Examination of the Effectiveness and Treatment Outcome of Craniosacral Therapy and Physical Therapy after Cranial and Brain Trauma - a Pilot Study

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ABSTRACT

Objectives: Determination of the effectiveness of Craniosacral Therapy vs. Conservative Physical Therapy for treatment of cranial and brain trauma.
Participants: 28 subjects completed the study. 23 male and 5 female have been equally distributed into 3 groups.
Primary outcome measurements: X-ray, Range of Motion, EMG
Results: Each treatment approach has shown to be equally effective. Subjects receiving Craniosacral Therapy and Physiotherapy had a significant change in the skull structure, which is an important finding for clinicians who manually treat the cranium using Craniosacral Therapy.
Conclusion: Physiotherapy and Craniosacral Therapy are both effective for patients suffering Cranial and Brain Trauma in a rehabilitation setting. A new measurement criterion for showing structural patterns in cranial radiographs demonstrated possible indicators for validating the effects of treatment.
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28 subjects, 23 male and 5 female, were studied to determine the effectiveness of Craniosacral Therapy (CST) vs. conservative Physical Therapy (PT) for the treatment of cranial and brain trauma. The primary outcome measurements of X-Ray, Range of Motions, and EMG were shown to be equally effective, while subjects receiving CST and PT together demonstrated a significant change in skull structure. A new measurement criterion for visualizing structural patterns in cranial radiographs revealed these changes, establishing the possibilities of indicators for validating the effects of cranial treatment. PT and CST are effective for patients suffering cranial and brain trauma in a rehabilitation setting.

INTRODUCTION

Craniosacral Therapy is reported as being able to deliver wide ranging, non-specific health benefits. [1] Increasing numbers of craniosacral practitioners worldwide have popularized this modality of therapy for health issues concerning the head and lower back.[2] As more and more health practitioners utilizing a craniosacral approach, third-party payers have been interested in establishing verification and validity of this form of therapy. Establishing causation from treatment application to objective, non-linked physiologic or functional changes in the individual being treated has been difficult to document.[3] The application of methods and techniques varies among practitioners in a non-standardized methodology. To this day, no inter-examiner reliability studies have been proven.[4 5] More significantly is the large body of research, clinical trials, and outcome studies published with largely improper study protocols and poor research design.[2] Craniosacral therapy is a non-standardized, manual treatment protocol with varying methods of application.[6] Direct techniques applied to the cranium to reduce palpated motion restrictions of the craniosacral system were used with the subjects in the study. The study was designed to investigate the effectiveness of craniosacral therapy in comparison to conventional physiotherapy on patients with cranial trauma.

METHODS

The study was conducted at a residential rehabilitation hospital in Austria. The enrolment period lasted from February 2004 to December 2006. 33 subjects were recruited for and entered this study during their stay.
Inclusion criteria:
To be eligible for inclusion the patients must have presented with a diagnosis of Head Injury, including a contusio capitis, commotio cerebri, intracranial haematoma, cerebral contusions, or combinations thereof. All subjects must have also been older than 18 years of age, and mentally able to follow the program.
Exclusion criteria:
Patients with mental disorders and an expressed lack of cooperation were excluded. Subjects with a diagnosis of Head Injury longer than 5 years prior, and any other injuries to the neck, without direct injury to the head or face were excluded. Data of patients who had not completed the program were excluded.

Subjects who did not follow the randomized therapeutic program were also excluded.
Randomization:
The patients were randomly allocated to one of 3 different groups by an independent office worker in the coordinating department of the clinic.

1. Craniosacral Therapy – Test Group I (TG I)
2. Physical Therapy – Control Group (CG)
3. Craniosacral and Physical Therapy – Test Group II (TG II)

DIAGNOSTIC EVALUATIONS
Baseline measures were taken by the medical department, physiotherapy, sports therapy, and radiology departments (external facility).
X-RAY: Using a PA skull-view with markers placed within the external auditory meatus to mark the posterior cranial horizontal reference line. Lines were also drawn through the zygomatic-frontal notches bilaterally, and visualizable maxillary landmarks to mark middle and anterior cranial relations respectively. Pre- and post radiographs were taken for comparison to evaluate any morphological changes in the cranium.
ROM: Range of motion was tested for the cervical, thoracic and lumbar spine in the beginning, and at the end.
EMG (Electromyography / Noraxon MRXP_Master 1.06): 4 external electrodes placed directly over muscles to be tested: ventral left & right sternocleidomastoid muscle and dorsal left & right suboccipital muscles. The muscle tension (μV) was measured in supine and sitting position and during the flexion and extension motion of the head in a sitting position. Comparison of any changes in the bilateral muscle tension in the beginning and end of the rehabilitation program, determined the overall EMG value.
BARTHEL INDEX: The Barthel Index is a tool for evaluation of the ability to perform ten activities of daily living independently or with assistance.
MANKOSKI PAIN SCALE: The pain scale was used to establish pain level in the beginning and end.

THERAPIES
All subjects were able to follow and complete the therapeutic program which was specifically designed for the study program, using individual parameters to match the different fitness levels of the subjects. All Groups received generalized therapies with individual parameters: Ergometer training, weight training, treadmill or Nordic Walking, back exercises, TENS (Transcutane Electrical Nerve Stimulation)

Test – Group I: CST
Craniosacral Therapy was performed utilizing selections of the following therapeutic procedures for 30 minute daily treatments (5 times/ week):

> Release of the myofascial tissues of the sub-occipital area and at the muscle-tendon junction at the occipital ridge. Direct mobilization of the atlanto-occipital articulation, posterior decompression of the occipital condyles from the atlas, and sustained lateral stretching through the alar portion of the occipital bone completed this 4 part procedure.
> Spreading of sutural articulations through direct sustained traction in specific vectors around fixed or restricted articular areas of the cranial vault.
> Testing of the cranial vault, determining precise patterns of lesion or restriction in classic cranial base lesion pattern nomenclature,[23] and direct mobilization through the lesion and motion barrier.

Control – Group: Physical Therapy
Conventional Physical Therapy consisted of active and passive treatment options. A selection of the following therapeutic procedures was done by each physical therapist for 30 minute daily treatments (5 times / week):
Passive therapies: Classic massage (effleurage & petrissage) to the neck, back and gluteal region, connective tissue therapy & fascial release treatment, manual traction of the cervical spine, passive sustained stretching targeting the trapezius and levator scapulae muscles, Trigger Point therapy[24] and Manual Therapy[25] for mobilization of the joints. Subjects did not receive any additional passive therapies. The only exceptions were subjects with oedemas of the foot or hand, which included a regional lymphatic drainage for these specific issues, and which did not influence the outcomes of this study.
Active therapies: Neurological training using multiple training devices to activate balance, motor function,

control, and neural reorganization; PNF – Proprioceptive Neuromuscular Facilitation: to improve neuromuscular function through active resistance and stretching; FBL –functional moving therapy by S. Klein-Vogelbach using various training devices; standard training with supports: mini trampoline, balance boards, gymnastic balls, stairs and outdoor activities for balance, strength and endurance.
If the subject suffered from multiple injuries, additional therapies were prescribed, following the mission statement of the rehabilitation hospital, (as there were expectations of the health insurance fund: e.g. Occupational Therapy was performed when motor problems with the hand were detected), which did not influence the outcome of this study.

Test – Group II: Craniosacral Therapy and Physical Therapy
Craniosacral Treatment and Physical Therapy were each performed daily for 30 minutes (3 times / week).

OUTCOME MEASURES
Initially, data was collected at arrival, and at the end of the rehabilitation program. Outcome measures were X-Ray, Range of Motion of the spine, EMG, Mankoski Pain Scale, and Barthel Index. Primary Outcome measures were: X-Ray, EMG and ROM. Secondary Outcome measures were: Pain Intensity and Disability (Barthel Index). The assessors for EMG and X-Ray, as well as the clinicians, were blinded, but a complete blinding for all assessors was not possible.

STATISTICAL ANALYSIS
Data was calculated by the statistical program SPSS.

RESULTS
SUBJECTS

Thirty-three subjects entered the study. Four subjects dropped-out immediately after the initial assessment. A criterion of the study was the opportunity for each person to drop-out for any particular reason. The main reason for the 4 people, who dropped-out after the initial assessment, was due to the large variety of therapeutic programs available at the clinic, and these particular subjects decided to join water and massage therapies, which was not part of the randomized program and had influence on the therapeutic outcome and therefore an exclusion criterion.
The training program was standardized for every subject of the study with individual parameters applied to their varying physical capacities. Twenty-nine subjects had signed up, and twenty-eight finished the program. The one person was excluded due to faulty subjective information about her pain level, skewing the collected data.

GENERAL INFORMATION
The baseline was similar in the different groups. The distribution was biased to the male population, 82.1 % male (n= 23) and 17.9% female (n=5) participated. The main population was in the age group under 50 years (n=18, SD = 9.92). The average age was about 46.21 years (SD = 19.09). 5 subjects were between 50-69 years of age (SD = 6.87) and 5 subjects were 70 years and older (SD = 4.62). The distribution in the groups was approximately equal (table 1). Eight subjects participated in TG I (28.6 %), ten in CG and ten in TG II (each 35.7%). The average rehabilitation – stay was 31 days (SD = 5.7). The average stay of the subjects in TG I was 28 days (SD = 2.42), CG 32 days (SD = 4.89) and TG II 33 days (SD = 7.56).

Gendermale: 23 (82.1%)female: 5 (17.9%)Age<50yrs.: n = 18 (34.33 yrs. av.)50-69yrs.: n = 5 (58.8 yrs. av.)>70yrs.: n = 5 (76.4 yrs. av.)Subjects: n=28TG I : n=8
(28.6%)CG : n=10
(35.7%)TG II : n=10
(35.7%)

Table 1: gender and subject distribution
EMG

The ‘pre-‘ and ‘post’ - muscle tone was tested (on the 3rd day of arrival and at the end of an average stay of

31 days). The electrodes were placed dorsally over the sub-occipital muscles at the left and right side, and ventrally at the sternocleidomastoid muscles, left and right side. No standardized baseline data exists to show normal physiological activity for the suboccipital muscles and sternocleidomastoid muscle (SCM) in a sitting and supine position. Differences were found in comparing the sitting and supine positions: less tone was found in supine, which indicates a stabilizing function of these muscles in sitting. (dorsal right p=0.08 / p=0.014) . The EMG analysis failed to demonstrate any specific results that would indicate a significance, or tendency of the muscle tone in sitting and supine, and in flexion and extension motion. The comparison of 'pre'- and 'post' testing of the suboccipital muscles showed less muscle tone at the end, but no significance was found, only a tendency due to the small number of subjects.
The SCM showed a higher tone in lying than in sitting at the beginning and end of the study period. In the beginning there was a significant difference present (p=0.021 & p=0.094), and at the end the data was narrowed (p = 0.374 / = 0.994). This data demonstrates a better relaxation in the SCM towards the end. In averaging all the tests, the tone of the sternocleidomastoid muscles decreased.

***RANGE OF MOTION (ROM)*:**

Cervical spine	Mean	SD	SD Error Mean	95 % CI		p - value (sign.= p < 0.05)
				Lower	Upper	
Flexion	0.78	2.95	0.59	-1.99	0.44	0.199
Extension	0.98	1.63	0.33	-1.65	-0.31	0.006
Right lateral flexion	1.14	2.28	0.46	-2.08	-1.99	0.020
Left lateral flexion	0.88	1.63	0.33	-1.55	-0.21	0.012
Right rotation	8.11	10.64	2.01	-12.23	-3.98	0.000
Left rotation	7.14	10.78	2.04	-11.32	-2.96	0.002

Cervical ROM	TG I	CG	TG II
Flexion	avg. 1.38 cm / SD 4.9	avg. 0.55 cm/ SD 1.69	avg. 0.43 cm / SD 1.36
Extension	avg. 1.06 cm / SD 1.63	avg. 1.15 cm/ SD 2.0	avg. 0.64 cm/ SD 1.14
Right lateral flexion	avg. 1.5 cm/ SD 2.1	avg. 0.45 cm/ SD 1.93	avg. 1.71 cm/ SD 2.94
Left lateral flexion	avg. 1.06 cm/ SD .98	avg. 0.65 cm/ SD 2.01	avg. 1.0 cm/ SD 1.8
Right rotation	avg. 5.88 º/ SD 9.4	avg. 10.5 º / SD 11.89	avg. 7.5 º / SD 10.86
Left rotation	avg. 3 º / SD 5.93	avg. 9.4 º / SD 13.87	avg. 8.2 º / SD 10.34

Table 2: Range of Motion – cervical spine, ROM of the cervical spine - group analysis

There was an overall improvement in cervical spine flexion within all groups, but no significance in either one of the Groups. TG I showed an increase in extension and left lateral flexion. The Control Group had more change in left rotation, and TG II had more improvements into right lateral flexion (table 2). No statement can be made about which treatment was more effective; every group showed improvement in mobility of the cervical spine.

Thoracic ROM	Beginning All subjects	End All subjects	p-value All subjects	TG I	CG	TG II
Ri lateral flexion	21.07°	24.07°	0.037	P=0.392	p=0.268	p=0.154
Le lateral flexion	19.44°	22.33°	0.023	P=0.571	p=0.027	p=0.118
Ri rotation	36.41°	42.26°	0.000	P= 0.019	p= 0.013	p=0.028
Le rotation	36.41°	41.3°	0.001	P=0.329	p=0.012	p=0.075

Table 3: ROM thoracic spine – group analysis

The mobility of the thoracic spine improved significantly in rotation and lateral flexion (table 3). No significance was found in flexion and extension, due to the small number of test subjects.

The mobility of the lumbar spine improved, but no significance was found.

***X-RAY*:**
The posterior reference line was measured, with the middle cranial line (alpha), and with the anterior cranial line (beta) in pre- and post x-rays for degrees of displacement. A decrease in degrees of displacement indicates improvement in the structural pattern of the cranium.

	beginning	end	P-value	TG I	CG	TG II
Alpha	2.33	2.15	0.666	p=0.871	p=0.631	p=0.760
Beta	2.52°	1.52°	0.014	p=0.685	p=0.136	p=0.028

Table 4: X-Ray results

The X-Ray analysis showed a significance in all subjects (n=27), comparing the data from beta in the beginning and the end (p=0.014 / table 4).
TG II had a significant change of 2.9 degrees off the normal horizontal reference in the beginning, and 1.22 degrees in the end (p=0.028 / table 5).

	TG I	CG	TG II
Alpha beginning	2.4	2.7	1.9
Alpha end	2.5	2.3	1.7
Beta beginning	1.8	2.8	2.9
Beta end	1.5	1.8	1.2

Table 5: X-Ray data from beginning and end

Secondary Outcomes
PAIN INTENSITY:
Subjects were evaluated subjectively for headache and spinal pain, using the Mankowski pain scale at the beginning and end of treatment. Pain reduction was not the main indicator for success. It was a secondary outcome measure, next to objective functional changes (e.g. improvement of mobility). Pain levels were low in general.

Pain Intensity	headache		cervical spine	thoracic spine	lumbar spine
general	avg	0,61	0,72	0,55	0,26
	SD	0,70	0,72	0,53	0,24
	avg.	0,36	0,91	0,52	0,28
TG I	SD	0,62	1,51	0,60	0,51
	avg	0,55	0,98	0,64	0,34
CG	SD	0,69	1,38	0,61	0,46
TG II	avg	0,56	0,88	0,45	0,28
	SD	1,27	1,62	0,59	0,47

PAIN	Beginning All subjects	End All subjects	p-value	TG I	CG	TG II
Headaches	1.03	0.52	p=0.070	p=0.351	p=0.093	p=0.343
Cervical spine pain	1.07	0.36	p=0.030	p=0.180	p=0.271	p=0.210

Thoracic spine pain	0.54	0.12	p=0.037	p=0.195	p=0.193	p=0.168
Lumbar spine pain	0.64	0.29	p=0.015	p=0.170	P=0.066	p=0.343

	Beginning	End	Significance	TG I	CG	TG II
Summary of total pain	3.29	1.27	p=0.002	p=0.037	p=0.13	p=0.138

Table 6: results pain intensity

The total pain levels were significantly decreased. TG I had a statistically significant improvement (table 6) in comparison to CG and TG II.

Barthel Index:
Most of the subjects (n= 20) were independent (BI = 100). All subjects with difficulties and a lowered BI, improved during their stay (p= 0.013). Due to low numbers in the single groups, no significance was found. Only group III showed a tendency (table 7).
Table 13: results BI

	Beginning	End	P - value All subjects	TG I	CG	TG II
Barthel Index	91.61	97.68	0.013	p=0.197	p=0.343	p=0.057

DISCUSSION
This study was undertaken to examine the effectiveness of Craniosacral Therapy after Cranial and Brain Trauma, compared with conventional physical therapy. Unfortunately, only 28 subjects finished this study, seriously undermining the statistical power that would have been possible with a larger study population. No follow up was done.
Another goal of this pilot study was to determine if the human adult skull is able to change its structural pattern after Craniosacral Therapy. We were able to provide data that demonstrated plasticity in the structure of a human adult skull after Craniosacral Therapy. Test group II had a significant change in the skull structure, which is an important finding for clinicians who manually treat the cranium using Craniosacral Therapy. A source of error in this measurement could be an improper or faulty positioning of the skull while performing the x-ray.
The ROM improved effectively in each group. No significant differences between the groups were found due to the low number of subjects.
The EMG testing was done with external electrodes. Placement discrepancies could be a source of error leading to inaccurate data. No standardized physiological data exists for the involved measures of muscle tone of the sub-occipital and sternocleidomastoid muscles in sitting, supine, flexion, or extension. The muscle tone of the SCM decreased towards the end of the rehabilitation period. It was observed that the muscle relaxation capacity improved at the end of the study period. An inter-group comparison did not reveal usable data due to the low number of subjects.
Pain was measured by the Mankoski Pain Scale. Farrar et al. (2001) reported that a 1-point difference on a pain scale was a threshold for patients to consider themselves to be at least ´minimally improved, and an improvement of 1.7 was ´much improved´. In the current study TG I improved by a 2.3 point difference. TG II changed by 1 point, with a low pain level at the baseline. The CG demonstrated the highest level at the baseline, and showed a 2.8 point difference in the pain scale. Significance was found with Test group I. The effect of Craniosacral Therapy was therefore equivalent to ´minimal´ (TG II), and ´much improved´ (TG I) and according to Farrar, et. al. (2001) is likely to be considered worthwhile treatment by patients with pain after Cranial and Brain Trauma.
The outcomes of the BI are not the result of a particular therapy. Rather the whole process of rehabilitation is responsible for improvement. Most subjects (n=20) achieved full scores in the beginning. The low-number of subjects with lowered BI was not representable for analysis.
As there is a lack of evidence in the literature demonstrating the effectiveness of CST, the results of the current pilot study should be viewed with some optimism.

CONCLUSION

Physiotherapy and Craniosacral Therapy are both effective for patients suffering Cranial and Brain Trauma in a rehabilitation setting. Both therapies decrease pain, increase relevant range of motion, and decrease excessive muscle tone. Craniosacral Therapy, in combination with Physiotherapy, demonstrated a significant structural change of the cranium on x-ray films taken on pre- and post-treatment evaluation.

The low number of test subjects in this pilot study limited the possibility of meaningful results for comparison between Physiotherapy and Craniosacral Therapy after Cranial and Brain Trauma. Further research is recommended, utilizing randomized controlled trials, for evaluation of significant outcomes comparing these treatment approaches.

APPENDIX I

Mankoski Pain Scale:

MANKOSKI PAIN SCALEINCLUDEPICTURE "../../nora%20kabisch/Local%20Settings/Temporary%20Internet%20Files/Content.IE5/Lokale%20Einstellungen/Temp/images/faint_pale.gif" * MERGEFORMATINET \d"		
0	Pain Free	No medication needed.
1	Very minor annoyance - occasional minor twinges.	No medication needed.
2	Minor annoyance - occasional strong twinges.	No medication needed.
3	Annoying enough to be distracting.	Mild painkillers are effective. (Aspirin, Ibuprofen.)
4	Can be ignored if you are really involved in your work, but still distracting.	Mild painkillers relieve pain for 3-4 hours.
5	Can't be ignored for more than 30 minutes.	Mild painkillers reduce pain for 3-4 hours.
6	Can't be ignored for any length of time, but you can still go to work and participate in social activities.	Stronger painkillers (Codeine, Vicodin) reduce pain for 3-4 hours.
7	Makes it difficult to concentrate, interferes with sleep You can still function with effort.	Stronger painkillers are only partially effective. Strongest painkillers relieve pain (Oxycontin, Morphine)
8	Physical activity severely limited. You can read and converse with effort. Nausea and dizziness set in as factors of pain.	Stronger painkillers are minimally effective. Strongest painkillers reduce pain for 3-4 hours.
9	Unable to speak. Crying out or moaning uncontrollably - near delirium.	Strongest painkillers are only partially effective.
10	Unconscious. Pain makes you pass out.	Strongest painkillers are only partially effective.

Appendix 1: Mankoski Pain Scale

References:

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