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A Novel Method for Auto-Suturing in Laparoscopic Robotic-Assisted Coronary Artery Bypass Graft (CABG) Anastomosis

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Summary

Coronary Heart Disease (CHD), which results from buildup of plaque in the heart's coronary arteries, accounts for 12.2% of all deaths worldwide. There are two major ways to treat CHD: if the plaque level is high (above ~70% blockage), then open-heart surgery is usually performed. However, if the plaque level is moderate (~40% to 70%), then a drug-eluting stent can be placed in the artery to hold the plaque back from interfering with the blood flow and reduce restenosis. Laparoscopic heart surgery, or heart surgery conducted through small holes made between the ribs and on the sides of the chest, has increasingly been used over traditional coronary artery bypass graft (CABG) surgery, however, laparoscopic robotic-assisted CABG surgery has shown many advantages in research over both. Despite improvements, these traditional operations still take vast amounts of time and can result in infection or other complications. In this study, we developed auto-sutures that are automated through the use of a helical suture needle. Due to the significant decrease of time to suture, we increased the amount of sutures per segment of the auto-sutured CABG anastomosis. The quality of the auto-sutures was tested in a tensile test as well as a burst test apparatuses designed for this research. A burst test was simulated by pumping a blood-mimicking solution into silicon tubing. In all 80 experiments conducted (40 tensile test & 40 burst test), five sutures per segment was the optimal suturing method, as it had the highest maximum pressure as well as second-highest tensile strength.

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Introduction

Coronary Heart Disease (CHD) is the leading cause of death worldwide, accounting for 12.2% of all deaths (1). Approximately 600,000 Americans die from CHD annually. CHD is a result of a buildup of plaque in the heart's coronary arteries that could cause a heart attack (2). CHD's symptoms include: myocardial infarction (heart attack), stroke, high blood pressure, arrhythmia (irregular heartbeat), shortness of breath, and angina (chest pain) (3). CHD's risk factors include, but are not limited to, physical inactivity, high cholesterol, high blood pressure, smoking, obesity, and diabetes mellitus (2). Smoking tobacco can increase the risk of CHD by 2-4 times. Physical inactivity and a high cholesterol diet can result in a high risk of plaque buildup along the coronary arteries. Furthermore, physical inactivity can result in a heart that is not fit enough to endure a wide frequency of heart rates. Limited exercise can promote excess fat storage at the waistline, which can result in CHD and diabetes. High blood pressure can lead to stiffening of the arteries and susceptibility of the coronary arteries to buildup of plaque (4).

CHD is usually treated through two methods. If the occlusion level in the coronary artery is below ~70%, a coronary angioplasty is performed. During a coronary angioplasty, a catheter is inserted into the body and a stent is placed in the occluded region (5). However, if the plaque is above ~70%, a Coronary Artery Bypass Graft (CABG) is typically performed. This surgery consists of a midline sternotomy and attaching a graft to allow for new blood flow to reach the heart muscle following the blocked area of the coronary artery. A graft is an artery or a vein that is taken from another part of the body, from the leg or thigh, to allow the rerouting of blood flow around the blacked area (5). Connecting the grafted blood vessel with the coronary artery is called anastomosis (**Figure 1**). Usually, a CABG is done through open-heart surgery, a procedure that is extremely invasive and may lead to complications with a long recovery time. CABG surgery also involves putting the patient's body on a heart-lung machine known as "the pump."

For years, graft anastomosis had been done using suturing by hand. Surgeons took a long time to complete the suturing by hand and extensive experience was needed to conduct it efficiently. As a result, only four sutures per segment were used to reduce time. Furthermore, very little was known about the impact of suture density on the CABG anastomosis's tensile strength and maximum pressure sustained. Prior

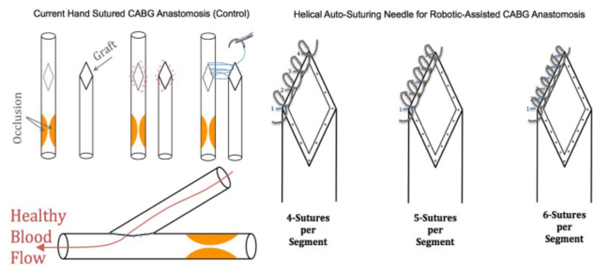

Figure 1. The design of the auto-sutures is shown compared to regular hand suturing.

literature indicated that considerable amount of research was conducted "towards attaining an optimal patency-enhancing CABG anastomotic configuration" (6, p. 3).

A new method known as minimally invasive or laparoscopic surgery has been introduced to the medical field (7). A robotic-assisted laparoscopy, or minimally invasive CABG, involves making small incisions between the ribs and inserting a robotic arm to conduct the operation. Robotic-assisted laparoscopic surgery does not necessitate a heart-lung machine and lowers the risk of infection (7). Laparoscopic CABG has also been shown to be less invasive and to reduce recovery time (8). Hand CABG suturing has been known to take long amounts of time, and resulting in increased risk of infections. Laparoscopic robotic-assisted CABG surgery can use auto-suturing, decreasing operation time and potentially infections. CABG anastomosis suturing has generally only been done with four sutures per segment, but due to the automation of suturing, more sutures per segment are viable. In order to assess the benefit of including more sutures in the automated process, the main goal of our study was to conducted a series of experiments to test the effects of the number of sutures per segment (**Figure 1**) and the effectiveness of the CABG anastomosis, measured via maximum blood pressure sustained and tensile strength. While the two apparatuses designed in this study mimic existing measurement tools in medical and biomedical engineering research, the helical suture needles we designed are the core novelty of this study and, to our knowledge, has not been designed or tested previously in the context of CABG (6).

Results

We compared the auto-sutures to hand suturing by testing the maximum pressure and time sustained to burst, as well as tensile strength and time sustained tearing (**Figure 1**). Additionally, the experiments called for artificial tissues that were sutured together with four sutures, five sutures, and six sutures using the helical suture needles, as well as by hand, representing the control (**Figure 2**). The artificial tissues were placed in the tensile test apparatus, and the tensile strength was measured (**Figure 3**). Moreover, silicon tubes were sutured together with four sutures, five sutures, and six sutures using the helical suture needles, as well as by hand, representing the control. Subsequently, the helical sutured anastomoses were inserted in the burst test apparatus and the maximum pressure sustained was recorded (**Figure 4**).

The independent variable was the number of sutures per segment in the auto-sutures (four, five, & six per segment). The dependent variables included the tensile strength of the sutures (measured in impulse) and maximum pressure sustained (measured in millimeters of mercury or mmHg) as well as time (seconds) until a burst or ripped. This study included several experimental control parameters such as: the nylon sutures, the type of the silicone tubes used, the pressure gauges used, the viscosity of the blood mimicking fluid, the temperature where the experiments were conducted, and the material used for making the auto-sutures.

We found that the simulated robotic-assisted CABG with four sutures per segment had the highest tensile strength (Mean tensile strength, $J_{Four\ Sutures}$ = 480.5 N*Sec; $St.Dev_{Four\ Sutures}$ = 57.59 N*Sec; **Figures 5 & 6**), although it nearly had the lowest pressure sustained (Mean Maximum Pressure, $P_{Four\ Sutures}$ = 130.2mmHg, $St.Dev_{Four\ Sutures}$ = 45.5 mmHg). Patients who undergo minimally invasive CABG anastomosis surgery receive four sutures per segment by hand in their anastomosis have to stay on bed rest. The simulated CABG with hand suturing (control, four sutures per segment) had the weakest results, including the lowest tensile strength (Mean tensile strength, $J_{Control}$ = 241.21 N*Sec; $St.Dev_{Control}$ = 60.15 N*Sec) and the lowest maximum pressure sustained (Mean Maximum Pressure, PControl = 128.3 mmHg; $St.Dev_{Control}$ = 32.7 mmHg; **Figures 5 & 6**). Although six sutures per segment might seem like the alternative to four sutures per segment, the six suture per segment had a low tensile strength (Mean tensile strength, $J_{Six\ Sutures}$ = 244.03 N*Sec; $St.Dev_{Six\ Sutures}$ = 41.39 N*Sec) and a low-pressure sustained (Mean Maximum

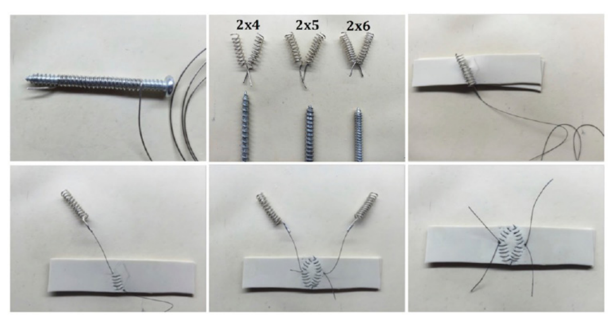

Figure 2. The assembly and implementation of the auto-sutures is shown.

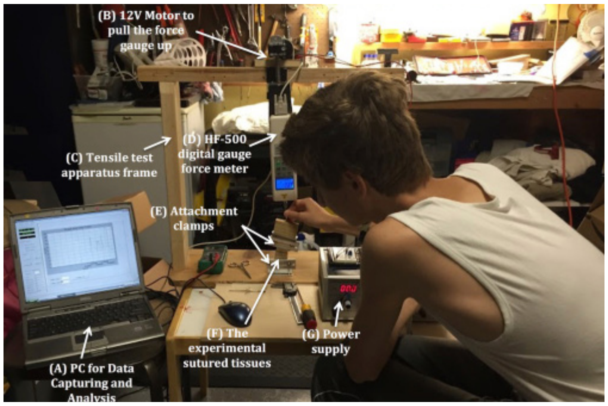

Figure 3. The developed tensile test apparatus during testing of the sutured artificial tissues. (A) PC for Data Capturing and Analysis; (B) 12V motor to pull the force gauge up; (C) Tensile test apparatus frame; (D) HF-500 digital gauge force meter; (E) Attachment clamps; (F) The experimental sutured tissues; (G) Power supply.

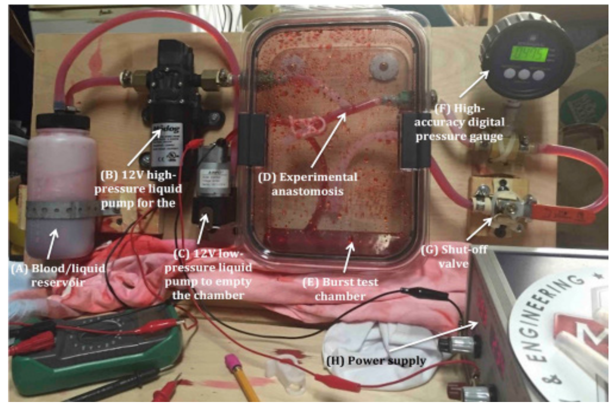

Figure 4. The developed burst test apparatus during testing of the sutured anastomosis. (A) Blood/liquid reservoir; (B) 12V high-pressure liquid pump for the burst-testing; (C) 12V low-pressure liquid pump to empty the chamber post-experiment; (D) Experimental anastomosis; (E) Burst test chamber; (F) High-accuracy digital pressure gauge; (G) Shut-off valve; (H) Power supply.

Pressure, $P_{Six\ Sutures}$ = 180.7 mmHg; $St.Dev_{Six\ Sutures}$ = 54.4 mmHg; **Figure 6**). Therefore, the simulated robotic-assisted CABG with five sutures per segment appeared to be the best compromise within those tested in this study, since it sustained the highest pressure (Mean Maximum Pressure, $P_{Five\ Sutures}$ = 226.3 mmHg; $St.Dev_{Five\ Sutures}$ = 32.2 mmHg) and second-highest tensile strength (Mean tensile strength, $J_{Five\ Sutures}$ = 322.08 N*Sec; $St.Dev_{Five\ Sutures}$ = 42.23 N*Sec), as demonstrated by the combined graphs in **Figure 6 and Table 1**. Analysis of Variants (ANOVA) was conducted on the 40 tensile test experiments. We compared the means of the four sets of experiments. We compared the experimental time (Sec), maximum force (N), and impulse (J), and results showed significant difference between the groups among all three measures ($F(df$=39) =60.523, 8.807, & 48.229, representing a significant level of p_{Exp_Time}<0.001, p_{Max_Force}<0.001, & $p_{Impulse}$<0.001, respectively). Additionally, we conducted another ANOVA on the 40 burst test experiments comparing the means of the four groups tested. The experimental time (Sec) and maximum pressure (mmHg) were compared and revealed a significant difference between the groups among both measures ($F(df$=39)=47.622 & 12.248, representing a significant level of p_{Exp_Time}<0.001 & $p_{Max\_Pressure}$<0.001, respectively).

Discussion

Ever since the introduction of laparoscopic surgery, patients have had lower recovery times. Although the CABG surgery still has flaws, the introduction of robotic-assisted CABG surgery has helped mitigate them (9). The original complication was that surgeons took a long time to complete the suturing by hand, reducing the total sutures attained to four sutures per segment (6). Moreover, many surgeons didn't appear to know the impact of the amount of suture frequency on tensile strength and maximum pressure of the CABG anastomosis. Thus, it was evident that additional research on comparing auto-suturing and hand suturing was necessary.

According to the results of this study, the auto-suture with five sutures per segment is the optimal technique due to having both the highest maximum pressure and second-highest tensile strength among the suturing techniques tested. This research shows the potential advantage of using robotic-assisted auto-sutures, since it appears that such a procedure requires less time and provides a higher quality of the CABG anastomosis. Also, surgery using the robotic-assisted auto-sutures can aid coronary artery disease patients because the sutures have a higher tensile strength and pressure

Experimental Set	Tensile Test - Impulse (J) (N*Sec)		Burst Test - Max Pressure (mmHg)	
	Mean	St.Dev	Mean	St.Dev
4-Sutures per Segment (10xExp4a & 10xExp4b)	480.5	57.6	130.2	45.5
5-Sutures per Segment (10xExp5a & 10xExp5b)	322.1	42.2	226.3	32.2
6-Sutures per Segment (10xExp6a & 10xExp6b)	244.0	41.4	180.7	54.4
Control - Hand-Sutured (10xExpCa & 10xExpCb)	241.2	60.1	128.3	32.7

Table 1. Aggregated results of all 80 experiments with comparison between the burst test and tensile test results to demonstrate the optimal solution for the four, five, six sutures per segment and the hand sutured control tested

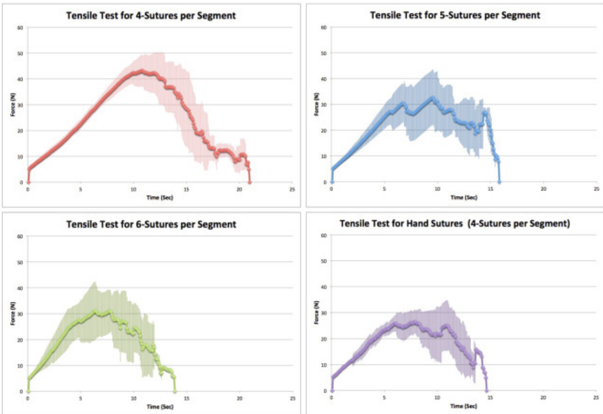

Figure 5. The 40 tensile test experiments depicting the mean force values and standard error of means vs. time for the four, five, and six sutures per segment methods and the hand-sutured control.

sustainment, which can help patients after the surgery by elevating some initial difficulties of getting up and walking. This research may help cardiac patients know how the treatment of such disease is operationalized, while allowing them to better understand the procedures and seek a higher-quality surgery. It is apparent that additional research is needed to further investigate the full effect of using robotic-assisted auto-sutures while maintaining a high-quality surgery for the cardiac patients.

The experiments in this research had several challenges and limitations. First, the auto-sutures had to have a uniform measurement between the coils of the helical needle. Such a challenge was overcome through the use of three different screws with treads that matched the distances needed for the three helical needles. Next, the helical suture needle was initially difficult to insert into the artificial tissue as well as the silicon tubes. When using the helical suture needle, experience in positioning the starting point was required as well as twisting out the suture needle and reinserting it. Such difficulty would be overcome in a robotic-assisted CABG surgery unit since it would precisely and accurately insert the helical suture needle driven by accurate spinning miniature motor. In the burst test, a sealed container was placed to hold lost blood mimicking solution. However, there was still some “blood” loss. The reservoir had to be refilled (similar to blood transfusion in real operations) throughout the experiments.

The models used in this study are valid when it comes to the testing of suturing techniques since they simulated the tension and pressure of a biological heart’s physiological conditions. Superficially, the model used in this study looked at a range of coronary artery pressure from 1 to 5 PSI, or about 50 mmHg to 260 mmHg, which is considered within the normal range of coronary artery pressure under normal conditions, including intense sporting activities (10). Furthermore, in current off-pump procedures, the existence of biological blood flow rate and pulsatility provides some complexity to the surgery; however, development in off-pump surgical tools allows for CABG anastomosis to be done even on a beating heart using an innovative tool called an ‘off-pump myocardial stabilization device with suction’ (9). The off-pump myocardial stabilization

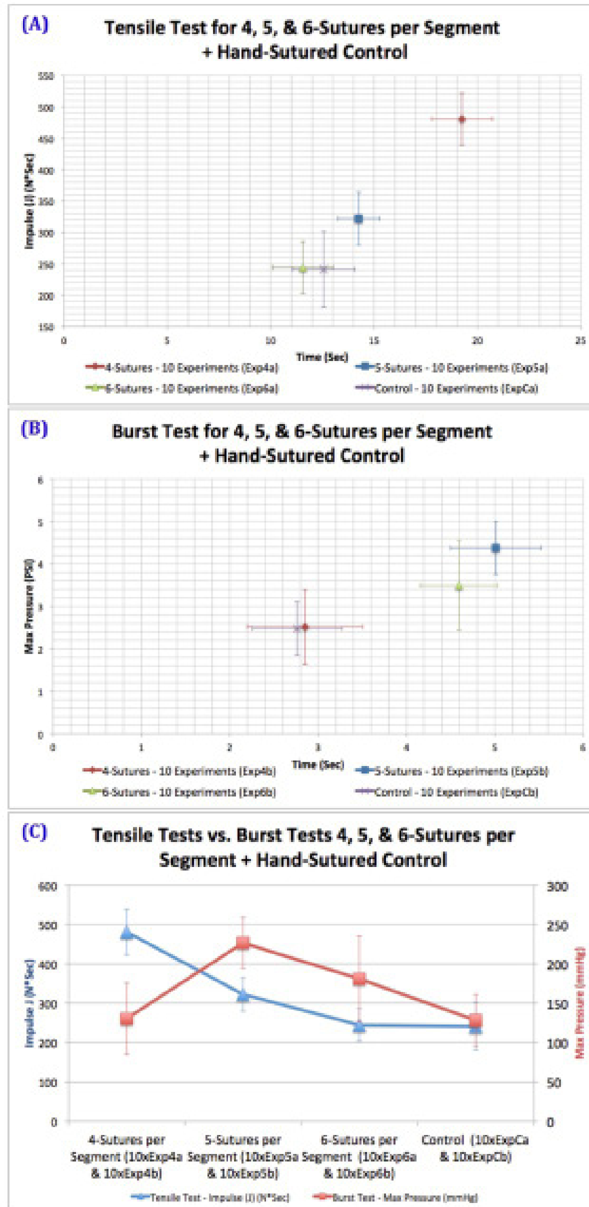

Figure 6. Simulated robotic-assisted CABG with four sutures per segment had the highest tensile strength. (A) The results of the overall mean strength (J) vs. time of the 40 tensile test experiments; (B) The mean maximum pressure (P) vs. time of the 40 burst test experiments; (C) An aggregation of all 80 experiments with comparison between the burst test and tensile test results to demonstrate the optimal solution for the four, five, and six sutures per segment and the hand-sutured control tested.

device with suction allows for the CABG anastomosis to be conducted on the beating heart while suctioning the blood resulting from the flow and pulsatility during the operation. This allows the surgeon to work on a relatively “dry” area of the heart around the blocked coronary artery, even when the artery is surgically cut. As such, the experiments conducted in this study on the CABG anastomoses appear to be a reasonably simulated model of off-pump CABG anastomosis using myocardial stabilization device with suction.

This study used a medical grade nylon suture that is similar to those used in CABG anastomoses. However, an actual procedure on a human would have differences compared to the artificial heart and tensile test. The current model does have several limitations as it applies to the use of the material properties of the arteries and how it may affect the results. The model tested in this study used silicone tubes to mimic the coronary arteries, however, some differences do exist between those and human coronary arteries, specifically as it pertains to the tensile strength. While testing with human coronary arteries is beyond the scope of this study, further research is warranted to explore the differences found in this study, particularly of the tensile strength using human coronary arteries.

To conclude, we found that increasing the number of sutures per segment in the tensile test induced more tearing, resulting in reduction of tensile strength. Since increasing the number of sutures per segment increases the number of holes made in the artificial tissues, the tissues lose strength and rip. Furthermore, the sutures done by hand (the control) did not yield a strong tensile strength despite having four sutures per segment. This is because the hand suturing had a non-uniform distance between the suture insertions and could not withstand increased tension, the tension was not distributed evenly, as was in the auto-suturing CABG anastomoses. During the burst test, we realized that auto-suturing with four sutures per segment did not result in enough sutures to sustain the pressure needed for quality CABG anastomosis. Additionally, in the six sutures per segment method, there was an excessive number of sutures, resulting in a low maximum pressure sustained. This may be due to the fact that the six sutures per segment made extra holes in the tubes, which resulted in early CABG anastomosis burst or a lower sustained maximum pressure. Therefore, among all types of CABG anastomoses tested in this research, the auto-suture with the five sutures per segment was the optimal solution because it had the highest sustained maximum pressure and second-highest tensile strength. Ultimately, more research is needed to investigate the impact of suturing techniques on the maximum pressure sustainment and tensile strength to provide better quality CABG anastomosis to CHD patients. Future research can be done with a more realistic artificial heart, and with more variety of suturing methods along with models that better mimic the human cardiovascular system.

Materials and Methods

Auto-sutures

To conduct this research, our procedure included designing and developing the helical suture needles, burst test, and tensile test apparatuses. The auto-sutures were designed to have uniform measurements between the coils of the helical suture needle. This is due to the connection between the arteries in an anastomosis, which is rhombus-shaped and has four segments, each requiring a set number of sutures (**Figure 1**). We developed and designed the auto-sutures with four, five, and six sutures per segment of the anastomosis by wrapping 16-gauge metal wire around three screws with differing lengths between the threads (**Figure 2**).

Burst test apparatus

We also developed and designed the burst test apparatus that was modeled after a biological heart at increased stress without pulsatility (**Figure 4**). It uses one 12V high-pressure liquid pump connected to a reservoir on one side, a burst test chamber in the middle with 12V low-pressure liquid pump to empty the chamber, and high-accuracy digital pressure gauge with shut-off valve on the other side, rung by a power supply.

Blood mimicking fluid

The blood mimicking fluid was made with water, red food coloring, and three grams of food thickener powder per liter water to achieve a viscosity of about 0.0033 Pa•s, similar to human blood. The blood mimicking fluid was pumped continuously into the experimental area (a sealed container) and then the pressure was closed with a valve. After the valve closure, the high-accuracy digital pressure gauge recorded the maximum pressure sustained before there was a burst in the experimental area. Then, the 12V low-pressure liquid pump was used to pump the blood-mimicking solution out of the experimental area and back into the reservoir (**Figure 4**). In the experimental area, the experimental suturing anastomosis were placed and tested for their maximum pressure and time until burst (**Figure 4**).

Tensile strength experiment

We also developed and designed the tensile test apparatus (**Figure 3**). It made use of wood planks that served as a frame, and a slow-moving 12V motor connected to a HF-500 digital gauge force meter. Moreover, the tensile test apparatus included an attachment clamp to the sutured artificial tissue (experimental auto-sutured anastomosis) on the digital gauge side, and another attachment clamp on the base side. The artificial tissues used were rubber-based tattoo practice artificial skin pads that were cut into 2 cm X 5 cm segments and sutured using a 19 mm reverse-cutting, 3/8 circle needle (3-0, 75 cm) and medical-grade nylon sutures. The tensile strength experiment was conducted by having the slow motor pull the force gauge and the sutured tissue, while one end of the sutured tissues was connected to the force gauge via the attachment clamp and the other is attached to the base of the tensile test apparatus (**Figure 3**). The force gauge measured the force and time every eight milliseconds, while connected to a computer that collected the data. The experimental constraints kept consistent between experiments include temperature (35° C), humidity (76%), the flow gauge, the force gauge, the type of silicon tubes (for the burst test), the radius of the silicon tubes (mimicking coronary arteries [4.375 mm inside diameter]), the viscosity of the fluid (mimicking blood [0.0033 Pa•s]), and the type of artificial tissue (artificial skin for the tensile strength test).

$$J = \int_{t=0}^{t=T_{Exp}} (F \cdot dt)$$

Equation 1. Equation used for calculating impulse (force / time)

We analyzed each of the four suturing methods: hand suturing (control), auto-suturing with four sutures per segment, auto-suturing with five sutures per segment, and auto-suturing with six sutures per segment. After the experiments, the impulse was calculated (Equation 1) using the force and time collected from the digital force gauge. The pressure collected in the burst test was later converted from (PSI) to mmHg. This research included a total of 80 experiments. Each suturing method had 10 experiments in each testing apparatus, resulting in 40 burst test experiments and 40 tensile test experiments.

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