Novel Device to Enhance Bone-to-Screw Interface in Spine Surgery 2-year results in an FIH Safety Study

Pr. B Boszczyk, M Shafafy, K Salem, K McRae

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INTRODUCTION

Optimal fixation between hardware and bone is essential to achieve successful outcomes in spinal surgery.

Currently, enhanced fixation is achieved through various techniques such as augmenting a procedure with larger diameter screws, cements such as polymethylmethacrylate (PMMA) or calcium-based polymers, or tissue grafts.

A new unique synthetic polyethylene terephthalate (PET) sleeve was inserted into a bone hole prior to inserting a screw, to enhance the screw-to-bone interface and increase screw stability and quality of fixation in worst case fixation scenarios, including revision surgery performed to correct screw loosening. Preclincal and biomechanical studies show very favorable results, and a clinical study was performed to investigate the safety profile for the use of such an implant in spinal surgery.

MATERIALS & METHODS

A prospective, single-arm, non-controlled clinical study was performed to evaluate the safety and performance of an implant designed to help enhance screw stability in patients undergoing interbody fusion with posterior rigid fixation or dynamic stabilization of the spine.

50 Ogmend® Implants were evaluated between September 2017 and April 2020 at Nottingham University Hospital, Queens Medical Centre. Sixteen patients were followed (4 Males/12 Females) with a mean age of 55.6 (Std Dev 13.7) years and BMI of 29.1 (Std Dev 5.4).

All patients were followed for 24 months to evaluate implant safety and the healing process. X-ray for evidence of radiological loosening, C-reactive protein, clinical status, pain scores, and adverse events were collected.

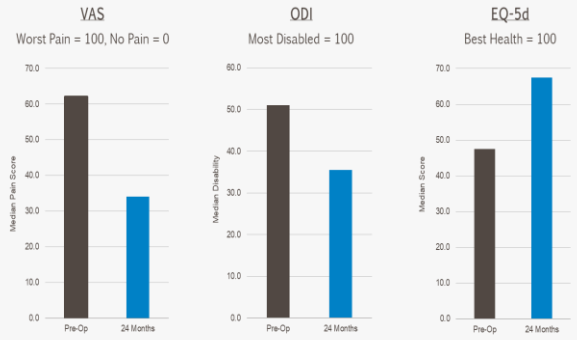
RESULTS

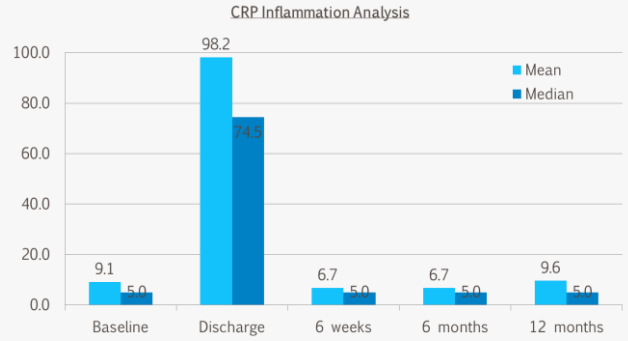
Patients were assessed at baseline, discharge, six (6) weeks, six (6) months, twelve (12) months, and twenty-four (24) months.

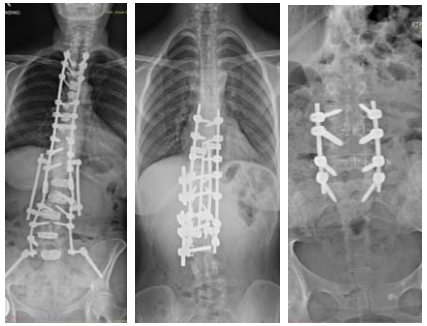
100% of patients completed their 12-month follow-up evaluations with adequate alignment and fixation of the screws augmented with Ogmend® as illustrated on radiographs, normal progression of healing as indicated on neurological exams, no signs of infection as determined by blood tests, no pain related to device migration or failure, and no additional surgical procedures required to correct loss of fixation.

100% of patients also completed their 24-month follow-up evaluations with normal progression of healing as indicated on neurological exams, no pain related to device migration or failure, no additional surgical procedures required to correct loss of fixation, and no Adverse Events (AEs) or Serious Adverse Events (SAEs) related to Ogmend®.

Mean scores pre-surgery and at 24-month follow-ups were as follows: VAS 61.8 (Std Dev 19.2) vs 40.7 (Std Dev 22.5), ODI 48 (Std Dev 18) vs 34.6 (Std Dev 18.3), EQ-5D% 49.9 (Std Dev 21.8) vs 64.8 (Std Dev 20.7). There was no evidence of radiological loosening for any screws augmented with Ogmend® reviewed at 12 months, no recorded complication or clinical evidence of local or systemic sensitivity, and no adverse events relating to the implant. CRP readings were 6.2 (Std Dev 3) pre-surgery, 100.4 (Std Dev 80) at discharge, and 7.2 (Std Dev 5) at 12 months.



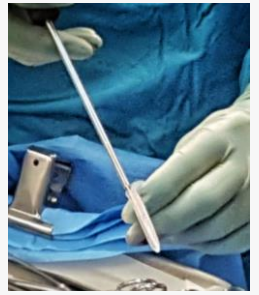




Examples of radiographs at 12 months follow-up showing instrumented fusion with the Ogmend® device

CONCLUSIONS

The findings support a conclusion that the Ogmend® implant system is a safe method for enhancing the bone-to-screw interface in spinal surgery. Healing progressed as expected and without



Ogmend® prepared on the inserter instrument

Screw being inserted into Ogmend® during screw fixation

LITERATURE CITED

1. Galbusera, et al. (2015)
2. Fletcher, et al. (2020)
3. Chao, et al. (2013)

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CONFLICTS OF INTEREST

Woven Orthopedic Technologies

FURTHER INFORMATION

Name: Dr. med. habil. Bronek Boszczyk
Tel: +49 1525 3081483
Email: bronek.boszczyk@nspine.com
Web: https://www.kiz-chiemgau.de/

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