Comparing the Effect of Stent Geometry on Blood Flow Rate of Curved Coronary Artery Stenosis

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Summary

One of the world's leading causes of death is Coronary Heart Disease (CHD); it has been implicated in about 12% of all deaths globally. Plaque accumulation within the heart's arteries causes CHD and leads to fatal complications including heart attack and stroke. Currently, the treatment for moderate plaque levels in CHD is placing a stent to hold plaque back from interfering with the blood flow and to deliver preventative drug treatment. Stents are constructed from longitudinal segments called struts, commonly having 8, 10, or 12 struts. Stent struts can change the amount of surface area available for drug delivery and also affect the blood flow rate. Recently, to maximize surface area, researchers have considered stents having a square instead of round strut cross-section. While the new square cross-section provides more surface area, its shape does not appear to be as efficient for the blood flow rate. However, limited investigations have been done on the relationship between the number of struts and their cross-section geometry on the blood flow rate. In this study, we tested the effect of strut design on simulated blood flow rate in a designed artificial heart. The results of this study showed that the 12-strut round cross-section had a higher blood flow rate than the other stent geometries. More research is still needed to investigate additional stent geometries to ensure both the added surface for the restenosis-prevention drug and a maximum blood flow rate are achieved simultaneously.

Introduction

One of the most significant causes of death, accounting for over 12% of global fatalities, is Coronary Heart Disease (CHD). National reports indicate that in the United States, the estimated number of fatalities due to CHD is around the 600,000 (1-2). CHD is caused by a "buildup of plaque in the heart's arteries that could lead to heart attack" (1). There are several risk factors that
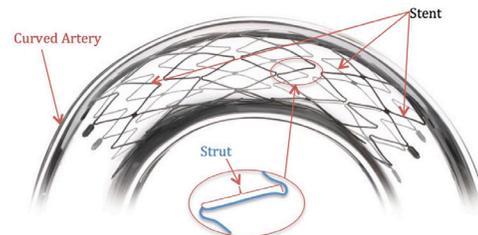

Figure 1: Curved Coronary Artery Stent.

are known to increase the likelihood of CHD including smoking, high-cholesterol diet, high blood pressure, physical inactivity, being obese and overweight, and diabetes mellitus (1-3). Additionally, being overweight or obese combined with having limited or no physical activity may also increase the likelihood of CHD (4-6).

CHD is treated by one of two common approaches depending on the level of plaque (i.e., occlusion) that accumulates in the coronary artery. When the patient's occlusion level is very high, a Coronary Artery Bypass Graft (CABG), Minimally Invasive Direct Coronary Artery Bypass (MIDCAB), or minimally invasive Percutaneous Coronary Intervention (PCI) procedure is conducted (6-8). However, when the patient's occlusion level is moderate, a minimally invasive procedure called angioplasty is performed (5, 9). During the minimally invasive procedure of angioplasty, a catheter and a balloon are inserted through a small puncture in the arm or leg, and then the balloon is inflated to either push the stent in place or contract the area where the occlusion is present. In recent years, many of these angioplasty procedures are combined with placement of the stent to lower the amount of plaque reappearance (2, 4).
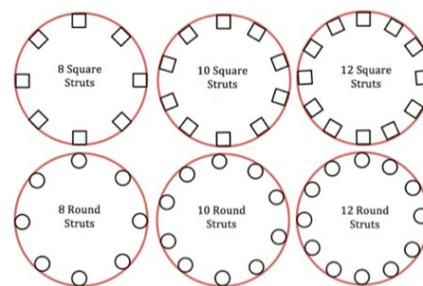

Figure 2: Cross Sectional View of Coronary Artery with Different Stent Geometry.

Figure 3: Lego® NXT™ Artificial Heart. Programmed to pump at 5 heart rates: rest (60 BPM), sitting (75 BPM), standing (90 BPM), walking (110 BPM), running (130 BPM).

After a stent is placed in an artery, occasionally the plaque comes back onto the stent in a process called 'restenosis' (10). To prevent restenosis, cardiac and biomedical researchers began covering the stents with a drug, known as 'drug-eluting stents' (9, 11-13). Nowadays, stents are put in place with two main considerations: 1) achieving a high blood flow rate by opening the narrowed area where the occlusion was building up, and 2) maximizing the area for the restenosis-prevention drug. (9, 10, 13) The number of struts (longitudinal segments that make up the stent) (**Figure 1**) and the shape of the cross-section affect the blood flow and surface area. Usually stents will have 8, 10, or 12 struts. (14-15) When stents were first made, they had a round cross-section for the stents' struts, but cardiologists began using a square cross-section to maximize the amount of surface area for the restenosis-prevention drug (**Figure**
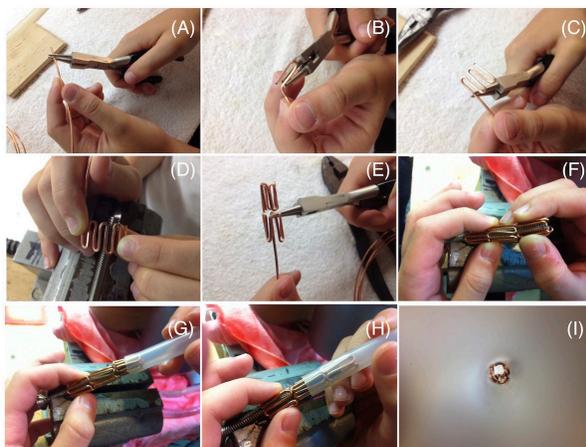
Figure 4: Implementation of the Stents into the Silicone Arteries. (A-F): Bending wire into stent shape; G-H: Inserting stent into the silicone tube; I: Stent inside the silicone tube).

2). While the new struts' square cross-section provides more surface area for the restenosis-prevention drug, its very nature of being a square does not appear to be as efficient when it comes to improving the blood flow rate. Foundational fluid dynamics supports the fact that square-shaped objects (noted as 'bluff' or 'blunt' bodies) have higher flow resistance, as measured by a greater
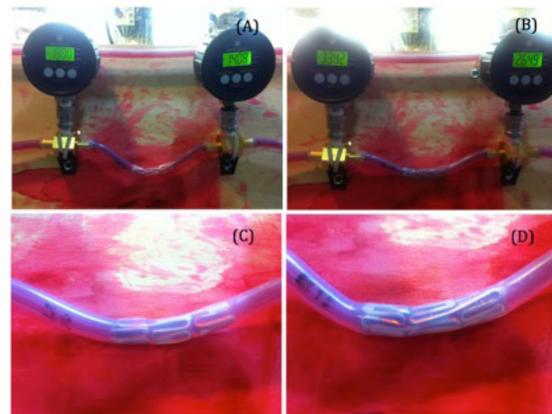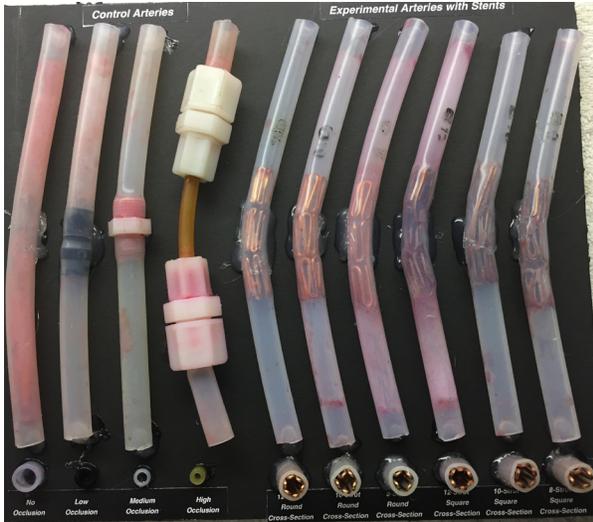

Figure 5: Simulated Curved Coronary Arteries with Square or Round Stents. A-B: Two simulated curved coronary arteries between the sensitive pressure gauges; C: Close-up of a 12 strut square cross-section stent (S12) D: 12 strut round cross-section stent (R12)

Reynolds number (a measure of fluid drag resistance), compared to more rounded shapes or even streamlined bodies, which have a much lower Reynolds number (i.e., lower flow resistance) (8, 16). However, there is limited research comparing square and round stent strut cross-sections, and additional research is still needed to learn more about the differences between stent geometries.

Therefore, the purpose of this study was to determine which stent geometry (round or square cross-section, and 8, 10 or 12 struts) in a semi-curved coronary artery stenosis provides a higher surface for the drug and simultaneously a higher blood flow rate. We hypothesized that the round cross-section stent with higher numbers of struts (i.e., higher overall stent drug-eluting surface) would be better then the square cross-section stent with fewer struts, because the round cross-section stents with higher numbers of struts provide less resistance to blood flow and provide higher surface area for the drug.

Results

In this study, a Lego® NXT™ artificial heart was developed and designed by the researchers (**Figure 3**). The system included a blood-mimicking fluid pumped by the artificial heart from a reservoir tank into silicone tubes that simulated the arteries. In simulating the stents, first silicone tubes were cut with a medical scalpel as well as

Figure 6: Simulated Arteries. The four control simulated coronary arteries with no/low/medium/high occlusion/stenosis levels, and six stent geometries.

operating scissors. Then, copper wire was made into a resolute integrity-style stent by the researchers (**Figures 2 & 4**). This was repeated for the three different amounts of struts (8, 10 and 12) using copper wires with round and square cross-sections (**Figure 4A-F**). Furthermore, these stents were inserted to a silicone tube, emulating an artery (**Figure 4G-I**). Within the silicon tubes, the flow rate was calculated from the measures of the distance between the gauges, the pressure differences between the two sensitive pressure gauges (**Figure 5**), and the measured radiuses using Poiseuille's Law as stated with more details in the Methods section.

There were 50 experiments in total: a control artery

(no plaque), three plaque levels (low, medium, and high), and the six arteries with stents over five different heart rates (**Figure 6**). The Lego® NXT™ artificial heart was designed and programmed to operate at these five different heart rates to emulate a person's different heart rate levels in Beats-Per-Minute (BPM): rest (60 BPM), sitting (75 BPM), standing (90 BPM), walking (110 BPM), and running (130 BPM). The experiments compared different stent geometries by comparing the pressure of the blood-mimicking fluid before, as well as after, the stent in order to determine the blood flow rate at the five different heart rate levels (**Figure 5**).

The three independent variables were the number of struts (8, 10 and 12), the cross-section (round and square), and the heart rate. The dependent variable was the blood flow rate (as calculated by Poiseuille's Law (17) using the pressure difference). This study had several control variables including the type of the silicone tubes used, the pressure gauges used, the temperature, the distance between the two gauges, the radius of the silicone tubes, the percentage of humidity in the room, and the viscosity of fluid.

Overall, the results of t-test analyses indicate that there was no significance difference in blood flow rate (t=1.766, p=0.38) between the round cross-section stent geometries (R8, R10 & R12) and the square cross-section stent geometries (S8, S10 & S12) for the low average blood flow rates (**Figure 7**). However, a significance difference (t=3.782, p=0.013) was indicated between the two cross-section stent geometries for the high average blood flow rates (**Figure 7**). Moreover, it was observed that the 12-strut round cross-section stent (R12) had the best flow rate out of all the stent
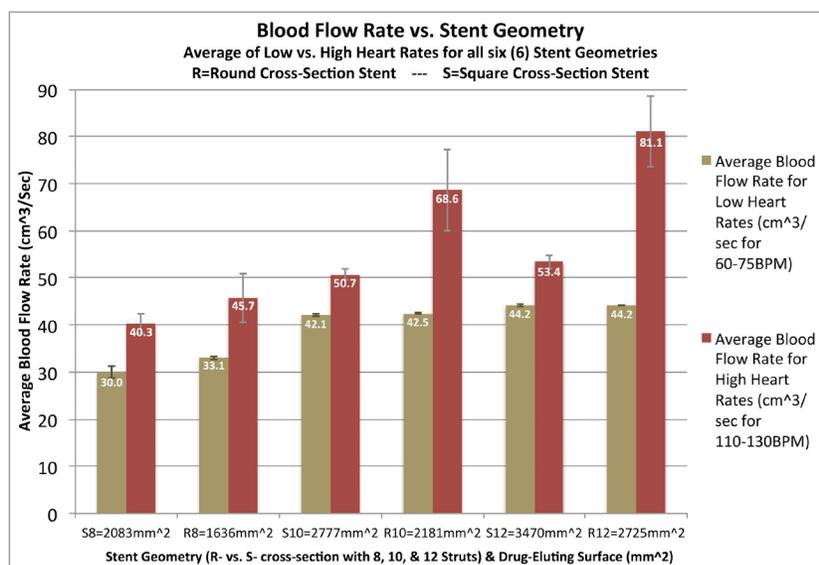
Figure 7: Average Blood Flow Rates for Low vs. High Heart Rates. Six different stent geometries - S8, S10, S12, R8, R10, & R12.

geometries tested (**Figure 8**), demonstrating a higher blood flow rate than the control experiments with high and medium occlusion levels (**Figure 9**). Though the 12-strut square cross-section stent (S12) had the most drug-eluting surface area, it provided a significantly lower blood flow rate compared to the 12-strut round cross-section stent (R12) (average of 53.4 cm^3/sec vs. 81.1 cm^3/sec at the high 130 BPM heart rate) (**Figure 8**). Furthermore, the second best stent geometry when it comes to blood flow rate was the 10-strut round cross-section (R10), with an average of 68.6 cm^3/sec blood flow rate at the high heart rates, compared to the other stent geometries tested (**Figure 8**). Overall, the 8-strut geometry provided the lowest blood flow rate both for the 8-strut round cross-section (R8) and 8-strut square cross-section (S8) with blood flow rates of 45.7 cm^3/sec and 40.3 cm^3/sec, respectively. Overall, the stents with a square cross-section provided more surface for the drug-eluting area than the round cross-section stents. As such, when considering stent geometry with similar surface areas for drug-eluting area and at the same time better blood flow rate, the 12-round cross-section (R12) is better than the 10-square cross-section (S10) because R12 has a surface of 2725 mm^2 vs. 2777 mm^2 for S10, while R12 provides blood flow rate of 81.1cm^3/sec vs. 50.7 cm^3 for S10 (**Figure 7**). Moreover, two other stent geometries with similar surface for drug-eluting area
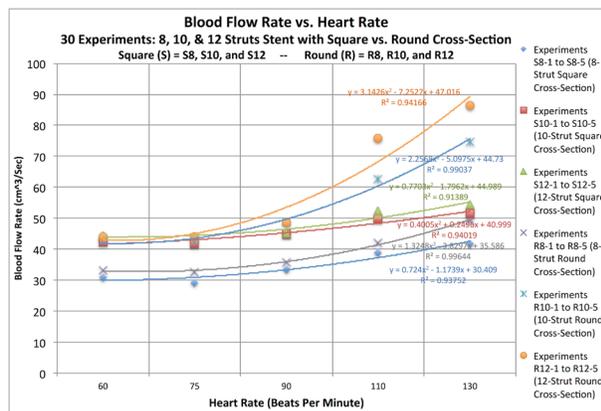

Figure 8: Blood Flow Rates of the Different Stent Geometries. S8, S10, S12, R8, R10, & R12.

are the 10-round cross-section (R10) and the 8-square cross-section (S8) with surface areas of 2181 mm^2 and 2083 mm^2 respectively; however, the R10 provides better blood flow-rate than the S8 with 68.6 cm^3/sec vs. 40.3 cm^3/sec, respectively.

Discussion

Ever since their introduction, drug-eluting stents with round cross-sections have been successful. However,

with the increased interest in more surface area on the stent for the restenosis-prevention drugs, cardiologists began to use square cross-section stents. The original dilemma between the round and square cross-section
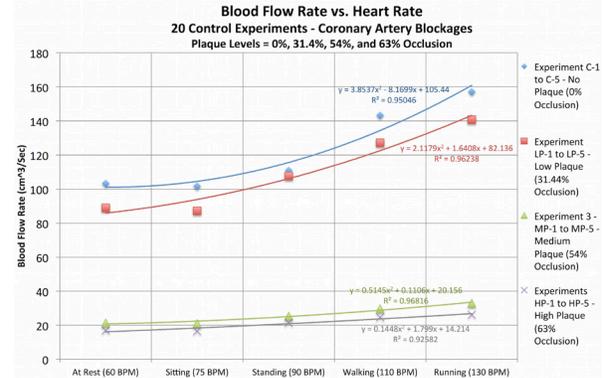

Figure 9: Blood Flow Rates for Each Occlusion Level. The blood flow rate for each of the occlusion levels, as well as the control artery, at each of the five heart rates.

was that surgeons and medical researchers were not entirely clear on which stent geometry provides a higher flow rate. Moreover, many surgeons do not appear to know the impact of the number of struts when it came to blood flow rate. As such, it seems that additional research on comparing square and round cross-section stents, as well as the number of struts in stents, is warranted.

According to the results of this study, the 12-strut round cross-section stent had the highest flow rate among all the stent geometries tested. This research suggests that the stents with high numbers of struts and round cross-sections should continue being utilized in drug-eluting stents so that coronary artery disease patients have a higher blood flow rate in their coronary artery after angioplasty. Such results in the differentiation between the two types, especially in the higher heart rates, may affect a person's health by allowing the person with the round cross-section stents to maintain the ability to be involved in activities like running, while the person with the square cross-section stents may experience some complications in running, but will have more restenosis-prevention drug on the stent. This research can possibly help patients worldwide to make better educated decisions concerning how to treat CHD, and help them have a higher blood flow rate after they are treated. Furthermore, it is evident that additional studies may be needed to further investigate the full effect of using different stent geometries while maintaining a quality blood flow rate for the patients.

There were some challenges with this experiment; the Lego® NXT™ robotic arm of the artificial heart wouldn't pump enough blood-mimicking fluid unless it

was put at a specific angle to start. Another problem was that when the arteries were switched, some "blood" loss occurred, so the artificial heart had to be refilled several times during the experiments (similar to blood transfusion in real operations), but there were some differences between the artificial heart used and an actual procedure on a human. Only at the higher heart rates was the difference in blood flow rate noticeable (**Figure 7**). In general, the objective of stent design is to balance the demand for high blood flow with more surface area for drug placement, while having fewer complications for the patient.

The model used in this study is still valid when it comes to the demonstration of the impact of differences in the occlusion level on flow rate, even though the model included was a simulation of a biological heart. However, an actual procedure on a human would have some differences compared to the artificial heart used. One of these differences includes the process of replacing the experimental artery in the device. The heart reservoir was refilled several times due to some blood loss while switching the artery (similar to blood transfusion in real operations). When the artificial heart was observed pumping and data was recorded, the square stents, due to their cross-section, caused more resistance in the bloodflow within the artery. This is due to the fact that the square cross-section was bulging into the stream of "blood" causing the blood to have a lower flow and increasing mini-turbulence within the flow. However, the round cross-section does not have edges and is round, causing the blood to flow by it with much lower resistance. More research is needed to investigate the difference of using varying stent geometries in the terms of blood flow rate and surface area. Future research can be done with a more realistic artificial heart and with a greater variety of stent geometries such as elliptical, rounded-corners rectangular, or variations of half-body streamlined cross-sections to assess their improvement of both drug-eluting surface and blood flow rate.

Methods

The procedure included designing, developing, and programming an artificial heart. A Lego® NXT™ artificial heart was developed and designed from ordinary Lego and Lego NXT™ 2.0 pieces. It uses one Lego NXT™ programmable "brain" brick and two Lego robotic motors (servos) to form a programmable arm, with other Lego components connected, which pressed on a fluid quart pump that sat on top of a 16 oz reservoir tank (**Figure 3**). Furthermore, the Lego Mindstorms® NXT™ application was used to make a specialized program for the artificial heart to run at five different heart rates using five different speeds of the servos. In the system, the blood-mimicking fluid that was circulated was held in a reservoir

tank (**Figure 3**). Two pressure gauges, connected to the artificial heart by a silicone tube, measured the pressure before and after the experimental area. In the experimental area, the occlusion levels or experimental tubes with the different stent geometries were placed to measure the pressure. Within the artificial heart, the data was collected from the readings from the measuring gauges (in Pound-per-square-inch or PSI). Afterward, the data was converted from PSI to millimeter mercury (mmHg), and then Poiseuille's Law was used to calculate blood flow rate (17) (**Equation 1**). Moreover, the length of the tubing between pressure gauges (L), the viscosity of the fluid (η), and the interior radius of the tubes (r) were used for the Poiseuille's Law calculations. There were other experimental constraints including the temperature
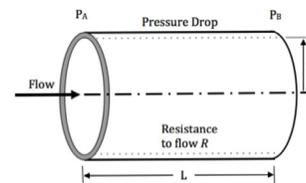
$$Volume\ Flowrate\ (F) = \frac{P_A - P_B}{R} = \frac{\pi \cdot (P_A - P_B) \cdot r^4}{8 \cdot \eta \cdot L}$$
$$= \frac{\pi \cdot (Pressure\ Difference) \cdot (radius)^4}{8 \cdot (viscosity) \cdot length}$$

$$Resistance\ to\ Flow\ (R) = \frac{8 \cdot \eta \cdot L}{\pi \cdot r^4}$$

Equation 1. Poiseuille's Law of calculating flow rate from pressure differences.

(35°C), the humidity (76%), the type of the silicone tubes used, the radius of the silicone tubes used (mimicking coronary arteries [4.375 mm for the control/clear artery]), the flow gauges used (high accuracy digital pressure gauges), and the viscosity of the fluid (mimicking blood [0.0033 Pa·s]).

The data collection was done on one control artery, three occlusion levels, and the six types of stents placed in silicone tubing, providing a total of 50 experimental readings. The experiment was done in two phases, where Phrase I started with the control and three occlusion levels, providing 20 readings (four arteries x five heart rates = 20), followed by Phase II with the six types of stents, providing an additional 30 experimental readings (six arteries x five heart rates). Phase I experiments included one clear (control) artery (r=4.375mm) and three levels of occlusions created with three plastic flow-narrowing couplings – low (r=3 mm), medium (r=2 mm), and high (r=1.625 mm). Each one of these was done on five simulated heart rates: rest (60 BPM), sitting (75 BPM), standing (90 BPM), walking (110 BPM), and running (130 BPM), yielding a total of 20 experimental readings. Through measuring the blood flow rate of a clear artery (simulated by a silicone tube),

the pressure differences, and the blood flow rate for five heart rates, we simulated a realistic range of cases. Subsequently, the three different occlusion levels were put in the artificial heart, yielding 16 additional readings of pressure variances that produced blood flow rates for the five levels of heart rates at low, medium, and high occlusion rates (**Figures 8 & 9**).

Afterwards, the stents were developed: 8, 10 and 12 struts with a round cross-section; as well as 8, 10, and 12 struts with a square cross-section. The stents were made from copper wire (16 gauge) and with round and square cross-sections. Each stent was put in a silicone tube of the same size and radius. After the construction of the six stents, they were placed in the artificial heart apparatus, yielding 30 readings more, which produced blood flow rates of the five different heart rates. The experiments included in Phase I and II produced a total of 50 readings (**Figures 8 & 9**).

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