Implantable Pulse Generators 'Stimulate' Medical Device Industry

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In recent years, there has been great excitement about the use of neuromodulation to treat a wide array of medical conditions and diseases. The technology uses electrical signals to stimulate or block different nerve impulses in the body and is adapted from technology used in cardiac rhythm management. It holds promise for a variety of conditions, including reducing or eliminating back pain, curing obesity, lowering high blood pressure, and controlling diabetes without daily injections of insulin.

Advanced ceramic materials are playing an important role in the technology and are poised to play an even greater one as these medical devices flood onto the market to treat an increasing number of ailments. Ceramic-to-metal brazed assemblies for hermetically sealed electrical feedthroughs, piezocomposite materials that facilitate ultrasonic device communication, and biocompatible ceramics as an alternative to titanium device casings are just a few of the ways that advanced ceramics are playing a part in enhancing this technology. These ceramic materials and technologies play an important part in developing new and innovative treatment methods that were simply not possible with traditional materials.

Research and development on new ceramic composite materials and assemblies, as well as high pin density feedthrough assemblies, is being pursued to enable a next generation of neuromodulation devices that will provide better treatment, improved patient safety and convenience, and better communication with other devices.

Implantable Pulse Generators—Key to the New Technology

Central to the technology is a neurostimulator, usually referred to as an implantable pulse generator (IPG). The IPG is a battery-powered micro-electronic device, implanted in the body, which delivers electrical stimulation to the nervous system. An essential part of surgically implanted systems designed to treat a wide array of conditions, the IPG delivers very small pulses of electricity to block or stimulate nerve signals (or impulses), depending upon the condition.

Figure-1_Feed-thrus.jpg

Figure 1: The different electrical feedthroughs (laser-welded to an IPG case) provide reliable transport of electrical signals from the IPG electronics hermetically sealed inside the case to the appropriate nerve locations to effect treatment of a patient.

Figure 1 shows an array of different electrical feedthroughs that are laser-welded to an IPG case. They provide reliable transport of electrical signals from the IPG electronics hermetically sealed inside the case to the appropriate nerve locations to effect treatment.

In some cases, the devices are applied to conditions for which medicines either haven’t been completely effective or have unpleasant side effects. In other cases, nerve stimulation is looked at as a way to control the condition more conveniently for the patient, either alone or in combination with medicine. The payoff would be significant if a device could be implanted in the body laparoscopically with only a very small incision. Imagine a twenty minute outpatient surgery, followed by years of 100% patient compliance, with no possibility of forgetting to take medication. The thought has doctors, patients, and insurance companies very excited.

The Feedthrough—Hermetic Structure Key to Success

One key component of the IPG devices is the feedthrough, the mechanical structure that provides the electrical connection for the leads to get in and out of the device housing.

This tiny component performs several key functions. First, the feedthrough provides the conduit for communication of signals between the IPG and the body. Second, the feedthrough’s hermetic seal keeps body fluids outside the IPG device and prevents electricity and battery materials from leaking out into the body. It must be completely and totally leak-free. It also has to be robust enough to withstand radio frequency and eliminate interference from MRI equipment and anti-theft scanners. This tiny piece of device real estate can contain as few as two leads up to around thirty.

“The feedthrough technology is changing rapidly, as next generation devices get smaller and more compact and device designers seek to add more leads to improve the therapeutic value of the devices,” says John Antalek, Morgan Technical Ceramics – Alberox (MTC-Alberox) medical unit business manager.

Antalek says that many device manufacturers often start with an off-the-shelf feedthrough to get their first generation device on the market. Their next generation devices are much smaller and more compact, which makes them more palatable to doctors and patients. “They also have a lot more bells and whistles and customers come to MTC to obtain a customized feedthrough that incorporates the additional features needed. Since we make our ceramic components in house, we have developed manufacturing processes capable of producing numerous sizes and shapes of feedthroughs to match the device design needs.”

Stimulating from Head to Toe —Examples of IPG Applications

New medical uses for IPG devices are patented frequently. Among the conditions for which the devices show the most promise are chronic back pain, hypertension, and diabetes. Examples of devices focused on these conditions (either available now or under investigation) follow.

Chronic back pain

IPG devices deliver mild electrical pulses to the spinal cord, which interrupt or mask the transmission of pain signals to the brain. In this application, the IPG is implanted in the back, in close proximity to the nerve that doctors are trying to block.

Hypertension (high blood pressure)

Most patients with high blood pressure control the condition by using a regimen of anti-hypertensive drugs. However, many studies have reported a persistence of refractive hypertension (elevated blood pressure despite using at least two anti-hypertensive drugs) in as much as 18% of the patient population. The IPG devices are being developed to provide a new and improved therapy for treating hypertension, which is not only safe and effective, but also, avoids undesirable side effects of drug therapy. The system includes an IPG, sensors and leads, external electronics for calibration, programming, and periodic adjustment of parameters by the attending physician.

For example, one hypertension treatment clinical trial is investigating whether an implanted device can help control high blood pressure by stimulating pressure sensors called baroreceptors located on the carotid artery and in the carotid sinus. These sensors measure and report blood pressure to the brain, where it is compared to the needs of the body.

Another example involves investigations on a device that stimulates the vagus nerve to control obesity; researchers testing the device have seen a dramatic drop in hypertension as an unexpected benefit of the therapy.

Diabetes

Several devices are being used or are under development, especially as an option for patients with diabetes who have proven unresponsive to drug therapy. An IPG is implanted and used to stimulate or inhibit the patient's vagus nerve to modulate its electrical activity to increase or decrease secretion of natural insulin by the patient's pancreas. The stimulator might be selectively activated in response to direct measurement of blood glucose or symptoms or could be activated automatically at predetermined times or intervals. Alternatively, it could be automatically activated using an implanted sensor to detect the blood glucose concentrations.

One implantable system, originally tested to control obesity and other gastrointestinal disorders, is showing some promise in controlling diabetes. The device is designed to precisely control nerve and organ function using the vagal nerves, which regulate much of the activity of the stomach and the pancreas. The device being studied delivers high frequency, low energy electrical signals through laparoscopically implanted leads to block vagal nerve transmission. The delivery of energy to the nerves is intermittent and the effects of the therapy on the nerves and end organs are intended to be reversible. The system is designed to be precisely programmed and noninvasively adjusted to meet individual needs.

Headaches, obesity, epilepsy, depression, Parkinson's, syncope, sleep apnea, and restless leg syndrome are a few of the many other conditions for which this treatment is being investigated.

Smaller but Better Devices with More Power and Features

The general trend in implantable devices is miniaturization. New devices tend to be smaller, but with a greater number of leads that get more signals into and out of a single device. It is clear that improving the feedthrough and expanding capability is central to the next generation of IPGs. Future neurostimulator applications are currently looking at 100 to 200 leads, which will give device manufacturers opportunities to add further treatment options to an implantable system.

"We know where the IPG device is headed and we want to proactively provide improved feedthrough capabilities to help the device manufacturers meet their needs," says Antalek. "Just look at how far we've come with cardiac rhythm management. Pacemakers were the size of a Blackberry just a few years ago and had only two leads. Now the typical pacemaker is about the size of a lighter and can have as many as 10 leads, some of which allow better communication to the device, monitoring of other patient information, and the ability to send information directly from the device to a doctor."

Additional leads could also build in intentional redundancy, which would reduce the device downtime and eliminate the need to remove the device if any of the leads fail.

One of the most exciting avenues of research to increase the number of leads is the development of new high density feedthroughs that could contain ten times the number of leads, while keeping the current size and spacing. Today's feedthroughs are constructed by assembling many different parts, stacking them into complicated arrays with braze materials, and putting them in a furnace for joining. However, researchers are now developing high density feedthroughs using cutting edge advanced ceramic materials and processing technologies that use miniaturization techniques to pack many more wires together in a much tighter space.

Body Communications

Another interesting development in the IPG arena is the development of “body communications,” in which ultrasonic devices are placed into a medical device casing and used to remotely power and communicate with other devices in the body.

“This next level of improvement has great advantages, because it could mean that no wires would have to be implanted,” notes Mark Bartrum, transducer design manager for the ElectroCeramics business of Morgan Technical Ceramics (MTC ElectroCeramics). MTC ElectroCeramics uses its piezo ceramic components (high density PZT and single crystal piezo materials) in medical device manufacturing.

“Implanting wires in the body can be a challenge. They may eventually fail and subsequent removal and replacement can be difficult. Also, using ultrasound, as opposed to radio frequency, means the communication stays within the body. This means one person’s medical device is less likely to interfere with another person’s device and it could be more readily protected against interference from MRI equipment, scanners, or other large electrical devices.”

Using ultrasound to both power and interrogate remote sensors is a likely development for many implantable devices, but wiring would still be needed for neurostimulators, where leads are attached to the skull, brain, or spine. However, in the future, the main implant might be able to communicate with other devices implanted in the body or the external programmer via ultrasound rather than radio frequency.

Another exciting development—the use of piezo ceramic components—is an outgrowth from the technology used in cochlear implants. MTC’s Bedford, Ohio plant has researched a custom assembly that uses piezo ceramic components to increase resolution for an annunciator that could be inserted into a main IPG and use intelligible speech to warn the user that an event is occurring.

New Biocompatible Materials for IPGs

Most IPGs are currently made of titanium—a strong and light metal that is lustrous and corrosion-resistant. However, along with efforts to improve the basic electrical feedthroughs so more leads can be added, research and development is being conducted using ceramic injection molding (CIM) to develop a thin-walled ceramic case that could be smaller and simpler, while providing more efficient communications to the device electronics. CIM enables production of small components with very high precision without the need for a secondary grinding process.

For example, MTC's Stourport, UK CIM facility is currently in the early stages of developing an implantable housing for use in migraine and cluster headache treatment that is made using Zirconia injection molding. Zirconia is the preferred material for this device because it has a high mechanical strength that allows the casing to be made with very thin walls. The ceramic casing would then be brazed and hermetically bonded to the feedthrough.

The Zirconia ceramic casing is stronger than titanium, allowing for a mechanically robust structure in a smaller sized housing. By comparison, an Alumina equivalent would be strong, but twice as thick. Both Zirconia and Alumina are transparent to radio frequency energy, so signals could be passed through the wall for communication and possible charging. The hope is that developing a device casing out of Zirconia would mean that no feedthrough wires would be needed to connect to an antenna. Keeping the antenna within the device improves function for the patient. The Zirconia material is also inherently insulating, so electrical wires can be placed closer together than a metal flanged feedthrough brazed into a metal housing. Such a device would have no need for a battery, so it would not require replacement, as long as it retains its hermetic seal. Finally, the injection molded Zirconia is a biocompatible material that complies with ISO 13356 implants for surgery.

Next Steps

The market for neuromodulation is estimated at more than $2 billion, with a compound annual growth rate (CAGR) estimated at 18% to 22% and a seemingly never-ending supply of new applications for the basic technology. With an increasing acceptance by the FDA and insurance companies, preference over some drug therapies, and increasing device complexity to deliver more features and tailored effect, it is clear that developing the next generation of IPGs is critical to advancing neuromodulation technology.

What is also clear is that advanced ceramics will be a major part of that quest. The same robust biocompatible materials already being used to make implantable drug delivery devices may now be used to develop a feedthrough that will be used in next generation IPGs.

Chris Vaillancourt is new business development manager at Morgan Technical Ceramics.

Medical Diagnostics