EFFECT OF HYDROXYAPATITE (HA) COATING ON THE SCREW-BONE INTERFACE IN THE DYNESYS® SYSTEM

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INTRODUCTION

When the Dynesys® system is used as an adjunct to fusion, optimal fixation in the early postoperative period is essential. Hydroxyapatite has been used as a coating on orthopaedic implants to improve fixation for a number of years. Many authors have proposed hydroxyapatite (HA) coating of pedicle screws. Sanden B et al., conducted a survival sheep study with HA coated pedicle screws. They concluded that HA coating of pedicle screws resulted in improved fixation with reduced risk of loosening of the screws using radiographs and screw extraction torques [1]. The purpose of this ongoing in-vivo animal study was to evaluate the effectiveness of HA coating of Dynesys pedicle screws during the early stages of screw fixation. We hypothesized that HA coating would enhance early screw fixation but that the effect would diminish in time.

METHODS

Each single-level Dynesys construct comprised four pedicle screws, two spacers, and two cords, Figure 1a. Twenty sheep – five animals per time point –were used for this study. Each animal had a single-level posterior spinal stabilization at two non-contiguous lumbar levels, L2-L3 and L3-L4, Figure 1b. Lateral placement of the components preserved the pars interarticularis and the facet joints. For animals sacrificed acutely (0 weeks), only screws were implanted. Since sheep lumbar vertebrae could not accommodate commercially available screws, 4.4mm x 25mm titanium screws (a size that has been used before in sheep studies) were implanted. All screws were identical except for the coated screws were plasma sprayed with HA in the thread region. The coated and uncoated screws were equally distributed between the two operated levels. Sacrifices were made at 0, 6, 10, and 16 weeks after the surgery. Lumbar spines (L1-S1) were harvested, screw extraction torques were recorded on one side. The remaining screws are being histologically evaluated (in process). For the statistical evaluation, the Wilcoxon signed rank test was used. P values <0.05 were considered statistically significant.

RESULTS:

Interoperative insertion torque for coated screws was 104% of that for uncoated screws. This difference was not statistically significant. Post-operative recoveries were unremarkable except that two animals (one 10 week and one 16 week) were euthanized prior to completing their respective follow-up periods. The euthanasia time of both animals was unrelated to the type of screw used.

Screws that recorded an extraction torque value below 40N-cm were considered loose. Three of the uncoated screws in the six week time period were loose in the vertebral body, with extraction torque values of 38 N-cm, 29N-cm, and 13 N-cm. One of the uncoated screws from the 16 week time period was loose and recorded an extraction torque of 8 N-cm. None of the coated screws were found loose. The coated screws tended to have higher extraction values than the uncoated screws at all the time points.

Figure 1 shows the normalized screw extraction torque as a percentage of uncoated screws. At 0, 6, and 16 weeks, the difference between the extraction torque values for coated and uncoated screws were not statistically significant. At the 10 week time-period the extraction torques for the coated screws was significantly higher (P<0.01) than the uncoated screws.

DISCUSSION:

In the present study, extraction torque is used as an outcome measure to assess the incorporation of the screws; this measure is consistent with previous studies [1,2].

The trends in the extraction torque results correlate with literature which suggests that differences between screw types (coated versus uncoated) may not be discernable prior to one month post-implantation, and bone incorporation may not be discernable past six-month post-implantation [2,3]. At the 10-week interval the coated screws were superior to the uncoated screws (P<0.01). Also, four of the uncoated screws were found loose in the bone or recorded low torque during the follow up periods. None of the HA coated screws were found loose.

These results may mean that the incorporation of HA coated Dynesys screws will be more rapid than the uncoated screws. However, after a longer follow up period (16 weeks) the coated screws provide fixation equal to an uncoated screw. This may be due to the resorption of HA coating into the bone. Conclusions that are more meaningful may be drawn from the further ongoing investigations including CT scans, scanning electron microscopy, and histology. Based upon the biomechanical data for extraction torques, our hypothesis (that HA coating may enhance early screw purchase) was valid.

REFERENCES:


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Figure 2 shows the normalized screw extraction torque as a percentage of uncoated screws. At 0, 6, and 16 weeks, the difference between the extraction torque values for coated and uncoated screws were not statistically significant. At the 10 week time-period the extraction torques for the coated screws was significantly higher (P<0.01) than the uncoated screws.

Figure 2: Normalized Screw extraction torque (% of uncoated) for different follow-up periods.