

MAGNETICALLY CONTROLLED GROWING RODS FOR THE TREATMENT OF EOS: EXPERIENCE FROM A SINGLE CENTER AND XPS SURFACE ANALYSIS OF THE RODS

MAGNETNO VODENE RASTOČE PALICE ZA ZDRAVLJENJE ZGODNJIH SKOLIOZ: IZKUŠNJE ENEGA CENTRA IN XPS ANALIZE POVRŠINE PALIC

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The treatment of early-onset scoliosis (EOS) remains one of the biggest challenges in paediatric orthopaedics. Magnetically controlled growing rods (MCGRs) have increased in popularity compared to traditional growing rods (TGRs), providing curve correction, spinal growth and a reduction of the associated surgical trauma. Between May 2015 and July 2022, 24 patients with EOS were treated with an MCGR system using a standardized implantation procedure. An ultrasonography- or radiography-controlled distraction of 3 mm every 3 months was performed. Whole spine radiographs were taken pre-operatively, post-operatively, and in six month interval. The Cobb angle, T1-S1 height, and growth were measured. All the patients had a dual-rod construct implantation. The mean age of the surgical patients was 8 years (6–11), and the mean follow up was 39 months (2–84). The etiology of the EOS was syndromic in six patients, congenital in two, idiopathic in three and neuromuscular in 12. One patient had a conversion from TGR, and one patient had a concomitant resection of hemivertebra. The mean preoperative Cobb angle was 69° (30–108°), postoperative was 38° (16–66°), and 38° (9–69°) at final follow-up. The mean pre-operative T1–S1 length was 289 mm, increasing to 326 mm post-operatively, and 353 mm at the final follow-up. The mean spinal growth was 64 mm (26–110 mm). Two retrieved rods were examined using X-ray photoelectron spectroscopy (XPS). A surface analytical technique to determine the surface chemistry after exposure of the rods in the body. The MCGR system represents a safe and less invasive option for the treatment of EOS.

Keywords: magnetically controlled growing rods (MCGRs), early-onset scoliosis (EOS), growth guidance, spine deformity, XPS

Zdravljenje zgodnjih skolioz ostaja med najzhtevnejšimi izzivi otroške ortopedije. Magnetno vodene rastoče palice (MVRP) v zadnjem času vse bolj zamenjujejo tradicionalne rastoče palice (TRP), saj omogočajo rast hrbtenice ob ustrezni korekciji krivine in zmanjšanju števila kirurških posegov. Med majem 2015 in julijem 2022 je bilo z MVRP zdravljenih 24 pacientov z zgodnjo skoliozo. Vzpostavljen je bil standardiziran protokol za implantacijo ter distrakcijo pod ultrazvočno ali rentgensko kontrolo za 3 mm vsake 3 mesece. Rentgenski posnetki celotne hrbtenice so bili narejeni predoperativno, pooperativno in nato vsakih 6 mesecev. Merjene vrednosti so bile Cobbov kot, razdalja T1-S1 in rast hrbtenice. Vsi pacienti v seriji so imeli vstavljene MVRP obojestransko. Povprečna starost pacientov je bila 8 let (6-11 let), s povprečnim sledenjem 39 mesecev (2-84 mesecev). Etiologija skolioze je bila pri 6 pacientih sindromska, pri 2 pacientih kongenitalna, idiopatska pri 3 pacientih in pri 12 pacientih nevromišična. Pri enem pacientu je bila napravljena menjava iz TGR, en pacient je imel napravljeno dodatno resekcijo hemivertebre. Povprečni predoperativni Cobbov kot je bil 69° (30-108°), pooperativni 38° (16-66°) ter 38° (9-69°) pri zadnjem merjenju. Povprečna predoperativna razdalja med T1 in S1 je bila 289 mm, 326 mm neposredno po operaciji ter 353 mm pri zadnjem merjenju. Povprečna rast je bila 64 mm (26 mm-110 mm). Dve palici po revizijskih operacijah sta bili raziskani s površinsko analitsko tehniko rentgenske fotoelektronske spektroskopije (XPS) z namenom ugotoviti kemično sestavo površine po izpostavi v telesu. Sistem MVRP predstavlja varno in manj invazivno možnost zdravljenja zgodnjih skolioz.

Gljučne besede: magnetno vodene rastoče palice, zgodnja skolioza, vodenje rasti, deformacija hrbtenice, XPS

1 INTRODUCTION

Magnetically controlled growing rods (MCGRs) were developed to reduce the number of surgeries, the concomitant morbidity and complications related to conventional growing-rod treatment. While treatment with traditional growing rods (TGRs) consists of an acute scoliosis correction and repetitive re-operations (every

6–12 months) for growth guidance and deformity maintenance, a MCGR treatment can achieve the same goals without repetitive surgeries.¹ Spinal growth enables the development of the thoracic cavity and prevents thoracic insufficiency syndrome (TIS), as well as cardiac, renal, and neural axis anomalies.²⁻⁵

Currently, only one MCGR system is available on the market. The rod is made of a titanium alloy and contains an enlarged part called 'the actuator,' which houses the internal magnet and the distraction portion of the rod

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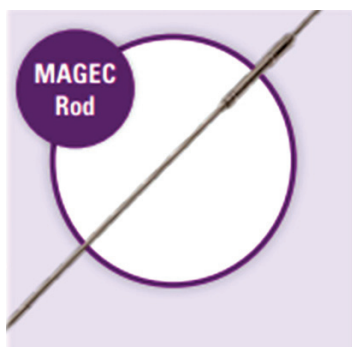


Figure 1: Illustration of MAGEC rod

(Figure 1). There are two types of rods: the standard and the offset rod. They differ in the position of the actuator, so that the standard rod distracts cephalad and the offset rod distracts caudally. As the external magnet affects the internal magnet, the internal magnet rotates and causes the rotation of the lead screw and the inner portion of the rod, causing the distraction. Rods can be lengthened with a manual distractor (used only during surgery to test the functionality of the rod) and with an external remote control (ERC) (Figure 2). Once the rods are implanted, an external magnet is used to locate the inner magnet, hence determining the optimal position for the ERC. The rod has a maximum extension of 48 mm. The number of distractions and the timing of the distractions are decided upon by the treating physician, based on the protocols used, the patients' deformity, and the condition. Distractions are performed in an outpatient setting, without the need for anaesthesia, analgesia, or sedation.⁶⁻⁸

MCGRs can be used on patients from the age of 2; however, the general recommendation is to try other measures first and wait with spinal instrumentation, possibly until the age of 7. At this age, firm fixation to the spine should be achievable. Patients with early-onset scoliosis (EOS) generally progress in their condition, and need treatment to enable good lung and heart function. Most of the patients have secondary scoliosis.^{2,9}

The MCGR was approved for clinical use in 2009, and was improved two times, in 2010 and 2012. The im-



Figure 2: External Remote Controller (ERC)

provements dealt with the stability of the implant to prevent unwanted breaks or shortenings of the rods.¹⁰ Our institution began implanting the MCGR in 2015. We currently have 24 patients under our care. The purpose of this paper is to present our experience with the MCGR, to report our results, and present the results of an XPS chemical analysis of the surface of two rods (Ti6Al4V alloy) after exposure in the body and compare them with literature data. The XPS analytical method providing specific information on surface chemistry was applied since we expected mainly changes in the surface region of the rods and not in the bulk.

2 EXPERIMENTAL PART

2.1 Materials and methods

Twenty-four patients were treated with MCGR (The MAGEC System, NuVasive inc., USA) at a single university hospital paediatrics orthopaedics unit from May 2015 until July 2022. Indications for operative treatment were congenital, syndromic, or neuromuscular progressive EOS. All surgeries were performed by the same team of two attendant surgeons. The analyses consisted of pre-operative, post-operative, and the latest spine radiographs. We determined the size of the deformity (Cobb angle)¹¹ and the length of the spine (T1-S1 length). Magnetically guided spinal growth was averaged for the T1-S1 length difference within the initial post-operative and final follow-up period. Overall, the



Figure 3: Pre-operative AP radiographs of patient with EOS

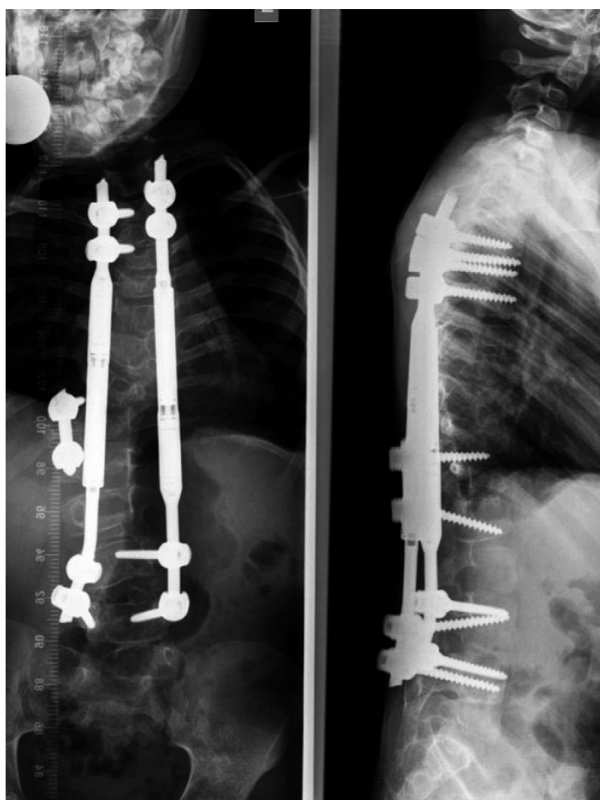


Figure 4: Post-operative AP and lateral radiographs of the same patient with EOS

spinal growth (summary of intraoperative distraction and magnetically guided growth) was averaged for the T1-S1 length difference between the pre-operative and final follow-up period. We regularly monitored and treated adverse events.

All the procedures were performed under total intravenous general anaesthesia (TIVA) in a prone position. The surgery consisted of a double midline approach, at the cranial and caudal portion of the deformity. Muscles were prepared and the spine was exposed. Fixation was primarily established with transpedicular screws. In cases with increased thoracic kyphosis, sublaminar bands were used on the most cranial levels to prevent further kyphosis of the proximal unfixed spine. The levels of fixation were individually determined given the type of deformity. In non-ambulatory patients, fixation to the pelvis was also considered an option. All patients had a dual-rod implantation. We aimed to implant a standard and an offset rod, and where that was anatomically impossible, two rods distracting in the same direction were used. The size and shape of the rods were customized according to the patient's height and spinal deformity. All the rods were tested for function with a manual distractor before the implantation. A subfascial tunnel was made and rods were inserted from the proximal to the distal end of the fixation. Deformity correction to a possible degree was performed using standard techniques (de-rotation, translation, distraction/compression) and the rods were firmly fixed to the anchors. Patients were hospital-

ized until in-patient lung function, wound closure, and analgesia management were needed.

According to the surgeons' protocol, the rods were evaluated and distracted every three months by 3 mm. For the distraction, patients were positioned prone, with their chest and abdomen supported by a pillow. Patients that cannot lie prone were distracted in lateral decubitus, one side at a time. The internal rod magnets were identified using a hand-held magnet. A hand-held magnetic ERC was placed over the internal magnet and 3 mm of distraction was performed. We always distracted the rod on the concave side of the deformity first. The distraction was primarily controlled by ultrasonography, and a follow up X-ray at every 6 months. After the recommendation of a follow-up X-ray at every 6 months, ultrasonography was abandoned, and in case of doubt, X-ray was performed sooner.

The X-ray photoelectron spectroscopy (XPS) analysis of the chemical composition of the surface was carried out on a PHI-TFA XPS spectrometer from Physical Electronics Inc equipped with Al-monochromatic source emitting photons with an energy of 1486.6 eV. The analyzed area was 0.4 mm in diameter. The surface composition was quantified from the XPS peak intensities by considering the relative sensitivity factors provided by the instrument manufacturer.¹⁹ To analyze distribution of elements in the sub-surface region up to 100 nm deep the XPS depth profiling was performed in combination with ion sputtering. The Ar ions with an energy of 3 keV were used. The velocity of the ion sputtering was estimated to be 2 nm/min, calibrated on a Ni/Cr multilayer structure of known thickness. This velocity can be different for other materials like a Ti6Al4V alloy by $\pm 30\%$. We presented the XPS elemental depth profiles as a function of depth to give a rough estimate of the analysed depth of the surface region. The sensitivity of the XPS method is about 0.2 at.%.

Two MAGEC rod samples were analysed in detail by XPS: Ti6Al4V-1 sample and Ti6Al4V-2 sample. The samples were produced in different series and extracted from patients after applications. Every sample was analysed on the surface and at a depth of about 100 nm. XPS depth profiles of the elements Ti, Al, V, O and C were recorded in the surface region from the surface to a depth of 100 nm to follow depth distribution of the elements.

3 RESULTS

Seven patients were male, and seventeen were female. All the patients had dual-rod construct implantation, and in patient No. 1 a pre-existing TGR was exchanged with a MGCR. The mean age of the patients during surgery was 8 years (5–11 years), and the mean follow up period was 39 months (2–84 months). The aetiology of scoliosis was syndromic in six patients, congenital in two patients, idiopathic in 3, while the remaining 12 patients had neuromuscular aetiology.

Table 1: Patient characteristics

Patient characteristics	Mean (range)
Age (years)	8 (5–11)
Gender	7 males 17 females
Aetiology	13 neuromuscular 6 syndromic 2 congenital 3 idiopathic
Primary surgery	23
Exchange surgery	1
Follow-up (months)	39 (2–84)
Number of levels	14 (10–17)

Patient No. 1 had a broken actuator 4 years after surgery, and had a rod exchange 55 months after the initial implantation. Patient No. 5 had growing rods exchanged because of an inability to distract. The underlying reason was not found, even after further analysis. Patient No. 10 had a congenital kyphoscoliosis and additional resection of hemivertebra L1 performed during the same procedure. Patient No. 11 had a revision surgery 2 months after the initial procedure due to proximal junctional

kyphosis (PJK) with three levels extension of fixation and kyphosis correction. Patient No. 12 had rods implanted upside down, due to anatomical conditions. Lengthening of this patient was uneventful. Patient No. 14 had a subcutaneously contained cerebrospinal fluid leak after the initial surgery, later a revision procedure to shorten the rods cranially due to pain and cutaneous fistula formation, and then another revision procedure with sublaminar bands placement cranially due to PJK. Patient No. 16 had a revision procedure to remove the screw that was causing local inflammation and wound dehiscence. This patient also had implantation of sublaminar bands at the two most cranial levels due to increased kyphosis during initial surgery. Due to repetitive wound dehiscence and sinus tract formation one growing rod was explanted. Half of the patients had screw placement in two cranial and two caudal vertebra, and two patients had additional screw placement on one side (cranial and caudal respectively) for construct strengthening. Nine patients had fixation extended to the ileum. The mean number of levels included in the construct is 14 (10–17).

Table 2: Results of 24 patients treated for early-onset scoliosis by magnetically controlled growing rods

Patient No.	Curve convexity (*C-shaped extending to pelvis)	Follow up (month)	Preop. Cobb angle	Postop. Cobb angle	Last Cobb angle	Preop T1-S1 distance (mm)	Postop T1-S1 distance (mm)	Last T1-S1 distance (mm)	Magnetic distraction (mm)	Spinal growth (mm)
1	left*	84	53	51	51	337	350	352	30	43
2	right*	77	81	48	56	294	345	370	49	100
3	left*	83	72	NA	44	296	303	339	45	52
4	right*	66	88	48	43	NA	437	471	34	NA
5	left*	73	48	21	29	306	320	343	42	56
6	left*	63	86	55	65	242	286	322	46	90
7	left*	55	48	29	33	325	355	378	47	77
8	left*	54	96	60	54	257	298	336	57	98
9	left (s-shaped)	51	76	33	38	313	340	342	12	39
10	right* (hemivertebra L1)	41	74	39	35	230	245	242	59	74
11	right*	39	63	42	37	298	302	328	26	30
12	left*	39	70	54	52	306	328	330	17	39
13	right*	38	100	66	67	NA	354	354	10	NA
14	left*	38	103	41	40	221	312	312	42	110
15	left*	37	54	30	32	290	303	310	40	53
16	left*	33	73	40	40	292	331	331	20	59
17	left*	22	79	30	24	235	329	343	14	108
18	right*	14	30	31	9	288	319	330	11	42
19	left*	11	54	27	16	293	311	NA	0	NA
20	left*	6	41	20	16	338	364	364	0	26
21	lumbar right, thoracic left*	5	108	41	40	341	338	339	1	-2
22	left*	4	58	31	31	272	301	303	2	31
23	left*	4	45	30	30	303	323	323	0	20
24	lumbar left, thoracic right*	2	na	16	17	NA	370	371	1	NA

NA – no measurement available

3.1 XPS surface analysis of two MAGEC rod's

3.1.1 Sample Ti6Al4V-1

Table 3 and **Figure 5** show the chemical composition of the sample Ti6Al4V-1 on surface and at depth of 100 nm. Figure 6a shows an XPS spectrum from the surface of this sample. The sample Ti6Al4V-1 contains on the surface mainly O and C, which are related to a presence of Al/Ti-oxide and/or surface contamination. Other elements present on the surface of the Ti6Al4V-1 sample were Ti, Al, N, Si, Ca, Fe and Zr. Elements S and Zn were detected in trace amounts. V was not detected on the surface at a concentration larger than 0.2 at.%, which is the sensitivity of the XPS method.

After removing a 100-nm-thick layer, an accurate analyses of the chemical composition was performed again. **Figure 6b** shows an XPS spectrum from a depth of 100 nm into this sample. At a depth of 100 nm the elements O, Ti, Al, and C were detected. In addition, N, V, Zr and Fe were also detected at a depth of 100 nm to a smaller extent (1–2 at.%).

An XPS depth profile of the sub-surface region of the Ti6Al4V-1 sample is shown in **Figure 7**. It can be seen that at depth of 100 nm a high concentration of O is still present. This is probably related to the Al oxide, since the Al 2p spectrum is mainly at 74 eV related to the Al³⁺ oxidation state.¹⁹ The Ti 2p spectrum at a depth of 100 nm is centered at 454 eV, which suggests the Ti-metallic state.¹⁹ Also, the ratio between Ti and Al seen in **Figure 7**

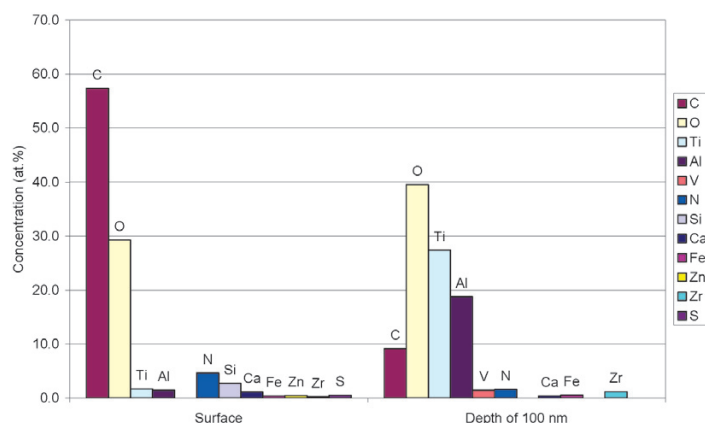


Figure 5: Chemical composition of sample Ti6Al4V-1 in at.%, on surface and at depth of 100 nm

Table 3: Chemical composition of sample Ti6Al4V-1 in at.% on surface and at a depth of 100 nm

Depth (nm)	C	O	Ti	Al	V	N	Si	Ca	Fe	Zn	Zr	S
Surface	57.4	29.3	1.7	1.5		4.7	2.7	1.2	0.4	0.5	0.2	0.5
Depth of 100 nm	9.1	39.5	27.4	18.7	1.5	1.6		0.4	0.6		1.2	

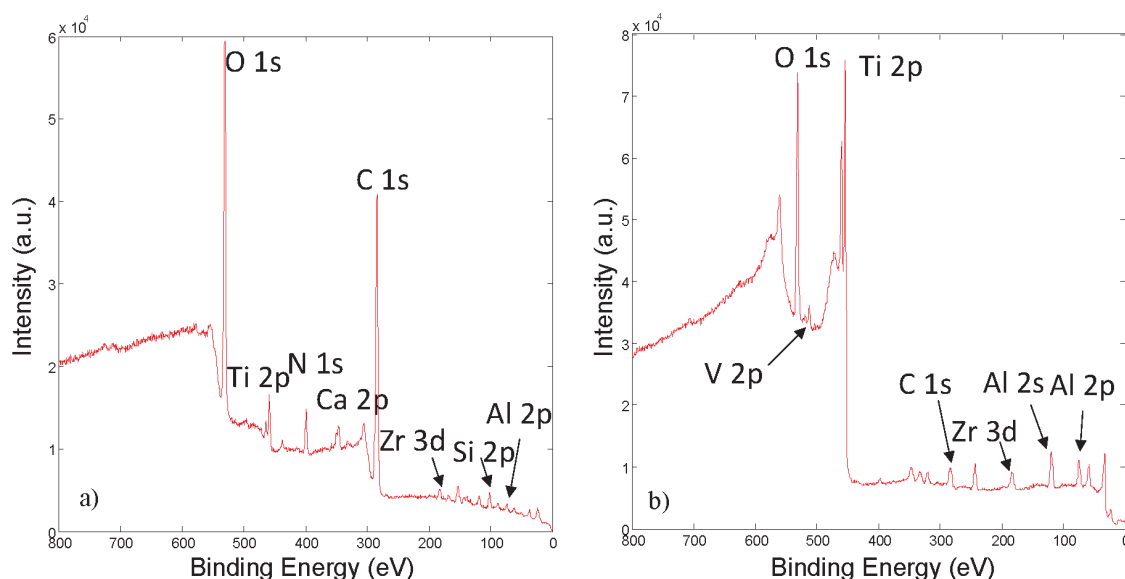


Figure 6: a) XPS spectrum obtained on the surface of the sample Ti6Al4V-1, b) XPS spectrum obtained at depth of 100 nm of the sample Ti6Al4V-1

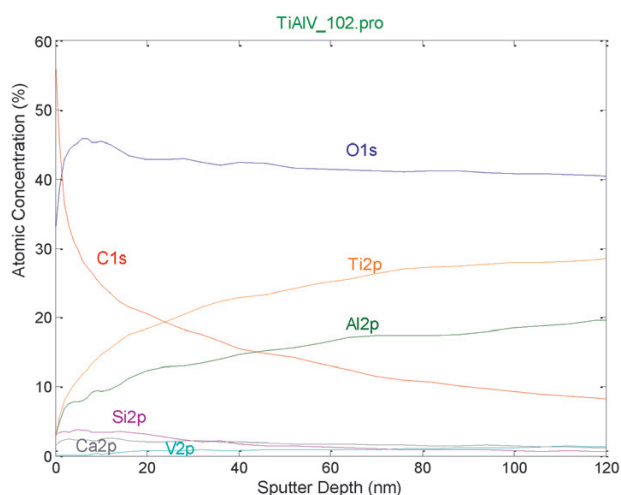


Figure 7: XPS depth profile of sample Ti6Al4V-1

indicates an enrichment of Al oxide in the 100-nm-thick layer with respect to Ti, as one would expect for the Ti6Al4V alloy, and should be much higher.

3.1.2 Sample Ti6Al4V-2

Table 4 and Figure 8 show the chemical composition of the sample Ti6Al4V-2 on the surface and at a depth of 100 nm. Figure 9a shows an XPS spectrum from the surface of this sample. XPS analyses on sample Ti6Al4V-2 were performed in a similar manner as an-

other sample. On the surface, mainly O and C are present, which are related to the Ti oxide and/or surface contamination. Other elements present on the surface of the TiAl sample were Ti, Al, N, Si, Ca, and Fe. Elements Zr, S, Zn were not detected as was the case for sample TiAlV. V was not detected on the surface at a concentration larger than 0.2 at.%, which is the sensitivity of the XPS method.

After removing a 100-nm-thick layer, an accurate analyses of the chemical composition was performed again. Figure 9b shows an XPS spectrum from a depth of 100 nm in this sample. At a depth of 100 nm the elements O, Ti, Al, and C were detected. In addition, also elements of V, N, Si, Ca and Fe were detected at a depth of 100 nm.

An XPS depth profile of sample Ti6Al4V-2 is shown in Figure 10. It can be seen that at a depth of 100 nm a high concentration of O is still present. This is probably related to the Ti/Al oxide, since the Ti 2p spectrum is at depth of 100 nm mainly at 458.6 eV, which suggests the Ti⁴⁺ oxidation state in a TiO₂-like compound.¹⁹ The Al 2p spectrum is mainly at 74 eV related with the Al³⁺ oxidation state.¹⁹ This means that both metallic elements, Ti and Al, are involved in the oxide layer, which is the dominant phase at a depth of 100 nm. The ratio between Ti and Al seen in Figure 10 is high (about 9) indicating a Ti-rich compound like Ti6Al4V.

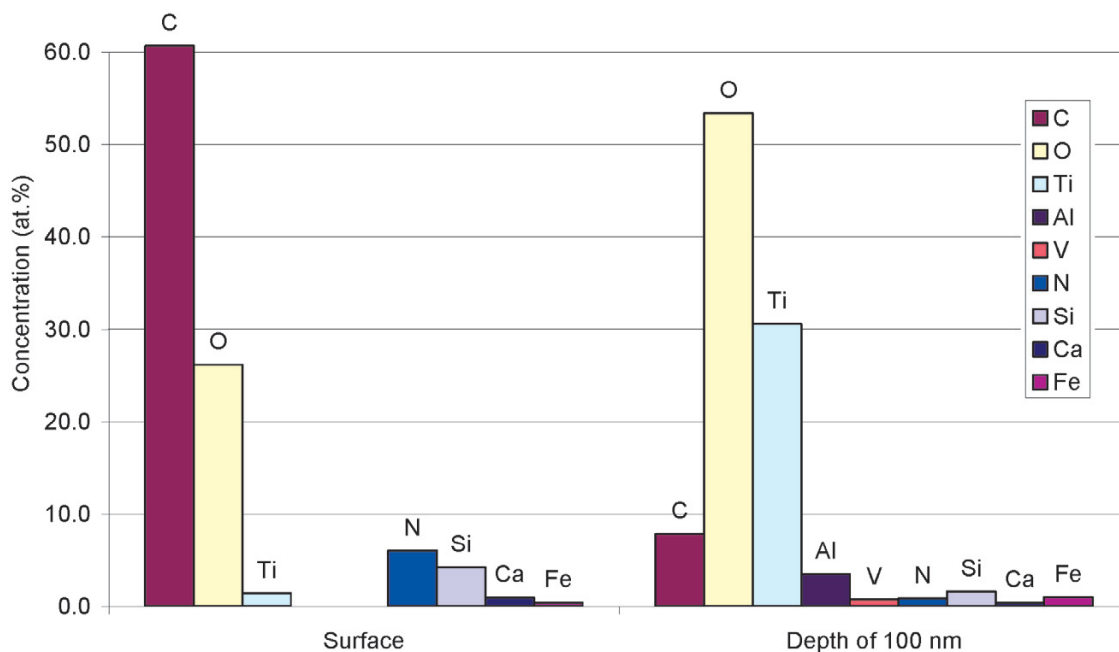


Figure 8: Chemical composition of sample Ti6Al4V-2 in at.% on the surface and at a depth of 100 nm

Table 4: Chemical composition of sample Ti6Al4V-2 in at.% on the surface and at a depth of 100 nm

Depth	C	O	Ti	Al	V	N	Si	Ca	Fe
Surface	60.7	26.2	1.5			6.0	4.3	1.0	0.4
Depth of 100 nm	7.8	53.4	30.6	3.5	0.8	0.9	1.6	0.4	1.0

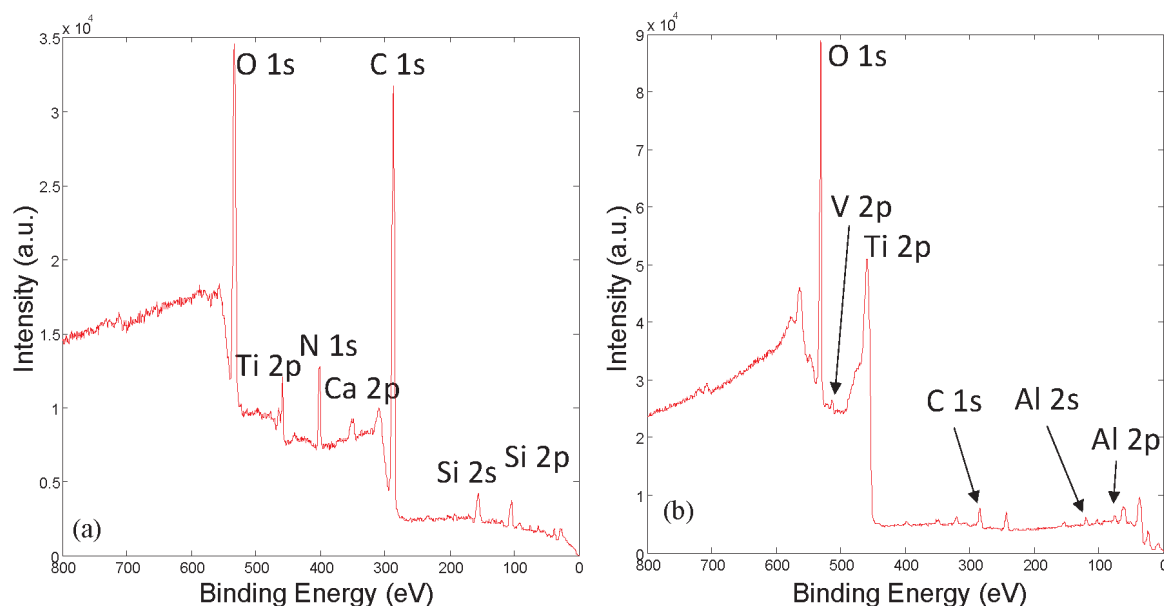


Figure 9: a) XPS spectrum obtained on the surface of the sample Ti6Al4V-2, b) XPS spectrum obtained at depth of 100 nm of the sample Ti6Al4V-2

4 DISCUSSION

The aim of the MCGR treatment is to partially correct the spinal deformity, and maintain the correction while allowing the spine to grow and hence, allowing the chest to grow and develop.¹² In our case series, the average correction of deformity achieved during surgery was 31 degrees of Cobb angle, resulting in average residual curves of fewer than 50 degrees. The curves did not deteriorate during follow-up, nor were improved. While the initial distraction during surgery was large (37 mm), gradual spinal growth was maintained during outpatient MCGR distractions (45 mm in 24 months, on average). This average, however, does not reflect reality because a larger number of patients have a shorter follow-up time. Strict adherence to the protocol should yield 12-mm of

spinal growth per patient per year. These results are in accordance with the existing literature.^{4,13}

Distraction strategies vary among surgeons and institutions. Current decision making is left to the surgeon's choice and the patient's needs. Protocols differ from monthly lesser distractions to three-monthly "as much as possible" distractions.¹⁴ Our protocol is based on the knowledge that maturing spines grow approximately 10 mm per year; therefore, distractions of 3 mm every three months are performed in all our patients. Further research is needed to standardize distraction strategies.¹⁴

Good fixation is crucial for a beneficial outcome. In this aspect, we added additional fixation (screws at more than two levels, iliac screws, or sub-laminar bands) for patients with inactivity osteoporosis or poor primary-screw purchase during surgery. We performed fusion of the fixed levels and have not had a screw construct stability related complication. Pull out, however, was described in 11.8 % in the literature.¹⁵

Adverse events included a cerebrospinal fluid (CSF) leak in one patient, a wound-closure problem due to screw-head pressure in one patient, requiring the removal of one rod, PJK in two patients, failure of the magnet mechanism in one patient and a rod mechanism break in one patient. The CSF leak was conservatively treated, while other adverse events required revision surgery. Previous literature reports a 44 % complication rate and a 33 % unplanned revision rate. Our current series needed fewer revisions, although the reported series had a larger number of patients with single-rod implantation, but with a higher failure rate. Based on this data, avoidance of single-rod implantation is recommended.¹⁵ Another study also found better coronal deformity correction and

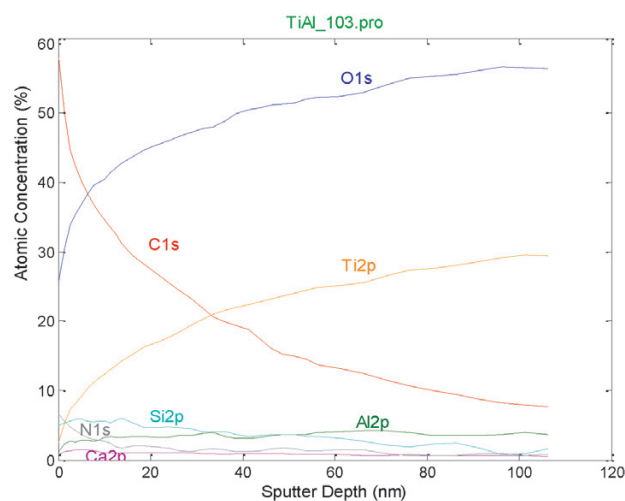


Figure 12: XPS depth profile of the sample Ti6Al4V-2

greater spinal growth with the dual-rod compared to the single-rod surgery.¹⁶

Planned or unplanned rod exchanges presented metal debris on the tissues surrounding the rod. Care was taken and serum metal-ion concentrations were measured with a significant increase in titanium and vanadium levels. Currently, it is believed that metallosis comes from the actuator, releasing the ion debris during the distraction process. So far, no clinical adverse correlation has been published; however, careful follow-up is needed and independent analyses of explanted rods are suggested.¹⁷

The spine length increases less with every subsequent distraction. This is a phenomenon called 'the law of diminishing returns,' and has not been explained in full. It is probably multifactorial, but for now it is believed that it is probably connected to the strength of the lengthening mechanism.¹⁸

The completion of growth is a sign of lengthening cessation. These patients are referred to as MCGR graduates. The manufacturer released a new recommendation to explant all the implanted devices after the completion of treatment; however, it is still unknown whether definitive fusion is needed for patients with idiopathic EOS for curves under 50 degrees.¹ In our case series, four patients had achieved full skeletal maturity. Some patients are scheduled for definitive fusion, while others (parents) do not consent to another surgical procedure, mostly due to the risk of medical complications.

4.1 XPS analysis of MAGEC rods Ti6Al4V-1 and Ti6Al4V-2

XPS analyses on the surface and at a depth of 100 nm show that the oxide is the main phase in this sub-surface region. On the sample Ti6Al4V-1 the oxide consists of mainly Al oxide, which is present in the metallic Ti matrix. A smaller number of Al atoms are also detected in the metallic state.

On the Ti6Al4V-2 sample the oxide is mainly from the Ti-rich phase with smaller amount of Al oxide resembling the Ti6Al4V alloy composition. On the surface and in the sub-surface region of the Ti6Al4V-1 sample, elements N, Si, Ca, S, Zn, Fe and Zr were also detected in smaller concentrations. On the surface and in the sub-surface region of the Ti6Al4V-2 sample the elements N, Si, Ca, and Fe were detected. We should note that no V was detected on the surface of the rods, but it appears in the subsurface region at depth larger than 10 nm.

The differences between the samples Ti6Al4V-1 and Ti6Al4V-2 are the following:

- On the Ti6Al4V-1 the main oxide phase is Al oxide (Al₂O₃-like) embedded in the Ti-Al metallic matrix. Also, the elements Zr, S, Zn were present.
- On the Ti6Al4V-2 the main phase is Ti oxide (TiO₂-like) with a small portion of Al oxide.

On both samples, the elements N, Ca, Si and Fe were detected in addition to expected elements like Ti, Al, V,

O and C. Differences in the chemical composition and the presence of Ti oxide and Al oxide show that the surfaces of the Ti6Al4V rods during exposure in the body might be due to different reactions of the individual patients to implanted rods. Another possibility for the different chemical composition of the surface of the rods may be the different positions of the XPS analyses with respect to a specific placement of the rod with respect to the magnetic element. Unfortunately, from the XPS surface analyses of the exposed rods extracted from the two patients we cannot conclude in a statistically significant way on the detailed surface modifications in the body.

With the XPS method it was not possible to estimate the total thickness of the oxide layer, since only the subsurface layer of thickness 100 nm was analyzed. It is evident that a complete oxide layer is thicker than 100 nm on both samples. It can be speculated that during manufacturing some surface modifications of the Ti6Al4V alloys were performed including the Zr-O, Zn-O, Al-O, Fe-O or Si-O materials.

5 CONCLUSIONS

The MCGR system presents a relatively safe alternative for EOS treatment. It enables partial deformity correction, allows for spinal growth, and prevents deformity deterioration and TIS. Further research is needed to determine and unify distraction strategies and final treatment. Chemical analyses of surface composition of rods exposed in the body for two patients show the formation of the TiO₂/Al₂O₃ oxide phases in the surface region.

6 REFERENCES

- ¹ J. P. Y. Cheung, K. Yiu, K. Kwan, K. M. C. Cheung, Mean 6-Year Follow-up of Magnetically Controlled Growing Rod Patients with Early Onset Scoliosis: A Glimpse of What Happens to Graduates, *Neurosurgery*, 84 (2019) 5, 1112–1123, doi:10.1093/neuros/nyy270
- ² S. Yang, L. M. Andras, G. J. Redding, D. L. Skags, Early-Onset Scoliosis: A Review of History, Current Treatment, and Future Directions, *Pediatrics*, 137 (2016), doi:10.1542/peds.2015-0709
- ³ B. A. Hickey, C. Towriss, G. Baxter, S. Yasso, S. James, A. Jones, J. Howes, P. Davies, S. Ahuja, Early Experience of MAGEC Magnetic Growing Rods in the Treatment of Early Onset Scoliosis, *Eur. Spine J.*, 23 (2014) S1, 61–65, doi:10.1007/s00586-013-3163-0
- ⁴ Dimeglio, F. Canavese, The Growing Spine: How Spinal Deformities Influence Normal Spine and Thoracic Cage Growth, *Eur. Spine J.*, 21 (2012) 1, 64–70, doi:10.1007/s00586-011-1983-3
- ⁵ C. C. Hasler, Early-onset Scoliosis: Contemporary Decision-Making and Treatment Options, *J. of Pediatr. Orthop.*, 38 (2018), S13–S20, doi:10.1097/bpo.0000000000001184
- ⁶ M. Jenks, J. Craig, J. Higgins, I. Willits, T. Barata, H. Wood, C. Kimpton, A. Sims, The MAGEC System for Spinal Lengthening in Children with Scoliosis: A NICE Medical Technology Guidance. *Appl. Health Econ. Health Policy*, 12 (2014) 6, 587–599, doi:10.1007/s40258-014-0127-4
- ⁷ U. Metkar, S. Kurra, D. Quinzi, S. Albanese, W. F. Lavelle, Magnetically Controlled Growing Rods for Scoliosis Surgery, *Expert Rev. Med. Devices*, 14 (2017) 2, 117–126, doi:10.1080/17434440.2016.1274230

- ⁸ W. Thompson, C. Thakar, D. J. Rolton, J. Wilson MacDonald, C. Nnadi, The Use of Magnetically-Controlled Growing Rods to Treat Children with Early-Onset Scoliosis, *Bone Joint J.*, 98-B (2016), 1240–1247, doi:10.1302/0301-620X.98B9.37545
- ⁹ P. R. P. Rushton, I. Siddique, R. Crawford, N. Birch, M. J. Gibson, M. J. Hutton, Magnetically Controlled Growing Rods in the Treatment of Early-Onset Scoliosis: A Note of Caution, *Bone Joint J.*, 99-B (2017), 708–713, doi:10.1302/0301-620X.99B6.BJJ-2016-1102.R2
- ¹⁰ The MAGEC System for Spinal Lengthening in Children with Scoliosis, Medical Technologies Guidance, <https://www.nice.org.uk/guidance/mtg18/chapter/2-The-technology>, 15.2.2020
- ¹¹ J. R. Cobb, The Problem of the Primary Curve, *J. Bone Joint Surg. Am.*, 42-A (1960), 1413–1425
- ¹² N. Figueiredo, S. F. Kananah, H. H. Siqueira, R. C. Figueiredo, M. W. Al Sebai, The Use of Magnetically Controlled Growing Rod Device for Pediatric Scoliosis, *Neurosciences (Riyadh)*, 21 (2016) 1, 17–25, doi:10.17712/nsj.2016.1.20150266
- ¹³ P. Hosseini, J. Pawelek, G. M. Mundis, B. Yaszay, J. Ferguson, I. Helenius, K. Cheung, G. Demirkiran, A. Alanay, A. Senkoylu, H. Elsebaie, B. A. Akbarnia, Magnetically Controlled Growing Rods for Early-Onset Scoliosis: A Multicenter Study of 23 Cases with Minimum 2 Years Follow-Up. *Spine*, 41 (2016) 18, 1456–1462, doi:10.1097/brs.0000000000001561
- ¹⁴ B. Akbarnia, K. Cheung, K. Kwan, D. Samartzis, A. Alanay, J. Ferguson, C. Thakar, P. Panteliadis, C. Nnadi, I. Helenius, M. Yazici, G. H. Demirkiran, Effects of Frequency of Distraction in Magnetically Controlled Growing Rod (MCGR) Lengthening on Outcomes and Complications, *Spine J.*, 16 (2016) 4, S56, doi.org/10.1016/j.spinee.2016.01.057
- ¹⁵ C. Thakar, D. C. Kieser, M. Mardare, S. Haleem, J. Fairbank, C. Nnadi, Systematic Review of the Complications Associated with Magnetically Controlled Growing Rods for The Treatment of Early Onset Scoliosis. *Eur. Spine J.*, 27 (2018) 9, 2062–2071, doi:10.1007/s00586-018-5590-4
- ¹⁶ B. A. Akbarnia, K. Cheung, H. Noordeen, H. Elsebaie, M. Yazici, Z. Dannawi, N. Kabirian, Next Generation of Growth-Sparing Techniques: Preliminary Clinical Results of a Magnetically Controlled Growing Rod in 14 Patients with Early-Onset Scoliosis, *Spine*, 38 (2013) 8, 665–670, doi:10.1097/brs.0b013e3182773560
- ¹⁷ C. Yilgor, A. Efendiyev, F. Akbiyik, G. Demirkiran, A. Senkoylu, A. Alanay, M. Yazici, Metal Ion Release during Growth-Friendly Instrumentation for Early-Onset Scoliosis: A Preliminary Study, *Spine Deformity*, 6 (2018) 1, 48–53, doi:10.1016/j.jspd.2017.06.005
- ¹⁸ S. Poon, H. T. Spencer, R. S. Fayssoux, R. Sever, R. H. Cho, Maximal Force Generated by Magnetically Controlled Growing Rods Decreases with Rod Lengthening, *Spine Deform.*, 6 (2018) 6, 787–790, doi:10.1016/j.jspd.2018.03.009
- ¹⁹ J. F. Moulder, W. F. Stickle, P. E. Sobol, K. D. Bomben, *Handbook of X-Ray Photoelectron Spectroscopy*, Physical Electronics Inc., Eden Prairie, Minnesota, USA, 1995.