

**Observation study
HighTone Therapy with the HiToP[®] device
in case of diseases of the locomotor system**

Evaluation dated January 2003

by

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Summary

The study has been conducted between August 2001 and January 2002 in the practice of Dr. med. Eckhard Rhades, Königstraße 3-7, 32545 Bad Oeynhausen. A total of 48 patients were included in the study, all of which participated in it until the end.

The following organs were treated (it was possible to treat several organs in one patient): cervical vertebral column: 9 treatments; lumbar vertebral column: 18 treatments; shoulder joint: 12 treatments (3 treatments only on the right, 1 only on the left and 9 on both sides); hip joint: 22 treatments (3 treatments only on the right, 1 only on the left, and 9 on both sides); knee joint: 33 treatments (3 treatments only on the right, 2 only on the left and 14 on both sides).

The average age of the patients was 67 years (minimum 31 years, maximum 86 years). 10 male and 38 female patients.

The doctor's and patients' evaluation was 'very good' or 'good' in 33 (69 %) patients regarding the efficacy and in 40 (83 %) and 39 (81 %) patients respectively regarding the tolerance.

6 patients were free of pain at the end of the therapy and in 33 patients the complaints were reduced. 30 patients considered the therapy as 'agreeable', 13 patients thought it 'less agreeable'. The average pain score (NAS score, between 0 and 10) was significantly reduced from 4.8 to 3.9 ($P=0,028$).

In the various organs the findings as regards quantity have significantly improved statistically. The average values and standard deviations of the findings at the first and the last therapy as well as their changes are listed separately in the report. In a follow-up examination within 10 to 14 days after the last therapy the findings showed even slightly more improved conditions in most cases.

4 patients experienced undesired results, which were all slight enough not to lead to a disruption of therapy. In one patient a light burning was registered on the right calf, another patient showed a deteriorating condition in the last third of the therapy and one patient suffered from exhaustion after each therapy. In a fourth patient an initial deterioration was registered.

At a whole the therapy can be described as efficient and well tolerable in most cases.

Hanover, 20 January 2003

Prof. Dr. B. Schneider

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1. Initial data

Age and sex

		Quantity	%
age group	< 60 years	12	25,0
	60-69 years	11	22,9
	70-79 years	22	45,8
	>= 80 years	3	6,3
total		48	100,0
sex	male	10	20,8
	female	38	79,2
total		48	100,0

The average age of the patients is 67 years (standard deviation 10 years), the minimum age is 31 years, the maximum age is 86 years. 10 (21 %) male patients and 38 (79 %) female patients.

Affected organs with complaints

		Quantity	%	
affected organs	lumbar vertebral column	6	12,5	
	cervical + lumbar vertebral column	5	10,4	
	shoulder joint	2	4,2	
	shoulder joint + cervical vertebral c.	3	6,3	
	shoulder joint + lumbar vertebral c.	2	4,2	
	hip joint	7	14,6	
	hip joint + lumbar vertebral column	4	8,3	
	knee joint	13	27,1	
	knee joint + cervical vertebral column	1	2,1	
	knee joint + lumbar vertebral column	1	2,1	
	knee joint + shoulder joint	2	4,2	
	knee joint + hip joint	2	4,2	
	total		48	100,0

Affected side of body (number of patients)

	only right side	only left side	both sides	total
shoulder joint	3	3	3	9
hip joint	3	1	9	13
knee joint	3	2	14	19

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2. Anamnestic data

Anamnesis

		Quantity	%
Duration of disease	up to 1 year	9	19,1
	1-5 years	11	23,4
	5-10 years	11	23,4
	more than 10 years	16	34,0
total		47	100,0
	no	15	31,3
	yes	33	68,8
total		48	100,0
	no	16	33,3
	yes	32	66,7
total		48	100,0
	no	37	77,1
	yes	11	22,9
total		48	100,0
	no	21	43,8
	yes	27	56,3
total		48	100,0
	no	25	52,1
	yes	23	47,9
total		48	100,0

Frequency of injections

		Quantity	%
Frequency of injections	rarely	6	29,6
	frequently	3	11,1
	sometimes	10	37,0
	repeatedly	6	22,2
total		27	100,0

patient number	operations
4	arthroscopy on the right on 10.2000 + 01.2001
6	acupuncture up to 3.8.0
7	bursectomy on the left
11	arthroscopy on the right in 1980
16	arthroscopy on the left on 27 Feb. 2001
23	arthroscopy on the left on 2 Jan. 2001
24	vascular occlusion in thorax 11/78
39	arthroscopy left knee 1997
46	arthroscopy on the left, 4/98
55	hip total endoprosthesis right on the right in 1992, on the left in 1998
57	arthroscopy on the left, 9/2000

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3. Additional diseases

33 patients suffered from additional diseases (mostly hypertension or other cardiovascular diseases). The diseases are listed in the table below.

patient number	additional disease
2	adipositas
3	hypertonia
4	osteoporosis
6	tinnitus
7	hypertension from diabetes mellitus
8	hypertonia
13	glaucoma from diabetes mell.
15	hypertonia, KHK
17	cardiac arrhythmia
20	hypotonia, cardiac arrhythmia
22	hypertension
24	gastritis, hypertension, after surgery of thyroid gland
25	hypercholesterinemia
26	hypercholesterinemia
28	psoriasis, arthritis
29	state after breast cancer
32	glaucoma, hypertension
33	state after partial resection of stomach, coronary cardiopathy
35	coronary cardiopathy
37	asthma, hypertonia
38	cardiac arrhythmia
39	partial paresis left leg
40	hypertension
41	struma
42	cardiac insufficiency, state after breast cancer, state after pulmonary embolism
43	hypertension
45	rheumatoid arthritis
51	Hypertonia
52	diabetes mell., hypertonia
53	osteoporosis
54	kidney insufficiency
55	hypertension
57	adiposity, cardiac insufficiency

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4. Additional medication and current additional therapies

patient number	additional medication
3	Beloc-Zok 1-0.0
4	Actonel 5mg 1x1, Atenolol ratio 50 1x1
6	Fluroxetin
7	Gilbenklamid 2x1, Nifedipin SL 1x1
9	L-Thyroxin
11	contraceptives
13	Insulin 4-0-6 IE, Novonorm 1-1-1
15	Monomak 1x1, ASS100 2x1, Medformin 150 2x0,5
17	ASS 100, 1-0-0, Novodigal 1-0-0
18	Eye drops
20	Nifidpad5 1x1, ophthalmic solution
22	Veratide 1-0-0; Boiserin 1-0-0
24	Nifihexal 10 mg, L-Thyroxin 100
29	L-Thyroxin 75 1x1
32	Diovan 1-0-0, Presomen Compositum
33	Co diovan 1x1, Nifedipat10 2x1, ASS100 1x1
35	Novodigal
36	Bisoprolal 1-0-0, ASS 100, 1-0-0, Arthrotec 1-0-0, Sortis 1-
37	Sortis 10 mg, Diovan 80, L-Thyroxin 75, Traumador 200D
38	Sotalex 1-0-0
40	Accupro5
41	Jodid200 1x1
42	Isoket 1-1, Diovan 80mg 0-0-1
43	Lendormin 1x1
45	Presomen
46	hormones
50	Imbun500, Decortin 5mg, Ranacor 1x0,5
51	beta blocker
52	Insulin 26-16-20 IE
53	Evista 1-0-0
55	beta blocker 1x1
57	Aquaphor 1-0-1

patient number	current therapies
2	pain medication (as required)
7	Diclo KD ret.
11	Diclo 50mg as required
13	Mianeurin 10 mg, 10mg-15mg
16	Diclo 25 mg as required
17	Fosamax 10 mg 1-0-0; Calcitac 1-0-0
21	Voltaren50 2x1
25	Vloxx25 1x1 as required
28	Celebrex 1-0-0; MTX 10mg/week
32	Diclac 50-75 as required
34	Ibuprofen 400, Tegal as required
35	Vioxx 12,5 as required
36	Arthrotec 1-0-0, antiphlogistic agent
37	Traumador 200ID 0-0-1/2
39	Tramal 20 drops as required
40	Diclophenac75 1x1, antiphlogistic agent
41	Vioxx25 1x1, MIX 10mg/week
47	Ibuprofen 1x1
48	Diclo KD 75 1-0-0 antiphlogistic agent
50	Decortin 5mg, Wobenzym 3x1
51	Voltaren 100 as required
53	Evista
57	Voltaren as required

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4. Side effects

Pat. no.	type	start	end	frequency	seriousness	progress	treatment necessary	connection with therapy
3	1-2° burning	23-08-2001	13-09-2001	once	light	enduring	no	likely
4	deterioration in the last third of therapy	02-09-2001	08-09-2001	several times after therapy	light	enduring	no	likely
8	exhaustion states after each therapy	14-08-2001	26-09-2001	several times after therapy	light	enduring	no	likely
57	initial deterioration							

5. Evaluation of the treatment

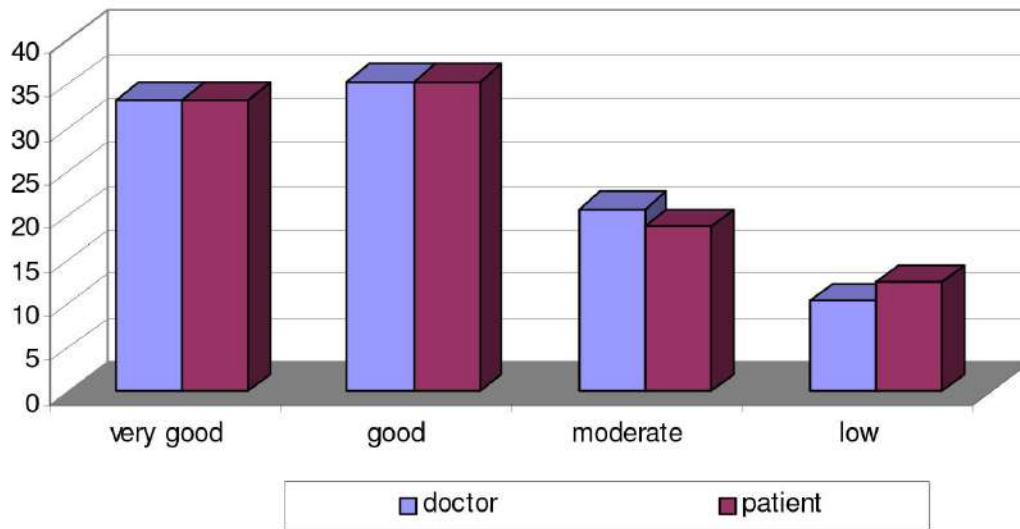
The following table shows the evaluation results of doctor and patient after the therapy. The evaluation was 'very good' or 'good' in 69 % regarding the efficacy and in 83 % and 81 % respectively, regarding the tolerance. 6 patients (13 %) were free of pain at the end of the therapy and in 33 patients (70 %) the complaints were reduced. The majority of the patients (68 %) considered the therapy as agreeable.

Evaluation of therapy

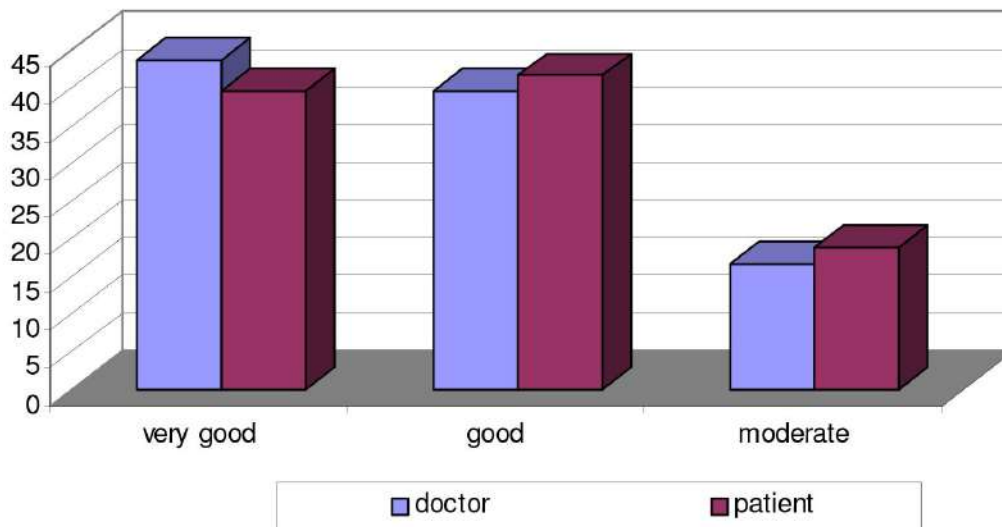
		Quantity	%
efficiency evaluated by the doctor	very good	16	33,3
	good	17	35,4
	moderate	10	20,8
	low	6	10,4
total		48	100,0
efficiency evaluated by the patient	very good	16	33,3
	good	17	35,4
	moderate	9	18,8
	low	6	12,5
total		48	100,0
tolerance evaluated by the doctor	very good	21	43,8
	good	19	39,6
	moderate	8	16,7
total		48	100,0
tolerance evaluated by the patient	very good	19	39,6
	good	20	41,7
	moderate	9	18,8
total		48	100,0
evaluation of the complaints	without complaints	6	12,8
	improved	33	70,2
	unchanged	8	17,0
total		47	100,0
evaluation of the therapy	agreeable	32	68,1
	less agreeable	13	27,7
	disagreeable	2	4,3
total		47	100,0

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evaluation of the **efficiency** of the therapy

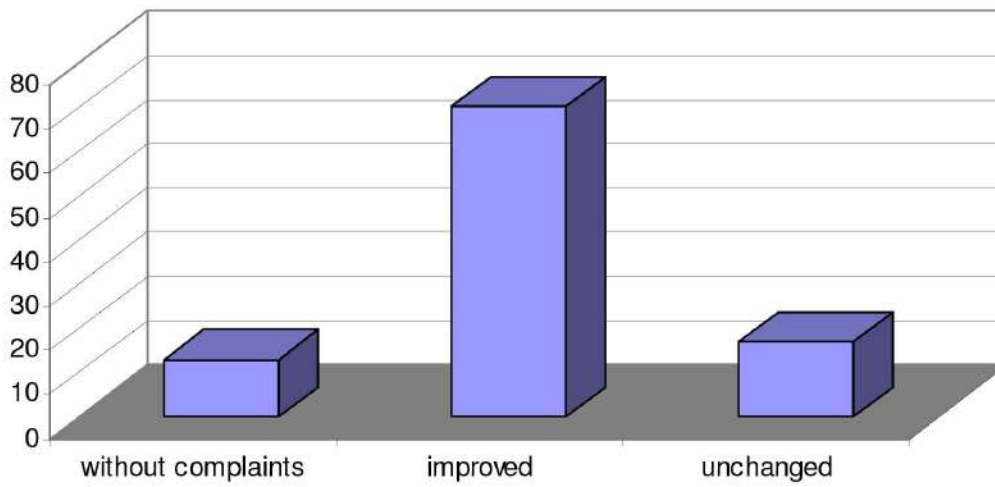


evaluation of the **tolerance** of the therapy

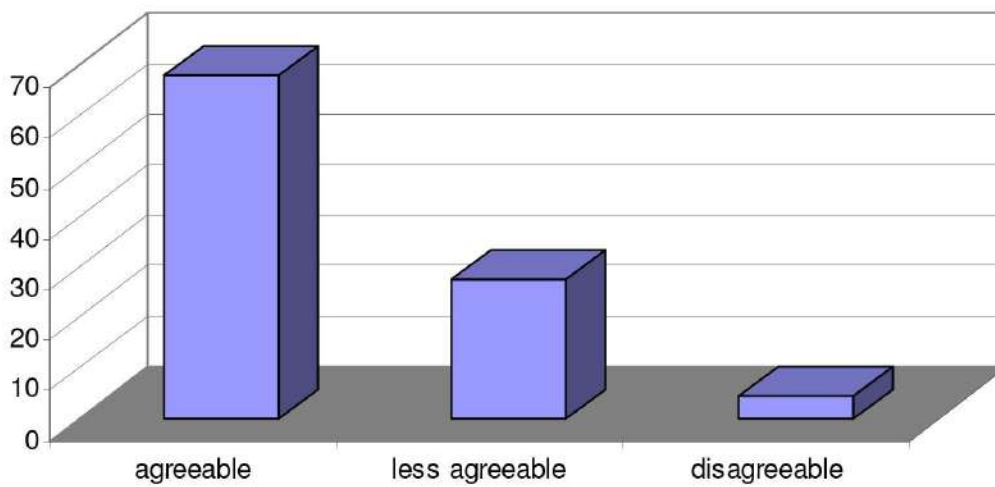


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evaluation of the complaints



evaluation of the therapy



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6. NAS Score: Numeric analogous scale (0 – 10) of the complaints

Average value \pm standard deviation

	before therapy	after therapy	change	sign. P
first therapy	4.8 \pm 2.1	4.5 \pm 2.2	-0.3 \pm 1.2	0.160
last therapy	3.9 \pm 1.8	3.4 \pm 1.2	-05 \pm 1.2	0.002
change	-0.9 \pm 2.7	-1.1 \pm 2.7		
sign. P	.028	0.004		

after last therapy	at follow-up examination	change	sign. P
3.4 \pm 1.2	2.7 \pm 1.7	-0.7 \pm 1.7	0.011

The differences in the average values (between the results before and after therapy, respectively at the first and last therapy and after last therapy and follow-up examination) were evaluated statistically with the connected t-test. In the tables the significance probabilities P are indicated. That is the probabilities of the observed or larger differences, if at a whole the evaluation values did not differ (zero hypothesis). If $P \leq 0,5$, the zero hypothesis is used to be dismissed and the differences are called 'significant'.

The average NAS score had slightly improved after therapy (after the first therapy by 0.3, after the last therapy by 0.5). The difference after the last therapy is significant. Before as well as after the therapy the average NAS score had significantly improved between first and last therapy (before therapy by 0.9, after therapy by 1.1). In the follow-up examination (10 to 14 days after the last therapy) the average NAS score had significantly improved (by 0.7) in comparison to the value after the last therapy.

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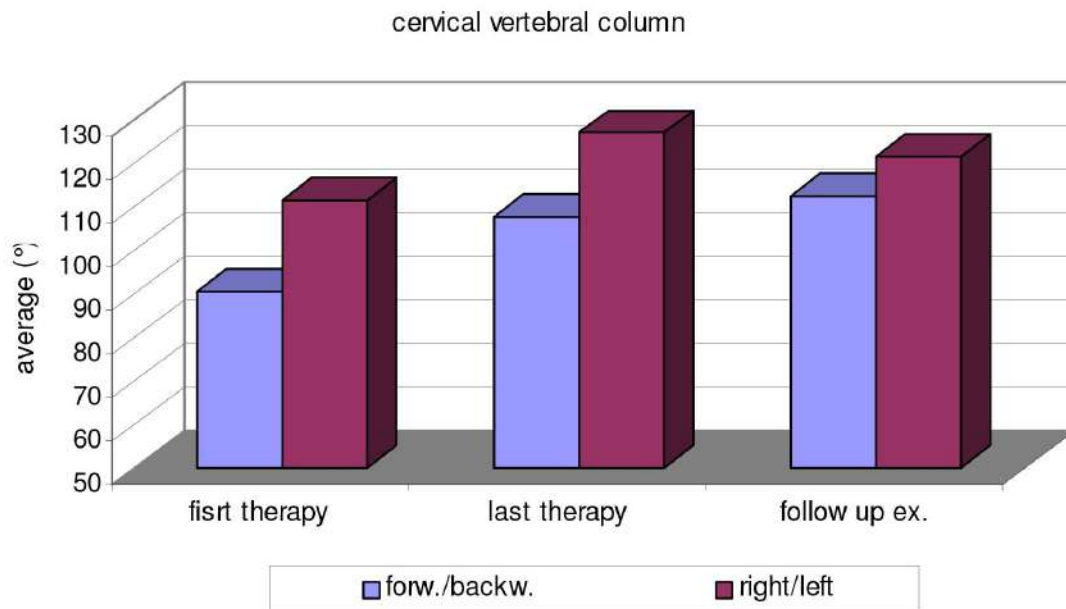
7. Findings in the various treatments

In the following the findings of the various treatments of the respective organs are statistically described at the first and last therapy as well as at the follow-up examination. Please note that in one patient several organs could be treated. The treatment of right and left organs of a patient is considered as separate treatments. The numbers of the organs treated are indicated in brackets. In quantitative findings average values \pm standard deviations are indicated, in findings as per category the frequency of categories. A statistical control with the coupled t-test has been carried out considering the changes between first and last therapy as well as between last therapy and follow-up examination. The significant probabilities are indicated in the last column each.

7.1 Cervical vertebral column (n=9)

	first therapy	last therapy	change	signif. P
forw./backward inclination	$90.6^\circ \pm 22.3^\circ$	$107.8^\circ \pm 21.2^\circ$	$17.2^\circ \pm 12.8^\circ$	0.004
rotation left/right	$111.7^\circ \pm 22.4^\circ$	$127.2^\circ \pm 19.9^\circ$	$15.5^\circ \pm 13.1^\circ$	0.007

	last therapy	follow-up examin.	change	signif. P
forw./backward inclination	$107.8^\circ \pm 21.2^\circ$	$112.8^\circ \pm 18.4^\circ$	$5.0^\circ \pm 8.7^\circ$	0.112
rotation left/right	$127.2^\circ \pm 19.9^\circ$	$121.7^\circ \pm 21.5^\circ$	$5.6^\circ \pm 13.3^\circ$	0.247



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Pain	first therapy	last therapy	follow-up examin.
no pain	0 (0 %)	1 (11 %)	1 (11 %)
pain in cervical spinal column	1 (11 %)	6 (67 %)	6 (67 %)
referred pain in shoulder-neck	4 (44 %)	2 (22 %)	2 (22 %)
referred pain in extremities	4 (44 %)	0 (0 %)	0 (0 %)

change of pain	last – first therapy		follow-up examination – last therapy	
	unchanged	improved	unchanged	improved
	2 (22 %)	7 (78 %)	9 (100 %)	--

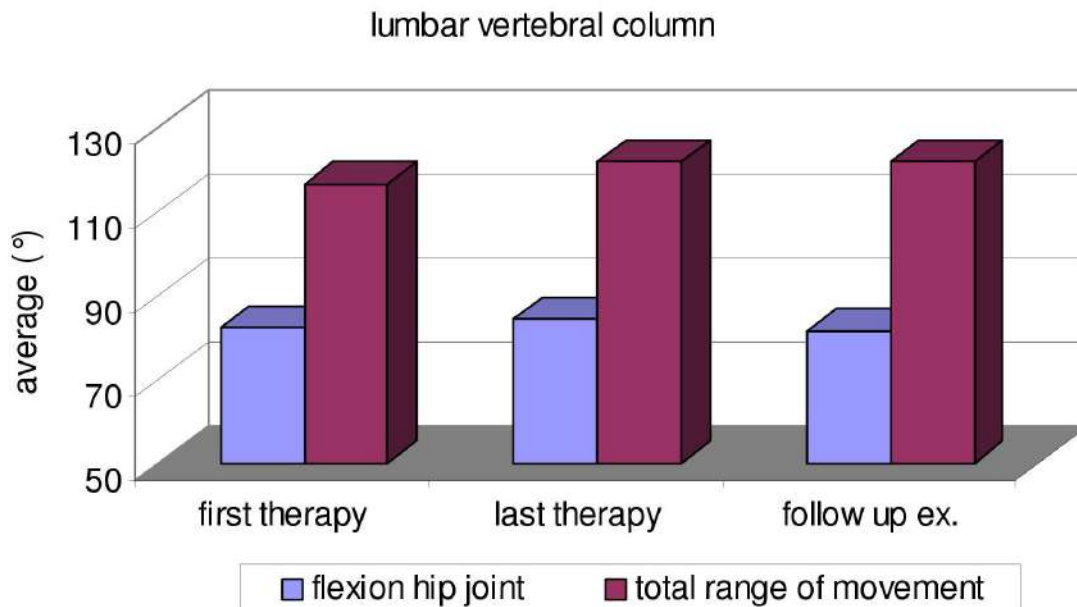
The mobility (forward/backward inclination, rotation right/left) has significantly improved between first and last therapy. Between last therapy and follow-up examination the forward/backward inclination has slightly improved, the rotation right/left has deteriorated slightly (but not significantly). The pain has decreased in 7 patients between first and last therapy, in 2 patients it remained unchanged. Between follow-up examination and last therapy the pain remained unchanged.

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7.2 Lumbar vertebral column (n=18)

	first therapy	last therapy	change	Signif. P
flexion of hip joint (°)	82.5° ± 25.5°	84.4° ± 12.9°	1.9° ± 16.8°	0.639
total range of movement (°)	116.9° ± 11.0°	122.2° ± 7.9°	5.3° ± 4.7°	<0.001
distance finger – floor (cm)	14.5 ± 10.0 cm	10.8 ± 7.7 cm	-3.7 ± 4.0 cm	0.001
Schober sign (cm)	1.9 ± 0.4 cm	2.3 ± 0.5 cm	0.4 ± 0.5 cm	0.003

	first therapy	last therapy	change	signif. P
flexion of hip joint (°)	84.4° ± 12.9°	81.74° ± 11.5°	-2.7° ± 9.5°	0.243
total range of movement (°)	122.2° ± 7.9°	122.2° ± 7.9°	-0.0° ± 0.0°	--
distance finger – floor (cm)	10.8 ± 7.7 cm	10.2 ± 7.5 cm	-0.6 ± 2.1 cm	0.282
Schober sign (cm)	2.3 ± 0.5 cm	2.3 ± 0.5 cm	0.0 ± 0.1 cm	0.331



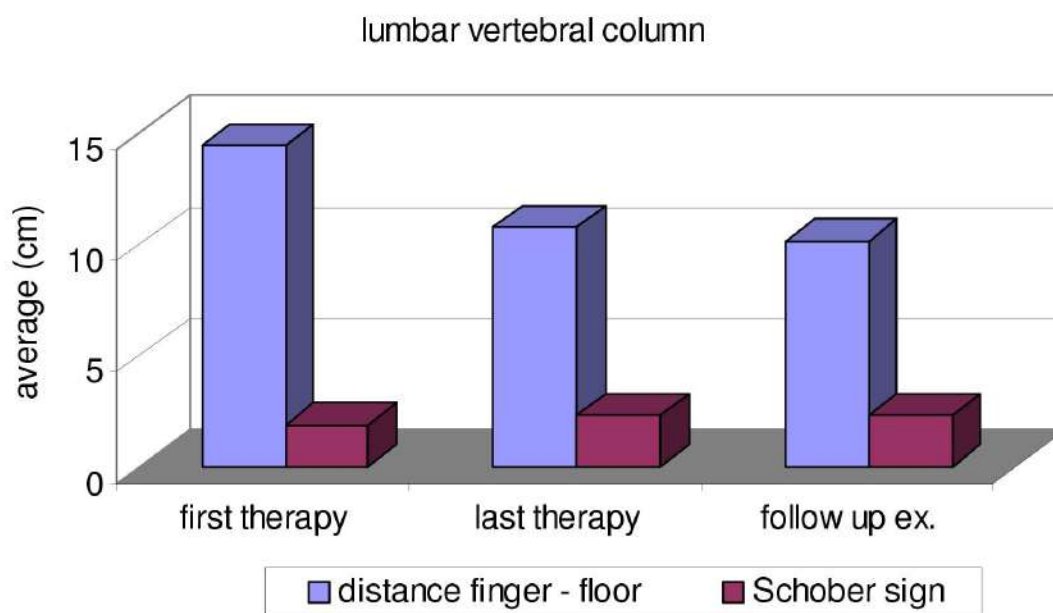
Pain	first therapy	last therapy	follow-up exam
no pain	1 (6 %)	0 (0 %)	1 (6 %)
pain in cervical spinal column	5 (28 %)	13 (72 %)	14 (78 %)
referred pain in extremities	12 (66 %)	5 (28 %)	3 (16 %)

change of pain	last – first therapy			follow-up examination – last therapy		
	deteriorated	unchanged	improved	deteriorated	unchanged	improved
	1 (6 %)	9 (50 %)	8 (44 %)	--	15 (83 %)	3 (17 %)

On average between first and last therapy the flexion of the hip joint has improved only slightly by 2°. In the follow-up examination it could be seen that it had principally returned to the initial value. The other quantitative findings have significantly improved and had stayed on this value even at the follow-up examination. In 8 patients (44 %) the pain has decreased

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between first and last therapy, only in 1 patient it has increased. At the follow-up examination this state of pain has remained unchanged in 83 % and improved in 17 %.

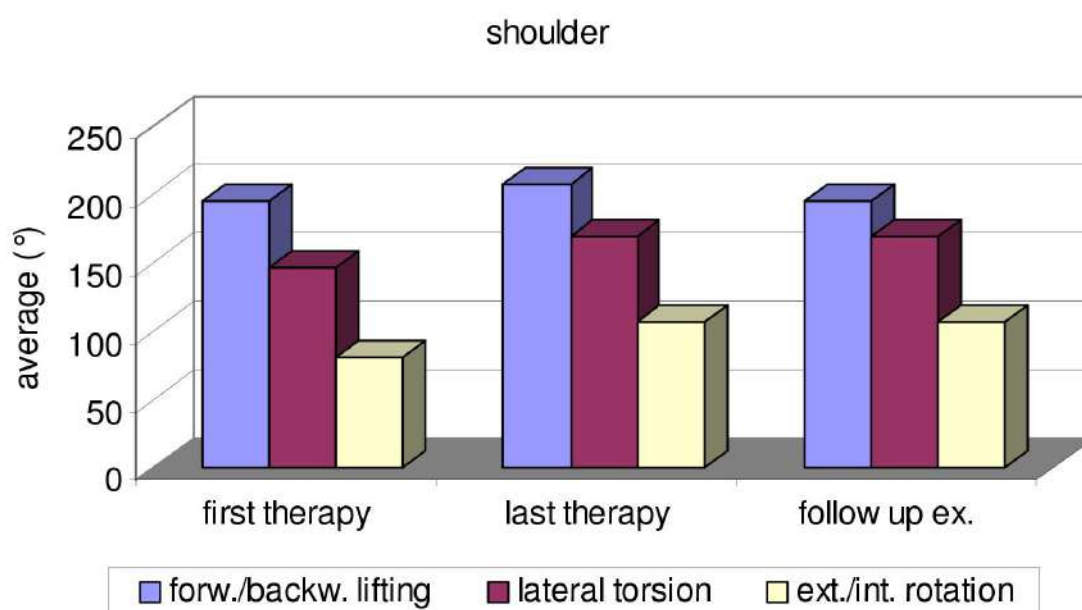


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7.3 Shoulder joint (n=12)

	first therapy	last therapy	change	signif. P
forward/backward lifting	194.5° ± 46.4°	206.7° ± 38.7°	12.2° ± 15.0°	0.018
lateral torsion	146.3° ± 39.9°	169.2° ± 37.9°	22.9° ± 12.3°	<0.001
exterior/interior rotation	81.3 ± 26.9 cm	106.3 ± 29.9 cm	25.0 ± 23.0 cm	0.003

	last therapy	follow-up exam.	change	signif. P
forward/backward lifting	206.7° ± 38.7°	194.6° ± 49.9°	-12.1° ± 39.0°	0.307
lateral torsion	169.2° ± 37.9°	168.8° ± 40.3°	-0.4° ± 6.2°	0.820
exterior/interior rotation	106.3 ± 29.9 cm	106.3 ± 29.9 cm	0.0 ± 3.7 cm	0.999



	first therapy	last therapy	follow-up exam
unspecific supraspinatus test positive	11 (92 %)	8 (66 %)	8 (66 %)
subscapularis test positive	4 (33 %)	0 (0 %)	0 (0 %)
infraspinatus test positive	5 (41 %)	0 (0 %)	0 (0 %)
impingement test positive	11 (92 %)	5 (42 %)	4 (33 %)
apron grip/neck grip aggravated	10 (83 %)	9 (75 %)	7 (59 %)
rest pain at night	9 (75 %)	2 (17 %)	1 (8 %)

change	last – first therapy			follow-up examination – last therapy		
	deteriorated	unchanged	improved	deteriorated	unchanged	improved
unspecific supraspinatus	--	9 (75 %)	3 (25 %)	--	12 (100 %)	--
subscapularis test	--	8 (67 %)	4 (33 %)	--	12 (100 %)	--
infraspinatus test	--	7 (58 %)	5 (42 %)	--	12 (100 %)	--

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impingement test	--	6 (50 %)	5 (50 %)	--	11 (92 %)	1 (8 %)
apron grip/ neck grip	1 (8 %)	9 (75 %)	2 (17 %)	--	10 (83 %)	2 (17 %)
rest pain at night	--	5 (42 %)	7 (58 %)	--	11 (92 %)	1 (8 %)

On average the mobility has significantly improved between first and last therapy (forward/backward lifting by 12°, lateral torsion by 23°, exterior/interior rotation by 25°). In the follow-up examination the average value of the forward/backward lifting had returned to the initial value, whereas regarding the other measuring values it remained practically on the value achieved. As regards the qualitative test findings between last and first therapy the values have improved by 25 % in the unspecific supraspinatus test, by 33 % in the subscapularis test, by 42 % in the infraspinatus test, by 50 % in the impingement test and by 17 % in the apron grip/neck grip. In comparison to the last therapy the results of the follow-up examination remained practically unchanged. The rest pain at night had improved by 58 % after the last therapy and had remained practically unchanged at the follow-up examination.

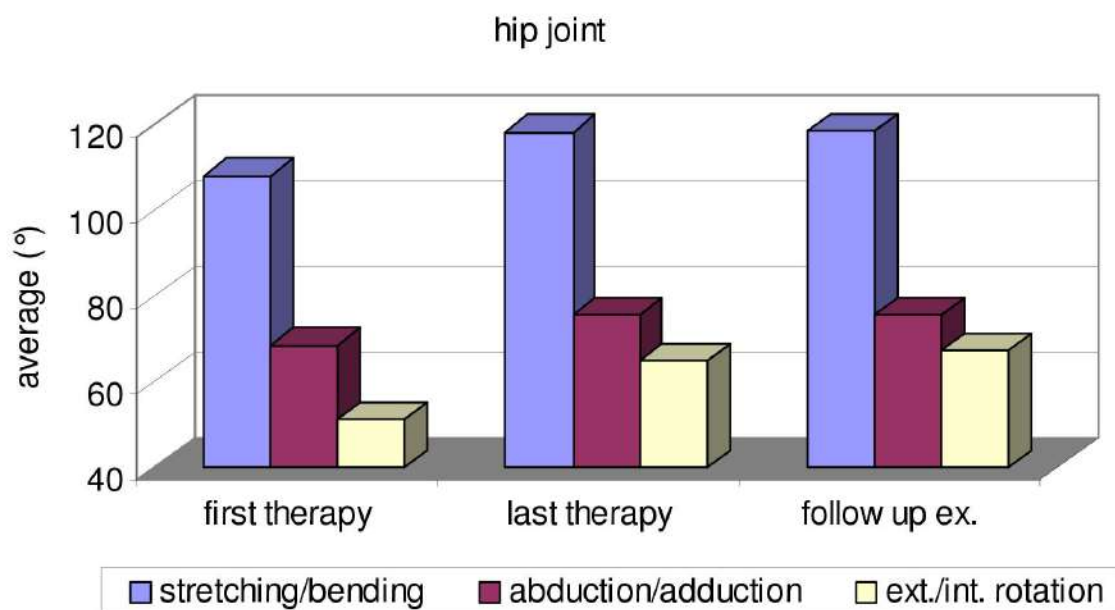
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7.4 Hip joint (n=22)

	first therapy	last therapy	change	signif. P
stretching/bending	108.0° ± 18.2°	118.2° ± 13.6°	10.2° ± 8.9°	<0.001
abduction/adduction	68.5° ± 16.7°	75.5° ± 16.8°	7.0° ± 7.6°	<0.001
exterior/interior rotation	51.4 ± 18.2 cm	65.0 ± 23.1 cm	13.6 ± 14.7 cm	<0.001

	last therapy	follow-up exam.	change	signif. P
stretching/bending	118.2° ± 13.6°	118.2° ± 13.6°	0.2° ± 3.3°	<0.747
abduction/adduction	75.5° ± 16.8°	75.7° ± 16.9°	0.2° ± 4.2°	<0.803
exterior/interior rotation	65.0 ± 23.1 cm	67.5 ± 23.0 cm	2.5 ± 4.8 cm	<0.024

On average the findings show significant improvement between last and first therapy (stretching/bending by 10°, abduction/adduction by 7°, interior/exterior rotation by 14°). The values of stretching/bending and abduction/adduction had remained practically unchanged at the follow-up examination. The interior/exterior rotation has further improved by 2.5 % on average.



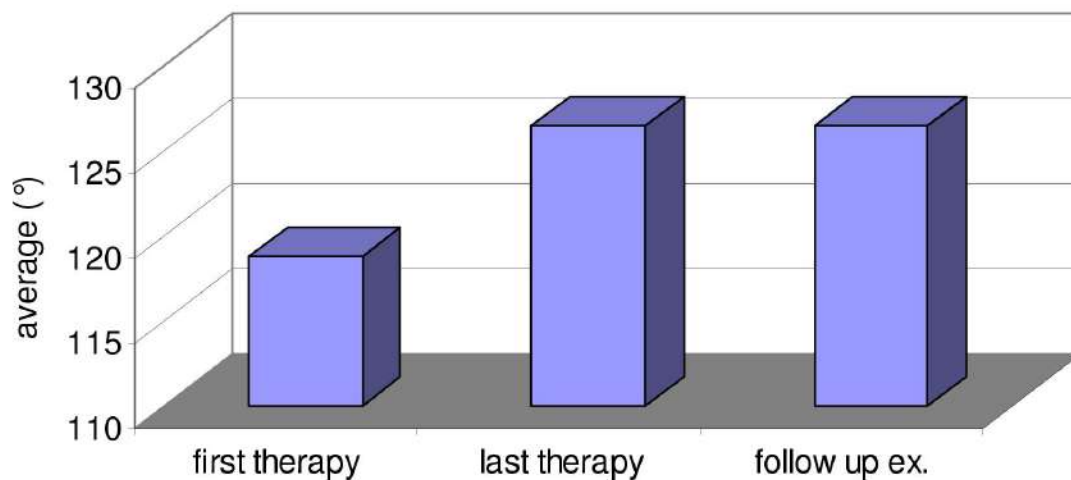
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7.5 Knee joint (n=33)

	first therapy	last therapy	change	signif. P
stretching/bending	118.8° ± 20.6°	126.5° ± 15.5°	7.7° ± 8.3°	<0.001
circumference (cm)	40.7 ± 3.6	40.3 ± 3,5	-0.4 ± 0.5	<0.001

	last therapy	follow-up exam.	change	signif. P
stretching/bending	126.5° ± 15.5°	126.5° ± 15.5°	0.0° ± 4.0°	<0.965
circumference (cm)	40.3 ± 3.5	40.3 ± 3,5	0.0 ± 0.4	<0.662

stretching and bending of the knee



	first therapy	last therapy	follow-up exam
tactile effusion	6 (18 %)	1 (3 %)	2 (6 %)
swelling	28 (85 %)	22 (67 %)	32 (70 %)
meniscus sign positive	28 (85 %)	15 (55 %)	11 (33 %)

change	last – first therapy			follow-up examination – last therapy		
	deteriorated	unchanged	improved	deteriorated	unchanged	improved
effusion	1 (3 %)	26 (79 %)	6 (18 %)	1 (3 %)	32 (97 %)	--
swelling	1 (3 %)	22 (67 %)	10 (30 %)	3 (9 %)	30 (91 %)	--
meniscus sign	--	20 (61 %)	13 (39 %)	--	29 (88 %)	4 (12 %)