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Measuring Tip and Side Forces of a Novel Catheter Prototype: A Feasibility Study

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Abstract— **Minimally Invasive Surgery (MIS) and robot surgery have opened new ways to perform surgical operations in a safer and simultaneously faster manner. In an effort to follow this minimally invasive trend, this paper presents the feasibility study of a novel fibre-optic catheter prototype. This prototype sensor has the ability to measure forces from the sides and tip. Classification of forces from multiple positions on a catheter provides valuable information for safe navigation inside the vasculature and heart of a patient. This sensor employs two fibre-optic schemes, one for the tip and one for the sides of the catheter; it is made entirely of plastic, making it compatible with Magnetic Resonance Imaging (MRI). A test bench was used to determine the linearity coefficients during static loading. These initial experiments on the prototype gave rise to an ideal linear force response coupled with low hysteresis. Finally, an experiment which tries to simulate the human blood vessel achieved satisfying results during dynamic sensor movement.**

I. INTRODUCTION

MINIMALLY Invasive Surgery (MIS) and the use of robots in surgery have developed promising methods for safer and faster surgical operations. Despite the advantages by these types of novel surgical operations, the loss of force feedback poses a serious problem which remains unsolved.

One of the most known minimally invasive approaches is the cardiac catheterisation. Stenosis of vessels, like coronary arteries, cause large suffering amongst the human population. A common treatment is the dilatation of the stenosis by using inflatable catheters which are usually inserted via peripheral blood vessels and manoeuvred into the desired locations in the patient's heart. Catheterisation is a delicate process and the means used to navigate the catheter today are not sufficient, forcing the physicians to rely mainly on their sense of touch. In addition, the diagnosis and treatment of cardiac arrhythmia involves the insertion of electrophysiology catheters to measure electrograms in the heart. Once the arrhythmogenic substrate is fully elucidated, then it is often possible to completely cure by using other catheters to perform radio frequency (RF) ablation (i.e. burning) of the tissue and thus blocking the propagation of the abnormal electrical activity. Although cardiac catheterisation is performed under image guidance the quality of the electrograms and the ablation lines strongly depends on the mechanical contact of the catheter with the tissue. Either the tip or the side of the catheter will touch the tissue depending on its orientation and bending. Therefore, additional information about the forces from the tip and from the sides of the catheter would be highly beneficial to speed up and to improve the accuracy of a regular or robotic assisted catheterisation.

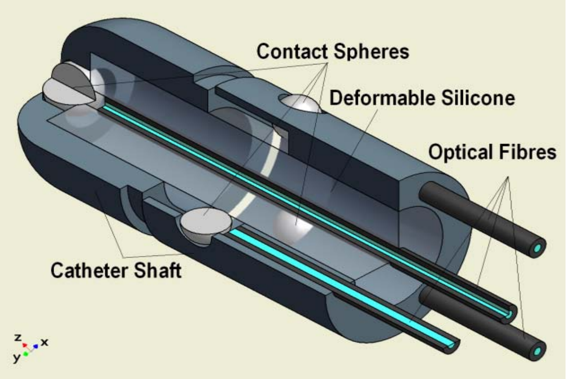

Fig.1. A section view of the proposed fibre-optic force sensor, showing the tip and side sensing elements.

Currently, cardiac catheterization is performed under X-ray fluoroscopy. However this imaging modality lacks 3D information and soft tissue contrast and involves high radiation dose to patient and staff. Recently, cardiac catheterisation has been performed using magnetic resonance imaging [1]. However, the unavailability of MR-compatible and safe catheters has hindered the widespread clinical use of MR-guided catheterization, so far. In this work we present a novel catheter prototype that can measure tip and side force while it is MRI compatible.

II. BACKGROUND

A. Minimally Invasive Surgery

Laparoscopic surgery or Minimally Invasive Surgery (MIS) is an alternative surgical process in which a patient receives treatment to their internal anatomy without the need of large tissue incisions. Performing surgery through small openings results in fewer traumas to surrounding tissues and therefore improves aesthetics. If the traumas are lesser, the recovery time of the patient is also reduced and with it the risk for post-operative infections. Consequently, the entire

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hospitalisation cost is reduced, producing a better economy for the hospital and allowing more patients to be treated [2].

Due to the advantages offered by a MIS, this procedure is establishing itself as a preference among physicians and patients. Despite the above, MIS has also some disadvantages. These disadvantages have been described by many scientists, such as [3]-[4] and are the following:

- The tissues cannot be palpated by hand anymore as the size of the incisions restricts their access.
- The contact interaction forces between the tissues and the tools are impaired due to the friction of the tools with the trocar ports and the torques needed to rotate the tools.
- The hand-eye coordination is lost because of the limitation in degrees of freedom of the tool and the difficulty of the surgeon to manipulate the tools.

The disadvantages of MIS do not noticeably outshine the advantages and as a result solutions are sought in order to allow MIS to flourish. Consequently, the need to overcome these restrictions has lead to development of mechatronic and robotic devices, which are able to take charge and assist in surgeries by solving those problems. The most known complete MIS robot developed for MIS is the da Vinci™ surgical system (Intuitive Surgical, Sunnyvale, California).

B. Catheterisation as a Minimally Invasive Procedure

Percutaneous coronary interventions (PCI and electrophysiology (EP) procedures requires the insertion of cardiac catheter which is a thin, flexible, small in diameter, elongated tube [5]. The intent is to reach certain locations through the blood vessels and to perform examination or offer treatment to tissues and organs within the human body that would otherwise require an open surgery. In cardiac catheterisation the insertion of the catheter can be achieved through a small incision on the groin (upper thigh), the arm, or the neck of the patient, where one of the main blood arteries can be found.

The interventional cardiologist has to navigate the catheter through a very delicate and complex network of blood vessels until he/she reaches the required location. Whilst performing the forwarding the interventional cardiologist uses image guidance to identify the position of the catheter. The most commonly used medical imaging modality is X-ray fluoroscopy. This technique involves the use of an X-ray source and a detector to obtain real-time images of the internal structures of a patient, who is placed in-between it. The images are taken in a sequence that can be showed to doctors as a form of movie, representing the internal moving body structures. From this technique two-dimensional images can be acquired, which can either show the skeletal structure (radiographic image), or the vasculature (angiogram) of the patient. In the case of a catheterisation, a contrast agent is injected into the blood vessels to improve their visualisation.

Nonetheless, this technique does come at a cost. The ionising radiation (X-rays), which is emitted by a fluoroscope, generates a health risk for the patient and for the physician performing the examination. This sets constraints to exposure time and the number of radiation doses emitted during the procedure.

Computed Tomography (CT), is another medical imaging technique which is used to allow physicians to obtain three-dimensional images of the interior anatomy of the human body. These images are taken around a number of rotations. The distinction comes with the increased amount of X-ray beams sent to the human body. Those distinctive features gives to CT far more detailed imaging results in comparison to an X-ray. However, due to the use of ionising radiations (X-rays), physicians do not recommend theses scans without a good reason, e.g. for better diagnosis and planning of the intervention.

The advantages of excellent soft tissue contrast and avoiding ionising radiation make MRI interesting for intervention procedures [11]. An MRI scanner has the ability to examine human soft tissues and networks of blood vessels without the need for a contrast agent, producing three dimensional digital images of superior quality. MRI is capable of not only providing images of the anatomical structures of a human body but it also provide functional information [13]. The physicians have the choice to select the scan plane which is best suited for any examination without the need of repositioning the patient. However, MRI techniques require the use of tools which do not affect the homogeneity of the magnetic field and its signal to noise ratio, and must be magnetically inert and MRI safe [13]. The uses of components that breach these rules cause either disturbance to the magnetic field and hence artefacts are produced in the resulting images, or make their operation completely useless. Furthermore, the patient's health might be harmed from heating-up effects, or missile effects caused by non-MRI compatible materials which are exposed to the magnetic fields of the scanner [12]-[13]. In particular, any conductive wire inserted into the patient's body can work as an antenna during MR-scanning, which can result in significant heating effect [21]. There catheter devices are required that do not involve long conductive wires for braiding, steering or electrical measurements.

Apart from image-guidance, physicians speak of a haptic feedback which they receive from the interaction of the catheter with the blood vessel. This feedback is used to avoid exerting excessive forces during the catheter's forwarding. Regardless of the haptic sense, physicians are incapable of indentifying the origin of the forces. It has been established that there are two different forces that are generated during the navigation of a catheter inside the human body. The first originates from the friction of the catheter's shaft with the blood vessels and the second from the contact of the tip of the catheter with the blood vessel walls [9].

These two forces are important in a catheterisation, but due to the complexity involved in distinguishing them, only surgeons with vast experience tend to perform them. Therefore, during a manual catheterisation the doctor must rely mostly on the visual guidance offered by one of the above techniques. The force feedback gained from the contact and the friction of the catheter with the blood vessel in most cases stays unexploited.

C. Vascular Interventional Robots

In the same way as robots developed for general MIS, robots which assist in catheterisation procedures have also been developed. These robots are called Vascular Interventional Robots (VIR). One of today's most commercial VIR is the Sensei™ robotic catheter system (Hansen Medical, Inc., Mountain View, California) [6]-[8]. This VIR allows the surgeon to perform a catheterization controlling a master-slave robotic system from a distance. In turn, this robot makes use of a modern CT scanner which can produce three dimensional images. This system is also equipped with a force sensor, called Intellisense™ Fine Force Technology, to provide the doctor with a source of force feedback.

One can immediately notice the advantages of using a VIR to perform a catheterisation. These are summarised as follows [9]:

- The exposure of doctors to ionizing radiation, such as X-rays, is eliminated as the navigation of the catheter is made through the use of direction controls from a safe distance inside the control room.
- The VIR control system master elements, and reconstructs two dimensional images captured by the fluoroscope or CT scanner and creates three dimensional images representing the vasculature system more accurately.
- The axial and rotational movements of the catheter are performed by the slave elements of the VIR and therefore the tremor from the doctors' hands is eliminated as it is filtered out.
- The contact and friction forces from the catheter with the blood vessels are identified with the use of force sensors allowing the robot to adjust the motion and position of the catheter.

Nevertheless, one can soon realize that there is no need to be concerned about hazardous radiation emissions using an MRI scanner to perform the catheter navigation. Another benefit is that the resulting images provided are in three dimensions, making image reconstruction obsolete and offering a far more detail than X-ray fluoroscopy or CT scanner. Therefore, recent interest has been focused on the development and the utilization of innovative sensors for use in MRI environments. These sensors are intended to be integrated with catheters and used either under manual or robotic catheterisation as indicators of excessive force inside the vasculature structures.

D. Sensors for Catheters

Many types of force and pressure sensors have been developed for use in the inside of the vasculature. Those sensors were used for different kinds of measurements, such as blood pressure, oxygen level, blood flow velocity and others. However, very few of them were developed for the detection of contact forces with the blood vessel walls. Such sensors were produced, alone or as part of tactile sensors [14], which employ several sensing principles, such as: strain-gauges [15], piezoresistivity [16], PVDF films [17] and fibre-optic technology [19]-[20]. The latter principle has been mainly used to measure blood pressure inside the veins.

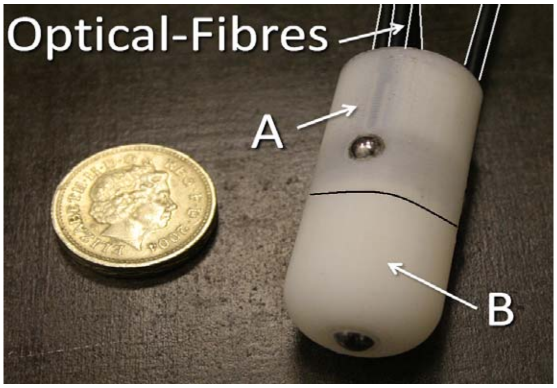


Fig.2. Picture of the developed prototype fibre-optic force sensor.

As the MRI compatibility of sensors appear to be the next step to a successful enhancement of the catheterisation procedure, fibre-optic technology seems to be suitable to provide all the necessary tools for it.

III. THE NOVEL PROTOTYPE FIBRE-OPTIC FORCE SENSOR

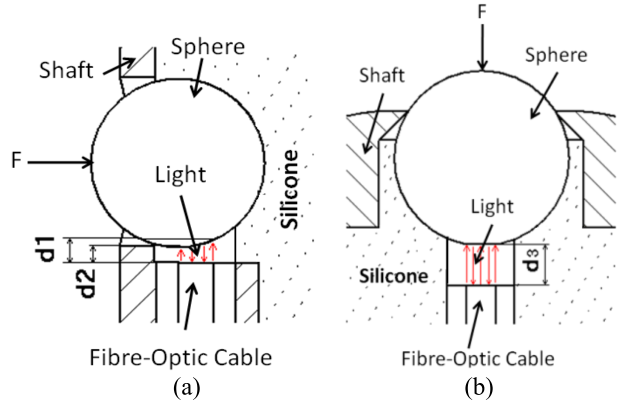
A. The Structure of the Novel Sensor

The novel fibre-optic sensor consists of two parts; a cylindrical shaft that serves as the main body of the catheter (A, Fig. 2) and another cylindrical shaft with a curvature at the end of it which represents the tip of the catheter (B, Fig. 2). The entire prototype was made form ABS plastic using a 3D prototyping machine (Dimension 768, Stratasys, Inc.).

The main body (A) is 25 mm long and hollow. The outer and inner diameters are 20 mm and 12 mm respectively. A gradation at the inner diameter takes place after approximately half way of the shaft's length. The inner diameter is increased to 18 mm in order to allow three peripheral metallic spheres of 6 mm in diameter to reside in 5 mm in diameter radial openings. The way the spheres are positioned exposes a part of them to the exterior environment. The remaining part of the spheres, which cannot be seen, leaves a 2 mm space from the inner gradation. (See d1 dimension in Fig. 3(a)). At the end of part A, where the optical fibres are shown, three holes of 2.2 mm in diameter are opened in a circular pattern with 120 degrees spacing. These holes are designed to accommodate one 1 mm plastic fibre-optic cable along with their jacket (Edmund Optics Inc., York, UK). These optical-fibres are inserted up to the point where the 'step' is formed by the gradation.

The tip of the prototype sensor (B) is 20 mm long and has the same outer and inner diameter as the main body. These dimensions change after 16 mm of length, where another gradation in the inner of the shaft is formed to create a pocket for the tip sphere. This pocket is 7 mm in diameter and 4 mm in length to allow positioning of a 6 mm sphere.

The sphere is exposing one part to the outer environment through a hole at the top of the shaft. The head of the shaft is given a curved shape to match the appearance of a catheter's



(a) (b)

Fig.3. Section views showing the light modulation principle of operation of the sensor's spheres. (a) The side's sphere light modulation and (b) the tip's sphere light modulation.

tip. The optical-fibres and spheres are placed in position, and the two parts are glued together to form the prototype as seen in Fig. 2. One additional optical-fibre cable is aligned with the inner centre line of the prototype passing through both parts A and B, with its end stopping 2 mm below the inner part of the tip's sphere. The entire sensor is filled up with a deformable material (silicone, RTV 6166 A&B, Techsil Ltd, UK). This material holds the spheres and the middle optical-fibre in position allowing deformation when a force is applied on the spheres.

B. Principle of Operation

The operating principle relies on light modulation. An ultra bright red LED emits light at 650 nm wavelengths through the one end of a 1 × 2 optical coupler with 50:50 ratios (Industrial Fiber Optics, Inc., AZ, USA). The light is guided through a plastic 1 mm optical-fibre to one of the prototype's side spheres. There the light travels for a distance of 2 mm (distance d1, Fig. 3(a)) using the air as a medium and is reflected back by the sphere's surface. The reflected light travels back using the same optical-fibre and reaches a fibre-optic photodiode detector, SFH 250V (Infineon Technologies Ltd, UK). Therefore, when a lateral force is applied to the sphere, it causes a deformation of the silicone and consequently a small displacement of the sphere on the horizontal plane. This displacement causes in turn the distance between the sphere and the optical-fibre to decrease (distance d2, Fig. 3(a)). This happens because as the sphere penetrates into the silicone the centre line of the optical-fibre aligns with the sphere's South Pole. When the force is removed the silicone retracts the sphere back into its initial position. The same light scheme is applied for the remaining two side peripheral spheres.

The tip sphere has a similar operating principle with some differences. The sphere here accepts a force that leads to a vertical displacement into the silicone. This vertical displacement decreases the distance between the South Pole of the sphere and the optical-fibre (distance d3, Fig. 3 (b)), changing the light intensity received from the detector.

Similarly, when the load is removed, the silicone returns the sphere to its initial position changing again the intensity of the light. In all cases the received light signal is converted by the photo-detector in milli-volts. These milli-volts are amplified using two 741 operational amplifiers in series. On the built circuitry, a low-pass Butterworth filter with cut-off frequency at 10 Hz is used after any amplification, to provide a low signal-to-noise ratio. In addition, dedicated current regulators with the LED's ensure drifting free signal and fewer fluctuations.

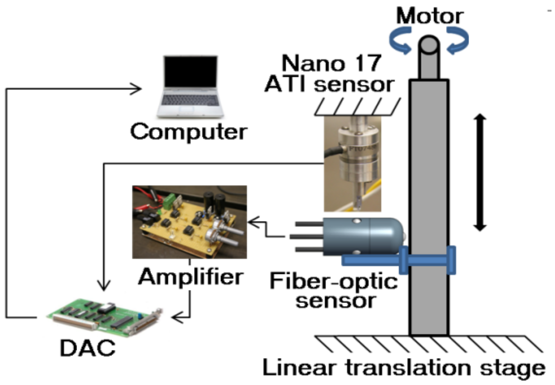


Fig.4. A schematic of the test bench employed to test the prototype fibre-optic force sensor.

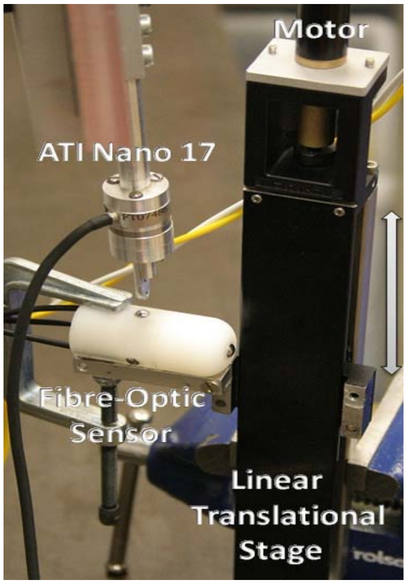


Fig.5. Picture of the test bench showing the dc motor operated millimetric linear translational stage, the ATI nano 17 force/torque sensor and the prototype fibre-optic force catheter sensor.

IV. LINEARITY OF THE PROTOTYPE FIBRE-OPTIC SENSOR

A. Test Bench

To test the newly developed fibre-optic prototype catheter, a test bench is employed consisting of: a) a dc motor (Maxon Motor-118428 with gearhead 275:1) operated linear translational millimetric stage, b) a Nano 17, 6 axes force/torque sensor (ATI Industrial Automation, Inc., NC, USA), c) a NI USB-6211 data acquisition card (National

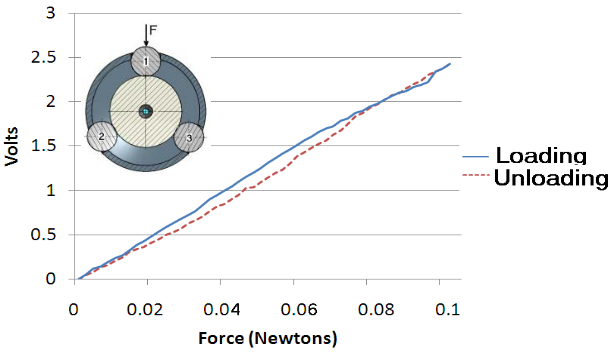


Fig.6. the normal hysteresis cycle obtained by loading and unloading the side spheres of the prototype sensor.

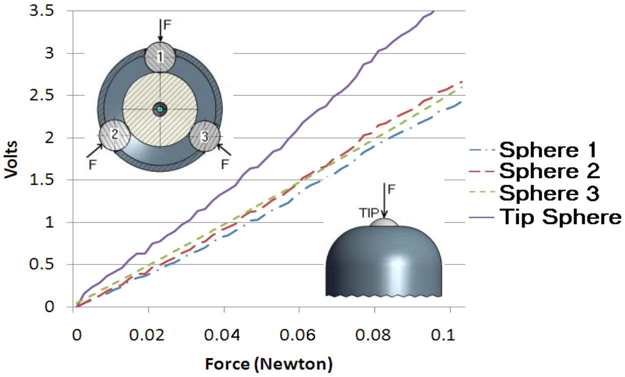


Fig.7. All the responses from the sensing spheres due to a normal loading condition.

Instruments Corp.), d) a computer with LabView 8.0 and e) a developed amplifying circuit. In Fig. 4 a schematic of the entire test bench is illustrated.

The translational stage is aligned rigidly on a vice to be in a vertical position of 90 degrees. It has the ability to move at slow speeds in the vertical axis by the rotating motor attached at the top of its structure with a coupling. A full rota tion of the motors shaft corresponds to 1 mm vertical displacement.

B. Linearity and Hysteresis Experiment

In order to test the force linearity of the side spheres, the prototype catheter sensor is mounted horizontally on the translational millimetric stage, as shown in Fig. 5. The dc motor translates the prototype fibre-optic sensor in the positive and negative vertical directions at a constant speed of 50 $\mu m s^{-1}$ so as to apply a contact load with the nano 17 tip directly on the centre of the sphere. The nano 17 is mounted to an external from the test bench surface to reside stationery. Therefore, as the translational stage is bringing the prototype sensor closer to the nano 17, a slowly increasing load is applied to the sphere. The voltage outputs from the electronic circuit amplifier along with the force output from the nano 17 are recorded using the data acquisition card. The rate of acquisition is set at 10 samples/second.

The method to test the force linearity of the tip sphere remained unchanged. However, the prototype sensor had to be repositioned vertically this time on the translational stage to allow force to be applied.

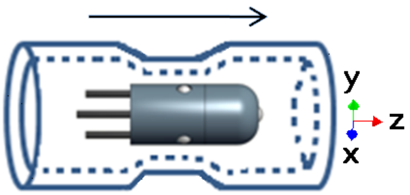


Fig.8. The insertion of the prototype sensor into the artificial blood vessel (tube), showing clearly the narrow passage in the middle and the sealed end.

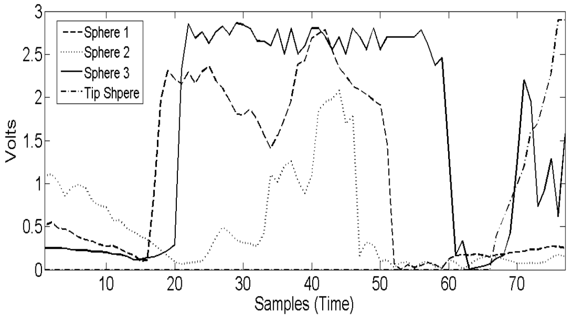


Fig.9. Voltage output of the contact spheres against the samples illustrating the response of the sensor during the insertion into the artificial blood vessel.

The loading and unloading cycle for every sphere took place three times with the same method.

C. Linearity and Hysteresis Experimental Results

A normal hysteresis cycle obtained by applying load at the centre of the spheres using the test bench previously described. Fig. 6 shows the hysteresis cycle obtained loading and unloading the sphere at around 10 grams (~0.1N). The coefficient of determination was found, for both parts of loading and unloading, to be approximately 0.97.

Accordingly, the prototype sensor's outputs for all the sensing spheres were determined by performing trials. The results on loading conditions are presented in Fig.7. The coefficient of determination is found to have a value of 0.98 for sphere 1, 0.96 for sphere 2, 0.97 for sphere 3 and 0.96 for the sphere on the tip.

V. BLOOD VESSEL SIMULATION EXPERIMENT

A. Experiment

The intention of this novel sensor is to be miniaturised and integrated with catheters so as to fit inside small in diameter blood vessels and give feedback in relation to the contact forces within the vessels. As the developed prototype sensor is big in dimensions, an artificial blood vessel in that size was build to test under realistic conditions the response of the sensor.

This experiment makes use of a short fixed tube (120 mm) with a diameter a few millimetres bigger (23 mm) than the prototype sensor. The tube comprises of a narrow passage in the middle which reduces the available diameter and brings it closer to the sensor's actual diameter (21 mm). It should be also noted that the one end of the tube is sealed.

During the experiment the sensor is inserted manually into the fixed tube at a relatively slow speed, in order to simulate the movement of a real catheter inside a real blood vessel. The sensor continues to be pushed even when it encounters resistance by the narrow passage until the tip of the catheter reaches the sealed end of the tube. The experiment concept is illustrated in Fig. 8.

B. Artificial Blood Vessel Experiment Results

The results obtained from each optical scheme sphere are shown in Fig. 9. In the graph the resultant force referred in Volts against the samples displayed. In the first 15 samples the catheter is inserted into the tube causing small signal fluctuations, from 15 to 60 samples the sensor passes through the narrow passage where all three spheres indicate contact with the walls and from 60 until the end the tip's sensor is activated as it touches the sealed end. The results demonstrate the feasibility of operation of this novel prototype catheter sensor.

VI. CONCLUSIONS AND FUTURE WORK

A novel fibre-optic force sensor was presented in a feasibility study which could sense forces on the tip and sides of a cardiac prototype catheter. Experiments showed good linearity and low hysteresis. Although, the working range of the prototype's determining forces are of the order of approximately 10 grams (~0.1 N). It is understood that if one reduces the stiffness of the silicone, there is a proportional increase in the sensitivity of the sensor.

Future work will aim at increasing the working range with the intention of reaching 50 grams (~0.5N), by moving the fibre-optic cables closer to the centre of the shaft in such a manner as to make use the entire sphere's radius for the lateral contacts. This means that when no force is applied to the sphere the light initially will not be reflected as it shall not have the sphere in its way. The tip's optical-fibre needs to be aligned prior to the silicone injection to ensure superior light alignment and hence a higher working range.

The sensor consists of MRI compatible materials making it feasible to be used with MRI scanners. In particular it avoids long conductive wires for the force measurements and is thus MR-safe. In future, the possibility to exploit the spheres as the electrodes for EP-ablation catheter shall be studied.

Apart from the aforementioned discussion, an issue of great importance is the study on how to miniaturise this sensor and integrate it into a real catheter. This is an important aspect that is currently under consideration.

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