Actuation and Control of a Steerable Catheter for Mitral Valve Repair

1st Mattia Magro
*DEIB, Politecnico di MIlano**
Milan, Italy

2nd Andrea Fortuna
*DEIB, Politecnico di Milano**
Milan, Italy

3rd Mariagrazia Quacquarelli
*DEIB, Politecnico di Milano**
Milan, Italy

4rd Domenico Riggio
*DEIB, Politecnico di Milano**
Milan, Italy

5th Angela Peloso
*DEIB, Politecnico di Milano**
Milan, Italy

6th Xiu Zhang
*DEIB, Politecnico di Milano**
Milan, Italy

7th Elena De Momi
*DEIB, Politecnico di Milano**
Milan, Italy

***Abstract*—In the field of Structural Heart Diseases, Mitral Regurgitation's incidence is rising because of an aging population worldwide, and it has reached an annual mortality rate near 34%. The procedures of Structural Intervention Cardiology have enlarged the number of treated patients, since their minimally invasive and trans-catheter approach. To provide a forward step-change in this procedure, the aim of this work is to improve the use of the commercially available MitraClip system®, suggesting an innovative robot-assisted platform with autonomous control for the aforementioned system. The presented methodology is constituted of two phases: in the first one, we design, in the Solidworks® environment, 3D print and integrate the mechanical support with electrical motors and micro-controller devoted to catheter's steering. In the second phase, we develop the closed-loop position control to improve the accuracy in the autonomous positioning of the catheter. The described approach was tested to demonstrate its feasibility and dexterity: a position accuracy of 1.1±0.54 mm in following a given optimal trajectory was obtained.**

***Index Terms*—Structural Intervention Cardiology, Robot-Assisted surgery, Tendon-Driven system, Control Algorithm**

I. Introduction

Nowadays, the Structural Heart Diseases (SHDs), i.e. pathological conditions of heart valves, heart wall and heart muscle structure, are treated by a trans-catheter/percutaneous implantation of repair or replacement devices [1]. This procedure is becoming increasingly popular as first-line approach in Structural Intervention Cardiology (SIC) due to lower trauma, shorter hospitalization time and equivalent efficacy to open chest surgery [2]. Conversely, the treatment is technically demanding and not ergonomic for the surgeon, which is obliged to follow a steep learning curve phase, since the procedural success is related to the operator's experience and ability [3]. The MitraClip (MC) system is considered as the Gold Standard for the percutaneous treatment of Mitral Regurgitation [4]. It is a tendon-driven manually actuated device, composed of two handles, i.e. Steerable Guide Handle (SGH) and Steerable Delivery Handle (SDH). The surgeon manages these two handles exploiting knobs and handles' standardized gesture to obtain the motion of the Steerable Guide Catheter (SGC) and the Steerable Delivery Catheter (SDC) (Fig 1A). The manual and standardize actions on the two handles provide the steps that allows the implant of a clip, which can be even extruded by pushing a further handle, i.e. MitraClip Delivery Handle (MDH). As a consequence, the clip passes through the mitral valve's functional plane, entering in the left ventricle (Fig 1B), and grasps the valve leaflets, recovering the functionality of the mitral valve. The procedure is described in [5], [6] and it is completely manual, guided only by imaging coming from fluoroscopy and ultrasound. Albeit the success of the surgical procedure is high [7], robotization can improve its efficacy and accuracy by performing repetitive and standardize task. This allows the surgeon to focus on critical and delicate steps of the surgical procedure [8], [9].

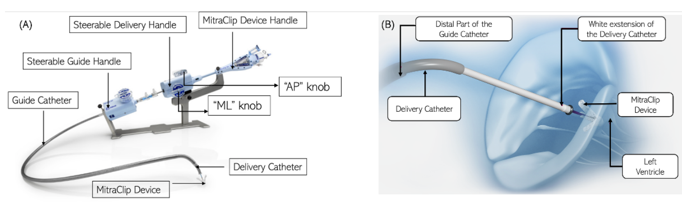

Fig. 1. (A) Overview of the MitraClip system®: different actions on the Steerable Guide Handle and Steerable Delivery Handle can control different bending of the Delivery Catheter and the Guide Catheter, respectively. The advancement of the Delivery Catheter inside the Guide takes place by simply pushing one catheter inside the other. (B) Details of the extrusion of the Delivery Catheter that allows the clip to enter in the left ventricle.

Thus, the aims of this work are (1) to design and propose a robotic support platform for the commercially-available MC system® and (2) to develop a remote control algorithm that drives the MC system to autonomously reach the target of the mitral valve repair percutaneous surgical procedure.

II. Methods

A. Modelling

A combination between Constant Curvature (CC) and Cosserat Rod Theory (CRT) was employed for the development of a Static Inverse Kinematic Model of the MC system, relating the distal end position ($\mathbf{p_d}$) in the task space and the

*Neuroengineering and medical robotics Laboratory (Nearlab), Department of Electronics, Information and Bioengineering (DEIB).

tendons' displacement ($\Delta \mathbf{d_i}$) and the backbone length s in the actuation space (Fig. 2). In this kinematic modelling, the tendons were assumed to follow a continuous curve parallel to the backbone, implying that tendon pathways were totally constrained. A number of nodes positioned along the backbone represented the catheter's configuration, and the deformation of the backbone was computed exploiting the CRT. The reference frames composed by a rotation matrix ($\mathbf{R}$) and a pose vector ($\mathbf{p}$) were attached to the nodes (Fig. 2), and its evolution along the body length (s) was described by means of a system of differential equations, which was numerically solved via Shooting method [10]: the solution was searched iteratively until boundary conditions were satisfied. Regarding the backbone length s, the CC algorithm was implemented.

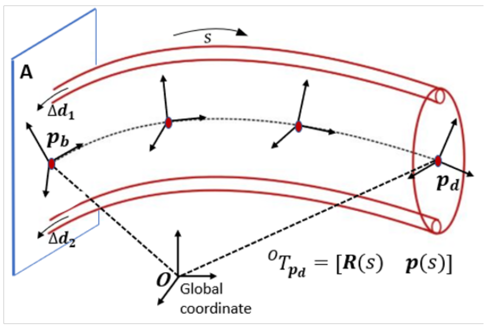

Fig. 2. Sketch of the Steerable Delivery Catheter: Kinematics of the Cosserat Rod Theory maps the distal position $\mathbf{p_d}$ and tendon displacement $\Delta \mathbf{d_i}$.

Thus, the Inverse Kinematic Model will be exploited in the control algorithm to provide the suitable inputs for the developed actuation plant.

B. Actuation and Control

The development and the design of the robotic platform [11]–[13] for the MC system started from the definition of the clinical requirements and specifications to be respected. To fully obtain a system able to resemble the main features exploited during the MC surgical procedure, five Degrees of Freedom (DoF) were considered: (1) Advancement/Retraction of the SDC, (2) Further extrusion of the SDC, (3) Bending in medio-lateral (frontal) plane of the SDC, (4) Antero-posterior (sagittal) plane of the SDC and (5) Rotation in antero-posterior plane of the SGC's base.

Then, the MC system was disassembled to both reveal the core of the actuation mechanism and to find the specifications for the electrical components, that will be exploited to obtain the actuation of both catheters. These latter requirements were found by pulling the tendons and measuring the value of the generated torque with a dynamometer.

Thus, the innovative platform was developed considering the following elements:

- Substitution of the AP knobs and ML knob with electrical motors. The choice was the Nema 23 Stepper Motors (JoyNano), with control precision $1.8° \pm 0.09°$ for each step and maximum holding torque 1.26 Nm (AP knobs) and 2.4 Nm (ML knob);

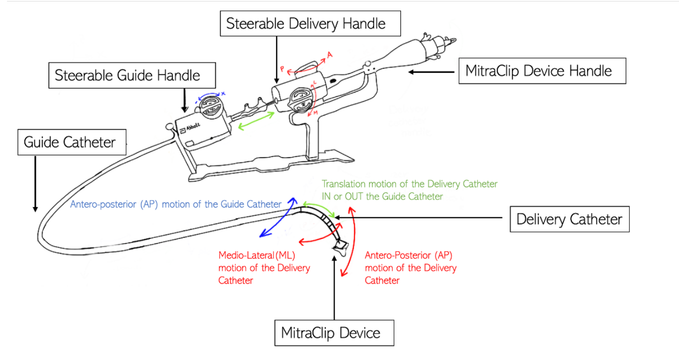

Fig. 3. Overview of the MitraClip system®'s Degrees of Freedom actuated: the further extrusion of the Steerable Delivery Catheter is depicted in Fig.1

- Use of a system of gears, linked to a Nema 23 Stepper Motor (JoyNano), for the rotation of the SGC's base;
- Substitution of the manual advancement of the SDC inside the SGC with electro-mechanical device. A Nema 17 Stepper Motor (Sainsmart) connected to a 300 mm linear guide, with precision of ±0,03 mm on the required position and maximum load of 10 kg, was selected.
- Automatization of the MDH's action exploiting a Nema 17 Bipolar Stepper Motor (Sainsmart) connected to a 100 mm linear guide.

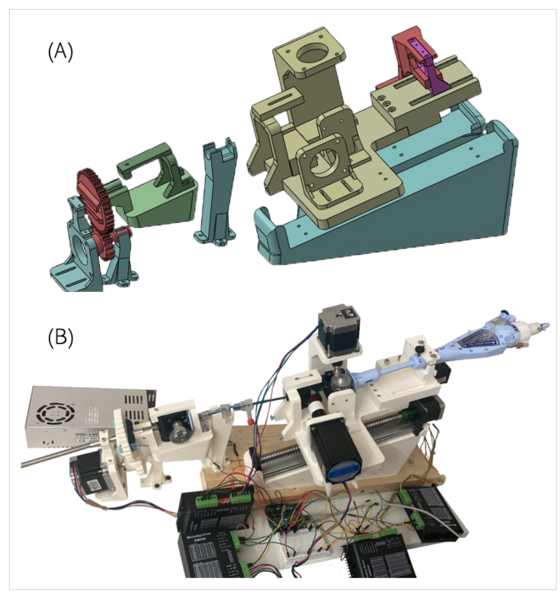

Fig. 4. (A) Design of the new prototype for the MitraClip system®'s actuation. (B) Corresponding 3D printed structure properly connected to the MitraClip system® and electrical components.

The aforementioned electrical components were chosen for their accuracy that made the devices exploitable for high precision operations. At this stage, the design of the actuation system was developed in Solidworks® and the result is shown in Fig. 4A. After the design phase of the robotic support, the Ultimaker s3 3D printer was exploited to print separately each mechanical parts which are then properly connected

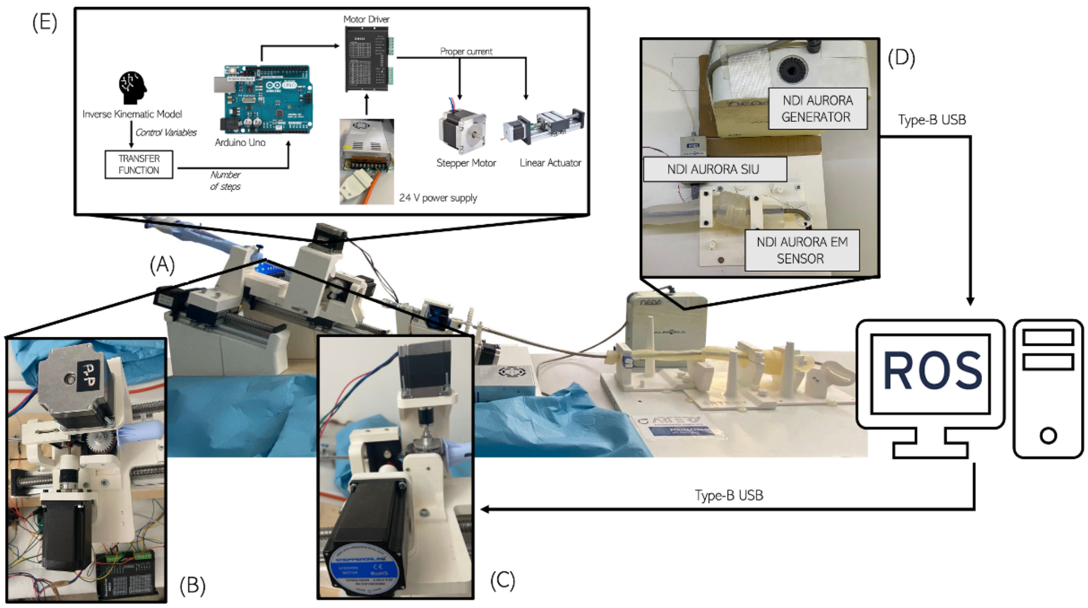

Fig. 5. (A) Global 3D printed system. (B) and (C) Details of the new proposal for the robotic actuation system. (E) Schema of the electrical connections among the different elements of the system. The controller Arduino Uno receives, as input, the displacements that has to be given to the tendons and the linear insertion (i.e. Control Variables), after proper conversion, from the computation of the Inverse Kinematic Model. The output of the Arduino Uno is a PWM signal to control the drivers of the stepper motors and the linear actuator, properly supplied. (D) Details of the NDI Aurora Electromagnetic tracking system.

(Fig. 4B). The Acrylonitrile Butadiene Styrene (ABS) material was chosen as printing material both because its weight could be sustained by the linear actuator and because it could support the weight of the original MC structure. Details of the support platform are reported in Fig. 5(B,C): a mechanical connector, i.e. Oldham adapter, was used to properly connect the original MC structure to the stepper motors.

Concerning the exploited micro-controller for the control section, an Arduino Uno board was used: all the motors, properly supplied, were controlled by DM556 drivers (Jadeshay), which were forced by the micro-controller to provide current to the motors with a resolution of 0.5 A on the desired current.

As depicted in Fig. 5(D), the input of the Arduino Uno was conveyed from the Inverse Kinematic Model, after a proper conversion. Indeed, a calibration procedure was performed to link the output of the Inverse Kinematic Model with the proper number of steps made by the motors. Regarding the control strategy [14], [15], a Proportional Integrative Derivative (PID) algorithm on the position reached by the MC system was implemented. This PID controller was employed to calculate the mismatch ($\mathbf{e_n}$) between the Desired position ($\mathbf{P_d}$) and the Real position ($\mathbf{P_r}$), and to apply a correction ($\mathbf{P_n}$) to increase the control precision (Fig. 6). A tuning phase was performed to find the best values of the parameters of the PID controller, i.e., the coefficient of the proportional term (K_p), of the integral term (K_i), and of the derivative term (K_d). The choice was to set $K_p = 1.5$, to impose an overshoot condition, $K_i = 1.8$ and $K_d = 3$.

The output $\mathbf{P_n}$ of the PID (Formula 1) corresponds to the new position that the system had to reach to minimize $\mathbf{e_n}$ and it is

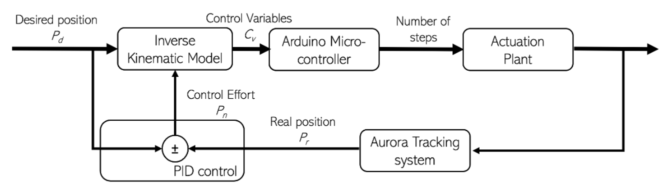

Fig. 6. Control algorithm schema. The Desired Position is sent to the Inverse Kinematic Model, which produces the Control Variables for the Actuation Plant. Then, the PID compares the Desired Position and the Real one and computes the Control Effort to reduce the position error.

defined as:

$$P_n = K_p * e_n + K_i * T \sum_{i=0}^{n} e_i + K_d \frac{e_n - e_{n-1}}{\delta t} \tag{1}$$

The tracking of the Real Position of the system was performed through the Aurora NDI electromagnetic tracking system (Fig. 5(E)), which is a solution that enables real-time tracking of microsensors embedded in rigid and flexible medical instruments and doesn't require line-of-sight. This tracking system consisted of four core components to deliver real-time instrument tracking capabilities: System Control Unit (SCU), Sensor Interface Unit (SIU), Field Generator (FG) and Sensor. The control algorithm was implemented in the Robot Operating System (ROS) framework since it was possible the integration and communication among the modules depicted in Fig. 6.

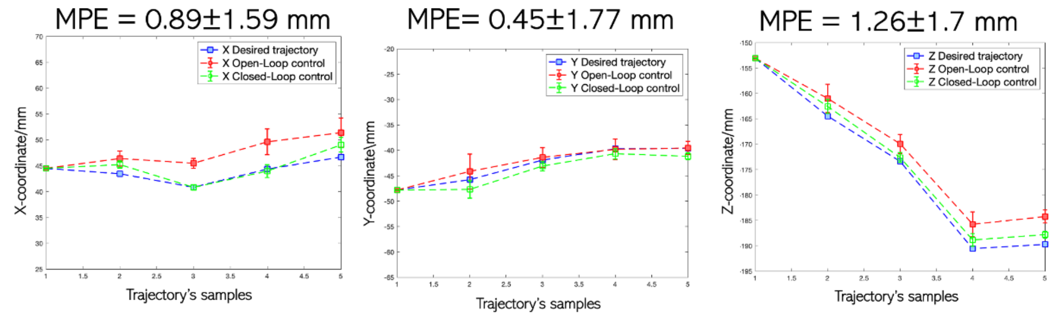

Fig. 7. Evaluation of the integrated system's performance: Mean Position Error along x, y and z axis.

III. Preliminary Results

The Experimental Protocol required to test (a) the repeatability and (b) the position accuracy, i.e position mismatch between the position measured in the Cartesian space and the desired one, in following a given optimal trajectory. The experiments were performed on one optimal trajectory and repeated 5 times, comparing the outcomes positions of open-loop control with the ones of the PID closed-loop control. The metric used was the Mean Position Error (MPE) along X, Y and Z coordinates separately (Formula 2).

$$MPE = (\sum_{i=0}^{N} e_i)/N \tag{2}$$

where e_i was the difference between the desired value of the coordinate considered and the one reached after the actuation and N was the number of considered points of the trajectory. Fig. 7 reports, for each axis of motion, the trajectories performed by the system with respect to the desired one. Thus, the system's capability to follow a trajectory suitable to reach the correct position, nearby the mitral valve, and orthogonal orientation with respect to the mitral valve's functional plane, was evaluated. The given trajectory was composed of four points and the commands that were given to the plant were such that each point was reached sequentially. The correction of the PID tried to align each point with the desired one: a sensible improvement was noticeable in X and Z directions of the trajectory, where the average corrections were 2.63±1.59 mm and 2.18±1.7 mm respectively, while on the Y direction the correction didn't affect the error committed. A Wilcoxon test was performed and the result showed a significance difference between the values obtained in closed-loop and open-loop, obtaining a rank of three stars.

IV. Discussion and Conclusion

The present work proposed a novel robotic actuation-platform for minimally invasive surgery coupled with an algorithm of autonomous control that involved the use of an Inverse Kinematic Model and a PID position control able reduce the MPE with an average value of 32.68% in all the directions. Although the use of manual device in SIC is currently successfully applied in the clinic, the use of a robotic system for automatic and standardize task can properly assist the surgeon. Accordingly to the actual State of the Art, the proposed system met the requirements of minimally invasive surgery in terms both of accuracy and time. Hence, autonomous robotic systems could have the ability to extend the use of percutaneous procedures to a higher number of patients, and this could be a step forward for SIC procedures.

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