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FDA Project Focuses On Imaging To Improve Stent Design

Firm: FDC Reports

Research supported by FDA's "critical path" initiative suggests that computed tomography is a useful tool for studying the mechanical dynamics of stents placed in leg arteries, among the more challenging parts of the body for device use.

There are few stents approved for use in the femoral artery and the agency has cracked down on manufacturers promoting stents cleared for bile duct placement to be used in the leg, where they are more likely to fracture because of the significant range of motion of legs (¹["The Gray Sheet" March 19, 2007](#), p. 10).

At least six firms are pursuing PMA approval for femoral artery stenting, but fracture rates, among other issues, remain a challenge.

The critical path initiative is a project established by FDA employing public-private partnerships to facilitate development of new technologies that can accelerate the path to market for drugs and devices. Using imaging as a tool for implantable device development is on FDA's critical path "opportunities list" (²["The Gray Sheet" March 27, 2006](#), p. 5).

Tina Morrison of CDRH's Office of Science and Engineering Laboratories presented research Sept. 16 conducted by one of FDA's partners, Charles Taylor, Associate Professor of Bioengineering at Stanford University. She spoke at a critical path initiative meeting sponsored by FDA and the Drug Information Association in Bethesda, Md.

Imaging Gauges Force Of Blood Flow On Stents

The research used CT imaging to measure the force of blood flow on stents in the femoral artery. Ultimately, the work could lead to stronger or more flexible stents, Morrison said.

In his research, Taylor cited one study showing that in 261 femoral stents, 37% fractured, while 25% broke into pieces. To test what forces might be acting on the femoral stents, he created a study for testing flexion of stents in younger subjects, approximately 30 years old, versus stents in subjects who were approximately 52 years old.

For imaging, Taylor preferred use of CT to view the aorta in legs because it allows the viewer to see the dynamics of the blood flow within arteries.

Taylor's lab employed software that can reposition views of vessels in two-dimensional and three-dimensional formats, Morrison explained.

As long as the subjects held their legs in a straight-leg position, blood flowed upward and downward through femoral arteries, as was expected. But when the older subjects slept, typically in a fetal position, the CT imaging showed "there was

a lot of localized buckling," of the vessels, Morrison said.

"From this analysis, they came up with a new range of motion," she added, which eventually led to new tests for the femoral stents.

Similarly, Taylor applied CT imaging to compare the blood flow forces acting on stent grafts used for abdominal aortic aneurysms.

There has been a lot of research on downward displacement forces on the stent grafts, but CT imaging shows that the sideways forces in the aortic vessel, and subsequently, on the stent, are at least three times faster and harder than the downward forces, Morrison said. And CT showed the angulation effects that lead to the increased force.

Virtual Clinical Trials Ahead?

Although CT certainly has its limitations, Morrison said she thinks manufacturers are under-utilizing this and other technologies in their development projects.

Ultimately, the agency wants to use imaging studies to help create 3-dimensional anatomical cardiovascular models and create "digital patients" that companies could use for virtual clinical trials. This could eventually lighten the load for enrolling actual patients in trials.

But to help make that a reality, Morrison said, industry, researchers and FDA need to more closely cooperate and device companies need to permit outside verification and validation of patented and proprietary product designs.

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