AN INSTRUMENTED SCAFFOLD TO MONITOR LOADING OF CARTILAGE IN THE KNEE JOINT

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Introduction

Tissue engineered cartilage covered scaffolds offer one solution to resurfacing damaged cartilage in young and active arthritis patients. Cyclically loading cells is expected to provide more rugged aligned tissues than those grown in static culture. No direct in vivo measurements of loads during gait, acting on cartilage tissues are available, making it difficult to select appropriate loads to apply during tissue growth. In addition no monitoring technique currently exists to monitor loading of implanted tissue engineered constructs. It was the goal of this study to develop a monitoring system and use it in an animal model to collect in vivo cartilage load measurements.

Methods

Polybutylene terephthalate(PBT) scaffolds were manufactured using an extrusion freeform fabrication rapid prototyping process. A grid pattern, which developed bone ingrowth in a previous study, was modified so that strands were rotated 45° between layers.



Figure 1: Scaffold showing cross layered polymer pattern. Layer labeled top is solid and has a dome shaped section above it to support tissue engineered cartilage.

Three 1000 ohm single element strain gauges were aligned and attached along the long axis of the scaffold surface with a 120 degree separation. Gauges were wired to a cable and waterproofed using a published procedure. Scaffolds were loaded in confined compression on an MTS at a load rate simulating gait speeds and load vs. strain calibration curves were prepared. Wired scaffolds were cleaned, sterilized using ethylene oxide and aerated.

Six tall male hounds weighing between 29 and 35 Kg were selected for implantation surgery. The NIH Guide-lines for animal care and use were observed during animal experiments. Following preparation of one hind limb of each of six hounds, an incision was made exposing the medial femoral condyle and a scaffold was implanted by drilling two concentric holes (one for the cable and the second for the scaffold). The cable exited the lateral aspect of the femur and was coiled subcutaneously for later retrieval. Following a 3 month holding period retrieved wires were connected to a hard wired and/or a radio transmitter system. Strains were collected while dogs walked on a treadmill and calibration curves were used to assess loading. Following *in vivo* monitoring bones were explanted and loaded using a bench top loading system. Finally bones were dehydrated and embedded using a published undecalcified tissue embedding technique. They were sectioned and stained and histomorphometry was used to assess bone growth.

Results

Strain vs. load curves for gauged scaffolds were noted to be linear up to the peak test load of 147 N (15 Kg). *In vivo* strain patterns were similar to patterns collected directly from the mid-diaphysis of the femora of dogs during earlier *in vivo* studies. Each gait cycle contained a low load swing phase which was assigned the zero strain value. Load vs. time graphs converted by using calibration curves indicated that peak loads ranged from approximately 80 to 120 N during gait (Figure 2) for this

test animal (weighing 34 Kg). Standing relaxed prior to and following gait, a load of 65 ± 6.5 N was recorded from this animal.

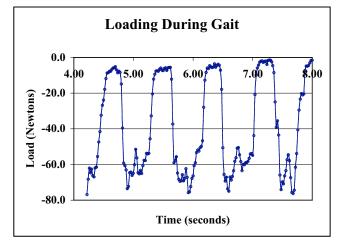


Figure 2: Representative load patterns determined from strains collected during gait. Measurements were zero adjusted assuming the lowest combination of bodyweight and muscle loads during swing phase. At this gait speed swing phase lasts approximately 0.3 seconds.

Gross examination of knee surfaces in the explanted hind limbs, showed that scaffolds were adequately recessed but mild scoring of the tibial cartilage was noted in some animals. Scaffolds were securely fixed by extensive bone in-growth with no visible adverse reaction to the scaffold material. Cables were surrounded by a thin fibrous tissue layer which prevented them from migrating. Fluid infiltration into cables lead to some visible corrosion and precluded monitoring of some strain gauges.

Discussion

Load measurements collected from strain gauged scaffolds were in general agreement with observations that dogs loaded at most 2 legs (one front and one back) simultaneously during gait at this speed. Results were also in agreement with evidence showing that, during stance, 40% of the dogs body weight is carried on the hind limbs (in this case 6.8 Kg/leg (67 N/per leg)). Telemetry was noted to function well when the exciting coil was accurately aligned with the subcutaneous transmitter but stopped transmitting when the power coil was slightly misaligned . Monitoring of telemetry output over a period of several days provided a consistent output suggesting that this system could be used over an extended period even though fluid infiltration was likely to incapacitate the system eventually.

Ongoing studies using cartilage covered "sensate" scaffolds are evaluating the effect of a tissue engineered cartilage layer. Development of better waterproofing coatings for connections between gauges and lead wires, and between lead wires and transmitters is expected to increase the length of time that these systems are able to provide measurements.

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