Original papers

The titanium-made growth-guidance technique for early-onset scoliosis at minimum 2-year follow-up: A prospective multicenter study

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Abstract

Background. The management of early-onset scoliosis (EOS) remains a serious challenge in pediatric orthopedics. The growth-guidance system (GGS) is a surgical option that allows continuous growth along a rod, averting the need for repeated operative lengthening.

Objectives. The objective of this study was to evaluate the outcomes of the GGS in the treatment of EOS.

Material and methods. A prospective study, including 81 patients from 4 departments treated with this method from 2013 to 2015, was conducted with a minimum follow-up period of 24 months. The follow-up data of 57 patients was available, thus the drop-out rate was 29.63%. There were 44 girls with a mean age of 10.03 years and 13 boys with a mean age of 8.04 years.

Results. The mean preoperative Cobb angle was 65.3° (range 36°–139°) was corrected to 23.7° (2°–94°), and at the end of the 2-year follow-up increased to 30.7° (8°–93°). The predominant proximal level of instrumentation was T5 and the distal was L1. The combined length of T1–T12 and T12–S1 increased on average by 33.19 mm in 24 months. The overall rate of serious complications was 43.86%. The most prevalent device-related complications were: the dislodgement of top screws because of the short length of the rod (14 cases), the implant failure (11 cases) and loss of correction (9 cases).

Conclusions. The results show that the GGS used in this study allows for a good and stable correction while preserving the ability of the spine to grow in at least a 2-year follow-up. The complication rate is acceptable and comparable with other growth-friendly techniques. To date, this is the largest successful study on the use of titanium-made GGSs.

Key words: early-onset scoliosis, scoliosis, spine, titanium

Introduction

Early-onset scoliosis (EOS) is a very serious, potentially life-threatening clinical condition,[1] which develops in young children under the age of 10. Patients with progressive thoracic scoliosis tend to develop, as a part of natural history, restrictive lung disease and possibly cardiac disease associated with early mortality.[1–3]

Despite progress in the field of spinal disorders, managing EOS remains a serious challenge. The first line of treatment consisting of conservative methods, such as bracing and casting, is often unsuccessful and is often used to buy time for skeletal maturity.[4] Early attempts to utilize a classical fusion technique, according to the belief that a short and straight spine was superior to a long and deformed one, failed miserably.[5] Studies have reported that early fusion leads to pulmonary compromise and poor overall quality of life,[6,7] as it is crucial to allow for accommodation of developing lungs. Campbell et al.[8] defined the term "thoracic insufficiency syndrome" as the inability of the thorax to allow effective respiration and growth of lungs. One of the most appealing concepts of surgical treatment, besides distraction-based methods, is the growth-guidance system (GGS), which was first introduced as the Luque trolley,[9] and further improved into the Shilla method.[10] This technique uses stainless steel rods and specially modified locking nuts that allow for fairly unrestricted sliding motion. Early results have shown good results with an acceptable complication rate.[11] The system described in the present study is based on a similar principle, though it is made of titanium. The purpose of this study was to analyze the results and complications in a group of patients with a minimum 24-months follow-up.

Material and methods

An approval No. DS240/2013 was obtained from the ethics committee of the Medical University of Lublin, Poland. In a prospective uncontrolled multicenter study, 81 EOS patients from 4 departments of 2 countries (Poland and Czech Republic) were enrolled. They underwent index surgery from 2013 to 2015. The 24-months follow-up data was available for 57 patients and they were included in this study. Thus, the overall follow-up rate was 70.37%. The demographics and basic characteristics are shown in Table 1. There were 44 girls and 13 boys; boys were significantly younger. The majority of the patients, 76.79%, belonged to Risser 0 grade; the difference between the sexes was not statistically significant. The median proximal end of deformity was T5 in both the sexes; the median distal end was L1 and T12 for females and males, respectively. The majority of the patients (76.09%) had single curve deformities, 80% in females and 63.64% in males; the difference between the sexes was statistically insignificant. Eighteen patients were syndromic. In all but 7 cases surgical treatment was preceded by unsuccessful conservative treatment (rehabilitation and bracing).

Table 1. Demographics and basic characteristics

Variables	Female	Male
Number of patients	44	13
Age at index surgery ±SD	10.03 ±4.82*	8.04 ±3.65*
Percentage of Risser 0 patients (the rest Risser 1)	81.82	61.54
Predominant proximal end level of scoliosis	T5	T5
Predominant distal end level of scoliosis	L1	T12
Percentage of patients with a single curve	80.00	63.64
Median number of instrumented levels (range)	12 (9–16)	11 (10–16)

*$p < 0.05$; SD – standard deviation.

Surgery

All the subjects underwent a 3-plane correction of scoliosis and instrumentation with Socore GGS (Novaspine, Salouël, France) pedicle screws. The spine was exposed in a standard subperiosteal fashion near the apex. In the apical zone, the rods were tightly fixed to screws using classical locking caps. A fusion-promoting environment was created to allow for 2–3 level spondylodesis. The goal was to make the apical level as neutral as possible. The transverse connector was used on a case-by-case basis. At both ends of the instrumentation, extraperiosteal dissection was used along with specially designed locking caps that enabled relatively unconstrained sliding movement of the rod inside the screw head (Fig. 1). The purpose was to convert the grow-friendly stabilization into rigid spondylodesis after some 2–3 years at the surgeon's discretion, when sufficient vertebral column growth has been achieved.

The patients did not use external stabilization such as bracing and/or casting. Radiographic analysis was

Fig. 1. Comparison of the sliding GGS screw cap (left) and a traditional locking cap (right)

Table 2. Device-related complications according to the classification system by Smith et al.[14]

Grade	Description	Number of cases
I	Does not require unplanned surgery	32
II	Requires unplanned surgery/surgeries	17
III	Requires abandoning growth-friendly strategy	8
IV	Death	0
Total		57

performed with taking standard standing X-rays just before and soon after the surgery, and at the follow-up. Besides the Cobb angle, the apical vertebral rotation (AVR) was evaluated using the Nash and Moe method,[12] which classifies the degree of rotation into one of the 5 groups (0–IV). The differences in mean values of Cobb angle were compared using the paired Student's t-test, while median values of AVR were evaluated using the Wilcoxon test.

The changes in the lengths from the point located right between the pedicles of the T1 and T12 vertebrae as well as between T12 and S1 were calculated and evaluated using the paired Student's t-test. The implant-related complications were categorized according to the classification system described by Smith et al.,[13] which is shown in Table 2.

Results

As shown in Fig. 2, the average angle of the major curve was 65.3° ±17.6° before surgical treatment, 23.7° ±15.77° immediately after surgery and 30.7° ±17.56° after 24 months of surgery. The changes in measurement were statistically significant at $p < 0.01$. The T1–T12 and T12–S1 lengths increased at each time point: they measured 197.7 ±27.33 mm and 136.93 ±21.14 mm before the surgery, 218.7 ±27.39 mm and 149.53 ±21.74 mm immediately after surgery, and 230.52 ±28.41 mm and 155.56 ±23.2 mm 24 months after surgery, respectively. The differences were statistically significant at $p < 0.0001$.

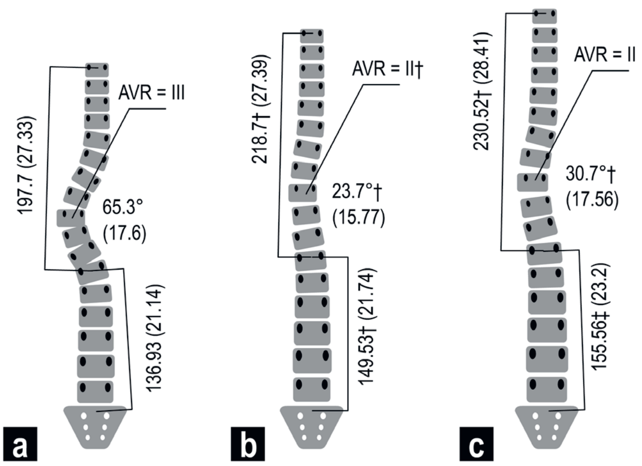

Fig. 2. Schematic diagram of the parameters before (a), soon after (b) and 2 years after (c) surgery

* $p < 0.0001$; † $p < 0.01$, SD – standard deviation (in parentheses).

The mean total length, measured by adding up both the lengths, was 325.11 ±61.62 mm before the surgery and increased by 26.38 mm on average after the surgery (351 ±73.03 mm). In the 2-year follow-up, it increased by further 33.19 mm to 384.66 ±42.03 mm. The differences were statistically significant ($p < 0.0001$) at every time point of measurement. The AVR decreased after the surgery from grade III to II ($p < 0.01$). This value was maintained at the 24-month follow-up.

The dropout rate from the study was also analyzed. The mean age and the mean values for the largest Cobb angle of the study participants and drop-outs were 9.65 and 8.38 years, and 66.37° and 60.43°, respectively. Both the differences were statistically insignificant.

A total of 57 device-related complications occurred (Table 2). The majority of the complications were minor, not requiring unplanned surgery. In 17 cases, unplanned surgeries were required, and in 8 cases, the growth-friendly technique had to be abandoned. Thus, the rate of serious complications was 43.86%. The most prevalent device-related complication was associated with the length of the rod, which was too short, leading to the dislodgement of top screws (14 cases), followed by implant failure in 11 cases and loss of correction in 9 cases. All the complications are summarized in Table 3.

Table 3. Details of complications

Description	Number of cases
Rod too short	14
Implant failure/fracture	11
Loss of correction	10
Implant migration	9
Infection	3
Other	10
Total	57

Discussion

Early-onset scoliosis is one of the most challenging problems in the field of spine surgery as the reasons are multi-faceted. The curves are often big and stiff; the patients frequently suffer from significant comorbidities, are underweight with poorly developed subcutaneous tissue, and are often osteopenic.[14] Early trials with definite, single-stage fusion techniques failed, and the only reliable measure was repeated surgery.[14] An obvious solution, considering the pathomechanism of EOS, would be to create a growth-friendly non-fusion method.[5,15]

Over the years, several different approaches have been attempted. Skaggs et al.[16] divided the non-fusion surgical

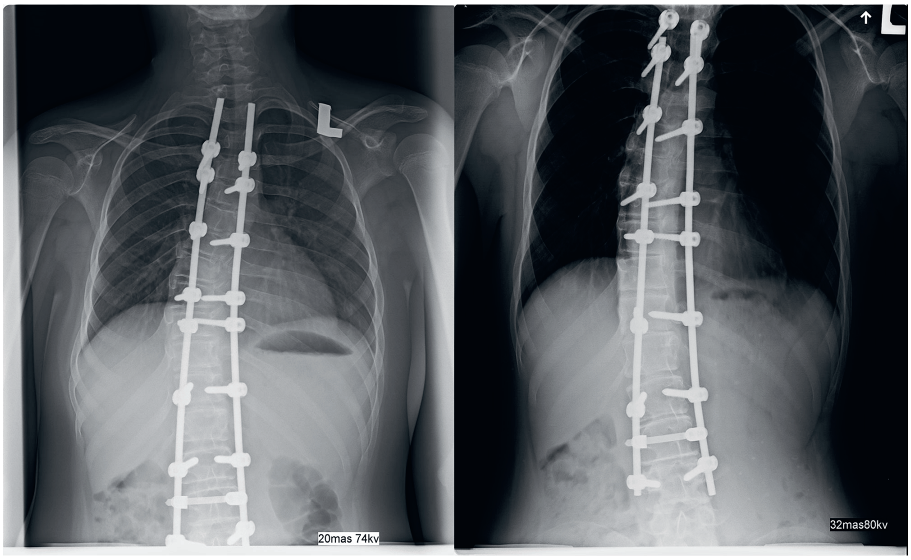

Fig. 3. The rod was too short for growth which occurred in 2 years after the index surgery (left to right)

techniques used in EOS into 3 groups: distraction-based systems, compression-based systems and GGSs. The latter is built around the idea of directing the growth of spine along rigid rods. The first GGS was the Luque trolley, introduced in 1977.[17] The trolley comprised multiple sublaminar wires placed along rigid rods. The driving force was the spine itself, as it maintained its growth potential, despite the deformity. The results were generally unfavorable,[15,18] and the main problem was premature fusion secondary to heterotopic ossification caused by periosteal stripping.[11] As a result, the technique fell into disuse.

The Shilla system was introduced by McCarthy et al.[19] It represents a major improvement over the trolley principle. The biggest advantage was the use of pedicle screws, instead of laminar wires, which allowed 3D manipulation of the curve. Furthermore, in theory, the lack of subperiosteal dissection for the placement of guide screws should limit the risk of premature fusion. Initial results were promising, and the authors were able to demonstrate the satisfactory growth of the trunk as well as good deformity correction, which was maintained after 2 years.[11]

The system described in the present study operates on the same principle as Shilla, the main difference being that titanium was used instead of stainless steel. This is particularly important in the case of sliding constructs as one of the major reported problems is metallosis,[20] a deposition of metallic debris in the vicinity of the sliding rod. Although the significance of this phenomenon is yet to be studied, it has been associated with several side effects, such as implant failure, loosening and local tissue necrosis.[21] Titanium metallosis is less studied, yet its toxicity requires extremely high circulating concentrations of the elements which are unlikely to occur from the degradation of an implant.[22] In the present study, the deposition of metal debris was apparent in each and every re-operation (including final fusion) case. The significance of this phenomenon in the setting of GGS is yet to be evaluated.[11]

The first publication on the use of Socore GGS used in present study was published by Latalski et al. in 2013.[23] In the present study, we were able to demonstrate good correction in the coronal plane, with only modest loss, over the period studied. In the present study, the loss of correction was near 7°, similar to the study using the Shilla system.[11] Ample derotation has been observed after initial surgery as AVR decreased from III to II, which was maintained over the 24-month period. To our knowledge, this is the first time this value has been reported for the guided growth technique.

The overall growth of T1–T12 + T12–S1 was 33.19 mm. This value is within the same ballpark as the data from studies on the growth of a normal spine, where the annual increase is roughly 1 cm and 1.8 cm/year between age of 5 and 10, and age of 10 and skeletal maturity, respectively.[24] As the majority of children in this study were around 10 years of age, the growth of the vertebral column seems almost unrestricted. Similar results were reported for magnetic MAGEC rods, with a comparable increase in the spinal growth; T1–S1 6 mm/year in primary, and 12 mm/year in revision cases.[25] In a similar article to this on Shilla system by McCarthy et al.,[11] instead of changes in absolute length, the relative growth of 13% was reported. It must be noted that in our case, instead of direct T1–S1 length, we used a combined length of T1–T12 and T12–S1; however, with the mean Cobb angle of 30.7°, this difference becomes irrelevant.

Our complication rate of 43.86% seems high for general standards of spinal surgery, but the EOS surgery is inevitably associated with high complication rates, even as high as 84%, particularly in syndromic children.[26] In a study comparing growth using magnetic rods and conventional rods, the overall complication rate was 76%.[27] On the other hand, 17 unplanned surgeries are far more acceptable than repeated lengthening surgeries required every 6 months. The most prevalent complication, i.e., the dislodgement of screws of rods that are too short, is a serious drawback

(Fig. 3). The length of the rod is decided by the surgeon during surgery; too long rods may cause extensive skin and subcutaneous tissue irritation on the top of the construct, and damage to facet joins at the bottom.

This study has certain limitations. Long-term follow-ups until skeletal maturity is required. Although we assumed that all patients require a definite fusion by means of replacing the locking caps and spondylodesis, it is yet to be determined if this step is required in each case. Our study lacks data on the sagittal profile, in particular, on the upper T-spine kyphosis and proximal junctional kyphosis. Last but not the least, the presence of metallosis is yet to be studied.

Conclusions

To our knowledge, this is the largest study with a titanium-based GGS, and the interim results are encouraging. We were able to demonstrate good growth while maintaining the proper level of correction. Despite the limitations, we hope this study would contribute to the management of EOS, as not much work has been done using the modern GGSs.

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