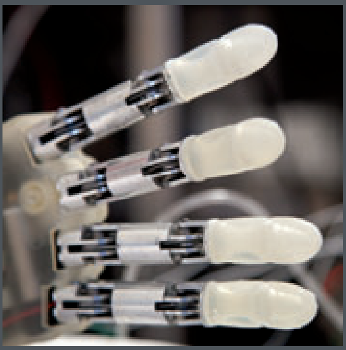


ÉCOLE POLYTECHNIQUE
FÉDÉRALE DE LAUSANNE

IRCCS San Raffaele
Pisana

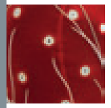
Scuola Superiore
Sant'Anna
di Studi Universitari e di Perfezionamento

Policlinico
Gemelli
IMPEGNO PER L'ECCELLENZA

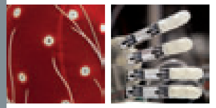
UNIVERSITÀ CAMPUS BIO-MEDICO
DI ROMA

IMTEK
Department of
Microsystems Engineering

LifeHand 2 | ENGLISH



LifeHand 2 | INDEX



1 | LifeHand 2: Introduction

At the end of the 1980s, Professor Paolo Dario from Pisa's Scuola Superiore Sant'Anna *launched the ambitious project of creating a neural controlled prosthetic hand, based on electrodes implanted in the arm's peripheral nerves. The project was started thanks to a series of international collaborations (including with Professor Gregory T. A. Kovacs of the* Stanford University *and Professor Patrick Aebischer, then of* Brown University *and currently President of the* Ecole Polytechnique Federale de Lausanne, *EPFL). Research integrated in the European INTER Project assumed a particular importance. Since then, Pisa's* Scuola Superiore Sant'Anna *has coordinated or has been involved in various European and international projects* (GRIP, CYBERHAND, NEUROBOTICS, DACTIN, NEBIAS) *also thanks to scientific backing from Professor Silvestro Micera who, over the years, flanked Prof. Dario, to eventually become his successor. Today Prof. Micera, the coordinator of the* LifeHand 2 *Project, is head of the Neuroengineering Department and activities relating to neural control of the prosthetic hand at* The BioRobotics Institute of Scuola Superiore Sant'Anna *of Pisa. Since 2011 he has furthermore been working at the EPFL's new Neuroprosthesis Centre in Lausanne.*

In this context, the Università Campus Bio-Medico di Roma *has also been cooperating. In 2008 the University and its Hospital provided the platform for the final stages of the* LifeHand *project, which led, in cooperation with the* Scuola Superiore Sant'Anna *of Pisa and other European partners, to the successful experimenting of the first direct control of a biomechatronic prosthetic hand via neural interfaces implanted in the peripheral nerves of an amputated patient.*

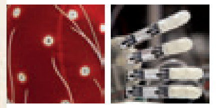
Since then, the group's research has continued via diverse Italian and European projects, with a central core of researchers, composed of the teams of Prof. Paolo Maria Rossini (Neurologist, current Chairman of Neurology at the University Policlinico Universitario 'Agostino Gemelli', *Rome), of the already-mentioned Prof. Silvestro Micera and of Prof. Eugenio Guglielmelli, Head of the Laboratory of Biomedical Robotics and Biomicrosystems of the* Università Campus Bio-Medico di Roma.

Studies, which have been carried out furthering the results achieved in 2008, led in 2013 to this latest experimental phase called LifeHand 2. *The research project enabling experimentation was named* NEMESIS (NEurocontrolled MEchatronic hand prostheSIS) *and was financed by the Italian Ministry of Health within the framework of grants awarded to 'young researchers'. The project's head researcher is Prof. Micera. On the other hand, the Coordinating Centre is the* IRCSS San Raffaele 'Pisana', *under the clinical guidance of Prof. Rossini.*

This is the second stage on a long-term journey, aiming to create a completely implantable prosthesis system, richly sensorized and controlled through the patient's nervous system, with a dexterity comparable to a natural limb in carrying out of daily activities.

During the course of LifeHand 2*'s experimenting the* OpenHand *biomechatronic prosthesis was employed, which has been developed in the laboratories of the* Scuola Superiore Sant'Anna *of Pisa as part of the research project of the same name funded by MIUR (PRIN 2009-2012). The personalized socket used to attach the prosthesis was created by* Ortopedia Italia *(Frosinone) within the framework of the DTB2\NEUROHAND project.*

The synergy between researchers is set to continue also with the HandBot *project (MIUR\PRIN 2013-2015 Programme), which has just been launched and is being coordinated by the* Università Campus Bio-Medico di Roma.



2 | The Aims

Feeling and manipulating objects with the prosthesis

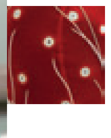
LifeHand 2 aims to experiment the skilful use of an upper limb biomechatronic prosthesis by an amputated patient. An artificial hand capable of directly conversing with the brain via four intraneural electrodes, implanted in the median and ulnar nerves of the patient's stump. It was a matter of assessing the capability of the prosthesis, equipped with tactile sensors activated on the index and small finger, in sending to the brain information about the shape, consistency and position of different objects. A flow of information which, starting from the prosthesis, had to reach the nerves via neural electrodes and from there the brain. As to the opposite process (communication from brain to the prosthesis) it was a question of demonstrating that the patient, on the basis of his free will or of the sensory feedback, would be able to grasp objects moving naturally and effectively as well as to apply, in real time, the appropriate strength to the grip. *LifeHand 2*'s goal was to create the first bidirectional control of a biomechatronic upper limb, from the prosthesis to the bran (feelings) and from the brain to the prosthesis (movement intentions).

Bidirectional communication in real time

This bidirectional circuit had to furthermore occur at such a speed as to restore motor and sensory experience in real time without any significant delay (feeling and reaction delays in relation to the patient's movement intentions). Obtaining this result meant the patient recovering the natural flow of sensations and movements between limb and nervous system, enabling him to use the robotic prosthesis in a very similar way to a human hand, including the ability to rectify any incorrect amount of strength applied during the course of a movement.

During the experimentation, *OpenHand* was employed, the biomechatronic limb prototype developed by *ArtsLab* of *The BioRobotics Institute of Scuola Superiore Sant'Anna* of Pisa. While in the *LifeHand* (2008) experimentation the prosthesis was placed on a surface in the patient's field of vision, in *LifeHand 2* it was directly fitted on the stump of the patient's arm via a specially made-to-measure socket.

A new experimentation is expected to take place in about two years.



3 | Surgery and Experimentation

LifeHand2's years of preparation have culminated in the implant surgery of intraneural electrodes, which were followed by nearly three weeks of exercises required in order to teach the patient to use the neural circuit and eight days of experimental usage of the prosthesis (exercises of sensory perception and of grasping objects).

19th – 24th January 2013:
Pre-surgery and Experimentation

The patient, who arrived in Rome 18th January 2013, was subjected to pre-surgery screening at the University *Policlinico 'Agostino Gemelli'* aimed at assessing his health and monitor the reorganization of his cerebral regions and functions following the amputation of his left hand in 2004. Listed below are the tests which were carried out:

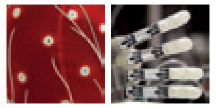
- Blood tests;
- Electrocardiogram;
- Chest X-ray;
- 32 Channel Electroencephalogram (EEG) while resting and with peripheral stimulation;
- Sensory Evoked Potentials (SEP) with motor imagery;
- Electroneurography (ENG) and Echography of the nerves in the stump and intact limb;
- Transcranial Magnetic Stimulation (TMS);
- EEG/TMS of three different cortical areas (frontal, central, posterior);
- functional Magnetic Resonance (fMRI) with motor and sensory cortex mapping;
- Clinical evaluation of missing limb syndrome pain levels;
- Neuropsychological Personality tests.

26th January: Surgery

Surgery to implant the four *TIME* intraneural electrodes in the median and ulnar nerves of the left arm of the patient was performed at the the University *Policlinico 'Agostino Gemelli'*, Rome. The operation began at 8.30 in the morning and lasted over seven hours. Neurosurgeon Professor Eduardo Marcos Fernandez and his team inserted the electrodes – placed in distal and proximal positions, two for the median nerve and two for the ulnar nerve, in the stump – transversally to the nervous fascicle. Four exit points in the patient's arm were created for the electrode wires, in order to enable them to be connected to experimental equipment during tests over the following weeks.

Surgery, carried out under general anaesthesia, required an incision approximately 15 cm long to be made on the inner side of the left arm, well away from the traumatic edge of the stump. Once the two nerves had been isolated from the muscular and adipose tissues, the implantation was carried out using a surgical microscope. The part of the electrode containing contact points used for transmitting signals was placed inside the nervous tissue via guided-needle. The remainder of the microscopic filaments was connected to the nerve and micro-stitched in order to guarantee greater stability.

Straight away in the operating theatre and with the patient still under anaesthetic, the stimulation system was tested as well as the correct functioning of the 64 contacts (or sites) located on the inserted electrodes (16 for each of the four electrodes) while their impedance was gauged. The patient was discharged from hospital two days after surgery so as to begin the prosthesis educational and experimenting phase.



30th January – 14th February: Training

The patient spent nearly three weeks with researchers, every day training for several hours in order to learn how to recognise and classify electric impulses, delivered via the intraneural electrodes, with characteristics identical to those which would be transmitted by the biomechatronic hand during experimentation.

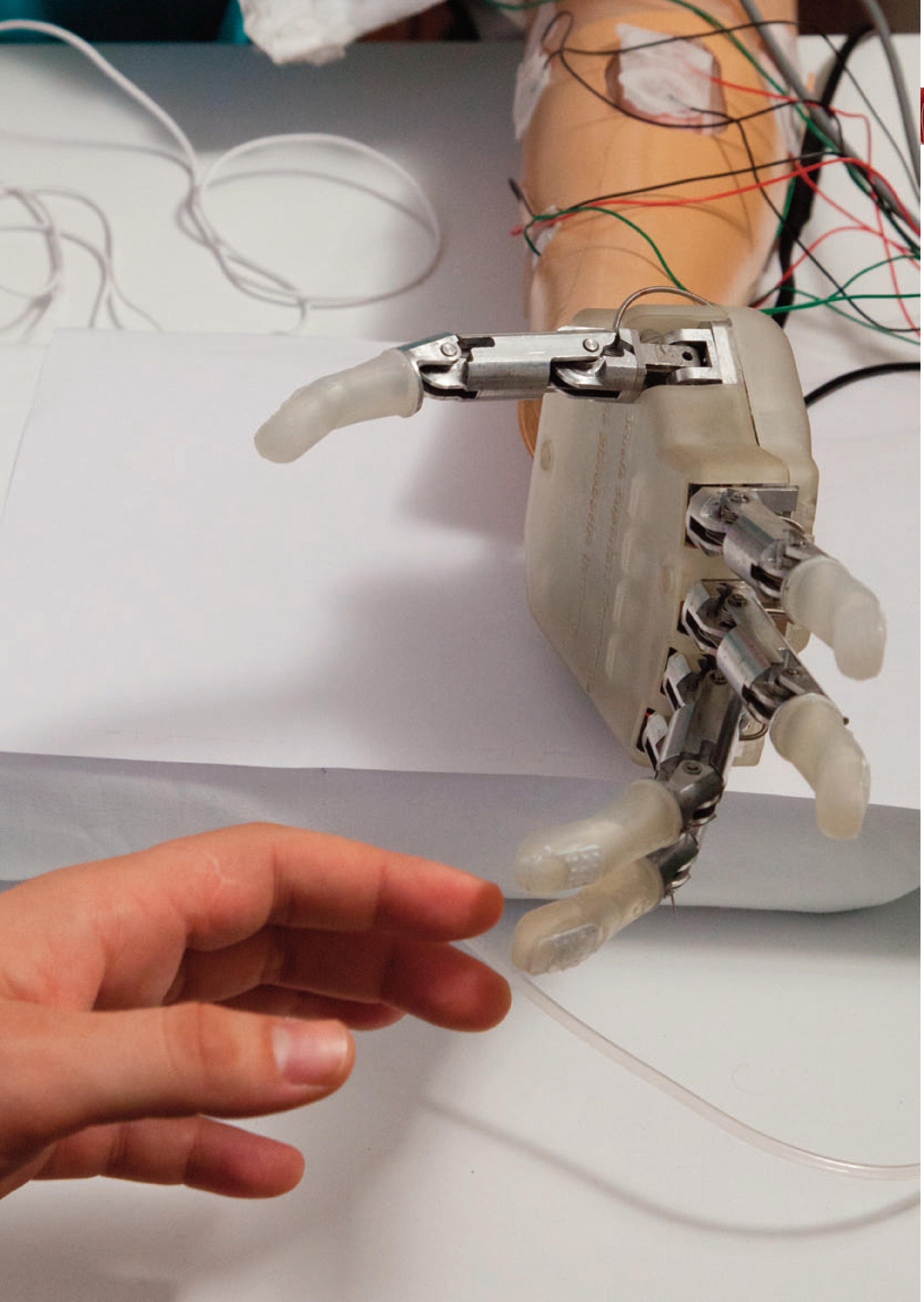
16th – 23rd February: Experimentation with prosthesis

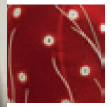
Experimentation with prosthesis lasted eight days, during which the patient faced two daily sessions of about four hours each. During sessions, he undertook tactile recognition exercises of objects and grasps. The objects were of different shapes and consistency. During the course of the exercises, the patient was blindfolded and acoustically insulated. In this way, researchers were able to assess the patient's ability to correctly perceive and handle objects solely relying on sensory information sent to his brain by the sensors positioned on the prosthesis, without the aid of sight or sounds in recognising their shape, consistency and position. The bidirectional communication flow between prosthesis and brain was recorded during the course of the sessions using appropriate equipment, providing data which was later studied by the researchers.

To create the bidirectional communication circuit from the prosthesis to the brain (sensory) and vice versa (movement and grasp intent), two algorithms were developed by researchers:

- one capable of "reading" the output from the tactile sensors of the robotic fingers and sending it to the nervous system through the intraneural electrodes in the form of electric impulses;
- the other capable of receiving, processing and decoding the surface electromyographic electrodes *(sEMG)* signals located on the patient's stump muscles and transforming them into appropriate motor commands for the robotic hand.

On **24th February 2013**, after the 30 days which had been authorized for the implant of the four electrodes in the patient's nerves, surgery was performed for their removal.





4 | The achieved results

Analysis of experimental data of the project *LifeHand 2* provided researchers with scientific feedback that confirmed the possibility of restoring, to a patient whose upper limb had been amputated, tactile sensations and the ability to handle objects near to a natural way.

The patient, in particular, was quickly able to:

- combine the sensory areas so to manipulate robustly the overall palm force;
- distinguish the different consistencies of hard, medium and soft objects (with more than 78.7% accuracy);
- recognise the basic shape and size of objects, such as the cylinder of a bottle, the sphere of a baseball ball and the oval of a mandarin (88% accuracy);
- understand the location of an object in relation to the hand, therefore sending to the prosthesis the most appropriate command in order to shape the best grasp (97% accuracy);
- self-rectify when applying the wrong amount of pressure on an object during the movement itself, thanks to a communication flow between the prosthesis and the brain in a reaction time of less than 100 milliseconds;
- manage in real time the different levels of exerted force for the two different nerve sensory areas (index finger-thumb, small finger) while holding an object in palm of hand (with 93% accuracy).

The pointers from experimentation also highlighted the importance of reactivating tactile *feedback* in order to enable the patient to use the robotic prosthesis with dexterity. When, in fact, the artificial circuit taking sensory information from the prosthesis to the brain was deactivated, the patient's dexterity markedly diminished despite being able to see (holding exercises with active sensory *feedback* were on the other hand undertaken blindfolded and in acoustic isolation).

A Problem to Solve

In the first *LifeHand* experiment in 2008, the biomechatronic prosthesis connected to the patient's nervous system was placed on a surface, about two metres away from the arm fitted with electrode implants. In the case of *LifeHand 2*, on the other hand, the prosthesis was fitted onto the arm, at a distance therefore of a few centimetres from the electrodes implanted in the patient's median and ulnar nerves.

The vicinity of the biomechatronic prosthesis' electronic circuits to the electrodes implanted in the nerves triggered an electronic interference – so-called 'background noise' – impairing the clarity of the intraneural communication signals between the prosthesis and nervous system.

For this reason, during the course of the experimental sessions, researchers decided to forsake sending the movement intentions from the brain to the prosthesis via intraneural electrodes, creating an alternative path through myoelectric electrodes applied to the surface of the arm in proximity to the amputation. Communication via intraneural electrodes was instead used so as to send sensory information from the prosthesis to the patient's nervous system. In *LifeHand 2* it was therefore a matter of prioritising assessment of the working, through the intraneural electrodes, of the communication flows in the opposite direction (from the prosthesis to the brain). Through improved shielding of the biomechatronic prosthesis, in future experimentation a successful completely intraneural bidirectional communication may be expected.

5 | The Patient

Why Dennis

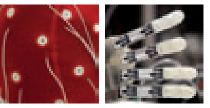
Agreeing to donate several weeks of his life to undergo two operations in one month (an implant and the removal of electrodes involving two nerves from the upper limb) with general anesthesia; being available, just 48 hours after the implant, for a team of doctors and engineers to carry out a long list of tests, exercises and trials; all of which in a foreign country, without guarantee the experimentation would be successful and without any personal gain: it suffices to bear all this in mind to realise that the success of an experimental programme such as *LifeHand 2* did not solely rely on technology and the know-how of the researchers involved, but mainly on the choice of the right patient, out of the several who arrived from different countries, candidates for this kind of test, who were hoping to be accepted by a working group capable of sooner or later solving their problem.

Dennis came through the selection because he had met all the correct psychological, physical and personal criteria. A patient had to be selected devoid of cognitive or psychological problems who had had an amputation close enough to the hand of the upper limb. The patient also had to be young enough, although at the same time sufficiently mature to give his consent and to manage the stress and fatigue of an intense schedule, including daily stimulation and exercise sessions. The candidate also needed to have a lively intelligence and a proactive attitude, capable of learning quickly and able to carry out carefully and precisely all the set tasks and to communicate correctly (in English) the sensations felt along with any other information that could be useful to the team. A healthy constitution was obviously crucial together with a physique strong enough to sustain two operations under total anaesthetic in the space of 30 days.

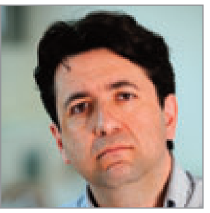
Who is Dennis Aabo Sørensen

The choice fell on 36 year old **Dennis Aabo Sørensen** from Aalborg, the third largest city in Denmark with a population of 200,000. It is a city located 400 km. and a 4 hour drive from Copenhagen. Married, father of 3 children, Denis owns a family interior house-painting business.

Ten minutes after midnight on New Year's Eve 2004 a firecracker went off in his left hand. Dennis immediately realised how serious the accident was. That night he underwent the amputation of his limb.



6 | The Research Centres involved (2008-2013)



Prof. Silvestro Micera
Ecole Polytechnique Federale de Lausanne
EPFL (Svizzera)
BioRobotics Institute
of Scuola Superiore Sant'Anna of Pisa
SSSUP (Italy)

The Team
Engineer PhD Stanisa Raspopovic
Engineer Marco Capogrosso
Engineer Marco Bonizzato
Engineer Jacopo Carpaneto
Engineer Jacopo Rigosa
Engineer Luca Citi (*visiting* dalla University of Essex)

Project Coordinator - *LifeHand 2*

- Development of the algorithms for the control of the hand prosthesis
- Development of software to create tactile feedback from the prosthesis to nervous system
- Protocol for experimentation
- Integration of all the components into the final system

The Team
Dr. Giuseppe Granata
Engineer Francesca Miraglia
Ms. Astrid Van Rijn

Coordinating Centre of the *NeMeSis* IRCSS Project

- Supply of technological material and equipment for TMS and EEG
- Logistic back-up for patient and family

Prof.ssa Maria Chiara Carrozza
BioRobotics Institute
of Scuola Superiore Sant'Anna of Pisa
SSSUP (Italy)

The Team
Engineer PhD Marco Controzzi
Engineer PhD Calogero Maria Oddo
Engineer PhD Christian Cipriani

- Planning and development of the sensitised biomechatronic prosthesis hand

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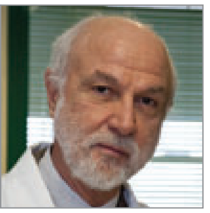

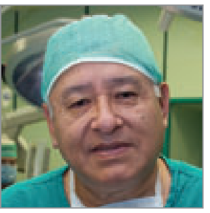

Prof. Paolo Maria Rossini
Chairman of Neurology Institute,
University *Policlinico 'Agostino Gemelli'*
of Rome (Italy)
IRCCS San Raffaele Pisana (Italy)

Clinical Director - *LifeHand 2*

Prof. Eduardo Marcos Fernandez
Neurosurgeon,
University *Policlinico 'Agostino Gemelli'*
of Rome (Italy)

He performed implant surgery of the electrodes on the patient

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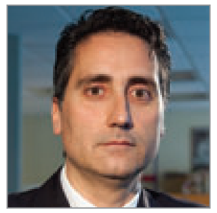

Prof. Eugenio Guglielmelli
Director of biomicrosystem and biomedical robotics laboratory,
Università Campus Bio-Medico di Roma
UCBM (Italy)

The Team (engineers):
Engineer PhD Loredana Zollo
Engineer Francesco Petrini
Engineer PhD Antonella Benvenuto
Engineer Anna Lisa Ciancio

The Team (neurologists):
Dr. Mario Tombini
Dr. PhD Giovanni Di Pino
Dr.ssa PhD Florinda Ferreri

- Cooperation for the development of the mechanical and electric models (analytic and computational) for animal and human peripheral nerve
- Cooperation for the definition of the technical and functional specifics for the creation of the electrodes;
- Development of protocol for experimentation
- Selection of patient
- Participation in carrying out the clinical and neurophysical protocol of experimentation
- Collaboration to integration of all the components into the final system

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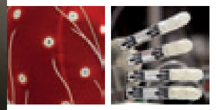
Prof. Thomas Stieglitz
Microsystem Engineering Department,
Freiburg University – IMTEK (Germany)

Engineer PhD Tim Boretius

- Planning and development of the *TIME* electrodes



7 | Technology: electrodes and prosthesis

The electrodes: the communication *hardware* between the nerve fibres and computer

Known as *TIME (Transverse Intrafascicular Multi-channel Electrodes)*, the intraneural electrodes placed in the patient's nerves for the *LifeHand 2* experimentation were designed and developed at the Laboratory of Biomedical Microtechnology at the IMTEK *(Institut für Mikrosystemtechnik)* of the University of Freiburg, supervised by Prof. Thomas Stieglitz.

Completely biocompatible, these *TIME* electrodes were designed, made and tested to be placed transversally to the nerve fascicles constituting a nerve (with a minimum diameter of 220 micrometres, about 3 human hairs). The transversal implant onto the nerves is aimed at establishing the largest amount possible of contact points between the communication channels of the electrodes and the nervous fibres, so as to amplify the possibility of communicating with the central nervous system. The width of the *TIME* electrodes is variable. The widest part inserted into the nerve is approximately 350 micrometres. Their overall thickness is approximately 22 micrometres.

The 16 electrical contacts (or active sites) that are incorporated in the electrodes, are made from platinum and iridium oxide on a sub-layer of polyimide, guaranteeing their isolation and flexibility. Each has a diameter of 80 micrometres (a human hair is equivalent to 70 micrometres). The electrodes are capable of supporting an electric charge of 120 nanoColumb. In the laboratory tests they were found to be functionally stable after receiving over 25 million electric impulses.

During experimentation, the electrodes proved to have an extremely high level – never before reached – of selective activation of the nerve fibre distributed across the length of the nerve. This helped generate sensations in the patient's nervous system using much lower intensity level impulses than with *LifeHand* 2008 experimentation. Lowering intensity of the impulses is important as it coincides with a reduction in pressure on the nerves during the experimentation stage and consequently of the risk of inflammation.

Up until the thirtieth day of experimenting, the four electrodes did not cause any type of discomfort or irritation to the patient. Even after their removal, the *TIME* implants were fully functional and performing soundly.

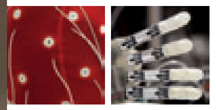
The prosthesis: a sensorized artificial hand

The biomechatronic prosthesis prototype used for the experimentation was developed and produced at the *ArtsLab* of *The BioRobotics Institute of Scuola Superiore Sant'Anna* of Pisa. Known as *OpenHand*, it represents the evolution of the CyberHand and SmartHand prototypes used in previous projects, also including the 2008 research project *LifeHand*.

The structure of the prototype was made in order to guarantee, at a mechanical level, greater freedom degrees.

OpenHand is the outcome of a biennial research programme (*OPEN* neuro-prosthetic *HAND* platform for clinical trials) promoted by the Italian Ministry of Education, University and Research (MUIR). Size, ability to move fingers and weight (just over 600 grammes) are equivalent to that of a human hand.

For this experimentation, the index and small finger, out of the tactile sensors on the five *OpenHand* fingers, were activated at the same time. The tactile sensors were able, thanks to a special conversion and decoding algorithm in the computer connected to the *OpenHand*, to send back an electric charge proportional to the amount of pressure used in touching objects or other external elements.

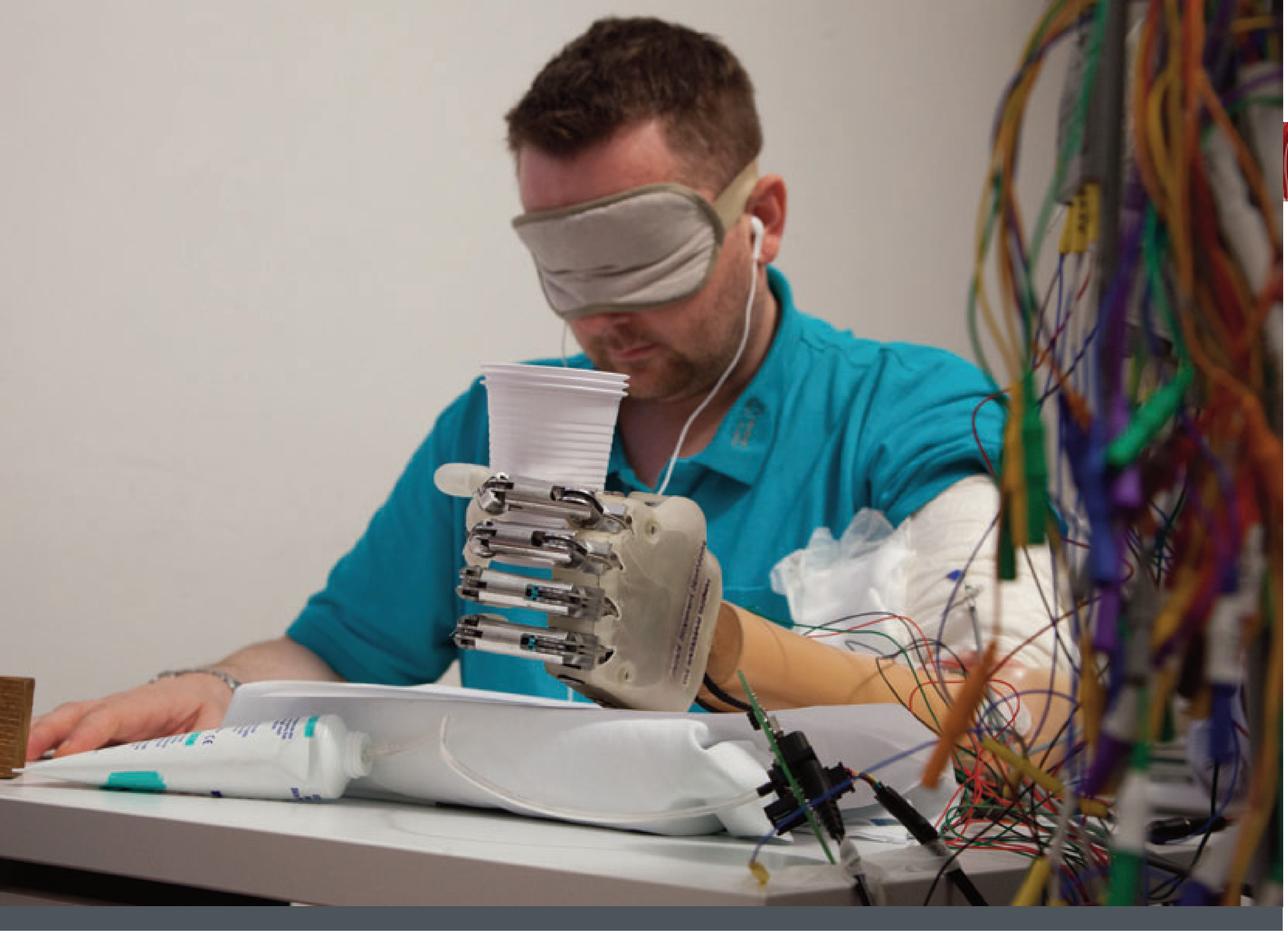


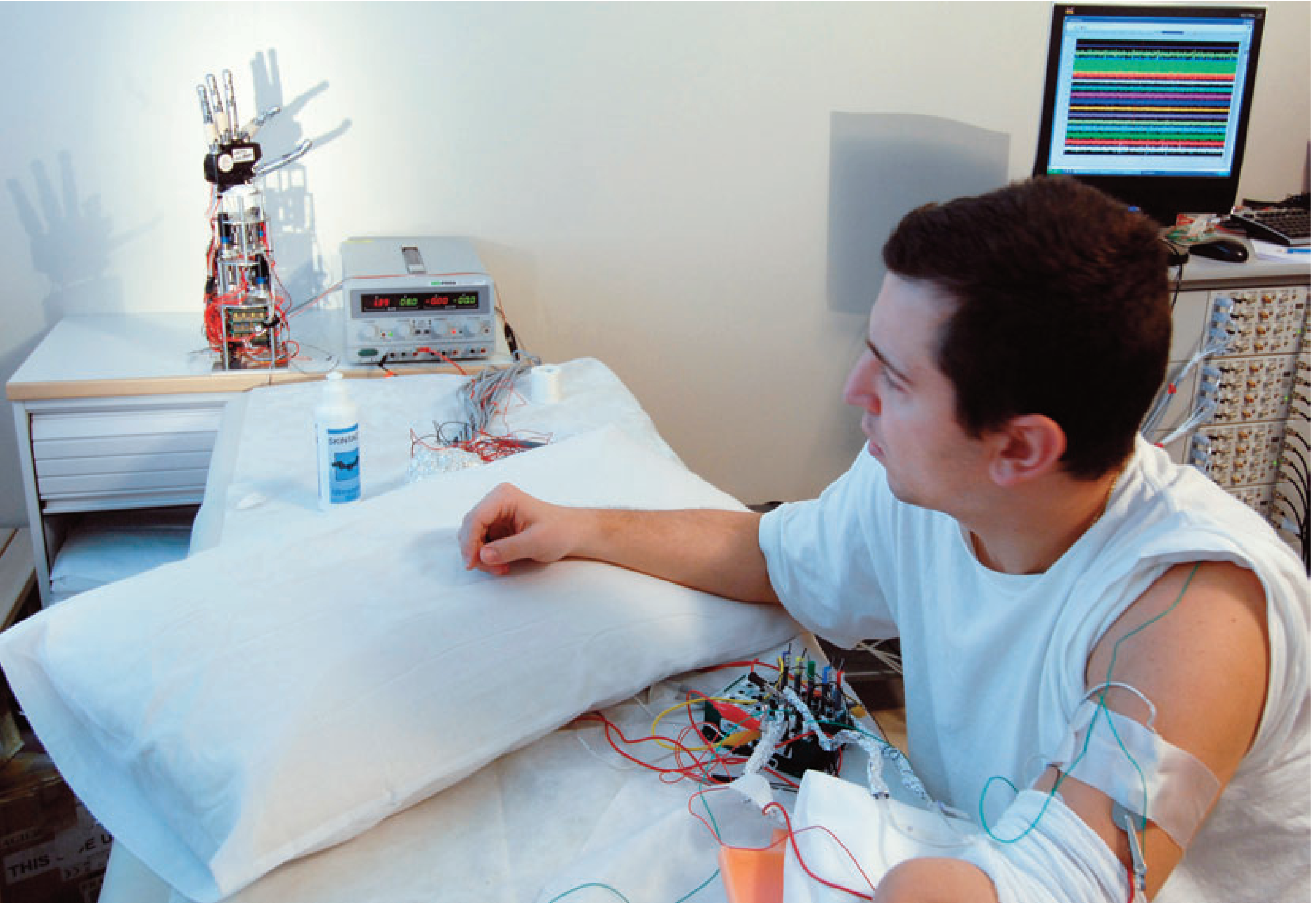
8 | Fresh Developments from *LifeHand*

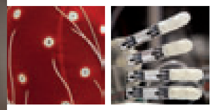
LifeHand 2 is the natural evolution of the research that led to the 2008 international success of *LifeHand*. The patient was at the time an Italian Brazilian national Pierpaolo Petruzziello, who had undergone the exact same amputation as Dennis Aabo Sørensen, the subject of this second experimentation (left limb immediately below the elbow). Also in that case the patient's median and ulnar nerves were implanted with four intraneural electrodes, connected to the biomechatronic prosthesis *CyberHand*, two generations older than the *OpenHand* used by Dennis. The results of that first experimentation were unveiled before public opinion during a press conference held at the *Università Campus Bio-Medico di Roma* in December 2009 with an impressive international feedback on mass-media.

LifeHand's objective was to enable the patient to carry out three basic hand movements (fist, claw and thumb to index finger) via direct communication between the prosthesis and the brain, passing directly and exclusively through the nervous system as opposed to unnatural communication. Motor commands despatched from the brain to the periphery may in fact also be collected by myoelectric electrodes fixed onto positions on the body surface corrisponding with specific muscular tissues, such as pectoral or arm muscles. In turn the myoelectric electrodes send back the movement signal to the prosthesis. While the communication is indeed effective, it is nevertheless unnatural. *LifeHand's* objective was reached, even if the neural control of the prosthesis was handled without the artificial hand being implanted on the patient's stump and without any sensory *feedback* being sent by the prosthesis to the brain.

Five years on from the first experimentation, with *LifeHand 2* researchers have been striving to also create a tactile response which, from the sensors of the prosthesis, would reach the patient's brain. The latter, thanks to sensory information, should succeed in recognising shape and consistency of objects, gauging as a result the amount of strength to be applied with every holding movement. In the case of *LifeHand 2*, the prosthesis was moreover fitted onto the arm of the amputated patient, thereby creating a more natural physical condition than in 2008, be it not yet definitive.

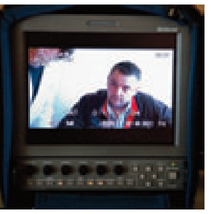






A comparison of the two experiments

	LifeHand (2008)	LifeHand 2 (2013)
Duration of Experimentation	30 days (including surgery)	30 days (including surgery)
Dimension of surgical incision	8 cm	15 cm
Number of implanted electrodes	4 electrodes in the median and ulnar nerves	4 electrodes in the median and ulnar nerves
Type of electrodes used	**tf-LIFE** *(thin-film Longitudinal Intra-Fascicular Electrode)* Biocompatible electrodes to be placed lengthwise on the nerve	**TIME** *(Trasverse Intrafascicular Multichannel Electrode)* Biocompatible electrodes to be placed across the nerves in order to increase the contact points with the nerve fibres and increase communication with the central nervous system
Diameter of contacts	80 micrometres	80 micrometres
N° of electrode contacts (active sites)	12 per electrode (8 + 2 controls + 2 grounds)	16 per electrode (14 + 2 grounds)
Material used for the contacts	Platinum on a sub-layer of polyimide	Platinum and iridium oxide on a sub-layer of polyimide
Potentially injectable electric charge	Approximately 4 nano-Coulombs	120 nano-Coulombs
Type of stimulation in order to move prosthesis	Neural impulses from patient's brain via connection with intraneural electrodes	Myoelectric impulses arriving from five surface electrodes placed on muscles of patient's left forearm
Method of extracting spikes from electrodes	Acquisition from one channel at a time	Simultaneous acquisition from several communication channels with peripheral nerves
Tactile feedback from the hand to the patient	Absent	Present (2 tension sensors placed within fingers of the prosthesis)
Environmental conditions of the experimentation	Biomechatronic hand placed on a surface remotely connected to the implanted electrodes	Biomechatronic hand directly attached to the patient's socket on the forearm of amputated limb
Main abilities observe during experimentation	Ability to move fingers through neural impulses so as to make three movements: · claw · small finger movement · fist	Precision control and manipulating abilities through the prosthesis in order to: · recognize the position of an object in relation to the hand · recognize different consistencies of the objects · recognize the basic shape of objects · apply the correct strength to hold objects · fine modulation of applied force over objects



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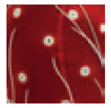

Dennis Aabo Sørensen,
Selected patient
for the* LifeHand 2 *experimentation

HOW DOES YOUR BIOMECHATRONIC HAND FEEL?
"I'd say I am using the prosthesis like a natural hand, I can sense and really 'feel' it, when I move it. It's as if some special vibrations let me understand when I get hold of an object and how it's made".

SENSORIAL FEEDBACK
"That sensorial feedback was an amazing experience as far I was concerned. It seems incredible being able to feel the different consistency of objects, understand if they're hard or soft and realise how I am clasping them. The feedback is furthermore extremely natural. I'm convinced that this is the future of prosthesis in the world".

Prof. Paolo Maria Rossini,
Neurologist,
LifeHand 2 *experimentation Clinical Director*
Policlinico Universitario Agostino Gemelli, *Rome*

EXPERIMENTATION PHASES
"All of the experimentation revolved around the idea of succeeding in, on the one hand, achieving an extremely high standard in the system's ability to interpret orders 'online' and have them properly carried out by the robotic hand. On the other, we aimed at exploring the changes in the organisation of Denis' brain, which would lead, as we were all hoping, to a full control of the prosthesis feedback within the control loop".

POSSIBLE DIFFICULTIES
"We started off like researchers on the first moon expedition: after so many years of work, you press the button, launch the rocket and then there's no turning back. We launched into experimentation knowing that we had done our best and hoping and being confident that there'll be no situations of no-return. But the risk that something could go wrong was always there".

Prof. Silvestro Micera,
Bioengineer
LifeHand 2 *experimentation Coordinator*
BioRobotics Institute
of Scuola Superiore Sant'Anna *of Pisa*
***and* Ecole Polytechnique Federale de Lausanne**

THE AIMS OF *LIFEHAND 2*
"The aim of the project is to develop and accurately employ a bidirectional neural-controlled prosthetic hand . This involves the peripheral nervous system, therefore the patient's motor commands, registering neural signals and controlling the prosthesis in the most natural way possible. In order to do this, the sensory nerves must be stimulated so as to send tactile information to the brain in real time. The goal is to imitate as closely as possible the bidimensional movements of a natural hand, like each one of does every day".

Prof. Eugenio Guglielmelli,
Bioengineer
Università Campus Bio-Medico di Roma (UCBM)

THE FUTURE OF RESEARCH IN THIS FIELD
"New stimulation methods are currently being developed. We are primarily looking at using magnetic fields rather than electric signals. Instead of electrodes we'd have therefore microprobes and micro-coils creating magnetic fields and in turn generating electric signals to stimulate the nerve. Interaction with the nerve tissue would therefore be less problematic. Another aspect we are focusing on is maximising the control functions and carrying out of movement between the artificial limb and brain. Despite being cutting-edge, the electrodes are not capable of understanding all the information that passes through the thousands of nervous fascicle. The idea, therefore, is to ensure the electrodes register the intended movement arriving from the brain, for example, the kind of grip to employ in taking hold of an object, and that the processing of the movement commands to the last detail is entrusted to a software system in the prosthesis, for example, with an aim to guaranteeing a firm grip and precise handling manoeuvre. We are expecting to experiment these innovations on a patient within the next two years".

Prof. Thomas Stieglitz,
Engineer
IMTEK, Freiburg University

THE TIME ELECTRODES
"Each TIME electrode is an interface between the world of technology and biology. Electric current from technological equipment can pass inside these interfaces directly to the patient's nerve. This is the first time ever that this type of electrode has been used for this purpose, but we are very pleased with the results and are hoping to be able in the future to transform these results into biomedical products".

Dr. Stanisa Raspopovic,
Bioengineer
BioRobotics Institute
of Scuola Superiore Sant'Anna *of Pisa*
***and* Ecole Polytechnique Federale de Lausanne**

DIFFERENT AIMS FROM LIFEHAND
"The LifeHand project was a milestone for us as it allowed us to understand that stimulation was effective in providing sensory feedback and that it was possible to register neural motor signals and relate them to different types of hand movement. The current experimentation is even more advanced. The patient had the prosthetic hand fitted onto the amputated arm and managed to control the types of hold in real time, undertaking different ones thanks to the sensory information sent to the patient's nervous system. This is the very first time this technique has been tested on a patient".

Dr. Giovanni Di Pino,
Neurologist
Università Campus Bio-Medico di Roma (UCBM)

CHOICE OF PATIENT
"A person who has to endure the fatigue of 30 days of such intense experimentation must be highly motivated, must have a high level of cognitive ability and be – leaving aside his amputation – healthy".

Prof. Eduardo Marcos Fernandez,
Neurosurgeon
Policlinico Universitario Agostino Gemelli, *Rome*

POTENTIAL DIFFICULTIES OF THE SURGERY
"We needed to create the correct balance between the microelectrodes, their surrounding environment and the nerve, so that no conflict would be created between the system to be implanted and the nerve. It was, for example, important to place the electrodes in the right direction so as not to create pressure on the nerves, thus causing the patient pain and potential damage to the nerves. The correct positioning of the electrodes inside the nervous fascicle was essential to maximising their function as communication channels".

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What is *LifeHand 2*?

It is the second stage of a long-term project aiming to create a controlled prosthetic hand that explores the environment via its sensors in a nearly natural way, which can carry out normal daily functions similar to that of a human hand. *LifeHand 2* is focused on the advanced control of a biomechatronic hand. On the one hand, it has been successful in giving the amputated patient back the feeling of objects touched through the prosthesis, creating a pathway starting from the sensors mounted on the fingers of the prosthesis, through electrodes implanted on the median and ulnar nerves of the patient, to reach the brain. On the other, on the basis of received sensory information, the patient has been able to handle objects by finely controlling the movements of the prosthesis via myoelectric control.

What, in order, were the experimental stages? How long did they last?

A series of pre-surgery tests and controls were carried out on the patient to assess his overall physical health and organisational state of his cerebral cortex (motory and sensory); implant surgery of electrodes; pre-experimental phase with mapping of communication channels between nervous system and electrodes and repeated stimulation of the patient's cerebral cortex through a string of specific impulses; creation of a communication circuit between robotic prosthesis, linked to the electrodes, and patient's nervous system, so as to re-establish tactile feedback. The entire experimentation lasted 30 days starting from the surgical implant (26th January 2013) and ending with another operation to remove electrodes (24th February 2013).

What results has *LifeHand 2* achieved?

The analysis of the experimental data showed that an effective sensory feedback in the patient's nervous system has been restored, through impulses arriving from the sensorized fingers of the prosthetic hand. This ensured control of the strength the patient used in holding objects using the artificial prosthesis and it enabled him to perceive and refer the different consistencies, sizes and basic shapes of objects apart, even understanding their position in relation to the artificial hand.

Why four electrodes? Why place them in the median and ulnar nerves?

The researchers needed to rely, at least hypothetically, on a connection between the nervous fibers as close to the distal (the hand) as to the proximal (the shoulder) limb segments. The insertion of two nerve electrodes per nerve at different angles and at opposite ends of the nervous surface visible to the surgical incision broadly speaking guaranteed this possibility. The median and ulnar nerves were chosen as almost all brain impulses to control the hand pass through them.

What is meant by 'closing the reaction circle' between the motor and sensory circles?

Researchers ensured that the patient could control a sensorized hand prosthesis relative well (movement commands from brain to prosthesis) thanks to his nervous system being able to receive tactile information in the form of electric impulses arriving from the sensorized fingers (flow of sensed information from prosthesis to brain).

Why were the neurophysical tests carried out before, during and after the experimentation stages?

Researchers needed to gather objective evidence about the condition of the patient's cerebral neuroplasticity prior to the beginning of experimentation and that this was going to be modified alongwith the learning process. They then monitored any changes that occurred during the stimulation and control of the prosthesis sessions. They finally verified any changes in the organization of the cerebral cortex (motor and sensory) at the end of the experimental phase.