Silicon Nitride Coatings for Improved Implant Function

Objective NMP.2012.2.2-1 – Biomaterials for Improved Performance of Medical Implants

Large Collaborative Integrating Project

Grant Agreement: 310477

Website: http://www.lifelongjoints.eu

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Consortium Members

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Publishable Summary

Context
Total Joint Replacement (TJR), particularly of the hip (THR) and also the knee, represents one of the most successful and common musculoskeletal, indeed of any, surgical intervention, bringing about quantifiable benefits to individual patients and society as a whole. This success has led to an unprecedented rise in the number of procedures being undertaken. Specifically, both the original patient group (elderly with osteoarthritis) has expanded and new cohorts including different disease states, high body mass index recipients and younger patients are increasingly being treated with THRs. For instance, THR has increased from 50 cases per 100,000 person years in the early ’70s to 145 per 100,000 this decade in the US and UK.

Through considerable advances in technologies, surgical techniques and rehabilitation short-term adverse events, such as infection, have reduced markedly. Even with failure rates as low as 5% at 10 years, the sheer number of primary operations (>1.5 million globally for hips and knees) means that the estimated number of revision procedures is about 50,000 in the EU alone at a cost of €500M in healthcare expenses. These salvage procedures are expensive, complex and have lower success rates than primary operations, impacting both on the morbidity of the, by then older, patient and the cost-conscious healthcare system. These longer-term failures are largely the result of device loosening secondary to wear of the bearing. For younger, hip replacement patients the need for longer wearing and robust bearings resilient to adverse loads is paramount in order to avoid multiple surgical interventions for TJR during their lifetimes. This requirement has to be positioned within a heightened regulatory regime due to the well-publicised, high failure rates within contemporary metal-on-metal hip and resurfacing prostheses, in which the regulatory authorities and professional bodies have acted to ban or significantly curtail the use of these prostheses and increase surveillance of those already in use.

LifeLongJoints Aims and Objectives
In response to these challenges LifeLongJoints will deliver next-generation, functional Silicon Nitride coatings for articulating surfaces and interfaces of total hip replacements (THR) that produce longer lasting implants. New solutions to these issues are required and are addressed in this project, in a multidimensional manner realising that the issue of wear has to be tackled with a material property combination that is low-wearing, produces debris that is soluble, which does not elicit an inappropriate biological This combination of attributes moves away from focusing on developing extremely low wear systems in isolation, to one that takes a more holistic view of wear in THR looking at all stages in the failure process. These improved wear characteristics will lead to (1) improved therapeutic outcomes through longer lasting and more robust implants and (2) overall improvements in the quality of life of the patients through reductions in implant failures and subsequent revisions. This will significantly reduce the risk of implant failure associated with wear, synergistic wear/corrosion processes and the resultant debris release as well as provide significant economic and societal benefit to Europe and its citizens. This will be supplemented by advances in the way hip replacements are tested using both mechanical simulators and computational models. The seven objectives for the programme are:

(1) Development and characterisation of a novel wear-resistant silicon nitride-based coating for both articulating (hard-on-hard and hard-on-polyethylene) and non-articulating bearing surfaces for three key bearing/interface applications (work packages (WP) 1 to 5);
(2) Development of advanced simulation methodologies, in vitro, together with the dissemination of new guidance documents and standards for the functional assessment of the novel silicon nitride coatings (WP1, 2 and 5);
(3) Production of in silico tools for the prediction of wear across the pertinent parameter space that reflects the variability in patient and surgical inputs with which to evaluate coating performance (WP1, 2 and 3);
(4) Production and pre-clinical testing of a series of prototype devices in each of the scenarios for the purposes of functional assessment and production evaluation, particularly the use of adverse conditions early in the assessment cycle (WP2 to 5);
(5) Finalise manufacturing scale-up through the translation of coating technology from a research to the industrial environment (WP1, 4 & 6);
(6) Delivery of the necessary in vivo data through the use of animal experiments to support the application of the coating in terms of cytotoxicity and joint functionality; and,
(7) Deliver the necessary regulatory evidence that is aligned with 93/42/EEC, to an advanced stage. (WP1 to 7).

Three different interface scenarios are targeted each with its own unique target profile:

(1) To reduce polyethylene wear
The Silicon Nitride coating to be applied here has the potential to reduce long-term UHMWPE wear, due to increased resistance to third body damage and scratch resistance compared to CoCr counterfaces, as well as possible improvements in lubricity.

(2) To reduce wear in metal-on-metal (MoM) surface replacements and large diameter metal bearings
Wear-associated ion and nanoparticle release is a direct consequence of surface wear and tribocorrosion. It is predicted that the application of the Silicon Nitride coating against Silicon Nitride counterfaces will substantially reduce the production of such particles (through wear) and ions (through corrosion of either the bearing surface as it is activated by wear or by dissolution of wear particles) leading to reduced adverse biological responses and enhanced biocompatibility of these devices.

(3) To reduce corrosion/wear at taper junctions
Taper junctions between the femoral neck and head have been identified as having increased wear in different bearing combinations (for instance, metal-on-polyethylene; metal-on-metal) as a direct result of fretting due to micromotion and crevice corrosion between either similar (CoCr/CoCr) or dissimilar (Ti/CoCr) metals, which has been associated with a “rocking” and torsional phenomenon. This issue has been highlighted by the increasing use of larger (>32mm) heads and there is an indication that the amount of wear and corrosion is positively correlated with head size, and induced frictional torques. Silicon Nitride coatings on one or both sides of the interface may have the ability to reduce the production of CoCr debris, reduce corrosion and possibly influence the locking mechanism at the interface.

LifeLongJoints Consortium
The Consortium comprises 15 partners, which in their own right are centres of excellence within the European research and technology transfer landscape. The Consortium is experienced at delivering collaborative projects over extended periods (≥4 years) with significant investment (≥€2M), including the current SPINEFX and VPHOP grants. Each partner brings a set of skills and/or expertise that, when developed within the Consortium, offers the opportunity for significant advances in the underpinning coating technology and the adjunct pre-clinical testing regimes for devices which comprise these coatings and those more generally. No two partners bring to the Consortium the same primary skills set.
Year 1 Highlights

In terms of the **science and technology** the **highlights** delivered in year 1 include:

- Significant deposition process parameters were identified by LiU together with UU and Ib with regards to silicon nitride coating properties;
- Functional prototypes of silicon nitride coated cobalt chromium discs were produced by LiU to meet target profiles;
- Bench testing of these functional prototypes of silicon nitride coated cobalt chromium discs was performed at UU (adhesion, roughness, hardness, wear resistance) and UNIVLEEDS (wear resistance, tribocorrosion) and compared to target profiles;
- Identification of wear processes from retrievals. Specifically the fretting wear around the taper junction;
- Simulators designed to advance the state or the art in terms of the “real life” cycles that cause adverse loading and motions;
- Fretting simulations *in vitro* conducted. Calibration measurements on CoCr material as a precursor to coating tests;
- Tribocorrosion in sliding conditions showing wear induced corrosion on the coating. Initial assessment of coatings with different N/Ar ratios. Wear of the coatings generally lower than the CoCr reference and the N/Ar ratio has a significant effect on all aspects of corrosion-wear;
- Particle isolation method defined. New methodology for Si$_x$N$_y$ coatings which behave differently to CoCr particles;
- Surgical technique for placement of prosthesis fixed (UZH, ETHZ); and,
- Preparation for GLP accreditation complete, Inspection of MSRU facility in its final phase, but status of GLP accreditation has been already acknowledged by Swissmedic at the time of first inspection.

In terms of **dissemination** and **exploitation** the major **highlights** have been:

- Setting up and maintenance of a public website;
- Setting up and maintenance of an internal website for consortium use;
- Presentation of LLJ at EuroNanoForum, Dublin, 18th to 20th June 2013;
- Visit of MEP Rebecca Taylor to LLJ team at the University of Leeds on 27th September 2013; and,
- Visits to companies within the LLJ Consortium to discuss their exploitation interests in the project.

**Expected Impact**

(1) LifeLongJoints will develop a new Silicon Nitride low wear coating which, for the first time, produces soluble debris with the potential for substantially reduced effects on the biological system and, hence, lower failure within the hip replacement.

(2) Advanced assessment procedures including novel membrane assay systems, beyond the state of the art simulator and an enhanced testing framework which will be utilised for predicting wear/corrosion performance *in vivo*.

(3) Increased competitiveness of European Industry – delivered through both improved product performance through the coating and enhanced testing.

These expected benefits if successful could lead to improved therapeutic outcomes and increased patient benefit.