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Technical Note

A theoretical model to predict tensile deformation behavior of balloon catheter

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ABSTRACT

In this technical note, a simple theoretical model was proposed to express the tensile deformation and fracture of balloon catheter tested by the ISO standard using piece–wise linear force–displacement relations. The model was then validated by comparing with the tensile force–displacement behaviors of two types of typical balloon catheters clinically used worldwide. It was shown that the proposed model can effectively be used to express the tensile deformation behavior and easily be handled by physicians who are not familiar with mechanics of materials.

1. Introduction

Balloon catheters have extensively and effectively been used in balloon angioplasty in order to expand blood vessels narrowed by pathological structural changes such as calcification due to diabetes mellitus (Tian et al., 2015). As one of the regulatory issues related to catheters, Japanese Ministry of Health, Labor and Welfare has enacted the standard for approval suggesting that two kinds of mechanical tests need to be conducted for new products. One is a pressure test to assess the burst pressure and can be conducted by ISO 10555-4, and the other is a tensile test to assess the force at fracture and performed by ISO 10555-1. These testing standards provide useful strength data of the product, however, they are not enough to understand the entire mechanical performance such as force–displacement relations. Such information might be useful for physicians who actually operate catheters and need to control their movement by hand during angioplasty. Furthermore, complications related to catheters such as stuck catheter or balloon rapture has sometimes been reported in actual clinical operations (Tegtmeyer, Bezirdjian, 1981; Katayama et al., 2010; Tsunoda et al., 2014; Vellanki et al., 2015) and fracture of catheter's shaft has also been reported (Trehan et al., 2003, Kim et al., 2012, Michael et al., 2012, Nomura et al., 2016). It is therefore important to characterize the deformation and fracture behavior of catheters. However, different kinds of mechanical modes such as tension, bending, twisting and squeezing are thought to be involved in the mechanical motions of the stuck catheters, and it is therefore very difficult to fully characterize the deformation mechanisms. As the first step of study, each of the mechanical modes may be able to be analyzed separately before the mixed mode of

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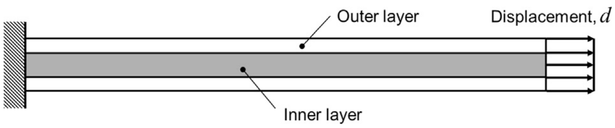

Fig. 1 – A schematic model of balloon catheter under tensile loading.

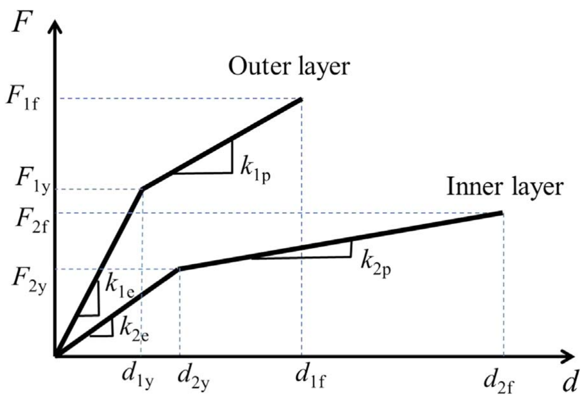

Fig. 2 – Piece–wise elastic–plastic force–displacement curves.

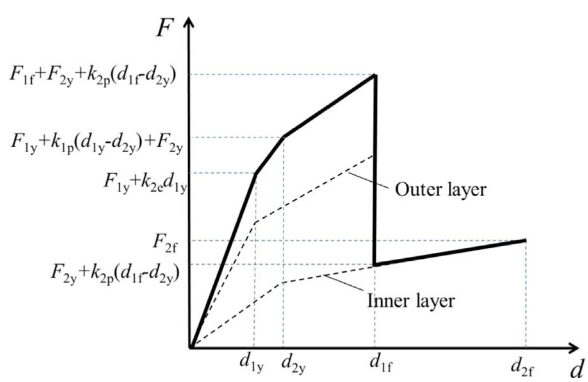

Fig. 3 – Piece–wise elastic–plastic force–displacement curve of a balloon catheter model.

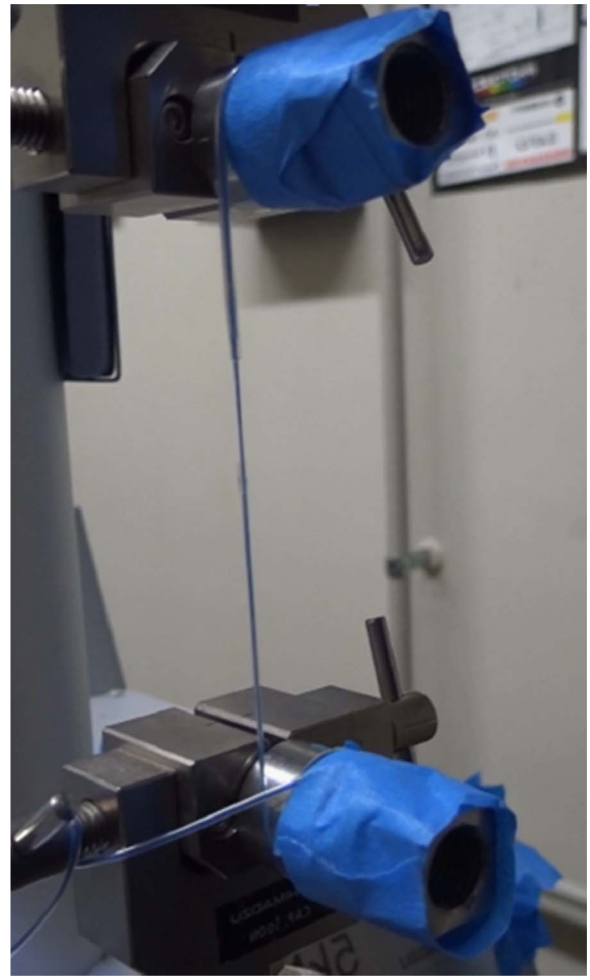

Fig. 4 – Tensile deformation behavior of BC-A.

deformation is analyzed. One of the most fundamental mechanical modes is tensile deformation, and actually, ISO 10555-1 describes a standardized testing method under tensile condition.

In addition, typical balloon catheters consist of outer and inner tubular layers and their deformation behavior may be different from single layered catheters that exhibit typical tensile behavior of ductile polymers (Ates et al., 2000). Furthermore, different kinds of polymers have been used as row materials of those layers (Polderman and Girbes, 2002), resulting in different types of tensile deformation behavior.

The aim of this technical note is to propose a simple theoretical model that can be used to express the tensile deformation and fracture of balloon catheter with dual layered structure tested by ISO 10555-1. Piece–wise linear force–displacement relation was introduced to express elastic–plastic deformation of outer and inner layers. The model was then validated by comparing with the tensile force–displacement behaviors of two kinds of typical balloon catheters clinically used worldwide.

2. Theoretical modeling

A typical balloon catheter tested by ISO 10555-1 can be reasonably modeled by a two layered cylindrical structure that consists of outer and inner tubes as shown in Fig. 1. It is assumed that one end of the catheter is completely fixed and a uniform tensile displacement is applied to the other end because the ISO standard requires tensile testing under a displacement control condition, in which constant displacement rate is applied to the catheter. It is also assumed that these two layers deform independently under tension so that the total force, F, acting on the catheter is expressed by:

$$F = F_1 + F_2 \tag{1}$$

where the subscripts 1 and 2 express the mechanical parameters related to the outer and inner layers, respectively. The elastic–plastic force–displacement (F–d) curves of the outer and inner layers are then assumed to be expressed by a piece–wise linear model such that: