EVALUATION OF THE CROSSING FORCES OF A VIBRATING GUIDEWIRE IN CONTACT WITH MODEL CALCIFIED MATERIALS

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INTRODUCTION

Peripheral arterial disease (PAD) affects millions globally, with over 21 million cases reported in the U.S. in 2020 [1]. It occurs when leg arteries become narrowed or blocked, leading to complications like critical limb ischemia, where blood flow is severely restricted. Standard treatments, such as bypass surgery and endovascular procedures, aim to restore blood flow [2]. However, advanced chronic total occlusions with calcified plaques, often prevent flexible guidewires crossing into the true lumen of the distal vessel, accounting for approximately 80% of procedural failure [3]. The use of high-frequency (20- 50 kHz) mechanical vibrations (0-50 µm) delivered to the distal tip of specialist guidewires has been shown to ablate calcified plaques, as shown in Figure 1 [4].

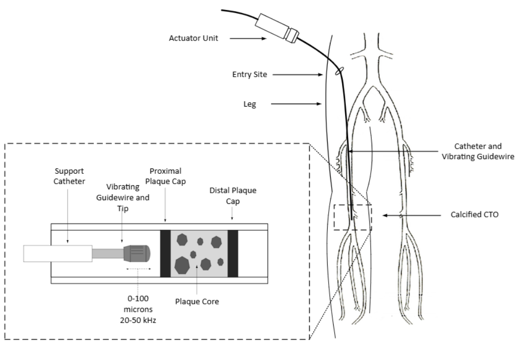

Figure 1 Vibrating guidewire in peripheral artery

This study evaluates the ability of a vibrating guidewire to ablate centrally though model calcified materials of known composition and measure the crossing forces under controlled feed- rates. The results aim to inform the optimal design parameters for vibrating guidewires, enhancing their ability to cross calcified lesions and improve PAD patient outcomes.

MATERIALS AND METHODS

An experimental setup was developed to control the feed-rate of a vibrating guidewire for precise measurement of forces during ablation of calcified samples. The NiTi guidewire (distal-tip diameter ~ 18 tau) was coupled to an actuator unit and vibrates with an amplitude of approximately 10-20µm in the 35- 45 kHz range. The guidewire, enclosed in a catheter, was submerged in a fluid-filled tank at 37°C, with calcified samples mounted on a load cell. The setup was controlled via LabVIEW software, which interfaced with a data acquisition system. BegoStone samples, prepared at three concentrations, were tested by advancing the vibrating guidewire through them and capturing the force data. Force profiles for all crossings (10 per concentration) and at three feed-rates were recorded and statistical metrics, including mean crossing force and maximum force and were extracted and compared across batches.

RESULTS

The plot of mean crossing force vs feed-rate in shown in Figure 2 As material concentration increased, the force required to ablate also increases, with a median of mean forces ranging from 0.2 to 3 cN. Higher feed-rates consistently led to increased mean forces across all concentrations. For the current test setup the active guidewire failed to penetrate the densest BegoStone batch at the highest feed-rate (40 mm/min). This issue resulted in the exclusion of this batch from the analysis.

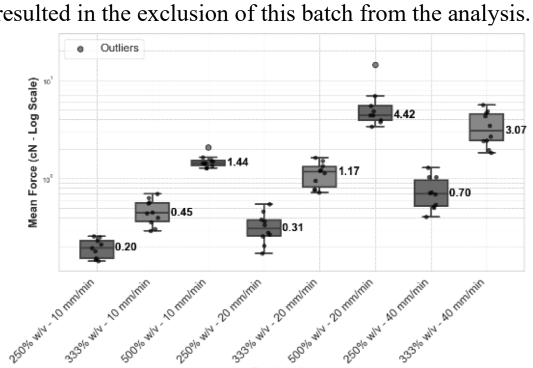

Figure 2 Box plot of mean forces for BegoStone batches.

DISCUSSION

The vibrating wire ablated centrally through all samples of Begostone concentration at feed-rates of 10 and 20 mm/min. At the highest concentration of Begostone and feed-rate of 40 mm/min the crossing force exceeded the buckling load of the wire.

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