Shock Wave Treatment for Achilles Tendinopathy

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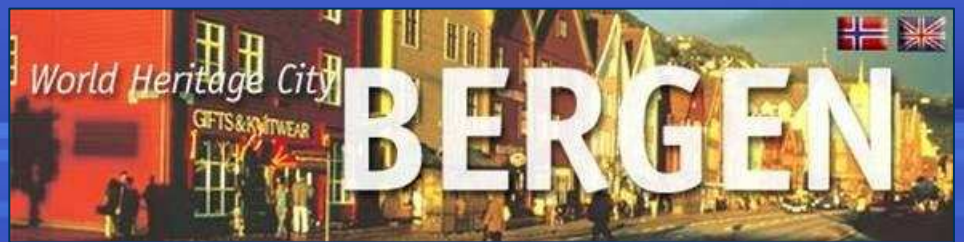


ESWT Summer Meeting
August 24 - 26, 2007

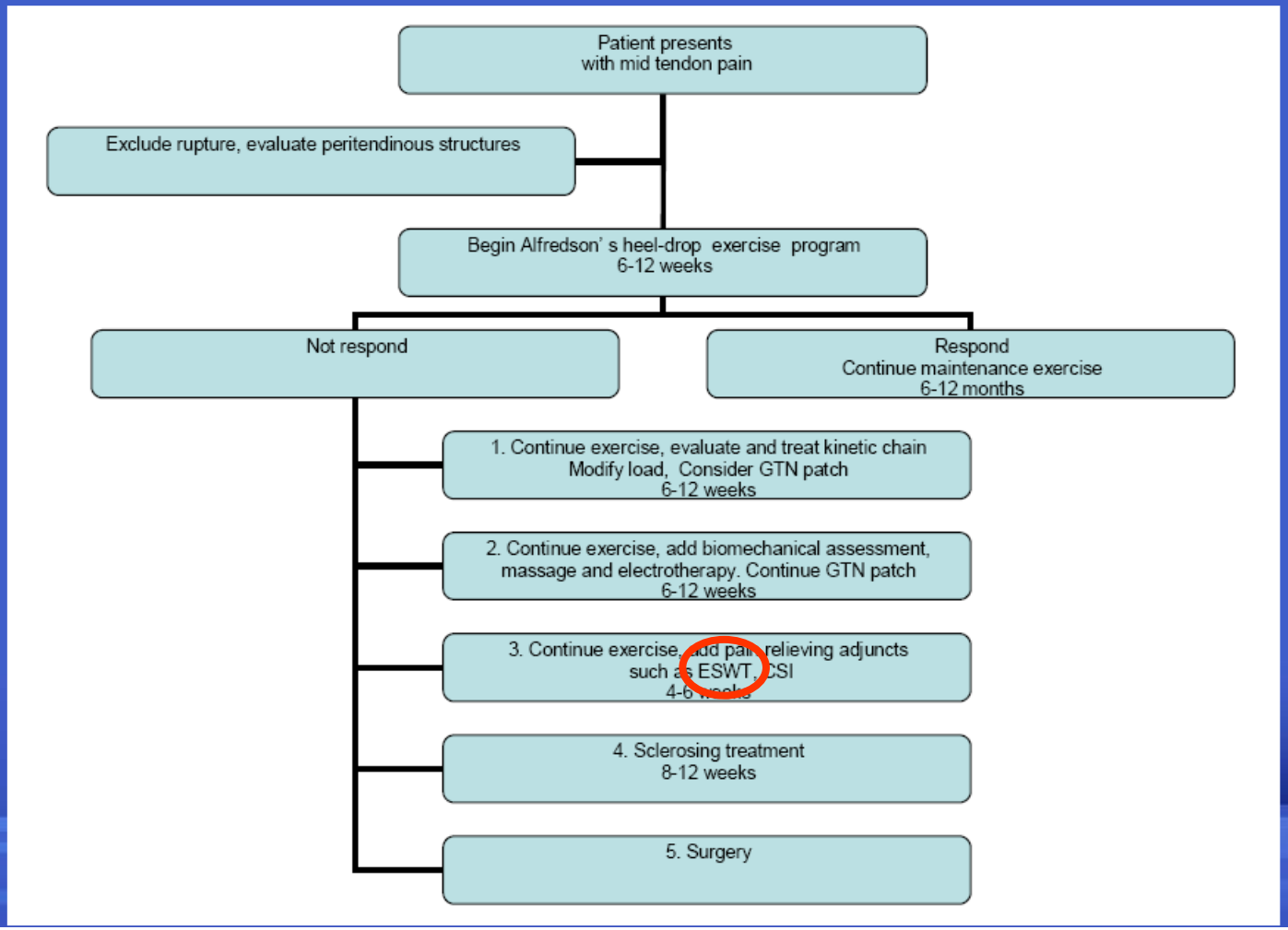
Treatment options for AT

Rest
Orthotic Treatment
Electrotherapy
Strength Training
Nonsteroidal Antiinflammatory Medication
Eccentric Loading
Glyceryl Trinitrate Patches
Corticoid Injections
Sclerosing Injections
Botulinum Injections
Surgical Revision

Alfredson and Cook 2007; Br J Sports Med 41:211

Although ESWT has been trialled in several tendons and fascial structures, **there have been no randomised controlled trials in the Achilles tendon.** In other structures ESWT when compared to placebo decreases pain, but may be beneficial in relieving pain while rehabilitation of the musculotendinous structures continues.

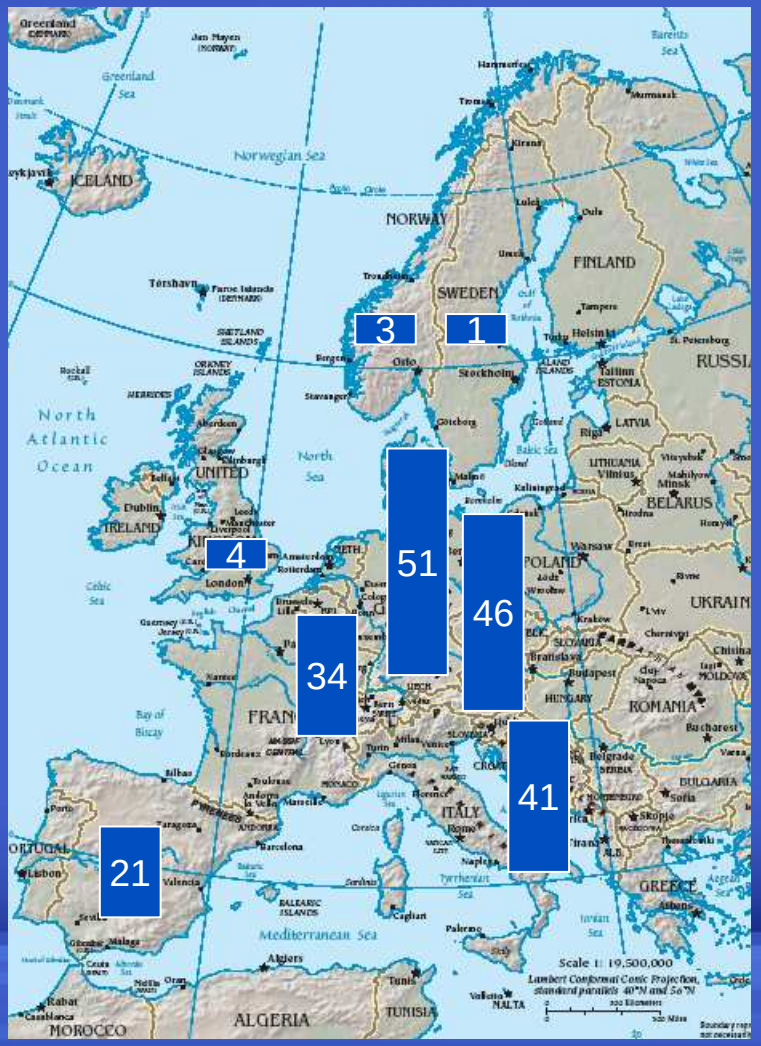
Alfredson and Cook 2007; Br J Sports Med 41:211-216



ISMST

Scandinavian Members ?

INTERNATIONAL SOCIETY FOR MUSCULOSKELETAL SHOCKWAVE THERAPY



Shock Wave Treatment

This is the first prospective pilot study performed to evaluate the effect of radial shockwave therapy in patients with unsuccessfully pretreated Achilles tendinosis. Forty Achilles tendons (Achilles tendinosis) were treated 3 – 5 times by radial shockwave therapy in a one-week interval setting.

Lohrer et al. 2002, Sportverletzung Sportschad 16: 108

UNCONTROLLED TRIAL

	Before treatment	After shockwave treatment				
		1 week	[illegible]	12 weeks	26 weeks	52 weeks
Achillodynia						
Pain at rest (VAS)	[illegible]	0.4±1.0**	0.3±1.3**	0.1±0.3**	0.1±0.2**	0.1±0.3**
Pain threshold (VA[illegible]	[illegible]±6.6	27.5±10.9**	31.2±13.4**	38.4±11.8**	43.3±9.1**	41.9±11.6**
Tenderness (30 N, VAS)	6.7±3.2	2.6±3.6**	1.8±3.4**	0.7±1.8**	0.5±1.8**	0.9±2.6**
Load-induced pain (VAS)	7.8±1.7	2.2±2.5**	1.3±2.2**	0.5±1.1**	0.4±1.0**	0.7±1.6**
Pain-free running time (min)	14.4±18.5	63.0±37.0**	75.4±38.1**	87.5±35.2**	96.7±34.7**	90.0±43.0**

- **Radial** shock wave treatment
- 2000 impulse, 2-4 bar
- No local anaesthesia
- „Clinical Focusing“
- 5x in weekly intervals
- Follow-up up to 52 weeks after SWT

Shock Wave Treatment

DOCTORS, TRAINERS AND CONDITIONING COACHES

RADIAL SHOCK WAVES FOR THE TREATMENT TO THE LOWER LIMBS

by François Tassery

by Thierry Allaire

Dr. Francois Tassery is the team doctor for the Division I men's basketball team, St. Thomas Le Havre, and the doctor for the HAC Women's Handball Division I team. Dr. Tassery is a member of both the French Society for Sport Traumatology and the Association of Basketball Surgeons, Physiotherapists, Doctors, and Chiropodists (ACKMPB).

In the early 1990s, medical machines originally used in the field of urology for breaking up kidney stones (lithotripsy) were increasingly used to treat pseudarthrosis and break up intra-tendinous calcifications.
The radial shock wave device used by us, the "Swiss Dolorclast" (Electronic Radial System-EMS) produces so- compressor), are administered through contact with the skin and penetrate the tissue to a depth of 3 to 4 cms. It's possible to treat superficial lesions to the soft tissues with RSWT. It is typically used for treating heels, elbows, and knees.
The treatment eases inflammation in afflicted area and

UNCONTROLLED TRIAL

	VS+S	I+N	A	Observations
Achilles tendinitis	89%	11%		17 high-level athletes
n = 37	33	4		
no. of sessions: 3				17 very good results

Tassery and Allaire 2003; FIBA Assist Mag 1: 57

- **Radial** shock wave treatment
- 2000 impulses, 2 - 2.5 bar
- No local anaesthesia
- „Clinical Focusing“
- 3x in weekly intervals
- Follow-up 6 weeks after SWT

Shock Wave Treatment

A prospective, randomized, double-blind, controlled clinical study performed in 102 subjects affected by intractable **non-insertional** Achillodynopathy, to compare the outcomes of a standard treatment with ESWT in the painful mid-portion of the Achilles tendon. All patients had failed to improve after current conservative treatments.

At 6 months of follow-up in the ESWT group 79.2% good/fair; in the placebo group 46.6% good/fair.

Astore et al. 2004; Isokinetic Congress Report

UNPUBLISHED TRIAL

- **Focused** shock wave treatment
- 2000 impulsea, 0.25 mJ/mm²
- No local anaesthesia
- „Clinical Focusing“
- 3x in weekly intervals
- Follow-up 24 weeks after SWT

Shock Wave Treatment

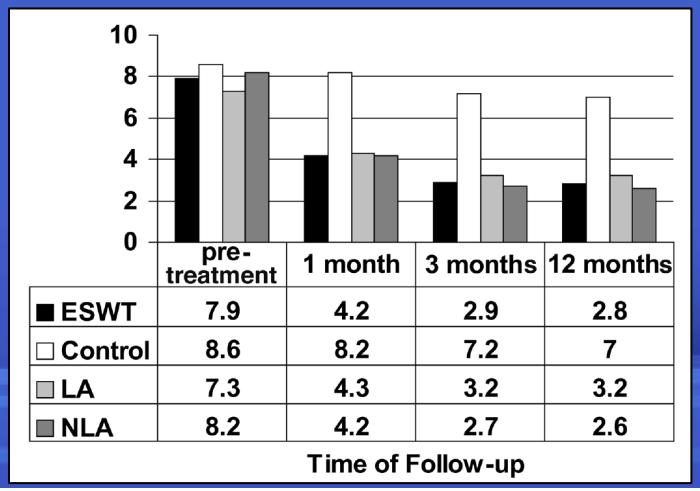
NO RANDOMIZED CONTROLS

Thirty-five patients with chronic **insertional Achilles te** [illegible] were treated with 1 dose of high-energy extracorporeal shock wave therapy and [illegible] treated with nonoperative therapy (control group).

One month, and 3 months, and 12 [illegible] treatment, the mean visual analog score for the control and ESWT group [illegible].2 (P < .001), 7.2 and 2.9 (P < .001), and 7.0 and 2.8 (P < .001), respecti[illegible]

Twelve months [illegible] the number of patients with successful Roles and Maudsley scores was st[illegible]ter in the ESWT group compared with the control group.

Furia 2006; Am J Sports Med 34:733



	pre-treatment	1 month	3 months	12 months
ESWT	7.9	4.2	2.9	2.8
Control	8.6	8.2	7.2	7
LA	7.3	4.3	3.2	3.2
NLA	8.2	4.2	2.7	2.6

Time of Follow-up

- **Focused** shock wave treatment
- 3000 Impulse, 0.2 mJ/mm²
- No local anaesthesia
- „Clinical Focusing“
- 1x
- Follow-up 12 weeks after SWT

Shock Wave Treatment

Forty-nine patients with chronic Achilles pain were enrolled in a double-blind randomized placebo-controlled trial. Each patient was **treated once a month for 3 months**. The primary outcome measure was a reduction in Achilles tendon pain during walking.

At 4 weeks after the last intervention, we found no difference in pain relief between the shock wave therapy group and the control group. There were two patients with tendon ruptures in the treatment group.

These results provide no support for the use of shock wave therapy for treatment of patients with chronic Achilles tendon pain.

Costa et al. 2005; Clin Orthop 440: 199

- **Focused** shock wave treatment
- 1500 Impulse, 0.2 mJ/mm²
- No local anaesthesia
- „Clinical Focusing“
- 3x in monthly intervals
- Follow-up 4 weeks after SWT

Why Shock Wave Treatment ?

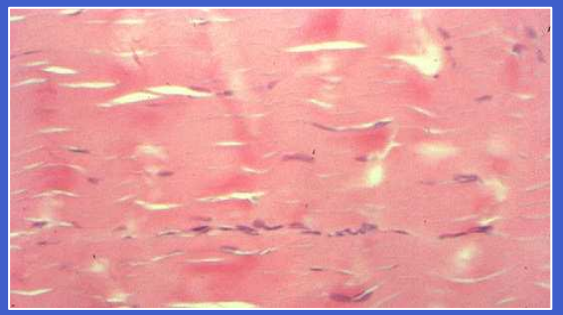
What can shock wave treatment do EXPERIMENTALLY ?

What can shock wave treatment do CLINICALLY ?

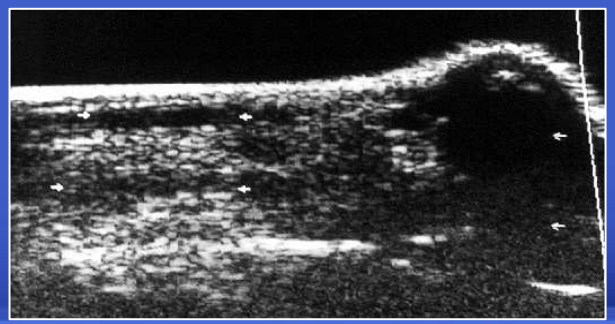
Shock Wave Treatment

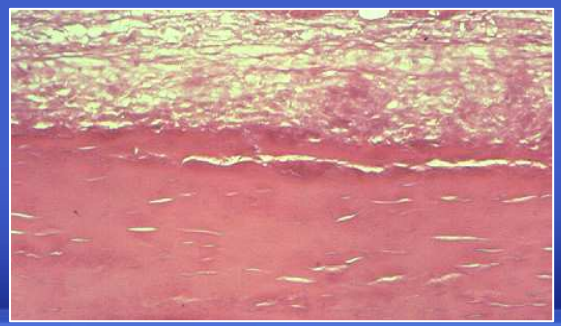
- may harm the Achilles tendon in a dose-dependent manner
  (2000 x 0.08 mJ/mm² vs. 0.60 mJ/mm²)

Rompe et al. 1998; JBJS 80-B: 546



Low-energy SWT
0.10 mJ/mm²



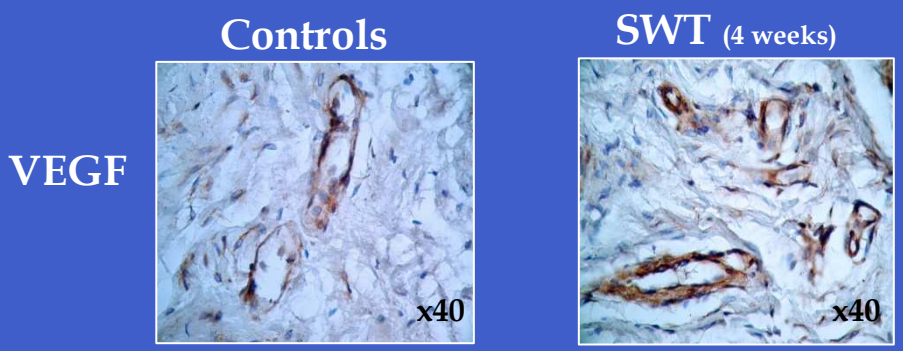


High-energy SWT
0.60 mJ/mm²

Low-energy SWT

- induces neovascularization at the Achilles tendon-bone junction (500 x 0.12 mJ/mm²)

Wang et al. 2003; J Orthop Res 21: 984



- induces healing, formation of capillaries and improves tensile strength of the Achilles tendon after a stab injury (0.16 mJ/mm²)

Orhan et al. 2004; JBJS 86-B: 613

Low-energy SWT

- induces healing of collagenase-induced Achilles tendinitis in a dose-dependent manner (0.16 mJ/mm²)

Chen et al. 2004; J Orthop Res 22: 854


Control
at 12 weeks

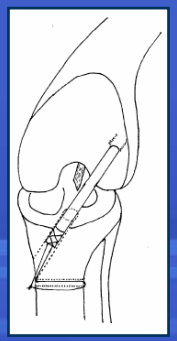

SWT
200 shocks
at 12 weeks

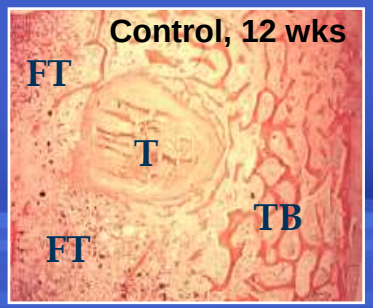

SWT
500 shocks
at 12 weeks

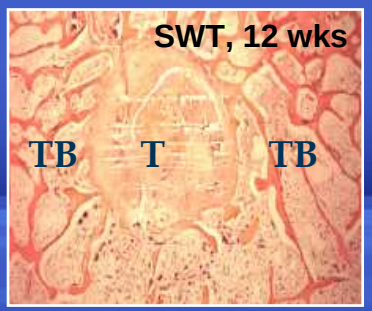

SWT
1000 shocks
at 12 weeks

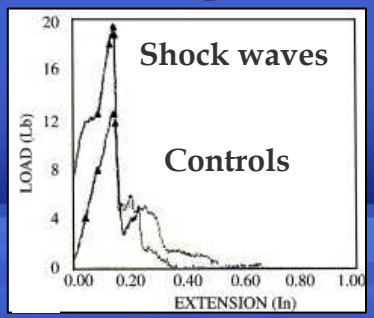
- improves the healing rate and tensile strength of the tendon-bone interface in a bone tunnel model (500 x 0.12 mJ/mm²)

Wang et al. 2005; J Orthop Res 23:274





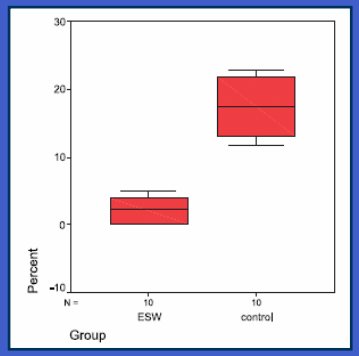




Low-energy SWT

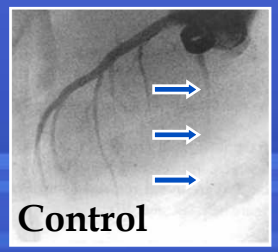
- reduces necrosis in a compromised - skin - flap model
  (1500 x 0.15 mJ/mm²)

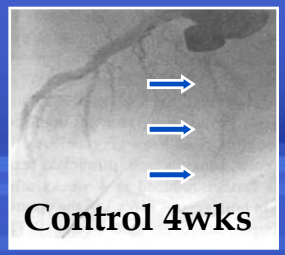
Meirer et al. 2005; Br J Plast Surg 58: 53
Meirer et al. 2007; J Reconstr Microsurg 23: 231

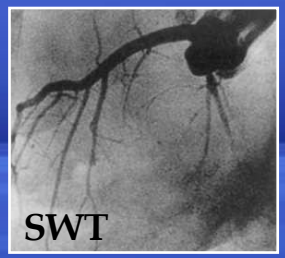


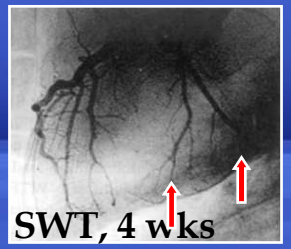
- induces collateral vessels and ameliorates ischemia-induced myocardial dysfunction (3x 4000 x 0.09 mJ/mm²)

Nishida et al. 2004; Circulation 110: 3055
Fukumoto et al. 2006; Cor Artery Dis 17: 63









Low-energy SWT

- induces healing of infected skin defects (5x 2000 x 0.06 mJ/mm²)

Schaden et al. 2005; ISMST Vienna

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

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Safety & Efficacy Study for the Use of Extracorporeal Shockwaves in the Treatment of Diabetic Foot Ulcers

This study is currently recruiting patients.
Verified by Tissue Regeneration Technologies August 2006

Sponsored by:	**Tissue Regeneration Technologies**
Information provided by:	Tissue Regeneration Technologies
ClinicalTrials.gov Identifier:	NCT00366132

Purpose

The purpose of this clinical study is to compare the safety and effectiveness of shockwave treatment combined with standard-of-care treatment, to standard-of-care treatment alone to induce healing of a chronic plantar foot ulcer in subjects with diabetes mellitus. For the purpose of this study, the definition of plantar foot ulcer is a wound or open sore that involves the plantar(bottom) aspect of the foot, and the definition of chronic is a duration of 6 weeks or greater with a lack of response to treatment.

Condition	Intervention	Phase
Chronic Diabetic Foot Ulcers	Device: Extracorporeal Shockwaves	Phase II

Why Shock Wave Treatment ?

What can shock wave treatment do EXPERIMENTALLY ?

What can shock wave treatment do CLINICALLY ?

- Achilles Tendinopathy

Trial # 1

Eccentric loading, shock wave treatment, or a wait-and-see policy for tendinopathy of the main body of tendo Achillis: a randomized controlled trial

Jan D. Rompe, Bernhard Nafe, John Furia, Nicola Maffulli

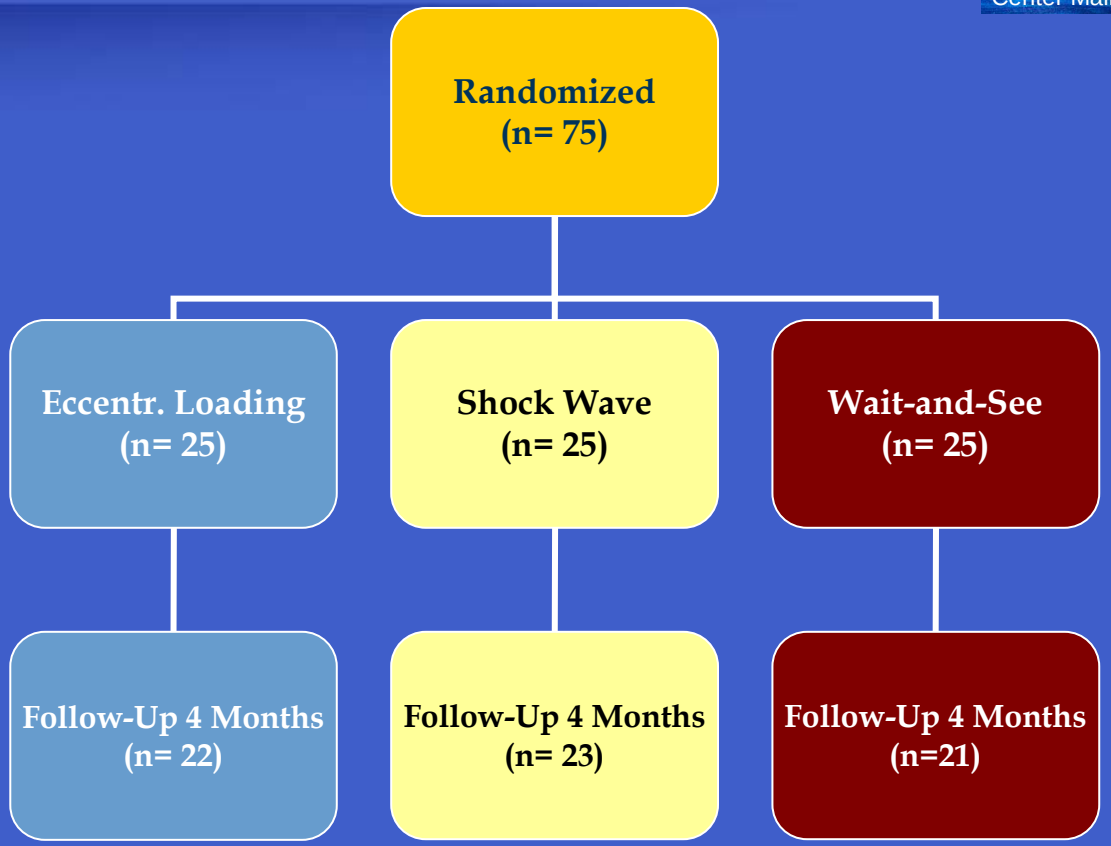
Am J Sports Med 2007; 35:374-383

Low-energy SWT

A Randomization Plan
from
http://www.randomization.com

1. Stretching
2. ESWT
3. Stretching
4. ESWT
5. ESWT
6. Wait and See
7. Wait and See
8. Stretching
9. Wait and See
10. ESWT
11. Wait and See
12. ESWT
13. Wait and See
14. Wait and See
15. Stretching
16. ESWT
17. Stretching
18. Stretching
19. ESWT
20. ESWT
21. Stretching
22. Wait and See
23. Wait and See
24. Stretching
25. Stretching
26. ESWT
27. Wait and See
28. ESWT
29. Wait and See
30. Wait and See
31. Stretching
32. ESWT
33. Stretching
34. Stretching
35. Wait and See
36. ESWT
37. ESWT
38. Wait and See
39. Wait and See
40. ESWT
41. ESWT
42. Stretching
43. Wait and See
44. Stretching
45. Stretching

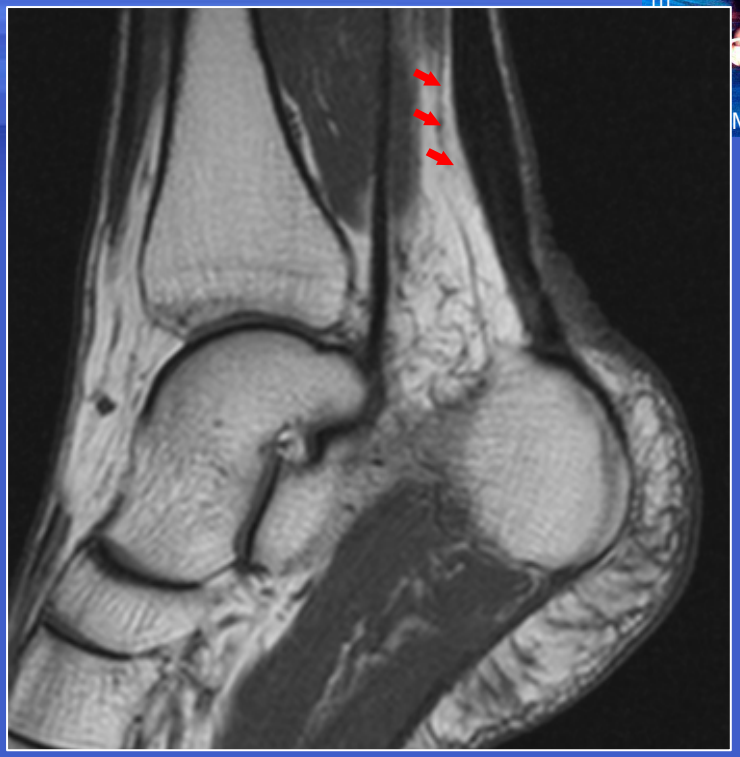
Computer-generated random number list
Subjects randomized into blocks

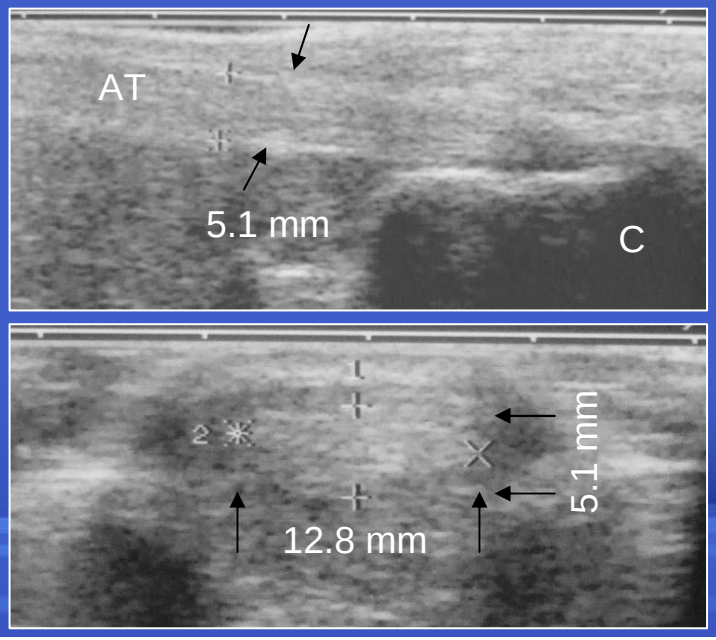


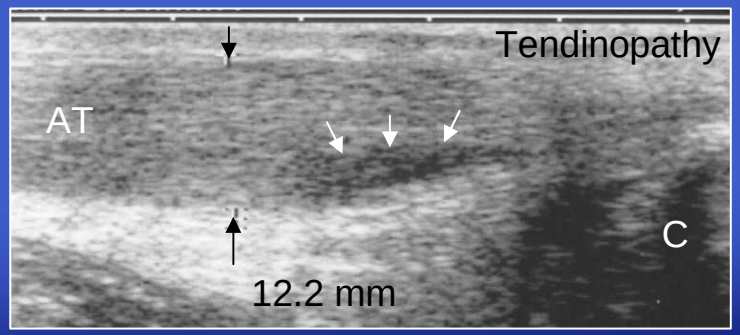
3 Groups
Blinded Observer
Evaluation: On-Intention-to-Treat

Inclusion Criteria

- Tendinopathy
- Body of tendo Achillis
- Painful > 6 Months
- > 3 conservative therapies
  (Local injection mandatory)
- Pain > 4 on NRS [0-10]
- No rupture in ultrasound / MRI







Group 1: Eccentric Loading

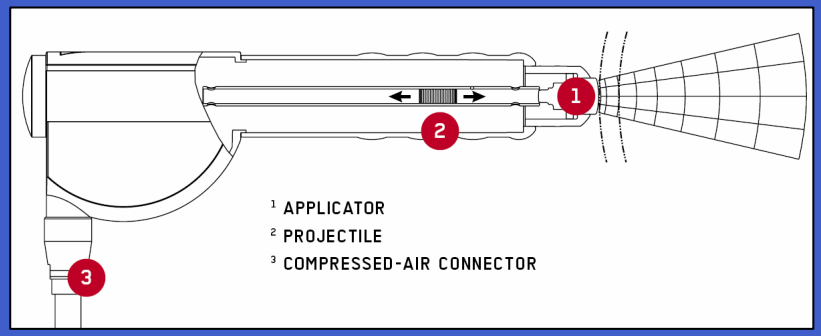
Seventy-eight consecutive patients, having chronic painful Achilles tendinosis at the mid-portion (2-6 cm level) in 101 Achilles tendons were treated with eccentric calf-muscle training for 12 weeks.

In 90 of the 101 Achilles tendons (89%) with chronic painful mid-portion Achilles tendinosis, treatment was satisfactory and the patients were back on their pre-injury activity level after the 12-week training regimen. In these patients, the amount of pain during activity, registered on the VAS-scale decreased significantly from 6.7 to 1.0.

Fahlstrom et al. 2003; Knee Surg Sports Traumatol Arthrosc 11: 327

Group 2: Shock Wave Treatment

Swiss Dolorclast, EMS, Switzerland



- **Radial** shock wave treatment
- 2,000 impulses, 0.12 mJ/mm² (~ pressure of 2.5 bar)
- No local anaesthesia
- „Clinical Focusing“
- 3x in weekly intervals

Group 3: Wait-and-See

Patients allocated to the **wait-and-see policy** group visited their family doctor once during the intervention period of 6 weeks. Activities that provoked pain, and practical solutions (including ergonomic advice) were discussed with the patient. If necessary, paracetamol (2000-4000 mg daily) or non-steroidal anti-inflammatory drugs (NSAIDs, naproxen 1000 mg daily) were prescribed. The patient was encouraged to await further spontaneous improvement.

Smidt et al. 2002; Lancet 359: 657

- 1 further visit during 3-month period
- Practical advice
- Control of running shoes (over-pronation)
- Shoe inserts
- Conventional stretching exercises
- Paracetamol (2000 mg/d) or
- Naproxen (1000 mg/d)

Outcome Assessment

VISA- A Score (0 points - 100 points)

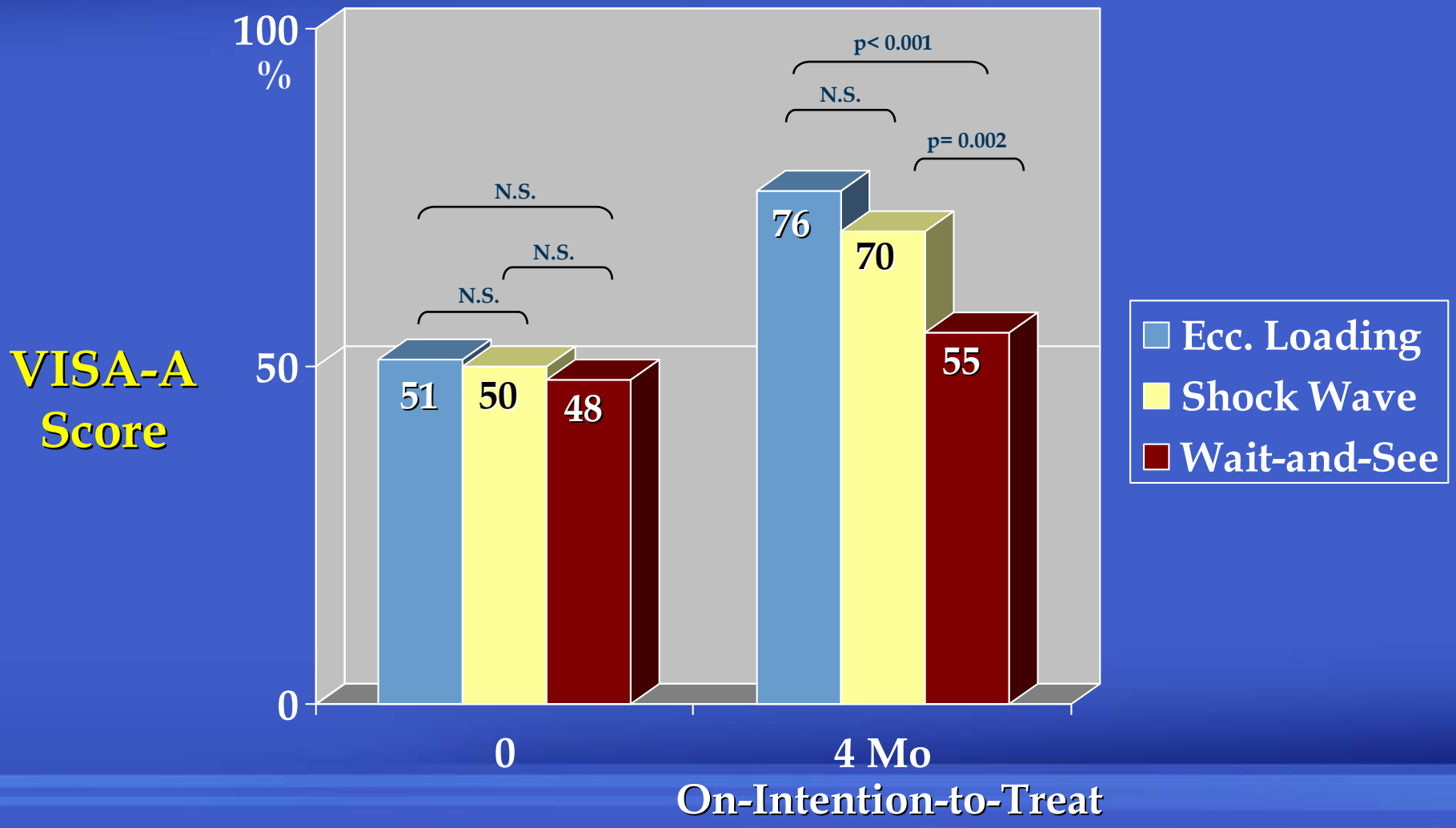
Pain Threshold: **minimum pressure (kg) which induced pain in the most tender area**

Algometer
(Pain Test-Model FPK,
Wagner Instruments, Greenwich, CT)

11-point Numeric Rating Scale (NRS) (0 [best] – 10 [worst])

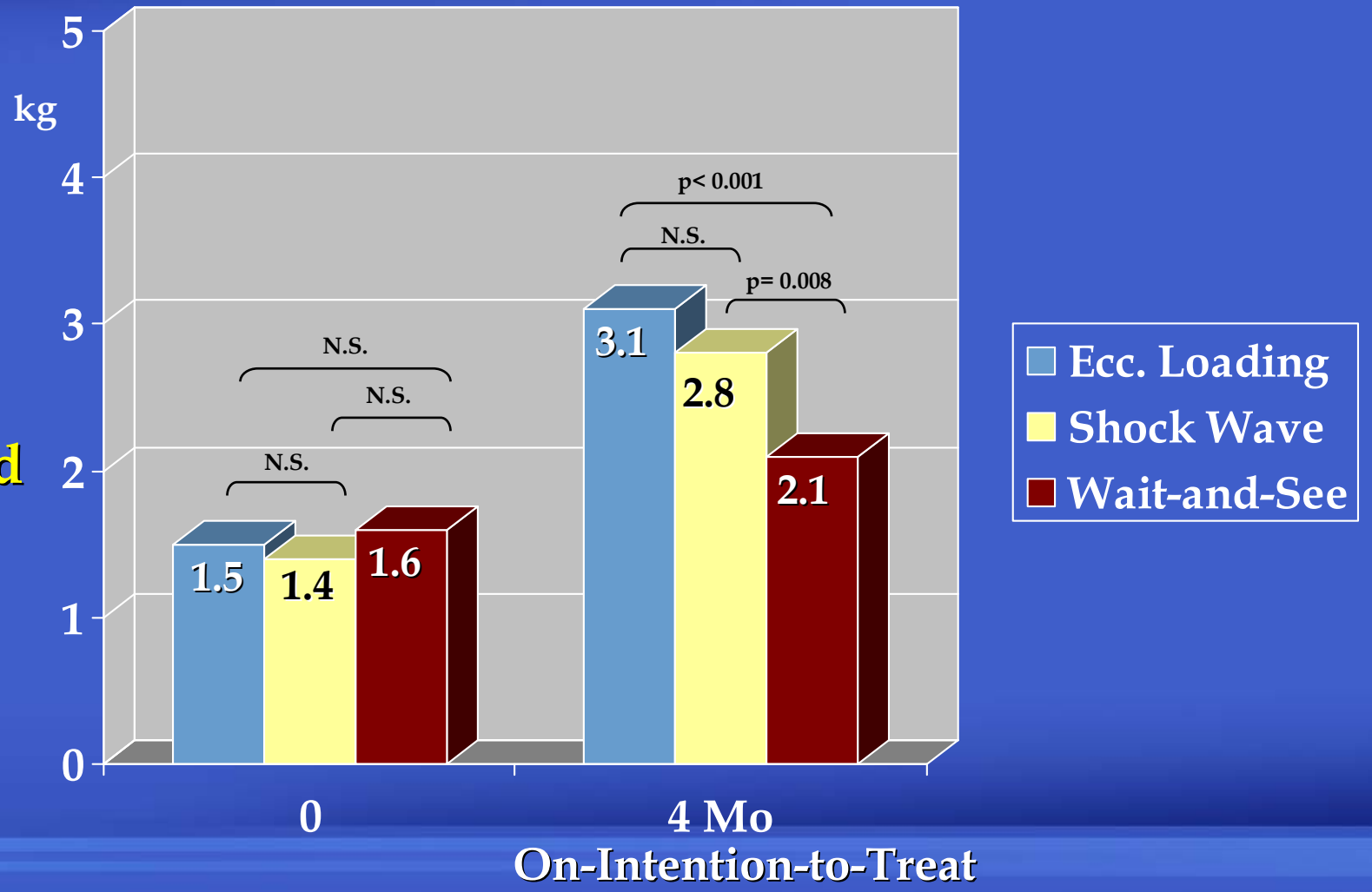
6-point LIKERT scale (1 [best] – 6 [worst])

Results: Main Outcome Measure

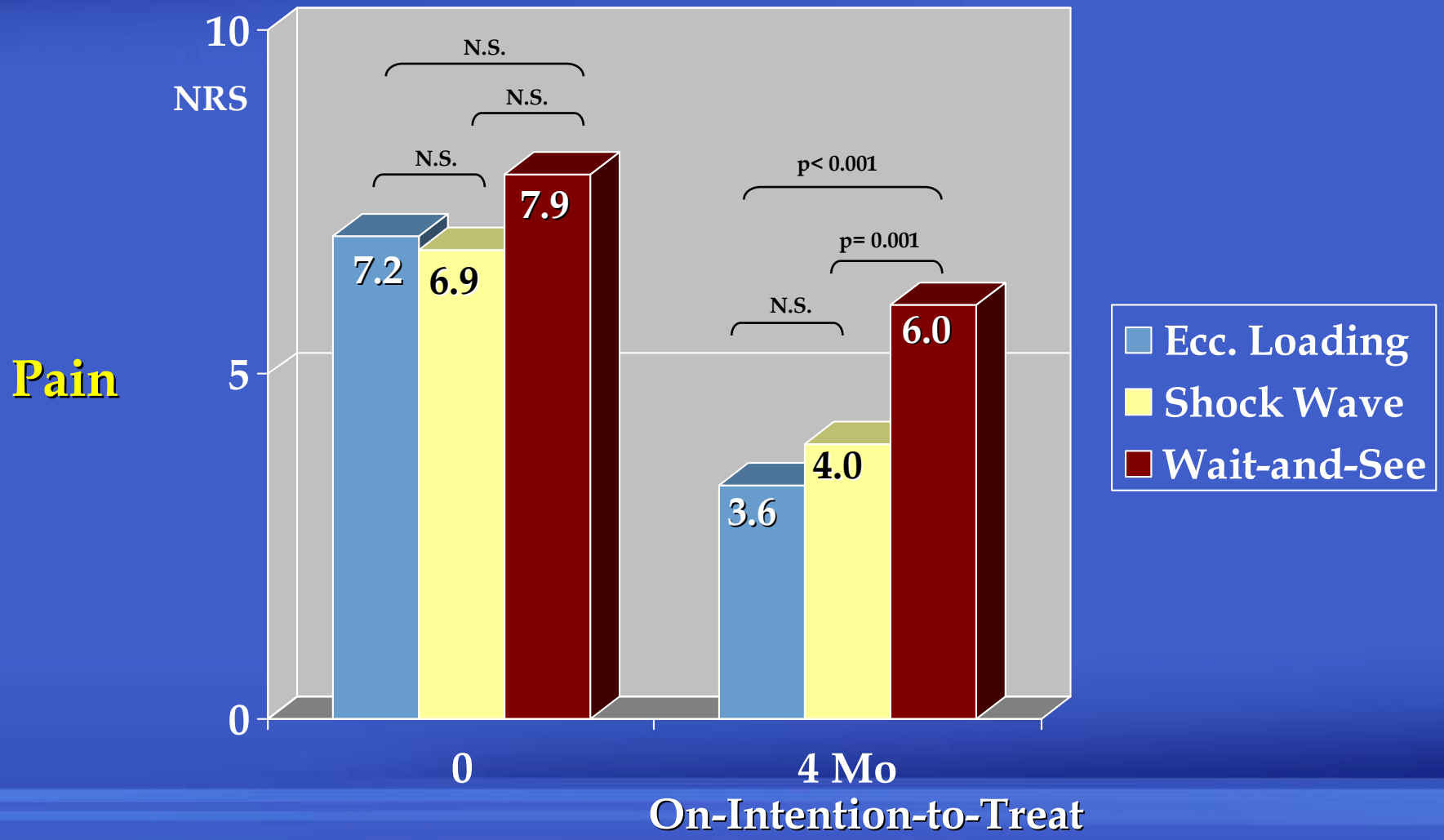


Results: Secondary Outcome Measures

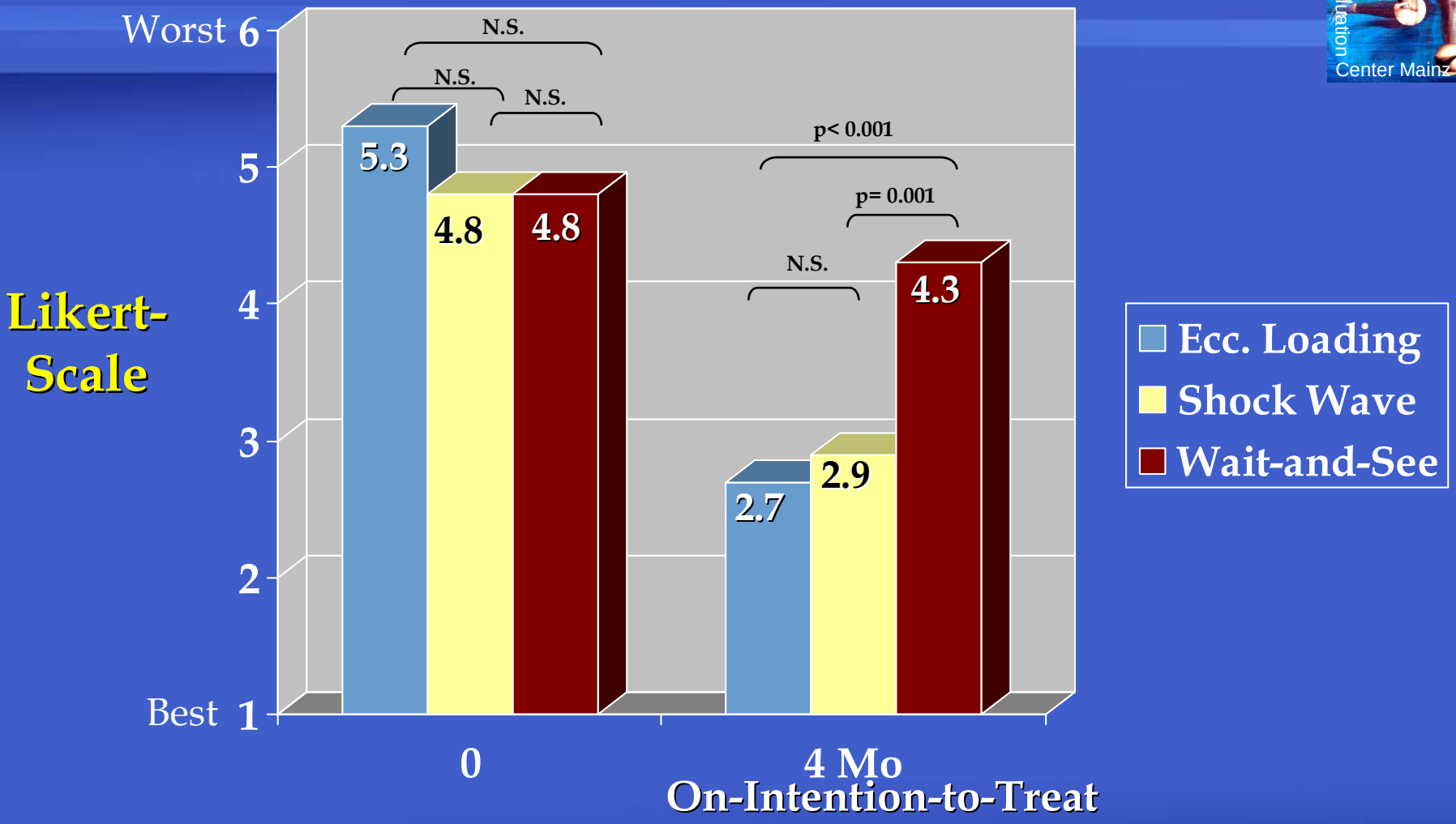
Pain Threshold



Results: Secondary Outcome Measures



Results: Secondary Outcome Measures



60% vs. 53% vs. 24% reported 1 or 2 points on the LIKERT Scale

Results: 12 Months

GROUP 1 (Eccentric Training, ET)
4 months from baseline
Analyzed (n= 25)

SUCCESS
n= 15

FAILURE
n= 10

Cross-Over

SWT
n= 8

Surg
n= 2

12 months from baseline
Analyzed (n= 15)
Contacted (n= 10)
Lost to FU (n= 5)
Last value carried forward
(n= 5)

12 months from baseline
Analyzed (n= 10)
Contacted (n= 7)
Lost to FU (n= 3)
Last value carried forward
(n= 3)

SUCCESS (S)
(n= 11)

FAILURE (F)
(n= 4)

S
(n=6)

F
(n=2)

S
(n=0)

F
(n=2)

GROUP 2 (Shock wave therapy, SWT)
4 months from baseline
Analyzed (n= 25)

SUCCESS (S)
n= 13

FAILURE (F)
n= 12

Cross-Over

ET
n= 7

Surg
n= 2

Inj
n= 3

12 months from baseline
Analyzed (n= 13)
Contacted (n= 9)
Lost to FU (n= 4)
Last value carried forward
(n= 4)

12 months from baseline
Analyzed (n= 12)
Contacted (n= 10)
Lost to FU (n= 2)
Last value carried forward
(n= 2)

SUCCESS (S)
(n= 11)

FAILURE (F)
(n= 2)

S
(n=4)

F
(n=3)

S
(n=0)

F
(n=2)

S
(n=1)

F
(n=2)

GROUP 3 (Wait-and-see, W/S)
4 months from baseline
Analyzed (n= 25)

SUCCESS (S)
n= 6

FAILURE (F)
n= 19

Cross-Over

ET
n= 4

SWT
n= 3

ET+SWT
n= 11

Surg
n= 1

12 months from baseline
Analyzed (n= 6)
Contacted (n= 4)
Lost to FU (n= 2)
Last value carried forward
(n= 2)

12 months from baseline
Analyzed (n= 19)
Contacted (n= 18)
Lost to FU (n= 1)
Last value carried forward
(n= 1)

SUCCESS (S)
(n= 5)

Failure (F)
(n= 1)

S
(n=2)

F
(n=2)

S
(n=2)

F
(n=1)

S
(n=9)

F
(n=2)

S
(n=1)

F
(n=0)

Summary I

- **Wait-and-See in chronic patients no better than placebo effect, ≤ 30%**

- **Eccentric loading and low-energy SWT comparably successful, ≤ 60%**

Concerns: ecc. loading – concept hard to standardize
– problem of compliance

SWT – cost considerations

Summary II

Low-energy SWT is NOT SUCESSFUL under all circumstances

Forty-nine patients with chronic Achilles pain were enrolled in a double-blind randomized placebo-controlled trial. Each patient was **treated once a month** for 3 months.

At **4 weeks after** the last intervention, we found **no difference** in pain relief between the shock wave therapy group and the control group.

Costa et al. 2005; Clin Orthop 440: 199

→ **chronic patients only**
repetitive, 3x in weekly intervals
2000 low-energy impulses
clinical focusing, NO local anaesthesia
follow-up 12 weeks after last SWT

Summary III

Eccentric loading is NOT SUCCESSFUL under all circumstances

We studied the effects of eccentric exercises in 34 sedentary non-athletic patients with Achilles tendinopathy.

19 patients (60%) improved with the eccentric exercise regimen. The overall average VISA-A scores at latest follow up was 50.

Sayana and Maffulli 2006; J Sci Med Sport; Epub ahead of print

→ **less effective in sedentary patients**

What are the alternatives ?

Debridement
(+ Plantaris Augmentation)

Percutaneous
Tenotomies

What are the alternatives ?

Surgery is NOT SUCCESSFUL under all circumstances

We matched each of the 61 nonathletic patients with a diagnosis of tendinopathy of the Achilles tendon with an athletic patient with tendinopathy of the main body of the Achilles tendon of the same sex and age (+/-2 years). A match was possible for 56 patients (23 males and 33 females). **All patients undwerwent open surgery for Achilles tendinopathy.**

Of the 48 nonathletic patients, 9 underwent further surgery during the study period, and **only 25 (52%) reported an excellent or good result at 3-year follow-up.** Of the 45 athletic subjects, 4 underwent further surgery during the study period, and 36 (80%) reported an excellent or good result.

Nonathletic subjects experience more prolonged recovery, more complications, and a greater risk of further surgery than athletic subjects with recalcitrant Achilles tendinopathy.

Mafulli et al. 2006; Clin J Sport Med 16: 123

Trial # 2

Eccentric loading versus shock wave treatment for chronic tendinopathy of the insertion of tendo Achillis: a randomized controlled trial

Jan D. Rompe, John Furia, Nicola Maffulli

J Bone Joint Surg [Am] 2007; in press

Low-energy SWT

Randomization Plan
from
http://www.randomization.com

1. EL
2. SWT
3. SWT
4. SWT
5. SWT
6. EL
7. EL
8. EL
9. SWT
10. EL
11. SWT
12. EL
13. SWT
14. EL
15. SWT
16. EL
17. EL
18. SWT
19. SWT
20. EL
21. SWT
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25. SWT
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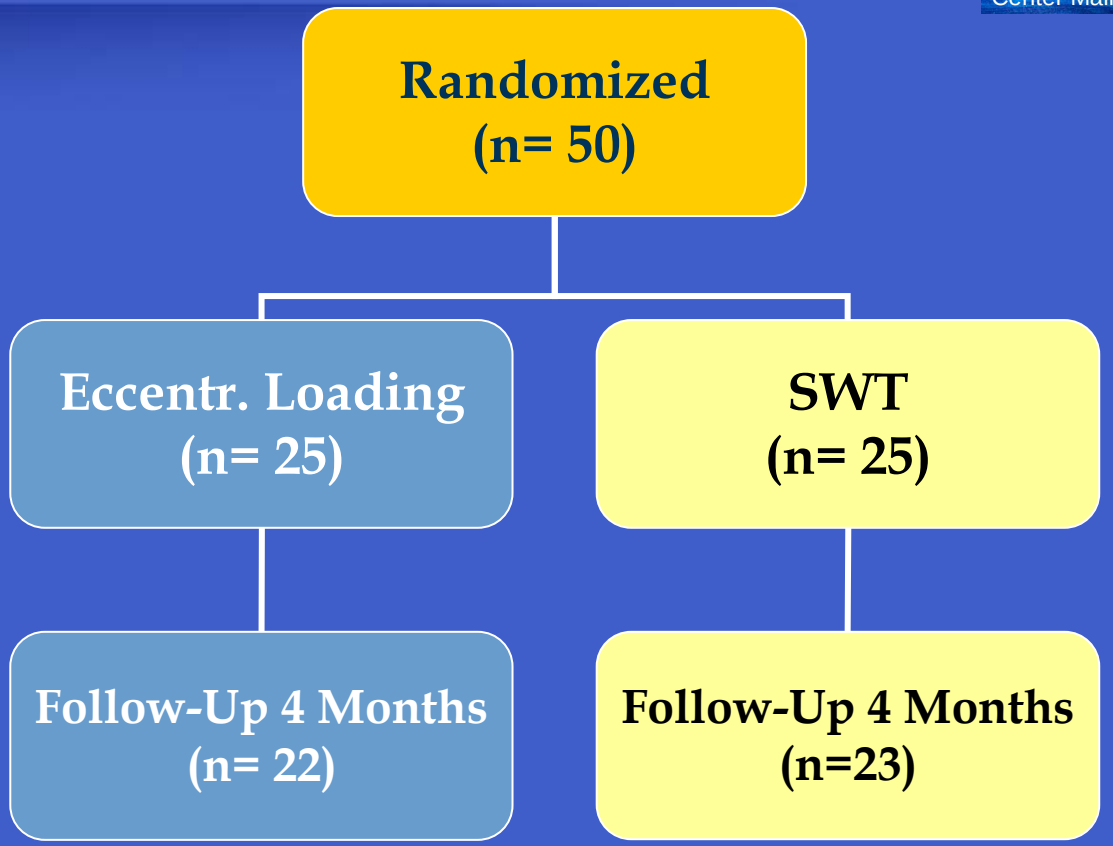
32. EL
33. SWT
34. SWT
35. EL
36. SWT
37. EL
38. EL
39. SWT
40. EL
41. EL
42. SWT
43. EL
44. EL
45. EL
46. SWT
47. SWT
48. EL
49. SWT
50. SWT

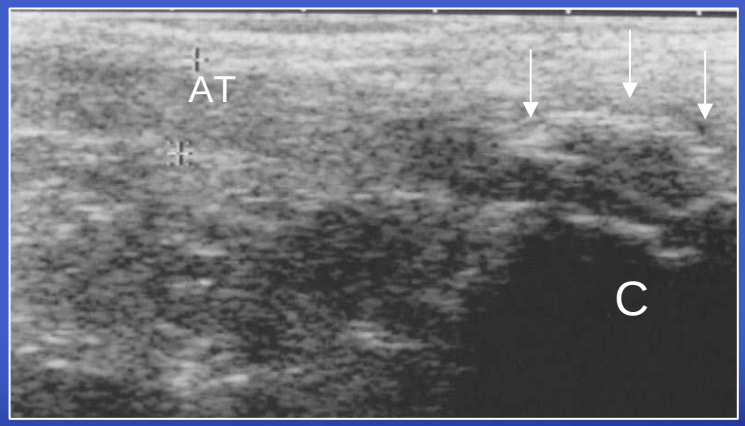


Computer-generated random number list
Subjects randomized into blocks

2 Groups
Blinded Observer
Evaluation: On-Intention-to-Treat

Inclusion Criteria

- Tendinopathy
- Insertion of tendo Achillis
- Painful > 6 Months
- > 3 conservative therapies
  (Local injection mandatory)
- Pain > 4 on NRS [0-10]
- No rupture in ultrasound / MRI



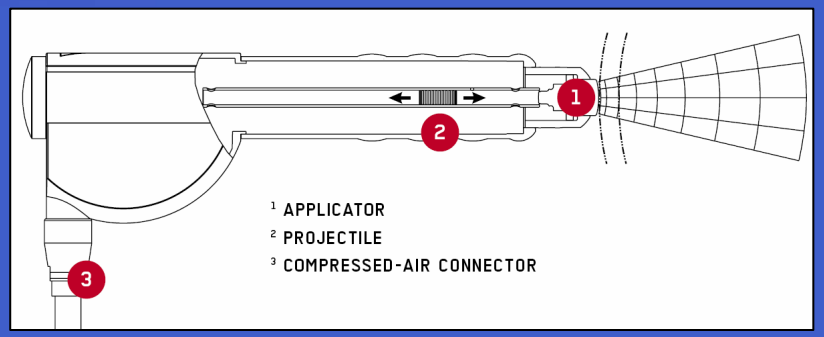
Group 1: Eccentric Loading

Seventy-eight consecutive patients, having chronic painful Achilles tendinosis at the mid-portion (2-6 cm level) in 101 Achilles tendons were treated with eccentric calf-muscle training for 12 weeks.

In 90 of the 101 Achilles tendons (89%) with chronic painful mid-portion Achilles tendinosis, treatment was satisfactory and the patients were back on their pre-injury activity level after the 12-week training regimen. In these patients, the amount of pain during activity, registered on the VAS-scale decreased significantly from 6.7 to 1.0.

Fahlstrom et al. 2003; Knee Surg Sports Traumatol Arthrosc 11: 327

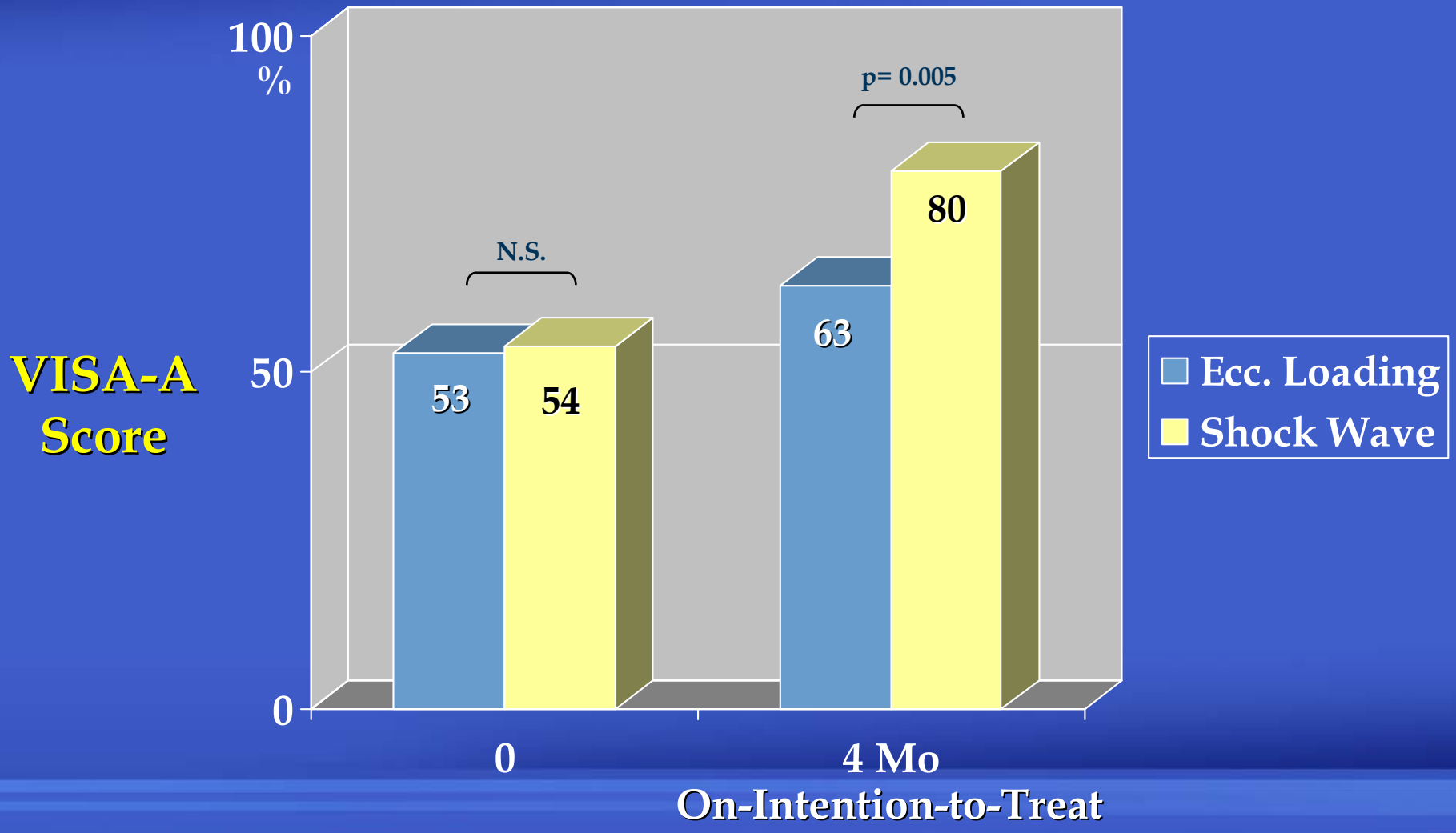
Group 2: Shock Wave Treatment



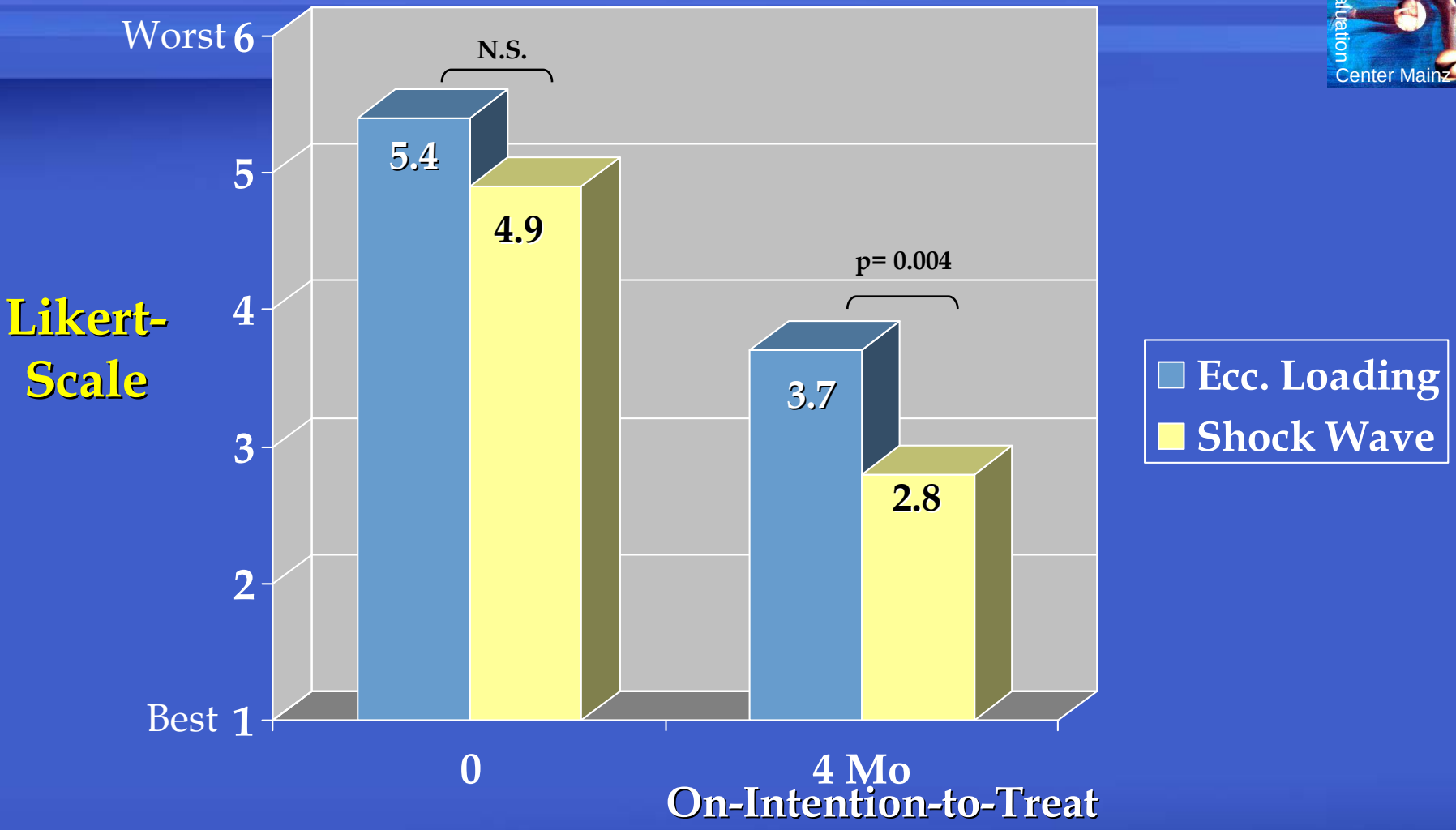
- **Radial** shock wave treatment
- 2,000 impulses, 0.12 mJ/mm² (~ pressure of 2.5 bar)
- No local anaesthesia
- „Clinical Focusing“
- 3x in weekly intervals

Swiss Dolorclast, EMS, Switzerland

Results: Main Outcome Measure



Results: Secondary Outcome Measures



28% vs. 64% reported 1 or 2 points on the LIKERT Scale

Summary

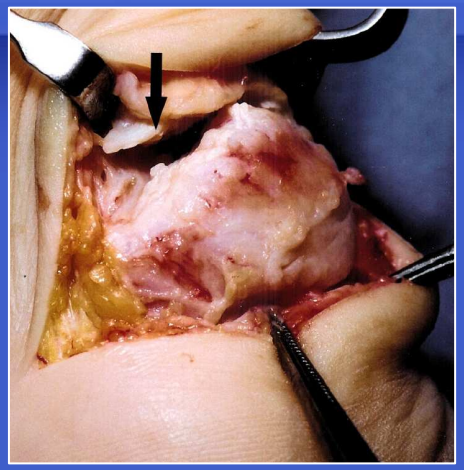
Eccentric loading is NOT SUCCESSFUL under all circumstances

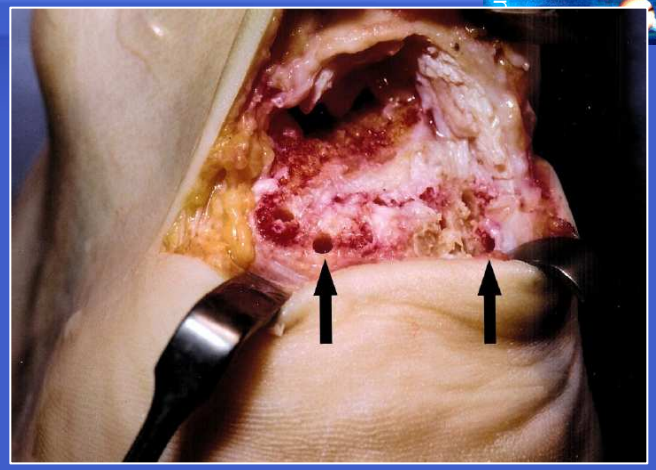
50 patients with a chronic recalcitrant **insertional Achilles tendinopathy** were enrolled in a randomized controlled study to compare the effectiveness of two management strategies: Group 1: **eccentric loading**; Group 2: repetitive low-energy **shock wave therapy** (SWT).

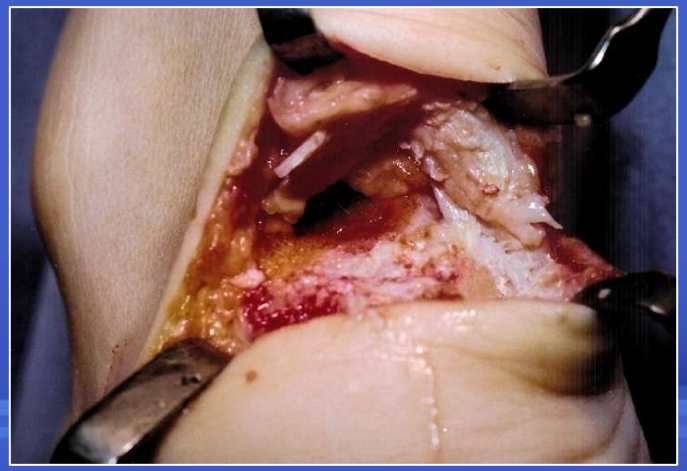
At 4 months from baseline, for all outcome measures, group 1 and 2 differed significantly in favor of SWT. On the LIKERT scale 28% of Group 1, and 64% of Group 2 reported “completely recovered” or “much improved”.

→ **less effective in insertional Achilles tendinopathy**

What are the alternatives ?







Take-home Message

Musculoskeletal SWT

- has completely gone beyond the concept of pure physical and mechanical implications known from lithotripsy of kidney stones
- produces biological healing responses at the tissue level, including the induction of neovascularization associated with increased expression of angiogenic growth factors - BIOSURGERY
- has demonstrated good outcomes in 50-60% of various refractory tendinopathies within 3-6 months in numerous RCTs
- is safe, noninvasive and, when performed adequately, is associated with virtually no side effects / morbidity
- circumvents the need for immobilization and restricted weight bearing, usually there is no lost time from work