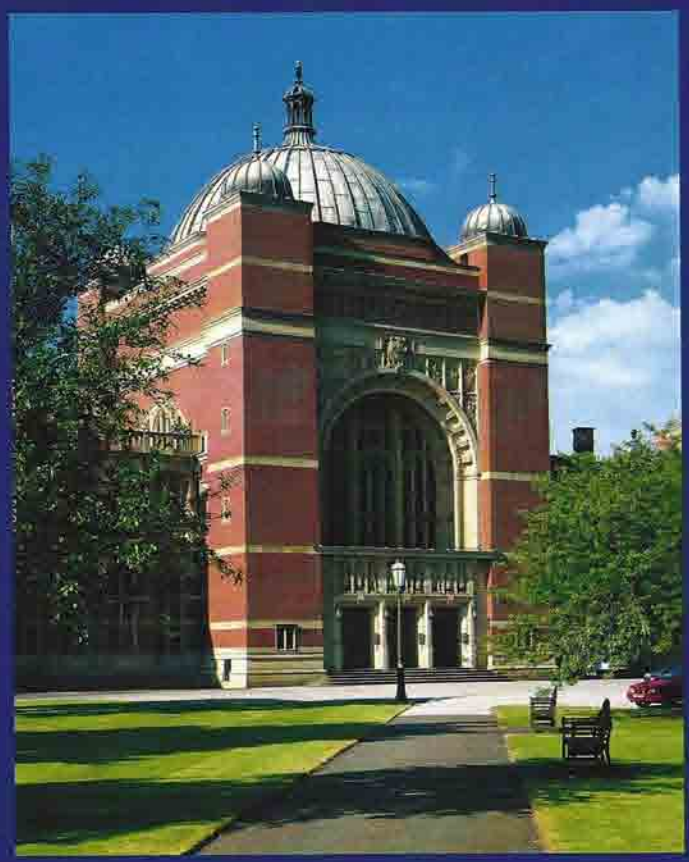
THIRTEENTH ANNUAL EUROPEAN PRESSURE ULCER ADVISORY PANEL MEETING

Theme:
The Flourishing of Science to support Prevention and Healing



University of Birmingham, England
1st to 3rd September 2010

epuap

Thursday September 2nd

Randomized controlled clinical study on the application of the treatment FREMS™ in the management of chronic ulcer of lower limb

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Introduction

In the past years electrical stimulation (ES) has been investigated as a coadjuvant in the treatment of chronic wounds. It is known that different kinds of ES technology leads to different results. It has been demonstrated that FREMS™ (Frequency Rhythmic Electrical Modulation System, Lorenz Biotech – Medolla Italy), an innovative and patented ES, enhances microvascular blood flow [1], promotes the release of some growth factors as VEGF [2] and reduce pain in painful leg ulcers [3]. We investigated the effectiveness of FREMS™ on chronic wounds of various etiology in terms of VAS scale to asses pain and Push Tool 3.0 [4] to assess ulcer healing.

Methods

60 patients with chronic limb ulcers were enrolled for the study. Patients were randomized in two groups (FREMS™ vs CONTROL, 30pt+30pt) in which FREMS™ group received conventional treatment plus FREMS™ while CONTROL group received only conventional treatment. FREMS™ treatment consisted of a cycle of 12 sessions performed in 4 weeks (3 sessions per week). All patients were treated until wounds healed for a maximum of 9 cycles of FREMS™, respecting 2 suspension weeks between each cycle. The FREMS™ treatment was performed at the wound healing clinic by the nursing staff.
Parameters were evaluated at different time; T0 enrollment, T1 end of first session, T6 end of the sixth session and T12 end of the twelfth and last session for each cycle performed.

Results

During follow-up some patients terminated the protocol because they reached the ulcer closure before the maximum planned of 9 cycles. The analysis of the effect of FREMS™ on pain (Table 1) and ulcer healing (Table 2) has been accomplished on patients who underwent at least two consecutive clinical evaluations (2 cycles) in order to reach a compatible sample size with the primary objective (it has been excluded 1 drop out). As regards the determination of the effectiveness of treatment in terms of complete ulcer healing, all subjects were considered in the analysis (Fig. 1).

Table 1: *VAS* (avg. ± SD), *in the first two FREMS cycles*

	T0	end cycle 1	end cycle 2
FREMS group (n=29)	3.3 ± 2.3	1.4 ± 1.5	0,4 ± 1.1
CONTROL group (n=30)	3.6 ± 2.9	3.3 ± 2.7	3.4 ± 3.1
p value	n.s.	0.002	< 0.0001

Table 2: *PUSH TOOL in the first two FREMS cycles*

	T0	end cycle 1	end cycle 2
FREMS group (n=29)	9.2 ± 2.9	7.1 ± 4.1	5.5 ± 3.8
CONTROL group (n=30)	11.1 ± 5.0	9.8 ± 5.4	9.0 ± 5.8
p value	n.s.	0.032	< 0.027

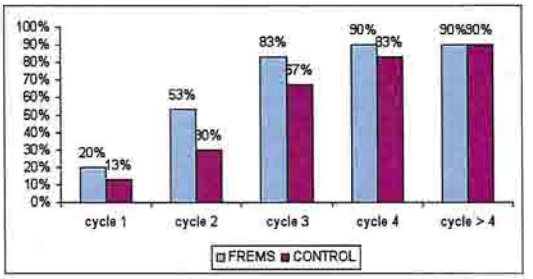

Fig. 1: Patient healing rate during follow up

Discussion

Data collected in this study confirm data in literature [3] with a wider population set. Single parameters making up PUSH TOOL didn't show major effects if analyzed separately. In order to possibly isolate additional factors influencing results, parameters like etiology of ulcers, (i.e. vascular, mixed, traumatic, burn) duration of ulcer and infection status have been investigated. . Statistical complex mixed effects models, applied to take into account all parameters, provided similar results.

Clinical relevance

Analysis of longitudinal data analyzed by simple models and complex models indicate that FREMS has a positive and significant effect on pain reduction (VAS) and on the improvement of ulcer healing process (PUSH TOOL total index) compared to conventional medical therapy. Also a significant acceleration of the healing process has been observed.

Acknowledgements / Conflict of interest

References

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[3] Jankovic et al. Arch. Dermatological Investigation. 300:377-383, 2008
[4] National Pressure Ulcer Advisory Panel. Push Tool Version 3.0 : 9/15/1998.