POLITECNICO
MILANO 1863

SCUOLA DI INGEGNERIA INDUSTRIALE
E DELL'INFORMAZIONE

Executive Summary of the Thesis

Model-free Control of Actuated Tendon-Driven MitraClip™ Catheter

Laurea Magistrale in Biomedical Engineering - Ingegneria Biomedica

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Academic year: 2021-2022

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1. Introduction

Cardiovascular Diseases (CVDs) are the leading cause of global mortality, with cases doubling from 271 million in 1990 to 523 million in 2019, and deaths increasing from 12.1 million to 18.6 million [1]. Structural Heart Diseases (SHDs) are the most common type of CVDs and involve defects/disorders in the structures of the heart. Among them, Mitral Regurgitation (MR) is the prevalent disorder due to Mitral Valve (MV) abnormalities, which can lead to blood backflow from the left ventricle into the left atrium. The past decade has seen advances in the diagnosis and treatment of SHDs, especially through catheter-based techniques, leading to the emergence of Structural Intervention Cardiology (SIC) as its own medical specialty. SIC procedures allow for minimally invasive intervention using a catheter-based approach, that repairs/replaces MV parts without the need for open-chest surgery. However, SIC procedures are characterized by costly requirements, such as a dedicated room (CATH-lab) and two leading operators. The Gold Standard device used for treating MR through percutaneous approach is the MitraClip™ (MC) system. However, its difficult manoeuvrability and fluoroscopy, used for catheter visual guidance, exposes patients to higher risks and interventionists to cumbersome mental-workload and damaging X-ray radiations. In recent years, robotic cardiac surgery is emerging as a minimally invasive approach that uses robot-controlled tools and small incisions for MV surgery and coronary artery revascularization. Robotic catheterization has the advantage to be less traumatic and painful for patients, with reduced radiations and risks of re-hospitalization, while maintaining surgical efficacy [2]. The ARTERY project aims at developing a fully autonomous robotic platform of the MC system for percutaneous treatment of MR that is easy to learn and perform, safer, and radiation-free. In a previous work [5], a first robotic platform with autonomous control for the aforementioned system was presented. However, it has limitations as reduced DoFs, modelling approximations and suboptimal control.

Therefore, this thesis aims at **(1)** improving the design of the MC robotic system and **(2)** developing a new control algorithm exploiting a model-free approach. In particular, for the first goal, a new support architecture and actuation is introduced. Then, a closed-loop control algorithm using a Feedforward Neural Network (FNN) is implemented and tested to determine path tracking accuracy of the system in the intra-cardiac phase of the MV repair procedure.

2. State of The Art

Minimally invasive heart surgery is performed via percutaneous access, using guidewires, sheaths, and catheters to operate inside the heart. Many types of heart procedures may be performed with minimally invasive surgery, including coronary interventions, ablation procedures for atrial fibrillation and heart valves repair/replacement. The vast majority of catheters used in clinics are tendon-driven. These are controlled through knobs on the catheter's proximal side, to bend through wires the catheter distal-end. Significant forces are required to pull them through friction, making manual control of the distal position difficult. Since the introduction of robotic manipulators in 1998, robotic catheterization gained more popularity for cardiac and vascular surgeries. Their dexterity facilitates the surgeon in manipulating the catheters inside heart structures. Today's systems are human extenders and device interfaces, not true robots. However, the safety and efficacy of this approach have been demonstrated [2]. Their popularity led to the development of commercial systems as the Magellan™and the Sensei™X from Hansen Medical and the CorPath GRX (Corindus Vascular Robotics Inc.). However, robotic systems disadvantages are several, as the need of larger operating rooms, higher costs, lack of haptic feedbacks and specialized trained staff. Focusing on MV repair procedures, manual percutaneous approaches are used, through two commercially available systems, PASCAL™and MitraClip™(MC). The latter is considered the Gold Standard. The MC system, involves manually actuating a set of two catheters, named Delivery and Guide (Fig.1-a, b), through the Guide Handle (Fig.1-e) and Steerable Delivery Handle (Fig.1-f) for catheter insertion and bending on two planes, named Medial-Lateral (ML) and Anterior-Posterior (AP). Then a Device Handle (Fig.1-g) is used for positioning the MC clip. The MC system has soft robot's characteristics, as high number of DoFs and non-linear, time-dependent material's properties. To achieve good position control of soft robots, different control strategies have been developed [4], that can be divided into open-loop or closed-loop, with the latter relying on sensors for feedback, necessary when the environment is uncertain. Soft robot control techniques can be also classified into model-based and model-free approaches. Currently, model-based controllers are the most commonly used [3], however, even with accurate physical and geometric models, there are uncertainties and model approximations that can affect control performance. On the other hand, model-free approaches, such as Neural Networks (NN) and Reinforcement Learning (RL), have the advantage of not requiring defined parameters in the configuration or joint space, which makes them suitable for highly non-linear and material-dependent systems operating in unstructured environments. However, they require a large amount of training data and have difficulty in generalizing to different environments or tasks. RL control strategies for continuum robots are relatively recent and hold great promises in solving the unique challenges posed by these robots. However, RL can be difficult to implement since it requires active exploration of the environment and its effectiveness highly depends on the reward signal used for guiding the learning process, which may be difficult to define for complex systems with multiple tasks. NN controllers have also been proposed and used for learning the inverse kinematics of a soft tendon-driven manipulator. These controllers operate easily in real-time and adapt to changes in the manipulator's environment thanks to the non-linear mapping between task and actuation space. While model-based controllers remain more accurate and reliable for rigid manipulators operating in known environments, model-free approaches are more flexible and adaptable to uncertain, non-linear conditions [4].

3. Material and Methods

3.1. Prototype Design

In this work, a new system is designed by adding key clinical features that were missing in the previous prototype from [5], such as a 20° inclination traditionally achieved by the Stabilizer (Fig.1-e), Device Handle actuator (Fig.1-d) to control tip insertion, and the Steerable Guide Handle rotation (Fig.1-f). SolidWorks® environment is used for modelling the 3D components, subsequently printed using the Ultimaker s3 3D printer with Acrylonitrile Butadiene Styrene (ABS) material.

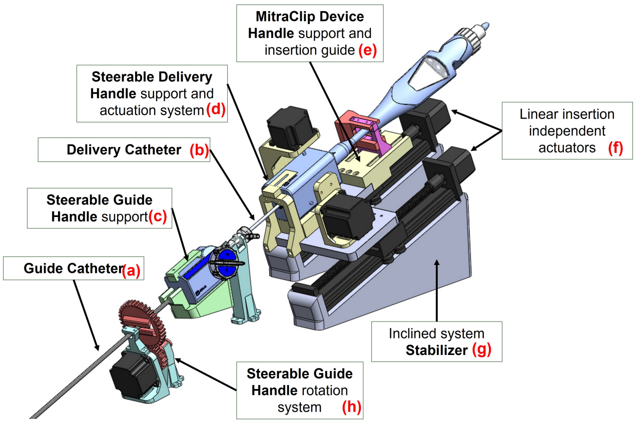

Figure 1: *Designed MC system: (a) Guide Catheter; (b)Delivery Catheter(c) Steerable Guide Handle support; (d) Steerable Delivery Handle support and tendons actuation with 2 stepper motors for ML and AP planes bending; (e) Device Handle support and guide rails for clip insertion; (f) two linear actuators for Delivery Catheter and Device Handle insertions; (g) 20° inclined support; (h) spur gears system for Steerable Guide Handle rotation.*

The system includes two Nema 23 Stepper motors (JoyNano) for ML and AP bending and one for Guide Handle rotation, which exploits spur gears to transmit torque. In addition, two Nema 17 Bipolar (Sainsmart) connected to linear guides are used for performing independent insertion motions of the Delivery Catheter and MC Device Handle. Lastly, an Arduino Uno board is used and connected to all motors, properly supplied and controlled by DM556 drivers (Jadeshay). The global system is shown in Figure 1.

3.2. Control Algorithm

The control of tendon-driven soft robots, which have a non-linear and complex nature is challenging. To overcome these challenges, model-free control techniques such as NN emerged. Indeed, the proposed control method is a model-free feedback data-driven controller, which exploits a Multi-Layer Perceptron (MLP) capability to fit any non-linear mapping function. A preliminary analysis of the maximum number of steps that the motors can perform, is done to acquire all feasible Delivery Catheter tip poses without exceeding the physical limitations of finite tendon length. For data collection, two motors attached to the Delivery Catheter's tendons and one linear motor that enables its insertion inside the Guide are used. The data are collected by making the robot explore its whole workspace, while recording the tip pose corresponding to a particular set of motor commands using the Electromagnetic (EM) tracking system (NDI Aurora®, Ontario Canada). The data is recorded using three 6-DoFs microsensors (RM-SPE 0.7-1.4 mm). The sensor on the tip is referred to the sensor on the Guide Catheter, then both are calibrated w.r.t. a fixed point sensor (Fig. 2). To control the system with a model-free approach, the mapping between tip poses and actuator state is established using data samples generated from the real robot setup. Then, for each possible catheter's motion, the relative tip pose is registered for two seconds at 4 Hz, discarding the first four samples and averaging the last four ones to reduce the hysteresis effect and also minimize sensors' uncertainties. The mapping of the workspace is covered by a total of 9808 points, which are further processed and reduced to discard all tip poses where tendons show backlash behaviour (no motion produced after actuation).

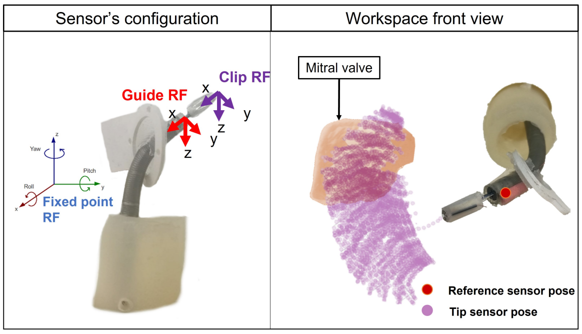

Figure 2: *Input/Output data generation setup. On the left: EM sensor configuration with their relative Reference Frame (RF). On the right: all recorded tip's sensor poses in space.*

Once the dataset of motor actuation and poses is obtained, MLP supervised training can be performed. The designed controller network has an input layer with 17 neurons, taking as inputs the **current pose** ($\hat{p}_k$) and **target pose** ($\bar{p}_{k+1}$) of the catheter's tip expressed with 3D Cartesian coordinates for position and quaternion for orientation, as well as the **current motor state** (q_k) of three actuators. The output layer has 3 neurons producing, for the three actuators, the predicted **number of motor steps** (Δq_{k+1}) needed to move the catheter's tip to the desired pose (Fig. 3). The optimal network hyperparameters are found using the Python Keras Tuner(https://keras.io), using Adam optimizer and Mean Absolute Error (MAE) minimization as objective function. The number of hidden layers found is 2 with 56 and 60 neurons respectively, hyperbolic tangent as activation function, and learning rate of 0.001.

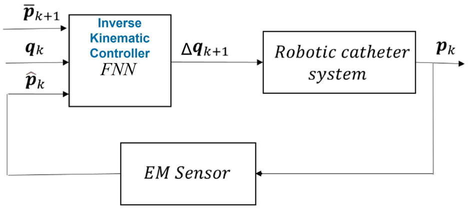

Figure 3: *Proposed* ***Inverse Kinematic Controller (IKC)*** *schema. The inputs are: (i) desired pose* $\bar{p}_{k+1}$*; (ii) current stepper motors state* q_k*; (iii) current tip pose* $\hat{p}_k$ *measured by the EM sensor. The output is the number of stepper motor steps needed to reach desired pose,* Δq_{k+1}*.*

Then, it is necessary to integrate the following four modules of the robotic MC system: **(1) Path Points** that communicates sequential target poses computed by the Path Planner to IKC Node; **(2) IKC** takes as input target pose, current tip pose from EM tracking system and actuators' state from Arduino, then computes the needed actuation to Arduino; **(3) EM sensors** that communicate poses; **(4) Low Level Controller** (Arduino) executes the actuation of IKC and communicates the new actuators state. Since these modules are developed in different programming languages, Robot Operating System (ROS) tool is used (Fig. 4). The ROS version is Noetic on Ubuntu 20.04.4 LTS.

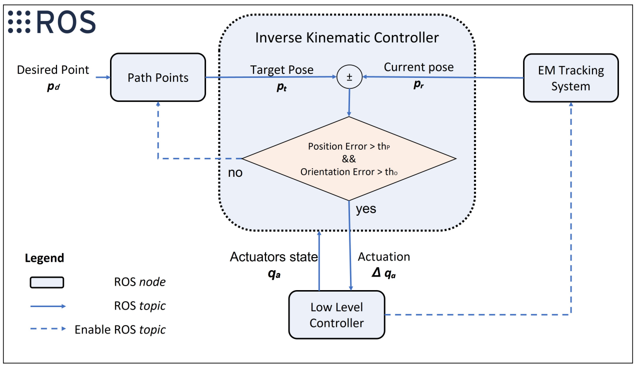

Figure 4: *Nodes communication with ROS.*

4. Experimental Method

To test the designed robotic system, together with the proposed controller, the physical setup is composed of the following components:

- two computers, PC1 equipped with ROS and PC2 for Unity simulation environment;
- EM tracking system;
- phantom to simulate the anatomical femoral vein and heart components;

This complete setup is shown in Figure 6. The experimental protocols involves three EM sensors placed on the MC device, as described for network data generation, and used for recording the real-time path tracking of the catheter's tip. The model-free IKC accuracy of tip position and orientation is evaluated respectively trough Euclidean Distance (ED) and MAE and compared to the performances the state-of-the-art model-based approach developed in [5] with a PID controller. Then, a second set of experiments is performed to analyse the accuracy of the IKC controller in relation to the number of points of the optimal path. ED and MAE are computed by Equations 1 and 2.

$$ED = d(p_t, p_r) = \sqrt{\sum_{i=1}^{n} (p_{t_i} - p_{r_i})^2} \tag{1}$$

$$MAE = \frac{1}{N} \sum_{i=1}^{n} |p_{t_i} - p_{r_i}| \tag{2}$$

where p_{t_i} and p_{r_i} are the i^{th} elements of vectors p_t and p_r. Some considerations on the choice of the paths are included. In particular, 9 paths with 4 repetitions each and a minimum number of 5 points are chosen. These paths are characterized by combinations of three different ML and AP catheter's curvatures, with a fixed insertion length which is the clinical one used in the traditional manual procedure (Fig. 5).

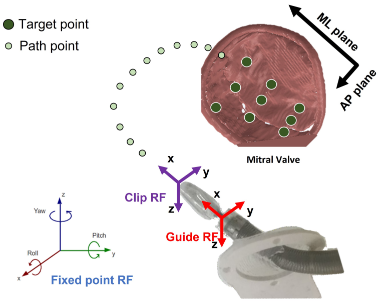

Figure 5: *Experimental path tracking setup. Nine paths are generated exploiting a fixed Delivery catheter insertion length and a combination of three ML and AP catheter bending.*

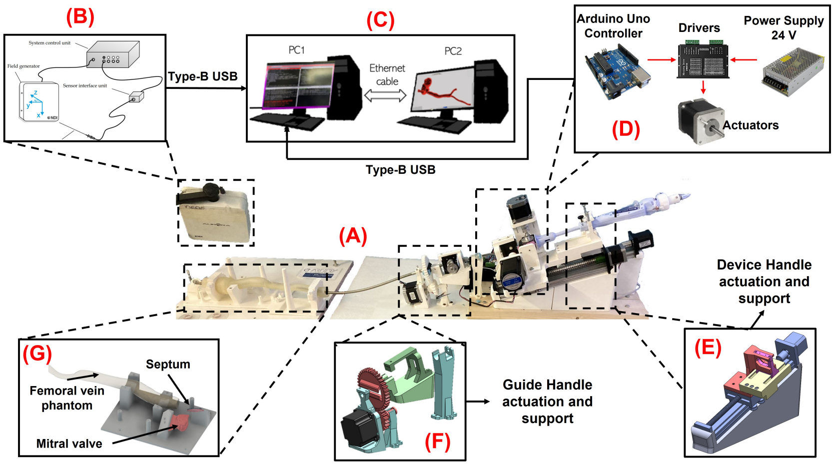

Figure 6: *Robotic MC system setup: (A) catheter actuation plant; (B) Aurora® EM tracking system; (C) PC1 for ROS tool on Ubuntu and PC2 for Unity simulation on Windows 10; (D) electrical devices and power supply; (E) designed inclined stabilizer and Device Handle's actuation for clip insertion; (F) motorized Guide Handle's rotation; (G) anatomical vein phantom and heart components.*

For the reader's convenience, the aforementioned experiments will be named respectively **PID-5** for model-based approach, and **IKC-5**, **IKC-10**, **IKC-15**, **IKC-20** for model-free.

5. Results

As previously mentioned, the tested paths are characterised by different combinations of ML and AP catheter's curvature, thus a first investigation is made to verify if they belong to the same distribution and assess the normality. Through quantitative and qualitative tests, it is demonstrated that all paths and their repetitions belong to the same non-normal distribution, both in ED and MAE data, thus the results can be grouped in a single one. However, by considering the path points separately for each experiment, the error is described by a normal distribution, thus *mean-value* and *standard deviation* are considered. No significant difference is emerged in position error in the 3D Cartesian axes, thus only ED is analysed. Then, a particular focus is made on the last point, which corresponds to the target on the MV. Between model-based and model-free ED data, the z-test is performed, and the results show a significant difference in the samples distribution, while between the experiments performed with different path points for model-free controller, a significant difference is obtained only up to 15 points. Concerning orientation MAE, a significant distribution difference results between model-free and model-based yaw and roll angles, while this do not happen when increasing number of path points. The analysis of two different approaches for controlling the robotic MC catheter in a path tracking task is performed: a model-free controller and a model-based one. Then, the accuracy of the IKC controller in relation to the number of path's points is evaluated. From the results, it is demonstrated that the model-free approach outperforms the model-based one in terms of position errors, with ED respectively of **3.95 ± 0.85 mm** and **7.54 ± 1.51 mm**. The model-based approach shows higher position errors due to internal/external factors that are not accounted for in the analytical model. As regarding the number of path points, the decreased distance is demonstrated to improve position accuracy, reducing ED error to **2.37 ± 0.13 mm** when 15 points or more are used.Concerning the orientation, a significant improvement is made in yaw angle, that is related to the ML bending plane, with a MAE of **10.56 ± 3.14 °** and **22.23 ± 9.16 °** respectively for model-free and model-based controller. Pitch angle, related to AP plane bending shows the smallest error, with a MAE of **3.39 ± 2.67 °** for the model-free approach. Lastly, roll angle is associated with the clip rotation around its axis, however, this DoF is not controlled in this system. The results are shown in Fig. 7 and 8.

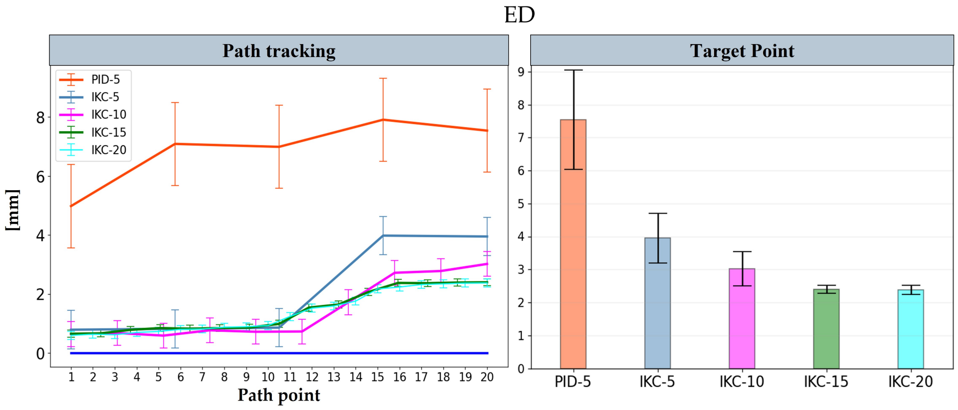

Figure 7: *Comparison between Euclidean Distance of model-based and model-free controllers for path tracking (left) and target point (right).*

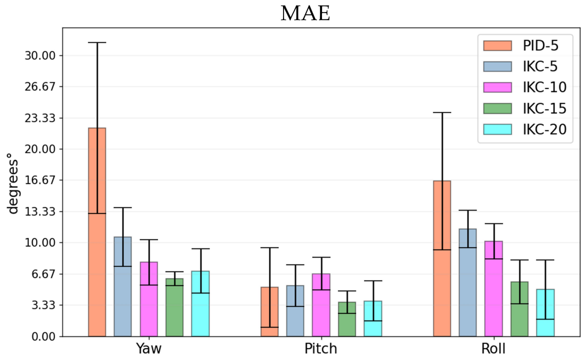

Figure 8: *Comparison between yaw, pitch and roll Mean Absolute Error of model-based and model-free controllers on target point.*

6. Discussion and Conclusion

From the results, model-free IKC, which uses data from the real catheter setup and sensor feedback, is able to compensate for non-linear uncertainties. However, errors are still present, mainly due to sensor accuracy and physical faults in the setup. Specifically, the control signals sent to the motor are not always actuated correctly, particularly when there is a change in the motor's direction. This limitation can be solved by introducing encoders in the setup, such that the correct motors state is always known. As regarding the number of path points, the error decreases when the points distance is reduced. This happens since the catheter is made with polymeric materials that show an increased hysteresis when higher forces or velocities are applied. Since smaller distances requires smaller forces, the hysteresis effect is minimized by keeping the material within a predictable and consistent range of deformation. Exceeding this range with higher forces can result in more unpredictable behaviour and greater hysteresis effects. In conclusion, in this work an autonomous control system for percutaneous mitral valve repair was developed. The primary goals were to redesign the previous robotic system and implement a novel control algorithm that improves pose accuracy. The control algorithm was based on a model-free controller using neural networks, which overcomes limitations of traditional control approaches. Overall, the results showed improved accuracy, but the system still has some limitations, including the need for a motorized actuation of the clip and susceptibility to interference from EM sources. In addition, neural networks are sensitive to noise and do not generalize well to other tasks or different environments. Future work includes introducing a more powerful micro-controller, encoders, and different controller architectures as Recursive or Radial Basis Function networks, which could be more suited for compensating the effect of highly non-linear systems.

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