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.

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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
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. 1. Schematic of the orbital atherectomy and the catheter including guidewire, drive shaft, crown, and sheath.](image1)

![Fig. 2. Experimental setup for orbital atherectomy.](image2)
C, nated tungsten, concentration long E-E shaft. The motor moves as ameter guidewire by plaque from of sive construction the shown Fig. 3. Catheter: (a) the guidewire, drive shaft and sheath, (b) cross-section B-B, (c) crown cross-section A-A, and (d) cross-section E-E. (unit: mm)

density polyethylene tube (1.8 mm OD and 0.16 mm wall thickness) and prevents direct contact between the high-speed rotating drive shaft and the vessel wall. Inside the sheath, saline, pumped via a roller pump at a flow rate of 45 ml/min to the treatment site, flows to provide lubrication and remove heat generated by the friction of the drive shaft between the guidewire and the sheath.

2.1.2. Arterial phantom

The arterial phantom meant to simulate the artery and the blood flow consisted of (1) a tissue-mimicking phantom, (2) a blood-mimicking water source, (3) a PVC tube connecting the phantom and water source, and (4) force isolators between the PVC tube and the tissue phantom.

The transparent tissue-mimicking phantom, as shown in Fig. 4(a) and (b), consisted of a PVC vessel and muscle phantom and a square polycarbonate (PC) tube to encase the soft material. Its geometry was designed to mimic the human proximal popliteal artery region, one of the most common locations of lower extremity atherosclerosis [22]. To measure the force during the procedure, the outer square PC tube (50.8 mm outer width, 2.03 mm wall thickness, and 150 mm length) was mounted to a piezoelectric dynamometer (Model 9256-C by Kistler) via a custom fixture (Fig. 2). Inside the tube were the PVC vessel and muscle phantoms. The vessel phantom, to accommodate the proximal popliteal
artery’s elastic properties [23] and anatomy [24], was made of soft PVC (45 kPa elastic modulus) and had a 4.8 mm inner diameter (ID) and a 2.0 mm wall thickness. The muscle phantom surrounded the vessel phantom and bounded by the outer PC tube was made of PVC with a lower elastic modulus (about 8 kPa). The mechanical properties and fabrication of this tissue mimicking PVC were introduced by Li et al. [25].

To fabricate the tubular vessel phantom, a 4.76 mm diameter aluminum rod was dipped into PVC plastisol (M-F Manufacturing Co., Fort Worth, TX) heated to 150 °C for 20 min and degassed in a vacuum chamber at ~90 kPa for 10 min. To make the muscle phantom, the PVC plastisol was mixed in a 1:1 ratio with the plastic softener (M-F Manufacturing Co., Fort Worth, TX) and poured into the space between the vessel phantom (supported by the aluminum rod) and the square encasing tube. After the PVC was cooled to room temperature and cured, the aluminum rod was removed. The inner diameter of the vessel phantom became 4.8 mm after cooling as a result of the PVC shrinkage.

The blood mimicking water source was raised 1 m above the rest of the experimental setup, as shown in Fig. 2, to force the water to flow through the PVC tube and the tissue phantom at a flow rate of 1.3 L/min. The PVC tube (ID of 6.35 mm, wall thickness of 1.59 mm, and 1.7 m in length) had a 0.7 m long horizontal section in the X direction connected to the tissue phantom and a vertical section in the Z direction connected to the blood mimicking water source. A 1.5 mm diameter hole was drilled into the PVC tube to allow the catheter to enter the horizontal section and access the tissue phantom. Fig. 4(c) shows the catheter (1.8 mm OD) inside the PVC tube. The cross-section C-C of the PVC tube and catheter from Fig. 4(c) is shown in Fig. 4(d).

Force isolators were implemented on both sides of the tissue phantom to isolate the forces on the PVC tube induced by the vibration of the catheter. The isolators were individually made of two round polyethylene terephthalate (PETG) tubes (7.94 mm OD and 4.76 mm ID) connected with a 5 mm clearance by wrapping the Teflon tape.

2.1.3. Measurement system

Two key devices were used in this study to measure the crown dynamics: a high speed camera (Model FASTCAM-1024PCI by Photron) and a force dynamometer (both can be seen in the Fig. 2). The camera was used to image the crown (through the transparent phantom) from the side or the front to record the crown motion. Recording at 18,000 frames per second (fps) allowed a minimum of 9 frames to be captured for each revolution of the crown even at its highest rotational speed setting of 120,000 rpm. A fiber optic light source (Model 8375 by Fostec) was used to deliver a bright, concentrated light necessary for proper image quality. The dynamometer was mounted under the tissue phantom, and measured the force in the Y and Z directions (Fig. 2) at a sampling rate of 5000 Hz. The Y- and Z-axis natural frequencies of this dynamometer (5500 and 5600 Hz [26]) were well above 2000 Hz, the frequency experienced at the 120,000 rpm crown rotational speed.

2.2. Image processing

The images in the videos were processed in MATLAB (R2014a by MathWorks) to analyze the crown motion. A technique utilizing multiple thresholds was applied to divide the pixels into
distinct regions based on the intensity. The sample image, shown in Fig. 5(a), had its pixels segmented into four levels of intensity, as shown in Fig. 5(b). The pixels with the highest intensity, marked in red, were the drive shaft and the crown, due to the focused illumination. Since this technique distinguished the drive shaft and crown according to their consistently higher intensity level relative to the surrounding phantom material, it was an effective means to track the crown, even as it moved slightly beyond the focal plane of the camera.

Connection and crown points, E and C defined in Figs. 3 (c) and (d), were detected for motion tracking. As shown in Fig. 5(b), the pixel with high intensity on the drive shaft closest to the crown was E. The pixel in the middle bottom of the high intensity region of the crown was C. The number of pixels from the bottom edge of the image to E or C represented E’s or C’s position within the image and was measured for every frame. The fast Fourier transform (FFT) was applied to identify peak frequencies in E and C motions.

### 2.3. Design of experiment

The crown motion in the vessel phantom was only axially restrained in X direction by locking the control knob during the tests. For each individual test, video and force data collection began 10 s after powering the device up and lasted for 5 s. Five tests were conducted for each crown rotational speed (60,000, 90,000, and 120,000 rpm). The mean and standard deviation (SD) of the results from each of these five repeated tests at the three rotational speeds are presented.

### 3. Results

The crown motion was found to be a combination of high-frequency rotation along the crown’s axis and low-frequency orbiting around the vessel lumen. The measured forces confirmed these rotational and orbital frequencies observed in the crown motion. Results from the three crown rotational speeds (60,000, 90,000, and 120,000 rpm) are presented in Tables 1 and 2 and the analysis of the crown dynamics at 90,000 rpm is here illustrated as an example in Figs. 6–8.

#### 3.1. Crown motion

Fig. 6(a) shows the displacement of the connection point E in the Z direction for 23.3 ms at 90,000 rpm crown rotational speed. It is the superposition of a small-amplitude high-frequency motion upon a large-amplitude low-frequency motion (the data marked in this figure by a dashed line have been low-pass filtered at 50 Hz cutoff frequency). Honing in on a single high-frequency period from 11.1 to 11.8 ms, as shown in Fig. 6(b), one can see via the video images of the crown at 9 time instances with a time step in between of 0.08 ms (Fig. 6(c)) that the point E circled around the crown centerline, indicating the crown rotation.

The displacement of the crown point C in the Z direction over the same 23.3 ms time period is shown in Fig. 6(d). The corresponding 9 images shown in Fig. 6(e) have a time step of 2.9 ms and demonstrate the crown orbiting around the vessel lumen. This orbital motion explains the large-amplitude low-frequency component in the displacement of E (dash line in Fig. 6(a)).

Frequency analysis results of the E and C displacement via FFT are shown in Figs. 6(f) and (g), respectively. The high frequency in E motion (Fig. 6(f)) was 1500 Hz, corresponding to the 90,000 rpm rotational speed of the crown, and is the rotational frequency. The low frequency in E motion (Fig. 6(f)) was 41.2 Hz, close to the crown orbital frequency (41.8 Hz peak frequency in Fig. 6(g)).

The mean and SD of the rotational and orbital frequencies (obtained from the frequency analysis of the E and C displacement, respectively) of the crown motion in the five tests at three rotational speeds (60,000, 90,000, and 120,000 rpm) are summarized in the Table 1. Measured rotational frequencies of 1003 and 1500 Hz matched the rotational speed settings for 60,000 and 90,000 rpm, respectively. At 120,000 rpm, the instability of the crown rotational speed caused this value to range from 1660 to 1870 Hz (corresponding to 99,600 to 111,200 rpm) and is likely due

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**Table 1**

Rotational (high) and orbital (low) frequencies in crown motion at three rotational speeds.

<table>
<thead>
<tr>
<th>Rotational speed (rpm)</th>
<th>Rotational (high)</th>
<th>Orbit (low)</th>
<th>Mean (Hz)</th>
<th>SD (Hz)</th>
</tr>
</thead>
<tbody>
<tr>
<td>60,000</td>
<td>1003.4</td>
<td>19.3</td>
<td>8.5</td>
<td>0.6</td>
</tr>
<tr>
<td>90,000</td>
<td>1499.6</td>
<td>38.2</td>
<td>3.0</td>
<td>1.7</td>
</tr>
<tr>
<td>120,000</td>
<td>1660–1870</td>
<td>40.5</td>
<td>0.4</td>
<td></td>
</tr>
</tbody>
</table>

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**Table 2**

Force measurement at three rotational speeds.

<table>
<thead>
<tr>
<th>Rotational speed (rpm)</th>
<th>Direction</th>
<th>( f_c ) (Hz) Mean (SD)</th>
<th>( A_c ) (N) Mean (SD)</th>
<th>( f_r ) (Hz) Mean (SD)</th>
<th>( A_r ) (N) Mean (SD)</th>
<th>( F_{peak} ) (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>60,000</td>
<td>Z</td>
<td>1006.4 (12.4)</td>
<td>0.074 (0.001)</td>
<td>19.5 (0.9)</td>
<td>0.025 (0.002)</td>
<td>0.099</td>
</tr>
<tr>
<td></td>
<td>Y</td>
<td>993.5 (4.3)</td>
<td>0.086 (0.009)</td>
<td>19.4 (1.0)</td>
<td>0.018 (0.001)</td>
<td>0.104</td>
</tr>
<tr>
<td>90,000</td>
<td>Z</td>
<td>1500.2 (0.4)</td>
<td>0.255 (0.014)</td>
<td>38.1 (1.3)</td>
<td>0.169 (0.010)</td>
<td>0.424</td>
</tr>
<tr>
<td></td>
<td>Y</td>
<td>1500.2 (0.4)</td>
<td>0.111 (0.011)</td>
<td>38.3 (1.7)</td>
<td>0.300 (0.013)</td>
<td>0.211</td>
</tr>
<tr>
<td>120,000</td>
<td>Z</td>
<td>1637–1927</td>
<td>0.202 (0.007)</td>
<td>40.5 (0.4)</td>
<td>0.116 (0.007)</td>
<td>0.318</td>
</tr>
<tr>
<td></td>
<td>Y</td>
<td>1645–1903</td>
<td>0.117 (0.002)</td>
<td>40.7 (0.3)</td>
<td>0.093 (0.002)</td>
<td>0.210</td>
</tr>
</tbody>
</table>
to limitations of the driving motor. The crown orbital frequency in the vessel lumen for each rotational speed was 19.3, 38.2, and 40.5 Hz.

Figs. 7(a) and (b) show the crown motion captured with the high-speed camera aimed along the vessel axis (X direction). Fig. 7(a) traces a cycle of crown rotation in 0.72 ms when E (turquoise dot) completed one circle counterclockwise around C (magenta dot). The crown rotated about its cylindrical axis and moved smoothly (no high-frequency C motion in Fig. 6(d)) against the vessel. Fig. 7(b) demonstrates a cycle of the crown orbiting to be about 24 ms with C traveling around the vessel lumen counterclockwise. The rotational and orbital directions of the crown were observed to be the same. To summarize the high speed camera observation of the crown rotation and orbiting, two schematic views are presented in Figs. 7(c) and (d).

3.2. Contact force

Fig. 8 shows the measured force in the Z- (F2) and Y-direction (Fy) for one orbital period (24.4 ms) at the 90,000 rpm crown rotational speed, the connection point E (a) measured motion, (b) zoom-in view of a high-frequency period, and (c) corresponding images; the crown point C (d) measured motion and (e) corresponding images; and motion frequency analysis of (f) E and (g) C.
rotational speed. The combination of high and low frequencies was clearly seen in Figs. 8(a) and (c). A low-pass filter (50 Hz cutoff) was applied, and the filtered data are shown in red dash line. The two dominant frequencies obtained from the FFT were 1500 and 40.6 Hz for $F_Z$ and 1500 and 41.3 Hz for $F_Y$ as shown in Figs. 8(b) and (d), respectively. These two frequencies agree with the image-based measurement of 1499.6 Hz rotational and 38.2 Hz orbital frequencies (seen in Table 1).

The amplitudes of a representative rotational and orbital frequency period are marked as $A_r$ and $A_o$, respectively, in Fig. 8(a). The force $F_Z$ can be represented as:

$$F_Z = A_r \sin(2\pi f_r t) + A_o \sin(2\pi f_o t)$$  \hspace{1cm} (1)

where $t$ is the time, $f_r$ and $f_o$ are the rotational and orbital frequencies, and $A_r$ and $A_o$ are the average amplitudes of the force components in the Z-direction in the rotational and orbital frequency, respectively. Adding $A_r$ and $A_o$ gives the average peak force, $F_{peak}$. The same analysis is repeated for $F_Y$. Table 2 summarizes the mean and SD of $f_r$, $f_o$, $A_r$, and $A_o$ for the five repeated tests and $F_{peak}$ at the three rotational speeds for $F_Z$ and $F_Y$. The $A_r$ and $A_o$ were the highest at a rotational speed of 90,000 rpm, with the $A_r$ and $A_o$ at 120,000 rpm close to those at 90,000 rpm and higher than those of 60,000 rpm. The $A_r$ and $A_o$ in the Z-direction were found to be higher than those in the Y-direction, possibly due to the effects of gravity and the dynamic response of the soft tissue phantom. More detailed study is required to understand the effect of crown rotational speed on $A_r$ and $A_o$. 

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**Fig. 7.** Crown rotation and orbiting: (a) one rotational cycle and (b) one orbital cycle observed by high-speed camera in axial direction when the crown rotates at 90,000 rpm (E in turquoise color, C in magenta color, and vessel lumen in circle), and (c) front and (d) perspective schematic views of the crown rotation and orbiting. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

**Fig. 8.** Force measurement at 90,000 rpm crown rotational speed: $F_Z$ in the (a) time and (b) frequency domain; $F_Y$ in the (c) time and (d) frequency domain.
4. Discussions

Herein we have investigated crown motion and its contact force based on high-speed image capture and force measurement in a tissue-mimicking phantom. The crown motion and contact force consist of two dominant, rotational and orbital, frequencies.

4.1. Comparison of $f_r$ and $f_o$ measured based on image and force

At 60,000 and 90,000 rpm, the values of $f_r$ in Tables 1 and 2 are very close. At 120,000 rpm, $f_r$ varied within a similar range without a conclusive value for comparison. For $f_o$, the image-based measurements (19.3, 38.2, and 40.5 Hz in Table 1) were almost equal to those in Table 2 for $F_r$ (19.5, 38.1, and 40.5 Hz) and $F_o$ (19.4, 38.3, and 40.7 Hz) with less than 1% discrepancy, possibly as a result of the different sampling frequencies and the accompanying signal processing done for each method. The rotational frequency term exists due to the wedge shape of the crown (Fig. 1) leading to the varying contact area with the vessel during the crown rotation. The orbital frequency component results from the crown orbiting centrifugal force. As shown in Fig. 9, a linear fit between $\ln(f_r)$ and $\ln(f_o)$ is observed with slope values of 2.41 and 2.34 and $R$-square values of 0.93 and 0.98 for $F_r$ and $F_o$, respectively, at three rotational speeds, confirming the quadratic relationship of the crown’s orbital frequency to its the centrifugal force.

4.2. Heat dispersion and plaque stress softening

The crown orbital motion could reduce the heat accumulation and tissue thermal injury. Abrasive sanding is an energy intensive process and its accompanying heat, if accumulated, can cause blood coagulation and tissue thermal injury during atherectomy. The combination of rotational and orbital motions of the crown avoids any continuous contact between a specific region of the vessel and the rotating crown and allows continuous blood flow. Such characteristic behavior of the crown motion could be exploited to aid in heat dispersion making orbital atherectomy safe with respect to thermal necrosis of the artery wall [17].

Cyclic loading on the vessel in orbital atherectomy could soften the plaque tissue. Several studies [27–30] have demonstrated the stress softening of atherosclerotic plaque, similar to the Mullins effect in rubber [31]. In orbital atherectomy, the plaque undergoes cyclic loading due to the crown’s orbital motion. The crown rotational motion contributes additional cyclic loading, elevating the local stress and further enhancing the stress softening. This pulsatile force into the tissue may increase the compliance of the lesion, facilitating higher rates of success in angioplasty and stenting, as was observed in the CALCIUM 360 [12], COMPLIANCE 360˚ [13], and ORBIT I and II [14,15] clinical trials.

4.3. Limitations

Currently the absence of any calcified plaque in the region of abrasion stands as a limitation to these results. However, a follow up study wherein calcified plaque will be embedded within a tissue phantom to study the abrasive crown and hardened plaque interaction is planned. Furthermore, the vessel of this study is straight and the flow rate is constant through the current tissue-mimicking phantom. The crown dynamics study in atherectomy needs to be expanded to vessel phantoms with curved geometry, varying diameters, and the pulsatile hemodynamics.

4.4. Conclusions

This work has revealed an important element of crown dynamics in orbital atherectomy, namely that the crown rotates about its axis and orbits around the vessel axis and that this motion results in the rotational and orbital frequencies in the contact forces between the crown and vessel, which could facilitate heat dispersion and tissue softening of the procedure. This study lays the foundation for future research in crown dynamics numerical modeling and the calcified plaque material removal mechanism in orbital atherectomy.

Conflicts of interest

None declared.

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Ethical approval

Not required.

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