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Survivorship analysis of Cotrel-Dubousset instrumentation in idiopathic scoliosis

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Abstract This study presents a survivorship analysis of Cotrel-Dubousset instrumentation in the surgical treatment of idiopathic scoliosis. Between 1987 and 1995, a total of 133 patients with idiopathic scoliosis received posterior spine fusion and instrumentation with the CD system at our center. The patients' mean age at surgery was 16.5 years (range 11–43 years). The magnitude of the thoracic scoliosis averaged 62.7° (range 40°–125°) and that of the lumbar curve was 58.8° (range 40°–100°). On average, 12.2 segments were fused (range 8–17) and, excluding the rods, 14.1 implants were set for each patient (range 10–21). Survivorship analysis was carried out using the Kaplan-Meier method. Implant removal was considered the terminal event, or “death”. The effect of several variables on survival rate was determined with the Cox regression method. The patients remained in the study for 56.7 months (range 2–120 months). One-hundred and ten patients were withdrawn (“censored”): 90 “alive” (did not require repeat surgery and attended follow-

up control in 1997) and 20 “lost” (did not attend control in 1997). Twenty-three patients attained the terminal event of implant removal for a variety of reasons: acute infection (three cases), late infection (ten cases), implant failure requiring revision (six cases) and local pain (four cases). The survival rate was 95.5% at 3 months, 94.7% at 6 months, 93.9% at 1 year, 91.5% at 2 years, 82.2% at 5 years and 76.5% at 10 years. The magnitude of the curves, total number of implants and number of fused segments did not correlate with survival probability. A positive correlation was found between survival rate and correction loss between surgery and last control. A survival rate of 76.5% at 10 years is unexpectedly low. Current data suggest that the incapacity to maintain correction after initial surgery plays a major roll in the long-term evolution of Cotrel-Dubousset instrumentation.

Keywords. Idiopathic scoliosis · Cotrel-Dubousset instrumentation · Survivorship analysis

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Introduction

The outcome of treatment for idiopathic scoliosis is usually assessed by radiologic study, to determine the angular correction obtained, and by analysis of the clinical results. Another datum of interest, particularly regarding vertebral

implants, is the incidence of reoperations. From the patient's viewpoint, an implant that achieves excellent correction but is very likely to require a second operation may not be considered satisfactory. The appropriate statistical method for evaluating this event is survivorship analysis, which allows one to determine the true reoperation rate and to predict the probability of reoperation in the long

term. Although this system has proved to be useful in the evaluation of total hip prostheses [9], survivorship analysis has been little used for the study of vertebral implants.

McAfee et al. [17] published a survivorship analysis of 526 pedicular screws (Cotrel-Dubousset and VSP-Steffee) used for the treatment of various degenerative conditions of the spine. In a work on VSP-Steffee instrumentation in vertebral fractures, Ebelke et al. [11] compared survival curves to determine the advantage of using an anterior structural graft in association with posterior osteosynthesis. Boos et al. [4] used survivorship analysis to compare the failure rates of Cotrel-Dubousset (CD) instrumentation and AO internal fixation in the management of degenerative spine disease. More recently, Cook et al. [7] reported a comparative survivorship analysis between CD and Isola instrumentation in scoliosis, though the main aim of the work was to analyze the cases in which the internal fixator had to be removed because of pain at the implantation site. Apart from these papers, we did not encounter any other survivorship analyses of vertebral instrumentation in idiopathic scoliosis.

The aim of the present work is to present a survivorship analysis of Cotrel-Dubousset instrumentation in surgery for idiopathic scoliosis.

Materials and methods

We retrospectively reviewed all patients consecutively operated at our center between 1987 and 1995 and diagnosed with idiopathic scoliosis. Clinical histories were reviewed and the following types of data were recorded: demographic (age, sex), surgical (number of implants, level of instrumentation), radiologic (magnitude of the curves before the procedure, after, and at the last control) and clinical (date of surgery, complications, date of reoperation, cause of reoperation and date of last control).

The series included 133 patients (27 men and 103 women), with a mean age at the time of surgery of 16.5 years (range 11–43 years). Posterior vertebral arthrodesis with CD instrumentation was performed in all cases. Additionally, 14 cases required anterior spine fusion. A mean of 12.2 segments were fused (range 8–17). The mean cephalic level of instrumentation was T3.8 (T1, 5 cases; T2, 21; T3, 20; T4, 45; T5, 30; T6, 6; T7, 5; and T8, 1). The mean caudal level was L3.1 (T11, 5 cases; T12, 3; L1, 11; L2, 20; L3, 27; L4, 47; L5, 19; and S1, 1). Excluding the rods, a mean of 14.1 implants was used per patient (range 10–21). These consisted of a mean (range) per patient of: 10.7 (4–16) hooks; 1 (0–7) screws; 2 (0–5) cross-links and 0.2 (0–3) other connectors (e.g. wedding connectors). Pedicular screws were used in only 33 cases (24.8%).

The mean preoperative thoracic curve magnitude was $62.7^\circ \pm 15.3^\circ$. After the procedure, the thoracic curve measured $28.1^\circ \pm 11.8^\circ$, giving a correction of $56\% \pm 12.4\%$. At the last control, the magnitude of the curve was $37^\circ \pm 13.2^\circ$. Lumbar curve magnitudes were as follows: before surgery, $58.9^\circ \pm 13.6^\circ$; after surgery, $28.6^\circ \pm 12.9^\circ$; correction, $52.6\% \pm 16.6\%$; last control, $38.5^\circ \pm 14.2^\circ$. Loss of correction is expressed as the relation between the degrees lost in the follow-up period and the degrees improved with surgery:

Loss of correction (%) = $[(\text{Postop angle} - \text{Follow-up angle}) / (\text{Preop angle} - \text{Postop angle})] \times 100$

Loss of thoracic curve correction was $8.7^\circ \pm 6.9^\circ$ or $25\% \pm 20.5\%$, and loss of lumbar curve correction was $9.9^\circ \pm 8.5^\circ$ or $32.5\% \pm 28\%$.

Survivorship analysis was performed using the Kaplan-Meier method. The period of observation of the sample closed on 31 December 1997; thus all patients had been operated on at least 2 years before. The terminal event was repeated surgery for partial or complete removal of the implants or for their replacement. The patients requiring reoperations were considered “dead”. Patients are reviewed annually at our hospital. Thus, those who did not require repeated surgery and attended the follow-up control in 1997 were considered withdrawn (“censored”) alive; and patients who did not attend the 1997 control were considered withdrawn (“censored”) lost. Survival curves were compared with the Mantel-Haenszel log-rank test. The influence of the different variables on probability of survival was evaluated with the proportional hazards model of Cox. Statistical analysis was computed with SPSS 6.0 software.

Results

Patients were under study for a mean of 56.7 months (range 2–120 months). Among the total, 110 were withdrawn (censored) – 90 “alive” and 20 “lost” – and 23 (17.3%) were reoperated and considered “dead”.

Reasons for implant removal

The reasons for implant removal included acute infection (three cases), late infection (ten cases), implant failure (six cases) and late operative site pain (four cases).

Acute infection cases

There were three cases of acute infection (2.2%). Two of these presented with fever and suppuration during the immediate postoperative period. They were treated with antibiotic therapy and debridement. Suppuration persisted in both cases and the instrumentation was removed at 2 and 4 months respectively. Intraoperative culture isolated *Staphylococcus aureus* in one case and *Staphylococcus epidermidis* in the other. The third infectious case presented high fever postoperatively and blood culture positive for *Staphylococcus aureus*. The infection was controlled with antibiotics, but instrumentation had to be removed at 11 months because of intermittent fever and suppuration.

Late infection cases

There were ten cases of late infection (7.5%). Seven patients presented with spontaneous exudation and three with subcutaneous fluctuation without exudation. All cases of late infection were treated by removal of the internal fixation, after which the clinical process resolved. Intraoperative culture was negative in five cases and positive in five other cases (*Staphylococcus aureus*, two cases, *Streptococcus viridans*, two cases, and *Propionibacterium acnes*, one case). Internal fixation was removed at 44.4 months (range 20–81 months).

Local pain at the operative site

There were four cases of local pain at the operative site (3%). In two of these, internal fixation was removed electively at 30 months and 4 years, respectively, because of local pain that the patients attributed to the implants. In the other two cases, local pain occurred over implants that were clearly palpable and painful. In both these patients there was a significant loss of correction in the 1st post-operative year, which later stabilized. The implants were removed at 2 and 3 years respectively.

Implant failure

There were six cases of implant failure (4.5%). Two of the patients had to be reoperated at 3 and 4 months, respectively, because of early dislodgment of the hooks. Another was reoperated at 4 years, because of distal hook detachment and evident pseudoarthrosis in the last fused segment. The remaining three cases presented with dislodgment, progressive loss of correction and imbalance due to short fusions, and they required extension of the instrumentation.

Survival rates

The implants were removed at a mean of 30.8 months (range 2–82 months) after the initial procedure. The probability of survival was 95.5% at 3 months; 94.7% at 6 months; 93.9% at 1 year; 91.5% at 2 years; 82.2% at 5 years and 76.5% at 10 years (Table 1). As can be seen in the survival curve (Fig. 1), the probability of survival decreased progressively until it stabilised at around 6.5 years after surgery.

Table 1 "Life" table (*SE* standard error, *CI* confidence interval)

Time (months)	Cumulative proportion surviving at the end	SE cumulative proportion	Lower 95% CI	Upper 95% CI
3	0.992	0.0075	0.977	1.00
6	0.947	0.0194	0.909	0.985
12	0.939	0.0207	0.899	0.980
24	0.915	0.0244	0.867	0.963
36	0.879	0.0294	0.821	0.937
48	0.836	0.035	0.767	0.904
60	0.822	0.0371	0.749	0.894
72	0.788	0.0425	0.705	0.872
84	0.764	0.0475	0.671	0.858
96	0.764	0.0475	0.671	0.858
108	0.764	0.0475	0.671	0.858
120	0.764	0.0475	0.671	0.858

Fig. 1 Survival curve for the overall group

Fig. 2 Survival curves of patients grouped according to a correction loss of less than or greater than 25%

In the multivariate analysis, there was no relationship between probability of survival and magnitude of the curves, number of segments fused, or total number of implants. A significant, though moderate correlation was found between survival probability and the loss of correction (Cox model Chi-square LR 7.1, $P=0.007$; coefficient β 0.02; exponentiated β 1.02; 95% confidence interval of Exp. β 1.00–1.03). These data indicate that every 1% loss of correction increases the risk of reoperation by 1.00 to 1.03. This relation can be graphically expressed by comparing the survival curves of individuals with a loss of correction greater than 25% with those of individuals with a loss smaller than 25%. This magnitude is the average loss of correction for the whole series (Fig. 2). A potential influence of the learning curve on the failure rate was also ruled out. The first half of the series of operated patients had a reoperation rate of 16.9%, while the second half showed a rate of 17.6% (log-rank test 1.8, $P=0.17$).

Discussion

Cotrel-Dubousset [8] instrumentation has a greater capacity than Harrington instrumentation for correction of sco-

liosis in both coronal and sagittal planes [5, 13]. Multisegmental fixation provides sufficient stability to make postoperative immobilization unnecessary. These facts have made CD instrumentation standard for the treatment of idiopathic scoliosis. Nevertheless, there are few series that have been investigated for the long-term results of this method [16], particularly regarding complications [6]. Long-term analysis of an implant should include data on the incidence of reoperations in order to determine the patient's satisfaction with the technique used.

The true rate of repeat surgery in our series was 17.3% over a mean study period of 56 months. In a series of 95 patients treated with CD instrumentation and a follow-up of 35 months, Lenke et al. reported a reoperation rate of 5.2% [15]. Follow-up was continued to 6 years in 76 of these patients, and the authors reported one additional reoperation [16]. In a series of 49 patients with CD and a mean follow-up period of 105 months, Cook et al. [7] reported a reoperation rate of 24%. The same paper contained a series of 69 cases treated with Isola instrumentation and a follow-up of 69 months, in which the rate of reoperation was only 14%. Guidera et al. [12], in a series of 52 patients with CD instrumentation and 23 months' follow-up, reported a reoperation rate of 13.4%. Over a total of 1247 instrumentations (917 CD, 330 Moss-Miami) during a 10-year study period, Clark and Shufflebarger [6] had to reoperate 2.2% of patients.

The reason for the largest number of reoperations in our series was late suppuration (7.5% of the total), followed by mechanical failure (4.5%), local pain at the operative site (3%), and acute infection (2.2%). Late suppuration is one of the most frequent causes of repeat surgery. Our rate of 7.5% is somewhat higher than those reported in other series using CD instrumentation, which range from 2 to 5.7% [2, 6, 7, 12], but our follow-up was longer. Regarding other types of multisegmental instrumentation, Cook et al. [7] reported a late suppuration rate of 2.9% with Isola instrumentation and Richards [18] a rate of 6.7% with TSRH.

The origin of late infection is still under debate. The infecting micro-organism was found in only half of our cases. Richards [18] suggested that late suppuration might be caused by anaerobic germs, and that longer incubation of the sample would be required for their identification. This technique was not used in our series. Dubousset et al. [10] attributed late infection to corrosion caused by a rubbing together of the open hook and the blocker, or the cross-link hooks and the rods. Richards [18] suggested an association with the number of implants used. However, we found that the number of implants did not influence the probability of survival.

Among the six cases requiring repeat surgery due to implant failure, one patient presented with hook dislodgment related to the presence of pseudoarthrosis. The other five cases involved misjudgment in surgical planning, mainly fusions that were too short in an attempt to preserve segments. This problem occurred fairly frequently

until optimal levels for instrumentation in selective fusion were determined [14]. In a series described by Lenke et al. [15, 16], four of five reoperations were performed for this reason. These findings might point to an influence of the learning curve in failure rates. Nevertheless, in the overall analysis we found no differences in the rate of repeat surgery between the first and second half of the series. The influence of the learning curve is difficult to evaluate, however, and our data only provide a simple estimate.

Local pain over the implant is relatively frequent after CD instrumentation, although it is rarely a motive for reoperation. The only series that stands out in this respect is one described by Cook et al. [7], who considered local pain the main reason for reoperation in 12% of cases in their CD group. In our patients this factor was responsible for 3% of the removals.

It is likely that use of a transversal study design to analyze the rate of implant failure provides an underestimation of the true rate. The most commonly used statistical methods, such as the Student's *t*-test, do not support the statistical uncertainty provoked by censored data. However, the censored patients contribute valuable information and should not be omitted from the analysis. One of the characteristics of survivorship analysis is that all the patients involved are taken into account.

In survivorship analysis, a cohort of patients is evaluated longitudinally over time, even though the cohort may be identified retrospectively. Patients are recruited during a period of time and followed until the end date of the study or until the terminal event occurs. This means that the last patients enrolled are observed for the shortest time; thus, it is less probable that these patients will experience the terminal event. An important assumption is that the prognosis for survival is similar for all patients all along the study, and that patients lost during follow-up have the same prognosis for survival as those who remain in the study [1]. Survivorship analysis takes into account the patients lost during follow-up.

The use of actuarial methods to construct survival tables allows one to determine the annual and overall failure rates for a group of patients who have been followed up for different periods of time [3]. Moreover, with survivorship analysis we can predict long-term failure rates that include patients lost to follow-up. Later refinements of the statistical techniques related to survivorship analysis allow one to analyze which factors have an influence on the probability of survival. Using logistic regression we found a significant relation between survival rates and postoperative loss of correction. Another important characteristic of survivorship analysis is that survival curves can be compared. Using this method, Cook et al. [7] found no significant differences in survival curves among patients who received Harrington, CD or Isola instrumentation.

On the other hand, survivorship analysis to evaluate the evolution of vertebral implants has some limitations. The most important arises from the need to define what

will constitute the terminal event in the study. In our case, the terminal event was established to be repeat surgery. This meant that the number of cases showing a loss of correction but not requiring reoperation would be underestimated. In CDI follow-up, one often observes small changes in the relation of the sleeves with the body of the hook. Of course, these are not important mechanical failures that require reoperation, but they are often associated with loss of correction.

Our results suggest that the risk of reoperation is greater when there is a loss of correction. Since the most frequent cause of reoperation in our series was late suppuration, it is reasonable to suppose that the sleeve system permits some micromobility that could provoke loss of correction and the fretting corrosion responsible for most

of these late suppurations. Other factors that do not depend on the implant could also contribute to this loss. The disparity of results among the different series is probably related to the degree of skill of the surgeons. Certain factors that are not covered in this study, such as type of bone graft and use of rigid postoperative orthosis, may also play a part. In any case, the data presented underline the importance of adequate adjustment of implants to obtain the maximum stability possible. Finally, these results are a basis for future research that will compare CD with other types of instrumentation.

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