INTRODUCTION

- Symptomatic lumbar etiologies are historically treated using lumbar interbody fusion (LIF) in unison with graft, cage, and pedicle placement.  

- The estimated historical fusion rate for LIF using posterior or transforaminal approach yields an 80% fusion success rate post-operatively when utilizing traditional graft, cage, and pedicle placement.

- The preferred graft has been an autologous bone graft (ABG), but many other options are available including demineralized bone matrix (DBM), bone morphogenetic protein (BMP), and amniotic suspension allograft (ASA).

- NuCel is a specific type of bioactive ASA used by surgeons since 2009 with no reported complaints regarding safety or immunogenicity.

PRELIMINARY RESULTS

- For 57 NuCel treated patients we found the average age to be 61.05 with a standard deviation of 10.39 years and the average BMI to be 29.13 with a standard deviation of 4.78 pounds. Of the 57 patients 14 were considered low risk using NIH approximations. These include a BMI > 30 and age ≥ 65 as a high risk for LIF.

- Using binomial conversion of nominal data we found the average 1-year fusion success rate to be 85.95% with a 95% confidence interval of 74.21% to 93.74% and a p-value of .1688 demonstrating non-inferiority.

- We found the 2-year fusion success rate to be 92.98% with a 95% confidence interval of 83.00% to 98.06% and a p-value of .0063 demonstrating non-inferiority and potential superiority.

MATERIALS & METHODS

- A retrospectively collected prospective non-randomized multi-center study of 57 patients were treated with NuCel intraoperatively for 1, 2, 3, and 4 level PLIF or TLIF from L1-S1.

- Fusion status was assessed through 1-year CT and x-ray, and 2-year fusion status if needed.

- Demographic data, surgical data, and post-operative data was collected to determine spread of patient risk and projected outcome.

DISCUSSION

- NuCel is non-inferior to traditional graft modalities when used as an adjunct for interbody cage and pedicle placement during PLIF and TLIF.

- Bioactive ASA may be used to minimize the risks of ABG complications with intra-operative bone harvesting and the potential carcinogenicity of BMP.

- There is promise in the superiority of bioactive ASA to traditional graft methods, however, this would require a control study for similar patient risk factors.

REFERENCES & ACKNOWLEDGEMENTS

1. Wu PH, Kim HS, Jang IT. Intervertebral Disc Diseases PART 2: A Review of the Current Diagnostic and Treatment Strategies for Intervertebral Disc Disease.


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HYPOTHESIS

- Radiological/clinical performance of NuCel bone graft system is not inferior to historical autograft when used for lumbar interbody fusion.