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TITLE: Do Capacitively Coupled Electric Fields Accelerate Tibial Stress Fracture Healing?

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14. ABSTRACT A convenience sample based on availability of tibial stress fracture cases at local Sports Medicine Clinics was selected. The study was designed to determine if electric field stimulation accelerates the healing of tibial stress fracture and whether there are gender effects. Only posteromedial mid to distal third and proximal medial tibial condylar stress fractures were investigated. Four imaging examinations were performed at diagnosis (radiographs, bone scan, MRI and CT). All subjects were treated identically in a double blind fashion using active or passive electric field stimulator devices (active units apply a sinusoidal wave of 3-6 V, 60 KHz, 5-10 mA), worn 15-20 hours per day, and other standardized rehabilitation treatments, until healed but not longer than 6 months. Subjects were considered healed when hopping on the affected limb was longer painful. A second MRI examination was performed for follow-up comparison. A grading system is being developed for each of the diagnostic methods and the ability of the MRI grading system is being assessed to predict time to recovery.					
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INTRODUCTION

This double blind placebo-controlled study was designed to determine if electric field stimulation can accelerate the healing of tibial stress fractures. Additionally a stress fracture severity grading system is to be developed for four different diagnostic imaging techniques (plain films, nuclear medicine scans, MRI and CT). The purpose of the imaging study is to determine the most cost effective approach for tibial stress fracture diagnosis and the most effective technique to predict time to healing. A convenience sample of men and women was recruited in order to discriminate gender effects. All subjects were treated identically with an active or inactive electric field stimulator device (active devices apply a sinusoidal wave of 3-6 V, 60 KHz, 5-10 mA.) Subjects wore the units for 15-20 hrs/day until healed, with a maximum allowable treatment time of 6 months. Subjects were considered healed when 30 seconds of hopping on the affected limb was non-painful.

BODY

Since the previous annual report of November 2004, a final 3 subjects were recruited to complete the treatment sample. Activities that remained to be completed included:

1. Complete analysis of radiological data
2. Complete analysis of subject characteristic data
3. Prepare final report
4. Present data at ACSM
5. Submit papers to journals

Update

In 2005 the final data sets were collected and data analysis initiated. Investigator Beck traveled to the US to confer with coinvestigators to ensure full consultation during the process of treatment data analysis and to perform the first grading of imaging with the US-based study radiologist (Bergman). In November 2005, an abstract was submitted to the American College of Sports Medicine in order to present primary study objective findings (treatment effects) at the annual scientific meeting in Denver, June 2006. On December 7, 2005 a no-cost extension was granted until December 15, 2006 in order to facilitate this and other reporting activities (i.e. secondary study objectives - radiological findings and subject characteristics).

KEY RESEARCH ACCOMPLISHMENTS

- To achieve adequate statistical power for analysis of treatment and gender effects, the study goal was to collect a minimum of 40 subjects (20 men and 20 women). Ultimately, data collection was initiated on a total of 50 subjects (21 male, 29 female) of which 44 were completed satisfactorily (see table below). The final data set to evaluate treatment effects includes 20 men and 24 women. Of subjects in the final data set, nine men and fourteen women had been allocated active devices. Thus eleven men and ten women were allocated placebo devices.
- The single male to be excluded from the data set was considered, on reflection, to suffer a tibial stress fracture sufficiently atypical as to not conform to study inclusion criteria. Of the five women to be excluded from the data set, one subject dropped out due to lack of motivation, one was dropped from the study for failure to use the device, one individual (treated as two subjects as she had bilateral symptoms) was dropped from the study after re-diagnosis with complex regional pain syndrome Type I, and one subject was excluded from the data set when follow-up MRI confirmed a large coexisting haemangioma which may have confounded perception of stress fracture symptoms.

SUBJECT #	SEX	AGE	PRIMARY SPORT	TREATMENT TIME (days)	RECRUITING UNIVERSITY
1	Female	32	Running	18	Stanford University
Excluded	Male	35	Running	19	Stanford University
2	Female	46	Running	23	Stanford University
3	Female	16	Running	25	Stanford University
4	Male	30	Running	14	Stanford University
5	Male	22	Running	14	Stanford University
6	Male	18	Running	21	Stanford University
7	Female	33	Running	18	Stanford University
8	Male	19	Running	6	Stanford University
Excluded	Female	35	Running	Dropped out	Stanford University
9	Female	20	Running	17	Stanford University
10	Male	28	Triathlon	24	Stanford University
11	Female	21	Running	38	Stanford University
12	Male	45	Running	30	Stanford University
13	Male	22	Ultimate Frisbee	22	Stanford University
14	Male	23	Running	23	Griffith University
15	Female	21	Aerobics	2	Griffith University
16	Female	18	Sprinting	25	Griffith University
17	Female	21	Sprinting	18	Griffith University
18	Female	34	Running	37	Griffith University
19	Female	18	Running	12	Griffith University
Excluded	Female	22	Running	Released from study after failure to follow protocol.	Griffith University
20	Male	37	Running	7	Griffith University
21	Male	37	Running	6	Griffith University

22	Male	33	Triathlon	17	Griffith University
23	Male	25	Running	8	Griffith University
24	Male	25	Running	8	Griffith University
25	Female	34	Triathlon	17	Griffith University
26	Female	23	Step aerobics	19	Griffith University
27	Female	32	Running	17	Griffith University
28	Male	21	Boxing/running	15	Griffith University
29	Male	21	Boxing/running	16	Griffith University
30	Male	42	Running	9	Griffith University
31	Male	24	Sprinting	6	Griffith University
Excluded	Female	24	Netball	Stress fractures 29 and 30 were bilateral injuries in the same individual. She was recruited following diagnosis by an orthopaedic surgeon. She was released from the study after 30 days of intervention and rest from pain-provoking activities as a total lack of change in symptoms was not consistent with the progression of normal stress fracture resolution. She was referred for further evaluation to a sports medicine physician who diagnosed a complex regional pain syndrome Type I.	Griffith University
Excluded	Female	24	Netball		Griffith University
32	Female	31	Aerobics	22	Griffith University
33	Female	31	Aerobics	44	Griffith University
34	Male	23	Australian Rules	3	Griffith University
35	Male	23	Australian Rules	14	Griffith University
36	Female	23	Running	8	Griffith University
37	Female	23	Running	8	Griffith University
38	Male	24	Australian Rules/running	11	Griffith University
Excluded	Female	32	Netball/weights	60	Griffith University
39	Female	29	Running	21	Griffith University
40	Female	21	Running	11	Griffith University
41	Female	21	Running	11	Griffith University

42	Female	22	Sprinting	13	Griffith University
43	Female	22	Sprinting	13	Griffith University
44	Female	36	Running/ boxing	26	Griffith University

An abstract describing the primary treatment outcomes has been submitted to ACSM for the 2006 annual meeting. A paper describing treatment outcomes in full detail has been written and is currently circulating among the authors. It is planned to submit the paper to the *Journal of Bone and Mineral Research* following presentation of the data at ACSM.

Grading of individual radiology datasets has been completed. Full statistical analysis will be completed in 2006.

REPORTABLE OUTCOMES

The following abstract has been submitted for presentation at the American College of Sports Medicine annual scientific meeting in June 2006.

Tibial stress fractures are an insidious overuse injury with limited effective management options aside from rest.

PURPOSE: To examine the effect of capacitively coupled electric field stimulation on rate of tibial stress fracture healing in men and women.

METHODS: A double-blind, randomised controlled trial was designed. A convenience sample of 20 men and 24 women with posteromedial tibial stress fractures was recruited and randomly assigned an active or placebo electric field stimulator (sinusoidal wave, 3-6 V, 60 kHz, 5-10 mA), to be used for 15 hours per day until healed. Subjects were given supplemental calcium and instructed to refrain from weight bearing activities aside from those of normal daily living.

Contact was made every second day to monitor symptoms of pain severity during the intervention. Healing was confirmed when painfree hopping 10 cm off the ground for 30 seconds on the affected limb could be achieved. Data was analysed for intention to treat via 2-way ANOVA for effects of treatment and sex on healing time. The influence of anthropometric and behavioural characteristics on time to healing was evaluated by multiple regression analysis.

RESULTS: There were no differences in time to healing between active and placebo groups, but women healed more slowly than men ($p = 0.05$). Closer examination of the data suggests, however, that hours of device use per day and weight bearing loading during treatment may have positively ($p = 0.003$) and negatively ($p = 0.05$) influenced effectiveness of the active device, respectively.

CONCLUSIONS

Capacitively coupled electric fields did not accelerate tibial stress fracture healing of the group as a whole in comparison with placebo treatment (rest), but women took longer to recover from tibial stress fractures than men. Superior treatment compliance was positively associated with reduced time to healing.

REFERENCES

NA

APPENDICES

NA