

Surgeons Implant Magnetic Growing Rods In Treatment For Scoliosis

In a revolutionary treatment for early-onset scoliosis (EOS), a team of surgeons implanted adjustable growing rods in two children from California. The pioneering surgeries — the first ever in the United States — were performed on May 7th at Rady Children’s Hospital in San Diego. The Food and Drug Administration (FDA) granted Compassionate Use approval to use the MAGEC (MAGnetic Expansion Control) System, developed by Ellipse Technologies, Inc., for these two patients.

Dr. Behrooz A. Akbarnia, a world-renowned pioneer in advanced treatments for scoliosis in young children, led the surgeries. Dr. Akbarnia is Medical Director of the San Diego Center for Spinal Disorders and Clinical Professor in the Department of Orthopaedic Surgery at University of California, San Diego. Orthopedic surgeons Dr. Burt Yaszay and Dr. Gregory Mundis, who are also members of the early-onset scoliosis program at Rady Children’s Hospital, participated in the procedures.

EOS is a rare condition that affects a small population of very young children. If not corrected, EOS can eventually interfere with lung function and growth and can be fatal. Current treatments for EOS are limited. Young patients implanted with traditional growing rods that are used today may undergo up to two surgeries per year for several years.

The magnetic growing rods are attached to one or both sides of the spine. Following surgery, these rods can be lengthened non-invasively as the child grows using an external remote controller. Rare earth magnets inside the rods communicate with the External Remote Controller (ERC) and allow physicians to modify the length of the rods without surgery. While the MAGEC System has not been approved for commercial distribution in the United States, Ellipse has a pending Humanitarian Device Exemption application under review and is working closely with the FDA through the approval process.

“This technology is one of the most significant advances in the treatment of this condition,” said Dr. Akbarnia. “Now children won’t have to suffer the stress and physical trauma of repeated open surgeries every six months for multiple years. The lives of children suffering from EOS will be significantly improved with this device.”

Nine-year-old Anthony Wainess from Chino Hills, Calif., was the first to undergo the surgery.

Anthony was diagnosed with EOS at 18 months of age. His scoliosis eventually progressed to a severe curvature that exceeded 100 degrees.

“The prospect of Anthony going through repeated surgeries was just impossible to

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bear," said Steven Wainess, Anthony's father. "Now I can see a path for my son in how to best treat his condition."

Five-year-old Tomas (Tommy) Loredo from Modesto, Calif., had the magnetic growing rods implanted later the same day. Tommy is medically fragile due to a neuromuscular disorder, and he is more susceptible to severe complications from anesthesia. This device is especially important to reduce the number of repeat surgeries for lengthening.

"It's a miracle to hear that the FDA has approved this surgery for Compassionate Use," said Tommy's mother, Rachel Thomas. "Most people cannot imagine the burden of treating this condition. The idea that Tommy will no longer be confined to wearing body casts is extraordinary."

"After many years of development, it is extremely gratifying to see this revolutionary product being used in the United States," said Ed Roschak, Chief Executive Officer of Ellipse. "MAGEC utilizes the Ellipse non-invasive remote control technology to vastly improve treatments and outcomes for children suffering with EOS. Our hope is that in the near future, MAGEC will be widely available in the United States to children like Anthony and Tommy."

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