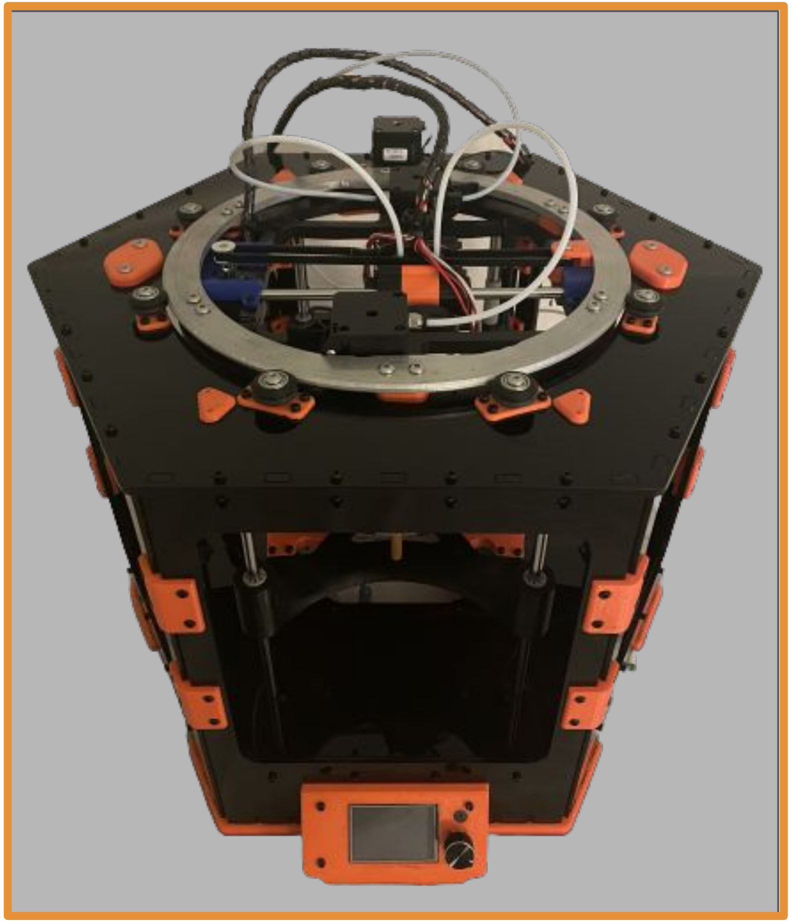
ARTHETA-0: An Innovative, Affordable, Approach to the Onsite, Rapid 3D Printing of Artery Stents, Parameterized to Fit Individual Patients' Needs

Connor Mitchell and Prabuddha Ghosh Dastidar

North Carolina School of Science and Mathematics,

Durham, NC, US



INTRODUCTION: Research Problem

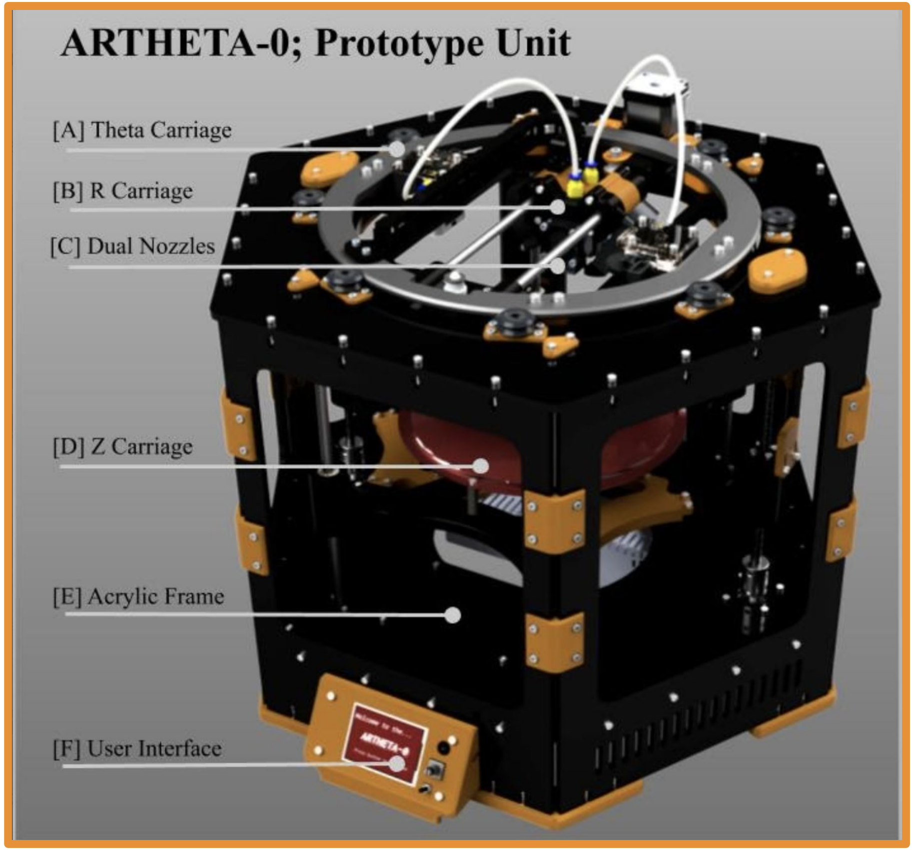
Vascular Stent

- Background About Stents
  - A vascular stent is a tube inserted into the lumen of a blood vessel to keep the passageway open
  - Over 2 million Americans undergo a stenting procedure every year, just for coronary arteries
  - Post-stenting complications are quite prevalent
    - The risk of re-narrowing of the artery is 10-20%
    - The risk of the artery clogging after stent placement is ≈5%
- The Problem: Shortcomings of the Stent Manufacturing Industry
  - The most common methods of stent manufacturing are laser machining, die-casting, & micro-EDM
  - Each of these machines are extremely expensive and can cost >$100,000
  - All stents that are manufactured follow a one-size-fits-all approach, which is not ideal
  - These methods require extensive infrastructure and capital and must be completed off-site
- The Problem: Shortcomings of Industry Innovations
  - PBF (Powder Bed Fusion) 3D printers are being developed to 3D print stents but these machines are far too expensive and they cannot be available on-site (extensive infrastructure and capital)

Image from: https://intermountainhealthcare.org/services/heart-care/treatment-and-detection-methods/stent-placement/

INTRODUCTION: Engineering Design Goals

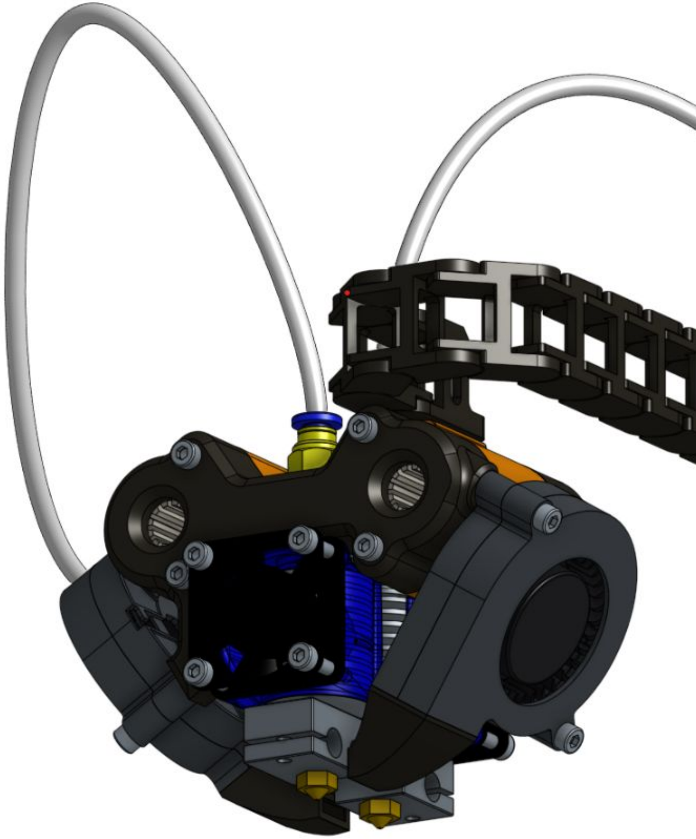
- The ARTHETA-0 is a 3D printer with a novel motion system, specifically designed for printing the small and complex cylindrical structures of vascular stents
- As opposed to one with cartesian coordinates, the ARTHETA-0 implements a polar motion system, consisting of R-, Theta-, and Z- axes, which requires only the movement of the Theta-axis to print circular geometries, eliminating the need for axial synchronization
- Print bed is horizontally static, leading to more accurate prints with lower failure rates
- Incredible affordable solution, <$500 per unit
- Simplistic Fused Deposition Modeling System to allow it to be available on-site, in hospitals
- Can print stents that are parameterized to patient specific dimensions, only needing a minor change in software input



A combination of affordability, accessibility, and parameterizability never before seen in the industry

TECHNICAL PROCEDURE & METHODS: R Carriage

- The R-axis (radius-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
  - The extruder, which is the motorized element which 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
  - Filament is pushed through a teflon tube after going through the extruder, which then feeds it into the hotend
  - 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
- Functionality tested for proof of concept (see slide 10)



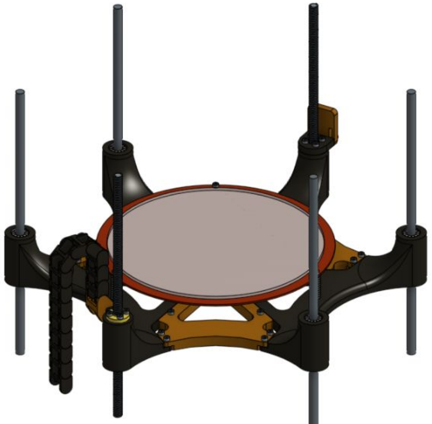
TECHNICAL PROCEDURES & METHODS: Theta Carriage

- The theta-carriage is supported by a circular aluminum plate, machined using a router, with a 45 degree chamfer on each side of the outer edge, which rests within 8 v-groove bearings mounted on the printer frame around the plate
- To ensure the plate is sufficiently held in place, 6 of the v-groove bearings are mounted to sliding, adjustable 3D printed plates, which are tensioned to constrain the theta carriage to only Z-axis rotations
- To rotate the carriage, a 472 tooth GT2 belt is inversely fastened to the PLA (Polylactic Acid) carriage body
    - In Theta Carriage iterations 1-3, the teeth were printed directly into the carriage body. This was revised to increase consistency
- A 1000mm, 6mm, GT2 belt is then used to transfer motion to it from a 14 tooth sprocket attached to a Nema 17 motor mounted to the printer frame

- The main theta sprocket is split into four in order to reduce part size, so as to meet our production restraints, 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-axis is bound directly to the frame, reducing mechanical complexity and failure points, as well as decreasing the overall weight of the carriage
- Functionality tested for proof of concept (see slide 10)

TECHNICAL PROCEDURE & METHODS: Z Carriage

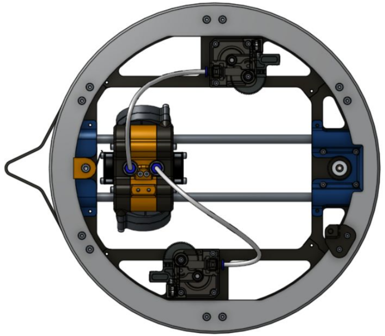
- The Z carriage consists of a pattern of six 3d printed plates, together forming the mount on which the spring secured print surface is mounted
- The print surface is a 0.125” glass plate attached to a PCB (Printed Circuit Board) heating plate, which heats print surface to 60℃, producing greater bed adhesion
- The z-carriage is then driven by 2 lead screws and guided by 4 8mm steel rods and drylin linear bearings
- The z-carriage implements a horizontally static print bed
  - Causes increased print quality: since bed is not moving as an axis, less mass is shifting and variability from material deposited on the surface is removed
  - This eliminates variable mechanical slop and resistance from the system
  - The print’s adhesion to the surface is therefore not worn down
- Functionality tested for proof of concept (see slide 10)



Z Carriage Render

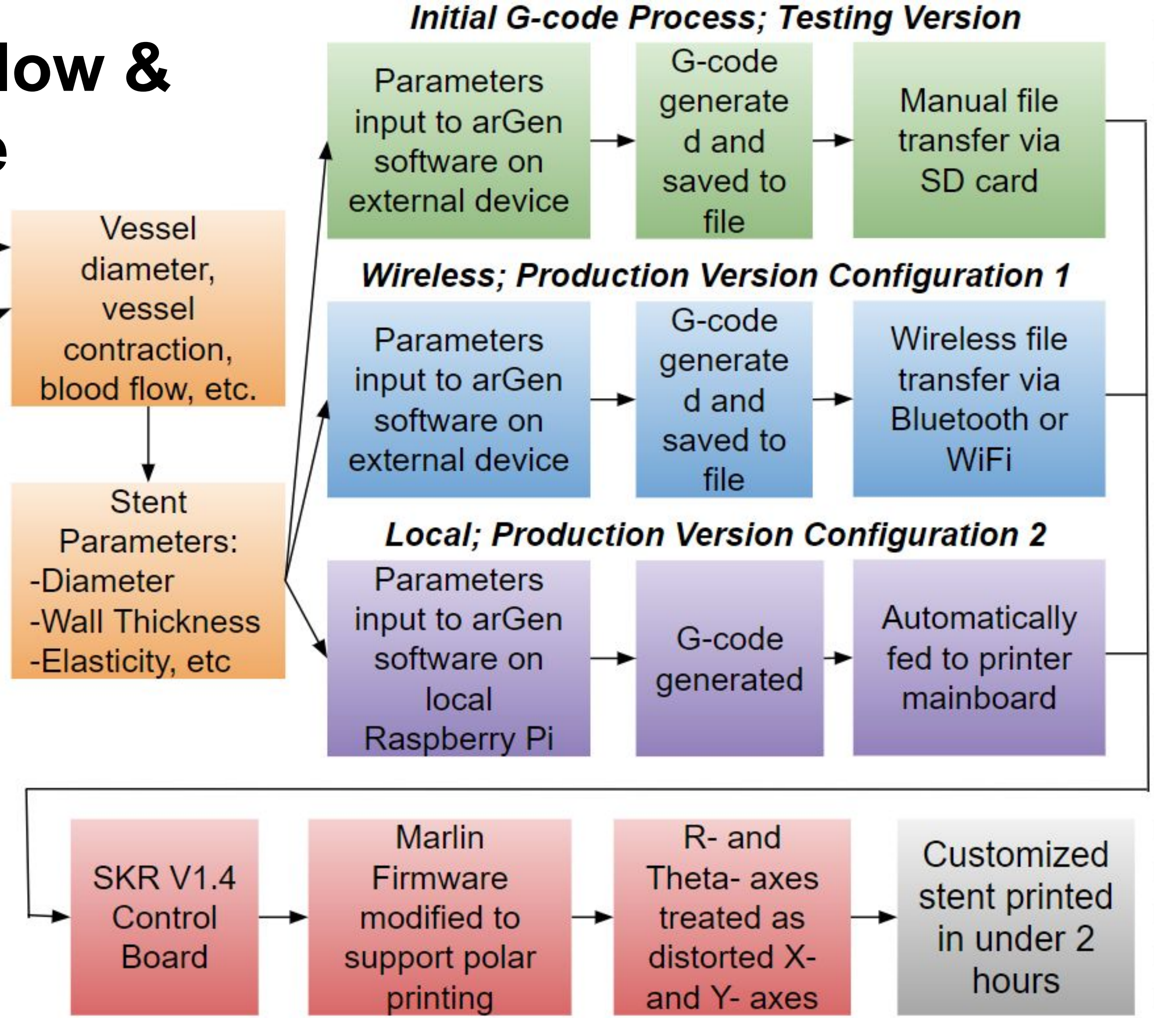
Additional Feature: Dual Extrusion

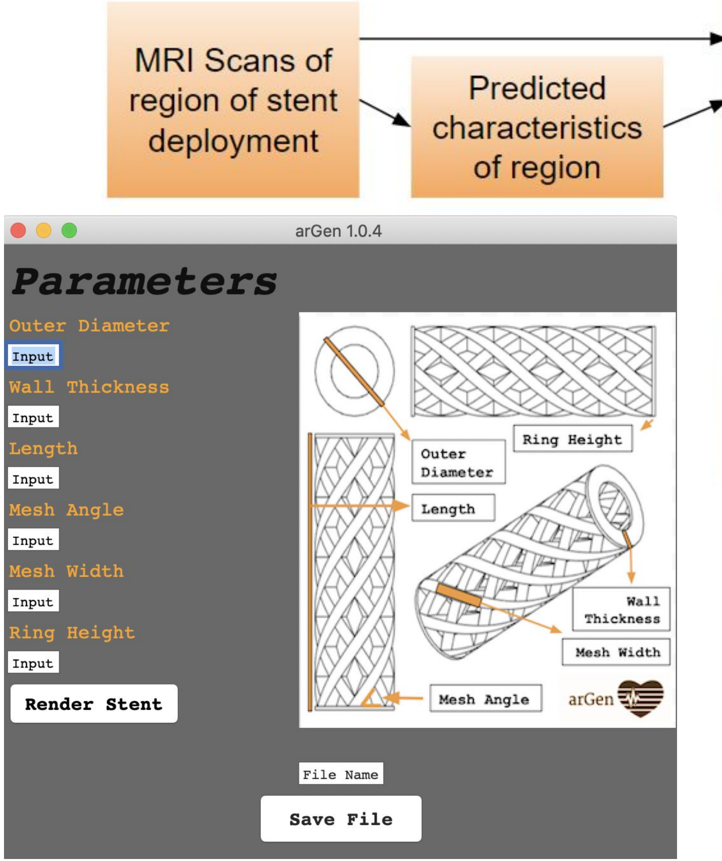
- The ARTHETA-0 is able to print two materials within the same print for more complex stent designs
- While some dual-extrusion printers extrude both filaments out of the same nozzle, the ARTHETA-0 contains two nozzles and hotends
- This allows it to print two different plastics:
  - The first, TPU (Thermoplastic Polyurethane) is used to make up the flexible body of the stent
  - The second, PVA (Polyvinyl Alcohol), is used as a waste support material which dissolves when placed in water



Dual Extrusion System

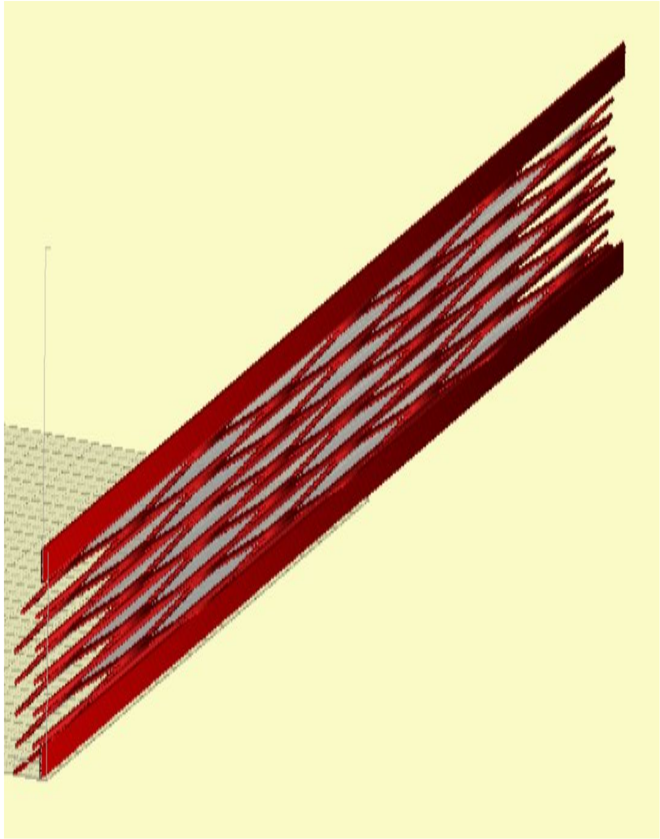
arGen Software Workflow & Graphic User Interface





TECHNICAL PROCEDURE & METHODS: Software

- arGen
    - Responsible for generating g-code (machine code), which gives the printer "instructions"
    - Completely original method for writing polar g-code
    - Instead of a CAD model, arGen takes stent parameters as inputs, cutting down on operation time and user complexity
- G-code deployment
    - G-code file transferred to printer in one of 3 ways, based off user preferences (see slide 8)
- Firmware
    - Runs on the printer control board; interprets g-code and controls the printer
    - ARTHETA-0 implements a modified version of the open-source Marlin firmware to provide for polar control. The axes are perceived as cartesian, but modifications to the motion dynamics distort the cartesian plane to provide functional polar output.



arGen G-Code render (cartesian form)

RESULTS: TESTING & OUTPUT

- Mechanical and Quality 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
  - Stents were printed by ARTHETA-0 using g-code developed by arGen for proof of concept
- Output: Stent Features and Specifications
  - The ARTHETA-0 is capable of printing vascular stents with extreme accuracy and precision
    - Outer stent diameter of as low as 2 mm
    - Stents printed with 15 micron total precision (assuming reasonable slop)
  - All stents are biodegradable/bioresorbable since they are made of flexible polymer, TPU
    - This reduces the probability of post-stenting complications such as restenosis
  - Parameters of printed stents can be easily adjusted using ArGen software

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

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

Discussions

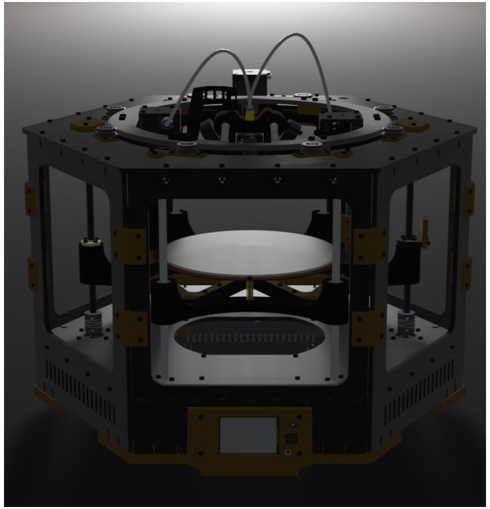
- Interpretations
  - The ARTHETA-0 is extremely affordable at **$471** unlike industry methods
  - Can print stents that are **parameterizable** to patient dimensions unlike industry standards, reducing post-stenting risks (ex. restenosis)
  - Can be implemented **on-site** (unlike industry standards) due to simple FDM system and non-extensive infrastructure (≈3 ft^3)
  - Increased observed printing **precision** compared to traditional cartesian 3D printers
  - All steps of user operation are meant to ensure **simplicity**
  - All subsystems **iterated** and **revised** to ensure **optimal** performance

- Issues that Arose During Engineering Process & Solutions
  - Theta carriage redesigned (5 iterations) to ensure maximum consistency, longevity, and precision
  - Z Carriage prototyped through 15+ iterations to optimize linear bearing compression
  - Several system electrical layouts prototyped to optimize performance and minimize wire length

3D printed artery stent

Conclusions and Future Directions

- Conclusions
  - 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 available for use within 2 hours of parameter inputs
  - All engineering goals have been met (see slide 3)
- Future Directions
  - Obtain utility patent for “Static Surface Polar 3D Printing” as well as a design patent
  - Utilize dual extrusion and modify arGen for more complex stent geometries and drug eluting stents with greater overhangs than would have been possible without a soluble support material
  - Implement theta-axis bearing for decreased manufacturing time and cost, as well as increased quality
  - Implement sheet metal frame for increased rigidity and longevity, and the implementation of medical-grade procedures after quantitative biocompatibility and biodegradability testing
  - Extend print materials to polycaprolactone and polylactic acid for further customizability in material rigidity/flexibility



ARTHETA-0 Render

Thank You

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