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First-in-man study shows that new magnetically controlled growing rods can treat scoliosis in children

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A first-in-man study published Online First by *The Lancet* shows that new magnetically-controlled growing rods can treat scoliosis in children by being extended using a non-invasive technique as their spine grows, without the repeated invasive surgery used with existing rod technology. The study is by Professor Kenneth Cheung and Dr Dino Samartzis, from the Department of Orthopaedics and Traumatology, The University of Hong Kong, Hong Kong, and colleagues.

Scoliosis is a spinal deformity characterized as lateral deviation of the spine, which occurs mainly in adolescents and young children. If left untreated, it can rapidly progress, causing cosmetic disfigurement and breathing problems. For children with severe scoliosis who are still growing, traditional practice has been to surgically insert growing rods under general anaesthesia across the segment of the spinal deformity's curve. These rods need to be lengthened (a procedure called "distraction") every 6 months, again under general anaesthesia using invasive surgery and requiring hospitalization. This "traditional" growing rod surgery is associated with various socioeconomic drawbacks. For instance, children miss school time, and parents might have to take time off work to support their child. Also, the heath-care costs associated with each surgery and hospital stay are substantial. Thus, in this new study, the authors assessed a new remotely distractible, magnetically-controlled growing rod (MCGR) system that allows frequent non-invasive outpatient distractions.

The authors implanted the MCGR in five patients, two of whom have now reached 24 months' follow-up. Each patient underwent monthly outpatient distractions. Radiography was used to measure the magnitude of the spinal curvature, rod distraction length, and spinal length. Clinical outcome was assessed by measuring the degree of pain, function, mental health, satisfaction with treatment, and procedure-related complications.

In the two patients with 24 months' follow-up, the mean degree of scoliosis was 67° before implantation and 29° at 24 months. Length of the instrumented segment of the spine increased by a mean of 1•9 mm with each outpatient distraction and in congruence with their normal growth. Throughout follow-up, both patients had no pain, had good functional outcome, and were satisfied with the procedure. No MCGR-related complications were noted.

The authors say: "MCGR will eliminate the need for repeated operations under general anaesthesia, wound complications, and socioeconomic and health-care costs associated with the procedure. The preliminary results from the first two patients to undergo the treatment for a minimum of 24 months suggest that this non-invasive outpatient procedure is effective and safe. Whether MCGR leads to significantly better outcomes than traditional growing rods is not yet known, but early results are positive and the avoidance of open distractions is a great improvement. Additionally, this new growing rod system has potentially widespread applications in other disorders that could benefit from a non-invasive procedure to correct abnormalities. MCGR could assist with correction of limb abnormalities, thoracic insufficiency syndrome, limb lengthening, limb salvage procedures, or any disorders or injuries in which slow, progressive change to bone structures is needed."

In a linked Comment, Dr John T Smith, University of Utah School of Medicine, Salt Lake City, UT, USA, and Dr Robert M Campbell Junior, The Children's Hospital of Philadelphia, University of Pennsylvania, PA,

USA, say that more patients need to be followed up for longer to substantiate the results in this study, and long-term functionality of magnetic rods must be proven.

They add: "Magnetically controlled growing-rod technology is being developed outside the USA, where, in our view, the pathway to develop and test new technology faces excessive barriers (growing rods remain unapproved by the US Food and Drug Administration). If this technology was available in the USA, we believe that it would be rapidly used to avoid repetitive surgeries and improve quality of life for children with spinal deformity. We strongly encourage Cheung and colleagues to continue to report their results—both positive outcomes and adverse events. We are hopeful that further development of the technology will make this treatment increasingly available to children worldwide."

More information: www.thelancet.com/journals/lan … (12)60112-3/abstract

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