A retrospective case note review of the Fenzian electrostimulation system: a novel non-invasive, non-pharmacological treatment

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Background: A non-invasive, non-pharmacological device has been developed (the Fenzian system) to explore, electronically, the effects of using skin expression of underlying neurological activity to communicate repair signals to the neurological network. We have explored the efficacy of Fenzian electrostimulation over a range of patient conditions to help select further groups for future studies.
Methods: This was a retrospective review of the medical notes of 600 consecutive patients who were treated with the Fenzian system in clinical practice.
Results: Of the 600 case notes reviewed, data from 591 patients were included in the analysis. Of these, 58% were female and the mean age was 41.4 years (range, 0.25–86 years). Most patients (77.8%) received up to five treatments. Median outcome overall was 'much better' and outcomes were significantly better than 'no change' both overall and in all subcategories defined by duration of complaint, diagnostic category, age, and sex ($P \leq 0.0001$). Patients whose duration of presenting complaint was up to 6 months had significantly better outcomes than patients with longer duration of complaint ($P < 0.0001$). Patients with respiratory complaints were more likely to be cured than patients in other diagnostic categories ($P = 0.02$). There was a highly significant relationship between age and outcome ($P < 0.0001$) with children doing significantly better than elderly patients. More than 70% of patients were 'cured', 'much better', or 'better' irrespective of duration of complaint, diagnostic category or age.
Conclusions: These preliminary results are highly encouraging and prospective controlled trials of this system are warranted.

Keywords: Fenzian, retrospective study, electrostimulation, non-invasive, acupuncture

Introduction

Acupuncture using needles was forbidden for a while in Soviet Russia, possibly because of concerns over sterility of the needles. Practitioners of acupuncture, therefore, explored alternatives that did not involve puncturing the skin, such as acupressure. Research by the Soviet aerospace and military scientists found that rapid changes in skin electrical properties occurred

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during acupressure, and that the sites of valuable response often correlated with known acupuncture sites. Regrettably, because of the secretive culture of the Soviet military, none of this research was published.

The Fenzian system was developed to build on principles from which modalities such as acupuncture arise, by stimulating the neurological network. The Fenzian system is a non-invasive therapy that detects changes in skin impedance and applies biofeedback using biphasic signals of 10–50 μs duration. Each subsequent signal amplitude depends on the skin electrical properties, as these alter through changes arising within the neurological network. Case report information suggests that this treatment system provides symptomatic relief and management of acute as well as chronic intractable illness and may also be useful as an adjunctive treatment in the management of post-surgical and post-traumatic situations. We have challenged its efficacy in our clinic by using it for a surprisingly wide range of complaints.

The Fenzian treatment system has been in use in England since 2000 and we believe that this novel, non-pharmacological, non-invasive treatment is worthy of further study. The objective of this study was, therefore, to explore the efficacy of Fenzian electrostimulation over a wide range of patient conditions to help select further groups for future studies.

Methods

Overall study design

This was a retrospective review of the medical notes of 600 consecutive patients who were treated with the Fenzian system in normal clinical practice. No ethical review was required as the study was an audit of routine practice and patients were not subject to any research-related procedures.

Patients

Patients were primarily self-referred, based on word of mouth, to an independent GP facility in Berkshire. Patients were of any age, of either sex, and could be seeking treatment for any medical condition, although there was an inevitable skew towards chronically ill patients seeking hope from something new after other options had been explored.

Treatments

Treatment with the Fenzian system was given according to standardised protocols that were dependent upon the physiological system or body part affected. The Fenzian system is a hand-held device that 'interrogates' the skin using nerve-like impulses and seeks areas of marked focal impedance change. Therefore, treatment was usually, but not always, applied primarily to the body site where the presenting complaint was most prominent.

Most treatments were of about 20-min duration and were repeated when necessary.

Outcome measures

A standardised data collection form was created to ensure consistency of the information gathered. Data were collected from the patients' case notes and were entered onto the data collection forms by two independent doctors. Missing information was obtained by telephone enquiry, when possible. The completed data sheets were sent to an independent statistician for analysis.

Data were captured on demographics, nature and duration of the presenting complaint, number of treatments, and outcome on a 7-point Likert scale (cured, much better, better, no change, worse, much worse, died).

Statistical methods

Outcomes were tested against the null hypothesis of 'no change' using the Wilcoxon signed rank test. Outcome was tested overall and for subgroups by: (i) duration of the presenting complaint (0–6 months, 6–24 months, 2–8 years, and 8 years and over); (ii) diagnostic category of the presenting complaint (CNS, musculoskeletal, ENT, respiratory, gastro-enterology, dermatology, other); (iii) age (0–17 years, 18–44 years, 45–59 years, and 60 years and over); and (iv) sex.

Ordinal logistic regression models were used to test whether outcome differed according to the duration of the complaint, diagnostic category, or age. Multivariate ordinal logistic regression models were used to investigate outcome as a function of diagnostic category and age, adjusting for duration of complaint.

The significance of the overall categories in the multivariate ordinal logistic regression models was tested with the likelihood ratio test.

Statistical analysis was done using Stata v.9.2 (StataCorp, College Station, TX, USA).

Role of the funding source

Both authors are directors of Eumedic Ltd, which provided funding for the study. They take full responsibility for the study design, collection, analysis, and interpretation of data, and for the decision to submit the paper for publication.

Results

Baseline characteristics

In total, 600 sets of case notes were reviewed. Of these, 8 patients were found not to have received Fenzian treatment and were excluded from the analysis and 1 patient, who received 200 treatments (palliative relief), was considered an outlier and was also excluded. Therefore, 591 patients were included in the analysis.

Demographic characteristics, diagnostic categories of the presenting complaint, and duration of the presenting complaint are shown in Table 1. Slightly more females than males were treated. Age was grouped into categories approximately representing children, adults, middle-aged, and elderly; there were slightly more patients in the young and middle-age categories than in the child and elderly categories.

Patients had a wide range of presenting complaints, of which the most common were (with numbers of patients): back pain (40), eczema (24), sinusitis (16), knee pain (16), neck pain (16), headaches (15), IBS (15), asthma (12), and abdominal pain (10). All other complaints were reported by fewer than 10 patients each. The duration of the presenting complaints varied widely, with three-quarters of the patients having had the complaint for up to 8 years.

Table 1. Baseline characteristics of the patients

Sex	Male	249 (42.1%)
	Female	342 (57.9%)
Age (years)		
	0–17	124 (20.7%)
	18–44	176 (29.3%)
	45–59	177 (29.5%)
	60 and over	123 (20.5%)
Mean (range) age (years)		41.4 (0.25–86)
Diagnostic category of presenting complaint		
	CNS	57 (9.6%)
	Musculoskeletal	188 (3 1.8%)
	ENT	49 (8.3%)
	Respiratory	49 (8.3%)
	Gastro-enterology	58 (9.81)
	Dermatology	69 (11.7%)
	Other	121 (20.5%)
Duration of presenting complaint		
	0–6 months	143 (25.9%)
	6–24 months	130 (23.5%)
	2–8 years	134 (24.2%)
	8 years and over	146 (26.4%)
Mean (range) duration of presenting complaint (years)		7.25 (0–76)

Treatments received

After exclusion of the outlier who received 200 Fenzian treatments, patients received 1–56 treatments (mean, 4.6 treatments); the distribution of the number of treatments is shown in Table 2. Most patients (77.8%) received up to 5 treatments.

Overall outcomes

Outcomes are presented in Table 3 for the 464 patients for whom outcome was known. For all patients combined, the median outcome was 'much better', and outcome was highly statistically significantly better than 'no change' ($P < 0.0001$, Wilcoxon signed rank test). Outcomes were also statistically significantly better than 'no change' when analysed by the subgroup sex ($P \leq 0.0001$).

Table 2. Number of Fenzian treatments received

Number of treatments	*n*	%
1	192	32.5%
2	120	20.3%
3–5	148	25.0%
6–10	77	13.0%
11–20	36	6.1%
20 and over	18	3.1%
Total	591	100.0%

Table 3. Overall outcomes

Outcome	n	%
Cured	89	19.2%
Much better	177	38.2%
Better	121	26.1%
No change	67	14.4%
Worse	1	0.2%
Much worse	0	0.0%
Died	9	1.9%
Total	464	100.0%

Outcome by duration of complaint

Patients whose duration of complaint was 0–6 months did better than patients with a longer duration of complaint (Fig. 1). Ordinal logistic regression showed that patients with up to 6 months' duration of complaint were significantly more likely to have better outcomes than patients presenting with complaints of longer duration, with little difference among the three longer duration categories (Table 4). However, more than 75% of the patients in the longer than 6 months' duration categories were 'cured', 'much better', or 'better'. Outcomes were statistically significantly better than 'no change' in all of the subgroups defined by duration of complaint ($P \leq 0.0001$).

Outcome by diagnostic category

Patients with respiratory complaints were more likely to be cured than patients in the other diagnostic categories (Fig. 2). Analysis by diagnostic category showed an overall effect of borderline significance, with significantly better outcomes in the 'respiratory' category than the reference category 'other' (Table 4). However, after adjusting for duration of complaint, the significance of the diagnostic category disappeared.

Overall, more than 80% of the patients in each diagnostic category were 'cured', 'much better', or 'better' (except the CNS category, with 79% in those categories) and overall outcomes were statistically significantly better than 'no change' in all diagnostic categories ($P \leq 0.0001$).

Outcome by age

There was a highly significant relationship between age and outcome, which persisted after adjustment for duration of complaint, with children doing significantly better than elderly patients (Fig. 3, Table 4). However, there were still more than 70% of patients in the age category 60 years and older who were 'cured',

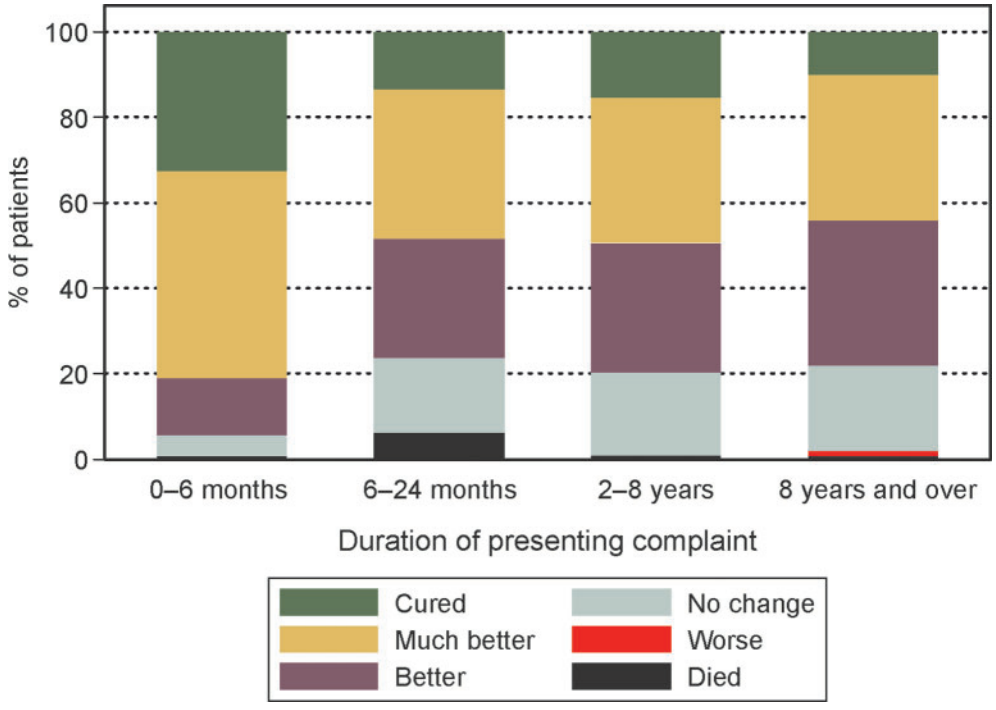

Figure 1. Outcome by duration of complaint.

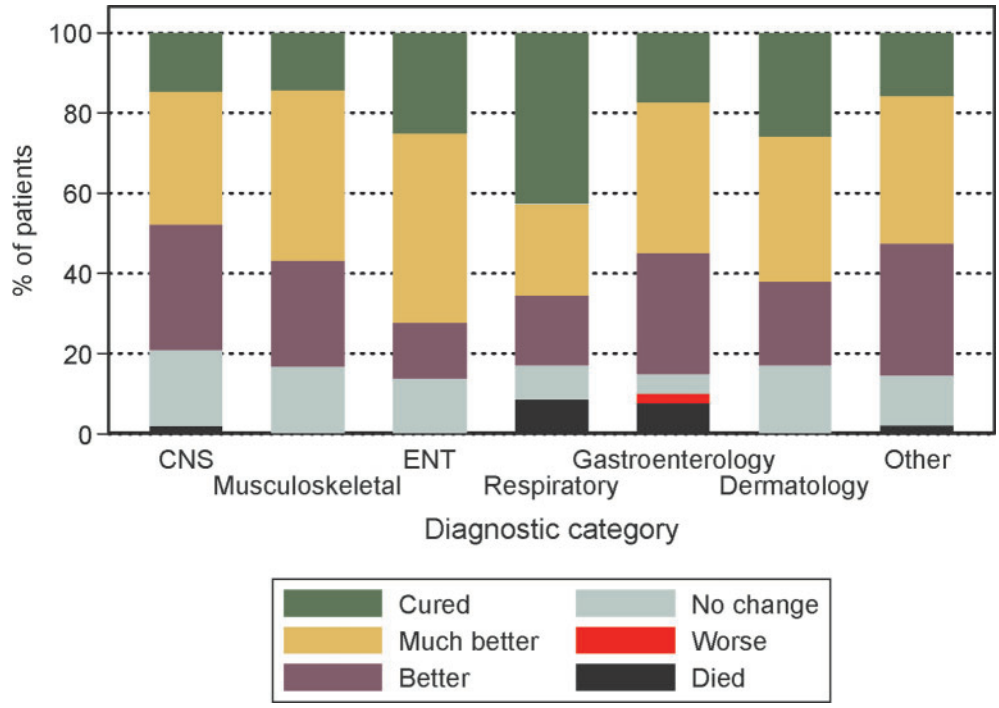

Figure 2. Outcome by diagnostic category.

'much better', or 'better'. Outcomes in all age groups were statistically significantly better than 'no change' ($P \leq 0.0001$). One patient whose condition worsened was in the 18–44 age category. This was a patient with a long history of abdominal pain, although diagnostic tests revealed no abnormality, and was also an habitual diuretic abuser for weight loss.

Safety of the treatments

No adverse effects were clinically obvious or documented in the patients' notes, and the procedure is painless. Nine of the patients whose notes were reviewed for this retrospective study died. All of the patients who died had advanced malignant disease before the start of treatment.

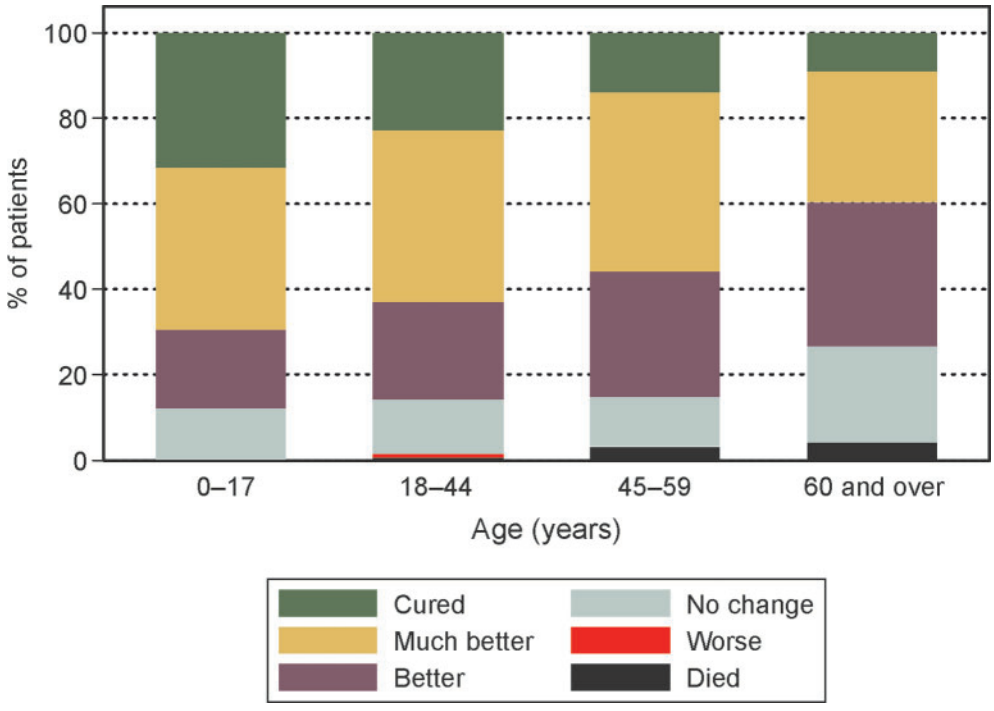

Figure 3. Outcome by age.

Table 4. Odds ratios from ordinal logistic regression of predictors of outcome

	Univariate analysis			Multivariate analysis		
Category	OR	95% CI	*P*	OR	95% CI	*P*
Duration of presenting complaint			< 0.0001			
0–6 months	Reference category					
6–24 months	4.04	2.44–6.71	< 0.0001			
2–8 years	3.43	2.10–5.60	< 0.0001			
8 years and over	4.33	2.67–7.03	< 0.0001			
Diagnostic category of presenting complaint			0.08			0.59
Other	Reference category			Reference category		
CNS	1.23	0.65–2.32	0.53	1.10	0.56–2.16	0.77
Musculoskeletal	0.93	0.59–1.48	0.76	0.89	0.54–1.46	0.65
ENT	0.53	0.26–1.06	0.07	0.64	0.30–1.34	0.24
Respiratory	0.41	0.19–0.88	0.02	0.58	0.25–1.31	0.19
Gastro-enterology	0.94	0.48–1.86	0.87	0.93	0.45–1.93	0.85
Dermatology	0.67	0.36–1.22	0.19	0.66	0.35–1.24	0.20
Age (years)			< 0.0001			0.0005
0–17	Reference category			Reference category		
18–44	1.42	0.88–2.29	0.16	1.12	0.67–1.88	0.66
45–59	1.99	1.22–3.23	0.01	1.53	0.91–2.57	0.11
60 and over	3.61	2.14–6.10	< 0.001	2.84	1.62–4.98	< 0.001

Multivariate analysis adjusted for duration of presenting complaint. *P*-values for overall group effects are from likelihood ratio tests. Odds ratios greater than 1 correspond to worse outcomes.

Discussion

This was a retrospective, uncontrolled study and, as such, the conclusions that can be drawn from the findings are limited. However, the objective of this study was not to test a theory but to make a preliminary evaluation of our observations and to guide us towards areas of further study. The Fenzian electrostimulation system has been in use in our clinic for several years and the positive results that we have observed lead us to believe that this treatment system is worthy of closer examination. Examples of the effects of Fenzian treatments on 3 patients are given in Figures 4–6.

Patient outcomes were better in complaints that were of shorter duration. This finding could be anticipated because recent complaints are likely to be self-limiting. However, the majority of patients (by duration) were 'worst case' patients, and most had already been through the 'normal' treatment mill. Furthermore, it is noteworthy that highly statistically significant improvements were seen even in patients with complaints of more than 8 years' duration, and these findings are unlikely to

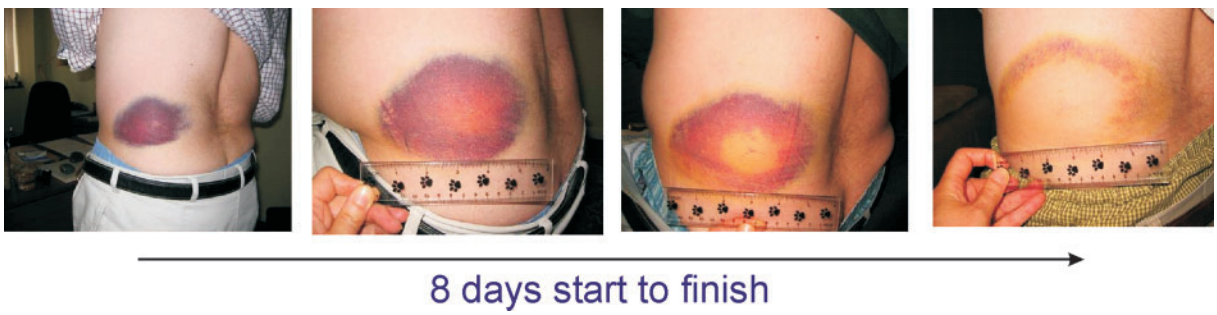

Figure 4 Fenzian treatment of painful bruise

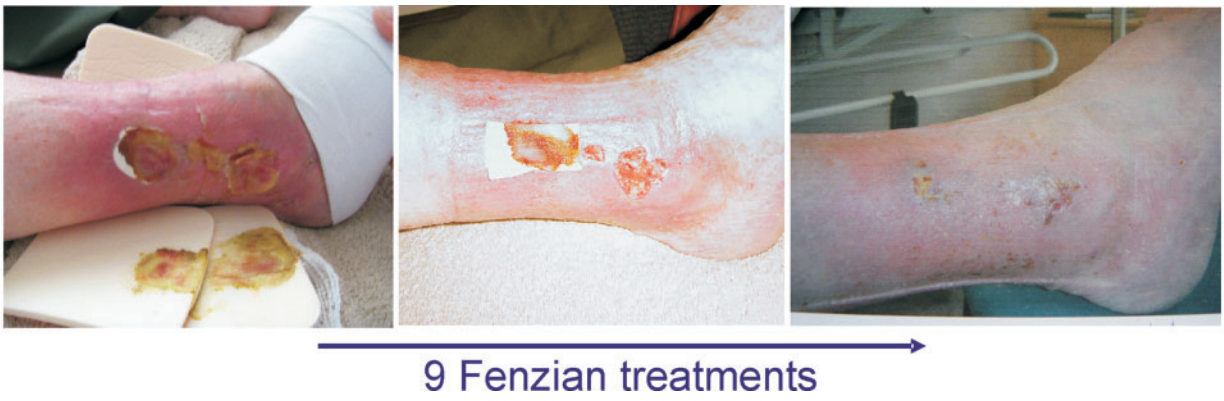

Figure 5 Fenzian treatment of leg ulcers

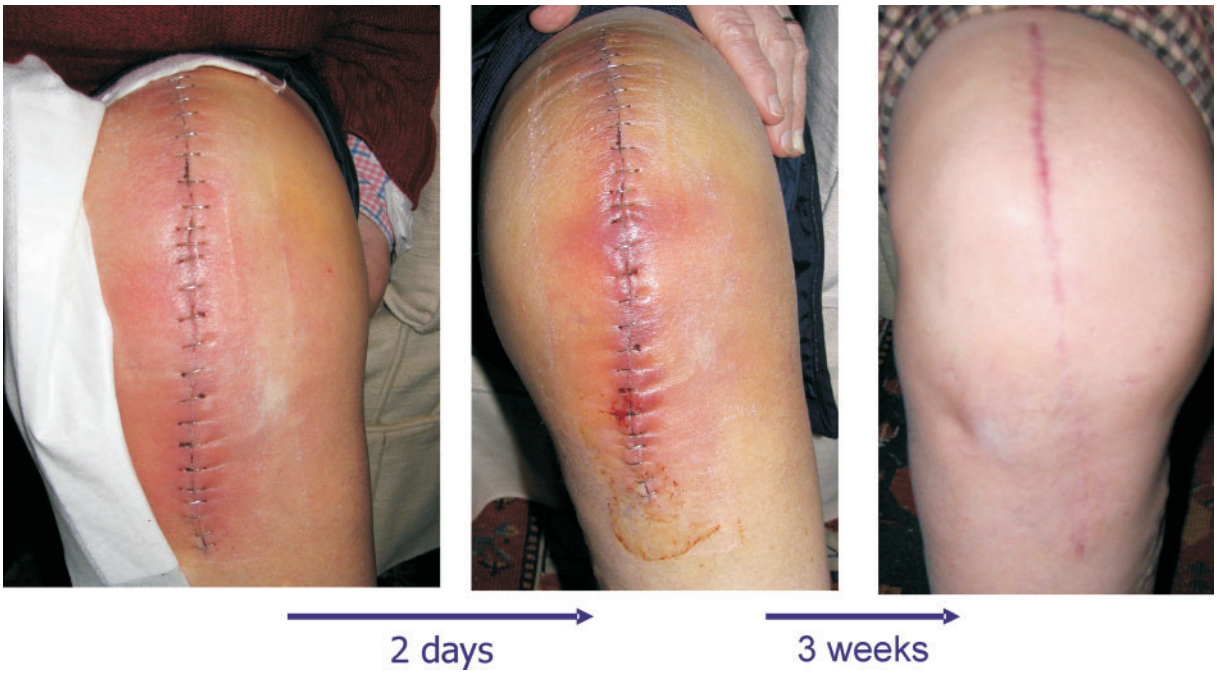

Figure 6 Fenzian treatment of patient after fall following knee replacement

result from spontaneous remission of the disease. It could also be argued that patients who have been through routine treatment pathways before presentation for Fenzian treatment have effectively acted as their own controls.

There was some evidence that outcomes were better for respiratory disorders than for other conditions, although there were no conclusive differences among different diagnostic categories. It was not our intention to compare categories as a primary task, only to select good targets for future trials. The range of specific conditions treated varied widely and most conditions were presented by only 1 or 2 patients. Therefore, grouping the conditions by diagnostic category was a rather crude approach that was adopted for this preliminary study but the findings were interesting. It is also noteworthy that the results in all of the diagnostic categories demonstrated that most of these patients, in whom previous treatments had been inadequate, had improvements with the Fenzian treatment.

There was clear evidence that results were better in children than in the elderly, even after adjusting for duration of the presenting complaint, although young patients usually have better outcomes than elderly patients in most treatments. There was a good balance of patients across the age groups, and similar numbers of records from children and elderly patients were included in the

analysis. Therefore, these two groups were well represented in the patient population overall. It is also valuable to note that the treatment is painless and, therefore, is of particular interest for the treatment of children.

It would have been interesting to examine time-to-outcome against the number of treatments. However, since this was a retrospective data collection study, this information was not documented at the time and, therefore, is not available for the present analysis. The practitioners believe that the outcome was reached more rapidly with more treatments but this will have to be examined in the future.

Conclusions

These highly encouraging preliminary results suggest that randomised controlled trials of the Fenzian system are warranted. Prospective studies have now begun.

Acknowledgements

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Conflict of interest statements

Dr James Colthurst, Mrs Pamela Giddings and Prof. Kim Jobst did not receive external funding during the patient treatments and subsequent data collection for this study. Subsequently, external funding became available to cover the cost of statistical analysis and external assistance with preparation of the manuscript. After the study had been completed, and following receipt of external investment, Dr Colthurst became Medical Director of Eumedic Ltd. The company's income was initially derived from private practice, though there is now some external financial support. Following completion of the study, Mrs Giddings was appointed to the board of Eumedic Ltd. Dr Antony Ashe and Dr Lisa Lofdahl were unfunded for their work. The contributions of Dr Carola Hillenbrandt, Dr Adam Jacobs and Dr Wendy Kingdom were funded at commercial rates by Eumedic Ltd.