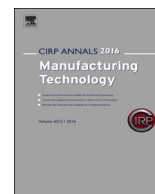




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Experiment and smooth particle hydrodynamics simulation of debris size in grinding of calcified plaque in atherectomy

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ABSTRACT

This research studies the debris size in grinding of hardened calcified plaque inside the artery. Experiments for grinding of bone surrogate for calcified plaque at 135,000, 155,000 and 175,000 rpm using a 2.5 mm diameter diamond wheel were conducted and the debris size was measured by laser scattering. The smooth particle hydrodynamics (SPH) simulation was developed to predict the debris size in grinding. Experimental results showed that debris size matched well by the SPH grinding simulation with a 0.91 Pearson correlation coefficient. The debris size was generally smaller than 40 μm and decreased with higher wheel speeds.

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1. Introduction

Internal grinding of hardened calcified plaque, clinically known as atherectomy, is a minimally invasive catheter-based interventional cardiovascular procedure to remove the atherosclerosis in the arterial wall to restore the blood flow using a diamond grinding wheel. Debris in atherectomy remains in the blood. Atherectomy has a high complication rate [1]. One of the complications in atherectomy is the slow-flow or no-reflow, occurred in about 1.2–7.6% [1,2] of clinical cases. The oversized debris blocking the vessel is the likely cause.

A debris smaller than 30 μm is generally considered to be safe to pass through or be absorbed by the microvasculature. In the blood, the size of red blood cells is 3–8 μm and platelets are about 2 μm [3]. Among five main types of white blood cells, monocyte has the largest size: 15–30 μm [3]. The goal of this study is to conduct experiments to measure the debris size and develop a smooth particle hydrodynamics (SPH) model to predict the debris size in atherectomy by grinding of bone surrogate.

Studies have been conducted to investigate the debris size in atherectomy [4–8]. In rotational atherectomy, Hansen et al. [4] found that about 98% of the debris was smaller than 10 μm using the rabbit iliac artery, Ahn et al. [5] discovered that 90% of debris was smaller than 20 μm using calcified plaque harvested from fresh cadaver, Zacca et al. [6] found that 90% of debris size was less than 8 μm , 5% from 9 to 41 μm and 5% from 41 to 250 μm using the hydroxyapatite/poly lactide (HA/PLA) surrogate and Kim et al. [7] found that 90% of debris was smaller than 10 μm with some large, over 200 μm , debris using the HA/PLA surrogate. In orbital

atherectomy, Kohler et al. [8] found the average debris size was 2 μm using the graphite surrogate. Our review shows that quantitative study of the grinding speed effect and modelling to predict debris size are lacking. In grinding, a high wheel speed can reduce the maximum undeformed chip thickness and debris size. In this study, atherectomy experiments and SPH modelling were conducted to study the effect of wheel speed on debris size.

SPH utilizes a set of discrete particles to model the workpiece. SPH is a mesh-free Lagrangian method and can avoid the mesh tangling issue of large deformation in finite element modelling (FEM). SPH has been applied to predict cutting forces and identify the transition from continuous to shear localized chip formation in orthogonal cutting [9] and simulate the shear band formation in turning of titanium alloys in 2D [10] and 3D [11]. For grinding, 3D SPH was applied to study the crack propagation in diamond grinding of silicon carbide [12]. This study advances the 3D SPH to model the grinding of bone surrogate and quantify the debris size distribution in atherectomy.

This study quantifies the debris size distribution in atherectomy using the SPH method. The rotational atherectomy experimental setup for grinding of bone surrogate to collect the debris is first introduced. The laser scattering measurement of the debris size and laser confocal microscopy measurement of grit tip geometry and ground surface grooves depth are presented. SPH model for bone grinding is described to calculate the debris size in simulation. Experimental and SPH modelling results of debris size distributions are compared and discussed.

2. Experiments setup

Fig. 1(a) shows the experiment setup, which consists of the grinding device, fluid delivery and arterial phantom.

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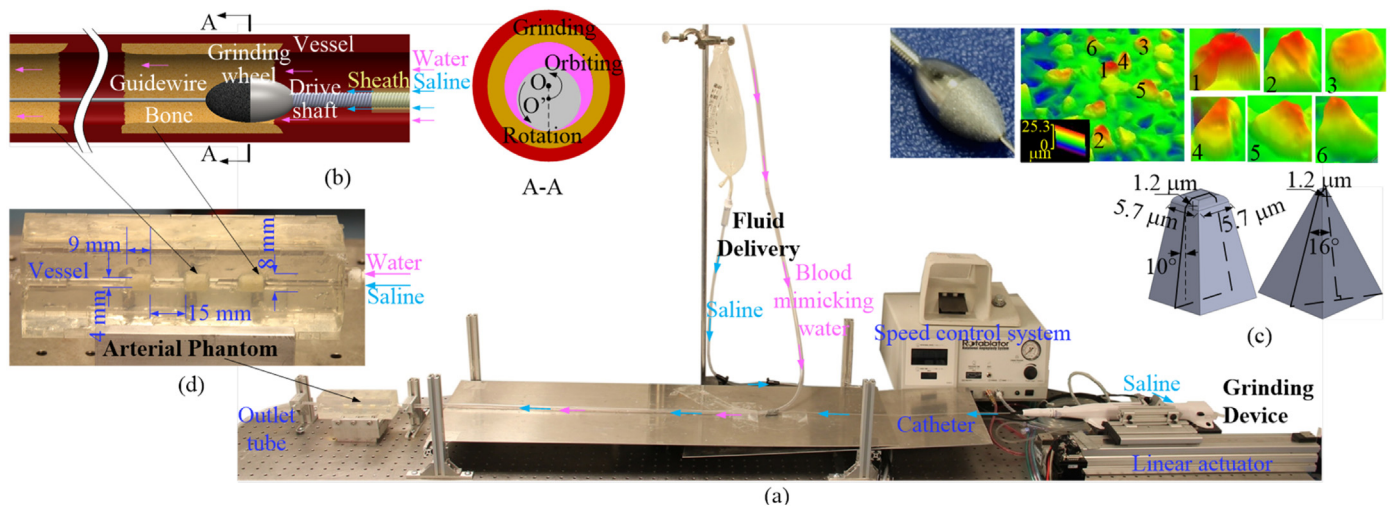


Fig. 1. Experiment setup for rotational atherectomy: (a) overview, (b) surrogate bone grinding and grinding wheel motion, (c) diamond grinding wheel and grit shape and (d) arterial phantom.

2.1. Grinding device

This study utilizes the rotational atherectomy device (Rotablator™, Boston Scientific) which consists of: (1) air turbine, (2) linear stage and (3) catheter [13]. The grinding wheel speed, ranging from 60,000 to 230,000 rpm, is set manually by adjusting the air pressure delivered to the air turbine. A servo-controlled linear stage (Model SM2315D, Moog Animatics) moves the grinding wheel across the bone surrogate at a given speed inside the arterial phantom. Fig. 1(b) shows the catheter includes the stationary sheath and guidewire and the rotational drive shaft and diamond grinding wheel. The drive shaft connects the grinding wheel to the air turbine's spindle motor. The metal single-layer grinding wheel has a spheroid shape with 2.5 mm in diameter and electroplated with diamond abrasive. The grinding wheel rotates along its axis (O') and orbits around the axis of bone surrogate (O), as shown in cross-section A-A. Fig. 1(c) shows the grinding wheel surface scanned by the laser confocal microscopy (Model LEXT OLS4000, Olympus) to measure the shape of diamond tips. Among 100 measured grits, two simplified types of grit tip, the flat and round tips (Fig. 1(c)), were identified for SPH modelling. The ratio of flat to round tips was about 1:1.

2.2. Fluid delivery

Two types of fluid were utilized in this atherectomy experiment, marked by arrows in Fig. 1(b). One was the blood mimicking water, which was filtered using a water purification system (EMD Millipore Milli-Q® by Merck KGaA) to remove contaminating particles. The flow rate was set to be 40 ml/min [13] to simulate the blood flow in the femoral artery. The other was saline, which flowed inside the catheter to provide the lubrication and cooling for the high speed rotating drive shaft. The saline flow rate was 40 ml/min [13].

2.3. Arterial phantom

Fig. 1(d) shows the arterial phantom with three ring-shaped bovine bone surrogates (representing the calcified plaque) embedded in polyvinyl chloride (PVC) phantom, which has the inside diameter (4 mm), thickness (2 mm) and elastic modulus (45 kPa) matching to those of peripheral artery [13]. The surrounding soft PVC has 8 kPa elastic modulus, which matches to that of muscle surrounding peripheral artery [13]. Three bones with 4 mm inside and 8 mm outside diameters and 9 mm in length were placed 15 mm in space in the arterial phantom.

Two arterial phantoms were used in the experiments, one for the debris study and another for the groove depth measurements. For the debris size study, the first bone surrogate in an arterial phantom was ground at 135,000 rpm wheel speed, 5 times across

the bone in the axial direction at 10 mm/s. The same grinding process was repeated in the second and third bone surrogates at 155,000 and 175,000 rpm, respectively. The mixture of water and bone debris was collected in each test for debris size measurement. Another arterial phantom was used to measure the depth of grooves on ground surface. Three bone surrogates were each ground in one pass at 135,000, 155,000 and 175,000 rpm wheel speed (at the same 10 mm/s axial feed rate). In summary, a total of 6 grinding experiments were conducted using two arterial phantoms.

The water and saline fluids were mixed and flowed through the grinding region. This water mixture carried grinding debris and was collected in three tests at 135,000, 155,000 and 175,000 rpm wheel speeds. For each test, the debris size distribution was obtained by measuring 10 fluid samples using the laser diffraction particle sizing technique (Mastersizer S2000 by Malvern). Before the particle size measurement, debris in water was dispersed for one hour by ultrasonic dispersing and deagglomeration (PS-30A by Shenhuatai). A small sample of debris and water mixture was dried and observed using the scanning electron microscopy (SEM) for the shape and size.

3. SPH model for grinding

3.1. SPH grinding model

Fig. 2 shows the SPH model to simulate the debris formation and size distribution in grinding of bone surrogate. The bone workpiece, meshed by SPH particles with initial distance of s , has the inner radius R , center axis O (Fig. 1(b)), and length, width and height of a , b and c , respectively. SPH particles on the bottom and right surfaces are fixed. The diamond grit is rotated around the axis grinding wheel O' (Fig. 1(b)) with a radius of r . The depth of cut a_p is the maximum distance between the bone top surface and the path of the grit tip. This value is determined experimentally by

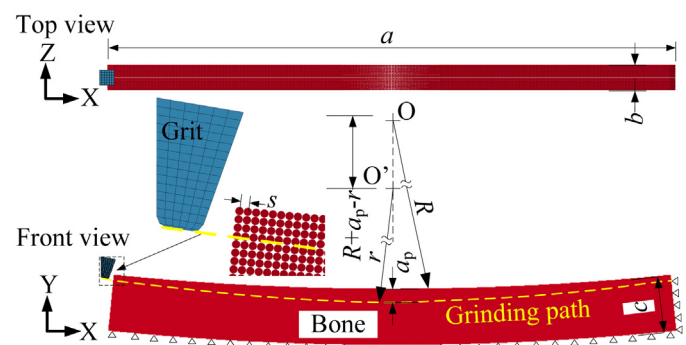


Fig. 2. The single flat tip grit engagement in SPH model.

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