

# **SHOCK WAVE TREATMENT for PLANTAR FASCIOPATHY**



A meta-analysis of the literature

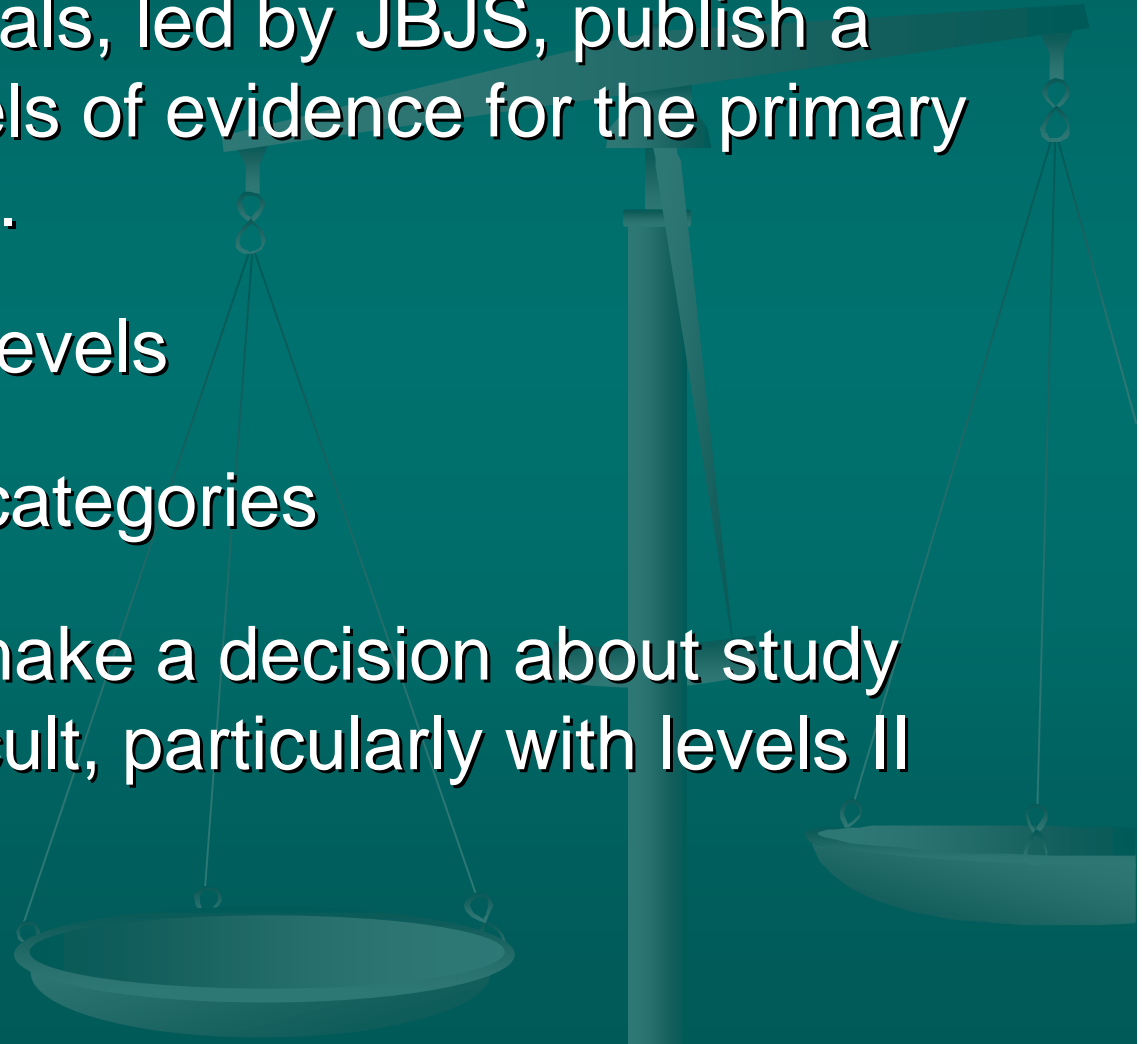
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# Levels of Evidence

- Orthopaedic journals, led by JBJS, publish a table defining levels of evidence for the primary research question.
- There are 5 (I-V) levels
- Each level has 4 categories
- The system can make a decision about study classification difficult, particularly with levels II and III



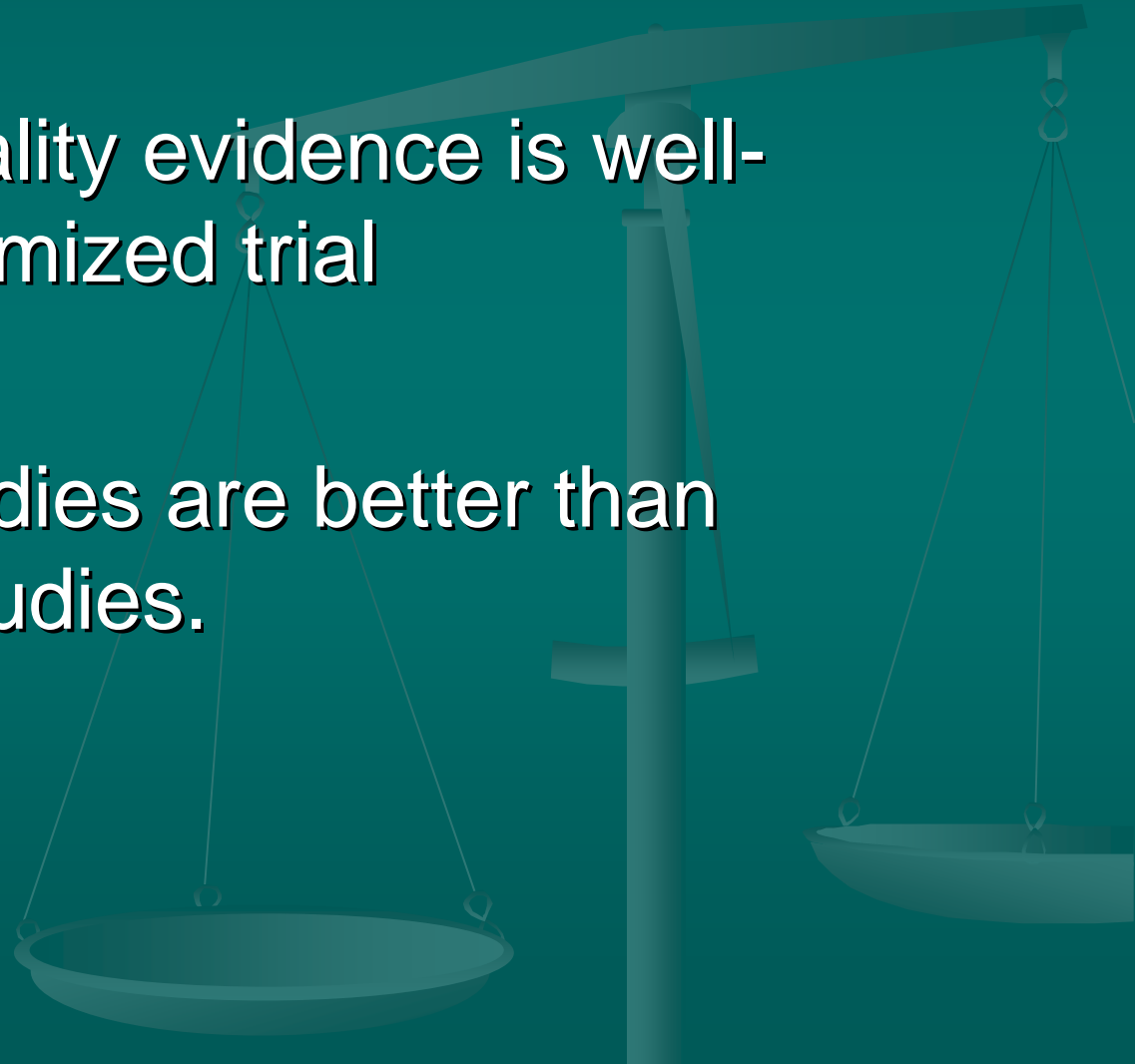
# Levels of Evidence



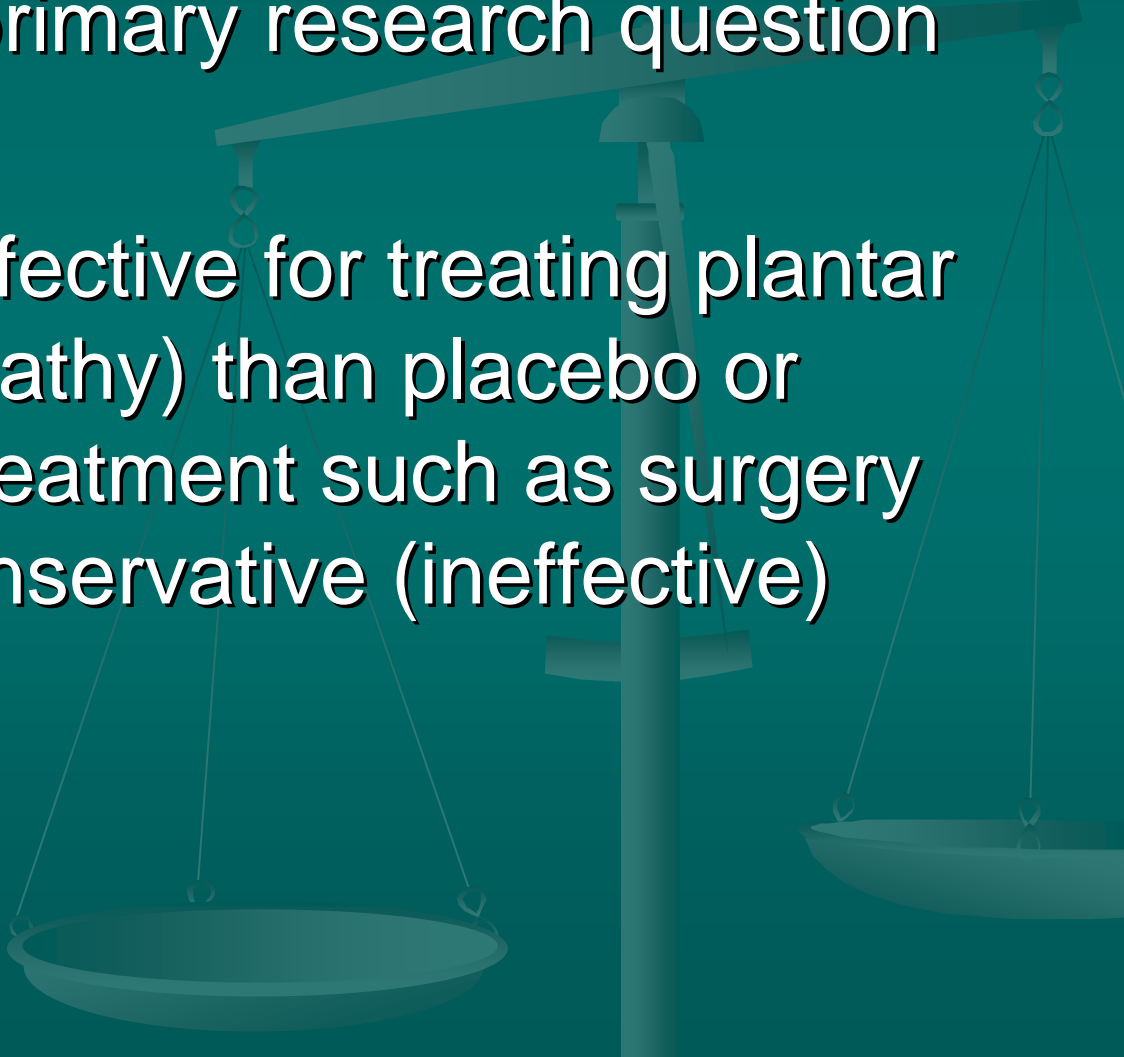
- A better understanding of how to grade any study you are reviewing or undertaking
- Wright, James G.:A practical guide to assigning levels of evidence. J Bone Joint Surg 2007;89-A:1128-1130 (May)

# Levels of evidence

- The highest quality evidence is well-designed randomized trial
- Prospective studies are better than retrospective studies.

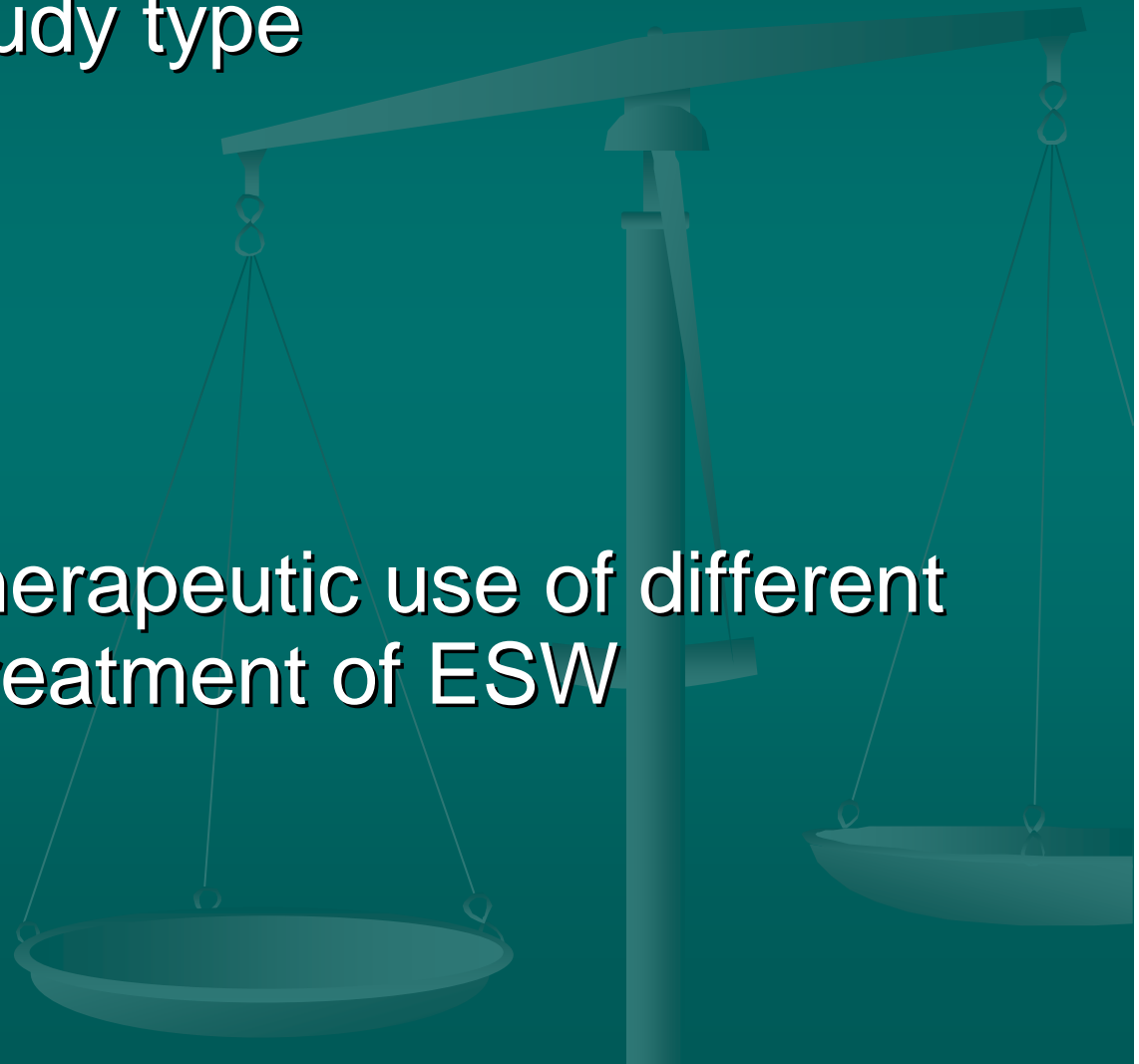


# Criteria

- Determine the primary research question
  - Is ESW more effective for treating plantar fasciitis (fasciopathy) than placebo or other types of treatment such as surgery or continued conservative (ineffective) treatments
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# Criteria

- Establish the study type
- Therapeutic
- Prognostic
- Diagnostic
- Economic
- We assessed therapeutic use of different devices in the treatment of ESW



# Criteria



- Assigning a level
- Therapeutic level I studies are defined as high quality positive OR negative randomized prospective clinical trials
- There usually is some type of blinding of treating and evaluating physicians

# Criteria

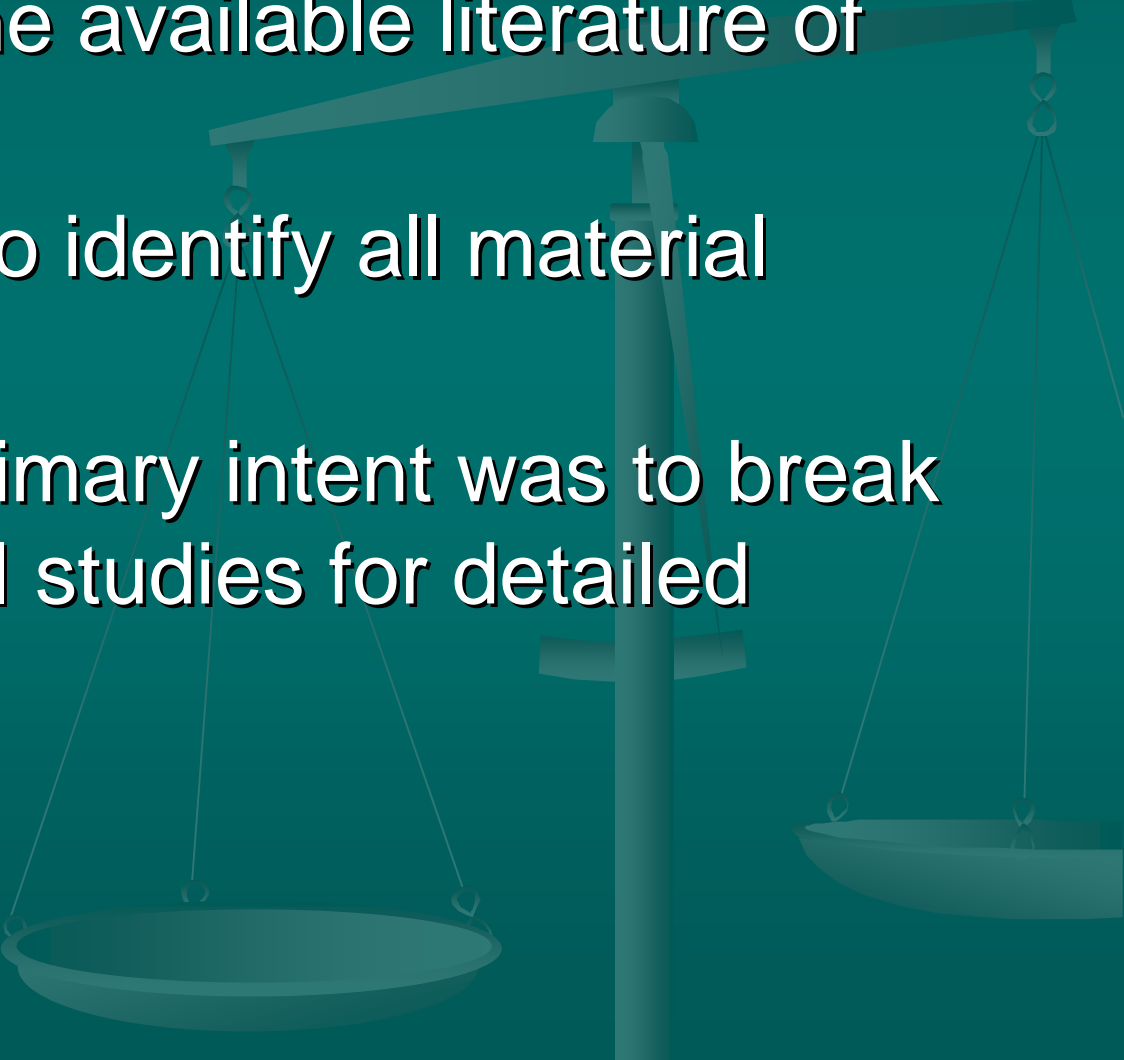


- Meta-analyses are summaries of multiple studies
- The level of evidence assigned to a meta-analysis is contingent upon the published studies used for the meta-analysis
- If only published level I studies are used, then the meta-analysis is considered level I

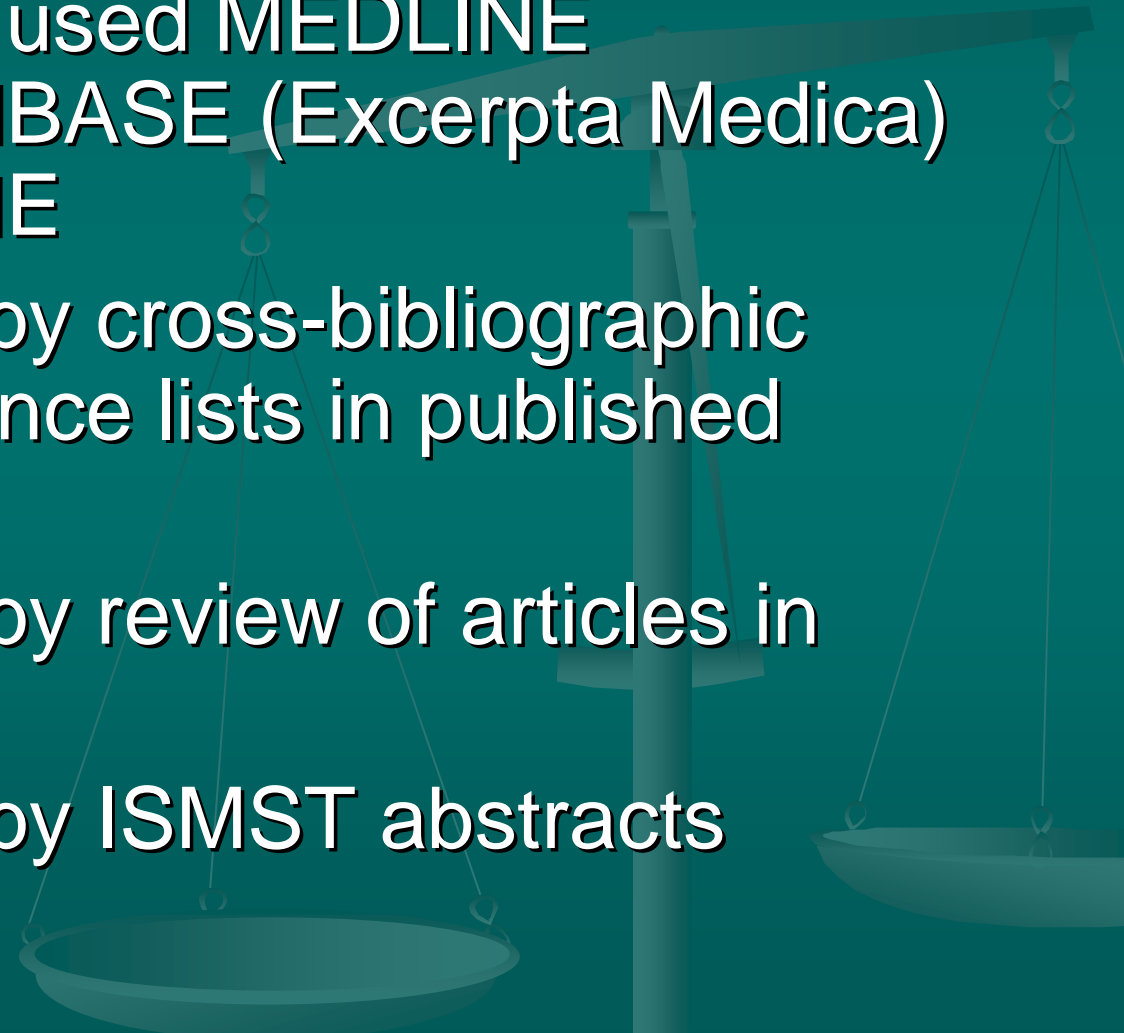
# Background

- The last six years have been associated with an increasing number of level I studies evaluating ESW and plantar fasciitis
- Several of these studies were conducted under the aegis of the FDA and led to device approval.
- Other studies were independent of the FDA

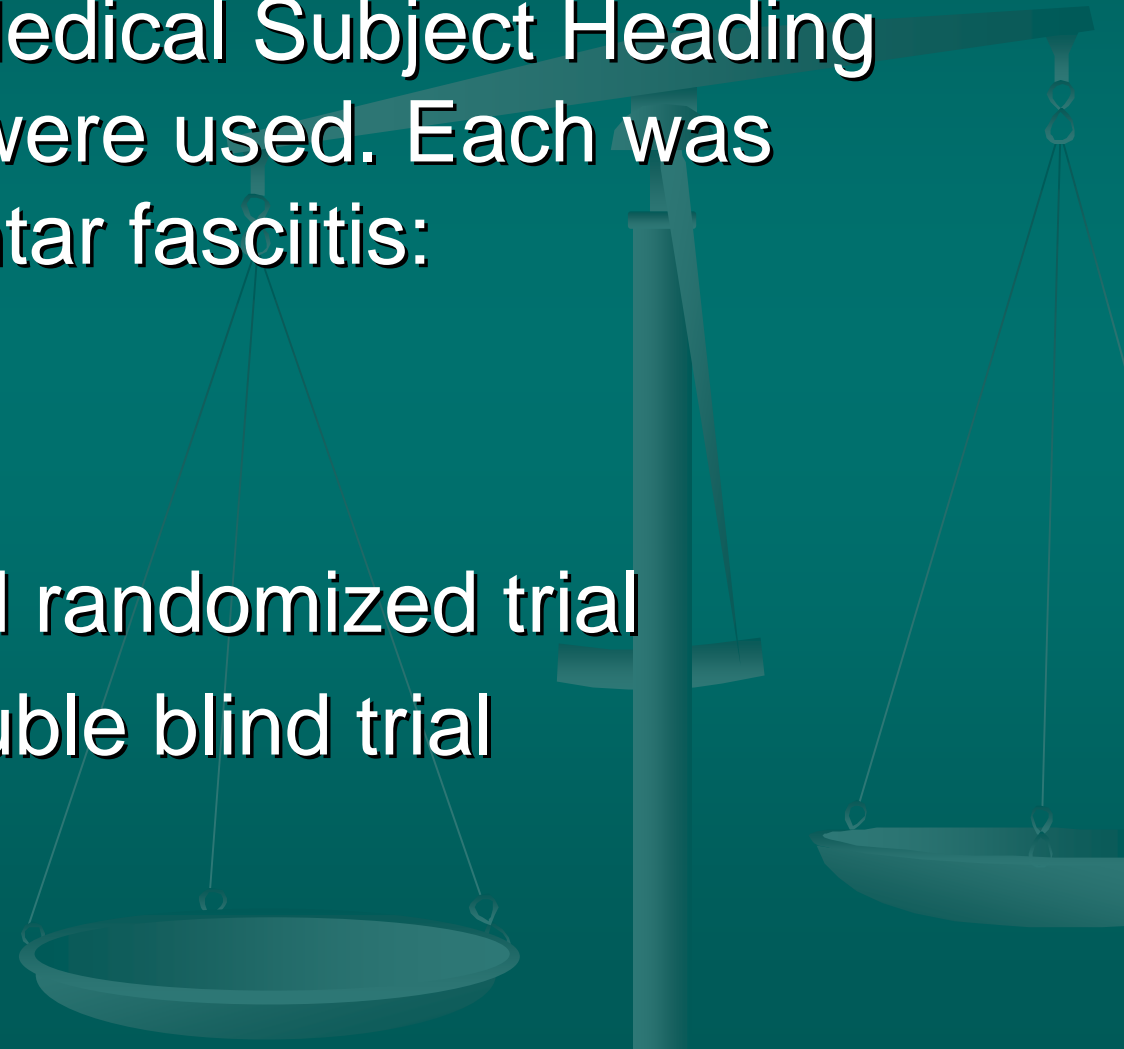
# Introduction

- We evaluated the available literature of ESW/PF
  - The intent was to identify all material available
  - However, the primary intent was to break out ONLY level I studies for detailed analysis
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# Method

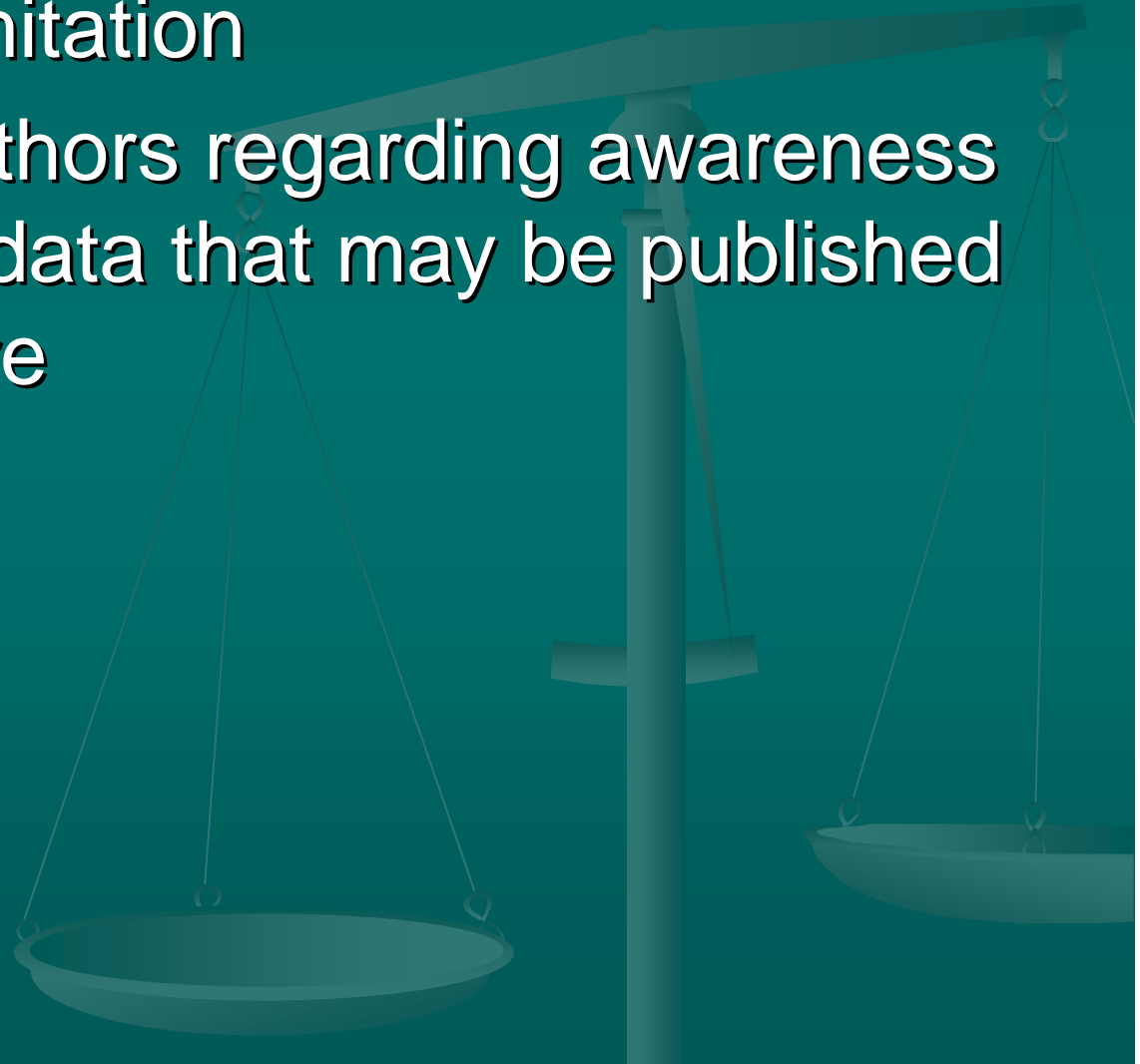
- Primary search used MEDLINE (PUBMED), EMBASE (Excerpta Medica) and COCHRANE
  - Supplemented by cross-bibliographic review of reference lists in published reviews
  - Supplemented by review of articles in ESW books
  - Supplemented by ISMST abstracts
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# Method

- The following Medical Subject Heading (MeSH) terms were used. Each was paired with plantar fasciitis:
  - Shock wave
  - ESW(T)
  - Clinical trial and randomized trial
  - Single blind/double blind trial
  - Placebo
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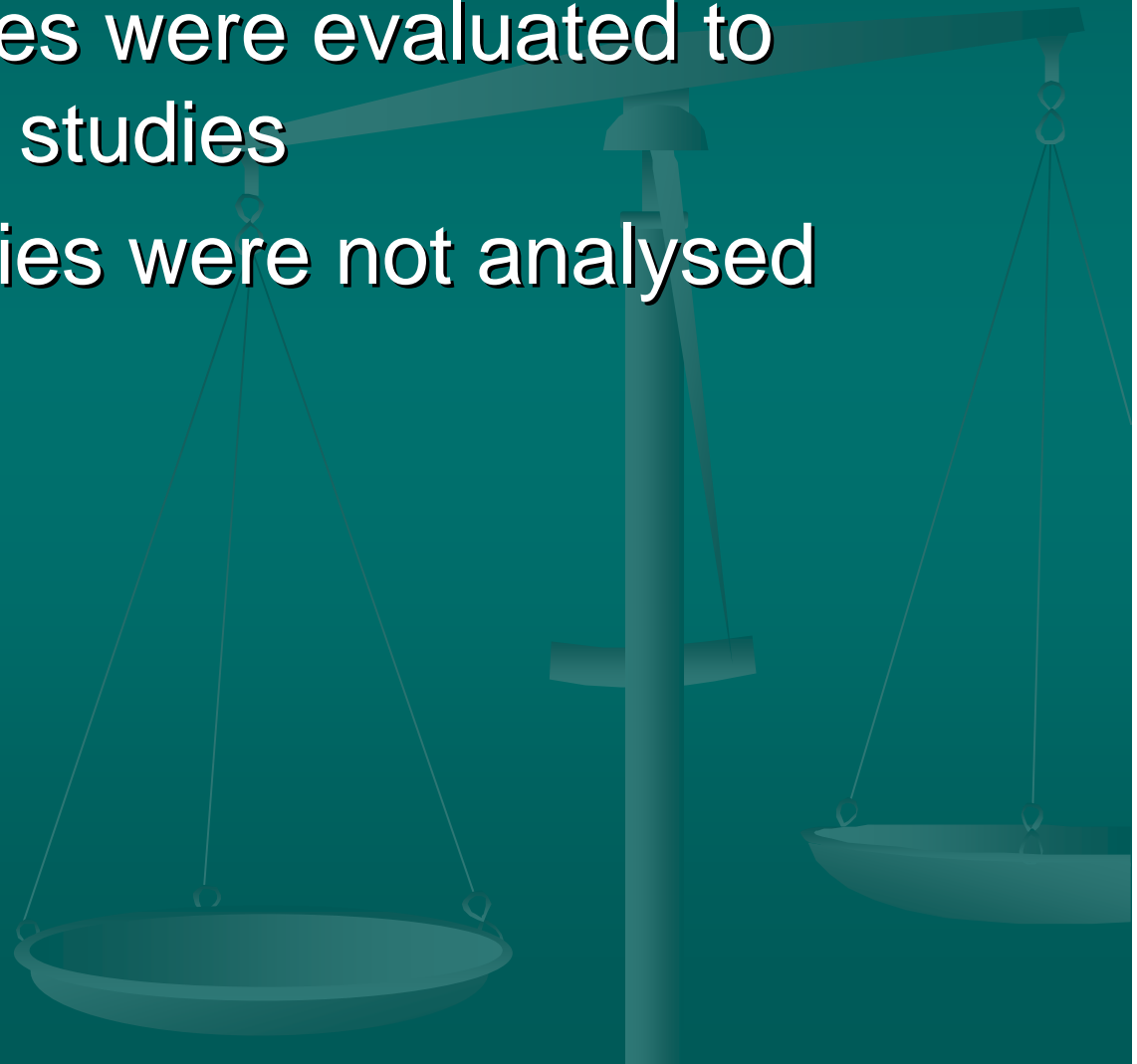
# Method

- No language limitation
- Contact with authors regarding awareness of unpublished data that may be published in the near future

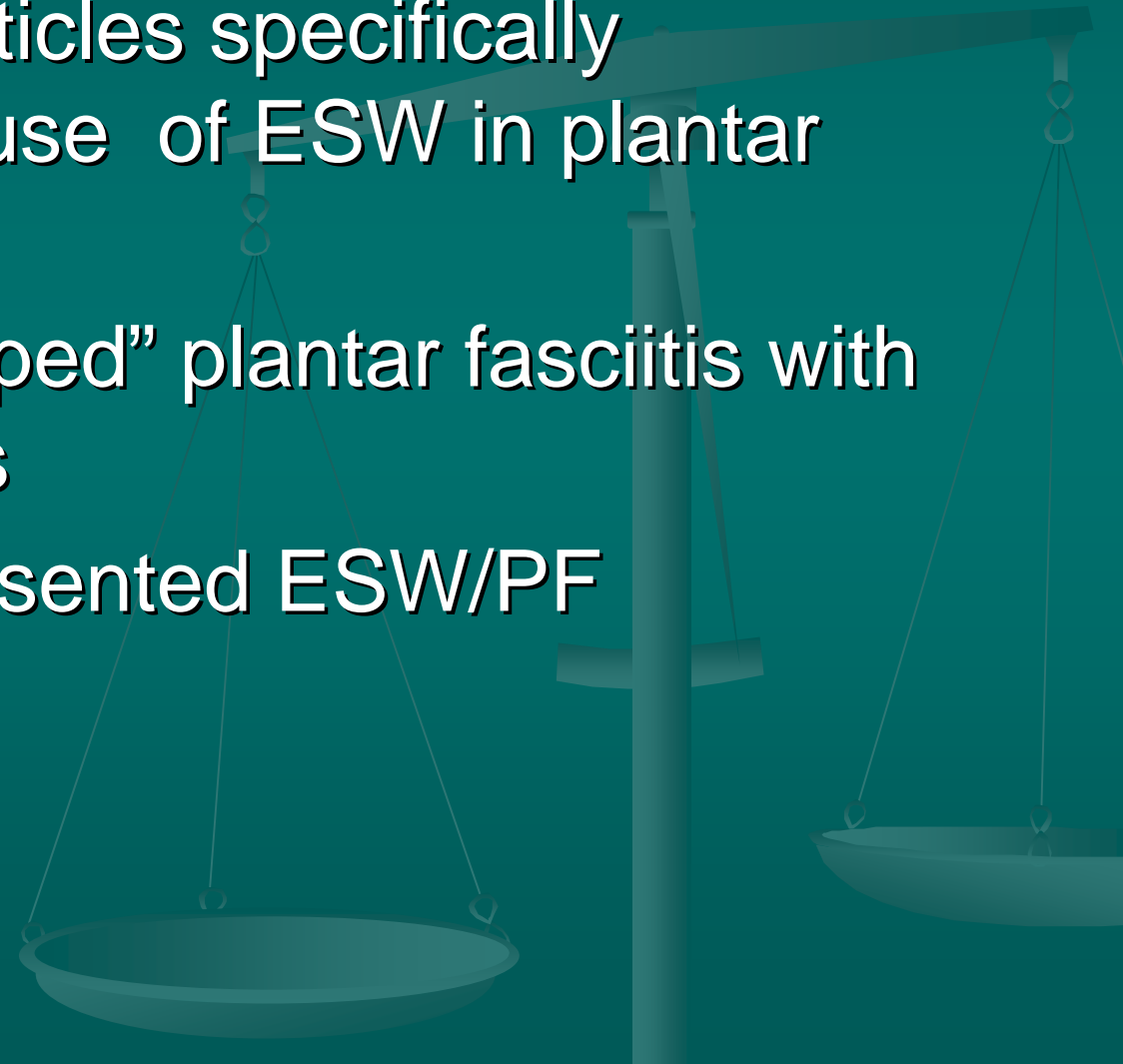


# Methods

- Discerned studies were evaluated to ascertain level I studies
- Non-level I studies were not analysed

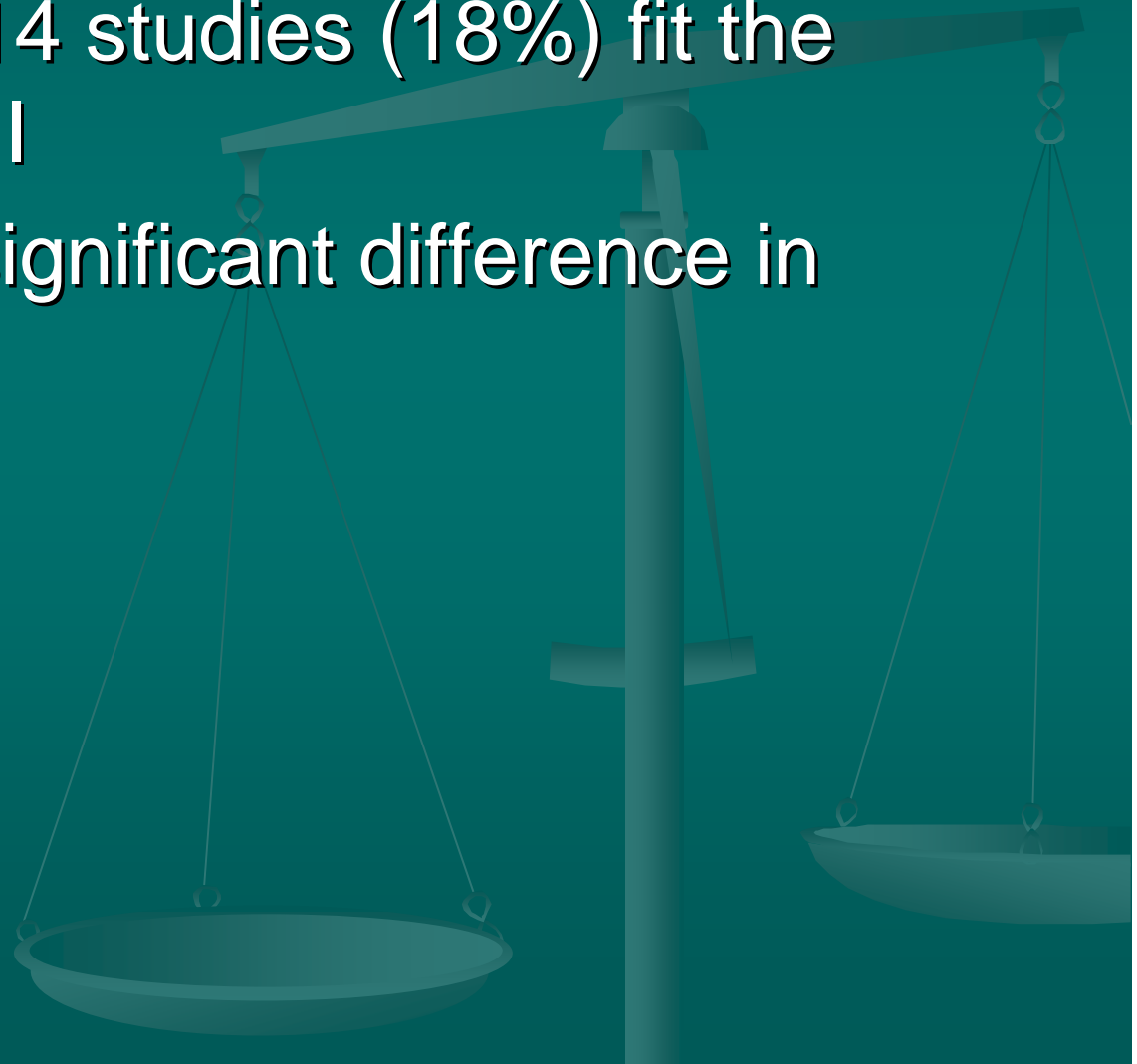


# Results

- 79 published articles specifically addressed the use of ESW in plantar fasciitis
  - 14 articles “lumped” plantar fasciitis with other conditions
  - 39 abstracts presented ESW/PF treatments
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# Results

- However, only 14 studies (18%) fit the criteria for level I
- 2 reported no significant difference in results



# Results

- All patients: 1633
- Treated: 826
- Placebo: 807



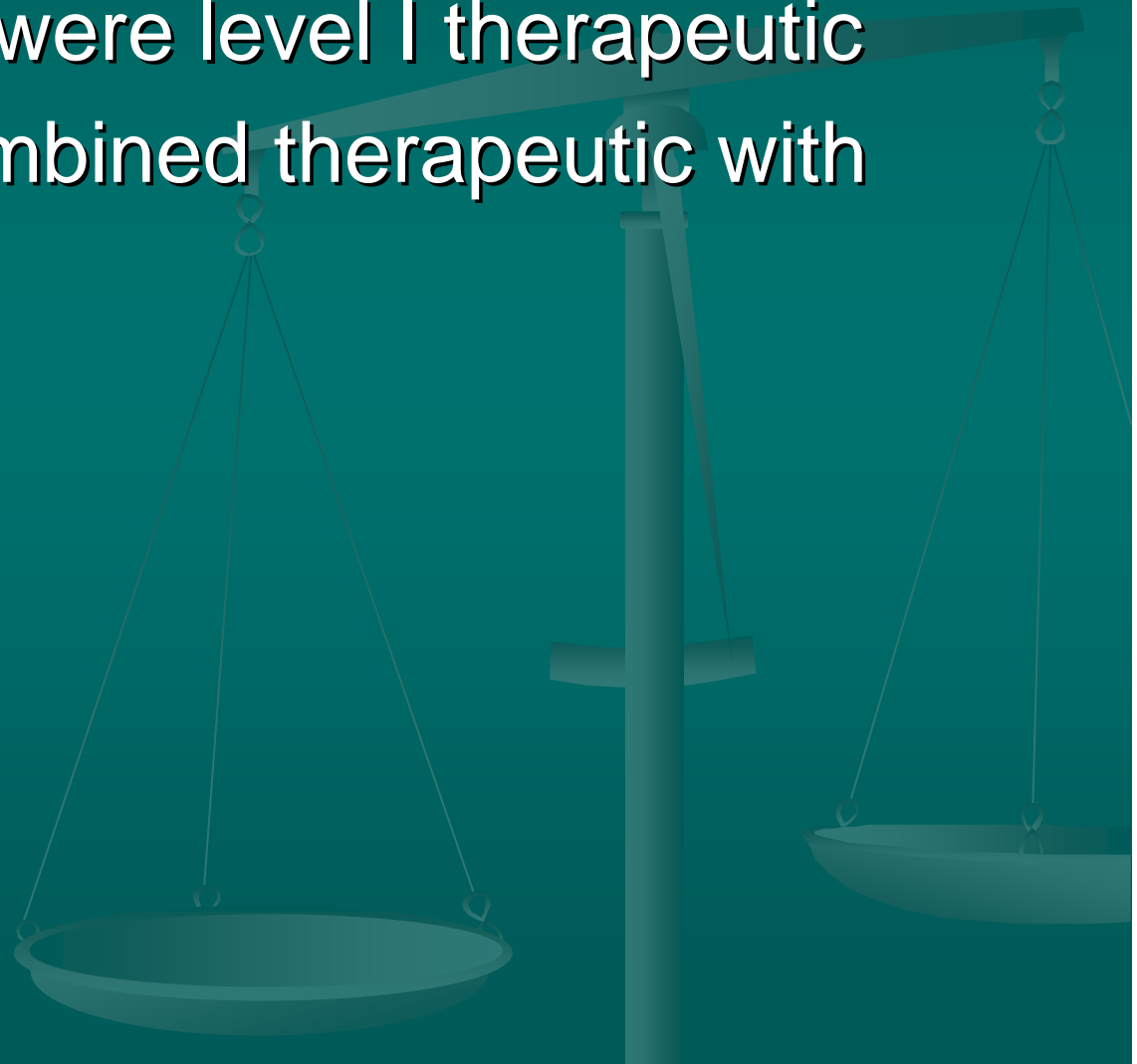
# Positive Results

- Total : 1379
- Treated: 701
- Placebo: 678



# Positive Results

- Twelve studies were level I therapeutic
- Two studies combined therapeutic with diagnostic



# Negative Results

- Total: 254
- Treated: 125
- Placebo: 129



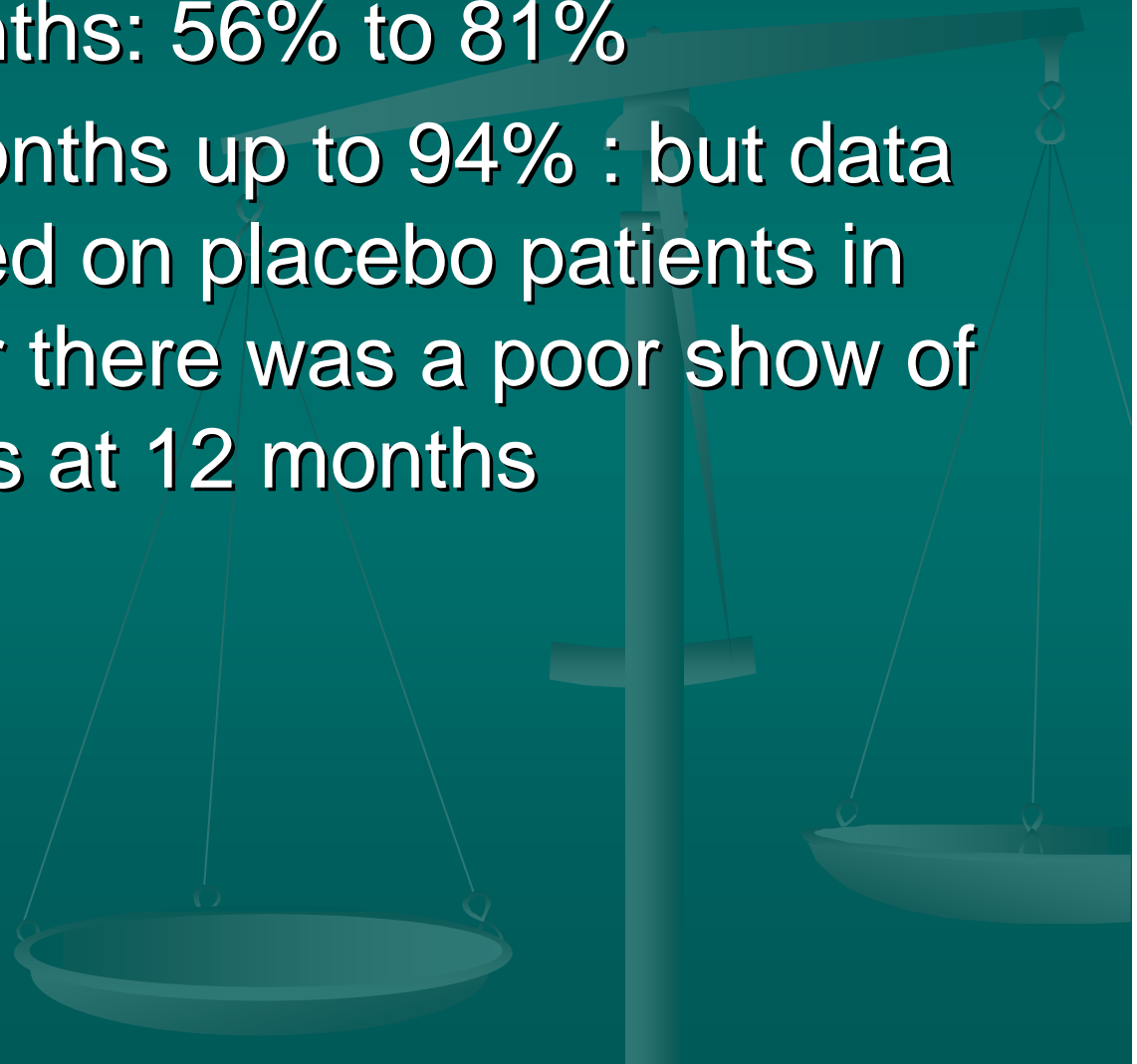
# FDA Outcomes

- Approval for 4 devices for plantar fasciitis
- Ossatron
- Epos ultra
- Orthospec
- Orthowave



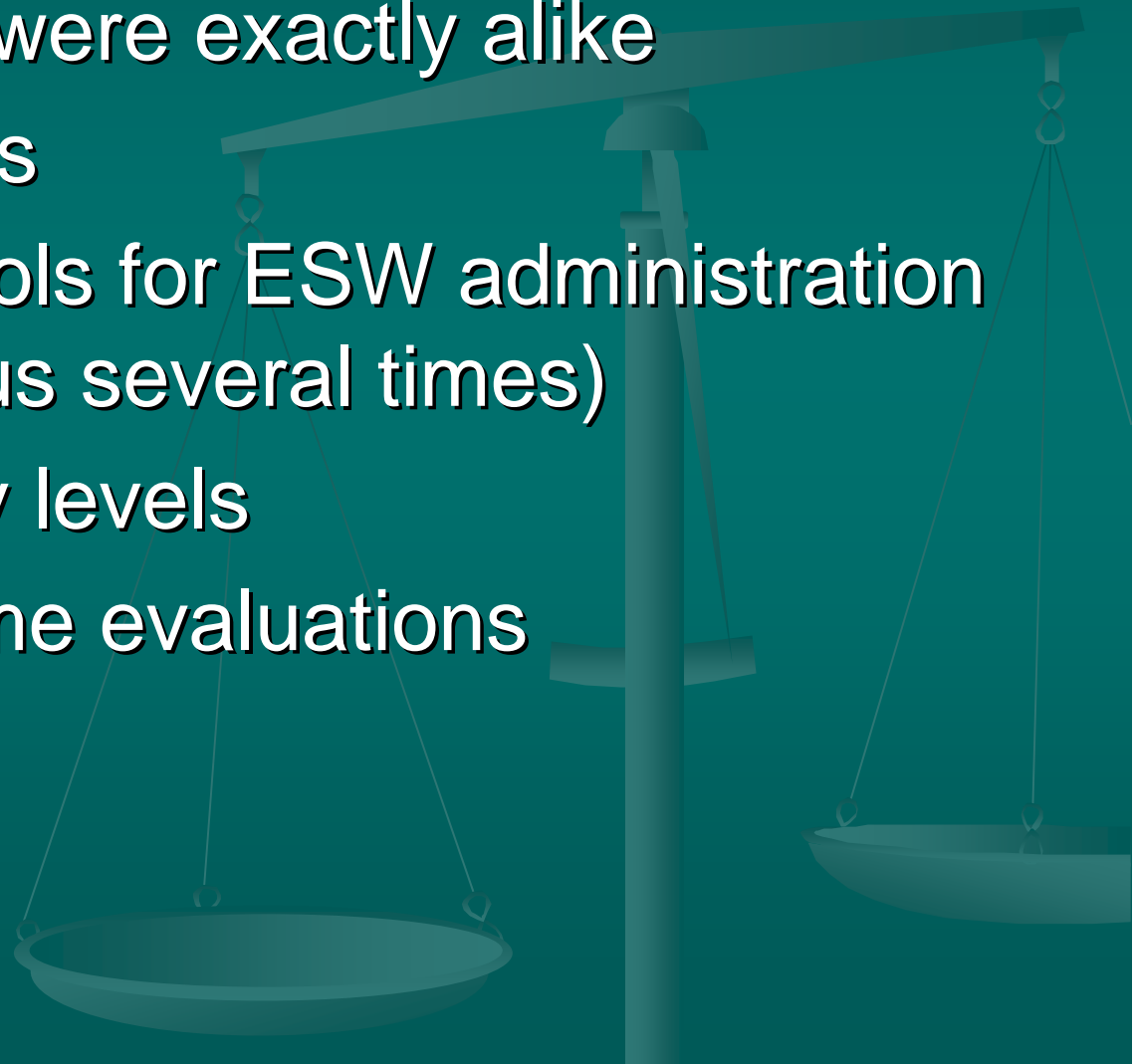
# Outcome Results

- Range at 3 months: 56% to 81%
- Range at 12 months up to 94% : but data was not collected on placebo patients in some studies or there was a poor show of placebo patients at 12 months



# Comparison Problems

- No two studies were exactly alike
- Different devices
- Different protocols for ESW administration (one time versus several times)
- Different energy levels
- Different outcome evaluations

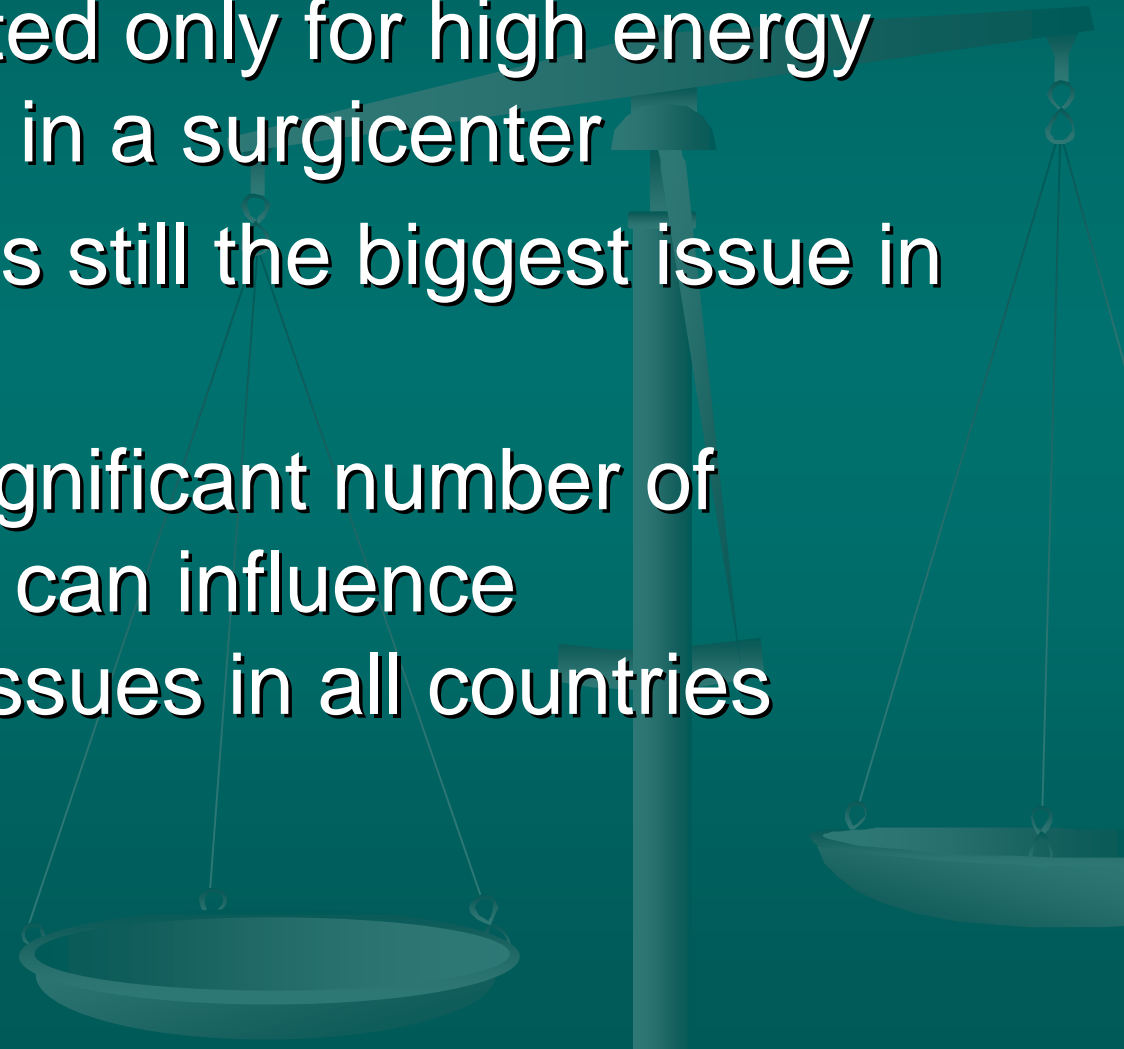


# Comparison Problems

- Validity of Roles and Maudsley
- Validity of VAS



# Economics

- CPT code granted only for high energy with anesthesia in a surgicenter
  - Compensation is still the biggest issue in the US
  - Hopefully the significant number of positive studies can influence compensation issues in all countries
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# Acknowledgements

- Thanks to Skeletal Educational Association and Tissue Regeneration Technologies for study support
- Thank you Dr Gordon and your staff for a terrific meeting

