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ORTHOPAEDIC OUTCOME ASSESSMENT

Implant removal after posterior stabilization of the thoraco-lumbar spine

Stavros I. Stavridis · Petra Bücking · Stefan Schaeren · Bernhard Jeanneret · Klaus John Schnake

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Abstract
Introduction Implant removal because of pain after posterior fusion in the thoracic and lumbar spine is a widely performed operation. We conducted a retrospective study to examine whether patients benefit from implant removal.
Patients and methods 57 patients (29 males, 28 females, mean age 46.5 years) who have undergone removal of pedicle screws because of pain and discomfort were interviewed 6–24 months postoperatively. Fracture was the initial diagnosis in 40% of the patients and degenerative spine disease in 58%. The following factors were evaluated: patient satisfaction and postoperative outcome, patients' native language and psychological background, operative data, hospital stay and complications.
Results Pain decreased significantly from 62 to 48 on visual analogue scale postoperatively. Complications occurred in five patients (8.8%). 36 patients (61%) stated they had some benefit from the operation, but only seven patients (12%) were free of pain completely. 36 patients (63%) would undergo the same procedure again. Outcome in the subgroup of foreigners was significantly worse, though the psychological background did not affect the outcome. Preoperative diagnostic infiltration was helpful in 9 of 13 patients.
Conclusion Removal of pedicle screws because of back pain may be effective, but complete remission of symptoms could be achieved in only 12% of patients. However, 63% of patients would undergo hardware removal again. Preoperative diagnostic infiltration can help to predict the outcome but results are inconsistent. Communication difficulties may worsen the outcome. Surgeons should consider these results when planning implant removal and patients should be informed thoroughly to avoid too high expectations.

Keywords Implant removal · Thoraco-lumbar spine · Pedicle screws · Clinical outcome

S. I. Stavridis
First Orthopaedic Department, G. Papanikolaou Gen. Hospital, Aristotle University of Thessaloniki, Exohi, Thessaloniki, Greece

P. Bücking
Department of Orthopedic Surgery, St Elisabeth-Hospital Herten, Herten, Germany

S. Schaeren · B. Jeanneret
Center for Musculoskeletal Diseases/Spine, University of Basel, Basel, Switzerland

S. I. Stavridis · K. J. Schnake (✉)
Center for Spine Surgery and Neurotraumatology, BG-Unfallklinik Frankfurt am Main, Friedberger Landstraße 430, 60389 Frankfurt am Main, Germany
e-mail: klaus.schnake@bgu-frankfurt.de

Introduction

Although implant removals account nowadays for almost one-third of all elective operations in orthopaedics [1], there is still an ongoing debate concerning the necessity of such procedures. A relatively high complication rate ranging from 3 to 20% [2–4] combined with issues of effective resources and time management has shifted the trend towards an implant removal policy only in presence of clear clinical indications justifying the procedure.

In spinal surgery the issue of routine implant removal after a successful fusion is by far more controversial. In the past decades, the number of instrumented spinal fusions has increased exponentially and so has the

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concern about the benefit-loss equilibrium after implant removal. The ill-defined borders between medical indications and patients' demands [5] render the routine implant removal after consolidation is achieved at least questionable.

Some indications for implant removal have gained wide acceptance in spinal surgery. Treatment of infection after failed repeated surgical debridement and prolonged antibiotic administration, pedicle screw misplacement, instrumentation failure and instrumentation protrusion are cases where the patient is expected to benefit substantially after implant removal.

Especially after degenerative lumbar spine surgery, there still remains a group of patients with persistent low-back pain that cannot be attributed to any of the aforementioned pain generators. In such patients, implant removal still remains controversial, although implant removal after thorough intraoperative fusion exploration may alleviate their pain [6, 7].

Spinal implant removal should under no means be considered as a benign, harmless procedure. It constitutes a second operative procedure with significant risks such as large vessel injuries, loss of sagittal plane correction or compression fractures [5, 8, 9].

There are only few studies in the literature addressing the issues of implant removal after spinal surgery.

The aim of this retrospective study was to evaluate safety and efficacy of implant removal and to determine predictors for success that would possibly preoperatively indicate those patients, who would most likely benefit from an implant removal, when pain and discomfort are the only indications for the procedure.

Patients and methods

Within 18 months, 726 patients underwent a thoraco-lumbar spinal operation at the Center for Musculoskeletal Diseases/Spine, University of Basel, Switzerland. Out of the 726 patients, 62 (8.5%) had undergone an implant removal procedure and fulfilled the inclusion criteria for this retrospective study. All patients had posterior transpedicular instrumentation in the thoraco-lumbar spine removed because of pain and discomfort and were in accordance with the following inclusion criteria:

- The indication for the primary procedure had been either degenerative spinal disease or spinal fracture.
- The patients had received either posterior transpedicular instrumentation alone or combined anterior fusion with posterior transpedicular instrumentation.
- The indications for implant removal had been pain and discomfort.
- The posterior transpedicular instrumentation had been removed.
- The preoperative radiographs indicated solid fusion.

Patients with routine implant removal after temporary bisegmental fracture stabilization and patients in whom infection was diagnosed were not included in the study.

The patients were interviewed 6–24 months postoperatively (mean 9 months) either per phone contact or vis-à-vis and the patients' hospital charts were reviewed.

Following data were collected through the patients' interviews:

- Patient's profile including native language and mental disorders.
- Intensity and temporal development of pain, by using a visual analogue scale (VAS for pain; scale: 0 = no pain, 100 = maximum pain).
- Subjective improvement following implant removal and its duration.
- Patient's satisfaction with the operation and willingness to undergo the same operation again.

Through the review of hospital's charts the following objective data were collected:

- Patients' demographics (age, gender).
- Indication for primary spinal surgery and existence of spinal comorbidities such as osteochondrosis, disc protrusions, spinal stenosis, spondylolisthesis etc.
- Preoperative evaluation and whether a diagnostic infiltration of the painful operative site had been undertaken before implant removal.
- Type of primary operation.
- Surgeon, duration, blood loss, intraoperative findings.
- Time interval between primary operation and implant removal.
- Intra- and postoperative complications.

Statistical analysis

For statistical analysis of the collected data the SPSS (Chicago, IL, USA) program for statistical analysis was used. The Chi-square test was used to determine the statistical significance of the examined parameters and the Kruskal–Wallis not parametric test and Wilcoxon test were used for non parametric values. P values lower than 0.05 ($P < 0.05$) were considered to be statistically significant.

Results

57 of 62 patients (92%) who had undergone an implant removal procedure and fulfilled the inclusion criteria for

this retrospective study could be interviewed and enrolled in the study. 29 of them were men and 28 women with a mean age of 46.5 years (range 21–84).

The native language of 46 (81%) patients was either German or French. 13 (23%) patients displayed an altered psychological profile, with six suffering from depression, three having a history of suicide attempt and two having a history of alcohol abuse.

Fracture was the initial indication for surgical treatment in 23 (40%) cases, while 33 (58%) patients were operated upon because of degenerative spinal disease, and in one case a vertebral haemangioma was diagnosed.

35 patients (61%) also showed further spinal comorbidities on radiographic examinations, among which osteochondrosis and intervertebral disc protrusion were the most common (24%).

In all cases a posterior fusion was performed, combined with a PLIF procedure in 6 (11%) and with anterior fusion in 12 (21%) cases.

Posterior stabilization included the following anatomic regions: 44% lumbosacral junction, 26% lumbar spine, 19% thoraco-lumbar junction, 9% thoracic spine and in one patient the fusion extended from the lower thoracic spine to the sacrum.

The indication for implant removal had been "implant-associated" pain in all cases. The mean preoperative VAS for pain was 62, ranging from 10 to 100.

Intraoperatively, two patients did not show solid fusions.

In 13 (23%) patients diagnostic infiltration was performed preoperatively, with 8 (62%) reporting at least 50% temporary improvement, including the 2 patients with pseudarthrosis.

The mean hospital stay was 7.1 days, ranging from 1 to 20, and in the majority of the cases the operative procedure was undertaken by residents (55%).

Complications were reported in five (8.8%) cases: one infection, one haematoma of the psoas and one case of transient brachial plexus paresis. Two patients reported immediate postoperative pain of unknown origin as a surgical complication.

On average, pain decreased significantly from 62 to 48 on VAS (ranging from 10 to 100) after implant removal ($P < 0.001$).

35 (61%) patients reported an improvement after surgery that was complete in 7 (12%) cases, incomplete in 25 (44%) and temporary in 3 (5%) of the cases. Temporary improvement lasted 3.3 weeks on average, ranging from 1 to 20 weeks. The remaining 22 (39%) patients reported no improvement after surgery.

36 (63%) would be willing to repeat the surgery, 18 (32%) would not and 3 (5%) were undecided at the time of follow-up.

In terms of overall patient satisfaction, 38 (67%) patients were very satisfied or satisfied, 6 (11%) were undecided and 13 (22%) were very dissatisfied or dissatisfied. Interestingly, the two patients with pseudarthrosis reported to be satisfied, too.

Out of the 13 patients who underwent preoperative diagnostic local infiltration, only 4 (31%) reported a similar effect of both infiltration and surgery. 5 (38.5%) patients stated that surgery was more effective reducing pain than infiltration.

The results from the subgroup of patients whose native language was other than either German or French are shown in Table 1. The postoperative results in terms of pain improvement were significantly worse in this subgroup compared to other patients ($P < 0.05$). The results from the patients with a conspicuous psychological profile are shown in Table 1, too. These results did not differ significantly compared to other patients.

Other parameters such as, age, gender, spinal comorbidities, type of primary operation (trauma or degenerative), type of implant and reported complications were found to have no impact on final outcome.

Discussion

In the past decades, the sharp increase of implant use for orthopaedic surgical treatment has lead to a respective raise in implant removal procedures, with the latter accounting for up to almost one third of elective orthopaedic operations and for 5–15% of all orthopaedic operations. Spinal implants rank among the five most common implants being removed after bone fusion is achieved [1].

In spinal surgery implant removal is performed for a number of indications, such as infection treatment, misplaced implants, implant failure, protruding instrumentation

Table 1 Pain improvement in subgroups of patients

Pain improvement	All patients $N = 57$	Patients with mental disorders $N = 13$	Neither French nor German speaking patients $N = 12$
Complete	7 (12%)	1 (8%)	0
Incomplete	25 (44%)	6 (46%)	4 (33%)
Temporary	3 (5%)	1 (8%)	1 (8%)
None	22 (39%)	5 (38%)	7 (58%)

and routinely after fracture treatment with instrumentation of non-fused segments [6].

Apart from this patient group with distinctive indications for implant removal, there still remain a number of patients with unknown official pain generators, but possibly still with "implant related" pain.

In our retrospective study we examined 57 patients with "implant-related" pain and found a significant pain reduction on VAS from a 62-point preoperative score to 48 points postoperatively. 56% of patients reported a complete or at least incomplete pain reduction after implant removal. 67% of patients were either very satisfied or satisfied with the operation and 63% would undergo the same procedure again.

Such surgical procedures should not be considered harmless for the patients. In our series the complication rate was 8.8% with none of them being characterized as serious. According to the literature, implant removals display relatively high complication rates ranging from 3 to 20% [1–4]. Especially for spinal implant removals, some complications (e.g. infections, loss of reduction) may be severe and require revision surgery [5, 9–11] or be even life threatening (e.g. vessel injury) [8]. Since implant removal is a highly elective surgical therapy, patients must be informed about possible complications thoroughly.

The first step in postoperative "implant-related" pain exploration is to rule out mechanical implant loosening and pseudarthrosis as two of the most common pain generators. There is an ongoing debate on the efficacy of modalities available to effectively rule out these diagnoses. It was proposed in an experimental study that in cases of solid bony fusions even a single loose screw could be considered as a pain generator through prostaglandin production and activation of complex pain-related pathways in molecular level [12].

Careful intraoperative examination is considered by many authors as the "gold standard" in excluding a pseudarthrosis [6, 7]. Implant removal for pain reduction in such cases of existing solid fusion is questionable with controversial findings reported [7, 13]. Two of our patients had pseudarthrosis, but both of them were satisfied after implant removal.

Increased loss of correction after spinal implant removal further challenged the efficacy of intraoperative exploration in manifesting a solid fusion [5]. A possible "pseudarthrosis-analogue" undetectable with imaging modalities or even direct surgical exploration may be held responsible, at least to some extent, for some cases of unsolved postoperative pain.

Another cause for postoperative "implant-related" pain is believed to be metal fretting, corrosion or an allergic response to the metalwork. In such cases implant removal would most likely alleviate pain but such a diagnosis still remains a diagnosis of exclusion, especially because of the widespread use of titanium implants nowadays [14].

It was recently proposed that even in the absence of typical signs of infection, an infection caused by low-grade pathogens (e.g. Propionibacteria) may still be present and remain undetected due to the unreliability of inflammatory diagnostic markers and inadequacy of sample collection and culture methods [15]. Thus a number of cases of "implant-related" pain of unknown origin could be attributed to such low-virulence bacteria. In our series, we excluded patients with obvious signs of infection. However, the cited study shows that histological and microbiological examination may be helpful in unclear cases.

Existing limited data render the results of spinal implant removal to address the problem of postoperative pain in the absence of a known pain generator highly unpredictable and our results do support this notion. In our study only 12% of the patients were "fully healed" after implant removal; still 56% of the patients gained long-term profit from the procedure.

Preoperative diagnostic infiltration of the screw heads under fluoroscopy control led to at temporary improvement of more than 50% in 8 of 13 patients. On the other hand, five (38.5%) patients stated that surgery had been more effective than infiltration in reducing pain. The results of diagnostic infiltration appear to have only moderate predictive value in contrast to other findings [7]. Nonetheless, diagnostic infiltrations are definitely helpful to indicate patients for implant removal.

Our data failed to reveal any possible predictive value for various objective factors. Age, gender, spinal comorbidities, type of operation, type of implant and reported complications were found to have no impact on final outcome.

This lack of objective predictive factors enhances the possible role of patient profile in determining the final outcome. In our study, patients with a different native language did profit less from the implant removal procedure. None of the 12 foreign patients was completely free of pain and only 4 (33%) foreign patients reported an incomplete pain reduction. This was the only factor in our study found to have a statistically significant predictive value. Misunderstanding caused by insufficient translation may have caused this.

On the other hand, psychological diseases (depression, suicide attempt, alcohol abuse) do not seem to constitute an exclusion diagnosis for implant removal since their outcome is comparable to the main group of patients.

Conclusion

Removal of pedicle screws because of back pain only leads in 12% of patients to complete remission of symptoms.

However, 63% of patients would undergo the same procedure again. Complications occur frequently (8.8%). Preoperative diagnostic infiltration can help to predict the outcome, but results are inconsistent. Communication problems caused by language difficulties may worsen the outcome.

Surgeons should consider these results when planning implant removal and patients should be informed thoroughly to avoid too high expectations.

The ideal patient, who will most likely significantly benefit from implant removal, should display preoperatively a well localized implant-related pain, and have undergone a conclusive diagnostic infiltration. Furthermore, the patient should be capable of limiting his expectations within realistic levels. Of outmost importance, he or she should under no means become obsessed with the implant and its removal, since the final result of such a procedure remains unpredictable.

References

1. Bostman O, Pihlajamaki H (1996) Routine implant removal after fracture surgery: a potentially reducible consumer of hospital resources in trauma units. J Trauma 41(5):846–849
2. Brown RM, Wheelwright EF, Chalmers J (1993) Removal of metal implants after fracture surgery—indications and complications. J R Coll Surg Edinb 38(2):96–100
3. Richards RH, Palmer JD, Clarke NM (1992) Observations on removal of metal implants. Injury 23(1):25–28
4. Sanderson PL, Ryan W, Turner PG (1992) Complications of metalwork removal. Injury 23(1):29–30
5. Deckey JE, Court C, Bradford DS (2000) Loss of sagittal plane correction after removal of spinal implants. Spine 25(19):2453–2460
6. Wild A, Pinto MR, Butler L, Bressan C, Wrobleswski JM (2003) Removal of lumbar instrumentation for the treatment of recurrent low back pain in the absence of pseudarthrosis. Arch Orthop Trauma Surg 123(8):414–418
7. Alanay A, Vyas R, Shamie AN, Sciocia T, Randolph G, Wang JC (2007) Safety and efficacy of implant removal for patients with recurrent back pain after failed degenerative lumbar spine surgery. J Spinal Disord Tech 20(4):271–277
8. Vanichkachorn JS, Vaccaro AR, Cohen MJ, Cotler JM (1997) Potential large vessel injury during thoracolumbar pedicle screw removal. A case report. Spine 22(1):110–113
9. Waelchli B, Min K, Cathrein P, Boos N (2002) Vertebral body compression fracture after removal of pedicle screws: a report of two cases. Eur Spine J 11(5):504–506
10. Potter BK, Kirk KL, Shah SA, Kuklo TR (2006) Loss of coronal correction following instrumentation removal in adolescent idiopathic scoliosis. Spine 31(1):67–72
11. Rathjen K, Wood M, McClung A, Vest Z (2007) Clinical and radiographic results after implant removal in idiopathic scoliosis. Spine 32(20):2184–2188
12. Johnson D, Tucci M, McGuire R, Hughes J (1996) Evaluation of the biomaterial-interface of screw threads in patients having clinical pain. Biomed Sci Instrum 32:127–133
13. Hume M, Capen DA, Nelson RW, Nagelberg S, Thomas JC Jr (1996) Outcome after Wiltse pedicle screw removal. J Spinal Disord 9(2):121–124
14. Gaine WJ, Andrew SM, Chadwick P, Cooke E, Williamson JB (2001) Late operative site pain with isola posterior instrumentation requiring implant removal: infection or metal reaction? Spine 26(5):583–587
15. Collins I, Wilson-MacDonald J, Chami G, Burgoyne W, Vineyakam P, Berendt T et al (2008) The diagnosis and management of infection following instrumented spinal fusion. Eur Spine J 17(3):445–450