Silicon Nitride Coatings for Improved Implant Function

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

Large Collaborative Integrating Project

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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 interventions. 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, 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 in excess of 30,000 in the EU alone with direct costs greater than €300M in healthcare expenses. 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 response. 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 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.

Highlights of the Project

The following are the highlights over the 5-years duration of the project:

WP1: Coatings deposited at Ib and LiU were characterized by XPS in terms of composition; SEM in terms of microstructure; and, nanoindentation was used to determine hardness and reduced Young’s modulus. All coatings showed a Si/N ratio within the specification limits. The coatings belonging to groups 1, 2, and 3 show an under dense and columnar microstructure under cross-sectional SEM, while the coatings from group 4 showed a dense and featureless structure. This resulted in significantly better mechanical properties of coatings from group 4 over all the other coatings.

WP2: Novel 6 station and 1 station simulators were designed and manufactured that exceed specifications for existing simulators and the performance required by the international standard ISO 14242-1. These simulators were validated using traditional polyethylene on metal hip components and then progressed to testing on SiN coatings and differing activities of daily living. A new particle isolation technique was developed that was the subject of a European CEN workshop agreement - CWA 17253-1. New methods for the testing of corrosive characteristics were developed. Assays demonstrated that SiN did not produce adverse reactions in both cell-lines and primary blood cells. Further, use of the SiN coating demonstrated a reduction in the ion release compared to metallic surfaces.

WP3: LTHT has delivered an unprecedented patient dataset of kinematics and kinetics. The dataset has proven to be a good foundation for the validation of the whole-body modelling framework, for the definition of severe loading scenarios for physical wear simulators, and for a comprehensive understanding of the role of critical patient-specific parameters on joint loading. The dataset is unique in the world for both the size of the measured group (>150 patients) and the broad assortment of activities of daily living that were measured. Simulated hip contact forces (HCF) have been comprehensively validated. The simulated data was based on the measured patient activities in the LTHT dataset. Results showed good agreement between in-silico simulations and experimental data following extensive improvements to the model muscle description. The resulting improved and validated model is part of the public AnyBody Model repository.

WP4: Extensive production of the SiNx coatings for the testing and assessment. Further, the HIPIMS equipment was up-scaled from an academic to industrial environment couple with Industrial qualification of the manufactured equipment and Operational and Performance qualifications of Silicon Nitride coating. Further investment will be made in delivering a coating of high quality.

WP5: This work package concerned itself with the *in vivo* assessment of the silicon nitride coating. These results confirmed the SiNx biocompatibility when compared to CoCr, the material often used in joint replacements. There was no tissue reaction evident in areas where SiN particles resided and were similar in appearance to control specimens.

WP6: This work package was focused on the dissemination and exploitation of the results within LifeLongJoints. Highlights include:

- Two CEN workshop agreements: CWA 17253-1 and CWA 17253-2.
- The commercial delivery of simulators within the UK and abroad.
- The transfer and enhancement of models and data in the AnyBody Repository.
- The development of HiPIMS technology and its installation.

In addition, *WP7* (Management) continued to provide 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.

Impact

(1) MoCaP has been refined and now displays very good concordance with direct determination of joint reaction force using instrumented implant. The refinement is derived largely from the enhancement of the musculature around the joint. The models provide insights into the muscle strength and patient recovery in implants. These improved models have provided new opportunities including the deposition of models in the AnyBody repository.

(2) The Simulator systems developed within LLJ are now continually marketed with a view to translating the cutting edge know-how developed within the project. The SE Asian and Chinese markets are the focus of this push. In addition, the control systems are being used widely in other simulation systems.

(3) Computational models have been validated using simulator data and appear to show a better match than existing finite element models that do not incorporate fluid lubrication.

(4) The research investigating the geno- and cytotoxicity have confirmed the result that the SiN particles of whatever constituency are benign. This includes the solution of these ions. This has been backed up by the *in vivo* experiments which have demonstrated the deleterious nature of CoCr particles and ions whilst showing little reaction to either Ti or SiN.

(5) A new model of the knee joint for use in *in vivo* testing was developed and utilised within the assessment regimes. This model will be made available to other researchers.

(6) Two CEN Workshops were conducted with the British Standards Institute, providing a pair of cutting edge Workshop Agreements around the assessment of particulate debris in joint replacement. These two CWAs: CWA 17253-1 and CWA 17253-2EN have now been published and are widely available to be utilised in the assessment of joint replacements, as required.

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