POLYJET BEST PRACTICE

Post-Processing 3D Printed Stroke and Aneurysm Flow Models

SOFTWARE / PRODUCT / FINISHING

OVERVIEW

3D printed vascular flow models are lifesaving medical devices, enabling access points to the full flow loop, sensors and blood-flow simulation. Their properties mimic precise vasculature, which enables surgeons to prepare for surgeries on models with a range of tissues, prior to surgery.

TangoPlus™ and Agilus30™ materials for the Stratasys Objet500 Connex3™ 3D Printer offer the flexibility and compliance to mimic a life-like feel. However, due to the thin nature of vascular model lumen walls, care must be exercised to avoid punctures during removal from the printer, through the cleaning process, and during the attachment of inflow and outflow connectors. This Best Practice document provides the instruction for working with these models, including specific water temperatures, water-flow pressures and handling procedures to avoid tears and punctures (Figure 1).

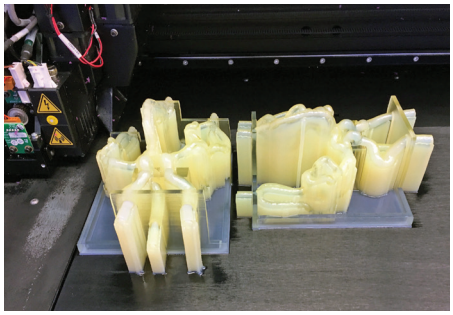

Figure 1: A vascular model, post-printing.

These are the steps from manufacture to post-cleaning:

1. Extract model from 3D printer
2. Irrigate with water and catheter
3. Chemical clean with CSIIP CleanStation
4. Irrigate with water and catheter
5. Attach inflow connectors
6. Attach outflow connectors
7. Fluid flow inspection and repair
8. Lumen patency inspection via X-ray angiography
9. Flow model set-up

RECOMMENDATIONS

During the model cleaning process, operators are likely to be splashed with water and support material. **Personal Protective Equipment** (PPE), including a lab coat, closed-toed shoes and long pants are recommended during this process. The PPE recommendation during the CSIIP Chemical Cleaning Station process includes the **addition of safety goggles, protective face mask and neoprene gloves**.

The models are susceptible to tearing at every stage of extraction and cleaning. Use care to minimize strain and stress on the models as they become inoperable if damaged.

When beginning the cleaning process, start with a slow flow of water, increasing flow gradually. Always use cold water when flushing or washing models. TangoPlus becomes very brittle when exposed to warm water.

Before advancing to the next step, allow models to dry fully. Once dry, the model will be transparent which aids in finding errors, including blocked lumens and holes, more easily.

Envision model anatomy when you are cleaning. Being aware of model anatomy will aid in determining where support material exists.

All 8 steps below require proper PPE.

1. Extract Model from 3D Printer

STEP 1: Wearing nitrile gloves, use a plastic scraper and gently scrape the model off the printer tray.

STEP 2: For transport to a processing location, place models on a tray to minimize strain.

STEP 3: Clean printer space with a 1:1 volumetric mix of Simple Green or equivalent cleaner, and water.

STEP 4: Clean printer heads with 95% ethanol and smooth/scratch resistant wipes (soft white cloth)

STEP 5: Clean wiper blade manually as needed.

STEP 6: Remove outer support material manually with scraper.

2. Irrigate Model with Water and Catheter

Prior to chemical cleaning, external support material needs to be removed from the model to create fluid pathways through the lumen to facilitate chemical cleaning.

STEP 1: Attach a 5FR catheter to a pressured COLD water source. The water flow should extend several inches from the distal tip of the catheter (Figure 2).

Figure 2: Use mid-low flowing water pressure when flushing model with catheter.

STEP 2: Flush Inflows.

Pinch each accessory branch to ensure all vessels are patent and interconnected, while varying the input flow location. Be sure water exits all vessels. Pinch alternative vessel routes to ensure proper flow through every vessel. Repeat steps until all vessels are patent and interconnected.

- Flush outflows in the same manner.
- Repeat, flushing inflows a second time.

Use care when advancing the catheter to avoid puncturing vessels. If any ballooning of the vessels is observed under flow, immediately remove the catheter and clear the blockage. Listen for potential leaks. Avoid deforming vessels during pinching as this increases the risk of tears. When flushing through outflows, try to have all material exit inflows until connected with inflow passageway. Post-cleaning, vessels will appear transparent. When water is absorbed after only a few minutes, the model will appear cloudy until completely dry.

3. Chemical Clean with the CSIIP CleanStation

The CSIIP Clean Station is a tool to dissolve the support material and any material in the inner lumens.

STEP 1: Place the model in CSIIP CleanStation.

STEP 2: Follow the Stratasys CSIIP CleanStation User Guide for operating instructions. The necessary cleaning time will be dependent upon the number of models in the bath and model geometry. Typical times range from 20 minutes to 1 hour.

STEP 3: Remove the model from the CSIIP CleanStation. Irrigate the model with cold water and manual cleaning to remove the alkaline cleaning solution. The solution will be predominantly removed/diluted when the model is no longer slippery to the touch.

4. Irrigate With Water and Catheter

After retrieving models from the CSIIP Clean Station, lumens should be flushed with cold water from outflows->inflows.

STEP 1: Flush the outside of the model with cold water

STEP 2: Add tubing and connect to model to flush:

a. flush, from outflows->inflows

b. then, from inflows->outflows

c. then, from outflows->inflows

STEP 3: Document any leaks on the model so they can be identified for future repair.

Dry the model in a lab oven at 35 °C until lumens are transparent (2-12 hours depending on lumen size and bifurcations). If a vessel remains opaque, support material remains. Flush again and dry until transparent.

5. Attach Inflow Connectors (if not included in model print)

To be performed in a fume hood:

STEP 1: Remove support material from the 3D printed connectors.

a. Ensure inflow connectors are clear of any support material on the inner diameter.

b. Allow connectors to dry before proceeding to the next step.

STEP 2: Apply Loctite Super Glue (Ultra Liquid Control) to the face of the connector that will be in direct contact with the model. Adhere connector to the inflow hubs.

STEP 3: When dry, apply Smooth-On Sil-Poxy silicone rubber adhesive around the perimeter of the joint between the connector and the model. Sil-Poxy working time is 5 minutes.

STEP 4: Dry the model in an oven at 35 °C until the Sil-Poxy is dry. Cure time is typically 12 minutes. Once cured the Sil-Poxy will provide a waterproof connection.

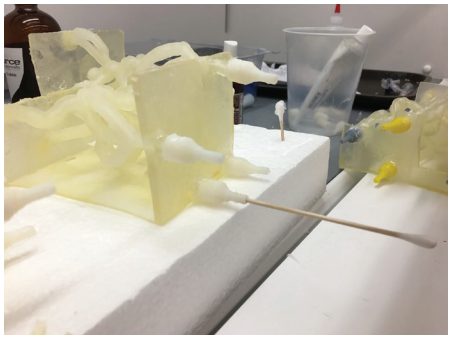

Figure 3: Outflow connectors are attached with cotton swab placed in connector to ensure lumen alignment and patency.

6. Attach outflow connectors

STEP 1: Clean (remove support material) from four 3D printed outflow connectors and allow to dry.

STEP 2: Place model in ventilated hood.

STEP 3: Apply Loctite Super Glue (Ultra Liquid Support) to the inner diameter of the connector on the end that will contact the model.

STEP 4: Manually break the tip off a cotton swab. Place the wooden end of the cotton swab into the outflow connector to make sure model and connector are aligned and patent (Figure 3).

STEP 5: Apply Loctite Super Glue (Ultra Liquid Control) to the face of the connector that will be in direct contact with the model. Adhere the connector to the inflow hubs.

STEP 6: Once dry, apply Smooth-On Sil-Poxy silicone rubber adhesive around the perimeter of the joint between the connector and the model. Sil-Poxy working time is 5 minutes.

STEP 7: Cure the model in an oven at 35 °C. Cure time is typically 12 minutes. Once cured the Sil-Poxy will provide a waterproof connection.

Figure 4: Flow model is connected to perfusion system with no leaks.

7. Fluid Flow Inspection and Repair Methods

STEP 1: Leak Testing

Attach the model to a flow system (pump, tubing, water reservoir). Turn on pump and perfuse the model with mid-low flowing water pressure (Figure 4).

a. Document any leak locations within the model

   i. Most common are the interfaces between the connectors and the model.

   ii. Gently manipulate bifurcations and to reveal any leaks that may be hidden.

   iii. Look at inflows and make sure inflows contain no holes (this is very important because the devices spend the most time in here).

   iv. Check outflows for leaks (minor leaks in these regions do not affect device performance).

b. If there are leaks, allow the model to dry, then repair using Smooth-On Sil-Poxy. Allow the Sil-Poxy to dry in the oven at 35 °C for 12 minutes prior to evaluating the model.

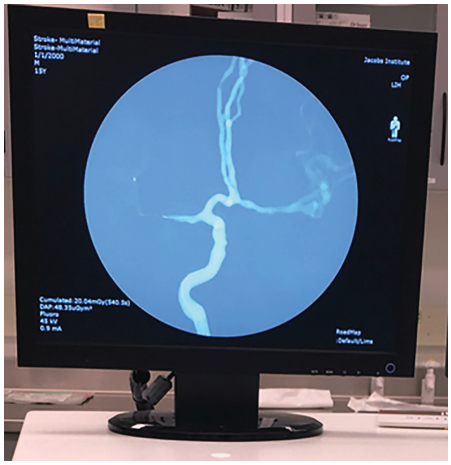

Figure 5: X-ray road map of a model showing occluded right carotid artery (left side of image).

8. Lumen Patency Inspection Via X-Ray Angiography

X-ray angiography is the best method to verify the vessels are completely patent and all support material has been removed.

STEP 1: Hook up the model to a water perfusion loop.

STEP 2: Insert the guide catheter (leading with a 0.35” guide wire), such that the distal end of the catheter is in the inflow for one of the vessels.

STEP 3: Activate the X-Ray and inject radiopaque contrast media, diluted 50% with water by volume. The contrast media will move through the vessels and highlight the inner lumen.

STEP 4: Obtain the vessel road map and visually inspect for any blockages or partial occlusions (Figure 5). Document any suspicious locations.

STEP 5: Repeat the road map of vessels with injection from each of the access ports.

STEP 6: If any vessel blockages or partial occlusions are identified, repeat the cleaning processes to remove the support material still in place. Repeat all inspections following any additional cleaning or repairs.

STEP 7: After using contrast, flush the entire model with water, as any residual contrast will be sticky during model use.

STEP 8: Allow the model to dry for storage.

NOTE If X-ray angiography is not available, food coloring can be used to verify the lumens are continuous and patent (Figure 6).

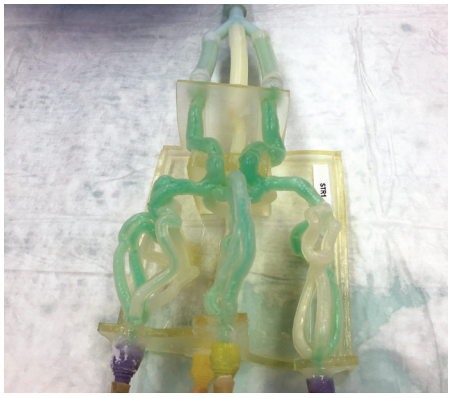

Figure 6: Flow model is connected and food coloring is injected into the model. Note that the right coronary artery is not green, indicating the occlusion shown in Figure 5.

POST-PROCESSING 3D PRINTED STROKE AND ANEURYSM FLOW MODELS

Safety

Personal Protective Equipment

- Lab coat
- Nitrile gloves
- Closed-toe shoes
- Long pants
- Safety goggles
- Protective face shield

Other

- Ventilation hood

Tools and Supplies

Equipment:

- CSIIP CleanStation
- Lab oven
- Water flow system (pump, tubing, reservoir)

Consumables:

- Radiopaque contrast media
- Simple Green cleaner or equivalent
- Scratch resistant cloths/wipes
- Loctite Super Glue Ultra Liquid Control
- Cotton swabs
- Sil-Poxy silicone adhesive

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