

**SHORT THESIS FOR THE DEGREE OF DOCTOR OF PHILOSOPHY  
(Ph.D.)**

**THE EFFECT OF TRANSPEDICULAR SCREW PLACEMENT  
ON THE MORPHOLOGY OF THE IMMATURE SPINE  
PROSPECTIVE STUDY IN AN IN VIVO PORCINE MODEL**

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## **1. INTRODUCTION**

Spinal growth and development in the first 5 years of life is especially important in terms of development of the lungs, alveoli, and chest wall. Therefore, early onset scoliosis (EOS), or more precisely, early onset spinal deformity (EOSD) can have a decisively negative effect on the development of the aforementioned structures. The resulting deformities cannot (or can only partially be) corrected later in life. The damage caused by the EOSD associated declined pulmonary function, deformed chest wall and extensive secondary spinal deformities is irreversible. Although the number of infantile or pediatric spinal deformities, which require surgical treatment in most cases with metal implants, is relatively low, the interventions are of paramount importance for the future of these young patients. The interventions can prevent secondary spinal deformities and their possible lethal consequences. Still, there is a certain reluctance to use transpedicular screws in small children or children who are still growing, because of the potentially negative effect of the screws on the development of the spinal column. They might damage one of the most important growth zones in the vertebra (neurocentral junction or cartilage, hereinafter NCC) and might theoretically contribute to spinal canal stenosis, which in turn could result in neurological compromise or cause further deformities (e.g. scoliosis). Neither the above mentioned potentially negative effect of transpedicular screws nor its degree is substantiated,

and the few studies published in specialist literature have arrived at contradictory conclusions.

## **2. LITERATURE REVIEW**

This chapter will first provide a short summary of the possible treatments of pediatric spinal deformities followed by the anatomy of the growing spine with special emphasis on the NCC. After that, the chapter introduces the demands for instrumented surgery of the growing spine, as well as biomechanical considerations. Finally, it ends with a summary of the studies available on the effect of spinal implants on the growing spine. There are several surgical techniques available to possibly correct or improve deformities of the pediatric spine. Unfortunately corset treatments and other conservative therapies have failed to bring the expected result. In fact, they have proved to be useless in the treatment of EOSD. There are several surgical interventions used to treat EOSD such as the in-situ bending, resection and stabilization, growing rod technique, or osteotomy with fixation, etc. The wide variety of surgical methods clearly shows the vast uncertainty that was or is prevalent even today in this challenging area of neurosurgery. When treating severe spinal deformities, we aim at a very good correction on the shortest possible section of the spine, concentrating on the pathologically affected one. It is a means to help as normal growth of the unaffected spine section as possible. As large

forces are involved in the treatment, perfect fixation of implants is of paramount importance. Owing to their excellent biomechanical properties, pedicular screw-rod constructs are suitable for the transfer (during correction) and subsequent maintenance of large forces in all planes. Although pedicle screw systems adapted in size to pediatric spinal surgery have been available for years, their use has not become widespread. The so-called reluctance of spine surgeons might have several reasons. First of all, pedicle screws crossing an immature vertebra might cause damage to the neurocentral junction, which in turn might cause dysfunction in growth, and could also, at least theoretically, contribute to further progression of the spinal deformity. Second, spinal deformities in early childhood are frequently accompanied by complex developmental disorders, and in cases with complex anatomical aberrations the safe insertion of pedicle screws might lead to technical difficulties for less experienced surgeons. Third, and probably most important of all, it is assumed that the inserted pedicle screws might inhibit vertebral and spinal canal growth, which might later result in spinal canal stenosis and subsequent neurological compromise.

## **2.1. The anatomy of the immature vertebra, with special emphasis on the growth cartilage ( neurocentral cartilage, NCC)**

NCC is a cartilaginous growth structure resembling a plate, situated between the body of the vertebra and the vertebral arch. It was first

described by Schmorl in 1932. The growth cartilage is located between two primary centers of ossification, which can be found in the body of the vertebra and the vertebral arch respectively. The two parameters that make the structure important are its role in the growth of the vertebra and the age at which it closes. Different researchers have completely different opinions on the age at which the neurocentral junction fuses. According to Vital et al. its most active role in growth is up to age 5-6. The authors say that after the age of 6 the thickness and activity of the NCC gradually decreases until the age of 15-16. In other researchers' opinion the most active growth period is between years 3-16. Fusion starts at the lumbar region, followed by the thoracic section and will take place last in the cervical region.

## **2.2. Instrumentation of the immature spine**

Treatment of EOSD is a great challenge for surgeons treating pediatric spines. The common use of corset is either ineffective or contraindicated. Fusion and instrumentation of the spine in adolescent or adult scoliosis is regarded as the gold standard method, although it can impede the growth of the trunk and can impair the development of chest and consequently that of the lungs in EOSD. The concept that the goal of surgical treatment is to correct deformities while maintaining maximum growth potential was introduced by Harrington in one of his early publications, where he urges instrumentation without fusion in

patients under 10. It was Moe et al. who first used a „subcutaneous rod technique”, which was further developed and today it is known as the „growing rod technique”. Its two basic types are the dual growing rod technique and the single rod system. In my opinion both techniques can successfully be applied; the choice between them depends on the type of scoliosis, weight of the patients and their growth potential.

### **2.2.1. Biomechanical concerns**

Several studies have been published on the biomechanical effects resulting from the placement of screws into the anterior vertebral body or the pedicle in the adult patient population. Today it is undoubtedly the instrumentation with screws and rods that results in the best three dimensional correction, no matter if it is an anterior or posterior operation.

To the best of my knowledge, no similar biomechanical studies have been carried out in EOSD population. Nevertheless, its use can be assumed to have the same biomechanical benefits as in the adult patient population.

### **2.2.2. Basic surgical principles**

The surgical principles in pediatric EOSD patients do not differ from the ones in other age groups. As mentioned above, the main goal of surgery is to secure growth and if it is needed to reach a solid fusion. It is essential to avoid damaging the periosteum as it could result in growth dysfunction. A very cautious preparation is needed, or if it is possible, it can be advantageous to insert a percutaneous, perfacial or intramuscular implant. If the goal is to obtain fusion a cautious preparation that includes the removal of the soft tissues and the periosteum and the proper resection of the joints or the discus is needed.

### **2.2.3. The choice of the implant**

As in the majority of EOSD patients other inborn organ malformations such as central nervous system alterations, heart or urogenital problems maybe present, use of titanium implants is recommended. This makes further diagnostics and examinations (e.g. MRI) easier. According to experience this group of patients may consist of those with different pathology, and their weight often lags behind the weight expected in this age group. In this respect I think a classification based on body weight seems to be more logical than one based on age.

Surgeons encounter big challenges especially in congenital patients with syndromes because of the anatomical variations. In an optimal spine well-defined, big pedicles are expected. The 3D CT reconstruction before the surgery can be very helpful during the surgery. According to medical literature pedicle screws can be used from the age of one. From my point of view in justified cases it can be used shortly after birth too.

#### **2.2.4. Patients and implants' size relations**

The use of implants in EOSD patients is obviously an effective treatment. In medical literature there are recommendations about how to use implants but mainly there are recommendations regarding age. For children under 3 a 3,2 mm or 3,5 mm diameter rod is recommended, for children between the age of 3 and 8 the 4,5 mm one and for children older than the previous age groups at 5,5 mm rod. According to experience this group of patients may consist of patients with different pathology, their weight often lags behind the weight expected in this age group. In this respect I think a classification based on body weight seems to be more logical than one based on age. When choosing the right implant it can be of further help to determine the speed of growth if it is possible. The diameter of transpedicular screws depends on anatomical features, so a CT before the surgery can be helpful during the planning.

According to my experiences it is important that the implants are not too rigid. That way the unwanted too early rigidity of the spine can be prevented or at least delayed.

### **2.2.5. The anatomical features of spine deformities in early childhood**

Surgeons encounter big challenges especially in congenital patients with syndromes because of the anatomical variations. In an optimal spine well-defined, big pedicles are expected. Of course if the transpedicular screws cannot be applied safely another solution has to be chosen.

### **2.2.6. Implant-dependant complications**

The implant-dependent complications in EOSD patients do not differ from the generally occurring complications known to occur in the surgery of deformities, namely: infections, weakness of the implant, transition problems between the proximal or distal implant and the healthy part (local kyphosis, local scoliosis (the phenomenon of „adding on”) and neurological complications. These complications can be reduced in well-planned and well-prepared cases. The preoperative CT 3D reconstruction can be of big help as well as the multimodal intraoperative monitoring (MIOM).

### **2.3. The effect of transpedicular screws on the growth of the spine**

Pedicle screw constructs are frequently used in the treatment of adolescents (adolescent idiopathic scoliosis) and sometimes also juvenile scoliosis without late effects manifesting as spinal stenosis. As it could be seen in Dimeglio's studies, growth is most active in the years up to age 5 and soon after so the question is whether the pedicle screws can be applied safely in patients under 5 years old, where the neurocentral junction is not fused and is indeed still active. One of the few publications on this topic is the study made by Ruf and Harms. They reported that the pedicle screws in patients of 1 or 2 years of age did not result in spinal canal stenosis, although their follow-up was very short, only 2 years.

The appropriate follow-up period would be 10-15 years, which is impossible or complicated to carry out. The follow-up period can be reduced with animal experiments. Only few studies have been published so far where in an animal experiment model the morphological effect of transpedicular screws on the growth of the spine was examined. However, these studies arrived at contradictory conclusions regarding the subsequent growth of the spinal canal.

## **2. GOALS**

In my study, I examined the surgical spine implants and more closely the structural deformity causing effect of the transpedicular screw in the growing spine, paying special attention to the alteration of the form of the vertebral body and the spinal canal. Considering the contradictions in the medical literature my goal was to determine the effect of transpedicular screws on the development of the growing spinal canal and on the possible development of spinal stenosis based on my own experiments. My purpose was to answer this question by carrying out both animal experiments and examining my human surgical practice retrospectively. With this study of mine I would like to contribute to the removal of contradictions in the medical literature.

## **3. MATERIALS AND METHODS**

Pigs are often used for experimental purposes in spinal research and implant testing mainly because of the anatomical similarities to humans. In addition, the accelerated life cycle of pigs compared to humans renders them especially suitable for conducting experiments concerning growth and development in a short time. We applied the same freehand screw insertion technique that we use in our daily surgical practice in humans. To get acquainted with the porcine anatomy, we first performed a pilot study with 10

domestic pigs that were being sacrificed for reasons unrelated to our study. CT scans between Th9-11 and L2-L4 were performed. Based on these findings the second lumbar vertebra was chosen as the level to use for instrumentation.

#### **4.1. Study design**

We used 13 domestic white pigs (9 females and 4 males) from two mothers. They were 38–45 days old and weighed an average of 8.3 kg (range 6.0–11.5 kg) at the time of surgery. The animals were killed 7 months later, at the age of 8.5 months, after they had reached a tenfold increase in their body weight (97.2 kg; range 94.5–103.0 kg). Using a calculation that considered data for skeletal maturity based on closure of the epiphysis of long bones and growth charts describing growth potential and immaturity, the model was designed to correspond to children growing from the age of 6 months to 4 years. The time span between the surgery and the final analysis was chosen to include the most active growth period of the neurocentral junction.

To reduce the stress on the pigs and to minimize the approach-related growth disturbance and complication rate, we chose to perform as minimal a surgery as possible, inserting just a single pedicle screw (L2) in each pig. We assumed that insertion of a screw on one side only would affect the growth of only that side.

The potential asymmetry resulting could be easily measured . The side of instrumentation (right or left) was randomly assigned.

#### **4.2. General anaesthesia**

Just before the surgery, Calypsovet inj. (ketamin) 8 mg/kg and Rompun inj. (xylasin) 1 mg/kg were delivered intramuscularly. Antibiotic prophylaxis using 0.4 ml/5kg Shotapen was administered in the immediate postoperative period. The animals were given Metacam inj. (meloxicam) subcutaneously for 3 days as postoperative analgesia.

#### **4.3. Surgical technique**

The animals were placed in a prone position. After making an 8-12 cm incision at the L2 level, the appropriate side (right or left) of the lumbar spine was exposed, taking care not to injure the periosteal layer and to reduce the risk of potential growth disturbance related to exposure (unrelated to the pedicle screws per se). Great care was taken to leave the L3 vertebra (control vertebra) intact. The transpedicular screw (length 18–22 mm, diameter 4.0 mm, titanium, ACE, DePuy) was inserted by freehand technique. Finally, the wound was closed in layers. The length of each surgical procedure averaged 30 min. Following surgery, the animals were kept under general anaesthesia, and a CT scan was performed to

obtain axial cuts at the L2 and at the L3 level. Based on the postoperative CT scans if each screw was not in the appropriate position, the pig had to be excluded from the study. Another CT scan was performed 7 months after the surgery. Following surgery, the animals were taken to the Large Animal Hospital of the Department of Surgery. During the observation period no abnormalities were detected. After 10 days the sutures were removed, and the experimental animals were delivered back to the farm, where they were kept in one group separated from the others for two months. They were then integrated with the other pigs.

#### **4.4. Radiological examination**

Following surgery, the animals were kept under general anaesthesia, and CT images were taken at the L2 and at the L3 level according to a carefully designed protocol. The postoperative CT scans showed that each screw was in the appropriate position and as a result no pig had to be excluded from the study. Other CT scans were performed in a similar fashion 7 months later.

#### **4.5 Postoperative period**

Following surgery, the experimental animals were taken into the Large Animal hospital of the Department of Surgery. Their general condition was closely observed and their temperatures were taken

daily. Two days after surgery benzathine penicillin, procaine penicillin and streptomycin (Shotapen inj. 0.4 ml/ttkg) were given as part of the perioperative prophylaxis. During the observation period no abnormalities were detected. After 10 days the sutures were removed, and the experimental animals were delivered back to the farm, where they were kept in one group separated from the others for two months. They were then integrated with the other pigs. Five months later the pigs were killed.

#### **4.6. Quantitative analysis of the radiological examinations**

Measurements were performed on the CT scans to quantify the symmetry of the spinal canal and the vertebral body. For these purposes, angles were measured describing each side of each vertebra.

Angles relating to vertebral body symmetry: a line was firstly drawn connecting the intersection of the neurocentral cartilage with the spinal canal and the most anterior aspect of the vertebral body (or the anterior crista of the vertebral body) on each side; the angle between this line and the horizontal plane was then measured on each side and defined as the vertebral body angle–non-screw side (VBa-ns) or vertebral body angle–screw side (VBa-s).

Angles relating to spinal canal symmetry: a line was drawn connecting the most posterior point of the spinal canal and the junction of the spinal canal and neurocentral junction; the angle between this line and the horizontal plane was defined as the spinal canal angle–non-screw side (SCa-ns) or spinal canal angle–screw side (SCa-s). An independent radiologist performed all CT measurements twice in each CT study. Intra-rater reliability calculations revealed no significant differences between repeated measurements ( $p>0.05$ ) with intra-class correlation coefficients ranging 0.92–0.99, indicating excellent reliability.

#### **4.7. Statistical analyses**

Descriptive data are presented as means and standard deviations (SD). The duplicate measurements for all dimensions were first averaged to give a representative value for the given vertebral level and side. The values for L2 (the intervention level) were then normalized to (i.e. expressed as a proportion of) the corresponding value at L3 (control level), to account for any possible alterations in the positioning of the animal during imaging at the two different time-points, and to account for normal changes in the angles over time due to growth. Non-parametric Wilcoxon Signed Rank tests were used to examine the significance of the difference between sides for: (1) the normalized L2 angles at the time of intraoperative

assessment; (2) the normalized L2 angles 7 months later; (3) the difference in the L2 angles at these two time-points. The anterior-posterior diameter values of the spinal canal were averaged and the results were related to values pertaining to pigs at the same level of maturity. The data were analyzed using Statview 5.0 (SAS Institute Inc., San Francisco, CA, USA). Statistical significance was accepted at the  $p < 0.05$  level.

## **RESULTS**

### **5.1. The results of the animal test model**

Three animals died during the study (2 deaths related to subsequent anesthesia, 1 death due to infection unrelated to surgery). At the end of the 7-month follow-up period 10 pigs were available for the final CT examination. The animals involved in the research were not separated from the other members of the herd after the first two months. According to our observations there was no difference between the gait of the treated and non-treated pigs. This fact led us to conclude that none of the treated animals had any apparent neurological disturbances.

#### **5.1.1. Measurements regarding the symmetry of pig vertebra**

There was no significant difference ( $p>0.05$ ) between the normalized values of the angles to determine spinal canal symmetry, no matter which period of the trial the values were derived from. The difference between the normalized values of the angles was slightly larger on the screw side than on the non-screw side but the difference did not reach the statistically significant level ( $p=0.24$ ). There was no significant difference between the vertebral body angles (VBa) at the start date (at the time of the surgery). However after 7 months the difference between the sides became significant ( $p = 0.005$ ). The change in normalized angle values between the starting and closing date of the experiment was significantly different on the screw and non-screw sides ( $p = 0.009$ ): the normalized angle had reduced on the non-screw side (VBa-ns) but had increased on the screw side (VBa-s), indicating asymmetry in the vertebral body growth. This deformation of the vertebral body is clearly perceptible on the CT scans in the axial plane, whereas the spinal canal cross-sectional area remained symmetrically elliptic in shape throughout.

### **5.1.2. The analysis of the absolute measures of the vertebral canal**

We show the aggregated values of the a-p diameter and width of the vertebral canal measured on axial CT scans. As a historic control group we used morphometrical data published by Dath and his colleagues in 2007. The aim of Dath and his colleagues' work was to set up a reference database as well as to describe the anatomical differences between the human and porcine vertebra. It can be seen from the values shown that the dimensions of the vertebral canal are smaller at the L2 level than at the L3 level, that is, the vertebral canal widens in the distal direction. The diametral – and so regional – difference between the instrumented and control vertebrae found in our experiment do not necessarily show negative effects of instrumentation, but only the physiological anatomical relations. That is to say that, the dimension of the vertebral canal at the L3 level is bigger than at the L2 level. Unfortunately, the structure of our analysis does not allow any observations regarding the extent of the difference. However, based on common sense it can be assumed that the narrowing of the vertebral canal may not have any clinical consequences. In the case of a 50% narrowing we can talk about stenosis of the vertebral canal causing significant clinical-neurological symptoms in human context. In fact, we did not observe any gait disturbance referring to a neurological deficit. From a practical perspective, the most important finding is that the vertebral canal of the instrumented

vertebra became bigger in spite of the transpedicular screw. Thus, the disturbance of the function of the neuro-central junction did not lead to the growth of the vertebral canal. Moreover, we did not even find any differences in the extent of the growth between the instrumented and control vertebrae.

## **5.2 Human research**

The above findings (in 5.1), like in the case of all animal research, can be applied to human conditions. Carrying out a human study is especially difficult due to the necessity of a long follow-up time. To illustrate this, I chose a cervical vertebral and a lumbar vertebral case among my previously operated pediatric patients. In both cases described there was a long follow-up time available. Practically, the patients achieved the completion of bone maturation and so completed their growth.

## **6. Discussion**

Little information can be found regarding how the pedicle screw affects the development of the vertebra. Most spine surgeons seem to be reluctant to use pedicle screws, especially in the case of very young children fearing that the inserted screws through the neuro-central junction which plays a central role in the development of the vertebra – and thus the vertebral canal - ultimately lead to

spinal stenosis and subsequent neurological disturbance. But the correction of the deformity is especially of major importance in the case of such children, which is almost impossible without the use of transpedicular screws. Transpedicular screw systems are often implanted during puberty (adolescent idiopathic scoliosis), or at a younger age (e.g. juvenil scoliosis), without causing stenosis of the vertebral canal. The question is whether these screws can be safely used in children younger than five, when the neuro-central junction is still active? According to the study carried out by Ruf and Harms the screws implanted to 1-2-year-old children did not lead to stenosis of the vertebral canal, although it should be noted that in their study the average follow-up period was only 2 years, thus the application of the results can be very limited in everyday life. To answer the question posed above, we should choose a sufficiently long follow-up period, which would require the completion of the development of the skeletal system, that is, it would require 10-15 years. After this time we could only say if the pedicle screws inserted in very young children lead to symptomatic stenosis of the vertebral canal. One solution to the problem mentioned above is the use of an animal model, so the follow-up period can be significantly reduced. For this purpose, one of the most suitable species is domestic pig, as the vertebrae with regard to their shape and size are very similar to the human vertebrae. Furthermore, they

have been raised for fast growth, which means shorter follow-up time in our case. Porcine models were initially used to study the development of spinal deformities. Later, experimental studies were carried out to study the effects of pedicle screws, however, results were controversial. The first study noting that the bilateral pedicle screws lead to stenosis of the spinal canal was published in 1961. Others (Zhang and Succato) studied the effects of unilateral epiphyseodesis in 8 adjunct spinal vertebrae. They did not find any signs referring to the development of stenosis of the vertebral canal, although spinal deformity was the focus of their study. The value of the statement can be further weakened by the fact that a surgical incision was also performed in the control group, which theoretically can influence the development of the vertebral canal. Cil and his colleagues found a significant stenosis of the lumbar vertebral canal at the level of the pedicle screws inserted into domestic pigs. Their measurements were performed on a vertebral canal (2 hemi channel) and vertebral body divided sagittally into two. The splitting dividing (reference) line passing through the vertebral body – as a result of distortion – did not give any reliable information regarding the geometry of the vertebral canal. Thus, in our opinion the validity of the asymmetry of the vertebral body can be questioned. The common feature of the works mentioned above is that the effects of the pedicle screws on growth were carried out

through the instrumentation of several adjacent segments. This is a relatively long incision, it means a large opening, which may increase the impact of growth alteration in connection with the theoretically possible incision. Furthermore, the instrumentation of several adjacent segments on the same side may cause deformity of the developing spine, which alone can affect the development of the vertebral spine. In our research, taking the aforementioned considerations in account and for these reasons, we performed an operation only on one side of a single vertebral body. Thus it became possible to examine the role of the neuro-central junction in isolation. Unfortunately, it is also necessary to mention that the application of one single screw in our model has some drawbacks. Apart from some cases, in the treatment of early childhood spinal deformities (EOS or EOSD) two pedicle screws per vertebra are needed, so the result of our one screw model may be extrapolated to only a certain extent. Furthermore, our findings similar to the ones of every animal research model can be applied in human medicine only taking certain considerations into account.

To sum up, in the present study the screw which was put through the still active neuro-central junction into the porcine pedicle that was still in developing made a significant change in the development of the vertebral body in the axial plane. However, it had no significant effect on the morphology of the vertebral canal.

The findings of our experimental research provide further arguments for the use of pedicle screws, which after considering the existing pros and cons can be and has to be taken into account in the treatment strategy of children suffering from certain forms of early childhood spinal deformities.

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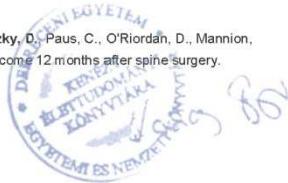
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