

EDISC – THE FIRST ARTIFICIAL SPINAL DISC WITH INTEGRAL FORCE-SENSING MICROELECTRONICS

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ABSTRACT

Theken Disc, LLC has developed an artificial spinal disc with an integrated microelectronics module to reduce post operative complications and speed return to work and function. During the first few months after implantation, it is very important to limit patient activity to prevent disc migration or dislodgement. The force monitoring capability provides real-time or stored data to assess patient's ability to return to work. The microelectronics module monitors any dynamic high-load events that may take place, and immediately warns the patient of the high load by sending a wireless signal to a belt-worn audible alert unit.

METHODOLOGY

The eDisc is comprised of two titanium plates with a polycarbonate polyurethane core between them (see Figure 1).

Each titanium plate has a vertical keel to assist in maintaining the intended surgical placement of the disc. In the center of the polymer core of the eDisc resides a microelectronic force monitor, which alerts the patient of high loading conditions. These high loading conditions could result in dislodgement or migration of the device if the vertebral bodies have not yet fused to the titanium end plates. Each time the patient is alerted to a high load event, the force values are recorded to on-board flash memory along



Figure 1: The eDisc

with a time and date stamp. This data can be downloaded at a later time using a handheld 'communicator', which is used by the surgeon to acquire the loading history of the implant.

A functional block diagram depicting the various aspects of the implant microelectronics is shown in Figure 2. The force data is acquired using three coplanar piezoelectric

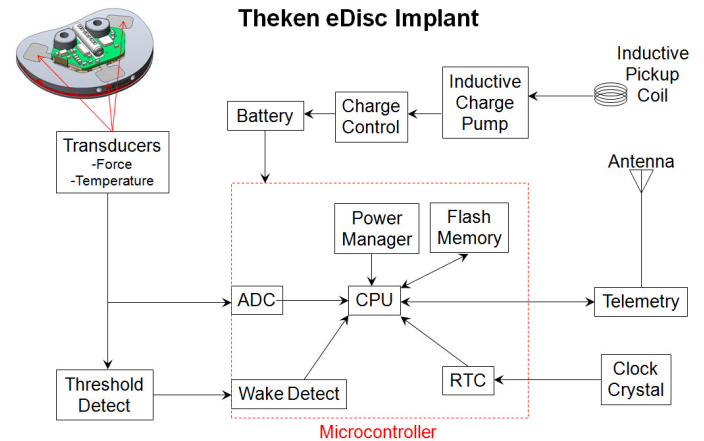


Figure 2: Functional block diagram

sensors embedded in the lower titanium plate of the eDisc. These sensors effectively convey the dynamic forces applied to the eDisc as the force is transmitted through the disc. Any force which exceeds a predetermined force threshold will wake the microcontroller from its sleep state, so that the forces can be sampled by the on-chip analog-to-digital converter (ADC).

The microcontroller used is a very low power Texas Instruments microcontroller in die form, which provides efficient space utilization and system functionality. The processor has integrated RAM, flash memory, real time clock,

temperature sensor, and 8 channels of analog to digital conversion.

The eDisc has an onboard low-power radio frequency (RF) transceiver, which is used for telemetry. The Medical Implant Communications Service (MICS) protocol is utilized by both the implant, as well as the hand-held communicator to transfer force data and operational parameters.

A magnetic loop antenna is used in both the implant, as well as the communicator. The design of the implant antenna is complicated by the deep nature of the implant and the effects of the surrounding biological tissues and fluids. This requires an agile antenna tuning system that can autonomously adjust the operational parameters of the transceiver to compensate for the impedance mismatch.

The electronics are powered by a miniature rechargeable lithium-ion battery with sufficient power to satisfy the needs of the design. The battery can be recharged in-vivo using inductive power coupling. Patients wear an electromagnetic belt coil to recharge the battery in about 30 minutes. Power is induced in the secondary coil would around the perimeter of the eDisc endplate (seen in Figure 1).

The whole microelectronics module (Figure 3) fits in a tiny ½ cc space in the center of the eDisc. The componentry is mounted to a Kapton flex circuit, which can be folded into a small form factor to fit inside the eDisc. A lead-free design and build process is employed to conform to RoHS standards.

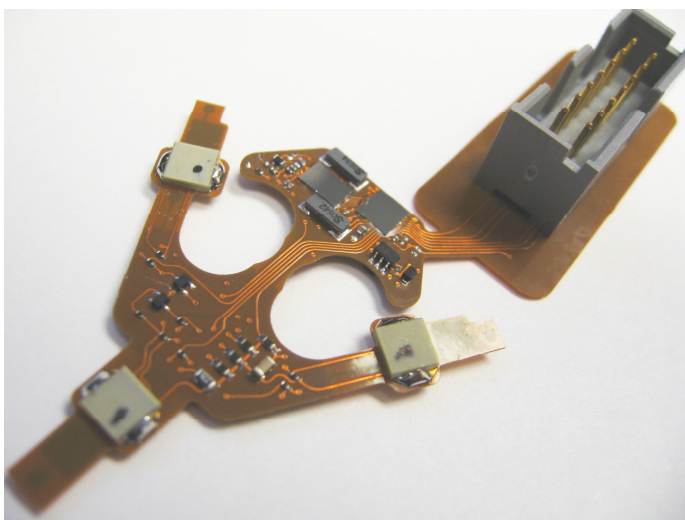


Figure 3: Microelectronics module with programming header

RESULTS AND DISCUSSION

A pilot primate implant demonstrated the feasibility of sensing and storing spine force data, telemetry and the battery recharging system. In Figure 4, an X-Ray image shows the anterior view of the intervertebral placement of the eDisc. Within the first week, 56 data events were triggered and saved

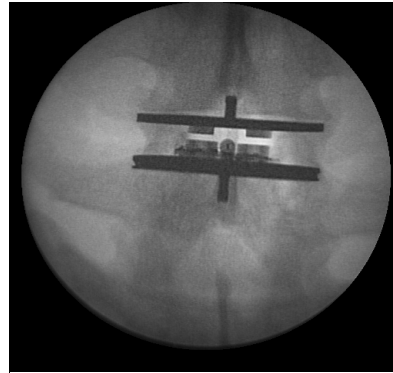


Figure 4: X-Ray of eDisc placement

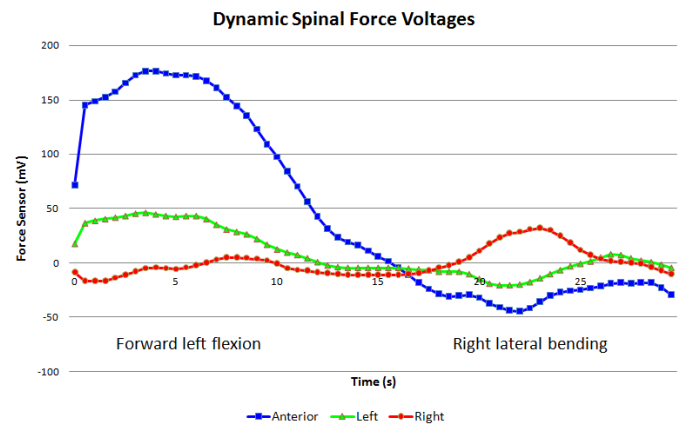


Figure 5: Data set from pilot

CONCLUSIONS

The pilot trial proved the feasibility of each of the microelectronics subsystems. The force threshold detection circuitry properly triggered on elevated loads from the force sensors. The force data that was saved to internal flash memory was successfully downloaded by the wireless communicator. The inductive coupling system successfully recharged the lithium-ion battery in the implant.

Through its ability to monitor high load events, and save the event data in its on-board memory, this electronics platform technology has the potential to improve total disc replacement patient outcomes by reducing the chance of post-operative complications and assessing capability of return to work. Other orthopedic implants may benefit from a similar microelectronics platform to improve patient outcomes.