The European Co-ordination Hub for Open Robotics Development

La Roses

Laser **A**ssisted **RO**botic **S**urgery of the anterior **E**ye **S**egment

Partners: Ekymed Srl, Fastenica Srl and IFAC CNR

Final Report

Table of contents

Section 1: Executive summary

Keep things short and simple here. The text should precisely and concisely answer to the following questions (see examples)

- **What was the goal of the project?** The goal of the La Roses project was to develop a "proof of concept" of a robotic platform dedicated to Laser assisted Keratoplasty.
- **Why the solution to the problem was important?** The present approach to laser assisted suturing (welding) of corneal tissue in keratoplasty is strongly dependent by the skills and training of the surgeon, as the laser tip is positioned and moved manually.
- **What was proposed as a solution?** The system is composed by a robotic arm able to position the end-effector over the eye of the patient. Three microstep motors are able to move the laser along the trajectory. Two cameras, one dedicated to the general vision and the other one devoted to the control of the temperature, together with the general control system based on a visual servoing, continuously adjust the trajectory.
- **What was proposed as an impact of your solution?** The overall accuracy of the system is doubled respect to the current state of the art. The efficacy and the safety are also assured by the presence of the thermal camera that evaluate the laser welding temperature during the surgical intervention.
- **What is the final impact at the end of the project and what are the deviations in achieving the impact?** The final prototype is a device that offers the possibility to perform laser welding of corneal tissue in a standardized procedure, surgeon-independent. Moreover, the system offers a real time control of the surgical scene, and information regarding the patient's safety. The device is unique: to the best of our knowledge there are no other systems that can induce an immediate suturing of connective tissues, without inducing any collateral damage. This device offers the possibility to reduce or eliminate the use of needles and stitches in suturing a biological tissue. When optimized, the designed system will be the only one system in the ophthalmological market that enables laser suturing of the cornea. This can have impacts also in other surgical fields, when the device will be optimized for other surgeries.

Section 1.1: Milestone overview

(Add a row and copy the contents for extending the table. Give a one point explanation for "deviated" and "not achieved" items)

#	Description	status
M1	System architecture	Timely achieved
M2	End of design and development phase	Achieved
M3	End of tests phase	Achieved
M4	System architecture	Achieved

- M2: Technical problems due to laser supplying according to our strict laser technical requirements and robotic arm problems have delayed the technical activities related to M2.

All the technical issues are now overcome and we are running fast in order to recover the time spent to solve those issues.

- M3: Assembly of mechatronic end-effector carrying the laser system allowing it to move around the cornea is under last finalization. Laser supply problems and changing of the robotic arm have delayed the system integration; hence the test phase has to be shifted and will begin after assembly finalization

Section 1.2: Deliverable overview

#	Description	status
SB	Story Board	submitted
MMR	Multi-Media Report	submitted
RIF	Report on RIF visit outcome	submitted
D 1.1	Report on management organization	submitted
D 1.2	Intermediate report on project activities	Not submitted
D 1.3	Final report on project activities	submitted
D 2.1	Surgical Method & System Architecture	submitted
D 3.1	Designing of eye handpiece	submitted
D 3.2	Control unit and consolle SW scheme	submitted
D 3.3	Eye hand-piece first version release	submitted
D 3.4	Test report	submitted
D 4.1	Vision system development	submitted
D 6.1	First release of integrated robotic platform	submitted
D 6.2	Preliminary tests report	submitted
D 7.1	Test report on silicone spheres	submitted
D 7.2	Test report on eye model	submitted
D 7.3	Histological test report	submitted
D 7.4	Eye hand-piece final version release	submitted
D 7.5	Final release of integrated robotic platform	submitted
D 7.6	Final test report	submitted
D 8.1	Dissemination, Exploitation & Training report	submitted

Section 1.3: Technical KPIs

#	Description	status
1	The development of the end effector (equipped with force feedback and distance sensor)	Deviated
2	The development of the mechatronic handpiece (Sensor integration to fix the	Achieved

	distance of the fiber tip of the diode laser)	
3	Image guided surgery	Achieved
4	Accuracy of the positioning for the integrated system with robot arm and end effector	Achieved

Note on KPI n. 1: At the beginning of the project activities, the LA-ROSES team decided to not develop the platform as planned during the proposal writing. For this reason, in the new idea of the robotic laser welding console no force feedback is needed. The first motivation is a safety issues: there is no laser accessories/part of the robotic device in contact with the patient's head. Redesigning a no-contact end-effector there is no need to a have a force feedback, because there is no force applied to the target tissue. As concern the distance sensor, it was planned in the first idea of LA-ROSES system (contact with the patient's eye), because in order to reach the patient's head with the robotic device it was important to know the distance to the final contact target. Another reason was that knowing the correct distance was important to calculate the final laser spot dimension, and thus the power density delivered to the tissue. In the final LA ROSES version, this last point is not necessary because a collimation tool was used to control the laser spot dimensions, so that the delivered power density is known *a priori*. Moreover, because of the patient head is fixed on the operating table, the LA-ROSES end-effector is positioned at first by using the teach-pendant before to start the operation and there is no need to adjust the vertical positioning during the welding phase, but only on the horizontal plan if needed.

Section 1.4: Impact KPIs

#	Description	status
1	Scalability: Application in different eye surgery operations (a universal joint to be connected to a generic robotic arm)	Deviated
2	Creation of new spin-off (one) with five people (one person at the end of the experiment and an additional 4 after one year)	Deviated
3	Certification / CE marking	Deviated

Comments:

Scalability: The proposed system can be easily scaled to the application in pediatric surgery. In the treatment of young patients the main difference is only the diameter of the cornea and thus of the dimensions of the surgical cut. The system can thus be used also in this case, without any particular tools to be added. Moreover, it could be of high importance, as the system provides an immediate suturing of the tissue, thus eliminating the risk of endophthalmitis (that is really high in pediatric patients). It can also be used in pediatric cataract, considering that the surgical cut is shorter than the one used in transplantation. Another application is the closuring of the capsular tissue, to easily solve the Phaco-Ersatz procedure, used for the treatment of cataract and presbyopia.

NewCo: the discussion on when to create a NewCo is still in course. Several aspect should be considered. Firstly the consortium is composed of a public company and two biomedical-devoted industrial companies. This means that an accurate analysis about the IPR should be yield into account because the public company does not have a participation in a manufacturing company. On the other

hand EKY and FAST would bring LA.-ROSES on the market as soon as as possible. In parallel funding rising activities have to be carried out such as the search of possible distributors on regional, national and European scale.

CE: The aim of the project was to define a proof of concept and it was too early to define a detailed CE pathway, just because there was not any kind of prototype available. On the other side, the experience gained during the project will be therefore useful also for the CE labelling.

Section 1.5: Dissemination KPIs

#	Description	status
1	Coverage in Technical Journals (e.g. Biomedical Optics Express Lasers in Surgery and Medicine, Journal of Biomedical Optics, Journal of Biophotonics)	Achieved
2	Coverage in Ocular Surgery Journals (e.g. British Journal of Ophthalmology)	Not Achieved
3	Conferences (e.g. Photonics Europe, European Conferences on Biomedical Optics)	Achieved
4	OASIS project dissemination activities (e.g. website)	Achieved
5	media coverage in local and national consumer press	Achieved
	General Public events/Fairs	Achieved

Note on KPI 2: the dissemination of the LA ROSES scope and results in the medical audience was performed thanks to the participation to Ophthalmology national and international conferences (the presentations are planned also in 2017), while the publication in medical journals will be planned during the next year (i.e. after the end of the project).

Section 1.6: Additional (unplanned) achievements

Section 2: Detailed description

Section 2.1: Scientific and technological progress

- The first task (T2.1 of the proposal) that was to understand the Surgical Methods. Starting from the medical and technological background relevant to the LA-ROSES objectives, innovative surgical procedures were identified. To achieve this goal IFAC activities were based on the acquired know-how about innovation transfer in ocular surgery, but the main inputs were acquired thanks to involvement in the project activities of the corneal surgeon Luca Menabuoni that was enrolled in the project. In order to reach this goal, several visits to the Ophthalmic Department of the Nuovo Ospedale S. Stefano, in Prato, were performed. At the same time Luca menabuoni was invited to participate to the experimental sessions held at IFAC.
- The second task (T2.2 of the proposal) was to define the system architecture: from the "Surgical Methods Task" the proposed one was different from the proposal idea. In fact the La Roses project started from a previous experience in the MILORDS project, funded by Tuscany Region. From the discussion among the LA ROSES team and the corneal surgeon, it came out that a completely new system was better responding to the robotic console concept. The new system thus had to be a no- contact device. This characteristics could avoid problems of safety and sterilization.
- The third task was the design and the realization of the end effector (Task 3 of the proposal). The End Effector is the "core" of the system. The final tool was different from the one described in the proposal, because some decisions were taken following T2.1 and T2.2 activities. Ones defined the technical specification, the design was of an "easy" end effector, respect to the initial idea. In particular the end effector is dedicated to carry out controlled laser irradiation of the corneal incision, with a vision sub-system that enables real time control of the surgical scene.
- The fourth task (Task 4 of the proposal) was the development of the visual servoing system. The aim of this task was the development of autonomously algorithms to perform robotic arm movements using a vision guided robotics approach. The task consists in allowing the end effector to be aligned on the vertical of the patient eye iris. Moreover, in the framework of this task the integration of a thermal camera in the end-effector was performed, so that a control of the welding efficacy and safety is performed real time.
- The fifth task (Task 5: Teleoperation & Robot Control) consisted in the choice and optimization of the robot arm and of the laser system. A different robot respect to the initial time of the projects was used in the final version of the robotic consolle (a Mitsubishi RV-13-FM model). A specific control system was developed, with a specific Graphic User Interface (GUI) able to provide full control capabilities of the robotic arm movements. The GUI also included the real-time camera view in order to provide information about current end-effector positioning. The final laser that was used in the final device was a NIR diode laser, with the delivery of the laser light thanks to an optical fiber (integrated in the end-effector) and a collimation tool to control the spot dimensions and delivered power densities.
- The sixth task (Task 6 of the proposal) was the implementation of the whole system, with the control of the end-effector by the use of the robotic arm.
- The final task (Task 7 of the proposal) was the experimental tests of the final device. The efficacy and the safety of the procedure was demonstrated in freshly enucleated porcine eyes.

Section 2.2: Scientific and technological achievements

- ➔ The first technical achievement of the project is the realization of the first surgeon-independent, safe and effective system for non-contact laser welding of connective tissue.
- ➔ The system represents a high revolution respect to the state of the art: the current experimental laser welding of biological tissue is performed manually, with no control of the photothermal effects. The final LA ROSES system is the first controlled system for a standard suturing.
- ➔ The team estimates that a TRL 4 has been achieved at the end of the project (Component and/or breadboard validation in laboratory environment).
- ➔ The project team is planning to deposit a patent during the next few months.

Section 2.3: Socio-economic achievements

- ➔ The first important social achievement is the realization of the first device for a "minimally invasive" suturing of biological tissue. This means the reduced use of stitches and needles in suturing, with a better restoration of the tissue reduced mechanical trauma and foreign body reaction with an overall good quality of life of the treated patients and reduced hospitalization costs.
- ➔ Another achievement is that during the framework of the project 1 new person was employed in the project at IFAC CNR.

Section 2.4: Dissemination activities

The dissemination activities were performed to spread the project purposes and goals to the scientific audience and to the ophthalmologists' audience. This goal was firstly reached by publishing a paper in an internationally reviewed Journal (JoVE) and thanks to the participation to international and national conferences as a speaker. These selected conferences are restricted to the Technical (Photonics/Life Science) community and to Ophthalmologists. Two internationally renowned conferences will be attended by the first part of 2017 (Photonics West 2017 and hopefully ARVO 2017).

During the project timespan the project idea has been presented to selected investors in the framework of an international startup competition (SPIE Startup Challenge 2015, San Francisco-CA USA, February 2015) and in the framework of a national event organized by Fondazione Filarete (Filarete Healthy Startups, July 2015).

A few communication activities were also performed. The first was an interview that was performed at the end of 2014, a few days before the project start. This interview has been broadcasted by a local TV channel and then published on YouTube:

https://www.youtube.com/watch?v=Gv8BBCS2WFA)

The project was then presented to the international Maker Faire that was held in Rome in October 2016: the event was addressed to the general public. The event was also disseminated through Twitter (and the Twitter account of the IFAC research group) and via the CNR web TV (http://www.cnrweb.tv/il-cnr-alla-fiera-delle-invenzioni/).

Section 3: Resource usage summary

Partner:	**Ekymed Srl**		
Item	Budget received	Consumed	Available
Personal	65.300	77.725	-12.425
Travel	2.000	600	1.400
Equipment	7.200	0	7.200
Consumable	6.000	4.920	1.080
		Remaining	-2.745

Partner:	**IFAC - CNR**		
Item	Budget received	Consumed	Available
Personal	76.958,00	83.324,65	-6.366,65
Travel	7.000,00	1.476,40	+5.523,60
Equipment	2.000,00	6.919,57	-4.919,57
Consumable	13.000,00	10.200,00	+2.800,00
		Remaining	0

Partner:	**Fastenica Srl**		
Item	Budget received	Consumed	Available
Personal			0
Travel			0
Equipment			0
Consumable			0
		Remaining	0

Section 4: Deviations and mitigation

The unique deviation from the original proposed achievements was the failure of the substitution of the presently used fiber optic laser by surgeon with a laser module. The major advantage of this solution was the avoid the use of a fiber optic in the surgical scene, thus reducing the problem related to the use of a disposable and to the sterilization of the system. Second, the laser module do not need to be in contact with the patient's eye, so as to avoid sterilization problems and accidental damage to the patient (excessive pressure). Unfortunately, the laser company we contacted provided

us a laser module not matching our requirements (details can be found elsewhere in already submitted report). Further tentative to obtain a laser module with designed characteristics were no successful. We overcome this problem modifying by ourselves a fiber optic laser introducing an optical collimator so that there is no need to keep in contact the fiber optic laser with the eye. This achieve the project objective - the unique drawback of this solution is related to the fiber optic that is very delicate and must be handled with extremely care when it has to be roll around the laser handling system.

Section 5: Future work

The main actions that the LA ROSES team is planning for the next future are:

- a critical overview of the entire project from technical /medical point of view in order to define the technical specification of the next version of the LA ROSES system
- some tests with the corneal surgeons in order to optimize the general speed of the process, the end user interface and, if possible, a test in an operating room (OR) in order to test the light conditions
- the definition of the team organization, with a NewCo
- the business plan finalization

Section 6: Lessons learned (optional)

Several lessons were learned from the technical point of view. In general, the project suffered some delays because we underestimated the availability of the laser companies in producing a customized laser. During the proposal writing we also discussed the possibility of involving a laser company, but we have not made this choice especially for budget constraints.