ARTHETA-0: An Innovative, Affordable Approach to the Onsite, Rapid 3D Printing of Artery Stents, Parameterized to Fit Individual Patients' Needs

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TABLE OF CONTENTS

I. ABSTRACT

The stent manufacturing industry, as it stands, uses extremely inefficient and unaffordable methods, such as laser-cutting, to fabricate stents. These methods require extensive infrastructure and must therefore be completed at an external location. Additionally, these methods follow a one-size fits all approach when manufacturing stents. The ARTHETA-0 is a 3D printer with a novel motion system that specializes in printing vascular-stents. It addresses all of the shortcomings of the stent manufacturing industry. It uses a novel, simplistic motion system that utilizes polar coordinates and a horizontally-static print bed to print stents made of Thermoplastic Polyurethane (TPU). This allows the ARTHETA-0 to be incredibly affordable at under $500 (versus industry standards which exceed $100,000), while still printing stents with incredible accuracy and precision (due to its innovative motion system that can print cylindrical structures with almost no ovality). The simplistic fused deposition modeling (FDM) system makes the ARTHETA-0 extremely accessible. It can be implemented on-site, in hospitals and can print stents that are customized to patient-specific dimensions, unlike anything seen before. Stents can be printed within two hours of parameter input, eliminating shipping times. Additionally, the actual stents are of high quality and are comprised of complex designs due to the dual extrusion system in the ARTHETA-0, which uses Polyvinyl Alcohol (PVA) as a support material to print the stent with TPU. Once placed in water, only the PVA dissolves. The stents are also biodegradable due to the usage of TPU, reducing the risk of post-stenting complications such as restenosis.

II. BACKGROUND

The main challenges the ARTHETA-0 will address are the inefficiency and unaffordability of the vascular stent manufacturing industry. The stent manufacturing industry, as it stands today, uses extremely expensive (>$100,000 per unit) methods, such as laser machining and micro-EDM (electro-discharge machining). Furthermore, these methods must be completed at an external location, outside of hospitals, and stents must be shipped to hospitals after fabrication. Additionally, due to the complex procedures, which are rigid in nature, stents cannot be made with customizable dimensions. Therefore, doctors are required to use a fixed stent size for every patient. The default stent sizes available in the industry may not fit every patient perfectly, leading to a higher risk of post stenting complications such as restenosis.

Vascular stents are a medical necessity as they are frequently needed (Mayo Clinic 2019). A vascular stent is a tube inserted into the lumen of a blood vessel to keep the passageway open, and they are needed when there is a blockage of the artery. For example, they can be used to prevent or treat heart attacks. It is estimated that over two million Americans undergo a stenting procedure every year, just for coronary arteries (Harvard 2019). Given that stents are critical medical equipment that are often needed in emergency situations, their manufacturing should not be completed off-site, and it should not follow a one-size-fits-all approach. Additionally, current practices in the stent manufacturing industry are complicated and expensive; they can cost upwards of $100,000 in capital costs.

Furthermore, post-stenting complications are not uncommon. The risk of re-narrowing of the artery is 10-20%, and the risk of the artery clogging after stent placement is about 5% (Mayo Clinic 2019). Moreover, these can lead to blood clots in the region of the stent, which can be deadly. To combat these complications, the ARTHETA-0 uses Thermoplastic Polyurethane

(TPU) to manufacture stents. TPU is a flexible, biocompatible polymer, making it an effective option to minimize complications after stenting. Additionally, it is biodegradable and bioresorbable, which means that it is designed to only stay in place for the time it is needed. This reduces the probability of the occurrence of a post-stenting complication.

III. INTRODUCTION

The ARTHETA-0 is a 3D printer that utilizes a novel motion system specialized for printing artery stents. Previously never seen in the stent manufacturing industry, it boasts an impressive combination of extreme affordability, stent parameterizability, print accuracy, and efficiency in production. The stents manufactured by the ARTHETA-0 have a high degree of biocompatibility and biodegradability, allowing for the reduction of post-operative risks.

Stents have been manufactured using etching, micro-electro discharge machining (micro-EDM), die-casting, and laser cutting. Etching involves the photolithography process in which the desired pattern is projected on a plain sheet coated with photoresist, which, after exposure, is etched to obtain the desired pattern. Micro-EDM utilizes material removal through electro-erosion to manufacture stents. In die-casting, molten metal is cast directly in a stent-like form. Laser cutting is the most frequently used technique today, and it is quite an extensive process. Initially, a high energy density laser beam is focused on the workpiece surface to manufacture the stent. This however leaves thermal damage, such as heat-affected zones (HAZ), recast layers, striation, tensile residual stress, microcracks, and dross. To repair the thermal damages, pickling techniques, soft etching, annealing, and electropolishing are applied. All these methods require extensive infrastructure and capital. They are often very expensive as they can exceed $100,000 per unit. Additionally, they are far too complicated to be completed on-site, and the complexity of these processes does not allow for a high degree of customizability for each individual stent. Overall, current practices in the stent manufacturing industry are expensive and far too complex, and the stents cannot be customized.

The ARTHETA-0 addresses all of the major shortcomings of previous stent manufacturing processes with a relatively simple, yet innovative system, as it utilizes a revolutionary motion system that uses cylindrical coordinates rather than cartesian coordinates for the printing process. It is capable of printing in circular motions with approximately no ovality. Additionally, the ARTHETA-0 has a static print bed allowing for increased adhesion of the stent to the surface and therefore increased print accuracy. This is in contrast to previous polar 3D printing technology, which uses the printing bed for theta axis motions (which could lead to printing inaccuracy). The groundbreaking technology in the ARTHETA-0 allows for great accuracy and precision in the stent manufacturing process.

The total cost of production per unit of the ARTHETA-0 3D printer is $471, which is significantly less expensive than industry standards (which can cost upwards of $100,000 per unit). The total cost of materials to produce each stent is ten to fifteen cents depending on stent parameters. In contrast, hospitals currently purchase stents for $1500-$3000 per unit. Maintenance costs for the printer are estimated to be extremely low at $30 per year, as its simplicity allows for high reliability.

Additionally, unlike previous stent manufacturing methods, the ARTHETA-0 boasts simplicity, which allows for it to be easily available on-site in hospitals; it is a fused deposition modeling machine, which is a far less complex system. Taking up just over three cubic feet, it is incredibly compact, especially compared to current industrial stent manufacturing capital. It

requires a 50 watt power source and has an estimated lifespan of over ten years, allowing for minimal infrastructure changes. All of these factors contribute to the simplicity of the ARTHETA-0, enabling its rapid, on-site production of stents, eliminating all shipping time.

Furthermore, the ARTHETA-0 is unique in the fact that it allows for great customizability in the production of each stent in order to fit individual patient needs. Only a software change is necessary to edit stent parameters such as diameter and length. This will allow a doctor to order a custom stent based on the patient's needs and receive it within just two hours of parameter input.

Lastly, all stents manufactured by the ARTHETA-0 are of incredibly high quality. They are made of Thermoplastic Polyurethane (TPU), which is a biocompatible and biodegradable flexible-filament. The TPU offers a biodegradable alternative to permanent nitinol (a metal alloy of nickel and titanium) and stainless steel stents. This reduces the amount of time the stent is lodged in the artery, and thus reduces the risk of post-operative complications such as blood clots. Furthermore, the stents produced can have increasingly complex geometric designs, made possible by the dual extrusion model of the ARTHETA-0. In this model, the TPU can be printed alongside a support material, Polyvinyl Alcohol, which dissolves once placed in water.

Overall, the ARTHETA-0 is the only stent manufacturing solution with a combination of affordability, accessibility, simplicity, stent customizability, and high quality biodegradable stents.

IV. ENGINEERING GOALS OVERVIEW

A. Implement a novel motion system, specialized for stents
    a. Polar motion system (r-, theta-, and z- axes)
    b. Horizontally static print bed for more accurate prints and lower print failure rate
    c. Dual extrusion for complex stent geometries
B. Produce ARTHETA-0 at an affordable price (<$500 per unit)
C. Implement a Simplistic Fused Deposition Modeling (FDM) system for on-site stent fabrication
D. Use custom-made ArGen software (G-code slicing → Deployment → Modified Marlin Firmware)

V. COMPETITIVE ANALYSIS

The ARTHETA-0 outperforms the current competition in the industry in terms of feasibility (for on-site stent production in hospitals), affordability, and stent customizability. Laser machining of stents from thin-walled tubing is the most common form of stent fabrication. It is being used by many companies in the industry today, including Abbott Laboratories. They have a patented process for the fabrication of polymeric stents using laser machining (US20070283552A1). Laser machining is a multi-step process that is expensive and requires extensive quality control procedures due to residual heat damage. Another method of stent fabrication is the tubular casting process where substrates from polymeric substances can be formed (by dip-coating) to manufacture stents. This method is being attempted by Amaranth Medical and is patented (US9908143B2). Similar to laser machining, this is an expensive, multi-step procedure. Consequently, none of the current industry methods can be available on-site at a hospital. Additionally, stent customizability is low as current manufacturing methods only allow for a one-size-fits-all approach. In contrast, with its affordable, simplistic, and

parameterizable system, the ARTHETA-0 addresses all of these concerns, making it a better alternative.

In addition to standard stent manufacturing practices, there have been attempts at innovation in the stent manufacturing industry, particularly in the field of 3D printing stents. However, none of the alternatives can fabricate stents with the affordability, parameterization, and productive efficiency of the ARTHETA-0. One of the most notable attempts at 3D printing stents is by the Commonwealth Scientific and Industrial Research Organization (CSIRO). They have developed a method for 3D printing nitinol stents. They used selective laser melting, through which they can shape nitinol, a metal alloy of nickel and titanium. To commercialize this, the researchers have founded their own company, Flex Memory Ventures. The downside to this method is that it is extremely expensive. Capital needed for this method can exceed $100,000 and requires extensive maintenance due to the complex laser technology involved. In contrast, the ARTHETA-0 can be manufactured at a per unit cost of $471, significantly lower. Additionally, unlike CSIRO's 3D printer, as mentioned previously, the ARTHETA-0 used a simplistic fused deposition modeling machine, allowing it to be easily available on-site in hospitals to quickly 3D print stents parameterized to individual patients' needs. Additionally, the ARTHETA-0 prints biodegradable, polymer stents unlike CSIRO's 3D printer. Overall, the ARTHETA-0 is a much more affordable and feasible alternative.

More affordable attempts at 3D printing polymer stents have been made using a 3D printer with a tubular motion system. One of the most notable attempts is by the University of Girona in Spain. This attempt has a major drawback that the ARTHETA-0 addresses. In the tubular motion system, the print bed is a rotating cylinder. This leads to minimal potential for parameterization of the stent, which is one of the main purposes in 3D printing stents. The parameters of the fabricated stent depend on the dimensions of the print bed, since the print bed serves as the cylindrical mold of the stent. Therefore, a hardware change is needed each time the stent diameter must be changed, resulting in low parameterizability. In contrast, the ARTHETA-0, with its flat and horizontally static print bed, can print stents that are customized to patients' needs with only software changes needed to adjust the parameters of the stent.

Examining the general field of 3D printing, the motion system of the ARTHETA-0 is truly novel. There have been a few attempts at 3D printing using polar coordinates in the past. However, none of them match the accuracy and precision of the ARTHETA-0, as its motion system is specifically built to 3D print stents, small prints that require extremely high accuracy and precision. As an example, Shaanxi Hengtong Intelligent Machine Company has a patented polar coordinate 3D printer (CN205167583U) with a circular print bed that rotates during the printing process. This motion system will serve for large prints, but the movement in the print bed will reduce adhesion of the material to the surface, resulting in micromovements that reduce accuracy and precision of the print. This is not an acceptable system for vascular stents as they are extremely small and require a high amount of accuracy and precision in the printing process. Conversely, the ARTHETA-0, with its horizontally static print bed, is capable of high quality fabrication of stents.

Overall, the ARTHETA-0 outperforms current industrial stent manufacturing methods in terms of cost, practicality, and parameterizabillity of stents, and it is leading the way in innovation.

VI. TECHNICAL CONCEPTS: METHODS AND PROTOCOL

The goal of the ARTHETA-0 is to produce patient-specific, parameterized artery stents rapidly on-site at an affordable cost. This is achieved by applying simple, low-cost technologies in a new, revolutionary way. Specifically, the ARTHETA-0 combines the tried and tested fabrication technique of Fused Deposition Modelling (FDM) 3D printing with a novel motion system implementation: polar, which uses cylindrical coordinate positioning.

While there are other methods of printing, this FDM process uses reasonably simple technology, requiring only a motion system, print surface, heating block, nozzle, and extrusion system; this allows FDM printers to be produced at costs much lower than other options on the market, such as PBF (Powder Bed Fusion) printers costing upwards of $100,000.

What truly allows the ARTHETA-0 to achieve its intended accuracy, however, is the polar motion system. Traditionally, FDM printers utilize a cartesian motion system in which there are independent X-, Y-, and Z- axes. This works well for the majority of parts, but in the case of some geometries, such as the small cylindrical shape of artery stents, cartesian positioning is not sufficiently accurate. This is because the X- and Y- axes must move in a perfectly coordinated manner when tracing circles, and any deviations from that will cause imperfections in the final product. These deviations can come from a wide variety of sources; the two most common are issues in stepper driver control and mechanical slop. Stepper drivers are used to control stepper motors, the most common motors in 3d printing applications. When scaled down to print parts under 10 mm across, the relative influence of mechanical slop in each individual axis is magnified greatly, which can significantly increase the ovality and disfiguration of circular geometries. The solution is a polar motion system, consisting of R-, Theta-, and Z- axes, in which the profile of a circular geometry with constant radius can be printed with only the actuation of the Theta-axis. This means that any problems stemming from mechanical slop and driver issues are mechanically bound along a circular path, defined by the nozzle location. This bound allows the ARTHETA-0 to print artery stents with an outer diameter as low as 2 mm, which would not be possible on a cartesian system.

In the development of the ARTHETA-0, there are two major iterations: the prototype unit and the production unit. Multiple iterations of all design components went into the printer throughout the development, but these two iterations define a distinction between two different models. The prototype unit (Fig. 6), which has already been designed, manufactured, and improved, was designed with cost, ease of manufacturing, and single-unit development in mind. As such, the printer frame is composed of extruded acrylic, which was laser-cut at Hangar6, a local machine shop. The production unit, however, which is currently in development, is being designed with medical-grade standards, mass production, and consistency as the primary goals. As such, the acrylic frame will be replaced with a more rigid and durable sheet-metal frame, significant printer openings are being sealed, and other parts that took significant time to manufacture are being re-evaluated.

A. MECHANICAL DESIGN

Delving into the design of the printer (Fig. 5), the theta-axis is perhaps the trickiest and most innovative element, especially as it relates to minimizing cost; it has been and will continue to go through numerous design iterations and revisions, as it has no precedent within the printing industry. The theta-carriage on the prototype unit is supported by a circular aluminum plate, machined using a router with a 45 degree chamfer on each side of the outer edge, and rests within 8 v-groove bearings mounted on the printer frame around the plate. In order to ensure that the plate is sufficiently held in place, 6 of the v-groove bearings are mounted to sliding,

adjustable 3D printed plates that can be tensioned to constrain the theta carriage to only rotate about the z-axis. In order to rotate the carriage, a 472 tooth GT2 belt has been inversely adhered to the 3D printed PLA (Polylactic Acid) carriage body which is in turn connected to the aluminum guiding plate. A 1000mm continuous GT2 6mm belt is then used to transfer motion to it from a 20-tooth sprocket attached to a Nema 17 motor mounted to the printer frame. The main theta sprocket, which was originally one part, has since been split into four distinct parts in order to reduce part size, so as to meet our production restraints. It also serves as the mount for the R-axis motor, the R-axis belt tensioner, R-axis limit switch, both extruders, and the 8mm steel rods of the R-axis. The Theta Carriage has undergone 5 main iterations over the course of its development. The initial design featured the carriage actuating along the Z-axis, which was altered to a static mounting point on the frame of the printer to reduce mechanical complexity and failure points, while also decreasing the overall weight and cost of the carriage. The second iteration of the carriage, while significantly lighter and simpler than the first iteration, lacked the mechanical rigidity required to maintain the printer's longevity. This motivated the development of the third iteration which added additional bracing support for the carriage body, as well as further optimization to the placement of the print extrusion system, allowing a reduction in size. In the fourth iteration, the design of the carriage body underwent the previously mentioned alteration into four distinct structural parts. Finally, in the fifth iteration, the carriage was redesigned a final time to optimize manufacturing and consistency. First, the driven belt teeth were redesigned from being printed directly into the sprocket to the inversely mounted GT2 belt approach; this worked to resolve issues with the belt along the sprocket's surface. Additionally, the carriage body's geometric layout was redesigned to allow an upper retention ring for the driving belt to be installed, ensuring more consistency over longer periods of machine use. Looking to future iterations, on the production model of the printer, the v-groove bearing and plate method of stabilizing the carriage will likely be replaced by a 12" turntable bearing, which would help to reduce weight and production costs as well as eliminate the complex manufacturing process used on the plate.

The R-axis is mounted within the theta-axis and slides along two 8mm steel rods mounted horizontally to each other. The R-carriage itself is constructed of 3d printed PLA and PETG parts and houses 4 drylin bearings (for r actuations), 2 part cooling fans, and 2 E3DV6 hotends. The hotend-extrusion system is configured in a bowden format, meaning that the extruder, which is the motorized element that pushes filament through the system, and the hotend, which includes the heating element and nozzle of the FDM process, are not mounted at the same location; instead, filament is pushed through a teflon tube after going through the extruder, which then feeds it into the hotend. While there are multiple advantages of this configuration, the primary reason for implementing a bowden setup is that it allows the extruder and motor to be mounted at a separate location, reducing the weight of the R-carriage. This reduction in weight leads to lessened inertia and greater controllability within the R-axis, in turn causing higher part quality. Additionally, the inclusion of two separate hotend-extrusion systems allows for, as noted previously, the printing of two different materials — TPU (Thermoplastic Polyurethane), to serve as the flexible body of the stent, and PVA (Polyvinyl Alcohol), to serve as a soluble support material. This combination of polymers allows the ARTHETA-0 to print stents with more complex mesh geometries and lower angles of elevation. This allows for adjustments of the stent's compressibility as well as the production of drug-eluting stents, which can release drugs that help to heal the vessel and prevent restenosis from occurring.

The Z-axis of the printer is not unlike traditional FDM printers, though slightly sturdier; it consists of a pattern of six 3d printed plates, together forming the mount on which the spring secured print surface is mounted. The print surface is a 0.125" glass plate attached to a PCB (Printed Circuit Board) heating plate, which warms the print surface to 60℃, producing stronger bed adhesion. The z-carriage is then driven by 2 lead screws and guided by 4 8mm steel rods and drylin linear bearings.

One of the features of the ARTHETA-0 that sets it apart from past attempts at polar printers is the implementation of a horizontally static print bed. This proves useful for two reasons: increased print quality and decreased print failure rates. The first of these, increased print quality, can be attributed to the fact that, as the bed is not moving as an axis, the weight of said axis is not increasing throughout the print as material is deposited onto the print surface. Traditionally, this change in mass of an active axis can lead to variable slop and resistance in the system – a problem that can be solved by removing the bed from motion. Furthermore, in a non-horizontally-static bed, the print's adhesion to the print surface is worn down as the bed continually accelerates and decelerates; this proves particularly true with print geometries with high part-height-to-surface-adhesion-area ratios, such as that of artery stents. This can all be solved by making the printer bed horizontally static, in turn removing all horizontal forces on the part.

B. SOFTWARE DESIGN

The entirely original motion system implemented on the ARTHETA-0 required the development of, in addition to entirely original hardware, new methods of generating g-code. G-code, or machine code, is a script used in most CNC (Computer Numerical Control) machines, which includes 3D printers, CNC routers, CNC lathes and many more tools; a g-code file itself is essentially a text file wherein each line consists of its own machine command. Instead of a traditional method of converting a CAD (Computer Aided Design) model into g-code for a printer through what is known as slicing, we chose to develop software that entirely bypasses the CAD process. Because artery stents are composed of a limited assortment of mesh geometries, to each of which a few minor dimensional changes are applied based off of stent parameters, a CAD conversion system would be unnecessary and inefficient.

There are two primary elements to the printer's software: the g-code generation software and the printer's firmware (Fig. 1). The g-code generation software, as the name suggests, generates the g-code that the printer uses when printing each customized stent. As mentioned previously, g-code, or machine code, is a programming script used in controlling automated machines such as 3D printers. Traditionally, printer g-code is generated from a 3D part file (STL, STEP, etc.) through a slicing process. In the case of the ARTHETA-0, however, very little previous work has been done with polar printers. As a result, the little software that has been developed is not publicly available, and no dual-extrusion polar printer has ever been attempted; therefore, we cannot use previously existing slicing softwares. However, the application of the ARTHETA-0 is such that it does not need to be able to print any part, only stents with a limited set of mesh geometries and their respective dimensional parameters; therefore, traditional slicing applications are not necessary. In fact, they would likely present more of an inconvenience during usage than would a simplified approach, as an operator would be forced to alter a CAD model, import it into slicing software, and then export g-code. As an alternative, arGen, the ARTHETA-0's software, accepts only an input of stent parameters such as mesh type, length, thickness, outer diameter, and others, and then outputs the respective g-code for the described

stent. Through this method, arGen bypasses the use of a CAD model altogether, streamlining the process and allowing quick and easy operation. ArGen consists of a front-end GUI (Graphical User Interface) to allow for easy parameter input (Fig. 3) and a convenient stent renderer. The core of the software is driven primarily by its backend slicing software, which implements a recursive, layer-based algorithm for each stent segment and stage of printing. These stages include initialization, skirt (nozzle priming technique), lower ring segment, mesh segment, upper ring segment, and print termination (Fig. 2). The g-code output (Fig. 4) from arGen is then transferred to the ARTHETA-0 control board in one of three ways. As currently implemented on the prototype model of the printer, the g-code file is manually transferred to the printer control board through the use of an SD card. Later in development, however, on the production model of the ARTHETA-0, there will be two configurations for file transfer between which each client is able to choose based on their preferences, each meant to streamline and simplify the process. The first of these helps to reduce the complexity of the process while still maintaining the use of an external computer; instead of having to be transferred manually, arGen will automatically transfer the file via either Bluetooth or WiFi. The second production model configuration eliminates the use of an external computer altogether, and the arGen software is run on a Raspberry Pi built into the printer, while parameters are input using the already existing user interface.

Once the control board receives the g-code, it is able to begin executing the included commands. Of course, the control board requires firmware to operate, for which the ARTHETA-0 implements a modified version of the popular, open-source Marlin firmware. Because Marlin does not have a configuration that works for polar printing, we have modified the motion measurements, such as velocity, acceleration, and jerk, of the theta- and r- axes to be defined algorithmically with respect to the positions and motion of the other axes. From there, to prevent major firmware changes, the axes in the g-code are cast to fit cartesian axes, where R maps to X and Theta maps to Y. Of course, the physical motion of the printer maps back to the original polar axes, but this eliminates the need for a complete firmware overhaul.

VII. FIGURES

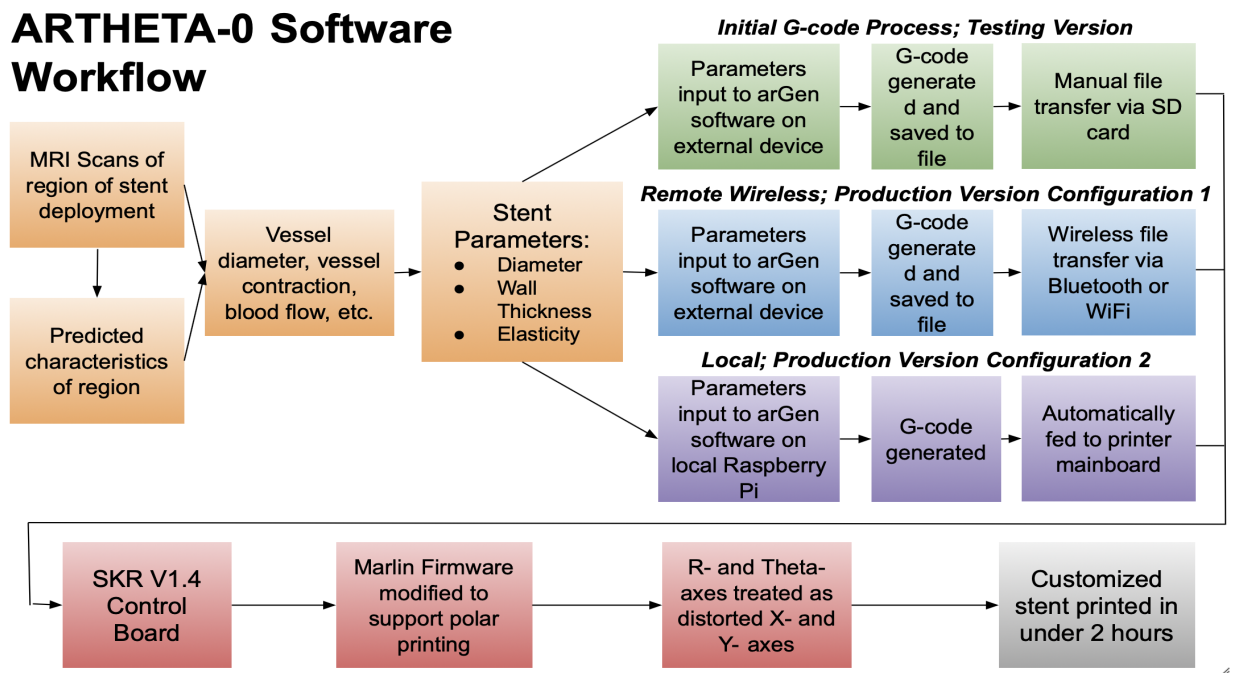

Figure 1: Upper level software workflow for ARTHETA-0. Based off measurements of stent deployment region from MRI scans, as well as predicted characteristics of the region, stent parameters are input into the arGen software, which generates the g-code necessary to print the specified stent. The g-code is then transferred to the printer control board in one of three ways, determined by the printer model and configuration, where it is processed by modified Marlin Firmware to execute the printing procedure.

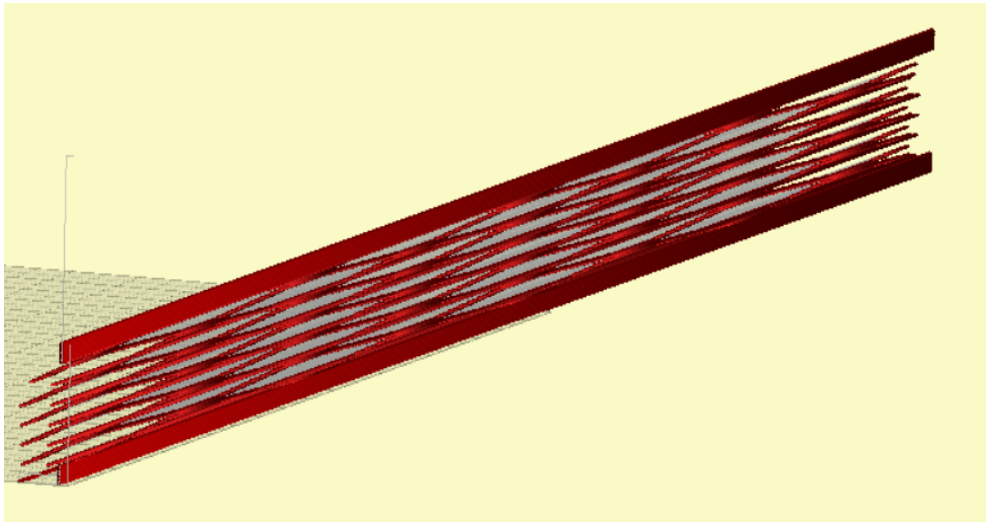

Figure 2: Visualization of arGen g-code output generated by Pronterface, a 3d printing control software, which renders g-code in a cartesian form. This causes the linear display shown above, even though the g-code is processed and printed in a polar manner.

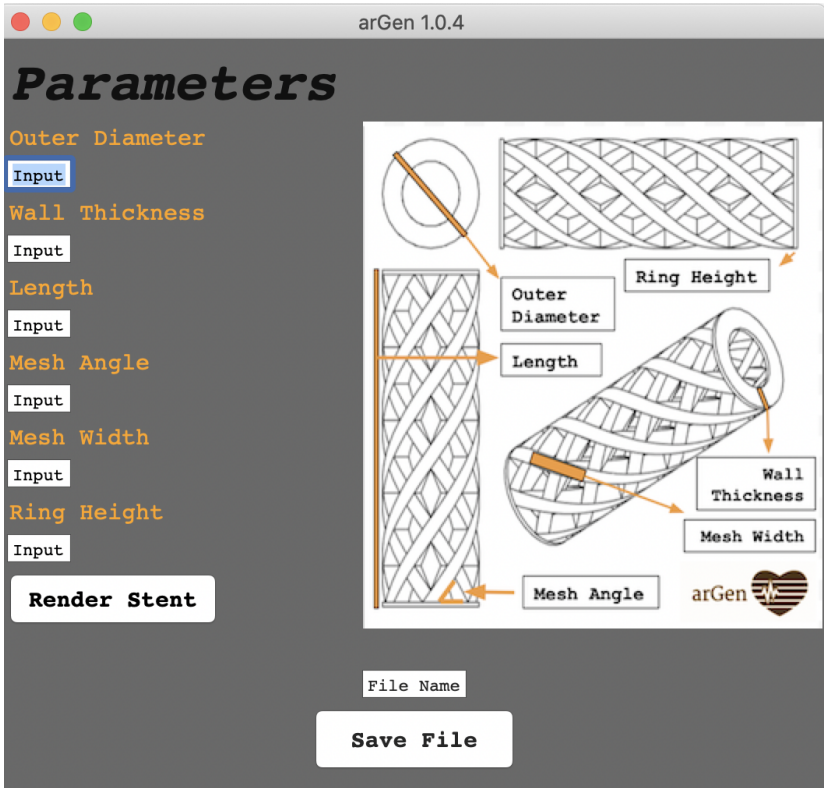

Figure 3: Visualization of the beta version of the arGen Graphical User Interface (GUI) Application. Users can input stent parameters, render the stent to observe a visualization, and export the file to a specified address.

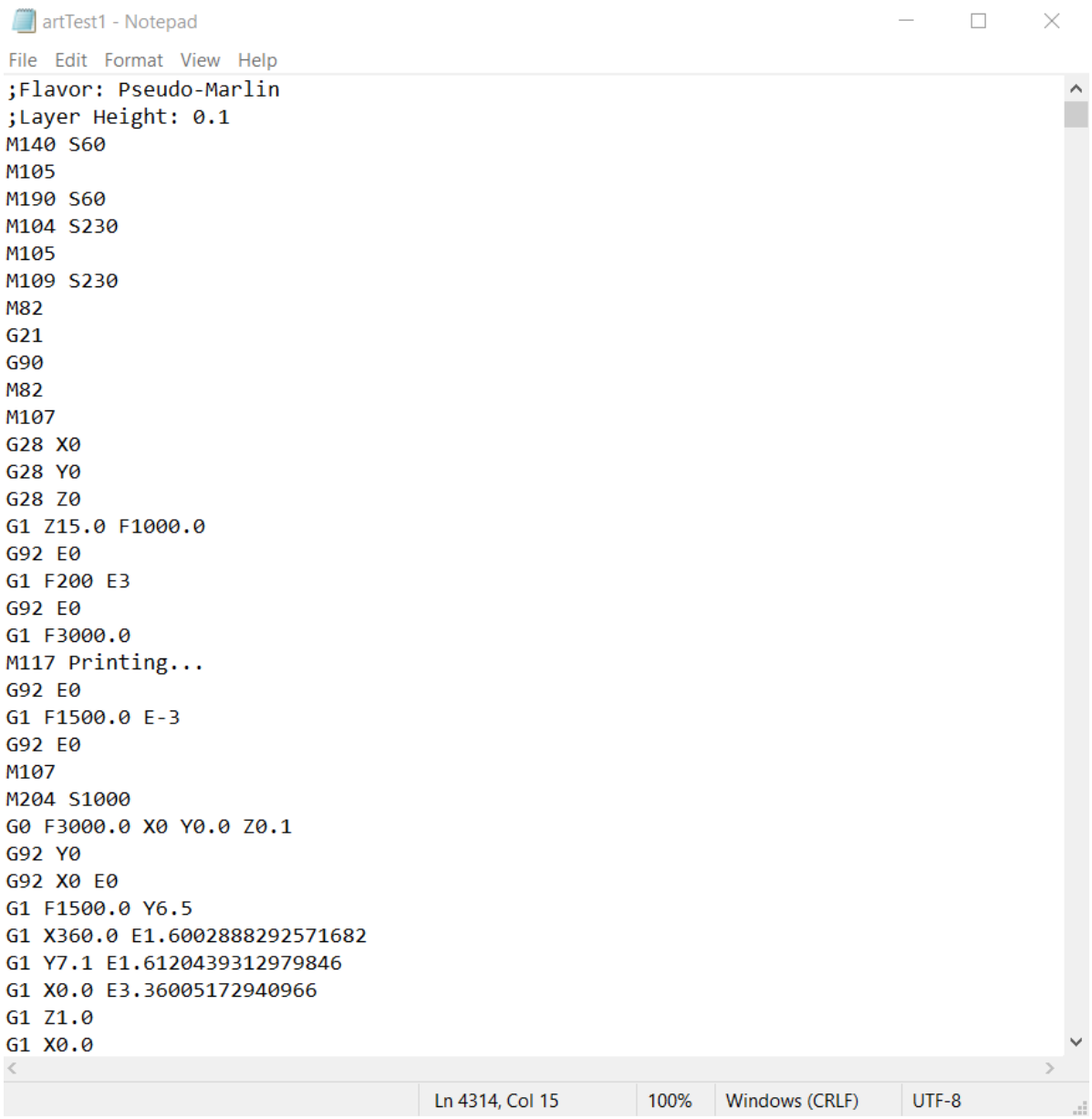

Figure 4: A sample of g-code generated by the arGen software for stent fabrication. The average g-code file for stents of similar specifications is approximately 5000 lines, where each line consists of a separate printer command.

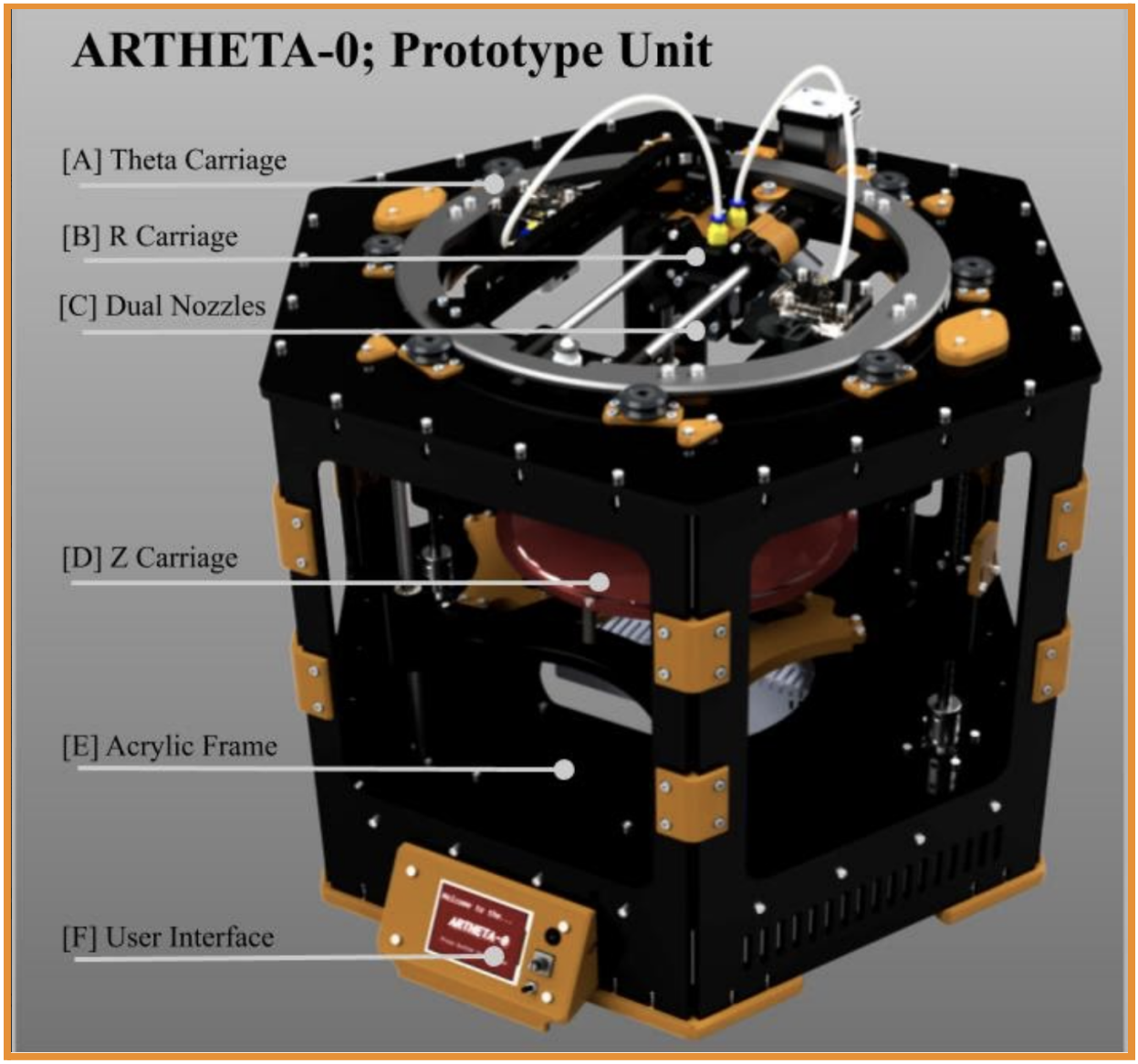

Figure 5: ARTHETA-0 prototype unit diagram. **A.** Theta Carriage. **B.** R Carriage. **C.** Dual Nozzles. **D.** Z Carriage. **E.** Acrylic Frame. **F.** User Interface.

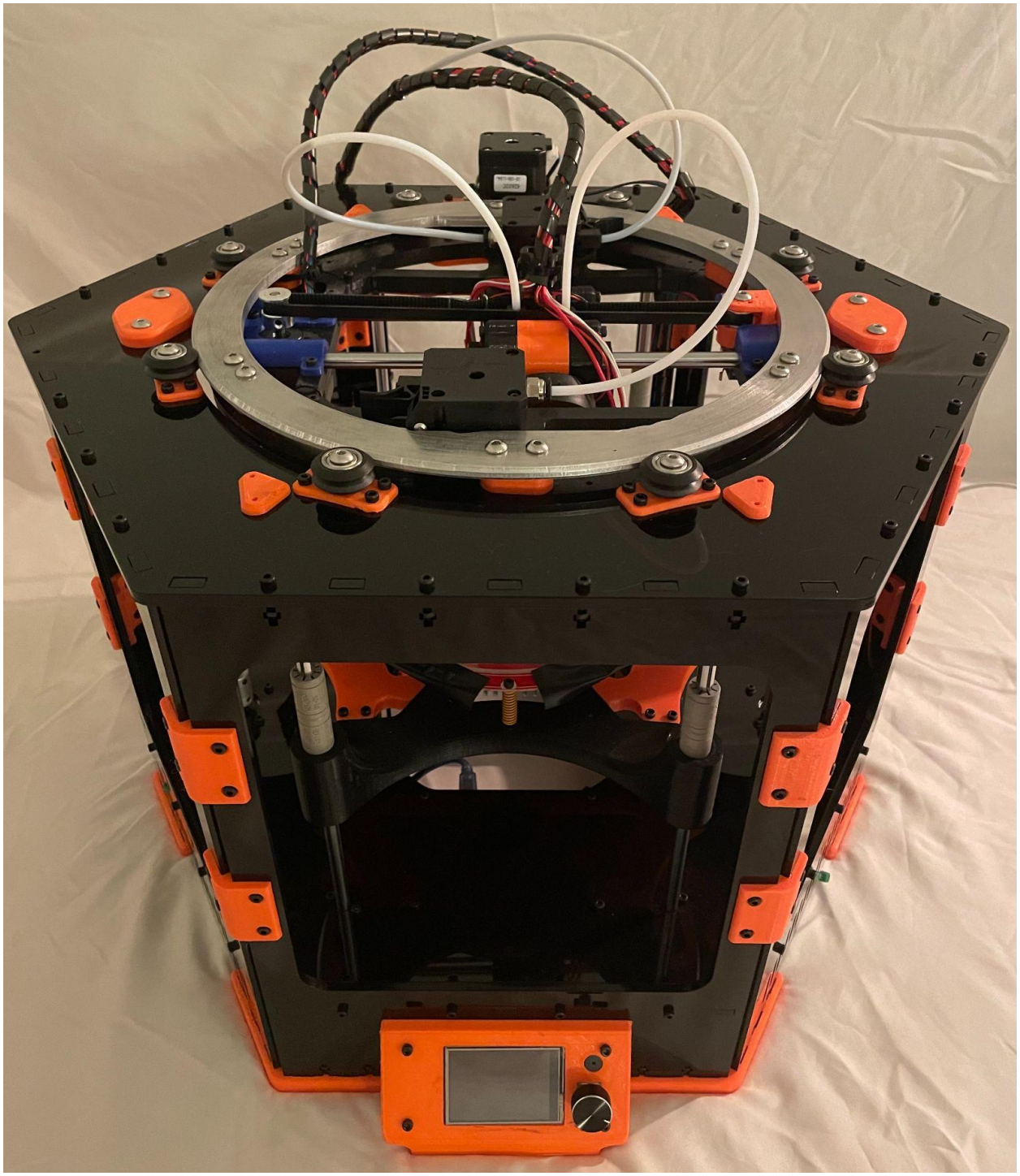

Figure 6: Image of the prototype unit of the ARTHETA-0

VIII. RESULTS AND TESTING

All parts of the ARTHETA-0 have been tested and revised to optimize functionality. Every subsystem has been proved to be mechanically viable through mechanical motion testing. The ARTHETA-0 has precision unmatched by any other Fused Deposition Modeling (FDM) at the price point (Table 3). The ARTHETA-0's output includes printing vascular stents with extreme accuracy and precision. It can print stents with a diameter of as low as 2mm (will be lower in future iterations) and a total precision of 15 micros. All stents are biodegradable/bioresorbable since they are made of flexible polymer, Thermoplastic Polyurethane, reducing the probability of post stenting complications such as restenosis. Additionally, stent dimensions can be edited using the ArGen software.

The ARTHETA-0 has an incredibly low production unit cost of $471 (Table 1). Its simplistic fused deposition modeling system allows it to be available on-site, in hospitals, eliminating shipping times. Furthermore, all stents can be parameterized to specific patient dimensions, eliminating the industry standard one-size-fits-all approach.

Table 1: Display of each component of the ARTHETA-0 prototype and production unit. Additionally, the cost of each seller unit is computed along with the cost of each unit as it is implemented into the ARTHETA-0 production unit.

Production Unit Cost Analysis				
Item	Amount per ARTHETA-0 unit	Amount per seller unit	Seller unit cost	Total Item Cost/unit
SKR V1.4 Turbo Control Board	1	1	24.47	24.47
Heating Pad - 200 mm	1	1	19.99	19.99
TMC2209 Stepper Drivers	5	5	20.48	20.48
Nema 17 Stepper Motors	4	5	25.88	20.704
Lead Screw + Coupler	2	1	8.69	17.38
8mm 300mm Steel Rod	6	2	7	21
Limit Switches	2	6	2.98	0.993
8mm Igus Drylin Bearing	12	12	14.24	14.24
12v PSU	1	1	25.53	25.53
AC04 Power Switch	1	1	1.63	1.63
1000mm GT2 Belt	1	1	1.69	1.69
1.75mm E3D Hotend	2	2	4.99	9.98
1.75mm Titan Extruder and Motor	2	2	7.55	15.10
12" Turntable Bearing	1	1	21.93	21.93

Drive Pulleys	1	1	15.99	15.99
5015 Radial Fan	2	1	0.90	1.80
TFT 24 Display	1	1	19.07	19.07
Cables	10	10	11.59	11.59
Bed Springs	3	10	0.57	0.171
Raspberry Pi 3 Model B+	1	1	35	35
M5, 30mm, Socket Head Bolt	12	10	2.18	2.616
M5, 12mm, Socket Head Bolt	5	10	1.80	0.90
M3 Bolt Set	2	1	8.38	16.76
0.25” 6061-Aluminum (4’x8’ Sheet)	0.41667	1	527.04	139.654
1.75mm PETG Filament (1kg)	0.75	1	20.99	15.74
1.75mm PLA Filament (1kg)	0.5	1	20.99	10.495
Total Parts Expenditure				470.67

Table 2: Display of estimated costs for full-stage manufacturing of the production units of the ARTHETA-0. All costs are single time expenses, except Hangar6 shop access

Future Fabrication Costs					
Machine Type*	Material	Machine Name	Purchase Cost	Alternate Access	Alt Cost
3d Printer	PETG + PLA	Prusa i3 MK3S+	999	Hangar6 Shop Access	200/month
Laser Cutter	Acrylic	51"x31" C02 Laser Cutter	8134	Hangar6 Shop Access	200/month
Router (Manual)	Aluminum	2.25 HP Router	182.02	No viable alternative	
Lathe (Manual)	Aluminum	12in Cast Iron Lathe	445.71	Hangar6 Shop Access	200/month
Drill Press	Aluminum	5 Speed Drill Press	77.59	No viable alternative	
Total Fabrication Expenditures			$259.61 - $9838.21		

*Machine models linked are not the same as those used in prototype production and are often significantly better.

Table 3: Display of pre-slop precision values of the ARTHETA-0 prototype versus a traditional FDM printer with a motion system consisting of cartesian coordinates.

Pre-slop Precision Based off Tech Specifications & Mechanical Design (ARTHETA-0 vs Traditional Cartesian)		
R-axis vs X-axis	Theta-axis vs Y-axis	Z-axis vs Z-axis
125µm* vs 125µm	2µm vs 125µm	25µm** vs 25µm

*The effect of R-axis precision error in the ARTHETA-0 is negligible (unlike x-axis) because structure restrains R-error.
**Due to reinforcements, Z-axis slop is much less than traditional printers, resulting in negligible effects on the print.

Table 4: Display of Technical Specifications of ARTHETA-0 unit.

Technical Specifications	
Motor Sprocket Tooth Count	20
Theta Sprocket Tooth Count	472
Nema 17 Precision	1.8°
Motor Sprocket Pitch Diameter	11 mm
Assumed Outer Stent Diameter	3 mm

Table 5: Display of ARTHETA-0 stent fabrication specifications. A maximum and minimum dimension is shown for each possible stent parameter that can be customized with the arGen software.

Stent Specifications		
Parameter*	Minimum Dimension	Maximum Dimension**
Outer Diameter	2 mm	80 mm
Wall Thickness	0.3 mm	39.3 mm
Total Length	0.6 mm	100 mm
Mesh Angle (from vertical)	0°	50°***
Mesh Width	0.3 mm	—

*Additional stent parameters exist, but they are either not bounded numerically (mesh geometry) or are defined relative to the listed stent parameters.
**Many of the maximum dimensions have been configure such that there is essentially no reasonable

restraint (ie. outer diameter and total length).
***Implementation of arGen software support for the dual-extrusion hardware system will allow greater mesh angles.

IX. DISCUSSION

The ARTHETA-0's implementation of a novel, efficient motion system that utilizes polar coordinates allows for the elimination of every major shortcoming in the stent manufacturing industry: low affordability, low stent parameterizability, and off-site stent fabrication, while not compromising stent quality.

The use of FDM printing allows for extreme affordability of the ARTHETA-0. It implements the application of simplistic technology in a sophisticated manner. This brings the total cost to $471 (Table 1) compared to >$100,000 for common industry methods such as laser machining, micro-EDM, and die casting. Materials cost for each stent will be less than 20 cents.

The novel software allows for stent parameters to be inputted prior to printing, which allows for customizable stents. Additionally, all stents are made of Thermoplastic Polyurethane in the prototype unit, and the printer is capable of printing Polycaprolactone and Polylactide Acid. These are all biodegradable and biocompatible and have proved to be adequate materials for stent printing as they can provide mechanical rigidity while still allowing for some flexibility. The biodegradability of the stents along with the incredible printing accuracy helps reduce the risk of post-stenting complications such as restenosis. As a result, the stents will only be in the artery lumen for the time it is required, attributed to the biodegradability of the materials, reducing the probability of a complication. Additionally, stents will be better fitted to individual patients, reducing failure rates,

Additionally, the entire unit requires a maximum 90 watt power source, and it is approximately 3 cubic feet in volume. Hence, it can be available on-site, eliminating shipping time and ensuring that patients do not have to settle for "off-the-rack" stents that have been previously ordered and kept in inventory. Indeed, stents can be printed 2 hours after parameter input.

Overall, the ARTHETA-0 has the potential to revolutionize the industry with cheaper and more efficient production methods that result in safer, more effective stents.

X. CONCLUSION AND FUTURE DIRECTIONS

The innovation of the ARTHETA-0 allows us to envision a future where doctors can use current medical scanning techniques to image a patient's arteries and receive a custom-fabricated stent within 2 hours of parameter input. Overall, the ARTHETA-0 fills a gap in the artery stent industry, paving the way to a future in which patients are not forced to settle for one-size-fits-all, off-the-shelf stents, but are instead given the opportunity to receive specialized stents, designed and fabricated specifically to meet their needs.

From a technical standpoint, future improvement aims for the printer to include the addition of arGen software support for the currently existing dual-extrusion system incorporated into the ARTHETA-0, which would allow for more complex mesh geometries and drug-eluting stents. Another improvement would be to implement a single turntable ball bearing to enable rotation of the theta-axis, which would help to increase print quality and decrease manufacturing time and cost. Furthermore, future iterations of the ARTHETA-0 will consist of a sheet metal

frame for increased rigidity and longevity and the implementation of medical-grade construction protocols.

From a medical standpoint, future testing will be needed to assess the biocompatibility of stent materials and obtain medical approval. A model cell line, such as Murine 3T3 fibroblast cells, would be obtained and cultured in DMEM (Dulbecco's Modified Eagle's Medium) with added nutrients. Fibroblast cells should be selected because of their rapid and stable growth kinetic. The second step would be to test on endothelial human cell lines in order to confirm biocompatibility as previous results have shown. The stents should be placed in non-adherent microplates, soaked with DMEM, and incubated at an appropriate temperature (according to the cell line) prior to cell seeding. To determine base biocompatibility, testing will be conducted under static conditions. The next step would be to test under more realistic, dynamic conditions in order to ensure feasibility.

Overall, with adequate engineering modifications and medical testing, the production unit of the ARTHETA-0 has the potential to change the stent manufacturing industry with the introduction of more efficient and inexpensive methods that enhance stent quality and thus improve patient safety and experience.

XI. ACKNOWLEDGEMENTS

We would like to thank Sam Dirani and Hangar6 for their work and support in providing laser cutting access and services, which were crucial in the fabrication of the ARTHETA-0. We would also like to thank the North Carolina School of Science and Mathematics and faculty for their educational guidance and support, which enabled the inception and completion of this project. A special thank you is extended to Dr. Tamar Avineri for her extensive guidance, support, and mentorship.

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