Adolescent idiopathic scoliosis: spinal fusion and beyond

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Chapter 9

Prospective clinical evaluation of a novel spinal implant for fusionless scoliosis correction: a preliminary report

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Abstract

Background: Brace therapy for adolescent idiopathic scoliosis (AIS) is associated with discomfort and cosmetic concerns, resulting in decreased compliance and thus treatment success. Conventional surgical treatment is invasive and based on rigid spinal instrumentation and fusion. Less-invasive and fusionless surgery could improve patient outcome. Here, a novel posterior periapical concave distraction device is investigated. The device is designed to correct the deformity without the need for spinal fusion.

Methods: This is a prospective cohort study. Inclusion criteria: aged 12-17 years, Lenke 1 or 5 curve, major curve Cobb angle 40-55° (reducing to <35° on lateral bending), Risser stage 1-4, and Bunnell Scoliometer rotation <15°. Exclusion criteria: previous spinal surgery, titanium allergy, active systemic disease, or mentally compromised. The preliminary data of this still on-going study are presented.

Results: Twenty patients aged 14.8 ± 1.4 years and with Risser 2.5 ± 1.1 were treated and followed for 1.4 ± 0.6 years. Surgical parameters: levels bridged 5.1 ± 0.9, operative time 1.1 ± 0.2 hours, blood loss 42.5 ± 43.8 ml, incision length 16.1 ± 1.9 cm, and length of stay 2.3 ± 0.7 days. The major curve corrected from 44.3° ± 4.1° to 32.4° ± 6.4° in the Lenke 1 curves (p<0.001) and from 46.8° ± 5.2° to 32.3° ± 7.6° in the Lenke 5 curves (p=0.002). Sagittal alignment remained unaltered. Six patients required revision surgery due to osteolysis (n=4), screw breakage (n=1), and pain without a known cause (n=1). Metallosis was observed in five of these patients and cultures showed infection with *Parvimonas Micra* in three. Pedicle screws were less aligned in the patients whom required revision surgery for osteolysis or breakage.

Conclusions: The use of a novel implant for fusionless scoliosis surgery resulted in promising surgical and early clinical parameters. Though, the high rate of serious adverse events was unacceptable and therefore the inclusion has been halted. Perfect screw alignment seems of paramount importance, but is often impossible. The role of metallosis and/or (low grade) *P. Micra* infection is unclear.

Introduction

Adolescent idiopathic scoliosis (AIS) is characterized by a deformity of the spine and trunk. The treatment depends on the location of the curvature, curve severity, and risk of curve progression. Brace treatment is indicated for curves between 25 and 45 degrees Cobb angle in children with significant remaining growth. The brace (a rigid corset from pelvis to chest) has to be worn every day for several years, depending on the amount of growth remaining, and is accompanied with significant discomfort and cosmetic concerns for this young patient group. This often results in a decreased compliance with brace wear, thereby negatively affecting treatment success [1–3].

Surgical treatment may be considered for patients with curves exceeding 45-50° at skeletal maturity [4,5]. During this surgical procedure, the curve is corrected and the spine is fused using multiple pedicle screws, which are rigidly interconnected with two rods, and bone grafting to achieve fusion. This type of surgery is rigorous and long-term complications such as wound infection and neurological injury are reported to occur in up to 5.1% of the patients [6]. Additionally, the surgery takes several hours, results in substantial blood loss, requires several days of rehabilitation in the hospital, and leaves the adolescent patient with a long scar over the back. In the long-term, sporting activity, physical function and physical activity are negatively affected, which is attributed to the loss of spinal flexibility [6–9]. Additionally, patients have increased risks of adjacent segment disease and proximal junctional kyphosis, potentially leading to back pain [10–13].

Twenty patients aged 14.8 ± 1.4 years and with Risser 2.5 ± 1.1 were treated and followed for 1.4 ± 0.6 years. Surgical parameters: levels bridged 5.1 ± 0.9, operative time 1.1 ± 0.2 hours, blood loss 42.5 ± 43.8 ml, incision length 16.1 ± 1.9 cm, and length of stay 2.3 ± 0.7 days. The major curve corrected from 44.3° ± 4.1° to 32.4° ± 6.4° in the Lenke 1 curves (P < 0.001) and from 46.8° ± 5.2° to 32.3° ± 7.6° in the Lenke 5 curves (P = 0.002). Sagittal alignment remained unaltered. Six patients required revision surgery due to osteolysis (n=4), screw breakage (n=1), and pain without a known cause (n=1). Metallosis was observed in five of these patients and cultures showed infection with Parvimonas Micra in three. Pedicle screws were less aligned in the patients whom required revision surgery for osteolysis or breakage.

Recently, the first results of a novel implant for the fusionless correction of scoliosis correction were presented (the ApiFix system, ApiFix Ltd, Misgav, Israel) [14]. The implant is based on a single expandable rod with an internal ratchet. This is connected to the spine via two pedicle screws with poly-axial joints. Patients perform postoperative physical exercises to induce elongation of the rod and thus gradually correct the scoliosis. The authors reported a correction of the Cobb angle from 45-53° to 22-33° in three AIS patients and it was hypothesized that the new implant is less invasive and preserves spinal motion. Additionally, it is designed to bridge a minimal amount of spinal levels, cause minimal blood loss, require short operative time, and result in a small scar. Due to the potentially motion preserving capacities and the less invasive surgery, the length of stay after surgery could be far less than regular posterior spinal fusion surgery.

The *in vitro* effects of the implant on the biomechanical properties of porcine and human spines have been analysed previously [15]. On average the ROM in flexion-extension decreased by 48% and in lateral bending 18.1%, while axial rotation ROM was unaffected. This was far less detrimental than the nearly completely diminished ROM observed when traditional rigid posterior instrumentation. Additionally, those results are based on an analysis using spinal specimens without the rib cage, which is reported to attribute 40-52% to spinal stability and thus the effect on *in vivo* spinal flexibility could be less detrimental [16,17]. However, the ROM was not left unaltered. This could pose a possible risk of implant failure, as forces are transferred from the spine to the implant. A previous pre-market approval study showed that the implant could withstand higher and more prolonged loads than regular posterior spinal instrumentation (unpublished results), thus reducing this risk. Based on these results a prospective cohort study was initiated with the focus on safety and effectiveness. The preliminary results of 20 patients treated with this novel implant are presented here.

Methods

Study design

This is a prospective, open label, non-randomized cohort study. Approval was obtained from the institutional ethical review board of the VU University Medical Center (IRB00002991). All subjects and their guardians/legal representatives signed written informed consent forms prior to study activities.

Study population

The possibly eligible subjects were screened at the outpatient clinic of a single university hospital. In order to be eligible to participate in this study a subject must meet all of the following criteria:

1. AIS patient 12 years - 17 years old;
2. 40-55° Cobb angle, single curves (Lenke type 1 or 5), Risser stage 1-4;
3. Curve flexibility: primary curve reduces to <35° Cobb angle on lateral bending radiograph, and;
4. Vertebral rotation <15° (based on Bunnell Scoliometer)

Ad 1: It is hypothesized that remaining growth is required for treatment success, due to the remodelling capacity of the tissues.

Ad 2: Patients with Risser stage 0 were excluded as these could potentially outgrow the elongation capacity of the rod.

Ad 3: It is theorized that enough flexibility is required for the curve to correct with the postoperative physical exercises.

Ad 4: The acceptable vertebral rotation was limited to a maximum of 15° as it is unknown how the distraction based implant corrects the rotational deformity.

Potential subjects who met any of the following criteria were excluded from participation:

1. Known allergy to titanium;

2. Active systemic disease, such as AIDS or HIV, or active infection, or;

3. Mentally compromised.

Surgical technique

Patients are positioned prone under general anesthesia. The correct levels are identified using intra-operative radiographic imaging. A standard posterior approach at the apex of the major curve is used to expose only the concave side of the spine with the aid of an electrosurgical knife. Special care is taken to not damage bone and ligaments. At the concave side one pedicle screw is inserted at the proximal end vertebra of the major curve and one pedicle screw is inserted in the distal end vertebra of the major curve (Cobb to Cobb) under intraoperative fluoroscopy. The expandable rod is then connected to the two pedicle screws. Careful intra-operative rod distraction is performed to ensure the rod properly lengthens and allow for initial curve correction, which is also performed under the control of intraoperative fluoroscopy. After initial postoperative compression on the wound during several hours, the patients are mobilized the same day. Patients are dismissed when pain is acceptable, the wound is dry and they are mobilized for activities of daily living.

Postoperative care

Two weeks after surgery patients start with an exercise protocol under guidance of a trained physical therapist. These exercises encompass lateral bending and stretching movements aiming to lengthen the expandable rod. All follow-up visits are scheduled as follows: two weeks, six weeks, three months, six months, one year, and minimally two year post-operatively. If end of growth/skeletal maturity (Risser 5) is not yet reached, the follow-up is increased until skeletal maturity.

Outcome measures

The Cobb angles of the major and minor curve and sagittal alignment were measured on preoperative and postoperative full spine standing radiographic films. Curve flexibility was measured on the preoperative lateral bending films. All radiographic measurements were performed using Surgimap Spine software (Nemaris Inc, New York, USA) [15]. The revised Scoliosis Research Society 22-item patient questionnaire (SRS-22r) was used to measure the outcome domains pain, self-image, function, and satisfaction with management. Patients answered the questionnaire pre-operatively, and 12 and 24 months after surgery. Blood loss during surgery, duration of surgery (skin-to-skin time), duration of hospitalization, and intra- and postoperative complications (e.g. infection, neurological or vascular injury, osteolysis, breakage of rod or screw, revision surgery, or death) were recorded.

Statistical analysis

Results are presented as mean ± standard deviation unless stated otherwise. All outcome measures were analysed using Student two-tailed **t** tests. P values below 0.05 were considered significant. Statistical analyses were performed using SPSS 23 for Mac OS X.

Results

Baseline patient characteristics

20 patients were included (on average 14.8 years old; 19 females and 1 male; 14 Lenke 1 curve types and 6 Lenke 5 curve types, Table 1). The average pre-operative Cobb angle of the major curve was 45.0° ± 4.5° and the minor curve 29.4° ± 7.3°. The two groups did not significantly differ regarding baseline major and minor curve Cobb angle (p=0.330 and p=0.645 respectively) or regarding lumbar lordosis and thoracic kyphosis (p=0.932 and p=0.089 respectively).

Table 1. Baseline patient characteristics

Number of patients	20
Age at surgery (yrs)	14.8 ± 1.4
Gender	
Male	1
Female	19
Risser	2.5 ± 1.1
Lenke	
1	14
5	6
Duration of follow-up (yrs)	1.4 ± 0.6

Surgical parameters

A mean of 5.1 spinal levels were bridged with the expandable rod (Table 2). A significantly (p<0.001) higher number of levels were bridged in the patients with a Lenke 1 curve (5.6 ± 0.51) versus a Lenke 5 curve (4.2 ± 0.41). The skin-to-skin time of the surgical procedure was 1.1 ± 0.2 hours. Blood loss averaged 42.5 ± 43.8 ml. Mean incision length was 16.1 ± 1.9 cm. Patients were discharged from the hospital in 2.3 ± 0.7 days after surgery.

Radiographic and clinical parameters

Results of the radiographic and clinical measures of deformity are presented in Table 3. The four patients in whom the implant was removed or revised to posterior spinal fusion (PSF) were excluded from the results below and in Table 3, and are presented separately in Table 5.

Table 2. Surgical parameters

Levels bridged	5.1 ± 0.9
Operative time (hours)	1.1 ± 0.2
Blood loss (ml)	42.5 ± 43.8
Length of incision (cm)	16.1 ± 1.9
Length of stay (days)	2.3 ± 0.7

Table 3. Deformity measures

	Baseline	Latest follow-up	P
Lenke 1			
Major curve (°)	44.3 ± 4.1	32.4 ± 6.4	<0.001
Minor curve (°)	28.8 ± 6.6	23.5 ± 8.6	<0.001
Lumbar lordosis (°)	58.6 ± 7.7	-54.7 ± 8.6	0.724
Thoracic kyphosis (°)	20.1 ± 8.5	17.3 ± 6.6	0.213
Bunnell Scoliometer rotation (°)	11.6 ± 2.6	10.5 ± 3.9	0.543
Lenke 5			
Major curve (°)	46.8 ± 5.2	32.3 ± 7.6	0.002
Minor curve (°)	30.8 ± 9.1	28.5 ± 10.3	0.328
Lumbar lordosis (°)	43.7 ± 11.0	-51.3 ± 15.2	0.165
Thoracic kyphosis (°)	6.2 ± 15.7	25.0 ± 10.1	0.49
Bunnell Scoliometer rotation (°)	11.6 ± 2.6	7.4 ± 4.6	0.133

Table 4. Patient reported outcome (SRS-22r)

	Baseline	Latest follow-up	P
Function	2.8 ± 2.0	4.5 ± 0.8	<0.001
Pain	1.8 ± 1.7	3.9 ± 1.1	<0.001
Self-image	2.6 ± 1.5	4.2 ± 0.9	<0.001
Mental health	2.7 ± 1.4	4.3 ± 0.8	<0.001
Satisfaction with management	2.0 ± 1.2	4.4 ± 1.0	<0.001
Total	2.5 ± 0.3	4.2 ± 0.6	<0.001

Table 5. Summary of serious adverse events

Case	Time after initial surgery	Relation	Description	Intervention	Follow-up after latest intervention	Outcome at latest follow-up
1	9 months	Implant	Pedicle screw osteolysis	Implant revision	11 months	Initial recovery. Later occurrence of pain with subsequent removal of ApiFix causing an increase in major curve Cobb angle from 34° to 49° with Risser 4.
2	14 months	Implant	Pedicle screw osteolysis	Implant revision	14 months	Recovered. Implant in situ. Deformity remained unchanged with Risser 5.
		Surgery	Wound infection (P. Acnes)	Oral antibiotics		
3	12 months	Surgery	Persisting pain e.c.i.	Removal	1 month	Recovered. Increase in major curve Cobb angle from 22° to 34° with Risser 4.
4	8 months	Implant	Screw breakage	Revision to posterior spinal fusion	5 months	Recovered. Posterior spinal fusion in situ. Decrease in major curve Cobb angle from 36° to 20°.
5	14 months	Implant	Pedicle screw osteolysis	Implant revision	5 months	Recovered. Implant in situ. Decrease in major curve Cobb angle from 49° to 34° with Risser 4.
		Surgery	Wound infection (P. Acnes)	Oral antibiotics		
6	19 months	Implant	Pedicle screw osteolysis	Removal	6 weeks	Recovered. Deformity remained unchanged with Risser 4.
		Surgery	Wound infection (P. Acnes)	Oral antibiotics		

At the latest follow-up the major curve was corrected by 27.3% ± 10.8% in the Lenke 1 curves (p<0.001) and 31.0% ± 13.2% in the Lenke 5 curves (p=0.002). The minor curve was corrected by 22.2% ± 18.0% in the Lenke 1 group (p<0.001), while this remained statistically unchanged in the Lenke 5 group (p=0.328). No adding on (curve progression cranial or caudal to the instrumentation) was observed. Lumbar lordosis and thoracic kyphosis remained unaltered. No changes in the Bunnell Scoliometer rotation measures were observed.

At baseline patients reported low scores on all subdomains of the SRS-22r questionnaire resulting in a total score of 2.5 ± 0.3 (Table 4). At the latest follow-up the scores of all domains were significantly improved with the most prevalent improvements occurring in the pain and satisfaction domains. The total score significantly improved to 4.2 ± 0.6. These results include the scores of the SRS-22r before revision surgery. The post revision surgery results were not available yet at the time of writing.

Complications

An overview of the seven serious adverse events that occurred in six patients (including two events in a single patient) is presented in Table 5. Six out of 20 patients required revision surgery. The events occurred at an average of 12.5 months after surgery (range 8-18 months). Five events were related to the implant, including four cases of osteolysis around a pedicle screw and one pedicle screw breakage. Revision surgery included revision of the implant to a different level, removal of the implant or revision to traditional PSF surgery. Two patients in whom the implant was removed demonstrated a loss of correction. The cultures from the tissue obtained during the first revision surgery of the cases with osteolysis revealed an infection with *Propionibacterium Acnes* in three cases, which were successfully treated with oral Clindamycin with retention of the implant in the two cases were revision was performed. Metal wear and reactive tissue changes were observed in five out of seven revision/ removal surgeries.

One patient experienced a breakage of the distal pedicle screw. In this case, the lumbar pedicle screw had a smaller diameter (5.5 mm) than the thoracic screw (6.5 mm) due to a small size of the lumbar pedicle. In all other patients in this study the distal screw was of a similar or larger diameter. To identify other possible causes of the complications we compared the patients that required revision surgery versus the non-revised group. No significant difference with regards to curve type, curve severity, or pre-operative curve flexibility at baseline was found. The two groups were significantly different regarding the angle between the screw shank of the two pedicle screws in the sagittal plane (with 0 degrees being optimal; i.e. the screws are parallel to each other); the average angle in the patients requiring revision surgery was 22.3° ± 4.4° kyphosis versus 13.9° ± 7.3° kyphosis in the non-revised group (p=0.006).

Discussion

Less-invasive and fusionless surgical treatment options are essential for further improvement of the surgical management of AIS. This paper presents the preliminary results of a prospective cohort study using a novel posterior concave periapical distraction implant. The two main objectives of the present study were to analyse the safety and efficacy of the new implant.

Surgical parameters demonstrated the less-invasive characteristics of the novel surgical technique; 5.6 levels bridged in Lenke 1 curves and 4.2 levels in the Lenke 5 curves, 1.1 hour surgical time, 42.5 ml blood loss, and an incision length of 16.1 cm. A significant correction of the major curve deformity was observed in both the Lenke 1 and Lenke 5 groups. The average postoperative Cobb angle of the major curve was 33.2° in the Lenke 1 curves and 32.2° in the Lenke 5 curves. No change in thoracic kyphosis or lumbar lordosis was observed. The rotational deformity did not correct. This may be because the rib hump and rotation were limited preoperatively by the inclusion criteria (i.e. <15° as measured using the Bunnell Scoliometer), thus leaving little room for improvement. Also, while distraction can induce a coupled rotation, the implant is not designed to actively improve the rotational deformity. The majority of the patients report good health and a significant improvement in SRS-22r function, pain, self-image and mental health domains. They report high satisfaction after treatment with the novel implant. Unfortunately, no post revision surgery SRS-22r scores were available at the moment of writing this report due to the short follow-up after revision surgery. This limits the quantification of their recovery and probably overestimates the patient reported outcome scores.

In comparison to the results presented here, conventional PSF surgery in patients with a similar curve severity as this cohort (Cobb angle 40-55°) results in a more substantial curve correction to a Cobb angle of 15-25° postoperatively [18–20]. The limited correction obtained with the periapical distraction implant could influence treatment outcome as some authors report a correlation between curve correction and patient satisfaction [21], although others contradict this finding [22]. Compared to the periapical distraction implant, traditional PSF results in substantially more fused levels: approximately 10 levels in Lenke 1 curves and 6.1 levels in Lenke 5 curves [23,24]. Also, the average blood loss after PSF ranges from 807 to 985 ml and surgical time is much longer for PSF (4 hours) [23,25,26]. Lastly, the average incision length in the present study (16.1 cm) is considerably smaller compared to the 28.5 cm needed for PSF surgery [23].

Despite the promising peri-operative surgical parameters and early clinical scores, six serious adverse events occurred affecting six out of 20 patients. Complications occurred around 1 year postoperatively and most were related to the implant. Of all implant failures, the occurrence of osteolysis around a pedicle screw was the most frequent problem. A significantly larger angle between the screw shanks of the two pedicle screws in the sagittal plane was observed in the patients that eventually required revision surgery (22.3° ± 4.4° kyphosis versus 13.9° ± 7.3°). This larger angle could limit the residual flexion and extension motion of the screw-rod interface, subsequently causing loads to be transferred to the screw-bone interface and finally resulting in osteolysis and even one case of screw breakage. These results concur with a previous *in vitro* biomechanical analysis of the implant, which reported that the implant roughly halved the spinal range of motion in flexion-extension [15]. Therefore, it is important that the screws are aligned parallel to each other in the sagittal plane to maintain the polyaxial properties of the screw-rod interface. Though, in many cases a perfect parallel alignment of the screws was impossible due to the anatomy of the spine.

Out of the 40 screws placed in the 20 patients included in this study, four screws had signs of osteolysis (10%). The observed complications concur with the relatively high rate (11.7%) of osteolysis seen with the Dynesys fusionless stabilization system used in surgery for degenerative diseases of the lumbar spine [27]. In comparison, only 2.6-2.8% of the screws placed in PSF surgery for AIS show signs of loosening within the first two years of follow-up [28,29]. The one broken screw was relatively small (5.5 mm diameter) and placed in a lower lumbar vertebra of a tall patient. Intra-operatively the pedicle was deemed to small to fit a larger diameter screw and in retrospect the small screw diameter may have played an important part in the failure mechanism.

Three out of the four patients suffering from pedicle screw osteolysis also had a positive culture with *Propionibacterium Acnes*. This pathogen is a known cause of late infections after PSF for AIS, and several authors contribute it to bulky instrumentation that include cross links causing bursa formation [30,31]. This could also be a cause for the infections with the implant studied here, as the screw heads are prominent compared to regular posterior instrumentation systems. Thus, it could have played a causative role in the screw loosening by forming a biofilm and prevent proper implant-bone interface. On the other hand, *P. Acnes* is also frequently found in intervertebral discs of patients

undergoing microdiscectomy without previous surgery [32]. Consequently, instead of *P. Acnes* being the cause of screw loosening, the positive cultures could simply represent these latently present pathogens and thus not play a causative role in osteolysis.

Adding to this, implant wear and metallosis was observed in five patients. The metallic debris was mostly observed near the ratchet of the rod and near the pedicle screws. The clinical relevance of metal debris remains a topic of debate and is mostly researched in hip replacement patients. Some reports on its occurrence in spine surgery hypothesize that the titanium particles could act as a stimulus for late-onset inflammatory or infectious complications or osteolysis [33,34].

Preservation of spinal motion while at the same time correcting the deformity is a major goal in the surgical treatment of AIS. Besides the implant investigated here, anterior spinal tethering has been proposed as a fusionless technique for scoliosis correction. This technique aims to modulate the remaining spinal growth in order to correct the scoliosis. Samdani et al. presented the 1 year postoperative results with the anterior tether in skeletally immature patients with AIS in a prospective cohort study [35]. Patients had a mean Risser stage of 0.42, a mean age at surgery of 12 years and a Cobb angle of 42.8° ± 8.0°. These were patients with a high risk of progression and a substantial amount of residual growth. An average of 7.7 spinal levels were tethered. Similar to the present study, blood loss was low (100 ml). Mean operative time was 286.2 minutes, similar to PSF. On the first radiographic the thoracic deformity was corrected to 21.0° ± 8.5° and at 12 months follow-up this was 17.9° ± 11.4°. Three patients overcorrected to 13°, 9°, and 6°. In contrast to the implant studied here, no implant-related complications occurred.

The present study is limited by a small number of included subjects. This is represented by the high standard deviations when dividing the included patients in the two Lenke types. Also, with a mean follow-up of only 1.4 years, the changes in deformity, patient reported outcomes, and long-term complications are not yet fully overseen. For example, most complications with the periapical distraction implant occurred around 1 year after surgery and three out of 20 patients have not reached this follow-up moment yet. Also, adding on occurs at prolonged follow-up and the current study may underestimate its true incidence.

To conclude, this preliminary report on the use of a novel implant for fusionless scoliosis surgery provided promising results regarding surgical and early clinical parameters, but also highlighted a high rate of implant failure. This negatively affects treatment quality as a reoperation in this young patient group can have a high impact on physical and emotional well-being. It could be possible that complication rates will further increase with longer follow-up. The negative effect of the implant on spinal biomechanics and the impossibility to perfectly align the screws in all cases could have played a causative role in the complications. Whether the *P. Micra* infections caused osteolysis or were a mere incidental finding of a latently present pathogen remains a topic of debate. Similarly, the role of the observed implant wear is unclear. Nevertheless, because of the unacceptable high complication rates, the inclusion of new patients for the present study has been temporarily halted until all patients in the current cohort have all been followed up to 1.5 years postoperatively after which a new evaluation will take place. The local medical ethical committee, and all included patients and their parents have received written information about the complications and the decision to halt further inclusion.

Conflicts of interest

ApiFix Ltd. financially supported this study. The payments were made directly to the institution (VU Medical Center). ApiFix Ltd. had no influence on the data gathering, data analysis, or writing of this report. The authors report no personal conflict of interest related to this study.

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