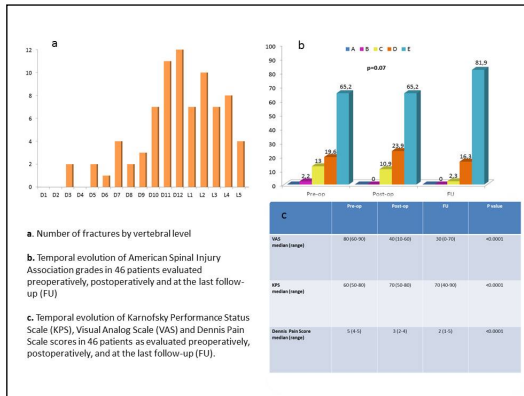


Kyphoplasty with silicone purified VK100 (Elastoplasty) for the treatment of spinal lytic lesions in cancer patients: a retrospective evaluation of 46 cases.

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Introduction

Balloon Kyphoplasty (BKP) for vertebral compression fractures (VCFs) in cancer patients is more challenging than for osteoporotic ones. Cord compressions are frequent and the incidence of cement intracanal and vascular leakages is ten-fold greater. PMMA is the gold standard for BKP. However, PMMA has some disadvantages: exothermic reaction, short working time, rapid solidification, absence of osteoconductive properties.

Methods

VK100 (BONWRx Ltd, Lansing Michigan, USA), is a mixture of Dimethyl methylvinyl siloxane, Barium Sulphate and Platinum catalyst. It is adhesive to bone, it has no exothermic reaction leaving up to 30 minutes before solidification and is more elastic. The surgical procedure required is called Elastoplasty. We treated 46 cancer patients (80 vertebral bodies) with VK100, through percutaneous BKP, open BKP and augmentation procedures to implement thoraco-lumbar stabilizations. Leakages and pulmonary embolism (PE) were evaluated with CT scans. 15 patients were affected by hematologic tumors; 25 by solid ones; 3 were Cordomas. Median follow-up was 14 months.

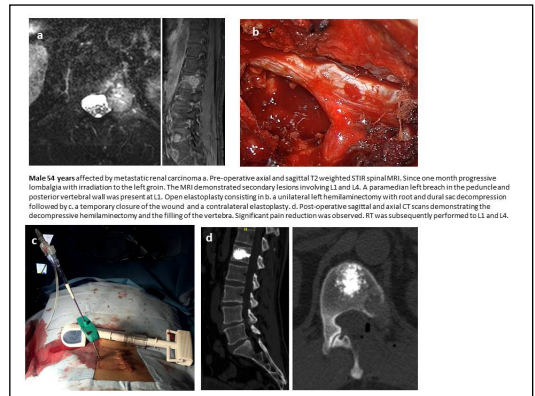
Results

Median Tokuhashi score was 10, median SINS score 12. Median operative time was 125 minutes (range 40-660). For each level it was 40 minutes (20-80) in percutaneous elastoplasty; 170 minutes (90-250) in open elastoplasty. Average working time allowed by VK 100 was 30 minutes (20-45). The mean volume of silicon inserted in each vertebra was 3.8 cc (1.5-6 cc). Complications included seven cases of leakages in 41 patients treated with BKP (17%), In six cases the leakages were asymptomatic (two intradiscal, two intraspedal, one anterior to the vertebral body and one intravascular). There were one transient motor impairment after an open elastoplasty and two permanent motor deficit unrelated to silicon injection, due to post-operative hematomas. Two asymptomatic PE (4.3%) and 3 postoperative adjacent fractures (7.3%) were detected. A significant improvement was observed in KPS, VAS and Dennis Pain Score ($p < 0.0001$).

The median LOS was 5 days (range 2-26), for percutaneous elastoplasty it was 3 days (2-15), for open elastoplasty it was 10 days (3-26), for mixed procedure it was 4.5 days (3-13), for "augmentation" techniques it was 15 days (10-20). Median follow-up of was 14 months (1-30 months). 37 patients did not change their ASIA scale following surgery, three patients deteriorated and six patients improved. The majority of patients preserved or improved their ASIA score after surgery till the last neurological follow-up before systemic deterioration occurred ($p = 0.18$). The 1-yr survival rate was 77.5%. and the 2-yr survival rate was 66.7%.

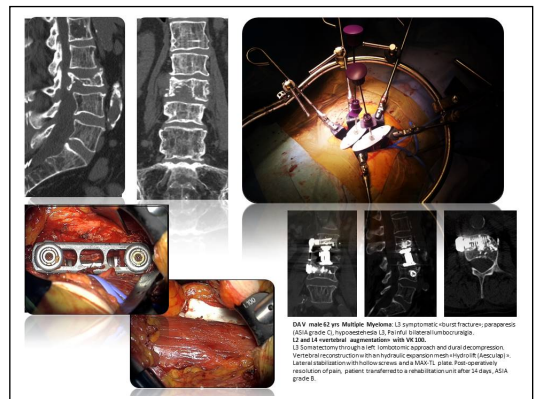
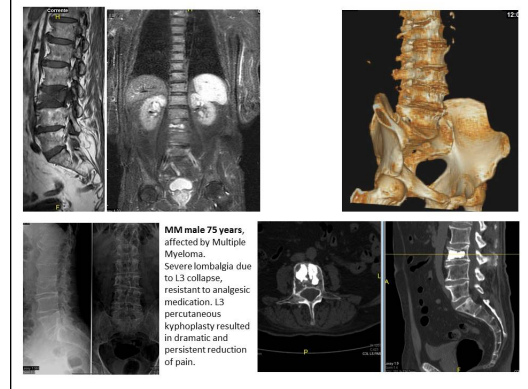
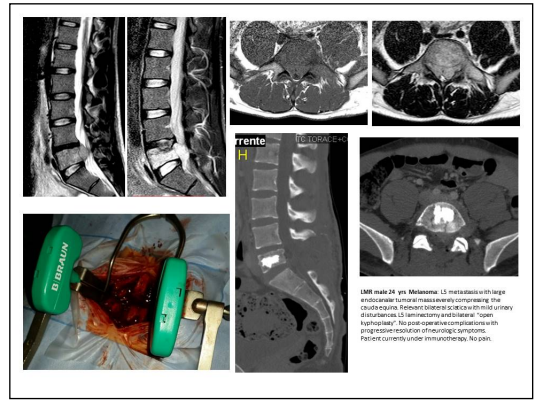
Conclusions

Elastoplasty with VK100 appears a safe and effective palliative treatment of VCFs in oncologic patients. Major advantages over PMMA are the lack of exothermic reaction and the wider working window. The influence of biomechanical properties of silicone on reduction of adjacent level fractures requires further investigations.

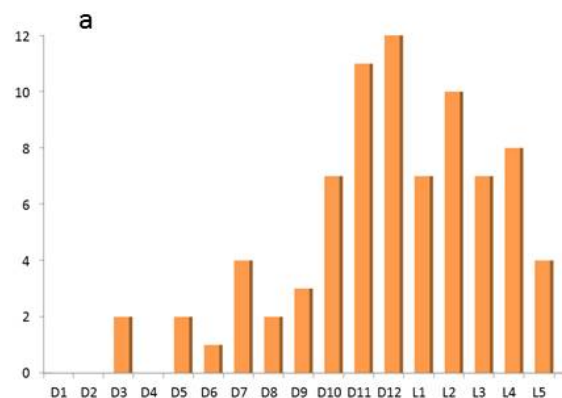


Learning Objectives

Participants should be aware of palliative treatments for pathological VCFs, including BKP and able to evaluate different materials that can be used for this purpose.



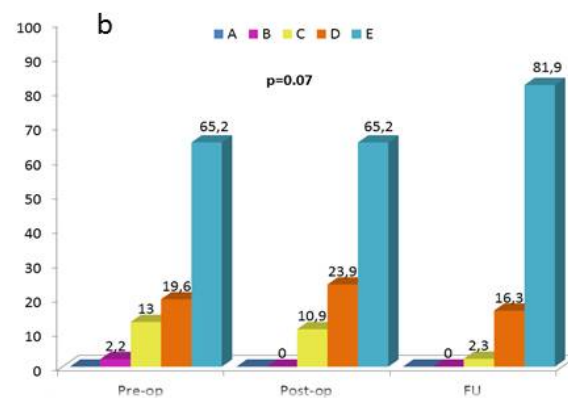




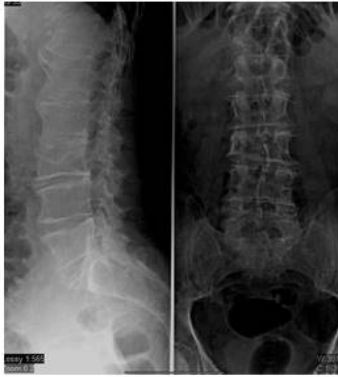
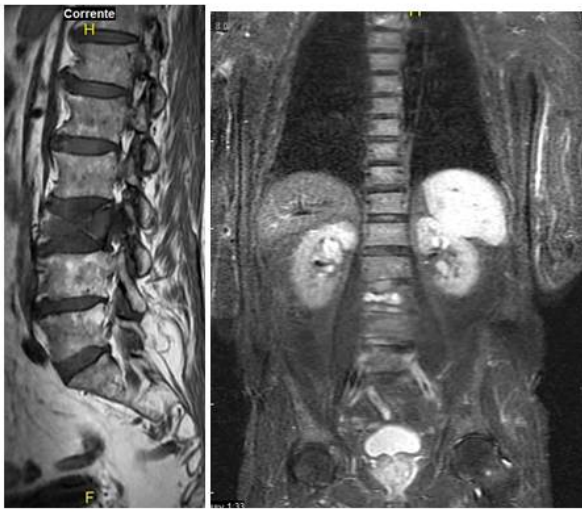
a. Number of fractures by vertebral level

b. Temporal evolution of American Spinal Injury Association grades in 46 patients evaluated preoperatively, postoperatively and at the last follow-up (FU)

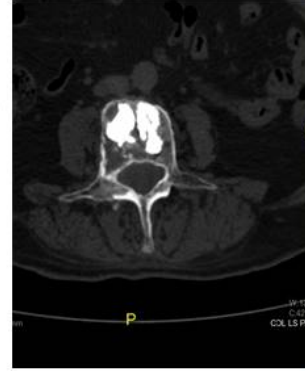
c. Temporal evolution of Karnofsky Performance Status Scale (KPS), Visual Analog Scale (VAS) and Dennis Pain Scale scores in 46 patients as evaluated preoperatively, postoperatively, and at the last follow-up (FU).

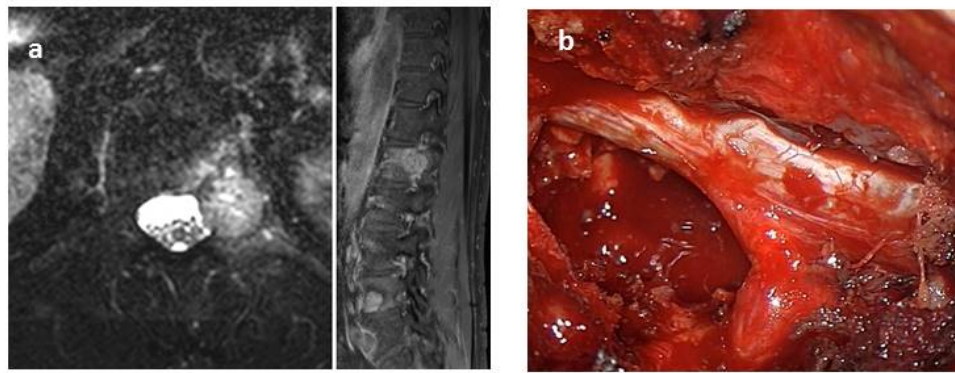


| C | Pre-op | Post-op | FU | P value |
|-------------------------------------|------------|------------|------------|---------|
| VAS median (range) | 80 (60-90) | 40 (10-60) | 30 (0-70) | <0.0001 |
| KPS median (range) | 60 (50-80) | 70 (50-80) | 70 (40-90) | <0.0001 |
| Dennis Pain Score median (range) | 5 (4-5) | 3 (2-4) | 2 (1-5) | <0.0001 |

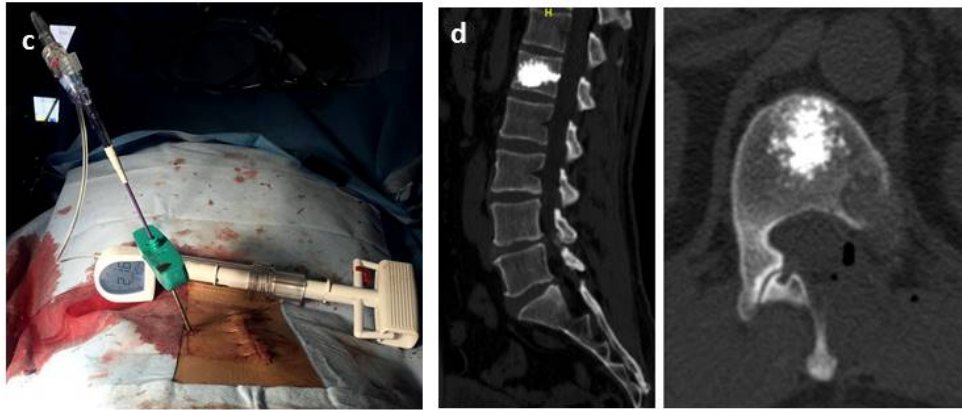


MM male 75 years,
affected by Multiple
Myeloma.
Severe lombalgia due
to L3 collapse,
resistant to analgesic
medication. L3
percutaneous
kyphoplasty resulted
in dramatic and
persistent reduction
of pain.



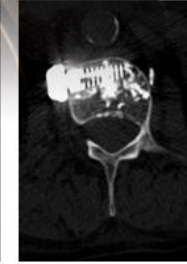
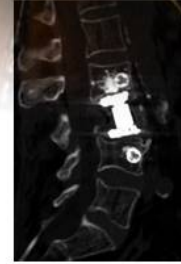
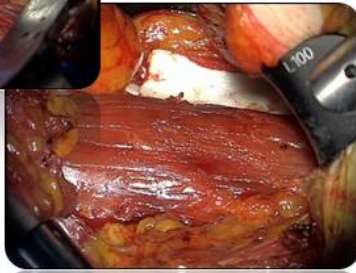
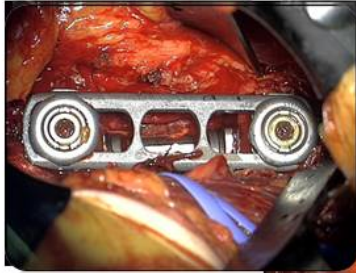
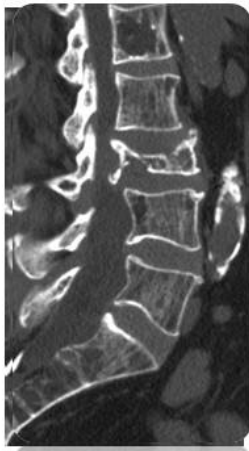


Male 54 years affected by metastatic renal carcinoma a. Pre-operative axial and sagittal T2 weighted STIR spinal MRI. Since one month progressive lumbalgia with irradiation to the left groin. The MRI demonstrated secondary lesions involving L1 and L4. A paramedian left breach in the peduncle and posterior vertebral wall was present at L1. Open elastoplasty consisting in b. a unilateral left hemilaminectomy with root and dural sac decompression followed by c. a temporary closure of the wound and a contralateral elastoplasty. d. Post-operative sagittal and axial CT scans demonstrating the decompressive hemilaminectomy and the filling of the vertebra. Significant pain reduction was observed. RT was subsequently performed to L1 and L4.





LMR male 24 yrs Melanoma: L5 metastasis with large endocanalicular tumoral mass severely compressing the cauda equina. Relevant bilateral sciatica with mild urinary disturbances. L5 laminectomy and bilateral "open kyphoplasty". No post-operative complications with progressive resolution of neurologic symptoms. Patient currently under immunotherapy. No pain.



DAV male 62 yrs Multiple Myeloma: L3 symptomatic «burst fracture»; paraparesis (ASIA grade C), hypoaesthesia L3, Painful bilateral lumbocruralgia.
L2 and L4 «vertebral augmentation» with VK 100.
L3 Somatectomy through a left lombotomic approach and dural decompression.
Vertebral reconstruction with an hydraulic expansion mesh «Hydrolift (Aesculap)».
Lateral stabilization with hollow screws and a MAX-TL plate. Post-operatively resolution of pain, patient transferred to a rehabilitation unit after 14 days, ASIA grade B.