

Presentation of the first German SpineMED® Study

- Doctor Dissertation: “Clinical Outcome of Back Pain after SpineMED® Therapy” by Alexander Dittmar
- Doctor Thesis Supervisor: PD Dr. med. Manfred Pfahler
- Ludwig Maximilian University of Munich
- Duration of Study: Sept. 2011 – Feb. 2013

Clinical Relevance

- Every 5th male and every 7th female suffers from chronic cervical and/or lumbar back pain
- Most common sort of pain in the population
- Large variety of back pathologies (Disc prolaps, Protrusion, Sciatica, Facet syndrome, Stenosis, etc.)

Study Design

- Examination of 100 patients treated with SpineMED® Decompression
- Standardized physical pre- and post outcome measures
- Standardized and consistent questionnaires (VAS, Oswestry-Disability-Index, Neck-Disability-Index)

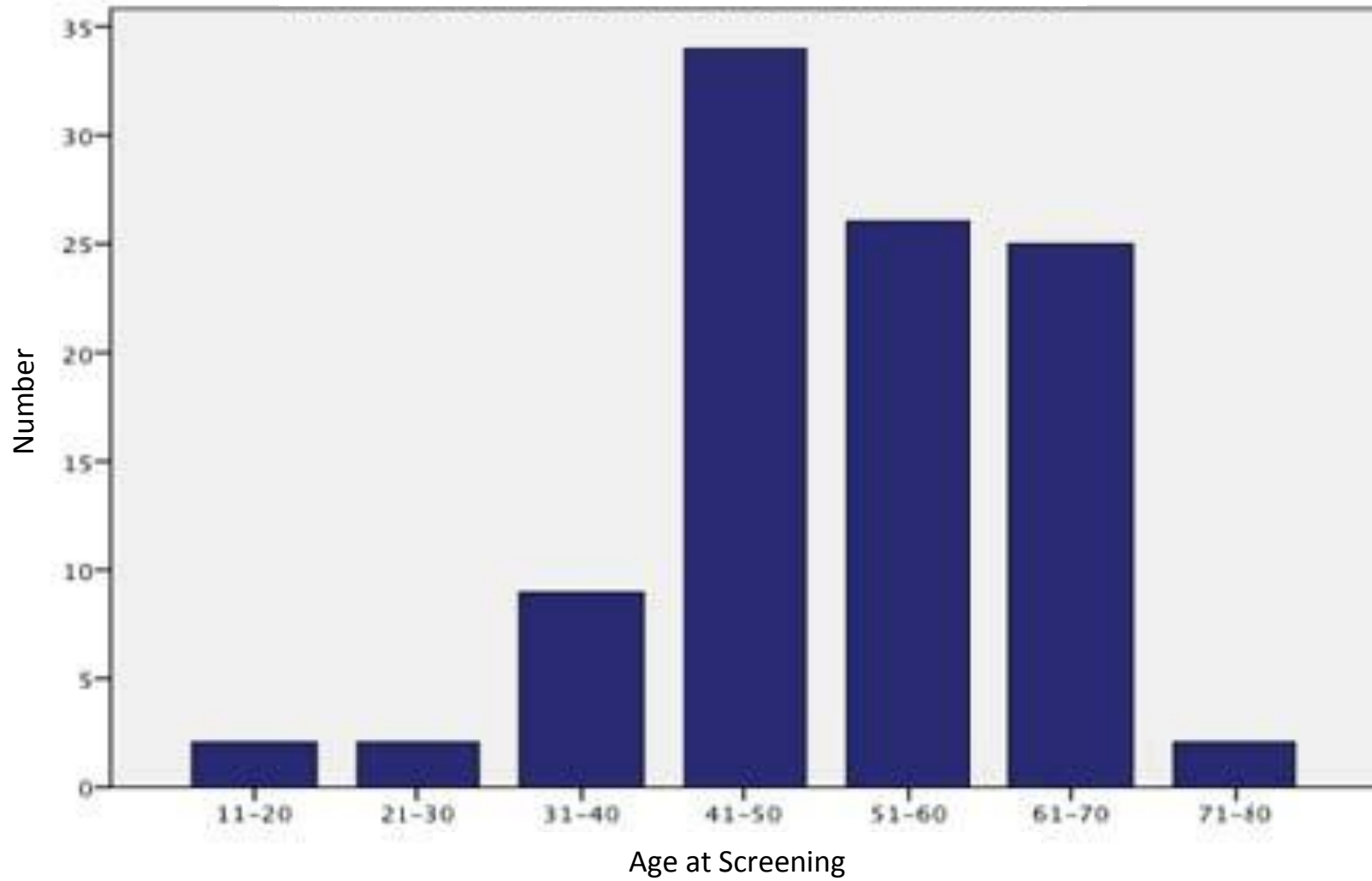
Study Design

- Minimum follow-up of 6 months.
- Maximum follow-up of 1 year.
- Inclusion criteria: 20 treatment sessions with SpineMED[®] following correct indication/diagnosis
- Exclusion criteria: patients post surgery.

Patient Sample

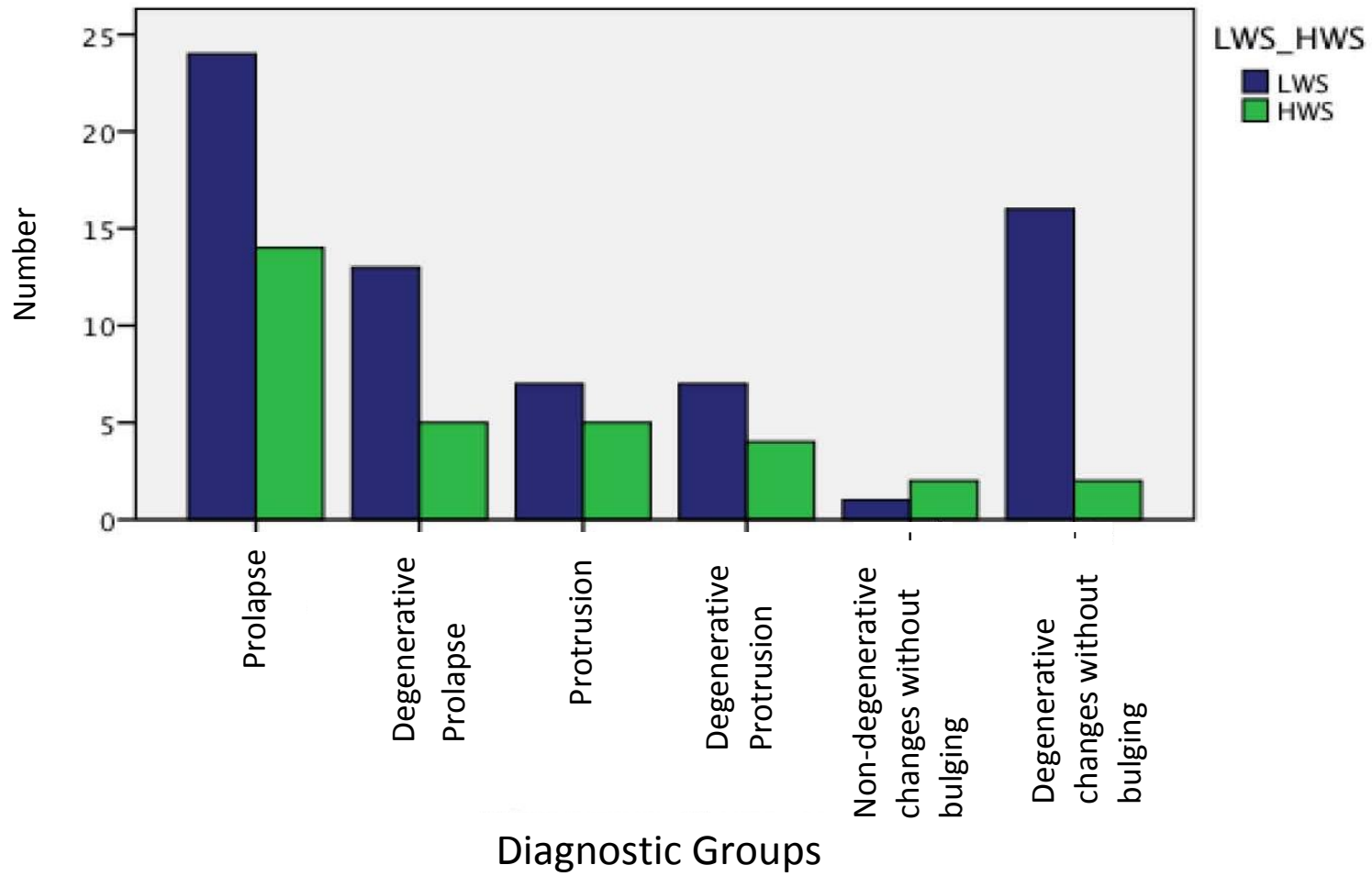
- 100 patients enrolled. 47 female, 53 male.
- 68 patients with Lumbar pathology (32 female, 36 male)
- 32 patients with cervical pathology (15 female, 17 male)
- Mean age 52.06 years

Age Distribution of Investigations



Methods & Materials

- Average treatment duration (for 20 sessions): 56 days
- Post Measurements average 8.04 months after last SpineMED[®] session
- Timeline between pre and post measurements average 10.2 months



Segment	Frequency	Percent
L1-3	1	1.5
L3-4	1	1.5
L4-5	18	26.5
L5-S1	20	29.4
L3-5	5	7.4
L4-S1	19	27.9
Multisegmental	4	5.9
Total	68	100.0

Segment	Frequency	Percent
C2-4	2	6.3
C5-6	12	37.5
C6-7	4	12.5
C3-5	2	6.3
C5-7	9	28.1
Multisegmental	4	5.9
Total	68	100.0

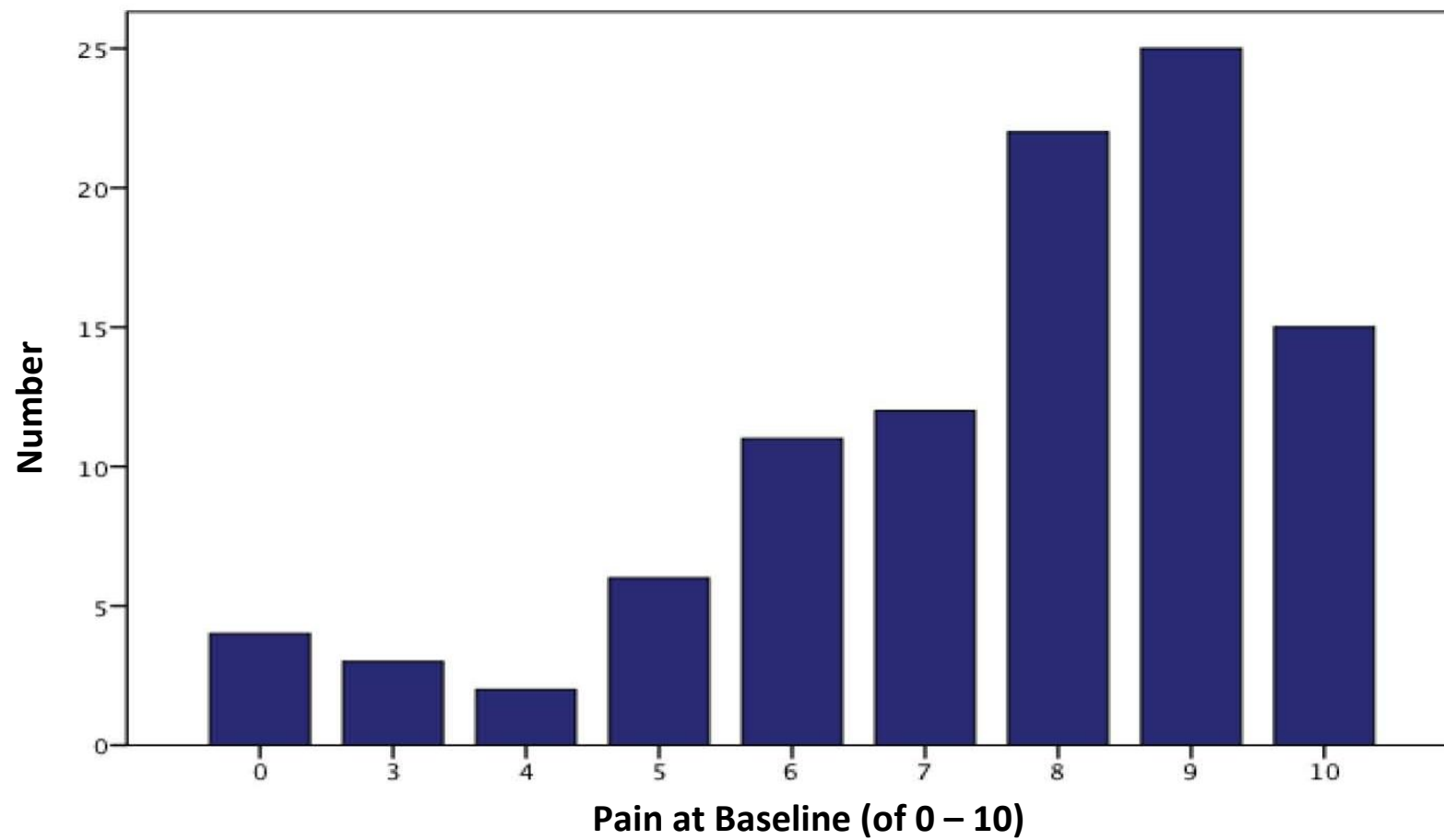
Investigation Type	Entrance Examination Lumbar	Check-Up Lumbar	Entrance Examination Cervical	Check-Up Cervical
Inspection	32	15	17	1
Farming	14	13	13	15
Toe-walking	2	1	0	0
Hack Gear	3	1	0	0
Legged Stance	3	3	0	0
Pelvic Obliquity	11	10	6	6
Local Tenderness	64	29	31	9
Scoliosis	14	14	8	8
Cervical Examination	14	4	23	9
Reflex Status	3	0	0	0
Referred Pain	57	14	31	8
Psoas Sign	27	12	1	1
Lasègue Characters	31	9	1	1
Bragard Characters	30	9	1	1
Velleix Pressure Points	43	6	1	0

Results

Paired t-test significant ($p < 0.05$) for the following measurements:

- Lumbar group:
Inspection, local tenderness on palpation, physical examination lumbar spine, pain radiation, Psoas-, Lasegue-, and Bragard-Test, Valleix's points.
- Cervical group: Inspection, local tenderness on palpation, physical examination cervical spine, pain radiation.

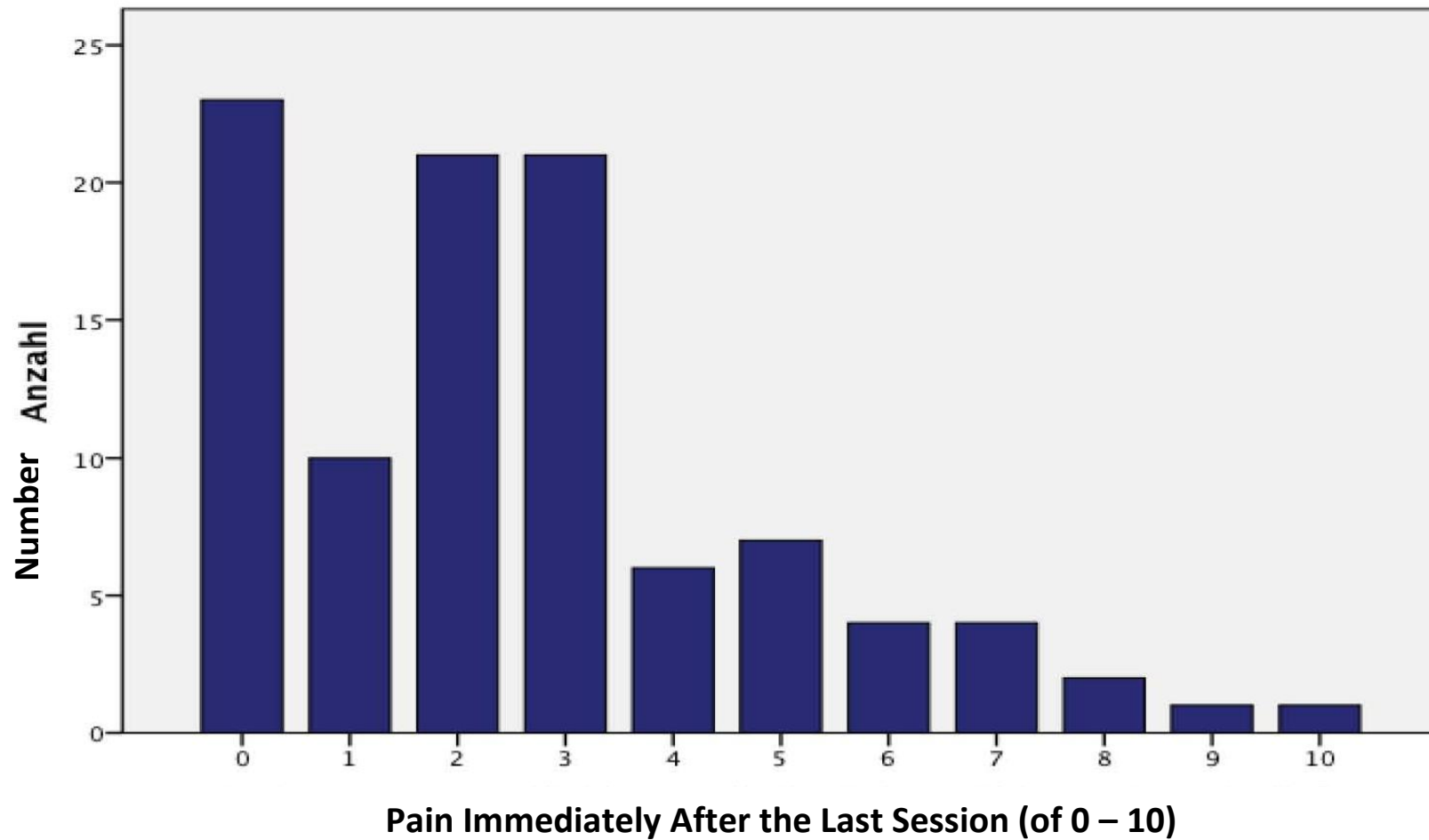
Visual Analogue Scale



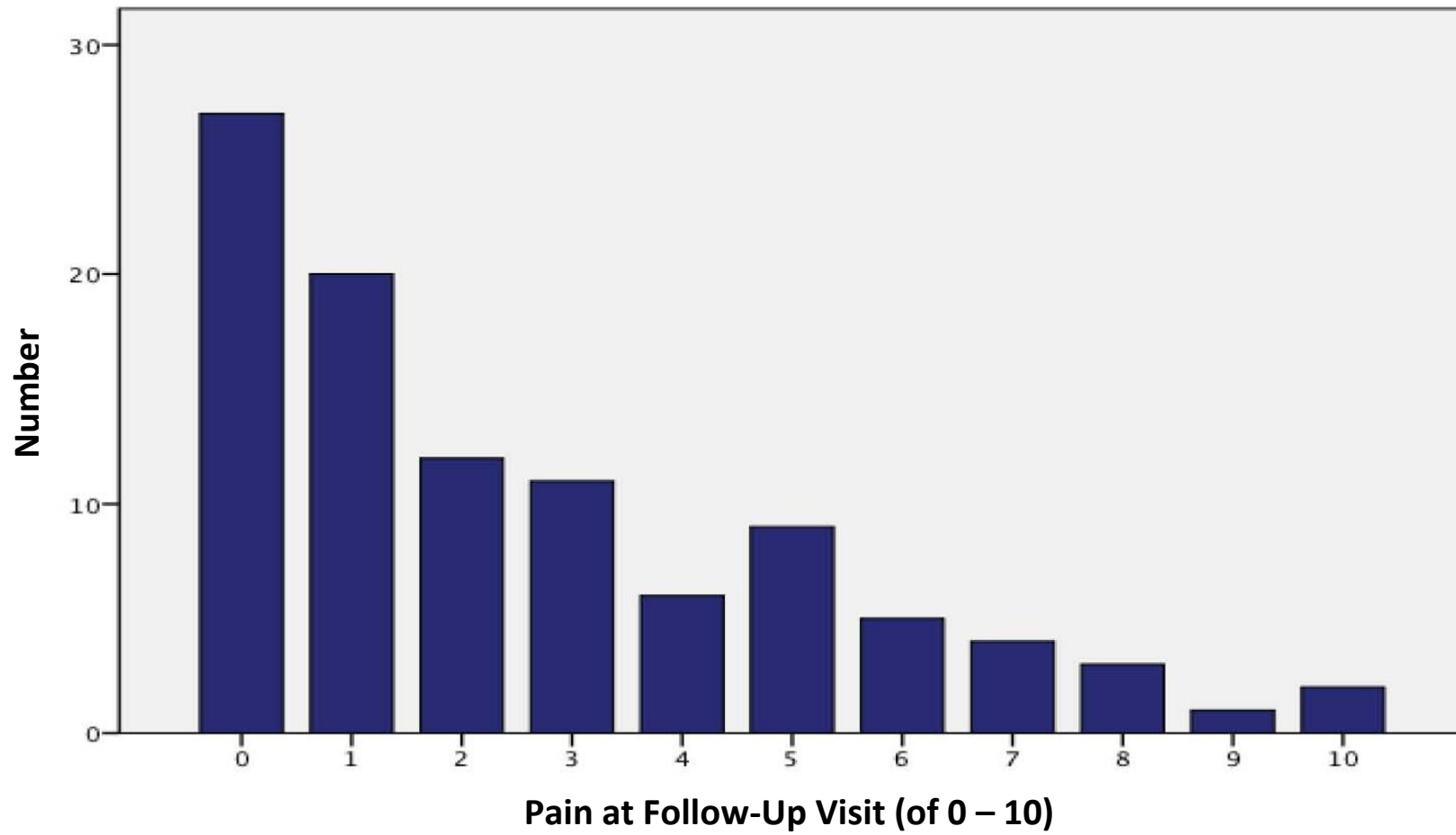
Results VAS

- Increase of pain in 2 patients
- Average reduction of pain from 7.48 to 2.57 (4.91 points) during therapy
- Post measurements showed a pain of 2.57 in average.

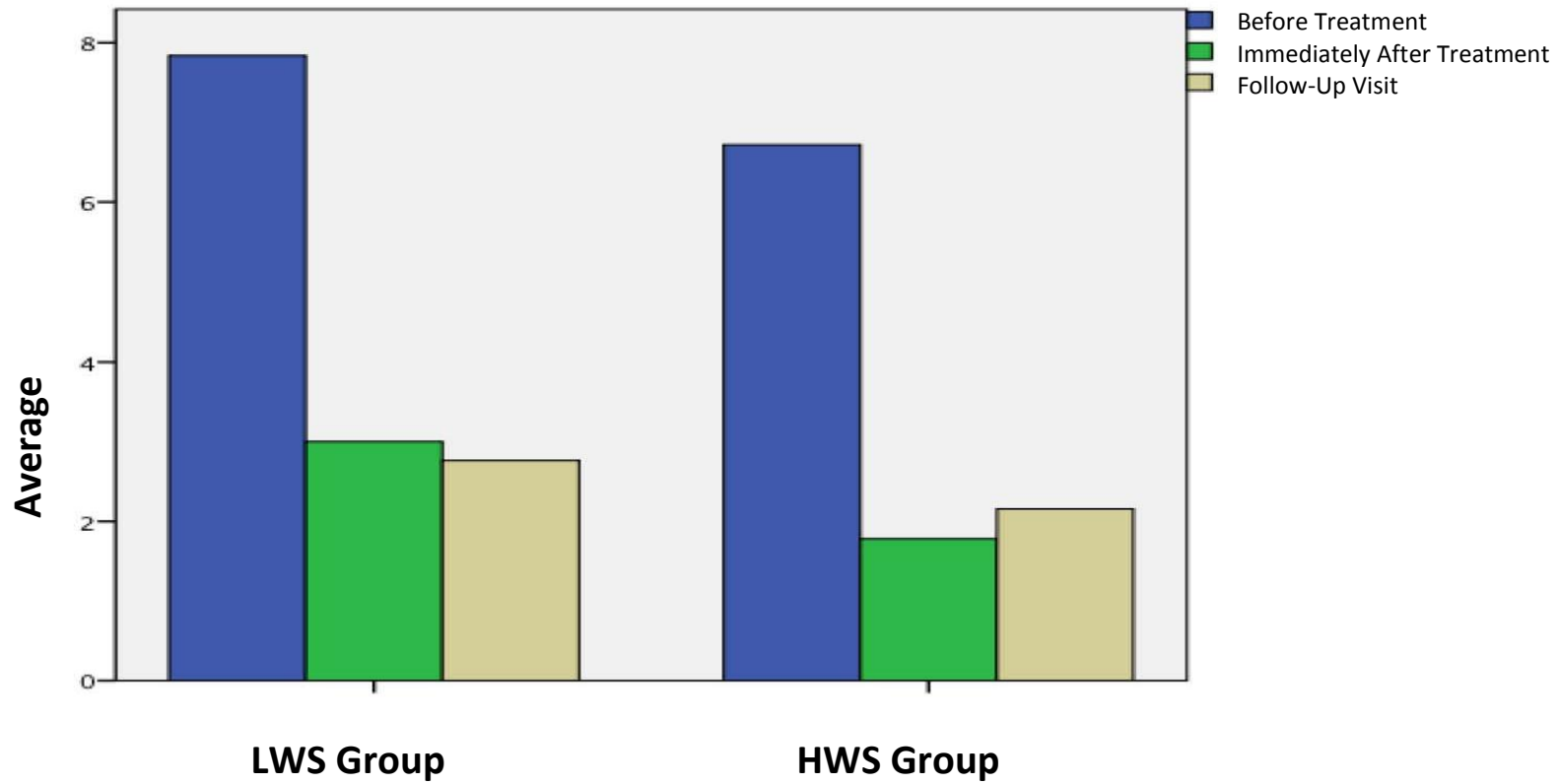
Visual Analogue Scale



Visual Analogue Scale



Visual Analogue Scale Over Time



Results:

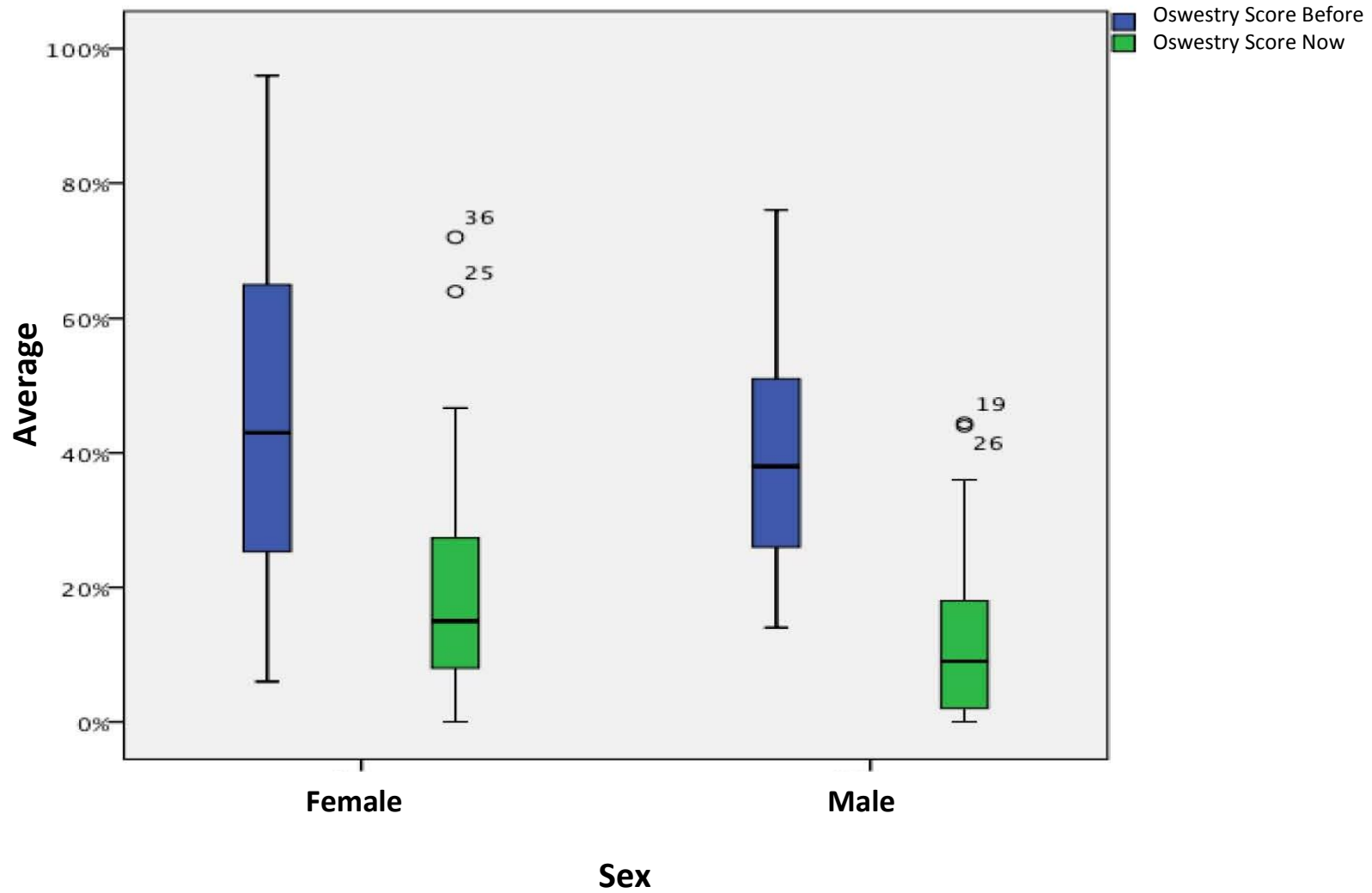
Oswestry-Disability-Index Pre

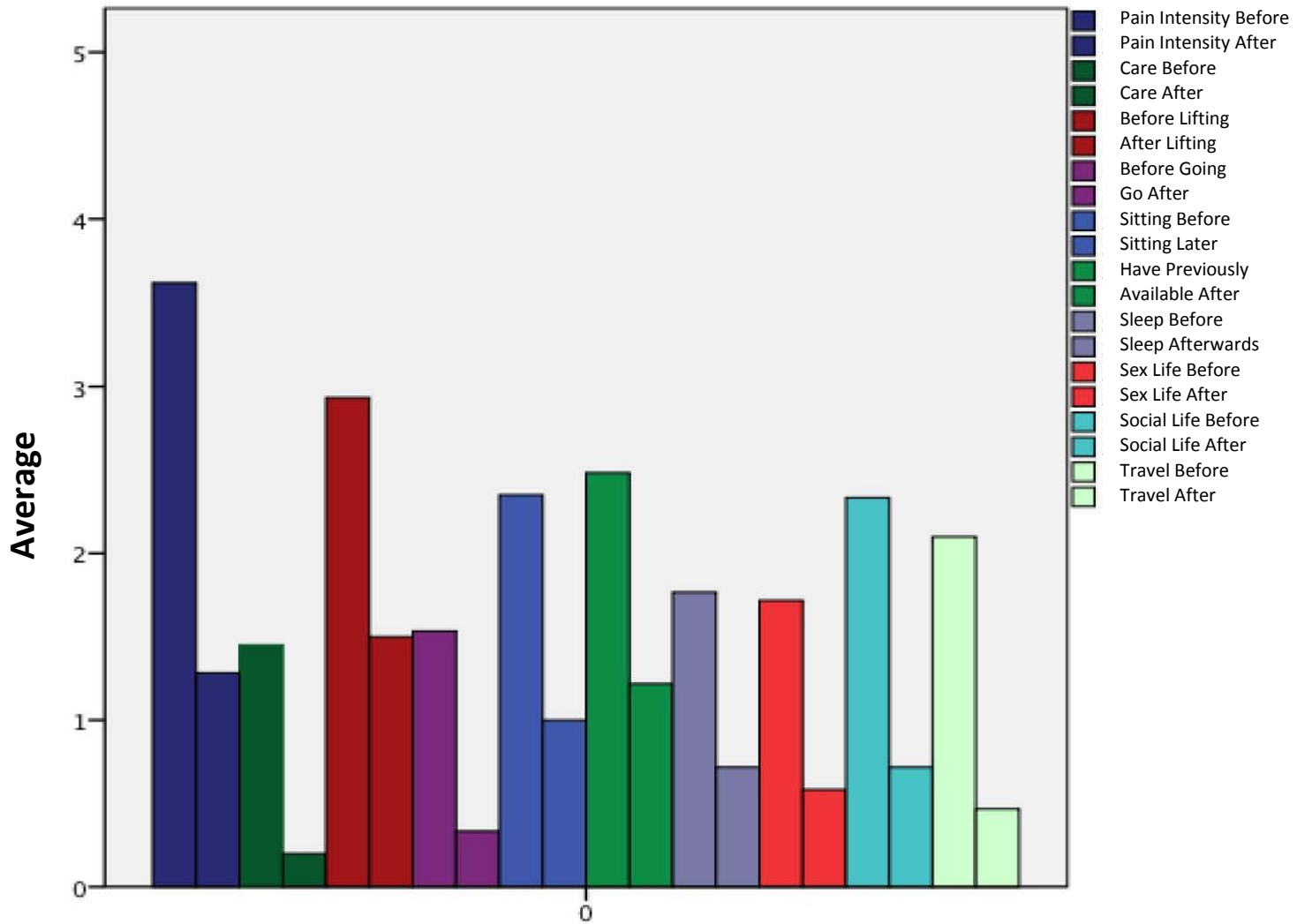
- Before therapy value of 43.15%.
- Among all patients, pain was experienced as the most limiting impairment (3 out of 5 possible points)
- Also, among all patients limitations in weight bearing activities and walking distance (average 1-2 km).

Results

Oswestry-Disability-Index Post

- Average value decreased to 15.97%
- Total decrease of 27.18%





ODI Question Categories in the Pre-Post Comparison

Results:

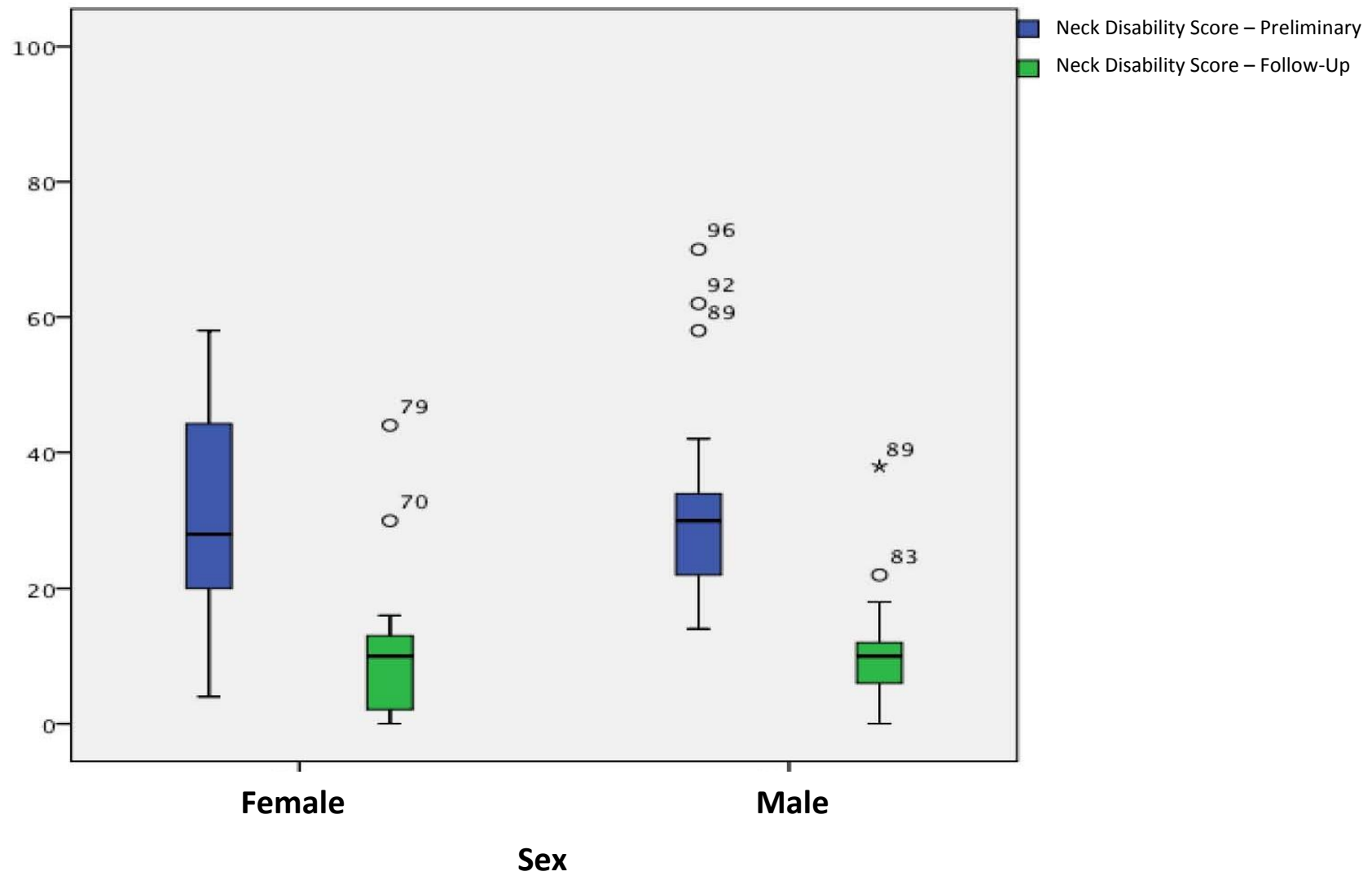
Neck-Disability-Index Pre

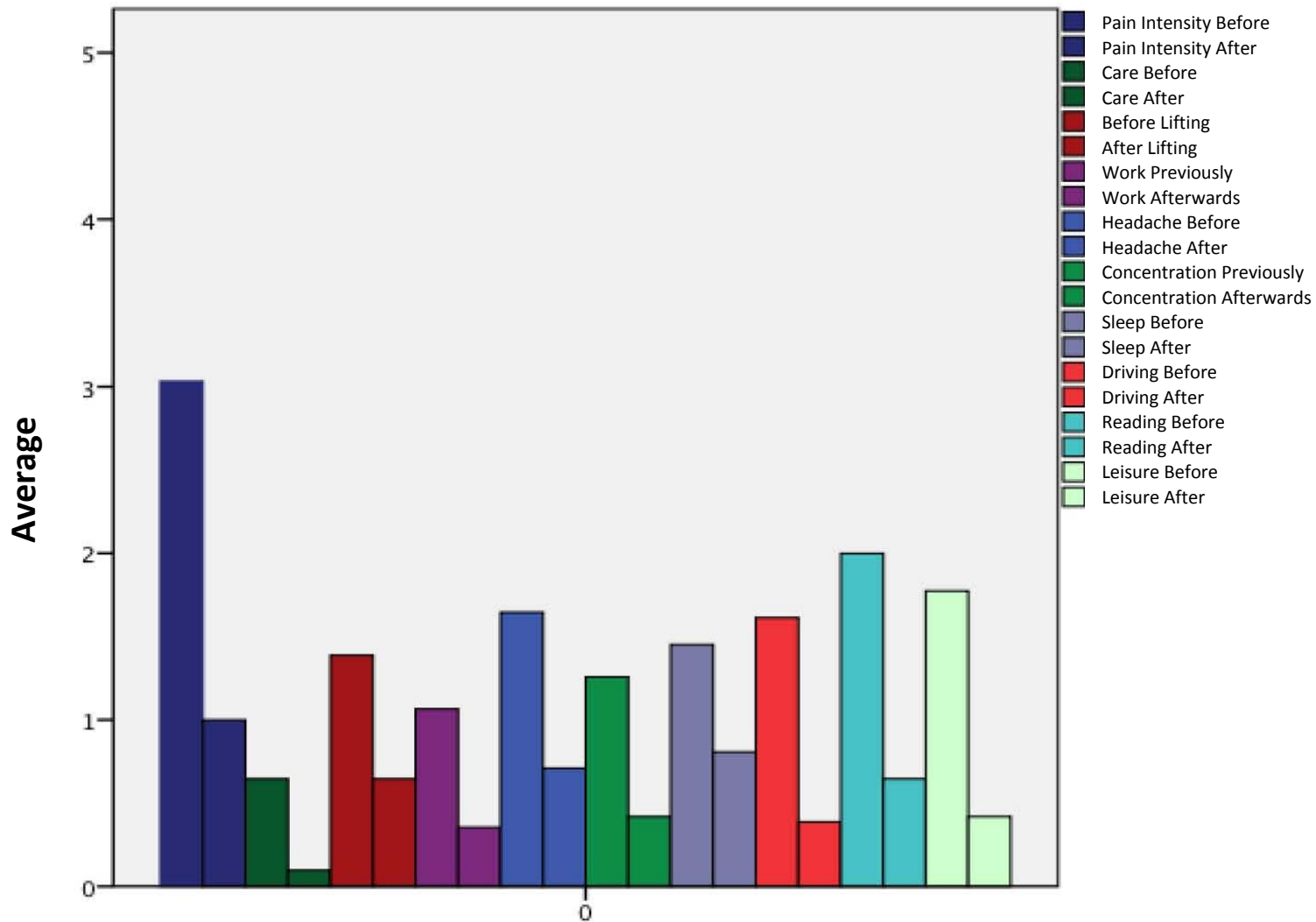
- Average value of 32.01%.
- Pain was experienced as the most limiting impairment (3.05 out of 5 possible points).
- 67.75% of all patients suffered from moderate headache

Results

Neck-Disability-Index Post

- Value decreased to 10.69%.
- Total NDI decrease of 21.32%.





NDI Question Categories in the Pre-Post Comparison

ODI	NDI
------------	------------

Category	Previously	Afterwards	Previously	Afterwards
1	10	47	8	28
2	26	15	15	3
3	15	4	7	2
4	14	2	2	-
5	3	-	-	-

ODI – Decline of 27.18%	NDI – Decline of 21.32%
-------------------------	-------------------------

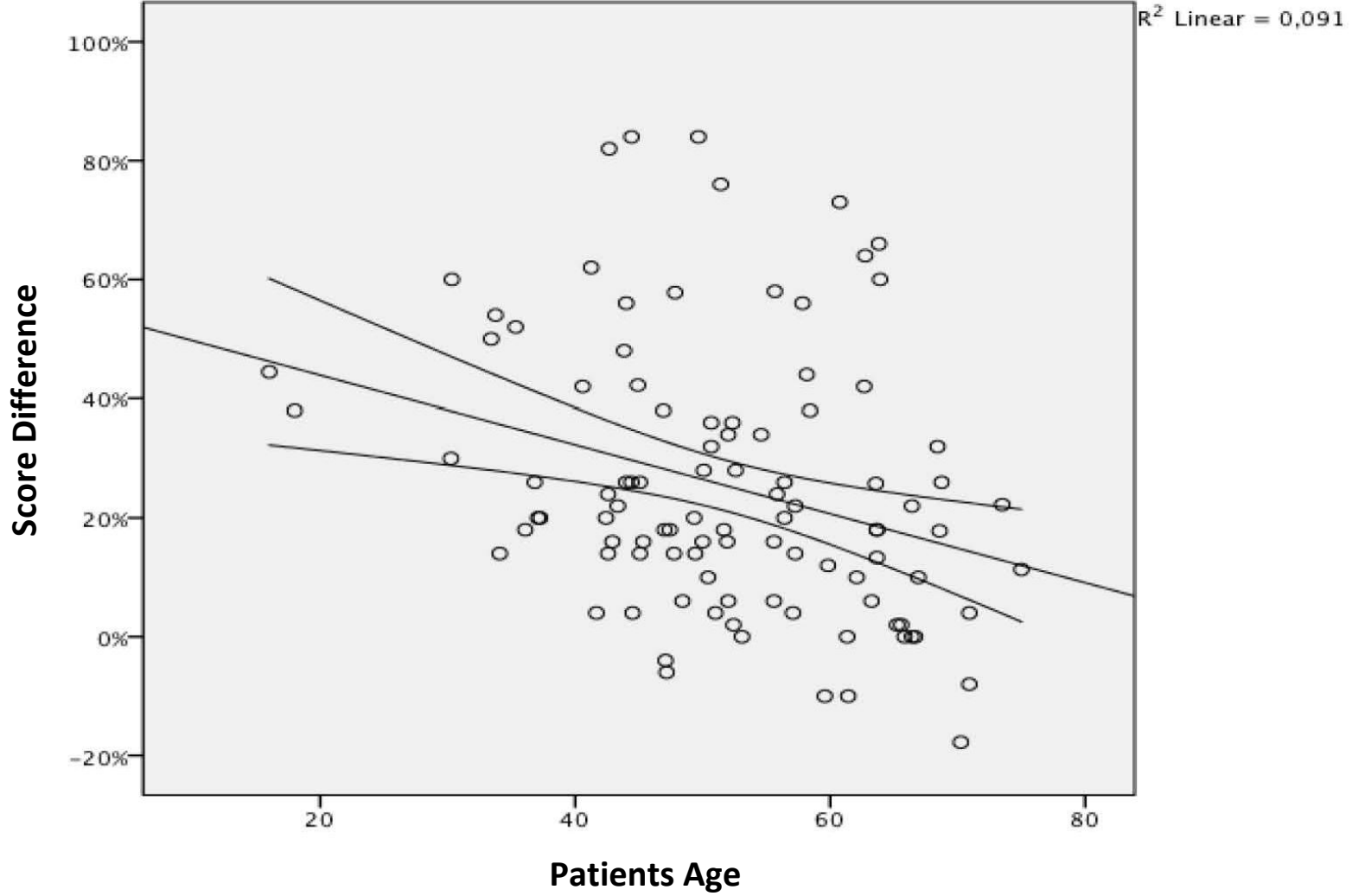
Other Influences on Results

Type of diagnosis

- Better outcomes for patients with non-degenerative diseases.

Patient Age

- Younger patients showed better results than older patients.

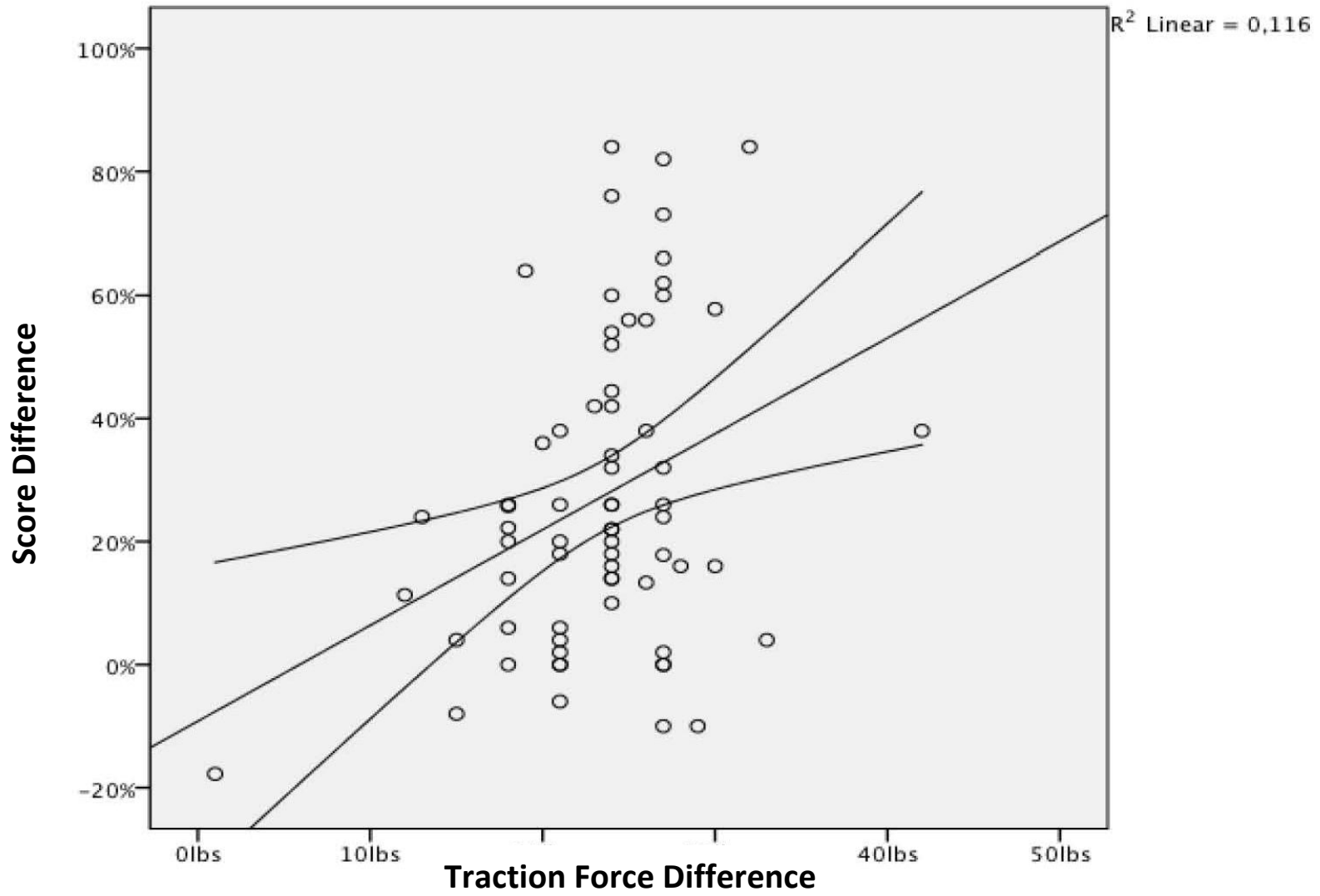


Other influences on Results

Intensity of tension force applied to the patient:

- Increase in pounds: Tension was increased in average 24 pounds in lumbar patients, and 6 pounds in cervical patients.

Optimal increase of tension could be recognized between 15-35 pounds (lumbar patients).



Other influences on Results:

There was no influence on long term results (post measurements) due to the following criteria:

- BMI
- Additional medical interventions: NSAR, muscle relaxants, infiltrations
- Duration of therapy (median 56 days)

Limitations

- No randomization
- No blinding
- No control group
- Sample size

Results-Summary:

- Clear/Considerable improvement in physical examination
- Significant reduction of pain (VAS)
- Significant Score-Improvements of ODI and NDI (pre/post)

Forecast

MRI-Study:

- 20 Patients (11 lumbar and 10 cervical), with non-degenerative disc prolaps or protrusion, underwent MRI examination pre and post SpineMED® treatment.
- The MRI Images partly showed clear remission of the discus and annulus repair.

Results will be published soon!!