Temperature Control at DBS Electrodes Using Heat Sinks: Experimentally Validated FEM Model of DBS Lead Architecture

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There is a growing interest in the use of Deep Brain Stimulation (DBS) for the treatment of medically refractory movement disorders and other neurological and psychiatric conditions. The extent of temperature increases around DBS electrodes during normal operation (joule heating and increased metabolic activity) or magnetic coupling (e.g., MRI) remain poorly understood, and methods to mitigate temperature increases are actively investigated. Indeed, brain function is especially sensitive to the changes in temperature including neuronal activity, metabolic functions, blood-brain barrier integrity, molecular stability, and viability. We developed technology to control tissue heating near DBS leads by modifying the thermal properties of lead materials. A micro-thermocouple was used to measure the temperature near DBS electrodes immersed in a saline bath. 3387 and 3389 Leads were energized using Medtronic DBS stimulators. The RMS of the driving voltage was monitored. Peak steady-state temperature was determined under different RMS values. A micro-positioning system was used, which allowed the generation of temperature field map. We developed and solved a finite element method (FEM) bio-heat transfer model of DBS incorporating realistic DBS lead architecture. The model was first validated using the experimental results (by matching saline thermal conductivity and electrical conductivity) and was then applied to develop methods to control temperature rises in the brain using heat-sink technology. Experimental measurements are consistent with theoretical predictions including: 1) Peak temperature increases directly with the RMS square of the applied voltage, such that different waveforms with the same RMS induce the same peak temperature rise; 2) Peak temperatures increases with contact proximity such the maximal temperature rise was observed using adjacent contacts of lead 3389; 3) Temperature decayed over ~2 mm distance away from energized contacts. FEM results demonstrated the central role of lead materials (material properties and geometry) in controlling temperature rise by conducting heat: namely by acting as passive heat sinks. We report that the relatively high thermal conductivity of exiting DBS lead wiring affects the temperature field, indicating the importance of detailed lead architecture. We then demonstrate how modifying lead design to optimize heat conduction can effectively control temperature increases; the manifest advantages of this approach over complimentary heat-mitigation technologies is that heat-sink controls include: 1) insensitive to the mechanisms of heating (e.g., nature of magnetic coupling); 2) does not interfere with device efficacy (e.g., the electric fields induced in the tissue during stimulation are unaffected); and 3) can be practically implemented in a broad range of implanted devices (cardiac/neuro-prothethics, pumps...) without modifying device operation or implant procedure.

Design of an Actuated Volume Compensating SLS Prosthetic Socket

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Studies have shown residual limb volume can vary −11% to 7% in a single day due to changing activity level or weight. However, volume changes of only 3% to 5% can cause users to have difficulty putting on their prosthetic socket. Many existing volume compensation methods are cumbersome, rely on the amputee to maintain the appropriate pressure level, or allow only for a decrease in limb volume. Automatic compensation for volume gain and loss is therefore needed; however, the complexity of designing such sockets renders a traditional fabrication methods cost prohibitive or technically infeasible. Selective Laser Sintering (SLS), a rapid manufacturing (RM) technology, addresses both of these concerns. SLS is a layer-based RM technology that relies on a high power laser to fuse powder particles into a solid object. Minute detail, directly from a 3D CAD model, is possible and a technique has been established for manufacturing prosthetic sockets with passive compliant regions using SLS. Based on this SLS RM technique, steps toward developing a transtibial Nylon prosthetic socket that automatically adapts to volumetric changes in a residual limb will be described. A design methodology was developed to use RM including concept generation, refinement, and final verification. In concept generation, analogies, such as “Chinese Fingertraps” and balloons, were coupled with a review of socket designs in literature and industry and interviews with prosthetists. Inflation of a bladder integrated into the wall of a SLS socket is one of the promising design concepts generated, but the concept needs further refinement. In order to confidently design an inflatable SLS prosthetic, it is critical to understand the relationship between applied pressure and deflection. A testing specimen—5.08 cm diameter thinwalled membrane—was designed to simulate a bladder integrated into the wall of a SLS socket. Several thicknesses were also used to investigate the effects of this parameter on inflation. Preliminary tests were conducted using compressed air for quantifying pressure vs. displacement. During the tests, leakage through open porosity (due to low density) was detected. Density is strongly related to energy transmitted to the part during sintering. The energy concentration is quantified as the Andrew’s Number (AN), the inverse relationship of laser power (LP) to laser scanning speed (SSP) and scan spacing (SS). Therefore, to determine the optimal AN—and therefore increase density—an experiment varying LP and SS (SSP is a manufacturer setting) to determine their effects on apparent density and tensile strength was completed. The optimal AN, 1.63 $\mathrm{J/cm^2}$ for Nylon 12 powder, was based on highest apparent density and tensile strength. Using this AN, additional deflection samples were tested. Initial results showed a maximum deflection of 2.1 mm at .145 MPa for a 1.3 mm thick membrane. In comparison, changing the volume of a 3D scan of a patient’s residual limb by 6% in a 10.9 cm diameter region on the posterior distal tibia socket end, as recommended by a prosthetist, requires a 5.8 mm displacement. Therefore, early results suggest that a single bladder will not meet deflection requirements, influencing the design of multiple larger regions and use of a more flexible material. Results from these experiments will help eliminate concepts which cannot deflect the necessary amount for the volume change, further refining the concepts towards a solution.