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Paper #1

Surface Degradation Linked to Actuator Pin Fracture in Magnetically Controlled Growth Rods (MCGRs)?

Vasiliki Panagiotopoulou, Stewart Tucker, Harry Hothi, Johann Henckel, Alexander Gibson, John Skinner, Alister Hart, Thomas Ember, Julian Leong

Summary: Our multi-disciplinary team of surgeons and engineers will present our work on retrieval analysis of MCGRs. Our aim is to better understand the in vivo performance of these medical devices using our forensic analysis techniques, combining retrieval analysis, clinical data and imaging, in order to identify surgical, implant and patient (SIP) risk factors.
Hypothesis: We hypothesize that increased surface degradation attributed to elongation treatments and implantation time, can be a cause for the actuator pin to fracture.
Design: This retrieval study involved 15 MCGRs, of a single design, revised from 8 female and 1 male patients; 7 cases were early revisions and 2 for final fusion; these were implanted as either dual or single rod constructs. All patients consented for their implants to be used in this study.
Introduction: MCGRs are used for the treatment of severe cases of early onset scoliosis; their main advantage is the non-invasive lengthening of the rods in Outpatients Clinic using an external controller. However there have been case reports documenting failure of distraction and 22% of MCGRs are subject to unplanned revision.
Methods: All retrieved MCGRs were radiographed to determine whether the actuator pin was fractured. We then assessed them macroscopically and microscopically for maximum length of surface degradation. Clinical and imaging data was also collected in order to identify the dominant surgical, implant or patient (SIP) risk factors.
Results: One third of the retrieved MCGRs that we received had a pin fracture. No difference in fracture rate was found between single and dual constructs. Rods with fractured pin had signs of increased surface degradation (Figure 1) compared to the MCGRs with intact pin, although not significantly different ($p=0.1818$). In dual rod constructs where only one MCGR had the pin fractured, the surface degradation was increased on the component with pin fracture, but no significant difference was documented ($p=0.3333$). We found no correlation between time of implantation and surface degradation ($p=0.6889$).
Conclusions: We found a trend towards increased surface degradation on the MCGRs with fractured pin compared to the MCGRs with intact pin, however the cause of failure appears to be multifactorial with SIP risk factors.
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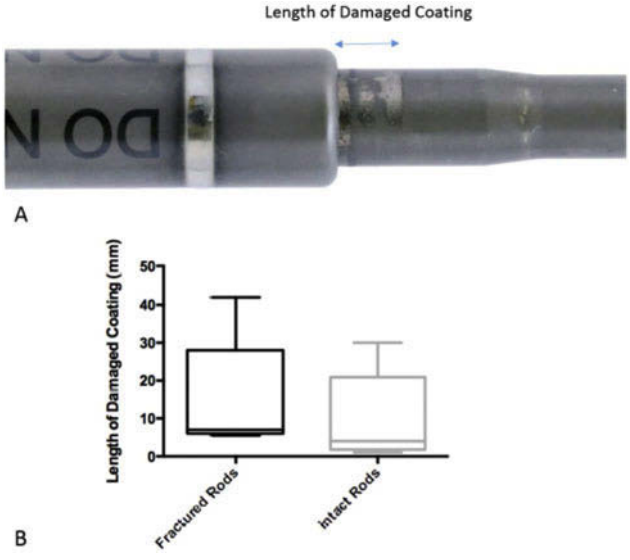

Paper #2

Surgeon Survey Shows No Adverse Events After MRI In Patients With Magnetically Controlled Growing Rods (MGCR)

David Skaggs, Regina Woon, Lindsay Andras, Hailali Noordeen, Suken Shah, Stephen Morris, John Hutchinson, Jeff Pawelek, Charles Johnston, Children's Spine Study GroupGrowing Spine Study Group

Summary: These are the first reported cases of MRI use in humans with MCGR. There were no adverse events observed. MCGR rods lengthened as expected following MRI. MRIs of the cervical spine were able to be interpreted, but MRIs of the thoracolumbar spine could not be interpreted due to MCGR artifact.
Hypothesis: MRI following implantation of magnetically controlled growing rods (MCGR) is not associated with any adverse events.
Design: Survey of surgeons.
Introduction: Magnetically controlled growing rods in the treatment of early onset scoliosis (EOS) significantly decreases the number of procedures compared to traditional growing rods. MRIs are contraindicated in patients with MCGRs as per the FDA. MRIs are often clinically indicated in the EOS population. An in-vitro study conducted by Budd et al. demonstrated there were no detrimental effects of MRI on MCGR, but there are no in-vivo studies on this topic.
Methods: Pediatric spine surgeons who are members of the Growing Spine Study Group, Children's Spine Study Group, or early international users of this technology were surveyed regarding MRI use after MCGR surgery.
Results: 118 surgeons were surveyed. Four surgeons reported 10 patients had an MRI with an implanted MCGR. Loss of fixation (0%, 0/9),

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