The Clinical use of Capacitively Coupled Electric Fields: A Ten Year Review

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SUMMARY

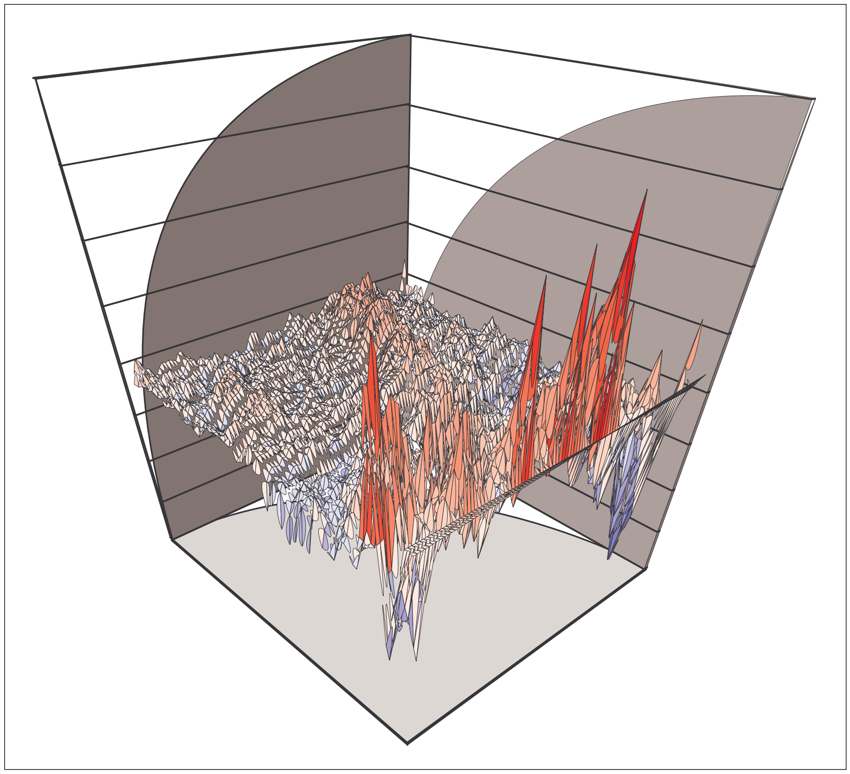
Presented here are the results of ten years of research into the use of capacitively coupled electric fields in the treatment of recalcitrant human fractures and related disorders.

Our initial results with salvage cases further demonstrated that capacitively(2) coupled electrical fields are equally as effective as pulsed magnetic fields in osteogenesis(3).

With ongoing success we attempted refixation of loosened hip prostheses(8), reasoning that the process was similar. As will be seen there has been rewarding clinical success(12).

These studies were criticized because of the unreliability of the imaging methods so we decided to use the tool of Dual Photon Densitometry to investigate the fine changes that occur in bone during electromagnetic stimulation.

This paper is concluded with our latest analysis of the use of this electromagnetic modality as imaged using dual photon (X-ray) absorptiometry (DEXA).



Bone Density Subtraction

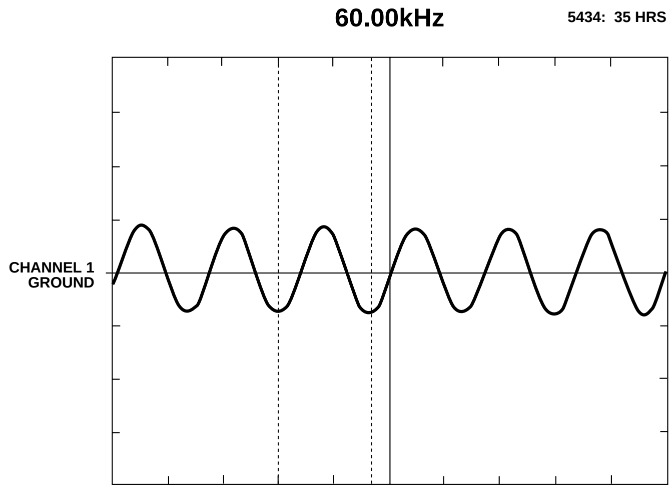
BACKGROUND ELECTRICAL STIMULATION

The concept of utilizing electricity to heal fractures is not new. In 1841, a case was reported of a patient with a non-union of the tibia who in 1812 was treated with "shocks of electric fluid passed daily through the space between the ends of the bone" for 6 weeks. As far as can be determined, this was the first attempt at treating a non-union with electricity.

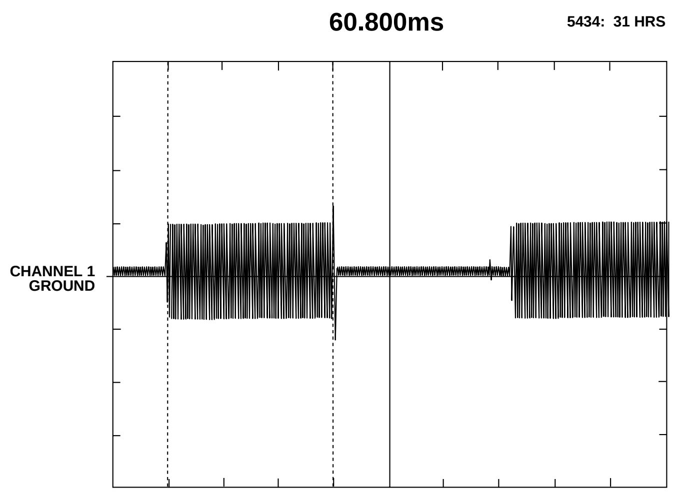
Interest in electrically-induced osteogenesis was reawakened in 1953 when the appearance of new bone formation in the vicinity of the cathode (negative electrode) was demonstrated when a current in the micro-ampere range was applied continuously for three weeks to a rabbit femur. Also described were stress generated potentials in bone in which the side of the bone under mechanical compression became electro-negative and the side under tension became electro-positive. Similar experiments were reported independently in the United States.

Technical Description of a Capacitively Coupled Device

FREE RUNNING SEQUENCE MEASURED AT TP2 (CURRENT) SENSE



BURST MODE SEQUENCE MEASURED AT TP2 (CURRENT) SENSE



The MATRIX-500* generates a symmetrical sine wave of high frequency (typically 50 to 60kHz) which is then modulated at a 50% duty cycle. The resulting wave form has a cycle period of 15 to 17 Hz with an active on time of 60 to 70 ms. (See wave form graphs.)

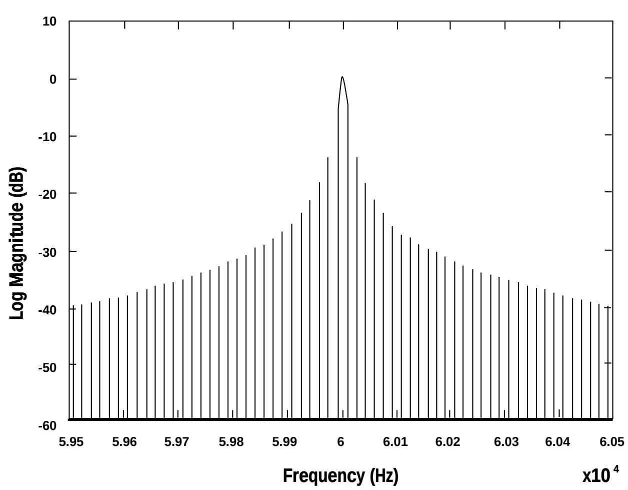
Since the device is a true capacitively coupled, current limited device, there is no need for conductive gels. A pair of flexible, self adhesive conductive carbon electrodes 2 inches by 4 inches are used to deliver energy to the treatment site.

The physical properties of this device are; weight with battery 5 oz., length 4.750 in., width 1.300 in., and depth .800 in. The MATRIX-500 has a battery life of 15 days, at 8 hours per day from a 9 volt alkaline battery. Batteries are changed at 14 day intervals.

One of unique features of the Biotronics MATRIX 500 design is the utilization of the biological system as an active component of a tuned circuit. This allows the MATRIX 500 to actively track changes in the biological impedance and automatically adjust the frequency for optimal delivery.

MEASURED AT TP2 (CURRENT) SENSE

AMPLITUDE SPECTRUM



Treatment of a Scaphoid with a Capacitively Coupled Electric Field

INTRODUCTION:

Scaphoid fracture is a common injury in athletes which frequently goes undiagnosed for a period of time and not uncommonly, despite good orthopaedic management, goes on to delayed or non-union. Treatment of scaphoid non-union presently includes ongoing immobilization, bone grafting, various internal fixators, and combinations of these[4]. Ultimately it may become necessary to insert a prosthetic scaphoid. To this therapeutic armamentarium has recently been added the use of pulsing electromagnetic fields[3] and capacitively coupled electric fields[2]; both of which methods claim a high rate of success. One report has suggested that the combined use of a bone graft plus electrical stimulation has a higher rate of success than either method alone[5,6]. The case presented here was initially diagnosed three months following fracture, was grafted, internally fixated and casted and which nevertheless failed to unite. A trial of capacitively coupled electrical stimulation was instituted and the fracture united. The imaging films show the progress of bone development over one year.

CASE HISTORY:

R.W. is a 29 year old white male who fell playing soccer on Dec. 15, 1989 injuring his left wrist. Because of ongoing pain a radiogram was taken March 15, 1990, which revealed a clear fracture line through the waist of the scaphoid with no evidence of callus formation. On examination the orthopaedic surgeon found pain, tenderness, and stiffness in the affected wrist. He proceeded to do a Russe bone graft and fixated the fracture with a C-pin, after which the patient was placed in an above elbow scaphoid plaster.

MARCH 15/90

MAY 14/90

JUNE 25/90

OCTOBER 2/90

NOVEMBER 23/90

MARCH 13/91

On May 14, 1990, repeat radiograms revealed a clearly evident fracture and sclerosis of the proximal fragment. Repeat films taken June 25, 1990, again revealed a clearly evident fracture and sclerosis of the proximal fragment. The orthopaedic surgeon felt this represented a failure of surgical management and elected to use electrical stimulation, which was begun on July 5, 1990. Check films taken October 2, 1990, along with tomograms demonstrate nearly complete obliteration of the fracture line, although some proximal sclerosis persists. The cast was removed and electrical stimulation discontinued. On November 23,1990, plain films and tomograms revealed ongoing bony union. On December 3, 1990 the pin was removed. The follow up films of March 13, 1991 revealed a deformity of the scaphoid as a result of the fracture, which was solidly united.

DISCUSSION:

This case features delayed diagnosis and a failure of surgical management. Despite good orthopaedic treatment, the fracture had failed to heal. This single case indicates that capacitively coupled electrical stimulation may have a role as adjunctive therapy in difficult scaphoid fractures.

Osterman, et al, state in their review article of scaphoid non-union[1] that the most appropriate indication for the use of electrical stimulation is in those patients who have failed the previous bone grafting and in whom the scaphoid has remained relatively aligned.

Treatment of an Impacted Hip Fracture with a Capacitively Coupled Electric Field

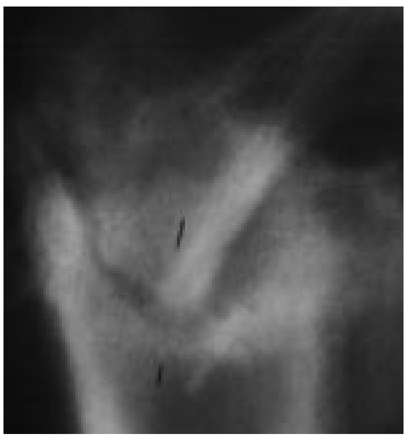
IMPACTED HIP FRACTURE

The patient is a 72 year old white female who suffered an intertrochanteric fracture of the right hip April 16, 1988. This was fixated using a pin and plate. Postoperatively she developed uncontrolled hypertension, unstable diabetes mellitus, congestive heart failure, urinary tract infection, deep vein thrombosis and pulmonary embolism.

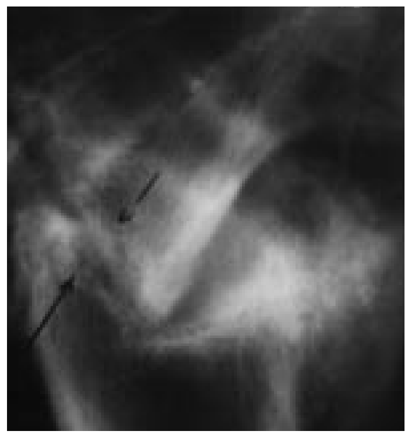
In August, 1988, she was readmitted with a gram positive septicemia (staph aureus) and an abscess of the right hip joint. On an urgent basis the internal fixation was removed, the abscess drained, and appropriate antibiotics given. Although the hip remained pain free, she continued to have difficulty walking and required a walker. The difficulty walking she attributed to a sense of instability in the hip. Tomograms performed revealed a nonunion of the impacted fracture.

In March, 1989, one year post fracture, we began electrical stimulation using a capacitively coupled[11] system designed to deliver five milliamperes of current at the skin surface. The patient wore the device eight hours daily. Serial tomograms done at two monthly intervals revealed progressive callus formation. Clinically, over the six month course of treatment, she progressed to two canes, then one cane, and finally was able to walk without support.

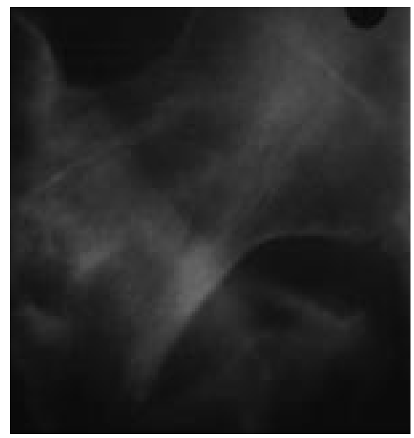
January 6,1989

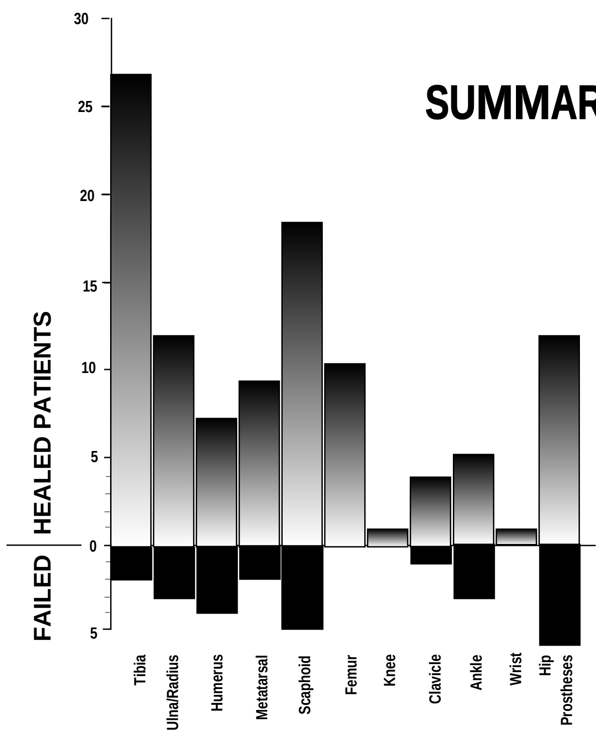


May 25,1989



September 25, 1989





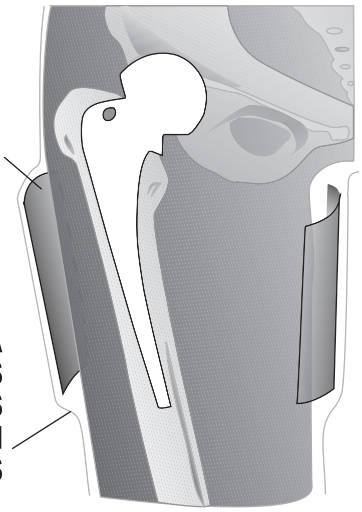
SUMMARY OF FRACTURE TREATMENT

OVERALL RESULTS OF 131 PATIENTS

The application of capacitively coupled fields as an adjunct for difficult fracture cases is illustrated in the graph to the left. This method has proven successful in the treatment of recalcitrant human fractures. The greatest rate of success has been with the tibia; the poorest with the humerus.

This is a graphic summary of ten years of ongoing research.

The Effect of Capacitively Coupled Pulsed Electric Fields on Painful Hip Prostheses



SUMMARY

The effect of capacitively coupled electrical stimulation on a loosened hip prosthesis is assessed clinically, by arthrography, and by Tc-99 scanning. The results show that the prosthesis has tightened.

INTRODUCTION

In 1985 Ascherl(7) reported clinical evidence of tightening in loosened hip prostheses using pulsed electromagnetic fields. Using a clinical scoring system, he reported a success rate of 69.5% in 348 loosened arthroplasties. In a similar study in 1988, Kennedy(8) reported a 55% success rate. Neither of these studies presented imaging evidence of refixation.

Brighton and Pollack(9,10) demonstrated that capacitively coupled electrical fields were as effective as inductively induced fields in the treatment of non-unions in long bones in humans.

The single case reported here is part of an ongoing study on the possible efficacy of capacitively coupled electrical fields on loosened endoprostheses.

CASE HISTORY

C.H. is an eighty year old white female with Parkinsons disease who fractured her right hip on February 19, 1989. She was operated on the same day with the insertion of an Austin Moore prosthesis.

Five months post-operatively she continued to complain of disability and pain in the hip. Plain radiograms done July 12, 1989 did not reveal any loosening but arthrograms done nine days later revealed dye between the upper three centimeters of the femoral component and the femur on the lateral aspect. This confirmed the evidence of a nuclear scan done the day prior. Cultures taken at the time of the arthrogram were sterile. A Harris Hip Score at that time was 34.

The electrodes of the previously described device were positioned under radiographic control to bracket the area of loosening. The patient was instructed in the use of the device and asked to use it eight hours per day. On January 7, 1990, a repeat Harris Hip Score was 73.

On February 21, 1990, the arthrogram and radionucleide scan were repeated. The arthrogram revealed no migration of the dye beyond the joint space. There remained evidence of increased uptake around the prosthesis on the nuclear scan although somewhat less than on the original scan. The drop in the third Harris Hip Score is due to a worsening of her Parkinsons disease.

Pre-Treatment

Post-Treatment

DISCUSSION

This single case is presented for three reasons. Firstly, because of the lack of confirmatory imaging data, it was not clear from the reports of Ascherl and Kennedy(7,8) if the effect noted was anti-inflammatory, analgesic, or actually represented tightening of the endoprosthesis. The case presented here offers objective evidence of tightening.

Secondly, no previous reports appear using capacitively coupled electric fields(12) in an attempt to tighten an endoprosthesis.

Thirdly, the field effect device used on this patient is truly capacitive in that no conductive gels are used and a gap exists between skin and electrodes.

The Effect of Capacitively Coupled Pulsed Electric Fields on Painful Hip Prostheses A Four Year Follow Up

SUMMARY

Fifteen patients with painful hip prostheses were exposed to pulsed electric fields for eight hours per day over a period of six to twelve months and followed with a clinical scoring system for four years. In twelve of the fifteen there was clinical improvement as measured by a modified Harris Hip score. three of the twelve went on to revision surgery because of insufficient relief of pain and the remaining nine avoided further surgery for an overall success rate of 60% at four years.

INTRODUCTION

Presently, the therapeutic options for a patient with a painful hip prosthesis are living with the pain and loss of function or having the arthroplasty revised. Revision surgery is problematic as well, for the patient, on average, is ten years older and has less bone stock.

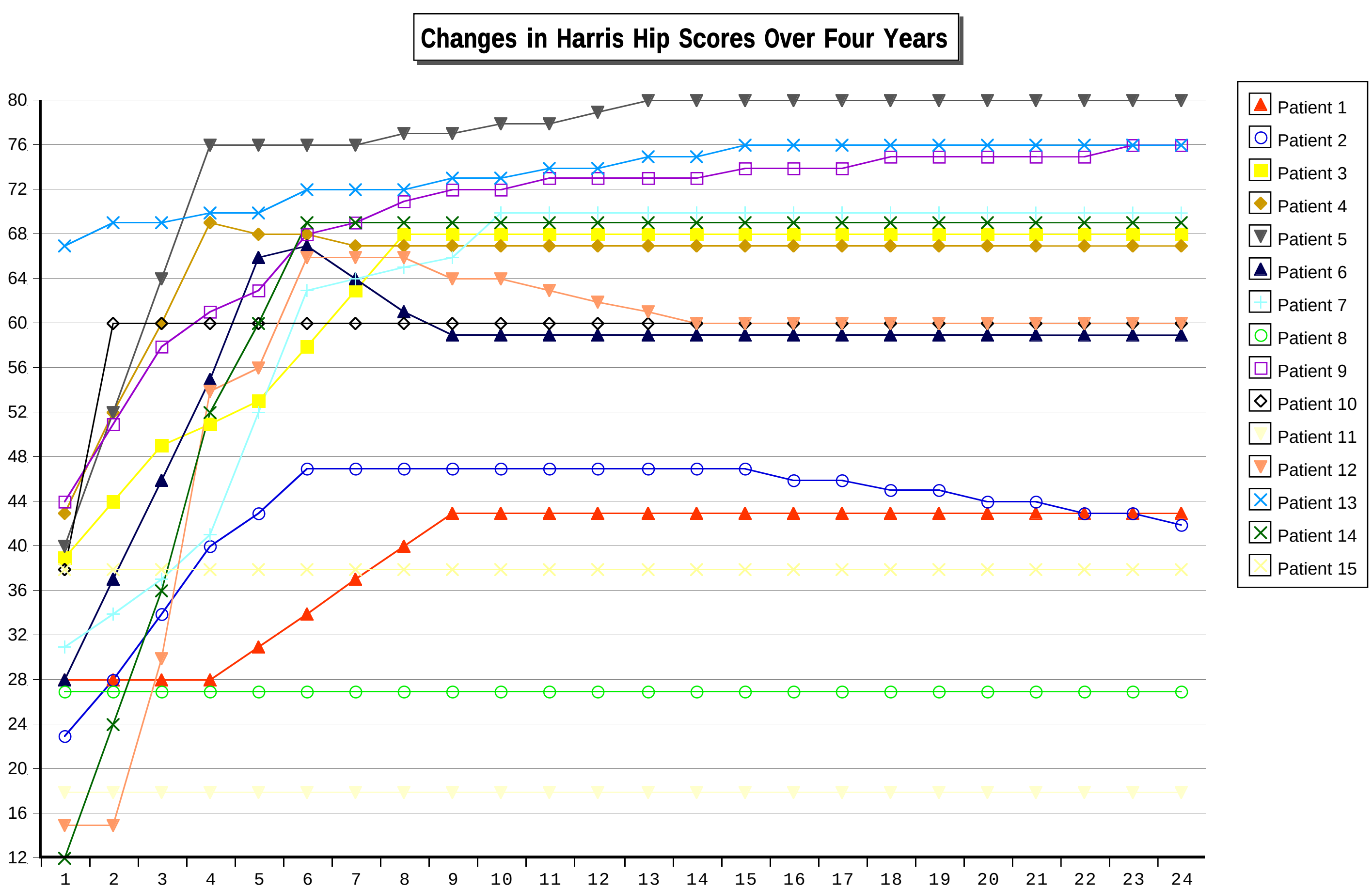
METHODS AND MATERIALS

This was a pilot study with no controls. Admission criteria included a painful hip prosthesis in patients being considered for revision arthroplasty. In almost all of the patients there was also some objective evidence of loosening either on plain films, arthrograms, or radionucleide scans, but the absence of objective confirmation of loosening did not exclude patients from this pilot. No restrictions were requested in day to day activities. Patients were evaluated using a modified Harris Hip score every two months for the next year and then intermittently for the following three years.

RESULTS & CONCLUSIONS

Fifteen patients entered the study; 6 males and 9 females. The average age was 72.3 years with a range of 63 to 93. The average increase in the hip score was 24.1 points overall. In failures (6) average increase in hip score was 11.50. In successes (9) average increase in hip score was 32.55. Almost all of the improvement clinically was seen within the first four months, as can be seen by the accompanying graph. Three patients died during the study, two of cardiac problems and on of carcinoma. Four of the fifteen patients went on to revision surgery. One required revision because of subsistence. The remaining three that went to revision were described as having "grossly loose" components at the time of surgery.

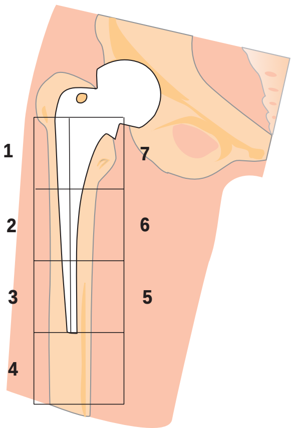
Given that the natural history of a loosened prosthesis is to remain loose or become looser, these results are very encouraging.



Bone Density Evaluation Around a Hip Prosthesis

ZONES

1 - 3.99% loss
2 - 4.26% loss
3 - 3.18% loss
4 - 2.63% loss
5 - 9.63% gain
6 - 1.74% gain
7 - 5.15% loss



Gruen Zones

WHAT IS BONE DENSITY

Bone density is a measurement of the mineral content of bone. It tells us how highly calcified the bone is.

HOW IS IT MEASURED?

Until fairly recently, the only way to measure bone density was to make an educated guess from standard X-rays. This method required at least a thirty percent difference in bone density to reliably detect a difference. More recently the use of radioactive isotopes has enabled more accurate measurements to be done. Even more recently, using a method called Dual Photon Absorptiometry, very accurate and highly repoducible measurements can be made. No ionizing radiation is used during measurement.

PATIENT HISTORY

The patient, a 73 year old retired nurse, had an uncemented total hip replacement performed in July 1992 for severe osteoarthritis. Post-operatively she was pain free but in July 1993 began to experience pain in the area of the implant. The pain persisted but an arthrogram performed in early 1994 did not reveal any gross loossening. A radionucleide scan done at the same time was suggestive of loosening. She was scheduled for revision surgery.

Using Dual Photon Densitometry, measurements of the bone density surrounding the prosthesis were made at intervals of six months over the next year. For additional evaluation, repeat radionucleide scans were performed and a Harris Hip Score was done at intervals as well.

At the end of one year, the Harris Hip Score had changed from 47 to 76, which is a marked clinical improvement. The radionucleide scan no longer showed a "tip" reaction and the bone densities, as shown above in the seven Gruen zones, had altered beyond the two percent range that is considered the reliability range of such scans.

OUR METHOD OF EXAMINING BONE DENSITY DATA

When we realized that the Gruen zones were inadequate to describe the subtle changes we wanted to display we returned to pixilated raw data.

By doing duplicate scans on the same day and then aligning and subtracting the databases, we were able to confirm the manufacturer's claim to two percent reproducibility of bone density information except in the zone within two millimeters of the metal prosthesis. At that point the data degenerated.

The images presented on this page graphically show where these differences have occurred and the degree of change. The actual value of these changes is yet to be determined.

Sample of Raw Numbers

7174,7190,7313,7245,7151,7176,7016,
7239,7115,7183,7305,7263,7197,7078,
7215,7154,7067,7098,7074,7085,7109,
7009,7236,6979,7104,7120,7171,7162,
6992,7098,7027,7070,6857,6958,7253,
7116,7243,7191,7031,7331,7065,7335,
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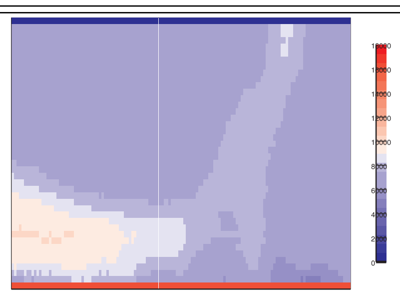
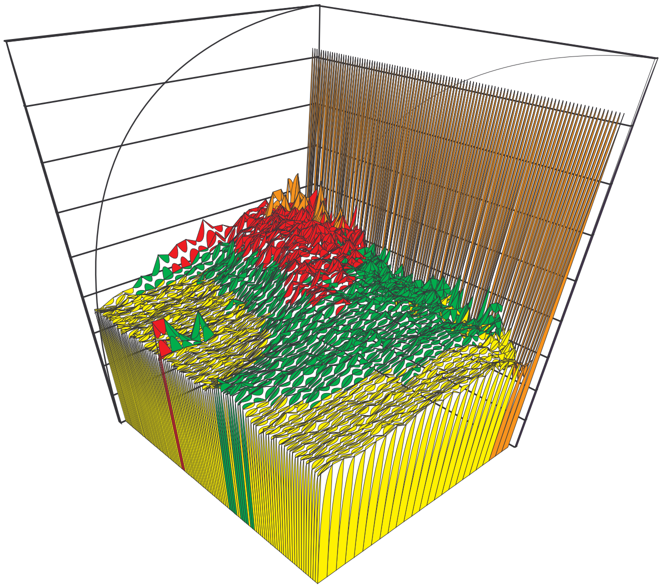


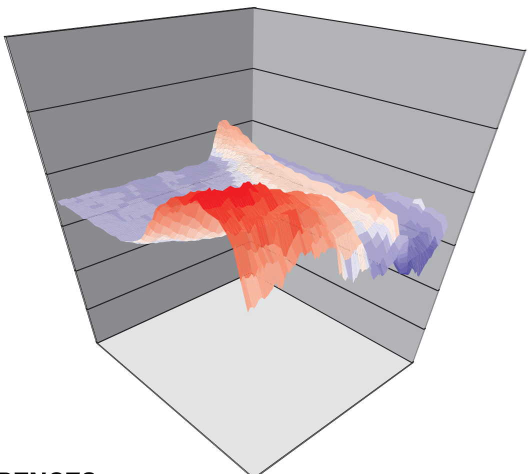
Pixel Data

ANALYTICIAL OVERVIEW

The raw scanning x-ray data files consist of a header, containing scan specific information, and data. The data is in the form of rows of numbers, with each row representing a scan line and each number the intensity of a scan pixel. (Pixel size: 1.2 mm vertical x 6 mm horizontal)   The number of rows in a file and the number of pixels in each row varies from scan to scan and is under operator control. The intensity for each scan pixel range from 0; full saturation (no blockage of the x-ray beam), to16383; unsaturated (full blockage of the x-ray beam). To process the raw data files, an algorithm was written to convert them to a readable ascii table, much like that shown in "Sample of Raw Numbers" to the left. However, our main interest was in the data close the prosthesis, to that end only the first forty-one scan pixel to the left and the right of the prosthesis (inclusive of one pixel in the prosthesis for orientation) were used for our analysis.

Through conversations with the manufacturer and preliminary analysis it became clear that some form of averaging would have to be applied to the data, in an effort to reduce the effects of random noise. The target area for the average consisted of ten pixels. The scheme employed here was a running average over ten consecutive rows pixel per pixel. Thus the base data for each scan comprised of an averaged table of forty-one scan pixel to the left of the





prosthesis and an averaged table of twenty scan pixels to the right of the prosthesis. From these tables of raw data as shown in "Pixel Data" on page 7, images were produced. These images provide for easy gross analysis of structure and features. As an extension of the analysis, a differencing algorithm was written to allow for the comparison of two scans done at different times. Herein we simply subtracted the corresponding pixel in each file from each other to come up with a difference table. In turn these tables were rendered as a three dimensional images, as shown to the left. It is through these difference images that the evolution of bone deterioration or augmentation can be tracked.

CONCLUSION

The results to date are extremely encouraging and warrant further exploration. We remain particularly interested in the use of DEXA to evaluate bone denisty changes during electromagnetic stimulation.

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* MATRIX-500 A field effect device produced by Biotronics Research Corporation, Suite 1104-3760 Albert Steet, Burnaby, B.C., V5C 5Y8 Specifications available on request.