Case-Control Study

Safety and Effectiveness of Transforaminal Epiduroscopic Laser Ablation in Single Level Disc Disease: A Case-Control Study

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Background: The non-operative treatment of herniated intervertebral discs has long been a fundamental challenge. A novel technique of laser ablation to ablate the nucleus pulposus under a transforaminal epiduroscope (TELA system, Lutronics, Seoul, Republic of Korea) was recently developed.

Objective: The purpose of this study was to evaluate the safety and effectiveness of transforaminal epiduroscopic laser ablation (TELA) for selective ablation of the nucleus pulposus in single-level disc disease.

Study Design: Prospective case control study

Setting: Multicenter study

Methods: This study included a group of 56 patients who underwent transforaminal epiduroscopic laser ablation (TELA) and 56 patients who underwent selective transforaminal epidural block (STEB) for single-level disc disease. Visual analog scale (VAS), Oswestry Disability Index (ODI), and SF-12 were assessed at admission and at 1, 3, 6, and 12 months postoperatively.

Results: The mean VAS of back pain was lower for the TELA group than for the STEB group 12 months postoperative ($P < 0.05$). The mean ODI was lower in the TELA group than in the STEB group at 12 months postoperatively ($P < 0.05$). There were no major complications related to the TELA and STEB procedures.

Limitations: The primary limitation is a small sample size. The control group was created from a database which was prospectively collected in a different time line.

Conclusions: The TELA procedure is superior to the STEB procedure in terms of patients reporting less pain and better quality of life over a year. TELA may be a reasonable alternative to conventional interventions or open surgery in single-level disc disease.

Key words: Laser-assisted spinal endoscopy, disc decompression, Nd:YAG laser, laser ablation, intervertebral disc disease, lumbar spine

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The non-operative treatment of herniated intervertebral discs has long been a fundamental challenge under investigation, and has spurred considerable technological innovation. Laser ablation has been used for percutaneous elimination of the nucleus pulposus and modulation of the annulus fibrosus (1,2). The advantage of percutaneous laser disc decompression (PLDD) includes avoidance of general anesthesia, a shorter hospital stay, a lack of postoperative epidural

scar formation, preservation of spinal stability, and an unencumbered ability to subsequently perform conventional open disc surgery.

Since its first introduction in by Choy 1986 (1), PLDD has been used widely. PLDD has been performed by laser ablation of the nucleus pulposus by means of a laser fiber under fluoroscopic guidance (1,3-5). The results of PLDD are good, but not without complications. Even with fluoroscopic guidance, dural puncture, nerve injuries, and thermal damage to the surrounding bone have been reported. The current scientific evidence is still limited, according to systematic reviews (6).

Transforaminal epiduroscopic laser ablation (TELA, Lutroics, Ilsan, Republic of Korea) was recently developed to inspect the epidural space and deliver therapeutic devices such as lasers or forceps, which can selectively eliminate or modulate pathologies. While PLDD removes the center of the nucleus pulposus under fluoroscopic view, TELA ablates the herniated part of the nucleus pulposus under epiduroscopic vision. It is assumed that the selective removal of the herniated portion will induce more effective decompression with minimal complications. The purpose of this study was to evaluate the safety and effectiveness of TELA for selectively ablating the nucleus pulposus in single-level disc disease.

Table 1. *Demographics of the study patients.*

Items		STEB group (n = 56)	TELA group (n = 56)
Age (years)		44.4 ± 15.0	43.2 ± 14.0
Sex	M:F	34:22	34:22
Body mass index		24.3 ± 4.0	23.9 ± 4.2
Combined disease	Diabetes	2	1
	Hypertension	6	5
	Cardiovascular disease	4	3
	Osteoporosis	5	4
Symptom duration (months)		3.2 ± 1.3	5 ± 1.0
Treated levels	L3-4	5	5
	L4-5	38	40
	L5-S1	13	11
Pain intensity (numeric rating scale)	Leg	6.3 ± 1.7	6.5 ± 2.6
	Back	5.5 ± 2.2	6.6 ± 2.0

Methods

This was a multicenter, prospective, case control study. Approval from the institutional review board was obtained in each institute. A total of 56 patients were consecutively enrolled in the TELA group from 2015 to 2016. Selective transforaminal epidural block (STEB) was the control. The same number of control patients matched by age and gender from a previously-collected patient database. The details are presented in Table 1.

Indications

All patients had suffered from chronic lower back or leg pain for at least 3 months. Inclusion criteria were single level herniated lumbar disc (HLD) at the level of L3-4 to L5-S1 in patients between ages 18 and 80. All patients had suffered from chronic lower back or leg pain for at least 3 months. Single level HLD diagnosis was based on MRI findings, clinical symptoms, and neurological examinations. For the TELA group, conventional epidural steroid injections had failed to provide acceptable pain relief. Patients with multi-level HLD, lumbar stenosis, lumbar spondylolisthesis, spinal instability, cauda equina syndrome, infections, tumorous conditions, litigations, and compensation problems were excluded. Informed consent was obtained for all patients.

TELA Procedure

TELA was performed with a fluoroscope in a sterile operating room with monitoring equipment for blood pressure, pulse rate, and pulse oximetry. The fluoroscope was adjusted over the lumbar area so that a transforaminal approach could be used for oblique views. After appropriate positioning of the fluoroscope, the needle was inserted and local manesthetic was injected. An 18-gauge needle was introduced through the intervertebral foramen into the nucleus pulposus under fluoroscopic guidance. A lumbar discogram was performed using approximately 2 mL mixture of a dye (indigo carmine, Korea United Pharm, Seoul, Republic of Korea) and a non-iodinated contrast (iohexol, Omnipaque, GE Healthcare Korea, Seoul, Republic of Korea). Then, a K-wire was placed though the inserted needle. A dilator and outer cannula was introduced into the epidural space over the K-wire. After the removal of the dilator, a flexible epiduroscope (NeedleView CH, Lutronics, Ilsan, Republic of Korea) was introduced (Fig. 1.). The epidural space and protruded disc was clearly visualized with saline irrigation. Using a straight laser fiber, laser ablation was performed using a 1414-nm

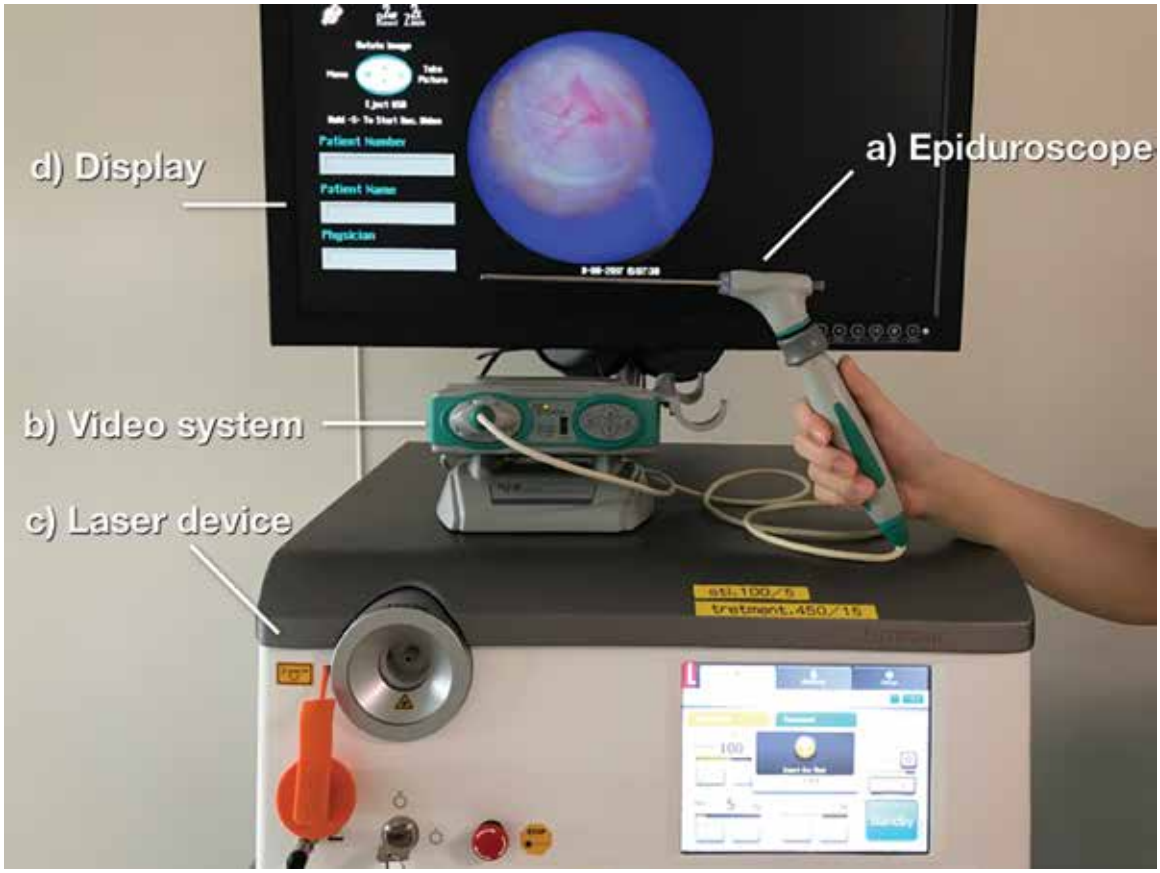

Fig. 1. *a) The epiduroscope (NeedleView CH, BioVision, Ilsan, Republic of Korea) with built-in fiber optics, 3.4-mm outer diameter, 1.85-mm working channel, 160-mm working length, and 17,000 pixels. This is disposable, and for single-use only. b) The video system with a non-disposable hand piece that contains a light source, camera, and video recording system (NeedleCam HD, BioVision, Ilsan, Republic of Korea).*

Nd:YAG laser device (Accuplasti, Lutronics, Ilsan, Republic of Korea) and a tiny hole was made on the annulus. The safety and efficacy of the 1414-nm Nd:YAG laser device were described in another article (7). Then, using a side-firing laser, more volume was ablated with rotation of the fiber. When the protruded lesion was checked as satisfactorily decompressed by the epiduroscopic view, 1 mL of 0.2% ropivacaine (AstraZeneca Korea, Seoul, Republic of Korea) and 1 mL of 0.5% dexamethasone (Yuhan, Seoul, Republic of Korea) was injected (Fig.2.).

STEB Procedure

STEB was performed in a sterile operation room equipped with a fluoroscope while the patient lay prone. After sterile preparation, draping, and local anesthesia with 1% lidocaine, a 12-cm-long, 22-gauge spinal needle was advanced into the region of the involved nerve root under fluoroscopic guidance. The target point was around the neural foramen. The needle position was checked by using the fluoroscope. Next, approximately 1 mL of contrast material (iohexol, Omnipaque, GE Healthcare Korea, Seoul, Republic of Korea) was injected to confirm epidural flow and to avoid intravascular, intradural, or soft-tissue infiltration. Posteroanterior and lateral spot radiographs were obtained to document distribution of the contrast material. After confirming epidural spread, 1 mL of 0.2% ropivacaine (AstraZeneca Korea, Seoul, Republic of Korea) and 1 mL of 0.5% dexamethasone (Yuhan, Seoul, Republic of Korea) were slowly injected.

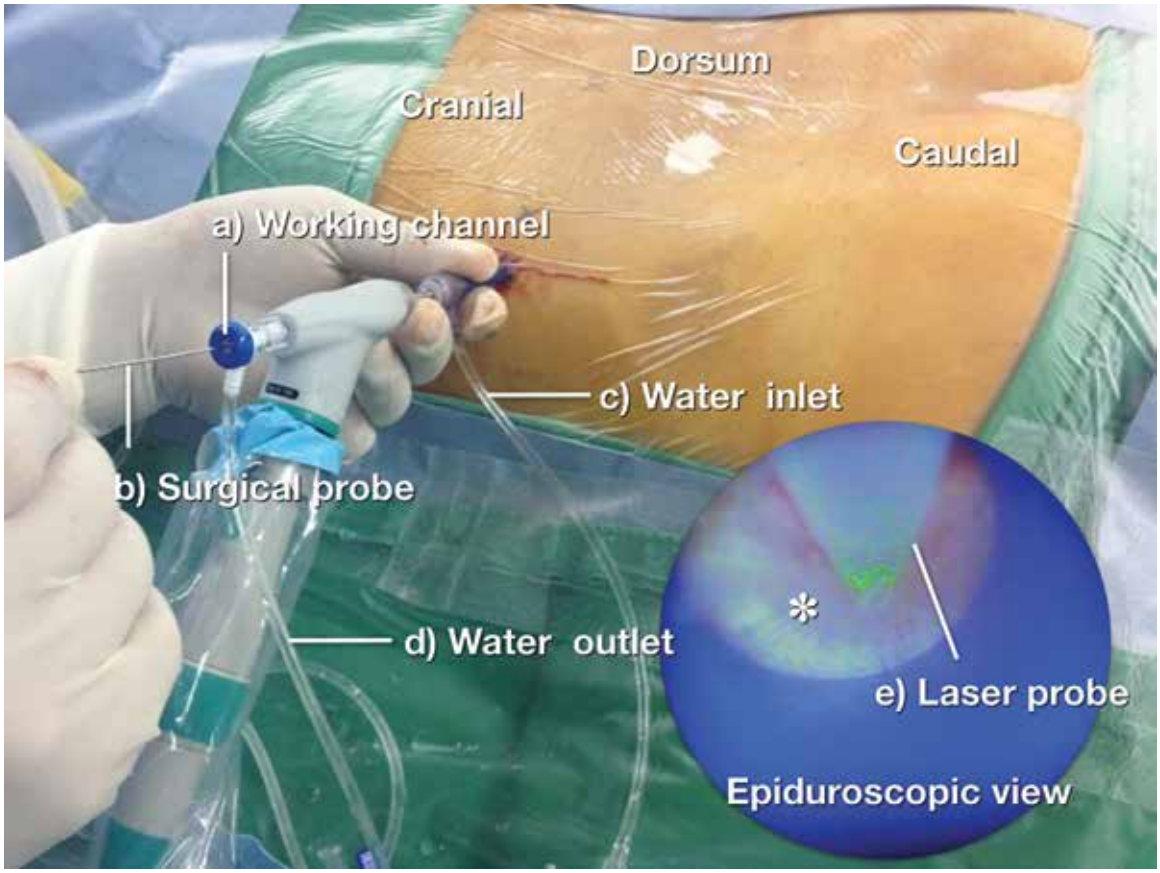

Fig 2. *Operative and epiduroscopic view. Through a) the working channel of the epiduroscope and b) the surgical probe introduced to palpate the lesion. During the procedure, normal saline is continuously irrigated through c) the water inlet and d) outlet. The epiduroscopic view shows e) the laser probe on the surface of the protruded disc.*

Outcome Measurement

The Visual Analogue Scale (VAS; score range: 0 to 10, with 0 reflecting no pain) for back pain (VAS back) and leg pain (VAS leg), Odom's criteria (which rates outcomes as excellent, good, fair, or poor), the Oswestry disability index (ODI), and SF-12 scores were used to evaluate the clinical effectiveness of TELA and TFSEB. Effectiveness was measured in terms of pain reduction and functional improvement before treatment (as a control) and then at 1, 3, 6, and 12 months after treatment. Successful pain relief was described as a 50% or more reduction in the patient's VAS score; good or excellent results by Odom's criteria were considered to reflect favorable outcomes.

Statistical Analysis

Cross-tabulation tables were analyzed using Fisher's Exact and Pearson's chi-square test. One-way ANOVA with repeated measures (RM-ANOVA) was used to identify a significant difference between the groups. Post hoc analysis among different groups was performed using the Bonferroni-corrected P-value. A P value < 0.05 was used a threshold for statistical significance. All statistical analyses were performed with SPSS 20.0 (IBM, Armonk, NY, USA).

Results

The baseline demographic characteristics are summarized in Table 1. There were no statistical differences in the age, gender ratio, body mass index, combined diseases, treated levels, and preoperative pain intensity between the groups.

In total, 73.6%, 62.5%, 66.1%, and 50.0% of the STEB group had successful treatment responses at 1,

3, 6, and 12 months, respectively, compared to 71.4%, 83.9%, 74.6%, and 76.4%, respectively, in the TELA group at the same time points. The TELA group had higher treatment success rates than the STEB group at 3, 6, and 12 months postoperatively ($P < 0.05$, Table 2).

The results of the repeated variance analysis (RM-ANOVA) on changes in pain intensity, ODI scores, and SF-12 scores of the STEB group and the TELA group at the 5 measurement time points are shown in Figs. 3-6. The results of these intent-to-treat analyses showed that there were no significant difference in pain intensity, ODI scores, and SF-12 scores between the STEB group and the TELA group at each measurement point. Both groups showed significant improvements in leg pain and back pain immediately after the procedure. While leg pain increased after 6 months in the STEB group, the TELA group continued to experience pain relief and the effect lasted up to 1 year (Fig. 4).

The TELA group had lower VAS scores for leg pain 6 and 12 months postoperatively ($P < 0.001$, Fig. 4). Low back pain tended to decrease steadily in both groups, but the declining trend in the TELA group was steeper (Fig. 5) and they had lower back pain VAS scores 3, 6, and 12 months postoperative ($P < 0.001$, Fig. 5). The ODI values 6 and 12 months after surgery were lower in the TELA group ($P < 0.001$, Fig. 6), while the SF-12 values 6 and 12 months after surgery were higher in the TELA group ($P < 0.001$, Fig. 7).

Table 2. *Proportion of patients who showed more than a 50% reduction in visual analog scale score compared to the preoperative state.*

Follow-up (months)	STEB group	TELA group	*P* value
1	73.6%	71.4%	0.035
3	62.5%	83.9%	0.002
6	66.1%	74.6%	0.004
12	50.0%	76.4%	0.001

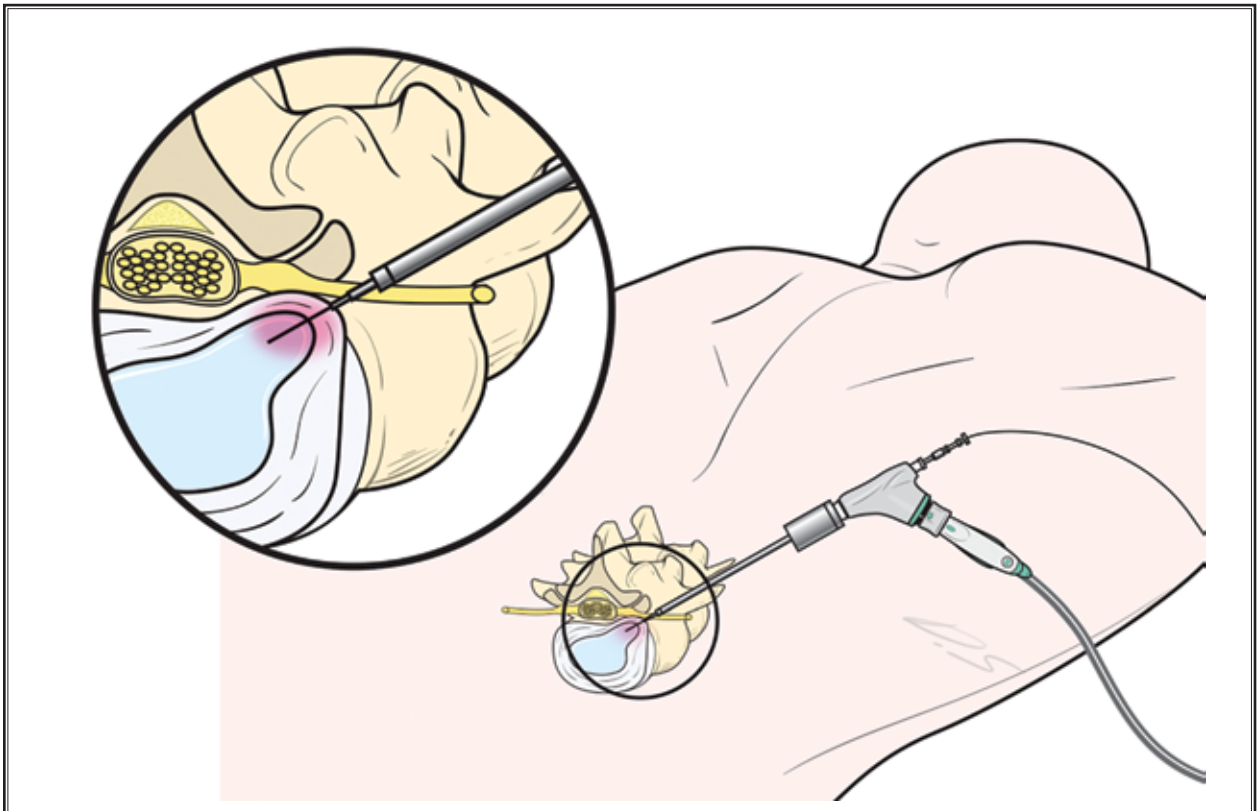

Fig 3. *Illustrated view. The epiduroscope was introduced into the safe triangle. Using a straight laser fiber, laser ablation was performed using a 1414-nm Nd:YAG laser device and a tiny hole was made on the annulus. Then, using a side-firing laser, more volume was ablated with rotation of the fiber.*

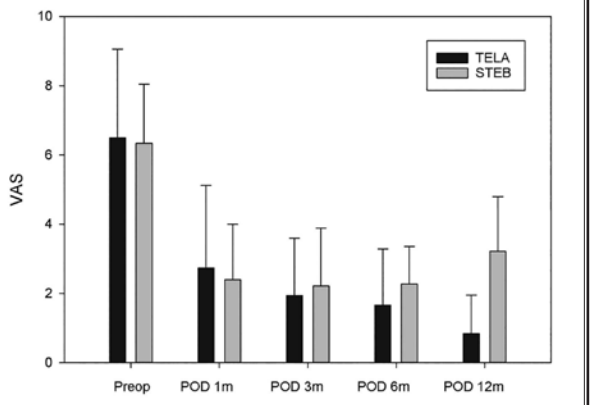

Fig 4. *The intensity of leg pain. (RM-ANOVA: Between groups, P = 0.002; within group P < 0.001; interaction P < 0.001).*

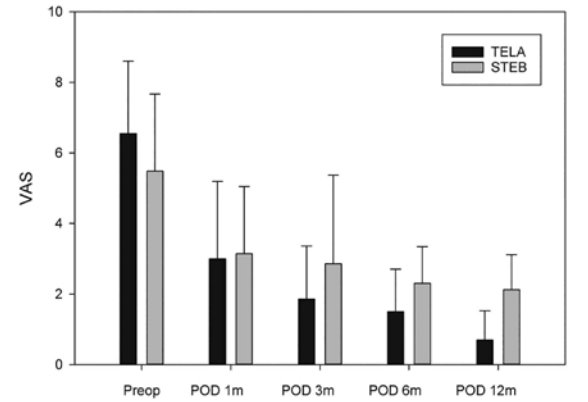

Fig 5. *The intensity of back pain. (RM-ANOVA: Between group, P = 0.679; within group P < 0.001; interaction P < 0.001).*

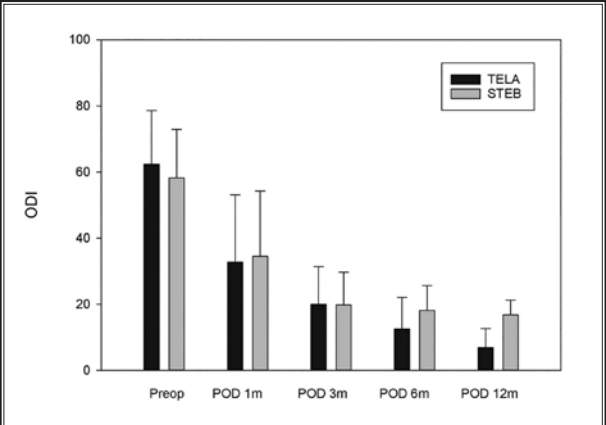

Fig 6. *ODI scores. (RM-ANOVA: Between groups, P = 0.603; within group P < 0.001; interaction P = 0.127).*

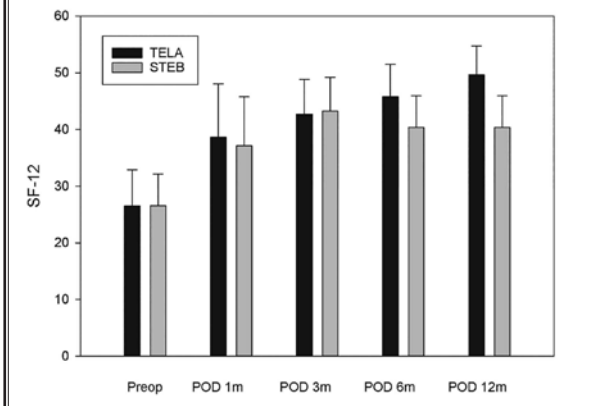

Fig 7. *SF-12. (RM-ANOVA: Between groups, P = 0.040; within group P < 0.001; interaction P = 0.048).*

Complications

No serious complications were noted in any of the participants. All complications were minor and self-resolving. No additional surgery or intervention was required. Transient numbness was the most frequent compilation. Pain aggravation and allodynia were relieved spontaneously. There were no differences in complications between the STEB and TELA groups (Table 3).

Discussion

Here, we investigated the role of transforaminal epiduroscopy with a 1414-nm Nd:YAG laser in mediating the positive effects of laser ablation on herniated lumbar discs. TELA was compared to STEB. ODI and SF-12 improvement followed a similar time course to VAS improvement in both groups. However, clinically and functionally, greater long-term improvement was observed in patients treated with TELA compared to STEB. The success rate was significantly higher in the TELA group 1 year postoperative. In our study, pain relief and functional improvement were found to be significantly greater statistically in the TELA group when compared to control group 1 year postoperative, indicating better

long-term sustainability. Clinically, numerous multicenter studies with patients undergoing percutaneous disc decompression augmented with laser ablation reported increased success rates ranging from 70 to 85% with laser ablation (2,8-13). In our study, 76.4% of the TELA group had a > 50% reduction in VAS 1 year post-surgery compared to 50.0% in the STEB group. There were no significant differences in complications between the STEB group and the TELA group.

Numerous studies have reported laser ablation with the use of laser as an alternative treatment to spinal surgeries, but the mechanisms of action of laser ablation has not been fully elucidated (2,8-13). Studies have shown that the biophysical mechanism of laser involves high-energy ablation which ablates the NP, decreases NP volume, and produces pain relief (7,14,15). A decrease in NP volume may enhance local circulation, whereas an increase in vascular supply stimulates macrophages and migrating macrophages may desiccate the NP. The higher reduction of NP in TELA compared with STEB results in a net increase in pain relief. In addition, macrophages have been found to desiccate the NP to decrease its volume, a factor crucial for pain relief (16,17). It is possible that good visualization and sophisticated ablation enhances safe removal. On the other hand, saline irrigation, which is known to decrease inflammatory cytokines, may play a role in pain reduction.

We believe that TELA enhances the resorption of the herniated intervertebral disc by drilling a hole in the annulus fibrosus and partially removing the slipped nucleus pulposus with the use of a 1414-nm Nd:YAG laser. This laser ablation may contribute to the increased success rates observed in the TELA group. In a previous study, the 1414-nm Nd:YAG laser has been found to significantly decrease intradiscal and intraspinal pressure (7). Moon et al (7) reported a decrease in intradiscal and intraspinal pressure with laser ablation using a 1414-nm Nd:YAG laser on porcine intervertebral discs. In the same model, but in combination with a 1064-nm Nd:YAG laser, Choy et al (15) showed that intradiscal pressure was significantly decreased without any adverse effects on the surrounding tissues. Others studies (1,18) have also demonstrated similar decreases intradiscal pressure in cadavers and animals after treatment with various lasers. In addition, Lee et al (19) reported that the epidural application of a 1414-nm Nd:YAG laser was effective for ablating the nociceptors on the surface of the annulus.

Table 3. *Complications*

	STEB group	TELA group
Increased pain	2	3
Intrathecal injection	0	0
Allodynia	1	1
Numbness	3	4
Infection	0	0
Hematoma	0	0
Nerve injury	0	0

There are limitations to this study. First, while this preliminary investigation into laser ablation suggests an association with nucleus pulposus desiccation, the results also suggest that further investigation is warranted into this phenomenon. Second, we did not perform MRI scans in every patient. It remains unclear whether a better outcome could be achieved by direct ablation of the annulus. Third, in this study setting, whether the true effect of TELA is due to immediate decompression or accelerated desiccation is also unclear. Despite these limitations, although the effectiveness of intradiscal laser ablation has been widely reported, this study is the first to report targeted disc ablation with a 1414-nm Nd:YAG laser.

Conclusion

The TELA procedure appears to be superior to the STEB procedure because is shows results of less pain and better quality of life over a longer time period. According to our results, TELA may be a reasonable alternative to conventional interventions or open surgery in single-level disc disease.

Acknowledgment

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References

1. Choy DS, Case RB, Fielding W, Hughes J, Liebler W, Ascher P. Percutaneous laser nucleolysis of lumbar disks. *N Engl J Med* 1987; 317:771-772.
2. Singh V, Manchikanti L, Calodney AK, Staats PS, Falco FJE, Caraway DL, Hirsch JA, Cohen SP. Percutaneous lumbar laser disc decompression: An update of current evidence. *Pain Physician* 2013; 16:SE229-SE260.
3. Hellinger J. Technical aspects of the percutaneous cervical and lumbar laser-disc-decompression and -nucleotomy. *Neurol Res* 1999; 21:99-102.
4. Goupille P, Mulleman D, Mammou S, Griffoul I, Valat J-P. Percutaneous laser disc decompression for the treatment of lumbar disc herniation: A review. *Semin Arthritis Rheum* 2007; 37:20-30.
5. Choy DSJ, Ascher PW, Saddekni S, Alkaitis D, Liebler W, Hughes J, Diwan S, Altman P. Percutaneous laser disc decompression: A new therapeutic modality. *Spine* 1992; 17:949.
6. Manchikanti L, Abdi S, Atluri S, Benyamin RM, Boswell MV, Buenaventura RM, Bryce DA, Burks PA, Caraway DL, Calodney AK, Cash KA, Christo PJ, Cohen SP, Colson J, Conn A, Cordner H, Coubarous S, Datta S, Deer TR, Diwan S, Falco FJE, Fellows B, Geffert S, Grider JS, Gupta S, Hameed H, Hameed M, Hansen H, Helm S, Janata JW, Justiz R, Kaye AD, Lee M, Manchikanti KN, McManus CD, Onyewu O, Parr AT, Patel VB, Racz GB, Sehgal N, Sharma ML, Simopoulos TT, Singh V, Smith HS, Snook LT, Swicegood JR, Vallejo R, Ward SP, Wargo BW, Zhu J, Hirsch JA. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: Guidance and recommendations. *Pain Physician* 2013; 16:S49-S283.
7. Moon BJ, Lee HY, Kim KN, Yi S, Ha Y, Yoon DH, Shin DA. Experimental evaluation of percutaneous lumbar laser disc decompression using a 1414 nm Nd:YAG laser. *Pain Physician* 2015; 18:E1091-E1099.
8. Duarte R, Costa JC. Percutaneous laser disc decompression for lumbar discogenic radicular pain. *Radiología (English Edition).* 2012; 54:336-341.
9. Menchetti PPM, Canero G, Bini W. Percutaneous laser discectomy: Experience and long term follow-up. *Acta Neurochir Suppl* 2011; 108:117-121.
10. Iwatsuki K, Yoshimine T, Awazu K. Percutaneous laser disc decompression for lumbar disc hernia: Indications based on Lasegue's Sign. *Photomedicine and Laser Surgery* 2007; 25:40-44.
11. Tassi GP. Comparison of results of 500 microdiscectomies and 500 percutaneous laser disc decompression procedures for lumbar disc herniation. *Photomedicine and Laser Surgery* 2006; 24:694-697.
12. Tassi GP. Preliminary Italian experience of lumbar spine percutaneous laser disc decompression according to Choy's method. *Photomedicine and Laser Surgery* 2004; 22:439-441.
13. Gronemeyer DHW, Buschkamp H, Braun M, Schirp S, Weinsheimer PA, Gevargez A. Image-guided percutaneous laser disk decompression for herniated lumbar disks: A 4-year follow-up in 200 patients. *J Clin Laser Med Surg* 2003; 21:131-138.
14. Kasch R, Mensel B, Schmidt F, Ruetten S, Barz T, Froehlich S, Seipel R, Merk HR, Kayser R. Disc volume reduction with percutaneous nucleoplasty in an animal model. *PLoS ONE* 2012; 7:e50211.
15. Case RB, Choy DS, Altman P. Change of intradisc pressure versus volume change. *J Clin Laser Med Surg* 1995 ;13:143-147.
16. Geiss A, Larsson K, Rydevik B, Takahashi I, Olmarker K. Autoimmune properties of nucleus pulposus: An experimental study in pigs. *Spine* 2007; 32:168-173.
17. Stich S, Stolk M, Girod PP, Thomé C, Sittinger M, Ringe J, Seifert M, Hegewald AA. Regenerative and immunogenic characteristics of cultured nucleus pulposus cells from human cervical intervertebral discs. *PLoS ONE* 2015; 10:e0126954.
18. Schenk B, Brouwer PA, Peul WC, van Buchem MA. Percutaneous laser disk decompression: A review of the literature. *AJNR Am J Neuroradiol* 2006; 27:232-235.
19. Lee MH, Kim IS, Hong JT, Sung JH, Lee SW, Kim DH. Temperature distributions of the lumbar intervertebral disc during laser annuloplasty : A cadaveric study. *J Korean Neurosurg Soc* 2016; 59:559-563.