

UT researcher calls on FDA to change rules to address spine screw contamination

By Tyrel Linkhorn

A University of Toledo researcher is calling for a revamp of how operating room personnel store and handle the screws used in spinal fusion surgeries after results from a multicenter trial found high levels of contamination on supposedly sterile implants.

“Our findings about the prevalence of contaminated pedicle screws are concerning, to say the least,” said Dr. Aakash Agarwal, an adjunct professor in the UT Department of Bioengineering. “We immediately need to ensure all surgical implants are truly sterile. Our research unequivocally demonstrates that we have not been doing things correctly.”

Spinal fusion surgeries generally require four to six pedicle screws, but in the vast majority of procedures performed in the United States, surgeons begin with a tray containing 100 or more screws of different sizes to ensure the right size is immediately available within the operating room.

Because so few implants are used in each procedure, most screws are washed and sterilized repeatedly with other contaminated instruments from the operating room before they are actually used during a surgery.

But Agarwal said that isn’t practical or safe, and he’s calling on the Food and Drug Administration to ban the process in the United States.

In a paper published in the *Global Spine Journal*, a team of experts led by Agarwal found screws that had been repeatedly reprocessed are harboring a number of contaminants, including corrosion, soap residue and organic tissue.

“We randomly selected screws from four different trays of cleaned, wrapped and sterilized screws. Every screw we took out was contaminated, and they were about to go into a patient’s body,” Agarwal said. “The health-care system and patients would really benefit if we start packaging screws

individually. The repeated reprocessing system in trays should be banned.”

The researchers recently submitted a formal petition along with their data to the FDA.

Agarwal and his fellow researchers — which included Dr. Steven R. Garfin, interim dean of the University of California at San Diego School of Medicine, and Dr. Jeffrey C. Wang, co-director of the University of Southern California Spine Institute and president of North American Spine Society — presented evidence in a separate paper that individually sterile-packed screws also are picking up contaminants as they are handled in the operating room.

The researchers devised a study in which two groups of individually packaged screws were used during live spine surgeries at multiple centers across the United States. One group of screws had a built-in intraoperative guard, while the other group did not have such a guard. The screws were prepared for insertion then sent away for analysis.

“All 26 surgeries in the study had bacterial growth on the unguarded screws. That was the major finding, which surprised everyone,” Agarwal said. “Even if you provide screws in an individually sterile package, the way it’s handled in the operating theater makes it unsterile.”

That could potentially lead to infection and biofilm formation at the screw-bone interface.

No microbial growth was detected on the screws that had integrated guards, which is meant to shield the screw itself from being exposed to air or touch while loading it onto the insertion device.

The findings were published in *Global Spine Journal* and multiple conference proceedings. It also has been published by news media, including *Becker’s Spine Review*, *Spinal News International*,



Photo by Daniel Miller

SAFEGUARD: Dr. Aakash Agarwal, shown here holding a prepackaged surgical screw, has petitioned the FDA to revamp how screws used in spinal fusion surgeries are handled to avoid contamination.

Orthopedic This Week and Orthopedics Today.

Also involved in the research were Dr. Vijay Goel, Distinguished University Professor and Endowed Chair and McMaster-Gardner Professor of Orthopaedic Bioengineering at UT; Dr. Anand K. Agarwal, professor at UT’s Engineering Center for Orthopaedic Research Excellence; Dr. Hossein Elgafy, professor of orthopaedic surgery at UT; and Dr. Boren Lin, postdoctoral fellow at UT’s Engineering Center for Orthopaedic Research Excellence.

Data on surgical site infections following spine surgery varies, but a recent randomized trial from Mount Sinai Beth Israel hospital in New York found a 12.7 percent incidence rate. Agarwal said that could represent up to 100,000 patients suffering from surgical site infection in the United States alone.

“We shouldn’t be knowingly putting bacteria and other contaminants inside a patient’s body. With the disclosure of these evidences, it would be impossible to not undertake necessary safety measures,” Agarwal said.

In addition to his faculty appointment at UT, Agarwal is the director of research and development for Spinal Balance, a private company that was founded in 2013 by a group of UT research professors. The firm, with its corporate office at the UT LaunchPad Incubation building, was created in part to address the problem of surgical site infection stemming from contaminated implants.

Agarwal also was recently appointed to the editorial board of the *Clinical Spine Surgery* journal by Lippincott Williams & Wilkins for his contribution toward original research and peer reviews in the spine field.

Faculty: Jan. 16 deadline to apply for research funding

Wednesday, Jan. 16, is the deadline for UT faculty members to apply for more than \$200,000 in internal funding administered by Research and Sponsored Programs.

“Our annual internal grant programs support a wide range of faculty research and scholarship at the University,” Dr. Richard Francis, director of research advancement

and information systems in Research and Sponsored Programs, said.

The Jan. 16 deadline is for the STEM Research Innovation Program, the Biomedical Research Innovation Program, the Interdisciplinary Research Initiation Award, and the Archaeological Research Endowment Fund.

In addition, there are several minor programs that faculty can apply for that do not have deadlines.

“We encourage all full-time, tenured and tenure-track faculty from all disciplines to find a program that could help advance their scholarly efforts,” Francis said. “These awards also provide support to help faculty gather preliminary data that will enhance

their ability to receive external competitive awards.”

For more information, including details on submitting proposals, visit the Research and Sponsored Programs website at utoledo.edu/research/rsp/urfo.