

Comments to 2 Controversial Publications

- **Buchbinder et al. Sept 2002 JAMA report**
No significant differences between active and placebo ESW-T , using low energy shockwave device.
Critics : protocol low energy, no real placebo, procedure
- **Haake et al. July 2003 BMJ report**
ESW-T is ineffective in the treatment of chronic plantar fasciitis.
Critics : radical, generalisation, protocol low energy

Conclusions require a positioning and reply.



Ultrasound guided ESWT for Plantar Fasciitis

(Buchbinder et al.)

conclusion

“all shockwaves are therapeutically ineffective”

should be corrected into :

**“the Verum group in the study treated with SW-device
and applied shockwaveparameter**

(3 treatments, weekly intervals, 2000 shocks)

has no advantage over the control group

(3 treatments, weekly intervals, 100 shocks)”

Weaknesses Statistical / Methodical :

- 1. Inclusion criteria – symptoms of > 6 weeks vs > 6 months according to ISMST**
- 2. Inclusion criteria – plantar fasciitis of at least 4 mm**
- 3. Bilateral fasciitis included but should have been exclusion criterium**
- 4. Placebo group received treatment – so no Placebo controlled study**
- 5. Placebo group SW frequency 60/min ; Verum group 240/min**
- 6. Verum group no uniform treatment parameters –pain level dependent**

Weaknesses Medical / Clinical :

- **All patients had “ultrasound confirmed lesion” – other Placebo controlled studies determined PF “solely on clinical grounds”.**
- **Patient selection for other studies - treated by physician / confirmed by second physician – knowledgeable and experienced in clinical (non-imaging) diagnosis of PF**
- **6 authors of study, only 2 physicians (rheumatologist, radiologist)**
- **Outcome assessment by interviews and questionnaires (patient self assessment scores / no evidence of post-treatment physical examinations and direct physician´s interaction)**
- **Treatment by ESW Therapist / aimed at thickest portion of the fascia and not maximal pain / no foot manipulation during treatment / small focus**
- **Device energy increased to the highest tolerable level of pain (no identical dose for each patient - nr of shocks and energy level)**
- **Potent analgetic drug was allowed during time of study**

Authors showed that :

The specific device, when evaluated for therapeutic effectiveness under the defined conditions of the study

- low energy**
- 3 weekly treatments**
- medial to lateral shockwave transmission**
- Ultrasound dependent targeting**

did not show marked differences between treated patients and treated control group.

- **ESW-T for Plantar Fasciitis : Randomised controlled multicenter trial**

(Michael Haake, Mathias Buch et al)

conclusion

“ESW-T is ineffective in the treatment of Chronic Plantar Fasciitis”, and

“we cannot recommend specific applications of ESW-T to be tested under further clinical studies”

should be

“the device in the study with the applied shockwave-parameter (3 treatments, 2-weeks intervals, 4000 shocks, local anaesthesia) has no advantage over the control group”

Reactions from :

- **Prof. James D. Michelson**
stretching exercises, questioning drastic/radical conclusion
- **Prof. Jan D. Rompe**
 - results are only valid for therapeutic variables applied
 - generalisations inappropriate
 - own effective study with positive result with athletes
(3 x 2000 shocks, low energy)
- **Prof. Frank J.J. Conijn**
conclusion should be : ESWT should not be used in orthopedic conditions unless there is evidence for its efficacy

Conclusion

Unsuccessfull studies of both Buchbinder and Haake are based on low energy regimes

Successfull FDA studies use high energy regimes

Differences

pilotstudy to define dose – response relation

focal size, applied energy, localization, retreatment, followup

Conclusion

other treatment regimes are more effective

optimal dose – response relation is crucial for success



Conclusion

FDA approved ESW devices, homologated by an independent Orthopedic Advisory Board of the AAOS, and AMA coding committee :

**Single Session Procedures using High-Energy Treatment
requiring anaesthesia
approved for use only by a physician**

**produced clinically and statistically significant results,
and approved both devices as safe and effective for
treating chronic PF**

**(over 13,000 patients successfully treated in the USA
with the Ossatron)**



FDA Situation

**Soft Tissue Trials for
Patellar Tendinitis
Achilles Tendinitis
Rotator Cuff tendinitis**

were FDA approved

Multiple Site Studies will follow shortly

**Tibial Non-Union Studies were modified to allow
easier patient selection**

**Non-Union Metatarsal Fractures – Jones fracture –
Studies were started March**



Future

The Randomised Controlled Trials by Buchbinder and now also Haake contributed to confusion and controversies in the media

“all shockwaves are ineffective”

International Shockwave Foundation

(Dr. Thiele and Dr. Schaden)

founded to define treatment guidelines

