U.S. Food and Drug Administration/Office of Women's Health: Evaluating the Effectiveness of Vertebroplasty for Improving the Mechanical Properties of the Spine in Patients with Osteoporosis

The objective of this project was to help surgeons identify osteoporosis patients for vertebroplasty surgery, optimize the quantity of cement being injected and provide information to FDA to facilitate regulatory decision making process on the use of cements for vertebroplasty surgery.

Lead Agency:

U.S. Department of Health and Human Services (HHS), U.S. Food and Drug Administration (FDA), Office of Women's Health (OWH)

Agency Mission:

The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

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Partner Agencies:

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University of California, San Francisco (Engineering Systems)

General Description:

Vertebral compression fractures are estimated to affect 33% of women over age 65, causing pain, disability, and increased mortality risk. An emerging surgical treatment is vertebroplasty, or injection of acrylic bone cement into the vertebral body. Previous work has suggested that bone porosity can have a significant effect on the integrity of cement fixation in joint replacement, so the potential benefit of vertebroplasty may depend on a patient's degree of osteoporosis. The hypothesis was to test whether bone mineral density

(BMD) can be used to predict mechanical strength and stiffness of the vertebral body after cement injection. A corollary hypothesis was to test whether the relationship between mechanical properties and BMD varies with amount of cement injected. Vertebral columns from thirteen adult Caucasian female cadavers were obtained and bone mineral density was measured with DEXA. Vertebrae were randomly assigned to five groups: intact, untreated, 4%, 12% and 24% cement fill treatment. Specimens were first compressed to simulate a vertebral wedge fracture and then treated with cement. Strength and stiffness of all specimens were measured. The results suggest that there may be significant differences between patients with high and low bone density in terms of the relative improvement in strength that vertebroplasty can offer them. In the study, only the highest cement dose used (24% fill) had any effect on mechanical strength or stiffness. More importantly, samples with very low bone density (i.e., highly osteoporotic) did not how as great an improvement in stiffness as high-density samples even when cement volume was increased to 24% fill. This study suggests that clinicians may be able to use DEXA to select a cement volume and to predict the mechanical integrity after vertebroplasty for a specific patient based on bone mineral density.

Excellence: What makes this project exceptional?

Among persons over 65, fracture rates are three times higher in women than in men, and women with osteoporosis are more likely to suffer vertebral compression fractures. Vertebral compression fractures are the most common injury resulting from osteoporosis, with an estimated incidence of 700,000 per year in the U.S. These fractures, if untreated, have been shown to cause acute and chronic back pain, disability, and increased mortality risk. In a 2000 study of 6,459 women with osteoporosis followed for 3.8 years, those women who sustained a spine fracture were 8.7 times more likely to die than those women who did not experience a fracture. One treatment for these fractures is vertebroplasty, or injection of acrylic bone cement into the vertebral body to restore its strength. This minimally-invasive approach is expected to result in earlier recovery times than other more conservative options, and it is used for severe, intractable cases where non-surgical treatments are not sufficient to relieve the pain and deformity caused by the fracture. Acrylic bone cement, normally reserved for joint replacement surgery, has not been FDA-approved for this procedure, but the cement is used “off-label” for vertebroplasty at the surgeon’s discretion. The objective of this project was to test two important hypotheses related to the safety and effectiveness of vertebroplasty surgery. The first hypothesis is that, by diagnosing a patient’s degree of osteoporosis with non-invasive clinical techniques, we will be able to predict the success of vertebroplasty as measured by improvement in mechanical strength of the vertebral body. The second hypothesis was that the volume of cement injected can be optimized to restore strength without causing an excessive stiffness of the vertebral body that might lead to secondary fractures.

This study suggests that clinicians may be able to use DEXA to select a cement volume and to predict the mechanical integrity after vertebroplasty for a specific patient based on bone mineral density.

Significance: How is this research relevant to older persons, populations and/or an aging society?

Vertebral compression fractures are estimated to affect 33% of women over age 65, causing pain, disability, and increased mortality risk. An emerging surgical treatment is vertebroplasty, or injection of reinforcing acrylic bone cement into the vertebral body. Cements have not been FDA-approved for this procedure, but they are used "off-label" at surgeons' discretion.

Effectiveness: What is the impact and/or application of this research to older persons?

Recent studies performed by FDA investigators have established that bone porosity can have a significant effect on the quality of cement fixation in joint replacement, so it was hypothesized that there might also be limitations to the benefits of vertebroplasty surgery depending on a patient's degree of osteoporosis. A secondary long term complication of the surgery is that adjacent vertebrae may fracture due to a redistribution of loads following the repair of the original fracture. It may be important to optimize the quantity of cement being injected in order to avoid excessive stiffening of the repaired segment relative to the adjacent bone. Such an optimization technique has not yet been studied or reported in the literature until this study was conducted.

As the off-label use of existing bone cements for vertebroplasty becomes more popular, the FDA anticipates a surge in submissions for new cement devices specific to this application. It is a very recent, emerging area with a lack of published data from the industry and very limited clinical follow-up data from surgeons. The results of this project could help FDA/ODE to develop a model for preclinical testing that could evaluate safety and effectiveness without the need for human studies. This project could provide important information to ODE reviewers about the proper clinical indications for these devices, thus reducing uncertainty in the review process and leading to faster review times. The results of this study should be beneficial to OSB by helping them to make informed decisions about actions that the FDA should or should not take in regulating these devices.

Innovativeness: Why is this research exciting and newsworthy?

Public health will be enhanced by helping surgeons use existing diagnostic tools to make better-informed decisions about benefits and limitations of vertebroplasty surgery for a specific patient.