Transforaminal Endoscopic Lumbar Decompression & Foraminoplasty: A 10 Year prospective survivability outcome study of the treatment of foraminal stenosis and failed back surgery

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Transforaminal Endoscopic Lumbar Decompression & Foraminoplasty: A 10 Year prospective survivability outcome study of the treatment of foraminal stenosis and failed back surgery.

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Abstract

Background

Conventional diagnosis between axial and foraminal stenosis is suboptimal and long-term outcomes limited to posterior decompression. Aware state Transforaminal Endoscopic Lumbar Decompression and Foraminoplasty (TELDF) offers a direct aware state means of localizing and treating neuro-claudicant back pain, referred pain and weakness associated with stenosis failing to respond to conventional rehabilitation, pain management or surgery. This prospective survivability study examines the outcomes 10 years after TELDF in patients with foraminal stenosis arising from degeneration or failed back surgery.

Methods

For 10 years prospective data were collected on 114 consecutive patients with multilevel spondylosis and neuro-claudicant back pain, referred pain and weakness with or without failed back surgery whose symptoms had failed to respond to conventional rehabilitation and pain management and who underwent TELDF. The level responsible for the predominant presenting symptoms of foraminal stenosis, determined on clinical grounds, MRI and or CT scans, was confirmed by transforaminal probing and discography. Patients underwent TELDF at the spinal segment at which the predominant presenting symptoms were reproduced. Those that required treatment at an additional segment were

excluded. Outcomes were assessed by postal questionnaire with failures being examined by the independent authors using the Visual Analogue Pain Scale (VAPS), the Oswestry Disability Index (ODI) and the Prolo Activity Score.

Results

Cohort integrity was 69%. 79 patients were available for evaluation after removal of the deceased (12), untraceable (17) and decliners (6) from the cohort.

VAP scores improved from a pre-operative mean of 7.3 to 2.4 at year 10. The ODI improved from a mean of 58.5 at baseline to 17.5 at year 10. 72% of reviewed patients fulfilled the definition of an “Excellent” or “Good Clinical Impact” at review using the Spinal Foundation Outcome Score. Based on the Prolo scale, 61 patients (77%) were able to return and continue in full or part-time work or retirement activity post-TELDF. Complications of TELDF were limited to transient nerve irritation, which affected 19% of the cohort for 2 – 4 weeks. TELDF was equally beneficial in those with failed back surgery.

Conclusions

TELDF is a beneficial intervention for the long-term treatment of severely disabled patients with neuro-claudicant symptoms arising from spinal or foraminal stenosis with a dural diameter of more than 3mm, who have failed to respond to conventional rehabilitation or chronic pain management. It results in considerable improvements in symptoms and function sustained 10 years later despite co-morbidity, ageing or the presence of failed back surgery.

Clinical Relevance

The long term outcome of TELDF in severely disabled patients with neuro-claudicant symptoms arising from foraminal stenosis which had failed to respond to conventional rehabilitation, surgery or chronic pain management suggests that foraminal pathology is a major cause of lumbar axial and referred pain and that TELDF should be offered as primary treatment for these conditions even in the elderly and infirm. The application of TELDF at multiple levels may further widen the benefits of this technique.

keywords:
Lateral Recess Stenosis, Axial Stenosis, Foraminal stenosis, Spinal Decompression, Failed Back Surgery, Endoscopic Decompression, Foraminoplasty, Foraminotomy, Failed Fusion Surgery, Failed Chronic Pain Management, Differential Discography, Transforaminal Spinal Probing, disc degeneration, Disc Protrusion, Long-Term Outcome
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Introduction

Foraminal, lateral recess or axial (central) stenosis with claudicant symptoms is a common condition in the elderly and as a consequence often associated with co-morbidities. Long-term treatment outcomes are often unsuccessful due to inaccurate identification of the relative contribution of axial, lateral recess and foraminal factors,[1] inadequate clearance of the foraminal stenosis and sequelae of the technique.[2]

In this study patients presenting with neuro-claudicant back pain and referred pain and weakness were evaluated by clinical examination, weight-bearing flexion and extension X-rays, MRI scans with or without CT scans, and definition of the causal levels by aware state foraminal probing and discography. Patients were treated by Transforaminal Endoscopic Lumbar Decompression & Foraminoplasty (TELDF). Those, in whom foraminal probing and discography indicated that a single spinal segment was responsible for reproducing the patient's predominant presenting symptoms, were entered in to the study for the purpose of assessing the long-term effect of foraminoplasty on back and leg pain arising from foraminal compromise whether arising from perineural scarring, anatomical distortion, facet joint hypertrophy, disc protrusion, failed back surgery or combinations thereof.

The technique of TELDF differs from endoscopic or conventional foraminotomy because it focuses on the liberation of the foraminal nerve by mobilising it from local tethering, removing the impingement upon the nerve by the superior foraminal ligament and incarceration by the remaining foraminal ligaments and perineural scarring. The technique undercuts the foramen and thereby removes hypertrophic facet joint capsule, facet joint osteophytes and osteophytes on the vertebral rim and the facet joint itself, interrupts the anterior articular nerve to the facet joint and allows the descending epidural nerve to be mobilised from the surface of the medial facet. Compression or irritation arising from the disc wall or disc contents is reduced by means of discectomy or herniectomy. The procedure enlarges the foraminal volume and reduces compression and irritation of the exiting nerve in particular.

Conventional wisdom purports that back pain arises from the disc[3] (discogenic pain) or the facet joint and referred pain, predominantly from compression of the nerve. Aware state transforaminal endoscopy has reported that the exiting nerve is a major cause of both back pain and referred pain.[4,5]

Currently where physiotherapy and conservative chronic pain management (including injections, nerve ablations, coping courses and cognitive behavioural therapy) fail, the patient with neuro-claudicant back and referred pain may be referred for microdiscectomy or foraminotomy, medial facetectomy, Interspinous spacers to decompress the nerve or instrumented intervertebral fusion to immobilise and restore the height and alignment of the disc and facet joints. The number of relevant 10 year outcome studies is limited. This prospective study is the first to report the clinical outcome ten years after aware state TELDF as a means of treating patients with this condition arising from degeneration or failed back surgery.

Methods

During 1997 prospective data were collected on a consecutive series of 114 patients with neuro-claudicant back and referred pain and weakness with multilevel chronic lumbar spondylosis and or prior surgery were admitted to the study after at least 3 months of failed muscle balance physiotherapy or failed chronic pain management. These underwent TELDF at the Spinal Foundation in the UK. These patients were fully informed and admitted to the study according to the Spinal Foundation Research Protocol and thereafter followed on a prospective basis. Patients were routinely followed up and ultimately

contacted at 10 years for an additional follow up. Where they declined this was respected and their data recorded as “refused”. In most cases this was due to the elderly status of the patient or co-morbidities rather than a poor outcome.

Eligibility criteria

Patients were included if they suffered back pain and combinations of referred pain in buttock(s), groin(s), thigh(s) and below the knee(s) and weakness in one or both limbs all aggravated by exercise of 5 minutes or less and whose walking distance was limited to 20 minutes or less.

Patients with severe bony axial stenosis as evidenced by marked medial facet joint overgrowth causing trifoliate narrowing of the epidural space combined with ligamentum flavum infolding reducing the dural diameter to 3 mm or less were excluded and referred for combination posterior and transforaminal endoscopic decompression or conventional decompression or Interspinous spacer elevation.

Patients were excluded if they were pregnant, evidenced facet joint cysts, cauda equina syndrome, systemic neuropathy or spinal tumours.

Eligible participants were consented for aware state transforaminal foraminal probing and discography on two or more spinal segments to establish which segment reproduced concordant back pain or peripheral symptoms. If the patient was unable to clearly define the source of their predominant pain at a single segmental level then they proceeded to Differential Discography and were excluded from the study

Once the spinal level responsible for the patient’s predominant presenting symptoms had been identified, patients progressed to TELDF at that level.

Surgical procedure

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

Transforaminal spinal probing and discography procedure

Under X-ray guidance, a transforaminal spinal probing cannula (Arthro Kinetics Plc) was inserted into the spinal foramen via a posterolateral approach optimised by the use of a specially designed X-ray alignment jig (Arthro Kinetics Plc).[6] 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 and the annulus itself. 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 gentle pressure discography.

Evoked sensations that reproduced the patient's predominant presenting symptoms in the back and leg were classed as 'concordant' symptoms. Patients in whom transforaminal foraminal probing and discography demonstrated concordant symptoms proceeded immediately to TELDF at the level evidencing the concordant symptom reproduction. Patients with symptoms that were discordant (similar but not identical to the predominant presenting symptoms) or overlapping (symptoms arising at more than one spinal level), progressed to differential discography, in which steroid (80mg Depomedrone) was inserted at the most responsive spinal level and anaesthetic (2mls of 0.5% Naropine) was inserted at the adjacent level. Where the acceptance volume was low, a radio-opaque dye-guided radiculogram was performed in place of the differential discogram. 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 transforaminal spinal probing cannula and replaced with a long guide wire. An endoscope cannula and dilator were railroaded along the guide wire to the foramen under X-ray control. The dilator was removed and the endoscope was inserted to offer visualisation 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 commencing at the inferior pedicle and progressively defining the bone margin of the pedicle and subsequently deepening the clearance to expose the anterior margin of the facet joint and capsule. Clearance was then extended along the anterior margin of the facet joint until the apex of the ascending facet was defined. This often provided the appearance of a short "notch" in the bone margin as the probe passed onto the anterior surface of the descending facet. At this juncture the surgeon normally returned to progressively remove tissue in the Safe Working Zone.[7] During this clearance the medial border of the nerve would be declared. The nerve medial margin was then followed up to the facet margin "notch" keeping the side fire laser beam pointing away from the nerve. Perineural scar and ligaments were physically removed from the surface of the nerve down to the inferior pedicle. The endoscope cannula was inserted securely and safely to the safe working zone and the nerve mobilised from the disc and vertebral body by means of a nerve root retractor. The surgeon then turned the shouldered endoscopic cannula superiorly to explore the nerve up to the superior pedicle where the superior foraminal ligament would be encountered and on occasions was found to be calcified. The superior foraminal ligament[8] was defined and removed and the ganglion exposed and pulsatility of the nerve root restored. Apical osteophytes on the superior facet were then removed with burrs, reamers, trephines and the side-fire laser. Where the foraminal volume was particularly small access to the superior third of the foramen was facilitated by the early use of serial manual reamers providing epidural access ultimately achieving the passage of 5.5mm diameter reamers or greater. The exiting nerve was mobilised with a nerve root retractor from pedicle to pedicle until free of tethering and pulsatility was restored. The descending nerve was mobilised from the medial surface of the facet joint under radiographic control by means of the nerve root retractor within the epidural canal. Where indicated, protruding disc was removed with care to avoid exposing intervertebral graft or cages in cases of failed back surgery. Where

there was a contributory disc protrusion, extrusion or sequestrum or radial tear, the disc was stained internally with indigo-carmine dye and a limited herniectomy of the disc material was performed. Only degenerate disc material accessed endoscopically through a 3.5 mm portal was removed. Where necessary, shrinkage of the posterior annulus and sealing of local tears (annuloplasty) was performed using the side-fire laser probe (Lisa Holmium 1250 J delivered at 20 pps and 20 watts).

Once the nerve had been mobilised and examination was made to detect the presence of a shoulder osteophyte[4] arising from the vertebral rim posterolaterally and anterior to the nerve. These were removed with burrs, trephines and laser ablation. Thereafter the nerve was returned to its natural pathway. After insertion of Gentamycin 80mg in to the disc and Depomedrone 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 for two years.

Outcome measures

Patients used a pain diagram (manikin) to demonstrate the predominant symptoms responsible for 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.

The severity of painful symptoms were assessed using the Visual Analogue Pain Scale (VAS). Functional impairment was assessed using the Oswestry Disability Score (ODI) and Prolo Activity Score and pain diaries for 6 weeks following surgery and at each review point.

Outcomes of TELDF were assessed by analysing the change in VAS and ODI preoperatively, at 3 & 6 months, annually for two years and ten years following surgery.

This study has employed the following outcome benchmarks[6]:

An “Excellent” result was defined as complete improvement in pain scores and restoration of functionality.

A “Good Clinical Impact” (GCI) was defined as at least a 50% improvement in pain scores in ALL three symptom clusters (back; buttock, groin, thigh; below knee) plus at least a 50% improvement in ODI. Failure in any cluster denoted failure overall.

Patients were deemed ”Satisfactory” if they met the 50% benefit but only in two of the three clusters.

Patients were classed as “Poor” if they failed to meet the “Satisfactory” criteria but were not worsened.

Patients were deemed worse if the symptoms were worse than prior to surgery 6 months after surgery in any one cluster even if benefit had been secured in other clusters.

After 10 years patients were independently followed up with a full questionnaire that included the VAS, ODI, Prolo Score and the results compared to the preoperative results. Where the patient was at a distance or elderly then a telephone consultation was performed to assist the patient to complete their questionnaire.

Those patients who had become lost to follow-up on the Spinal Foundation database were then referred to City Enforcements Limited, Stoke on Trent to be traced.

Results

Baseline characteristics

During 1997 prospective data were collected on a consecutive series of 114 National Health Service and insured patients with multilevel chronic lumbar spondylosis and activity aggravated back and or referred pain with or without prior surgery. They were admitted for surgery after at least 3 months of failed muscle balance physiotherapy or failed chronic pain management. These underwent aware state foraminal probing, discography and TELDF and symptoms were reproduced at a single segmental level. The deceased (12), the untraceable (17), and those declining to participate (6) were excluded from the study resulting in an available survivability group of 79 who met the claudicant "stenotic" single segmental level inclusion criteria. Of the 35 responders excluded, 24 were reviewed at 2 years from surgery and 19 were categorised as "Excellent", "Good" or "Satisfactory". The cohort integrity at 10 years was 79/114 (69%).

The failed back surgery patients had been variously diagnosed compressive radiculopathy, lateral recess stenosis, axial stenosis, graft failure, implant failure, perineural scarring and persistent nerve memory pain and neuroplasticity. A summary of the baseline demographics is shown in Table 1 and Table 2.

Table 1. Summary of patient clinical demographics

Total number of eligible patients with foraminal claudication	79
Entire Cohort Age at 10 year review (years)	
Mean ±SD	56 ± 10.5
Range	40–82
Duration of symptoms (years)	
Mean ±SD	10.1 ± 4.9
Range	3–29
Males	37
Predominant presenting activity related symptom(s)*	
Back pain predominating over leg symptoms	42

Predominant buttock, groin or proximal limb pain & weakness	12
Predominant limb pain extending below the knee	15**
Equivalent predominance of back, buttock and limb pain	6
Bilateral or oscillating limb pain	4
Interventional Level	
L1-2	0
L2-3	1
L3-4	3
L4-5 or Transitional	35
L5-S1 or Transitional	40
Predominant Pathology Combinations	
Disc protrusion & axial stenosis & foraminal narrowing	37
Spondylolisthesis & foraminal narrowing	12
Perineural scarring ± osteophytosis	14
Foraminal & lateral recess stenosis	10
Pedicle wall fragmentation compromising the foramen	1
Cage implant foraminal compromise	2
Retrolisthesis & foraminal compromise	3
Prior pain management	
Chronic pain management	62
Coping courses	42
Residential cognitive behavioural therapy	24
Eligible for dorsal column stimulator	9

*The symptom cluster responsible for most suffering and functional impairment; other symptoms may also be present. **In 8 cases the symptoms were bilateral.

Table 2. Summary of prior failed back surgery procedures

Discectomy Group	26	
1 Level laminectomy and discectomy	2	
2 Levels laminectomy and discectomy	3	
3 Levels laminectomy and discectomy	1	
Laminectomy revisions by microdiscectomy		1
Laminectomy revisions by Fusion		3
1 Level microdiscectomy	10	

2 Levels microdiscectomy	5	
Microdiscectomy revisions by microdiscectomy		1
Microdiscectomy revisions by stenosis decompression		4
Microdiscectomy revisions by fusion		3
Primary axial "Decompression" & discectomy	2	
Primary lateral recess "Decompression" & discectomy	3	
Primary Fusion Group	13	
1 Level posterior lumbar interbody fusion	5	
2 Level posterior lumbar interbody fusion	4	
1 Level anterior lumbar interbody fusion	2	
2 Level anterior lumbar interbody fusion	1	
2 Level posterolateral instrumented fusion	2	
2 Level Graf Ligament fusion	1	

Twenty-six patients presented after failed lumbar discectomy and 13 after failed fusion surgery amounting to 49% of the survivability cohort. This group of 39 patients had undergone 53 conventional procedures followed by repeated chronic pain management. There was no significant statistical demographic difference between the failed surgery and no prior surgery groups.

The survivability group (79) suffered a number of systemic co-morbidities: Diabetes Mellitus (13), Hypertension (18), Coronary Stentage (11), Coronary Artery Bypass Grafting (5), Cardiac Pacing (7), Obstructive Airways Disease (6), Kidney Disease (1), Cancer History (9), Osteoporosis (8), Prior Deep Venous Thrombosis (2).

TELDF outcomes

Symptomatic Outcomes

65/79 (82%) patients treated with TELDF experienced a consistent and marked reduction in pain that was maintained at their 10-year review, as shown in Table 3. 35% were pain free or "Excellent". 36% were categorised as "Good" indicating that 72% of reviewed patients fulfilled the exacting criteria of an "Excellent" or "Good" Clinical Impact at year 10 and 82% fulfilled the criteria of an "Excellent", "Good" or or "Satisfactory" Clinical Impact.

Table 3. Categorisation of patient outcomes

	Patients	Percentage of Stenotic Cohort	Good & Excellent Clinical Impact & Satisfactory	Good & Excellent Clinical Impact
Excellent	28	35.4%	82.2%	72.1%
Good	29	36.7%		
Satisfactory	8	10.1%		

Poor	11	13.9%		
Worse	3	3.8%		

Table 4 demonstrates that TELDF achieved a 67% reduction in mean pain at 10 years.

Table 4. Comparison of Mean VAS and ODI scores prior to surgery and at 10 years postoperatively.

	Preoperative VAS	Post-Operative VAS	% Change
Mean	7.3	2.4	67%
S.D	1.8	2.1	
	Preoperative ODI	Post-Operative ODI	% Change
Mean	58.5	17.5	70%
S.D	14.7	15.2	

VAS = Visual Analogue Pain Score, ODI = Oswestry Disability Index.

Functional outcomes

Improvement in functionality was assessed by the Oswestry Disability Index and Prolo Scores.[9]

In Table 4, at the preoperative baseline, the group manifested a mean ODI of 58.5 indicating significant impairment of functionality. TELDF provided an improvement in the group mean of 70% at 10 years.

The Prolo[9] scores were sub-stratified for those in the working age group below 65 and patients who were retirees. Table 5 indicates that of the 79 patients, prior to surgery, 18 were unemployable due to the severity of their symptoms. A further 17 patients were retired but deemed the quality of their retirement severely degraded as a result of their symptoms. Ten years after surgery the majority of patients (61/79) 77%, whether in the working or retired age groups maintained full or part time activity.

Table 5. Preoperative and 10 year postoperative Prolo mean scores

	Working Age		Retired	
	Preoperative Prolo score	Post-Operative Prolo score	Preoperative Prolo score	Post-Operative Prolo score
Mean	3.4	1.7	3.6	1.9
S.D	0.9	0.8	0.8	1.0
Level 1	0	22	0	18
Level 2	5	15	2	6
Level 3	20	5	17	10
Level 4	12	1	11	2
Level 5	6	0	6	0

Prolo Definitions: 1) Able to work at previous occupation or full retirement activity with no restriction of any kind; 2) Working at previous occupation or retirement activity on part-time or limited status; 3) Able to work or pursue retirement activity but not at previous occupation or retirement activity levels; 4) No gainful occupation or retirement activity (able to do housework or limited self help activities); 5) Invalid (unable to cope with self-help activities without help)

Analysis of "Poor" and "Worse" outcomes

The 9/14 "Poor" or "Worse" patients 10 years after TELDF were investigated by weight-bearing flexion and extension X-rays and MRI scans and independently clinically examined by the co-authors. The outcome of these investigations is shown at Table 6.

Table 6. Summary of causation of "Poor" or "Worse" outcomes.

Recurrent operative site symptoms	2	
	Stenosis	2
	Concurrent Perineural Scarring	1
Contra-lateral same level stenosis	3	
Adjacent level deterioration	6	
	Disc Protrusion	2
	Degenerative Spondylolisthesis	2
	Foraminal Stenosis	2
Self-excluded to physical review	Multiple Sclerosis	1
	Ovarian Cancer & Fusion	1
	Sequelae of Fusion	2

In the "Poor" group of eleven patients, six patients deteriorated due to symptoms arising at an adjacent level and three developed symptoms on the other side. Two patients deteriorated at the operated site, one with foraminal perineural scarring. Two patients went forward to a fusion and one became paraparetic as a consequence and both self-excluded from further follow up.

In the "Worse" group (3), one patient underwent a fusion procedure and was then diagnosed with ovarian cancer and pelvic nerve involvement, one has undergone a multi-level fusion without benefit and one has developed Multiple Sclerosis. All three self-excluded from further physical review.

Analysis of effect of prior surgery on outcomes

Table 7 shows that there was very little difference in the groups prior to TELDF and at review. Classification revealed the following outcomes: failed back surgery group, "Excellent" 15, "Good" 15, "Satisfactory" 3, "Poor" 5 & "Worse" 1. Whilst the Primary Surgery group (with no prior open intervention) the outcomes were: "Excellent" 13, "Good" 14, "Satisfactory" 5, "Poor" 6 & "Worse" 2.

Table 7. Comparison of "Failed Back Surgery" & "Primary Surgery" outcomes

FBS Group	Preoperative VAS	Review VAS	Preoperative ODI	Review ODI
Mean	7.6	2.2	60.8	16.3
S.D	1.9	2.0	15.3	14.7
Primary Surgery	Preoperative VAS	Review VAS	Preoperative ODI	Review ODI
Mean	7.0	2.6	56.3	18.6
S.D	1.7	2.2	13.9	15.8

Complications

Postoperatively 15/79 (19%) patients had "flares" marked by a transient recurrence of the patient's predominant presenting symptoms commencing a week after surgery and lasting 2–4 weeks.

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

Discussion

This study has reviewed the long-term survivability of outcome of patients undergoing unilateral single segmental lumbar TELDF for neuro-claudicant back pain, referred pain and weakness derived from foraminal and spinal stenosis.

Outcome Criteria

This survivability study relies upon clinically relevant outcome parameters derived from patient feedback[6] and formulated in to The Spinal Foundation Outcome Score. The definition was based on observations in 150 patients who were asked if treatment had met their expectations and had made a meaningful improvement to their lifestyle. It was evident that a reduction in overall pain was not enough unless all three pain zone clusters were reduced by 50% or more and functionality was at least doubled. The three anatomical clusters of pain sites are namely:

- Lower back,
- Buttock, groin, anterior and/or posterior thigh,
- Symptoms arising below the knee.

Failure to achieve a 50% reduction in pain in any of these "clusters" resulted in impaired functionality and satisfaction. Based upon this patient feedback this study has employed the following outcome benchmarks:

We have employed these outcome benchmarks because according to patients they represent a meaningful measure of the outcome impact on their functionality and lifestyle. These measures are comprehensive and take in to account pain and functionality as these impact upon the whole outcome in the lower spine and limbs rather than just examining the changes in back pain or the changes in leg pain.

TELDF 10 Year Outcomes

This cohort had an age range of 40 – 82 years (mean age of 56: SD 10.5) at the time of their operation. In 12 cases the lower limb symptoms were bilateral and in 39 cases (49%) the patients had undergone prior decompression, microdiscectomy or fusion surgery. The preoperative state of the group was that of marked to severe pain and disablement (As seen in Table 4: Mean VAS of 7.3 (SD 1.8), Mean ODI of 58.5 (SD 14.7)). Following TELDF there was a substantial sustained improvement of 67% and 70% respectively at review 10 years later. 35% remained in the "Excellent" clinical impact category, 37% in the "Good" category with a further 10% who fell in to the "Satisfactory" category making a combined total of 82% evidencing sustained improvement from the intervention. Cohort integrity was 69%.

Prior to surgery 18 patients were unemployable due to the severity of their symptoms. A further 17 patients were retired but deemed the quality of their retirement severely degraded as a result of their symptoms (Table 5). Ten years after surgery the majority of patients (61/79: 77%) whether in the working or retired age groups maintained full or part time activity. These results compare favourably to conventional treatment options.

Complications

These benefits were achieved without complications despite the severity of presentation, the presence of failed back surgery, the age range or the incidence of co-morbidities.

Transient post-operative "flares" were noted in 19%. The "flare" is typified by a transient recurrence of the patient's predominant presenting symptoms commencing a week after surgery and lasting 2–4 weeks depending upon the severity of the intervention and the age of the patient. These short-lived symptoms are most likely due to irritation of the nerve in the narrow confines of the spinal foramen as it is consistent with the phase of engorgement noted in the healing phase following surgery and coincides with the normal pattern of post-surgical recuperation. These symptoms were managed with regular analgesia and non-steroidal anti-inflammatory therapy. There were no cases of myocardial infarction, pulmonary infection, cerebrovascular accidents, deep venous thrombosis, infection, dural tears, foot-drop or nerve damage. This is in keeping with our earlier findings that complications were limited to minor complications in 2.4% of our first 958 TELDF procedures.[10]

Distinction between foraminoplasty & foraminotomy

Transforaminal surgery has evolved along the pathway of radiologically guided percutaneous discectomy developed by Hijikata[11] in 1989 and subsequently the biportal endoscopic discectomy of Kambin[7] to uniportal transforaminal endoscopic discectomy currently promulgated with encouraging results by Yeung[12,13] and others.[14-27]

Our early results[6,28] revealed that transforaminal endoscopic discectomy without foraminoplasty could aggravate incipient lateral recess or foraminal stenosis. This led to the inception of Transforaminal Endoscopic Lumbar Decompression & Foraminoplasty. The term foraminoplasty was coined by the lead author to differentiate the technique from Foraminotomy which seeks merely to enlarge the bony foramen. By contrast Foraminoplasty addresses not only the optimisation of the bony foraminal volume but focuses upon restoring the mobility of the exiting nerve root and correction of the pathology in and around the foramen. This consists of removal of perineural scarring from pedicle to pedicle and the superior foraminal ligament, facet joint overgrowth and osteophytes of the facet joint, vertebral rim and vertebral "shoulder", granulations within the safe working zone and then ensuring that the exiting nerve is mobilised from the vertebra and disc wall and the descending (transiting) nerve is mobilised from the medial surface of the facet joint. The disc pathology is addressed by herniectomy and annuloplasty as and when appropriate.

Comparative outcomes

Conventional treatment alternatives include posterior decompression by laminectomy, laminotomy, medial facetectomy, microdiscectomy, fusion and interspinous spacers, endoscopic posterior decompression transforaminal endoscopic foraminotomy but long-term studies of these procedures are limited.

Findlay et al.[29] evaluated eighty-eight consecutive patients undergoing lumbar microdiscectomy with an assessment at 10 years after surgery in 79 (90%) of the treated cases. Outcomes were assessed retrospectively 6 months after surgery using the Macnab classification and then by a postal modified Roland-Morris disability questionnaire completed by the patients themselves. Whilst a successful outcome in regard to leg pain was achieved at 6 months in 91% of cases, at 10-years, this result had declined to a success rate of 83%. This study ignored the presence of on-going back and buttock or groin pain. By contrast to our study Findlay's group of patients suffered from compressive neuropathy arising from disc protrusions and did not involve the treatment of lateral recess stenosis or failed back surgery or failed fusion surgery or multilevel disc degeneration.

Brantigan et al.[30] reviewed the outcome of carbon reinforced cages after 10 years implantation in patients with degenerative disc disease who had at least one failed lumbar discectomy or decompression procedure at one or more levels. Thirty-three of 43 eligible patients (77%) were evaluated using a modified Prolo scale alone. Clinical success was achieved in 29 of 33 patients (87.8%) at 10 years with successful fusion integration reported in 29 of 30 patients (96.7%). Patient satisfaction was reported in 31 of 33 (93.9%). However these results are at variance with the requirement that further lumbar surgery was required in 23 patients: 18 patients required elective removal of pedicle screws and in 5 patients the fusion required to be extended to include adjacent levels. Adjacent segment degeneration occurred in 61% of patients and was clinically significant in 20%. These findings compare controversially to the contemporary results of randomised controlled clinical trials of fusion which evidence much lower success rates.[31-33]

In a 10 year study of 100 patients treated by conservative measures or posterior foraminotomy, Amundsen et al.[34] found that surgical intervention was superior to conservative care. However only 51% of patients fitted the equivalent of the “Good Clinical Impact” criteria used in this study.

In a 10 year study of decompressive laminectomy for spinal stenosis, Iguchi et al.[35] reported that 56% of 37 patients achieved a good result using the JOA score. 3 patients developed a disc protrusion at the laminectomy level and patients requiring multi-level laminectomy with more than a 10 degrees sagittal rotation were at risk of earlier deterioration and the authors advised that concurrent fusion be considered in such cases. Katz et al.[2] reviewed 68 patients over 7 years after decompressive laminectomy: 20 had undergone a re-operation and 35% were severely disabled and 53% were unable to walk two blocks and 33% had severe back pain.

Interspinous spacers have been used to tighten and retract the interlaminar ligamentum flavum and increase the foraminal volume as a means of treating spinal stenosis. Kim et al.[36] reported on the use of the DIAM as an adjunct to microdiscectomy or laminectomy. At a mean of 1 year there was no statistically significant differences in visual analog scale (VAS) pain scores or Macnab outcomes between patients with or without the Diam implant but the implant group had sustained three intraoperative spinous process fractures and one infection.

Sobottke et al.[37] compared the radiographic and clinical outcomes following insertion of the X-Stop, Wallis, Diam Interspinous spacers in the treatment of neurogenic claudication. In this study the X-Stop implant improved (in some cases significantly) the radiographic parameters of foraminal height, width, and cross-sectional area, more than the Diam and Wallis implants; however, there was no significant difference among the three regarding symptom relief. During follow up there was a loss of the correction but pain scores did not deteriorate despite this "loss of correction." This study indicates that the spacers are achieving a benefit that does not rely upon upon increase in foraminal volume. Some of the benefit may arise from correction of the abnormal micro-movements occurring in the foramen noted in our endoscopic studies of the patho-anatomy of the degenerate foramen.[4]

Beyer et al.[38] in a 2 year study found that open decompression proved superior to percutaneous stand-alone spacer implantation.

Some authors have equated foraminotomy with Foraminoplasty and used the term in their reports which confuses readers. Relevant reports of unilateral endoscopic transforaminal decompression or foraminotomy for the treatment of stenosis include Ahn et al.[39] who studied 12 patients with foraminal stenosis and associated leg pain treated by posterolateral (transforaminal) percutaneous endoscopic lumbar foraminotomy (PELF) for foraminal or lateral exit zone stenosis at L5-S1 level The mean follow-up period was 12.9 months. The authors using the Macnab score, reported excellent or good results in 10 patients without complications.

Alimi et al.[40] reported the results of a unilateral minimally invasive lumbar foraminotomy through tubular retractors via a contralateral epidural approach for unilaterally dominant radiculopathy arising as a consequence of root compression. In a 12 month follow up of

32 patients they reported excellent functional outcome in 95% with one patient requiring revision by fusion. They advocated this technique for lumbar spinal stenosis and bilateral lateral recess decompression without the need for fusion.

Chang et al.[41] described their 2 year clinical outcomes following transmuscular microsurgical decompression of the foramen laterally or by a medial contralateral approach in 39 patients. Using Macnab criteria they reported 85% excellent and good results.

Mechanism of Foraminoplasty

Aware state foraminal probing and palpation under direct vision reveals that superficial pressure on the nerve produces local back pain and deeper pressure produces pain referred down the body to the buttock, groin, thigh and below the knee to the foot. We did not use the term dermatomal because in our experience many patients have pain distributions that involve overlapping classical distributions of pain or atypical combinations of dermatomal distribution. For instance the exiting L5 nerve root may produce combinations of pain over the sacro-iliac joint, the front of the thigh, outer groin or even the little toe.

The fact that the distant or referred pain is radicular is confirmed because it was reproduced during foraminal probing of the nerve. Only in 11% of our cases did annular probing reproduce back pain and it did not produce distant pain. Discography reproduced back pain and distributed (referred) pain due to distortion of the nerve where it was tethered to the weakened disc wall.

The outcome analysis is based upon the Spinal Foundation Outcome Score which was built upon patient's perception of benefit. The Spinal Foundation Outcome Score divides the pain territories in to Zone A Lower back, Zone B Buttocks, Groin and Thigh and Zone C Below knee symptoms. This covers the distribution of the predominant presenting symptoms and obviates the need to commit to the diagnosis of whether the pain is radicular or not.

Foraminoplasty is not just a decompressive foraminotomy or foraminal bony undercutting nor just decompression by discectomy. In many cases we do not even enter the disc. As described in the discussion "Distinction between Foraminoplasty & Foraminotomy", Foraminoplasty focuses on liberating and mobilizing exiting and descending nerve roots from the epidural space to beyond the external boundaries of the foramen. Thereby it removes the factors that irritated, distorted or compressed the nerve roots and caused the pain, reproduced during foraminal palpation, which reproduced the patient's predominant presenting symptoms.

The predominant presenting symptoms included weakness arising from a combination of direct compression with an additional claudicant element arising from arterio-venous engorgement. By removing the compression occasioned the superior foraminal ligament, foraminal ligaments and perineural scarring as well as increasing the foraminal volume by undercutting the hypertrophic or osteophytic often overriding facet joint, by removing disc protrusions and vertebral osteophytes, the nerve is cleared, pulsatility restored and arterio-venous engorgement removed. The restoration of neural function thereby reverses the motor weakness as well as relieving back and referred pain.

Patients underwent weight-bearing X-rays in flexion and extension both sitting and standing prior to surgery. In many cases these exhibited dynamic anterior olisthesis or retrolisthesis. Our experience deemed that these features were not an exclusion criterion because the role of Foraminoplasty was to mobilise the nerve root(s) and remove the impaction from hypertrophic or overriding facet joint and local osteophytes. Foraminoplasty thereby removes the features causal of symptoms of "instability."

Consequences of Foraminoplasty

In 12 patients the predominant presenting symptoms were bilateral. These cases were treated with a unilateral Foraminoplasty and in all cases the symptoms were cleared bilaterally. At 10 years 3 patients presented with contra-lateral leg symptoms and one of these patients was amongst the original patients with bilateral symptoms.

We can only surmise on the mechanism by which Foraminoplasty achieves a bilateral benefit and that it does so by addressing several underlying factors:

By reducing the size of a concomitant protrusion that this improves the volume dimensions of both foraminae and the axial epidural volume.

By reducing the inflammation within the disc by means of Laser Disc Decompression and Annuloplasty that this has an affect on swelling in both foraminae and also inflammation and nerve root irritation bilaterally.

By reducing the pain arising from the more severely affected side that there is a reduction in protective muscle spasm on both sides of the spine and thereby lessens compression and irritation on the contralateral exiting nerve root.

By increasing the volume of the foramen and undercutting the lateral recess that the increase in the epidural volume serves to relieve the contralateral dural compression,

By reducing the pain, the posture improves and the implementation of a graduated regimen of Muscle Balance Physiotherapy serves to rehabilitate the deep muscle atrophy that attends this condition. This reinforces the postural correction and improves the load transportation through the spinal segment. This in turn reduces the in-folding of the ligamentum flavum into the epidural space and the foramen and may reduce concomitant facet joint synovial effusions with further improvement of foraminal and epidural volumes. The improvement in deep muscle control afforded by the rehabilitation of Multifidus may serve to reduce the abnormal micro-movements of the segment consequent upon olisthesis which serve to cause irritation of the foraminal contents. Improved segmental control may also serve to limit the overriding of the facet joints and secondary irritation or compression of the exiting nerve root(s).

These features may also contribute to the longevity of outcome of Foraminoplasty.

Relevance of Foraminoplasty

The long term outcome of TELDF in severely disabled patients with neuro-claudicant symptoms arising from foraminal stenosis which had failed to respond to conventional rehabilitation, surgery or chronic pain management suggests that foraminal pathology is a major cause of lumbar axial and referred pain and that TELDF should be offered as

primary treatment for these conditions even in the elderly and infirm and those suffering with failed back surgery. The application of TELDF at multiple levels may further widen the benefits of this technique.

Failure Analysis

At ten years from surgery 3 patients were “Worse” due to ovarian cancer, fusion sequelae and multiple sclerosis with impaired postural control. In those patients whose outcome was classified as “Poor”, six patients deteriorated due to symptoms arising at an adjacent level and three developed symptoms on the other side. Two patients deteriorated at the operated site, one with foraminal perineural scarring. Two patients went forward to a fusion and one became paraparetic as a consequence and both self-excluded from further follow up.

The low incidence of adjacent disc degeneration (ADD) in patients presenting with multi-level spondylosis is attributable to the preservation of segmental movement at the operative site and our focus on post-operative postural correction with Muscle Balance Physiotherapy.

Conclusion

TELDF is a beneficial intervention for the long-term treatment of severely disabled patients with neuro-claudicant symptoms arising from spinal or foraminal stenosis with a dural diameter of more than 3 mm, who have failed to respond to conventional rehabilitation or chronic pain management. It results in considerable improvements in symptoms and function sustained 10 years later despite co-morbidity, ageing or the presence of failed back surgery.

The outcomes compare favourably to the long-term reviews of conventional surgery and are endorsed by similar benefits noted in patients with spondylolytic spondylolisthesis[26] and transforaminal foraminotomy.[39] These findings indicate that foraminal pathology is a major cause of lumbar axial and referred pain.

The application of TELDF at multiple levels may further widen the benefits of this technique.

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Disclosures

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