

OPINION

From Prof. Dr. Hristo Georgiev, MD, DSc
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Subject: dissertation "Free-hand" technique for placement of pedicular screws in the surgical treatment of idiopathic scoliosis in childhood "for the award of educational and scientific degree" PhD".

By Order №185 / 08.04.2021 of the Executive Director of Acibadem City Clinic MHAT Tokuda Sofia I was appointed a member of the Scientific Jury and by decision of the latter (Minutes №1), I was appointed to present an opinion on the dissertation of the Adelin Georgiev Ivanov, PhD student of independent training at the Clinic of Bile, Liver, Pancreatic and General Surgery of Acibadem City Clinic Tokuda Hospital EAD, in the field of higher education 7. "Health and Sports" in professional field 7.1 Medicine and doctoral program "General Surgery".

Surgical treatment of high-grade scoliosis with vertebrotheses and polysegmental vertebrotomies with posterior or anterior instruments is a highly productive and established method in modern spinal surgery. It is directly related to the applications of the scientific and technical process in medicine. The use of high-tech implants (screws, hooks, longitudinal rods, etc.), intraoperative electromyographic monitoring, magnetic resonance and CAT imaging methods are essential, but not sufficient to improve surgical technique.

One of the ways for stable fixation, early mobilization of the patient, low levels of X-ray exposure, shortened operative time, reduced blood loss and neurological complications is the use of "Free - hand" technique for placement of pedicular screws. The dissertation work of Dr. Ivanov is dedicated to this topic. The relevance of the work is related to the application of the technique in children with idiopathic scoliosis. Disease with three-dimensional deformities, requiring corrections in the three planes in individual, often difficult to place spatially located pedicles. He was the first in the native orthopedic science to study the technique in this scientific volume.

The dissertation is presented according to the usual structure for this type of works in 114 pages with 38 tables, 10 graphs, 54 figures and three protocols. It includes an introduction (2 pages), a literature review (33 pages), a bibliography with 144 literature sources. The literature review is sufficiently extensive, while not exceeding the accepted 30% of the work. The pathogenesis of idiopathic scoliosis and modern classifications of the disease are considered. The orthopedic treatment of the deformity, including that in Bulgaria, the neurophysiological monitoring, the biomechanical analysis of the screw synthesis and the anatomical features of the vertebrae in the thoracic and lumbar area and techniques for free-hand instrumentation were followed. The literature data on biomechanical, neurological, dural, vascular, etc. are presented in detail. complications and relapses. The review ends with a summary of the issue in 8 points. In the rest of the dissertation Dr. A. Ivanov formulates the goal and the 7 tasks arising from it. Presents the clinical material, the research methodology, its own results and their discussion and its conclusions.

The goal is clearly stated - By analyzing the results of the application of Free-hand operative technique to develop protocols for planning, implementation and verification in order to reduce the risk of complications in its application for the surgical treatment of idiopathic scoliosis.

The opportunity of Dr. Ivanov to work in one of the leading centers for spinal surgery in Bulgaria, in Acibadem City Clinic Tokuda Hospital - Sofia provides him with conditions to collect clinical material sufficient for statistically reliable conclusions. It includes 68 retrospectively followed patients with surgical treatment for idiopathic scoliosis for the period

June 2013 - December 2019. All are under 18 years of age - average age 14 years, with a predominance of females - 56, adolescent scoliosis - 66%. , Lenke severity 3 - 30%, mean preoperative Cobb angle - $66.44 \pm 4.31^\circ$ and rotation from 0 to 20° - 78%.

In all patients the considered operative technique was performed with posterior instrumentation. In 57 only screw stabilization was used, at 2 in combination with sublaminar bands and at 9 with hooks. The average instrumented levels of the cases included in the dissertation are 11.29 ± 0.50 , the average number of screws per patient is 19.43 ± 0.90 , most often 12 levels and 22 screws, respectively. Minimum instrument level is 5 with minimum 10 screws, maximum - 15 levels and 30 screws respectively. The number of instrumentation levels depends on the type and number of structural curves.

In the chapter Methodology of the research, the dissertation presents in great detail the stages of the Free - hand technique. These include surgical planning, limited surgical access and facet resection, initial vertebra selection (preferably neutral), dorsal cortex perforation and pedicular hole formation, ball probe hole verification, screw length measurement and screw measurement, secondary drilling and screw insertion. This is followed by fixation of the longitudinal rod to the pedicular screws and derotation in several stages. Subsequent techniques are segmental compression and distraction with the aim of correcting curves. This stage is at high risk of neurological complications and requires active IONM control. The presented steps are described in detail with scientific-practical and methodological contribution. Especially valuable for those working in spinal surgery are the guidelines for intraoperative control for verification of screw malposition - manual with a probe and X-ray.

In this chapter, the dissertation also presents its own Screw Position Verification Protocol. It is accurate and correct, but I think its place is in the discussion, as the logical conclusion of the dissertation, not in this chapter.

In processing the results, Dr. Ivanov uses reliable modern statistical methods used in biomedical sciences. The dissertation shows an understanding of statistics.

The results of the study are correctly presented in Section III. In summary, they address the risks of incorrect tracing of the screw and show:

- The reported Cobb angle correction rate averaged 64%, with a pre- and postoperative difference of 36° , averaging 42.49 ± 3.50 .
- A directly proportional, linear, average effect correlation between the preoperative Cobb angle and the number of screw malpositions has been demonstrated.
- There is a proportionally statistically significant relationship, with increasing levels of patient correction increasing the number of screw malpositions.
- The number of instrumentation levels depends on the type and number of structural curves, which determines the preoperative planning. They are the least in thoracolumbar scoliosis type Lenke 5, and the most widespread are the surgical interventions in scoliosis type Lenke 6 and Lenke 4.
- The risk of malposition is more than twice as high in scoliosis type Lenke 4 (three structural curves) and Lenke 3 (two structural curves) compared to scoliosis type Lenke5 (one structural curve).
- In juvenile scoliosis the number of malpositions is statistically significantly higher.
- At levels of the screw stimulation test below 7mA, a mandatory verification of the screw stroke at the appropriate level is performed, regardless of the postoperative X-ray control.
- The reported number of malpositions in the thoracic area is 8.43% and in the lumbar area - 9.3%. The number of lateral malpositions is higher - thoracic 66.7%, lumbar 67.7% of the total number of malpositions, medial are thoracic 30.9%, lumbar 25.8% of the total number of malpositions. The more common lateral malpositions are associated with the desire to avoid penetration into the spinal canal and the denser medial pedicular wall.

- A statistically significant, linear relationship between the number of malpositions in the thoracic department and thoracic apical rotation has been proven.

- Average levels of blood loss during interventions is high - $969.7 \text{ ml} \pm 117$.

Correctly in this section Dr. Ivanov reports the complications that have occurred in the application of "Free - hand" technique for placement of pedicular screws. Postoperative transient problems were observed in 17 patients or 33.8%. Postoperative complications have been identified in 6 cases. No permanent neurological or visceral complications were reported, and transient complaints resolved within 1 month.

Chapter IV presents an extensive comparative analysis of the views and results of the dissertation on the subject with those of other authors who have worked on the problem. This chapter is the most creative part of the dissertation. It convincingly proves the high erudition of Dr. Adelin Ivanov on the presented issues. The discussion reasonably imposes the opinion that the protocol of the dissertation for step-by-step verification and mandatory application of BSM results in low levels of reported problems in the technical implementation of the synthesis and reposition.

Thirteen important conclusions for the practice are presented in Chapter V. Despite their significant number and possibility for their unification, I firmly accept that with their formulation the set goal of the dissertation is fulfilled.

In general, the dissertation is written in the correct literary language. There is an excellent illustration with highly informative color figures, facilitating the perception of the material. All tables and graphs fully meet the goal.

In the presented scientific work of Dr. Adelin Georgiev Ivanov I can point out the following more important contributions:

With original character:

1. The interrelation between the type of scoliosis, its degree, the zone of stabilization, etc. has been studied and proved. and the probability of helical malposition.

With scientific-applied and confirmatory character:

1. The therapeutic efficacy of helical posterior stabilization in idiopathic scoliosis has been confirmed.

2. The safety of "Free-hand" technique for placement of pedicular screws in the surgical treatment of idiopathic scoliosis has been confirmed.

3. A real Screw Position Verification Protocol has been developed in detail and put into practice.

I have no significant critical remarks on the dissertation and the attached abstract.

On the dissertation topic Dr. A. Ivanov presents 5 scientific papers. They contain separate parts of the developed material and meet the Minimum requirements for Area 7. Health and Sports, according to the Regulations for the implementation of the law on the development of academic staff in the Republic of Bulgaria from 2018. The same compliance applies to my dissertation abstract. .

In conclusion, the dissertation fully meets the qualitative and quantitative criteria set out in the Legal requirements for dissertation for the acquisition of educational and scientific degree "Doctor" in the Republic of Bulgaria. Therefore, I give a positive assessment of the work and call on the members of the Scientific Jury to award Dr. Adelin Georgiev Ivanov educational and scientific degree "DOCTOR" in the scientific specialty "General Surgery".

07.05.2021 Prof. Dr. Hristo Georgiev, MD, DSc