Clinical Report- Osteoflex radiopaque bone cement for vertebroplasty and kyphoplasty
INTRODUCTION

Over a period of 2 years, 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.

The innovation in the 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.

It was developed to resolve all the problems met with conventional preparations.

- This work reports the first clinical use of this cement.

It is true that the technique of percutaneous minimal invasive vertebroplasty found increasing recognition.

The current indication for treatment is the management of pain caused by vertebral metastatic disease, vertebral osteoporotic fracture and hemangioma.

Procedural complications were mostly related to leakage of PMMA into the adjacent structures because of vertebral cortical destruction or fracture, or because the non adapted materials such us low cement viscosity.

This study was undertaken to report the clinical experience with vertebroplasty using a new generation of medium viscous cement ready to use for a consecutive group of patients.

The treatment was performed in prone patient position and under local or general anesthesia.

The treatment protocol involved a percutaneous transpedicular access for thoracic and lumbar spine and anterolateral access was used for the cervical spine.

The direction of the needle was controlled under fluoroscopy and between 2 to 5 ml of the OSTEOFLEX® PMMA was injected.

Injection of cement was done under fluoroscopy control in order to perform the vertebral filling
and to detect PMMA leakages.

We report the clinical experience with percutaneous minimal invasive procedures using the OSTEOFLEX® for a consecutive group of 50 patients.
MATERIALS AND METHODS

Patients

During 2 years, 50 patients were treated at 58 vertebral segment levels with the intention of relieve pain related to vertebral body lesions.

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.

Pre-treatment imaging evaluation was performed within 3 weeks preceding the procedure, using standard radiography, CT or MRI.

In the presence of tumor extension with lysis of the posterior wall, involvement of the pedicule or of the epidural or foraminal spaces, an increased risk to produce PMMA contact with nerve roots or the spinal cord was considered.

Such anatomical conditions were, however, not excluded from treatment, but lead to particular caution during cement injection to avoid complication by compression.

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

Clinical follow-up involved an evaluation using a questionnaire for assessment of pain, pain medication, and mobility.
Principal indications:

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<th>Diagnosis</th>
<th>Men</th>
<th>Woman</th>
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<tbody>
<tr>
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<td></td>
<td>16</td>
<td>16</td>
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<tr>
<td>Primary tumor</td>
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<td>3</td>
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<tr>
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<td>7</td>
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<td>Breast vertebra metastasis</td>
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<tr>
<td>Lymphoma</td>
<td>7</td>
<td>8</td>
<td>15</td>
</tr>
<tr>
<td>Others</td>
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<td>1</td>
<td>3</td>
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<tr>
<td><strong>Total</strong></td>
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<td>36</td>
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<table>
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<th>Women</th>
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</thead>
<tbody>
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<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Thoracic</td>
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<td>15</td>
<td>22</td>
</tr>
<tr>
<td>Lumbar</td>
<td>11</td>
<td>23</td>
<td>34</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>19</td>
<td>39</td>
<td>58</td>
</tr>
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Transpedicular approach

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.
Cement:

**Osteoflex**® is a special cement that was developed for this indication with many advantages according to the entire request to this procedure.

It is 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.

The cement flow can be easily controlled under real time imaging fluoroscopy.

It ensures an optimal and homogenous application.

Because the well adapted viscosity, the injection can be easily performed through 11 gauge needle as well through a thinner **13 gauge**.

The long setting time of this cement (20 mn), gives the surgeon sufficient time to extrude the cement into the vertebral body.

Conventional barium sulphate containing bone cements with their short setting times can not achieve such a challenge and so are less adequate for this application.

The handling time of this ready to use bone cement have been specially designed to give the physician a comfortable application phase with a high level of control of the flow during injection then reducing potential complications.

It has a good mechanical properties regards to ISO 5833 standard.

The injection time, from 4 to 20 minutes, allows performing injection in more than one vertebra at the same time. (Picture 1)
Before injection of the OSTEOFLEX®, the bevel of the needle is located to know the future direction of cement flow.

The PMMA was injected very slowly, the physician followed continuously the flow of the cement to detect any leakage.
RESULTS

The patient’s pain level was assessed before vertebroplasty with use of a visual analogue scale (VAS) of 0-10.

The clinical follow-up included next-day evaluation, reported according to a follow-up questionnaire.

Total follow up was 2 years, evaluated parameters included subjective pain felt in the period, pain medication used in the follow-up period and mobility in comparison with pre-treatment status.

At 12-24 hours, patient were seen and asked to subjectively report their pain has being improved, unchanged, or worse than before the procedure.

As far as the pain matter is concerned, the results show a large improvement for the patient from their initial state.

They efficiently have a good and actual comfort of live with less and largely reduced pains.

Before the surgery, 100% of the patients were between disabled (80%) severe (22%) and moderate (5%) state.

After the surgery, 98% of these 100 % patients are relieved such as follows:

- None (without any remaining pain): 83%
- Mild: 15%

As far as the functional matter is concerned, at the beginning, 96% of patients were in bad state (35% disabled, 55% severe, 5% moderated).

After the surgery, 100% of these patients recover a comfortable functional state as follows:

- Normal: 80%
- Mild: 20%

For the Total Score Rating, the final state of the patients is better than the initial state.

Before the surgery 98% (48/50) of the patients were in poor state.

After the surgery, the repartition was such as follows: 25% good and 75% excellent

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.

All the patients were satisfied with percutaneous vertebroplasty and all patients reported that they would undergo the procedure again.
We were technically successful in all treated vertebrae.
SAFETY

No major complications occurred in all the patients, no systemic events were registered. There were no major adverse events in our patient population.

Leakage was detected in 25 patients, radiographics showed evidence of leakage through the endplate fracture in disk space, because cortical fracture or osteolysis of the vertebral endplates.

2 anterior and 2 small posterior leakages without acute spinal cord or nerve root compression, 5 local venous leaks and 1 leak in soft tissue.

The disc leakage happened in the case of vertebral compression fracture with cortical fractures. This situation is an increased risk for cement leakage into the disk space during vertebroplasty when compared with those without these features.

There were no any consequences of these leakages.

The recommendation is that the injections of the cement begun at 4 minutes, the physicians have to control the viscosity of the cement depending on the room temperature and have to inject the cement at the ideal moment to avoid the leakage.

The long-term follow-up radiographic did not show any modification of the vertebral bodies that had been treated.

At the end of the second year we did not detect a new vertebral fracture in these patient, the physicians respected the protocol to not inject a big volume of cement if not necessary.

We can suggest that vertebroplasty can prevent the progression of vertebral collapse at the level of the treated vertebrae.
DISCUSSION

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.

Previous open studies have demonstrated that percutaneous injection of PMMA into osteoporotic vertebral fractures rapidly produces significant pain relief. (1,2,3)

Our study shows that this rapid analgesic effect is persistent.

Follow-up was obtained in all the patients for 2 years.

The long-term follow-up radiographic did not show any modification of the vertebral bodies that had been treated.

The clinical result was very good, all the patient had a final state pain better than before the procedure as reported in many studies (6)

At the end of the second year we did not detect a new vertebral fracture in these patients, this is perhaps because the physicians respected the recommended protocol to inject a limited volume of cement.

Our results reproduced published data (3, 4, 5) and we can recommend use of vertebroplasty for painful vertebral lesions.

The choice of the material is important, the length of the needle is chosen regarding the corpulence of the patient.

The OSTEOFLEX PMMA was chosen because it has been tested and used with good safety record, and because all the advantages for the biomechanical aspect and specially the high viscosity of this product, its low exothermicity and the long working time.
CONCLUSION

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

Before:

After:

Lateral approach
Complete filling of the lesion
Case 2:

Woman 60 years
Breast metastasis

Before

After:
Case 3:

Man 68 years
L1: Myeloma

Before:

After:
Case 4:

Man 70 years
Myeloma L1 – L2

Before:

After:
Case 5:

Woman 59 years
Gynaecologic metastasis
Vertebroplasty of L3

Before:

After:
Case 6:

Man 60 years
L3 Lung metastasis

Before:

After:
Case 7:

Man 65 years
T4: Lung metastasis

Before

Double approach
Complete filling
Case 8:

Woman 63 Years
Breast metastasis

Before:

Vertebroplasty of T12

After:

Good filling of the vertebra
SAFETY


6. Treatment of painful compression vertebral fracture with vertebroplasty: results and complications. ( Il trattamonto 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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