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ScienceDirect
Medical Engineering & Physics 29 (2007) 918–922
Medical Engineering & Physics
www.elsevier.com/locate/medengphy

Technical note

An evaluation method for the mechanical performance of guide-wires and catheters in accessing the upper urinary tract

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Received 17 January 2006; received in revised form 7 September 2006; accepted 12 September 2006

Abstract

The placement of guide-wires and catheters to gain access to the upper urinary tract can induce undesirable stresses on tissues. Previous studies have characterized the performance of wires and catheters by evaluating their physical properties such as stiffness and friction coefficient. However, the results of these studies do not directly quantify the wire's effects on tissues. Furthermore, the individual physical properties of wires and catheters investigated in previous studies cannot be simply summed up to characterize the behavior of an entire wire/catheter ensemble. This paper presents an objective method for testing guide-wires and catheters that estimates the forces applied by these instruments to anatomical structures during urological procedures. Our model utilizes a computer-controlled test stand that simulates a urological environment by including a tortuous path and a stone obstruction. Experimental results using this model show significant promise in reflecting the performance of guide-wires and catheters measuring the stress exerted upon relevant anatomical structures. Furthermore, due to the modularity of the approach, the model can be easily reconfigured to simulate environments relevant to other medical fields.

Keywords: Biomedical engineering; Guide-wire; Catheter; Ureter; Stone obstruction; Tissue stress; Biomedical model

1. Introduction

A guide-wire is frequently used to access the upper urinary tract and as a support for catheter placement [1]. Such a wire typically contains a core composed of a superelastic nitinol alloy, covered by an exterior coating of a low friction material such as polytetrafluoroethylene (PTFE) or a hydrophilic polymer. This particular construction, along with a straight or angled flexible tip of the wire, provides the properties necessary for a guide-wire to negotiate a tortuous ureter path and pass possible stone obstructions.

The performance of a guide-wire is influenced mostly by its flexibility and the friction coefficient of its coating. Clayman et al. [2] tested the individual mechanical properties of nine different types of wires, classifying the wires according to their tip bending resistance, pull force, shaft bending resistance, and tip puncture force. Ceschinski et al. [3] analyzed the torquability of 13 different guide-wires using a static loading stand. Both of these methods evaluate the instrument (wire) independently, without considering its interaction with the environment. Ilic et al. [4] reported a method of measuring the interaction forces between a guide-wire and an artery in radiological interventions. This method used an optical strain gauge at the wire tip to take measurements in a rigid artery model with simulated blood flow. The method provided valuable localized measurements at the region of interest, but did so at the expense of modifying the tip of the instrument with the addition of the sensor. In comparison, the method we present, while not offering as fine measurement localization, performs measurements with the actual instruments.

A virtual reality simulation of the interaction between a guide-wire, a catheter and a blood vessel was presented by Lenoir et al. [5]. The guide-wire and catheters are considered pure elastic by assuming small velocities. The authors present algorithms that appear to realistically emulate the interaction between guide-wire, catheters and blood vessels in cardiology interventions. Since the system was designed

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doi:10.1016/j.medengphy.2006.09.002

mainly for training purposes no data are available about the forces exerted by the wire on the surrounding anatomical structures.

Previously reported studies [2,3] provide valuable data concerning the individual physical properties of wires. Thus far, studying the wire/catheter ensemble within its path has only been addressed in a single cardiological simulation, with localized measurements, and modified wires [5]. Rather than modifying the wire in order to add measurement sensors, our approach uses a mechanical model to determine this data. Coupled wire–catheter–ureter measurements are clinically more relevant than measurements of individual physical properties. Take, for example, a hypothetical situation involving a catheter placement. Selecting an excessively elastic wire for its reported flexibility and inferable tendency to exert little pressure upon the walls of the ureter may not be sufficient for catheter placement, which requires a relatively rigid wire to support placement. In this case, deciding on how much stiffer the wire should actually be may be somewhat puzzling.

Without the ability to take clinical measurements on patients during actual procedures, a model of the wire and catheter placing routine in real procedures is required to objectively evaluate the properties of guide-wires and catheters and produce procedurally relevant data, as presented below.

2. Materials and method

2.1. Test stand structure and design

The system is designed to acquire and process the force exerted by a wire/catheter on different stages of a model during its controlled advancement. The system consists of three main components, as presented in Fig. 1: a computer, a motorized test stand and a charge-coupled device (CCD) camera.

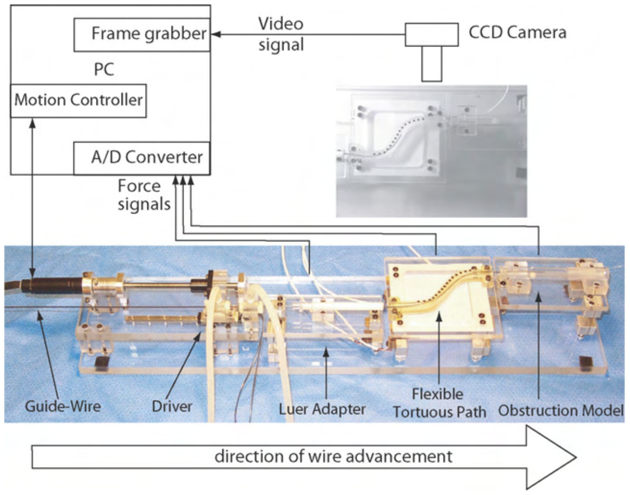

Fig. 1. Guide-wire and catheter test stand.

The computer is equipped with a frame grabber MATROX Meteor II by Matrox Inc., a motion control card PCX-DSP by Motion Engineering Inc., and an analog to digital acquisition board PCI-DAS1000 by Computer Boards. The computer controls the motion, records, and processes the resulting data.

The test stand comprises a motorized instrument (wire/catheter) driver and three stages instrumented with force sensors. These stages emulate the three main obstacles that need to be passed by the guide-wire when pushed up an urinary tract. The first stage simulates a straight urological path by utilizing a luer-lock like adapter, the second stage models a tortuous ureter path, and the last stage simulates a stone obstruction.

The driver is computer-controlled, allowing a step-by-step movement of the wire through the model. The driver presents two pneumatic grippers. One gripper is fixed and is used to hold the wire in place. The second one is connected to a linear actuator assembly and is used to advance the wire. The wire is advanced by alternatively holding and pushing it with the grippers, like with two hands. This mechanism offers the possibility of advancing the wire for arbitrary lengths using a natural repetitive sequence.

The luer-like adapter of the first stage is attached to a platform. The platform is instrumented with a force sensor that records the axial force applied by the wire/catheter to the luer.

The tortuous path, which comprises the second simulation stage, is molded of thermoplastic rubber and its ends are attached to a flexure-mounted platform instrumented with force sensors. The force sensors measure the axial forces applied by the wire to the path. The model is designed to allow the path to freely deform under the pressure applied by the wire/catheter on its walls. The path deformation is detected by tracking 15 markers $mk_1, \ldots, mk_{15}$ with a calibrated CCD camera. Those data are used to compute the transverse forces applied to the model walls.

A discrete model is used to estimate the forces induced in the ureter during the wire advancement. This model uses closely spaced markers at distances of four millimeters one from each other. Also, the relative deformations are small allowing for each segment to be approximated with a linear spring. While a continuous model using finite elements or splines could possibly provide finer localization of the simulation data, it is also much more computationally expensive. The discrete model was chosen for its simplicity, reliability, and task sufficing accuracy.

The ureter is approximated with a sequence of seventeen point masses labeled p_0 to p_{16}. Point masses p_0 and p_{16} are rigidly attached to the platform while the other 15 point masses are constrained to move only in the horizontal plane. The location of point masses p_1 to p_{15} coincides with the position of the markers mk_1 to mk_{15} and the point masses are sequentially connected with linear and torsional springs (Fig. 2). Since the wire is advanced slowly, with approximately 10 mm/s, the viscous friction forces between guide-wire and tube can be safely ignored [6]. Also, the mate-

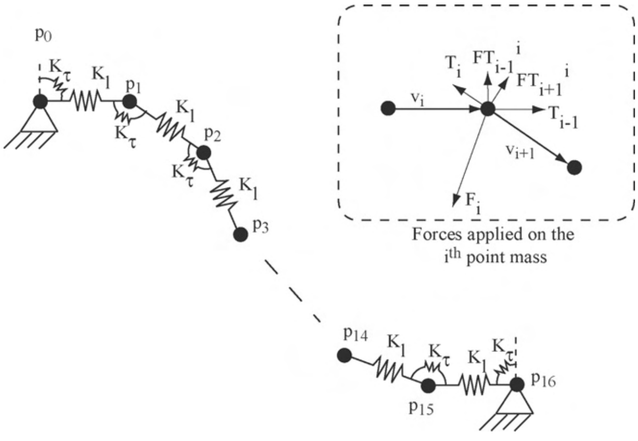

Fig. 2. Tortuous path elastic model.

rials are assumed to behave in a purely elastic manner [7]. We also make the reasonable assumption that the system is always in quasi-static equilibrium, and thus the inertial forces are also ignored; the system is assumed to be initially in a relaxed, known position. The spring constants are computed experimentally.

Given the configuration of point masses, it is then possible to compute the force applied on each point mass that led to that particular configuration. The current position of point mass p_i coincides with the position of the marker mk_i and the marker position is automatically computed from the video stream. The markers are automatically identified in the image using the MIL library by MATROX Inc. which provides in our setting an accuracy of 0.3 mm or less.

The point mass positions are computed as a bi-dimensional vectors $v_i \in \mathbf{R}^2$; $i = 0, \ldots, 16$ and the positions in relaxed state are $v_i^0 \in \mathbf{R}^2$; $i = 0, \ldots, 16$. The elastic force generated by the compression of the ith link is

$$T_i = \frac{v_i K_l(||v_i||_2 - ||v_i^0||_2)}{||v_i^0||_2 ||v_i||_2}$$

where K_l is the elastic constant and $||v||_2 = \sqrt{\sum v_i^2}$. The torque generated by the ith torsional spring is $\tau_i = K_\tau \theta_i$, where K_τ is the torsional spring constant. Then, the forces induced by τ_i in point masses $i-1$ and $i+1$ are

$$FT_i^{i-1} = -\frac{\tau_i}{||v_i||_2^2} \begin{pmatrix} 0 & -1 \\ 1 & 0 \end{pmatrix} v_i$$

respectively

$$FT_i^{i+1} = -\frac{\tau_i}{||v_{i+1}||_2^2} \begin{pmatrix} 0 & -1 \\ 1 & 0 \end{pmatrix} v_{i+1}$$

Since the sum of the forces applied on each point mass equates to zero, the force applied by the wire/catheter in that particular point mass is computed as

$$F_i = T_i - T_{i-1} - FT_{i-1}^i - FT_{i+1}^i$$

The stone obstruction model is represented by a plastic ball with a 5.5 mm diameter inserted in a thin wall silicone tube with 7 mm internal diameter. The entire model is attached to a flexure-mounted platform instrumented with force sensors.

The modules of the test stand (i.e., the tortuous ureter path and the stone obstruction) emulate the obstacles encountered by a wire when it is pushed through the upper urinary tract providing an objective measurement.

2.2. Standard test

The following tests were performed for each type of wire tested:

- lubricated tests—a water-lubricated wire was advanced through the testing stand in an automated fashion using the computer controlled driver;
- catheter over the wire lubricated tests—after the previous lubricated test, the wire was used as a coaxial guide for catheter placement. The catheter, lubricated using a generic surgical lubricant, was advanced and data was acquired as for the wire test.

Twenty-five runs were performed for each test, wire, and catheter combination. The following statistical data were computed:

- The mean over the number of trials of the maximum axial force applied on the tortuous path stage F_G;
- The mean over the number of trials of the maximum force applied on the obstruction stage F_O;
- The mean over the number of trials of the maximum force applied on each node of the tortuous path model F_i; $i = 1, \ldots, 15$;
- The mean over the number of trials of the maximum stress on each segment of the torturous path model T_i; $i = 1, \ldots, 16$.

The previous measures characterize the quality of the wire. The forces F_G and F_i describe the wire/catheter ability to negotiate a ureter while F_O describes the wire/catheter ability to pass a stone obstruction. While these complex measures are determined by the wire stiffness, tip flexibility, and coating properties; they provide a working measure of the combined properties, which may be more relevant than characterization of their individual material properties.

3. Results

The initial batch of tested wires included the six types of wires presented in Table 1. The catheter used in the “catheter over wire lubricated tests” was a 6.0 Fr. “open-end tapered tip ureteral catheter” by Cook Urological Inc. Also tested was a prototype everting film catheter by Percutaneous Systems Inc. that does not require a guide-wire. The results

Table 1
Types of guide-wires tested [*proprietary material]

Wire number	Wire name	Company	Core material/coating material
1	Hydro-Glide^{TM}	Bard	Stainless steel/hydrophilic polymer*
2	Glidewire^{TM} with straight tip	Boston Scientific	Superelastic alloy*/hydrophilic polymer
3	Lubriglide^{TM}	Boston Scientific	Superelastic alloy*/Lubriglide^{TM} coating
4	Sensor^{TM}	Boston Scientific	Nitinol/PTFE
5	Hiwire^{TM}	Cook Urological	Nitinol/hydrophilic polymer*
6	PTFE coated wire guide	Cook Urological	Superelastic alloy*/PTFE

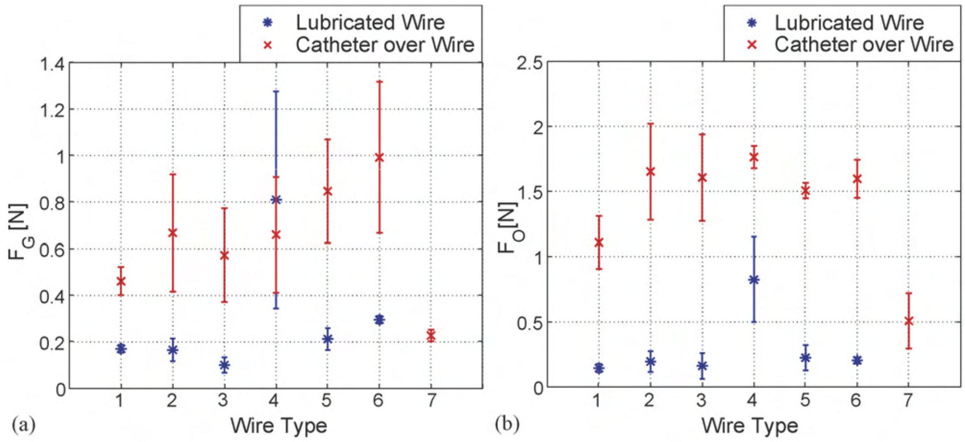

Fig. 3. Axial force exerted by wires and catheters on (a) obstruction stage and (b) tortuous path. The error bars represents the standard deviation.

corresponding to this catheter are labeled with [7] on the subsequent plots.

This set of wires was selected as it was estimated to be the most frequently used in urological procedures. The force data on the obstruction stage is presented in Fig. 3a. In the lubricated case, the best performing wire was Hydro-Glide^{TM} by Bard; and for the catheter test the lowest force was recorded for the everting film catheter of Percutaneous Systems.

The results demonstrating the axial force on the tortuous path are presented in Fig. 3b. Within the lubricated wire only tests, the lowest force was recorded for Lubriglide^{TM} by Boston Scientific and within the catheter placement tests the lowest force was recorded for the everting film catheter by Percutaneous Systems Inc.

The results illustrating the transversal force applied on the walls and induced stress are summarized in Fig. 4. In the case of the lubricated test, the lowest values were recorded for the PTFE coated guide-wire by Cook Urological. For the catheter placement test, the lowest force was recorded for the everting film catheter by Percutaneous Systems Inc.

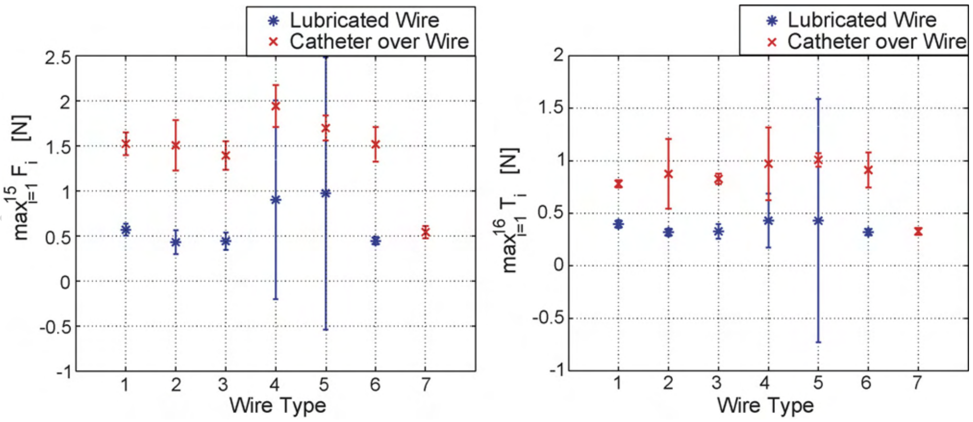

Fig. 4. (a) Transversal force exerted on the tortuous path by wires and catheters placed over wires and (b) stress induced in each segment of the tortuous path. The error bars represents the standard deviation.

Those results show that there is not a definite “best” or “worst” wire, but there are wires and catheters that perform better for certain procedures.

4. Discussion and conclusion

We present a system and methodology for guide-wire and catheter evaluation. To the best of our knowledge, this is the first system developed for guide-wire and catheter evaluation that emulates a real environment. In the current setting, the proposed system provides informations about the ability of a wire to pass an ultra-flexible tortuous tubular path followed by a stone obstruction.

The stand has several stages that mimic an actual urological environment. The testing procedure is as follows. First, a naked wire is automatically advanced through the stand and force data are gathered. Then, in a second step, a catheter is automatically advanced over the wire and force data are acquired again. This approach provides a more realistic estimation of the wire/catheter ensemble properties than previously reported approaches [2,3].

Other important features of the proposed methodology are its modularity and extensibility. Guide-wires and catheters are also used in other medical specialties such as interventional radiology [8–10] and neurology [11].

While the current test stand was purposely developed to simulate a urological environment, it is readily adaptable to also simulate procedures related to other medical fields.

Each stage of the test stand is fully configurable allowing the simulation of different obstacles. For the researcher, the controlled environment of this modular stand could not only allow testing of wire prototypes for wire evaluation and wire selection, but could also be utilized for investigating different wire building options for wire design.

For the clinician, the presented methodology provides a quantitative measure of the wire/catheter ability to gain access and traverse obstacles. The objectivity of wire grading compared to the real surgical environment is hard to evidence, but the grading scale between different wires gives an objective comparative measure of wire performance.

Acknowledgments

This work was supported in part by a grant from the AFUD/AUAER Research Scholar Program and Dornier MedTech. We also gratefully acknowledge the partial support of this research by Percutaneous Systems Inc., CA.

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