Is it possible to intensify the effect of an osteopathic treatment through automobilisation (in a structural and visceral way), regarding success of treatment and long-term result instancing chronic low back pain patients?

Master Thesis in order to obtain the academic title
Master of science in osteopathy
at **Donau university Krems**

set down

at **Vienna School for Osteopathy**

from

Elisabeth Bilgeri

Feldkirch, November 2006

Supervised by *Mag. Katharina Musil*
Translated by *Mag. Wolfgang Bauer*

DECLARATION IN LIEU OF AN OATH

I hereby declare that I have written the submitted Master Thesis on my own.

All passages that have been taken over literally or roughly from other persons´published or unpublished work have been marked as such. All sources and aids I have used for the thesis are mentioned. The thesis of the same content has not yet been presented to another examination authority.

Feldkirch, November 2006 Signature

In the course of this master thesis I would like to thank everybody who has supported and accompanied me over the past six years of my osteopathy training:

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Abstract

Objective: Revision of hypothesis, whether the success of osteopathic treatment at patients with chronic lumbago is bigger with automobilisations, or respectively whether the long-term result can be improved.

Design: Controlled, randomised, single-blinded follow-up study.

Subjects and methods: Randomised separation of the 20 patients into 10 patients of group 1 (test group) and 10 patients of group 2 (control group).

Interventions: 3 treatments at intervals of 10 days and a check-up 8 weeks after the last treatment.

Results: Regarding intensity of pain and quality of life the success of treatment was higher for the group without automobilisations than for the group with automobilisations. The long-term result of osteopathic treatment showed that the group with automobilisations did better than group 2 regarding the intensity of pain and was even statistically significantly better regarding the quality in life.

Conclusion: Automobilisations do not improve the success of osteopathic treatment. However the long-term result of osteopathic treatment that is supported by automobilisations is statistically significantly better.

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1. Preface

In the course of my osteopathy training at the Vienna School for Osteopathy I would like to present a study on the basis of which I would like to evaluate whether the effect of osteopathic treatment can be improved through automobilisation.

During my whole osteopathy training I always engaged myself in the question whether osteopathy was limited to the implementation of passive techniques? By the loosening of primary lesions „a certain potential energy" is released which gives the body the power for self-healing. This process takes place unconsciously to the patient. In my therapy sessions it is very important that the patient receives the opportunity to co-influence the easing of his discomfort by using self-activity and self-responsibility.
I can fortunately notice that Robert Fulford, who was regarded as one of the leading American osteopaths, stated *„dass der Erfolg einer osteopathischen Behandlung durch spezifische Übungen gesichert würde und eventuellen Rückschlägen vorgebeugt werden" [*the success of osteopathic treatment could be secured through specific exercises and possible setbacks could be avoided by them*]*. (Fulford quoting Mayer 2002, p. 26)
Even Guido F. Meert, osteopath und technical leader of D.F.O. Regensburg replies to the question whether osteopathy was limited to the implementation of passive techniques: *„Für mich ist Osteopathie eine „zärtliche" Anwendung von manuellen Techniken, deren Stärke und Einzigartigkeit in ihrer feinen Abstimmung auf die Bedürfnisse des Individuums liegt. Ich persönlich als Osteopath der „älteren Garde" glaube, dass es auch wichtig ist, den Patienten aufzufordern, nach der Behandlung aktive Eigenmobilisationen und Übungen auszuführen, sozusagen als „Hausaufgabe" [To me, osteopathy represents a „tender" application of manual techniques, the strenghts and uniqueness of which lie in the fine tuning and requirements of the individual. I personally believe as an osteopath of „some experience", that it is also important to ask the patients to accomplish active self-mobilisation and exercises after the treatment, as it were "homework"].* (Meert 2002, preface in Visceral automobilisations)

The two above quoted statements are dear to my heart. For that reason I would like to examine in my thesis paper the aspect of the meaningfulness of automobilisations supporting osteopathic treatment.
As I am confronted with the disease pattern of chronic low back pain in my practise on a daily basis I decided to inspect this clinical picture. 50%

of my patients come for treatment because of pain in the lower back. Furthermore, back pains are of vital medical and socio-economic importance due to the impressive epidemiologic frequency and chronic progression. It ranks among the most cost-intensive health problems at all.

2. Introduction

The aim of my study is the clarification of the following problem:

Is it possible to intensify the effect of an osteopathic treatment through automobilisation (in a structural and visceral way) regarding success of treatment and long term result instancing chronic low back pain patients.

My hypothesis is as follows:

The success of osteopathic treatment regarding levels of pain and quality in life is higher through directed automobilisations, and respectively the long term result is better.

The relevancy for osteopathy lies therein that on the basis of my study I primarily capture what can be achieved with chronic low back pain patients by using 3 osteopathic treatments regarding levels of pain and quality in life. Secondary I try to detect to what extent the result of osteopathic treatment can be improved with directed automobilisations regarding levels of pain and quality in life.

Osteopathic treatment has already been proved effectively in scientific studies in Paris in 1996 and in Munich in 1999. Admittedly the treatment of both studies focused only on 5 zones that verifiably showed the most significant dysfunctions (thoracolumbar junction, os coccygis, m.iliopsoas, art. iliosacral, small intestine and colon). [12]
There are many studies that examine and compare the effectiveness of various methods of treatment for patients suffering back pain.

As a consequence of my research in scientific literature about low back pain it appears to make most sense and to be most effectively to treat low back pain patients firstly according to the general and basic principles of osteopathy and subsequently to guide them to individual automobilisations to stabilize the achieved condition.

3. Theoretical basics

3.1 Osteopathy

Osteopathy is booming in German speaking countries like no other treatment method. But what is actually meant with that term? There is no fixed definition as osteopathy can hardly be limited with words.
Looking at the two parts of the term "osteopathy" separately helps understanding the meaning. "osteon" means bone and "pathos" is the ability to stir sympathy, affliction and emotions.
D.L. Tasker states in „Principles of Osteopathy" (1916): „Es gibt viele Definitionen von Osteopathie. Jede hat die Tendenz, sich selbst einzugrenzen. Eine Definition limitiert immer die Sache, die definiert wird. Deswegen ist keine Definition von Osteopathie komplett. Wir reden über ein Prinzip, nämlich über das Universelle, das niemand kennt."[There are many definitions of osteopathy. Each has got the tendency to limit itself. A definition always limits the matter that is defined. Therefore no definition of osteopathy is complete. We speak of a principle, i.e. about the universe, that no-one knows (Tasker 1916 quoted according to [36], p. 9)
Hartmann (2002) also stresses that osteopathy is more than just a method of treatment. „Osteopathie ist eine Philosophie, eine Lebenseinstellung, ein ethisches Fundament, ein Glaubensbekenntnis und noch vieles mehr"[Osteopathy is a philosophy, an attitude towards life, an ethic foundation, a confession and many other things]. ([3], preface) The resulting methods of treatment would only be a logical development of the extraordinary fate of Andrew Taylor Still.

The basics of osteopathy were developed by the American physician **Dr. Andrew Taylor Still** (1828-1917) already in the second half of the 19th century. Through extensive research he discovered the coherence between health and functional balance of the whole structure of the human organism.
Based on the fundamental knowledge of anatomy and physiology osteopathy is a manual way of medicine that aims via manual techniques to give the body the opportunity to regain metabolic and structural balance that represents a basic requirement for the preservation and recreation of health.

An osteopath doesn't add anything to the body. He trusts in the strength of nature and its self-healing- and self-regulating potential at free bloodflow.

A.T.Still writes: *„Ich glaube, dass die menschliche Maschine die Apotheke Gottes ist und alle Heilungen der Natur in seinem Körper zu finden sind."[I believe that the human machine is god's pharmacy and all cures of nature can be found in the human body]* (Still 2002 quoted according to [3], preliminary remark)
Looking at the human body in a broader context Dr. Still embraced his 5 basic principles, that even today have unreserved validity:

1. Life is motion
2. Structure and function correlate
3. All fluids must be able to flow well in the body
4. The human body works as a unit
5. The human body disposes of self-healing mechanisms

3.2 Low back pain

The following chapter is dedicated to the topic of low back pain. At first I would like to give a definition and to classify back pain according to duration and cause of existing symptoms. Furthermore, I will try to sift out the possible causes and risk factors from various studies and subsequently describe the typical symptoms of lumbago patients.
After listing the prevalent basic clinical diagnostics I will try in chapter 3.2.6 to examine currently well-established methods of therapy and their effectiveness. Finally I will give a short insight into the epidemiology of lumbago patients.

3.2.1 Definition

Chronic unspecific low back pain is defined as a complex of symptoms of locally restricted pain and a varied distinctive dysfunction of the spine; the proneness for recrudescences and with repeated occurences the development of a chronic painful illness is typical. Unspecific low back pain is no nosologic diagnosis. A neurological pathology does not exist. [4]

3.2.2 Classification

The difficulty is to come up with a consistent classification, as the pathological process of lumbago has not yet been explained ultimately.[13,29] The most common and most simple classification is the one according to the duration of the back pain. The second, already not so clear classification, is the one according to the cause of the existing symptoms.

Classification of back pain according to duration of existing symptoms: [5]

Acute back pain	0 – 6 weeks
Subacute back pain	6 weeks up to 3 months
Chronic back pain	more than 3 months

Classification of back pain according to the cause of the symptoms: [5,15,19]

1. Mechanical or unspecific back pain:
   90% of lumbago back pain have a mechanical reason. The symptoms arise locally around the lumbar region, the fundament and possibly around the thighs without any suspicion of a participation of the spinal nerves or any other serious pathology.
2. Secondary back pain:
   Applies to about 10% of lumbago patients. Refers to a non-mechanical cause of pain or a fracture and is mostly associated with a serious underlying pathology. Among these are:
   - Inflammable-rheumatic mediated diseases (eg. Mb. Bechterew)
   - Infections (eg. epidural abscessus, spondylodiscitis)
   - Tumors (skeletal metastasis, primary bone tumors)
   - Visceral diseases (especially retroperitoneal and urogenital)
3. Back pains that can be traced back to compressions of nerve roots. Among these are mostly discus hernias.

3.2.3 Causes of low back pain / risk factors

There are many epidemiologic studies about the risk factors of back pain and therefor many different results as well.
According to Paul Shekelle, who compared different studies, the highest risk factors for back pain are the following:

- Present anamnesis of back pain problems
- Increasing age (up to 65 years, then the prevalence between pain and increasing age is on the decline)
- Dissatisfaction at work, depression and emotional pressure
- Repeated or heavy lifting of loads (esp. frequent flectional and rotational movement)
- Physical labor
- Sustained sitting or standing

Shekelle regards vibrations, smoking, obesity, height and physical fitness as moderate risk factors. [6,9]

Levangie's study (1999) positively associates back pain with smokers, people who are exposed to daily heavy industrial vibrations, people who spend more than an hour in a car per day and women who have delivered one or more children vaginally. [7]
The risk factor for smokers consists in less blood circulation of the small arterial vessels which in turn affects tissue around the facet joints. [11]
According to Levangie daily lifting of loads, body mass index, physical fitness and sustained sitting and standing were only small predictors for chronic lumbago disease. [7]

G. Waddel (1999) assumes that the respective social class represents the highest prognostic factor in relation to back pain.
This in turn refers to heavy physical work and partly social discrimination. Heavy manual work mostly leads to short-term back pain; however this can very quickly merge into chronic inability under the influence of psycho-social factors. [10,8] Psychosocial factors play an important role regarding back pain and the inability resulting thereof and affect the reaction of the patient regarding treatment and rehabilitation. [15] It is also interesting that timid people have a reduced ability of tolerating painful stimulus. They perceive pain in stronger way and interprete it as more severe than non-timid people. [32]

3.2.4 Symptoms

There is a mechanic, constant pain with varying expression that is occasionally accompanied by a short-term feeling of stiffness in the morning. Blockages of vertebra and episodes of inflammable kind are possible. The intensity varies from moderate to strong. [13]
Relieving posture, restrictions to movement due to pain, muscular myogelosis of back muscles and pressure-sensitive spinal processes are common symptoms of lumbago diseases. [14]

3.2.5 Diagnosis

Back pain is a symptom and not a diagnosis. As a result of the many possible causes (mechanical, inflammable, metabolic, neoplastic dysfunctions or transmitted pain from the pelvis) the generation of a specific diagnosis is mostly nearly impossible. [32] The current basis diagnostics of chronic lumbago disease contains: [4]

- Anamnesis and analysis of pain
- Assessment of general condition
- Manual examination of the spinal column
- Laboratory for basis diagnostics und possibly x-raying

X-raying is not routinely indicated with mechanic back pain [15] Ilka aus der Mark (2005) states that a diagnosis based on image-forming procedures mostly doesn't correlate with the symptoms of those affected. Experts even assume that image-forming procedures (x-raying, computertomography and magnetic resonance imaging) can be seen as co-originators for the increase of back pain. British scientists confirmed in a study that back pain patients that get to see their own x-ray complain about stronger pains and see a doctor considerably more frequently. [16] There is hardly any other region of the human body where radiologic findings and clinical symptoms correlate as badly as with the back. As radiology only creates few relevant, therapeutically crucial findings with the majority of unspecific back pain cases, image-forming procedures should serve more to exclude severe pathologies such as tumors, big discus hernias, osteoporotic fractures etc. [18]
Warning signs or „red flags" (see Table 1) refer to a non-mechanical cause of pain or a fracture and must be clarified medically at an early stage. [19]

Extension of diagnostics through:[4]

- neurological status
- radiography
- CT or MRT
- extended laboratory examinations

age below 20 or above 50 years
malignoma at anamnesis
unaccounted loss of weight
adequate trauma
increasing pain
no improvement through bed rest
predominantly pain in the night
stiffness in morning for more than an hour
intravenous consumption of drugs
long-standing cortison therapy
concurrent urine infection
concurrent dermal infection
bladder- and rectum dysfunction

Table 1: Warning signs for low back pain(„red flags") [19]

3.2.6 Current therapeutic measures

Literature research in connection with the existing record has shown that there is no established and promising method of treatment for chronic

lumbago disease so far. There is a high number of therapy possibilities whereupon no method is said to work sustain ably better than any other. Even meta-analysis regarding the quality and the effectiveness come up with the same result and demand further research [19,20,21,22,24]

Pharmacotherapeutically it has been proved that the combination of muscle relaxants with non-stereoid anti-rheumatic drugs (NSAR) work most analgetic with back pain. [5,15] The side-effects that can be caused by these drugs are not to be underestimated though.
Non-stereoid anti-rheumatic drugs frequently cause gastrointestinal mucosa which can lead to gastrointestinal problems. The most common side effects of muscle relaxants are tiredness, vertigo and sickness. [5]

The results of different studies such as Malmivaara et al. (1995) or Hagen KB et al. (2000) show that ordered bed rest and protection cause more disadvantages than advantages. The trend in the management of lumbago patients clearly heads towards early mobilisation, return to day-to-day activities and work hardening. By motivating the patient with an acute back pain attack to continue everyday activities, the patient is lead to an as fast convalescence and smaller inclination to chronification as when ordered traditional medical therapy with bed rest. [18,15]

According to the clinical guideline spinal manipulations within the first 4-6 weeks, without any signs of a nerve root compression, can result in a short-term improvement regarding pain and activity level and in a higher satisfaction of the patient. [15,25]
On the other hand the profitableness of spinal manipulation is questioned. [20] According to Assendelft et al. (2003) there is no proof that manipulative therapy of the spinal column of patients with acute or chronic pains in lumbar areas is better than other methods of treatment. [21]
A study by Assendelft et al. (2003) as well as the study by Cherkins et al. (2003) point out that the manipulation of the spinal cord is better than placebo treatment, and compared to other established interventions (massage, acupuncture) can be seen as equal. [21,22]
Nevertheless, there is no reason to eliminate the manipulation of the spinal cord from the clinical bag of tricks as there are more and more signs that the manipulation of the spinal cord has clearly defined neuro-physiological effects and counteract to the central pain mechanisms. [23, 31]
Andersson et al.(1999) also found out in a study that the group treated with osteopathic manipulation needed much less drugs (periphal muscle relaxants and non-stereoid anti-rheumatic drugs) to achieve the same

result as the group with the medical standard (Analgetica, NSAR, active physiotherapy, TENS, ultrasonic treatment, lumbar corset). [26]
Concluding to this topic I really like to mention the statement by Gibbons (2004).
Gibbons states that as it is difficult to prove the effectiveness of single interventions, a multi-modal approach of medical care would probably be a forward-looking step under certain conditions. He believes that different kinds of interventions at various stages of the natural history of origins of a problem are more effective and therefore physical exercise can lead to better results in some cases than acute treatment. [20]

Over the last 15 years many studies have proved the positive effects of active exercises for the abatement of chronic back pain.
Many evidence-based medicine studies have been carried out as well to confirm this statement. [34]
According to clinical practical guidelines specific exercises for the back at an early stage lead to a significant improvement of acute back pain. [15]
Active therapy plays an important role especially for the therapy of chronic back pain. More and more the combination of active exercises for the back, ergonomics training and psychologically accompanied pain management is regarded as meaningful in the therapy of chronic lumbago disease. [34,27,35] The problem is to be found in the compliance of the patients concerning the exercises.
A survey found out that one to two thirds of the patients are not compliant with the execution of active exercises. [34] A study by Maul I. et al. (2005) showed that with targeted exercise programmes the intensity of the back pain and inability can be lowered as well as an improvement of functionality such as muscular back stability, mobility and endurance can be achieved. But not only functional and mental effects can be expected from an active training therapy, such as an augmentation of activity levels, of self-confidence and a change in the perception of pain and inability. However, there is still a lack of knowledge about the long-term effects (extending over many years) of treatment. [27]

3.2.7 Epidemiology

60-90% of all adults suffer in the course of life at least once from back pain. For men back pain is the most frequent reason for inability to work, for women it's the second most frequent reason. Acute back pain normally has good prognosis. However, only among a small group of 10% of patients a chronification takes place. This small group generates 80% of costs through inability to work, measures for rehabilitation and early-retirement pensions.

Due to the impressive epidemiologic frequency and due to the often chronic course of the disease, back pain is attributed with a huge medical and socio-economic relevance. Nowadays impairment of functions and diseases of the spinal cord represent the most common and most cost-intensive health problem in modern industrial societies. [19, 28]
Back pain is linked to major consequences for the single person as well as to national economy.

Consequences for single persons	**Socio-economic consequences**
• impairment of quality in life • impact on inability and willingness to work due to pain and functional impairment • handicap in everyday life	• number of days of inability to work • stays at hospitals • medical rehabilitation • inability to work / occupational invalidity

Economic matters:

- Every 5th early retirement pension is caused by back pain;
- On average every back pain patient accounts for about 18 hospital days;
- The sick certificate lasts for about 16 days on average;
- About 70% of the total costs for back pain patients arise through inability to work;
- Every 5th sick certificate is effected by back pain;
- Every 3rd day of inability to work is caused by back pain;

Cost estimation:

The **direct costs** (consultation with doctors, medicaments, treatment in hospital, rehabilitation, physiotherapy) add up to 0,8 billion Euros per year in Germany.

The **indirect costs** arise from the costs that are produced by the high number of inability-to-work days, e.g. wage continuation, costs for replacement workers or loss of production The indirect costs in Germany in 1997 amounted to 1.7 billion Euros.

This therefore results in total costs of 2.5 billion Euro per year. [28, 29]. Hence, it can be seen that the direct costs represent about the half of the indirect costs.

A study carried out in Sweden (Hansson, 2005) came to the very same conclusion that the direct costs only constitute a minor part of the total costs and hence the biggest potential for cost reduction would be the reduction of loss of production. This implies that sick certificates bring about questionable if not counterproductive effects regarding the treatment of chronic back pain. It has been proved as effective that a reduction of sick certificates not only reduces the indirect costs but also leads to a quicker improvement of pain and function by supporting the patient in physical activities as soon as possible. [30]

3.3 Low back pain as viewed by osteopathy

In the following chapter I will describe the possible functional correlations of the lumbar spine and its surrounding structures.
At first I will deal with the osseous, muscular, connective tissue encapsulated, neuronal and vascular connections and later will go into further detail about visceral functional relations.

3.3.1 Structural functional relations to lumbar spine

3.3.1.1 About osseous, muscular, connective tissue encapsulated structures

Here I will shortly describe the importance of the lower extremities (foot, hips and pelvis) in relation to the lumbar spine and will discuss their shock-absorbing function. Subsequently I will explain the meaningfulness of the thoracolumbar junction and the closely related diaphragm. Eventually I will deal with the function of the lumbal fascias and give an explanation of the polygon according to Little John, which points out a global survey of possible functional relations within the spinal cord.

3.3.1.1.1 The foot

Dysfunctions of the fibula, the os cuboideum, os naviculare and indirectly of the talus at disruptions of m. tibialis posterior and of mm. peronei longus and brevis can induce ascending lesions. [36] A typical example for this would be the supination trauma. Through that trauma mechanism the cuboid bends lateral – the fibula glides caudal – fixation of the proximal art. tibiofibularis – increased tension of m.biceps femoris – continuation of tension into lig. sacrotuberal and sacrospinal, aponeurosis of m. piriformis and m. obturator internus. The aponeurosis of piriformis is continued in lig. longitudinal anterius of the spinal cord. Membran obturatoria is influenced by m. obturator internus and has a direct connection to the bladder. [38, 39] This chain of lesion could be traced back further cranial up to the cranium, but this would go beyond the scope of this unit.

Furthermore the architecture of the foot disposes of important shock-absorbing systems: [37]

- connective tissue below calcaneus
- spongy assembly of talus and calcaneus
- double pivotal point system at calcaneus
- tibiocalcaneal dislocation at front layer
- arch of foot
- spring hanger in metatarsus (deep lig. and sinews of the foot, os cuneiformia)

3.3.1.1.2 The hips

The hip joint is a primarily muscle-lead joint. The least muscular dysbalance affects the balance of the pelvis and therefore that of the spinal cord. [37]
The two hips and the pelvis form the bottom of the lower triangle of the polygon according to Little John (lumbar triangle with L3). The lower triangle secures the abdomen function via rhythmic activity of the thorax on L3. There is reciprocal action between the dysfunctions in the hip area and the gravity lines of the spinal cord.
The shock-absorption of the hip joint is mostly ensured through the shock-absorbing mechanisms of the foot (architecture of the foot, lower ankle) and the loin-pelvis-clasp. The hip is linked to the bladder through m. obturatorius internus and its fascias and through the umbilical-prevesical aponeurosis to the abdominal organs. A hypertonus of the ischiocrural muscles can lead to dysfunction of L5-S1 or of art. tibiofibularis proximalis. A hypertonus of the adductors can be the reason for a dysfunction of the symphysis pubica or of the hip joint. [36]

3.3.1.1.3 The pelvis

The pelvic girdle represents a closed osseous-jointed ring. From a biomechanical point of view the thoracolumbar junction as well as the two hip joints can not be separated from the pelvis. The function of the pelvis also is in a very close relation to the function of the knee joint and foot. The balance of the pelvis area is of significant importance to the balance of the whole spinal cord. This is emphasized in the functional unit of the loin-pelvis-clasp, which represents an important shock-absorbing system to the body. The loin-pelvis-clasp is normally described in the sagittal plane. It consists of a lever system, the principal axis of which lies in the sacroiliacal joint. [37]

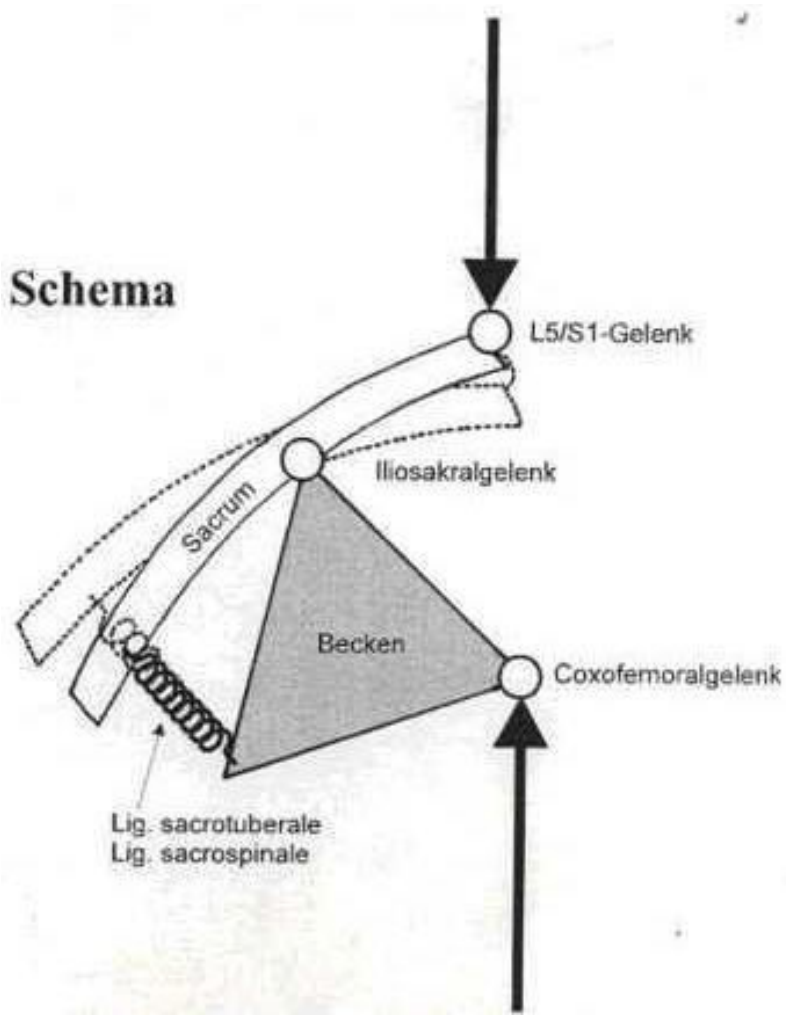


Figure 1: The loin pelvis-clasp [37]

The lumbar spine, pelvis and hip joint are in very close functional relation through the following muscular structures: [36,37]

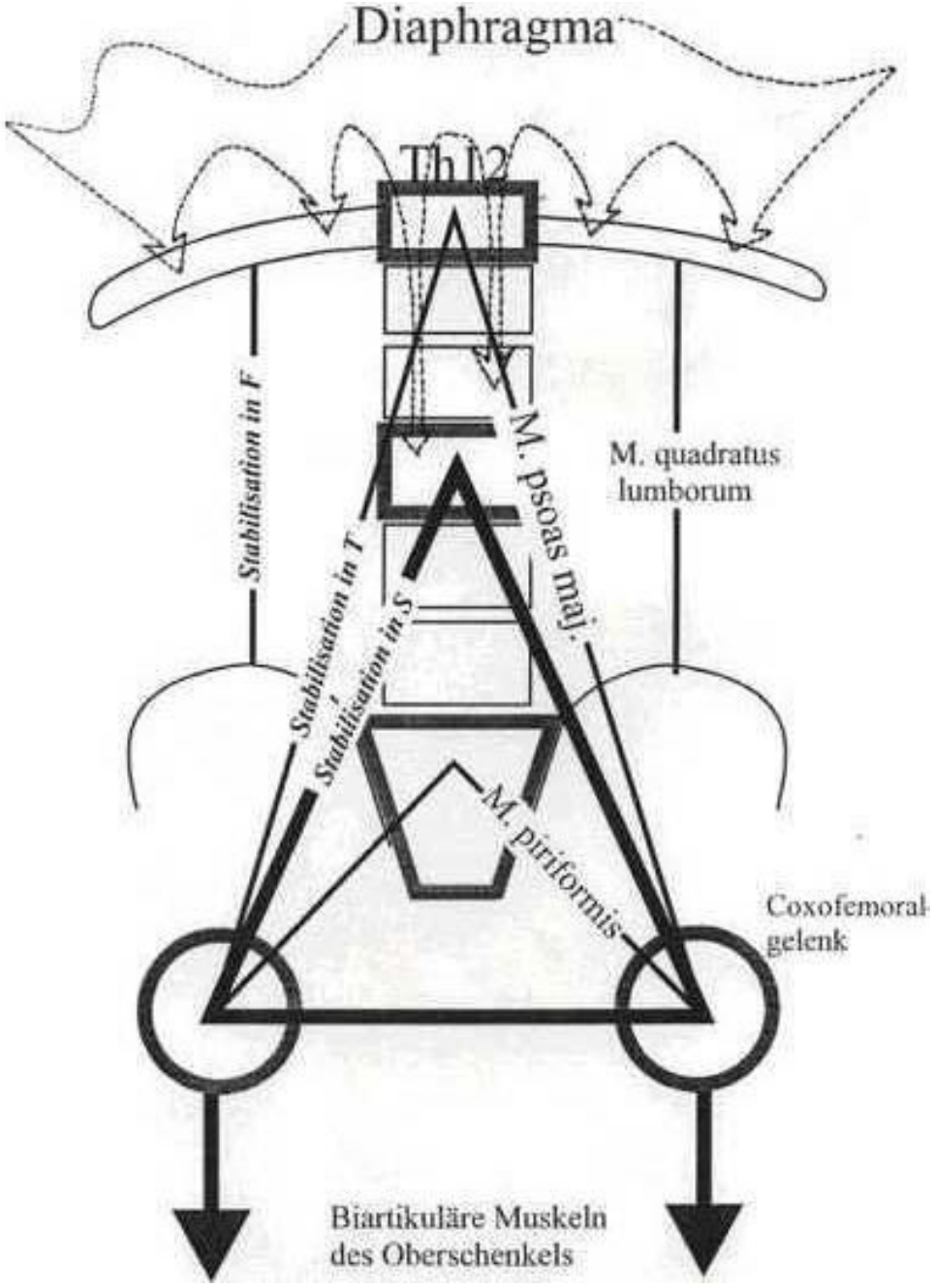


Figure 2: Muscular functional relation between hip joint, pelvis and lumbar spine [33]

M. iliacus:

is often responsible for relapsing problems in the lumbosacral junction (L5/ S1).

M. psoas major:

Because of its origin at Th12-L4 it is frequently co-responsible for dysfunctions at Th12/L1, L1/L2 or through the lever arm effect at L5. The narrow fascial connection of m. psoas with the kidney, colon ascendens and diaphragm is also very crucial. Thus, the psoas represents an important connection between the thoracolumbar joint, lumbar spine, pelvis, hip, intestine and kidney. Plexus lumbalis runs between the layers of m. psoas.

M. quadratus lumborum:

Bilateral-symmetric tonus relations of the left and right m. quadratus lumborum lead to a stabilisation of Th 12 above the 12^{th} rib. Ascending chains of lesions, coming from the lower extremities, can alter the tonus unilaterally especially through lesions of the pelvis. An asymmetric tension ratio and the destabilisation of Th 12 follow. A hypertonus can be the reason for lesions in Th12/L1, 12^{th} rib or iliosacral joint.

M. piriformis:

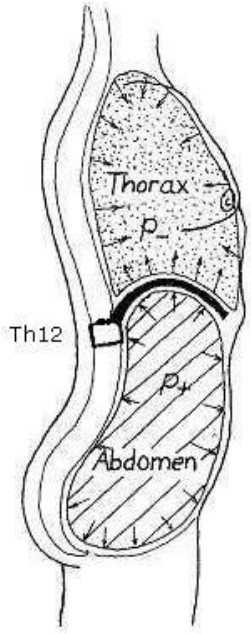
can be the reason for pain in the hips, dysfunctions of the iliosacral joint and of L5/S1 via sacral torsions and can be the reason for dysfunctions between L4/L5.

3.3.1.1.4 The shock-absorbing mechanism

The shock-absorbing systems of the lower extremities (architecture of the foot, lower ankle joint, tibiarotation, art. femorotibial, art. femoropatellaris, m. quadriceps, loin-pelvis-clasp) have a strong impact on the loading of the lumbar spine while walking or running.
Functional impairment of one of the named parts can lead to overstraining of the vertebral body itself and especially of the intervertebral discs. [36]

3.3.1.1.5 The thoracolumbar junction

Dysfunctions in the thoracolumbar junction affect the mechanics of the whole lumbar spine and are often responsible for relapsing problems in the L3-S1 region. With a good mobility of L5 towards the rest of the lumbar spine loss of mobility through the thoracolumbar junction could be compensated there, however, with the consequence of cumulative dysfunctions in that area. [36]
Due to its manifold anatomical and functional relations to inner organs, muscular, vascular and neurogene structures the thoracolumbar junction is starting point to many dysfunctions.



Th 12 has got the function of a turning platform that keeps the balance between (negative pressure) and abdomen (positive pressure). The connection between the two pressure chambers is carried out via the diaphragm. Interferences in the stress ratio of these chambers (viscerale problems) implicate a repercussion on the diaphragm and on Th12. Inversely, there are repercussions on the diaphragm, thorax and abdomen, when Th12 is in lesion.

Figure 3: The thoraco-abdominal balance [37]

3.3.1.1.6 The diaphragm

There is a connection between diaphragm to L1-2 and to 12 rib via ligg. arcuata (Psoasarcade and quadratusarcade). Among other functions the diaphragma serves the stabilisation of the 12th rib in the frontal plane.
The crus medial dextra reaches up to vertebral body L3-L4. The crus medial sinistra from vertebral body Th12-L2. The hiatus oesophagus and –aorticus are positioned exactly at the level of Th 12. Therefore hernia problems can originate secondarily from lesions of the thoracolumbar joint. Inversely, the cardia can reflectively be influenced via the level of Th12/L1. [36,37]

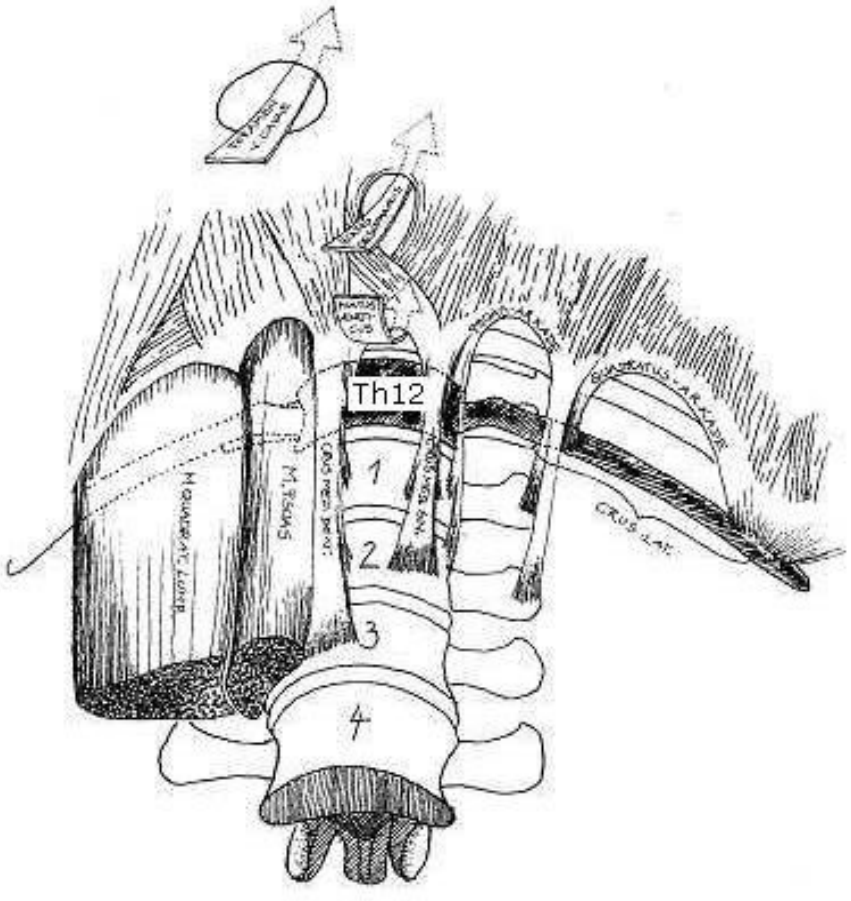
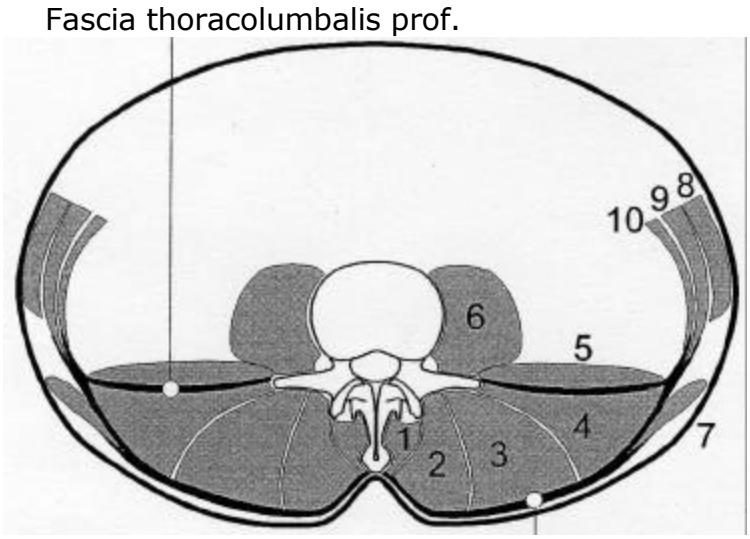


Figure 4: Diaphragm and thoracolumbar joint [37]

3.3.1.1.7 The lumbar fascias

The posterior system of fascias in the lumbar area consists of two layers:



Transversal section on the level of lumbar spine. Scheme of lumbar fascias system and its muscelloges.

1...M. spinalis & Mm. interspinales	*6…..M. psoas major*
2...M. multifidus	*7…..M. latissimus dorsi*
3...M. longissimus	*8…..M. obliqu.abd.ext.*
4...M. iliocostalis	*9…..M. obliqu.abd.int.*
5...M. quadratus lumborum	*10…M. trans.abd.*

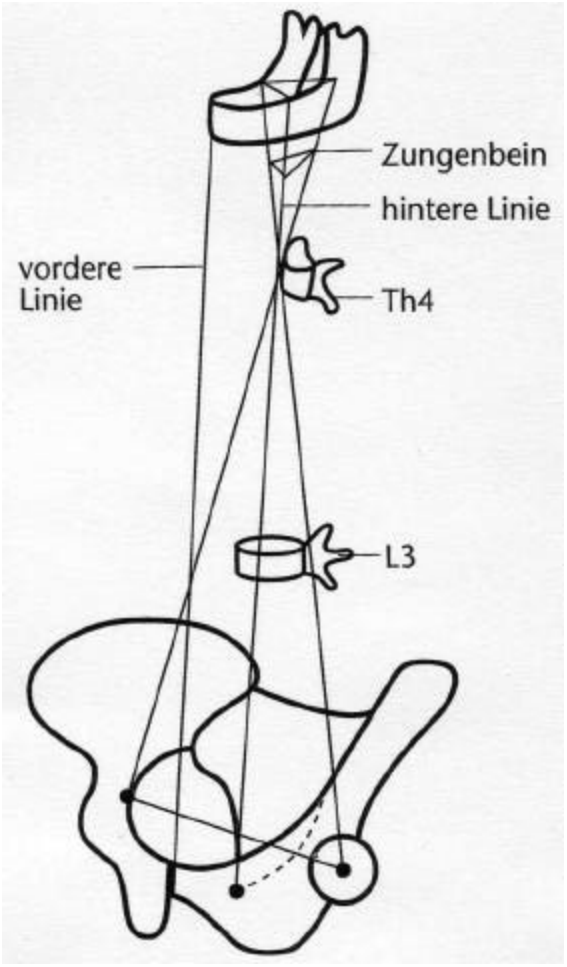
Figure 5: The lumbar fascia system [37]

- Fascia thoracolumbalis superficialis:
  The superficial location starts at proc. spinosus and forms lateral a part of the origin of m. latissimus dorsi as well as m. serratus posterior inferior. Below these muscles the fascia turns towards the body, where it is joined with the deep fascia.
- Fascia thoracolumbalis profunda
  On the spot where both fascias are connected they form the insertion area of m. obliquus abdominis internus and of m. transversus abdominis.

Factors that put the system of fascias in tension:

- The flectional movement of the lumbar spine (passive system).
- The extension of pressure in the loge of deep musculature. Exertion and contraction of muscles of erector spinae lead to an inflating of the loge at constant volume. This results in an increasing tension in the superficial fascias with subsequent extension of pressure in the loge. A smaller development of the erector spinae could bring about a reduction of effectiveness, whereas well-developed back muscles would increase it.
- The traction of lateral attached muscles (active system). The two deepest abdominal muscles (m. obliquus abdominis internus und m. transversus abdominis) as well as m. latissimus dorsi originate at the thoracolumbar fascias. Through contraction of these muscles a lateral traction on the dorsal system of fascias takes place. This lateral traction is transmitted through the crossed fibres of the thoracolumbar fascias into a longitudinal traction and it can therefore be seen as an active system of extension.
- Intra-abdominal pressure.
  This pressure increases with an extension movement with simultaneous contraction of the abdominal musculature. According to Gracovetsky (1988) the main reason for the intra-abdominal extension of pressure is to be seen in the maintenance of the intra-abdominal volume at a constant level. The onset of power of the lateral muscles can only remain efficient in that way. However, the statement that with systematic treatment of lumbar pain syndromes by means of abdominal training aiming to increase the intra-abdominal pressure in order to relieve the lumbar spine has not been accounted for yet. [37] Changes in the intra-abdominal pressure can affect the statics and consequently the mechanics of the lumbar spine, e.g. an overstraining of the front abdominal wall leads to insufficiency of the lumbar system of fascias through alteration of lordosis or pelvis-thorax-relationship when standing. [36]

3.3.1.1.8 The mechanical triangles according to Little John



Littlejohn designed the polygon of power, that affect the vertebral column. This polygon is formed by many different lines of force: [36]

The antero-posterior line (ap-line) runs from the anterior edge of the foramen occipital magnum up to the top of the coccygis. It corresponds to the musculo-ligamentary tension of the column, incorporates the column into a functional system of joints and is vital for the maintenance of the antero-posterior curves of the column.

Figure 6: Polygon of forces according to Littlejohn [36]

The postero-anterior lines (pa-lines) run from the posterior edge of the foramen occipital magnum to the anterior edge of the vertebral body of L3, where they separate and further on in the course of the psoas muscles to the hip joints. The pa-lines co-ordinate the pressure of the visceral cavities and support the organs of the pelvis and abdomen as well as the vertebral column.

The lines of forces cross each other and by doing so form two triangles that are balanced on top of each other. The cross-over point is situated on the level of Th4.
The **upper triangle** represents the basis of the occiput and is balanced with its top on Th4.
The bottom of the **lower triangle** is formed by the two hip joints and the pelvis. The top runs cranial to Th4. As the pa-lines separate on the level of L3 into two lines and pull towards both hip joints a **smaller lower**

triangle is formed. Since the pelvis and the two hip joints form the bottom for the „big" and „small" lower triangle, their normal function is prerequisite for the support of abdominal tension. The upper and lower triangle sustain the pressure ratio of the visceral cavities and by doing so support the organs and the vertebral column. [Wernham 1985 quotet after T. Liem]
L3 as centre of gravitation and top of the small triangle as well as **Th4** as cross-over point of all lines of forces and point of balance between upper and lower triangle play an important role in statics. Dysfunctions in these two areas usually are a sign of static imbalance. If only L3 is affected, this may hint to an imbalance below L3 up to the pelvis and the lower extremities. If only Th4 is affected, this can hint to an imbalance above Th4 of the structures of the upper triangle and the shoulder girdle. [36]

3.3.1.2 About neuronal structures

In this chapter coherences with the lumbar spine via vegetative and somatic nerve tracts will shortly be described.

3.3.1.2.1 Vegetative

a) Sympathetic

Plexus coeliacus:
Cross linking of the ganglia paravertebralia in the region of truncus coeliacus towards plexus coeliacus on the level of Th 12/L1

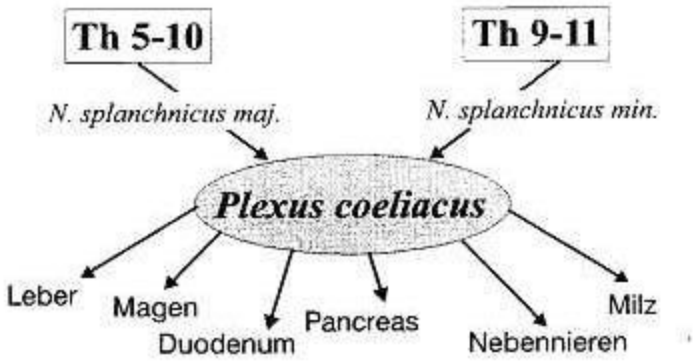


Figure 7: Neurovegetative relations [33]

Ganglion mesentericum superius and Ganglion mesentericum inferius:
The ganglion mesentericum superius is situated topographically on the level of L1 and the ganglion mesentericum inferius on the level of L3. [33,45]

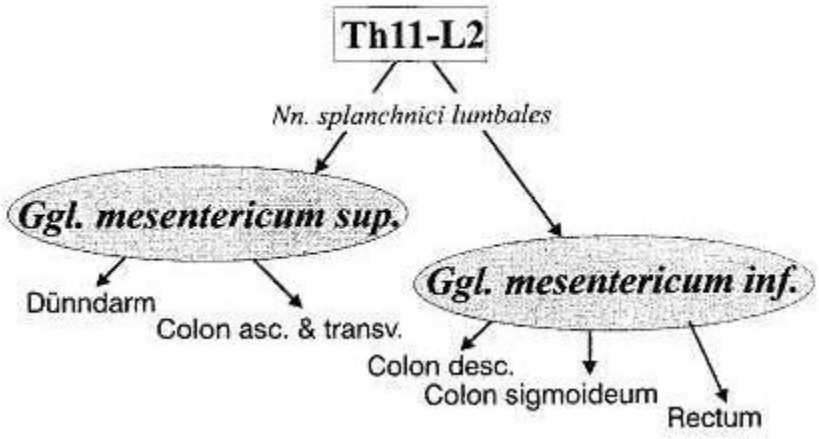


Figure 8: Neurovegetative relations [33]

b) Parasympathetic

Rami coeliaci and – renales of n. vagus in the region of truncus coeliacus and of aa. renales. An irritation of N. vagus through lesion of Th12/L1 is possible. [37]

3.3.1.2.2 Somatic

a) Sensory and motor nerves from thoracolumbar junction [37]

N. subcostalis (Th12) can lead to gluteal pain or pain in the region of crista iliaca when irriated.
N. iliohypogastricus (Th 12/L1) also leads to gluteal pain.
N. ilioinguinalis (L1) clinically presents itself in terms of inguinal pain.
N. genitofemoralis (L1/L2) also leads to inguinal pain in case of a dysfunction.

The innervation of m.psoas major and minor (Th12/L1) as well as the innervation of the abdominal muscles (Th12-L2) also takes place from nerve roots of the thoracolumbar junction.
Mechanic or vascular problem of level Th12/L1 can effect ischialgias, glutealgias and similar symptoms in further caudal lying areas. [37]

b) Diagram of plexus lumbalis

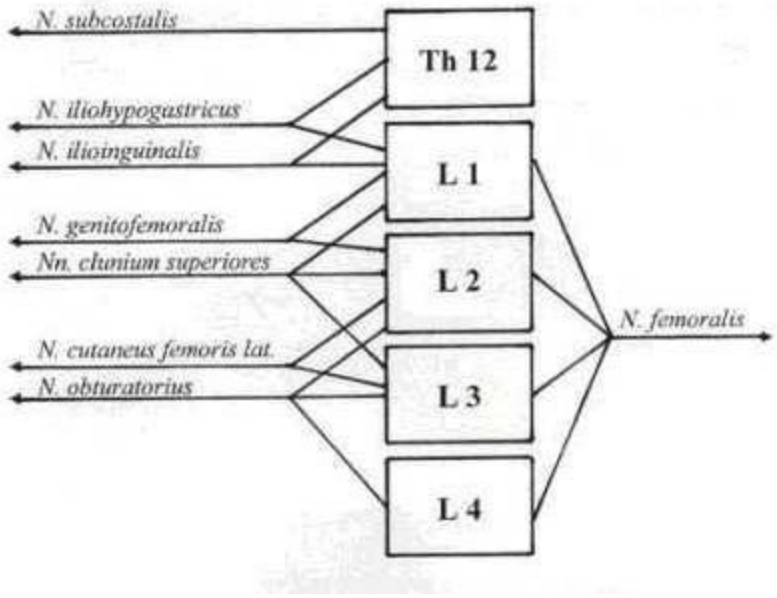


Figure 9: Plexus lumbalis [37]

The innervation of biarticulary femoral muscles that have an important function for the position of the pelvis, lordosis and that of the hip joints is carried out from nerve roots L3-S1. [33,37]

3.3.1.3 About vascular structures

As the law of the artery or respectively fluids is a vital principle of osteopathy I would like to point out important venous, lymphatic and arterial functional relations to the lumbar spine in the last chapter.

3.3.1.3.1 Venolymphatic:

Via the valveless plexus venosus and the vv. lumbales drainage into the v. lumbalis ascendens and into the v. cava inferior, connection to venous system especially of the left kidney and to the organs of the pelvis and indirectly to v. portae as well as cranial to veins of the base of the skull and sinus venosus duralis. [36] Cisterna chyli, a bulge of the starting ductus thoracicus, that carries the lymph from truncus lumbalis and –intestinalis, is situated in the area of the hiatus aorticus and therefore on the level of Th12. [37]

3.3.1.3.2 Arterial:

- Aa. lumbales from the aorta.
- Outlet of truncus coeliacus (supplies arterially spleen, stomach and the liver) from the aorta on the level of Th12.
- Outlet of a. mesenterica superior on the level of the junction of Th12/L1.
- The a. renales branch off from the aorta on the level of L1.
- On the level of L2 the aa. ovaricae/testiculares and a bit distal from that the a. mesenterica inferior leave the aorta.
- The separation of the aorta into left and right a. iliaca interna takes place at L3 [37]

3.3.2 Visceral functional relations to lumbar spine

In the following chapter I will describe possible visceral coherences that could co-produce lumbago. The osteopathic chains often follow fascial structures or can be explained in a reflectory way because of the vegetative innervation of the organ. As a result of the organisation of the fascia as a continuum of tissue interrelated to each other parietal or functional symptoms far away from the actual cause can materialize (here through dysfunction of an organ). In this context an osteopathic chain describes the anatomic-functional, often fascial way of the cause to the symptom. [39]

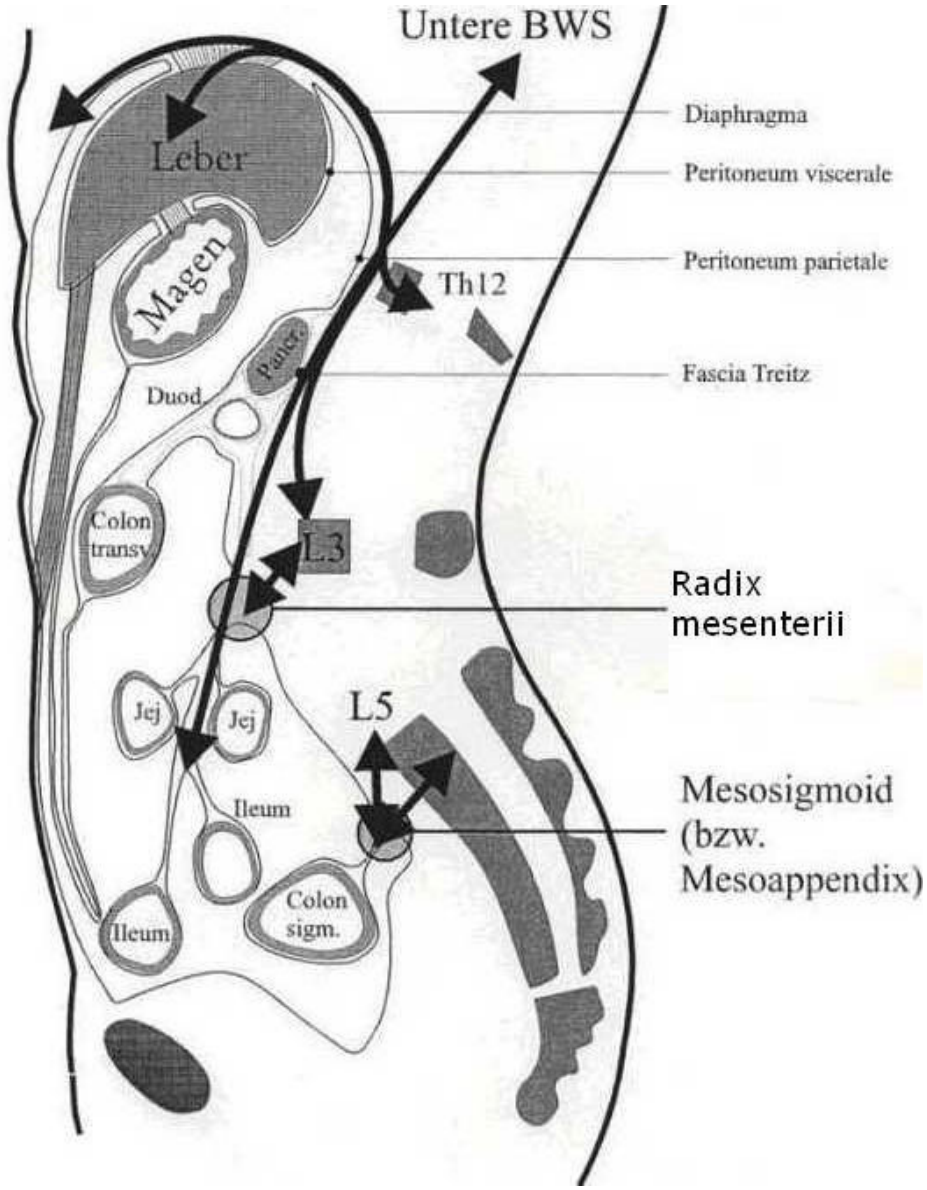


Figure 10: Fascial relations between lumbar spine and gastrointestinal tract [33]

In the gastro-intestinal system the following sections have an impact (referred pain) on the lumbar region:

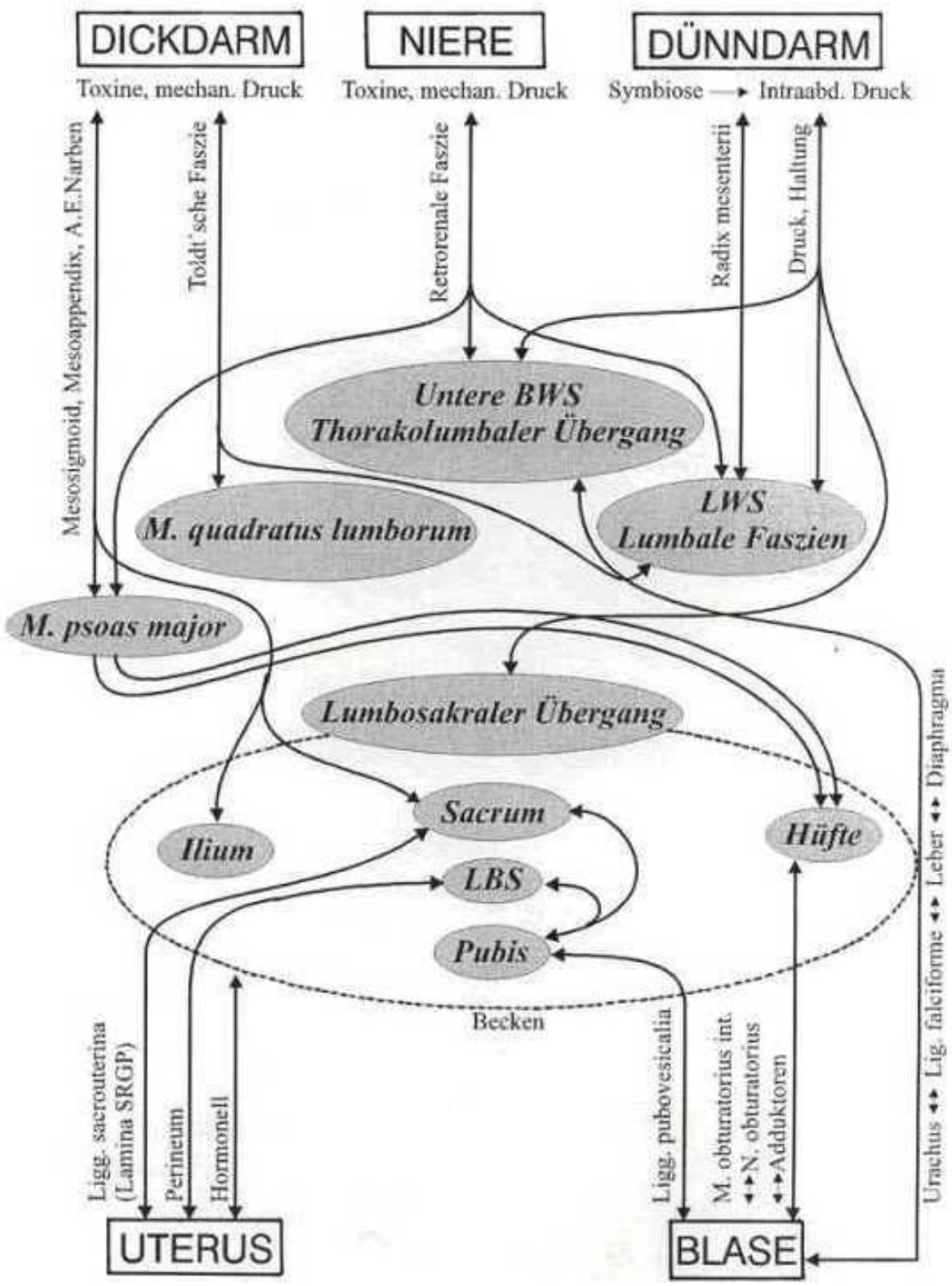


Figure 11: Visceral functional relations to the lumbar spine [33]

3.3.2.1 Small intestine

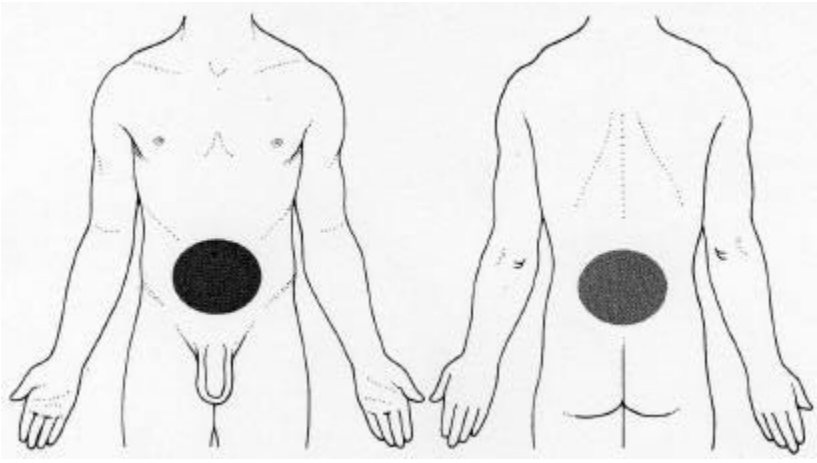


Figure 12: Midabdominal pain (dark grey) caused by disturbances of the small intestine is centered around the umbilicus and may be referred (light grey) to the low back area at the same level. [32]

- Associated structural dysfunctions of the duodenum:
  - Th 12 / L1
- Atypical symptoms of the duodenum:
  - Pain in the area of the thoracolumbar junction with relapsing structural dysfunctions.

The duodenum has connections to the lumbar spine as its pars descendens runs at the right lateral edge of the upper lumbar spine.
The last part of the duodenum is connected with the crurae of the diaphragm through the Treitz ligament, which has contractile fibres. The rest of the small intestine is fixed with its root, radix mesenterri to the back wall of the abdominal cavity. This root crosses the axis on the level of L3. Therefore the lumbar spine is especially at L3 influenced by the root of the small intestine. [44]

- Associated structural dysfunctions of the jejunum and ileum:
  - Th 10 – L2
- Atypical symptoms of the jejunum and ileum:
  - Pulling feeling below the navel about 3-4 hours after a meal.
  - Malaise when wearing tight trousers.
  - Lumbalgo after standing for a long time.
  - Visible ptosis often combined with hypomobile cervicothoracal junction. [39,40]

- Associated signs and symptoms of small intestine problems:
  - Nausea
  - Fever
  - Diarrhea
  - Pain relief may not occur after passing stool or gas.

- Possible Etiology:
  - Obstruction (neoplasm)
  - Increased bowel motility
  - Crohn`s disease (regional enteritis) [32]

3.3.2.2 Large intestine and colon

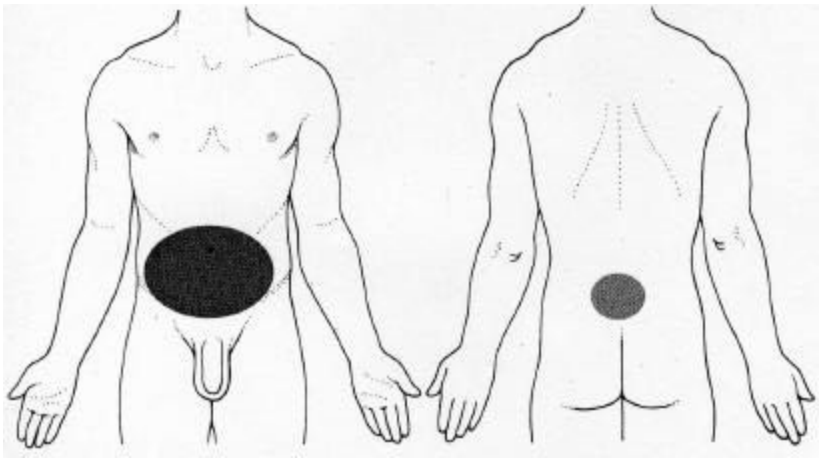


Figure 13: Pain associated with the large intestine and colon (dark grey) may occur in the lower midabdomen across either or both abdominal quadrants. Pain may be referred to the sacrum (light grey) when the rectum is stimulated. [32]

- Associated structural dysfunctions of the colon:
  - L5 / S1
  - Iliosacral joint

Very often the problems of the iliosacral joints are associated with a constraint of the colon: on the level of the appendix on the right side and on the level of the colon sigmoideum on the left side. This especially applies on the right side when an appendectomial scar exists. Tensions in the psoas-muscles on the one or on the other side correspond to a spasm or a limitation in movement of the colon ascendens or descendens particularly on the right side, as a spasm of the valvula ileocoecalis occurs very often. Each irriatation of the colon seems to influence this valve. For

that reason a treatment in this area can often contribute to relax limitations in the right pelvis.
A "heavy" colon (due to obstruction) can affect the lower ribs.
A treatment for the improvement of the colon would solve the limitation of movement of the ribs and could therefore also relax the lower thoracal area of the vertebral column. [44]

- Atypical symptoms:
  - feeling of heaviness and cramps in the abdomen
  - prone position is uncomfortable
  - covered tongue and halitosis
  - flat respiration [39,40]

- Associated signs and symptoms of large intestine- and colon problems:
  - constipation
  - bloody diarrhea
  - pain relief may occur after defecation or passing gas

- Possible Etiology:
  - Colitis ulcerosa
  - Mb. Crohn
  - carcinoma of the colon
  - Colon irritabile
  - irritable bowel syndrome (IBS)
  - long-term use of antibiotics [32]

Very often the m. iliopsoas is influenced by the intestine as it is situated right behind the colon ascendens, an area where toxins can enter the psoas which leads to hypertonocity of the psoas and problems of Th12. The cumulative occurence of ischialgia, psoitis und lumbalgo in autumn can be traced back to the excessive consumption of raw vegetables in summertime because of the strong development of gas in the colon ascendens and the high level of toxical storage in the psoas. [37]

3.3.2.3 Pancreas

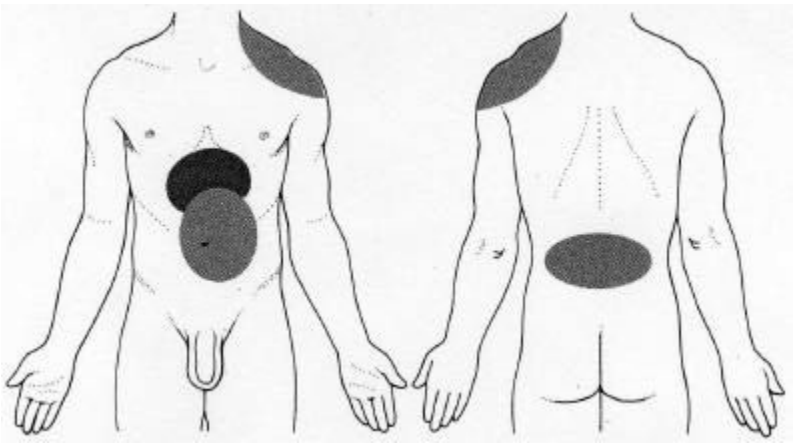


Figure 14: Pancreatic pain (dark grey) occurs in the midline or left of the epigastrium, just below the xiphoid process, but may be referred (light grey) to the left shoulder or to the middle or low back. [32]

- Associated structural dysfunctions of the pancreas:
  - Th 9
  - Iliosacral joint left
  - Levator-scapulae-base irritation left

- Atypical symptoms:
  - Epigastric complaints after meals (sickness, abdominal fullness, feeling of pressure, hot flashes).
  - tiredness
  - Slight forward bent relieving posture.
  - Colourless stool
  - Olfactorial sensitivity [39]

- Associated signs and symptoms of pancratic problems:
  - Sudden weight loss
  - Nausea and vomiting
  - Jaundice
  - Tachycardia
  - Fever
  - Weakness
  - Pain relieving through walking, lying supine and sitting flexed.

- Possible Etiology:
  - Pancreatic carcinoma
  - Pancreatitis
  - Alcoholabuse, too much eaten [32]

In the urogenital system the following sections influence the lumbar region:

3.3.2.4 Kidneys

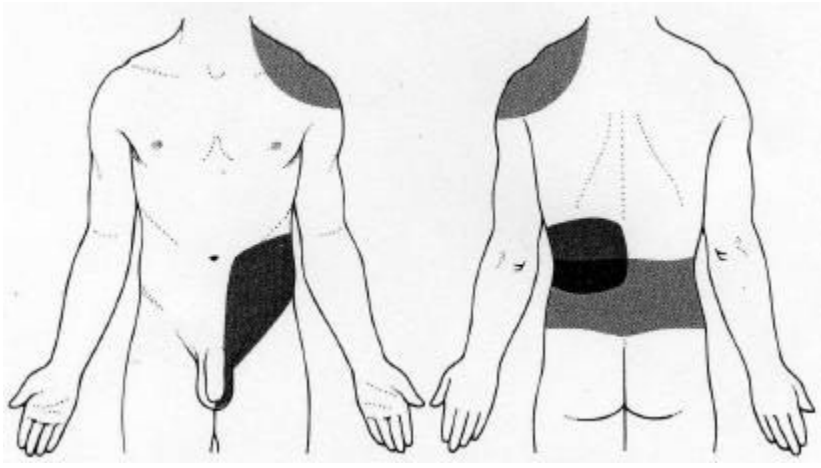


Figure 15: Renal pain is typically felt in the posterior subcostal and costovertebral region (dark grey). It can radiate across the low back (light grey) and / or forward around the flank into the lower abdominal quadrant. Ipsilateral testicular pain may also accompany renal pain. Pressure from the kidney on the diaphragm may cause ipsilateral shoulder pain. [32]

- Associated structural dysfunctions of the kidneys:
  - Th11/12 and costovertebral joints of Th 10-L1.
  - The nerves of Th6/7 or respectively L1/2 can be affected in a reflectory way.
  - Os coccygis, as very often a limitation of movement at the coccygis goes along with a nephroptosis. Otherwise the connection between kidneys and coccygis is not so coherent.
  - Dysfunctions of os ilium.
  - Proximal art. tibiofibularis or os cuboideum, as it is assumed that the tibia could be connected to m. psoas through a muscle chain.

The kidneys are strongly linked to mm. psoas, and this relation could be seen as the most important relation between the visceral and somatic system. Many mechanical problems of the lumbar spine cannot be solved because of a dysfunction of the mm. psoas. One of the most frequent causes for these dysfunctions is an irritation of the kidneys. The kidneys are connected with the thoracolumbar area of the vertebral column (via the sympathetic nerve system) as well as with the 11^{th} and 12^{th} ribs, because they lie anatomically so close. Every time when there is a dysfunction of the m.psoas, it initially has an impact on the lumbar spine and later on the dysfunction of the ileo-sacral-joint; even a dysfunction of

the hips can be caused, as m. psoas originates at femur. A dysfunction of the kidnyes can also be related to a neuralgy of the plexus lumbalis. Its remaining connections consist of organs, that are connected to renal fascias. [44]
It is also interesting that the position of the kidneys is mostly maintained through diaphragmal adduction, the tension of the abdominal muscles and the connections with the colon (flex. coli dext. et sin.) and the liver (right kidney). [38]

- Atypical symptoms:
  - Pain in the lumbar spine disappears shortly after getting up.
  - Pain in the lumbar spine during the day because of exposure such as coughing, sneezing, long sitting or standing and tight belts.
  - Polyuria with big thirst early in the morning or in the night.
  - Dry skin.
  - Symptoms in connection with hypertension.
  - The patient is bent, holds his belly or the lower dorsal ribs. [39,40,44]

- Associated signs and symptoms of kidney problems:
  - Fever
  - chills
  - Blood in urine
  - Hyperesthesia of associated dermatomes (Th9 and Th 10)
  - ipsilateral or generalized abdominal pain
  - Spasm of abdominal muscles
  - Testicular pain may occur in men
  - Headache
  - Nausea and vomiting when severely acute
  - Unrelieved by a change in position

- Possible Etiology:
  - Renal Infections, such as pylonephritis
  - Several disorders of the upper urinary tract [32]

3.3.2.5 Ureter

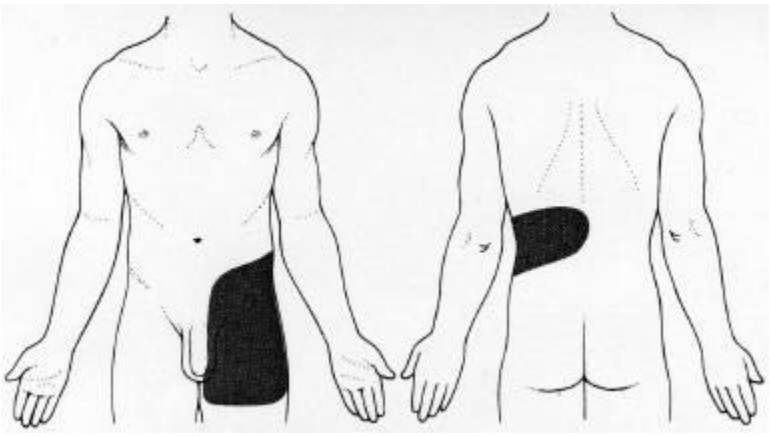


Figure 16: Ureteral pain may begin posteriorly in the costovertebral angle. It may radiate anteriorly to the ipsilateral lower abdomen , upper thigh, testes or labium. [32]

The 25-30 cm long ureter runs on the m. psoas major towards caudal, at the entrance to the small pelvis it intersects the separation point of a. iliaca communis (left) and respectively the a. iliaca externa (right) and descends at the lateral wall of the pelvis near the peritoneum further towards caudal. Therefore the ureters are closely connected to mm. psoas. [39]
Ureterpain is usually acute and caused by renal calculi. Lesions outside of ureter are principally without pain until the disease reaches an advanced level.

- Quality of the pain caused by ureter as a result of renal calculi:
  - Terrible cramp- and colic-like pain that are intermittent or constant, until the stone has passed the constriction.

- Associated signs and symptoms as a result of a kidneystone passing the ureter:
  - Rectal tenesmus (painful spasm of anal sphincter with urgent desire to evacuate the bowel/bladder; involuntary straining with little passage of urine or feces).
  - Nausea, abdominal distension, vomiting.
  - Hyperesthesia of associated dermatomes (Th10 to L1).
  - Tenderness over the kidney or ureter.
  - Unrelieved by a change in position.
  - Movement of iliopsoas may aggravate symptoms associated with a lesion outside the ureter. [32]

3.3.2.6 Bladder / Urethra

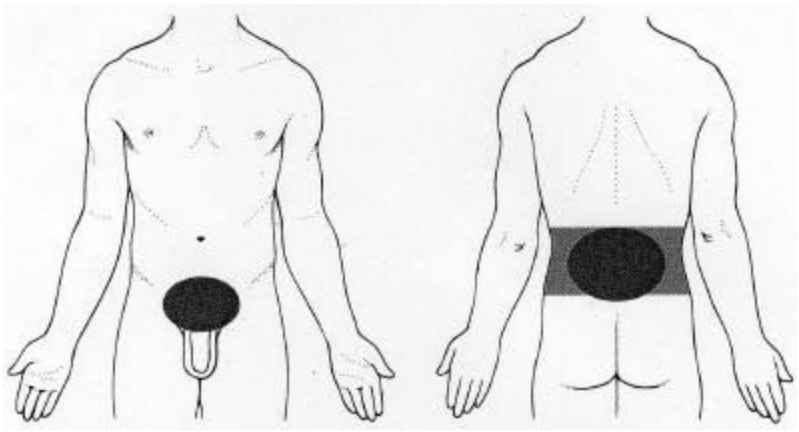


Figure 17: Left, bladder or urethral pain is usually felt suprapubically or ipsilaterally in the lower abdomen. Right, bladder or urethral pain may also be perceived in the low back area (dark grey: pimary pain center; light grey: referred pain). Low back pain may occur as the first and only symptom associated with bladder/urethral pain, or it may occur along with suprapubic or abdominal pain or both. [32]

- Associated structural dysfunctions of the bladder:
  - Sacrum
  - Sacrococcygeal joint
  - Symphysis
  - L 1/2
  - Proximal and distal tibiofibular joint (chain of m. obturatorius internus via lig. sacrospinal and sacrotuberal towards m. biceps femoris)
  - Footarea

- Atypical symptoms:
  - Relapsing pain and blockages at lumbosacral junction.
  - „Feeling of penetration" in the lower lumbar spine and in the area of the iliosacral joint.
  - Cramps of the bladder in case of extension of spine and maximum arm lifting. [39,40]

- Associated signs and symptoms of bladder-/urethraproblems:
  - Great urinary urgency
  - Tenesmus
  - Dysuria
  - Burning sensation during urination.
  - Possible relief of symptoms after emptying of bladder.

- Possible Etiology:
  - Lower urinary tract infection(cystitis, urethritis)
  - Prolaps of bladder
  - Calculus
  - Carcinoma of bladder [44]

3.3.2.7 Uterus

The uterus has got a direct anatomical connection to the sacrum via the lig. sacrouterina and lamina sacrorectogenitopubalis. Fibre of the lig. sacrouterina run directly into the origin of m. piriformis at facia pelvina of the os sacrum. This functional correlation again is interesting in regard to hip mobility and the opening of the mouth of the uterus during the expulsion period when giving birth. The lower back-up system of the uterus is formed by m. levator ani and muscles of the perineum, which also fulfil an important function in the loin-pelvis-clasp. [33]

- Associated structural dysfunctions of the uterus:
  - Lumbosacral junction
  - Th12/L1
  - Because of the topographical nearness to n. obturatorius a reflectory pain in the knee can arise
  - Proximal and distal tibiofibular joint
  - Os naviculare

- Atypical symptoms:
  - Illness in the lower part of the underbelly
  - Low back pain
  - Dysmenorrhoea
  - Dyspareuny
  - Dysfunctional ovulation [39,40]

- Possible Etiology:
  - Endometriosis
  - Prolaps of the uterus
  - Hormonal disturbances
  - Infection of the uterus
  - Ectope pregnancy [44]

4. Design of the study

The trial is a controlled, randomised user observation.

Reasons:

- Controlled study:
  Effects of intervention are not quantifiable without a control group. For that reason the control group is a group that is treated osteopathically but not instructed to use automobilisations.
- Allocation:
  The allocation corresponds to the current demands in quality for clinical studies. An experimental group is formed by means of random selection out of the population available. The allocation is carried out through a randomisation list that divides the patients into two different treatment groups.
- Single-blinded study:
  The patient doesn't know his group membership, the treating osteopath necessarily has to be informed. The blindedness is necessary to avoid an influence of the results through the expectations of the patients. When working manually blindedness of the therapist is not possible; for that reason a single-blinded design was chosen. The blinding offers the possibility to avoid systematic mistakes that could arise through conscious or unconscious preoccupation of the people involved in the study towards the hypothesis. [41]

4.1 Criteria for inclusion

All patients included in the study had to fulfil the following criteria:

- Clinically secured lumbago without radiculary symptoms for at least 3 months
- 18-55 years old
- Intensity of pain (via the visual analogue chart) > or equaling 30%
- Patient can read and understand German (questionnaire, instructions for exercises)
- Patient takes part voluntarily

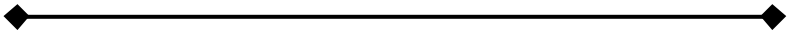
4.2 Criteria for exclusion

Patients will not be included in the trial if at least one of the following criteria appears:

- Younger than 18 years or older than 55 years
- Visual analogue chart < 30% (chart for the assessment of pain intensity)
- Patient does not understand German sufficiently and cannot read
- Patient doesn't sign the letter of consent
- pregnancy
- carcinomas
- osteoporosis
- positive neurological report
- acute cases with massive limitations of movement
- Operative intervention at vertebral column
- Indisposition of one of the illnesses listed in the Borenstein-chart
- Lumbago solely caused by menstruation
- Any analgetic, myorelaxative or antiphlogistic treatmet, that hasn't been discontinued at least 48 hours before the start of the osteopathic treatment

4.3 Primary target parameter: pain

Pain is a subjective matter, that is very hard to quantify. In practise pain is best assessed by the patients themselves. For that reason the classic visual analogue chart is being used (VAS). [42] Structured questionnaires and charts to estimate pain intensity proved as valid and reliable instruments in order to evaluate the efficiency of a certain therapy for the abatement of pain and impairment. [31]
VAS is a horizontal chart, that can be used easily and that is sufficiently sensitive. It measures 10 cm and its extremities are labelled „ 0% pain" and „100% pain". The patient indicates with a cross on the below depicted chart the intensity of pain on the starting day of the treatment. When starting the first treatment, after the third treatment and 8 weeks after the last therapy the patient gets an empty chart, without being able to see the earlier results of the self-assessment.



0% pain 100% pain

4.4 Secondary target parameter: quality of life

For the assessment of functional impairment with lumbago the Roland &Morris life quality-score is being used. The Roland & Morris-score is an abbreviated form of the „Sickness Impact Profiles" (of a quality-of-life-questionnaire) especially for back pain patients and therefore represents a specific measure for functional impairment. In randomised, controlled studies the Roland-Morris Low Back Pain Disability Questionnaire proved valid with back pain patients. [31,43]
The Roland&Morris-score is particularly adequate for the measuring of target parameters in reference to chronic lumbago.

The functional impairment and the extent of pain are being measured in the course of the study before the first treatment, after the third appointment and on the last check-study taking place after 8 weeks in order to follow up the developments of the patient.

5. Realisation of the study

5.1 Recruiting of patients

The recruiting of patients took place via the local doctors that had been earlier informed about the study by me personally (see information for doctors in appendix). The doctor checked the patient already for in- or exclusion criteria, examined the neurological status and the Borenstein chart (see status file in appendix). If the patient fulfilled the conditions required he was sent to Practice for Osteopathy and Physiotherapy Bilgeri, Färberstraße 10, 6700 Bludenz by the following doctors:

Dr. Ehrle (medical specialist for orthopaedics)
Dr. Jenny (general practitioner and sports physicst)
Dr. Jeleff (general practitioner and sports physicist)
Dr. Tschol (general practitioner)
Dr. Schallenberg (general practitioner)
Dr. Tschanett (general practitioner)
Dr. Heuschneider (general practitioner)

5.2 Information for and consent by patients

Before entering the study the patients were handed out an informational leaflet (see appendix letter of consent). This document included the following points:

- aim of the trial
- information about possible reactions and risks
- length of the study
- length of the treatment
- Before the start a letter of consent for the participation in the trail had to be presented

5.3 Randomisation

It is the intention of the trial to demonstrate the effectiveness of osteopathy and to assess whether the effectiveness can be increased through automobilisations. Thus, there are two groups:

Group 1: treated according to the basic principles of osteopathy and instructed for 3-4 individual automobilisations. The length of treatment is about 50-60 minutes.

Group 2: treated according to the basic principles of osteopathy. The length of treatment is also 50-60 minutes.

The randomisation took place via a randomisation list (see appendix). The patients were divided into the two groups of treatment through the order of the randomisation list.

5.4 The course of treatment

The patients received three 60-minute treatments at intervals of 10 days. 8 weeks after the last treatment there was a check-study. The total length of the study therefore came up to three months.

Before the first treatment the patient fills in the questionnaires: (see appendix)

- Letter of consent
- Entry form
  The entry form as well as the letter of consent were put together by me. In the entry form data about the person and information about possible riskfactors that were labelled as relevant in various studies.
- Questionnaire 1 Form to register the intensity of pain (VAS)
- Questionnaire 2 Roland and Morris

Subsequently a detailed anamnesis, an examination and treatment on the basis of a diagnostic findings report (see appendix) followed.
At the end of the third treatment the patient once again fills in the form to register the intensity of pain (VAS) and the questionnaire Roland and Morris. In order to prove the long-term effects the patient is called in again 8 weeks after the last treatment. At that point the two forms have to be filled in a last time by the patient. Patients of group 1 additionally have to fill in questionnaire 3 (see appendix) that can be handed in a box anonymously. By means of questionnaire 3 I want to find out how consistently the patients carried out the exercises learnt in therapy.

5.5 Osteopathic treatment

In this chapter I roughly describe the techniques applied in the study. All techniques were acquired at the Vienna School of Osteopathy. By means of anamnesis and the results taken from preceding examinations, the patients were treated according to the general basic principles of osteopathy. Every patient was treated individually for his complaints. As the reason for chronic back pain can differ from patient to patient, the

treatment complies with the preceding osteopathic findings. Dr. Arthur Still, founder of osteopathy once said: „The human body is a unit, no part of it works independently".
The osteopathic treatment consisted of passive techniques. The patients were not instructed for any exercises of mobilisation, stabilisation or invigoration. Structural techniques, visceral and cranio-sacral techniques were used in the treatment.

Structural treatment:

- For the global examination as well as for the preparation of the soft parts I used TGO.
- Trust-techniques I used with many patients in the thoracolumbar junction, and occasionally in the segments L3 and L5. On the thoracic spine (TH4,TH 9, TH12) I also acted in a mobilising or respectively corrective way on hypomobile segments.
- Corrections of the ilia (ileum anterior or posterior), for the ilea-sacral-joint and mobilisations of the sacrum or respectively relaxations of iliosacral – and sacrotuberal ligaments were necessary sometimes. On 2 patient I conducted an indirect correction of the os coccygis.
- With the lower extremities the hip joint and the ankle joint (inclusive membran interossea) were the joints I applied the most correction or mobilisation techniques.
- I applied inhibition techniques at m. iliopsoas on nearly every patient, as well as techniques or loosening the fascia thoracolumbalis.
- Rarely I used the model of fascia distorsions in order to loosen a trigger fascia at the lumbar spine or a trigger point hernia on the side.
- The frogtechnique was also very helpful to effect a balance between diaphragm, iliopsoas and fascia thoracolumbalis.
- With 2 patients I worked on the connection of occiput – atlas and hence tried to work from cranial on the lumbar spine pains.

Visceral treatment:

- The effect of a kidney mobilisation (left kidney) stayed in my mind especially as the patient declared an improvement of his long-lasting pain from 60% to 30% immediately after the treatment. Fortunately this result remained unchained even after 8 weeks. As tensions in the kidneys were showing with some patients, these were treated correspondingly.

- With three female patients I worked intensively on the connection uterus – sacrum.
- A relaxation of the instestinal tract also proved effectively with 4 patients (Mobilisation of small intestine, radix mesenterii, mesosigmoid, mesoappendix, colonflexures).
- I located tensions in the diaphragm quite frequently and treated it correspondingly.

Cranio-sacral treatment:

- I mostly used cranial techniques at sacrum as for example the sacrumecoute or membranous and intraosseous compensation techniques.
- With two patients I made a synchronisation between sacrum and occiput.
- With many patients I applied a technique for the relaxation of the dura mater and for the balance of SSB.

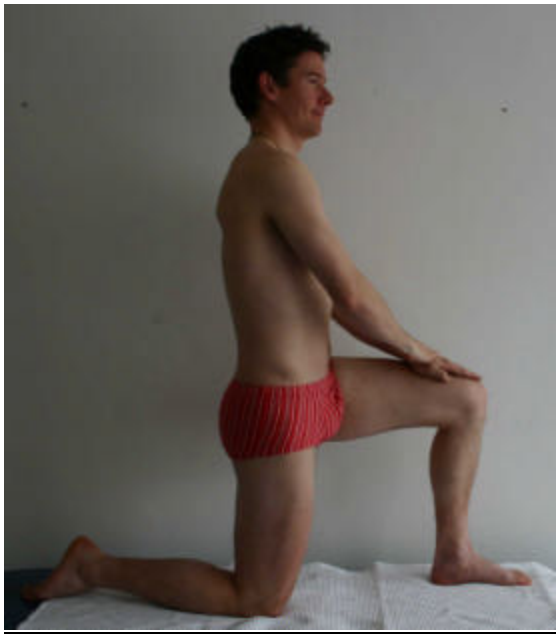
5.6 Automobilisations

Here the automobilisations used with the patients of group 1 are described. Every patient of group 1 received a lesson on good posture and was instructed for 3-4 individually adjusted exercises. The exercises aimed at mobilisation, stabilisation and coordination. The following pictures should give a short insight thereof.

The following photos were taken at Practice of Osteopathy and Physiotherapy Bilgeri in May 2006.

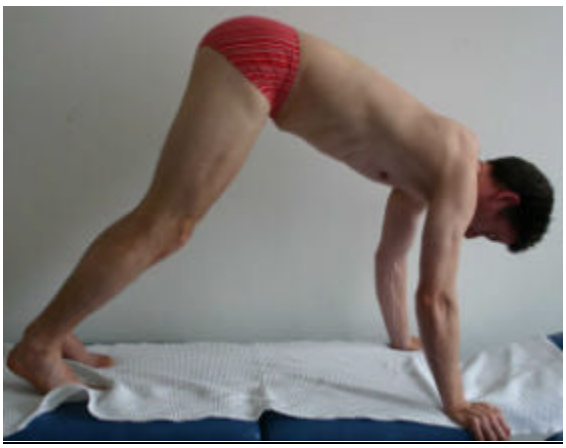
5.6.1 Exercises for mobilisation

- Stretching of m. iliopsoas and respectively hip extension mobilisation



- Stretching of m. piriformis

- Stretching of dorsal leg muscles



Specification: lordosis of lumbar vertebral spine and simultaneous pushing of heels towards caudal

- Stretching of diaphragm thoracic

Specification:

Lateral pulling of the costal edge when breathing in and maintenance of position when breathing out. In subsequent periods of breathing-in try to pull the ribs further towards the chest – so far until they can't be raised any further by pulling the belly inwards. Repeat 2-3 times.

- Stretching of central fascial chain

Specification:
During a continuous abdominal respiration push the lumbar spine towards the mat, keep the cervical spine in retraction and simultaneously brace the shoulders towards posterior and caudal. Stay in this position for 3-4 minutes.

- Automobilisation of the kidneys

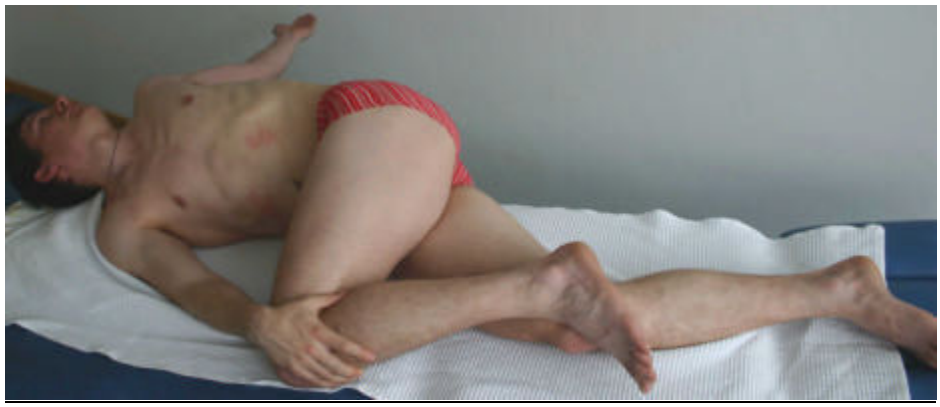
Specification:

The arm rest parallel to the body, towards the top, stretched above the head and the cervical spine is stabilised when retracted. When breathing-out lift the pelvis by putting the knee towards the chin. 3 series with 10 repetitions.

- Automobilisation of small intestine

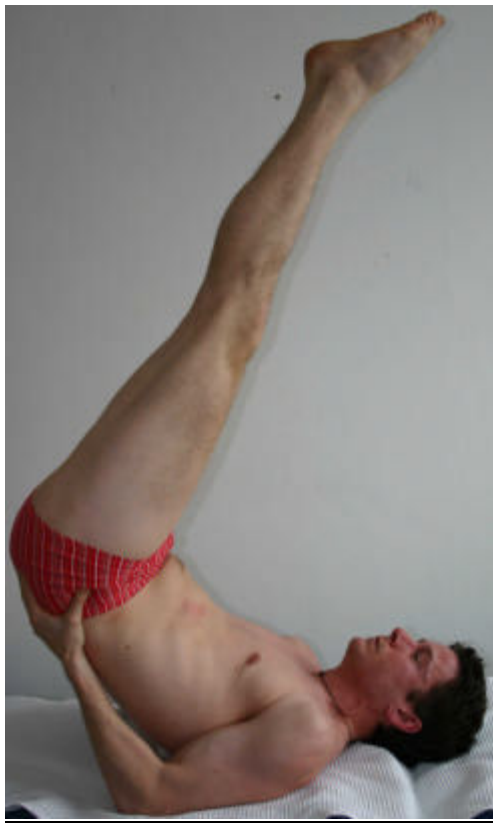
Specification:
The chin is again stabilised when retracted while both legs are pushed towards the stretched arms. Keep position for 10 seconds with 4-5 repeats.

- Automobilisation of colon



Specification:
The upper leg is flected at 90° and fixed on the floor by the lower hand. The upper arm and the head are moved backwards in an antipodal way until a muscular tension arises. Stay in this position and continue breathing deeply, until the muscular tension disappears.

- Mobilisation with visceral lowering



Specification:

When breathing in move your legs high up und when breathing out lower them towards the chest. Do 3 series with 10 repetitions.

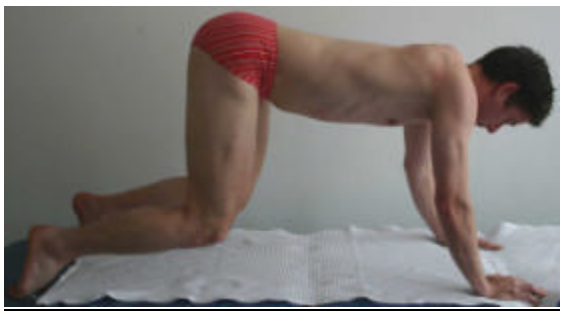
5.6.2 Exercises for stabilisation and coordination

- Selective lumbar spine stabilisation in dorsal position

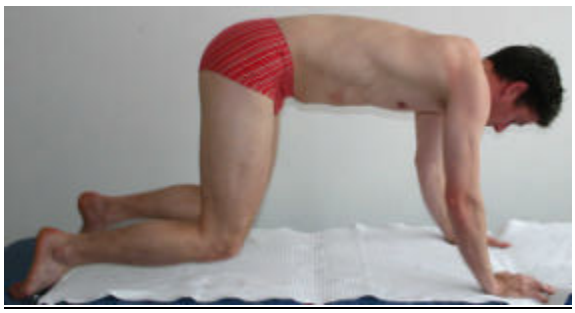
Specification:
Tightly stretch the lumbar spine onto your own hands without releasing pressure from your legs Keep the tension for 10 seconds and repeat the exercise 3-4 times.

- Forearm press-up with raised pelvis

- Quadruped with raised knees and tilting of pelvis



Phase 1



Phase 2

- Forearm press-ups sideways with raised pelvis

5.7 Statistics

The analysis and interpretation of the data was carried out with „Statistical Package for Social Sciences 11.0" (SPSS) for Windows. In doing so the German version of the programme was applied. The following techniques were used for the analysis of the data [46]:

Mann-Whitney-U-Test
The U-test according to Mann and Whitney is a technique that is not tied to normal distribution conditions and incorporates the original information of data. This test examines whether the middle ranks differ significantly from two independent spot tests.

Rangcorrelations after Spearman
The correlation of two variables can be shown by using the correlation coefficient that specifies the amount of correlation and respectively the size of the correlation of the variables.

In the illustration of the results for all applied techniques the levels of significance have been arranged and denoted as follows:

Level of significance	denotation	symbol
p = 0,05	significant	*
p = 0,01	highly significant	**

Table 2: Levels of significance

6. Results of the study

In this chapter the results of the two groups of patients will be shown.

6.1 Patients

This section describes the socio-demographic details of the selected patients and the composition of group 1 and group 2 being the result of the randomisation.

6.1.1 Gender

	Group 1		Group 2		**Total**	
female	5	50%	4	female	5	50%
male	5	50%	6	male	5	50%
Total	10	100%	10	**Total**	10	100%

Table 3: Composition of the group, broken down by gender

Table 3 shows a homogenous apportionment of men and women in the two groups.

6.1.2 Age

	Group 1		Group 2		**Total**	
= 41 years	4	40%	4	40%	10	50%
> 41 years	6	60%	6	60%	10	50%
Total	10	100%	10	100%	20	100%

Table 4: Composition of the group, broken down by age

The separation of younger and older than 41 years in table 4 was carried out by divisions of median. Table 4 shows a well-balanced formation of the groups regarding age.

6.1.3 Weekly sports activities

	Group 1		Group 2		**Total**	
= 2x/ week	5	50%	5	50%	10	50%
> 2x/ week	5	50%	5	50%	10	50%
Total	10	100%	10	100%	20	100%

Table 5: Composition of the group broken down by weekly sports activities

Table 5 shows that in each group 5 patients do sports fewer or twice a week and respectively 5 patients do sports more than twice a week.

6.1.4 Smoking

	Group 1		Group 2		**Total**	
Smokers	2	20%	3	30%	5	25%
Non-smokers	8	80%	7	70%	15	75%
Total	10	100%	10	100%	20	100%

Table 6: Composition of the group broken down by smokers / non smokers

Table 6 reveals that surprisingly the majority of the group were non-smokers. In group 2 there was only one smoker more than in group 1.

6.1.5 Job related sitting or standing

	Group 1		Group 2		**Total**	
< 5 hours	5	50%	6	60%	11	55%
> 5 hours	5	50%	4	40%	9	45%
Total	10	100%	10	100%	20	100%

Table 7: Composition of the group broken down by static stress

The separation in table 7, whether the patients have to sit or stand a lot in their job was carried out again by division of median. 9 patients had to sit or stand more than 5 hours per day.

6.1.6 Job related weight lifting

	Group 1		Group 2		**Total**	
yes	4	40%	4	40%	8	40%
no	6	60%	6	60%	12	60%
Total	10	100%	10	100%	20	100%

Table 8: Composition of the group broken down by physical stress

Table 8 also shows that in each group 4 patients had to do a lot of job-related weight lifting.

6.1.7 Job related exposure to vibrations

	Group 1		Group 2		**Total**	
yes	0	0%	2	20%	2	10%
no	10	100%	8	80%	18	90%
Total	10	100%	10	100%	20	100%

Table 9: Composition of the group broken down by physical stress

Table 9 features a small difference between the two groups.
There are two people of group 2 that are frequently exposed to job-related vibrations whereas there is none in group 1.

6.1.8 Job satisfaction

	Group 1		Group 2		**Total**	
very high	7	70%	6	60%	13	65%
medium	3	30%	3	30%	6	30%
no	0	0%	1	10%	1	5%
Total	10	100%	10	100%	20	100%

Table 10: Composition of the group broken down by job satisfaction

According to table 10 job satisfaction was a bit lower in group 2, as one patient was discontent with his occupational situation.

6.1.9 Private contentment

	Group 1		Group 2		**Total**	
very high	6	60%	8	80%	14	70%
medium	4	40%	2	20%	6	30%
no	0	0%	0	0%	0	0%
Total	10	100%	10	100%	20	100%

Table 11: Composition of the group broken down by private contentment

Private contentment was higher in group 2. Table 11 shows that only two patients in group 2 as opposed to four patients in group 2 are fairly content with their private situation.

6.1.10 First period of pain before

	Group 1		Group 2		**Total**	
< 72 months	6	60%	5	50%	11	55%
= 72 months	4	40%	5	50%	9	45%
Total	10	100%	10	100%	20	100%

Table 12: Composition of the group broken down by the first occurrence of a period of pain

The separation in table 12 into more or less than 72 months was carried out again by division of median. Group 1 was a bit better, as the first occurrence of pain was more than 72 months ago for only 4 patients.

6.1.11 Previous treatments

	Group 1		Group 2		**Total**	
yes	5	50%	7	70%	12	60%
no	5	50%	3	30%	8	40%
Total	10	100%	10	100%	20	100%

Table 13: Composition of the group broken down by previous physiotherapeutic or osteopathic treatment

Table 13 illustrates that there are more patients that have made previous use of physiotherapeutic or osteopathic support in group 2 than in group 1.

The tables show no severe differences between the two groups. Therefore the randomisation regarding these parameters has been successful.

6.2 Correlation between VAS and R&M

			VAS
Spearman-Rho	RM	Correlation coefficient	,781 (**)
		Sig. (2-sided)	,000
		N	60

** The correlation is significant on the 0,01 level.

Table 14: Correlation VAS and R&M

Table 14 shows that the two applied instruments, that is the VAS and the RM-questionnaire, correlate statistically highly significant.
This leads to the conclusion that both techniques collect similar parameters of pain and experiencing of pain. For that reason it can be assumed from a scientific basis that a valid collection of the construct of pain has taken place.

6.3 Initial situation from a clinical view

This section describes and compares the initial situation for the two groups at the very beginning of the study.

	Group 1	Group 2
Average value VAS before first treatment	46 %	59,8%
Average value RM before first treatment	4,2 points	5,9 points

Table 15: Initial situation of the two groups from a clinical view

Table 15 exemplifies that the initial situation was worse for group 2. On average the patients started with 13.8% more pain and the quality of life was 1.7 RM-points worse. Regarding these two parameters the randomisation wasn't successful.

6.4 Changes during the time of treatment for the whole group

In this section I want to illustrate what can be achieved at chronic lumbago patients with 3 osteopathic treatments regarding pain and quality of life.

6.4.1 Primary target parameter: pain

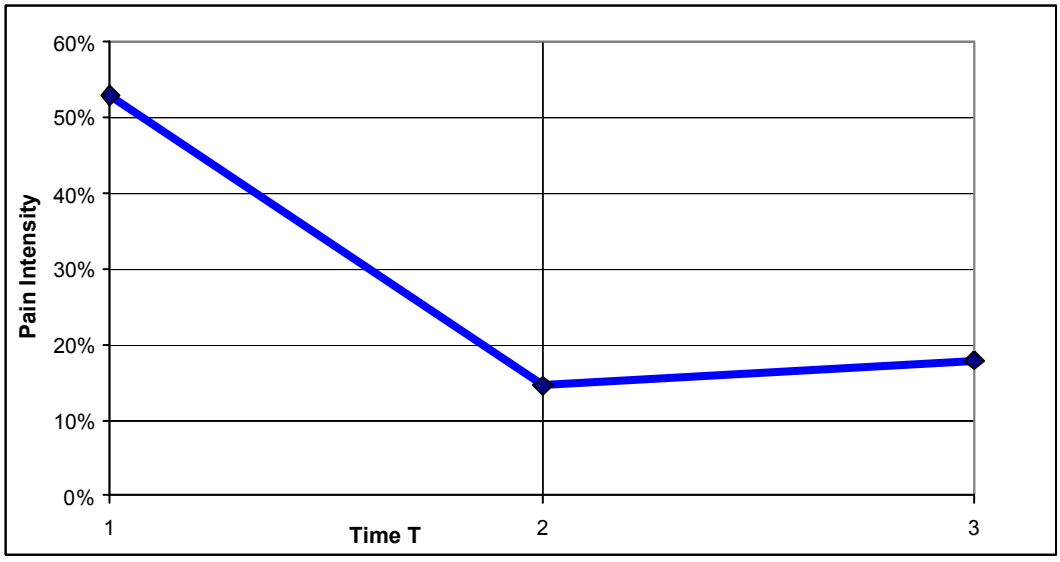
The change of pain is illustrated at the following points of time:

T1 = just before the first treatment
T2 = just after the third treatment
T3= 8 weeks after the third treatment (control)

		VAS T1	VAS T2	VAS T3
N	valid	20	20	20
	missing	0	0	0
Average value		52,9%	14,6%	18,0%
Standard deviation		17,2%	17,6%	15,2%
Minimum		30	0	0
Maximum		96	66	55

Table 16: Change of the average value of the pain intensity compared over a period of time (whole group)

The following diagram graphically shows the progression of the average value:



Graph 1: Change of pain intensity over a period of time (whole group)

Diagram 1 (see above) clearly shows that after 3 osteopathic treatments a reduction of the intensity of pain of 38.3 % took place. At the control meeting (T3) there was a surprisingly low increase in pain intensity of

3.4 % compared to T2.
The success achieved in three treatments therefore could be relatively well saved over the period of 8 weeks.

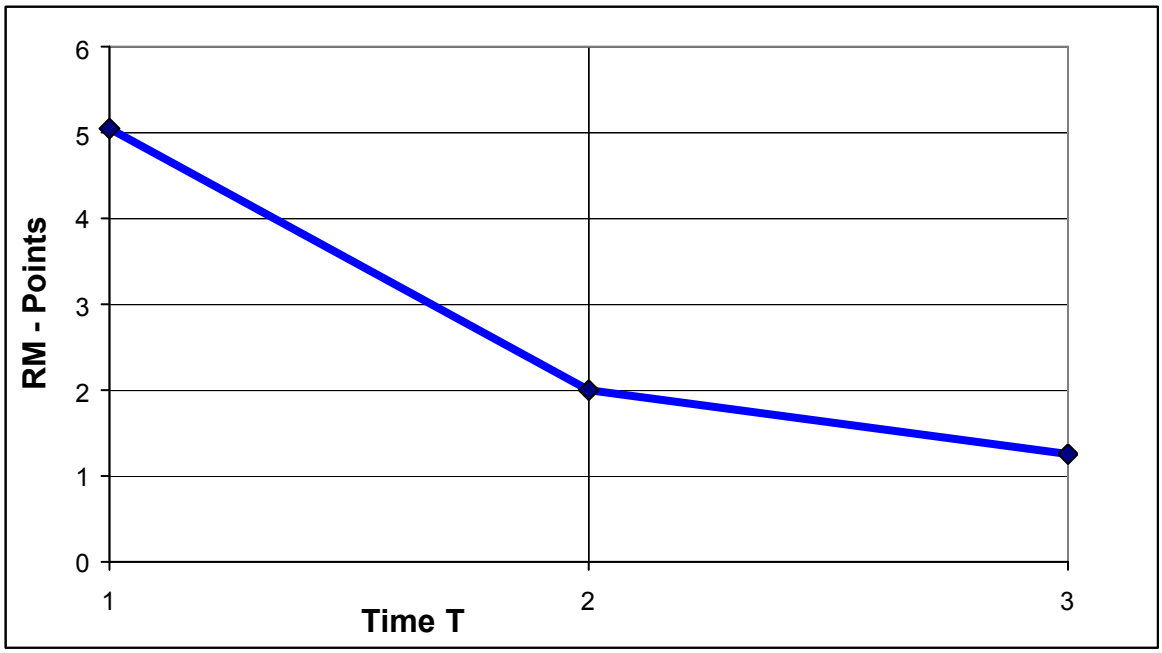
6.4.2 Secondary target parameter: quality of life (R&M)

The change of the RM-values is depicted again in comparison to the points of time T1, T2 and T3 (see 6.4.1). The total range of values of RM reaches from 0 to 24. A decline in points indicates an improvement in quality of life.

	RM T1	RM T2	RM T3
N	20	20	20
Average value	5,05	2,00	1,25
Standard deviation	1,90	1,97	1,65
Minimum	1	0	0
Maximum	9	7	5

Table 17: Change of the average value of RM-points over time (whole group)

The following chart graphically shows the progression of the average value:



Graph 2: Change of R&M over time (whole group)

Diagram 2 illustrates that a continuous improvement in quality of life was achieved. Whereas on average 5 questions were marked with „yes" at point of time T1, it was only 2 at T2 and even only 1.2 questions at the control meeting.

6.5 Comparison between group 1 and group 2

In this chapter I will deal with the main question of my thesis paper, i.e. whether the effect of osteopathic treatment can be intensified through automobilisations, regarding success of treatment and long-term result.

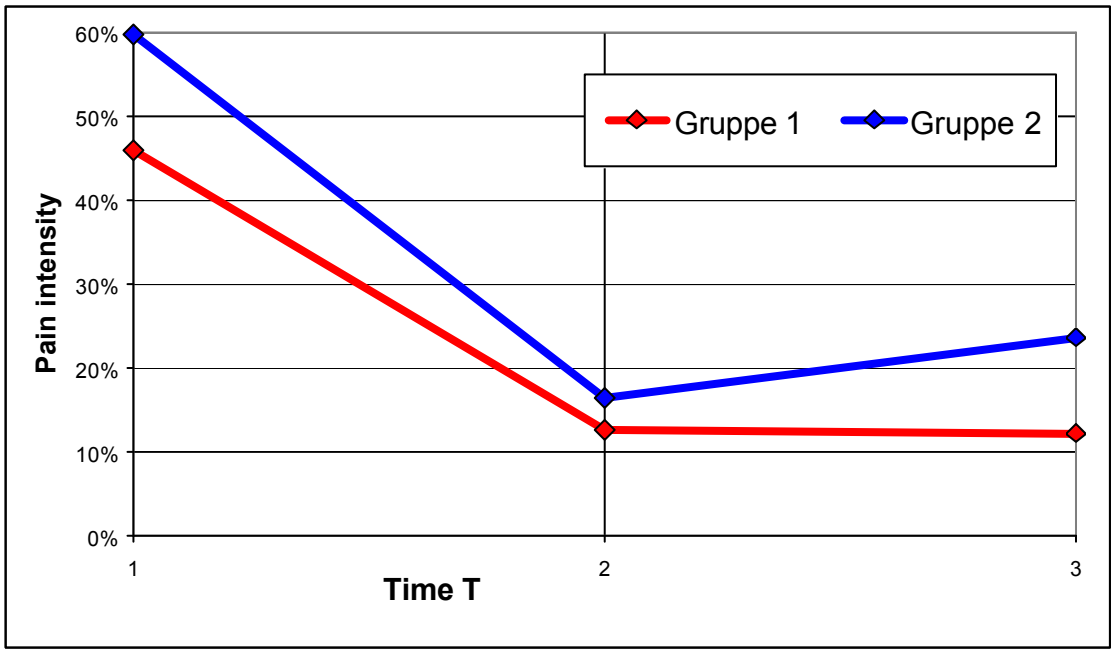
6.5.1 Primary target parameter: pain

The change of pain intensity at the points of time T1, T2 and T3 is illustrated separately in the two groups.

	Group 1			Group 2		
	VAS T1	VAS T2	VAS T3	VAS T1	VAS T2	VAS T3
N	10	10	10	10	10	10
Average value	46%	12,6%	12,2%	59,8%	16,5%	23,7%
Standard deviation	12,6%	14%	11%	19%	21%	17%
Minimum	30%	0%	0%	30%	0%	0%
Maximum	67%	48%	37%	96%	66%	55%

Table 18: Change of average value of pain intensity over time (seperated in the two groups)

The following chart graphically shows the progression of the average value of pain of group 1 and of group 2:



Graph 3: Change of intensity of pain over time in group 1 and group2

Diagram 3 exemplifies that the intensity of pain significantly declines towards point of time T2 for both groups. In group 1 the intensity of pain falls 33.4 %, in group 2 it falls 43.3 %. 8 weeks after the last treatment (T3) there is a further reduction of pain of 0.4 % for group 1. In group 2 the graph slightly rises, as the intensity of pain decreases for 7.2 % from T2 to T3.

	Group 1	Group 2		
	Median rank	Median rank	U-value	Significance
VAS T1	8,15	12,85	26,5	0,75
VAS T2	10,5	10,5	50	1,00
VAS T3	8,25	12,75	17,5	0,89

Table 19: U-Test „Statistic Significance towards VAS"

The calculations depicted in table 19 show that there is no statistically significant difference between group 1 and 2 regarding VAS.

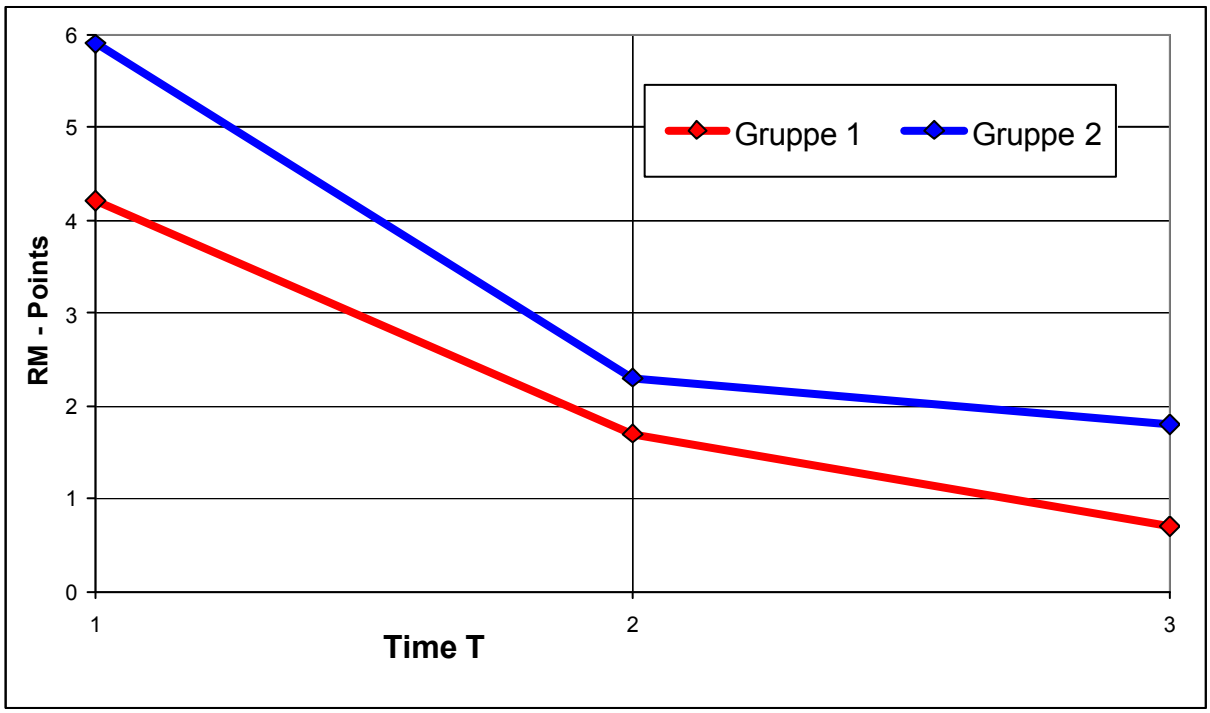
6.5.2 Secondary target parameter: quality of life (R&M)

The change of the RM-value of both groups is again shown in comparison to the points of time T1, T2 and T3. The total range of values of RM reaches from 0 to 24. A reduction of the points indicates an improvement of quality of life.

	Group 1			Group 2		
	RM T1	RM T2	RM T3	RM T1	RM T2	RM T3
N	10	10	10	10	10	10
Average value	4,2	1,7	0,7	5,9	2,3	1,8
Standard deviation	1,68	1,25	1,56	1,79	2,54	1,61
Minimum	1	0	0	3	0	0
Maximum	6	4	5	9	7	5

Table 20: Change of the average value of RM-points over time (seperated in the two groups)

The following diagram graphically shows the progression of the average values of RM-points for group 1 and group 2:



Graph 4: Change of R&M of group 1 and group 2 over time

Diagram 4 shows that in both groups a continuous improvement of the quality of life took place. After three osteopathic treatments (T2) the quality of life increased in group 1 for 2.5 RM-points, in group 2 for 3.6 RM-points. 8 weeks after the last treatment a further improvement of quality of life for one RM-point in group 1 and 0.5 RM-points in group 2 takes place.

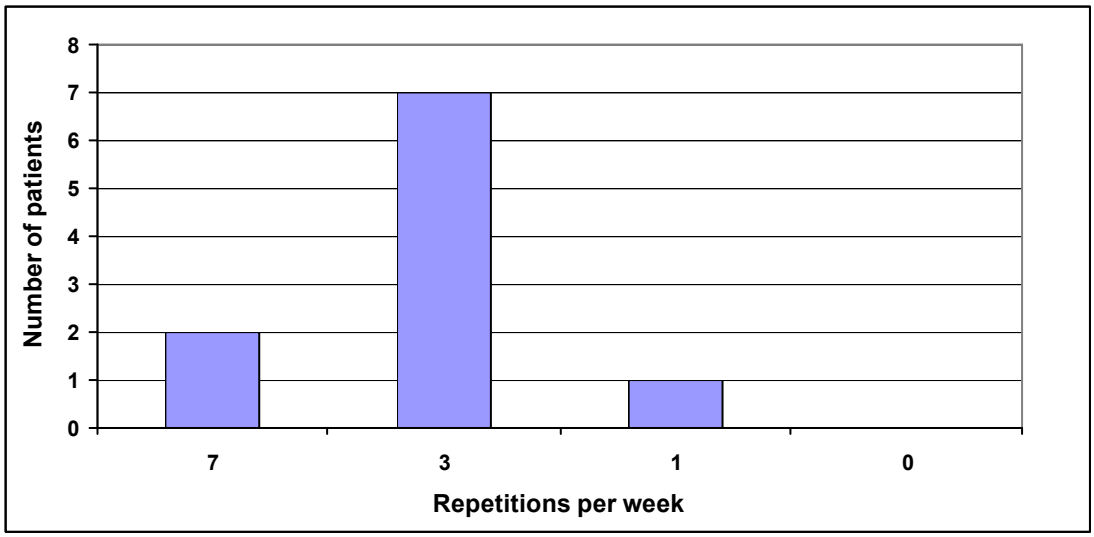
	Group 1	Group 2		
	Median rank	Median rank	U-value	Significance
RM T1	8,0	13	25	0,063
RM T2	10,4	10,6	49	0,971
RM T3	7,6	13,4	21	**0,029***

Table 21: U-Test „Statistical significance towards RM"

The calculations shown in table 21 demonstrate that there is a statistically significant difference between group 1 and 2 at point of time T3. This means that 8 weeks after the last treatment group 1 achieved a statistically significantly higher quality of life than group 2. This fact speaks for a positive effect of automobilisations regarding the long-term result.

6.6 Compliance of patients of group 1

In this section I will analyse the self-activity of the patients in order to get insight how frequently the acquired exercises were practiced. The survey was carried out by means of an anonymous questionnaire to get answers as honest as possible.



Graph 5: Compliance of patients

Diagram 5 illustrates that the majority (70%) of group 1 practiced the exercises acquired in the therapeutic sessions three times a week. Two patients even performed automobilisations on a daily basis, one patient only once a week and none didn't practice at all.

6.7 Drop-Outs

Fortunately all of the 20 patients have completed the study consistently. There were no drop-outs.

7. Discussion

In this chapter I will scrutinise the methods chosen and the results obtained in the study.

7.1 Discussion of the chosen methods

The visual analogue scale reproduced the subjective perception of the patients well and seemed adequate to me due to its easy handling.

As the Roland & Morris-Scale is a short form of the internationally frequently used „Sickness Impact Profiles" especially for lumbago patients and therefore represents a specific measuring instrument for functional restrictions, it seemed to make sense to use it for my study.

In the initial questionnaire I dealt with private contentment and job satisfaction, but I have noted that especially with lumbago patients the precise recording of the psycho-social situation is of utter importance. For that reason I can recommend for subsequent studies to examine the psycho-social status by means of a specific questionnaire.

The osteopathic experience shows, that after three treatments success regarding pain and functional restrictions can be seen with patients. This is confirmed by the study, so that the number of treatments undertaken seems meaningful.

A further essential point of criticism is the relatively low number of participants (10 persons per group) which puts the explanatory power of the results of the study into perspective. With regard to the results I will therefore only speak of developments and tendencies.

The study was carried out in the form of a single-blinded study. The patient doesn't know which group he or she belongs to, out of necessity the treating osteopath knows. In order to increase the internal validity of the study it would be ideal if the treating osteopath wasn't the author of the master thesis. Unfortunately this wasn't possible for organisational and financial reasons.

During the realisations of the exercises in group 1 I relied on the self-responsibility of the patients. I was positively surprised that two patients practiced the exercises on a daily basis, 7 patients three times a week and only one patient practiced only once a week. Of course it would have been better to install a training group where the patients could have practiced

2-3 times a week under supervision. This could have been possible if the study had been carried out in a team, yet it would have gone beyond the scope for a single person study.

7.2 Discussion of results

When comparing the results of the two groups it can be noticed that there are hardly any differences.

In **group 1** (test group) a continuous decline of the intensity of pain with time can be noticed. Before the first treatment (T1) the average value was at 46% pain, after three therapeutic sessions (T2) at 12.6% and 8 weeks after the third treatment at 12.2%. Through the 3 osteopathic treatments combined with automobilisations an improvement of 33.4% in the intensity of pain has been achieved (T2 compared to reference point T1). At the check-study 8 weeks later there a further reduction of intensity of pain of 0.4% (T3 compared to reference point T2) could be noticed.
This shows that the group with automobilisations tends to stabilisation and respectively even to a slight improvement of the condition in the long run. The quality of life has improved continuously too. Whereupon in the beginning 4.2 points were attributed on average, it was only 1.7 after the third treatment and at the check-study even only 0.7 points. The group with automobilisations achieved at reference point T3 a statistically significantly higher quality of life than the group without exercising. This speaks for the positive impact of automobilisations regarding the long-term effect.

With **group 2** (control group) the intensity of pain was at 59.8% before the first treatment (T1), at 16.5% after the third treatment and 8 weeks after the last treatment it climbs back to 23.7%.
Therefore a reduction of intensity of pain of 43.3% (T2 compared to reference point T1) could have achieved through the 3 osteopathic treatments (without automobilisations). However, in the long run there is a slight increase of pain intensity of 7.2% (T3 compared to reference point T2).
Thus pain intensity between the reference points T1 and T2 could have been lowered in group 2 by 9.9% more than in group 1.
However, the long-term result (changes from reference point T3 to T2) was better in group 1.
On the other hand quality of life has also improved continuously in group 2. Whereas in the beginning 5.9 points were given, after the last treatment it was only 2.3 points and at check-study it was only 1.8 points.

In my opinion the space of time between the last treatment (T2) and check-study (T3) has been too short to obtain more distinct differences between the two groups. Nevertheless it seems important to me to mention that in group 1 pain intensity has declined for 0.4% and quality of life has improved for 1 RM-point (both values viewed from reference point T2). At the same point of time pain intensity has deteriorated for 7.2% and quality of life has improved for 0.5 RM-points in group 2.
Thus the trend in group 1 goes towards stabilisation and respectively improvement of the condition achieved through therapy.
Group 2 tends to deterioration of pain intensity at the comparison of T3 with reference point T2. But the differences of the values of pain intensity between the two groups are so small that there is no statistical significance.

The initially posed question whether the effect of osteopathic treatment can be intensified through automobilisations regarding success of treatment and long-tem result, has to answered after the study with yes and no.
The **success of osteopathic treatment** (T2 viewed against reference point T1) could not be improved through automobilisations. On the contrary, the success of treatment regarding pain intensity and quality of life was even higher in group 2 than in group 1. This can probably ascribed to the fact that in group 2 there was more time for osteopathic treatment whereas in group 1 time had to be used for instructions to the exercises.
However, the **long-term result** (T3 viewed towards reference point T2) could be **improved** through automobilisations. Thus pain intensity improved a further 0.4% which can be described as stabilisation of the achieved success. Statistically no significance regarding VAS could be seen as the differences between the two groups were too small. The quality of life improved at reference point T3 statistically significantly more in group 1 than in group 2. That way an improvement for one RM-point could be achieved through the automobilisations that were practiced over 8 weeks.

To me it seems important to mention that with the whole group an improvement of 38.8% in pain intensity and an improvement in life quality of 3.8% could be accomplished by means of three osteopathic treatments. Although there is no control group to confirm these results, it can be assumed that the over-all concept of osteopathy can secure a high efficiency at the treatment of chronic lumbago.

7.3 Conclusion

"It doesn't matter whether with or without automobilisation - osteopathy works!"
Osteopathy can be regarded as an efficient method of treatment without major side effects for patients suffering from chronic lumbago!
Automobilisations have a positive effect on the positive sustainability of the osteopathic treatment.

Scientific studies are important and support the reasoning platform of the osteopaths, but these carefully carried out studies with their study design are still obliged to the basic acceptance of the law of causation principles (axioms).
Therefore osteopathy runs the risk of reducing health only to its causally measurable effects.
Osteopathic development and power should not only go towards controlled, randomised single-blinded studies but should focus on what A.T. Still demanded in his first principle of osteopathy:

„The body is a unit of body, soul and spirit."
(Still 2002 quoted after [3])

8. Synopsis

As a question that always interested me throughout my whole osteopathy training was whether osteopathy was restricted to the performance of passive techniques I have examined in my master thesis the meaningfulness and respectively the efficiency of automobilisations being supportive to osteopathic treatment. I have decided for the treatment of chronic lumbago as the majority of my patients are lumbago patients and back pain is reckoned to be one of the most frequent and costly illnesses.

Against this background I have carried out the study with 20 patients.

The aim of the study was the review of the following questions:
Is it possible to intensify the effect of an osteopathic treatment through automobilisation (in a structural and visceral way), regarding success of treatment and long-term result instancing chronic low back pain patients?

20 patients were accepted for this controlled, randomised, single-blinded interventional study. Before the study the criteria of inclusion and exclusion were laid down in a study record book. The 20 patients were separated according to a randomisation list into group 1 (test group) and group 2 (control group).

Three treatments at intervals of 10 days took place over the period of a month. 8 weeks after the last treatment the patients were called in again for a check-study. The patients were asked to fill in certain questionnaires before the first treatment, after the third treatment and at the check-study.

For the **primary target parameter** pain, which I examined by means of the visual analogue scale, the following result came up:

Group 1:
Decline of pain intensity from T2 towards reference point T1 of 33.4% (success of treatment)
Decline of pain intensity from T3 to reference point T2 of 0.4% (long-term result)

Group 2:

Decline of pain intensity from T2 to reference point T1 of 43.3% (success of treatment)
Increase of pain intensity from T3 to reference point T2 of 7.2% (long-term result)

The **secondary target parameter** quality of life, which I examined with the lumbago-specific, validated Roland & Morris scale showed the following results:

Group 1:

Improvement of quality of life from T2 to reference point T1 of 2.5 RM-points (success of treatment)
Improvement of quality of life from T3 to reference point T2 of one RM-point (long-term result)

Group 2:

Improvement of quality of life from T2 to reference point T1 of 3.6 points (success of treatment)
Improvement of quality of life from T3 to reference point T2 of 0.5 points (long-term result)

The results of the study at hand prove that the success of treatment regarding intensity of pain and quality of life were better in group 2 (control group) than in group 1.
Nevertheless the long-term result was better in the group with automobilisations.

As a conclusion it can be said that automobilisations do not improve the success of osteopathic treatment.
Yet the long-term result of an osteopathic treatment that is supported by automobilisations is statistically significantly better.

9. Appendix

9.1 Letter to GPs

The following letter served as additional information for the 10 GPs who I personally presented my concept in order to gain patients for my study.

Subject: Osteopathic study about the treatment of chronic lumbago

Dear Dr.

I am Elisabeth Bilgeri, a physiotherapist. At the moment I am working on my master thesis of a six-year osteopathy training at Donau-University Krems.
In order to obtain the title of Master of Science-Osteopathy a scientific thesis paper is required.

Osteopathy is a therapeutic method that diagnoses and treats restrictions in movement o various structures of the human body. It also corrects consequential imbalances in the state of healthiness.
I have decided to dedicate my study to the treatment of lumbago as this disease:

- is very frequent
- leads to huge restriction of quality in life
- often lasts for many years
- produces high costs for our health system

The **aim of my study** is the examination of therapeutic efficiency of osteopathic treatment. It is to be shown that this method of treatment can reduce functional restrictions as well as pain of the patients suffering from lumbago without causing unwanted effects.

For that reason I'd be very grateful if I could count on your support!

I need 20 patients to carry out the study to meet scientific stipulations. These patients have to fulfil certain criteria. Only you as an experienced GP can help me with your diagnosis to find the right patients. By doing so you will support the improvement of after treatment, for the sake of the patients and the successful continuation of your own therapy.

All treatments for this study are free for patients and health insurance companies!

If you find interest in supporting my study and if you treat lumbago, you will find all necessary information on the following page.

I am looking forward to a possible co-operation in the interest of the patients and to hearing from you soon.

Yours sincerely,

Elisabeth Bilgeri
Färberstr. 10, 6700 Bludenz
Fon: 05552 / 68110

Osteopathic study about the treatment of chronic lumbago

Procedure

A „match controlled study" with two groups is being carried out.
Group 1 is being treated osteopathically and in addition is being instructed to individually customised automobilisations. Group 2 is being treated osteopathically.
Apart from the effect of the osteopathic treatment on lumbago patients I am interested to which extent the result can get improved through well directed automobilisations.

- The patients are being tested on inclusion and exclusion criteria.
- The patients are classified into the two groups by means of a random selection.
- The patients receive 3 treatments within a month.
- 2 months after the last treatment there is a check up examination.
- The extent of the functional limitations and intensity of pain is being assessed.
- After completion of all treatments a methodological assessment follows.

Criteria of inclusion

- Clinically secured lumbago without radiculary symptoms for at least 3 months.
- 18-55 years old.
- Intensity of pain (via the visual analogue chart) > or equaling 30%.
- Patient can read and understand German (questionnaire, instructions for exercises).
- Patient takes part voluntarily.

Criteria for exclusion

- Younger than 18 years or older than 55 years.
- Visual analogue chart < 30% (chart for the assessment of pain intensity).
- Patient does not understand German sufficiently and cannot read.
- Patient doesn't sign the letter of consent.
- pregnancy
- carcinomas
- osteoporosis
- Positive neurological report.
- Acute cases with massive limitations of movement.
- Operative intervention at vertebral column.
- Indisposition of one of the illnesses listed in the Borenstein-chart.
- Lumbago solely caused by menstruation.
- Any analgetic, myorelaxative or antiphlogistic treatment, that hasn't been discontinued at least 48 hours before the start of the osteopathic treatment.

Before you send the patient to me, please may I ask you to fill in the enclosed form and hand it over to the patient.

Thank You!

Form of status (to be filled in by GP)

Name of patient:

1.) Neurological status OK

Was asserted, from a neurological point there is no demur to take part in the study.
Remark:

2.) Examination of Borenstein-chart OK

List of secondary Lumbago has been asserted.
Remark:

Rheumathological:

- Spondyloarthritis ancylosans
- Rheumatoid polyarthritis
- Fibromyalgia
- Vertebral osteochondritis

Infectious:

- Vertebral osteomyelitis
- pyogene sacroileitis

Neoplastical:

- Osteoidosteom
- Osteochondrom
- Chondrom
- Giant cell tumor
- Medullary plasmozytom
- Metastasis
- Lymphom

Radiation into the lumbar area:

- Ulcera duodenali
- Renal colic
- Aneurisma of abdominal aorta

Hämatologic:

- Hämoglobinopathia
- Mastozytosis

Endocrinological / metabolical:

- Osteoporosis
- Osteomalazie
- Problems of the parathyroid
- Fluorcachexia

Various:

- Subacute bacterial Endocarditis
- Osteodystrophia deformans paget
- Retroperitoneal fibrosis

Date: Signature of treating physican:

9.2 Letter of Consent (to be filled in by the patient)

Name:

Aim of the study:
The assessment of an osteopathic treatment for patients suffering from chronic lumbago. It is planned to do a therapy study about effective treatments regarding chronic lumbago.

It is known to me that manipulative osteopathic techniques may be carried out on the vertebral spine, pelvis lower extremities or the head. If necessary, treatments in the region of inner organs (colon, small intestine, diaphragm…) may be applied out too.
The techniques used do not represent any risk for the patients with the exception of the following: temporary functional complaints, like small enhancement of pain after the manipulation, slightly sore muscles in the region of the loins and tiredness may occur.
The patient receives 3 osteopathic treatments within a month (i.e. about every ten days) and is asked to come again for a check-up examination which is necessary for the study 2 months after the last treatment.
The treatments are free, in case the patient doesn't put an end to them without giving a reason. As the realisation of this study involves a lot of time and work expenditure.
The usual tarif for treatments is being charged in case of a premature drop out. Reasons accepted for abandonment of participation are:
Pregnancy, serious diseases, fractions and injuries because of which an osteopathic treatment is not prior at the moment.

I was told that the data used in the course of the study are used very confidential according to the valid laws of data protection.

I,....., assure to have read the above letter of consent and declare to take part in the study in the know of all aims, limitations and risks of the study.

Place, date Signature of participant of study

9.3 List of randomisation

Patient 1	Group 1
Patient 2	Group 2
Patient 3	Group 1
Patient 4	Group 1
Patient 5	Group 1
Patient 6	Group 2
Patient 7	Group 1
Patient 8	Group 1
Patient 9	Group 2
Patient 10	Group 2
Patient 11	Group 2
Patient 12	Group 1
Patient 13	Group 2
Patient 14	Group 2
Patient 15	Group 1
Patient 16	Group 2
Patient 17	Group 2
Patient 18	Group 1
Patient 19	Group 1
Patient 20	Group 2

9.4 Entryform (to be filled in by the patient)

Name: Date:

Address: Telephone number:

Physican who sent you:

Date of birth: Sex: m f

Height: Weight:

Do you do sports regularly: yes, how many times a week: no

Smoker: yes no

Occupation:

Do you spend a lot of time sitting or standing in your job? Yes, for how long: no

Do you have to lift heavy goods or do you have to lift repeatedly in your job? yes no

Are you exposed to heavy vibrations in your job? yes no

How happy are you with your current job situation?

Very happy average unhappy

Are you pregnant at the moment? yes no

How many pregnancies have you had already?

How many vaginal deliveries have you had?

How happy are you with your current private situation?

Very happy average unhappy

How would you describe your current state of health?

excellent average bad

Place, date: Signature:

9.5 Questionnaire 1 Form to assess intensity of pain VAS

Please tick how you would assess your pain for yourself. The left and right end always symbolise the most extreme you can think of. The following example should tell you how it works.

Today's weather is?

perfect absolutely unbearable

Intensity of pain:

My pain at the moment is....?

Non existant absolutely unbearable
0% 100%

I had my first back pain episode

3 months ago 6 months ago 1 year ago .....years ago

Previous episodes of similar symptoms I had

0 1-2 times 3-5 times more often

Have you ever undergone treatment regarding back pain?

Yes (if yes, what kind of treatment?) No

9.6 Questionnaire 2 Roland-Morris Low Back Pain and Disability Questionnaire

I would to find out which effects the pain in the region of your lumbar spine has on your ability to do everyday tasks.

Please turn to the next page and answer the following questionnaire.

There is a selection of statements to choose from. These statements describe certain difficulties for everyday physical activities that could relate to your pain in the lumbar spine area.

Whenever you read a statement that corresponds to a limitation you experienced because of the back pains please tick the box.

If it does not apply, please leave the box empty and go to the next question.

Remember to mark only the sentences that describe you today!

1.	I stay at home most of the time because of my back.
2.	I change position frequently to try to get my back comfortable.
3.	I walk more slowly than usual because of my back.
4.	Because of my back, I am not doing any jobs that I usually do around the house.
5.	Because of my back, I use a handrail to get upstairs.
6.	Because of my back, I lie down to rest more often.
7.	Because of my back, I have to hold on to something to get out of an easy chair.
8.	Because of my back, I try to get other people to do things for me.
9.	I get dressed more slowly than usual because of my back.
10.	I only stand up for short periods of time because of my back.
11.	Because of my back, I try not to bend or kneel down.
12.	I find it difficult to get out of a chair because of my back.
13.	My back is painful almost all of the time.
14.	I find it difficult to turn over in bed because of my back.
15.	My appetite is not very good because of my back.
16.	I have trouble putting on my sock (or stockings) because of the pain in my back.
17.	I can only walk short distances because of my back pain.
18.	I sleep less well because of my back.
19.	Because of my back pain, I get dressed with the help of someone else.
20.	I sit down for most of the day because of my back.
21.	I avoid heavy jobs around the house because of my back.
22.	Because of back pain, I am more irritable and bad tempered with people than usual.
23.	Because of my back, I go upstairs more slowly than usual.
24.	I stay in bed most of the time because of my back.

9.7 Questionnaire 3 (to be filled in by patients of group 1)

This questionnaire goes into a box anonymously. I would like to ask you to answer honestly the following questions.

How often have you practiced the exercises learnt in therapy over the last 8 weeks?
Please circle the appropriate answer. Thank you!

Daily 3 times a week one time a week not anymore

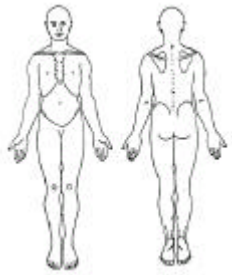
Sex: male female

9.8 Diagnostic findings form

Date:

Name:	Group: 1 2	
AUF because of current episode: yes no	marital status: s m d	
Previous findings:	Medicaments:	

Current complaints: Where?How?When?Since when?First time or more often?Progression



Corse of the day? Better, worse because of….?

OP:
Accidents/injuries:
Dental interventions:
Diseases:
Psych. traumata:

Respiration (Lu D1-6): frequently having a cold bronchitis pneumonia
HNO: ear middle ear paranasal sinus tinnitus
Nutrition: incompatability(LeGa D7-10)
allergies
diets
eating /drinking behaviour
Digestion: heartburn abdominal pain obstipation diarrhoeal exhalation blood in stool
Ösophagus, Magen (D6-9)
Duodenum(D9-12)
Dünndarm(D10-12)
Dickdarm(D10-L2)
LeGa (D7-10)
Pancreas(D5-9)
Fluid balance:
Niere (D10-L1)
Blase(L1-2)
Urogenital: Uterus / Ovarien(D10-L2)
Prostata(D9-L2)
Hormones: Zyclus PMS Osteoporosis Thyroid
Vegetativum: sleep disorder yes no
Chron. tiredness yes no
Level of stress (von 0 – 10) :
Visceral conspicuities:

Cranielle conspicuities:

Osteopathic hypothesis:

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