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# COMPLICATIONS OF PROLONGED HALO-GRAVITATIONAL TRACTIONAL IN SPINAL DEFORMITY SURGERIES

## *COMPLICAÇÕES DA TRAÇÃO HALO-GRAVITACIONAL PROLONGADA EM CIRURGIAS DE DEFORMIDADE DA COLUNA*

## *COMPLICACIONES DE LA TRACCIÓN HALO-GRAVITACIONAL PROLONGADA EN CIRUGÍAS DE DEFORMIDAD DE LA COLUMNA*

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## ABSTRACT

Objective: Spinal traction by a cranial halo is a method with more than half a century of application, presenting the possibility of gradual correction of deformities while the patient is awake, also improving respiratory and nutritional patterns. This study aimed to evaluate the complications of pins and traction during their use in treating severe spinal deformities. Methods: We evaluated 27 patients undergoing surgical treatment using halo-gravitational traction pre or interoperatively between 2014 and 2020. Inclusion criteria were the presence of severe deformity (>100º) in the coronal and/or sagittal plane and traction for at least seven days. Two subgroups were identified: patients presenting only severe coronal deformity (Group 1) and patients with severe deformity in the sagittal plane accompanied by coronal deformity (Group 2). Clinical and radiological data were analyzed retrospectively, evaluating the variables: age, sex, weight, height, etiological diagnosis, number of pins, traction time, sagittal and coronal Cobb angle before and after traction, and complications related to pins and traction. Results: Age and weight showed a significant correlation with the occurrence of complications related to the pins (p=0.007; p<0.001), as well as the congenital etiology of deformity (p=0.001), and those patients in group 2 (p=0.006). There was no significant correlation between the variables studied and the occurrence of neurological complications. Conclusion: Halo-gravitational traction is an important adjunctive method in treating severe spinal deformities. Despite having a considerable complication rate, there were no serious events. ***Level of evidence IV; Case series.***

**Keywords:** Traction; Postoperative Complications; Scoliosis.

## *RESUMO*

*Objetivo: A tração espinhal por halo craniano é um método com mais de meio século de aplicação, apresentando a possibilidade de correção gradual de deformidades com o paciente desperto, além da melhoria do padrão respiratório e nutricional. Este estudo teve como objetivo avaliar as complicações relacionadas aos pinos e à tração durante o seu uso no tratamento de deformidades graves. Métodos: Foram avaliados 27 pacientes submetidos a tratamento cirúrgico com uso de tração halo-gravitacional pré ou inter-operatória, entre 2014 e 2020. Os critérios de inclusão foram a presença de deformidade grave (>100º) coronal e/ou sagital, e duração mínima de 7 dias de tração. Dois subgrupos foram identificados: pacientes com deformidade grave coronal (Grupo 1) e pacientes com deformidade grave sagital acompanhada de deformidade coronal (Grupo 2). Os dados clínicos e radiológicos foram analisados retrospectivamente, incorporando as variáveis: idade, sexo, peso, altura, diagnóstico etiológico, número de pinos, tempo de tração, ângulo de Cobb sagital e coronal pré e pós tração, complicações relacionadas aos pinos e à tração. Resultados: Idade e peso demonstraram correlação significativa com a ocorrência de complicações relacionadas aos pinos (p=0,007; p<0,001), assim como etiologia congênita (p=0,001), e os pacientes incluídos no grupo 2 (p=0,006). Não houve correlação significativa com a ocorrência de complicações neurológicas. Conclusão: A tração halo-gravitacional é um importante método adjuvante no tratamento de deformidades graves da coluna vertebral. Apesar de ter apresentado taxa de complicações considerável, não ocorreram eventos graves.* ***Nível de evidência IV; Série de casos.***

***Descritores:*** *Tração; Complicações Pós-Operatórias; Escoliose.*

## *RESUMEN*

*Objetivo: La tracción espinal por halo craneal es un método con más de medio siglo de aplicación, presentando la posibilidad de corrección gradual de las curvas con el paciente despierto, mejorando el patrón respiratorio y nutricional. Este estudio evaluó las complicaciones relacionadas con los tornillos y la tracción durante el tratamiento de deformidades espinales graves. Métodos: Se evaluó a 27 pacientes sometidos a cirugía con uso de tracción halo-gravitatoria pre o inter quirúrgica, entre 2014 y 2020. Los criterios de inclusión fueron la presencia de deformidad severa (>100º) en el plano coronal y/o sagital y tiempo mínimo de tracción de 7 días. Dos subgrupos fueron identificados: pacientes con deformidad severa en el plano coronal (Grupo 1), y pacientes con deformidad sagital severa acompañada de deformidad coronal (Grupo 2). Los datos clínicos y radiológicos se analizaron retrospectivamente, evaluando edad, sexo, peso, talla, diagnóstico etiológico, número de tornillos, tiempo de tracción, ángulo de Cobb sagital y coronal pre y post tracción, complicaciones*

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*relacionadas con los tornillos y tracción. Resultados: Se demostró que la edad y el peso eran factores significativamente correlacionados con las complicaciones de los tornillos (p=0,007; p<0,001), así como la etiología congénita (p=0,001), y los pacientes incluidos en el grupo 2 (p=0,006). No hubo correlación significativa entre las variables estudiadas y complicaciones neurológicas. Conclusión: La tracción halo-gravitacional es un método adyuvante importante en el tratamiento de deformidades espinales severas. A pesar de haber presentado una tasa de complicaciones considerable, no hubo eventos graves.* ***Nivel de evidencia IV; Series de casos.***

***Descriptores:*** *Tracción; Complicaciones Posoperatorias; Escoliosis.*

## INTRODUCTION

The cranial halo traction device was initially described by Nickel and Perry et al. in 1968, having been an important milestone in treating post-polio paralytic deformity. It consisted of a stainless-steel ring fixed to the skull by threaded pins connected to a thoracic orthosis.[1] Since then, it has been used for deformity correction and cervical stabilization in adults and children.[2] Correction of severe and rigid spinal deformities comes with significant neurological risk. In this context, pre and inter-operative traction devices have the advantage of a slow and gradual correction, making the spine, chest, and anterior structures more flexible.[3] Traction improves lung function, promoting separation of the ribs in the concavity with consequent better diaphragmatic excursion and partially eliminating the restrictive component.[4] Besides, emphasis can be placed on improving the patient's nutritional status, often on a low weight-for-age percentile curve.[4] Other related subjective factors are the strengthening of the relationship with the patient and family, established during daily visits to monitor traction, which is fundamental before major surgery.[3]

The force is applied longitudinally through a cranial halo, and countertraction is possible through the femur, tibia, pelvis, or body weight (halo-gravitational).[5] Popularized by Stagnara, halo-gravitational traction is a method that can be applied with the patient resting in bed, in a wheelchair, or even in a walker.[6] Halo-pelvic and halo-femoral methods present significant morbidity due to prolonged bed rest, the possibility of incorrect positioning of pelvic pins, hip subluxation/dislocation, and femoral fractures after the removal of the pins in the femur.[7] We consider that halo-gravitational traction has less morbidity, being more tolerated by the patients because they are not confined to bed. Another benefit over halo-pelvic and halo-femoral traction is the lower incidence of complications, especially severe neurological events.[8] Even so, it has its own adverse events related to the pin interface or traction.[2,6]

Complications related to fixation pins are mainly ostium infection and loosening, with intracranial penetration also possible, presenting consequent dural injuries and eventual abscesses formation.[2] The longitudinal force exerted by traction is mainly related to complications concerning neurological status.[2] There may be involvement of the upper and lower limbs, as well as the cranial nerves.[8] The present study sought to report a series of patients submitted to pre and interoperative halo-gravitational traction and evaluate the complications that occurred in patients submitted to halo-gravitational traction for a prolonged period, both related to pins and traction.

## METHODS

A total of 32 consecutive patients undergoing surgical treatment using pre- or inter-operative halo-gravitational traction were identified between May 2014 and August 2020, reviewing the Spine Surgery group's database. Inclusion criteria were the presence of severe deformity (>100º) in the coronal and/or sagittal plane and permanence with halo-gravitational traction for a minimum period of 7 days, as well as the availability of adequate x-rays preoperatively and after the final period of traction. Patients with pathologies restricted to the cervical spine were excluded. Twenty-seven patients met the criteria. A further division into two subgroups was performed: Sixteen patients with severe deformity only in the coronal plane, called Group 1, and Eleven patients with severe deformity in the sagittal plane associated with coronal deformity, called Group 2. Clinical data were analyzed retrospectively through consultation of medical records, using a specific collection instrument to incorporate the variables: age, sex, weight, height, etiological diagnosis, number of pins used, traction time, sagittal and coronal Cobb angle preoperatively and after the traction period, complications related to pins and traction.

### Radiographic Evaluation

Anteroposterior (AP) and lateral full-length x-rays of the spine were evaluated with the patient in the standing or lying position. Patients underwent weekly x-rays during the traction period to assess the magnitude of the main and compensatory curves and evaluate the cervical spine for evidence of over-distraction and/or facet subluxation. The final radiograph was considered the last taken before the definitive procedure. To assess the Cobb angle, both in the coronal and sagittal planes, the same terminal vertebrae were used in the initial preoperative images and at the end of the traction period. The coronal and sagittal percent correction index was calculated as Preoperative Cobb – Post traction Cobb / Preoperative Cobb x 100%. Radiographic measurements were performed using Surgimap software version 2.3.2.1.

### Halo-Gravitational Traction

The halo application was performed in a standard way in all patients, being performed in the operative room under general anesthesia or deep sedation. The procedure started with antisepsis with 2% aqueous chlorhexidine, with a local anesthetic block performed before inserting the pins. Four to six pins were inserted, the anterior ones being positioned 1 cm above the lateral portion of the eyebrows and the posterior ones 1 cm above and posterior to the auricle. Medial positioning can endanger the supraorbital and supratrochlear nerves and may later damage the masticatory muscles.[4] The halo should be positioned slightly below the equator of the skull to avoid scalping. Torque was applied to obtain a satisfactory bone grip. Re-tightening of the pins was not performed routinely, only when there was some evidence of loosening during daily inspection.

Traction started the day after the halo application gradually in most cases, starting later only when the patient's clinical condition required greater care. In these cases, traction is initiated at the moment of clinical stabilization. The initial weight was, on average, 4 to 5 kg, having been adjusted according to the physical characteristics of each patient. The objective was a gradual daily increment of 1kg, increased once a day, aiming at a final weight between 30-50% of body weight or up to tolerance. The traction was continuous and could be switched from the bed to the wheelchair, also used as a walker.

Patients with walking ability were encouraged to remain in orthostasis with the help of a walker to reduce the potential of disuse osteoporosis during the prolonged period of traction and to provide better physical conditioning, improved self-esteem, and psychological status. The clinical examination included the evaluation of headache, pain, or paresthesia in the oral cavity, a neurological examination of the cranial nerves and the roots of the upper and lower limbs, and a careful inspection of the pins, performed daily by an orthopedic surgeon. The hygiene of the pins was also performed daily by the nursing team. Multiple factors decided the final period of traction, the main one being that traction had reached a plateau about deformity correction.

### Statistical analysis

Data were processed using R® software, version 4.0.2. The sample was characterized using descriptive and comparative analysis. Comparison between groups with and without complications

related to traction/pins was conducted using the Student's t-test (continuous variables) and Fisher's exact test (categorical variables). For correlation purposes, variables with $p<0.05$ were considered significant.

### Ethical aspects

This study was approved by the Research Ethics Committee (CAAE: 39364420.0.0000.5273) under National Health Council Resolutions 466/2012 and 580/2018. As a retrospective study, the Informed Consent Term was not required.

## RESULTS

Among the 27 patients evaluated, 13 (48%) were male, and 14 (52%) were female. The age at the time of surgery ranged from 6-47 years, with a mean of 19.6 years. The initial diagnosis was idiopathic scoliosis in 14 patients, congenital scoliosis in 5, neuromuscular scoliosis in 3, neurofibromatosis in 3, and 2 cases of syndromic scoliosis. The general information about the patients and their distributions in the groups were summarized in Table 1.

In the subgroup of patients with severe deformity only in the coronal plane, the mean Cobb angle was 123º (100-153). The subgroup of patients with combined deformity had a mean value of the Cobb angle for the coronal deformity of 125º (71-159), and in the sagittal plane, a mean value of 121º (100-178). In 26 cases, four pins were used for cranial fixation, and in only 1 case, six pins. Patients remained under traction for an average of 27 days (7-108). The mean percentage correction was 18.4% in the coronal plane and 19.8% in the sagittal plane in group 2, and 22.7% in group 1. The prevalence of complications in the subgroup with severe sagittal deformity was 63.6%, of which 18.1% were neurological, and 45.5% were related to pins. In comparison, in the subgroup with only severe coronal deformity, it was 6.25% (neurological only). (Table 2)

The overall complication rate was 29.6%. The mean age in patients where complications occurred was 18.4 years (6-47), with a mean traction time in days of 40.7 (7-108). The prevalence of complications related to the pins was 18.5%, with 4 (14.8%) of these due to loosening treated with retightening and 1 (3.7%) local infection that did not have an adequate response to antibiotic therapy, being solved after repositioning the pins. Neurological events had a prevalence of 11.1% (Table 3). Three patients developed less severe neurological conditions attributed to traction – two cases of diffuse paresthesia in the limbs and one with blurred vision, which resolved after decreasing the load. No serious complications related to pins and traction were identified.

Age and weight proved to be factors correlated with complications related to the pins ($p=0.007$; $p<0.001$, respectively), with lower means than the group without complications. Patients diagnosed with congenital scoliosis also showed a significant correlation with the occurrence of pin complications ($p=0.001$), as well as those in group 2 ($p=0.006$) (Table 4). There was no significant correlation between the variables studied and the occurrence of neurological complications.

**Table 2.** Comparison between the evaluated subgroups.

| | Group 1 | Group 2 |
|---|---|---|
| Cobb angle (mean) | 123º | Coronal 125º<br>Sagittal 121º |
| % correction (mean) | 22,7% | Coronal 18.4%<br>Sagital 19.8% |
| Age (mean) | 20.8 (11-47) | 16.06 (6-25) |
| Weight (mean) | 45.9kg (22-65) | 39.14kg (14-72,6) |
| Traction time in days (mean) | 24.06 (7-97) | 31.9 (7-108) |
| Sex (M/F) | 5:11 | 8:3 |
| Complications | 6.25% | 63.6% |
| **Diagnosis** | | |
| - Syndromic | 1 | 1 |
| - Idiopathic | 11 | 3 |
| - Neuromuscular | 3 | 0 |
| - Neurofibromatosis | 0 | 3 |
| - Congenital | 1 | 4 |

**Table 1.** Demographic data of the patients included in the study.

| ID | Age | Sex | Diagnosis | Weight (kg) | Traction time (days) | Main deformity Cobb (group 1*/2*) | Complications |
|---|---|---|---|---|---|---|---|
| 1 | 16 | F | Syndromic | 22 | 23 | 110 (1) | absent |
| 2 | 10 | M | Congenital | 20 | 35 | 159 (2) | loosening |
| 3 | 22 | F | Idiopathic | 52,6 | 13 | 124 (1) | absent |
| 4 | 24 | M | Neuromuscular | 52 | 27 | 145(1) | absent |
| 5 | 19 | M | Neuromuscular | 37.6 | 97 | 132 (1) | absent |
| 6 | 15 | F | Idiopathic | 65 | 14 | 119 (1) | absent |
| 7 | 8 | F | Congenital | 14 | 32 | 111 (2) | loosening/visual disturbance |
| 8 | 19 | F | Congenital | 38 | 24 | 153 (1) | absent |
| 9 | 18 | M | Neuromuscular | 50 | 18 | 139 (1) | absent |
| 10 | 15 | F | Idiopathic | 49 | 8 | 102 (1) | absent |
| 11 | 11 | F | Idiopathic | 42 | 18 | 130 (1) | absent |
| 12 | 47 | F | Idiopathic | 50 | 26 | 115 (1) | RLL* paresthesia |
| 13 | 6 | F | Syndromic | 15 | 108 | 114 (2) | ostium infection |
| 14 | 23 | M | Idiopathic | 56 | 15 | 150 (2) | absent |
| 15 | 23 | M | Neurofibromatosis | 72.6 | 21 | 178 (2) | absent |
| 16 | 21 | M | Neurofibromatosis | 50 | 14 | 121(2) | absent |
| 17 | 23 | M | Idiopathic | 51 | 14 | 100 (1) | absent |
| 18 | 23 | M | Idiopathic | 42 | 14 | 156 (2) | absent |
| 19 | 15 | F | Idiopathic | 39.8 | 40 | 131 (1) | absent |
| 20 | 19 | M | Congenital | 49 | 7 | 115 (2) | loosening |
| 21 | 16 | F | Congenital | 30 | 32 | 172 (2) | loosening |
| 22 | 25 | F | Idiopathic | 48 | 31 | 104 (1) | absent |
| 23 | 24 | F | Idiopathic | 41.5 | 7 | 114 (1) | absent |
| 24 | 22 | M | Idiopathic | 62 | 7 | 127 (1) | absent |
| 25 | 19 | F | Idiopathic | 35 | 18 | 130 (1) | absent |
| 26 | 25 | M | Neurofibromatosis | 44 | 28 | 128 (2) | absent |
| 27 | 23 | M | Idiopathic | 38 | 45 | 144 (2) | RUL* paresthesia |

Group (1): Severe coronal plane deformity only; Group (2): Severe coronal and sagittal planes deformities; RLL: Right lower limb; RUL: Right upper limb

**Table 3.** Characteristics of the complications that occurred during the halo-gravitational traction period.

| Complications (8 events, seven patients) | |
|---|---|
| Age (mean) | 18.4 years (6-47) |
| Sex (M:F) | 3:4 |
| Weight (mean) | 30.8kg (14-50) |
| Traction time in days (mean) | 40.7 (7-108) |
| Pins complications | 5 |
| - Loosening | 4 |
| - Ostium Infection | 1 |
| Neurologic complications | 3 |
| **Diagnosis** | |
| - Syndromic | 1 |
| - Idiopathic | 2 |
| - Neuromuscular | 0 |
| - Neurofibromatosis | 0 |
| - Congenital | 4 |

**Table 4.** Results of the statistical analysis between the studied variables and the pin complications.

| Statistical analysis – Pins complications | | | |
|---|---|---|---|
| | **Complications** | **No complications** | **p** |
| | **mean** | | |
| Age | 11.8 | 21.5 | 0.007 |
| Weight (kgs) | 25.6 | 47.2 | <0.001 |
| Height (cms) | 135.3 | 152 | 0.075 |
| BMI | 17.3 | 20.6 | 0.278 |
| Traction time (days) | 42.8 | 23.7 | 0.110 |
| Coronal Cobb | 122.2 | 123.8 | 0.878 |
| Sagittal Cobb | 123.6 | 105.5 | 0.281 |
| Coronal correction % | 18.7 | 22.5 | 0.541 |
| Sagittal correction % | 23.7 | 15.4 | 0.272 |
| | **n** | | |
| Sex | | | 1.0 |
| Male | 2 | 11 | |
| Female | 3 | 11 | |
| Diagnosis | | | 0.001 |
| Syndromic | 1 | 1 | |
| Idiopathic | 0 | 14 | |
| Neuromuscular | 0 | 3 | |
| Neurofibromatosis | 0 | 3 | |
| Congenital | 4 | 1 | |
| Group | | | 0.006 |
| 1 | 0 | 16 | |
| 2 | 5 | 6 | |

## DISCUSSION

Despite the technological advances in the evolution of materials and techniques available in spinal surgery, severe and rigid deformities remain challenging. The definition of severe deformity remains vague, considered by McIntosh et al.[4] as an angulation in the coronal or sagittal plane greater than 100º. In this context, adjuvant methods such as traction provide adequate corrective forces for such pathologies.

The halo-gravitational traction, popularized by Stagnara, is a safe alternative in which body weight is used as a counterforce.[9] There are a few absolute contraindications to this procedure: severe skull deformities, the presence of an intra- or extra-dural mass/lesion, and severe spinal stenosis, with or without neurological impairment.[4] Cervical kyphosis and significant ligamentous instability or laxity are relative contraindications to the use of halo traction.[6]

In a study published in 2013, Bogunovic et al.[8] evaluated 33 patients who underwent preoperative halo-gravitational traction, with a mean sagittal Cobb angle of 83.3º and coronal angle of 96.4º. In that study, the overall complication rate was 27%. Garabedian et al.[7], in 2014, published a retrospective study of 21 patients undergoing halo-gravitational traction in which the complication rate was 19%. In this series, the mean coronal Cobb angle was 101º. Our series found a slightly higher complication rate of 29.6%. Although our sample included patients with more severe curves, we did not find a statistically significant correlation between this data with the presence of complications to justify a higher rate compared to other series. (Figura 1)

Complications of the pins can be related to ostium infection, loosening, incomplete or complete penetration of the material into the skull, and the cosmetic aspect of the scar.[2,10] In addition to these, halo migration, extradural and subdural intracranial abscesses, and cerebrospinal fluid leakage are reported.[11-13] Dormans et al.[14] defined ostial infection as a local inflammatory process accompanied by drainage, classifying according to the drainage aspect: non-purulent (Grade I) and purulent (Grade II). Rinella et al.[15] categorized according to their location into superficial, comprising ostial infections, and deep, covering reports of skull osteomyelitis, intradural and extradural infections. In a systematic review involving 351 patients, Yang et al.[16] found a prevalence of 16% of complications related to pins, the most common adverse event related to this treatment method. In our study, we identified a prevalence of 18.5% of pin complications, with the vast majority corresponding to aseptic loosening. We did not have any cases of pin penetration into the skull or intracranial abscess or dural injury, or CSF leak. Only one patient developed an infection of the pins, being classified as superficial, which, despite having required repositioning the affected pin, did not present any impairment of the general condition. In general, we consider pin complications low complexity and easy resolution.

The longitudinal force exerted by traction can be mainly responsible for neurological complications.[2,17] There may be involvement of the spinal nerves for the upper and lower limbs and the cranial nerves. The pathophysiology of cranial nerve injury is not well established, but it is believed that stretch neuropraxia may occur. Due to its trajectory, the VI cranial nerve would be the most vulnerable, although there are reports of hypoglossal, vagus, glossopharyngeal and trochlear palsy.[8,18] Oral paresthesia and nystagmus, paresthesia in upper limbs, unilateral miosis, and weakness in lower limbs are also reported.[8] In our series, we did not observe severe neurological alterations or involvement of the cranial nerves. All patients with neurological conditions attributed to traction showed complete improvement after being discontinued for a brief period. Upon returning to the traction protocol, we used a lower load than previously established and did not observe new intercurrences.

There is no consensus regarding the appropriate length for maintaining halo-gravitational traction, with reports ranging from weeks to months.[17,19,20] In a retrospective study, Park et al.[20] observed no significant increase in correction with more than three weeks of traction. Han et al.[21] showed a negative impact of halo-gravitational traction on the bone mass index, with a reduction associated with the period of traction. In our practice, we consider the correction obtained and the patient's tolerance to traction, making a case-by-case judgment of the treatment time. In staged surgeries where traction is used interoperatively, we avoid a period of traction longer than three weeks due to the wound healing process and increased difficulty in the second surgical approach.

Several general systemic conditions are related to severe spinal deformity, including pulmonary dysfunction and nutritional deficit.[22]

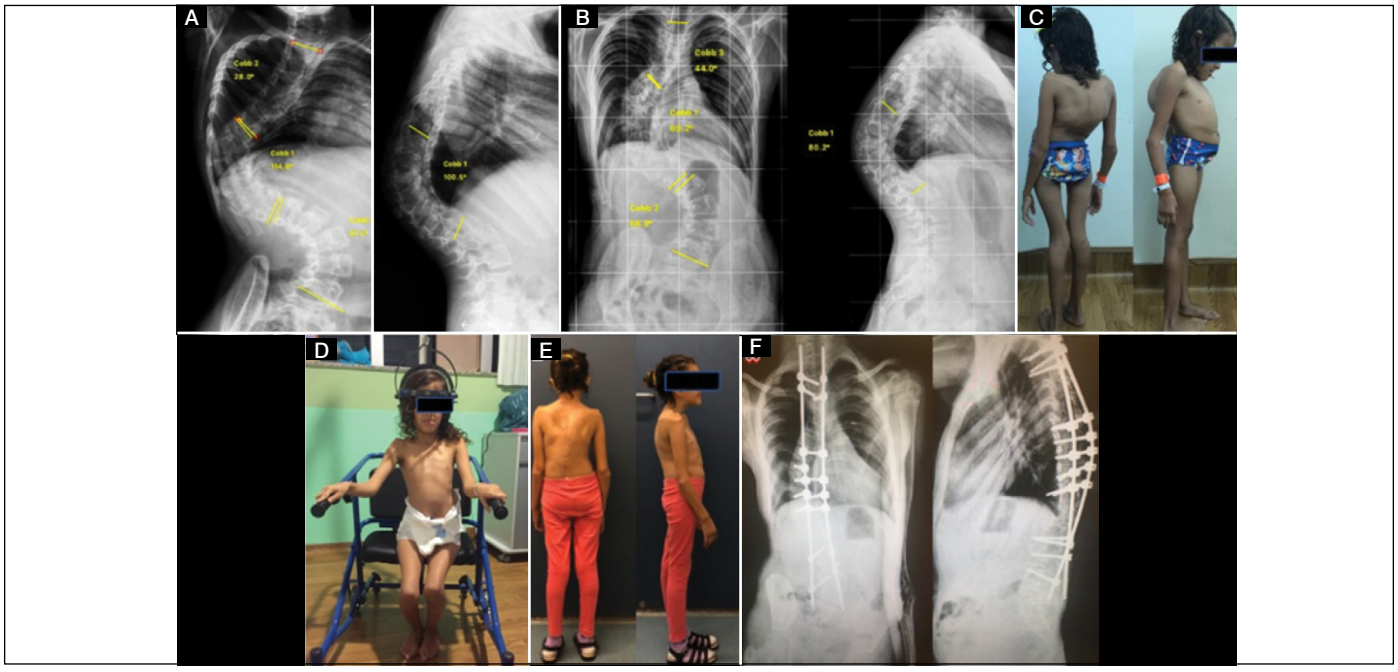


**Figure 1.** Female patient, 6 years old, diagnosed with Ehler-Danios Syndrome and severe kyphoscoliosis. She underwent preoperative halocranial traction for a period of 108 days. 6 pins were used for fixation in the skull. She had a local infection, which was treated with antibiotics and repositioning of the pins. Initial radiographic image (A) and after 90 days of traction (B). Preoperative (C), during traction in a specific wheelchair (D) and postoperative (E) clinical images. Preoperative traction enabled surgical treatment using the Shilla technique (F).

According to Garabekyan et al.[7] spinal resections and osteotomies add morbidity to the treatment and may not be tolerated in this patient population. In this context, halo-gravitational traction can improve respiratory function, nutritional status, and general medical condition in the preoperative period or between staged procedures.[17,20] However, no protocol has been established in the literature regarding the number of pins, initial weight, additions, or total traction duration. (Figura 2)[8]

## CONCLUSION

Halo-gravitational traction is a safe and useful adjunctive method in treating severe spinal deformities. Despite having a considerable complication rate, there were no serious events. The presence of sagittal deformity >100º was correlated with pin complications. However, all of these were of low complexity and easy resolution.

All authors declare no potential conflict of interest related to this article.

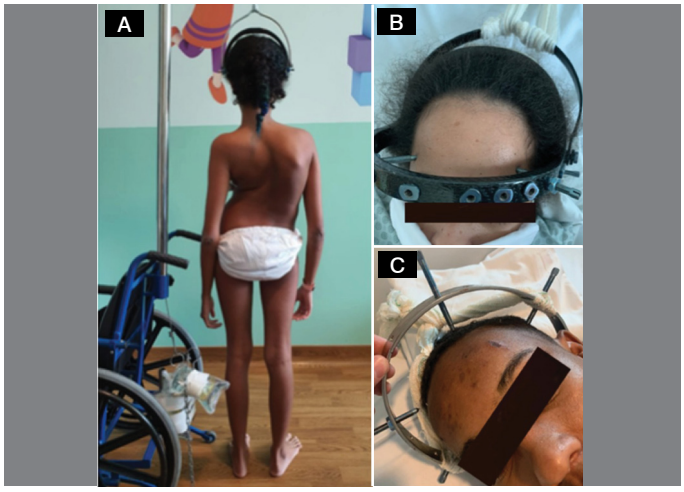


**Figure 2.** A) Patient under preoperative halo-cranial traction with a specific wheelchair. B) Usual pin placement in 4-pin configuration. C) Loosening of the anterior pins with consequent skin injury, requiring repositioning.

**CONTRIBUTIONS OF THE AUTHORS:** Each author contributed significantly to this manuscript. IEC: writing, statistical analysis, and preparation of the entire research project; GFA: writing, review, and statistical analysis; AGCB: performing the surgeries, review and intellectual concept; LECTS: performing the surgeries, review and intellectual concept.

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