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

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[1] Dissemination Level:
PU Public
PP Restricted to other programme participants (including the Commission Services)
RE Restricted to a group specified by the consortium (including the Commission Services)
CO Confidential, only for members of the consortium (including the Commission Services)

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Summary

1 Executive Summary

The present deliverable D 3.1 aims to describe the LA-ROSES project general activities. In this report we want to describe in particular 5 main points

1. an update on the dissemination actions, continued after the end of the projct,
2. an over view on IP aspects
3. a preliminary evaluation on CE labelling pathway
4. the list of the future action
5. the "lesson learned".

2 Overall Scheme

The general scheme of the LA-ROSE concept, as we imagined at the beginning of the project, is composed including:

① the hospital bed
② the patient
③ the robot arm
④ the End-Effector.

In the next picture the general concept of the system.

The object of the project was dedicated to development of the End-Effector, the Laser, the integrated Vision System and the General control. For the Ethical Issues constraints annexed to the proposal, tests on humans but also on human tissues were not possible.

The overall work was focused on the development of a surgical platform according to the indications of our medical consultant corneal surgeon MD Luca Menabuoni, taking into account the the experience gained in over 300 keratoplasty interventions. The main recommendations were:

1. a compact system that enables an effective welding of the corneal tissue during the keratoplasty;
2. a full control of the surgical scene, so that it is possible to make a decision during the surgery (stop the laser, increase the effects, change the laser position, etc.); in other words a result that is "surgeon independent".

The solution proposed comprehends:

- End-Effector system: mechanical solution and laser motor handling implementation
- Laser subsystem: laser motors control system and synchronization electronic circuit
- Robotic arm solution
- Vision system: HW components

- LA-ROSES master controller system

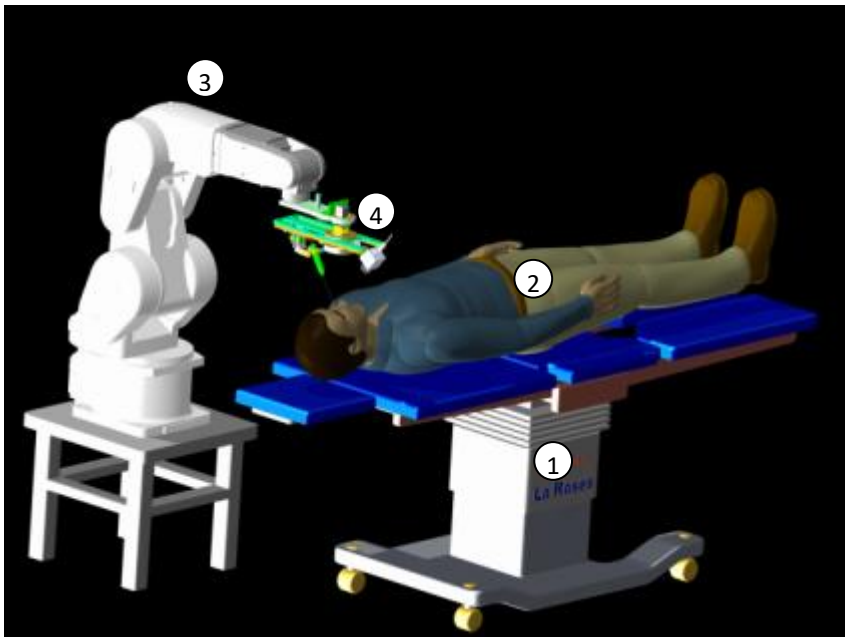

Fig. 1 - La Roses overall view

The La Rose system functional diagram can be depicted as follows:

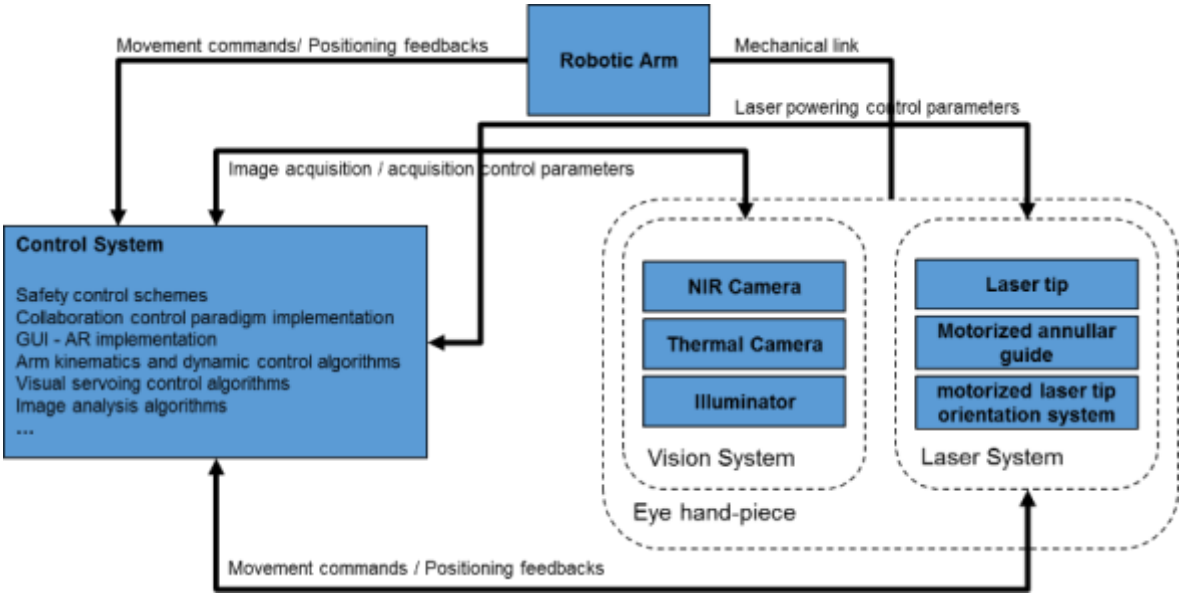

Fig. 2 - LA-ROSES overall system diagram

3 Main Technical Activities

From technical point of view, the technical activities are fully described in the following reports:

Activity	reference report(s)
End effector development and laser integration	D 3.1 - Designing of eye handpiece D 3.3 - Eye hand-piece first version release D 7.4 - Eye hand-piece final version release
Vision system and general control development	D 4.1 - Vision system development D 3.2 - Control unit and consolle SW scheme
Overall integration and tests	D 7.1 - Test report on silicone spheres D 7.2 - Test report on eye model

	D 7.3 - Histological test report D 7.5 - Final release of integrated robotic platform D 7.6 - Final Test report
Dissemination	D 8.1 - Dissemination, Exploitation & Training report

Tab. 1 -report reference

4 Disseminations Actions

The dissemination activities were performed to spread the project purposes and goals to the scientific audience and to the ophthalmologists' audience.

This goal was reached by publishing a paper in an internationally reviewed Journal and thanks to the participation to conferences as a speaker. We attended the "ISOCS-MiNaB-ICT-MNBS. Sensing for Smart Anything Everywhere: Materials, Technologies, Applications", a joint event with The International Society on Olfaction and Chemical Sensing (ISOCS) and the European Commission (June 2016) with 1 oral presentation. We will present as an oral the results of this project at Photonics West 2017, attending the conference "Design and Quality for Biomedical Technologies X". We also attended the DIITET CNR Conference on 22nd November 2016 with 1 video presentation, sharing the results with the scientific community. An abstract has been submitted to ARVO 2017, the most important international conference for ophthalmologists that will be held in Baltimore (USA) in May 2017. Moreover, the work will be presented at the XXXIII Annual Conference of the Italian Society for Laser in Ophthalmology (Cortina d'Ampezzo, 2-4 February 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/).

5 IP aspects

The IP aspects and the need to deposit a patent was discussed between the LA-ROSES partners. With the support of the IP team of the CNR, the LA-ROSES team is preparing a draft of a patent that will be deposited in the next few months.

6 Certification aspects

The main steps to be followed to obtain the CE labelling can be summarized as following:

1. definition of the intended use
2. classification of the device and selection of the Conformity Assessment Route
3. production of the Technical Files
4. undertaking a Conformity Assessment procedure
5. obtaining the conformity certificate by the Notified Body
6. registration at the Competent Authority.

This general scheme can be illustrated in the Fig. 3.

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.

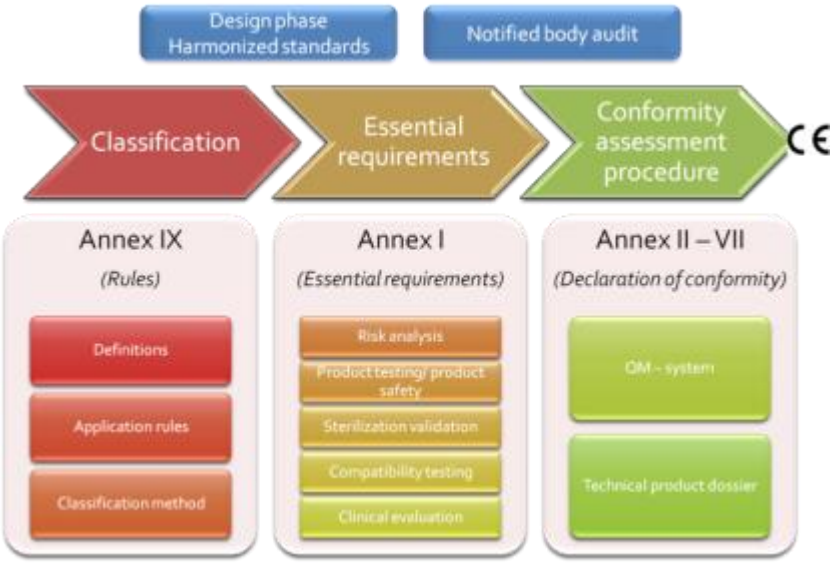

Fig. 3 - Main Steps to CE mark according to 93/42.

7 Future actions

The LA Roses team strongly wants to continue the work performed. Taking into account the indications reported in the paragraph 2.**Errore. L'origine riferimento non è stata trovata.**, these are the next steps to be carried out:

- 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:
  - mechanical structure and components
  - vision and general control low level system
  - HMI and welding strategy(s)
  - laser component
- some tests with the medical responsible in order to optimise:
  - the speed of the motors (in particular ω-axis and x axis)
  - the end-user interface, in order to remove all the information not useful for the medical doctor leaving only the essential,
  - if possible, also a test in an operative room should be very useful for testing the light conditions in particular
- definition of the team organization, with a NewCo. Three possible solutions are possible:
  - the creation of a NewCo with the direct participation of Ekymed, Fastenica and IFAC-CNR, and our scientific responsible
  - the creation of a NewCo with the direct participation of Magnani, Leoni, Rossi and our scientific responsible
  - a mix of the previous solutions
- business plan finalization: in the SME Inst initiative we have already developed a detailed business plan focused on the main 5 main EU countries (Italy, Germany, UK, France and Spain). This work represents a good base of work, giving many indications on the market segmentation and possible strategies regarding the market access modalities. The limits of this BP resides on the cost of the product, at that time just estimated, considering the presence of the Mitsubishi robotic arm we know is oversized in terms of performances and costs

- funding opportunities: at the moment several possibilities are *theoretically* available: own funds, public funds (EU, or locally based) until Venture Capital. In our opinion a VC at the current state of the art is a premature solution, for the characteristics of a VC. The others should be carefully evaluated.

8 Conclusions

The LA-ROSES prototype system developed and realized during the lifetime project has proven that the laser manual up-to-date welding of the cornea in keratoplasty surgical applications can be automated by a complex robotic system with success. Moreover the LA-ROSES prototype system has shown great repeatability, accuracy and safeness. In addition the system provides out standardization capabilities in terms of quality of the weld proven by histological results carried out on ex-vivo porcine eyes.

Even though the LA-ROSES prototype system achieves project results expectations more and more work has to be done in order to bring an industrialized version of such system on the worldwide medical devices market (see paragraph 6). Several lessons were learned:

1. general design configuration. As outlined in many reports, the objective of present configuration of the La Roses system was developed as a "proof of concept", having in mind that the next version will be quite far from this one. In our vision, the used Mitsubishi robot (see next point) can be substituted by a three axis stages systems in order to set-up a macro positioning of the system upon the cornea; a second module, with a similar structure of the End Effector we developed, will be linked to the previous one with the same functions of the present End Effector but with limited displacements and rotations as described in the next point 4. Further, a critical issue is the exposure of the motorised axis to the operator and the patient: for safety reasons, it is fundamental to encapsulate all the moving parts in a case.
2. Mitsubishi robot:
    a. an anthropomorphic robot like the Mitsubishi we used, is oversized in terms of performances and costs
    b. it is not possible (or at least not easy) to be integrated in a medical device
    c. it can be substituted in 3 axis assembled linear modules.
3. Vision system:
    a. we use a Near-InfraRed camera (NIR) because it has greater output response in the spectral way-length in within the working range of the laser is positioned. This response enhances the recognition and detection of the laser spot despites of different environmental light conditions.
    b. the thermal camera is an essential device of the LA-ROSES system. Its use allows the detection of the temperature due to the laser irradiation. We use a very sensitivity thermal camera. The drawback of this camera type is the not so little size. Technology advances will bring on the market smaller and faster camera in some months.
    c. Ring-light illumination is not really necessary, at least. The implemented system, thanks to the NIR camera response range, allows the system to detect and recognize the corneal wound and the laser spot in varying illuminations conditions even without the use of the ring-light illumination system.
4. End Effector design and realisation:
    a. the motors and the gearheads used components were reliable, after many hour of work, and the accuracy is several order of magnitude higher than the necessary. The configuration allows more than 40 cm of displacement for the x-axis: this value was necessary in order to develop the prototype, but in the next version the x-axis should have a displacement in the order of 3 mm, considering the diameter of the cornea cut in the range of 11 - 9 mm. Similar considerations can be done for the α-axis: there is no necessity to have an angle between 0° to 90°, but for anatomical constraints, the optimal angular rotation must be in the range of 30°-70°
    b. laser cabling handling in particular, must be carefully evaluated, but the experience with the La Roses project is a great added value
5. Laser:

The laser unit design has been deeply discussed among the LA ROSES team. It is really important to have a very compact laser that can be remotely and fully controlled.

In the framework of the project we realized the optimization of the laser spot and the optimization of the dimensions and control. We believe that the best solution will be of design a customized laser source, 1W emission power, with a controlled dimension of the spot at target. This can be done by specialized companies that can provide smart solutions for laser packaging, optimizing the laser output with a fibre directly mounted on the diode itself, and with a cooling unit that guarantees the optimal working conditions of the laser unit. To the best of our knowledge, there are currently no commercial solutions that could be used in the LA ROSES prototype. However this activity can be part of the next version of the project.