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Technical note

Design optimization of a deflectable guidewire

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ABSTRACT

Over the years, the design of the tip of available catheters and guidewires has evolved into various shapes whose geometry is mostly based on common sense and experimentation. However, while the tip shape of conventional instruments can be easily modified and tested, the length of the tip of a deflectable guidewire cannot. Hence, other approaches are necessary in order to determine the proper dimensions of original instruments. In this paper, we formulate the length of the different parts of the deflectable tip of a guidewire as an optimization problem with the objective to obtain a design that is suitable for cannulating several target bifurcations of the peripheral vasculature. A direct relationship between the design of the deflectable tip and the geometry of the target bifurcations was found and the optimal dimension of the tip of the instrument was computed. Following the length specifications defined by the optimization, a new prototype was assembled, and evaluated. The deflectable guidewire could successfully cannulate most of the pre-selected branches except those bifurcations with an angle $\alpha > 70^{\circ}$. The latter limitation could be ascribed to the mechanical properties of the instrument.

1. Introduction

In order to deal with difficult endovascular navigation, several endovascular instruments with improved maneuverability at the tip have been developed. Articulated catheters that can be steered and orientated via a magnetic field were proposed as early as 1951 [1]. This solution is similar to currently available systems, e.g., the one of Niobe Magnetic systems (Stereotaxis, Saint Louis, MO, USA). This type of methodology was also adapted to magnetic resonance imaging (MRI) [2]. In addition to the mentioned magnetic techniques, simple endovascular instruments, e.g., Venture (St. Jude Medical, Little Canada, USA) catheter or Morph guide-catheter (BioCardia, Inc., San Carlos, USA), with improved maneuverability were developed. A basic MRI-compatible guidewire with a deflectable tip has been developed by Clogenson et al. [3]. These instruments can be manipulated in the same way as conventional endovascular instruments, with the exception of the extra degree of freedom (DOF) at the tip. A simple handle with a slider or a node enables the user to apply the desired curve.

Apart from the ability to deflect, the exact geometry of the tip also determines the potential of the instrument to cannulate certain branches. Traditionally, the geometry of the tip of catheters and guidewires is obtained by trial and error: various tip shapes are sequentially tried until one was found to be satisfactory. This is how Judkins developed his coronaries catheters [4], as explained by Watson and Gorski [5]. However, while the tip shape of catheters could easily be modified by heating [6,7], the length of the deflectable guidewire cannot. In this case, this approach of trial and error would not only be time consuming but also very costly. Therefore, another solution needs to be found. In this paper, we formulate the design of the length of the deflectable tip as an optimization problem in order to determine the proper dimensions of the instrument. The method presented in the article is in line with current research approaches in the optimal design of medical devices, although most of the research on endovascular interventions focuses on stent design [8–11]. Some work on guidewire optimization has been reported by Burns et al. [12] but the main goal of this work is to improve controllability.

The aim of this study is to apply a simple yet effective optimization-based design to determine the length of the deflectable tip that enables the instrument to cannulate several target bifurcations of the peripheral anatomy. The paper first specifies the main requirements of the developed guidewire and then describes the optimization approach that was used to define the dimensions of the deflectable tip. In this approach, the geometries of the bifurcations in the peripheral anatomy define the constraints for the optimization. Following the length specifications defined by the optimization, a new prototype was assembled and evaluated.

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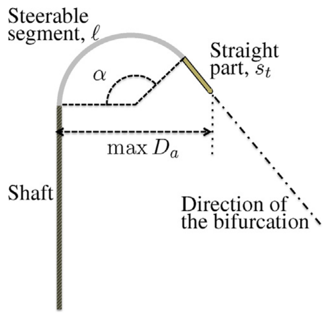

Fig. 1. Shaft and deflectable tip parts of the deflectable guidewire. For a given angle α, the guidewire can be used in a vessel of diameter of max D_a, diameter or smaller.

2. Method

The prototype consists of the guidewire itself, composed of a shaft and a deflectable tip, and a detachable handle. The design requirements for a deflectable guidewire (shaft and a deflectable tip) were defined and justified by Clogenson et al. [3]. Apart from the target diameter of the instrument, which was modified to 0.038″, these requirements were kept the same.

In this article, we specifically focus on the length of the deflectable tip, which is defined based on the geometry of the bifurcation of the target arteries. While the deflectable guidewire described by Clogenson et al. [3] was designed to accommodate the cannulation of branches between 30° and 120° in a 20 mm vessel only, the current instrument should be designed to be more polyvalent. For this reason the length of the deflectable tip was optimized using the dimensions of the main bifurcations of the peripheral anatomy as input. The aim is to have an instrument with the shortest deflective tip possible that still allows navigation in all the peripheral vasculature.

The tip of the guidewire consists of two parts: a deflectable segment ℓ, that can bend and a straight tip, s_t at its distal end (Fig. 1). The possible target bifurcations and their geometry were collected from the literature, X-ray scans, anatomical pictures, and drawings and are listed in Tables 1 and 2.

Our computational approach had to answer the following questions: (1) Can one automatically determine the shortest tip dimensions that allow the guidewire to cannulate all the bifurcations of the peripheral vasculature? (2) Can one still do it if the exact geometry of the vasculature is known only approximately? In the following, the two questions will be answered by two optimization problems that, once solved (by off-the-shelf freely available solvers [13,14]), allow us to design the guidewire tip dimensions optimally.

First of all, the tip dimensions of the design were obtained under the assumption that a direct relationship existed between the different parameters that are involved in the cannulation of a branch. Conventional guidewires, as well as catheters, require support from the vessel walls. When the shaft of the guidewire is placed along the vessel wall and the tip is deflected to have the same angle α as the target bifurcation to cannulate, the distal end of tip must at least touch the diametrically opposed wall of the vessel (and therefore the entrance of the bifurcation). In other words, it is difficult to direct the tip of the instrument into a target vessel when its shape is smaller than the vessel diameter. This observation leads to the definition of a maximal diameter, indicated as max D_a, in which a steerable guidewire of a given steerable tip length ℓ and the straight tip length s_t can be used to cannulate a bifurcation with a given angle. In fact, assuming that

1. the deflectable segment of the tip ℓ adopts a round shape when actuated,
2. the straight tip s_t is tangent to the deflectable segment at its distal end (Fig. 1),

a direct relationship, Eq. (1), can be found between the deflectable segment ℓ, the straight tip s_t, the angle α in radian, and the maximal artery diameter max D_a as

$$\max D_a = \frac{1-\cos\alpha}{\alpha}\ell + s_t \sin\alpha \quad (1)$$

Thus, given certain values for ℓ, s_t, and α the deflectable guidewire can be used for navigation in a vessel, whose diameter D_a is less than max D_a, that is: $D_a \le \max D_a$. Assume that the couple (α, D_a) is available for all the bifurcations one wishes to cannulate. The bifurcations are labeled with i from 1 to N, being N the total number of bifurcations. In particular, the set of data is

$(\alpha_i, D_{a,i})$ for $i = 1, \ldots, N$.

In this case, finding the smallest values of ℓ and s_t that can accommodate the navigations for all the N bifurcations would be

Table 1
Inner diameter of the mother arteries included in the optimization.

Mother artery	Average vessel size, inside diameter (mm)		
	Terumo [16]	Noordergraaf (1963) [17]	Other sources (mm)
AA*	15–20	17.0	AA* (diaphragm): 23 (female), 25 (male) [18] AA* (suprarenal): 20 [19] AA* (Renal level): 18 (male), 16 (female) [20] AA* (Infrarenal): 15 [21]; 16 [19]; 19 (male), 17 (female) [22] AA* (distal part): 17 (male), 15 (female) [23]; 17.5 [24] AA* (just above the iliac bifurcation): 21 (male, range 16–31) and 18 (female, range 13–24) [25]; 19 (male), 16 (female) [22]
Celiac trunk (coeliac artery)	6–8	7.8	7.98 ± 0.4 [26]; 7–9 [27]; 7.8 ± 0.8 [28]; 8 [29]
Common iliac artery	7–10	10.4	10 (male) and 9 (female) [23]; 8–10 [21]; 9 (proximal) and 10 (distal) [19]; 8 [27]
Common femoral artery	6–8	6.8	10 (male) and 8 (female) [30]; 10.6 ± 0.4 [31]; 9.3 ± 1.1 (male), 8.4 ± 0.8 (female) [32]; 6 [27]
Popliteal artery	–	5.6	6.8 ± 0.8 (male), 6.0 ± 0.7 (female) [32]; 5.4 ± 1.2 [33]; 4 [27]
Posterior tibioperoneal trunk	–	–	4 ± 0.4 [33]

*Abdominal aorta.