

To Zimmer MedizinSysteme GmbH, Neu-Ulm

Progress report

Radial shockwave therapy has been successfully used for a number of years in various orthopaedic and surgical indications as well as for pain relief.

Shockwave therapy also made a big impression on my practice over many years and, until recently, we were operating a pneumatic system.

Then we had an opportunity to test an electromagnetic system, which initially appealed to us because of its small, light, compact design and associated mobility.

The fact that the majority of our patients gave a more positive feedback following treatment with the electromagnetic system compared to the pneumatically driven system convinced us to carry out a comparative study.

The enPuls Version 2.0 was compared with a similar pneumatic system in a study conducted in our practice.

A total of 55 patients were enrolled in the study. Twenty-six (26) patients were treated with the pneumatic system and 29 with the enPuls Version 2.0. The diagnoses were evenly spread out in both groups (bursitis, heel spurs, backache and epicondylitis). Between 2 and 10 treatments were administered with a 3-7 day interval between each session.

The results were clearly in favour of the enPuls Version 2.0 from both an operator and a patient perspective: 59 % of the users found the system to be "very good", 21% "good", 7% "satisfactory", 3% "average" and 7% "poor".

The patients' assessments were consistent with the good user evaluations.

The study findings were thus presented from two different angles: the evaluation was better for the enPuls Version 2.0 system than the pneumatic system. The results show a clear-cut trend in favour of the enPuls Version 2.0.

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Comparative Study

enPuls
Version 2.0



Study of Shockwave Therapy

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Summary

Radial shockwave therapy has been successfully used for many years in various orthopaedic and surgical indications as well as for pain relief. This report compares the use of two different shockwave products.

The one system is pneumatic and the other electromagnetic.

The systems have rising edges of varying steepness on impulse generation but the resulting energies are, however, comparable.

This shows a preference for electromagnetically driven radial shockwave therapy (*enPuls Version 2.0*, Zimmer MedizinSysteme).

Introduction

Radial shockwave therapy is a modern technique used to treat various disorders affecting the musculoskeletal system.

Extracorporeal radial shockwaves are high-energy sound waves that are generated pneumatically for example outside the body. They are transmitted over the surface of the human body, penetrating tissue near the site of pain from where they are radially (spherically) disseminated. The treatment is found to be particularly conservative because of this radial dissemination. After treatment, the tissue surrounding the affected area responds to the shockwave with increased metabolic activity, setting the endogenous repair mechanisms in motion.

Method

Shockwave treatment was administered using an electromagnetic shockwave therapy system, on the one hand, and a comparable pneumatic shockwave therapy system, on the other.

One applicator head measuring 14 mm in diameter was used for the pneumatic shockwave therapy system and two applicator heads measuring 22 mm (large) and 15 mm (small), respectively, were used to administer electromagnetic shockwave therapy.

The large applicator head was always selected with one exception.

To ensure total energy transmission, ultrasound gel (Sono Plus) was used as the coupling medium. A protective silicone cap was put on the applicator head to keep the handpiece clean.

Different frequencies could be selected: 10 Hz was used exclusively for the pneumatic shockwave therapy system. The electromagnetic shockwave system operated once at 5 Hz, twice at 16 Hz and the rest of the time at 10 Hz.

Energy was applied continuously via the pneumatic shockwave system with 2000 impulses and at 2.2 bar.

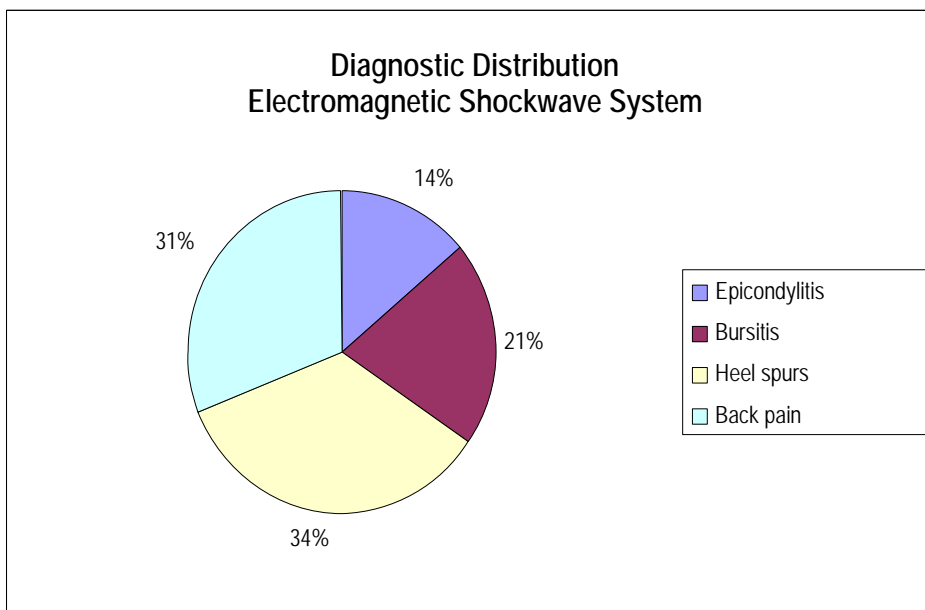
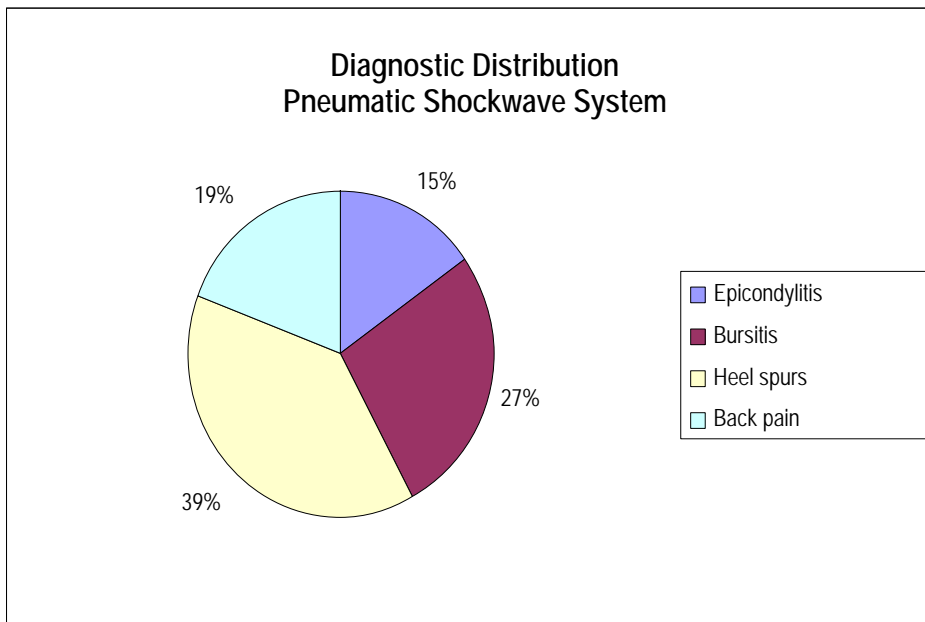
The electromagnetic shockwave therapy device mostly operated continuously with an 8-shock burst with 1500 to 2000 impulses and shock energy of 60 to 90 mJ in 9 cases.

Between 2 and 10 treatments were administered, with a 3-7 day interval between each session.

Results

A total of 55 patients were enrolled for treatment. Twenty-six (26) patients were treated with the pneumatic shockwave therapy system and 29 with the electromagnetically driven system.

The diagnoses were similarly distributed in both groups: 15% of patients in the pneumatic shockwave therapy group presented with epicondylitis, 27% bursitis, 39% heel spurs and 19% with back pain. 14% of patients in the electromagnetic shockwave therapy group presented with epicondylitis, 21% bursitis, 34% heel spurs and 31% with back pain.

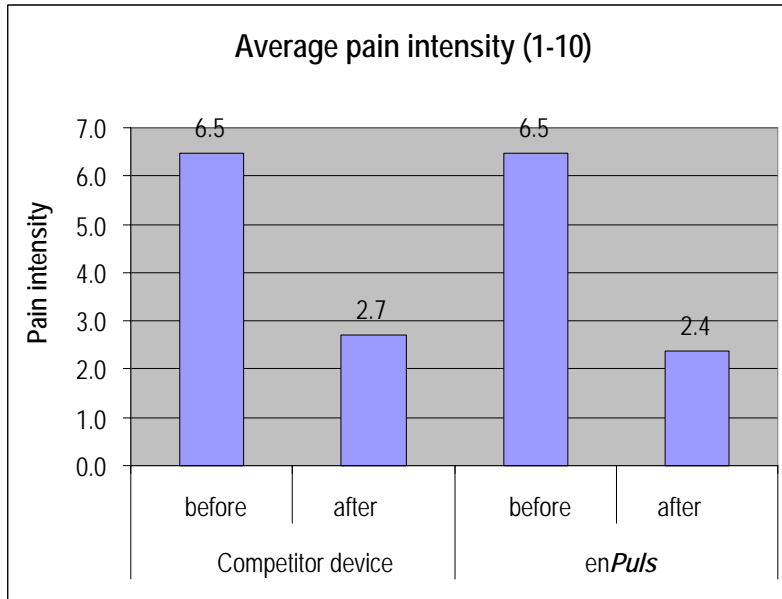


A visual analogue scale was used to assess pain. Patients were interviewed before and after the study phase. The scale ranges from 0 (= no pain) to 10 (= intolerable pain).

Comparability was good since an average baseline pain score of 6.5 was recorded in both groups.

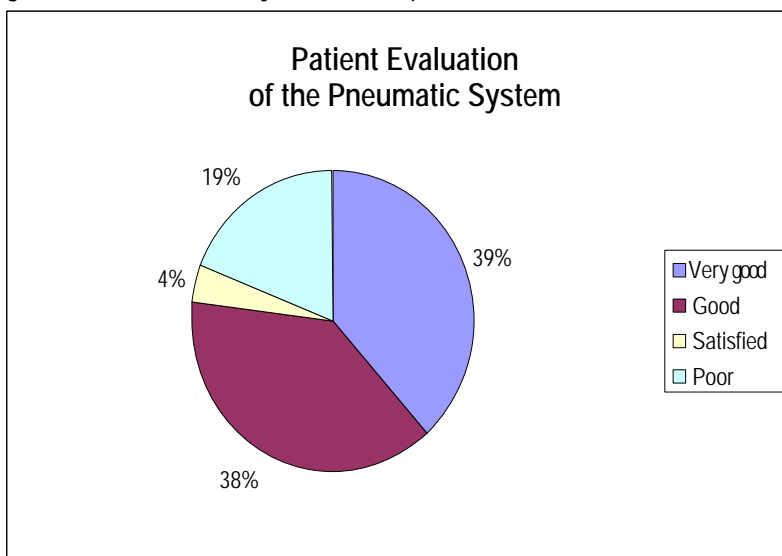
At the end of the study, an average pain intensity of 2.7 was recorded in the group treated with the pneumatic system compared to an average value of just 2.4 in the group treated with the electromagnetic system.

Pain relief was therefore greater in this group.

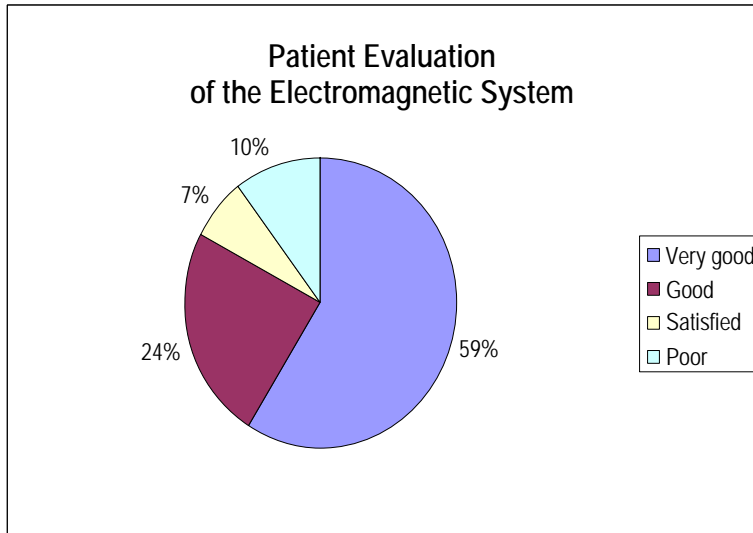


Patients and users were asked to assess the therapeutic outcome.

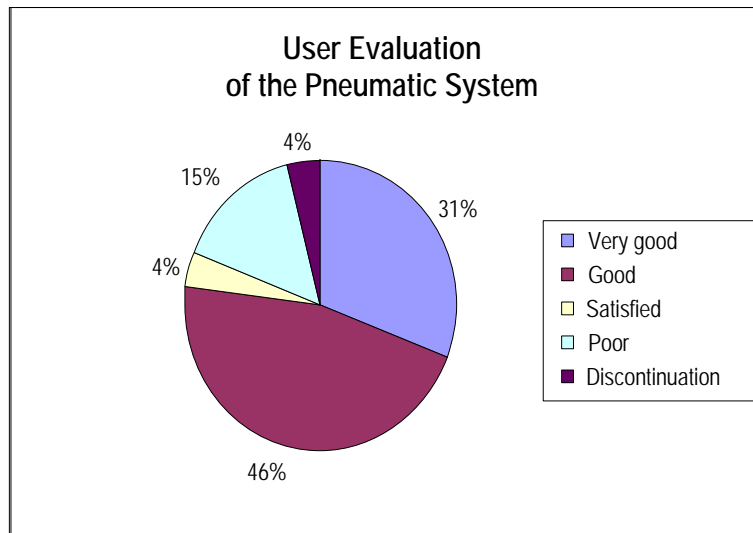
39% of the patients treated with pneumatic shockwave therapy found the system to be "very good", 38% "good", 4% "satisfied" and 19% "poor".



59% of the patients treated with electromagnetic shockwave therapy found the system to be "very good", 24% "good", 7% "satisfactory" and 10% "poor". Once again, there was greater satisfaction with the electromagnetic system.

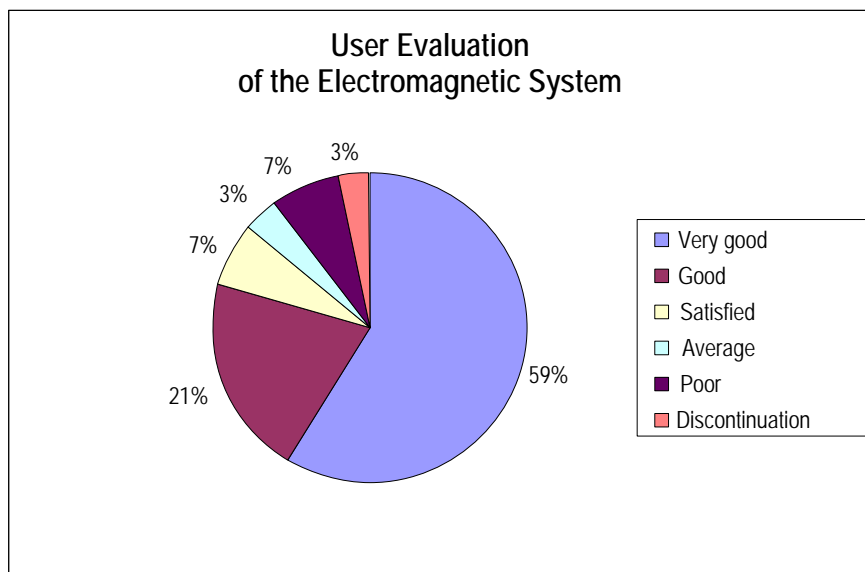


Similar results were recorded in the user evaluation: Pneumatic system therapy was deemed to be "very good" in 31% of cases and "good", "satisfactory" and "poor" in 46%, 4% and 15% of cases, respectively. Treatment had to be discontinued due to a lack of improvement in 4% of cases (one patient).



Following *enPuls Version 2.0 electromagnetic* shockwave therapy, 59% of the users found the system to be "very good", 21% "good", 7% "satisfactory", 3% "average" and 7% "poor". Treatment was also discontinued in one case due to a lack of improvement.

From a user perspective, good results were obtained with both systems. However, the electromagnetic shockwave therapy system had a slight edge over the pneumatic system as corroborated by the patient evaluation.



Discussion

Considerable pain relief was achieved with shockwave therapy in both groups. Slightly better results were obtained with the electromagnetic shockwave therapy system compared to the pneumatic system.

Conclusion

The patient and user evaluations highlight a clear-cut trend in favour of the *enPuls Version 2.0* shockwave therapy system (Zimmer MedizinSysteme GmbH Neu-Ulm) compared to the pneumatic shockwave therapy system.

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