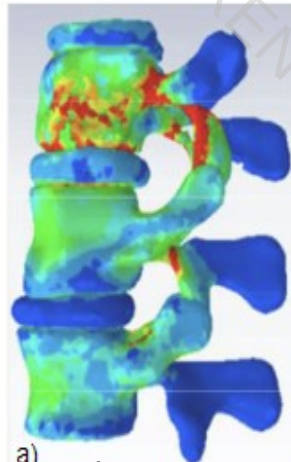
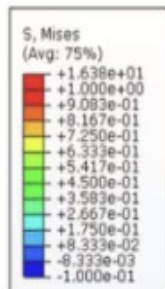


Figure 2



How to Bridge the Middle Column (Site of Greatest Stress)

- V-Strut – PEEK Transpedicular System
- Force across FSU is redistributed



V-Strut

- Initial clinical trial of 24 consec pts (f/u 1.1 mos)
 - osteoporosis (19 pts) trauma (1) & mets (4)
- Mean procedure duration - 42.4 minutes
- Cement extrav - 21%
- ALF 1 & Non-ALF 1/24 (8%)
- No SAEs were reported
- VAS 82mm to 30mm ($p=0.000000008$) @ 1 month

V-STRUT is Safe & Effective & may
↓ Add'l Fxs a multi-center study is
currently underway



ITEM	Part Number	DESCRIPTION	QTY
1	4-0001	10 mm Outer Balloon	1
2	4-0002	5mm Inner Balloon	4
3	4-0003	Outer Shaft and Injection Port Coupling	1
4	Quosina: 80146	Outer Balloon Injection Port	1
5	4-0004	Injection Chamber Divider	1
6	Quosina: 80165	Inner Balloon Injection Port	1
7	4-0005	Support Wire	1

DETAIL H
SCALE 2:1DETAIL F
SCALE 5:1

KyphoCube

0001

DETAIL I
SCALE 8:1

SCALE 6:1

SCALE 6:1

KyphoCube

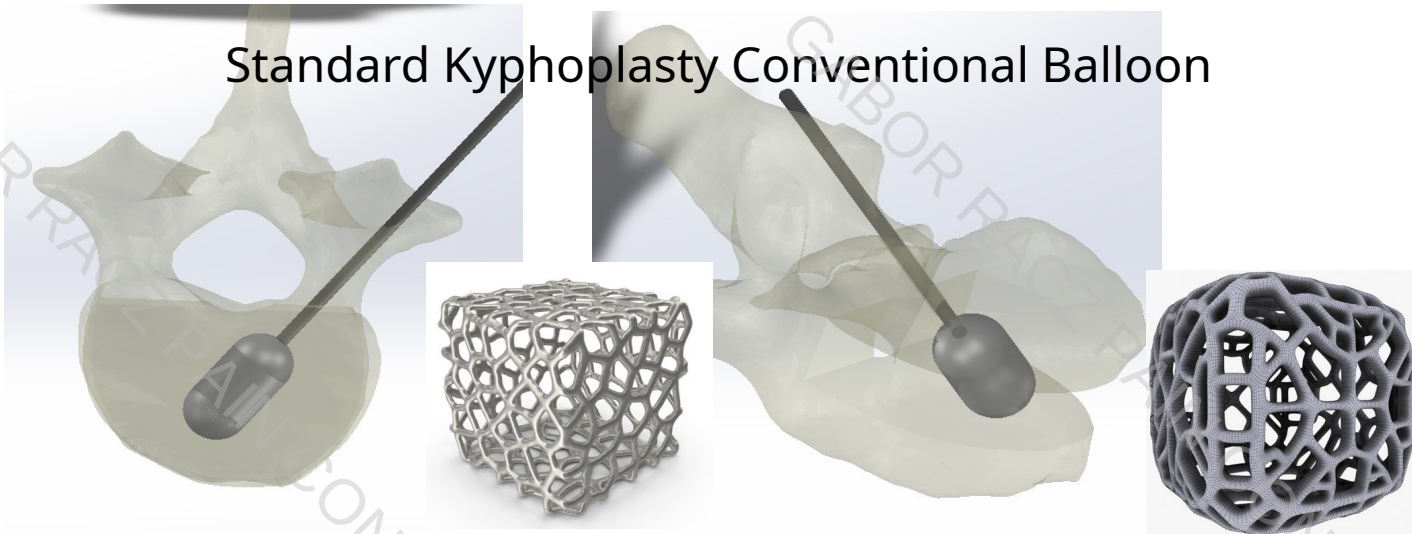
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Why It's Hip To Be Square

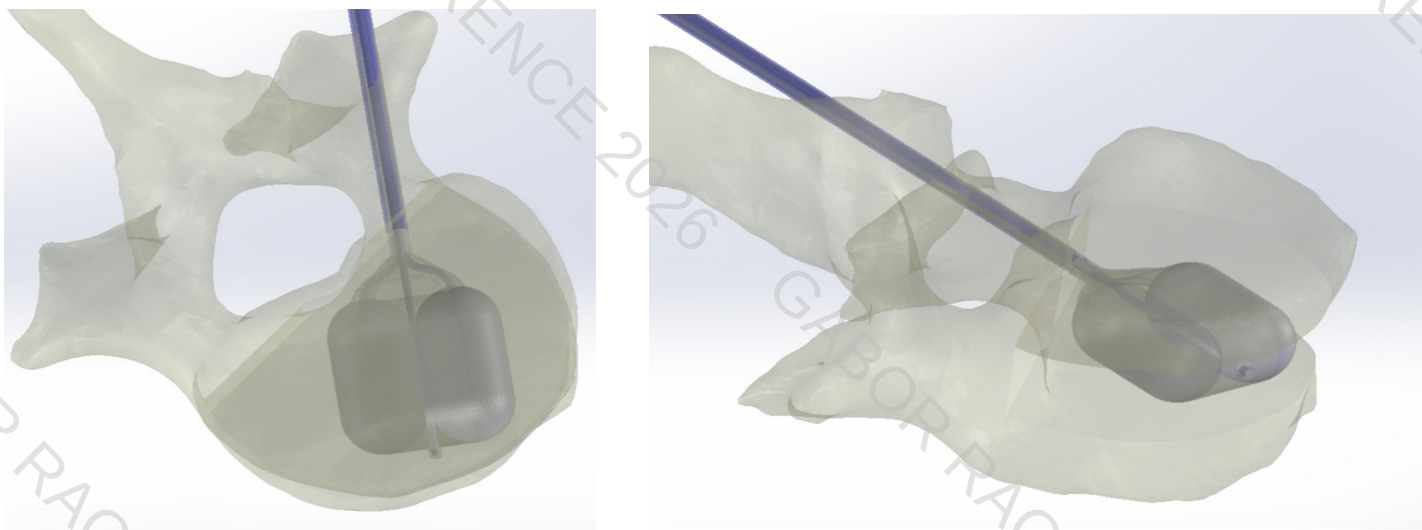
Kypho



Standard Kyphoplasty Conventional Balloon

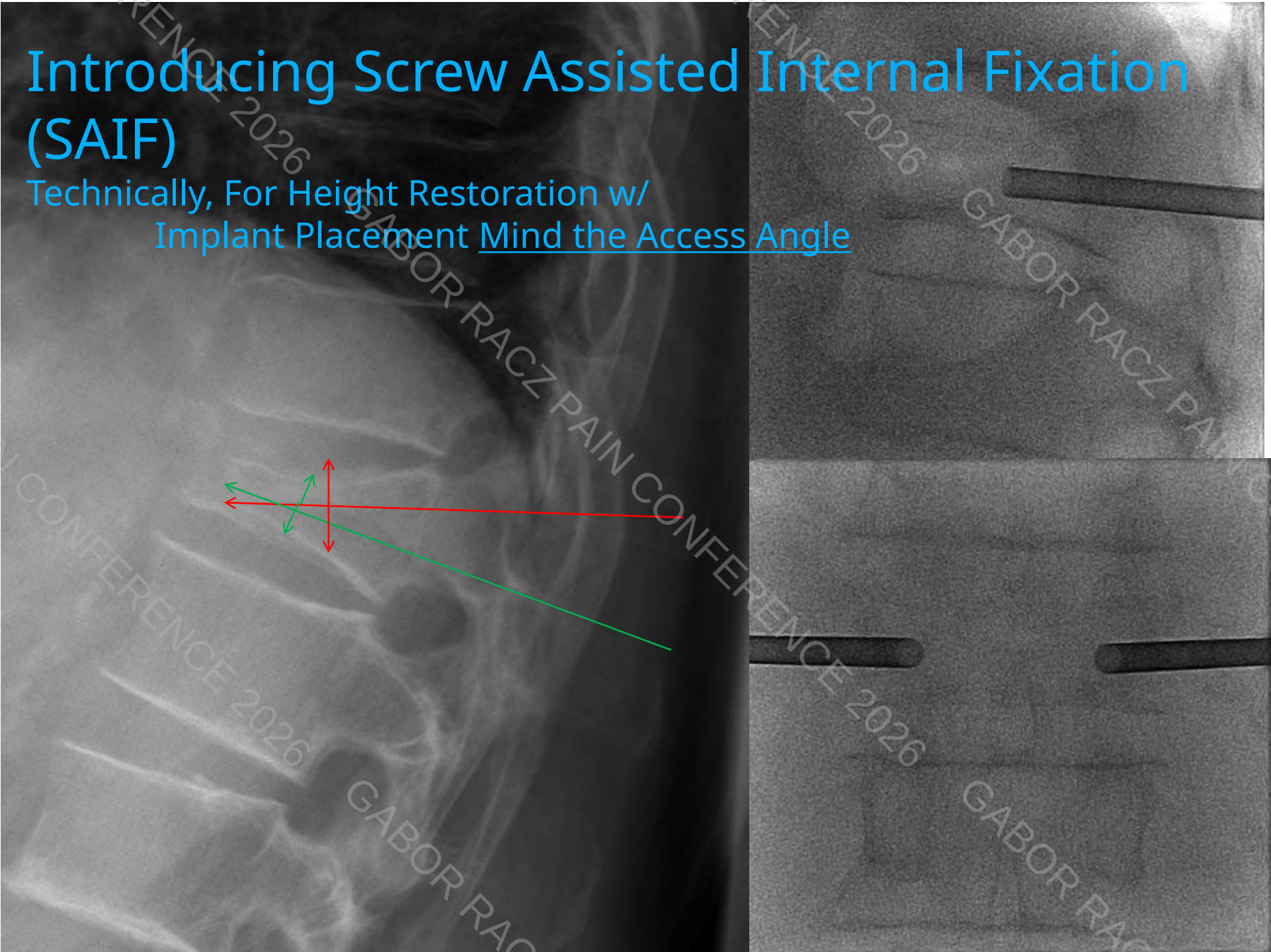


KyphoCube Kyphoplasty Balloon



Introducing Screw Assisted Internal Fixation (SAIF)

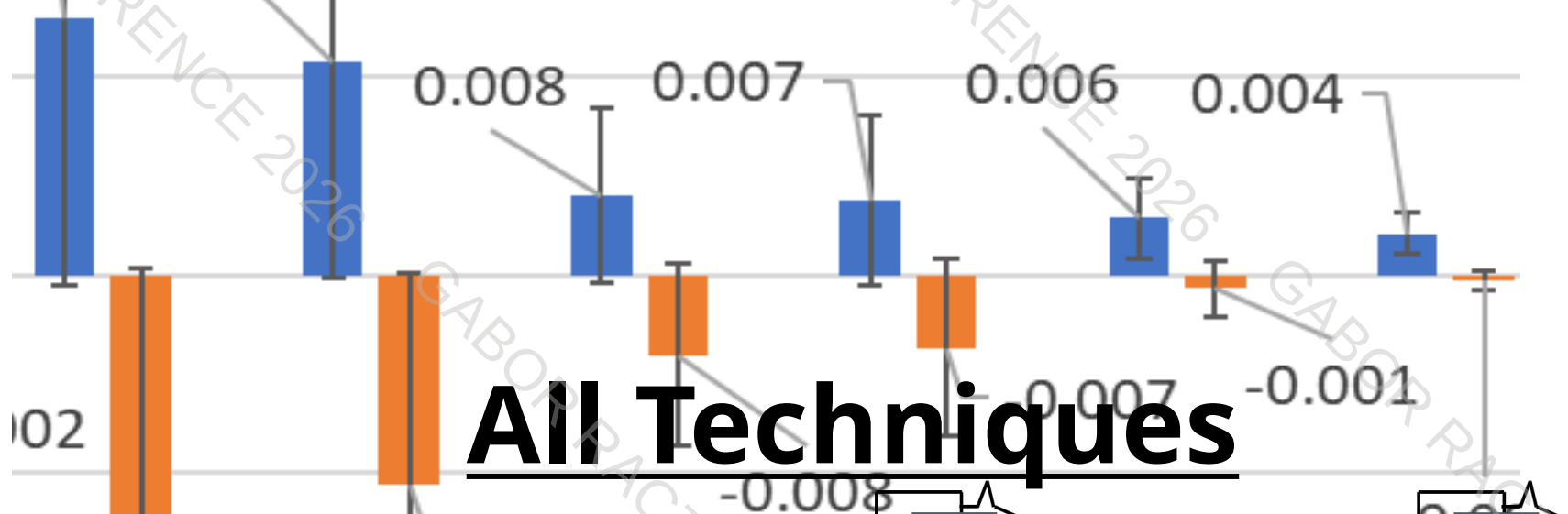
Technically, For Height Restoration w/
Implant Placement Mind the Access Angle



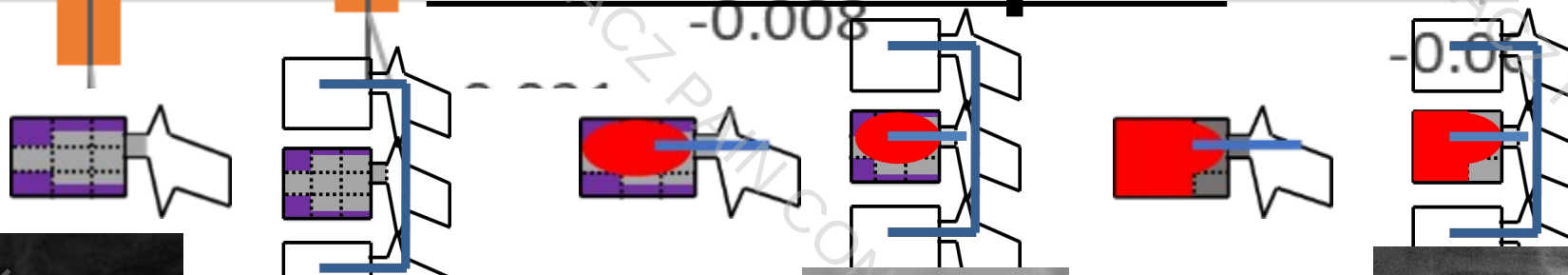




-



All Techniques



VCF



VCF +
Screw/Rod
Construct



BKP &
Screws



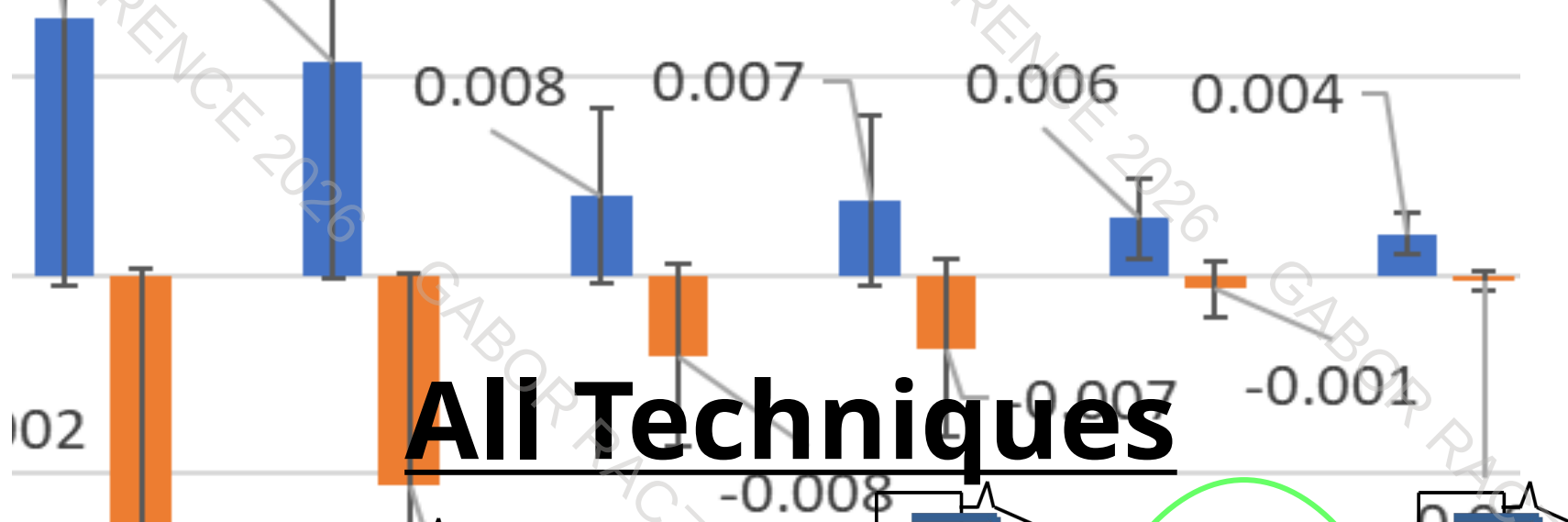
BKP +
Screw/Rod
Construct



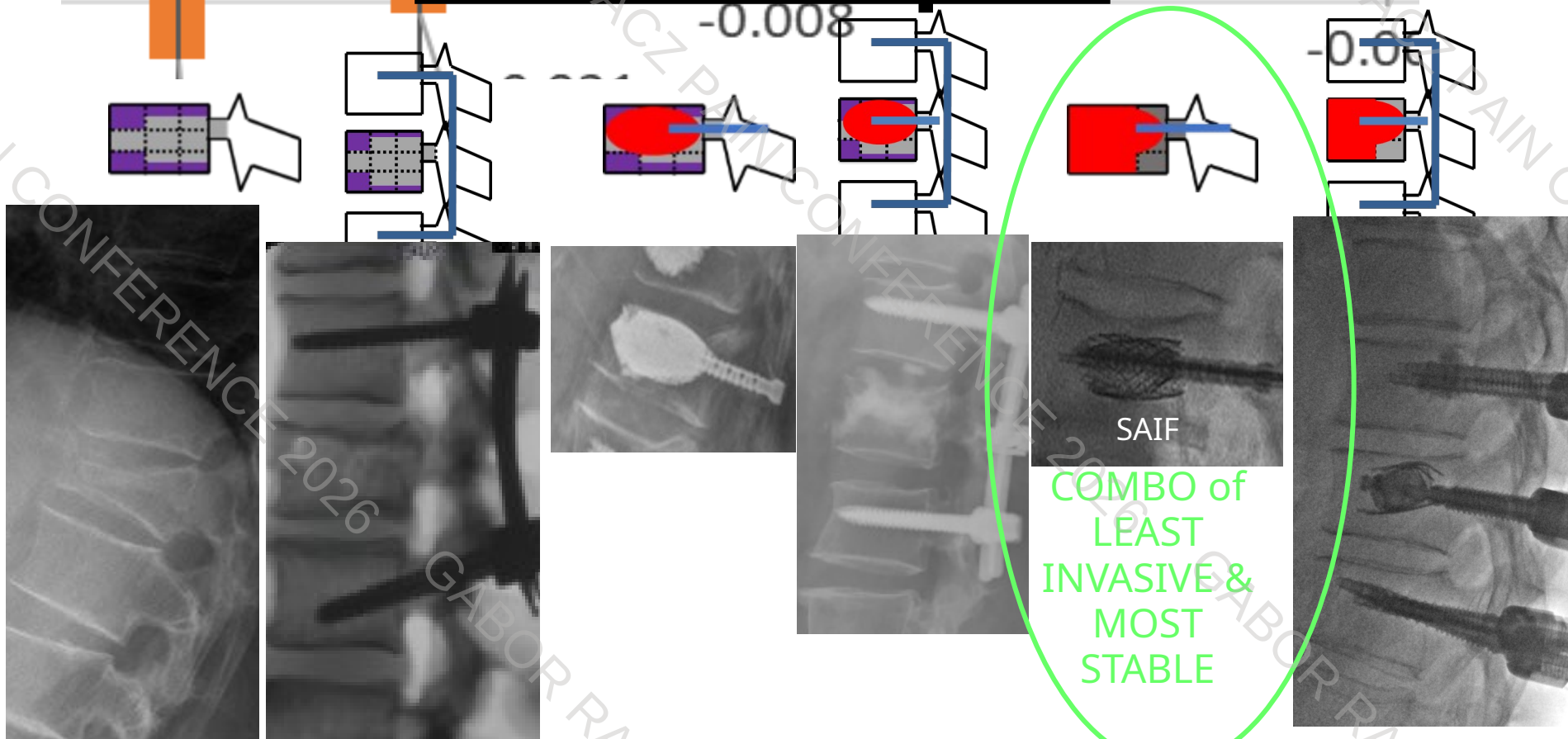
SAIF



SAIF +
Screw/Rod
Construct



All Techniques



Conclusion

- Vert Augmentation is One of the Most Effective Treatments of Anything We Do & is Demonstrably Life Saving & Life Prolonging for Pts & Overwhelmingly Supported by Data
- Do More Vertebral Augmentation....the Patients will Love You For It



Thank You



Have a Nice Day