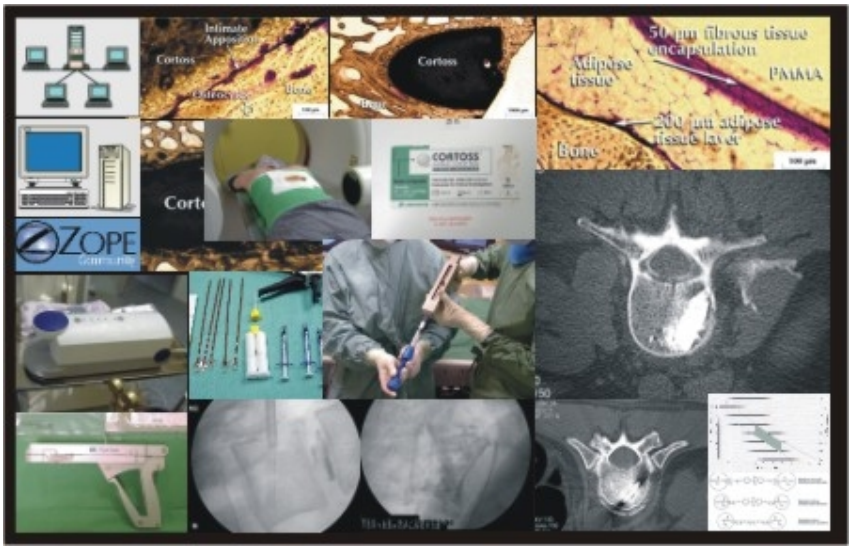

Percutaneous Vertebroplasty: Indications, Advantages and Drawbacks of Different Cements Afshin Gangi MD, PhD. Jean-Pierre Imbert MD. Stephane Guth MD. Horia Marin MD. Lisa Wong. Catherine Roy MD.

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Abstract: Polymethyl methacrylate (PMMA) is the most used cement in vertebroplasty. The new PMMA vertebroplasty cements had resolved the insufficient radiopacity but it needs always a hand mixing. The biocompatibility of PMMA with its exothermic effect is the major drawback (fibrous tissue layer between cement and bone). Another synthetic cement Cortoss® (Orthovitha, Malvern, USA) is developed for vertebroplasty. Its mix-on-demand delivery system allows direct injection of the cement and sets a lower exotherm than standard PMMA. The disadvantages are: less viscous than PMMA (risk of leakage), faster polymerization, and the cost. The Calcium Phosphate Bone Substitute Norian® SRS resorbs via normal cellular remodeling, and maintains strength during remodeling. Norian is very difficult to inject in the vertebrae and the radio opacity is not sufficient. A new calcium phosphate cement, Calcibon®, should be used in percutaneous vertebroplasty because of its better radiopacity. PMMA is cost effective, but its major drawback is the biocompatibility and its exothermic effect particularly criticize in osteoporosis. The Cortoss® seems to be promising in vertebroplasty particularly in osteoporotic patients. The indications of the most expensive cements,calcium phosphate cements, are limited to the vertebroplasty (and sometimes kyphoplasty) of the recent burst fractures.

1) Introduction

Vetebroplasty is a percutaneous imaging-guided technique used for the treatment of pain and the strengthening of bone by injecting bone cements into a vertebral body.

The indications of this procedure are osteoporotic compression fractures and tumors (primary or secondary) of vertebral bodies.

Different kinds of cements are used and this study will describe the properties and the modalities of each cement and will illustrate the best indications for each of them.

2) Historical review

Bone cements were used for several decades in orthopaedic surgery in order to fix material and to strengthen bones. Vertebroplasty was originally an exclusively open procedure performed to fill voids resulting from tumor resection or to fix pedicle screws. However, this open procedure includes risks that should be avoided.

Therefore, Galibert and Deramond performed the first percutaneous procedure in 1984 in the treatment of a painful vertebral hemangioma of the C2 vertebra. This technique was used in conunction with a first surgical laminectomy.

Encouraged by an excellent response, they continued their investigations and first published the results of seven patients treated by percutaneous vertebroplasty in 1987. They proposed the injection of polymethylmethacrylate (PMMA) in vertebral bodies with symptomatic hemangiomas in order to reinforce the bone and to relief the pain.

Following these first encouraging results, the indications of the vetrebroplasty were significantly expanded and now osteoporotic compression fractures, myeloma and metastatic osteolytic bone lesions account for the majority of them.

The first cement used with good clinical results was PMMA which is still used effectively. However, the chemical and physical properties of this cement made it a less than optimal cement for some indications.

Therefore, other cements are now available such as composite cements (e.g., Cortoss®-ORTHOVITA®) and calcium phosphate cements (e.g., Norian SRS®, Calcibon®). Their properties tend to make them more biocompatible and less toxic with bone tissues.

3) Review of injectable cements

PMMA is no longer the only injectable cements available for vertebroplasty. In the past few years, new cements, some of which were already used in other indications, were modified to an injectable form. The goal of each manufacter is to find the best cement in terms of biocompatibility, injectability, mechanical properties, radiopacity, and rheological properties.

This chapter will describe the properties in each broad category of injectable cements:

- PMMA
- Composite cements
- Calcium phosphate cements

4) polymethylmethacrylates : Review of injectable cements: Polymethylmethacrylates (PMMA)

4a) Properties

- It is the first and most widely used cement in vertebroplasty. Its mechanical properties allow a durable result to be obtained in the treatment of osteoporotic compression fractures and tumor invasion with low complication rates.
- PMMA cements are, due to their low viscosity, easy to inject into vertebral bodies.
- The composition of PMMA consists of:
  - Methylmethacrylate/dimethyl-p-toluidin monomer (liquid)
  - Methylmethacrylate/methylacrylate polymer (powder).
- PMMA is generally unreactive in bone formation. Pathological examination demonstrates a fibrous tissue layer between implanted PMMA and bone.
- During the polymerization of the PMMA, the temperature of the cement reaches 80° to 120°Celsius. Moreover, this exothermic reaction could potentially damage adjacent tissues in case of cement leakage. Although, this thermal effect induces cell coagulation that could be useful in the pain management of malignant tumors (e.g., metastatic lesions).

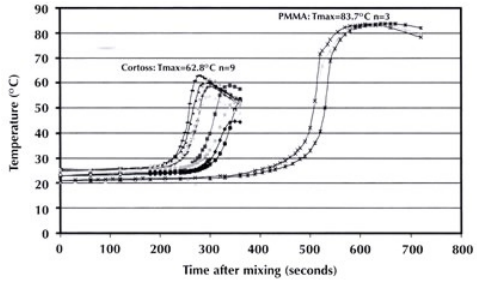

Figure 1: Exotherm temperature profile of Cortoss® and PMMA as a function of time.

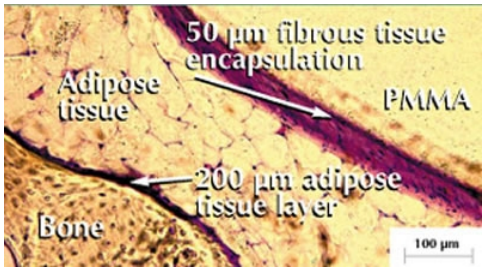

Figure 2: 78-week PMMA histology (sheep). Soft tissue encapsulation of prepolymerized PMMA.

- The mechanical properties of PMMA are detailed in the next chart:

The mechanical properties of PMMA	
Compressive strength	82 Mpa
Tensile strength	27 Mpa
Flexural strength	100 Mpa
Modulus	2,76 GPa

4b) Modalities of use

4b1) Preparation of the cement

- Before the injection, the two components (20 g of powder and 20 ml of liquid monomer) of PMMA (Osteopal®-Biomet Merck, Palacos® or Simplex® P-Stryker Howmedica Osteonics) need to be well mixed in order to obtain a homogenous mixture.

Figure 3: Mixing of the monomer (liquid) and the polymer (solid).

- The monomer-to-polymer ratio recommended by the manufacturers is 0,5ml/g. However, most of the time, physicians do not respect this ratio in order to obtain a longer setting time and to decrease the viscosity of the cement. This modification may increase the unreacted monomer (liquid) content available to enter the circulatory system and induce arterial hypotension, cardiac or neurological dysfunction.
- The radiopacity of those cements is also not sufficient for fluoroscopic monitoring in vertebroplasty procedures. To obtain a safe radiopacity of the cements, a radio-opaque contrast should be used. Those agents available are tungsten, tantalum, barium sulphate, titanium, zirconium or gadolinium powders.
- Meanwhile, the different changes in and manipulation of the cement composition (addition of contrast, modification of the polymer-to-monomer ratio, withdrawal of some quantity of cement mixture) increase the risk of sterility mistakes and alter the mechanical properties of the cement, especially the strength and the compressive properties.

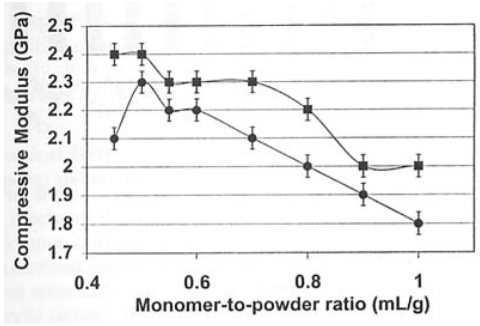

Figure 4: Cement compressive modulus as a function of the monomer-to-powder ratio for Simplex® P.

- Moreover, those different changes of the initial composition of the cement induce a modification of the approval of the cement by the different authorities and manufacturers.
- Therefore, there are now new “ready for use” PMMA cements for vertebroplasty (Osteopal® V- Biomet Merck, Vertebroplastic® - Johnson and Johnson®) which allow safe injection without manipulation of the cement.

Figure 5: Presentation of the Osteopal® V (specific cement for vertebroplasty).

- In this cement, the addition of zirconium to the composition makes it radiopaque enough for fluoroscopic monitoring. The composition of one of this cement (Osteopal® V) that we use in our departement is:
- Powder (26 g): polymethyl acrylate, methyl methacrylate, zirconium dioxide, benzoyl peroxide
- Liquid (10 ml): methyl methacrylate, N,N-dimethyl-p-toluidine.
- This new presentation allows an easier, faster and safer injection of the cement into vertebral bodies.

4b2) Injection of cement

- PMMAs have a long setting time (8 minutes, depending on the ambient temperature) and during that time, the cement keeps almost the same viscosity. Those two conditions allow a safe injection in the bone with an appropriate injection set.
- The optimal temperature is as close as possible to 20°C. Higher temperatures will reduce the setting time.
- In our department we use an injection set with a special bevelled needle for the introduction of the cement into the vertebral body.

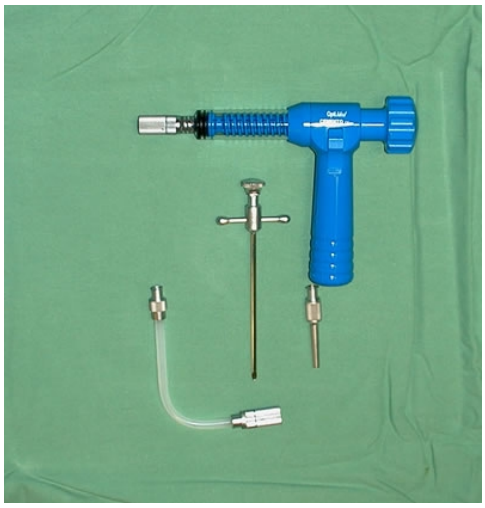

Figure 6: Injection set (Cemento®-Optimed Merck)

- After the positioning of the needle, the pressure syringe allows us to maintain constant pressure during the injection of the cement by slowly turning a screw.
- When minor leakage occurs, we can immediately stop the injection by removing the pressure inside the syringe to avoid more significant leakage (see Vertebroplasty with PMMA section).

5) composite cements : composite cementoplasty cements

5a) Properties

- Bisphenol-a-glycidyl dimethacrylate (bis-GMA) resins have been used since the late 1970's in orthopaedic applications (pedicle screws augmentation). Those cements were developed in order to offset such disadvantages of PMMA as exothermic reaction, possibility of the release of unreacted monomer in the circulatory system and modification of the initial composition of the PMMA (changes in the monomer-to-polymer-ratio and addition of contrast materials).
- The research was also directed to obtain more biocompatible, easy-to-handle cement with sufficient radiopacity and with good biomechanical properties.
- One of these composite cements is Cortoss® developed by Orthovita (Malvern, USA).

Figure 7: Presentation of Cortoss® synthetic cortical bone void filler.

- This product was already used in craniofacial surgery and for dentistry. Now a multicenter study has evaluated Cortoss® as bone void filler for percutaneous vertebrobplasty.
- Major components that make up Cortoss® are:
  - Bisphenol-a-glycidyl dimethacrylate (Bis-GMA)
  - Bisphenol-a-ethoxy dimethacrylate (Bis-EMA)
  - Triethylene glycol dimethacrylate (TEGMA)
  - Glass and ceramic fillers (to stimulate bone apposition)
  - Barium boroaluminosilicate glass (for radiopacity and strength)
  - Silica (for improved viscosity)

- A study compares the biocompatibility and interfacial bond strengths of Cortoss® synthetic cortical bone void filler with a PMMA use in percutaneous vertebroplasty (Simplex® P) implanted into rabbit femurs for up to 52 weeks and in sheep long bones for up to 78 weeks.
- This study showed that new periosteal and endosteal bone were formed within defect sites filled with either both of the cements but that the initial response was greater with Cortoss® than with the PMMA. Concerning the bone formation, new blood vessels invaded the periphery of Cortoss® implants whereas PMMA was unreactive.
- Both cements were surrounded by bone in the long term but half the Simplex® P specimens were separated from bone by a layer of fibrous connective tissue at 24 weeks.
- In terms of displacement forces, this study shows an augmentation with time for both cements but these displacement forces were greater for a rod held in place with Cortoss® than with PMMA. A relative strength difference of 4,5 Newton was observed between the two cements after 24 weeks. This difference is attributed to a faster initial bone response and a greater degree of mineralization around Cortoss®.
- Another advantage of composite cements is the low temperature at which they become solid. The major temperature does not exceed 58 °C.
- This property avoids adjacent tissues alterations but also avoids the cell coagulation.

- Other properties of Cortoss® are described next:
  - The fatigue strength is measured to 10 million cycles in load compression for both Cortoss® and PMMA cements.
  - Cortoss® survived 10MM cycles at 80 Mpa in compression.
  - Cortoss® survived 10MM cycles at 15 Mpa in tension.
  - PMMA failed at 10MM cycles at 45 Mpa in compression.
  - PMMA failed at 1MM cycles at 15 Mpa in tension.
  - Highest creep of Cortoss® in 24 hours was 22% (at 180 Mpa).
  - Highest creep of PMMA in 24 hours was 82% (at 80 Mpa).

The mechanical properties of Cortoss®	
Compressive strength	210 Mpa
Tensile strength	57 Mpa
Flexural strength	118 Mpa
Modulus	5,8 GPa

5b) Modalities of use

5b1) Preparation of the cement

- Cortoss®, contrary to PMMA, does not need any manual mix of the 2 components (monomer and polymer).
- Cortoss® is a two-part paste system that is packaged sterile in a delivery cartridge. Disposable mix tips blend the 2 pastes automatically at the time of injection. The cement is also never mixed at once (“mix-on-demand system”) that allows physicians making the injection not to hurry.
- While the exotherm of Cortoss® remains low, the temperature of the material as well as the temperature of the body can affect the set time.
- The optimal temperature of Cortoss® to be used is as close as possible to 20°C. Higher temperature will reduce the setting time.
- To obtain a good fluoroscopic visualisation, there is no need to modify Cortoss®. It contains over 65% of radiopaque fillers.

5b2) Injection of the cement

Cortoss® system use syringes and catheters for the injection in the vertebral bodies.

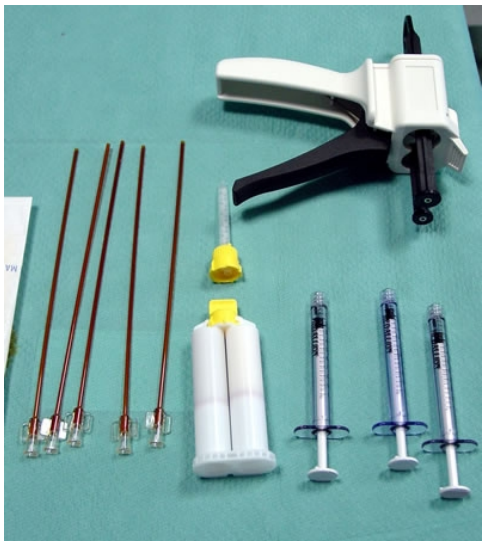

Figure 14: Material used for Cortoss® (delivery gun, cartridge of pastes, syringes and catheters).

- 1 cc Luer-Lock syringe is connected to a catheter and both are filled with the cement using the delivery gun and the mix-tips. After that, the catheters are inserted successively in the needle until obtaining the optimal filling of the vertebral body.
- Concerning the viscosity, Cortoss® remains at the same viscosity state during a large percentage of its set time until a “snap-set”.
- This could be an advantage or an inconvenience:
- An advantage, for an easier injection during all the filling time of the vertebrae.
- An inconvenience, because of the continuous risk of leakage during all the injection. After approximately 8 minutes, fast setting would occur with risk of blockage of the needle inside the vertebrae.

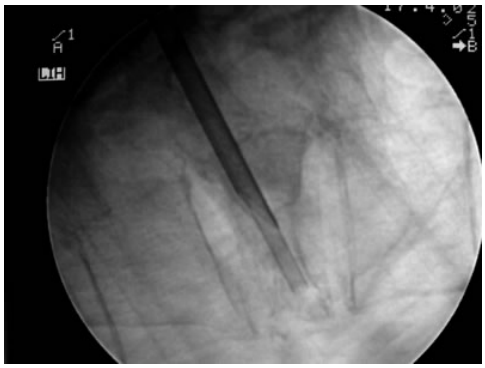

Figure 15: Treatment of an osteoporotic compression fracture with Cortoss® . Lateral fluoroscopic view. Introduction of the catheter through the needle.

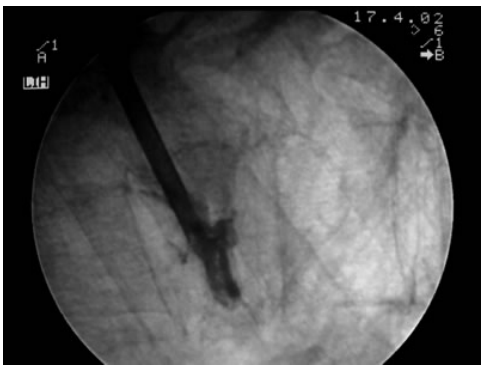

Figure 16: Injection of Cortoss® in the vertebral body under lateral fluoroscopic guidance. Good radio-opacity.

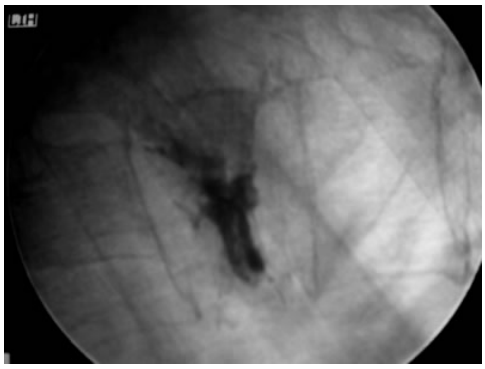

Figure 17: Lateral fluoroscopic view. Final result.

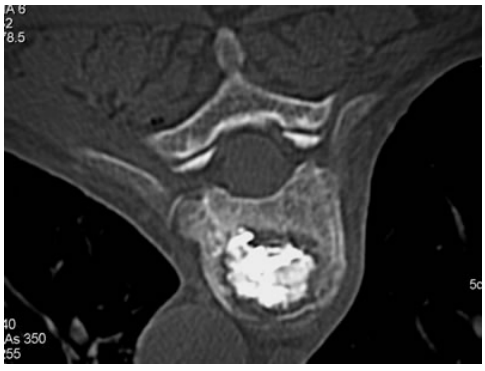

Figure 18: Axial CT. Good distribution of Cortoss® in the vertebral body.

- Moreover, in our experience, the catheter-and-syringe system for cement injection is also not so easy and safe. It compels the physician always to prepare new syringes during the injection of the same vertebral body. The pressure of the injection created by the fingers of the physicians varies with each person and the progression of the cement through the catheter does not stop immediately when the physician removes the pressure. The major consequence of these drawbacks is an increase risk of cement leakage.

6) The calcium phosphate cements : Calcium Phosphate Cements (CPCs)

6a) Properties

- The introduction of an external component in the human body brings up the general problem of biocompatibilty. Bone cements also need to be bioactive and stimulate bone formation. Calcium phosphate cements (CPCs) are now injectable and are used in vertebroplasties.
- CPC are made of one or several calcium phosphate (CaP) powders and an aqueous solution. CPCs belong to the category of the low-temperature CaPs that are obtained by precipitation from an aqueous solution at or around room temperature.
- Low temperature CaPs are made of precipitated hydroxyapatite (PHA) and are very similar to the mineral part of bone. They have also a very large specific surface area (100m²/g) which makes CaP biologically much more reactive. Two broad categories of CPCs exist, depending on the end product obtained: apatite (PHA) and brushite (DCPD).
- Considering their properties, CPCs might potentially be used in vertebroplasty to reinforce osteoporotic vertebral bodies and thoracolumbar burst fractures.
- The compressive strength is always greater than the tensile strength because of the fragility of the CaP; nevertheless, the mechanical properties of CPC are lower than those of PMMA.

The mechanical properties of calcium phosphate cements	
Compressive strength	10-100 MPa
Tensile strength	1-10 MPa

- These initial mechanical properties may vary with implantation time and animal studies have shown that mechanical properties of apatite CPCs tend to increase continually, in contrast to those of brushite CPCs, which initially decrease and then increase when bone grows. This is the result of different porosity and bioresorption between apatite and brushite CPCs.
  - Furthermore, in comparision with PMMAs, CPCs have longer cure times and maximum compressive strength is achieved over a 24-hours period.
  - Concerning the bioresorption, apatite CPC is less bioresorbable than brushite CPC. Moreover, when the crystal size increases or the porosity decreases, the bioresorption will be longer. Norian® SRS (Norian) and a-BSM® (Etex-Merck) are therefore expected to bioresorb faster than BoneSource® (Orthofix-Howmedica), Biopex® (Mitsubishi) and Cementek® (Teknimed). A study

reported a 30% decrease in the amount of Norian® SRS in a rabbit femur after 24 months.

- Another calcium phosphate cement is also now available on the market in Europe: Calcibon® (Biomet-Merck). This cement is injectable and both animal and clinical studies have shown that it has appropriate mechanical properties which allow good results in the filling of cancellous bone defects.

Figure 19: Presentation of Calcibon®.

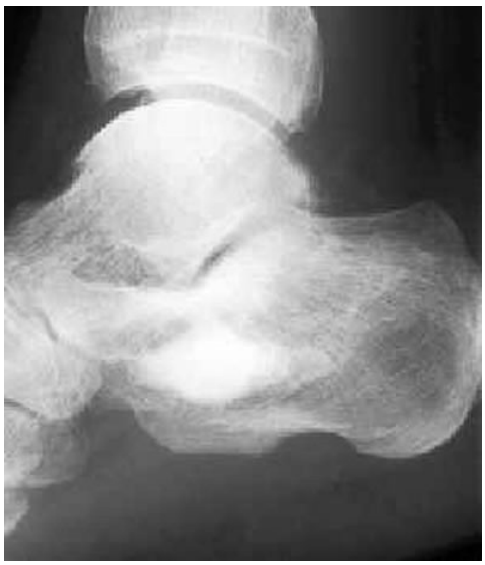

Figure 20 : Lateral radiographic view. Filling with Calcibon of a cancellous bone defect in a calcaneum. Better radio-opacity than Norian®.

- This cement hardens at body temperature in about 10 minutes and reaches its final compressive strength after 3 days (about 60MPa). This strength exceeds the

compressive strength of cancellous bone (5-20 MPa) and is as strong as some cortical bone (25-100 MPa).

- The biocompatibility of Calcibon® is due to its chemical composition and its crystalline structure that mimic the chemical composition of natural bone mineral. The histological evaluation after 2 weeks shows an abundant bone apposition on the Calcibon® surface without any inflammatory reaction or fibrous encapsulation. Osteoclast-like cells were resorbing the bone substitute.
- The mechanical and rheological properties of Calcibon® should permit its indication in vertebroplasty. It appears more radio-opaque than Norian® and its injection under radiologic guidance would be easier and safer in comparision with others CPC. Further studies have to evaluate its efficiency in terms of pain relief and technique of injection.

Figure 21: Rheological property of Calcibon®.

- Moreover, the mechanical properties of the different CPC depend on the composition of the cement. The main factor is the ratio between the amount of cement powder (P) and the mixing liquid (L).
- If the P/L ratio is large, the porosity of the cement is low. In addition, the mechanical properties of a CPC increase when the porosity is low. However, the less porous the cements are, the less bioresorbable they are. So, there is a balance to find between the porosity and the mechanical properties of CPC to obtain a cement with good resorption, with sufficient compressive and tensile strengths as well as good rheological properties in order to inject them into bones.

6b) Modalities of use

6b1) Preparation of the cement

- Calcium phosphates hqve been known as bone repair materials for the last 80 years but they have only been used in spinal surgery more recently as granules or blocks in interbody fusion and scoliosis surgery. CPCs, due to their biocompatibility, represent a new and interesting product which can be used as injectable cement for vertebroplasties.
- However, to be injected in the vertebral bodies, those cements must have two features: injectability and cohesion.

- To avoid the demixing (separation of the mixing liquid and the cement powders), manufacturers have adapted the composition of the cements in order to obtain good cohesion, always keeping the best porosity, fluidity and mechanical properties as possible.
- Concerning the radio-opacity, CPCs are intrinsically radio-opaque. Their radio-opacity should depend on the porosity of each cement and in practice they are often not radio-opaque enough . The addition of radiopacifers in bioresorbable cement is not recommended due to the unknown biological outcome of these small radio-opaque particles.
- The preparation of the cement needs to be mixed well and there are mixing devices or instructions provided with the cement in order to obtain a paste ready for injection.

Figure 22: Presentation of Norian® SRS.

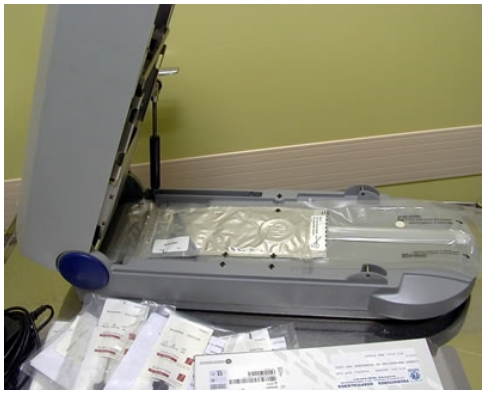

Figure 23: The mixing device for Norian® SRS.

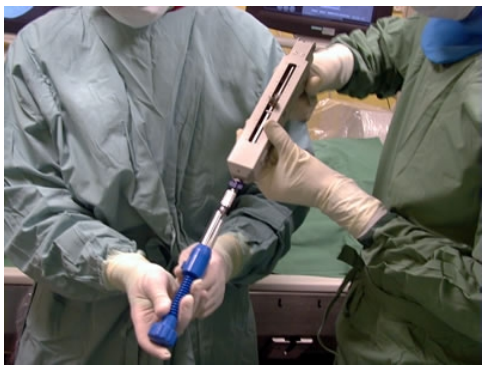

Figure 24: Introduction of Norian® SRS in the injection set (Cemento®).

6b2) Injection of the cement

- When the paste is ready, the cement can be injected, but it is always very difficult to inject these cements in the vertebrae. This is due to the cements that are more viscous in order to maintain their cohesion and also to the hydrophilic property of CPC. They tend, therefore, to mix with body fluids and lose their cohesion.
- **Concerning their injectability, they are the opposite of the PMMA cements, which are hydrophobic and tend to stay compact within the vertebral bodies.**
- In order to prevent this problem, two solutions exist:
  - **creation of a cavity in the vertebral body with an expandable balloon and filling of the new cavity with CPC.**
  - **removal of bone marrow from the vertebrae using a suction device and injection of the CPC.**
- In our department, we use CPC in the treatment of recent burst fractures of thoracolumbar vertebral bodies in young patients. In such cases, the use of a bioresorbable cement is justified. Most of time, the consolidation of these fractures requires a complementary kyphoplasty.
- Therefore, the use of an expandable balloon has two indications:
  - **correction of the kyphosis**
  - **creation of the cavity for an easier injection of the cement**

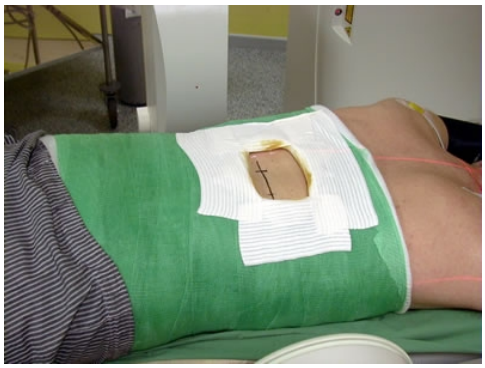

Figure 25: Position of the patient before percutaneous vertebroplasty. Burst vertebral fracture stabilised by brace.

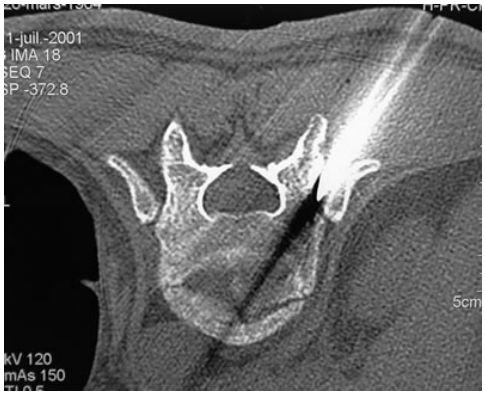

Figure 26: Axial CT. Introduction of the spinal needle inside the vertebral body through an intercosto-transverse approach.

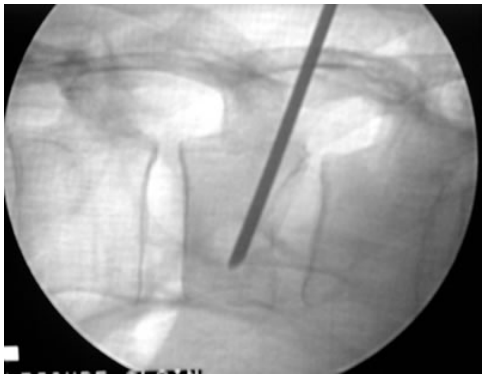

Figure 27: Lateral fluoroscopic view. Definitive positioning of the needle.

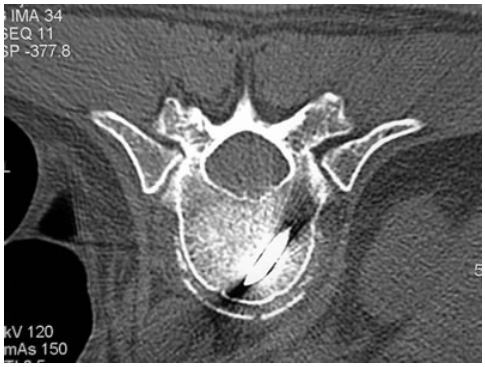

Figure 28: CT. Final result after injection of Norian® SRS.

7) discussion

The different properties of injectable cements will be analysed and we will try to propose how to choose the most appropriate cement for each indication.

All cements need to have some properties to be indicated in percutaneous vertebroplasty:

- Injectability
- Easy and safe injection (viscosity, appropriate injection set)
- Long setting time
- Sufficient radio-opacity
- Adapted mechanical properties.

The three categories of cements we have described share these properties. Each cement has some specificities which could be used and adapated to each pathological case.

As **PMMAs** are the most widely-used and were the first cements available for vertebroplasty, they combine the advantages of long trial experience, low cost, good radio-opacity with some drawbacks. The major drawback of the PMMAs is their toxicity and their non-biocompatibility. This toxicity, due to a **significant exothermic effect,** is an inconvenience in the treatment of vertebral bodies without any malignant component (osteoporotic or post-traumatic vertebras).

We have seen, however, that this thermal effect will provoke a cell necrosis (coagulation) that could be an interesting property in the malignant vertebral body lesions.

The recent development of **new radio-opaque PMMA** (osteopal V®) makes the preparation and the injection of the cement inside the vertebral body easier and safer. Malignant tumors which sometimes present large osteolysis of the cortical bone, particularly on the posterior wall, require very accurate and careful injection of the cement. To avoid leakage, particularly difficult cases would be better treated with such a radio-opaque cement combined with an **appropriate injection set.**

The **Composite Cements** (Cortoss®) combine biocompatibility and easy handling **("mix-on- demand system").** The initial clinical results show that pain relief occured in a percentage near that for PMMAs. This effect obtained on pain at a low curing temperature cement seems to support the theory of the **mechanical effect** of the injection of cement as the **major reason of pain relief in opposition to the exothermic effect.**

With composite cements, the consequences of leakage are offset by the **non-toxicity** of the cement. However, the system of syringes and catheters for the injection of the cement is not ideal. The snap-set could also be dangerous and could lead to a blockage of the needle inside the vertebral body. In our opinion, an optimized product would include a modified **injection system** designed for greater safety.

Because of the **low curing temperature** and the **mechanical properties** of these composite cements, the treatment of **osteoporotic compression fractures should be, in our opinion, the best indication for this category of cements.**

The next figure will summarize the advantages and drawbacks of the different cements and specify, according to our experience, which indication we propose for each of them.

Common properties of bone cements - Injectability - Adapted and lasting mechanical properties - Biocompatibility (toxicity)		
PMMA	COMPOSITE CEMENTS	CALCIUM PHOSPHATE CEMENTS
Advantages		
Exothermic effect with cell coagulation (tumors) Easy and safe injection with an appropriate set Good radio-opacity(new PMMA) Low cost	Low curing temperature (osteoporosis) Biocompatibility	Low curing temperature Bioresorption Greatest biocompatibility
Drawbacks		
Exothermic effect (osteoporosis) No bioresorption	Injection system Low viscosity Abrupt setting (8mn) Cost	Difficulty of injection Insufficiency of radio-opacity (Norian®) Risk of demixing at high pressure of injection High cost
Best indications in order		
1.Tumoral lesions 2.Osteoporotic fractures	1.Osteoporotic fractures 2. Tumoral lesions	Recent post-traumatic burst fractures

8) conclusion

We propose a decisional tree to determine the suitability of different injectable cements according to specific pathologies (see discussion). The recent development of PMMAs and the market introduction of new bone cements (composite cements and calcium phosphate cements) allow physicians to choose the best material for the treatment of different lesions causing vertebral pain. Further study and progress will be required to allow better management of spinal pain due to vertebral lesions. A larger selection of cements dedicated to specific indications will optimize the future role of cements in the application of percutaneous vertebroplasty.

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