INTRODUCTION

Spinal instrumentation with arthrodesis is commonly used in the surgical treatment of scoliosis because rigid fixation leads to higher fusion rates. However, stiff instrumentation causes device-related osteopenia due to “stress shielding.” Earlier patient rehabilitation during which loading can be insured through monitoring, may be able prevent this problem. Currently no diagnostic technique is available to adequately assess when spine fusion has occurred. Fusion is judged using serial radiographs even though animal studies have shown that fusion occurs much earlier than is evident on radiographs. The aim of this study was to develop a technique to detect fusion in vivo in order to facilitate adequate bone loading during rehabilitation and an early return of patients to unrestricted activity.

CPC coated strain gauges were implanted into a patient in conjunction with a subminiature radio transmitter to monitor bone strain changes which were measured during specific exercises over the course of the occurrence of fusion. Bone strain changes were expected as the fusion mass stiffened.

METHODS

Strain Gauge Preparation: A blended CPC coatings consisting of 15% of an amorphous tricalcium phosphate (TCP) and 85% of a microcrystalline hydroxyapatite (HA), obtained from Biointerfaces (San Diego, CA), were attached to three FAE-12-100-S6ET subminiature 1000 ohm single element strain gauges (BLH Electronics, Canton MA) using a medical grade polysulfone dissolved in a solvent. The particles were attached by coating and baking the polysulfone solution (Amoco, Huntington Beach, CA) with particles sprinkled onto it. Each gauge was wired using two conductor NMUF 2/32-4046SJ (Cooner Wire, Chatsworth, CA) shielded cable and waterproofed with a series of three waterproof coatings. A fourth gauge was not coated on the sensing surface but was wired and waterproofed using the same procedure described for the CPC coated gauges. All wires were soldered to a 4mm by 14 mm, 14 pin receptacle which was coated in epoxy. This was then connected to a subminiature 4 channel digital radio transmitter (Microstrain Inc, Burlington, Vermont). The connector-transmitter junction was waterproofed and the gauges and transmitter were ethylene oxide sterilized and aerated.

Surgical Approach: A 17 year old female with a seventy degree right thoracic curve underwent same day thoracoscopy anterior release and fusion followed by posterior instrumentation and fusion. A posterior midline approach was used. The dissection was carried down to the posterior elements and the fascia were separated. Paraspinal muscles were reflected subperiosteally and stripped from the posterior elements. All hooks and screws were placed utilizing a standard right thoracic implant pattern. After decortication of the posterior elements the gauges were applied to the lamina of the T9, T10, and T11 vertebrae. Gauges were initially held in place with a resorbable sutures and mesh. One wired single element gauge was attached to the left rod using a sterile cyanoacrylate adhesive to allow monitoring of deformation of the hardware. The sensors were connected to a subminiature digital radio transmitter implanted in a subcutaneous pouch. The patient was radiographed monthly to monitor fusion. Clinical evaluation was also carried out to determine patient mobility and success of fusion.

Measurement Collection: One week after gauge and transmitter placement strain measurements were collected from the gauge on the left rod only during bending and twisting through a limited range of motion. Strain measurements from all four gauges were recorded biweekly after this measurement. During each recording session, the power coil was placed on the patients skin so that it was parallel to the orientation of the transmitter inside the patient. The coil powered up the transmitter and measurement collection was initiated. After 4 weeks post op measurements were collected during various activities. These included forward, backward and lateral bending as well as clockwise and counter clockwise twisting. Activities normally performed by patients such as sitting up in bed, sitting into a chair and bending down to tie a shoe were also measured and evaluated using a custom data acquisition and analysis software running on a laptop computer.

Each activity began with the patient standing or sitting up right. Once a signal had been established the patient was instructed to begin and data collection continued until the patient was back in the original starting position. Peak strain levels for the same activities were tabulated between monitoring sessions.

RESULTS

The first measurement session, five days after surgery, provided consistent strains from the left rod during bending and twisting activities. No strains were noted from any of the CPC coated strain gauges on the vertebra. Maximum peak strains of 500 µstrain were noted from the rod during lateral bending activities. This represents a peak stress of approximately 95 MPa which is well below the fatigue limit of the rod.

Measurements collected from the bone-bonded CPC coated strain gauges four weeks post-op were noted to have extensive noise. However, consistent patterns were observed when a third order line fit of the measurements was utilized (Figure 1). The monitoring session 12 weeks after gauge placement showed clearer patterns with much less noise. Serial radiographs did not shown evidence of fusion.

Figure 1: Representative graph of strains from a patient during counter clockwise twisting. Peak is approximately 480 µstrain relative to stance. Twisting activities produced the most consistent bone strain patterns. After 12 weeks, clockwise twisting resulted in peak bone strains of – 1450 µstrain ± 5% and counter-clockwise twisting resulted in peak bone strains of 400 µstrain ± 8%. Left and right lateral bending produced more variable peak strains of -800 µstrain ± 12% and 1000 µstrain ± 10% respectively. Activities such as sitting up on an exam table and climbing off the exam table produced relatively small bone strains compared to strains measured when sitting down on a chair which produced peak strains in excess of 1200 µstrain. Comparison of measurements over the 12 week period showed increases in the peak bone strains for 6 weeks followed by a leveling off of peak strains. Lifting activities produced the most variable results over this time course with measurements ranging from 350 to 1250 µstrain.

DISCUSSION

An increase in strains during standardized activities over time indicates bone bonding is occurring to CPC coated gauges in agreement with published results(1). In vivo bone strains collected from the lamina of the patient during twisting activities were more consistent than strains collected during bending activities. This was in agreement with bench top cadaver testing results. Strains measured during activities patients usually perform in clinic (such as sitting up on an exam table) were generally similar in magnitude to those measured during bending and twisting. The highest and most consistent strains were noted when the patient sat in a chair. The least consistent strains were noted during lifting activities suggesting a need for a standardized lifting activity in future studies.


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