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The Olerud Cervical Fixation System; A Study of Safety and Efficacy

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ABSTRACT

To evaluate safety and efficacy of the Olerud Cervical Fixation System a one-year follow up study was done by an independent observer. There were 30 patients (14 women) with a mean age of 68 (37-85) years. Indications were rheumatoid arthritis in 10, spinal stenosis in 6, trauma in 6, metastases in 4, revisions in 3, and painful spondylotic deformity in one patient. Short fusions were performed in 8 patients and long fusions in 22. Four patients were fused to occiput. C1-C2 fusion was performed in 3 patients. Nineteen of the 20 still alive were evaluated at follow up. One patient was deliberately fused in hyperlordosis, in the rest the alignment was acceptable. Primary stabilization was achieved in all but one. 107 pedicle screws were used; one screw in Th2 was placed lateral to the pedicle. 42 subaxial transarticular screws were used. There were no complications related to these screws. One patient experienced a non-instrument related neurological deterioration. Two infections and one hematoma drainage healed on conservative treatment. Loss of fixation and non-union developed in 2 patients. Patients with metastasis or myelopathy due to rheumatoid arthritis carried a high mortality risk. The Olerud Cervical Spine Fixation System is versatile in posterior fixation of the cervical spine and has proven to be both safe and efficient.

INTRODUCTION

Posterior cervical spine fixation has previously been done with cerclage wiring or lateral mass plates. Recognized drawbacks of wiring have been insufficient stability and the risk involved with passing sublaminar wires. Drawbacks of posterior plates are limited variability in screw positioning and mechanical insufficiency due to screws backing out. A solution to these problems would be a fixation instrument where screws and hooks are mechanically locked to longitudinal rods. Available down-sized "pediatric" scoliosis systems may be considered, but most of these are still too big in

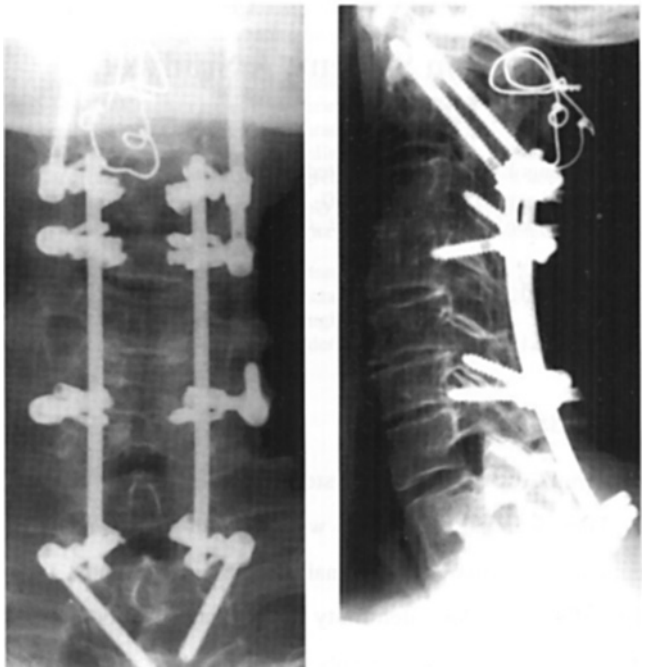

Figure 1 The system allows different screw positioning techniques to be used in the same construct. This 76 year old man (patient #1) with rheumatoid arthritis and a previous C1-C2 fusion developed subaxial subluxation with mainly local pain. He was fused from C1 to Th1 with transarticular screws in C1-C2, pedicular screws in Th1, and lateral mass screws on the left side and subaxial transarticular screws on the right side in the lower cervical spine. The one-year follow-up radiographs show solid fusion in good alignment.

our opinion. The AO/ASIF Cervifix is of appropriate size and allows a somewhat freer choice of fixation points compared to plates, but does not meet our requirements as the screws are not mechanically locked to the rods and there are problems with combining various screw positioning techniques in the same construct.

To meet our need of a rod-based device for posterior fixation of the cervical spine the Olerud Cervical Fixation System was developed. The instrument can be used in single- as well as multilevel fixation from occiput to the upper thoracic spine for a variety of different conditions

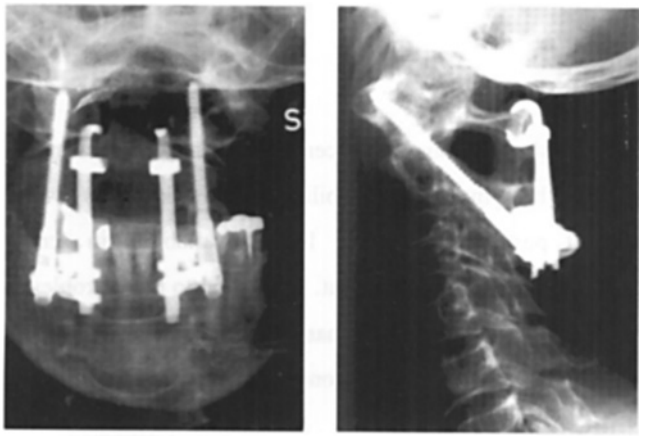

Figure 2. The C1-claw device combined with transarticular screws and autologous bone chips graft were used to treat this patient (#27) who had both rheumatoid arthritis and an odontoid fracture. The one year follow-up radiographs reveal a mature posterior fusion mass.

including: trauma, tumor, rheumatoid arthritis,malformation, deformity, and degenerative conditions. The system is made of titanium. It includes both bone screws and lamina hooks which are independently mechanically locked to longitudinal rods. Different screw or hook positioning techniques can be combined in the same construct (Figure 1). The screws are first fixed to the vertebrae, then the rod construct is attached to the screw ends. A special device, the C1-Claw, is designed to grip the C1 arch (Figure 2). Before the clinical application the system was tested biomechanically by Bryan W. Cunningham, M.Sc. at the Orthopaedic Biomechanics Laboratory, Union Memorial Hospital, Baltimore, Maryland, USA. An experimental setting identical to that of a previously published study by the same research group was used [16]. The system had an immediate stability equal to that of posterior plates. After cyclic loading the system retained its stability better than the compared fixation techniques (Data on file). To evaluate the safety and efficacy of the device we performed a one year follow up study of the first 30 cases. The follow up was done by an unbiased observer from another university institution not involved in the surgery (BL).

PATIENTS

The series consisted of the first 30 consecutive patients (14 women) fitted with the implant system. The mean age was 68 (37-85) years. Patient demographics are seen in the general table (Table 1). Ten of the patients underwent surgery for rheumatoid arthritis, 6 for cervical spinal stenosis, 6 for trauma, 4 for malignant metastases, 3 for revision of failed previous fixations, and one for a painful spondylotic deformity. For the rheumatoid patients the indications were severe pain or impending neurological threat. One of the rheumatoid patients underwent a C1-C2 fusion for instability, the

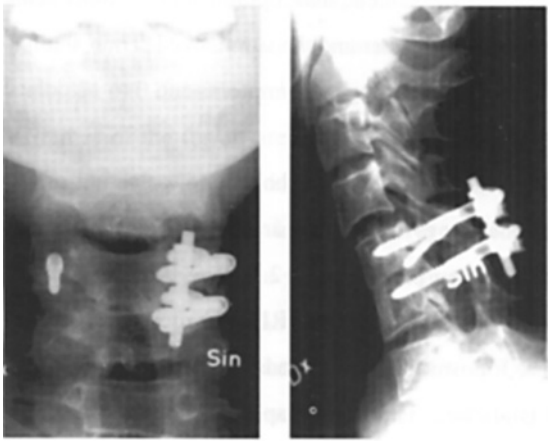

Figure 3. Example of a short construct. This 39 year old man (patient #21) suffered from posttraumatic kyphosis at C5-C6. The treatment consisted of anterior release, posterior release, reduction, and fixation with trans-pedicular fixation on one side and a single transarticular screw on the other, followed by anterior bone grafting. The one year follow-up radiographs revealed solid fusion.

others longer fusions for subaxial subluxation. In addition, two other patients also suffered from rheumatoid arthritis; one of the trauma patients (odontoid fracture) also had rheumatoid arthritis with C1-C2 pathology, and one of the revision cases was a rheumatoid patient with a previous failed fusion from occiput to C5. Short fusions, 1-2 levels (Figure 3), were performed in 8 patients and long fusions, 3 or more levels, were performed in 22 patients. 4 of the patients were fixed to occiput. Isolated C1-C2 fusion was performed in 3 patients. The neurological status of the patients was graded according to Frankel et al. [5]. Preoperatively 16 of the patients were Frankel B or C (non-ambulatory), none was totally plegic (Frankel A). Seven of the patients were neurologically intact.

METHODS

The methods consisted of a review of medical records and radiographs, a standardized questionnaire, a clinical examination, and plain radiographs. The patients' records were evaluated with respect to preoperative symptoms, diagnosis, peroperative findings and notations, postoperative course, and complications. The questionnaire consisted of 3 sections where the first covered local neck symptoms using visual analogue scales for neck pain, movement pain, neck fatigue, and neck stiffness. The second section covered neurological symptoms: The patient was to indicate from 0 (no problems) to 4 (maximal problems) their experience of pain, numbness and weakness of each of the 4 extremities. The third section, global function, consisted of 4 visual analogue scales: Ability to enjoy spare time, ability to travel with public transportation (bus or train), ability to eat independently, and ability to independently get dressed. The patients were also asked if they had experienced any complications, and if they had any additional symptoms. The questionnaire was evaluated as follows. For the visual analogue scales in section 1 and 3, 0 points were given if the mark was within the lowest 10 per cent of the line, 1 point if the mark was between 10 and 40 per cent, 2 points between 40 and 70 per cent, and 3 points above 70 per cent. For the neurology section the points were simply added together and the sum halved. Thus, 0 to 12 points were given for local symptoms, 0 to 24 points for neurological symptoms and 0 to 12 points for global function, giving a total "neck score" of 0 to 48 points.

In the clinical examination 5 topics were evaluated: Inspection of the wound, palpation of the neck, evaluation of head and neck position, global range of motion, and neurological function. Each topic was graded on an arbitrary scale from 0 (no problems) to 2 (severe problems). Plain radiographs and at least one neuroradiological investigation, usually MRI, were routinely obtained preoperatively. Postoperatively the patients were followed with plain radiographs in four standard projections positioned under fluoroscopic guidance. The radiographs were examined for diagnosis, correctness of placement of the fixation device, gross alignment, and device-related

complications such as loosening or mechanical failure. Fusion was evaluated according to an arbitrary scale; healed (bone trabeculae bridging the fusion area), no healing disturbance (bone trabeculae could not be seen bridging the fusion area but no signs of mechanical failure of the fixation were present), or not healed (a radio-lucent zone across the fusion mass, a radio-lucent zone around a screw, implant failure, or change in alignment or signs indicating non-union).

RESULTS

Twenty of the 30 patients were still alive after one year. Nineteen of these could be interviewed according to a standardized questionnaire and clinically examined by the independent observer. Radiographs were obtained in all 20 surviving patients. For the 10 deceased patients a thorough analysis of the clinical situation until death and the cause of death was performed by examining medical records, correspondence with the attending physician, and by interviewing relatives.

Subjective outcome (n=19). Mild local neck symptoms were reported by 14 patients whereas 5 reported severe problems, usually stiffness or pain. Mild or no neurological symptoms were experienced by 14 patients whereas 5 had severe problems. With regard to global function 6 patients reported slight or no impairment, 6 moderate impairment, 5 serious impairment, and 2 severe loss of global function. Some additional symptoms were noted by patients with long fusions not including the occiput: 5 patients reported a sensation of loss of balance with their eyes closed, 4 patients reported a clicking noise from immediately above the fusion area, and one patient complained of discomfort when attempting to rotate the head. When asked their own opinion of the operation, 3 were very satisfied, 11 were satisfied, and 5 were dissatisfied. Both of the paretic non-ambulatory patients and one patient with an endogenous depression were among the dissatisfied.

Clinical examination (n=19). Fourteen patients were considered not to have any problems on inspection. Five had broad scars, a mild problem. The two infected patients were in this group. No patient was considered to have a severe problem on inspection. On palpation, 6 patients were considered to have no problems, whereas 13 had mild problems, usually due to tenderness at the extremes of the fusion area. This tenderness seemed to emanate from the first unfused segment above or below the fusion. A few patients with thin musculature also had tenderness over protruding parts of the instrument. No patient was considered to have severe problems on palpation. Fourteen of the patients had no problems with respect to head and neck position, while 5, all with long fusions, had a slight flexion position considered to be a mild problem. No one had severe problems with head and neck position. Only one patient did not have any problems with range of motion, 8 had mild problems, and 10, all with long fusions, were considered to have severe restrictions. On comparing the preoperative and postoperative Frankel class all but 3

remained in their original Frankel class. One Frankel B patient had improved to C, and one Frankel C patient had improved to E. One patient deteriorated from E to D.

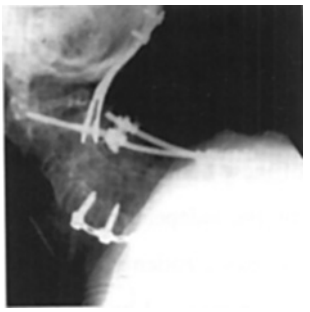

Figure 4 This 65 year old man (patient #2) with ankylosing spondylitis had previously been treated for fractures of the upper cervical spine and was well adapted to his spinal deformity. When he sustained a new fracture of the lower cervical spine he was deliberatly fused *in situ* with a residual hyperlordosis but with good clinical outcome. Unfortunately he died at 9 months from an unrelated intestinal obstruction.

Radiology. Preoperative radiographs were available for all 30 patients. Early postoperative radiographs could be evaluated in all but the patient who died during surgery. 12 months' radiographs were obtained in 19 of the 20 patients still alive at follow up. In addition one patient's radiographs taken at 9 months and 3 patients' radiographs taken at 3 months could be examined. In 12 patients the alignment was considered satisfactory, whereas a small residual deformity, usually kyphosis, was present in 16. One patient with ankylosing spondylitis and well adapted to a hyperlordosis was fused in situ (Figure 4). The instrument was considered to have achieved satisfactory primary stabilization in all 29 patients with postoperative radiographs (after the revision in patient #29). No postoperative radiographs were obtained in the patient who died during surgery but according to the operation notes the surgeon who performed the operation claimed satisfactory stability which was confirmed at autopsy.

In total 107 pedicle screws were inserted, 50 in the cervical and 57 in the upper thoracic spine (Table 2). In this series there were no complications associated with placing pedicle screws in the cervical spine. All screws except one in Th2 were in the correct position (Figure 5). The misplaced screw was lateral to the pedicle, but had a satisfactory purchase in the costovertebral process. The

Table 2. The applied screw placement techniques (count).

Vertebral level	C1	C2	C3	C4	C5	C6	C7	Th1	Th2	Th3	Th4	Th6	Total
Pedicle screw		16	2	2	6	8	16	27	22	2	4	2	**107**
Lateral mass screw			4	1	6	1							**12**
Transarticular screw (Cranlial vertebra)	23		5	13	15	9							**65**

subsequent clinical course for this patient was uneventful. Sixty-five transarticular screws (23 in C1-C2 and 42 in the subaxial cervical spine) were used (Table 2). All screws contributed satisfactorily to the stability and in no case was there a complication related to these screws. In addition twelve screws were placed in the lateral masses; 4 screws were placed in the thick bone in the rim of the foramen magnum, "foramen magnum screws", 3 sets of C1-Claws were used, and cerclage wire around the C1 arch was used in 3 patients. The fusion was considered healed in 15 patients, no healing disturbance was present in 3, and non-union with loosening of the implant had developed in 2, both with fixation from occiput to the upper thoracic spine. Three additional patients showed no healing disturbance in radiographs obtained at 3 months.

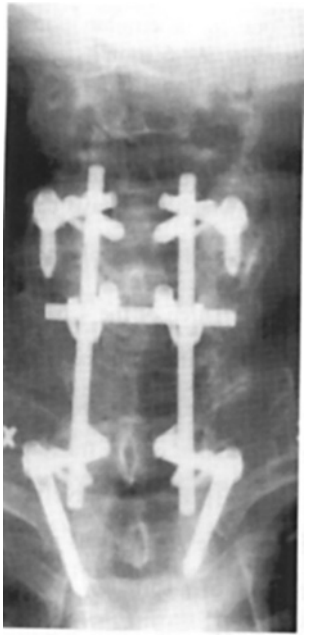

Figure 5 The only malpositioned pedicle screw in the series. This 78 year old woman (patient #15) was stabilized from C5 to Th2 for a breast cancer metastasis of C7. The right pedicle screw in Th2 was placed lateral to the pedicle but apparently with a good purchase in the costotransverse process. The malpositioned screw had no consequence to the patient.

Complications. One neurologically intact patient with rheumatic subaxial subluxation experienced a neurological complication. The preoperative investigations revealed translatory deformity at C3-C4, and central as well as foraminal stenosis at C3-C6. She underwent laminectomy of C3-C7 and fusion from C1-Th1. No foraminal decompression was performed. At follow up she had a partial injury of the left C7 root. The follow up radiographs revealed no misplaced screws and that the fusion was solid. The probable cause was considered to be contusion or traction during surgery, or foraminal stenosis at the C6-C7 level. The degree of the symptoms does not warrant reoperation. Loss of fixation was experienced in two patients with fixation from occiput to the upper thoracic spine. The cause in both patients was insufficient deformation of the occiput screws which allowed the screws to back out. In one of these patients a

screw link coupling also failed (Figure 6). In both patients the fusion has healed after revision. Infection that responded to local wound care and antibiotics was experienced in two patients. One patient developed a hematoma that drained spontaneously. The subsequent course in these patients was uneventful. In one rheumatoid patient with C1-C2 instability and an odontoid fracture a fusion was attempted with a lamina hook construct but no primary stability was achieved. The patient was reoperated within a few days with a combination of transarticular C1-C2 screws and the C1-claw device. After the reoperation the fixation was stable.

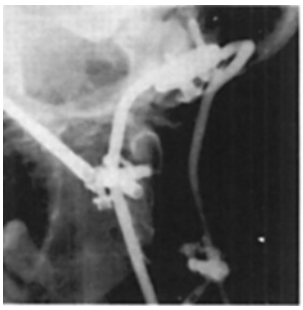

Figure 6. This 62 year old woman with rheumatoid arthritis (patient #3) was fixed to the occiput for a combination of cranio-cervical and subaxial subluxation. At 6 months a non-union had developed with a failure of the occipital fixation. Also the connection between the C1-C2 transarticular screw and the connector had failed. The patient was subsequently successfully revised. At revision is was evident that the collar of the occiput screws had not been deformed properly which may have been a contributory factor for the failure.

Survival analysis. Ten patients died during the first postoperative year. Three of the 4 patients with malignancies died. Four patients with severe rheumatoid arthritis and subaxial subluxation; two with Ranawat 3b [15] and 1 with Ranawat 3a neurological injury died. The fourth rheumatoid patient died at 8 months from an unrelated pneumonia. One 85 year old woman with a fracture of the lower cervical spine was initially stabilized with an anterior plate [13]. Postoperatively she aspirated and was held on a respirator when the anterior fixation failed. The patient was in very poor condition but had to be re-stabilized for nursing purposes. She died of respiratory failure 3 weeks post surgery. Two additional patients died from unrelated causes; one from intestinal obstruction, the other from empyema and heart failure.

DISCUSSION

What is safety and efficacy for an implant system? Safety deals with implant-related complications: neurologic deterioration, vascular compromise, infections, *et cetera.* In the present study there were few instrument-related complications; one mild neurologic deterioration, probably not instrument related, and two infections that healed on conservative treatment. We therefore conclude that the implant system is safe. Efficacy, on the other hand, deals with the ability of the implant system to "do the job". Primarily this is the ability to achieve stability in the patient in whom the implant is used. In the intermediate term the implant should not fail, i.e.

loosen from the bone, disconnect at the mechanical coupling of the implant itself, or simply bend or break, until solid fusion has occurred. In the long term the efficacy should be reflected in a high frequency of fusion. Primary stability was achieved in all but one patient. The alignment was good or fair in all but one patient in whom the residual deformity was deliberately accepted. In the intermediate and long term there were two fixation failures, both at the occipital fixation. The experience of these two patients has resulted in the development of an improved pincer pliers for the screw collar. With the new pliers we have not experienced any occiput screw loosening. For the rest of the patients the stability and longevity of the instrumentation was satisfactory. The overall fusion rate in the series was thus good, and was fully compatible with other publications [7]. Thus, we can claim that the instrument system is effective in the short as well as in the "long term" (one year).

The mortality rate encountered in this study may seem high but the series consisted of an elderly and not very healthy population with an above-average expected death risk. The malignant patients are at high risk of dying; the median survival time after a spinal metastasis is less than a year [9]. Also patients with rheumatoid arthritis have a high mortality risk, especially if they start to develop myelopathy [4, 6, 14, 17]. In all deceased patients the cause of death has been established and the implant system was in no case responsible. Thus, it is safe to conclude that the implant system *per se* is not responsible for the high mortality rate. The presence of local neck symptoms is more difficult to distinguish. These could very well be (and probably are) associated with the preoperative condition, and the fact that a fusion has been performed. On the other hand these symptoms may also be enhanced by a bulky implant. However, as is evident from other studies, local neck symptoms are quite frequent after posterior cervical spine surgery and the results from the present study do not stand out negatively [10]. Interestingly we found a previously seldom recognized problem in long cervical fusions; some patients experienced loss of balance with their eyes closed. One hypothesis for this may be that the musculature, ligaments, and joints of the cervical spine are involved in the balance keeping process through special proprioceptive afference to the CNS [11]. Maybe these systems do not work properly after a long cervical fusion, either because the systems themselves or their nervous supply are damaged by the exposure, or more likely, because their function relies on motion in the underlying motion segments to signal properly.

In the present series 107 consecutive pedicle screws were used. There were no complications and only one misplaced screw in a thoracic vertebra. There may be a systematic error in that the screw position has been evaluated on plain films (even though these were obtained under fluoroscopic control); minor violations of the bony channel for the vertebral artery may have been missed with this method. However, no major violations were present. This low incidence of screw

misplacement is in accordance with the data presented by Abumi and collaborators [1, 2] and may well be the incidence one may expect in an institution with long experience of the technique. Others have reported higher incidence of misplacement of cervical pedicle screws [8, 12]. This difference might reflect a learning curve or it may be a matter of insertion technique. We use the technique for screw placement described by Abumi: Wide exploration to get a good overview of anatomical landmarks, a large hole in the dorsal cortex, careful probing of the pedicle channel using a blunt probe, and supervision by image intensifier in the lateral projection [1, 2]. Transarticular screws of the subaxial cervical spine, on the other hand, have not been used previously at our institution as they require this special type of fixation instrument to work. From a theoretical point of view the transarticular screw has certain advantages. In contrast to an ordinary lateral mass screw it bridges four lamellae of hard cortical bone; the dorsal cortex of the proximal vertebra, the subchondral bone of both facets, and the cortex of the ventral surface of the facet of the distal vertebra which should secure a good purchase. Another advantage is the "interfragmentary" fixation of the vertebrae. When placing the screw it is important not to drill too deep as the emerging nerve root passes in front of the screw projection; the vertebral artery is further ventral and should not constitute a major problem. No complications related to these neurovascular structures were encountered in the present series. However, the transarticular screw should not be used as the most proximal bone anchor in a construct as the purchase in the upper vertebra is small. As an "in-between" screw within a fusion area it has proven very useful. The Olerud Cervical Spine Fixation System is versatile in posterior fixation of the cervical spine. The system has proven to be both safe and effective in this consecutive series of the first 30 patients treated.

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