The assessment of the effectiveness of extracorporeal shock wave therapy (ESWT) for soft tissue injuries (ASSERT): two year results

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Summary
Introduction: Extracorporeal shockwave therapy (ESWT) is popular, and effective in the management of chronic tendon conditions in the elbow, shoulder, and pain at and around the heel.

Methods: An online database for the Assessment of Effectiveness of Extracorporeal Shock Wave Therapy for Soft Tissue Injuries (ASSERT) was implemented to prospectively collect information on the effectiveness of ESWT across the UK. All clinicians followed a standardised method of administration of the ESWT. The primary outcome measures are validated outcome measures specific to the condition being treated. A Visual Analogue Score for pain and the EuroQol were completed alongside the condition specific outcome tool at baseline 3, 6, 12 and 24 months post treatment.

Conclusion: The development of the ASSERT database has enabled the evaluation of the effectiveness of ESWT for patients suffering from chronic conditions (plantar fasciopathy, tennis elbow, Achilles tendinopathy, greater trochanter pain syndrome and patellar tendinopathy).

KEY WORDS: chronic soft tissue injuries, extracorporeal shockwave therapy, effectiveness, short and long-term effects.

Introduction
Soft tissue injuries and tendinopathies are common, and account for a large number of chronic musculoskeletal disorders1,2 and patients may suffer long term pain and disability3,4.

Shock wave therapy (SWT) has been successfully employed for nearly three decades for the management of various musculoskeletal disorders5. Some trials have produced negative results6-9, but many well performed randomized, double-blind, clinical trials support the use of SWT10-20 showing that extracorporeal shockwave therapy (ESWT) is effective in the management of such musculoskeletal ailments.

The clinical effectiveness of ESWT remains controversial21, and the National Institute for Health and Clinical Excellence (NICE) has published guidance on the use of ESWT in calcific tendinopathy of the shoulder22, recommending that the results of the procedure are monitored, and clinicians undertaking the procedure make special arrangements for audit. According to NICE, ESWT produces clinically relevant results in selected patients23-25; this makes it necessary to provide scientifically robust data.

In 2011 we developed the Assessment of Effectiveness of Extracorporeal Shock Wave Therapy (ESWT) for Soft Tissue Injuries (ASSERT) database to ascertain the effectiveness of ESWT in patients suffering from refractory plantar fasciopathy, tennis elbow, Achilles tendinopathy, greater trochanter pain syndrome, patellar tendinopathy in both the short and long term. The details of ASSERT have been reported in a previous scientific article26, and the readers are referred to that publication for greater details.

We collected information on the effectiveness of ESWT across the UK using standard ESWT equipment and a standardised treatment protocol, togeth-
er with standardised baseline measurements and outcome measures and time points in centres across the UK.

ASSERT followed the principles of the Helsinki declaration and following Good Clinical Practice Guidelines (GCP). Ethical approval for ASSERT was granted from the South East London NRES committee (REC Ref: 11/LO/0253).

We recruited participants over the age of 16 who:
- had received a diagnosis of plantar fasciopathy; tennis elbow; Achilles tendinopathy; greater trochanter pain syndrome; or patellar tendinopathy confirmed by the recruiting clinician and validated by MRI scan or ultrasound scan with power Doppler;
- underwent a course of conservative therapy which has not been effective in relieving pain and other symptoms;
- been recommended to receive ESWT at one of the identified centres;
- had no evidence of inflammatory arthropathies;
- were able to give informed consent.

Use of ESWT machine

Standardisation of the machine and the process of administration of ESWT had been agreed to ensure consistency, reproducibility and generalisability of the results. All clinicians using the index ESWT equipment were trained and certified to ensure adherence to the protocol. All clinicians delivered an initial 500 sensitising impulses at a low air pressure (1.5 bar of air pressure) which reduces the pain the patient experiences during the treatment. Based on patient feedback, the clinician increased the air pressure to 2.5 bar or above. Overall, irrespective of the area being treated, the total dose of impulses remained constant at 2500 per session, with one session a week for 3 consecutive weeks, with a maximum gap between treatments of 2 weeks.

Database

The ASSERT database is a web based system (www.assert.org.uk). Each clinician received a study number for each participant. Only unidentifiable information with the patients study number was entered into the database. Sensitive data was held on secure servers.

Monitoring the ASSERT database’s systems and procedures

A data monitoring committee consisted of members of the study team, including a lay member and an independent chair. They met on a six-month basis to review the progress of ASSERT and database management.

Following a two-year recruitment span, and two-year follow-up period, we collected data on a total of 619 patients. This makes the ASSERT study the largest of its kind in the field of ESWT administration for musculoskeletal disorders.

As in the original research plan, we analysed the data after the end of the study period on 577 patients who fulfilled the inclusion criteria (if two or more of the follow-up datasets were missing the patient was excluded).

The ensuing series of articles in presented: they give a unique picture of real life use of ESWT in an unselected population of patients suffering from a variety of musculoskeletal ailments.

Compliance with ethical standards

Conflict of interest

All Authors declare no conflict of interest.

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We thank all the clinicians recruiting participants onto the ASSERT database and the participants of ASSERT. Professor Nicola Maffulli developed the concept of ASSERT.

Ethical approval

All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent

Informed consent was obtained from all individual participants included in the study.

Ethics

The Authors declare that this research was conducted following basic ethical aspects and international standards as required by the journal and recently updated in the Helsinki declaration.
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References


