

- Percutaneous bone augmentation. State of the art
Injections percutanées intra osseuses (état de l'art)
S Becker (Vienna), P Sharrock (Castres)

- Injectable polymeric biomaterials. State of the art
Biomateriaux polymeriques injectables (état de l'art)
G Maestretti (Fribourg), N Dunne (Belfast)

- Bone Remodeling
Remodelage osseux
F E Mc Kiernan (Marshfield)

- Injectable bone substitutes
Substituts osseux injectables
M Bohner (Bettlach), G Maestretti (Fribourg)

Polymerization of acrylic bone cement and environmental temperature

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We have prepared a low viscosity bone cement containing 7% by weight of Hydroxylapatite powder. The polymerization of this cement was studied as a function of the cement's temperature at the moment of mixing and as a function of the environmental temperature. The cement was placed in an isolating medium (pelvic duck bone) or a conducting medium (stainless steel) in various quantities. A thermocouple was placed in the hardening cement to follow the temperature rise during the polymerization reaction. Simultaneously, an infrared temperature sensor was used to record the temperature on the outside of the holding medium.

We observed that the temperature peak decreases as the mass of cement decreases. In bone, it goes from 55°C for 8g of cement to 38°C for 2g of cement when the initial temperature is near 20°C. The maximum temperature is reached at 10 minutes for 8g of cement and at 14 minutes for 2g of cement. There is a significant temperature difference between the inside and outside temperature of the bone ranging from 2°C to 8°C.

For 2g of cement placed in stainless steel sandwich, the initial cement temperature was set at 15°C and the metal at 10°C, 15°C or 20°C. The corresponding temperature rises were 19.3°C, 21.0°C and 28.8°C, while the

Tmax times were 14, 11 and 13 minutes. When both the metal and the cement were at the same initial temperature (15°C), the polymerization began at 5 minutes and a constant temperature difference near 1.5°C was observed between the cement and the metal. When the metal was at 10°C, the cement's temperature decreased to 13°C after 6 minutes then rose slowly to reach at 4°C difference above the metal's temperature. When the metal was at 20°C, its temperature decreased to 17°C at 7 minutes then followed closely the cement's temperature rise with less than one degree difference. We conclude that the metal acts as a heat sink for the exothermic polymerization and retards the time to reach the maximum temperature except when the metal is initially warmer than the cement.

DSC measurements revealed the heat of reaction to be constant for the different conditions but split into one broad and one sharp exothermal peak. Residual monomer analyzed by GC was less than 1% in all cases. The mechanical shear strengths were statistically equal for all temperatures. This leads us to propose that pain relief during vertebroplasty is not related to monomer release or temperature effects but simply to mechanical stabilization.

Surgical technique of associated percutaneous fusion and kyphoplasty for high energy thoraco-lumbar spine fractures

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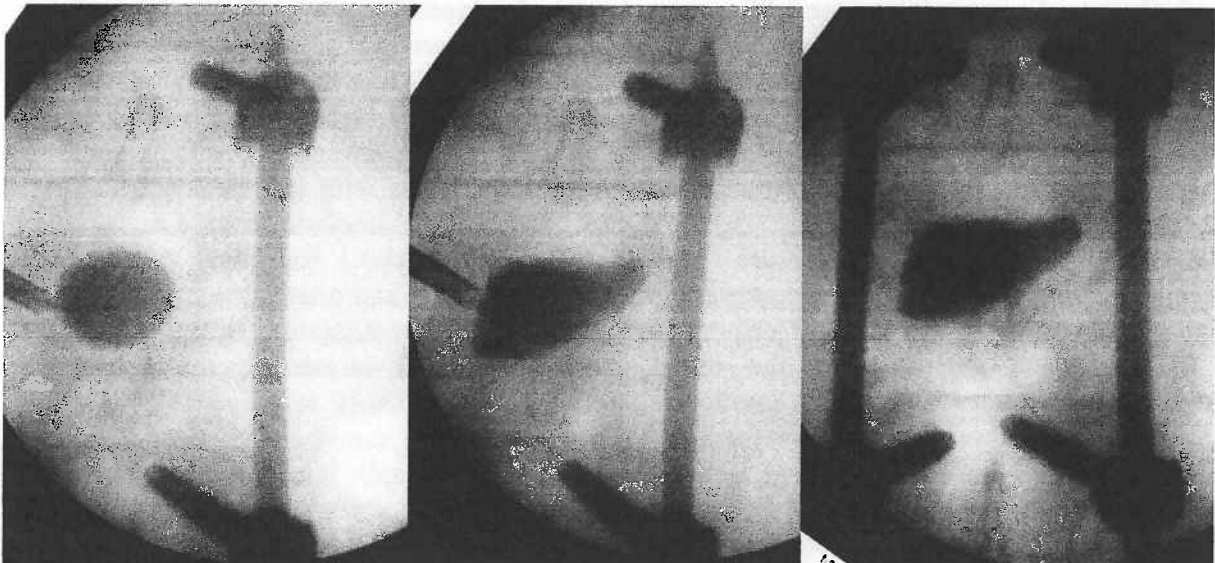
Type of communication: operative technique

We report and describe through operative pictures, and radiographies the installation tricks, surgical technique and operative steps of percutaneous fusion coupled with kyphoplasty. Illustrations of patient and radioscopy equipment are operative photographs.

Surgical technique is illustrated by operative photographs and radioscopy image step by

step. Tricks and pitfalls are illustrated along the description of the procedure

Specificities of our experience are indications (including high energy fracture usually treated by open posterior procedure or double anterior/posterior procedures) and use of unilateral approach for one-balloon kyphoplasty.



Monomer release from PMMA bone cements during vertebroplasty

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INTRODUCTION:

Vertebroplasty is now regarded as a safe and effective treatment of osteoporotic vertebral body compression fractures in terms of pain relief and disability improvement [1]. But despite these demonstrated benefits, vertebroplasty using PMMA bone cements has to be done with caution because of the potential complications due to the material, such as the toxicologic effects related to the MMA monomer released during polymerisation. Taking into account these considerations, a necessity exists for investigations of the amount of monomer released during vertebroplasty under conditions that more closely approximate in vivo use.

Accordingly, the aim of this study was to determine the release of monomer from PMMA bone cement during polymerisation.

MATERIALS & METHODS:

The experimental procedure involved immersion of reacting monomer powder mixtures into distilled water and subsequent assay of the aqueous media for MMA monomer measurement by gas chromatography.

Commercial vertebroplasty bone cements were used for this study: Spineplex, Stryker; Osteopal V, Heraeus Medical; Opacity+, Teknimed and SpineFix, teknimed. Each cement formulation was analysed in duplicate.

Mixing was performed for 1 minute for all cements with the Mini Malax vertebroplasty kit at a constant temperature of $23^{\circ}\text{C} \pm 1^{\circ}\text{C}$.

To measure the monomer release, 4 ml of mixed bone cement were injected into aqueous media at 37°C . Aliquots of liquid samples were withdrawn at different periods of time following injection and analysed.

RESULTS & DISCUSSION:

As already observed in previous studies [2], the main proportion of monomer release occurred within the first minutes after

injection and then remained constant. This first period corresponds to the time during which the monomer powder mixture is curing and cannot be avoided as the cement has to be inserted into the vertebra while it is still injectable before final setting occurs. The amount of released MMA ranged between 3 and 8 mg/ml of bone cement volume, the highest levels being obtained for Spineplex bone cement. These amounts are quite comparable to results reported by other authors [3]

The test quantity of 4ml used in this study, the mean quantity injected into a vertebra, represented volumes two to three times lower to those used for hip and knee arthroplasty. We can then reasonably think that the risks encountered by the patients during vertebroplasty are less important than for an arthroplasty, provided that manufacturer recommendations are respected.

CONCLUSION:

The amount of monomer released during polymerisation was found to be comparable for all cements except Spineplex which exhibited a higher release.

By increasing the time interval before injecting the cement, a technique employed in vertebroplasty to get the optimal viscosity that permits to avoid leakages, the amount of monomer released should be reduced.

More studies taking into account the viscosity and then as a consequence the injected volume and effective surface could help to improve the safety of the vertebroplasty technique.

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Cement leakage and filling pattern study of low viscous VERTEBROPLASTIC versus high viscous CONFIDENCE cement

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INTRODUCTION: Vertebral body augmentation has recently evolved as a medical procedure for the treatment of vertebral compression fractures related to osteoporosis. Though this procedure has been reported to be effective, cement leakage into the spinal canal and/or the cardio vascular system may lead to serious complications. This study compared the cement leakage, filling behaviour and intravertebral pressure of two existing delivery systems (CONFIDENCE and VERTEBROPLASTIC). The comparison was performed using an established benchmark model [1] wherein the cement leakage, filling behaviour can be assessed.

METHODS: Three groups related to VERTEBROPLASTIC system and cement were injected at 3.5, 6.5, and 9.5 minutes after admixing the powder and monomer respectively. The two other groups related to the system in that the first and second groups were injected at 3.5 and 6.5 minutes, respectively. An experimental leakage model developed in a previous study [1] was used to examine the filling and leakage behaviour of the two spinal augmentation systems. Cement-filling patterns in the model were quantified by analyzing the filling images with a special Matlab code. Furthermore, the intravertebral (IV) pressure value in the simulated vertebral model was measured using a double-conduit introducer needle.

RESULTS: The CONFIDENCE groups showed significantly less leakage than the VERTEBROPLASTIC groups. The average leakage masses of 0.93 g (± 0.6) and 1.52 g (± 1.17) were observed for the CONFIDENCE groups injected at 6.5 and 3.5 minutes respectively. In the case of the VERTEBROPLASTIC system, the average leakage masses were 2.32 g (± 1.08), 3.20 g (± 1.05) and 4.32 g (± 0.57) for the group delivered after 9.5, 6.5 and 3.5 minutes

respectively. The CONFIDENCE groups showed significantly higher filling uniformity compared to the VERTEBROPLASTIC groups [Fig.1]. However, there were no significant differences between the two groups of the CONFIDENCE systems as the ANOVA showed ($F=0.88227$, $P=0.43099$). The minimum IV pressure was 0.39 psi and the maximum was 0.65 psi ($F=0.44$, $P=0.65$) in the case of the VERTEBROPLASTIC system. The minimum IV pressure 0.16 Psi, and the maximum was 0.82 psi ($F=0.02$, $P=0.89$) for the CONFIDENCE system.

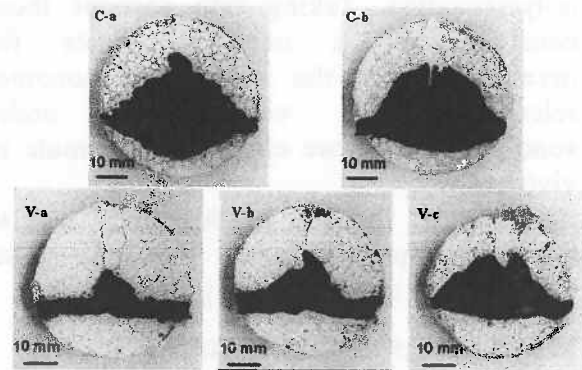


Fig. 1: Representative sample of the filling pattern. C: CONFIDENCE system, V: VERTEBROPLASTIC system, a: injection started after 3.5 min, b: injection started after 6.5 min, c: injection started after 9.5 min.

CONCLUSIONS: The CONFIDENCE system is a high viscous cement system with the objective to curtail the cement leakage and improve the cement filling uniformity. The results of the study showed significantly superior results for the CONFIDENCE system. Specifically, the filling uniformity increased and the cement leakage reduced in all CONFIDENCE groups if compared to the VERTEBROPLASTIC groups. There was no significant increase in the intravertebral pressure when the cement was delivered at a later point of time.

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A Novel Pmma-Ha Composite Bone Cement For Kyphoplasty S Lee¹, R Wenz², J Meyer², S Marcinek¹, A Mehta¹, T Slater¹.

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INTRODUCTION: Balloon kyphoplasty is a minimally invasive surgical procedure for treatment of osteoporotic vertebral compression fractures. The vertebral body is accessed transpedicularly using a cannula through which an inflatable bone tamp (IBT) is inserted and inflated to reduce the fracture and create a void; this IBT is then removed and a viscous fixation material is injected to fill the void and stabilize the fracture. This material is usually either non-resorbable polymethylmethacrylate (PMMA) bone cement or resorbable calcium phosphate (CaP) bone substitute. Implantation of PMMA can result in fibrous tissue formation, but osseointegration (direct apposition of bone on the cement surface) is considered desirable. A new composite bone cement, ActivOs™ Bone Cement with Hydroxyapatite, has been formulated, combining hydroxyapatite (HA) particles with PMMA powder to produce a PMMA-HA material possessing the handling characteristics and mechanical strength of PMMA and the osteoconductive properties of HA. Product development included evaluation of handling, visibility, mechanical and biological properties.

EXPERIMENTAL METHODS: The powder and liquid components of PMMA-HA were mixed for 30 seconds and transferred to specialized devices for dispensing (KyphX Bone Filler Devices, Kyphon, Sunnyvale, CA). Dough time (as judged by the "sticky glove test") and working period (time from dough time until it becomes difficult to dispense) were measured. Injection into a cadaver vertebral body was viewed under live fluoroscopy to verify its visibility. Cylindrical specimens (6mm diameter x 12mm length) were molded and mechanical testing was performed according to ASTM F451 and ISO 5833. A sheep study was performed to evaluate the biological response.

PMMA-HA and PMMA were implanted into 8mm cylindrical defects in the lumbar vertebrae of skeletally mature sheep. After 1, 3 and 6 months, sheep were sacrificed, the vertebrae harvested and processed into stained, histological sections. Qualitative interpretation and quantitative histomorphometry analyses were performed to assess the extent of direct bony apposition on the perimeter of the cement surface.

RESULTS: The cement reaches a doughy consistency in 4-6 minutes, and can be dispensed until 13-18 minutes, for a working period of up to 7-14 minutes. The cement was confirmed to be sufficiently radiopaque such that extravasation out of the vertebral body could be visualized on fluoroscopy. The average compressive strength was 84 ± 3 MPa, above the 70 MPa minimum. PMMA-HA was observed to exhibit frequent direct apposition (mean: 40.5%, range: 11-98%) compared to infrequently (mean: 8.1%, range: 2-12%) for the PMMA control, a statistically significant ($p < 0.05$) five-fold increase.

CONCLUSION: A composite PMMA-HA bone cement formulation has been developed for kyphoplasty. This formulation exhibits appropriate handling properties for delivery, sufficient radiopacity for fluoroscopic visualization, good compressive strength, and greater osseointegration than a PMMA control in a sheep model. This PMMA-HA cement provides the kyphoplasty surgeon with another choice of material for vertebral body augmentation.

ACKNOWLEDGMENTS: ActivOs™ Bone Cement with Hydroxyapatite is CE-marked by Medtronic.

Osteopromotive capacity of injectable bone cements

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INTRODUCTION: Recent developments focus on injectable calcium – phosphate – cements and biphasic HA / PMMA cements for different indications in orthopaedics and traumatology including spinal fractures and osteoporosis. We compared four different CPC and two different biphasic cements versus a control (pure β -TCP) regarding toxicity, cell growth and cell differentiation.

METHODS:

Four injectable bone cements (ChronOS inject – Synthes, Calcibone – Biomet Merck, KyphOs – Kyphon, Cerament – Bonesource) and two biphasic cements (Vertecem – Synthes, Activos – Medtronic) were compared (control Chronos cylinder). Mesenchymal stem cells from sheep were seeded for the cytotoxic test on 6-well plates (50.000 cells /well). After 3 days of cultivation, a toxicity test (trypanblue), cellproliferationtest (MTT, Absorption 550 nm) and histology was performed. After 16 days of cultivation cell growth/differentiation (2 mio cells seeded onto the sample) was performed by histology, AP synthesis, protein absorption and histology.

RESULTS: No significant toxic influences were found in Calcibone and ChronOS inject. KyphOs showed a 16.7% increased toxicity if compared to control. The same results were seen on cell growth, best growth in the Calcibone and ChronOS inject groups followed by 50% less growth in the KyphOs groups. After 16 days all surviving cells produced similar AP levels with again the ChronOS group showing the highest levels. No protein absorption was found in the Calcibone and Cortoss groups. The remaining results will be presented in the talk.

DISCUSSION & CONCLUSIONS: The tested cements show different behavior on cells according to their chemical structure. Calcibone and ChronOS inject are in our experiment superior to KyphOs. It is difficult to simulate the actual ingrowth and remodeling of bone cements as the in vivo situation with blood flow etc. are different. All cements are in clinical use; however the indications for the cement vary due to their composition and toxicity.

Design of injectable bisphosphonate – calcium phosphate cement combinations for the local treatment of bone pathological resorption

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INTRODUCTION: Many groups in industry and academia worldwide are actively developing drug/medical device combination products for local drug therapies and infection prophylaxis. The use of such combined devices in orthopedics represents an emerging promising field, in particular for those based on calcium phosphates (CaP). In this context, calcium phosphate cements (CPCs) have been considered as carriers for local and controlled supply of various drugs, thus potentially providing a reliable means of producing efficient pharmacological effects only to specifically intended target sites. In particular, such an approach could be of interest in the case of osteoporosis.

METHODS: The optimized CPC formulation had the following composition for the solid phase: α -TCP ($\text{Ca}_3(\text{PO}_4)_2$, 78 wt%), DCPD ($\text{CaHPO}_4 \cdot 2\text{H}_2\text{O}$, 5 wt%), MCPM ($\text{Ca}(\text{H}_2\text{PO}_4)_2 \cdot \text{H}_2\text{O}$, 5 wt%), 0.67wt% alendronate-doped CDA ($\text{Ca}_{10-x}[\text{HPO}_4]_y(\text{PO}_4)_{6-y}(\text{OH})_{2-z}$], 10 wt%) prepared as reported previously¹, hydroxypropyl methyl cellulose [HPMC] (2 wt%). The liquid phase consists in a 5 wt% Na_2HPO_4 solution, with a liquid/powder ratio of 0.5 mL g⁻¹.

RESULTS: Our purpose was to design an injectable CPC-based medical device capable of providing mechanical bone reinforcement and delivering bisphosphonate BP antiresorptive drugs, for the prevention of the osteoporotic fracture. Indeed, cement augmentation of the proximal femur by minimally invasive surgery (femoroplasty) may increase mechanical stability and reduce fracture risk as the primary effect, in addition to the ancillary action of the BP itself. Accordingly, we have examined whether BPs (e.g. Alendronate) can be incorporated in a CPC cement, without affecting the properties of the curing and cured cement (injectability,

setting time, resorbability, strength). Various Alendronate-loading (up to 0.40 wt% with respect to the solid phase) were investigated, for which the BP was introduced under five different conditions: (i) dissolved in the liquid phase (ii) added to the ground solid phase (iii) or combined to one of the calcium phosphate components of the solid phase (i.e. α -TCP, CDA, DCPD).

CONCLUSIONS: Not surprisingly, the Alendronate doping increases the setting time at 20°C regardless and independent of the method used for its incorporation, while this trend becomes more and more significant as the BP-loading increases. However, the retarding effect of the BP on the setting time was found to be limited when combined to CDA. Accordingly, an optimized CPC formulation² (see experimental method) was thus obtained, showing a short cohesion time along with setting times appropriate for pre-clinical uses (initial setting time (37°C): 5-7 min.; final setting time (37°C): 15-18 min.). Cement augmentation of the proximal femur was performed with this BP-loaded CPC, using an osteoporosis animal model (ewe), and investigation of the *in vivo* properties of the implant is currently under progress.

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Reinforcing Bone Micro-Architecture In Vertebrae By Injecting Calcium Phosphate Cement Associated With Gem-Bisphosphonic Acid: A Sheep Study

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INTRODUCTION: Osteoporosis has been defined as "a systemic disease characterized by low bone mass and micro architectural deterioration of bone tissue, with consequent increase in bone fragility and susceptibility to fracture"[1]. Resorbable calcium phosphate (CaP) biomaterials have proved a noticeable efficacy in bone reconstruction surgery. Furthermore bisphosphonates (BPs) are well known antiresorptive agents largely used in systemic clinical treatments of osteoporosis. An injectable BP-combined CaP matrix has been developed in order to reinforce locally osteoporotic bone by increasing bone mineral density and improving bone micro architecture [2-4]. The purpose of this study was to implant such a combined device in ewes' vertebrae and to quantify bone structure modifications. The properties of bone reinforcement after implantation of BP-loaded and unloaded CaP cements were investigated by three-dimensional microtomography (3D- μ CT) that was first developed for nondestructive analysis of trabecular bone architecture [5]

MATERIALS AND METHODS: Calcium deficient apatite was loaded with alendronate (7%w/w) according to a method previously described [3]. The resulting powder was gamma sterilized and integrated within a specific apatitic cement formulation. Two cubic centimeters of the tested biomaterials were implanted in three vertebral bodies of 4 mature ewes. 3D- μ CT analysis was conducted on the 12 implanted vertebral bodies. Bone specimens were collected immediately after sacrifice and conserved frozen. Vertebrae were sectioned with respect to the implanted area to fit into the analysis chamber of the μ -CT device. For the analysed samples, bone or newly formed bone volume density (BV/TV), trabecular thickness (TbTh), space between trabeculae (TbSp) and number of trabeculae (TbN) were measured. A non-parametric Mann & Whitney test ($\alpha=0.05$) was applied for statistic analysis.

RESULTS AND DISCUSSION: After 12 weeks of implantation significant differences of the bone density and micro architecture were observed between the two groups. Those modifications have been quantified by measuring

conventional histomorphometric parameters [5]. Comparing BP-loaded cement implants with unloaded ones for μ -CT histomorphometric measurements showed significant increases ($p<0.05$) for bone volume density (+50.4%), trabecular thickness (+5.4%) and trabecular number (+60.4%) and a significant decrease for trabecular space (-15.0%). For the first time to our knowledge, a local combined effect of calcium phosphate cement and bisphosphonate is evidenced on sheep vertebral bodies. Those preliminary results can be considered as a first step for a local approach that aims in delaying or even preventing osteoporotic fractures. Reinforcing specific bone sites like vertebral bodies, proximal femurs or wrists by implanting calcium phosphate cements that can promote bone ingrowth and release controlled quantities of bisphosphonates could be considered, in the near future, as an alternative to current systemic injections. Indeed, this combined device allows using small quantities of BPs that present a pure local effect because of the high affinity of BPs for bone apatite. This way of delivery could then decrease described side-effects (e.g. jaw osteonecrosis), due to regular and long-term BPs treatments. Obviously complementary *in vivo* experiments (mechanical tests, undecalcified histology) have to be conducted in order to better characterize the potential efficacy and eventual limits of such a local approach.

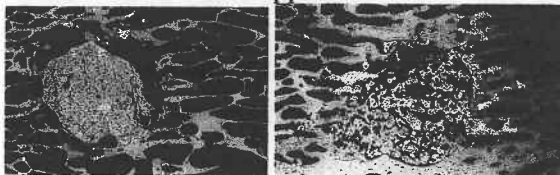


Figure : Scanning electron microscopy images of vertebrae implanted respectively with cement (up) and BP-loaded cement (down)

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Simulation of Cell-mediated Resorption of Porous Bone Substitutes

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INTRODUCTION: A mineral bone substitute is a resorbable porous structure to support healing of a damaged bone. Predicting the in-vivo behaviour of a mineral bone substitute is of significant importance to design an effective scaffold. Recently, a theoretical model has been developed [1] developed that estimates the cell-mediated resorption rate of a bone substitute by assuming that (i) the linear resorption of the solid surface is constant (ii) provided the surface can be reached by blood vessels and cells (interconnection diameter > 0.05mm). This study presents a numerical algorithm applied to bone substitutes with complex geometries. The substitutes were reconstructed using fuzzy image processing tools. The proposed algorithm is validated by comparing its results with the analytical results of a simple geometry and experimental data of a more complex scaffold.

METHODS: A porous bone substitute was first scanned by a micro-computed tomography system. The pores of the sample were then reconstructed using skeleton points that extracted based on the 3D fuzzy distance transform map and ridge detection method.

The resorption simulation was performed in two steps: (a) colonization of a pore by resorbing cells, (b) resorption of the bone substitute material. For the colonization step, it is required to enlarge (or create) the pores and interconnections to enable in-growth of blood vessels. Hence, at the skeleton points, the algorithm compares the size of pores and interconnections with the size of the blood vessels to find the new accessible pores for resorbing cells. Once the pore is invaded by resorbing cells, the next step is started to resorb the bone substitute material at the interface surface. In addition, resorbing the material leads to enlarge the pores and interconnections which are too small for blood vessels. These steps were repeated for each pore until the structure was fully resorbed.

RESULTS: Fig. 1 compares the simulation results of the algorithm against the analytical results of the theoretical model [1] for a simple cubical block with constant width of 5 mm and average inter-pore distance of 22 μm . Due to the proportionality of resorption time and total layer thickness resorbed for full resorption of scaffold

material, a similar ratio was expected for all cases. The discrepancy among the results can be justified by the limitation of voxel size, especially for models with small pore radius (e.g. 100 and 200 μm).

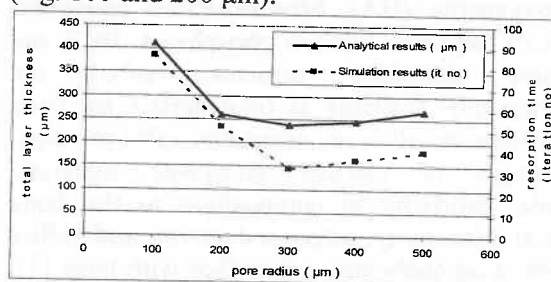


Fig.1- Analytical and simulation results of FCC lattice of pores with various pore size.

Fig. 2 compares the simulation results against the experimental data presented in [2]. The correlation coefficient (R^2) between experimental and simulation data is above 0.8. Consistent with experimental results, the algorithm indicates that the resorption rate decreases as the time marches. The fastest resorption rate is experienced at the beginning of the process.

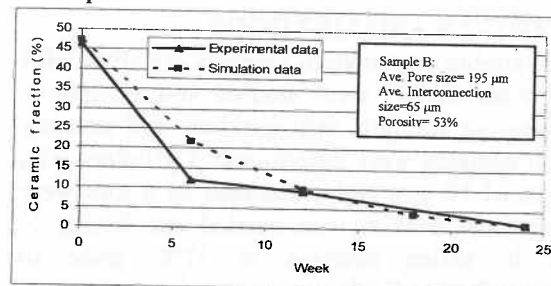


Fig.2- Experimental and simulation data of real bone substitute structure.

CONCLUSION: The proposed algorithm estimates resorption process of mineral bone substitutes that helps to better understand the in-vivo behavior of them. The algorithm can also be used as a design tool to improve the geometrical parameters of bone substitutes.

ACKNOWLEDGMENT: The authors would like to thank S. Allen for the supports provided to optimize the resorption simulation code.

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Comparison between two calcium phosphate cements: *in vitro* and preclinical evaluation

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INTRODUCTION

Calcium phosphate biomaterials, principally hydroxyapatite (HA), beta-tricalcium phosphate (β -TCP), biphasic calcium phosphates, BCP and calcium phosphate cements (CPC) are commercially available as biomaterials for bone repair, augmentation or substitution. The principal advantages of calcium phosphate materials include: similarity in composition to the bone mineral, bioactivity, osteoconductivity and ability to form a uniquely strong interface with bone [1]. Calcium phosphate materials are available as granules, blocks, coatings on dental and medical implants, and as cements. The CPC present good mechanical properties and reasonable setting times. After setting, most of these materials remain dense and do not provide rapid bone substitution because of the lack of macroporosity [2]. The purpose of this study was to compare between two commercial CPC in terms of physico-chemical properties and *in vivo* behaviour.

MATERIALS AND METHODS

Two available commercial cements (Graftys HBS and Norian SRS) were studied and compared. Compressive strength, setting times, and porosity of both cements were determined. Cylinders with a height of 12 mm and a diameter of 6 mm were prepared and soaking was carried out during 24 hours in saline solution at 37°C prior to determination of the compressive strength. Porosity data were performed by mercury porosimetry. Scanning electron microscopy SEM were used for microstructural analysis.

Implantations were performed bilaterally on six female New Zealand white rabbits in aseptic conditions and under general anaesthesia. The tested cement pastes were injected for 4, 8 and 12 weeks into critical bone defect (6 mm diameter) at the distal end of rabbit femora. Light microscopy and SEM were used for histological studies. The

quantity of remaining cement was determined using a semiautomatic image analyser.

RESULTS

All cements after setting they transformed to poorly crystalline apatite. Respectively for Graftys HBS and Norian SRS, the compressive strength values were 12 MPa, and 33 MPa, total porosity values were 65% and 45%. The setting times were 45 min and 15 min respectively. Contrary to Norian SRS, porosity results showed some macroporosity in Graftys HBS.

After all periods of implantation, there was no intervening or fibrous layer between the host bone and the implants (Graftys HBS and Norian SRS). For both products, new bone had grown on the surface and progressed centripetally towards the core of the defects. Mineralised and mature bone was observed between and in contact with the implants. Newly formed bone, after 4, 8 and 12 weeks were, (10%, 9% and 18%) and (11%, 17% and 31%) for Norian SRS and Graftys HBS respectively. The histology analysis showed for both products (Graftys HBS and Norian SRS) mineralized collagen fibers with haversian structures and osteocytes. In all cases, no fibrous layers or foreign body were observed.

CONCLUSION

This study showed that Graftys HBS is less resistant, more porous and resorbable than Norian SRS.

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Injectable Multiphasic Biomaterials Developments

Performance of Microporous Biphasic calcium phosphate and hydrogels

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INTRODUCTION:

Calcium phosphate bioceramics granules associated to hydrosoluble polymers were developed as bone substitutes for various maxillofacial and orthopaedic applications (1). These Injectable Bone Substitutes should support and regenerate bone tissue and were resorbed after implantation. The efficiency of these multiphasic materials was due to the osteogenic and osteoconductive properties of the Microporous Biphasic Calcium phosphate. The hydrosoluble polymers associated were considered to be only a carrier to achieve rheological properties and to be a carrier alone for the granules (2, 3). The aim of this study was to demonstrate that the nature of the polymer may interact with the osteoconductive property of the BCP granules.

MATERIALS AND METHODS: In this study we have used 2 hemisynthetic hydrosoluble polymers of polysaccharidic origin. The Hydroxy propyl methyl cellulose HPMC with and without silane were combined with microporous BCP granules (mixture of HA and β -TCP solid phase). Silane grafting on HPMC (4) was used as gelling agent of the suspension. The 2 IBS used (without gelling property IBS1, with gelling IBS2) were implanted in rabbits in critical size femoral epiphysis defects. HPMC Si alone without granules was also tested as control.

RESULTS AND DISCUSSION: The results demonstrated the resorption of the BCP and

bone ingrowth at the expense of the two IBS. However faster bone ingrowth was observed of HPMC without silane. Higher inflammation process with multinucleated giant cells reaction and s were observed for HPMC with silane. This study demonstrates what the hydrogel cannot be considered as only a carrier. The hydrosoluble polymers modify the osteoconduction and osteogenic property of the Bioceramics. HPMC (without Si) interaction with Calcium phosphate have been reported at the unit cell level using high resolution electron microscopy (5). Particularly when additional product like silane was used as gelling agent, the polysaccharides kinetics for cells colonization, bone ingrowth and bone regeneration were largely modified.

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Use Of Injectable Resorbable Bone Substitut For Proximal Humerus Fractures Reconstruction: Technical Note About A 15 Cases Serie

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Introduction:

Osteoporotic bone fracture is challenging surgeons even using new locking head screws devices ;in proximal humerus fracture, the difficulties are not in reducing but in stabilising for the healing time which needs few weeks;in the same time the surgical approach should not destroy the soft parts and the precarious vascularity of the fractured and displaced pieces of bone .

Method:

Since 2004 we try to stabilise the bone reduction and fixation using injectible phospho tri calcic(beta) bone substitute. The substitute is injected after bone reduction :the bone cement is injected inside the bone gap which is created by the reduction of impacted fractured bone pieces.

To preserve the vascularity of the bone pieces while reducing them under Xrays,we do a latero-superior approach which is more well adapted to get a good control and less soft parts destroying ;after injection we do a osteosynthesis with locking head screws devices .

Results:

15 cases of proximal humerus fractures have been operated by this method from 3parts fractures to dislocated fractures or articular fractures ;

The bone substitute stabilized the fracture so well we did not see any disturbing secondary displacement :we did not notice any adverse effect due to the substitut

The used volume of injection was between 5 to 10 cc .

The evolution of the substitut was good for all the cases ;the disappaerance is depending of the injected volume

The tri calcic phosphate (beta) is not a foreign body and does not disturb the creeping substitution described by many authors during the bone healing

Functional result is depending of the survey of the apophysis and this is moore frequent when they are fixed specifically to the metallic device (as in prosthetic surgery) after gentle reduction

We do believe that the use of a completely resorbable injectible bone substitut filling the bone gap due to the anatomical reduction added to a gentle latero-superior approach and a locking head screws device is most of time the best way to preserve the function and avoid the need of prosthetic surgery

Calcium alluminate bone cement in percutaneous vertebroplasty. Early *in vivo* results during one year follow up.

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INTRODUCTION:

Percutaneous Vertebroplasty (PV), first introduced by Galibert and Deramond in 1987¹, is gaining acceptance as a first choice treatment for painful osteoporotic compression vertebral fractures and malignancies in the spine when conservative medical therapies failed. Several large clinical studies showed good long-lasting pain relief, rapid rehabilitation and, consequently, improvement of the quality of life^{2,3,4,5,6,7,8,9}. Polymethylmethacrylate (PMMA) still now represents the most commonly used bone cement in vertebroplasty while different polymers, even with low toxicity and good mechanical properties are still difficult to inject.

The purpose of this preliminary single center study, part of a multi-centric *in vivo* experimentation, is to define ease and safety of use of a new water-based Calcium Alluminate bone cement (Xeraspine, Doxa). A further goal was to monitor pain, quality of life and any potential adverse events during a one year follow up.

EXPERIMENTAL METHODS: After informed consent 15 patients (12 women, mean age: 73 y.o. age range: 57-91), suffering from painful osteoporotic vertebral collapses (1 to 3) with hyperintensity at MRI fat suppressed sequences, underwent transpedicular PV with a new Calcium Alluminate bone cement called Xeraspine. Vertebral access was obtained with a standard trans-pedicular right approach by means of a 13 Gauges beveled needle inserted under fluoroscopic guidance. Bone cement liquid and powder components were mixed using an electric shaker coming with the cement prototype and 1mL syringes were filled and stored in saline iced bath to prolonge polymerization during PV. Under continuous fluoroscopic control Calcium Alluminate was slowly injected through the beveled needle. Visual Analogue Scale score of pain (VAS from 0 to 100mm) was asked before, within 24hours and at month 1, 3 6, 12 from PV. Oswestry Disability Questionnaire was obtained before PV, after three months and after one year. MRI and lab tests were requested afer one year.

RESULTS: No neurologic or pulmonary complications related to PV procedure nor toxic effects of bone cement occurred. Injectability, radioopacity and filling pattern were good in all cases. A significant backpain regression was achieved in all patients within 24 hours from the procedure. 2 patients (13.3%) had a new fracture respectively within one month and two months. In one patient a further collapse of Th11 (already treated with PV) was detected with MRI performed after one year (VAS increased from a stable 20 to 45 in the last month of the follow up). One patient died within a month for causes unrelated to PV (car accident). The remaining 12 patients had a long lasting pain relief during the first year of follow up (mean pre-PV VAS: 84±14; mean VAS post-PV: 33±20; mean VAS at 12 months: 17±12; mean pre-PV and post-PV Oswestry back pain score were 58±19 and 21±15). Two patients didn't performed the MRI as scheduled for study termination (one for logistic issues; MRI will be available at month 15 and one, 91 y.o., refused) both patients had an excellent pain relief (VAS 0/100 and 10/100 respectively) and plain x-rays showed any new fracture. No alteration depending on bone cement, nor new fractures were seen in the remaining 10 pts at month 12 MRI. Percutaneous vertebroplasty with Calcium Alluminate was safe and feasible. Pain relief during one year follow up were substantially comparable to expected according to our experience on osteoporotic patients undergone PV with standard PMMA¹⁰. Overall new fracture rate (20%: 2 new fractures and one re-fracure) was comparable to the risk of new fracture (19.2%) found in a wide osteoporotic population not treated with PV within one year after the first fracture¹¹.

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