# Brief Report

Evidence Based Healthcare Advisory Group

## *Fenzian treatment*

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| **Reviewer** | **Amanda Bowens** |
| **Date report completed** | **December 2007** |

***Please note: this brief report summarises information on Fenzian treatment. It has not been systematically developed according to a predefined methodology. It is not intended to replace clinical judgement or to be used as a clinical protocol.***

## Background

ACC has reviewed the evidence for the effectiveness of Fenzian treatment, a non-invasive therapy delivered by a hand-held electrical impulse device. The device was launched by a UK company named Eumedic Ltd[a] around the year 2000. Eumedic Ltd markets the device to qualified health practitioners such as doctors, physiotherapists and osteopaths. The company has developed an accompanying training programme, which practitioners are required to undertake before they offer Fenzian treatment as part of their practice.

According to the manufacturers, Fenzian treatment works by detecting changes in skin impedance using biofeedback, then stimulating the underlying neurological network to relieve symptoms and promote healing. The Fenzian device resembles a transcutaneous electrical nerve stimulation (TENS) machine. However, Fenzian treatment uses alternating current with a short wavelength rather than the direct current used in TENS. Each Fenzian treatment session lasts about 30 -60 minutes. The manufacturers advocate the use of Fenzian treatment for a wide range of complaints including musculoskeletal and respiratory disorders.

Fenzian treatment was granted US Food and Drug Administration (FDA) approval in 2004 as a TENS-type device for "***symptomatic relief and management of chronic, intractable pain***" and "***adjunctive treatment for post-surgical and post-trauma acute pain***"[b]. It appears to be fairly widely used in the US by sports physiotherapists and chiropractors. Eumedic Ltd is now attempting to build a network of practitioners in the UK.

[a] The main UK and US websites for Fenzian are available via http://www.fenzian.co.uk/
[b] See http://www.fda.gov/cdrh/510k/sumjul04.html

## Methods

A range of medical, nursing, allied health and evidence based medicine databases was comprehensively searched on 11 November 2007 to identify published research on Fenzian treatment. The manufacturer's website and related sites[c] were also checked on or around the same date for details of unpublished and/or ongoing studies.

## Results

The literature search identified one published paper[1] and the websites outlined four trials in progress. As well as formal research, the manufacturer's websites feature several practitioner and patient testimonials. Details of the published and ongoing research studies are summarised below.

***Table I. Fenzian treatment: published research***

| **Colthurst J, Giddings P (2007). A retrospective case note review of the Fenzian electrostimulation system: A novel non-invasive, non-pharmacological treatment[1]** | | |
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| **Methodology** | **Outcomes** | **Comments** |
| Retrospective case note review of 591 consecutive patients who received Fenzian treatment at a private clinic in the UK (58% female, median age 41 years, age range 0.25 – 86 years)<br><br>Patients presented with a wide range of (predominantly chronic) complaints; most common were back pain, eczema, sinusitis, knee pain and neck pain<br><br>Main diagnostic categories were *musculoskeletal* (32%), *other* (20%), *dermatology* (12%), *gastroenterology* (10%), *central nervous system* (10%), *ear-nose-throat* (8%), *respiratory* (8%)<br><br>Data was collected on number of treatments, demographics, and nature & duration of complaint<br><br>Treatment outcome was rated on a seven point Likert scale (*cured, much better, better, no change, worse, much worse, died*) | Most patients (78%) received up to five treatments (range = 1-56)<br><br>Outcomes were known for only 464 (79%) of the patients<br><br>Of those, over 70% were rated *cured, much better* or *better*, irrespective of duration of complaint, diagnosis or age<br><br>Outcomes were significantly better in patients whose presenting complaint was of < 6 months' duration<br><br>Patients with respiratory complaints were significantly more likely to be rated *cured*<br><br>Children did significantly better than elderly patients<br><br>No adverse effects were documented and the procedure was reported to be painless | Lack of baseline information on patient characteristics, e.g. severity of disorders, co-morbidities<br><br>Limited information on presenting complaints<br><br>Treatment outcomes not clearly defined<br><br>Losses to follow-up >20% (21%)<br><br>The study was sponsored by Eumedic Ltd and the study authors were both involved with the company; however, independent assessors were used to collect and analyse the data |

[c] For example, websites of university departments carrying out research on Fenzian treatment.

***Table II. Fenzian treatment: ongoing research*** [d]

| Focus | Setting | Study details |
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| Coronary care | Hammersmith Hospital, London, UK | According to the Fenzian website, trials on the use of Fenzian treatment in the post operative care of coronary patients have recently started. |
| Respiratory illness | University College of Los Angeles (UCLA), US | A randomised placebo-controlled trial of Fenzian treatment versus inhalers containing the drug Albuterol in the treatment of asthma is underway. Adults with mild to moderate persistent asthma have been recruited to the 10 week study. Findings are due in 2007. Lead researcher: Dr Christopher Cooper, Adjunct Professor, Pulmonary and Critical Care Medicine. |
| Sports injuries | Central College, Pella, Iowa, US | Fenzian treatment is being used by five collegiate athletic trainers conducting a clinical trial of the treatment of chronic and acute athletic injuries. Analysis is currently underway on data from the first year of the study. The study will continue through the 2006-07 academic year. Lead researcher: Dave Pavlat, Chair, Exercise Science Department. |
| Sports injuries | Duke University, North Carolina, US | Four physical therapists are using the Fenzian treatment system in an ongoing clinical trial. Lead researcher: Bob Bruzga. |

## Discussion

Formal published research on Fenzian treatment is limited to the retrospective case note review[1] described in Table I above. A number of trials appear to be underway, two of which might be of interest to ACC as they focus on sports injuries. However, the Fenzian website gives only brief details of the trials in progress and no results are available yet.

The findings of the case note review are described as "highly encouraging", but they do not in themselves constitute strong evidence for the effectiveness of Fenzian treatment; the treatment outcomes were not clearly defined, there was insufficient information about the patients and their complaints to make judgements about generalisability, and the authors were both involved with Eumedic Ltd.

As the authors themselves point out, the review findings need to be backed up by well-designed, prospective, randomised trials with appropriate control treatments. Prospective trials do appear to be underway but little information is available on their design.

## Conclusions

There is currently a lack of evidence with which to assess the effectiveness of Fenzian treatment. ACC should await the findings of the ongoing trials, particularly those involving sports injuries, and carefully assess the methodologies used.

[d] Details of the four ongoing research studies were taken primarily from the Fenzian website; however, no trials involving Fenzian treatment were found on the Current Controlled Trials (www.controlled-trials.com/) or ClinicalTrials.gov (http://clinicaltrials.gov/) databases (checked 4 December 2007). The trials outlined here appear to be wholly or partly funded by Eumedic Ltd.

## References

1. Colthurst J, Giddings P. A retrospective case note review of the Fenzian electrostimulation system: A novel non-invasive, non-pharmacological treatment. ***Pain Clinic*** 2007;19(1):7-14.