

EFFECTS OF IMPLANT REMOVAL AND REMOVAL TIME ON CLINICAL OUTCOMES IN LENKE TYPE-I IDIOPATHIC SCOLIOSIS PATIENTS WHO TREATED WITH 3RD GENERATION INSTRUMENTATION SYSTEM

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ÖZET

Son bir kaç dekattır, 3. jenerasyon enstrümantasyon sistemlerinin idiopatik skolyoz cerrahi tedavisinde kullanıma başlamasıyla, frontal ve sagittal plandaki deformite daha yüksek oranlarda düzeltilmeye başlamıştır. Deformitenin düzeltilmesindeki yüksek başarıya rağmen, hastaların sırt ağrısı yakınmaları önemli bir sorun olarak karşımıza çıkmaktadır. Son yıllarda bunun başlıca, özellikle çapraz bağlantılardan kaynaklanan bir metal hastalığı sonucu olduğu ileri sürülmektedir. İmplantların çıkartılması füzyon olana kadar, ki bu süre yaklaşık 9 - 12 aydır, implant yezmetliği ve benzeri bir sorun da gelişmemiş ve hasta da ısrarla istemiyorsa, cerrahlar tarafından yeni morbidite riski nedeniyle tercih edilmektedir. Literatürde implant çıkartılmasının klinik sonuçlara etkisi üzerine bir çalışma da yoktur. Bu amaçla bu çalışmada, yaşları 12-16 arasında yer alan (ortalama 13.9 ± 1.4), cerrahi tedavileri için 3. jenerasyon enstrümantasyon sistemi kullanılan ve takiplerinde belirgin sırt ağrısı yakınması olan ve bu nedenle implantları sadece hastaların kendi istekleri nedeniyle çıkartılan ve Lenke tip 1 eğriliğe sahip 30 hasta bu çalışmaya dahil edilmiştir. Bu hastalar implant çıkartılmasından itibaren minimum iki yıl (ortalama 42.3 ± 8.2 ay) süre

ile takip edilmişlerdir. 15'er hastadan oluşan, implantları 2 veya 3. yıl içinde çıkartılan (1. Grup) ve 4. yıl içinde veya daha geç çıkartılan (2. Grup) iki grup teşkil edilmiştir. Bu iki grubun yaş ortalaması (13.8 ± 1.4 ve 14.1 ± 1.3 , t: 0.61, $p > 0.01$), kadın / erkek oranı (7/8 ve 7/8), preoperatif ($51.6^\circ \pm 10.6^\circ$ ve $52.6^\circ \pm 7.7^\circ$, t: 0.29, $p > 0.01$) ve postoperatif frontal plandaki eğriliğin Cobb açıları ($9.4^\circ \pm 6.3^\circ$ ve $9.8^\circ \pm 7.0^\circ$, t: 0.16, $p > 0.01$), korreksiyon oranları (% 82.8 ± 8.7 ve % 82.5 ± 10.4 , t: 0.09, $p > 0.01$) ve korreksiyon kayıplarının ($3.5^\circ \pm 3.2^\circ$ ve $2.5^\circ \pm 3.3^\circ$, t: 0.84, $p > 0.01$) ve preoperatif ($18.7^\circ \pm 24.3^\circ$ ve $21.1^\circ \pm 17.1^\circ$, t: 0.31, $p > 0.01$) ve postoperatif torakal kifoz açıları ($37.2^\circ \pm 5.9^\circ$ ve $34.5^\circ \pm 8.3^\circ$, t: 1.22, $p > 0.01$) istatistiki olarak benzer olduğu belirlenmiştir. Her iki grupta da hastalarda postoperatif enfeksiyon, implant yetmezliği, nörolojik defisit gibi bir komplikasyona rastlanmamıştır. Her iki grubun postoperatif ve son kontroldeki ağrı, fonksiyon, mental durum ve sel-image ve tedaviden tatmin olma domainleri ve bu skorların toplamından oluşan toplam SRS-22 anket sonuçları mukayese edilmiştir. Postoperatif ve son kontrolde, sırasıyla toplam SRS-22 skorlarının, 1. grupta 19.89 ± 1.24 ve 21.03 ± 1.22 , 2. grupta 20.28 ± 1.38 ve 20.65 ± 1.37 olduğu saptanmıştır (p: 0.0). Her iki grupta da self

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image, mental status domainlerinde istatistiki olarak anlamlı bir değişme görülmemiş, ağrı, fonksiyon ve tedaviden tatmin domainlerinde iyileşme olduğu, bu iyileşmenin ise implantları daha erken çıkartılan 1. grupta daha fazla olduğu belirlenmiştir. Ayrıca, SRS-22 anket sonuçları ile implant çıkartılma zamanı arasında istatistiki olarak anlamlı bir korelasyon olduğu da tespit edilmiştir. Bu görüşlerin ışığı altında, Lenke Tip I idiopatik skolyoz hastalarında, füzyon kitlesi geliştikten sonra, hasta da istiyorsa implantların 4. yıldan önce çıkartılması, hastanın özellikle ağrı yakınmalarının azaltılması ve fonksiyonlarının artırılması yönünden klinik sonuçları olumlu etkilediği fikri elde edilmiştir.

Anahtar Kelimeler: Skolyoz, cerrahi tedavi, SRS-22 anketi, enstrümantasyon.

ABSTRACT

Due to new morbidity risk, implant removal is not preferred by surgeons until the development of fusion, which takes about 9 to 12 months, unless implant fails, a similar complication develops or the patient requests. The effect of implant removal on clinical outcomes has not been previously investigated. For this purpose, 30 patients with Lenke type I adolescent idiopathic scoliosis (age range: 12-14 at the time of corrective surgery) treated with a third generation instrumentation system, experiencing apparent back pain at

follow-up examinations and had their implants removed upon their request were included in this study. These patients were followed-up for a minimum of two years (mean 42.3 ± 8.2 months) after implant removal. Patients were assigned into two groups based on the timing of implant removal: at the second or third year (Group 1, n=15), and at the fourth year or later (Group 2, n=15). Groups were similar in terms of all preoperative and postoperative parameters ($p>0.05$). None of the patients had complications like post-operative infections, implant failure, and neurological deficits. Results of early post-operative and final follow-up visits SRS-22 questionnaires are compared between groups. Total SRS-22 scores were 19.89 ± 1.24 and 21.03 ± 1.22 in Group 1 and 20.28 ± 1.38 and 20.65 ± 1.37 in Group 2, respectively ($p:0.0$). No statistically significant change was observed in terms of self image and mental status domains in either of the groups, however, improvements was detected in terms of pain, function and treatment satisfaction domains. Our findings suggest that in patients with Lenke Type I idiopathic scoliosis, removal of implants before the forth year upon the request of the patient reduces pain and increases functions, provided the fusion has been developed.

Key Words: Scoliosis, surgical treatment, SRS-22 questionnaire, instrumentation.

INTRODUCTION

During the last decade, the three-plane deformity concept of idiopathic scoliosis has led to the evolution of spinal instrumentations correcting the deformity in all three planes. Multiple level fixation with wires or hooks at strategic vertebrae, double rods and transverse connecting devices have become the state-of-the-art technology in addressing this complex problem^(3,14-18). Multiple hook applications to the strategic vertebrae, 'claw' applications to the proximal and distal part of the curve, new locking mechanisms and improved transverse connectors made these systems biomechanically safer and led higher correction rates to be achieved⁽²⁶⁾.

The most significant late complications of adolescent idiopathic scoliosis include implant failure, correction losses, deep infection and pseudoarthrosis⁽²⁶⁾. The removal of implant is not suggested unless these complications have occurred. Bago et al. reviewed the survival for Cotrel–Dubousset instrumentation performed to 133 idiopathic scoliosis cases operated between 1987 and 1995. After a 10 year period, the implant was removed due to implant failure only in 23.5 % of the patients. Authors also suggested a strong correlation between implant failure and preoperative planning⁽¹¹⁾.

Another major reason for implant removal is the presence of postoperative infection. Debridement and antibiotics are usually successful for the treatment of early postoperative infection and implant removal is often not required^(14,26). Benli et al. reported that they found early superficial infection following posterior corrective surgery with Texas Scottish Rite instrumentation in 5 patients and they removed the implants due to deep infection in 3 patients in their idiopathic scoliosis series of 217 patients⁽¹²⁾. Muschik et al. reported easy wound healing in late infections following implant removal at the expense of a decreased

chance of surgical corrective revision⁽¹⁸⁾. Hahn and Zbinden reported deep infection caused by propionibacterium acnes in 6.9% of their 101 operated adolescent idiopathic scoliosis patients. They successfully eradicated infections by removing implants and use of antibiotics⁽²³⁾.

Regarding the long term results of the idiopathic scoliosis, it seems that idiopathic back pain is one of the most important problems^(14,26). The most significant cause of pain at early phases seems to be the injury of paravertebral muscles, in these patients undergoing aggressive surgery⁽²²⁾. The second possible mechanism may be related to the metal disease seen in total hip replacements, which may lead to late back pain. In their study published in 2001, Gaine et al. clinically and histopathologically demonstrated that the most important cause of the late back pain was the metal accumulation around the cross links used to construct a rigid frame⁽¹⁹⁾.

In the literature, there is no study on implant removal due to back pain and subsequent clinical findings. In the present study, we prospectively followed 30 patients operated for idiopathic scoliosis with posterior third generation instrumentation who developed severe idiopathic back pain during the postoperative period. The present study is the first study on this particular subject. Furthermore, the effect of the timing of implant removal was also assessed by categorizing the patients into two groups based on the timing of removal: at the second or third year vs. fourth year or later.

The public surveys on preoperative and postoperative self-image, pain, function and the mental status of the patients with idiopathic scoliosis point out the subjective satisfaction of them and their families. These studies also help us to find out the effect of the treatment on the overall life quality of the patient. The questionnaires like SRS-22, SRS-24 and Short Form-36 are mostly

used ones in recent years^(6-10,22,33-36). In the present study, Turkish version of SRS-22 questionnaire adapted and validated by Alanay et al. was used to evaluate the effect of implant removal on back pain, function and patient satisfaction level⁽¹⁾.

PATIENTS AND METHODS:

Thirty adolescent idiopathic scoliosis patients operated by Dr. Benli in SSK Ankara Diskapi Training Hospital between 1994 and 2001 for the correction of Lenke Type I (Flexible right thoracic scoliosis) deformity were included in the present study. Texas Scottish Rite Hospital system was used for all patients. These patients had admitted to the hospital for severe back pain after at least one year following surgery. The average time to hospital admission for back pain after corrective surgery was 33.1 ± 16.1 months (14-58 months). Implant failure, pseudoarthrosis and infection were excluded by clinical, laboratory, electrophysiological and radiological examinations. After elimination of any possibilities of organic causes, idiopathic back pain was attributed to the implant, as also claimed by the patients. Implant removal was planned following necessary routine laboratory examinations and consultations.

In prone position, entering from the previous incision scar, muscles were exposed gently and implants were achieved. Implants were removed and fusion area was examined carefully, and also the presence of any pseudoarthrosis area was searched thoroughly. Intraoperatively, combined SEP and MEP monitoring and cell saver autotransfusion device were used. Antibiotic prophylaxis was initiated with 1 gram of a first generation parenteral cephalosporin one hour before the operation and maintained with 0.5 gram BID for two days. Approximately 1.8 ± 1.2 unit of blood was transfused to the patients. Culture specimen was obtained from the operation area and biopsy was taken from the fusion area. Thereafter, the

layers were closed in order. Postoperatively on the first day the patients were mobilized. On the fifth day postoperatively, patients were discharged from the hospital. Their sutures were taken at Day 12 and they were called back for follow up visits at 3rd, 6th and 12th months. The final follow-up visits were done in June 2005. At these visits patients were evaluated clinically and radiologically.

Preoperatively and at the end of follow up, SRS-22 questionnaire was administered. It had pain, function, mental state, self-image and treatment satisfaction domains. Each of the first four domains had 5 questions whereas treatment satisfaction domain had 2 questions. Each question was scored over 5 points and total score was divided to 5 for each domain to obtain domain score; and total score for questionnaire was evaluated over 22 points.

In addition, in this study patients were categorized into two groups on the basis of time to postoperative implant removal in order to assess the effect of timing on clinical outcomes. Group 1 and 2, each included 15 patients, had implant removal at the 2nd/3rd year and 4th year or later, respectively. Groups were compared with respect to age, gender, preoperative and postoperative Cobb angle of the curve at frontal plane, correction rates, correction losses and preoperative SRS-22 questionnaire score. Then the effect of implant removal timing on the clinical outcomes was assessed by comparing the questionnaire scores at the end of follow up.

SPSS for Windows 9.0 software was used for the statistical analyses. "Significance test of the difference between two pairs" and "student t-test" were applied. A p value <0.01 was considered significant.

RESULTS:

The mean age of patients at the time of corrective surgery and at the time of implant removal was 13.9 ± 1.4 years (range 12 - 16 y) and 15.9 ± 2.4 y (range 14-18 y), respectively. Female to male ratio was 14:16. The mean time from corrective surgery to implant removal was 33.1 ± 16.1 months, and the mean follow up period was 42.3 ± 8.2 months (minimum 2 years of follow-up).

- Frontal and Sagittal Plane analysis before and after corrective surgery:

When all patients were included in the analysis before corrective surgery, the mean Cobb angle for the curves at the frontal plane was $52.1^\circ \pm 9.1^\circ$ and they were reduced to $9.6^\circ \pm 6.6^\circ$ postoperatively, resulting in a statistically highly significant mean improvement of $82.7\% \pm 9.4\%$ (t: -3.6, p= 0.001) (Table -1). At the last follow-up visit before implant removal, when all patients were included in the analysis, a correction loss of $3.0^\circ \pm 3.2^\circ$ was seen in the scoliotic curve and a statistically significant improvement of the mean Cobb angles ($13.1^\circ \pm 6.8^\circ$) was obtained compared to preoperative values (t: 32.1, p < 0.001).

When all patients were included in the analysis for sagittal plane, mean thoracic kyphosis angle, which was $19.9^\circ \pm 20.7^\circ$ before corrective surgery significantly improved to $36.1^\circ \pm 7.3^\circ$ postoperatively (t: -3.6, p= 0.01). At the last visit before implant removal, there was a minimal loss and mean thoracic kyphosis angles were maintained as $35.8^\circ \pm 8.5^\circ$ (Table-1).

— The assessment of patients before and after implant removal:

All patients were suffering from severe back pain before implant removal surgery and there were no findings suggesting infection, implant fa-

ilure or pseudoarthrosis in the preoperative clinical, radiological and laboratory evaluations. Patients described their pains as localized on the paravertebral region, unresponsive to medical treatment, partially relieved by rest, usually blunt and occasionally penetrating.

No signs of infection or pseudoarthrosis were found during the implant removal operation. There was no growth in the cultures obtained from painful area and no pathology was found in biopsies taken from fusion area. The only notable finding was the relatively thickened fibrous tissue particularly around the rods and cross link plates, and the darkening of this tissue with the appearance of metal residue. Histopathological examination of this fibrous tissue revealed phagocytic metal inclusions.

No early or late complications occurred during and after implant removal and in the follow up period. No infection or neurological deficit was observed.

— End of follow-up evaluation:

In the end of follow-up evaluation following the removal of implants, frontal X-rays revealed a $2.1^\circ \pm 2.0^\circ$ correction loss after a mean duration of 42.3 ± 8.2 months, and the final improvement rates ($81.8\% \pm 8.6\%$) were statistically similar to the improvement rates obtained after corrective surgery (p > 0.05). Also, similar improvement rates were obtained for sagittal plane (mean $34.9^\circ \pm 8.6^\circ$).

The mean scores for pain, function, self image, mental status, treatment satisfaction domains of SRS-22 questionnaire before implant removal operation were 3.97 ± 0.28 , 3.97 ± 0.28 , 4.03 ± 0.29 , 4.05 ± 0.27 and 4.17 ± 0.24 respectively, and total score was 20.18 ± 1.24 (Table-2). When all patients were included, statistically significant improvements were found in pain ($4.06 \pm$

TABLE-1. The results of the patients.

	Follow-up	Age	Preop. Cobb	Postop. Cobb	t	p	Postop. Correction Rate (%)	Follow-up Cobb	t	p	Loss of Correction	Preop. Thoracic Kyphosis	Postop. Thoracic Kyphosis	t	p	Follow-up Thoracic Kyphosis	t	p
2-4. year	42.7 ± 7.4	13.8 ± 1.4	51.6° ± 10.6°	9.4° ± 6.3°	24.20	0.0	82.8 ± 8.7	13.3° ± 5.3°	18.90	0.0	3.5° ± 3.2°	18.7° ± 24.3°	37.2° ± 5.9°	-0.69	0.018	37.7° ± 8.8°	-2.59	0.021
Over 4-y.	42.0 ± 9.1	14.1 ± 1.3	52.6° ± 7.7°	9.8° ± 7.0°	41.9	0.0	82.5 ± 10.4	12.9° ± 8.2°	28.40	0.0	2.5° ± 3.3°	21.1° ± 17.1°	34.5° ± 8.3°	-2.37	0.032	34.0° ± 8.1°	-2.28	0.039
t	0.23	0.61	0.29	0.16	-	-	0.09	0.16	-	-	0.84	0.31	1.22	-	-	1.19	-	-
p	> 0.01	> 0.01	> 0.01	> 0.01	-	-	> 0.01	> 0.01	-	-	> 0.01	> 0.01	> 0.01	-	-	> 0.01	-	-
Total	42.3 ± 8.2	13.9 ± 1.4	52.1° ± 9.1°	9.6° ± 6.6°	42.8	0.0	82.7 ± 9.4	13.1° ± 6.8°	32.1	0.0	3.0° ± 3.2°	19.9° ± 20.7°	36.1° ± 7.3°	-3.6	0.001	35.8° ± 8.5°	-3.5	0.002

TABLE-2. The results of SRS-22 questionnaire

	PAIN			FUNCTION			SELF IMAGE			MENTAL STATUS			SATISFACTION			TOTAL SCORE								
	Preop.	Postop.	t	Preop.	Postop.	t	Preop.	Postop.	t	Preop.	Postop.	t	Preop.	Postop.	t	Preop.	Postop.	t						
2-4. y.	3.86 ± 0.28	4.17 ± 0.32	(-8.06)	0.0	3.91 ± 0.27	4.19 ± 0.32	(-6.38)	0.0	3.99 ± 0.33	4.04 ± 0.29	(-0.41)	0.69	3.99 ± 0.26	4.07 ± 0.23	(-2.16)	0.48	4.15 ± 0.22	4.45 ± 0.29	4.53	0.0	19.89 ± 1.24	21.03 ± 1.22	(-7.15)	0.0
Over 4 y.	4.01 ± 0.32	4.09 ± 0.29	(-3.21)	0.006	3.97 ± 0.33	4.06 ± 0.29	(-3.76)	0.0	4.03 ± 0.29	4.07 ± 0.27	(-2.10)	0.54	4.07 ± 0.29	4.11 ± 0.29	(-1.78)	0.96	4.19 ± 0.27	4.32 ± 0.33	(-3.19)	0.006	20.28 ± 1.38	20.65 ± 1.37	(-5.82)	0.0
t	1.38	0.54	-	-	0.55	1.16	-	-	0.36	0.29	-	-	0.8	0.42	-	-	0.5	1.73	-	-	0.81	0.8	-	-
p	> 0.01	> 0.01	-	-	> 0.01	> 0.01	-	-	> 0.01	> 0.01	> 0.01	-	> 0.01	> 0.01	> 0.01	-	> 0.01	> 0.01	> 0.01	-	> 0.01	> 0.01	-	-
Total	3.97 ± 0.28	4.06 ± 6.6°	(-5.11)	0.0	3.97 ± 0.28	4.12 ± 0.31	4.12 ± 0.31	0.0	4.03 ± 0.29	4.06 ± 0.27	(-1.44)	0.16	4.05 ± 0.27	4.09 ± 0.26	(-2.85)	0.8	4.17 ± 0.24	4.38 ± 0.31	(-5.18)	0.0	20.18 ± 1.24	20.84 ± 1.29	(-6.37)	0.0

0.66), function (4.12 ± 0.31) and treatment satisfaction scores (4.38 ± 0.31), whereas no change was obtained for self image and mental status domains. Hence, a statistically significant improvement was found in total score (20.84 ± 1.29) ($p < 0.001$).

- The effect of timing of implant removal on clinical outcomes :

Of 30 patients included in this study, in 15 patients implants were removed at the second and 3rd year following corrective surgery, and in 15 they were removed at the fourth year or later. These two groups were statistically similar with respect to follow up duration (t: 0.23, $p > 0.01$), mean age at the time of primary operation (t: 0.61, $p > 0.01$), female to male ratios, Cobb angles before (t: 0.29, $p > 0.01$) and after (t: 0.16, $p > 0.01$) corrective surgery, postoperative correction rates (t: 0.09, $p > 0.01$), mean Cobb angles before implant removal (t: 0.16, $p > 0.01$), correction losses (t: 0.84, $p > 0.01$), mean thoracal kyphosis angles before corrective surgery (t: 0.31, $p > 0.01$), mean thoracal kyphosis angles postoperatively (t: 1.22, $p > 0.01$) and before implant removal (t: 1.19, $p > 0.01$) (Table-1).

Regarding preoperative SRS-22 domains before implant removal operation, both groups had statistically similar scores with respect to pain (3.86 ± 0.28 vs. 4.01 ± 0.32), function (3.91 ± 0.27 vs. 3.97 ± 0.33), self image (3.99 ± 0.33 vs. 4.03 ± 0.29), mental status (3.99 ± 0.26 vs. 4.07 ± 0.29), treatment satisfaction level (4.15 ± 0.22 vs. 4.19 ± 0.27) and total score (19.89 ± 1.24 vs. 20.28 ± 1.38) ($p > 0.05$) (Table-2).

These two groups with similar clinical and radiological characteristics and same number of patients were clinically compared at the end of follow-up visit after implant removal operation.

Their SRS-22 scores were also compared (Table-2). Thus, it was shown that statistically similar results were obtained in all domains. Although there were favorable increases in most individual scores and in total scores at the last visit compared to the assessments before implant removal in both groups, improvement in group 1 was greater in terms of pain scores (Table - 2).

DISCUSSION :

Instrumentation systems, first introduced with Harrington Rod system in 1960s, are commonly used in the surgical treatment of adolescent idiopathic scoliosis, basically in order to protect the fusion field until solid fusion formation, to eliminate need for external immobilization (such as a plaster body cast) and the possible related problems, and to enable early movement and rehabilitation^(14,26). As yet, metallurgic and biomechanical instrumentation systems have highly developed. These implant systems have been evaluated in terms of rigidity and biomechanical endurance. Many papers related to high three-dimensional correction and increased fusion rates were reported upon introduction of the third generation instrumentation systems^(3,14-18,22,26).

During recent two decades, several methods have been applied for better correction, especially for scoliosis, which is accepted as a cosmetic deformity. Combined surgical procedures, such as posterior instrumentation following anterior releasing of rigid curves, are among these^(14,26). Fixation of each level of the curve by transpedicular screws and augmentation through sublaminar wiring are the other methods used for the same purpose^(13,24).

In recent years, long-term results of these surgical techniques applied in scoliotic patients demonstrated that, despite high patient satisfaction rate, there are still problems about these techni-

ques, especially with regard to pain and function^(22,25,27). Subjective patient response questionnaires, such as SRS-22, are commonly and increasingly used for the evaluation of clinical results. These studies appear to support surgical success in the long-term^(2,4-10).

Asher et al. reported in their studies that in idiopathic scoliosis patients treated with Isola instrumentation, the self-imaging scores raised at 3rd and 24th months while the function scores lowered at the 3rd month, returned to the baseline at the 6th month and raised again at the 24th month. They also found a reverse correlation between postoperative curve magnitude and the scores^(7,8). White et al. reported the effect of fusion rates on pain scores, and Peres Guesco et al. demonstrated in their CD instrumented 10 year follow-up study that the changes causing pain was not different than the normal population⁽³⁵⁻³⁶⁾. Takahashi et al reported 23 % degenerative change rate at the un-instrumented lumbar site during five to nine years follow-up⁽³⁴⁾. White et al. reported an improvement in functional scores with surgery⁽³⁶⁾.

As the follow-up period got longer and the patients' ages got older, the satisfaction from the treatment increased in the study of Rinella et al., however, the final curve status did not correlate with the satisfaction level⁽³³⁾. Asher et al. could not find a relation between the trunk deformity at the last follow-up visit and the treatment satisfaction level⁽⁴⁾. Haheer et al. also reported that the radiological status did not correlate with the satisfaction level⁽²²⁾.

Review of the studies with long term results demonstrates that pain complaints of the patients are mainly caused by infection, pseudoarthrosis and implant failure⁽²⁶⁾.

One of the main causes of aseptic loosening and pain in total hip replacement procedures is defined as a metal disorder resulting from metal

deposits. Gaine et al. suggested that, especially due to axial plan compulsions and rotational forces, metal accumulation takes place around crosswise connections and this is the main cause of pain with unknown origin⁽¹⁹⁾. In this study, the cause of pain in these 30 idiopathic scoliosis patients with severe idiopathic back pain without any clinically, biochemically, or radiologically identified cause such as implant failure, infection, or pseudoarthrosis, may be metal dust deposits, as also suggested by Gaine et al. Our previous observations also support this explanation. In order to ensure patient homogeneity, only Lenke Type I-A cases were enrolled into this study. After removal of the implants, initially metal deposits are seen macroscopically, then this finding was confirmed histopathologically. Based on our results, a firm conclusion may not be drawn regarding the mechanism how metal deposition leads to pain formation. However, inflammation, phagocytic activity and subsequent release of pain mediators appear to be the most reasonable explanation.

Removing an implant is often considered when there is an implant failure or infection. 10-year survey studies have demonstrated that only one fifth of the implants used in surgical scoliosis therapy are removed. Our literature search failed to identify any study investigating the effect of removing implants on clinical results. Implants were removed in these patients with severe idiopathic back pain, considering this procedure would eliminate the possibility of a permanent metal disorder. Implants were removed average 33.1 months after corrective surgery and clinical results were evaluated after a mean duration of 42.3 months. At the end of this period, a minimal - and less than when implants were in place - correction loss ($2.1^\circ \pm 2.0^\circ$) was observed; and corrections were maintained at both frontal and sagittal planes, due to the development of solid fusion mass.

Statistically significant improvement was detected in SRS-22 query scores, including pain, function, mental status, self-image, and satisfaction domains, at the last follow-up visit compared to the preoperative period. Total score was increased from 20.18 ± 1.24 to 20.84 ± 1.29 . These data appear to support the hypothesis that removing implants is favorably affecting clinical outcomes.

In addition, the possible effect of implant removal timing on clinical outcomes was also investigated. We could not also find any previous study investigating this subject. Two groups each with 15 patients were formed on the basis of the timing of implant removal, either in the second and 3rd postoperative year or at the fourth year and later. All clinical and radiological features of these two groups were statistically similar before and after corrective surgery and at the visit just before the removal of the implants. SRS-22 query results were also similar for these two groups for all domains at the final visit after the removal of implants. Although these results suggest that the timing of implant removal is not important in terms of clinical outcomes, patients in group 1 (earlier removal) had higher scores for pain, function and satisfaction domains compared to group 2 (later removal).

These findings suggest that, removal of implants before the 4th year, even upon the request of the patient, favorably affects the outcome in Lenke Type I idiopathic scoliosis patients, particularly in terms of pain complaints and function, provided that fusion has been developed.

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