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## Screening of factors influencing catheter rotation of a vascular interventional surgical robot using design of experiment approach

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1 Highlights

- 2
- The optimization of catheter gripping mechanism for a vascular interventional surgery robot is carried out using design of experiment method.
- 3
- The vascular interventional surgery robot under study rotates the catheter by rolling it between two planar surfaces.
- 4
- An experimental setup was designed and used to investigate the parameters of the gripping surfaces during catheter rotation.
- 5
- Soft and large gripping surfaces provides maximum torque and requires less forces.
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Journal Pre-proof

31           **Screening of factors influencing catheter rotation of a vascular**  
32           **interventional surgical robot using design of experiment approach**

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46 **Abstract**

47 Over the past decades, Vascular Interventional Surgery Robots (VISR) have been developed to  
48 address the risks associated with X-rays used in minimally invasive vascular surgery procedures.  
49 Manipulation of over-the-wire catheters is necessary to perform complex surgery but requires high  
50 forces on the robot's end effector during rotational movements. The VISR under study mimics the  
51 physician's fingers by rolling the catheter between two planar surfaces to rotate it. In this study, an  
52 experimental set-up is used to replicate this grasping method, also used in other VISR [1], [2]. The  
53 parameters of the gripping surfaces are investigated to maximise the torque delivered to the  
54 catheter and minimise the forces required at the robot's end-effector. The implemented design of  
55 experiment (DOE) demonstrated that large and soft gripping surfaces could achieve this compromise.  
56 By adjusting these parameters, sufficient torque can be achieved on the catheter.

## Introduction

Cardiovascular diseases, including ischaemic heart diseases and strokes remain the leading cause of death worldwide [3]. Coronary angioplasty, coiling and mechanical thrombectomy are the gold standard procedures to treat these diseases and involve inserting guidewires and catheters into the patient's vascular system. To see the devices progressing through the body, physicians need to inject a contrast agent (iodine) and use X-rays-based techniques such as fluoroscopy. Thus, radiation exposure and musculoskeletal disorders justify the use of Vascular Interventional Surgery Robots (VISRs) [4], which also increase positioning accuracy and improve patient care.

In this paper, the patented manipulation principle of the R-One™ robot, designed by Robocath and which has already been shown to be safe and effective on Human [5], is investigated. This method mimics the movements of the physician pushing and rolling the catheter by squeezing it between his or her thumb and forefinger. The physician's fingers are replaced by two planar surfaces called "pads" to perform millimetric tasks with high accuracy and repeatability. Each pad has three translational degrees of freedom (DOF), one of which manages the clamping and unclamping of the device along the  $\vec{y}$  axis of Figure 1.

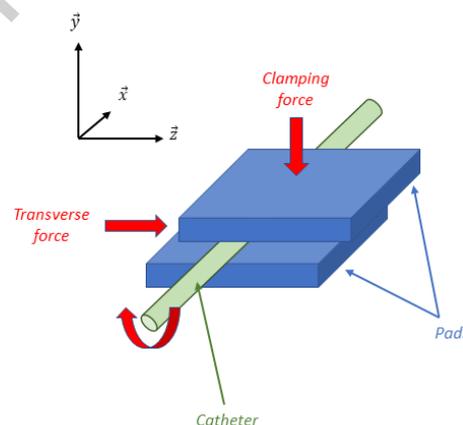


Figure 1 – The studied method for the rotational manipulation of catheters, from the Robocath patent [6]

The translation is simply achieved by moving the two clamped pads along the axis of the device ( $\vec{x}$  axis of Figure 1). The rotation of the device is achieved by rolling it between the two pads moving

vertically in an asymmetrical way along the  $\vec{z}$  axis, as explained in Figure 1. The force applied by the robot pads on the device along the  $\vec{y}$  axis is called “clamping force” while the force applied along the  $\vec{z}$  axis is called “transverse force”.

To successfully perform the procedure, the robot will need to transmit sufficient axial force and torque to the catheter. The quantification of the required torque on the device is the subject of the first paragraph of this article. Then, to determine the specifications of the robot, these forces expressed at the catheter level will have to be translated to the pads level to determine the forces required on each of the  $\vec{x}$ ,  $\vec{y}$  and  $\vec{z}$  axis. Assuming that there is no slippage between the pads and the catheter, the force required on the  $\vec{x}$  axis will be directly equal to the axial force required on the catheter. On the other hand, the rotation of the catheter induces a multifactorial phenomenon which is the rolling, and which will be specifically studied in this article.

The objective of this paper is to provide a generic approach to optimise the gripping and manipulation performance of a VIRS, as well as to determine its technical specifications in terms of the forces required on the end effector, that is the pads, with a particular focus on the most complex movement which is the rotation of the catheter. Since the overall goal is to miniaturise the robot, these forces must also be minimised.

Beyond the numerical results and observations, the contribution of this paper is to provide a standard process for characterising the forces involved in the rolling of a medical device between two planar surfaces. The key steps of this proposed process are the following:

- 1- Identification of the parameters to be studied.
- 2- Development of a dedicated test bench.
- 3- Characterisation of this test bench in terms of reproducibility of measurements.
- 4- Setting up a design of experiment.
- 5- Verification of the response models thus obtained.
- 6- Analysis of the results with regard to the objectives pursued.

In the first part of this article, the physician's gestures are under study, and the torque required to manipulate a catheter in rotation is quantified. The first step of the proposed process is also addressed in this first part, by studying the rolling phenomenon in order to deduce the gripping parameters to be studied. These parameters will be the factors of the DOE developed in this paper, the objective of which is to find an optimal combination of these factors in order to maximise the torque applied to the catheter and minimise the forces developed at the end effector.

The second and third steps are dealt within the second part of this article, through the description of the developed test bench, as well as its characterisation in terms of reproducibility of measurements. The test protocol will also be described in this part.

The third part of this article will be devoted to the fourth and fifth steps of the process, by presenting general trends of the DOE results and by verifying the obtained models.

Finally, in the fourth part, the response surface graphs will be used to determine the optimal combination of factors, and the results and limitations of this study will be discussed.

## **1 Context of the study**

### *1.1 Operating torques for catheters manipulation*

The required forces to handle rotating catheters are complex to quantify, due to the large number of factors impacting their values [7]. Indeed, between the physician's hands and the distal end of the catheter located into the patient's body, the catheter is subjected to resistive forces that can be classified into four categories [1], [8], [9]: the frictional forces between the manipulated device and others devices (introducer sheath, haemostasis valve...), the contact and collision forces between the distal end of the catheter and the vessel walls, the frictional forces between the surfaces of the catheter (along its length) and the vessel walls and the viscous resistance forces caused by the viscosity of the blood.

As the robot is located at the proximal end of the catheter and it must reproduce the movements the physician's hands, the values retained correspond to the measurements made on the physician's

hands in the literature [10]–[12]. The average of the maximum values presented in these studies is 5.5 mN.m. This value will be considered as the torque that should be applied to the catheter by the VISR end effector. The torque required on the catheter will determine the forces required at the VISR end effector, that is the forces required on the  $\vec{y}$  clamping axis and the  $\vec{z}$  rotation axis of the pads.

A review of the literature presented in the following section has contributed to identify the gripping parameters that are essential to work on, to allow both minimization of these forces and maximization of the operating torque on catheter.

### *1.2 Factors influencing catheter handling and rotation*

The rotation of the catheters between two pads induces a multifactorial phenomenon which is rolling. This phenomenon can be characterized by the rolling resistance, which is due to the deformation of both the rolling object and the surface on which it rolls near the contact area [13]. To ensure sufficient torque on the catheter, the dynamic friction coefficient between the two surfaces must be high enough to prevent sliding. However, the greater the rolling resistance, the greater the forces required for rotation. Since the overall goal is to miniaturise the robot, these forces must be minimised. Hence, a literature review is required to identify the gripping parameters that are essential to work on to enable this optimisation.

Research has been conducted to model the rolling of a cylinder on a surface [13]–[18]. However, due to the many factors and their interactions, the chosen approach, for example in the automotive sector, is the DOE method. Several studies in this area [19]–[21] have shown the importance of vertical load, diameter and pressure of the tyre, rotational speed and contact width, on the overall performance of the system.

In the case of the present study, and following preliminary tests, it therefore appears essential to study the hardness of the material of the pads, the width of the pads and the rotational speed.

These 3 parameters are the 3 factors of the DOE.

In order to study the impact of these 3 factors on the required forces at the end effector (clamping force and transverse force) and on the torque applied to the catheter, an experimental set-up was developed.

## 2 Material and methods

For the sake of confidentiality, the numerical values, including the axis of the graphs, and the nature of the material (apart from the fact that it is a biocompatible polymer) will be omitted, but this will allow the scientific approach detailed in this article to be presented, and the results to be compared.

### 2.1 Experimental set-up

The 3 factors and 3 responses studied are the following:

- $X_1$ : The pads width, which is the dimension along the  $\vec{x}$  axis of Figure 1.
- $X_2$ : The hardness of the biocompatible polymer of the pads.
- $X_3$ : The rotational speed of the catheter.
- $Y_1$ : The minimum required clamping force.
- $Y_{2i}$ : The maximum torque applied to the catheter, corresponding to a given clamping force.
- $Y_{3i}$ : The minimum required transverse force, corresponding to a given clamping force and to obtain a given torque on the catheter.

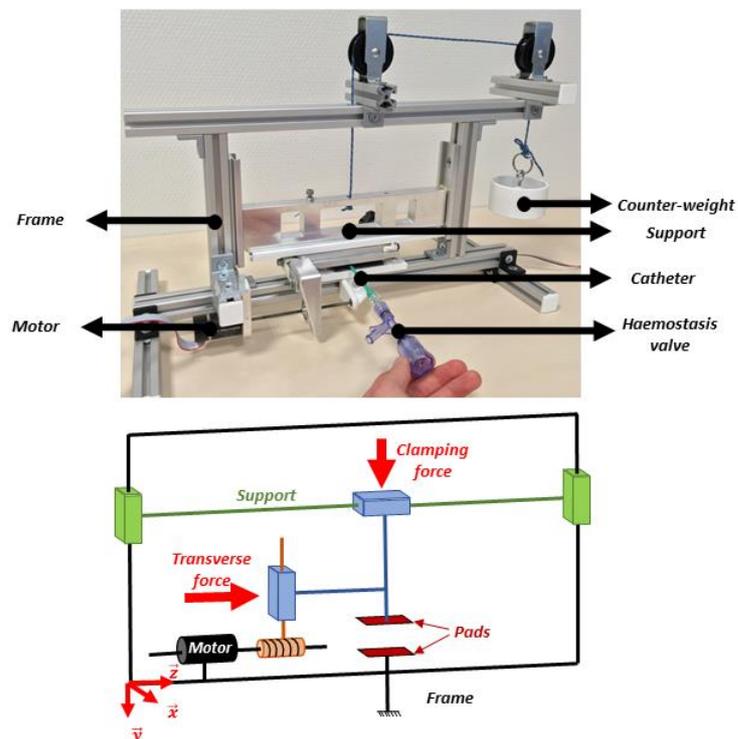
Each of the factors will take three values in the experimental design, coded -1, 0 and 1, and the formula that gives the coded variable value as a function of the physical variable value is as follows:

$$x_{coded} = \frac{2x_{physical} - level_{high} - level_{low}}{level_{high} - level_{low}}$$

Equation 1 - Coded variable according to physical variable

The experimental set-up detailed in *Figure 2* was developed to study these 3 factors and 3 responses.

The upper pad, which is linked to a load cell [*Micro Load Cell (0-5kg) - CZL635, Phidget*], is driven in translation. along the  $\vec{z}$  axis by a stepper motor and a ball screw transmission (*AM2224R3025086 with M3x100T and PE22-120, Faulhaber*). This rotates the catheter placed between the two pads on which the tested material is placed. The clamping force can be varied by placing weights on this support, and the counter-weight mechanism is used to compensate for gravity.



*Figure 2 - Experimental set-up*

The torque applied to the catheter is determined statically. The tip of the catheter is bent at  $90^\circ$  so that its rotation causes a beam to be lifted, on which weights are positioned. By increasing the weights until the catheter slips, the maximum permissible torque is determined.

## 2.2 Experimental protocol

The test procedure can be stated as follows:

1 - The clamping force is increased until the catheter rolls continuously (without sliding). This value corresponds to  $Y_1$ .

2.1 – With this clamping force  $Y_1$ , the load  $P$  on the catheter is increased until the catheter slips, thus determining  $Y_{21}$ .

3.1 – With this clamping force  $Y_1$  and a load  $P$  corresponding to a torque  $Y_{21}$ , the transverse force  $Y_{31}$  is measured.

2.2 – The step 2.1 is performed again with an increased clamping force of  $F_d$ , thus determining  $Y_{22}$ .

3.2 – The step 3.1 is performed again with an increased clamping force of  $F_d$ , thus determining  $Y_{32}$ .

2.3 – The step 2.1 is performed again with an increased clamping force of  $2F_d$ , thus determining  $Y_{23}$ .

3.3 – The step 3.1 is performed again with an increased clamping force of  $2F_d$ , thus determining  $Y_{33}$ .

Thus, the impact of clamping force can also be studied.

In addition, the pads will be continuously humidified with a saline solution, to get closer to the real conditions, and the used catheter has a diameter of 1.33 mm, which corresponds to the diameter mainly used in interventional cardiology (angiographic and guiding catheters) [22].

The arrangement of factors levels for the Box-Behnken DOE for three factors is described in Table 1.

The total number of required experiments is 15 and the total number of different factor combinations is 13, as the last three experiments correspond to the same factor levels.

<i>Experiment</i>			
<i>no.</i>	$x_1$	$x_2$	$x_3$
1 → 4	±1	±1	0
5 → 8	±1	0	±1
9 → 12	0	±1	±1
13 → 15	0	0	0

*Table 1 – Box-Behnken experimental design matrix of three variables*

In addition, a repeatability and reproducibility (R&R) study was conducted to ensure that the variability of the observed results are due to the studied factors. This study determined the variability of the measurements by calculating a confidence interval for each response, which is expressed as detailed in Equation 2.

$$\mu_R = \bar{y}_{ij..} \pm t_{\frac{\alpha}{2}; n-1} \frac{s_{ij}}{\sqrt{n}} = \bar{y}_{ij..} \pm t_{\frac{\alpha}{2}; n-1} \sqrt{\frac{\sum_{u=1}^r \sum_{v=1}^t (y_{ijuv} - \bar{y})^2}{N-1}}$$

*Equation 2 - Reproducibility standard deviation*

N is the total number of experiments during R&R study, and n = 3, as the considered value for each response for each combination of factors during the DOE will be the average of 3 measurements.

Hence, the 95% confidence intervals (for which the Student variable  $t_{\frac{\alpha}{2}; n-1}$  is equal to 4.30) are the

following:

- Clamping force: +/- 1.3 N,
- Torque: +/- 0.7 mN.m,
- Transverse force: +/- 2.2 N.

These confidence intervals will be used as safety margins.

### 3 Results

#### 3.1 Trends in clamping force, transverse force, and torque evolutions

The torque and transverse force evolutions with clamping force are respectively given in Figure 6a and Figure 6b, and the torque evolution with transverse force is given in Figure 6c. Each line corresponds to one combination of factors and each point of these lines corresponds to one value of clamping force (it means  $Y_1$ ,  $Y_1 + F_d$  or  $Y_1 + 2 F_d$ ). The colours of the lines indicate the hardness of the polymer.

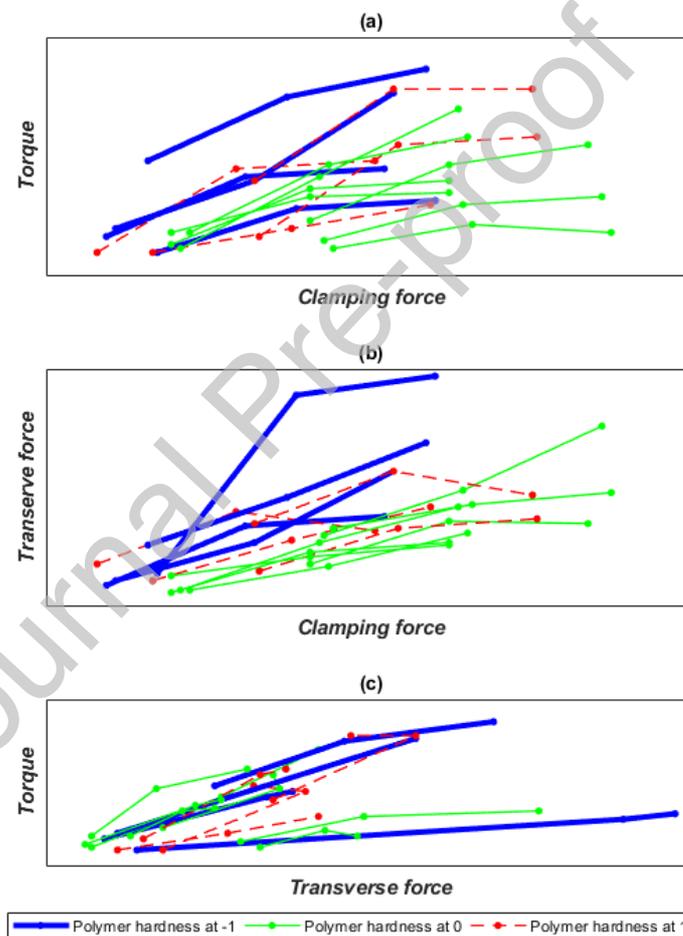


Figure 3 - (a) Clamping force effect on torque, (b) Transverse force effect on torque and (c) Clamping force effect on transverse force, for each combination of factors.

Thus, Figure 3 demonstrates the non-linear impact of polymer hardness on forces and torque.

Increasing the clamping force does not indefinitely increase the torque applied to the catheter. This means that in order to both maximise the torque and minimise the required forces, it is unnecessary to increase the clamping force beyond the minimum value  $Y_1$  with an additional force of  $2F_d$ . Thus, the models of transverse force and torque corresponding to this minimum clamping force with an additional force of  $2F_d$  ( $Y_{33}$  and  $Y_{23}$ ) will be determined and analysed.

### 3.2 Models

The determined models are polynomial functions of the 3 factors, their second-order interactions, and quadratic effects. The model of a response  $n^{\circ}i$  is denoted by  $\hat{Y}_i$  and is detailed in Equation 3.

$$\hat{Y}_i = \beta_{0_i} + \beta_{1_i}x_1 + \beta_{2_i}x_2 + \beta_{3_i}x_3 + \beta_{12_i}x_1x_2 + \beta_{13_i}x_1x_3 + \beta_{23_i}x_2x_3 + \beta_{11_i}x_1^2 + \beta_{22_i}x_2^2 + \beta_{33_i}x_3^2$$

Equation 3 – Model for a response  $n^{\circ}i$

A coefficient  $\beta_{j_i}$  corresponds to the response  $n^{\circ}i$  and the factor or interaction of factors  $n^{\circ}j$  and is determined as described in Equation 4.

$$\beta_i = \begin{bmatrix} \beta_{0_i} \\ \beta_{1_i} \\ \beta_{2_i} \\ \beta_{3_i} \\ \beta_{12_i} \\ \beta_{13_i} \\ \beta_{23_i} \\ \beta_{11_i} \\ \beta_{22_i} \\ \beta_{33_i} \end{bmatrix} = (X^T X)^{-1} X^T Y_i$$

Equation 4 – Calculation of the coefficients of the models

With  $X$  the design matrix described in Table 1.

The p-values associated with the models for the three responses  $\hat{Y}_1$ ,  $\hat{Y}_{23}$  and  $\hat{Y}_{33}$  are 0.11, 0.097 and 0.007 respectively. With the confidence level set at 0.1, this means that the models are globally relevant.

The analysis of the coefficients of each of the models showed that the width of pads  $x_1$  is the most influential factor. Moreover, the interaction between the width of the pads  $x_1$  and the polymer hardness  $x_2$  has a great influence on transverse force. Indeed, for a constant clamping force and torque, these two parameters will determine the relative deformation of both pads and catheter and will therefore determine the force required to rotate the catheter on the pads.

On the contrary, the rotational speed  $x_3$  has a negligible impact on all three responses. This may be due to the fact that the viscosity of the saline solution is very low (about  $1,9 \cdot 10^{-3}$  Pa.s [23, pp. 8–77]), making the dynamic viscous friction force negligible.

Thus, in order to maximise the torque and minimise the required forces, the two factors that need to be optimised are the width of the pads and the hardness of the material of the pads, so the rotational speed will be set at its 0 level (300 °/s).

## 4 Discussion

### 4.1 *Optimum levels of factors for torque maximization and forces minimization*

The response surface methodology (RSM) is an effective tool when studying the impact of factors and their interactions on responses [24, p. 568], [25, p. 414]. Hence, this method is used and the response surfaces for all three models as functions of the hardness of the polymer and the width of pads are given in Figure 4.

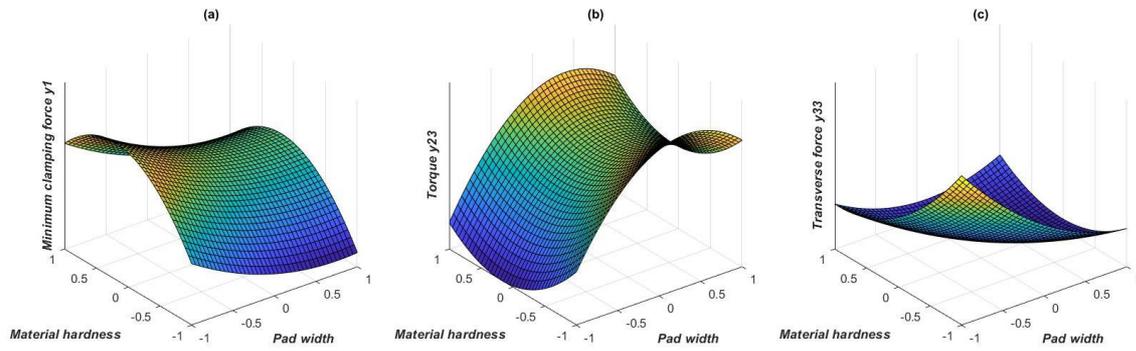


Figure 4 - Response surface showing the effect of pad width and polymer hardness on (a) the minimum required clamping force  $\hat{Y}_1$ , (b) the torque  $\hat{Y}_{23}$  and (c) the required transverse force  $\hat{Y}_{33}$

It can be seen that the interaction of these two factors is non-negligible on the transverse force. Hence, as Figure 8c shows, for low polymer hardness, the transverse force increases as the width of the pads decreases, which is not the case for high polymer hardness. This can be explained by the fact that a small pad width concentrates the clamping pressure on both catheter (which can become oval) and material of the pads (which becomes more compressed as its hardness decreases), and lead to an increase in the transverse force.

The optimum value for the width of the pads is therefore set at 0.5 (coded level), and Figure 5 shows the models of the three responses as a function of polymer hardness, for this level of width. The sum of the required clamping force and the required transverse force (which is  $\frac{Y_{33}}{2}$  per pad if the two pads are movable along the  $\vec{z}$  axis) is also shown.

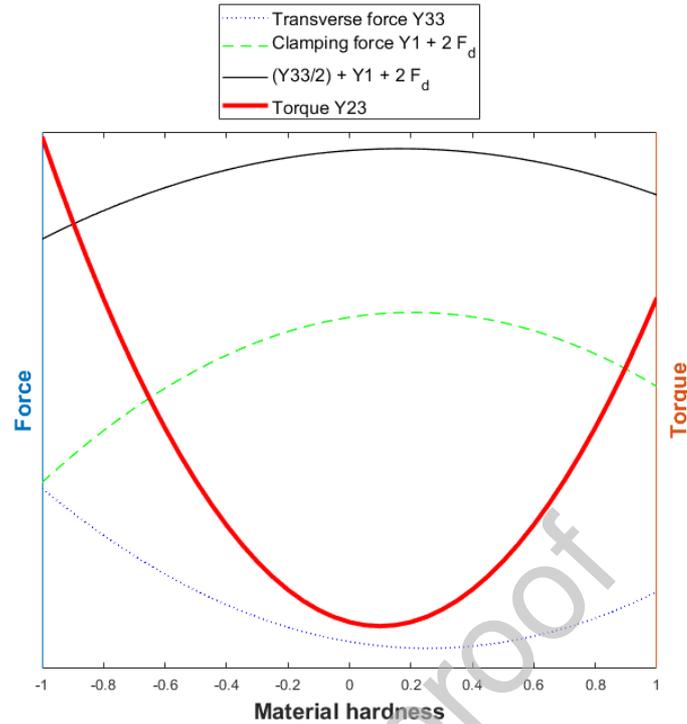


Figure 5 - The effect of polymer hardness on minimum clamping force with additional force of  $2F_d$  (large dotted green line), transverse force (thin dotted blue line) and torque (wide red line) with a pad width of coded level equal to 0.5. The thin black line corresponds to the sum of the clamping and transverse forces

The sum of the forces required on the  $\vec{y}$  and  $\vec{z}$  axis of the end effector robot is almost constant but seems to be minimised for low hardness values. It is also observed that the torque is minimised for polymer hardness at its coded value of 0.1, and it is maximised for low hardness values. This could be explained by a higher deformation of the soft polymer and thus a better holding of the catheter. However, compared to a hard polymer, a soft polymer leads to the concentration of the saline solution on the areas of high deformation, which increases catheter sliding. This explains the good performances also obtained with very hard silicones. However, when the hardness is at its 0 level, neither of these advantages apply, and the performance decreases.

The optimal configuration is therefore a width of pads of 0.5 and a polymer hardness of -1.

Under these conditions, a torque of 3 mN.m and 5.5 mN.m were measured respectively on a 1.33 mm and 1.67 mm diameter catheter, which falls precisely within the required torque range defined in the introduction.

Moreover, further testing has shown that the optimum hardness of the polymer decreases as the diameter of the catheter being handled increases. In the case of a large diameter catheter, this may be due to the fact that the material must deform strongly to optimise its grip. Conversely, when handling a small diameter catheter, using a material that is too soft could cause the two pads on either side of the catheter to come into contact with each other, thus increasing friction and decreasing performances.

#### 4.2 Conclusion

In this paper, the rotation of catheters by a VISR whose end-effector consists in two planar surfaces that mimics the movements of the physician's thumb and forefinger is studied. During the manipulation in rotation, the catheter is rolled between these two planar surfaces. This paper presents a general method for optimising gripping performance and determining the forces required for this handling kinematics.

A test bench was developed to determine the optimum value of the rotational speed and the width and hardness of the pads. A DOE approach was used to determine the models of each of the three responses (clamping force, transverse force, and torque applied to the catheter) through a minimum of experiments. These models were then verified by the statistical method ANOVA, and the RSM was finally applied to find the combination of factors that minimised the clamping and transverse forces

while maximising the torque applied to the catheter. Further tests were then carried out to validate the results.

Thus, the optimal parameters are a relatively large width of pads (coded level of 0.5) and a very soft polymer (coded level -1). Under these conditions, the required forces to achieve sufficient torque on the catheter were determined. The results of this study were used to develop an industrial prototype of VISR which was successfully tested on pigs. However, the information about these tests is confidential.

This study provides a promising methodology for the optimisation of grasping parameters for robotic manipulation of over-the-wire catheters and the design of appropriate actuation. However, the limitations of the study (including the method of torque measurement or the exclusive use of a 1.33 mm diameter catheter) should be considered and further investigated in future works.

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## **6 Declaration of Competing Interest**

None.

## **7 Ethical approval**

Not required.

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None

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