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PUTTING A CHARGE IN HEALING: ELECTRICAL STIMULATORS SHOW GREAT PROMISE, ESPECIALLY FOR SPINAL FUSIONS

Deborah Schenberger, Ph.D.

Medical Device Team
Nerac, Inc.
One Technology Drive
Tolland, CT, USA

ABSTRACT

Spinal fusion is the latest application of electrical stimulation as a fracture healing. This exciting new application has been proven over 30 years of use, and the market is now poised for rapid growth. Patent activity shows an increased interest in this technology, and both start-up companies and orthopedic giants can thus benefit from introducing new products in this field..

INTRODUCTION

Since the times of Queen Elizabeth I in the 1600s, even royal physicians have touted electricity for its healing properties. Benjamin Franklin, famous for his kite flying experiment of 1752 to prove that static charge and lightning were the same phenomenon, was actually interested in electricity for its medicinal properties. He experimented with electric treatments for people recovering from strokes to see if it improved their health.

By the late 1800s, many electric “cures” were being patented, from prostrate warmers to electromagnetic bath salts. Now, electricity is being used to speed up healing and bony fusion.

DISCUSSION

Spinal Fusion Surgery On The Rise

Spinal fusion is the most rapidly growing orthopedic surgical procedure in the United States. Between 1996 and 2001, the number of operations has increased 75 percent, and now more than 300,000 procedures are performed each year. With a mean hospital charge of \$34,000, not including professional fees,

spinal fusion is a \$2 billion market with an annual growth rate of 18-20 percent [1,2].

But how do medical device manufacturers capitalize on this growing market? Although there are numerous competitors in the spinal implant and device area, there is plenty of opportunity to develop devices that aid in healing. The most recent of these are electrical stimulators that actually shorten bone fusion time and reduce complications while also making the fusion more solid [3-5]. For the millions of people with diabetes or other conditions that make healing difficult, this is an incredible breakthrough.

Before electrical stimulation, spinal fusion took at least four months to occur. Unlike a fracture, no stem cells are released from the bone marrow to form a callus around a spinal surgical site. Electrical stimulation mimics the body’s natural process of fracture repair, signaling it that a fracture has occurred and activating the embedded bone growth factors to work with the body in creating new bone.

Electrical Stimulators Have Other Applications

According to market studies, these new, anatomically specific units are designed to improve patient comfort and ease-of-use, creating a market estimated at \$418.7 million in 2005, growing to \$690.1 million by 2012 [6]. And the market for electrical stimulators is poised to venture into numerous other surgical and fracture healing fields [7].

Electrical stimulators work in conjunction with new recombinant growth factor products, and the stimulators work by encouraging the release of growth factors, so the potential

applications are much farther reaching than just spinal fusion. Recently, pSivida Limited received a patent for stimulating orthopedic tissue to improve bone growth around hip and knee implants.

In the femur, a common site for non-union fractures and thus extensive disability, electrical stimulation is providing an important new tool [7]. Unlike casting, which relies on immobilizing a region, electrical stimulation works in conjunction with some movement of the fracture or fusion site. This then stimulates the body's natural fracture healing properties to focus on healing a specific region. Some surgeons are considering using electrical stimulators within casts to prevent bone and cartilage deterioration in immobilized patients. Dentistry also has begun investigating the use of electrical stimulation to improve bone healing around dental implants.

Stimulators Can Reduce Risk Factors

With an aging population in the United States, the advent of electrical stimulation to aid healing in patients after spinal fusion and other surgical procedures is truly revolutionary. Often, high-risk patients are denied unnecessary surgeries due to the surgeon's concerns about healing. But electrical stimulation can alleviate these risk factors and provide access to these procedures to much larger populations. As a result, this market has tremendous growth potential, as the devices are noninvasive, carry low risk, and can be developed using widely accessible existing technology.

Patent Review

Although electrical stimulation for spinal fusion has an almost 30 year history, widespread use has only been prevalent for the last few years. Early systems used direct current coupling, but newer systems have employed capacitive coupling and inductive coupling techniques. Along with these changes in stimulation methods, inventors have begun to use therapeutic drugs, waveform patterns, vibration, and chemicals to enhance the spinal fusion process [8-11].

US 06937905 Osteogenesis stimulator with digital signal processing describes an electrical stimulator for spinal fusion with a specific, unique sine wave-like waveform. This waveform aids in the upregulation of stem cells and boosts the quantity of these stem cells.

20040015189/US-A1 Electrical stimulation combined with a biologic to increase osteogenesis includes a biologic agent to improve the conversion of bone growth factors into bony fusion.

20070105769/US-A1 Methods of treating tissue defects combines electrical stimulation with a bone growth factor to physically repair defects in bone, intervertebral discs, and connective tissues. It can also be used to stimulate fusion, but

the main thrust of the patent application is the healing of tissue defects without the necessity of surgery.

20080009927/US-A1 Combination Electrical Stimulating and Infusion Medical Device and Method uses a pulsed waveform and chemical infusion in a device designed to enhance spinal fusion.

Marketplace Review

The medical device marketplace is expected to grow at a rate of over 5-6% for the next five years. Already at a market size of \$12.6 billion, the market for medical devices in orthopedics and electrical stimulation is expected to top \$40 billion by 2012. Spinal fusion electrical stimulators make up about 9% of this market, and are now being included as part of the total solution offered by orthopedic surgeons to their patients [6,12].

CONCLUSIONS

Fracture healing and spinal fusion are the latest application of electrical stimulation to aid in healing of the body. This exciting new application has been proven over 30 years of use, and the market is now poised for rapid growth. Both start-up companies and orthopedic giants can thus benefit from introducing new products in the field of electrical stimulation for bone and tissue healing.

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