

## 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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Website: <http://www.lifelongjoints.eu>

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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 Hochschule 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 about 50,000 in the EU alone with direct costs of €500M 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???. 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-polyethylene<sup>16</sup>; 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 ( $\geq 4$  years) with significant investment ( $\geq \text{€}2\text{M}$ ), 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 4 Highlights**

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

- (1) WP1: main focus has been on material analysis of the coatings plus supportive development. This work has resulted in recommendations to WP4 on routes towards improvements to deposition parameters and better end coating properties. Results from the wear testing with WP2 simulator testing contributed to the theory that we require high nitrogen content. A current investigative track in WP4 on the addition of C to the coatings was also suggested by the work undertaken under WP1, and further detailed in the main body of the report.
- (2) WP2: delivered several significant highlights. The taper solution, which is the most promising route to exploitation, has undergone investigation within *ex vivo* and *in vitro*. This has included a novel methodology for the assessment of micromotions in pristine and revised components. Some of the *ex vivo* components exhibited wear in excess of 20 mm<sup>3</sup> which is considered sizable for metal on metal contacts and certainly a magnitude that would have clinical significance. In general SiN has been shown not to be cytotoxic or genotoxic.
- (3) WP3: Advances have been made on a number of fronts in terms of the modelling including:

- The essential elements of the task, 3.3, have been completed, through the measurement of kinematic and kinetic data in a large patient population for a variety of activities of daily living.
  - The measured ADLs motions for the patient cohort at LTHT has provided a unique dataset to be exploited both in this project and beyond.
  - We have outlined also the future translation of these population simulations into representative "daily loading scenarios", for use in both T3.6 and WP2.
  - This task has finished, with the initial models of elasto-hydrodynamic lubrication and wear extended with new techniques considering also asperity-to-asperity contact and wear. The results of these models, and their comparison with experimental data, are outlined in D3.5.
- (4) WP4: The focus of the work undertaken has been on the modification and optimization of deposition parameters, identified in D4.3 and 4.4. A significant challenge has been that despite the provision of coatings that meet both the preliminary and intermediate coating specifications deposited films have achieved only limited success to date in simulator tests articulating against either themselves or polyethylene, whereas pin-on-plate reciprocating testing have demonstrated much more promising performance. However, one important point of success has been the benefit which the coating has provided when applied to taper junctions where it has resulting in a marked reduction in the fretting current compared to the use of uncoated CoCrMo and Ti64 tapers.
- (5) WP5: Rat study completed demonstrating the biocompatibility of SiN. Problems with manufacturing the rabbit prosthesis have been solved. Coating of the prostheses could be completed. Instruments and guides for surgery were customized and also specifically produced. Cadaver tests were successful. GLP study plan is finalized and signed.
- (6) WP6: Significant activities including:
- An External Expert Advisory Board met at the University of Leeds, February 2017.
  - A Patient Event was delivered at the Schulthess Klinik, Zurich in September 2017.
  - Two CEN Workshops have been planned and advertised at the BSI for delivery in Summer 2017: *"Tiered Toolkit Approach to Evaluating the Biological Impact of Wear Particles from Joint Replacements and Related Devices"*; and, *"Novel Isolation Methods for Wear Particles, Produced in Joint Replacement Implants and Related Devices, Based on Density Gradient Centrifugation"*.

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 (Zurich, Switzerland and Manchester, UK).

## 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.
- (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.
- (3) Computational models have been validated using simulator data and appear to show a better match than existing, large finite element, models.
- (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 on the rats which have demonstrated the deleterious nature of CoCr particles and ions whilst showing little reaction to either Ti or CoCr.
- (5) Increased competitiveness of European Industry – delivered through both improved product performance through the coating and enhanced testing.
- (6) Two standards are to be developed. Two associated workshops are to be delivered with the British Standards Institute, which will provide a pair of cutting edge Workshop Agreements around the assessment of particulate debris in joint replacement. The CEN Workshop Agreements will be published widely and will be available to the joint replacement community to utilise as required.

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