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3D-Printed Anatomical Models: Clinicians, Companies Hash Out Issues

by Ferdous Al-Faruque

Industry, health-care providers and FDA discussed major issues in using additive manufacturing for making anatomical models at the agency's headquarters last month. The findings will be presented in a white paper from the Radiological Society of North America to help FDA figure out how to regulate the technology.

Ensuring repeatability and accuracy in creating 3D-printed anatomical models to help guide surgery and other patient care is a crucial challenge ahead for clinicians, device-makers and third-party service suppliers.

That was a key takeaway from a workshop co-convened last month by US FDA and Radiological Society of North America (RSNA), which highlighted some disagreements between industry and clinicians over proper requirements for 3D printing tools used by clinicians, but much alignment in identifying some of the key technical challenges with the practice of 3D printing patient-specific anatomical models

A central challenge is the process of segmentation, where radiologists collect images of a body part that are used to create a 3D rendering and, subsequently, a physical model. More controls and improvements are needed in this area, participants agreed at the Aug. 31 meeting at FDA's Maryland headquarters. In addition to segmentation, proper training and establishing appropriate rationales for when to rely on 3D-printed models were other key themes at the gathering.

The findings of the workshop will be incorporated into a white paper that will help guide regulation and best practices.

For the past several years, according to FDA, more and more clinical centers have begun to use 3D-printed models of patient anatomy. The models are produced by the hospital, a medical

device manufacturer or a separate service provider. But a lot of open questions remain about the quality of the models and how they should be appropriately employed.

After the workshop, *Medtech Insight* spoke with James Coburn, a senior research engineer at FDA's device center (CDRH) and a top agency FDA official the issue of 3D printing. (*Listen to the entire conversation in the podcast player below to hear his takeaways.*)

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"These two distinct areas, of clinical practice, which isn't regulated by FDA, and medical devices, which are regulated by FDA, overlap a lot in this particular area," he said. "It led us to talk a lot more with the RSNA 3D printing Special Interest Group and we decided to jointly sponsor a meeting that could bring together the clinicians, industry and regulatory participants."

Avoiding Inconsistent Imaging

Jane Matsumoto, a radiologist at the Mayo Clinic and vice chair of RSNA's 3D Printing Special Interest Group (RSNA-SIG), presented factors in weighing benefit versus risk from using additive manufacturing, and, in particular, highlighted the issue of ensuring proper segmentation. She spoke during a breakout session on benefit vs. risk considerations.

"The concerns around [segmentation] is there are a lot of inputs that may go into it and that there are a lot of ways you can process [the images]," Coburn said. "So the quality of those scans depends greatly on how they're made, the technique used to make them and the segmentation technique used on them."

Matsumoto says stakeholders agreed that the segmentation process is likely the biggest risk area for potential errors. She stressed that it's important for all parties to know what level of accuracy is expected when making a 3D model, as well what the limitations are of a final model. Segmentation relies heavily on image acquisition and sometimes there is not a lot of control over how the image is captured, she cautioned. In such cases, clinicians are left wondering if they should use the data to create a 3D model for a particular application if the image quality is lacking.

"[Segmentation] was the area where we could probably work on to get the most consistency and improve practices and make recommendations," said Matsumoto.

Matsumoto's group came up with multiple recommendations to help improve segmentation data and accurate reproducibility of the data.

Among the best practices they recommend is to consistently use phantom models to compare to

the original source model. They also recommend two different people read the captured data on complex cases to ensure there is agreement on the imaging used to make the models.

"Having two people with high-level skills looking at those and have double reading, that really brings up the level of accuracy," Matsumoto said.

Another recommendation that was floated by members of RSNA-SIG is using a certification system to ensure everyone involved is qualified to capture the images, interpret them and create the models.

Matsumoto notes that certification is already common in the radiology field and could be applied more broadly. She added, however, that it may take some time and "nobody wants to do it tomorrow."

"In order to credential someone, you have to have a training program," she said. "Doing this will ultimately become part of residencies, someday."

Todd Pietila, a senior business development manager at the 3D printing software company Materialise, who presented a summary of a "clinical practice insight" breakout session held at the workshop, echoed the need for proper certification for people tasked with creating the anatomical models, regardless of whether they are radiologic technologists or engineers. The skillset, motivation and experience should be the deciding factors for determining whether they should be creating the anatomical models, he said.

"In cases where a model is created for diagnostic use, quality control should always be performed by a physician," said Pietila. "The radiologist and subspecialists should be involved in the segmentation process in cases that involve more complex and anomalous anatomy."

Participants also recommended pursuing deeper research into how 3D models are affected by varying data quality and segmentation. As an example, Matsumoto said they could look at images ranging from 1mm to 5mm accuracy, with and without contrast dye, to see what the quality of the 3D model is and, perhaps, understand if there is a significant difference in quality.

Similarly, experts say a statistical review of 3D printing cases is needed to better predict when certain 3D printing models and practices can be relied on.

Indication-Specific Requirements?

There was general agreement at the meeting about the challenges of segmentation and ensuring appropriate images are collected to construct a model. But it is up for debate how precisely to ensure that tools intended to help develop the models are sufficient.

Dimitrios Mitsouras, director of magnetic resonance physics and engineering at the Applied Imaging Science Laboratory at Brigham and Women's Hospital in Boston, spoke about the matter during a breakout session on the technical aspects of 3D printing that need to be addressed to ensure safety.

Mitsouras says some contention persisted between clinicians and manufacturers about how to go about ensuring safety. Clinicians, according to discussion at the session, favor guidelines and requirements to validate engineering, design and human considerations related to 3D printing for specific indications.

It may be necessary to develop minimum-requirement guidelines that clinicians can use to ensure that the imaging they are relying on is sufficient to support models for specific indications, Mitsouras said. On the other hand, manufacturers and third-party 3D-printing vendors tend to what to follow more general industry standards allow the radiologists and clinicians to devise how best to use 3D-printing tools in clinical practice.

Scott Rader, who leads the medical consultancy group Stratasys and recently collaborated on an analysis in *Medtech Insight* of the implications of 3D printing for the device industry (Also see "*Market Intel: How 3D Printing Can Enhance And Expand Medtech Opportunities*" - Medtech Insight, 7 Sep, 2017.), spoke out on behalf of the manufacturers during the breakout session. He notes that all members of the group "violently" agreed on the need for safety and assurance that 3D anatomical models meet the needs of clinicians and radiologists.

But, he said, "How it's done is where the rubber hits the road."

Rader argues the kind of regulatory oversight Mitsouras advocated would be too burdensome and goes against the very general regulatory oversight process that FDA is used to implementing.

"If we are making tools that are segmentation tools, which are 'region-growing' tools, it's not a region-growing tool for the toe and a different region-growing tool for the aortic root and a different region-growing tool for the ear, it's a region-growing tool," argued Rader.

Instead, he says, there needs to be a very broad regulatory pathway that gives clinicians the power to decide how to use 3D printers and whether the models made from those printers are appropriate for the job at hand.

"I don't want to make a TAVR [transcatheter aortic valve replacement] printer, I want to make a printer, which when the users, whether they are in a hospital or they are in a consulting firm or they are in a mom-and-pop medical model shop, and they want to go through the process, that they can actually have the process certified because my printers are neutral," said Rader. "It's not efficient to create a printer for a specific indication."

However, he said that if a 3D printer manufacturer markets their product for a specific indication, then it makes sense to require FDA oversight of the product to ensure it is safe and effective for that indication.

3D Printing In Clinical Practice

3D models should generally not be used to make diagnoses, participants at the workshop said. While the image may be used to support diagnoses by the radiologist, the resulting model should be relied on to help clinician gain a better understanding of a patient after the diagnosis.

A key benefit of 3D printing models highlighted at the workshop is that the tactile characteristic of the model helps clinicians better understand their patient and the anatomy they may have to address with surgery.

"One thing we all noticed is that with surgeons, it makes such a difference for them to have this physical model that they use to look at, that they think about before they do surgery," said Mayo Clinic's Matsumoto. "Again, they're not using it for diagnoses; a lot of times they are not using it for any measurements, but just having that, rotating it, holding it ... that adds so much to the care of the patient."

Participants at the workshop recommended the need for a study to understand how clinicians interpret the tactile information, how important that is for their work, and how the information overlaps and is used with imaging data captured by radiologists.

Pietila, from the company Materialise, stated that, ultimately, 3D models should only be used as adjunct to original image sources used to make the models, according to consensus from the "clinical insights" breakout session.

Another practical issue Pietila emphasized is that 3D-printed anatomical models need to be printed to scale to accurately represent the spatial relationships between anatomical structures. In addition, 3D anatomy models need to be relevant to support their indented use and free of artifacts. This means radiologists need to have enough time to clean up 3D images before they are used to print models.

Pieta also emphasized that it was important to manage expectations between radiologists and clinicians so the limitations of the models are understood.

FDA Perspective

FDA's Coburn says the agency has noticed a significant uptick in 3D printing and is trying to move as fast as possible to try resolve any regulatory issues. Last year, the agency drafted a guidance in a bid to let industry have a better understanding of its perspective on 3D printing broadly. *(Also see "US FDA Works To Finalize 3D Printing Guidance; Industry Asks For More*" -

Medtech Insight, 14 Jun, 2017.))

Coburn said he thought the workshop was valuable to helping reach consensus on how to make sure 3D-printed models are safe and used appropriately to improve patient outcomes.

"Overall, I think we agree on a lot of the benefits that these models can bring to clinical practice, also some of the possible risks that they have in their use," he said. "But I think depending on everybody's experience, every group or every person might not have appreciated those benefits or appreciated those risks and the variety of steps that go into making these models that can change those benefits and risks."

He notes the discussions during the workshop centered around the best practices to improve safety and repeatability in clinical settings. Coburn also acknowledged that segmentation was a key topic of discussion during the meeting noting that it creates a lot of variabilities in creating 3D anatomical models, which means there needs to be good controls in place that allow proper validation, repeatability and accuracy.

"There was discussion how do we make that repeatability more accessible to large groups. Manufacturers use quality systems to do that and they have the resources to do that, maybe other places don't. So we talked about training, standard operating procedures and areas like that," said Coburn. "From the FDA's perspective, it's part of that regulatory process that we review normally. We use segmentation in many other aspects of medical devices in addition to printing anatomical models, so we treat it and review it like any other process where a sponsor has to show they repeatedly produce their intended outcome."

He also notes that a lot more data on the technology needs to be gathered. He suggested clinical societies may be able to help develop consensus on what are appropriate requirements for 3D-printed models in clinical settings and what standard operating procedures need to be in place.

Ultimately, Coburn says one of the most important outcomes of the meeting will be RSNA white paper. "Hopefully we'll have a nice record of that that people can use as a nice reference and a baseline moving forward," he added.

From the editors of The Gray Sheet