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Evaluation of Stent Performances using FEA considering a Realistic Balloon Expansion

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***Abstract*—**A number of previous studies were rarely considered the effects of transient non-uniform balloon expansion on evaluation of the properties and behaviors of stents during stent expansion, nor did they determine parameters to maximize the performances driven by mechanical characteristics. Therefore, in order to fully understand the mechanical characteristics and behaviors of stent, it is necessary to consider a realistic modeling of transient non-uniform balloon-stent expansion. The aim of the study is to propose design parameters capable of improving the ability of vascular stent through a comparative study of seven commercial stents using finite element analyses of a realistic transient non-uniform balloon-stent expansion process. In this study, seven representative commercialized stents were evaluated by finite element (FE) analysis in terms of the criteria based on the itemized list of Food and Drug Administration (FDA) and European Standards (prEN). The results indicate that using stents composed of opened unit cells connected by bend-shaped link structures and controlling the geometrical and morphological features of the unit cell strut or the link structure at the distal ends of stent may improve mechanical characteristics of stent. This study provides a better method at the realistic transient non-uniform balloon-stent expansion by investigating the characteristics, behaviors, and parameters capable of improving the ability of vascular stent.

***Keywords*—**Finite Element Analysis, Mechanical Characteristic, Transient Non-uniform Balloon-Stent Expansion, Vascular Stent.

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I. Introduction

GENERALLY, three of the most common treatments for a vascular disease that does not respond to pharmacologic therapy are vascular bypass grafting, percutaneous transluminal balloon angioplasty, and percutaneous transluminal stenting with the aid of balloon angioplasty. Of these, at present, the vascular intervention market for stents has increased rapidly because of their high initial success rate, minimal invasive nature, and improved long-term effectiveness compared to vascular bypass grafting or percutaneous transluminal balloon angioplasty [1, 2, 3].

Stent features either an expandable wire or perforated tube that is inserted into a vascular to prevent or counteract a disease-induced localized blood flow constriction. However, potential limitations, such as restenosis, migrations, collapses, or positioning difficulties are still seen in clinical utilization of stents. Issues with respect to the design of vascular stents include: 1) maximal radial stiffness, 2) maximal flexibility, 3) minimal foreshortening, 4) minimal dogboning, 5) minimal longitudinal recoil, 6) minimal radial recoil 7) minimal coverage area, and 8) maximal fatigue durability [14, 34]. Particularly, foreshortening driven from unfavorable shearing between the stent and the vascular or dogboning induced from penetration at the edges of the stent, can be a primary cause of potential limitations such as a restenosis [3, 7, 8]. Thus, new stent designs should focus on features related to mechanical performances while considering the other issues described above to mechanical characteristics.

Many studies provide how the finite element (FE) analysis could be used to developed stent designs. It is widely accepted that FE analysis is effective methods for rapid development and improvement of design concepts prior to clinical trials.

However, previous studies have not investigated transient non-uniform balloon expansion during stent deployment. They thought that it seemed justifiable to model balloon expansion by considering uniform radial internal pressure. Such assumption was based on the fact that stent is almost uniformly dilated and finally evenly expanded. Therefore, in order to fully understand the mechanical characteristics and behaviors of stent, it is necessary to consider a realistic modeling of transient non-uniform balloon-stent expansion when FE analysis. Thus, in study of the mechanical characteristics of stent, the realistic transient non-uniform balloon-stent expansion should be considered.

The aim of the current study is to suggest design parameters capable of improving a performance of vascular stent, which could be induced by mechanical characteristics, through a comparative study of recently developed seven commercial stents using FE analysis of the realistic transient non-uniform balloon-stent expansion process.

II. Methods

A. Finite Element Models

Three-dimensional FE models of seven commercial stents (Palmaz-Schatz PS153, Tenax, MAC Standard, MAC Q23, MAC Plus, Coroflex, RX Ultra Multi-link) and stent balloon were created based on the manufactures' specifications. The structural specifications of the stents are summarized in Table I.

The material properties for the seven stents were determined from literatures [9]. Material properties required for the analysis were summarized in Table II.

The balloon was assumed to be made of high-density polypropylene that had an isotropic linear elasticity. The mechanical properties of the material were then determined from literature (E: 1 GPa, Ys: 90 MPa, and v: 0.33) [10].

B. Analysis Conditions

Two boundary conditions were assigned to the ends of the balloon and to the shaft of the catheter, and two contact conditions were used between the folded membranes of the balloon and between the stent and the balloon. A pin joint boundary condition was used for the balloon based on the fact that the balloon generally expands to an ellipsoid form. A fixed joint boundary condition was assigned to the rigid-body shaft of the catheter to avoid movement of the catheter in all directions during the balloon expansion. Surface-to-surface contact conditions were used between the stent and the balloon, while surface-to-surface and self-contact conditions were used for the folded membranes during the expansion of the balloon.

TABLE II
Material Properties for Finite Element Model [9]

Material	Yield Stress (MPa)	Elastic Modulus (GPa)	Poisson's Ratio
Stainless Steel 316LN	205	196	0.33

Material Properties for Fatigue Analysis

E (MPa)	UTS (MPa)	K' (MPa)	n'
22000	969.5	1977	0.335

Sf'	Ef'	b	c
1366	0.314	-0.156	-0.460

K' : Cyclic hardening coefficient, n' : Cyclic hardening exponent,
Sf' : Fatigue strength coefficient, Ef' : Fatigue ductility coefficient,
b : Fatigue strength exponent, c : Fatigue ductility exponent

C. Simulation of the Stent Expansion

The balloon-stent expansion was performed by controlling the features of the hydrostatic fluid elements. A pneumatic flow at 1atm and surgical room temperature was used for the stent, with an amplitude option that allowed arbitrary time variations of the amount of fluid mass (fluid mass flow rate) to be supplied throughout the simulation. A fluid flux option was used to specify changes in the fluid mass of the fluid-filled cavity modeled with the hydrostatic fluid elements. Thus the balloon-stent expansion was controlled by a change in the amount of fluid mass (volume controlled process).

D. Evaluation of Stents

The evaluations of the stents were performed based on the following items suggested by FDA Guidance 2005 [11] and prEN [12]: flexibility, radial stiffness, foreshortening, longitudinal recoil, radial recoil, dogboning, coverage area, and fatigue durability.

Flexibility is an index to identify how much well the stent can be placed on a desired region within the artery. It is evaluated by bending equation of simple canti-lever beam such as (1) [13].

TABLE I
The Structural Specifications of the Stents

Stent \ Item	Type of Unit Cell	Type of Link Structure	General Structural Parameters for the Stent				Unit Cell Structural Parameters	Structural Parameters in the Link Structure	
			Outer Diameter (mm)	Inner Diameter (mm)	Strut Thickness (mm)	Length (mm)	Strut Width (mm)	Strut Width (mm)	Strut Length (mm)
Palmaz-Schatz PS153	Closed	No Connector	1.484	1.389	0.095	16.0	0.106	0.106	3.720
Tenax		Bar	1.780	1.695	0.085	15.1	0.083	0.199	0.834
MAC Standard	Opend	Bend-Shaped	1.800	1.715	0.085	16.8	0.125	0.125	3.581
MAC Q23			1.800	1.715	0.085	16.8	0.126	0.100	2.764
MAC Plus			1.764	1.669	0.095	15.0	0.125	0.125	3.487
Coroflex			1.725	1.630	0.095	15.9	0.136	0.135	1.647
RX Ultra Multi-link		Straight-Line	1.764	1.669	0.095	15.0	0.097	0.096	1.382

$$EI = \frac{PL^3}{3\delta} \quad (1)$$

(EI : Bending Stiffness, P : Pressure, L : Length of stent, δ : Deflection)

Radial stiffness is an index to judge how much well the stent can support the artery wall after stent implantation [14]. It was calculated as in (2). For comparison, the value of radial stiffness was normalized by that of radial stiffness predicted for Palmaz-Schatz stent.

$$Radial\ Stiffness = P_{initial} \times E.V. \quad (2)$$

($P_{initial}$: Initial pressure, E.V. : Eigen value)

Longitudinal recoil is an index to represent a degree of shortening of the stent after removing the balloon catheter [15]. It was calculated as in (3).

$$Longitudinal\ Recoil = \frac{L_{load} - L_{unlaod}}{L_{load}} \quad (3)$$

(L_{load} : Length of stent before removing the balloon catheter, L_{unload} : Length of stent after removing the balloon catheter)

Fore-shortening is explained in terms of a deformation in longitudinal direction after expansion of the stent [15]. It was calculated as in (4).

$$Foreshortening = \frac{L - L_{unload}}{L} \quad (4)$$

(L : Original length of stent, L_{unload} : Length of stent after removing the balloon catheter)

Radial recoil is an index to explain a degree of contraction of stent after removing the balloon catheter [15]. It was calculated as in (5).

$$Radial\ Recoil = \frac{R_{load} - R_{unload}}{R_{load}} \quad (5)$$

(R_{load} : Radius of stent before removing the balloon catheter, R_{unload} : Radius of stent after removing the balloon catheter)

Dogboning could be influenced by the characteristics of the balloon-stent expansion, to identify potential design parameters that reduce restenosis induced by undesirable mechanical stress on the vascular wall[3, 7, 8, 9]. It was calculated as in (6).

$$Dogboning = R^{load}_{distal} - \frac{R^{load}_{central}}{R^{load}_{distal}} \quad (6)$$

($R_{load\ distal}$: Distal radius of the stent, $R_{load\ central}$: Central radius of the stent)

Coverage area can explain a possibility of restenosis occurrence [15]. It is important to minimize coverage area between stent and arterial wall to prevent the restenosis. It was calculated as in (7).

$$Coverage\ Area = \frac{Surface\ of\ stent}{Area\ of\ artery} \quad (7)$$

Product life is estimated by fatigue durability to be measured. FDA and prEN recommend product life of ten years corresponding to 420,500,000 loading cycles. It was calculated as in (8).

$$Target\ Life = Pulse\ per\ min. \times 1day \times 10years \quad (8)$$

The index of the fatigue durability in current study was determined by dividing the loading cycles at failure time predicted from FE analysis by 420,500,000 loading cycles targeted.

III. Results

The pattern of the transient non-uniform balloon-stent expansion at four different instants during the expansion process is shown in Fig. 1. Only the expansion pattern for Palmaz-Schatz PS153 stent is shown because all stents had similar expansion patterns. These results compared favorably with those reported in the literatures[3, 7, 16].

TABLE III
RESULTS OF MECHANICAL PERFORMANCES OF SEVEN STENTS

	Palmaz Schatz	Tenax	Coroflex	MAC Standard	MAC Q23	MAC Plus	RX Ultra Multi-link
Flexibility (EI)	1334	17	40	75	42	66	22.77
Normalized Radial Stiffness	1.0	0.7	0.8	1.3	1.2	0.8	0.80
Foreshortening (%)	7.1	8.0	3.1	2.1	2.3	3.1	5
Longitudinal Recoil (%)	1.0	1.3	0.6	0.4	0.4	0.6	0.8
Radial Recoil (%)	3.1	3.3	3.1	2.4	2.6	3.1	2.83
Dogboning(%)	7.1	8.0	3.1	2.1	2.3	3.1	5.0
Coverage Area (%)	18	12	24	15	13	24	15.59
Fatigue Durability	2.3	1.6	1.6	2.2	1.2	1.0	2.3

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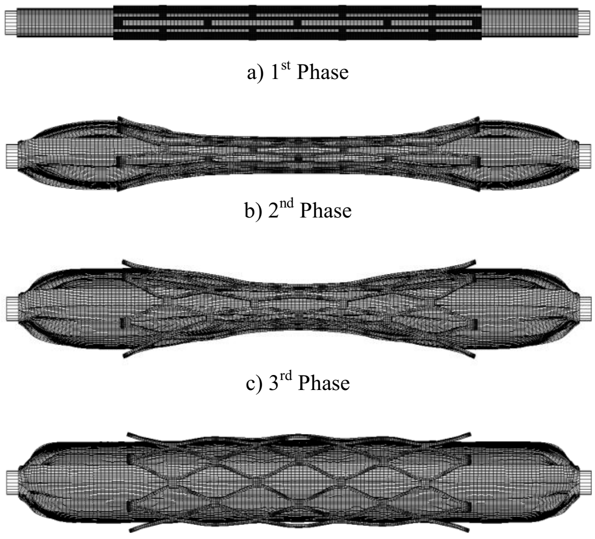


a) 1st Phase

b) 2nd Phase

c) 3rd Phase

d) Final Phase

Fig. 1 The pattern of the transient non-uniform balloon-stent expansion at four different instants during the expansion process

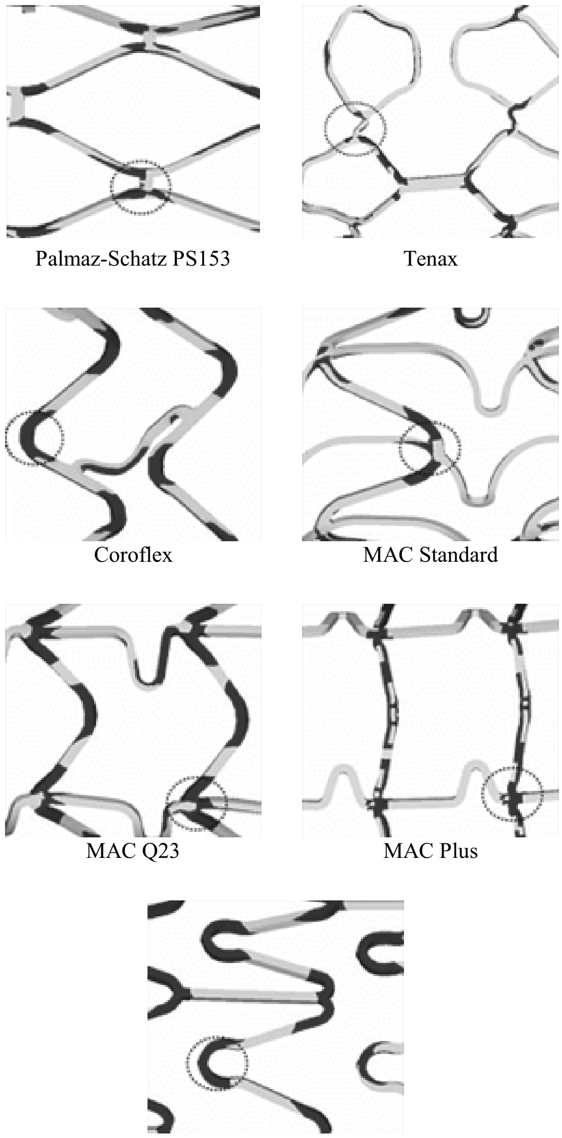
The results of flexibility, radial stiffness, fore-shortening, longitudinal recoil, radial recoil, dogboning, coverage area, and fatigue durability were summarized in Table III. Tenax was excellent in flexibility and coverage area, compared with other stent. MAC standard was excellent in radial stiffness, fore-shortening, and longitudinal and radial recoil, compared with other stents. Palmaz-Schatz was excellent in fatigue durability, compared with other stents. However, Palmaz-Schatz showed improper flexibility, compared with other stents.

As shown in Fig. 2, the potential possibilities of fractures, which could be induced by fatigues, were generally expected at large deformation regions after a time corresponding to 10 years in FE simulations. Additionally, other results of mechanical performance were showed in Fig. 3.

IV. Discussions and Conclusions

This study evaluated strengths and weaknesses for seven commercialized stents through the FE analysis. Unlike other studies, the advantage of current study was in consideration of a realistic balloon expansion effect in evaluating the strengths and weaknesses for seven commercialized stents.

The results for all stents analyzed in the current study showed that foreshortening, longitudinal recoil, radial recoil and dogboning were higher in stents with closed unit cells connected by straight-line or bar link structures, and were lower in stents with opened unit cells connected by bend-shaped link structures. This finding indicates that using a stent composed of opened unit cells connected by bend-shaped link structures may prevent side effect caused by foreshortening, recoil or dogboning. This finding is supported by Wang et al.[3] and Migliavacca et al.[17]. Wang et al. reported that broadening the strut of the unit cells in the distal part of the stent may decrease dogboning, and the configuration of the link structure connecting the unit cells



Palmaz-Schatz PS153 Tenax

Coroflex MAC Standard

MAC Q23 MAC Plus

RX Ultra Multi-link

Fig. 2 Results of fatigue analysis (After 10 years)

of the stent may determine the foreshortening characteristics of the stent. Wang et al. also found that the absence of dogboning can decrease the foreshortening of the stent to a certain extent, but this effect is limited. Migliavacca et al. investigated the influence of the geometry of the stent on dogboning, foreshortening, and longitudinal recoiling by using FE methods and found that the thickness of the stent influenced its performance. By combining the current study with the findings of Wang et al. and Migliavacca et al., we found that mechanical performances of stent-balloon systems were closely correlated with the configurations of the unit cells and the link structures as well as the distal geometry and morphology of the stent. Foreshortening and dogboning of the stent could be weakened both by using a stent composed of opened unit cells connected

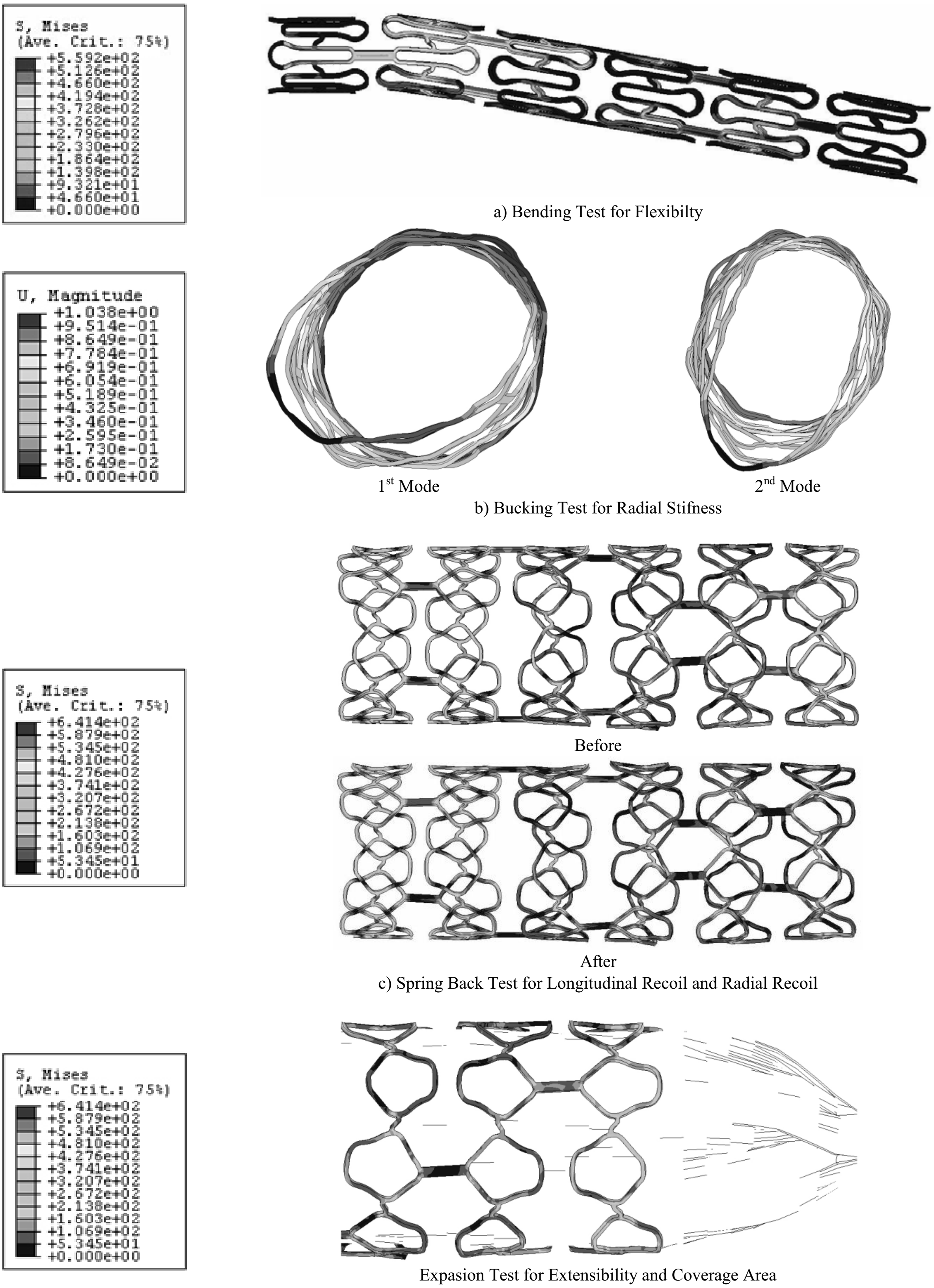


Fig. 3 Results of the FE tests performed to calculate the mechanical performance. (Only representative the Tenax stent is shown.)

by the bend-shaped link structures and by controlling the distal stent strut width and thickness; the combination of these two methods will increase the value of mechanical performances of vascular stents.

This conclusion was, however, limited by following facts: 1) No consideration of blood flow characteristics, 2) No consideration of interaction between the stent and artery, and 3) Limitation in application of realistic loading and boundary conditions in FE analysis. These limitations will be solved and explained on our on-going study incorporated with actual clinical study.

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