A prospective, cohort study comparing translaminar screw fixation with transforaminal lumbar interbody fusion and pedicle screw fixation for fusion of the degenerative lumbar spine

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In a prospective observational study we compared the two-year outcome of lumbar fusion by a simple technique using translaminar screws (n = 57) with a more extensive method using transforaminal lumbar interbody fusion and pedicular screw fixation (n = 63) in consecutive patients with degenerative disease of the lumbar spine. Outcome was assessed using the validated multidimensional Core Outcome Measures Index. Blood loss and operating time were significantly lower in the translaminar screw group (p < 0.01). The complication rates were similar in each group (2% to 4%). In all, 91% of the patients returned their questionnaire at two-years. The groups did not differ in Core Outcome Measures Index score reduction, 3.6 (SD 2.5) (translaminar screws) vs 4.0 (SD 2.8) (transforaminal lumbar interbody fusion) (p = 0.39); ‘good’ global outcomes, 78% (translaminar screws) vs 78% (transforaminal lumbar interbody fusion) (p = 0.99) or satisfaction with treatment, 82% (translaminar screws) vs 86% (transforaminal lumbar interbody fusion) (p = 0.52).

The two fusion techniques differed markedly in their extent and the cost of the implants, but were associated with almost identical patient-orientated outcomes.

Extensive three-point stabilisation is not always required to achieve satisfactory patient-orientated results at two years.
suitability for inclusion in the study was assessed once it had been decided that surgery was indicated. Because translaminar screw fixation is only suitable for treating up to two adjacent degenerative levels of the lumbar spine, the inclusion criteria for the study became degenerative disc disease at one or two levels, degenerative spondylolisthesis or a facet syndrome. In addition, the completion of self-rated questionnaires required the patient to have a good understanding of written German. The only exclusion criteria were previous surgery other than discectomy, and a refusal to give informed consent to surgery and/or completion of the questionnaire.

A total of 120 patients satisfied the inclusion criteria and were recruited to the study. There were 57 in the translaminar screws group (group one) (one surgeon; DG) and 63 in the transforaminal lumbar interbody fusion group (group two) (four surgeons; VB, DJ, FSK, FL). Spine Society Europe (SSE) surgery forms documenting the details of surgery and the fusion material used were completed for 111 of 120 (93%) cases. Pre-operative questionnaires were completed by 111 of 120 (98%) patients and the 24-month post-operative questionnaires by 109 (91%) patients. Table I shows the baseline characteristics of the two groups. Gender distribution was almost identical in the two groups, with 67% women. However, group one patients were significantly older than those in the second group and had significantly higher ASA scores (Table I). There were no significant initial differences between the groups for any Core Outcome Measured Index domain scores (see outer lines of the radar chart in Fig. 1).

Surgical procedures. Each surgeon consistently used his or her pre-stated, preferred method (TS or TLIF) for each patient who fulfilled the inclusion criteria to assure optimal technical performance and motivation for the surgery.

Both procedures were carried out through a standard midline approach to expose the relevant segments of the lumbar spine. Decompression with undercutting facetectomy was undertaken if necessary.

Autologous bone, harvested through a separate incision over the posterior iliac crest, was used in all 53 patients in the translaminar screws group and in 52 of 57 (91%) of the other group. Allograft was used to augment or replace autologous bone in 6 of 53 (11%) patients in the translaminar screw group and in 25 of 57 (44%) patients in the second group. Bone substitute was not used in any patient in the former group, and in only one (2%) patient in the latter group. Both techniques were performed in the standard manner and every patient was subject to the same post-operative regimen.

Documentation forms and questionnaires. SSE Spine Tango Surgery forms were used to document the operating time (ten categories, from < 1 hour to > 10 hours), blood loss (five categories: none, < 500 ml, 500 ml to 1000 ml, 1000 ml to 2000 ml, > 2000 ml), comorbidities assessed by using the American Society of Anesthesiologists Physical Status Score (ASA score), from 1 (no disturbance) to 5 (moribund), fusion material used, surgical and general complications, and time in hospital.

Patients completed the Core Outcome Measures Index questionnaire pre-operatively and after two years. On each occasion after their surgery the questionnaires were sent to the patients to complete at home, to ensure that the information given was free of surgeon influence. The Core Outcome Measures Index is a multidimensional index consisting of validated questions covering the domains of pain (leg and back pain intensity, each measured separately on a graphic rating scale of 0 to 10), function, symptom-specific well-being, general quality of life, and social and work disability. It was originally developed as a result of recommendations from an expert group and subsequently validated by three research groups. At the follow-up after two years there were also further questions about satisfaction and the global outcome of surgery (Table II).
The hospital records were examined to identify any re-operations that had taken place in the years following the index surgery up to the time of preparation of the manuscript (mean 3.4 years, 2.1 to 4.3); this was further supported by the information on re-operations given by the patients in their questionnaires.

Statistical analyses. Descriptive data are presented as means and SD. The significance of the difference between the two groups was analysed using unpaired Student’s *t*-tests. Analysis of covariance was used to examine the difference between groups while controlling for potential confounders. Chi-square contingency analyses were used to analyse the association between treatment group and categorical variables. The global outcome was divided into ‘good’ (= operation helped, or helped a lot) and ‘poor’ (= operation only helped a little, didn’t help, or made things worse) for the purpose of some of the subsequent analyses.

Results

Group one had a significantly shorter operation (*p* = 0.0001) and less blood loss (*p* = 0.01) than group two (Table III), but the amount of blood transfused did not differ significantly between the groups (Table III). There was a non-significant tendency for the number of blood units administered to be higher in group one, although this was thought to be a consequence of the greater average age of these patients. It is known that older people are more susceptible to hypoxaemia after blood loss, and the amount of blood transfused did indeed show a significant relationship with age (corrected *ρ* = 0.28, *p* = 0.003).

The time in hospital was slightly but significantly longer in group one than in group two (*p* = 0.005; Table III). This was also the result of group one being slightly older, as age was significantly related to the duration of stay (*r* = 0.29, *p* = 0.015). When analysis of covariance was used to control for the effect of age there was no longer a significant difference between the two groups (*p* = 0.25).

The surgical and general complication rates prior to discharge were similar in each group (0% to 4%; Table III). There was one case of bleeding in the spinal canal, one wound infection and one case of anaemia in group one, and two cases of anaemia in group two. After two years, there was no difference between the two groups in the mean reduction in the Core Outcome Measures Index score, and ratings of global outcome or satisfaction with treatment (Table II; inner lines of Figure 2). When outcomes were divided into ‘good’ and ‘poor’ (see Table II), 78% of patients in group one and 78% in group two reported a ‘good’ global outcome (*p* = 0.99); 82% in the former and 86% in the latter group showed ‘good’ results regarding their satisfaction with treatment (*p* = 0.52).

Neither mean age 61.5 years (SD 13.4) in the good outcome group; 61.4 years (SD 13.9) in the poor outcome group; (*p* = 0.98) nor comorbidity (70% good outcome for ASA 1; 81% good outcome for ASA II; 80% good outcome for ASA III; *p* = 0.52) were associated with outcome. Because age and comorbidity were not distributed equally...
between the groups it was important to confirm that these were not confounders of outcome. The same lack of association between outcome and age/comorbidity was seen when the two treatment groups were examined separately.

Table IV shows that 17.5% of group one and 12.7% of group two required further surgery after a mean of 3.4 (SD 0.5) years (p = 0.62). The main indications were pseudarthrosis (three cases (5.3%) in group one, and one...
(1.6%) in group two) and problems in adjacent segments (four cases (7.0%) in group one and six (10%) in group two).

**Discussion**

This cohort study showed similar patient-rated outcomes after two years for two different surgical techniques performed for similar indications. No significant difference was found between the groups for any of the outcome measures. A tendency for a non-significant and non-clinically relevant difference favouring the more extensive surgery was observed, a possible explanation for this could have been the strict study protocol that demanded that every eligible patient was included in the study. The TLIF procedure, representing the most extensive intervention possible, can by definition be applied in all pathologies. In contrast, the TS procedure typically has somewhat more selective indications. With the strict rules of the study protocol, some potentially less suitable patients might have been included, contributing to a slightly inferior result in this group. Studies indicate that the ideal indication for translaminar screw fixation is degenerative monosegmental or bisegmental pathology with a disc space narrowed by at least 20% and with no anterior translation of the upper vertebra. The present protocol did not allow the option for exclusion for patients that did not fit this description of the ‘ideal’ case. In relation to the three different indications for surgery, it was difficult to do reliable sub-group analyses, owing to the relatively small sizes of the sub-groups. However, the facet group appeared to respond less well than the other two indications, regardless of treatment group (data not shown). We recommend that future studies investigate the influence of the specific pathology being treated on the outcome achieved with the two techniques, in order to further refine the indications in each case.

One of the few significant differences between the groups was the operating time. This is easily explained as it is far quicker to insert two screws than four pedicle screws and an anterior intervertebral cage. There is also a considerable difference in the potential risks from the two procedures. Inserting two screws under direct vision through the posterior bony parts of the spine causes substantially less trauma and carries less risk than inserting four pedicle screws under conditions that demand significant knowledge and experience of three-dimensional anatomy, as well as regular practice. The anatomical findings of Crock suggest that the transforaminal lumbar interbody fusion procedure has the potential to cause damage to the venous epidural plexus, with a resultant deleterious impact on outcome. In this study, all the operations were carried out by experienced surgeons and complication rates were similarly low in both groups. However, they may be higher in other centres or smaller units if the procedures are not carried out on such a regular basis.

Several authors have suggested combining an anterolateral, transforaminal or posterior lumbar interbody fusion with translaminar screws instead of pedicle screws, to capitalise on the relative ease of percutaneous insertion. The biomechanical results appear to be as good as those of pedicle screw fixation techniques.

We intentionally avoided clinical and radiological assessment in our study, as we believe that the discrepancy between ‘objective’ results (e.g. solid bony union) and clinical outcome, highlighted in numerous studies, may disguise the ultimate goal of surgery, a satisfied patient. We did, however, assess the re-operation rate, and this was not significantly different between the two groups. There tended to be slightly more cases of pseudarthrosis in group one and more adjacent segment problems with group two, but the differences were not marked. Previous studies in this area have yielded conflicting findings. Using thin-section computed tomography, Cain et al and Anjarwalla, Morcom and Fraser revealed significantly lower rates of solid fusion in patients whose anterolateral lumbar interbody fusion was augmented by...
translaminar screws (20%27 and 58%28) rather than pedicle screws (80%27 and 88%28), although the impact of this on either re-operation rates or patient outcomes was not discussed. By contrast, when comparing re-operation rates in patients who had undergone a combined circumferential lumbar fusion with either pedicle screws or translaminar fixation, Best and Sasso29 found that 37.5% of the pedicle screw group required re-operation for removal of their instrumentation compared with only 4.7% of the translaminar facet screw group. In a retrospective study of posterolateral fusion augmented with translaminar facet screws, Reich, Kuflik and Nuewirth30 reported a radiological fusion rate of 98.4% at a mean five months post-operatively, which they suggested compared favourably with other methods; good to excellent clinical outcomes were reported by 93% of patients.

Whether our results are sustained in the longer term will be the subject of future studies. Some authors have reported procedure-specific deterioration in the clinical outcome of fusion surgery with time. Videbaek et al31 found significantly less favourable clinical results with posterolateral fusion than with 360° fusion after five to nine years, whereas no significant differences between the procedures for the improvement of functional outcome (their primary outcome measure) had been observed after two years.32 Tuli, Eichler and Woodard33 found favourable results for translaminar screw fixation in terms of short-term outcomes such as blood loss, hospital stay and peri-operative complications, but in a later study they reported an increased re-operation rate for pseudarthrosis after four years compared to patients who had undergone pedicle screw fixation.34 Nonetheless, a very recent study of the long-term patient-rated outcome after translaminar screw revealed almost identical findings to those reported here after two years, using the same outcome instruments.17

In recent years there has been a tendency to apply, universally, a kind of ‘super-stabilisation’ to all pathologies, even those where there is no proven benefit for the patient. In view of the results of our study, one might question why a relatively simple, low-complication technique does not enjoy greater popularity. There are several possible answers, that the technique is not able to fulfil the requirements of the surgeons, the surgeon feels the need to do ‘more’ in favour of the patient or the surgeon is influenced by external factors.

From a mechanical point of view there is evidence that, with the possible exception of slightly less stiffness in extension loading, translaminar screws provide comparable in vitro stability to pedicle screws.35,36 This is also true when they are used to provide posterior stability in interbody fusions.20,23,37 There is no proof that non-medical factors influence the choice of surgical procedure, but the issue should at least be raised. The difference in the cost of the implants alone is enormous: the translaminar screw technique costs approximately $50, whereas the cost of implants for the transfemoral lumbar interbody fusion procedure amount to some $3000. Yet both appear to yield similar clinical results. The 60-fold difference in costs gives credence to the suspicion that non-medical considerations may be involved in the selection of procedures.38

We consider that the study design used in this investigation is worthy of special mention. Randomised controlled trials are considered to represent the pinnacle in the ‘hierarchy of evidence’, but they often involve only a limited selection of the typical patient population suffering from the condition, and hence have limited external validity, i.e. the results cannot always be assumed to apply to the ‘patient at large’.39,40 Furthermore, if surgeons are required to use a technique which they do not favour and with which they are unfamiliar, solely for the purposes of a comparative trial, then factors concerned with experience and practice may influence the overall outcome. Hence, although the study design used in the present investigation is not the highest in the hierarchy of evidence, it nonetheless included every single eligible patient who required surgery and allowed each surgeon to use his or her regular surgical procedure. Consequently, it represents a practicable, first-line and complementary approach to the randomised controlled trial, with greater relevance to and generalisability within daily clinical practice.

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References