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Early results on the safety profile of a novel pedicle plug in - a First in Humans trial of the OGmend® Implant system.

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Introduction:

A compromised pull out strength of spinal instrumentation in the setting of osteoporosis is challenging. To date, a number of strategies have been adopted to mitigate this risk.

More recently, a braided Polyethylene Terephthalate (PET) sleeve was proposed to act as a plug in bone prior to the insertion of the pedicle screw to improve pull out strength particularly in weaker compromised bone. With biomechanical studies having proven very favourable, the study aim is to investigate the safety profile for the use of such an implant in spinal surgery.

Material and Methods:

Following obtaining Ethical Committee approval, Patients aged 21 to 75 years, undergoing a short-segment lumbar posterior instrumentation for degenerative lumbar spine pathology in one institution, were approached for participation in the trial. After completing a structured consenting process; data on age, gender, body mass index (BMI) and co-morbidities was collected. Additional data on visual analogue score (out of 100) (VAS), Oswestry disability index (ODI), EQ-5D, adverse events, evidence of radiological loosening on X-ray and C-reactive protein with clinical and CRP being collected at baseline, 6 weeks then 6, 12 and 24 months. Continuous data is presented as mean (SD).

Results:

Over the period of 10 months commencing September 2017, seventeen patients were recruited (4 Males/13 Females) with a mean age of 55.6 (13.7) years and BMI was 28.4 (5.4). The data on 14 patients who completed their 6 months review will be presented. The pre surgery scores *vs* at 6 months follow up were as follows: for VAS (59.6 (25) *vs* 44.9 (28)), ODI (48.7(16) *vs* 34.3(17)), EQ-5D-VAS (51.2 (24) *vs* 66(21)). There was no evidence of radiological loosening in any of the cases reviewed at 6 months, no recorded complication or clinical evidence of local or systemic sensitivity. CRP readings were 6.2(3) pre surgery, at discharge 100.4(80) and at 6 months 7.2(5).

Conclusion:

The findings to date support the OGmend® Implant system to be a safe adjunct to instrumentation in spinal surgery. The design of the implant and technique of insertion will be discussed.