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Experimental investigation of the abrasive crown dynamics in orbital atherectomy

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ABSTRACT

Orbital atherectomy is a catheter-based minimally invasive procedure to modify the plaque within atherosclerotic arteries using a diamond abrasive crown. This study was designed to investigate the crown motion and its corresponding contact force with the vessel. To this end, a transparent arterial tissue-mimicking phantom made of polyvinyl chloride was developed, a high-speed camera and image processing technique were utilized to visualize and quantitatively analyze the crown motion in the vessel phantom, and a piezoelectric dynamometer measured the forces on the phantom during the procedure. Observed under typical orbital atherectomy rotational speeds of 60,000, 90,000, and 120,000 rpm in a 4.8 mm caliber vessel phantom, the crown motion was a combination of high-frequency rotation at 1000, 1500, and 1660.4-1866.1 Hz and low-frequency orbiting at 18, 38, and 40 Hz, respectively. The measured forces were also composed of these high and low frequencies, matching well with the rotation of the eccentric crown and the associated orbital motion. The average peak force ranged from 0.1 to 0.4 N at different rotational speeds.

1. Introduction

Atherectomy—a catheter-based procedure to remove atherosclerotic plaque from diseased arteries to treat coronary and peripheral artery diseases—is used to increase artery compliance and reduce plaque burden in complex lesions, including calcification, bifurcation, ostial stenosis, and in-stent restenosis, where typical balloon angioplasty and stenting are ineffective [1–3]. Current atherectomy devices eliminate the plaque by abrasive sanding, blade excision, or laser ablation, and, depending on the debulking motion, can be categorized as rotational, directional, or orbital atherectomy [4–6]. Orbital atherectomy is common for treating peripheral artery disease [7] and has demonstrated safety and efficacy in the treatment of *de novo* calcified coronary artery disease [8,9].

Orbital atherectomy, as shown in Fig. 1, begins with the insertion of a catheter, equipped with a diamond abrasive eccentrically mounted crown for plaque removal and modification, into the vessel of interest. The crown is then rotated to sand the plaque at a high speed (>60,000 rpm) by a drive shaft. As the shaft rotates between the stationary guidewire and sheath, saline flows between the sheath and drive shaft to lubricate and cool the catheter.

Extensive clinical studies have been conducted to evaluate and improve orbital atherectomy and the conclusions of major multicenter trials can be summarized as follows:

- Three early clinical studies were conducted to prove the safety and efficacy of peripheral orbital atherectomy. In a review by Staniloae *et al.* [7], two studies in Europe achieved success rates of 94% and 91% in treatment by Zeller *et al.* and Scheinert *et al.* The OASIS [10] study in the US had a 90% 6-month freedom from major adverse events (death, amputation, and revascularization).
- The peripheral orbital atherectomy procedure was improved by utilizing a smaller crown size (1.25 mm diameter) and a shorter plaque sanding time (100 s) in the CONFIRM clinical study [11], which lowered complication rates for slow flow, vessel closure, and spasm from 7%, 2%, and 10% to 3%, 1%, and 5%, respectively.
- Two randomized trials to date have studied the effects of peripheral orbital atherectomy for calcified lesions. In CALCIUM 360 [12], the procedural success rate was 93% for orbital atherectomy followed by low pressure balloon angioplasty and 82% for the angioplasty alone. In COMPLIANCE 360° [13], orbital atherectomy assisted angioplasty showed lower complication rates of dissections (16% versus 48%) and restenosis at 1 year (19% versus 22%) than balloon angioplasty.
- Studies on coronary orbital atherectomy in calcified lesions, ORBIT I [14,15] and ORBIT II [9,16], have reported procedural

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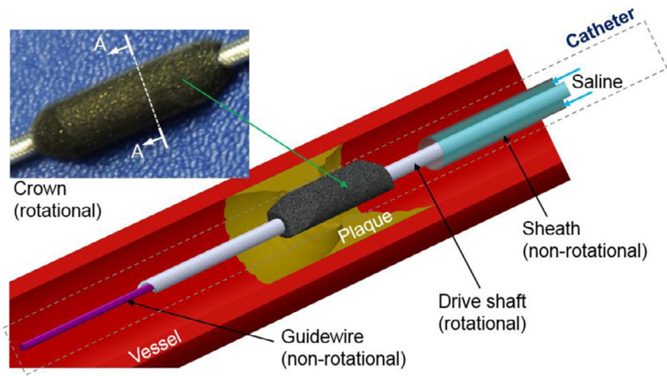

Fig. 1. Schematic of the orbital atherectomy and the catheter including guidewire, drive shaft, crown, and sheath.

success rates of 94% and 89%. The incidence of major complications included 9.8% in-hospital major adverse cardiac events (death, myocardial infarction, and target vessel revascularization), 3.4% severe dissection, 1.8% abrupt closure, 1.8% perforation, and 0.9% persistent slow flow in complex severely calcified lesion [16].

Engineering studies that have been conducted on orbital atherectomy include Lovik *et al.*'s assessment of tissue thermal damage by the finite element simulation model and accompanying experimental validation [17], Ramazani-Rend *et al.*'s numerical and experimental proof of the absence of cavitation [18], Helgeson *et al.*'s investigation of plaque debris trajectory and agglomeration within the blood [19], Adams *et al.*'s [20] and Kohler *et al.*'s [21] experimental examination of particle size and analysis of the crown dynamics without the arterial wall interaction. Missing from this literature review are descriptions, qualitative or quantitative, of the crown motion and contact forces with lesions in orbital atherectomy associated with the procedure safety, efficacy (vessel lumen enlargement and tissue softening), and complications such as dissection and spasm.

This research seeks to address this dearth by experimentally investigating the motion and contact forces of the crown in orbital atherectomy. A high-speed camera and image processing technique were utilized to visualize and quantify the crown motion and its interaction with the wall of a transparent arterial phantom made of tissue-mimicking polyvinyl chloride (PVC). Forces were measured simultaneously by a piezoelectric force dynamometer with sufficient sensitivity and bandwidth for such rapid dynamic measurements.

Within the body of this paper, the experimental setup and image processing techniques are first introduced, the measured results of the crown motion and contact forces are then presented, and finally the agreement between the observed crown motion and contact forces is discussed.

2. Materials and methods

2.1. Experimental setup

The experimental setup, as shown in Fig. 2, consisted of three modules—the atherectomy device, an arterial phantom, and the measurement system—discussed in the following sections.

2.1.1. Atherectomy device

The orbital atherectomy device used in this study was the Diamondback 360® (2 mm solid crown) by Cardiovascular Systems Inc. (St. Paul, MN). This device consists of three units: (1) a motor and control unit, (2) a catheter, and (3) saline and a saline pump.

The motor and control unit (Fig. 2) includes an electric motor, a control knob to axially move the catheter, and a set of speed selection buttons to generate three rotational speeds: 60,000, 90,000 and 120,000 rpm.

The catheter, as illustrated in Fig. 1, is the part inserted into a patient's vessel during atherectomy. The catheter (whose detailed

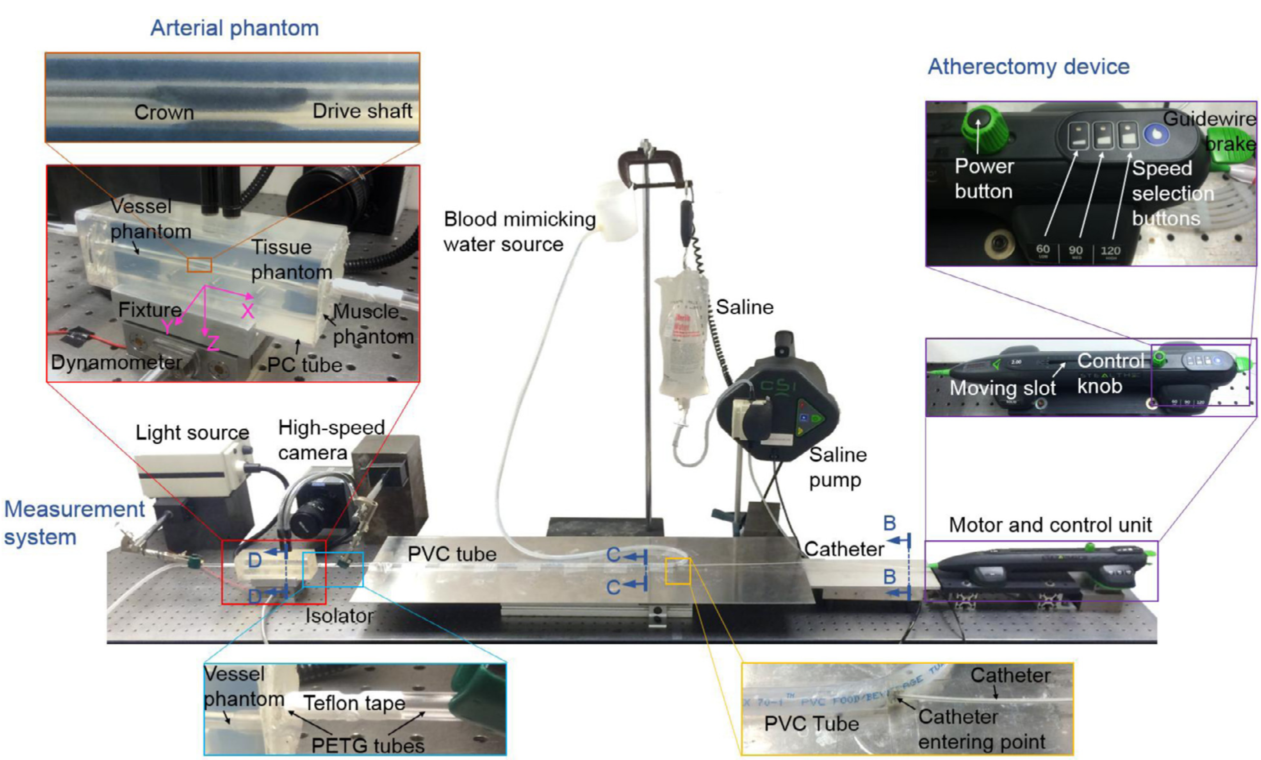

Fig. 2. Experimental setup for orbital atherectomy.