Failed Fusion Surgery treated by Transforaminal Endoscopic Lumbar Decompression and Foraminoplasty – a 3 year prospective cohort study

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Abstract

Background

Treatment of back pain is often unsuccessful due to suboptimal identification of the pain source. Aware state Transforaminal Endoscopic Lumbar Decompression and Foraminoplasty (TELDF) offers a direct means of localizing and treating pain persisting after fusion. This study examines the outcomes of TELDF in a cohort of 65 patients after Failed Fusion Surgery.

Methods

For 3 years prospective data were collected on 65 consecutive patients with failed but immobile fusions who underwent TELDF. The level responsible for the predominant presenting symptoms was defined by spinal probing and discography or differential discography. Patients then underwent TELDF at the appropriate level. Outcomes were assessed using the Visual Analogue Pain Scale (VAPS), the Oswestry Disability Index (ODI), the Prolo Activity Score, SF36 Health Survey and Zung Depression Index.

Results

Cohort integrity was 100%, 98% and 92% at 1, 2 and 3 years respectively. VAP scores improved from a mean of 8.2 at baseline to 3.0, 3.1 and 3.2 at years 1, 2 and 3 respectively. ODI improved from a mean of 40 at baseline to 13.3, 13.4 and 13.2 at years 1, 2 and 3 respectively. In total, 86% of reviewed patients fulfilled the definition of “Good Clinical Impact” at year 1, 78% at year 2 and 76% at year 3. Based on Prolo score, 44 patients (68%) were able to return to work or retirement activity post-TELDF. Complications of TELDF were limited to transient nerve irritation, which affected 18% of the cohort.
Conclusions

TELDF is an effective intervention for the treatment of severely disabled patients with multilevel Failed Fusion Surgery, resulting in considerable improvements in symptoms and function.

Clinical Relevance

The efficacy of TELDF in patients with immobilised segments suggests that extradiscal foraminal pathology may be a major cause of lumbar axial and referred pain.

Keywords

Failed Fusion Surgery, Endoscopic Decompression, Foraminoplasty, Foraminotomy, Differential Discography, Spinal Probing
Introduction

Back pain is a common condition in the developed world but treatment is often unsuccessful due to inaccurate identification of the pain source. Localization of back pain conventionally relies upon clinical examination, X-ray findings, CT-myelography, CAT and MRI scan results and, in certain centres, discography. With the exception of discography, these techniques are indirect methods of assessment that are not able to demonstrate definitively correlation between a given abnormality and the patient’s predominant presenting symptoms.

Conventional wisdom purports that back pain arises from the disc (discogenic pain) or the facet joints. Where physiotherapy and conservative measures (including injections and nerve ablations) fail, the patient may be referred for an intervertebral fusion to immobilise the disc and facet joints. However, randomised controlled clinical trials have shown that fusion procedures are not significantly more effective than regimens of exercise and Cognitive Behavioural Therapy. Only 63% of patients are satisfied with the results of such therapy and fusion is attended by complications in 11–18% of interventions.

The persistence of symptoms in patients undergoing intervertebral fusion may be due to pain arising from pathology in the spinal foramen rather than the intervertebral disc or facet joints. With the exception of transforaminal lumbar interbody fusion most commonly-used fusion techniques do not address the entirety of foraminal pain sources, which could explain the equivocal results of spinal fusion surgery.

Transforaminal endoscopic lumbar decompression and foraminoplasty (TELDF) is a minimally invasive technique that allows real time, aware-state evaluation of the
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foraminal zone, disc and epidural space to identify clinically relevant foraminal pathology and to treat such using endoscopic foraminotomy and foraminoplasty.

This prospective study assesses the outcome of aware state TELDF as a means of treating patients with Failed Fusion Surgery by monitoring clinical outcome over a 3 year post-operative period.

**Methods**

Between January 2000 and 2001, prospective data were collected on 65 consecutive patients with failed secure fusion surgery who underwent TELDF at the UK Spinal Foundation.

**Eligibility criteria**

Patients presenting with a secure multi-level lumbar fusion performed at least 1 year previously with persistent back, buttock or leg pain despite at least 3 months of muscle balance physiotherapy were eligible to participate in the study. Patients were excluded if intersegmental movement was detected on flexion/extension standing and sitting X-rays or if they were pregnant, evidenced facet joint cysts, Cauda Equina syndrome, systemic neurology or spinal tumours.

Eligible participants were consented for a staged procedure consisting initially of aware state spinal probing and discography on two or more spinal segments to establish which segment concordantly reproduced their back pain or peripheral radiation. If the patient was unable to define the source of their predominant pain then they proceeded to Differential Discography. Once the spinal level responsible for the patient’s predominant presenting symptoms had been identified
either by spinal probing and discography or by differential discography, patients progressed to TELDF at the appropriate level.

**Surgical procedure**

TELDF was performed under aware-state analgesia with the patient in the prone position on a humpback radiolucent table extension. It consisted of two phases of: 1) transforaminal spinal probing and discography; and 2) TELDF.

**Transforaminal spinal probing and discography procedure**

Under X-ray guidance, a spinal probing cannula (Arthro Kinetics Plc) was inserted into the spinal foramen via a posterolateral approach optimized by the use of a specially designed X-ray alignment jig. The distribution of evoked sensations and the degree to which they reproduced the patient’s predominant presenting symptoms was recorded on a data sheet by a trained observer during probing of the paravertebral musculature, the lateral facet joint surface, the anterior facet joint margin, the interval between the anterior facet joint margin and the annular (disc) wall. Radio-opaque dye (Omnipaque® 240 [Nycomed Ltd, Romsey, Hampshire, England]) was then injected into the intervertebral disc to evaluate its integrity. The pattern of dye distribution, acceptance volume and leakage were recorded, together with pain reproduction during discography pressurization.

Evoked sensations that reproduced the patient’s predominant presenting symptoms were classed as ‘concordant’ symptoms. Patients in whom spinal probing and discography demonstrated concordant symptoms proceeded immediately to TELDF at the level evidencing the most concordant symptom reproduction. Where symptoms were discordant (similar but not identical to the predominant presenting symptoms) or
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overlapping (symptoms arising at more than one spinal level), patients progressed to differential spinal probing and discography\textsuperscript{35-37}, in which steroid (80mg Depomedrone) was inserted at the most responsive spinal level and anaesthetic (2mls of 0.5% Narpine) was inserted at the adjacent level. Where the acceptance volume was low, a radio-opaque dye-guided radiculogram was performed. Care was taken to keep the medication located to the segment under evaluation. The temporal modification of individual symptoms determined the source of the pain and the site for subsequent TELDF.

**TELDF procedure**

Using the Arthro Kinetics Plc system, the needle used to perform discography was removed from the spinal probing cannula and replaced with a long guide wire. An endoscope dilator and cannula were railroaded along the guide wire to the foramen under X-ray control. The dilator was removed and the endoscope was inserted to offer visualization of the foraminal contents. A side-fire irrigated laser probe (Lisa Laser Gmbh) was inserted through the endoscope’s working channel. The laser was used to define the margins of the foramen and to progressively remove tissue in the Safe Working Zone\textsuperscript{38} until the nerve could be mobilized and the endoscope cannula inserted securely and safely. The superior foraminal ligament\textsuperscript{35, 37} was defined and removed. Any osteophytes were then removed with burrs, reamers and the side-fire laser. Perineural scarring was removed from the dorsal root ganglion to the inferior pedicle and the dorsal root ganglion and the nerve were mobilized with a nerve root retractor until free of tethering. The foramen was enlarged with trephines, powered reamers and manual burrs until clear access to the epidural space was achieved. Where indicated, protruding disc was removed with care to avoid exposing intervertebral graft or cages. Where there was a contributory disc protrusion, extrusion or sequestrum or radial tear, the disc was stained with indigo-carmine dye
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and a limited herniectomy of the disc material was performed. Only degenerate disc material accessed endoscopically through a 3.5mm portal was removed. Where necessary, shrinkage of the posterior annulus and sealing of local tears (annuloplasty) was performed using the side-fire laser.

Once the nerve had been mobilized, it was returned to its natural pathway. After insertion of Depomedrone 80mg and Gentamycin 80mg in the operation zone, the wound was closed with a single suture.

Postoperative management

Patients were discharged the day of, or morning following, surgery. A muscle balance physiotherapy staged regime was re-commenced on the first day following surgery, amplified with neural mobilization drills and continued on a monitored self-help basis for 3 months. Patients were reviewed at 6 and 12 weeks unless clinical symptoms required closer supervision, and annually according to the study protocol.

Outcome measures

Patients used a pain mannikin to prioritize the predominant symptoms responsible for most of their suffering and functional impairment. Three zones corresponding to target symptom clusters were defined as: back pain; buttock, groin or thigh pain; and below knee pain.

Symptoms were assessed using the Visual Analogue Pain Scale (VAPS). Functional impairment was assessed using the Oswestry Disability Score (ODI) and Prolo Activity Score together with the SF36 Health Survey and Zung Depression Index and pain diaries at each review point.
Outcomes of TELDF were assessed by analyzing the change in VAPS and ODI for up to 3 years post-operatively. “Good Clinical Impact” (GCI) was defined as $\geq$50% improvement in pain scores in all symptom clusters (back, buttock, groin, thigh and legs) plus $\geq$50% improvement in ODI. Failure in any cluster denoted failure overall.

Patients were followed up annually with a full questionnaire that included the VAPS, ODI, Prolo Score, SF36 Health Survey and Zung Index. Patients were additionally reviewed where there was deterioration or upon demand.

**Results**

**Baseline characteristics**

A cohort of 65 consecutive patients was recruited into the study. A summary of their baseline demographics is shown in Table 1. All patients had multilevel chronic lumbar spondylosis with back or referred pain and multilevel degenerative disc disease on MRI scan. All had undergone a lumbar fusion at 1–3 disc levels and had been deemed untreatable by further surgery. All had been referred for chronic pain management. Post-fusion diagnoses included compressive radiculopathy, lateral recess stenosis, axial stenosis, graft failure, implant failure, perineural scarring and persistent nerve memory pain or neuroplasticity.

Of the 65 patients in the cohort, 26 were unemployable due to the severity of their symptoms. A further 24 patients were retired but deemed the quality of their retirement severely degraded as a result of their symptoms.
Table 1  Summary of baseline patient demographics & post-fusion treatment

<table>
<thead>
<tr>
<th>Total number of eligible patients</th>
<th>65</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td></td>
</tr>
<tr>
<td>Mean ±SD</td>
<td>53 ± 9.2</td>
</tr>
<tr>
<td>Range</td>
<td>42–81</td>
</tr>
<tr>
<td>Males</td>
<td>37</td>
</tr>
<tr>
<td>Predominant presenting symptom*</td>
<td></td>
</tr>
<tr>
<td>Back pain</td>
<td>32</td>
</tr>
<tr>
<td>Buttock, groin or proximal limb pain</td>
<td>12</td>
</tr>
<tr>
<td>Limb pain extending below the knee</td>
<td>10</td>
</tr>
<tr>
<td>Equivalent predominance of back, buttock and limb pain</td>
<td>8</td>
</tr>
<tr>
<td>Bilateral or oscillating limb pain</td>
<td>3</td>
</tr>
<tr>
<td>Duration of symptoms (years)</td>
<td></td>
</tr>
<tr>
<td>Mean ±SD</td>
<td>9.2 ± 4.2</td>
</tr>
<tr>
<td>Range</td>
<td>5–27</td>
</tr>
<tr>
<td>Lumbar intervertebral fusion</td>
<td></td>
</tr>
<tr>
<td>1 level</td>
<td>30</td>
</tr>
<tr>
<td>2 levels</td>
<td>32</td>
</tr>
<tr>
<td>3 levels</td>
<td>3</td>
</tr>
<tr>
<td>Prior pain management</td>
<td></td>
</tr>
<tr>
<td>Post-fusion chronic pain management</td>
<td>65</td>
</tr>
<tr>
<td>Coping courses</td>
<td>35</td>
</tr>
<tr>
<td>Residential cognitive behavioural therapy</td>
<td>22</td>
</tr>
<tr>
<td>Eligible for dorsal column stimulator</td>
<td>12</td>
</tr>
</tbody>
</table>

* The symptom cluster responsible for most suffering and functional impairment; symptoms; other symptoms may also be present
Prior surgical interventions

The cohort had undergone a total of 164 open spinal procedures addressing at least 230 discs, with a range of 1–6 procedures per patient (Table 2). A variety of different fusion procedures had been performed. Importantly, however, none of the patients in the cohort had undergone a transforaminal lumbar interbody fusion (TLIF).

Revision of the primary fusion had occurred in 16 patients and a separate procedure to remove metal implants had been required in 7 patients, although the exact extent of these procedures was not well documented.

Table 2 Prior surgical interventions

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Number of levels</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Discectomy</td>
<td>22</td>
</tr>
<tr>
<td>Decompression</td>
<td>7</td>
</tr>
<tr>
<td>Re-exploration</td>
<td>7</td>
</tr>
<tr>
<td>Primary fusion</td>
<td>30</td>
</tr>
</tbody>
</table>

TELDF outcomes

Spinal probing and discography was performed at levels ranging from L2 to S1. In 52 patients, spinal probing and discography evoked concordant symptoms and was sufficient to identify the appropriate spinal level for TELDF. The remaining 13 patients required differential discography to identify the spinal level responsible for their predominant presenting symptoms. All patients proceeded to TELDF.
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No patients were lost to follow-up during the first year post-operatively. During year 2, one patient was lost to follow-up, and an additional four during year 3 which sadly, included two patients who died from causes unrelated to their spinal symptoms and their data have not been included in the year 3 results. Cohort integrity was 100%, 98% and 92% at 1, 2 and 3 years respectively.

**Symptomatic improvement**

Patients treated with TELDF experienced a consistent and marked reduction in pain that was maintained up to 3 years post-operatively, as shown in Figure 1. In total, 86% of reviewed patients fulfilled the exacting definition of “Good Clinical Impact” at year 1, 78% at year 2 and 76% at year 3.

**Figure 1  Mean VAP score from baseline to 3 years post-operatively**

![Mean VAP score graph](image)

**Functional improvement**

Improvement in functionality, as assessed by the Prolo Score, is shown in Figure 2. At baseline, over half the patients in the cohort were assessed at Category 4 or 5 of the Prolo Scale, indicating significant impairment of function; only one was classed at
Category 2, indicating limited impairment of function; and none were classed at Category 1 (no functional restrictions of any kind). One year following TELDF, only seven patients fulfilled the criteria for Categories 4 or 5 (including only one at the most severe classification) and 46 patients (71%) were classed as Category 1 or 2, indicating an ability to return to work or retirement activities on at least a part-time or limited basis. These improvements were maintained. By years 2 and 3, no patients were assessed at Categories 4 or 5 (indicating the most severe disability).

Figure 2  Prolo Score categorization from baseline to 3 year post-operatively

Functionality was also assessed using the Oswestry Disability Index, as shown in Figure 3. This confirms the improvement in function sustained over the three year period noted in the patients’ Prolo Scores.
Requirement for further intervention

During years 2 and 3, two patients experienced deterioration in their symptoms attributable to the level of the original TELDF procedure, one of which was on the opposite side to the procedure. Neither of these patients considered further surgery was necessary.

During year 2, three patients experienced a deterioration in symptoms attributable to another site within the fusion (i.e. due to residual pathology arising from the original failed back surgery), increasing to five patients by year 3. Three of these patients underwent further TELDF at the additional pain site within the fusion with 'excellent' (≥90% improvement in VAP score) or 'good' (≥50% improvement in VAP score) outcomes.
In year 2, three patients exhibited symptoms arising from disc levels adjacent to the fusion, increasing to five in year 3. Three of these patients underwent additional TELDF at the adjacent level with 'excellent' and 'good' outcomes.

This pragmatic use of additional TELDF at painful or deteriorated levels increased “Good Clinical Impact” outcomes to 86% at year 1, 83% at year 2 and 85% at year 3.

**Complications**

Postoperatively 12/65 (18%) patients had flares marked by a transient recurrence of their predominant presenting symptoms commencing a week after surgery and lasting 2–4 weeks. During this period one patient had a transient recurrence of numbness in the great toe and another had transient calf allodynia. These short-lived symptoms are most likely due to irritation of the nerve in the spinal foramen as it swells in the healing phase following surgery.

There were no cases of disc or wound infection, deep venous thrombosis, chest or urinary infections or cardiac dysfunction. All patients were discharged the morning following surgery.

**Discussion**

TELDF represents a novel approach to the treatment of Failed Fusion Surgery because it is conducted in the aware state, allowing patient feedback to guide the surgeon accurately to the source of pain. This improves diagnostic accuracy and allows precise endoscopic targeting of the intervention with minimal disturbance of surrounding tissues. The procedure can be conducted under local anaesthesia as a day-case or with a single overnight hospital stay and does not require expensive
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implants. Due to its minimally invasive nature, TELDF can be used in the elderly and in those with clinically significant co-morbidities.

In this cohort of 65 patients with Failed Fusion Surgery, TELDF demonstrated a significant improvement in both symptoms and functionality that was sustained over 3 years. At all time points, over 75% of patients demonstrated a “Good Clinical Impact”. Unlike many other studies, which use ≥20% improvement in symptoms or functionality as an indicator of efficacy,41-43 “Good Clinical Impact” required a minimum of 50% improvement in both pain and function outcomes. This definition was based on observations in 150 patients who were asked if treatment had met their expectations and made a meaningful improvement in their lifestyle. It was evident that a reduction in overall pain was not enough unless all pain zones were reduced and functionality was at least doubled. Despite using such a rigorous endpoint, TELDF achieved positive outcomes in a severely disabled group of patients, many of whom were elderly and suffering significant co-morbidity and all of whom had been deemed untreatable by further surgery.

The “Good Clinical Outcome” result is supported by a clinically significant reduction in VAP score (from a mean of 8.2 at baseline to 3.0, 3.1 and 3.2 at years 1, 2 and 3 respectively) and ODI (from a mean score of 40 at baseline to 13.3, 13.4 and 13.2 at years 1, 2 and 3 respectively). The activity-related Prolo Score also indicates a significant and progressive improvement: 44 patients in the cohort (68%) were able to return to work or retirement activity post-TELDF (15 on a full-time basis and 29 in a part time capacity). These findings indicate that TELDF is an effective technique capable of improving both symptoms and function in patients with long-standing, multi-level back or referred limb pain for whom other interventions had failed.
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Only one patient experienced deterioration of symptoms arising from the site of TELDF, probably because adequate clearance of the scarring and bone impingement could not be achieved and the nerve sufficiently liberated. The patient did not consider further surgery necessary and the procedure was not, therefore, revised.

The revision rate to treat residual pathology arising from the original Failed Back Surgery within the fused segments was 3/64 (5%) over the 3 year review. Similarly, the requirement for surgical intervention in levels adjacent to the fused segments was 3/64 (5%). The aggravated degeneration above the fusion may be related to the increased activity enabled by the primary TELDF procedure. The revision rate for TELDF may be reduced in the future as improved instrumentation allows more rapid and extensive surgery to be applied at additional levels during the same procedure without diminishing the quality and completeness of nerve root liberation.

Complications of TELDF were limited to the transient recurrent irritation of the nerve as it swelled in the healing phase following surgery within the narrow confines of the minimally disturbed foramen. This affected 18% of the cohort but resolved spontaneously with symptoms minimised with analgesia and Non Steroidal Anti-Inflammatory Therapy.

The efficacy of TELDF in patients with long-standing back or referred pain despite immobilised segments indicates that foraminal pathology (e.g. persistent nerve irritation in the lateral foramen) rather than discal pathology may be a major cause of back pain. Unlike most fusion procedures, TELDF comprehensively addresses foraminal pathology through a combination of complete foraminotomy and foraminoplasty: liberation of the nerve root from impingement or tethering,
enlargement of the spinal foramen and correction of any misalignment of the nerve. Further research on the role of foraminal pathology in chronic back pain is warranted.

In conclusion, TELDF has been shown to be an effective intervention for the treatment of severely disabled patients with multilevel Failed Fusion Surgery, resulting in considerable improvements in symptoms and function. Its efficacy in patients with immobilised segments suggests that foraminal pathology may be a major cause of back pain.
References


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