Elastic Material Damage of Rotational Atherectomy and Orbital Atherectomy: An *in Vitro* Assessment

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Abstract

Purpose

Rotational atherectomy (RA) and orbital atherectomy (OA) are effective procedures for severe calcified coronary artery disease. Nonetheless, vessel perforation remains an adverse complication of these procedures. This study aimed to evaluate factors affecting elastic material damage caused by RA and OA.

Methods

An *in vitro* assessment was conducted in which the damage to the rubber latex, an elastic material, after RA was evaluated under various conditions, including burr rotational speed (100,000–220,000 rotations per minute), approaching curve, burr size (1.25 mm, 1.75 mm, and 2.0 mm), and fluid viscosity (water and low-molecular weight dextran). Similarly, the rubber latex damage after OA was evaluated in the same experimental system under various conditions, including crown rotational speed, approaching curve, and fluid viscosity.

Results

In RA, the rubber latex was damaged at lower rotational speeds ($p = 0.003$), tighter approaching curves ($p < 0.0001$), and lower fluid viscosity ($p = 0.03$). In OA, the rubber latex was generally severely damaged.

Conclusion

A higher rotational speed, coaxial approach for the wall, and higher viscosity contributed to lesser elastic material damage in RA. The safety mechanism for elastic material in OA proved less effective.

Introduction

Percutaneous coronary intervention (PCI) is an effective revascularization technique that is employed in patients with coronary artery disease (CAD). Among those with CAD, severe calcified coronary artery lesions are present in nearly one third of patients undergoing PCI are at risk for poor clinical outcomes of PCI [1–3]. Thus, calcified lesion modification prior to stent implantation is performed. In this procedure, rotational atherectomy (RA) and/or orbital atherectomy (OA) plays an important role in stent expansion [4–7]. However, they may result in complications, of which vessel perforation is the most serious [8–10]. Thus, a mechanism for preventing vessel perforation in RA should be developed. This safety mechanism has been called the differential cutting (DC) effect. In the DC effect, the rota-burr ablates only calcification and avoids damage for elastic material such as the normal vessel wall. Logically, the safety mechanism for elastic vessel wall is based on the elastohydrodynamic lubrication (EHL) theory [11]; however, the evaluation of the safety mechanism of RA and OA has been limited.

The aim of this study was to evaluate the factors that affected damage for elastic material in RA and OA.

Methods

In Vitro Assessment

To evaluate the factors that affected damage for elastic material under various conditions, we performed *in vitro* experiments. We molded the simulation models using a 3D printer, which was composed of nylon resin. The system consisted of two parts: the pedestal part and the curve part. The curved parts were molded into three patterns: loose, moderate, and tight curves (Fig. 1). In the role of the virtual elastic vessel wall, rubber latex (thickness=200 μm), which consisted of sterilized surgical gloves, was rolled along the curved parts (Fig. 2). The guiding catheter (Hyperion, Asahi Intecc, Japan) was equipped with a simulation system and was dipped in the fluid in the form of either water or low-molecular weight dextran. The temperature of the fluid was approximately 20^{o}C. We evaluated the damage of the elastic material that was rolled along the curved parts in the three degrees of damage during RA or OA. The damage was classified as severe, mild, or no damage with visual recognition. Severe damage corresponded to a complete hole through the material. Mild damage corresponded to some surface damage; however, there was no complete hole. No damage with visual recognition is shown in Fig. 3.

Rotational Atherectomy

In RA experiments, the wire used was RotaWire Drive Extra Support (Boston Scientific, Massachusetts, USA), and the tip of the wire was pulled using a weight of 15 g. RA was performed using Rotablator Pro (Boston Scientific, Massachusetts, USA). The validated parameters in RA experiments were burr size (1.25 mm, 1.75 mm, and 2.0 mm), burr rotational speed (100,000 rotations per minute [rpm], 140,000 rpm, 180,000 rpm, and 220,000 rpm), and three types of curves (loose, moderate, and tight curves). To evaluate the effect of fluid viscosity on DC, we performed an RA experiment in each burr size and rotational speed condition with a moderate curve system in low-molecular weight dextran instead of water. The rota-burr was manipulated by a well-experienced operator in real-world clinical practice, and the burr was passed through the top of the curve five times or until it reached the maximum ablation time of 20 s. Thus, in the case of burr passage difficulty, the burr either passed the curve below five times or did not at all.

Orbital Atherectomy

In OA experiments, the wire used was ViperWire Advance Flex Tip (Cardiovascular Systems Inc., St Paul, MN, USA), and the tip of the wire was pulled using a weight of 15 g. OA was performed using Diamondback 360® New Classic Crown Type (Cardiovascular Systems Inc., St Paul, MN, USA). The validated parameters in OA experiments were crown rotational speed (80,000 rpm and 120,000 rpm), two types of the curved part (loose and moderate curve), and filled fluid viscosity (water and low-molecular weight dextran). After OA, we evaluated the degree of rubber latex damage using the same criteria as those used in RA experiments.

Statistical Analyses

In 48 *in vitro* RA experiments, we investigated factors affecting elastic material damage, which included the burr size, types of curves, burr rotational speed, and filled fluid viscosity, using multivariate analysis of variance. Statistical analysis was conducted by a physician using JMP software version 10.0 (SAS Institute Inc., Cary, NC, USA). Statistical significance was set at $p<0.05$. The authors had full access to and took full responsibility for the integrity of the data.

Results

In vitro **Rotational Atherectomy Experiments**

In the loose curve system experiments, the rubber latex had no damage, and the burr rotational speed was reduced by approximately 1,000 rpm when the rota-burr passed through the strongest wire-bias point for the wall in all the atherectomy tests. In the moderate curve system experiments, a 1.25-mm burr with a rotational speed of over 180,000 rpm could pass without damage. However, there was mild damage in the 140,000-rpm test and severe damage in the 100,000-rpm test. In the same curve system, a 1.75 mm burr with a 140,000-rpm rotational speed could pass without damage; however, there was mild damage in the 100,000-rpm test. In addition, the 2.0 mm burr could not pass without damage at all rotational speeds. In the tight curve system, the 1.25 mm burr test caused severe damage to the rubber latex at all rotational speeds. Burrs that were 1.75 mm and 2.0 mm in size with over 180,000 rpm rotational speed could pass with mild damage. However, there was severe damage when the two burrs were subjected to the 140,000-rpm test (Table 1). In the comparison of fluid viscosity, 1.25 mm and 1.75 mm burrs could pass the moderate curve system without damage in the low-molecular weight dextran in all rotational speed (100,000 rpm-220,000 rpm). Furthermore, there were some damages in the lower rotational speed with the same burr size and curve in water. Moreover, the 2.0 mm burr could pass without damage at 220,000 rpm and with mild damage at 140,000 and 180,000 rpm in low molecular dextran. The damage to the rubber latex was lower in the low-molecular weight dextran than in water (Table 2).

Table 1
Wall damage of rotational atherectomy (experiments in water)

	Burr size		
	1.25 mm	1.75 mm	2.0 mm
Loose curve	Damage level (rotational speed down [rpm])		
220000 rpm	● (1000)	● (1000)	● (1000)
180000 rpm	● (1000)	● (1000)	● (1000)
140000 rpm	● (1000)	● (1000)	● (1000)
100000 rpm	● (1000)	● (1000)	● (1000)
Moderate curve	Damage level (rotational speed down [rpm])		
220000 rpm	● (10000)	● (20000)	△ (21000)
180000 rpm	● (10000)	● (13000)	× (40000)
140000 rpm	△ (15000)	● (15000)	× (not pass)
100000 rpm	× (30000)	△ (30000)	× (not pass)
Tight curve	Damage level (rotational speed down [rpm])		
220000 rpm	×(8000)	△ (10000)	△ (15000)
180000 rpm	×(10000)	△ (10000)	△ (20000)
140000 rpm	×(15000)	× (20000)	× (30000)
100000 rpm	×(not pass)	× (20000)	× (not pass)
●: no damage, △: mild damage (not complete hole but surface damage), ×: severe damage (complete hole)			

Table 2
Wall damage comparison of rotational atherectomy between water and low-molecular weight dextran

	Water	Low-molecular weight dextran
Burr size: 1.25 mm		
220000 rpm	● (10000)	● (9000)
180000 rpm	● (10000)	● (9000)
140000 rpm	△ (15000)	● (6000)
100000 rpm	× (30000)	● (10000)
Burr size: 1.75 mm		
220000 rpm	● (20000)	● (9000)
180000 rpm	● (13000)	● (10000)
140000 rpm	● (15000)	● (9000)
100000 rpm	△ (30000)	● (10000)
Burr size: 2.00 mm		
220000 rpm	△ (21000)	● (20000)
180000 rpm	× (40000)	△ (21000)
140000 rpm	× (not pass)	△ (22000)
100000 rpm	× (not pass)	× (not pass)

●: no damage, △: mild damage (not complete hole but surface damage), ×: severe damage (complete hole)

Effective Factors for Differential Cutting in Rotational Atherectomy

Multivariate analysis was performed to determine the factors that could significantly influence the elastic material damage, including the degree of approaching curve, rotational speed, burr size, and fluid viscosity. The degree of curve was the most significant factor (moderate-loose, $p < 0.0001$; tight-moderate, $p = 0.013$). Among the controllable factors, rotational speed was the most significant ($p = 0.0032$); subsequently, fluid viscosity was significant ($p = 0.03$) (Table 3).

Table 3
Multiple regression analysis for wall damage of rotational atherectomy

Term	Estimate	Chi-square	P value
Curve; moderate-loose	-18.6	100000	<.0001
Curve; tight-moderate	-2.51	6.16	0.013
Higher burr rotational speed (rpm)	0.00	8.7	0.0032
Bigger burr size (mm)	-2.03	2.46	0.12
Low-molecular weight dextran	1.08	4.70	0.03
p value for the whole model < 0.0001, R square = 0.49			
(Wall damage level was defined as per the following ordinal index; severe: 2, mild: 1, none: 0)			

In Vitro **Orbital Atherectomy Experiments**

The OA test could be performed in 20 s without rubber latex damage if the rotational speed was 80,000 rpm and if low-molecular weight dextran was used. Other tests under various conditions, including low and high rotational speed and fluid viscosity (water or low-molecular weight dextran), caused severe damage to the latex (Table 4). In the OA experiments, we confirmed that there were multiple holes on the rubber latex, whereas in the RA experiments, those with severe damage to the rubber latex had a single complete hole (Fig. 4).

Table 4
Wall damage assessment of orbital atherectomy

	Water	Low-molecular weight dextran
Loose curve		
80000 rpm	×	●
120000 rpm	×	×
Moderate curve		
80000 rpm	×	×
120000 rpm	×	×
●: no damage; △: mild damage (not complete hole but surface damage); ×: severe damage (complete hole)		

Discussion

The primary findings of this study are as follows: 1) in the RA procedure, the factors that affected the safety mechanism to avoid damage to the elastic material included a larger minimum turning radius of the approaching curve, higher burr rotational speed, and higher viscosity of the filled fluid; 2) in the OA procedure, the safety mechanism for elastic material was less effective than RA.

The EHL theory was based on the classical one-dimensional Reynolds equation, $Ps = 6\eta u / h$. In this equation, P is the pressure between the rotational material and the opposite wall, η is the viscosity, u is the speed of the moving surface, and h is the distance between the rotational material and the opposite wall [11]. Currently, several tenets, including elastic deformation caused by fluid pressure, have been included in the theory. According to the EHL theory, laminar fluid flow caused by rotational forces creates pressure between the rotational material and the opposite wall. During RA, this pressure causes micro-elastic deformation in the elastic vessel wall and maintains the distance between the rota-burr and the vessel wall. This phenomenon seems to be the key mechanism within the safety mechanism of the rotablator; therefore, the present *in vitro* study has attempted to demonstrate this logic. We found that a higher burr speed and a higher viscosity were effective for preventing elastic damage; however, a larger burr size was not effective. Subsequently, we must pay attention to fluid viscosity and control optimal rotational speed during the RA procedure. The viscosity of H_2O at 20^{o}C is approximately 1.0 mPa·s, and that of low-molecular weight dextran is 3.5-4.5 Pa·s. In real-world RA procedure, fluid viscosity represents the blood viscosity. Low-molecular weight dextran is reported to be the same as 50% hematocrit blood viscosity [12]. With respect to the correlation between blood viscosity and hematocrit and between blood viscosity and blood protein levels [13], patients with severe anemia and low blood protein levels may not be expected to have a good DC effect during RA. In such cases, transfusion and/or supplementation of albumin before PCI may be required.

Logically, a larger burr size results in a higher speed of the moving surface and increases the DC effect. However, the shape of the rota-burr depends on the burr size, and the approaching degree of the vessel wall is more coaxial in the 1.25-mm burr than in the 2.0-mm burr (Online Resource 1). As suggested in a previous study [14], the difference in shape results in a higher perpendicular reaction force of the opposite wall in a 2.0-mm burr than in a 1.25-mm burr. This might have caused a missing DC effect in the larger rota-burr (Online Resource 2). Moreover, the surface point of the rota-burr attached to the vessel wall is not necessary at the maximum radius point; therefore, the theory that a larger burr size increases the safety for elastic material is not necessarily true. For the same reason, a tighter approaching curve results in a higher perpendicular reaction force between the rota-burr and the vessel wall; therefore, a tighter curve may decrease the safety for elastic material. However, a higher perpendicular reaction force teaches procedural operators the power limitation of pushing the burr controller; thus, well-experienced operators might avoid vessel perforation before the perpendicular reaction force becomes excessive. In clinical practice, PCI operators should evaluate the strong wire bias for the tight curve in the normal vessel wall via angiography and imaging devices such as optical coherence tomography and/or intravascular ultrasound when the rota-burr must pass through the tortuous point in the rota-mode. Regarding the burr rotational speed, the Boston Scientific formally recommended a speed of 140,000-190,000 rpm [15]. With respect to the safety effect for the elastic vessel wall, this speed is adequate; however, excess burr speed might result in thrombus formation. Therefore, operators should consider the appropriate settings for each rotational atherectomy case.

Khan et al. reported that the incidence of coronary perforation was significantly higher in OA patients than in RA patients [16]. In the orbital atherectomy system, the center of gravity of the asymmetric crown is far from the wire, which is the axis of rotation; therefore, the rotational surface is not continuous. This makes it difficult to produce a laminar fluid flow and apply the EHL theory. In the RA *in vitro* experiment, the rubber latex could not be damaged in the loose curve system under various conditions, even at low rotational speeds. However, OA could easily damage the same model without 80,000 rpm in low-molecular weight dextran. Although a higher viscosity might confer the benefit of possibly avoiding vessel damage in OA, a strong wire bias point for the elastic vessel wall should be mentioned for severe vessel perforation in OA more than RA. Moreover, perforation caused by OA may be more complex than that caused by RA.

This study has several limitations. First, this was an *in vitro* assessment. To evaluate the damage of the rubber latex that might have been tougher than the real vessel wall, we prepared a strong wire bias by pulling the wire using a weight. Second, the curve models were not duplications of the real coronary artery. Thus, the approaching degree for the wall of the rota-burr or OA catheter might differ from real-world practice. Moreover, in the present study, we investigated the damage on the strong forced inner side of curve. In the RA practice, the perforation was experienced at the outer side of curve just after the tortuous vessel route. This might be related burr manipulation. However, it seemed to be essentially the same principle of the safety mechanism for elastic material in RA. Therefore, the results of the experiment should be interpreted as a comparative assessment in various conditions, including rotational speed of the rota-burr or OA catheter, rota-burr size, fluid viscosity, approaching curve, and RA or OA.

From a clinical perspective, RA has an advantage in its safety mechanism compared to OA. Moreover, RA operators could decrease the possibility of vessel perforation with controlling factors, higher rotational speed, and blood viscosity.

In conclusion, a higher rotational speed, coaxial approach for the wall, and higher viscosity contribute to the safety mechanism of RA. The safety mechanism for elastic material in OA proved less effective.

Declarations

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Competing Interests

The authors have no relevant financial or non-financial interests to disclose.

Author Contributions

All authors contributed to the study conception and design. Material preparation, data collection, and analysis were performed by HH and HT. The first draft of the manuscript was written by HH, and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Ethics Approval

This study did not use biological data or clinical data. Therefore, there was no ethical approval. The Japanese Red Cross Otsu Hospital Research Ethics Committee has confirmed that no ethical approval is required.

Consent to Participate

Any human participants was not involved in this study.

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Figures

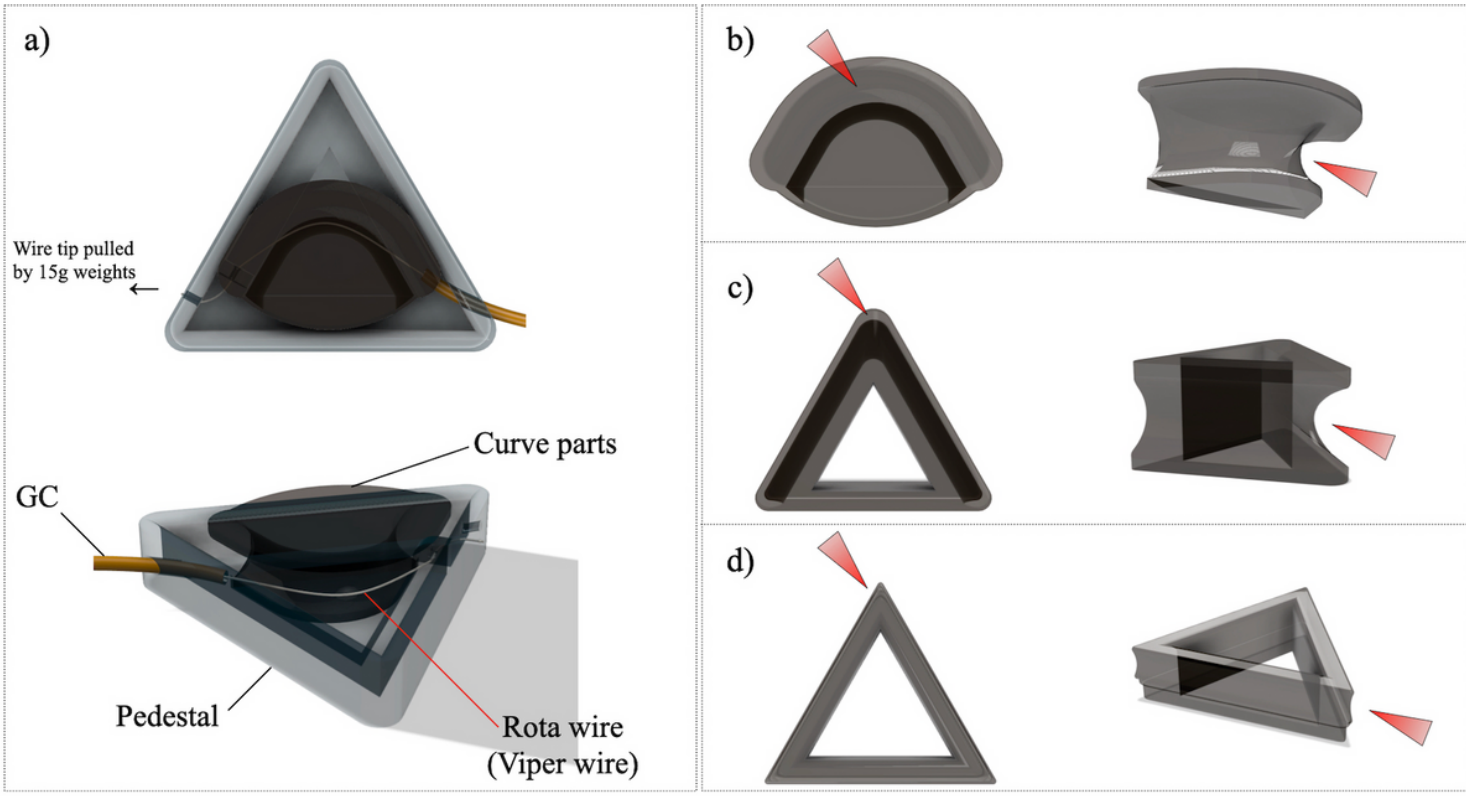

Figure 1

System parts used in the *in vitro* experiments. All experimental system parts without a wire, rotablator, orbital atherectomy catheter, and guiding catheter were made using a three-dimensional printer with nylon resin. (**a**) The pedestal part is set on the bottom of the water tank, and the curved part is engaged on the pedestal part. A straight guiding catheter (GC) is inserted and placed in the side hole of the pedestal part. The tip of the wire is removed from the water tank through the side hole on the tank wall and pulled by a 15 g weight. (**b**) Loose curve part. The red arrow shows the groove of the curve passing through the wire. (**c**) Moderate curve part. The red arrow shows the groove of the curve passing through the wire. (**d**) Tight curve part. The red arrow shows the groove of the curve passing through the wire.

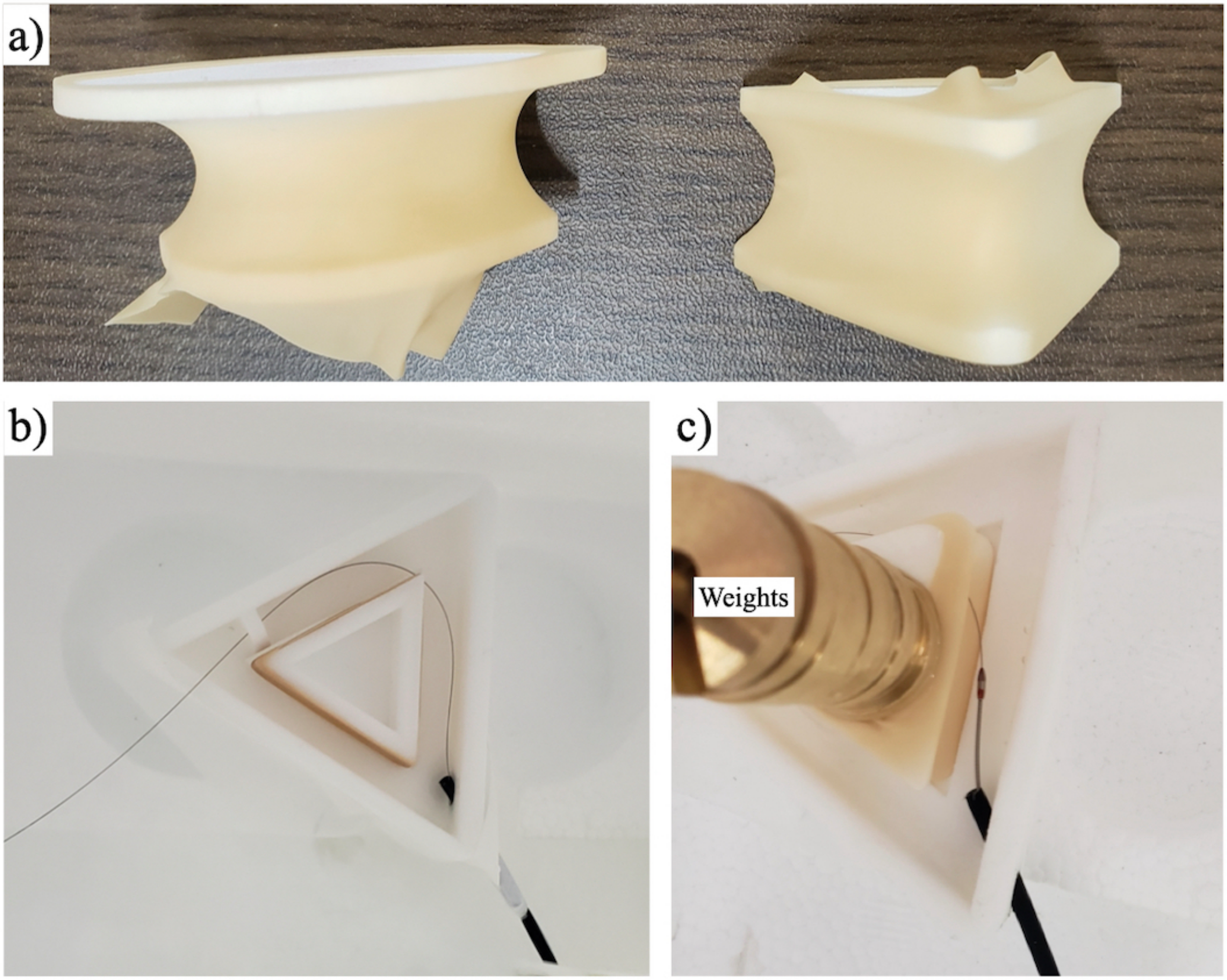

Figure 2

Rolled-up rubber latex as elastic material for the curve parts. (**a**) Representative settings of the rolled-up rubber latex around the curve parts (left: loose curve, right: moderate curve). (**b**) Real representative experiment system (curve part: tight curve, wire: RotaWire Drive Extra Support). (**c**) Real representative experiment system (curve part: moderate curve, wire: RotaWire Drive Extra Support, and 1.25 mm rota-burr on the wire). During rotational atherectomy or orbital atherectomy, enough weights pulled on the curve part ensuring system stability.

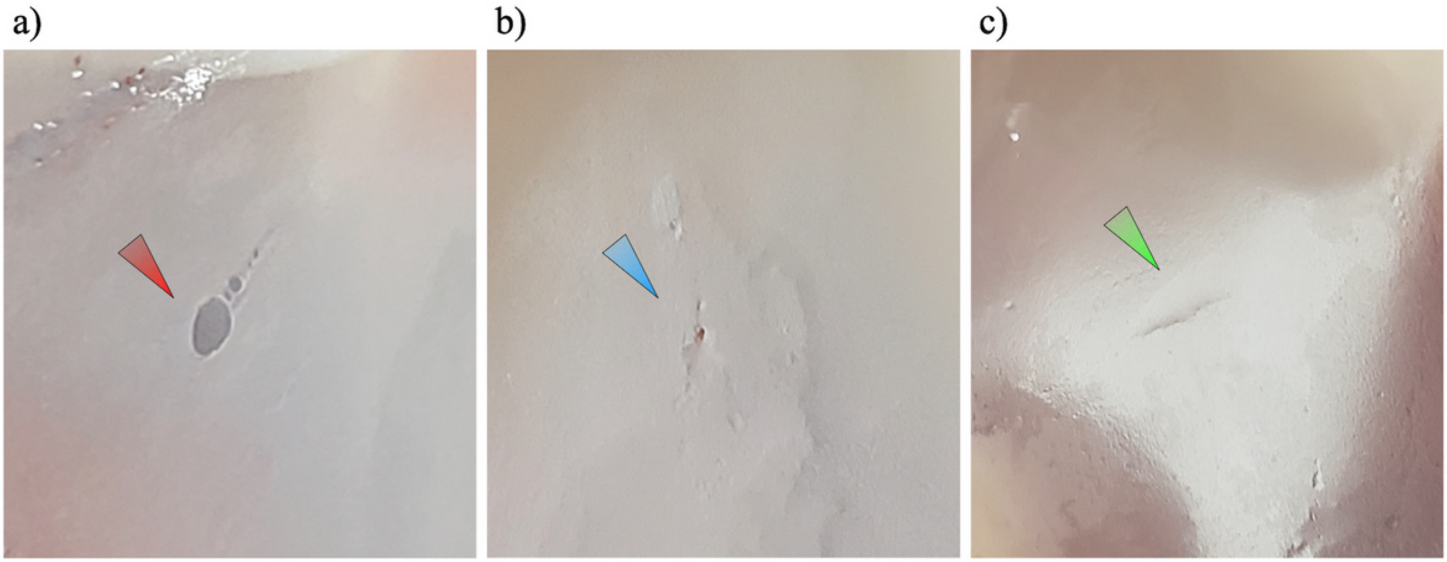

Figure 3

Criteria for damage on the rubber latex. (**a**) Severe damage: rubber latex had a complete hole. (**b**) Mild damage: some visible damage on the surface of the rubber latex without a complete hole. (**c**) No damage: there was no visible damage on the rubber latex.

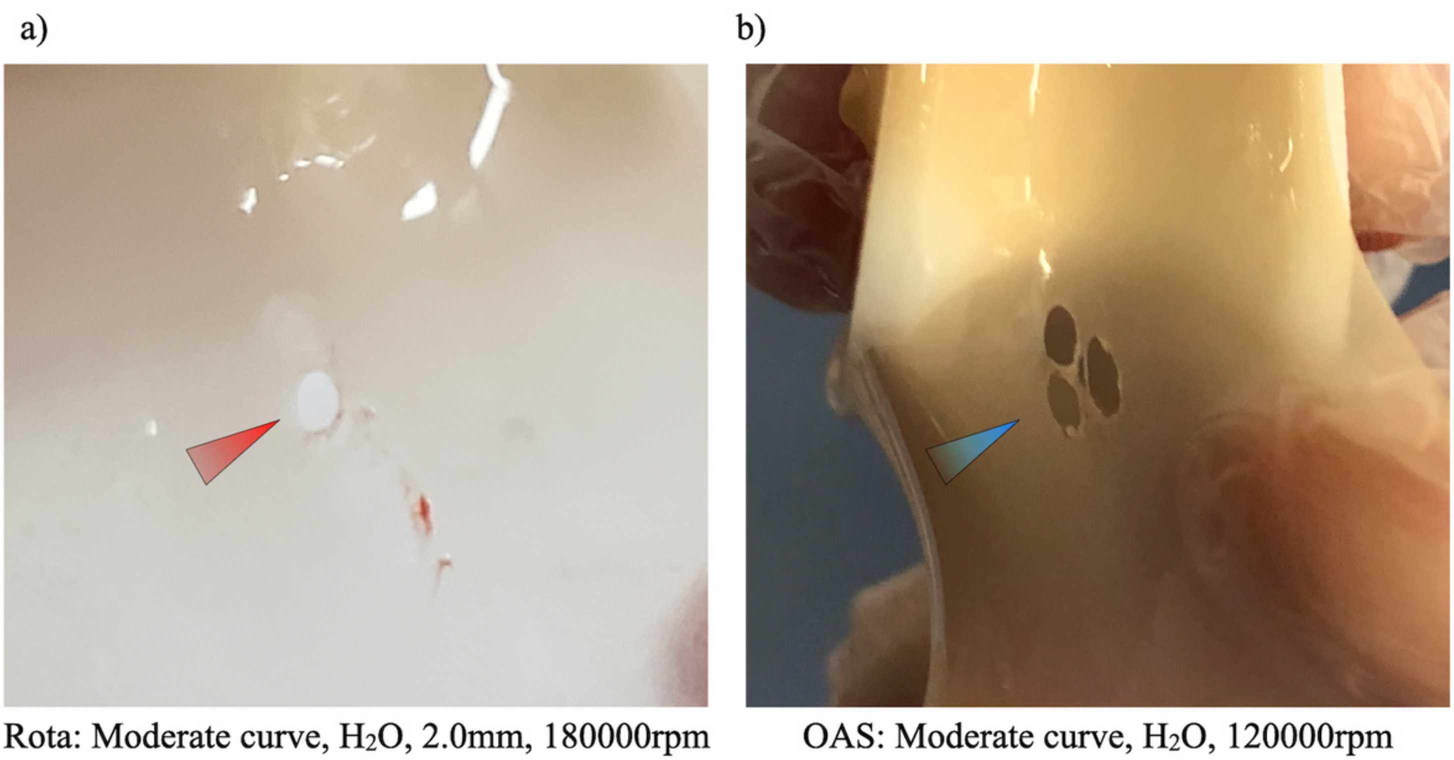

Figure 4

Comparison of the shape of the damage on rubber latex between rotational atherectomy and orbital atherectomy. (**a**) Representative single complete hole after rotational atherectomy (moderate curve system, in water, burr size: 2.0 mm, 180,000 rpm rotational speed). (**b**) Representative multiple complete holes after orbital atherectomy (moderate curve system, in water, 120,000 rpm rotational speed).