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Comparing Suturing And Stapling In Coronary Bypass Grafting Anastomosis

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Summary

Coronary heart disease (CHD) is the number one killer worldwide and is responsible for 12.2% of all deaths. CHD is caused by a plaque buildup in the heart's arteries, which can lead to a heart attack. If the plaque buildup level in the coronary arteries is high (i.e. 'occlusion'), the most common treatment that involves surgery is the coronary artery bypass graft (CABG), which essentially bypasses the blocked area with a grafted blood vessel to bring blood to the heart muscle. Connecting the grafted blood vessel with the coronary artery is called anastomosis. For years, graft anastomosis has been done using suturing by hand. In the past several years, the U.S. Food and Drug Administration (FDA) approved products that allow a surgeon to do stapling anastomosis. However, while limited research has been done, additional research is still needed to learn more about the differences between suturing and stapling of such grafting anastomosis. Therefore, the purpose of this study was to investigate which suturing type (suturing vs. stapling) of coronary bypass grafting anastomosis provides a higher blood flow rate. After designing, developing, and programming an artificial heart capable of operating at different heart rates using a Lego® NXT™ robotic arm, we recorded the pressure on two gauges in order to calculate blood flow rate using Poiseuille's Law.

The results showed the suture anastomosis had a higher flow rate than the staple, because the staple slightly deformed the artery. Moreover, the results of this research follow Poiseuille's Law in that a small reduction in an artery radius indeed can have a significant effect on the reduction the blood flow rate. Future research is recommended to learn more about how to improve the staple anastomosis in terms of improving blood flow rate in the grafted artery.

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Introduction

Coronary heart disease (CHD) is a major heart condition. It is the number one killer worldwide, and it is responsible for 12.2% of all deaths (1). Although this percentage sounds low, the number of deaths resulting from CHD is about six times more than the number caused by driving accidents (2.2%) (1). Every year, about 600,000 Americans die from CHD. Of those, some are unaware that they have CHD, while others are under the care of cardiologists for heart conditions. CHD is caused by a "buildup of plaque in the heart's arteries that could lead to heart attack" (2). Symptoms of CHD range from stroke, heart attack, extremely high blood pressure, arrhythmia (irregular heartbeat), chest pain, and shortness of breath (3). Some of these symptoms vary in strength and duration.

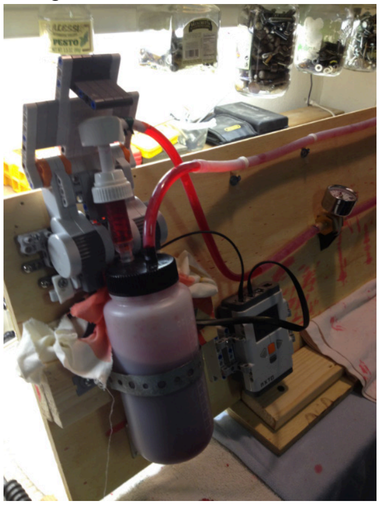


Figure 1: The Lego® NXT™ artificial heart was programmed at five different heart rates (rest (60 BPM), sitting (75 BPM), standing (90 BPM), walking (110 BPM), and running (130 BPM)).

There are several risk factors that can increase the likelihood of CHD, including smoking, high cholesterol, high blood pressure, physical inactivity, being obese and overweight, as well as diabetes mellitus (2). People who smoke tobacco are 2-4 times more likely to get CHD compared to nonsmokers. A high cholesterol diet is another major risk factor for CHD, because it increases the plaque in the coronary arteries. Additionally, high blood pressure increases the heart rate, which causes the heart to stiffen and results in improper heart function. Moreover, physical activity provides many benefits to the heart, because it helps the heart to become accustomed to different heart rates. However, physical inactivity leads to being overweight and to obesity. This excess fat, usually stored at the waist, results in a higher demand on the heart for blood circulation and an increase of the risk for diabetes. Diabetes can increase the risk of developing heart diseases, including CHD (2).

There are two common ways to treat CHD. First, if the plaque level in the coronary arteries (i.e. occlusion) is not high, a common, nonsurgical procedure, known

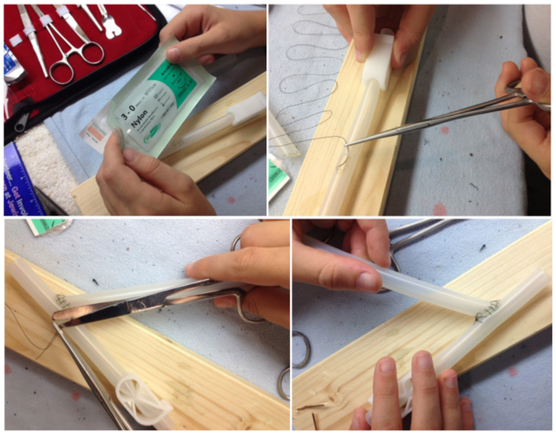


Figure 2. The suturing of simulated coronary bypass graphing anastomosis.

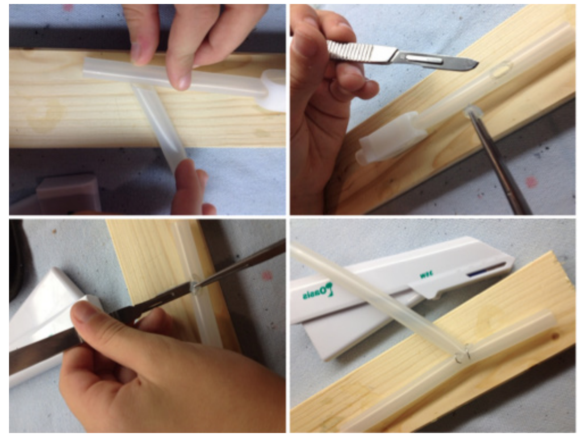


Figure 3. The stapling of simulated coronary bypass graphing anastomosis.

as angioplasty, can be performed (4). Angioplasty is a procedure where a catheter and a balloon are inserted through a small puncture in the leg or arm, and where the balloon is inflated when the catheter reaches the blocked artery. Angioplasty is usually done with a stent to lower the risk of plaque reappearing (i.e. restenosis) (2). When the occlusion level is very high, a surgery is done to do a coronary artery bypass graft (CABG). CABG "treats blocked heart arteries by creating new passages for blood to flow to [the] heart muscle. It works by taking arteries or veins from other parts of [the] body - called grafts - and using them to reroute the blood around the clogged artery" (3). Connecting the grafted blood vessel with the coronary artery is called anastomosis (5).

For years, graft anastomosis has been done using suturing by hand. Several years ago, the U.S. Food and Drug Administration (FDA) approved a product that allows a surgeon to auto-suture (i.e. staple) anastomoses (7, 8). The key reason that the FDA approved the stapled anastomosis is due to the proposed reduced time to conduct the anastomosis, which may lead to reducing the risks associated with long surgeries. Such risks include an increase in the risk of complications and longer rehabilitation time (8). Therefore, this study investigated if hand suturing or staple anastomosis will result in a higher blood flow rate. In the case of patents with occlusion, a small decrease in the artery radius produces a significant reduction in their blood flow rate to their coronary artery, which cause an increase on the pressure the heart has to function in order to provide the minimum blood flow rate for its own operation. Therefore, a higher blood flow rate is deemed better when it comes to individuals with occlusion in the artery. This study found that the suture anastomosis indeed had a higher blood-flow rate than the staple because the staple slightly deformed the artery.

Results

In this study, a Lego® NXT™ artificial heart was designed and developed (**Figure 1**). The system included blood-mimicking fluid pumped by the artificial heart from a reservoir tank into silicone tubes that simulated the arteries. Tubes of varying radii were used to simulate different plaque levels. In simulating the suturing anastomosis, first the silicone tubes were cut using medical scalpel and sharp operating scissors. Then the tubes were sutured using nylon sutures with attached reverse cutting circle needle with the aid of a straight locking Kelly forceps (surgical clamp) (**Figure 2**). In simulating the stapling anastomosis, the silicone tubes were cut using medical scalpel and sharp operating scissors. Then the tubes were stapled using disposable sterile stapler with the aid of a straight locking Kelly forceps (surgical clamp) (**Figure 3**). Both the suturing and stapling anastomoses were done under the supervision of an experienced surgeon. The flow-rate within the silicon tubes was calculated from the measure of the pressure differences between the two pressure gauges, along with the distance between the gauges, and the measured radiuses using Poiseuille's Law. The experiment compared suturing and stapling anastomoses by comparing the pressure of the blood-mimicking fluid before and after the anastomosis, in order to calculate the blood flow rate, at five different hear-rate levels (**Figure 4**). The Lego® NXT™ artificial heart was designed and programmed to operate at these five different heart-rates to emulate a person's different hear-rate levels in beats-per-minute (BPM): rest (60BPM), sitting (75 BPM), standing (90 BPM), walking (110 BPM), and running (130 BPM).

Figure 4. The two types of simulated coronary bypass graphing anastomoses in the Lego® NXT™ artificial heart.

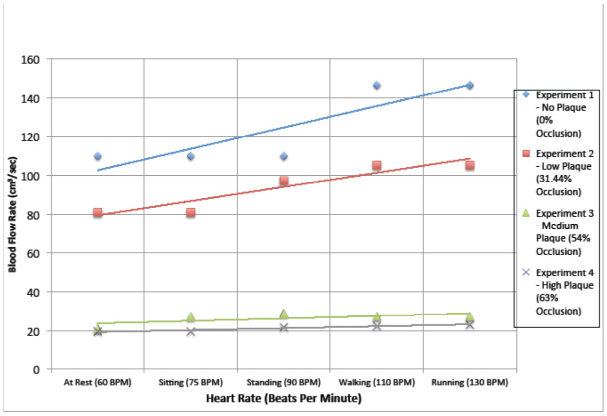


Figure 5. Blood flow rate vs. heart rate on three simulated levels of plaque occlusion level and a control.

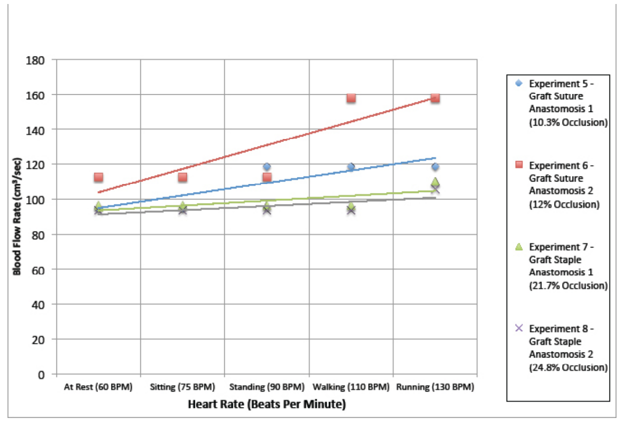


Figure 6. Blood flow rate vs. heart rate on sutures and stapled simulated coronary artery bypass graft anastomosis.

The two independent variables included the suturing type (hand suturing vs. stapling) and the heart rate as well as the tube radius. The dependent variable was blood flow rate (as calculated by Poiseuille's Law (9) using the pressure difference).

Overall, there were 40 experiments conducted to measure the blood flow rate. These included three occlusion levels, a stapling anastomosis (2 replicates), a suturing anastomosis (2 replicates), and a clear artery control over five simulated heart rates. **Figure 5** provides the graphical results of the average blood flow rates (in cm^3/s) for the following experiments: 1 (control – no plaque – "A" in **Figure 8**), 2 (low plaque – "B" in **Figure 8**), 3 (medium plaque – "C" in **Figure 8**), and 4 (high plaque) over the five simulated heart rates. **Figure 6** provides similar graphical results for the following experiments: 5 (graft suture anastomosis 1), 6 (graft suture anastomosis 2), 7 (graft staple anastomosis 1), and 8 (graft staple anastomosis 2) over the five simulated heart rates. Results of experiments 5 and 6, as well as 7 and 8 were aggregated by calculating the mean scores of each of the two experimental types (mean of experiments 5 and 6 for suturing, mean of experiments 7 and 8 for stapling) in Microsoft® Excel, which is represented in **Figure 7**.

In our study, we observed that the suture had a higher flow rate than the staple anastomosis with an average of 120.04 cm^3/s for the suture experiments compared to an average of 97.64 cm^3/s for the staple experiments. In comparison to the plaque levels, the staple had a flow rate similar to the low plaque artery (average blood flow of 97.64 cm^3/s compared to 94.03 cm^3/s, respectively). The suture provided a blood flow rate similar to the clear artery (120.06 cm^3/s vs. 124.65 cm^3/s, respectively) (**Figures 5, 6, and 7**). The suture might take more time, but it allows much higher flow rate then the fast stapling procedure. Additionally, the difference between the suturing and the stapling is minimal in the two lower heart rates: at rest and sitting (**Figure 7**). However, the difference between the two anastomosis types (suturing & stapling) does appear to increase in the three higher heart rates: standing, walking, and running (**Figure 7**). Such results in the difference between the two types, especially in higher heart rates, may affect a person's health by allowing the person with the sutured anastomosis to conduct a healthier life, as they may maintain the ability to engage in activities like running, while it appears from the results shown here that the person with the stapled anastomosis may experience some difficulties in running.

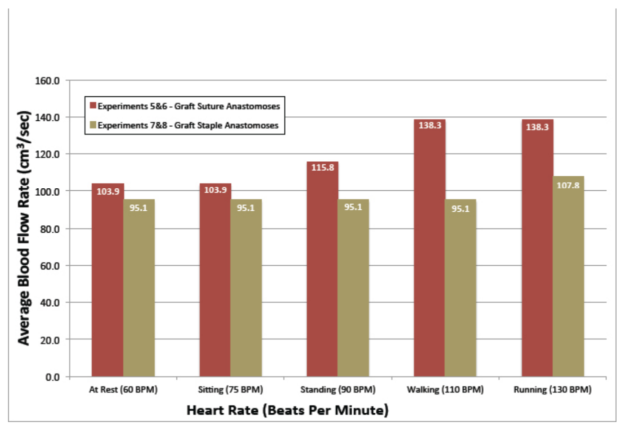


Figure 7. Average blood flow rate vs. heart rate on sutures and stapled simulated coronary artery bypass graft anastomosis.

Discussion

For decades, the use of hand-sutured CABG has been widely successful. However, with the increased interest in reducing surgery time to potentially reduce the risks associated with longer surgeries, a new interest in staple anastomosis devices has emerged (10). The original problem between the staple and suture was that surgeons and medical researchers were not fully clear on which method provides a higher flow rate. Moreover, while increased benefits are recognized from new medical devices related to heart surgeries, results of a clinical study indicated that three patents who had undergone stapling had to be converted to hand-sutured anastomoses due to "inadequate blood flow" (10). As such, it appears that additional research on comparing stapling and suturing anastomoses is warranted.

According to the results of this study, the sutured artery appears to have had the higher flow rate between the two graft types measured. This research shows that suturing should continue being utilized in coronary bypass grafting anastomosis because it appears to have a higher flow rate as demonstrated by Poiseuille's Law. According to Poiseuille's Law, even a minimal reduction in the artery's radius could make a big impact on the blood flow rate, with all other factors remaining constant (**Equation 1**). Also, suturing can continue helping many coronary artery disease patients to have a higher blood flow rate in their coronary artery after surgeries. Coronary heart disease is a worldwide disease, so this research can help people worldwide to better understand this disease, how to cure it, and how to still have a good flow rate after it is threated. Moreover, with the results of this study, it is evident that additional research may be needed to further investigate the full impact of automated suturing (also known as arterial stapling) while maintaining a quality blood flow rate for the patients.

There were some limitations with this experiment, including inaccuracies in measuring tools, along with some differences between the artificial heart used and an actual procedure on a human. Inaccuracies in measuring tools included a need for a more precise gauge that can measure PSI. A more accurate gauge with a sensitivity of 0.1 PSI could have helped obtain more precise measurements. Additionally, the Lego® NXT™ arm had to be put at -120° to begin or else it wouldn't have provided sufficient starting pumping power, and as a result, wouldn't pump enough blood for circulation.

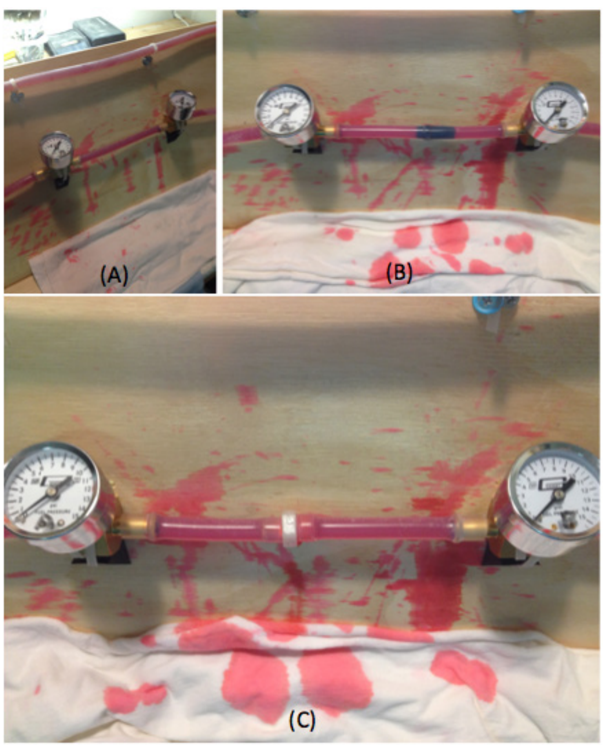
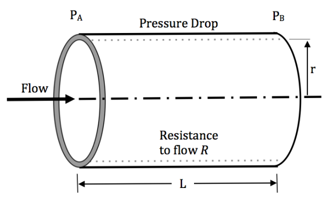


Figure 8. A simulated clear coronary artery (A) and low as well as medium occlusion levels (B & C) in the Lego® NXT™ artificial heart.

While the model used in this study included a simulation of a biological heart, the model is still valid when it comes to the demonstration of the impact of differences in the occlusion level on flow rate along with a novel application of Poiseuille's Law. However, there were still some differences between the experiment on the artificial heart used and an actual procedure on a human. These differences include the experimental artery/anastomosis replacement in the device and type of staple. Specifically, switching the arteries was difficult due to short blood loss, so the heart reservoir had to be refilled several times during the experiments (similar to blood transfusion in real operations). Another limitation is that the staples used in this experiment were the ones for skin, rather than those used for actual coronary anastomosis; however, the ratio of coronary-radius to staple size was maintained. Using the skin stapler distorted the artery's shape even more than it would have with actual coronary stapler, but due to the very high price of the coronary stapling device, its use was not feasible. As a result, it caused a slightly lower flow rate, and the stapling reported here most likely shows more blockage than a real coronary stapling device would. However, coronary stapling still needs technical improvements and more scientific research. It has been documented that suturing takes much more time, stress, and skill compared to stapling. A surgeon can press the handle of the coronary stapling device and the artery is connected; however, if it isn't stapled correctly, additional procedures will be required to fix it (10). In general, the aim is to reduce time and complications for the patient, while attempting to save their life. Additional research is recommended to learn more about how to improve the staple anastomosis in terms of improving blood flow rate in the grafted artery. Future research can be done using more precise digital gauges, more accurate and delicate staplers, as well as a more realistic artificial heart.

Methods

The procedure included the design, development, and programming of an artificial heart. A Lego® NXT™ artificial heart was designed and developed from ordinary Lego and Lego NXT™ 2.0 components by the researcher. It uses one Lego NXT™ programmable brick, two Lego Robotic motors (servos) connected with other Lego components to form a programmable arm, which presses on a fluid quart pump that sat on the 16oz reservoir tank (**Figure 1**). Moreover, a unique program was developed using the Lego Mindstorms® NXT™ application to program the artificial heart at the five different heart rates using five different speeds of the servomotors. The reservoir tank included blood-mimicking fluid that was circulated in the system (**Figure 1**). The fluid viscosity was approximately 0.3 cm^2/s or 0.0033 Pa·s at 30 °C and the normal flow rate was assumed to be 100 cm^3/s. The artificial heart was connected to silicone tubing and two pressure gauges were placed 17.5 cm apart to measure the pressure before and after the experimental area. The different occlusion levels and anastomoses were placed in the experimental area between the two pressure gauges. The data were collected by recording the readings on the two pressure gauges (in pound-per-square-inch or PSI) within the artificial heart. Then, using Microsoft® Excel, the data readings were converted from PSI to millimeter mercury (mmHg), followed by calculating the blood flow rate using Poiseuille's Law (9) (**Equation 1**). Moreover, the study included experimental parameters such as the level of humidity in the room (76%), the temperature (35 °C), the type of the silicone tubes used, the radius of the silicone tubes (mimicking coronary arteries [4.375 mm for the control/clear]), the viscosity of fluid (mimicking blood [0.0033 Pa·s]), the distance between the two gauges (17.5 cm), and the flow gauges



$$\begin{aligned} \mathit{Volume\ Flowrate}\,(F) &= \frac{P_A - P_B}{R} = \frac{\pi \cdot (P_A - P_B) \cdot r^4}{8 \cdot \eta \cdot L} \\ &= \frac{\pi \cdot (\mathit{Pressure\ Difference}) \cdot (\mathit{radius})^4}{8 \cdot (\mathit{viscosity}) \cdot \mathit{length}} \end{aligned}$$

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

Equation 1. Illustration of Poiseuille's Law.

used (fuel pressure gauges).

The readings were done on all eight types of silicone tubing: one clear artery control (r=4.375 mm); three levels of occlusions created with three plastic flow-narrowing couplings (**Figure 5**) – low (r=3 mm), medium (r=2 mm), and high (r=1.625 mm); two from each of the anastomoses (**Figure 4**). These were done over five simulated heart rates: rest (60 BPM), sitting (75 BPM), standing (90 BPM), walking (110 BPM), and running (130 BPM), yielding a total of 40 experimental readings.

In order to make a comparison and simulate a real-life experience, the experiment started by measuring the blood-flow rate of a clear artery (simulated by a silicone tube) by measuring the pressure differences and calculating the blood flow rate on five heart rates. Then, three different levels of occlusions were placed into the artificial heart, producing 15 more readings of pressure differences, which yielded blood flow rates for the five levels of heart rates for low, medium, and high occlusion rates (**Figure 8**).

Subsequently, two types of anastomoses were developed: suturing (two replicates) and stapling (two replicates). The two suturing anastomoses were done using the same silicone tube but were sutured by hand under the supervision of an experienced surgeon with a 3-0 75 mm nylon-suture - medium (FS-2/C-13) 19mm reverse cutting circle needle (**Figure 8**). Given the high cost of anastomosis staplers (>$10,000), skin staples were used to mimic the anastomosis stapling. Thus, two stapling anastomoses were done using the same silicone tube and were stapled by hand (**Figure 3**).

Following the construction of the four anastomoses (two from each type), they were placed into the artificial heart contraption producing 20 more readings of pressure difference pairs, which yielded blood flow rates from the five levels of heart rates (**Figure 4**).

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