Project:

Biophotonic technologies for tissue repair (BI-TRE)

Technological keywords:
laser, minimally-invasive treatment, simplified surgical procedures, fast healing

Industrial sectors addressed: medical laser market; surgical items market

Total Project Costs: 2.776.000 €

Partners' descriptions:

ELEN (Tuscany Region). El.En. S.p.A. is the Italian leader in the design and production of high-tech laser sources and systems for medical and industrial applications. Its skills are in the mechanical, optical, electronic and technological fields. Activities: development of laser sources and light delivery systems; testing and validation of the proposed laser techniques for vascular repair in partnership with the Department of Neuroscience of the University and Hospital of Pisa as a subcontractor.

IFAC – Coordinator (Tuscany Region). The Institute of Applied Physics "Nello Carrara" is part of the Italian CNR. IFAC has a solid background in the development of laser applications for minimally-invasive laser surgery. Activities: implementation of a laser-activated vascular repair technique in collaboration with the Agostino Gemelli Hospital of Rome (subcontractor); supervision in the development of the laser system and in experiments on animal model; final optimization of the laser procedure.

ECOPOL (Tuscany Region). ECOPOL S.p.A. has experience in the prototypal and pre-clinical development of intraluminal temporary stents for the engineering of small calibre blood vessels in end-to-end and end-to-side anastomoses. Activities in collaboration with the BIOLab group of the Department of Chemistry & Industrial Chemistry University of Pisa: development of integrated solutions for the computer-aided design and manufacturing of biodegradable stents with customized micro/nano-structure.

ULA (Latvia). The Biophotonics Laboratory of the IAPS of the University of Latvia develops advanced optical methods and devices for real-time and post-surgical cardiovascular monitoring and in-vivo assessment of skin. Activities: study of the vascular healing process and tissue remodeling during the follow-up period by a) laser-excited autofluorescence bleaching of fixed tissue samples; b) fluorescence microimaging of surgical items during their biodegradation at the laser-repaired site.

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ILT (Germany). The Fraunhofer-Institute for Laser Technology develops laser beam sources and optical components for medical micro systems for diagnosis and therapy. Activities: development of a 2-wavelength laser system for fixation of silk/ protein patches to intra-oral wounds; integration of a temperature sensor for temperature-controlled tissue coagulation and an optical backscatter sensor for detection of morphological tissue changes.

UMC (Germany). In the Department of Oral and Maxillofacial Surgery of the University Medical Center Hamburg the entire spectrum of surgery in the regions of head and neck is covered. This comprises traumatology, facial fractures and muscular defects, cancer surgery, treatment of skin and oral cavity tumors. Activities: supply of medical expertise and structural requirements for the laser repair of oral wounds and assessment of its clinical effectiveness; in vivo tests on different animal models.

LiPho (Germany). LifePhotonic GmbH works on the development, certification and production of medical devices. Activities: development of the medical laser system for intra-oral surgery based on a 2-wavelength-module. In particular implementation of the system architecture and control circuit for the laser source, of the feedback loop for temperature control and reaction of optical back scatter signals, and design of the laser applicator.

Botiss (Germany). botiss biomaterials GmbH produces regenerative biomaterials for implantology, oral surgery, CMF and periodontology, which includes long-term proven biologic materials (bovine, synthetic, allografts, collagen, granules, blocks, membranes, soft tissue matrix) matched for specific indications. Activities: optimization of the production process for silk membranes and supply of wound dressings/intra-oral patches.

DILAS (Germany). Diodenlaser GmbH manufactures high-power diode laser components and systems in a wide range of output powers and wavelengths including fiber-coupled, direct beam and integrated solutions. Activities: supply of fiber-coupled diode laser modules consisting of 2-wavelengths emitters. A third optical channel is available to extract optical signals from the fiber tip and can be used for process control.

OPTICUL (Israel). Opticul Diagnostics Ltd. is a biotech company specialized in biophotonics application of mid-infrared optics. Recent production includes an infrared thermal imaging bundle for real-time recording and analysis of temperature maps and a photo-thermal system for the detection of oral lesions and for early-diagnosis of cancer. Activities: development of a thermal imager and of a fast single-channel temperature sensor for real time recording and analysis of temperature elevation.

Project abstract:

BI-TRE project intends to realize an efficient, reliable and cost-effective laser technology for minimally invasive repair of vascular tissues and wounds of the oral cavity. Specifically we will set-up customized laser procedures that will be adapted from already established laser techniques including corneal and vascular laser welding among others. The minimally invasive repair will rest on the photothermal activation, i.e. mediated by laser, of endogenous or biocompatible absorbing materials that are already present or are applied at the site to be repaired, respectively. The laser platforms will integrate sensors and real-time controllers for the photothermal process. The whole application system is expected to provide a dependable management of the surgical procedure, a rapid and selective treatment, minimal invasive procedure and precise control over laser action. The proposed Biophotonic technologies for Tissue Repair (BI-TRE) based on laser action will be validated by end-users in a pre-clinical environment in the context of clinically-relevant surgical procedures, specifically for:

1) repairing of arterial wounds and performing of end-to-end and end-to-side anastomoses. An arterial injury should be repaired as soon as possible to preserve the arterial flow and to avoid permanent ischemic injuries. Laser welding can replace stitches reducing the surgical-related occlusion time and improving the wound healing. End-to-end and end-to-side anastomoses are relevant in minimally occlusive bypass neurosurgery. Here the surgeon combines two arterial stumps in a single duct, which is simplified and expedited through the use of an intra-luminal stent. The laser welding is expected to perfectly seal the donor to the recipient artery without stitches so that the occlusion and the wound healing time are considerably reduced.

2) fixation of wound dressings to treat oral wounds. Studies on large collectives obtained the presence of lesions and modification of normality of oral mucosa in 41.2% of population. Most frequent lesions are hyperkeratosis, fibroma, opportunistic infections, and malign neoplasias. After surgical resection, those patients would directly benefit from a minimally invasive intraoral adhesion of a silk implant consisting of 1) a three dimensional nonwoven structure for ingrowth of the oral tissue and 2) a membrane as wound cover and barrier for bacteria invasion fixed through laser illumination in order to cover the mucosal defect and improve wound healing.

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Expected results and exploitation plan:

The BI-TRE project will pursue its goal by implementing the following aims:

- development of innovative laser platforms for minimally invasive repair of vascular tissue and wounds of the oral cavity;
- integration with systems for temperature control;
- set up of safe and dependable repair procedures;
- test and validation in a pre-clinical environment on vascular and oral tissues.

The consortium has an optimum combination of industrial partners, hospitals and research centres, which offers a wide range of exploitation possibilities. The implementation of the new laser platforms will enter into a robust and tested process aimed at reaching the stage of clinical validation and subsequent industrialization up to production and distribution, which can take advantage of a commercial network at both national and international level. Research centers will take advantage of the collaboration with industries to improve their scientific and technologic know-how. Finally a major goal of the project is the launch of one or more products in the emerging global market of biodegradable stents and wound dressings.

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