Comparison of open versus percutaneous pedicle screw insertion in a sheep model

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Received: 21 August 2007 / Revised: 17 January 2008 / Accepted: 4 March 2008 / Published online: 4 April 2008
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Abstract Minimally invasive surgery has become more and more important for the treatment of traumatic spine fractures. Besides, some clinical studies, objective data regarding the possible lower damage to the surrounding tissue of the spine is still missing. Here we report a sheep model where we compared a percutaneous versus an open approach for dorsal instrumentation with pedicle screws to the spine. Twelve skeletally mature sheep underwent bilateral pedicle screw fixation at the L4–L6 level. Forty-eight pedicle screws were bilaterally inserted into the pedicles and connected with rods using either an open dorsal standard or a percutaneous approach. Operation time, blood flow, compartment pressure, radiation time, loss of blood, laboratory findings and EMG were evaluated to objectify possible advantages for the percutaneous operation technique. Loss of blood and the distribution of CK-MM as a marker for muscle damage were significantly lower in the percutaneous group. However, radiation time

was significantly longer in the percutaneous group. Other parameters like compartment pressure, blood flow and also measurement of the EMG at different time points did not reveal significant differences. Based on the results we found in the present study, percutaneous screw insertion can bring moderate advantages but it should be noted that essential functional deficits to the muscle could not be detected.

Keywords Spine · Minimal-invasive surgery · Pedicle screw · Animal study

Introduction

The use of pedicle screws for dorsal spinal stabilization has been established worldwide and multiple studies suggest that this procedure is a safe and effective method for many spinal disorders [2, 8, 9, 15, 35]. It has also been shown, however, that the open approach and instrumentation possibly adds relevant damage to the dorsal musculature and as a consequence continuous impairments can remain [19, 32]. The development of minimally invasive techniques for various fractures of the whole skeleton has also been realized for the operative treatment of spinal fractures. Initially, Magerl [22] described the technique for pedicle screw placement used for temporary external fixation. This procedure has been developed in particular by Dick et al. [7] to the “fixateur interne” and has been taken further to percutaneous internal fixation [26]. Herewith tissue dissection, blood loss and hospitalisation should be reduced. This raises hope that the treatment of patients can be improved and some promising results have been published [8, 11, 21, 26]. A derivative design of the percutaneously inserted spinal fixation systems that are

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available has already improved the surgical technique. For this purpose various considerations were made as for example the use of flexible rods for pedicle screws that can be inserted in a flexible state and which then harden following deployment. Kandziora et al. [14] suggested a new percutaneous stabilization technique, the so called lumbar facet interference screw, to improve the use of a minimally invasive dorsal approach after anterior lumbar interbody fusion in degenerative spinal disorders. To date, the percutaneous approach for the treatment of fractures remains challenging as the reduction and correct alignment of the vertebral body is not completely sufficient as with an open approach. Nevertheless, from the present development we can proceed from the assumption that the usage of minimal invasive procedures goes further.

However, until now, objective data remains missing that determines the effects of open versus percutaneous instrumentation to the spine. Therefore we used a sheep model to investigate multiple effects to the musculature of the spine.

Methods

Twelve skeletally mature black head sheep (weight 47–60 kg) underwent bilateral pedicle screw fixation at the L4–L6 level after approval from the institutional animal care and use committee. Forty-eight Click'X screws (Clinical House, Bochum, Germany) with a 5.2 mm external diameter were bilaterally inserted into the pedicles of L4 and L6 and connected with rods using either an open dorsal standard (Group I) or a percutaneous approach (Group II).

Procedures were performed on a radiolucent operating table (Maquet, Rastatt, Germany). Six sheep underwent the open procedure and six underwent percutaneous insertion of the screws. Postoperative immobilization devices were not used, and the animals were allowed to move within their cages. They received two doses of 0.5 g of metamizol-natrium (Novaminsulfon, Ratiopharm GmbH, Germany) intramuscularly per day for 5 days. EMG, measurement of the compartment pressure, laboratory findings and computed tomography (CT) evaluation were performed. The animals were euthanized 3 months post-operatively for gross inspection. At this time the implants were removed.

Surgical procedures

All sheep were pre-anaesthetized with ketamine and diazepam, then placed on the surgical table in the lateral position. Isoflurane and intravenous fluids were administered throughout the remainder of the surgery. The sheep

were shaved, prepared and draped in a sterile manner. In the group undergoing the open pedicle screw fixation, after the skin incision and sectioning of the fasciae, the lumbar vertebrae (L4–L6) were exposed and the pedicles of L4 and L6 were marked with K-wires. After control of the correct position with antero-posterior and lateral radiographs, the pedicles were opened by a machine drill and the screws were implanted and the rods inserted. Surgical wounds were then sutured.

In the percutaneous group, were the same levels (L4–L6) as in the open group were instrumented a 16-gauge spinal needle was inserted 2 cm lateral to the midline at a 10–15 deg angle and directed toward the lateral aspect of the facet joint as indicated by the fluoroscopic images. After a small incision about 1 cm length the soft tissue was edged out with scissors. A K-wire was docked on the lateral facet and after control of the entry point in antero-posterior and lateral fluoroscopies, the screws were inserted. In order to determine the optimal position of the screws within the pedicles again fluoroscopic images in both planes were taken. For final assembly, the rods were introduced through the caudal skin incision, underneath the fascia and were bluntly advanced through the muscle until the head of the cranial pedicle screw was reached. The rod was inserted into the clamp with the help of one finger in the cranial incision. The inferior clamp was attached to the rod, which was then lowered to the caudal screw head and fixed with anchor bolts.

Two experienced spinal surgeons performed all of the above procedures in an alternate pattern. The animals were euthanized 3 months after surgery with an intravenous injection of sodium pentobarbital. The lumbar spines from L4 to L6 were then harvested for examination and comparison.

Screw positions were post operatively assessed using multiplanar reformed CT-scans (140 kV, 40 mA s, collimation 3 mm, pitch 0.7) with a 16-slice spiral CT (XM 8000, Philips). Cross-sectional, sagittal and coronal views were obtained from each specimen. A blind evaluation of screw positions was performed by a radiologist. Any screw penetration of bony cortices was valued as a malposition.

Time (min) per screw placement was measured for subsequent radiation exposure as well as for the total time elapsed for every trial of each method, which included all work steps and intraoperative measurements.

Blood flow

Blood flow was recorded from a laser Doppler small straight probe (PeriFlux 407-1; Perimed AB, Järfälla, Sweden) connected to a laser Doppler flowmeter (PeriFlux System 5000; Perimed AB). This system emits 780 nm wavelength light, has 0.25 mm fiber separation and

0.5–1 mm measuring depth. Doppler values were expressed in arbitrary perfusion units (PU). We used a 30 s time constant and recorded peak flow 1 cm both sides of L4 before and after each operation, and again 21 days after surgery.

Loss of blood

During the surgical procedure the loss of blood was evaluated for each animal by collecting the blood with a syphon.

Compartment pressure

Intramuscular pressures were measured bilaterally in the erector spinae muscle with Stryker instruments (Stryker Quick Pressure Monitor instrument, Kalamazoo, MI). In the percutaneous group the needles were placed 1 cm lateral from L4 as close to parallel with the muscle fibres as possible. In the group that underwent the open procedure, the needles were placed directly lateral to the retractor blades, where we expected the highest compartment pressure and 0.3 cm volume of saline was infused in each catheter. Measurements were taken before, during and immediately after surgery and once again after 21 days.

Laboratory findings

Peripheral venous blood samples were collected serially before and after surgery. Serum concentration of total CPK Creatine Phosphokinase (CK-MM) was measured immediately postoperatively and also 1, 3, 7 and 14 days after surgery.

EMG

The animals were measured during implantation, after 6 weeks and after 3 months. The EMG was conducted during sedation with ketamin. Such sedation allowed investigation of spontaneous activity at rest and during voluntary activation of the paraspinal muscles in all animals. We used concentric 60 mm standard EMG needles and a standard EMG amplifier (high pass filter of 10 Hz, low pass filter of 20 kHz). In each animal EMG activity was analysed at 14 different sites, of which 2 were positioned 2 cm medially and laterally of each of the 4 pedicle screws. Another four sites were defined at the same distance to the midline between the screws. Two sites were used as control sites. The following EMG patterns were analysed: spontaneous activity (fibrillation potentials, positive sharp waves, fasciculations and complex repetitive discharges), activation pattern during voluntary contraction, and polyphasia of muscle unit potentials.

Statistics

Sample size was calculated by performing power analysis. A total of $n = 6$ animals was identified as being sufficient to verify statistical differences between the trial groups concerning procedure and fluoroscopic time. The difference in mean values between the test groups was calculated as being at least 1.5 times the standard deviation in Group I. According to this sample size estimation, a total of $n = 6$ animals was used in each group.

All data were given as mean value $\pm$ standard deviation. Differences between the trial groups were evaluated using a standard t test. If the sample data was not normally distributed, the Mann–Whitney rank sum test was used instead. Fisher's exact test was used to detect differences between the groups regarding the precision of screw position. All tests were calculated with a desired power of $\beta = 0.8$ and a significance level of $\alpha = 0.05$. Statistical analysis was performed with SigmaStat (version 2.03) by SPSS.

Results

Forty-eight pedicle screws (Click'X, Clinical House, Bochum, Germany) were inserted on the lumbar spine L4–L6. Two malpositions appeared in both groups each to medial side of the pedicle so that no significant differences between the two methods could be found regarding the screw position. None of these malpositions resulted in a neurological deficit (Fig. 1).

The mean total operating time required to insert the pedicle screws was 100.81 ± 18.54 (range 124–80) min in Group I and 101.6 ± 16.02 (120–80) min in Group II (Fig. 2). Relevant technical problems did not occur. These included the whole technical procedure with measurement of the compartment pressure, blood flow and EMG.

The mean total radiation time required to insert the pedicle screws was 1.88 ± 0.66 min in Group I, and 3.2 ± 1.4 min in Group II ($P < 0.05$).

Blood flow was 124 ± 1 g/cm² in Group I versus 103 ± 65 g/cm² in Group II. Therefore no significant differences in the blood flow could be found.

The difference in peri-operative blood loss was statistically significant ($P < 0.05$, 391 ± 94 ml in Group I and 62.5 ± 35 ml in Group II).

There was no difference in the intracompartmental pressure of the back muscles. The pressure before operation was 13 ± 3.04 mmHg in Group I, 13.75 ± 9.1 mmHg in Group II. During the operation the pressure increased to 28 ± 4.31 mmHg in Group I and 22 ± 4.43 in Group II. After the operation we found this to be 24.17 ± 23.19 mmHg in Group I and 17.7 ± 14.1 mmHg in Group

Fig. 1 **a,b** show the percutaneous insertion of the pedicle screw and the connecting rods. After a small incision the soft tissue was edged out with scissors. A K-wire was docked on the lateral facet and, after control of the entry point in antero-posterior and lateral fluoroscopies, the screws were inserted. The longitudinal rods were then slid in percutaneously and the wounds were sutured. **c, d**: Antero-posterior and lateral radiograph of the instrumented spine. **e, f**: Postoperative CT scan to evaluate possible malpositions of the screws (**e**: Showing a medial malposition of the screw. **f**: Correct position of the screw in the pedicle)

II and at 21 days after operation this was 14.83 ± 4.5 mmHg in Group I and 14.5 ± 10.6 mmHg in Group II. Even if the pressure in the compartment of the percutaneous group was lower during the operation due to the high standard deviation, no significant differences could be detected.

Time-related changes of creatine phosphokinase MM isoenzyme (CPK-MM) activity after posterior lumbar spine surgery were recorded. The activity increased after surgery with its peak one day after surgery. It subsequently

recovered to the normal value in both groups 1–2 weeks after the procedure. The mean CK-MM was 1390 ± 162.95 U/l min in Group I and 982.2 ± 520.29 U/l in Group II ($P < 0.05$) immediately following surgery. In the course of time the values decreased again as shown in Table 1.

The examination of the EMG revealed surprising findings. Activation patterns in the region of interest were not different between animals and also did not differ from the control site. At multiple sites, equally distributed across all

Fig. 2 Graphical analysis of the different parameters that were examined in the study. Each graph demonstrates the mean value in the different patterns in the open (*left*) versus the percutaneous group (*right*). Compartment pressure and CK-MM shown here are the results during surgery, respectively, immediately after surgery. ** statistically significant ($P < 0.05$)

Table 1 Detailed chart showing the CK-MM during the time course after surgery.

Day	CK-MM Group I	CK-MM Group II
1	1390 ± 162.95	982.2 ± 520.29
3	812 ± 66.5	433 ± 15.5
7	160 ± 23	100 ± 31
14	71.18 ± 8.77	76.8 ± 21.04

Within 2 weeks the CK-MM revealed normal findings in both groups

animals, we found short sharp potential fulfilling the criteria of fibrillation potentials. It should be noted that motor unit potentials during voluntary activation in paraspinal muscles can have an equal duration and shape compared to fibrillation potentials. Therefore, it was not possible to clearly distinguish fibrillations from a pattern of minimal voluntary activity in these lightly sedated animals. After 3 months the same finding was again observed. At two

sites in the middle of the implant we found fasciculation potentials in the percutaneous group. EMG findings were normal at the control sites of each animal.

To summarise we found a normal activation pattern in all animals and at all points where EMG was performed indicating that there was no relevant neurogenic damage in the investigated muscles. Other findings were rare and did not allow for discrimination between both types of intervention.

Discussion

Traditionally, implantation of spinal instrumentation requires extensive tissue dissection to expose the entry points and provide the required lateral-to-medial orientation for optimal screw trajectory. Lengthy operations with significant blood loss and an increased risk of infection are not uncommon [1, 12, 20, 25]. Dissection may result in denervation of muscles and facet capsules, damage to the proximal facet joint, and a weakening of other supportive structures, resulting in prolonged post-operative pain and disability [28, 29, 32]. The length of hospital stay and total cost of the treatment are also adversely affected by open pedicle fixation and spinal fusion techniques [31]. Minimally invasive techniques are therefore potentially desirable, although it should be taken into account that the facet joint and the capsule can potentially be spared much more easily by its visualization.

Percutaneous lumbar pedicle screw insertion techniques are becoming more popular [8, 20, 21, 24, 27, 30]. However, some reported results of existing minimally invasive methods have been shown to be suboptimal. Lowery and Kulkarni [21] reported their experience with 80 consecutive patients who underwent fluoroscopy-aided percutaneous pedicle screw placement. In this study, 10 patients (12.5%) had misplaced screws that required revision, as determined by post-operative CT scans. Others like Wiesner et al. [33, 34] reported an experimental pedicle violation rate of 6.6% for 408 percutaneous screws inserted from L2 to S1 in lumbar spine. Lee et al. [20] reported clinical results of 73 patients with low-grade isthmic spondylolisthesis who underwent mini-anterior lumbar interbody fusion followed by percutaneous pedicle screw fixation. In that study, their misplacement rate was 4.1% (3 pedicle violations out of 73 screws).

The procedure described herein offers distinct advantages over conventional pedicle screw fixation techniques. This technique eliminates a large midline incision and minimizes paravertebral muscle dissection. The paravertebral muscle is bluntly split. The preoperative plan allows precise positioning of all of the screws, thus avoiding damage to the proximal facet joints. This should

shorten the length of hospital stay and expedite recovery. Even if some clinical results for the postoperative outcome have been reported objective data regarding EMG, compartment pressure etc. is still missing. And as we know from other studies the quality of life after spinal surgery is dependent on a plurality of different factors [3, 4]. We therefore performed this study in sheep to close this gap. An ovine model was used since the available experience [13, 23] from the routine screw interventions does not have any effect, due to the differing anatomy and marked soft tissue layer in sheep.

The pedicle/screw diameter relation of the sheep is generally smaller than in humans [13, 23]. This might lead to higher misplacement rates. In our study we could not detect higher misplacement rates compared to the studies mentioned above. Another error possibility lies therein: that percutaneously implantation without trokar was compromised by its instability, due to the small and uneven insertion area. This sometimes led to drilling, which did not cohere exactly to the plan. A direct implantation using the drill would have been more fitting; however, this could not be done with the available drills.

The use of a machine drill to open pedicles in the open group was advisable. However, in clinical routine this was hardly necessary but it is not clear if the drilling influenced the measurement of some of the parameters. With cautious preparation and accurate exposition of the entry point we proceed with the assumption that this did not affect the compartment pressure and the CK-MM in a crucial way.

Currently, there are only a few clinical studies, which describe the percutaneous placement of pedicle screws [8, 13, 21, 24, 34]. Despite the misplacement rate of 6.6 and 12.5% reported, it should be kept in mind that the surgical procedure is technically demanding and should be performed only by experienced spine surgeons [21, 34]. These percutaneous techniques were previously performed with the help of landmarks, located on the facet joint, which are difficult to find with such limited access. When doing so, numerous X-rays had to be taken throughout the procedure for orientation. Therefore, the advantages of a minimally traumatic access also carried the disadvantages of longer operating times and higher radiation exposure.

However Grass et al. [11] found no significant difference in operation time, radiation time and accuracy of screw placement. In our own clinical experience and in the present study we found indeed longer radiation times within the percutaneous group. At this point the surgeons experience in minimal invasive surgery should not be neglected. The operation time was not different, and the perioperative blood loss in this study was also significantly

lower in the percutaneous group which is consistent with our data.

In the clinical situation the use of a wound drainage in the open procedure is commonly performed. To standardize the surgical procedure we did not use a wound drainage in either the open or the percutaneous group. Therefore we could be sure that the various parameters are not influenced by this procedure.

Kim et al. [18] showed that percutaneous versus open internal fixator stabilization is associated with less multifidus muscle atrophy, a superior postoperative trunk muscle strength, lower blood loss and less postoperative demand for analgesics. However, these parameters did not translate in a superior clinical outcome in terms of patient satisfaction and pain score. Thus, the main advantage seems to be within the immediate post-operative period, where a significant reduction in pain is conspicuous [26].

Muscle damage may also be in part a result of direct mechanical compression by the muscle retractor. It may be related to muscle ischemia and necrosis. Indeed, in animal studies, paraspinal muscle retraction with self-retaining retractors has been shown to produce reduced blood flow, interstitial edema, and necrosis of muscle and nerve fibers [6, 10, 16, 17, 29, 32].

One aspect that is always mentioned for the use of minimal invasive techniques for skeletal surgery is the reduction of devascularization to the bone. However, in spinal surgery the devascularization throughout a dorsal approach appears to be secondary. The main blood supply to the thoracic and lumbar spine is derived from the intercostal and lumbar arteries [5], therefore the muscle dissection accompanied with the dorsal approach plays a tangential role.

The comparison between open versus percutaneous screw insertion in a sheep model confirmed some of these preceding studies: that blood loss and the laboratory findings in view of the CK-MM, as an impression for the muscle damage, were significantly reduced. Beyond this, compartment pressure was also lower in the percutaneous group, even if this was not significant due to the high standard deviations.

Conclusion

The percutaneous screw insertion with lower blood loss and lower distribution of CK-MM offers some advantages compared with the open procedure. Therefore this data adds some aspects to support the use of percutaneous approaches for dorsal spinal stabilization. However, essential functional deficits to the muscle by a gently open approach could not be detected in this animal study.

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