

**Early Clinical Experience With
CONFIDENCE:
Occurrence And Degree
Of Cement Leakage As Compared To
Kyphoplasty.**

Bassem A. Georgy, MD,
North County radiology
Assistant Clinical Professor of Radiology
University of California, San Diego, USA

Introduction

- Significant data available on Vertebroplasty & Kyphoplasty:
 - Both procedure successfully alleviate pain from vertebral compression fractures (VCF)
- Key reported differences:
 - Leakage Rates
 - Height Restoration

Leakage Rate Related to Cement Viscosity?

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High-Viscosity Cement Significantly Enhances Uniformity of Cement Filling in Vertebroplasty: An Experimental Model and Study on Cement Leakage

Gamal Baroud, PhD,* Meghan Crookshank,* and Marc Bohner, PhD†

Higher-viscosity cements associated with lower leakage rates in laboratory vertebral compression model

Hypothesis

Vertebroplasty with high-viscosity cement has leakage rate similar to Kyphoplasty, despite lack of bone tamp.

Materials & Methods

- Retrospective review of postoperative images
- Consecutive patients treated for VCF with:
 - CONFIDENCE (DePuy Spine) : N=40
 - Kyphoplasty (Medtronic) : N=35
 - Total levels: N= 105
 - Kyphoplasty using Zimmer dough-type cement
- Evaluate leakage, using 4-point scale:
 - No leakage / Mild / Moderate / Severe
- Pre- and Post-operative VAS score:
 - CONFIDENCE: VAS available on 10 patients
 - Kyphoplasty: VAS available on 11 patients

Patient Demographics

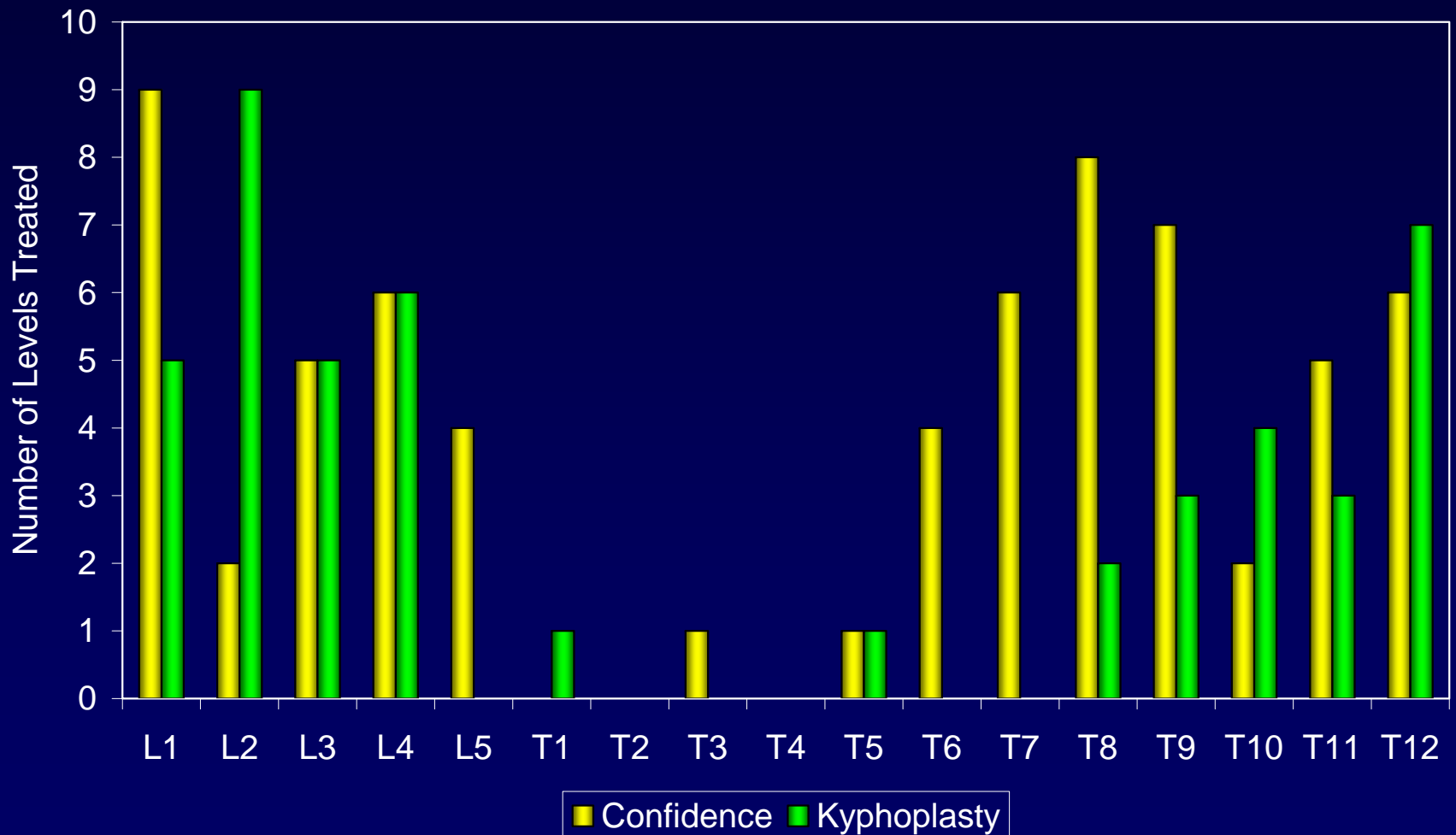
- CONFIDENCE

- N= 40
- Age: 82.0 ± 9.7
- Age range: 53-94
- Average # of levels, per patient: 1.65
- Max # of levels, per patient: 5

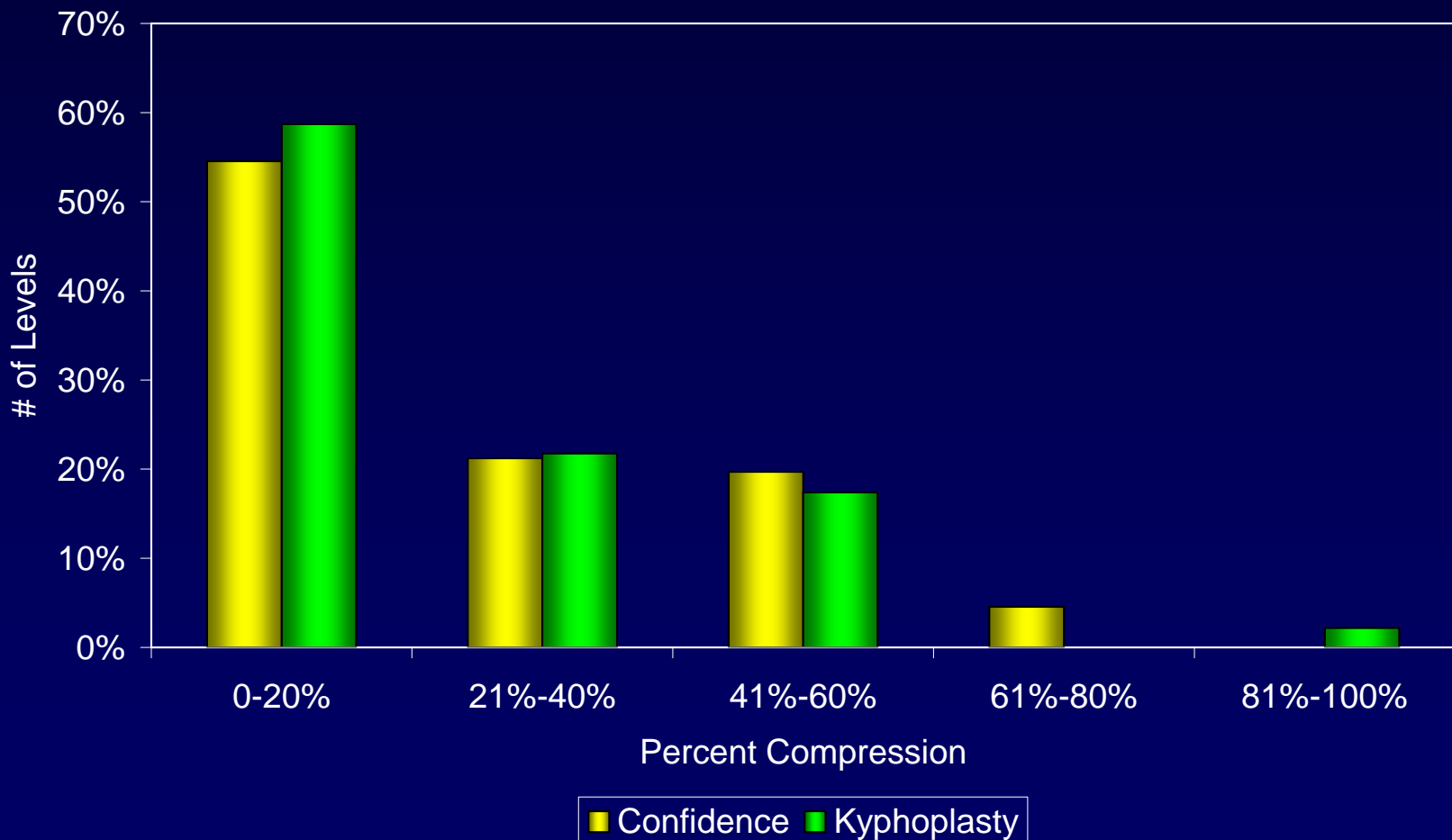
- KYPHOPLASTY

- N=35
- Age: 80.9 ± 12.0
- Age range: 40-93
- Average # of levels, per patient: 1.31
- Max # of levels, per patient: 5

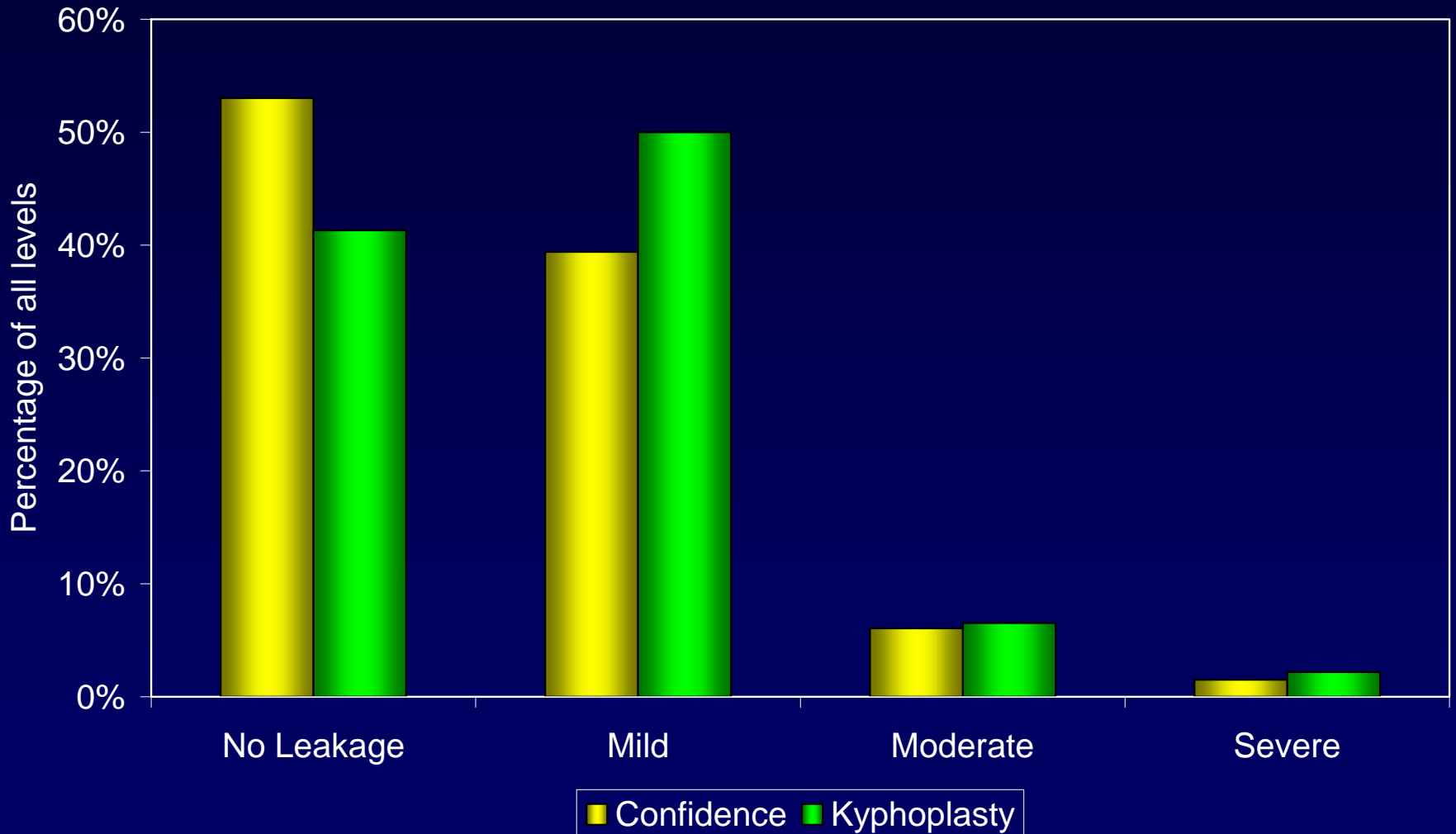
Operated Levels from T1-L5 in Both Groups



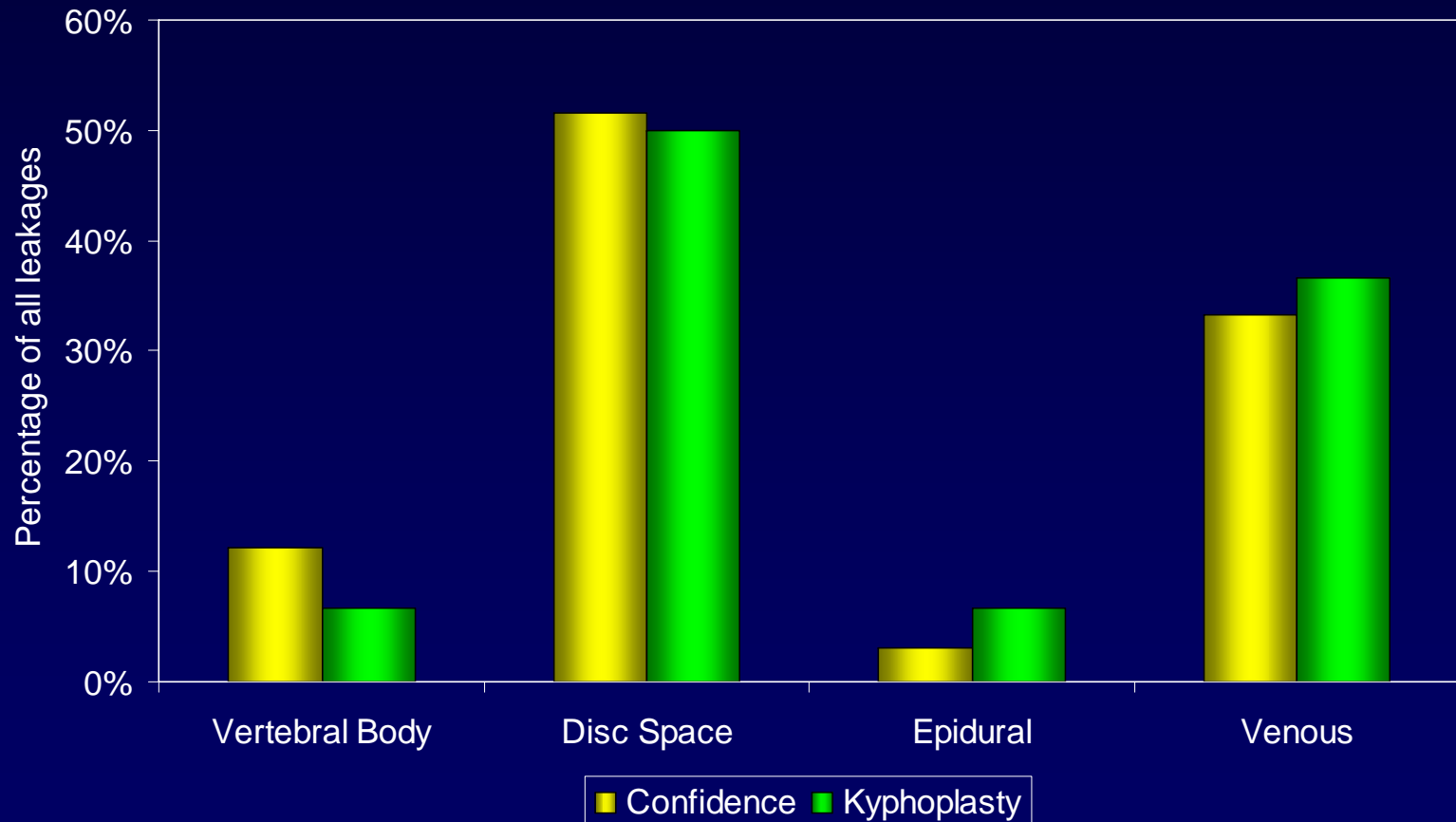
Similar Range of Compression Fracture Between Groups

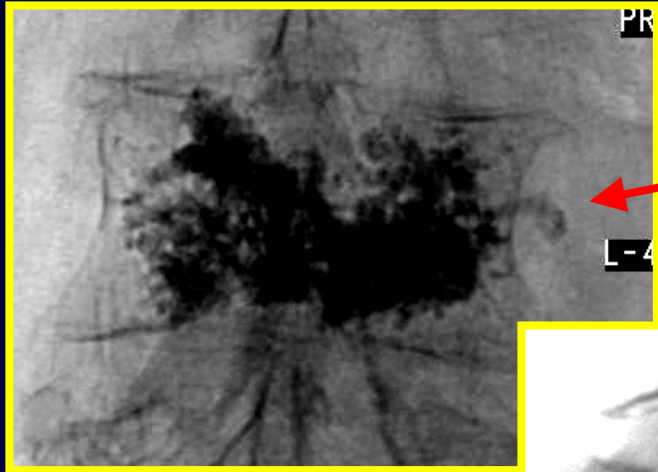


Leakage Rates Similar Across Groups

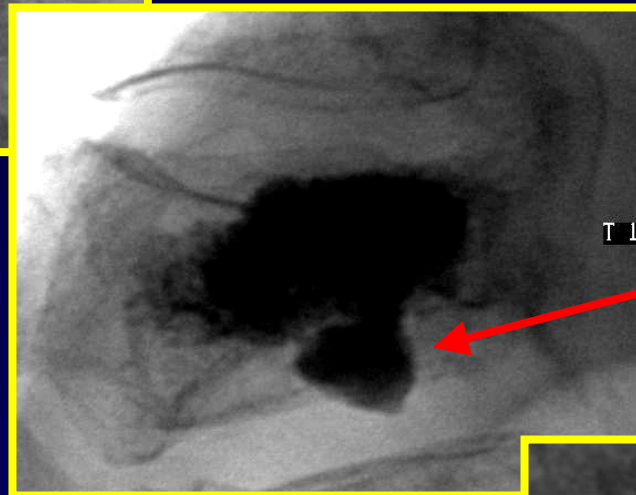


Location of Leakage Similar Between Groups





Mild venous leakage



Moderate Disk leakage



Severe Disc leakage

Conclusions

- **Hypothesis confirmed:**
 - leakage rate with high-viscosity cement similar to that of kyphoplasty
 - Cavity creation may not have a role in controlling cement leakage
 - Location of leakage also comparable
- Highly viscous cement may increase the safety of standard Vertebroplasty techniques