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Clinical Article

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Efficacy of Spinal Implant Removal after Thoracolumbar Junction Fusion

Objective : The purpose of this study was to evaluate the efficacy of spinal implant removal and to determine the possible mechanisms of pain relief.

Methods : Fourteen patients with an average of 42 years (from 22 to 67 years) were retrospectively evaluated. All patients had posterior spinal instrumentation and fusion, who later developed recurrent back pain or persistent back pain despite a solid fusion mass. Patients' clinical charts, operative notes, and preoperative x-rays were evaluated. Relief of pain was evaluated by the Visual Analog Scale (VAS) pain change after implant removal. Clinical outcome using VAS and modified MacNab's criteria was assessed on before implant removal, 1 month after implant removal and at the last clinical follow-up. Radiological analysis of sagittal alignment was also assessed.

Results : Average follow-up period was 18 months (from 12 to 25 months). There were 4 patients who had persistent back pain at the surgical site and 10 patients who had recurrent back pain. The median time after the first fusion operation and the recurrence of pain was 6.5 months (from 3 to 13 months). All patients except one had palpation pain at operative site. The mean blood loss was less than 100ml and there were no major complications. The mean pain score before screw removal and at final follow up was 6.4 and 2.9, respectively ($p<0.005$). Thirteen of the 14 patients were graded as excellent and good according to modified MacNab's criteria. Overall 5.9 degrees of sagittal correction loss was observed at final follow up, but was not statistically significant.

Conclusion : For the patients with persistent or recurrent back pain after spinal instrumentation, removal of the spinal implant may be safe and an efficient procedure for carefully selected patients who have palpation pain and are unresponsive to conservative treatment.

KEY WORDS : Spinal implant · Back pain.

INTRODUCTION

With the increasing prevalence of posterior segmental spinal instrumentation, many patients live with prominent spinal implants or persistent back pain after surgery. This is especially true in the cases of multi-level fixation that often extend into the thoracic spine where soft tissue coverage is limited. These screws or rods tend to be prominent and often irritating. The etiology of failed fusion surgery may include a wide array of conditions including pseudoarthrosis, infection, flat back adjacent level failures, and painful implants[7]. There is a small group of patients who have recurrence of pain despite the lack of broken implants and pseudoarthrosis or any other obvious pain generators. In patients who presented with recurrent persistent back pain and with no other specific causes proven to be pain generators, implant removal and exploration of fusion may be an appropriate procedure to attempt to alleviate their pain[9]. However, any a few reports have been published on the effects of hardware removal after instrumented spinal fusions[6,9]. The goal of this study was to evaluate the efficacy and safety of implant removal for patients who had persistent or recurrent back pain after a multi-level spine fusion surgery at the thoracolumbar junction.

MATERIALS AND METHODS

This was a retrospective study evaluating patients who underwent removal of spinal implants due to persistent or recurrent back pain after posterior fusion surgery in our institute between January 2003 and May 2005. The patients who had posterior spinal instrumentation and fusion as the surgery due to various etiologies before removal of

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implants involving thoracic spine, who later developed recurrent back pain or complained of persistent back pain despite a solid fusion mass and underwent removal of implant were included (Table 1). All patients had persistent or recurrent back pain unresponsive to medication, physical therapy or all kinds of block. There were 4 patients who had persistent back pain at surgical site and 10 patients who had recurrent back pain. Thirteen out of fourteen patients had palpation pain at the surgical sites whereas one patient had no pain during palpation. All patients were believed to have a solid arthrodesis and no other pain generator such as adjacent segment degeneration, flat back deformity, pseudoarthrosis investigated by the rigorous diagnostic methods such as simple radiographs and computed tomography. Preoperative x-rays were evaluated for the number of fusion levels, type of implant, and the presence of a "halo sign" around screws to identify loosening at the pedicle screw-bone interface. A halo sign of more than 2 mm of thickness around the screws were accepted as a sign of loosening and the patients with halo sign were excluded from this study. Those who required a secondary fusion procedure during the implant removal due to pseudo-arthrosis were also excluded. Pain outcome was evaluated by using the visual analogue scale (VAS). Patients rated their pain on the VAS (0=no pain to 10=imaginable severe pain) prior to surgery, 1 month after surgery, and at final follow up. Patients were stratified according to the modified MacNab's criteria. Lateral plain radiographs were obtained before implant removal, 1 month after implant removal, and at final follow up. Radiological measurements of preoperative and postoperative sagittal plane angulation after the procedure were performed. For determination of the kyphotic angle, measurements were taken from the intersection of superior and inferior endplate of the involved body. Comparisons between different time points were done using paired student's test. Differences were considered as statistically significant with p value less than 0.05.

Table 1. Clinical characteristics of patients

Case	Age	Sex	Indication for fusion Surgery	Palpation pain	Implant +PF Level	Follow-up period (months)
1	37	M	T12 bursting fx	+	T10-L1	12
2	22	M	L1 compression fx	+	T11-L2	17
3	32	F	L1 compression fx	+	T11-L2	21
4	48	M	T12 tbc spondylitis	+	T11-L1	22
5	38	M	L1 compression fx	+	T11-L2	17
6	40	F	T12 compression fx	+	T10-L1	19
7	43	M	T12 compression fx	+	T11-L1	22
8	49	F	T11-T12 ossification of yellow ligament	+	T11-T12	18
9	54	M	T12 bursting fx	-	T10-L1	13
10	42	F	L1 compression fx	+	T12-L2	14
11	67	M	L1 bursting fx	+	T11-L2	15
12	27	M	L2 compression fx	+	T12-L3	25
13	39	M	T10 compression fx	+	T8-T11	21
14	51	M	T12 bursting fx	+	T10-L1	13

PF : posterior fusion fx : fracture

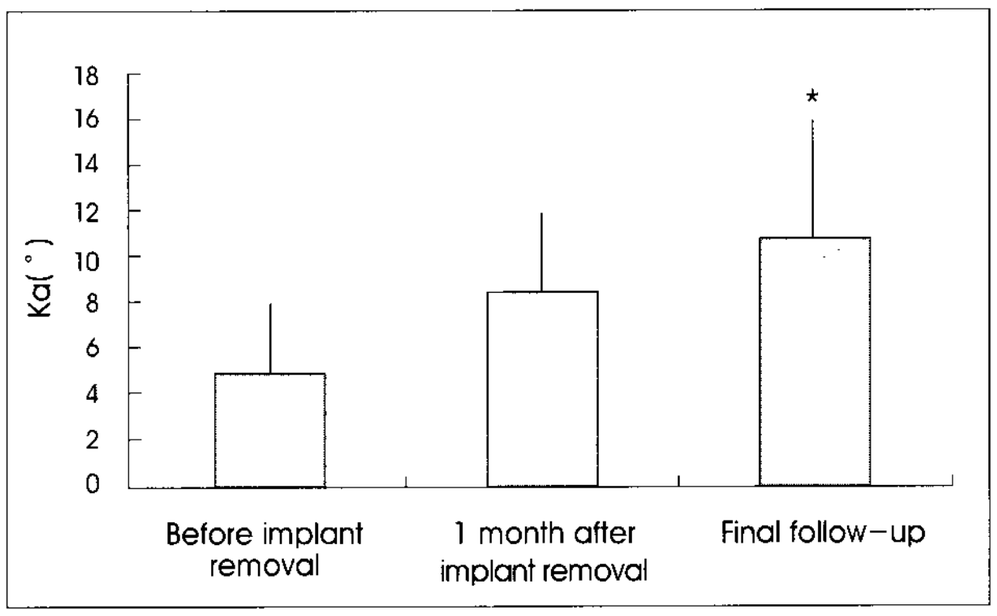

Fig. 1. Radiographic measurement of pre- and postoperative kyphotic angle. *p>0.05 for preoperative versus final follow up.

RESULTS

The average follow-up period was 18 months after implant removal (range 12-25 months). In patients with recurrent back pain, the median time after first fusion operation and the recurrence of pain according to patients' reports was 6.5 (from 3 to 13 months). The median time interval between the fusion procedure and implant removal was 15 months (range 11-24 months). The levels from which the implant was removed are listed in Table 1. None of the patients had clinical or hematologic signs of infection at the time of implant removal. All patients were noted to have bursae tissue formation around the implants meaning solid fusion. None of them were reported to have corrosion. No patient showed loosening of the screw-bone interface in the operative fields. The mean pain score immediately before implant removal was 6.4 and the mean pain score 1 month after implant removal was 2.6. The mean pain score at final follow-up (12-25 months) was 2.9. There was statitistically significant pain relief (p<0.005). The average

Table 2. Modified MacNab's outcome assessment of patient satisfaction with the surgical procedure at final clinical follow-up

Outcome	Description of criteria	Number of patients
Excellent	No pain; no restriction of mobility; return to normal work & level of activity	9
Good	Occasional nonradicular pain; relief of presenting symptoms; return to modified work	4
Fair	Some improved functional capacity; still handicapped and unemployed	1
Poor	Continued objective symptoms of root involvement; additional operative intervention needed at the index level irrespective of length of postoperative follow-up	0

preoperative, 1 month after implant removal and final follow-up kyphotic angles are listed in Fig. 1. The overall preoperative kyphotic angle was 5.0 degrees. Approximately 3.5 degrees of correction loss was observed 1 month postoperatively in this series. At final follow-up, the average amount of kyphotic angle obtained overall was 10.9 degrees, representing a 5.9 degrees change in angulation from the original but it was not statistically significant ($p<0.05$). Thirteen out of 14 patients were graded as having a excellent or good result according to the modified MacNab's criteria (Table 2). The patient without palpation pain showed "fair" outcome according to the modified MacNab's criteria.

DISCUSSION

Although patients' outcomes are improving and fusion rates are high, some patients may have persistent back pain or recurrence of back pain after spinal fusion accompanying pedicular screw fixation. The etiology of failed degenerative spine surgery may include a wide array of conditions. Recurrent back pain after fusion may be caused by pseudoarthrosis, flat back deformity, failure of adjacent segments, painful discs under a posterolateral fusion and painful implants[4]. Among them, painful implants are usually a consequence of loosening or breakage of implants due to pseudoarthrosis. Some patients may have back pain over the operative site despite the lack of pseudoarthrosis. The removal of spine implants for pain relief in patients with solid fusion has been a matter of debate[1,2,6]. The role of spinal implant removal continues to be vague regarding the management of persistent pain and symptoms after spinal fusion. The mechanism as to how the implant generates pain is not completely understood. The indications and results of spinal implant removal with respect to pain relief are unknown. Although the outcome appears to be unpredictable, the removal of instrumentation often is believed to be a relatively benign procedure. Therefore, neurosurgeons will consider removal of instrumentation in an attempt to alleviate patients' symptoms. However, De Palma and Rothman reported 5 of 9 (56%) patients had either temporary or no relief of pain with solid fusions after removal of implants[3]. In another study, Hume et al retrosectively reviewed 30 patients after implant removal after a previous posterior spinal fusion using Wiltse pedicle screw fixation[6]. Ten patients were confirmed to have pseudoarthrosis whereas 20 patients had a solid arthrodesis. All 30 patients had persistent back pain limiting activities and motion range. Patients found to have pseudoarthrosis were significantly more likely to have less pain, use fewer narcotic medications, and had improved quality of life after reoperation compared to those patients found to have solid fusions. The authors concluded that patients who had a solid fusion and had removal of implants did not benefit from surgery and removal of implants should not be favored in this group of patients. However, others advocated that implant removal can reduce back pain. Wild et al. in a retrospective study, have demonstrated significant pain relief after the removal of implants in the absence of pseudoarthrosis in a group of 45 patients who underwent prior anterior and posterior lumbar spinal fusion[9]. They noted increased success rate in patients with loose implants. However, the outcome evaluation done in a retrospective manner like this study was a major drawback. In this setting of patients with persistent back pain after a successful fusion without an obvious pain source, the present study demonstrated a significant reduction in pain after implant removal. Although still unproven, there are some theories as to why retained implants can be a source of recurrent back pain. Inflammation due to infectious or noninfectious causes such as metallic corrosion, debris, and local irritation by prominent implants have been postulated to cause implant-related pain. Hume et al, proposed that thin patients might be expected to have better outcomes due to prominence of instrumentation at thoracolumbar area[6]. Gaine et al, also found that although bacterial cultures were often negative, histologic evidence revealed that low-grade infection played a important part in late operative site pain, based on the abundant granulation tissue containing many neutrophils and plasma cells found around implant[5]. Due to its retrospective character, it is not the purpose of this study to define the etiology of implant-related pain. However, there is a consensus that the final pathway among these hypotheses is the inflammatory process. In the current series, although

there was no statistical significance, the localized palpation pain at the surgical areas of the retained implants in a majority of patients, and these patients had more improvement in pain relief after implant removal. We believe that the correlation of this finding with the relief of pain after implant removal indicates the inflammatory process may be the main pain generator related to implants. We favor the existence of palpation pain as a helpful tool to predict the efficacy of implant removal in those particular patients based on the high correlation of pain relief after the implant removal. Pain around the operative site and increasing pain during palpation are usually typical clinical findings. The most consistent predictor of pain relief after implant removal is the percent pain relief after the diagnosis of the painful regions on and around the operative site.

CONCLUSION

We believe that retained implant may be one of the pain generators in patients with back pain after spine surgery. Removal of the implant may provide a significant pain relief and be a safe procedure for carefully selected patients with implant-related pain.

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