

The Effect of Capacitively Coupled Electric Fields on Painful Hip Prostheses

(A Pilot Study with a four year follow-up)

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The only options presently available to the patient with a painful loosened prosthesis are either to live with the pain and disability or have a revision arthroplasty. Eighteen painful hip prostheses being considered for revision arthroplasty were exposed to capacitively coupled electric fields for eight hours a day for a period of one year, the clinical course being followed with a Harris Hip Score. Minimum follow up (excluding death) was four years. With one exception, the study looked at femoral stem component loosening only. The clinical results were good, as seen by an overall average increase of 24 points in the hip scores in the first year. There were 6 clear failures and 12 clear successes. An analysis of the results indicates probable failure if pain was present soon after surgery and there was no response to the treatment within three months. In the group considered successes there was significant clinical improvement within three months which persisted for four years.

Introduction

The rationale for using pulsed electromagnetic fields in the treatment of loosened prostheses has remained the same since the earliest studies: the histological appearance of the interface tissue is similar to that seen in acquired non-unions which have been shown to be clinically responsive to these fields (2).

Early animal work in canines using various implants and direct current (3,8,10,11,12) indicated an increase in shear strength between the controls and the stimulated animals, the electromagnetically stimulated animals having greater shear strength. Clinical studies in humans followed.

In a study of 348 hip arthroplasties being considered for revision surgery, Ascherl (1), using an inductive (coil) system, reported a clinical success rate of greater than 65% over a follow-up period of ten years. Success was observed within three months. Sepsis, dislocations, implant fracture, cement fracture and broad radiolucent lines indicated probable failure.

Rispoli (9), using a similar delivery system on 42 painful uncemented hip arthroplasties and a scoring system which combined clinical assessment and radiographic findings, reported a success rate greater than 65%. No follow up data was presented.

Kennedy (5,6), in a doubly blinded study of 37 cemented arthroplasties, again using an inductive system and similar entrance criteria, observed an initial success rate of 53% in the group that had the active coils, with an average increase in Harris Hip Score of 27 points in that subgroup during the first six months. This initial positive response deteriorated to 1 remaining success at three years.

The present study differs from previous studies in that capacitively coupled electric fields have been used rather than direct current or induced fields. The broad question asked of this pilot study was: would there be a beneficial effect from pulsing electric fields and, if so, would that effect be lasting?

Materials and Methods

Population

18 patients met the criteria for acceptance which included presence of a total hip replacement, pain associated with the prosthesis, consideration being given to revision surgery, absence of sepsis and informed consent. The average age was 76.5 years. There were 12 females (avg. age 84 yrs, range 72-93) and 6 males (avg. age 69, range 63-79). There were 8 cemented hips & 10 uncemented hips. There was one case of acetabular loosening (VS); the remainder were loosened femoral components. Eight of the original procedures had been performed for osteoarthritis, 6 for osteoporotic fractures and 4 for other reasons (rheumatoid arthritis, avascular necrosis, caisson disease and infection).

Device Description

The generator, previously described (7), is 13.5 cm in length, 3.3 cm in width and 2.0 cm in depth and weighs 140 grams with battery, a standard 9 volt "transistor" battery. It generates a symmetrical sine wave of high frequency (50-60 KHz) which is further modulated (pulsed) at 15-17 Hz with an active "on" time of 60-70 milliseconds. The parameters are electronically adjusted to changing biological impedance to deliver an RMS value of 5 milliamperes at the level of skin and theoretically 20 microamperes at the level of bone.

The electrodes are 4.5cm by 10.3cm, carbon based and flexible.

The signal delivered is similar in amplitude and frequency to those used in the studies quoted.

Method

Patients were fitted with comfortable elastic shorts. Cotton pockets were sewn in place to bracket the area of pain described by the patient. They were instructed in the use of the device, asked to use it 8 hours a day and asked to report back at regular intervals. There was no direct measurement of patient compliance.

Initially, the patients were clinically scored using a modified Harris Hip Score(4) (modified for pain and function only, total possible score=80) Fig.1 and had preliminary imaging done, including plain films, radionuclide scans and arthrograms. During the first year clinical scoring was done regularly, after which the patients were scored on a yearly basis. As often as was possible, the imaging was repeated at one year.

At the end of one year, the patients who appeared to be benefiting were asked to continue to use the device one day a week for eight hours.

HIP SCORING SYSTEM
(Modified Harris Hip Score)

1. Pain (44 possible)	
A. None or ignores it.....	44
B. Slight, occasional, no compromise in activities.....	40
C. Mild pain, no effect on average activities, rarely moderate pain with unusual activity, may take aspirin.....	30
D. Moderate pain, tolerable but makes concessions to pain. Some limitation of ordinary activity or work. May require occasional pain medicine stronger than aspirin.....	20
E. Marked pain, serious limitation of activities.....	10
F. Totally disabled, crippled, pain in bed, bedridden.....	0
 11. Function (36 possible)	
A. Gait	
1. Limp	
a. None.....	11
b. Slight.....	8
c. Moderate.....	5
d. Severe.....	0
2. Support	
a. None.....	11
b. Cane for long walks.....	7
c. Cane most of the time.....	5
d. One crutch.....	3
e. Two canes.....	2
f. Two crutches.....	0
g. Not able to walk (specify reason).....	0
B. Activities	
1. Stairs	
a. Normally without using a railing.....	4
b. Normally using a railing.....	2
c. In any manner.....	1
d. Unable to do stairs.....	0
2. Shoes and Socks	
a. With ease.....	4
b. With difficulty.....	2
c. Unable.....	0
3. Sitting	
a. Comfortably in an ordinary chair one hour.....	5
b. On a high chair for one-half hour.....	3
c. Unable to sit comfortably in any chair.....	0
4. Enter public transportation.....	1

*Maximum possible score=80

Figure 1

Results

Clinical Outcome

No patient deteriorated. The average initial hip score of 33.11 increased to 38.72 at one month, 45.22 at two months, 50.28 at three months and 57.87 at one year.

Failures

Failure defined itself as insufficient clinical improvement to avoid revision surgery or, in the case of death, no improvement in the hip score.

Using these criteria there were 6 failures (2 males, 4 females) when the data were examined at the four year mark. One patient died four months into the study with no improvement in hip score and the remaining five went on to revision surgery within an average of two years. At revision, these prostheses were described in the operative reports as “grossly loose”, “frank loosening”, “obviously loose”, “grossly loose-finger extraction” and “grossly loose”.

On average this group was 76.8 years old (range 63-93), had been in pain for 1.2 years prior to this study and had an average time to onset of pain following surgery of 1.3 years. In 5 of the 6, pain had been present from the time of surgery. With one exception, there was no improvement in hip scores in this group over the first three months of treatment. Average initial hip score in this group was 32.2 .

Initially they all had plain film evidence of loosening and evidence of loosening on arthrograms. Four of six had radionuclide scans suggestive of loosening and in the remaining two scans were not performed.

Four of the six had cemented prostheses.

Successes

In the 12 patients who avoided revision surgery (4 males, 8 females) there was an average increase in hip score of 22 points in the first 3 months (range 10-40 pts), 28 points at one year (range 13-40) and 30 points at four years (range 13-44.). The average hip score of the 10 survivors in this group at four years was 66.7 (range 52-76), and 71% of this increase in hip score in this group was due to a decrease in pain, as measured by the pain portion of the hip score. Two died of unrelated causes, one at 6 months with an increase in hip score of 40 pts. and the other at three years with an increase in hip score of 23 pts.

On average this group was 76.3 years old (range 63-90), had been in pain for 1.1 years prior to this study and had an average time to onset of pain following surgery of 5.5 years. Average initial hip score in this group was 33.5.

Initially, plain films were positive for loosening in 7/12, radionuclide scans were positive for loosening in 7/12 (2 not done) and arthrograms were positive for loosening in 6/12 (3 not done).

Four of the twelve had cemented prostheses.

The shortest period of follow up has been 4 years, the longest 7 years.

The average hip scores over the first three months of the successes and failures are presented in Figure 2.

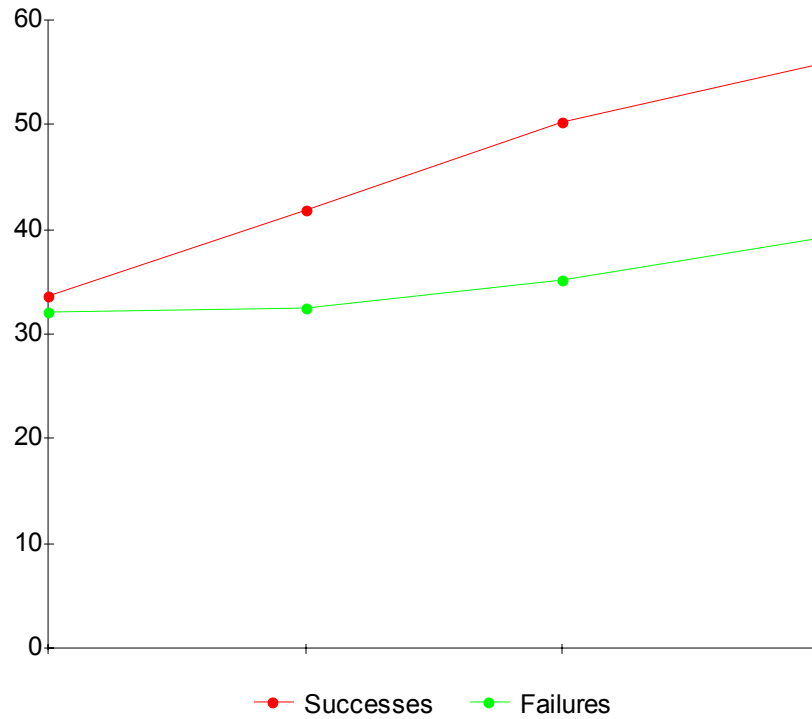


Figure 2

Imaging Results

Failures

Patients	Plain Film 1	Nuclear Scan 1	Arthro-gram 1	Plain Film 2	Nuclear Scan 2	Arthro-gram 2
VB©	+	+	+	-	-	-
HR1©	+	+	+	+	-	o
AR©	+	+	+	-	-	-
IP©	+	o	+	o	o	o
DW(u)	+	+	+	-	+	+
FK(u)	+	o	+	+	+	+

Legend: + = evidence of loosening, - = no evidence of loosening, o = no record or examination not done
(c)= cemented, (u) = uncemented

Figure 3

Successes

Patients	Plain Film 1	Nuclear Scan 1	Arthro-gram 1	Plain Film 2	Nuclear Scan 2	Arthro-gram 2
HR2©	+	+	+	+	-	o
ID©	-	+	+	-	o	o
VH©	+	-	o	-	o	o
VS©	+	-	o	o	o	o
WL(u)	+	+	+	+	+	+
MG(u)	+	+	-	-	o	o
AP(u)	+	+	-	-	-	o
CH(u)	-	+	+	-	-	-
AE(u)	-	-	+	-	-	-
GW(u)	-	+	-	-	-	o
ES(u)	-	o	+	-	o	-
EG(u)	+	o	o	-	o	o

Legend: + = evidence of loosening, - = no evidence of loosening, o = no record or examination not done (c)= cemented, (u) = uncemented

Figure 4

Discussion

Despite the small numbers in this study, the successes and failures separated into two distinct groups. The two groups were comparable in terms of age (Failures=76.8, Successes=76.3), initial hip score (F=32.2, S=33.5), sex ratio (F= 2 males/ 4 females, S= 4 males/ 8 females) and length of time they had been in pain prior to entry into this study (F=1.2 yrs, S=1.1 yrs).

A typical failure had early onset of pain following surgery, evidence of loosening on all of the three imaging modalities and no clinical response to the treatment within three months.

A typical success had late onset of pain following surgery, evidence of loosening on two of the three imaging modalities and a marked clinical response to treatment within three months.

This was an older population (76) than Ascherls' (61 yrs) or Rispolis' (66 yrs). Our results do not conflict with Kennedys' negative findings, as that study dealt with cemented prostheses and our results with cemented prostheses were poor. There is no success reported with this method in loosened cemented prostheses.

Our observations coincide with those of Ascherl, who stated: "The application of pulsed electromagnetic fields to loosened hip prostheses appears to avoid revision surgery in early aseptic loosening".

Conclusions

Our conclusions from this pilot study are: that there is a beneficial effect on loosened painful hip prostheses from capacitively coupled electric fields; and that it is a lasting effect in 2/3 of the described population.

References

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