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Abstract of the Doctoral Thesis

Modern treatment of the osteoporotic vertebral fractures

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CONTENTS

Keywords: osteoporosis, vertebral osteoporotic fractures, vertebroplasty, biomechanics.

The biomechanics of the spine is severely influenced by aging and osteoporosis. This is due to the changes in spine density, morphology and geometry, which results in decreased strength of spine and occurrence of osteoporotic fractures as a result of minor efforts or trauma. Kyphosis occurs in case of compression of the vertebral bodies, thus we experience a modification of the centre of mass which leads to increased degenerative phenomena.

All these can result in persistent pains and loss of spine mobility increasing the risk of new osteoporotic vertebral fractures. Accentuated kyphosis and changes in lumbar lordosis is also associated with respiratory difficulties and decreased vital capacity, increasing the risk of chronic lungs and visceral diseases.

Thus, prevention of osteoporosis and adequate treatment of the vertebral osteoporotic fractures is extremely important.

Although the treatment of the osteoporotic vertebral fractures is more or less standardized, the evolution under the treatment can be uncertain. This is due mainly to the local biomechanical characteristics which are modified by the occurrence of the fracture and the general biological changes (degenerative changes and osteoporosis).

The theme of the Doctoral Thesis complies with the interests of the author in daily medical practice and represents an up-to-date problem, widely discussed in the past years due to extended life expectancy of the elders, new different medicine therapies meant to prevent and treat osteoporosis, various immobilization methods, as well as surgical techniques to stabilize spine.

The objective of the thesis is the theoretical and experimental analysis of spine osteoporotic fractures occurrence of in case of compression, as well as the observation performing vertebroplasty on the vertebral segment. Besides these we also present the statistics of the osteoporotic vertebral fractures.

The conclusions of the present work are the result of a detailed analysis, biomechanical tests and synthesis of the current research in the field of osteoporotic vertebral fractures.

The Doctoral Thesis is structured in eleven chapters approaching aspects related to the anatomy of the vertebra, radiological investigations of spine, biomechanics of normal and osteoporotic dorsal and lumbar spine, treatment options in case of osteoporotic spine fractures, statistical analysis of the occurrence of osteoporotic spine fractures, presentation of the testing equipment as well as a series of research studies to determine the biomechanical characteristics, the manner how vertebral fractures occur and the behaviour of the vertebral segment in case of compression before and after vertebroplasty.

The final part presents the conclusions reached within every phase of research and the possible directions to continue the biomechanical and statistical studies.

Chapter 1 presents concepts of dorsal and lumbar spine anatomy. The first part presents the anatomy of the dorsal and lumbar vertebra, and the main characteristics differentiating them, extremely useful in surgical practice. The orthopaedists must be familiar not only with the bone architecture of the spine, but with the vascular and nervous structures, visceral organs and adjacent muscular – ligamentous structures, as well. The geometry of the vertebral trabecular bone is strongly influenced by the manner how the vertebral bodies are loaded.

Further on we have a detailed presentation of the main vertebral intervertebral joints. Thus the macroscopic and microscopic architecture of intervertebral disc is presented, emphasizing its chemical content which in turn is severely influenced by the aging process.

Besides the bone and capsular ligamentous structure of the spine an important role is played by the body muscles. From point of view of their position, they can be divided into two groups: superficial muscles and deep muscles of the spine. Muscles represent the main source of the force which governs the movement of the spine.

The final part briefly presents the vascular and nervous system of the spine.

Chapter 2 presents concepts about the radiological anatomy of the thoracic and lumbar spine, necessary in order to make the diagnosis and select the best therapy, based on the anatomy of the vertebral injuries and its degree of stability.

The radiological examination of the spine in currently done nowadays, this type of investigation being available in all emergency units, and can be done using fix or mobile equipment. Planar radiographs show details about existence and location of a bone injury, regarded as standard investigation in case of firs aid in all protocols referring to investigating patients suspected of vertebral injuries. Standard radiological procedures conducted to investigate dorsal and lumbar spine are the anterior and the posterior ones, the profile radiographs and the transversal ones. It is very important to do the radiological examination of the lumbar spine in orthostatic position, if we consider the biomechanics of the lumbar spine. But this aspect is not possible especially in the case of lumbar spine trauma.

The number of anterior and posterior radiographs, as well as the profile one, are usually enough to investigate the lumbar spine in case of emergencies. Thus, radiographs represent an easy and rather inexpensive method for spine investigation, which provides a large set of information on the spine. But this does not offer information on the neural, vascular and ligamentous structures. Thus in the case of many acute and chronic diseases of the spine CT and MRI investigations are also necessary.

Conventional radiographs followed by CT investigations represent a very efficient examination cost – efficiency wise, when investigating vertebral trauma.

Computer Tomography allows an accurate visualization of the sponge and cortical bone, so in the cases of spine trauma it offers us information about fracture location (vertebral body, posterior arch), type of fracture, size and position of the fragments, luxation of the interapophysary articulations. It also allows estimating bone fragments rates in relation with the medullary cavity and the level of medullary compression. Sagittal and coronal reconstructions are useful in terms of a better analysis of fracture line.

Sometimes the MRI investigations are also necessary. The great advantage of MRI is the fact that it offers the possibility to investigate the medullary cavity internal structures, as well as the paraspinal ones, to evaluate changes at the level of intervertebral articulations, or lesions of the ligaments. Highly important in the case of osteoporotic vertebral fractures is the fact that MRI investigations allow estimating when the fracture occurred based on the oedema at the level of the vertebral body, in T1, T2 and especially STIRS sections.

Chapter 3 approaches the biomechanics of normal dorsal and lumbar spine. It is important that the biomechanics of the spine is known well for a better understanding of the clinical aspects of any disease, the way it may occur and the possibility to manage it. Biomechanics is regarded as application of the classic laws in mechanics in the study of biological systems. The biomechanics of the musculoskeletal system is very important when analysing the forces which affect the structures forming the human body and their reactions.

From the functional point of view the spine has three major functions: protection of the medulla, static function and biomechanical function.

From the biomechanical point of view the spine has three important functions:

1. Transfers weight and loads from the superior part of the body to the pelvis and limbs;

2. Allows fluidization and correlation of the movements between head, body and pelvis;
3. Plays an important part in protecting the medulla.

The spine presents an intrinsic stability due to the intervertebral disc and the intervertebral ligaments and at the same time an extrinsic stability due to the muscles.

The curves in the sagittal section present convexity which either anterior – called lordosis, or posterior – called kyphosis. These curves in sagittal plane are necessary in order to maintain the orthostatic position of the body, the increased strength of the spine and for absorbing shocks. In the case of healthy individuals the sagittal equilibrium of the spine when orthostatic is a compromise between the curves of the spine and the position of the pelvis.

The curves in the frontal section present right or left convexity. At a thoracic level it is presented to right and at the other two levels (cervical and lumbar) the convexity is presented to the left to compensate.

In physics it is well known the fact that a flexible spine with curves in more resistant than a straight spine. The curves reduce vertical shocks, reducing thus the effort on the spine muscles. Several biomechanical studies proved that the number of curves in the sagittal plane increases spine strength by double number and one of the curves. Thus, in the case of the human spine resistance is approximately 10 times higher than in the case of a straight spine. The transfer segments, the joints, are areas prone to degenerative lesions and traumas due to the transfer from a highly mobile area (the cervical and the lumbar areas) to reduced mobility areas (thoracic and sacral). Any change in shape and orientation of a vertebral segment automatically triggers changes in shape of the entire spine influencing all segments involved in sagittal equilibrium.

An important step in understanding the biomechanics of the spine is represented by the concept of motor segment, introduced by Junghans in 1950, which, later on, associated to muscular, vasculars and neural elements was reffered as motion segment. A **motion segment** consists of adjacent vertebrae with all the structures involved in forming intervertebral articulations, the intervertebral disc (in theory, each motion segment consists of two halves of vertebrae with its corresponding intervertebral disc), the ligamentous system, the adjacent muscular and vascular-nervous structures, meant to support the segments, the spinal nerves crossing the intervertebral foramina. This way the motion segment is functionally and anatomically independent.

Approximately 70-90% of axial load is supported by the vertebral body, in normal circumstances. The structure and the strength of the vertebral bodies varies from one level to another. The load supported by the vertebrae in the superior part of the spine is reduced than the load supported by the inferior segements of the spine. The strength of the vertebral body is given by the density of trabecular bone, reduced values causing an important decrease in strength of the vertebral bodies. The trabecular bones are positioned according to the orientation of the forces which affect the vertebral body, so that we can identify three main orientations, but the vertical one is dominating. The strength of the vertical trabecular bone decreases from the anterior to the posterior edge. The vertebral end-plates are important for a uniform distribution of the compressive forces on the trabecular system of the vertebral body. The strength of the vertebral bodies with a normal structure is mainly due to the trabecular structure, and secondly to the strength of the vertebral end-plates.

The intervertebral disc consists of the fibrous ring and the pulpy nucleus and is considered to have a decisive role in the motion capacity of the musculoskeletal system. The fibrous system is strongly fixed on the vertebral end-plates due to its fibres, where they are extended by the collagen fibres of the trabecular bone. In normal circumstances there are approximately 40% of them act on the anterior side and 48 % on the posterior side. These values are modified in the case of degenerative processes.

Due to their shape and disposition, the zygapophyseal articulations control the movement orientation at the level of spine following certain directions which differ from one area to another. Along with the intervertebral disc, the zygapophyseal articulations transfer the compressive forces from the superior segments the inferior ones. Generally, the compression force is reduced in seated position (approximately 8%), but in case of bending almost the entire compression force is taken by the intervertebral disc. In pathological cases this value can be extended up to 90% of the compression force.

The ligamentous system consists of the entire ligamentous apparatus of the spine. Altogether they form the passive element which supports the motion segment. The role of the ligaments is to reduce spine movement amplitude, to return spine to the initial position, and to absorb a large amount of the stress of the spine.

This ligamentous system along with the intervertebral disc ensures a certain balance which *Steindler* defined as **intrinsic balance** of the vertebral segment.

Spine muscles are numerous and form the motion element of the spine involved in movement of the spine.

The movements of the spine are complex due to the fact that several motion segments are involved. The movement at the level of each motion segment is reduced but summing them generates different movements at thoracic and lumbar level, with an amplitude which supports the functions of the skeleton. The multitude of mechanical factors and the numerous intervertebral articulations ensure that spine becomes an complex motion apparatus which allows balancing the body in the most difficult positions.

Chapter 4 presents concepts connected to changes in spine biomechanics due to osteoporosis and osteoporotic spine fractures.

Osteoporosis is a systemic skeletal disease characterized by a decreased mineral density of bones and modifications at the level of bone micro-architecture resulting in increased bone fragility. Osteoporosis is mainly experienced by women in menopause, but it can also affect men and young adults, as well, if there are risk factors to induce it. In Romania osteoporosis has become a real social problem. This is due mainly to bad eating habits of the elders, to sedentary life, lacking geriatric medical assistance. Unfortunately, there are no clear data to show the impact of osteoporosis on social and economic life in our country.

Standard radiographs cannot make a diagnosis, but they can suggest the osteoporosis diagnosis. Mineral bone density can be determined by means of a new method called x-ray dual absorptiometry. This is generally used to measure bone density in the case of spine and hips.

Degenerative and osteoporotic changes of the functional vertebral units influence spine biomechanics to a great extent, which subsequently generates abnormal loads on spine. Vertebral microstructure, spine mobility, transfer and absorption capacity of spine are all altered. Altogether they represent important changes which affect the spine anterior and posterior structure of the functional spine unit.

Aging determines a loss of connectivity and thinner trabeculae, especially of the horizontal ones. Micro-fractures occur as a result of reduced strength of vertebrae in relation with external forces. This is a common aspect for both genders, but is more frequently met in the case of females after they reach the menopause age.

Vertebral deformity degree is directly influenced by the integrity degree of the trabecular microstructure and the status of the vertebral cortical bones. The forces which affect the vertebral bodies grow from proximal to distal site, and this represents one of the causes why the vertebral fractures are more frequent in the lower part of the thoracic spine and in the lumbar area. The forces affecting the vertebra deform it and results in an elastic deformation curve until a specific efficiency point. When this force is no longer active, the vertebral body returns to its initial shape. The size of the area where the vertebral body is flexible is time-dependent, both in the case of males and females. The presence of a vertebral body fracture can increase the risk for a new vertebral body fracture in the first year up to 19,2%, whereas the presence of one-to-two fractures increases the risk for a new fracture in the second year up to 24%. Spine kyphosis which occurs after a vertebral body fracture also increases the risk of a new vertebral fracture.

Changes will be seen in spine structure and shape when aging, therefore the way forces act and are distributed at the level of the vertebra is also modified. Compression fractures in the case of osteoporotic vertebrae of the elders occur as a result of minor trauma and in most of the cases they present no clinical effect and are discovered accidentally. But as the vertebral body loses its height and the fracture heals and becomes permanent, the vertebral kyphosis grows and the patient adopts a kyphotic posture (“Dowager’s Hump”). This change in shape of the spine leads to changes of the mass centre and instant centre of rotation to the anterior side. Due to these changes the anterior part of the vertebral body is overloaded and the result is the increased risk of new compression fractures of the vertebral body. All these further determine overloading of the posterior muscle groups and of the capsular ligamentous apparatus, increased oxygen consumption and increased muscle fatigue due to the fact that the patient tries to keep his posture as close as possible to the normal one. This phenomenon can explain the concept of *’vertebral fracture cascade’,* which in turns makes the patient prone to new vertebral fractures. Enhanced thoracic kyphosis is accompanied by malfunctioning of the respiratory system reducing life capacity (only one compression of the vertebral body can result in reducing life capacity by 9%), and can further lead to chronic pulmonary diseases, such as chronic obstructive bronchopneumopathy.

The end of the chapter presents a series of factors which cause and favour vertebral osteoporotic fractures.

Chapter 5 presents a classification of the osteoporotic spine fractures. Without a clear diagnosis and a correct classification it is not possible to have an adequate prognosis to allow the possibility of selecting an efficient therapy in order to prevent complications. The most frequently used investigation to classify osteoporotic spine fractures is radiography. The fracture classification system can be considered a treatment guide.

The classification made by the University of Kyoto (2005) is frequently used in literature. The scientist tried to identify early radiological signs of the vertebral fractures, to allow an accurate prognosis of its evolution. Thus, by means of profile radiographs the compression fractures of the vertebral bodies were classified in five types, mainly based on the existence of a fracture line on the anterior wall of the vertebra (Figura 23):

1. *swelled front type* – more than 50% of the anterior edge of the vertebral body is swelled;
2. *bow shaped type* – the superior end-plate of the vertebra is broken or cracked, as well as the anterior edge;
3. *projecting type* – more than 50% of the prominent anterior wall appears swelled but there is no fracture line;
4. *concave type* – both vertebral end-plates are broken but the anterior wall is intact; no fracture line;
5. *dented type* – the central part of the anterior vertebral wall shows a fracture line which has a dented aspect.

This classification can be very useful in classifying acute fractures which occur as a result of minor trauma, but it cannot be used in the case of older fractures. Based on these characteristics it is possible to evaluate the future evolution of the fracture starting with the instance when the patient had a specialized check. The images characteristic for a good prognosis are the concave and the dented types. The concave type is a stabile lesion so long as it is localized. The dented type is not a characteristic fracture in the case of osteoporotic spine fractures, but according to Denis' three column theory, it is a stable fracture as it occurs only at the level of the anterior spine.

The MRI investigation is practically the only easy method of investigation, in hand, to establish the age of the fracture and to make a differential diagnosis in relation with a vertebral tumour or metastasis at its level. In the case of recent fractures, due to the vertebral oedema, in T1 mode at the level of the vertebral body we can identify a reduced intensity signal. T2 mode shows an increased intensity of the signal. As the fractures heal the vertebral body is almost recovering its normal sponge bone aspect in the MRI.

Chapter 6 presents treatment possibilities for osteoporotic vertebral fractures of the thoracic and lumbar spine. The treatment principles of the vertebral fractures are based on the type and location of the fracture. Treatment management involves a multidisciplinary approach (orthopaedist, neurosurgeon, endocrinologist, generalist, physiotherapist, physiotherapist) with a specialized team who work together from diagnosing and starting treatment until the end. It is known that only a certain part of the fractures are checked by doctors and an even smaller part need hospital admission.

The osteoporosis prophylaxis is meant to increase bone mineral density and to prevent osteoporosis in the case of elderly people. Physical exercises, active lifestyle and healthy food, rich in calcium and vitamin D, avoiding excessive drinking and smoking, weight control, all together help preserving healthy bone mass. Besides these prevention methods there are also drug methods to help in case of osteoporosis. They all can help to reduce the number of osteoporotic spine fractures up to 60% in the first year of treatment.

The conservatory treatment recommending 7–10 day rest in bed, along with anti-inflammatory, muscle relaxing and analgesic drugs represent the first step in treating this kind of fractures. Thoracic-lumbar-sacral orthosis immobilization is also a treatment method, but it can be used only for the patients who can be quickly mobilized, who present a stable fracture with reduced perspectives of spine collapse. Thoracic-lumbar-sacral orthosis immobilization represents only a relative solution in the case of elder patients. The first thing to be followed when selecting a conservatory treatment of osteoporotic spine fractures is monitoring patients in order to prevent the vertebral body. The average length of a conservatory treatment is about 6-8 weeks. The disadvantages which encourage more aggressive methods in treating this type of fractures are:

- necessity to immobilize patients;
- prolonged immobilization can lead to complications such as: vein thrombosis, pulmonary embolism, decubitus pneumonia, etc.;
- paravertebral muscle atrophy which can lead to persistent dorsal and lumbar pain.

If pain persists or there are signs of progression of the vertebral collapse it is recommended to stop the conservatory treatment and to consider surgical intervention in order to stabilize the fracture of the vertebral body. Although the conservatory and drug treatments have encouraging results, an important part of the patients do not respond to such treatments.

Surgical treatment in osteoporotic vertebral fractures is recommended in the case of:

- mechanical pains;
- neurological manifestation;
- severe modifications of spine;

- increased vertebral collapse.

The purpose of surgical treatment is:

- to stabilize spine;
- neural and nerve root decompression;
- to re-establish spine anatomy.

Selection of a surgical treatment depends on: type of the vertebral fracture and its location, the number of affected vertebrae and the degree of neurological involvement. A very important aspect to consider when treating osteoporotic spine fractures is the fact that the entire spine is affected by osteoporosis not only the fractured vertebra.

The types of surgical procedures to be used for the treatment of osteoporotic spine fractures are rather limited, due to its characteristics and can include the following procedures:

- strengthening vertebra using polymethylmethacrylate (vertebroplasty);
- strengthening and restoring the height af the vertebral body using polymethylmethacrylate (kyphoplasty);
- stabilizing the vertebral body and decompressing the medullary channel;
- combining stabilizing with strengthening procedures.

Percutaneous vertebroplasty represents the procedure in which polymethylmethacrylate, bone graft or bone substitute are used to reduce pain, correct local kyphosis and the height of the affected vertebral body.

Kyphoplasty represents a surgical procedure in which the vertebral body is approached using a transpedicular or extrapedicular method by means of a trocar under fluoroscopic control; followed by inflation of a balloon by means of a air-pressure gauge, which partially reconstructs the height of the vertebral body, and after that the empty space is injected with acrylic cement. The main purpose of kyphoplasty is to reconstruct the height of the collapsed vertebral body and to prevent extravasation of the polymethylmethacrylate. These are the main aspects which makes the difference between kyphoplasty and vertebroplasty.

Chapter 7 presents a study conducted to analyse the occurrence of the osteoporotic spine fractures within the pathology treated by the Orthopaedics and Traumatology Clinic of Sibiu, between 1st January 2008 and 31st December 2012.

Certain selection criteria were considered both for male and female patients. strategic factors in classifying a vertebral body fracture as being an osteoporotic fracture. The acceptance criteria for the study of ***female*** patients:

- aged more than 50;

- the patient reached menopause;
- low energy trauma (fall on the same level, lifting heavy weights, etc.); the radiograph of the fracture has to be characteristic for a osteoporotic vertebral fracture (osteoporotic signs on the radiograph at the level of the vertebral body, anterior wedge fracture, biconcave fracture, crush fracture or type A compression fracture according to AO classification).

The acceptance criteria for the study of ***male*** patients:

- aged more than 65
- male patient with a major risk of osteoporosis (according to O.M.S.);
- low energy trauma (fall on the same level, lifting heavy weights, etc.);
- the image of the fracture is characteristic to osteoporotic vertebral fracture (osteoporotic signs on the radiograph at the level of the vertebral body, anterior wedge fracture, biconcave fracture, crush fracture or type A compression fracture according to AO classification).

In order to be relevant the study analysed all spine fractures of patients meeting the selection criteria referring to osteoporotic fractures. They were reported to the total number of dorsal and lumbar spine fractures admitted to hospital and treated, between 1st January 2008 and 31st December 2012 the Orthopaedics and Traumatology Clini.

Thus, during the study there were 385 cases of dorsal and lumbar spine fracture patients admitted to hospital, out of which 193 (50.12%), met the clinical and radiographic acceptance criteria of osteoporotic spine fractures. 121 patients (62.70%) of our subjects were female patients whereas 72 (37.30%) were male patients. When analyzing the occurrence of the vertebral fractures we notice the peak values registered in the case of patients aged 40 to 70. In the case of patients aged 30 to 60 vertebral fractures are more frequent with men, and when this age limit is exceeded these values reverse order and are more frequently met in the case of female patients. The date of our study correlate to the results of most of the studies in literature, therefore we compared our study to a study published in 2003 frequently referred to in the literature, *European Prospective Osteoporosis Study (EPOS)(39).* Both studies show an increased occurrence of osteoporotic spine fractures, regardless of the patient's gender, as they grow older and older, reaching a peak value in the case of patients aged 70 to 80.

The first part of this statistical study presents the division of the vertebral fractures according to their location. If we divide the fractures based on the trauma centre of the spine, we refer to two level classification: the thoracic and the lumbar level, to facilitate counting fractures, taking into consideration that it was a retrospective study. We can also observe that the most frequent fractures occur at the level of L1 vertebra, either when related to the total number of vertebral fractures or when related to the number of osteoporotic fractures. The next values point out the fractures of the L1 adjacent vertebrae, the L2 and T12 vertebrae. The results of our study show similar values with the international literature in the field, which show that vertebral fractures are more frequent at the level of L1 vertebra, followed by the adjacent vertebrae. (29) Analysing the statistics and the imagistic results we can also underline the fact that most of the low energy compression fractures occur at the level of the dorsal –lumbar junction. The dorsal – lumbar jonction is the connection between the stiff toracic segment and the mobile lumbar one. The sudden transfer from a stiff segment to a mobile one makes this section be more sensitive and trauma prone.

It is also worth analysing costs with the total number of osteoporotic spine fractures. The entire sum spent on the patients with osteoporotic spine fractures is 243244 RON, of which 66878 RON represent costs of vertebroplasty and the rest of 176366 RON represent costs with conservatory treatments.

It is also interesting to analyse the associated pathology of the patients admitted to clinic with osteoporotic fractures. It can have an important impact on the evolution under treatment of these patients, with severe efects on the morbidity and the mortality of the patients suffering from it. Figures emphasize that the most frequently associated comorbidity in the case of osteoporotic fractures is represented by the cardio-vascular diseases diagnosed with 118 patients (61,13%). In this category the most frequent are the arterial hypertension and the cardiac ischaemia. The study showed that practically there is no patient suffering from osteoporotic spine fracture who does not present an associated disease. These aspects altogether result in increased morbidity, severely affected lifestyle, subsequently increased mortality if compared to the values registered by the population who did not suffer any vertebral spine fracture.

An examination chart was issued for each patient to record the Visual Analogue Score) and the Owestry score. The examination chart was filled by patients treated with the conservatory method and the patients treated with the surgical method (vertebroplasty or rachisynthesis), as well.

The study included 193 patients; 162 (83.93 %) of these patients chose a conservatory treatment. 109 (56.47 %) of them were immobilized using thoracic – lumbar – sacral orthosis, and the other 53 (27.46 %) were not immobilized. The latter were immobilized in bed for 10 –14 days and afterwards progressively mobilized according to the pain limits avoiding flexion and associated with extension exercises to strengthen paravertebral muscles. The remaining 31

(16,06 %) patients were treated surgically by means of vertebroplasty and rachisynthesis.

Chapter 8 presents statistic data referring to vertebroplasty treated patients. Vertebroplasty is recommended in order to reduce pain and to stabilize the site of the vertebral fracture. It is recommended for the patients complaining of persistent pain during daily activities which is not relived by a conservatory treatment. There is no clear recommendation criterion for vertebroplasty based on the age of the fracture, but in the cases of extremely painful fractures which cannot be relieved with parenteral treatment and need hospital admission, measures have to be taken the soonest possible.

Absolute Contraindications of vertebroplasty are: stable osteoporotic vertebral fractures and those which have a good evolution under conservatory treatment, young patients, bone fragments in the medullary channel and severe neurological manifestations, vertebral infections, coagulation deficiencies, general infections (eg. septicaemia), in case the patient is allergic to one of the components of polymethylmethacrylate, and reduced life expectancy patients (eg. severe cardio-vascular diseases, severe respiratory deficiencies), they all represent absolute contraindications.

Relative contraindications of vertebroplasty are: bone fragments in the medullary channel, patients with radiculopathies after fracturing. In cases of osteoporotic vertebral fractures when the vertebral body height is affected to an extent of 70% or the when the height of the vertebral body is less than 8 mm, the toxic risk of the polymethylmethacrylate monomers during the exothermic hardening process and the risk of pulmonary embolism, infections such as urinary tract, dental infections, old asymptomatic vertebral infections.

The study included fractures with the following clinical and para-clinical characteristics:

1) major local pain at the level of spine associated after radiological examination with a vertebral body fracture, which is not relieved by the by analgesic, anti-inflammatory intravenous treatment and bed rest during patient’s hospitalization;
2) patients who began a conservatory treatment, but who still present persistent pain although with decreased intensity;

3) progressive compression of the vertebral body during the conservatory treatment, which results in increased kyphotic vertebral;
4) radiological signs of osteopenia or osteoporosis (the vertebral body presents increased radio-transparency, while the cortical presents a density close to normal value, but thinner;
5) specific signs of osteoporotic vertebral fractures, identified by means of MRI examination;
6) delayed consolidation of the vertebral body (Kummel-Verneuil, identified by means of CT or MRI examination);
7) patients also undergo CT examinations after the surgery;
8) the vertebral fracture is located between T5 and L5 levels;
9) the patient was able to walk and sit before the vertebral fracture occurred;
10) the patient can be observed at least for an year after the surgery and can fill in the charts before and after the surgery.

For the patients who were not accepted for the study the following criteria were followed:

1) neurological manifestations as a result of radicular or medullar compression of a bone fragment migrating in the medullary channel or which causes intraforaminal compression;
2) stable fracture with favourable evolution as a result of a conservatory treatment;
3) presence of ankylosing spondylitis;
4) infections;
5) coagulation deficiencies, cardio-vascular diseases or other diseases which severely affect patient's quality of life, increasing the risk anaesthesia or surgery;
6) patients who were not able to walk before the occurrence of the osteoporotic spine fracture;
7) in case it was decided that the patient can benefit more from open surgical procedures (for example vertebral fractures which occurred as a result of a high energy trauma which generated comminuted fractures with severe compression, alteration of the posterior vertebral wall and of the posterior neural elements of the vertebra).

The study was conducted on 20 vertebroplasties between 2009 – 2012 within the Orthopaedics and Traumatology Clinic of Sibiu, located between T11 and L3 levels. All the fractures occurred as a result of a minor trauma (most frequently as a result of a fall at the same level, or lifting a heavy thing). The number of vertebroplasties is relatively reduced, but this fact was influenced by subjective and objective aspects at the same time. All the patients filled in the examination chart and agreed to surgery. Each patient had to follow a specific preoperative protocol. Polymethylmethacrylate is needed in order to perform vertebroplasty; the most commonly used are PMMA Simplex™ and VertaPlex. The surgical technique for vertebroplasty by means of transpedicular approach is described further on.

The patients were observed up to a year after the surgery. The 20 patients are divided as follows: 13 female patients and 7 male patients. The average age of the patients was 73.63, aged between 60 and 83. In the case of female patients the average age was 72.42, and in the case of male patients 75.75. The results of our study are similar to the results presented in the literature, where the female patients represent majority also in cases of vertebroplasty and the average age is higher in the case of male patients. Thus, average hospitalization in the case of patients with vertebroplasty was 10.5 days (between 6 to 17 days), and in the case of patients with conservatory treatment it was 6.96 days. The classification of vertebroplasty according to their location we notice that most of the vertebroplasties were performed at the level of L1 vertebra (8 cases), followed by T12 level (5 cases), the rest of the cases are located proportionally at L2, L3 and T11 levels.

The average VAS score before the procedure was 7.66, and the values were between 7 and 8.5. Post-operative, on the first day, we notice a reduced VAS score, the average value being 2.18, with values between 1 and 3. One year later, during the examination the VAS average score was 2.92, with vales between 2.1 and 3.5. Thus, we can notice that there are important variations of the preoperative VAS score and the postoperative score a year after the surgery and the values in the first day, postoperative.

At the same time with VAS score evaluation the quality of patient's life was evaluated as well, using ODI questionnaire, by evaluating day-to-day activities. Analysing data we notice a clear improvement of the ODI score a year after the procedure compared to the vales recorded before the procedure (this is also available for all the patients who were examined).

The data of the study are similar to the ones in literature, where there is a major difference between the preoperative and first day postoperative VAS score, which proves that vertebroplasty has a great impact in relation with patient's satisfaction and relieving pain immediately after performing vertebroplasty and beginning of recovering program, to strengthen paravertebral muscles the soonest possible after the procedure. We can notice that VAS score and the values of life quality a year after the procedure are almost equal, with a very small difference to the disadvantage of the conservatory treatment. Therefore we can conclude that the great advantage of vertebroplasty is the reduced pain and increased quality of life much sooner than the conservatory treatment. But this advantage reduces in one year's time.

Cobb angle was measured before and after the procedure, in order to evaluate the degree of degeneration of the zygapophyseal joins adjacent to the vertebroplasty vertebra, and by means of MRI the degree of stress and degeneration was evaluated observing the level of their fluid and the degeneration degree of the articular cartilage. Following the measuring of Cobb angle consisting of a 3 vertebra complex (the superior and the inferior vertebrae of the vertebra affected by vertebroplasty), on profile radiographs. In 19 cases there were no modifications of the vertebrae when comparing preoperative and postoperative values, a year after the procedure. There was only one exception where postoperative we noticed a decrease of the height of the vertebral body where the polymethylmethacrylate was injected accompanied by an increase of the kyphotic angle from 15 to 25 degrees. In this case the MRI examination showed an increase of the synovial fluid at the level of adjacent zygapophyseal joints and a slight oedema at the interface between polymethylmethacrylate and the spongy bone of the vertebral body.

During the vertebroplasty procedures in the 20 cases there were also complications but none of the resulted in neurological manifestations. In 5 cases the cement reached the intervertebral disc, in 2 cases the cement reached the medullary channel and in 1 case it reached paravertebral circulation (very small quantity).

In the end of the chapter there are some presentations of the most relevant cases.

Chapter 9 presents an analysis of the biomechanics of the spine. It is not clearly known what happens after the polymethylmethacrylate is injected inside the vertebra, as it is never incorporated and is remains a foreign body in the vertebra changing the biomechanical characteristics of the vertebral segment. Most of the studies evaluate the intervertebral stress in case of continuous compression. Only few of them study what happens in case of cyclic compressions of spine for a definite period of time, after performing vertebroplasty. It is very interesting to study displacements and strains at the level of the intervertebral body, the end-plate and different areas of the vertebral body**:**

1. during normal stress of the vertebral segment;
2. during fracturing the vertebral body;
3. after injecting the polymethylmethacrylate inside a vertebra with no fracture and a fractured vertebra.

The research required testing equipment mounted on Instron 5587 tensile - compression testing machine. The optical equipment Aramis 2M was used to evaluate displacements and strains of intervertebral discs, end-plates and vertebral bodies by means of two high resolution video cameras (Coupled Charged Device sensors) which cam measure the displacement of a graphite network applied on the articular and intervertebral surfaces. The experimental layout used for the compression tests of the vertebral body was especially designed for the study, to follow the anatomic shape of the spine body, and at the same time to allow it to be fixed. The equipment is designed to allow it to be mounted on the “T” channel base plate of the test machine. Two special light sources of approximately 300 W were used to evenly illuminate the examined vertebral segments, so as to ensure that there are no shadows on their surface.

For the study we harvested several T12 – L3 spine segments, which were preserved in saline solution at 20 degrees below 0 temperatures before the biomechanical tests. Before the tests, all the vertebral segments followed a common protocol, which was rigorously followed in order to replicate tests and insure compliance of the results.

Before beginning the tests CT examinations were conducted in order to avoid any type of fracture or large osteophytes which could form connections between the vertebral bodies (which could influence results in a negative way).

Before the tests the vertebral body was taken from its container and gradually dried at room temperature. After drying, the vertebrae were covered in white matt paint dust and a fast drying black point network.

Therefore we could conduct two types of biomechanical tests: the first type studied the biomechanics of vertebral body fracture, ant the other assessed the changes which occurred after the vertebroplasty.

For the first test the spine segment was loaded increasingly from 0 to 2000 N, observing frontal and side strains of the vertebral segment. First the rotation center of the vertebral body was identified. The specific strains which occur during compression at the level of intervertebral discs and different areas of the vertebral body were observed, before and after occurrence of the fracture. Target segments for this study were L1 vertebra as well as the superior and the inferior discs. For higher accuracy of the data the pairs of load displacement points have been acquired at a 200 pairs/ second. Further on two successive test were conducted, for the first test the loading was generated mainly on the neural elements at a 2 cm distance behind the rotation center (corresponding to the extension), and for the second test we had an axial loading, corresponding to the rotation center (205). Loading was progressive from 0 N to 2000 N in both tests. During stress important differences could be seen between the manner of loading and deforming or the vertebral body, in the case of the first test – extension – as well as in the second test axial loading. The manner how the osteoporotic spine fractures occur is a very complex one, and it involves all the structures of the vertebral segment, staring with the vertebral body, neural arch, and ending with the ligamentous and capsular system, influenced by their degenerative changes. Using this study method and this first test we can conclude:

- As the vertebral body is loaded, the intervertebral disc are loaded simultaneously but the superior discs stand higher values than the inferior ones (emphasised by means of deformations);
- In both cases – extension and axial – we can observe a higher stress on the posterior part of the intervertebral disc and neural elements;
- In extension we can first identify the loading of the neural segments and the posterior part of the intervertebral disc until to a certain value and from that moment on the anterior part of the intervertebral disc and vertebral body is loaded;
- The anterior area of the vertebral end-plate and body are loaded progressively until a peak value. After reaching this value the trabecular system of the vertebra started failing in the anterior area which resulted in *anterior wedge fracture;*
- After the fracture occurred there is a reduced strain at the level of the intervertebral disc, the load is dissipated by the trabecular system of the fractured vertebral body;
- In extension cases loads are higher at the level of intervertebral discs and reduced at the level of vertebral bodies;
- In axial cases besides the maximum values on the intervertebral discs we notice the maximum strain at the level of the vertebral body;
- At the moment when fracture occurred in the target vertebral body, strain values at the level of the intervertebral disc on top of the fractured vertebra are approximately equal to the ones at the level of the fractured vertebral body;
- Occurrence of osteoporotic spine fractures is highly influenced by degenerative changes suffered by intervertebral discs.

The second test studies the effects of vertebroplasty on vertebral body biomechanics. For the study we harvested a human L1– L3 spine segment (age 75, female gender), which was prepared respecting the same protocol as the previous one. The changes at the level of the vertebral body were observed from lateral position. First we generated progressive axial load on the vertebral segment without injecting cement inside the target L1 vertebral body. The entire vertebral segment was loaded axially until 1600 N, after injecting cement inside the vertebra to comply with the technical requirements of the initial test. While loading we observed the changes at the level of the intervertebral discs, vertebral end-plates and posterior elements of the vertebrae. The target vertebra was chosen the L2 one in order to observe changes involved one level above and beneath the target vertebra. The changes generated by vertebroplasty on vertebrae and adjacent intervertebral joints are complex. The results of the test confirm several results from test using other biomechanical methods as well as the finite element method. The conclusions of the study can be summarized as follows:

- The polymethylmethacrylate reduces the strains of the vertebral body where it is injected;
- The vertebroplasty increases strains of the adjacent intervertebral discs and of the zygapophyseal articulations between the vertebra where vertebroplasty was performed and the above and beneath vertebrae;
- Similar to the spine affected by degenerative modifications but without vertebroplasty or fractures, first we notice the stress on the posterior area of the intervertebral disc and vertebral neural elements when the compression began, yet the strains are more important than the strains recorded before the vertebroplasty;
- Strains of the vertebrae adjacent to the vertebroplasty are not larger than the strains recorded before performing the vertebroplasty;
- Compression strains ε_y of the superior disc have higher vales before vertebroplasty, whereas the inferior intervertebral disc registers reversed value, with higher values after performing vertebroplasty;
- Vertebroplasty is not the main aspect which leads to increased number of osteoporotic fractures in the adjacent vertebrae;
- The increased number of osteoporotic fractures is actually generated by combined local and general factors which become active while spine is loaded.

Chapter 10 presents the importance of the anatomic relations of the vertebral pedicle with the nervous roots and the dura mater. For this study we dissected four adult cadavers, to males and two females aged 45 to 57. We underline the fact that the patients died of natural causes and did not present malformations or traumas of dorsal spine. We used total laminectomy beginning with T4 vertebra until T12 vertebra, removing the spinous processes and the yellow ligaments (the costovertebral articulations were preserved untouched). We also performed a medial longitudinal incision of the dura mater along the laminectomy area in order to visualize and identify better the nervous roots. Electronic morphometric determinations were performed using an electronic calliper with an standard deviation of maximum 0.01 mm. The final image of the dissection is shown in Figure 99, where the posterior elements of the thoracic vertebral spine can be observed. We considered that the following values are important to be determined in order have a clear image of the size of the vertebral pedicle and its relation to the superior and inferior nervous roots ant the dura mater:

1. sagittal and transversal diameters of the vertebral pedicle;
2. the distance between the inferior edge of the superior vertebral pedicle and the nervous root;
3. the distance between the superior edge of the inferior vertebral pedicle and the nervous root;
4. transversal and sagittal diameters of the vertebral pedicle.

Analysing the above mentioned morphological data we reached the following conclusions: there is no clear increasing or decreasing evolution of the values based on the level of the vertebra in relation with the distance between the inferior and edge of the superior pedicle and the root of the spinal nerve; determinations of the distance between the superior edge of the inferior pedicle and the nervous root show a gradual decrease in the craniocaudal direction; transversal and sagittal diameters of the thoracic pedicles present progressive values from the level of T4 to T12.

Complications which may appear during surgical approach of the thoracic vertebral pedicles can be prevented if the surgical techniques are strictly respected and the surgeon is familiar with spine anatomy.

Chapter 11 is a short presentation of the findings of the thesis. Following the bio-mechanical tests and morphometric determinations performed within this thesis, from my point of view, we can draw a series of conclusions that might be helpful in understanding and treatment of osteoporotic vertebral fractures.

The conclusions that can be drawn from this work can be summarized as follows:

- osteoporotic fractures of the spine cover a significant part of in traumatic pathology of the dorsal spine – lumbar area. In our case this issue represents half of the total cases of column fractures that received hospitalisation in the Orthopaedics - Traumatology Clinic of Sibiu;
- osteoporotic spine fractures are more frequently met in the case of women(62.70%),if compared to men;
- A classification into age groups, without taking into consideration the age as a marker, highlights as a peak of incidence, osteoporotic vertebral fractures in people aged between 70 and 80 years. After 75 years, the difference between women/female and men/male subjects, increases in favour of women subjects. One explanation is higher life expectancy, according to the 2009 WHO report, in the case of the females (77 years) if compared to male ones, which is lower (70 years).
- An important feature, that must be mentioned in our statistics, is the number of cases with male subjects, aged between 60 and 74.In this situation, the number of male patients is almost equal to that of the females, due to the social and biological status of male patients. (abuse of cigarettes, alcohol cosmic, life diet and poor hygiene, disease liver - cirrhosis etc.).
- A classification based on localisation of the fracture, shows that there is a greater number of cases of L1 vertebra fractures, if the total number of vertebral fractures and of osteoporotic vertebral fractures is taken into consideration.
- The group fractures in terms of location, it is shown that prevalent fractures at L1 vertebra, both relative to the total number of. The following position in this classification highlights the number of fractures that are adjacent to L1 vertebra, that is, L2 and T12 vertebrae;
- Hospitalisation costs, in the case of one patient, reach a higher number in the case of vertebroplasty versus conservative treatment of osteoporotic vertebral fractures (in our case about 3 times bigger, 1082 RON for the conservative treatment, compared to 3343.9RON for vertebroplasty);
- An analysis of comorbidities associated with osteoporotic vertebral fractures, shows the fact that cardiovascular diseases are more

frequently met, as they reach a number of 61.13 patients in the studied cases.

- An analysis of the data of the present study,the number of conservative treatment(85.95%) is bigger, if compared to surgical treatment(16.05%) of the osteoporotic vertebral fractures.
- Pain evaluation in the case of vertebroplasty, in terms of VAS score, highlights the fact that it decreases significantly on the fist day after surgical intervention.
- Vertebroplasty and treatment evaluation, by means of VAS score and ODI questionnaire, carried out one year after surgical intervention, shows the fact that the results are almost the same/equal. Thus, the advantages that stand out in the following days after surgery in the case of vertebroplasty, disappear in the evaluation carried out after one year, a fact that highlights the importance of conservative treatment in the treatment of osteoporotic vertebral fractures. To conclude, in my view, vertebroplasty is indicated in those cases when the quality of life is directly influenced by pain factors, and when conservative treatment has failed.
- It is very important when performing the vertebroplasty to reconstruct the entire height of the vertebral body and to introduce a sufficient quantity of polymethylmethacrylate. Failure to comply with these criteria can result in overloading the zygapophyseal articulations of the adjacent vertebrae, increasing their depreciation and subsequently generates pain and increased VAS and ODI score.
- When introducing the trocar and the trans-pedicular screws it is important to consider the local anatomic aspects of the vertebral pedicle and of the vertebral body as well as their relation to the medulla and the nervous roots. There is no clear data referring to increasing or decreasing evolution of the values of the distance between the inferior edge of the superior pedicle and the root of the spinal nerve root based on the level of the vertebra.
- A gradual decrease in craniocaudal direction can be observed when measuring the distance between the superior edge of the inferior pedicle and the nervous root.
- The transversal and sagittal diameters of the thoracic pedicles increase gradually from the level of T4 to T12.
- As the vertebral segment is overloaded, when falling or during efforts, the intervertebral discs are simultaneously loaded, but the

superior discs can stand higher values then the inferior discs (this aspect was emphasized by the determinations of intervertebral disc strains);

- A higher stress can be observed on the posterior area of the intervertebral disc and the neural elements in both cases, compression and axial loading of spine with degenerative changes;
- In case of extension loading we initially notice a higher stress on the neural segments and the posterior area of the intervertebral disc, until a certain peak value, and after this value is reached the anterior area of the intervertebral disc and the vertebral body is progressively loaded;
- The anterior area of the vertebral end-plate and body is progressively loaded until a certain peak value, and after this value is reached the trabecular system fails in the anterior area causing *anterior wedge fracture;*
- After the osteoporotic vertebral fracture occurred we can observe the reduced values of strains of the intervertebral discs, as the stress is taken over and dissipated towards the trabecular system of the fractured vertebral body;
- In case of extension the stress is higher on the intervertebral discs and lower on the vertebral bodies than, compared to the axial loading;
- In case of axial loading besides the maximum values on the intervertebral discs we can also notice a maximum strain on the vertebral body where fracture occurred;
- The moment the target vertebral body is fractured, strain values of the superior intervertebral disc of the fractured vertebra are approximately equal to the values of the fractured vertebral body. This can explain to a certain extent the changes recorded by the superior discs of the fractured vertebra after the fracture of the vertebral body. Degenerative changes recorded at the level of the intervertebral disc above the fracture can be shown by means of MRI examination;
- Occurrence of osteoporotic spine fracture is highly influenced by the degenerative changes of the intervertebral discs;
- The polymethylmethacrylate injected inside the vertebral body leads to reduced strains of the vertebral body while the vertebral segment is loaded;

- After vertebroplasty, while the vertebral segment is loaded we can observe increased strains of the adjacent intervertebral discs and the zigapophyseal articulations between the vertebra where vertebroplasty was performend and the inferior and superior vertebrae;
- When compression begins first we notice stress on the posterior area of the intervertebral disc and the neural elements of the vertebra in both case of spine presenting degenerative changes without vertebroplasty or fractures, and spine where vertebroplasty was performed, but the strains have higher values than the strains which are recorded before performing vertebroplasty;
- Strains of the vertebrae adjacent to vertebroplasty do not have much higher values than the values recorded before performing vertebroplasty;
- Compression strains of the superior disc of the vertebroplasty differ from the ones of the inferior disc. The values recorded on superior intervertebral disc are higher before the vertebroplasty was performed, whereas the inferior intervertebral disc presents a reversed situation, and strains have higher values after performing vertebroplasty;
- Vertebroplasty is not the main factor which influences the number of osteoporotic vertebral fractures of the adjacent vertebrae. The increased number of osteoporotic vertebral fractures is actually influenced by combined local and general factors which are active before and after the compression of the spine;
- The method selected for the study allows us to receive in real time a large range of information from several component structures (vertebral body with the superior vertebral end-plate, intervertebral discs, zigapophyseal articulations) of the vertebral segment. It allows us to simultaneously collect data from different parts of the vertebral segment, therefore we could gather complex information helping us to understand the complex phenomena occurring when spine is compressed in various positions;
- The advantage of this method is that the whole study is conducted experimentally, using optical methods, different from the studies using the finite element method, where besides the difficulty met in building the geometric model of the vertebral body (aspect which nowadays can be eliminated by importing the model from the CT),

there is also an important issue regarding the precision of material data input. It is well known the fact that both, the vertebral body, and the intervertebral discs are highly anisotropic with different mechanical characteristics for different sections;

- This method also presents disadvantages due to the fact that the vertebrae have o complex structure without straight lines, which raises technical difficulties when it comes to lighting the part in order to eliminate shadows. Therefore results may be wrong. This aspect is very important for analysing the matt black point network. In order to prepare the spine segment, it had to be dried to apply the matt white paint, and the thin matt black points. For this reason the obtained data can be modified through the dehydration of the intervertebral disc and of the ligamentous system. Moreover, for a real validation of this method larger cohorts are needed;
- This study method is very useful to observe the influence of the treatment methods in case of osteoporotic spine fracture on the vertebral biomechanics (vertebroplasty, kyphoplasty, rachisynthesis).

This method is used for the first time for the study of compressive strains of spine. It is well known the fact that there are many studies on vertebral bodies before and after vertebroplasty, but none of these studies present in real time the strains of the studied segment. The results of our study were compared to the results of other studies in literature so as to have an objective bibliographic synthesis of the results and the study methods.

The Thesis by means of the statistical study brings its contribution to building a clear image in relation with the occurrence of the osteoporotic spine fractures (as the real number is not known), in general spine traumatology. The clinical studies allow us to better understand the evolution of the osteoporotic fractures based on the conservatory treatment with or without immobilization with thoracic – lumbar sacral orthosis and the treatment using vertebroplasty.

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