• Treatment carried out over a 2-year period

• 50 patients (32 women and 18 men), mean age 61.8, were treated at 58 vertebral segment levels with the intention to relieve pain related to vertebral body lesion, into 24 thoracic, 32 lumbar and 2 cervical vertebrae, under fluoroscopic guidance.

• It has been shown that a few quantity of bone cement (between 2 and 6ml) is most of the time enough to obtain pain relieve in vertebral osteoporosis or tumoral fractures.

• Bone cement formulation offers better adapted procedure to the technique

• **OSTEOFLEX®** bone cement is low exothermic bone cement for vertebroplasty with a medium viscosity which allows a comfortable and secure application.
Patients were enrolled in the study according to the inclusion criteria:

- Osteoporosis compression fractures
- Primary tumors or metastatic localisation
- Not more than 3 levels involvement

All of the patients had vertebral fracture, all of them suffered from a persistent high level of pain despite the medical treatment.

All the procedures were performed under local anaesthesia and sedation except in 16 patients, in prone position of the patient with imaging control using mostly biplane fluoroscopic guidance.
### Principal Indications

#### Diagnosis

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Men</th>
<th>Women</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Osteoporosis</td>
<td></td>
<td>16</td>
<td>16</td>
</tr>
<tr>
<td>Primary tumor</td>
<td>2</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Lung metastasis</td>
<td>7</td>
<td></td>
<td>7</td>
</tr>
<tr>
<td>Breast vertebra metastasis</td>
<td></td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Kidney metastasis</td>
<td>4</td>
<td></td>
<td>4</td>
</tr>
<tr>
<td>Lymphoma</td>
<td>7</td>
<td>8</td>
<td>15</td>
</tr>
<tr>
<td>Others</td>
<td>2</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>22</td>
<td>36</td>
<td>58</td>
</tr>
</tbody>
</table>

#### Localisation

<table>
<thead>
<tr>
<th>Localisation</th>
<th>Sex</th>
<th>Men</th>
<th>Women</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cervical</td>
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<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Thoracic</td>
<td>7</td>
<td></td>
<td>15</td>
<td>22</td>
</tr>
<tr>
<td>Lumbar</td>
<td>11</td>
<td></td>
<td>23</td>
<td>34</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>19</td>
<td>39</td>
<td></td>
<td>58</td>
</tr>
</tbody>
</table>
Except in 13 patients, all the control of the percutaneous procedure was performed by visualisation with fluoroscopy.

Percutaneous approach was made under sterile conditions with special bevelled Luer-lock needles of 11 and 13 gauge, 12.5cm length.

Introduction of the needle was performed by transpedicular approach.

A special biopsy needle ready to use, allow performing by a simple gesture a bone biopsy.
Osteoflex® is a special cement that was developed for this indication with many advantages according to the entire request to this procedure.

Low exothermic polymethyl methacrylate bone cement charged with high concentration of contrast agent.

This allows a good visualization of the cement during filling of the vertebral body.

The viscosity and setting time of this cement have been specifically designed for vertebroplasty applications.
At 12-24 hours, patients were seen and asked to subjectively report their pain as being improved, unchanged, or worse than before the procedure.

**Before surgery** Disabled (80%) Severe (22%) Moderate (5%)

**After surgery** None – no remaining pain (83%) Mild (15%)

**Functional matter at the beginning** 96% of patients were in bad state: Disabled (35%) Severe (55%) moderated (5%)

**After the surgery** 100% of these patients recover a comfortable functional state as follows: Normal (80%) Mild (20%)

80% of all the patients were able to stop the medication for their pain, 20% of all the patients were able to decrease the amount of oral pain medication that they required on a daily basis.
No major complications occurred in all the patients

Leakage was detected in 25 patients
- 2 anterior and 2 small posterior leakages
- 5 local venous leaks
- 1 leak in soft tissue

*There were no consequences of these leakages*

Recommendation that the injection of the cement at 4 minutes

At the end of the second year we did not detect a new vertebral fracture in these patients

*We can suggest that vertebroplasty can prevent the progression of vertebral collapse at the level of the treated vertebrae.*
This study demonstrated that percutaneous injection of OSTEOFLEX® for treatment of refractory pain resulting from osteoporosis, (16 patients), primitive tumor (3 patients) vertebral fractures, Lymphoma (15 patients), metastasis vertebral fractures (24 patients), rapidly produces significant pain relief and improves mobility.

Our study shows that this rapid analgesic effect is persistent.

The clinical result was very good.

Results reproduced published data and we can recommend use of vertebroplasty for painful vertebral lesions.
Vertebroplasty is very efficient for pain treatment. As we have shown in our study, this procedure restores patient mobility and provides immediate and extended pain relief of symptomatic vertebral body fractures.

Complications were mostly related to excessive PMMA injection, so, in this study, the physicians were conscious to use just the necessary quantity of cement.
**Case 1:**

Cervical vertebroplasty
Lung metastasis
Case 2:
Woman 60 years
Breast metastasis

BEFORE

AFTER
Case 3:

Man 68 years
L1: Myeloma
Case 4:
Man 70 years
Myeloma L1 – L2

BEFORE

AFTER
Case 5:
Woman 59 years
Gynaecologic metastasis
Vertebroplasty of L3
Case 6:
Man 60 years
L3 Lung metastasis
Case 7:

Man 65 years
T4: Lung metastasis
Case 8:
Woman 63 Years
Breast metastasis

Vertebroplasty of T12
Good filling of the vertebra
SAFETY


6. Treatment of painful compression vertebral fracture with vertebroplasty: results and complications.( Il trattamento delle fratture vertebrali dolorose con vertebroplastica: Risultati e complicanze); Giovani Carlo Anselmetti, Andrea Corginier, Felicio Debernardi, Daniele Regge; Instituto per la Ricerca e la cura del cancro Candiolo (Torino) Italy

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