Finite Element Analysis of the Cutting Balloon With an Adequate Balloon-to-Artery Ratio for Fracturing Calcification While Preventing Perforation

Xiaodong Zhu; Mitsuo Umezu, PhD; Kiyotaka Iwasaki, PhD

Background: The appropriate balloon-to-artery ratio (BAR) for cutting balloons (CBs), to expand calcified lesions without increasing the risk of coronary artery perforation is unknown. This study investigated the effects of BAR on stress levels in the calcification and at the borders of the coronary artery adjacent to the calcification to determine an appropriate BAR.

Methods and Results: A custom-designed folding process of the CB model was developed. The CB models were deployed in a coronary artery model with a reference diameter of 3.0 mm, length of 24 mm, and wall thickness of 0.8 mm equipped with a 50% diameter stenotic, 360° concentric, 400-µm, and 5-mm-long calcification. Finite element analysis of the expansion of CBs with diameters increasing from 2.0 to 3.0 mm in 0.25-mm increments, corresponding to BARs from 0.67:1 to 1:1, was conducted with pressures up to 12 atm. Decreasing the CB by 0.25 and 0.5 mm (relative to the reference diameter of 3 mm) preserved maximum principal tensile stress levels comparable to that of a CB with a BAR of 1:1 while distinctly reducing the stress at the border of the artery adjacent and calcification.

Conclusions: Selecting a CB that is 0.25 or 0.5 mm lower than the 3-mm reference diameter may be the first choice to effectively fracture calcifications without increasing the risk of severe artery dissection and perforation.

Key Words: Calcified coronary artery; Cutting balloon; Fracturing calcification; Maximum principal tensile stress; Perforation
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and 3.0 mm) with a length of 10 mm, as well as a 3.0-mm NC balloon with a length of 12 mm, were analyzed using data from the compliance charts. The initial diameters for each balloon model were 1.83, 2.05, 2.28, 2.52, 2.79, and 2.71 mm. Young’s moduli for each balloon model were 337.88, 364.86, 418.54, 446.75, 533.73, and 908.21 MPa, respectively. Balloon models with taper tips were prepared. Approximately 100,000 4-node quadrilateral membrane elements (element type: M3D4R) with a uniform 0.02-mm wall thickness were assigned to the balloon model. Furthermore, a rigid cylindrical inner shaft surface model with a diameter of 0.8 mm and a length of 18 mm was created along the center axis of the balloon model. A Poisson ratio for the balloon model of 0.4 was assumed and a density of 1,100 kg/m³ was assigned to the cast pad and balloon models.

In a randomized controlled trial in patients with myocardial ischemia and severely calcified coronary artery lesions, luminal diameter reduction of ≥50% is considered as the main inclusion criterion of coronary lesion modification using CBs. A clinical study reported that 60% of calcium fractures were observed in lesions with large calcium arcs ranging from 270° to 360° and that the threshold of calcium thickness for calcium fracturing was 0.24 mm when only balloon angioplasty was used before stent implantation. Another clinical study showed that the median calcium fracture thickness was 450 µm when CB angioplasty or rotational atherectomy were frequently used. Furthermore, it was observed that a calcium length of ≤5 mm in patients was the most detected by intravascular ultrasound. Therefore, a coronary artery model with a 3.0-mm inner diameter, 0.8-mm wall thickness, and 24-mm length was prepared as the non-stenotic artery, and a 360° calcification model was placed in the middle of the non-stenotic artery model (inner diameter 1.5 mm, thickness 0.4 mm, and length 5 mm). The coronary artery and calcification models were meshed using the 8-node hexahedral element (element type: C3D8R) with approximately 400,000 and 20,000 elements respectively (Figure 1C). The Mooney-Rivlin

The 3-dimensional structure of the cast pad was modeled with a length of 9.2 mm, a height of 0.1 mm, and a width of 0.58 mm (Figure 1B). For the cast pad, we used approximately 30,000 8-node brick elements (element type: C3D8R), which have elastic behavior, with a Young’s modulus of 441 MPa and Poisson ratio of 0.3, provided by the manufacturer.

De Beule et al and Ragkousis et al introduced a linear isotropic membrane balloon model with an initial diameter at balloon inflation pressure of 0 atm and Young’s modulus obtained from the product compliance chart. The relationship between the pressure and the diameter of the balloon model has been verified to be consistent with the actual balloon expansion. Therefore, based on the algorithm, the initial diameters and Young’s moduli of different CB diameters ranging from 2.0 to 3.0 mm (2.0, 2.25, 2.50, 2.75, and 3.0 mm) with a length of 10 mm, as well as 3.0-mm NC balloon with a length of 12 mm, were analyzed using data from the compliance charts. The initial diameters for each balloon model were 1.83, 2.05, 2.28, 2.52, 2.79, and 2.71 mm. Young’s moduli for each balloon model were 337.88, 364.86, 418.54, 446.75, 533.73, and 908.21 MPa, respectively. Balloon models with taper tips were prepared. Approximately 100,000 4-node quadrilateral membrane elements (element type: M3D4R) with a uniform 0.02-mm wall thickness were assigned to the balloon model. Furthermore, a rigid cylindrical inner shaft surface model with a diameter of 0.8 mm and a length of 18 mm was created along the center axis of the balloon model. A Poisson ratio for the balloon model of 0.4 was assumed and a density of 1,100 kg/m³ was assigned to the cast pad and balloon models.

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Boston Scientific, Marlborough, MA, USA), with a nominal pressure of 6 atm and a rated pressure of 12 atm. Wolverine CBs with diameters of <3.25 mm have 3 sharp metal microsurgical blades bonded on cast pads that are fixed longitudinally on the balloon outer surface, whereas devices with diameters of 3.5 and 4.0 mm have 4 blades. The 3 blades are ensconced inside the folds of the wrapped balloon and expand out radially during inflation, making longitudinal incisions in the calcified plaque. A typical non-compliant (NC) balloon (NC Emerge™; Boston Scientific), with a nominal pressure of 12 atm and a rated pressure of 20 atm, was used as a comparison to gain an understanding of the effects of the blades in fracturing calcifications.

A 3-dimensional computer-aided design geometrical model of the blade was constructed with a length of 8.8 mm, a height of 0.25 mm, and a width of 0.18 mm (Figure 1A). The blade was discretized using 8-node brick elements with reduced integration (element type: C3D8R) and consisted of approximately 6,000 elements. For the blade, the material properties of 316L stainless steel was used as an elastic plastic model with isotropic hardening, with a Young’s modulus of 193 GPa, a Poisson ratio of 0.3, a yield stress of 366 MPa, ultimate tensile strength of 675 MPa, and density of 7,950 kg/m³. The 3-dimensional structure of the cast pad was modeled with a length of 9.2 mm, a height of 0.1 mm, and a width of 0.58 mm (Figure 1B). For the cast pad, we used approximately 30,000 8-node brick elements (element type: C3D8R), which have elastic behavior, with a Young’s modulus of 441 MPa and Poisson ratio of 0.3, provided by the manufacturer.

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Balloon-to-Artery Ratio for the Cutting Balloon

A CB catheter is folded radially to decrease its diameter so it can be inserted into a narrowed artery, after which the CB expands. A novel folding process was developed to generate a 3-folded shape for the CB (Figure 2A) and NC balloon (Figure 2B). First, 3 rigid surface models were created radially outside the balloon model to be used as a crimping device. Displacement was applied to the 3 surfaces towards the center and the balloon model was then crimped into a 3-folded shape via contact condition between the 3 rigid surface models and the balloon model. Next, a cylindrical surface was used to compress the 3-folded balloon model in order to decrease its diameter to 1.45 mm by radial displacement. Finally, 3 blades and cast pads were merged with the 3-fold balloon model using a tie constraint to complete the final CB model. For the NC balloon, the balloon model was crimped into an oblique 3-folded shape by 3 rigid surface models and then compressed into a diameter of 1.1 mm. A type S4R shell element was used to mesh the balloon model to avoid numerical instability, and the ends of the balloon and shaft models were fixed in this process.

Figure 2. Fold process for the 3-folded cutting balloon model: (A) cutting balloon; (B) non-compliant balloon. Red arrows indicate the directions of compression towards the center of the balloons.

Hyperelastic model was used to describe the mechanical behavior of the artery model and the strain energy density function as follows:

\[ W = a_{10} (I_1 - 3) + a_{01} (I_2 - 3) \]  \hspace{1cm} (1)

where \( I_1 \) and \( I_2 \) were the first and second invariants of the Cauchy-Green tensor, respectively, and \( a_{10} \) and \( a_{01} \) were the constants. In this study, the constants were obtained from the cited uniaxial and biaxial experiments on human femoral arteries, taking into consideration that human femoral arteries from elderly individuals were similar to the diseased coronary artery undergoing coronary angioplasty.\(^{20}\) The density and Poisson ratio of the coronary artery model were assumed to be 1,000 kg/m\(^3\) and 0.49, respectively. A nanoindentation study of human calcified plaques collected from the superficial femoral artery wall showed that the elastic modulus was 20.1 GPa and the density was 1,632 kg/m\(^3\).\(^{21}\) Therefore, in this study, the calcification model was assumed to be an elastic isotropic material model with Young’s modulus of 20.1 GPa and a density of 1,632 kg/m\(^3\), and the Poisson ratio was assumed to be 0.3.

Mesh sensitivity tests were performed to confirm the convergence for each model. Mesh densities for the CB models and calcified artery model showed negligible divergence (i.e., accepting a difference in the maximum radial displacement of <1%) compared with finer meshes.

Modeling of the 3-Folded Balloon

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Simulation of Expansions
The folded CB and NC balloon models were deployed at the center position of the calcified artery model. Pressure was applied to the inner surface of the balloon model up to 1.216 MPa (12 atm) for the CB and 2.026 MPa (20 atm) for the NC balloon. Expansion simulations of CBs with different diameters and the NC balloon were conducted in the calcified artery models (Figure 3). The calcification and artery models were combined using a tie constraint, and the shaft model, the ends of the artery model, and the balloon model...
Balloon-to-Artery Ratio for the Cutting Balloon

Finite element analyses were performed with an Abaqus/Explicit solver (Dassault Systèmes, Tokyo, Japan). Each analysis was conducted with an adequate analysis time step and loading rate to ensure a quasi-static analysis while the kinetic energy remained almost below 5% of the internal energy for each material model. The contact condition between each model was defined using the general contact algorithm with a static friction coefficient of 0.2 in Abaqus/Explicit.

Stress Analysis in the Calcified Artery Model

Three principal stress components (maximum, intermediate, and minimum) with normal vectors (tensile and compression) were calculated at each node in the mesh part. Previous studies reported that high tensile stress resulted in plaque fracture and arterial dissection at the junctions between the plaque and vessel wall during balloon inflation in a lesion. Therefore, the present study used the maximum principal tensile stress to designate the stress level in the calcification and artery models.

Results

Stresses in the Calcification Models

Figure 4 shows contour plots of the maximum principal tensile stress in the calcification models for expansions using CBs with different diameters at the rated pressure of 12 atm (Figure 4A) and for the 3.0-mm diameter NC balloon at the nominal pressure of 12 atm and at the rated pressure of 20 atm (Figure 4B). Higher values of the maximum principal tensile stress were always generated at the end regions of the calcification models and, in the cross-sectional views, the peak values occurred at the regions where the 3 blades were positioned. Moreover, larger-diameter CBs (diameter 2.5, 2.75, or 3.0 mm) resulted in higher tensile stress in the middle region between the positions of the blades in the calcification models.

Figure 5 shows the maximum principal tensile stress yielded in the artery model and the cross-sections of the artery models for each expansion at the rated pressure of 12 atm for the CB and at 12 and 20 atm for the NC balloon.

Figure 6A illustrates the peak values of the maximum principal tensile stress in the calcification models for CBs with different diameters under balloon inflation pressures of 0–12 atm, as well as for the NC balloon under pressures of 0–20 atm. Table 1 shows peak values of the maximum principal tensile stress that were yielded in the calcification models under balloon inflation pressures of 6, 12, and 20 atm. The larger-diameter CBs induced higher stress levels in the calcification model. Moreover, compared with the maximum principal stress with the 3.0-mm-diameter CB (BAR 1:1), the maximum principal stress values obtained in the calcified models were preserved for the
were comparable to those of the CB downsized by 1 mm (relative to the 3.0-mm reference artery diameter) at the nominal balloon inflation pressure of 6 atm.

Stresses in the Artery Models
As shown in Figure 5, high tensile stress was noted at the junction regions between the calcification and artery models. The cross-sectional views for the CB expansions showed that higher stresses were induced between the regions where the blades came in contact with the calcification.

The effects of balloon size on stress levels were higher at the rated than nominal pressure. Moreover, the peak values of the maximum principal tensile stress with the NC balloon at the rated balloon inflation pressure of 20 atm were comparable to those of the CB downsized by 1 mm (relative to the 3.0-mm reference artery diameter) at the nominal balloon inflation pressure of 6 atm.

Table 1. Peak Values of the Maximum Principal Tensile Stress in the Calcification Models

| Balloon diameter (mm) | 2.0 | 2.25 | 2.50 | 2.75 | 3.0 | 3.0 | NC balloon |
|-----------------------|-----|------|------|------|-----|-----|------------|
| Inflation pressure (atm) | 6   | 12   | 20   |      |     |     |            |
| 6                     | 35.52 | 35.98 | 36.12 | 36.19 | 36.42 | 13.21 |
| 12                    | 56.53 | 59.61 | 61.17 | 65.39 | 67.14 | 21.68 |
| 20                    | NA   | NA   | NA   | NA   | 35.51 |     |            |

NA, not available; NC, non-compliant.

Table 2. Peak Values of the Maximum Principal Tensile Stress in the Artery Models

| Balloon diameter (mm) | 2.0 | 2.25 | 2.50 | 2.75 | 3.0 | 3.0 | NC balloon |
|-----------------------|-----|------|------|------|-----|-----|------------|
| Inflation pressure (atm) | 6   | 12   | 20   |      |     |     |            |
| 6                     | 0.15 | 0.19 | 0.33 | 0.53 | 0.66 | 0.22 |
| 12                    | 0.38 | 0.59 | 0.82 | 1.21 | 1.47 | 0.54 |
| 20                    | NA   | NA   | NA   | NA   | NA   | 1.24 |

NA, not available; NC, non-compliant.
principal tensile stress generated in the artery models for each diameter of the CB under pressures from 0 to 12 atm and of the NC balloon under pressures from 0 to 20 atm. Table 2 lists peak values of the maximum principal tensile stress in the artery models under balloon inflation pressures of 6, 12, and 20 atm.

The larger CB diameter resulted in higher stress in the artery model. Moreover, compared with the maximal principal stress using the 3.0-mm-diameter CB, the values were decreased to 80.3%, 50%, 28.8%, and 22.7% for the 2.75-, 2.5-, 2.25-, and 2.0-mm-diameter CBs, respectively, at the nominal inflation pressure, and to 82.3%, 55.8%, 40.1%, and 25.9%, respectively, at the rated inflation pressure. The maximum principal stress in the artery model for the 3.0-mm-diameter NC balloon was 81.8% and 84.4% of that for the 3.0-mm-diameter CB at the nominal and rated inflation pressures, respectively.

A distinct decrease in the stress level in the artery model was observed when smaller-diameter CBs were used. When using the NC balloon, the peak values were even higher than noted for the 2.0-, 2.25-, 2.5-, and 2.75-mm-diameter CBs at both the nominal and rated pressures.

**Discussion**

This study revealed that CBs with a BAR < 1:1 had a comparable ability to induce the maximum principal tensile stress level in the calcification model while distinctly reducing the stress levels at the border of the artery adjacent to the calcification.

Generally, when selecting balloons for lesion preparation, a BAR of 1:1 is recommended in clinical practice. However, the present study suggests that for the CB, a BAR of 1:1 is not necessarily appropriate.

The maximum principal tensile stress yielded in the calcification for the NC balloon at the rated balloon inflation pressure (20 atm) was smaller than that for the CB downsized by 0.5 mm (2.5 mm) at the nominal balloon inflation pressure (6 atm). Moreover, for the NC balloon, the maximum stress yielded in the artery at the rated balloon inflation pressure (20 atm) was higher than that for the CB downsized by 0.25 mm (2.75 mm) at the rated balloon inflation pressure (12 atm). Clinically, coronary artery perforation is the major disadvantage of the CB. The findings of this study imply that choosing a CB that is 0.25 or 0.5 mm smaller than the reference artery diameter of 3.0 mm may be effective for expanding calcification without increasing the risk of artery dissection and perforation. The effects of time with balloon inflation and frequency may enhance calcification fracture, although these issues cannot be dealt with using the present numerical analysis. Balloon inflation 3 times for 20 s each time is currently used as a standard treatment in coronary interventions, based on our previous bench test using a stenotic coronary artery model. We will investigate affects of time with balloon inflation and frequency on calcification fracture by developing calcified coronary artery model. This study indicates that the stress levels occur in the calcification model where the blades contact the lesion or between blades. This study implies that calcified nodules or nodular calcification may remain unsolved challenging lesions that need to be further addressed in future work.

There are some limitations to the present study. First, we studied a concentric calcification model as a first step. Variations, such as calcium arc, diameter stenotic ratio, and the thickness and length of the calcification, need to be considered to further understand the abilities of the CB. Second, modeling the mechanical properties of lesions is a challenge for future consideration. Third, although the expansion of the CB could be solved with quasi-static analysis, it may have been difficult to exclude an inertia effect on CB expansion. However, in clinical settings, high-speed inflation of the CB may increase the risk of artery dissection and perforation. We initiated a study to develop clinically relevant in vitro calcification models and to investigate the fracture behavior of the calcification models. These studies may increase our understanding of the response of the calcified lesion to lesion modification devices, like the CB, and improve modeling in finite element analyses. Nevertheless, to the best of our knowledge, this is the first report of modeling of the folding of balloons with blades. The folding process of the CB device presented in this study is essential to prepare an unexpanded model to analyze realistic expansion behavior.

**Conclusions**

This findings of this study imply that the selection of a CB that is 0.25 or 0.5 mm smaller than the reference artery diameter of 3.0 mm may be the first choice in terms of effectively fracturing the calcification without increasing the risk of artery dissection and perforation. In using the CB, our data suggest that a BAR of 1:1, which is currently recommended for conventional balloons, is not necessarily appropriate.

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**Disclosures**

K.I. is a member of Circulation Reports’ Editorial Team. The other authors declare that they have no conflicts of interest.

**IRB Information**

Name of the Ethics Committee: None. Reference Number: None.

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