

FOR IMMEDIATE RELEASE

STUDY FINDS WIDE USE OF COMPUTED TOMOGRAPHY (CT) FOR POST-OPERATIVE ASSESSMENT OF SPINE SURGERY, DESPITE RADIATION RISKS FOR PATIENTS

One CT Scan Equivalent to More Than 400 Chest X-Rays for Patients

Non-Metal Simplify Cervical Artificial Disc Designed to Enable Accurate Post-Operative MRI Imaging and Minimize Need for CT Imaging

SUNNYVALE, Calif. – March 8, 2017 – [Simplify Medical, Inc.](#), maker of the [Simplify® cervical artificial disc](#) designed to be clearly viewed on MRI with minimal artifact, announced findings from a [new study](#) published in BMC Musculoskeletal Disorders that is the first to estimate the magnitude of computed tomography (CT) imaging for post-operative assessment of spine surgery, which exposes patients to high doses of radiation. The Simplify Disc is considered an investigational device in the U.S.

The study found that CT prevalence following complex spine surgery increased more than two-fold from six months to five years, with patients averaging two scans over that period. Each CT scan has been estimated to deliver the equivalent radiation of 400 to 550 chest X-rays to the patient. The retrospective study utilized data drawn from a Humana database covering eight consecutive years from 2007 through 2014 and comprising adjudicated claims for more than 130,000 complex spine procedures.

While magnetic resonance imaging (MRI) is widely used pre-operatively for surgical planning, surgeons often switch to CT post-operatively because spinal implants usually include metal components. The metal creates artifacts in the MRI image, making the implants difficult to view and affecting visualization of the facets and adjacent levels.

The study authors state, “we detected a high frequency of CT utilization following complex spine surgery. There is emerging evidence of an increased cancer risk due to ionizing radiation exposure with CT. Thus, in the setting of complex spine surgery, actions to mitigate this risk should be considered...(including) adopting non-ferromagnetic implant biomaterials that facilitate MRI post-operatively.”

One device that may minimize the need for post-surgical CT scans is the Simplify Disc, a cervical artificial disc designed to be clearly viewed on MRI without artifact. Composed of PEEK-on-ceramic materials, the Simplify Disc is intended to minimize patient exposure to high-dose ionizing radiation from CT and its associated risks. With no metal in its articulating components, the disc is also designed for low levels of wear to optimize long-term durability. The Simplify Disc is anatomically designed with low height implant options for patients with smaller cervical disc spaces for whom larger implants are not optimal.

The Simplify Disc is currently enrolling patients in a non-randomized pivotal clinical trial in the U.S. – where all patients will receive the device – comparing one-level cervical implantation of the disc between C3 to C7 with cervical fusion surgery from a historical nonconcurrent control group. More information about the clinical trial is available at www.SimplifyTrial.com.

The Simplify Disc has received the CE Mark and has been used to treat 600 patients outside the U.S. over the last three years. Early clinical data has shown substantial improvement in patient pain scores after treatment.

The Simplify Disc is designed to comply with two principles developed by the International Committee on Radiological Protection and endorsed by the U.S. Food and Drug Administration (FDA), which mandate that exams using ionizing radiation – such as CT – be performed only when medically necessary, and that patients should be exposed to the lowest possible radiation.

The BMC Musculoskeletal Disorders article was authored by Vikas Patel, MD, of the University of Colorado Hospital, Denver; Gunnar Andersson, MD, of Rush University Medical Center, Chicago; Steven Garfin, MD, and Donald Resnick, MD, both with the University of California, San Diego; and Jon Block, Ph.D.

ABOUT SIMPLIFY MEDICAL

Simplify Medical is focused on cervical spinal disc arthroplasty, using innovative MRI-friendly materials designed to decrease the need for ionizing radiation and enhance patient options. Simplify Medical is located in Sunnyvale, California. To learn more, visit www.simplifymedical.com.

Caution: The Simplify Disc is an Investigational device in the United States and is limited by law to investigational use.

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