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

Coordinator: Professor Richard Hall
School of Mechanical Engineering
Faculty of Engineering
University of Leeds, UK

Email: r.m.hall@leeds.ac.uk

Consortium Members

Beneficiary Number	Beneficiary name	Beneficiary short name	Country	Date enter project	Date exit project
1 (Coordinator)	University of Leeds	UNIVLEEDS	UK	M1	M60
2	Eidgenoessische Technische Hochscule Zurich	ETH Zurich	Switzerland	M1	M60
3	Uppsala Universitet	UU	Sweden	M1	M60
4	Ionbond AG	Ib	Switzerland	M1	M60
5	Simulation Solutions Limited	SimSol	UK	M1	M60
6	Universitaet Zuerich	UZH	Switzerland	M1	M60
7	Wilhelm Schulthess Stiftung	KWS	Switzerland	M1	M60
8	The Leeds Teaching Hospitals National Health Service Trust	LTHT	UK	M1	M60
9	Aesculap AG	AAG	Germany	M1	M60
10	AnyBody Technologies A/S	ABT	Denmark	M1	M60
11	Linkopings Universitet	LiU	Sweden	M1	M60
12	TuTech Innovation GmbH	TuTech	Germany	M1	M60
13	Technische Universitaet Hamburg-Harburg	TUHH	Germany	M1	M60
14	Peter Brehm	PB	Germany	M1	M60
15	Imperial College of Science, Technology and Medicine	Imperial	UK	M5	M60

Publishable Summary

Context

Total Joint Replacement (TJR), particularly of the hip (THR) but also the knee, represents one of the most successful and common musculoskeletal, indeed any, surgical intervention. These operations bring about quantifiable benefits to both individual patients and society as a whole. This success has led to an unprecedented rise in the number of procedures being undertaken. 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. 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.

Through considerable advances in technologies, surgical techniques and rehabilitation short-term adverse events, such as infection and catastrophic implant failure, have reduced markedly. However, 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 with direct costs of €500M in healthcare expenses alone. These procedures are more expensive, have added complexity and 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. For younger, hip replacement patients the need for longer wearing and more 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. Here 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 are soluble and 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. In parallel new methods of assessing the performance of the coating are being both developed and improved to take account of the fact that the materials are thought to be extremely low wearing and are soluble as well as being able to simulate adverse scenarios. This will be supplemented by advances in the way hip replacements are tested using both mechanical simulators and computational models in a holistic manner.

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 to support the application of the coating in terms of cytotoxicity and joint functionality.

(7) Deliver the necessary regulatory evidence that is aligned with 93/42/EEC, to an advanced stage. (WP1 to 7).

Tribo-corrosion Scenarios

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 counter-faces, 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 tribo-corrosion. It is predicted that the application of the Silicon Nitride coating against Silicon Nitride counter-faces 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-polyethylene16; metal-on-metal) as a direct result of fretting due to micro motion 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 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 former 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 3 Highlights

Highlights of the research and innovation over the past year have included:

(1) Within WP1 researchers have focused on improvements in the coating culminating in the SiN_x being applied to 3D objects representing each of the three scenarios outlined above that is hard on hard bearings, hard on polymer bearing and modular interfaces. Analysis of the coating thickness demonstrated this matched expectations for the modular interfaces and the coating for hard on polymer bearings but required longer deposition times within the hard on hard scenario. The compositional variation was less than 10 % between deposition runs. Bench testing noted improvements in the coating performance with the use of the appropriate interlayer. Over the next 2 years cycles of improvement and assessment (principally within WP2 and WP5) will be undertaken to ensure the best possible quality of coating in pursuit of the aims and objectives of LifeLongJoints.

(2) WP2 delivered several significant highlights within LifeLongJoints. The University of Leeds received an eight station (6 active stations and 2 load-soak controls) simulator, which at the time constitutes the most advanced machine of its type globally has largely been commissioned and demonstrates wear rates in keeping with other wear simulators under standard ISO conditions. Preliminary tests of the SiN_x on SiN_x coating in comparison to other commercially available coatings have been completed. Biocompatibility assessment of the wear particles has been completed for Ti and CoCr (which are the base materials for the prostheses) and SiN_x. These assessments have demonstrated the deleterious performance of the CoCr in terms of cytotoxicity whilst both Ti (a poor bearing material and SiN_x are much more benign. This is reflected in the comet assay as well.

(3) Advances have been made on a number of fronts in terms of the modelling including:
   a. completion of the large-scale collection of patient related data;
   b. the patient data sets provide a suite of different scenarios for use within the ABT model itself and the joint simulators;
   c. integration of the patient data sets with the ABT models;
   d. advanced modelling of the wear process in the prostheses has been accomplished including the inclusion of a non-Newtonian lubricant and changes in surface roughness to allow wear predictions more akin to those observed experimentally; and,
   e. validation of the simulated hip contact forces and the development of a sit to stand model; and,
   f. fluoroscopic treadmill gait trials completed by ETHZ.

(4) The work carried out within WP4 during period 3 had two principal objectives; (1) the development of the 'Installation qualification' of the production scale coating machine, and delivery of the 'Installation qualification for production scale coating machine', and (2) to progress the work in the production coating of medical devices. Two important milestones were delivered. Important results for the optimisation of the coating, process stability and coating distribution were developed. In the former 'arcing' is of critical concern and this the use of mid-frequency pulsing reduces this deleterious effect significantly. In terms of coating distribution, the most complex geometries show a difference in coating thickness of approximately 10 % which is adequate for the applications being discussed here.

(5) A new design concept for a large knee joint prosthesis has been completed and preliminary surgical trials have been undertaken.

(6) Significant activities within exploitation and dissemination have been made over the last year including:
   a. An External Expert Advisory Board met in Amsterdam in February 2016 and delivered significant debate, items for future investigation and further information on context – especially the ongoing debacle over metal-on-metal prostheses.
   b. A patient event was delivered at Leeds University in September 2015 with just under 100 hip replacement patients along with friends/family gathering to meet the LLJ team and be put into the picture as to how their contribution to the project has been used. They were shown how data from LLJ selected patient volunteers was used to developing simulation and test systems, with the data being fed into a virtual patient model to provide realistic movement patterns for implant research. This virtual patient could then help to develop better implants faster and at a lower cost.

In addition WP7 (Management) has provided leadership and management for the Consortium including the organisation of the Technical Management Committee, which is the principal operational body of LifeLongJoints, as well as the Partner Assemblies (Brussels, Belgium; Leeds and Manchester, UK) and other subcommittees.

Impact

(1) The delivery of a MoCaP model which is specially aimed at processing data from motion capture systems.

(2) Commissioning of the single station Universal Simulator which can accommodate a complete joint system has been designed, developed and delivered to Leeds and commissioning is ongoing. This machine, which will be rigged specifically for tribo-corrosion research, has the capability of delivering pathologically relevant, adverse loading and motion characteristics to the joint under test using advanced control capability.

(3) 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*.

(4) 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.