

11th of November  
2015

# RESTORATION

Resorbable Ceramic Biocomposites for Orthopaedic  
and Maxillofacial Applications

## RESTORATION NEWSLETTER nº1

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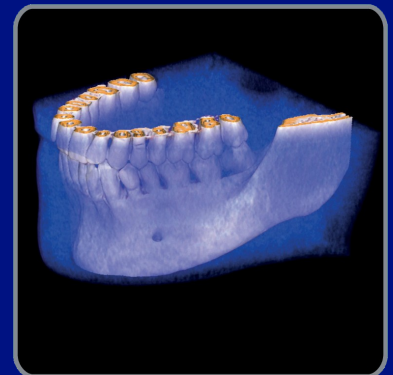
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# RESTORATION

## Project presentation

**RESTORATION** project develops resorbable bioceramic composite materials for three main applications: Osteoarthritis, Vertebroplasty (VP) and Kyphoplasty (KP), and Maxillofacial Fracture Fixation.

The RESTORATION bioceramic cement offers new biological, mechanical and rheological properties thanks to advances in cellular medicine.

Working in tandem with cells, proteins and other biologically active agents, RESTORATION aims to revolutionise many treatments and therapies. With the help of highly effective and early stage clinical interventions, bioceramics can offer solutions where no approach existed before.

RESTORATION combines mechanical design, materials, processing, clinical delivery and biological interaction.

The project addresses these underlying research and technological challenges in order to develop new bioceramic products for five SME partner companies.

The three applications of RESTORATION include:

- Osteoarthritis: The project develops functionally gradient bioceramic composite plugs for osteochondral applications
- Vertebroplasty and Kyphoplasty: a new generation of vertebral cements with appropriate biological, mechanical and rheological properties are being developed
- Maxillofacial Fracture Fixation: the project develops new bioceramic composites, which will possess sufficient stiffness and strength to protect and support the broken bone



## Work progress

**Work Package 3: Materials Development for VP and KP Applications** - This WP was completed with injectable cement and composite materials having been developed, and characterised in terms of their properties, injectability and radiopacity. These materials were then taken forward to be further developed towards medical devices in WP7

**Work Package 4: Materials Development of OA Application** - The work package was structured so as to generate a number of materials for use and evaluation in the subsequent stages of the project, in essence these were to develop a route for nano-hydroxyapatite (nanoHA) / polymer hydrogel composites based, to develop and evaluate processing routes for in-

## Work progress

jectable polymer-ceramic composites based on nano HA.

A separate task developed seven brand new bioceramic formulations with improved combinations of mechanical and biological properties. This would then lead to new ceramic and ceramic-polymer composite structures capable of being implanted using minimally invasive surgical techniques, along with evaluation of in-hospital processing routes for the implantable materials.

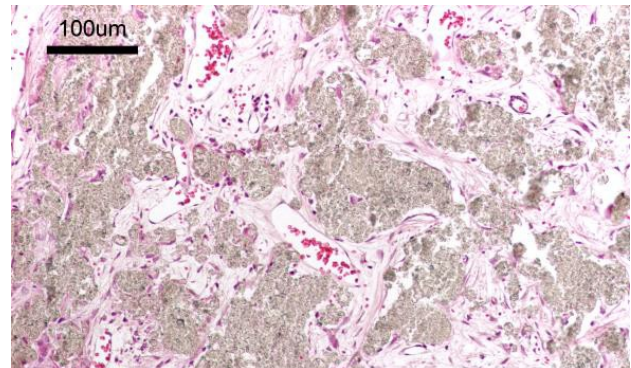
**Work Package 5: Materials Development for Maxillofacial Applications** - For this WP new materials and in-hospital processing routes were developed. The WP was completed with all objectives achieved, and with materials having been developed and characterised for further development into devices in WP9.

A novel resorbable copolymer of polylactic acid and polyglycolic acid was developed with vinyl functionalisation of end groups. Composites were then created with the addition of hydroxyapatite powder as filler. The composites were shown to maintain their flexural strength over 6 weeks storage in an aqueous environment, exhibiting better performance than commercially available resorbable polymers.

**Work Package 6: Biological enhancement and assessment** - This WP focuses on the biological assessment of the novel biomaterials. It comprises cell culture (human and rat primary fibroblasts, osteoblasts, adult stem cells) in the presence of the biomaterial in vitro in order to understand basic cell-compatibility and cell-biocomposite interaction.

In addition, the assessment concentrates on osteogenic and chondrogenic proper-

ties, craniofacial bone defect treatment with the selected biomaterial in vivo in order to evaluate tissue repair and regeneration, and the biomaterial-tissue integration (interaction). This allows the identification of the biomaterials which best meet the clinical requirements to be carried forward for the device development.



**Work Package 7: VP and KP Device Design and Development** - This WP develops designs of medical devices for use in vertebroplasty and kyphoplasty. It models the mechanical and biological performance from implantation through to resorption and induced bioactivity.

Both the cement and the polymer composite with platelet rich fibrin have been successfully produced at scales which would allow pre-clinical testing to take place.

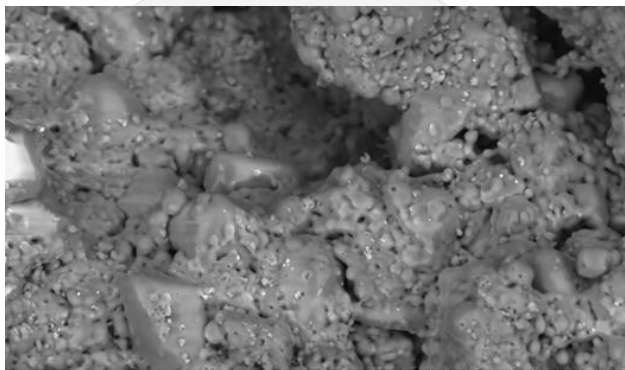


## Work progress

**Work Package 8: OA Devices Design and Development** - This WP aims to develop specific full scale designs of medical devices, model the mechanical and biological performance and evaluate the devices.

Two designs of osteochondral plug have been designed, evaluated and taken forward to the large animal model in WP11, one based on apatite-wollastonite glass ceramic, and another on porous polylactic acid structure.

**Work Package 9: Fracture Plate Device Design and Development** - UNEW developed a novel PLGA plate design and a series of adhesive formulations for evaluation in WP6. Whilst a plate material has successfully been developed, an adhesive formulation which was both effective and non-toxic has not been found, and the plate material requires evaluation as a composite in order to introduce a bioceramic phase to act as a buffer for the release of degradation products in vivo.



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**Work Package 10: Life Cycle and Environmental Assessment** - This WP performs an environmental and economic assessment of the three types of devices/applications developed and the different current alternatives, based on Life Cycle Assessment (LCA) and Life Cycle Cost-

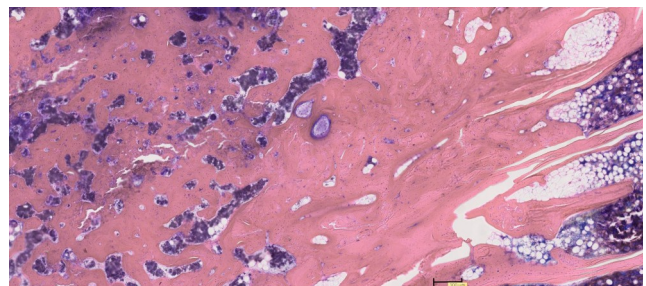
ing (LCC) methodologies.

LCA and LCC allow quantifying the potential environmental and economic impacts of the 3 devices during all their life cycle including design (concept, prototype, and pre-clinical), materials, manufacturing of devices, clinical assays, surgical and post-surgical stages, and end-of-life.

The final results will show the overall economic and environmental load of each phase, with the aim of prioritising improvements.

**Work Package 11: Biological Assessment of Medical Devices** - This WP has three objectives, to evaluate the in vivo bone response to the novel injectable bioceramic vertebroplasty treatments. to study in vivo the potential of the developed devices for osteochondral repair in load-bearing conditions, and to assess in vivo the bone response and potential of the developed devices for maxillofacial fracture fixation.

The animal trials have focussed on one cement material and two osteochondral plug designs. A total of 40 animals have undergone surgery; two groups of eight ewes were implanted with two different devices for osteochondral repair, eight ewes underwent vertebroplasty with Spineghost III and control groups for both models were also completed.



## Final Event

For the last months of the project, RESTORATION aims to disseminate largely its results to the scientific community and industry. Therefore, it will hold a **final event** from the **10th-11th of March in Brussels**. This will be the occasion for interested parties to get in touch with the consortium members and have a closer look at their research activities.

For more information, contact Debbie

Wilde, Project Administrative Responsible [debbie.wilde@ncl.ac.uk](mailto:debbie.wilde@ncl.ac.uk).

In addition, the consortium is preparing a presentation video about the project and its objective. Its purpose is to inform non-experts about the project and the progress of science in the field of bioceramics.

A last newsletter will be published in March 2016 containing the last results about the project.

### 42M Review Meeting

(13-14/10/2015) The meeting was hosted by the [University of New Castle](#) at the [Dove Marine Laboratory](#) on the sea front. Each partner gave an update about the research results, especially about the bioceramic and polymer materials. Dissemination was also a trending topic as the project slowly reaches its end.



### 36M Review Meeting

(16-17/04/2015) The meeting was held at [IQS](#) facilities in Barcelona and during the second day, partners met at LEITAT. The Consortium counts with the presence of Dr Mathias Lucas, the Project Officer, and maintained fruitful discussions. Everything is prepared for facing RESTORATION'S

final year!



### 30M Review Meeting

(16-17/10/2014) The Consortium met at [University of Évora](#) and had the chance of visiting the animal facilities of the University where experimental models in sheep are being developed. During the meeting partners discussed last outcomes and



## Meetings

planned last month of the second reporting period.

### eMRS Fall Meeting

(14-18/09/2014) RESTORATION project was presented during eMRS meeting in September in Warsaw. The Special session "Bioceramics for Bone and Joint Repair" was organized by four EC funded projects: [BIOBONE](#), RESTORATION, [GLACERCO](#) & [MATCH](#). RESTORATION has in total 8 presentations related to the project's results.



### 24M Progress Meeting

(3-4/04/2014) The 24 Month progress meeting of RESTORATION Consortium was hosted by [JRI Orthopaedics](#) and [GTS](#) in Sheffield, UK. The Consortium presented promising results reached during the first half of project's execution and planned the following months strategy.



### 25th European Conference on Biomaterials

The Special Session "Bioceramics for the Future" during the 25th European Conference on Biomaterials chaired by RESTORATION's Co-ordinator Professor Kenneth Dalgarno and Dr. Jerome Chevalier was attended by 108 experts. During 90 minutes, 5 presentations exposed novelties in the field of Bioceramics.



### 12M Progress Meeting

(17-19/04/2014) It was held at [Karolinska Institute](#) in Stockholm. Partners had the opportunity to attend the Exploitation Strategy Seminar offered by EC with the aim of identifying possible weaknesses in the exploitation of the results. We would like to thank Emmanuel Sofianopoulos, the expert in exploitation of results who held the seminar.



## Partners



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