The Curative Effect of Miniscalpel-Needle Combining with Spinal Minimally Invasive Technique for the Treatment of Lumbar Spinal Stenosis

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Abstract

Objective

Using Miniscalpel-Needle (MSN) combining with minimally invasive surgery to treat degenerative lumbar spinal Stenosis (DLSS), and meanwhile, to assess the related clinical outcome.

Methods

A total of 102 patients with DLSS were included in the study and divided into two groups randomly. Forty-seven cases of Group I were treated with MSN combining with minimally invasive surgery (three dimensional minimally invasive therapy, TDMIT), while 55 cases of Group II accepted the traditional therapy in the Department, i.e. intervertebral foramen loosening with MSN combing with conservative medication. All patients were followed-up regularly, and the clinical efficiency was evaluated at both six months after the surgery and the final time point. Scores of Visual Analogue Scale (VAS), JOA, and Oswestry Disability Index (ODI) were calculated and recorded. These scores at different time points were analyzed and compared, and also, the clinical treatment efficiency was calculated.

Results

The mean follow-up periods were 19.4 ± 8.4 months in Group I and 16.6 ± 9.0 months in Group II. At the final follow-up time point, the effective rate in Group I was 89.36% and the rate in Group II was 65.45% which presented a significant difference in the two groups ($P<0.05$). Compared with the preoperative state, both groups had significantly improved score values in VAS, JOA and ODI scales ($P<0.05$). No serious complication occurred. And further comparison of the two groups confirmed that Group I presented a more satisfactory efficiency than that Group II did ($P<0.05$).

Conclusion

Both TDMIT and intervertebral foramen loosening can achieve certain clinical curative effect, but the former technique is more effective and reliable.
Keywords
Degenerative; Lumbar Spinal Stenosis; Minimally Invasive Surgery; Miniscalpel-Needle; Clinical Outcome

Introduction
Degenerative Lumbar Spinal Stenosis (DLSS) is one of the main spinal diseases which harassed the aged. Their lumbar spinal columns degenerate with ages, while the activity space for lumbar vertebra nerve and blood vessels become narrowed. The clinical symptoms often present lumbago and lower limb radiation pain accompanied by intermittent claudication. As a clinical syndrome, the pathological change of DLSS is very complex and the clinical symptoms are various, which brought great difficulty to minimally invasive spine surgery. In most of time, the sole minimally invasive spine surgery on specific location could not solve the complex symptom of DLSS [1]. Anatomic variation, mechanical imbalance and nucleus protrusion are three key factors of lumbar degenerative disease. A variety of minimally invasive spinal surgery on the herniation of intervertebral disc and compression of the nerve root has a better therapeutic effect, but the mechanical balance disorder caused by degenerative disease of lumbar spine is the blind area in the treatment of spinal minimally invasive technique. Base on this condition, the author raised his treatment method of three dimensional minimally invasive therapy (TDMIT), which meant by combining the mature technologies of minimally invasive spine surgery and Miniscalpel-Needle (MSN), with considering of the different pathologic changes on anterior, middle and posterior lumbar spine columns, to achieve optimal efficacy with minimum injury and physiological interference.

MSN is a new medical instrument based on Traditional Chinese Medicine (TCM) and modern anatomy medicine, which is originated from acupuncture but has the therapeutic effect of both “needle” and “knife” and has been developed in China. Specifically, TDMIT includes: radio-frequency combined ozone ablation for degenerated intervertebral disc, impulse stimulation combined ozone on lumbar nerve in intervertebral foramen area anti-inflammatory and decompression, Radio-frequency (RF) thermocoagulation or MSN-lysis on posterior ramus of lumbar nerve, limited cut and decompression by visual MSN on ligamentum flavum on the vertebral canal and exit of nerve root canal, MSN-lysis on soft tissue outside the spinal canal. Under accurate positioning with C-arm machine and constant

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monitoring with digital subtraction angiography. RF thermosetting target therapy can be beneficial for the direct coagulation and shrinkage of protruded nucleus pulposus (NP), repair of broken anulus fibrosus (AF) and inactivation of newborn hypersensitive nerve endings without the damage to the surrounding healthy tissues. Ozone has the effect of anti-inflammation, analgesia and oxidation of intervertebral disc proteoglycan and NP cells.

1. Material and Methods
1.1 General Material

From March 2013 to July 2016, our department treated 102 DLSS patients, with full records saved. All patients were divided into two groups randomly. Nineteen male and twenty-eight female patients, who were between 56 to 87 years of age (average 69.5 ± 17.1), were included in group I (TDMIT). Their follow-up (FU) visit time points were 6 to 24 months (average 14.4 ± 8.4 months). Patients in group II were treated with traditional methods, which meant MSN-lysis on the exit of intervertebral foramen of responsible segments integrating with triamcinolone and cobamamide injection. There were 55 patients in group II with 20 males and 35 female. The ages of patients ranged from 57 to 85 (average 68.4 ± 16.2) with FU visit time from 6 to 24 months (average 13.9 ± 9 months). All patients in the two groups presented symptoms of lumbago and chronic pain and lower leg numbness, which lasted 3 months to 20 years (average 5.6 ± 4.3 years). Before treatment, the patients received X-ray check of L-Spine PA & LAT, CT and MRI inspection. The index segments of lumbar spine were between L3 to S1, among whom 42 patients with single degenerative segment (7 in L3-4, 24 in L4-5, 11 in L5-S1), 39 patients with double index segments (12 in L3-5, 22 in L4-S1, 5 in L3-4 and L5-S1), 21 patients with triple index segments. The age, gender composition, course of disease, and regression segment were similar and comparable in two groups.

1.2 Clinical Diagnosis and Selection Criteria
1.2.1 Clinical Diagnosis

A. Symptoms mismatch with signs, the chief complaints are more than signs;

B. Change of position would bring about the change of symptoms, which meant in sitting and lying position the clinical symptoms would alleviate, while in standing and walking symptom would aggravate;

C. Intermittent claudication;

D. Imaging inspection showed the change of spinal canal or lateral recess distance, which meant the anteroposterior diameter of spinal canal < 1.0 ~ 1.2 cm, or lateral recess distance < 0.3 ~ 0.5 cm;

E. CT or MRI inspection showed the stenosis of lumbar spinal canal and ligamentum flavum thickening more than 5 mm.

1.2.2 Inclusion Criteria

A. Mild-to-moderate DLSS patients (compression inside spinal canal less than 1/2) or patients with lumbar disc herniation combined with lateral crypt nerve root canal narrow;

B. Patients with soft compression inside spinal canal or nerve root canal;

C. Patients who can tolerate surgery after entire body access;

D. Patients who sign the operation agreement voluntarily.

1.2.3 Exclusion criteria

A. Patients who had minimally invasive lumbar surgery before, but there is no improvement or got worse, should considering adopting open surgery;

B. Patients whose symptoms focused on synostosis narrow for spinal canal or lateral crypt without obvious soft compression should not be treated by TDMIT;

C. Patients whose physical condition was too weak to receive systematic treatment.

1.3 Treatment Method

Patients were divided into two groups randomly, and were notified detailedly about the treatment plan and its risk. After confirmation of patients, they signed on the operation informed consent.

1.3.1 Group I

Patients were treated by TDMIT. On the basis of clinical symptoms, signs, and image data, doctors chose the responsible segments to make the comprehensive treatment proposal, which meant in view of the pathologic
change on different segments of anterior, middle and posterior columns of lumbar vertebra, to apply MSN and various minimally invasive techniques to treat individually.

A. Making the Surgery Plan

The surgery plan was mainly composed of Radio-frequency combined ozone ablation intervertebral disc. Impulse stimulation combined ozone on lumbar nerve in intervertebral foramen area anti-inflammatory and decompression. Radio-frequency thermocoagulation or MSN-lysis on posterior ramus of lumbar nerve, limited cut and decompression by visual MSN on ligamentum flavum on the vertebral canal and exit of nerve root canal. MSN-lysis on the paraspinal soft tissue (Figure 2, 3). In view of the specific condition of patients, the doctor chose some item from the method mentioned above, made individual treatment plan, and completed the course. Three to five days after surgery, the clinical effect was assessed and for residual symptoms, the doctor chose MSN-lysis on soft tissue out of the spinal canal for one or two times.

Figure 2: TDMIT guided by CT

Figure 3: TDMIT guided by C-arm
B. Intraoperative Position

Position was applied under the guidance of CT or C-arm. The patient chose prone position or lateral position with soft mat beneath belly or lumbar and treatment zone on lumbar exposed clearly. Doctor located the treatment zone and marked the position. Normally, the conventional puncture point would be 7 to 9cm from the lumbar midline at the same level of intervertebral disc. The doctor would adjust the puncture point and direction according to the position of intervertebral foramen area and intervertebral disc targets, confirm the puncture point for cutting-open of ligamentum flavum in the middle of spinal canal according to the intraoperative image data, confirm the projecting zone for junctional zone between upper edge of process transversus root and zygopophysis as the puncture point for lysis or heat cure of posterior ramus of lumbar nerve and ligamentum flavum lysis of intervertebral foramen area. The lysis puncture point for soft tissue out of spinal canal would be projection zone for transverse process of sophisticated.

C. Operation Technique

The operation technique mainly meant radio frequency thermoagulation, Ozone ablation, and MSN-lysis on soft tissue.

After reaching the treatment point, CT or C-arm perspective should be applied to locate the surgery point. Before Radio frequency treatment, common detection of electrophysiology should be applied to check the feeling (by 50HZ, 1V) and motor (by 2HZ, 0.5V) of patients. Patients would feel the same pain as normal. The pulse treatment would be 42°C and last 300 seconds. The radio frequency thermoagulation treatment on nerve root would be 60°C /65°C /70°C, each for 60 seconds, while the movement feeling of leg was monitored to ensure the parameter could be adjusted or the treatment could be suspended at any time. The radio frequency thermoagulation treatment on intervertebral disc would be 70°C /75°C /80°C, each for 60 seconds. During treatment, the concentration of ozone inside intervertebral disc would be 50μg/ml, while the dosage would be 2-7ml. For foramen intervertebral zone, it would be 30μg/ml and 5-10ml. Before radio frequency thermoagulation treatment on posterior ramus of lumbar nerve, 50HZ feeling function and 2HZ motor function test would be applied to confirm there were no abnormal status on the lumbar and legs muscle of the patients. Then after ensuring the targeting nerve in the scope of thermoagulation, treatment of 75°C /80°C /85°C would be applied.

When applying the limited cut-open lysis by MSN on ligamentum flavum, the doctor would choose the No.7 spinal needle to puncture into the epidural space, then injected 5-10ml normal saline to push the endorhachis to the middle line. Then the doctor would choose No.3 MSN to puncture slowly along the inside and beneath of zygopophysis, till it reached the upper edge of nether lamina, then to cut the end of ligamentum flavum on lamina and the point of junction between articular capsule and ligamentum flavum. When applying MSN-lysis and decompression on soft tissue out of spinal canal, the target of surgery would be soft tissue lesion on lumbosacral portion spinous, spinous process, ending point of process transversus and buttocks. After MSN reached the bone, rip cutting and crosswise peel would be applied, and the final step was to transverse the knife-edge to lose some muscle fiber.

1.3.2 Group II

The patients would receive the treatment of MSN-lysis on the exit of intervertebrale foramen integrated with injection of triamcinolone and cobamamide. The patient chose clinostatism and relaxed. The doctor located the root of transverse process for specific segment firstly, then applied MSN-lysis on the soft tissue around the transverse process, and then inclined the MSN upward or downward or inward to penetrate into the exit of intervertebrale foramen. According to paresthesia on the nerve root for this segment, the direction and depth of MSN should be adjusted to fulfill the requirement of lysis and decompression. Finally, the mixed medicine liquid consisted of 0.6-0.8ml triamcinolone + 1.5mg cobamamide + 8ml normal saline.

1.3.3 Treatment Course

Patients in Group I should receive the TDMIT for only once. Three to five days after surgery, the curative effect would be assessed. If some symptom still appeared, the MSN-lysis would be applied for 1-2 times. Patients in Group II should be treated once for 1 to 2 weeks, and treatment for 3 times should be regarded as a course.

1.4 Nerve function and Clinical Curative Effect Assessment

1.4.1 Neurologic Function Assessment

Neurologic function assessment included VAS scale for pains on legs and lumbar, lumbar vertebra affection JOA grade, ODI scale. The score of patients in
Group I and II at different phrase, such as before treatment, six months after treatment and at the last follow-up visit, were assessed, calculated and recorded.

1.4.2 Curative Effect Assessment
Criteria: Nakai standard and JOA scores

\[
\text{Improvement rate} = \left( \frac{\text{score in last visit} - \text{score before treatment}}{29 - \text{score before treatment}} \right) \times 100\% 
\]

Result assessment: excellent meant the pain/numb/limp in lumbar and legs disappeared completely, with improvement rate greater than 75%; good meant most of symptom disappeared, and pain appeared only after long-time exercise, with improvement rate between 50% to 75%; acceptable meant the symptom got improved significantly, but pain would be serious after bear load or strenuous exercise, with improvement rate between 25% to 50%; poor meant no improvement on symptom and improvement rate less than 25%.

The total efficiency rate = (number of patients with result of excellent, good and acceptable) / total quantity

1.5 Statistical Method
SPSS13.0 would be applied for statistical processing to get the mean value for sample scores and standard deviation. For the comparison among scores of neurological function in the same group, matched pair design weighted mean difference t-test would be adopted; for comparison among scores of two groups, random mean difference t-test would be adopted. The curative effect would be assessed by \( \chi^2 \), and \( P<0.05 \) would be regarded as statistical significance.

2. Result
2.1 Comparison between Scores before and after TDMIT Treatment
After treatment, all conventional assessment for the recovery of neurological functions showed that (table 1) in Group I, the score of VAS, JOA and ODI were all in satisfactory level, which meant significant improvement than before treatment \((P<0.05)\). The symptom record in 6 months after treatment and the last visit showed satisfactory improvement with pain in legs and lumbar relieved. In Group II, the score of VAS, JOA and ODI were less than Group I. But compared with before treatment, the JOA score right after surgery, the VAS score 6 months after treatment and the ODI score in the last visit still showed obvious difference \((P<0.05)\). According to the record 6 month after treatment and the last visit, many patients experienced the repeatedly appearing of symptom and the improvement on their pain in legs and lumbar showed no so clearly. By the way, the JOA score right after surgery and VAS/ODI score in the last visit in Group I were much better than those in Group II.

2.2 Clinical effects Evaluation between Different Treatment Methods
The result of last follow-up visit after TDMIT in Group I:
Excellent: 12; good: 12; acceptable: 18; poor 5. Total effective rate = 89.36%

The result of last follow-up visit after MSN-lysis integrated with medical injection in Group II:
Excellent: 8; good: 11; acceptable: 17; poor 19. Total effective rate = 65.45%

There was significant difference between the two groups. The clinical outcome in Group I was better than that in Group II. (Table 2, \( \chi^2=8.46, P<0.05 \))

3. Discussion
DLSS is a kind of senility lumbar vertebra degeneration with complicated pathologic change, which would bring various and stubborn symptoms [4]. Hypertrophy of facet and incrassation of ligamentum flavum would narrow the spinal canal and reduce the flow in the neurotrophy vessels, which will cause intermittent claudication. Regression and hyperplasia of spine and herniation of intervertebral disc would stimulate the sinus vertebral nerve and bring pain in low back, buttocks and hip. Intervertebral facet joint arthritis would also accompany, which would bring the same pain as above [5]. Ordinary drug therapy and conservative treatment would not always bring satisfying effects. Traditionally, the method used the most frequently is posterior laminectomy or marsupialization, which curative effect could reach the excellent and good rate of 80% in the mid-long-term. But the open operation might cause iatrogenic lumbar spinal segmental instability, so posterior lumbar interbody fusion is always adopted for auxiliary. Even this integrated method can relieve the patients’ pain, but it would also lose the mobility of fixed segment and increase the range of motion of adjacent for anteflexion and rear protraction. Though it would accelerate the degeneration of adjacent
segment [6], it had to be mentioned that the DLSS patients are aged and with complications, which meant they usually could not bear the open surgery [7].

Minimally invasive spine surgery would bring less damage to spinal structure and soft tissue around, and the lumbar and dorsal pain caused by iatrogenic injury occurred rarely, so it would be suitable for the patients of the aged [8]. The method of MSN-lysis on the external of intervertebral foramen of responsible vertebral section integrated with medical injection was common in clinical treatment, which was also effective on certain degree for the aged patients. Using MSN to penetrate on the outside of inferior centrum upper zygopophysis and the root of transverse process, applying cutting on the external of intervertebral foramen and around the nerve root, could release the nerve root. Meanwhile, a small quantity of injection of hormone and neurotrophic medicines would relieve the inflammatory reaction of nerve root and the pain. But for complex DLSS, sole minimally invasive surgical technology was always unsatisfactory, which defects included narrow scope of application, poor effect of decompression, limited holding time and reappear of symptom, and so on [9]. TDMIT is comprehensive method with whole treatment pattern. By using combine traditional Chinese and western medicine, TDMIT can reduce or eliminate the clinical symptom of DLSS patients with lowest trauma and can improve the life quality of patients effectively. Radio-frequency [10, 11] combined ozone [12, 13] ablation intervertebral disc, impulse stimulation combined ozone on lumbar nerve in intervertebral foramen area, radio-frequency thermocoagulation [14] on posterior ramus of lumbar nerve, MSN-lysis on soft tissue outside the spinal canal, were all mature minimally invasive spine surgery and applied clinically extensively. Under the direct surveillance of CT or C-arm, by using special radio frequency therapy instrument to apply thermocoagulation on the nucleus pulposus extruded, curdling it and reduce its volume, could release the compression and repair the nucleus pulposus and anulus fibrosus, and eliminate the compression of intervertebral disc on the nerve. Ozone has strong oxidation susceptibility, anti inflammatory and analgesic function. By injection of ozone in the outstanding herniated nucleus pulposus, the high polymer such as protein polysaccharide could be solved by oxygenation, while the nucleus pulposus size could be narrowed and pressure in the intervertebral disc reduced. The pain and aseptic inflammation caused by compression of nerve root was also be eliminated [15, 16]. While in RF treatment in intervertebral foramen, the doctor should penetrate RF needle into scheduled location, then applied common

### Table 1: Comparison between two groups before and after treatment (VAS, JOA, and ODI score)

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>VAS</th>
<th>JOA</th>
<th>ODI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Before treatment</td>
<td>6 months after treatment</td>
<td>The last visit</td>
</tr>
<tr>
<td>I</td>
<td>47</td>
<td>6.26±3.19</td>
<td>3.30±1.84*</td>
<td>3.40±1.71**</td>
</tr>
<tr>
<td>II</td>
<td>55</td>
<td>6.44±3.71</td>
<td>4.82±2.28*</td>
<td>5.87±2.32</td>
</tr>
</tbody>
</table>

*Compared with before treatment, P<0.05; # Compared with Group II, P<0.05

### Table 2: Clinical curative effect of two groups on the last visit after treatment (Case)

<table>
<thead>
<tr>
<th>group</th>
<th>n</th>
<th>Excellent</th>
<th>Good</th>
<th>Fair</th>
<th>Poor</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>47</td>
<td>12</td>
<td>12</td>
<td>18</td>
<td>5</td>
</tr>
<tr>
<td>II</td>
<td>55</td>
<td>8</td>
<td>11</td>
<td>17</td>
<td>19</td>
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The clinical outcome in Group I was better than that in Group II (P<0.05)
motion and sensation test. After confirming touching the main nerve root, the pulse treatment might be applied. Then, adjust the direction of needle little by little and applied radiofrequency ablation treatment around nerve root, shrink the compression source tissue and relieve the pressure of nerve root. The ablation treatment or MSN-lysis on posterior ramus of lumbar nerve could affect the nerve and tissue around, remit the compression symptom on posterior ramus of lumbar nerve caused by regression of Lumber facet joint [17-19].

Using MSN to cut in and release soft tissues around the lumbar and sacral spine, i.e. joint capsule, ligamentum flavum, and muscle and ligament between transverse process, could achieve the decompression of spinal canal and nerve root recess, which called “relax for relieving pain”. Meanwhile, MSN has the function of “dredging the channel” in traditional Chinese medicine, which called “unblocked meant no pain”. Studies showed that the mechanisms of MSN-lysis were as follows:

A MSN-lysis could improve the histomorphology manifestation on focus location of spondyloarthropathy degeneration and chronic soft tissue injury, help the repairing of lesion tissue and improve the function.

B. MSN-lysis could reduce the inflammatory factor of local position, restrain inflammation, reduce the pain and improve function.

C. MSN-lysis had strong abirritation, which meant adjustment of neurotransmitter about pain on the central nervous system of many level of human body, to improve the High Pain Threshold and pain tolerance threshold, finally reduce the pain.

Therefore, combine traditional Chinese and western medicine integrated with many minimally invasive surgical techniques could reach the effect of “1+1>2”.

The technology of MSN limited cut-open on ligamentum flavum was always overlooked or denounced by clinical doctors. In fact, for experienced minimally invasive spinal surgery or MSN doctors, this technique is feasible and reliable. While in MSN-lysis of ligamentum flavum, the doctor should inject normal saline out of endorhachis and push it to the middle line, which could confirm the safety of surgery. In the next phrase, the doctor should confirm the depth of penetration of needle no more than 5mm and the needle always out of spinal canal. During surgery, the patient would be in local anesthesia, which meant the patient had the feeling of touching of MSN and the doctor could adjust the direction of MSN accordingly to keep the nerve safety. The MSN-lysis of ligamentum flavum mainly focused on its stopping point (upper edge of inferior laminar), and the action of needle would be limited tightly along the surface of bone. For it was difficult and unnecessary to cut off the ligamentum flavum completely, there would be no ligamentum flavum retraction or increase of pressure on nerve root. The adhesion of ligamentum flavum, disc ligamentum flavum and adipose tissue were main ligamentum flavum of compression of nerve root in intervertebral foramen. The open surgery for DLSS also emphasis on the clean and decompression of nerve root canal while in extirpation of nucleus pulposus and cutting-off ligamentum flavum, which actually meant the MSN-lysis of soft tissue of nerve root canal and inspired the MSN decompression method.

Considering of the different pathologic changes on the anterior, middle and posterior columns of lumbar spine, by using individualization and comprehensive methods on DLSS, TDMIT could be realized having the effect of “accuracy, delicacy, and exquisite”. As confirmed by short-time follow-up visit, the TDMIT overcome the difficulty of degenerative disorders of the lumbar spine on certain degree and broaden the adaptation of spinal minimally invasive surgery.

It should be mentioned that TDMIT is not sole combined spinal minimally invasive surgery, which needed the doctors understand deeply the pathology, iconography information and clinical symptom of DLSS, and make the feasible surgery proposal, ensure accurate and normalized operation, to obtain relatively satisfactory clinical effects.

Another unavoidable problem for DLSS patients was the reappear of pain in waist and legs after surgery. The author believed that to treat the reappear properly, the first step was to analyze deeply the change of symptom, especially distinguishing whether it was the reappear of same symptom or degenerative pathologic change [20]. Additionally, the advantages of TDMIT mainly focus on obvious effect and minimal trauma, while further treatment would not be affected. For the aged and extremely aged patients, TDMIT is safe and “green”, which can sustain the clinical effect for a relatively long period, improve the life quality of patient effectively and prolong their life span. And if allowed by the physical condition of patients, even the pain of waist and leg reappeared, TDMIT could be applied repeatedly on the basis of careful clinical and
iconographic check and accurate positioning of responsible segment and surgery point. The clinical study showed that TDMIT is one of the safest and the most painless treatment method for the aged DLSS patients which can lower the probability of complication for the aged.

References


