



**PERCUTANEOUS LASER DISC DECOMPRESSION
FOR TREATMENT OF LUMBAR DISC PROLAPSE**
A Technology Assessment

INTRODUCTION

The California Technology Assessment Forum (CTAF) is asked to review the scientific evidence for the use of percutaneous laser disc decompression in the treatment of symptomatic lumbar disc herniation. The last time this topic was reviewed by this panel we in 2001.

BACKGROUND

Low back pain is a major cause of chronic pain and morbidity in the United States, is the fifth most common reason for physician visits and is responsible for significant social and economic costs¹. It is estimated that persons with back pain incur 60% more health expenditures compared to those without back pain². Herniation of a lumbar disc is responsible for less than five percent of all low back problems but are the most common cause of sciatica³. It is estimated that 90% of sciatica is caused by a disc herniation with nerve entrapment or compression⁴. The incidence of disc herniation in the U.S. is approximately 1.7%⁵. The disc is composed of a series of firm, fibrous rings (annulus fibrosis (AF)) surrounding a soft, jelly-like core (nucleus pulposus (NP)). Herniation occurs when the nucleus material escapes through the annulus. Even in the absence of frank disc herniation, however, degeneration and bulging of the disc may itself be the source of the low back pain as there are nerve endings and fibers in the outer half of the AF⁶.

The vast majority of acute sciatica attacks resolve without surgical intervention within two to six weeks^{4, 7, 8}. The usual treatment for a patient with a symptomatic, nonsequestered herniated NP first involves conservative measures, such as nonsteroidal anti-inflammatory drugs, physical therapy, muscle relaxants, selective nerve blocks, epidural steroids, and in some cases chiropractic care⁹. Bladder dysfunction and muscle weakness are clear indications for surgery, but fortunately these complications are rare⁸. More commonly, surgical treatment for prolapsed disc to

relieve nerve root irritation is recommended for patients to provide more rapid relief from pain and disability when recovery with conservative measures is unacceptably slow. Surgical treatment for a disc herniation that has been unresponsive to conservative measures has traditionally involved either open laminectomy or discectomy^{10,11}. Patients may undergo complete surgical removal of the intervertebral disc and vertebral fusion. A measurable decrease in preoperative pain has been noted in >80% in some series¹². Minimally invasive intradiscal techniques and percutaneous procedures have been employed for the past decade or more as an alternative to conventional surgical methods. In fact, one review estimates that over 500,000 percutaneous disc decompression procedures have been performed over the past 20 years¹³. These have included chemonucleolysis, manual percutaneous discectomy, automated percutaneous discectomy, endoscopic posterolateral discectomy, laparoscopic discectomy and fusion, intradiscal electrothermal annuloplasty (IDET[®]), the DeKompressor[®] Percutaneous Discectomy Probe and percutaneous laser disc decompression (also known as percutaneous endoscopic laser discectomy (PELD))¹⁴⁻¹⁶.

Percutaneous Laser Disc Decompression

Percutaneous laser disc decompression (PLDD) is a “minimally invasive” procedure to provide symptomatic relief of pain caused by a herniated intervertebral disc¹¹. First introduced about 20 years ago¹⁷, it is estimated that more than 30,000 patients were treated with PLDD in 2001¹⁸. PLDD is performed in the outpatient setting under fluoroscopic guidance and local anesthesia. Choy (1992) and others have reported the techniques employed in PLDD, however, techniques vary, with some surgeons using laser ablation alone and others using mechanical instruments to remove disc material^{19, 20} together with laser ablation²¹. There is no clear consensus on type of laser used or duration of application¹⁸. In PLDD, the target tissue is the NP of the intervertebral disc, the main constituent of which is water²².

During the procedure, the patient is placed in the lateral position with the affected side up. After localization of the disc level, a thin gauge (18- to 20-gauge) hollow needle with a stylet is introduced into the intervertebral disc and positioned halfway between the two vertebral endplates and penetrating the AF into the NP. The optic fiber is then introduced and extends past the end of the needle by 5 mm¹⁸. The needle position is verified with the use of biplane fluoroscopy,

sometimes along with CT scan (CT)²³ or MRI-guidance^{24, 25}. Once the needle is inserted, the stylet is removed and a laser fiber introduced. The most commonly used laser is the holmium:yttrium-aluminum-garnet (Ho:YAG) laser; occasionally, a neodymium (Nd):YAG laser is used. Laser energy is then delivered with 15 W of power in pulses of 0.5 to 1 second followed by a four to ten second pause^{18, 25}. The laser energy is usually delivered until the patient's subjective response indicates complete relief of radicular pain or approximately 2000 joules of energy has been delivered⁹. Patients may experience some pain due to heat sensation at the level of intervention that subsides following cessation of the laser light^{25, 26}. Magnetic resonance (MR) images are sometimes obtained post-operatively²⁷. Patients are generally instructed to rest for a few days, use analgesics as needed and to avoid hyperkyphotic positions for two weeks.

The laser light energy is transformed into heat, which can simultaneously cut, coagulate and vaporize the NP²⁸. There is some experimental evidence that this leads to a decrease in the intradiscal pressure^{18, 29-31}, and it is theorized that this pressure change allows the herniated material to retreat toward the center of the disc²⁸. The destruction of the disc is determined by the ability of NP to absorb the energy, so the ideal wavelength should be close to the absorption band of water. However, laser treatment does not obliterate the herniated disc material. MRI scans immediately after the procedure show no change in the height of the intervertebral disc or radial bulge³² or in the extent of disc herniation^{25, 27}. Successive MRI scans reveal a modest to moderate decrease of herniation at four to six months after treatment in only one third of cases²¹. The accuracy of placement of the introducer cannula, as well as the timing and firing of the laser, are of critical importance for the safety and efficacy of PLDD¹⁰.

Indications for PLDD include: 1) Contained disc herniation demonstrated on CT or MRI; 2) Neurological findings referring to a single nerve root; and 3) No improvement after conservative therapy for a minimum of six weeks. Exclusion criteria include spondylolisthesis, spinal stenosis, prior surgery at the target disc level, significant disc space narrowing and others^{18, 33}. Proponents of PLDD cite several potential advantages over open discectomy procedures: reduced morbidity, less potential for perineural scarring, less intraoperative blood loss, fewer complications of epidural fibrosis, transverse myelitis or disc space infection, reduced patient recovery times, and a faster

return to normal activity⁹. In addition, nuclear ablation is not limited to what can be plucked or suctioned out²², the procedure can be repeated, and it does not preclude future surgical treatment¹¹.

The procedure's efficacy remains controversial, however, with skeptics reporting high rates of subsequent open surgery³⁴ and its inability to treat sequestered fragments, therefore its limited applicability^{11, 35}. Some have suggested that PLDD may be no more effective than conservative treatment or no treatment³⁶. Potential complications from PLDD include injuries from thermal effects of the laser; infection of the disc (discitis); disc rupture; epidermal hematoma; lateral stenosis; transient nerve block; contralateral transient dermatomal discomfort; and rarely, abdominal perforation and partial cauda equina syndrome^{11, 18, 21, 22}.

PLDD has been used to treat cervical and thoracic disc herniation^{5, 12, 22, 37-39}, however, this evaluation will focus on the efficacy and safety of PLDD for lumbar disc herniation as the main body of experience and literature is for this indication.

TECHNOLOGY ASSESSMENT (TA)

TA Criterion 1: The technology must have final approval from the appropriate government regulatory bodies.

Trimeddyne OmniPulse Holmium:YAGE laser received FDA 510(k) clearance in 1991 for percutaneous laser discectomy (Trimeddyne, Inc., Lake Forest, CA). Other lasers approved by the FDA for laser discectomy include the KTP/532 Surgical Laser System with the KTP DiscKit (Laserscope Surgical Systems, San Jose, CA) and the Coherent Laser-Assisted Spinal Endoscopy (LASE)TM kit and Versa Pulse LaserTM (Coherent, Inc., Palo Alto, CA).

TA criterion1 is met.

TA Criterion 2: The scientific evidence must permit conclusions concerning the effectiveness of the technology regarding health outcomes.

The Medline database, Cochrane clinical trials and reviews database and the Database of Abstracts of Reviews of Effects (DARE) were searched using the key words “percutaneous laser disc decompression”, “percutaneous endoscopic laser discectomy” and “lumbar disc” or “disc herniation” from 1966 to April 2008. The bibliographies of systematic reviews and key articles were manually searched for additional references. Abstracts of citations were reviewed and all relevant articles reviewed in full.

No randomized, concurrently controlled, blinded trials comparing outcomes of PLDD with conventional conservative measures or open discectomy or laminectomy have been published. The published articles concerning PLDD are almost all uncontrolled case series. Two nonrandomized comparative trials^{40, 41} and one systematic review¹¹ of PLDD have been published.

Patients included in the various published studies have generally had: single nerve-root symptoms (radicular leg pain with or without low back pain) and signs (motor, sensory, or reflex deficits, and/or diminished straight-leg-raising); evidence of nonsequestered herniated NP on MRI; and no response to a minimum of six to twelve weeks of conservative treatment. Patients were generally excluded from studies if they had previous surgery, spinal stenosis, severe osteoarthritis, greater than first-degree spondylolisthesis, facet (zygapophyseal) joint syndrome, significant disease at more than one level, MRI evidence of extruded or sequestered disc fragments, vertebral fracture, cancer, or a hemorrhagic diathesis.

Outcomes assessed in the various clinical trials of treatment of spinal disorders generally include relief of pain and improvement in level of function⁴². In the published trials, pain relief is often assessed with the Visual Analog Scale (VAS), ranging from 0 = no pain, to 10 = worst possible pain⁴³. Functional results have been scored according to the MacNab (1971) or Andrews et al (1990) rating scales. The MacNab scale classifies as

surgical “success” as those with either “excellent” results (free of pain, no restriction of mobility, and able to return to normal work and activities) or “good results” (occasional nonradicular pain, relief of presenting symptoms, and able to return to modified work). The MacNab scale classifies as surgical “failure” those with either “fair” results (some improved functional capacity, still handicapped and/or unemployed) or “poor results” (continued objective symptoms of root involvement, and additional operative intervention needed at the index level, irrespective of repeat or length of postoperative follow-up). The Andrews scale is an 8-point scale that stratifies outcome with respect to pain relief, functional recovery, and time to recovery.

Overall, the scientific evidence does not permit conclusions concerning the effectiveness of PLDD regarding health outcomes.

Fifty two additional references were reviewed, but did not meet criteria for inclusion in this assessment. (References 71-121).

Level of evidence: 4,5

TA Criterion 2 is not met.

TA Criterion 3: The technology must improve net health outcomes.

Table 1 summarizes 29 uncontrolled clinical trials of patients undergoing PLDD. Most studies report immediate or short term results; in less than half of the studies has follow-up data at ≥ 1 year been provided. Results from the majority of these studies suggest that 64% to 87% of patients experience “success” (“excellent-good” on MacNab ratings) following PLDD; however, many of these studies suffer from significant methodological shortcomings that may bias their results in favor of effectiveness. In addition to the lack of blinding and use of an appropriate comparison group, several investigators failed to use reproducible and independent assessment of key outcome variables and few provided appropriate statistical analysis of results.

Table 1. Published Uncontrolled Case Series of Percutaneous Laser Disc Decompression

Study	Participants and Methods	Device Used	Outcomes	Complications	Comments
Choy et al, 1991 ⁴⁴		Nd: YAG	71%		21.6% had later operative interventions
Choy et al, 1992 ²¹	n=333; case series	Nd: YAG	(Macnab criteria) Good-fair: 78%; poor response 22% (26 months)		
Davis et al, 1992 ⁴⁵	n=40; case series	KTP	Good-fair: 85%		2.5% had later open laminectomy
Mayer et al, 1992 ¹⁹	n= 6 case series; no end assessment of outcomes	Nd:YAG	100%	none	3 pts had 'stress dependent' back pain
Siebert et al, 1993 ⁴⁶	n=100	Nd:YAG	78%		
Mayer et al, 1993 ²⁰	n=40; case series; no definition of how ratings scale derived	Nd:YAG	60%good to excellent (2 years)	none	10% reoperations; also used forceps to remove herniated nuc pulp
Sherk et al, 1993 ⁴⁷	n=48	Holmium	85%		
Ohnmeiss et al, 1994 ⁴⁰	n=41	KTP	71% "success rate"	1.2% Reflex sympathetic dystrophy 7.3% dysesthesias	Wide range of outcomes depend on pt selection
Casper et al, 1995a ⁴⁸	n=223; no controls; outcomes ind. evaluated by phone	Holmium YAG	Excellent-good: 84% (1 year)	1.8% Discitis, dermatomal discomfort, nerve block	4.5% later had open laminectomy
Choy et al, 1995a ⁴⁹	n=322; no controls	Nd:YAG	75% (58 months)	1% Discitis	5% had later recurrence; 10% required surgery
Liebler, 1995 ²⁶	n=46 (117 pts originally treated--most lost to f/up)	KTP YAG	Excellent-good: (1 year): 75% (2 years): 72%(33% response rate)	not reported	Many pts lost to f/up and low response rate to mail survey

Schatz et al, 1995 ⁵⁰	n=16	Nd:YAG	Pain-free: 64% (early) (1 - 6 months)	none reported	7.1% required discectomy
Bosacco et al, 1996 ²⁸	n=61; case series; Andrews and Lavayne rating scale	KTP YAG	Excellent-good: 66% Fair-poor: 34% (32 months)	1.6% Acute urinary retention, ileus	54% relief from back pain; 23% "failed" treatment
Casper et al, 1996a ¹⁰	n=100; no controls; outcomes ind. evaluated by phone:	Holmium: YAG	Excellent-good: 87%at 2 years; 10% required 2nd PLDD	None reported	4% had open laminectomy
Casper et al, 1996b ⁹	n=31 (65 y/o and older) case series; no controls; independent f/u by phone	Holmium:YAG	Excellent-good: 80%(modified Macnab criteria) (1 year); 10% had second PLDD at same or different level	None reported	
Tonami et al, 1997 ²⁷	n=26, case series Assessed w/ JOA for LBP	MRI Holmium YAG	Recovery (defined as > 25% on JOA) (24 hrs): 53% (1 year): 65%+/- 26%	None	11.5% later had open laminectomy No sig change seen in size of disc herniation
Choy, 1998a ⁵¹	n=518, case series		75-89%	<1%	
Dangaria, 1998 ⁵²	n=15, case series	ND: YAG	Excellent: 0% Good: 20% Fair: 33% Poor: 47%		
Steiner et al, 1998 ²⁵	n=8, case series	Nd:YAG	Good: 50%	Disciitis	
Gevargez et al, 2000 ⁴³	n=26, case series	Ceralas - D diode	Pain-free (>85% VAS): 46% (1 month)	None	

Knight et al 2002 ⁵³	n=576; case series; Assessed w/ Oswestry Index	KTP-LDD	At 3 years: 52% Good to excellent backpain; 12% pain free by VAS; 61% pts satisfied overall	aseptic discitis n 4 pts; further disc prolapse in 2%	17% required further intervention
Gronemeyer et al 2003 ⁵⁴	n=200 case series	NdYAG with CT/fluoro	73% success (pain reduced or eliminated); 74% "satisfied" (4 yr follow up)	discitis in one pt	Use of pain medications increased slightly overall
Black et al, 2004 ⁵⁵	n=37; case series	not reported	Good: 44% Fair: 44% Poor: 12.5%	none reported	
McMillan et al, 2004 ⁵⁶	n=32 case series	ND:YAG	80% reported improved sciatica at 3 months; 75% reported improved discogenic pain	63% new onset or worsened "mechanical" LBP	LBP thought to be procedure related
Tassi 2004 ⁵⁷	n=92; case series; MacNab criteria	Nd-YAG	83% good /excellent (5 months)	none reported	
Tassi 2006 ⁴¹	n=500 microdiscectomy n=500 PLDD non-contemporaneous comparison group	Nd:YAG	microdisc gp - 86% good/excellent PLDD grp - 84% good/excellent (2 years for both)	2.2% microdisc; 0 in PLDD	Non-randomized design; ? pts truly comparable
Ishiwata et al 2007 ⁵⁸	n=32; case series	MR guided Nd:YAG	69% success at 6 months (MacNabb criteria)	none reported	Location of needle tip strong predictor of clinical response

The two major outcomes reported (pain relief and patient function) are measured almost exclusively by patient report. Only one study reported results of objective findings on neurological examination⁵⁹ and one used the Oswestry Index⁵³ a validated measure of function in back pathology. In the Choy analysis (1996), they reported post-operative neurological improvement, including return of absent ankle jerks in 54% of 67 cases, return of knee jerks in 64% of 69 cases, and disappearance of positive straight-leg-raising tests in 81% of 134 cases by one week after PLDD⁵⁹.

Without control patients, it is difficult to assess the magnitude of a placebo response from the PLDD procedure. The lack of matched control groups also precludes comparison of PLDD with traditional conservative therapies or open surgical procedures.

Systematic Reviews

A recent Cochrane review concluded that: "Surgical discectomy for carefully selected patients with sciatica due to lumbar disc prolapse provides faster relief from acute attack than conservative management . . . The evidence for other minimally invasive techniques remains unclear . . ."^{3, 8}.

Goupille et al (2007) recently published a comprehensive systematic review of PLDD for the treatment of lumbar disc herniation¹⁸. They concluded that: "Although the concept of laser disc nucleotomy is appealing, this treatment cannot be considered validated for disc herniation-associated radiculopathy resistant to medical treatment".

Boult et al (2000) conclude that the level of evidence for the safety and efficacy of PLDD is low due to the lack of controlled, blinded or randomized studies¹¹. The authors conclude: "Given the extremely low level of evidence available for this procedure it was recommended that the procedure be regarded as experimental until results are available from a controlled clinical trial, ideally with random allocation to an intervention and control group."

Patient Risks and Complications

Deep tissue penetration of laser energy has the potential to produce serious side effects but cannot generally be assessed during the procedure²⁵. PLDD has occasionally been complicated by cases of septic discitis occurring in up to one percent of treated patients^{5, 25, 30, 37, 60-62}; causalgia related to damage to the spinal nerve or sympathetic chain⁶³; paraspinal muscle spasm⁵; L4-L5 neuropathic pain and neural damage with foot drop⁶⁴; and partial cauda equina syndrome²². Structures beyond the intervertebral disc are also at risk for damage during PLDD. For example, there have been reports of psoas muscle hematoma⁶⁵; and even abdominal perforation²². Nerve and disc root injuries from excessive heat have been documented following failed PLDD⁶⁶.

Many of the published series have small numbers (≤ 100) of patients. With such small numbers, data regarding safety may be unreliable, especially for infrequent complications.

TA criterion 3 is not met.

TA Criterion 4: The technology must be as beneficial as any established alternatives.

The established alternatives to PLDD for treatment of a symptomatic disc herniation include **conservative measures**, such as nonsteroidal anti-inflammatory drugs, physical therapy, selective nerve blocks, epidural steroids, and chiropractic care; **open surgical techniques** consisting of either open laminectomy or discectomy; and other **percutaneous techniques**. A minority of patients suffering from low back pain ultimately require surgical intervention. The goal of surgery is to relieve symptoms by removing all or a portion of the affected disc that is exerting pressure on nerve roots. In eligible patients, standard open discectomy results in better short-term relief of sciatica (65-85%) than conservative treatment (36%)⁶⁷ and a meta-analysis of randomized studies has concluded that surgical discectomy produces better results than placebo treatment⁶⁸.

Microdiscectomy is more commonly performed than standard open discectomy with laminectomy. In this procedure, a small incision is made in the back and, following

removal of a portion of the lamina (hemilaminectomy), the offending disc fragment is removed with the aid of an operating microscope. Microdiscectomy has been found in randomized clinical trials to be as good as or superior to conservative therapy in relieving symptoms, time to recovery and improving function^{69, 70}. Overall, these trials have found that early surgery is associated with quicker recovery, but one year outcomes are similar to outcomes in patients who begin with conservative treatment and undergo surgery only if symptoms do not improve. A recent Cochrane review concluded that surgical discectomy is superior to placebo for treatment of selected patients with sciatica from lumbar disc herniation who have not improved with conservative care³. This same review concluded that chemonucleolysis with chymopapain is also superior to placebo for treatment of sciatica not responsive to conservative treatment; however, enzymatic dissolution of disc tissue with chymopapain is no longer used due to severe allergic reactions in some patients⁴⁷.

Other percutaneous or minimally invasive techniques for removal or destruction of prolapsed and extruded intervertebral discs such as automated percutaneous lateral discectomy (APLD) and arthroscopic microdiscectomy (AMD) have been used for a number of years but have not been thoroughly evaluated in randomized clinical trials or in trials comparing them with PLDD. PLDD has not been compared to microdiscectomy in a randomized clinical trial, but the Cochrane review⁸ concluded that “outcomes following (laser discectomy) are at best fair and certainly worse than after microdiscectomy”.

TA criterion 4 is not met.

TA Criterion 5: The improvement must be attainable outside of the investigational setting.

The number of centers performing PLDD has remained limited and the published data are not sufficient to conclude that the efficacy and safety of PLDD has been established in the investigational setting, let alone under conditions of usual medical practice.

Whether PLDD will be effective in improving health outcomes when used to treat individuals with herniated lumbar discs in the community setting under conditions of usual medical practice remains to be demonstrated.

TA criterion 5 is not met.

CONCLUSION

No randomized, concurrently controlled, blinded trials comparing outcomes for patients with chronic symptoms referable to lumbar disc herniation treated with PLDD compared with conventional conservative measures, open discectomy or microdiscectomy have been published in the peer reviewed literature. The published articles concerning PLDD are almost all uncontrolled case series. In these trials, the procedure appears to provide subjective pain relief in about half to 3/4 of patients with relatively short follow up; long term success rates are inferior to this and re-intervention rates range from 5% to 25%. As with all case series that lack a control group involving pain as an outcome, a placebo effect cannot be excluded. The methodology used in most of the PLDD trials to date is of poor quality. Patient selection is generally inadequately described and is not consistent across the trials. The case series often report on findings from a single site; the surgeon and evaluator are usually the same individual; and the evaluation criteria are not uniformly applied. Results are infrequently subjected to statistical scrutiny and complications of the procedure are poorly tracked and inconsistently reported. Many of the published series have small numbers (≤ 100) of patients. With such small numbers, data regarding safety may be unreliable, especially for infrequent complications.

Patients suffering from chronic, symptomatic disc herniation do have evidence based established alternatives to PLDD, such as open or microdiscectomy, to turn to that have been shown to provide more rapid relief of symptoms than conservative therapy.

The published data are not sufficient to conclude that the efficacy and safety of the percutaneous laser disc decompression procedure have been established in the investigational setting, let alone under conditions of usual medical practice. Percutaneous laser disc decompression requires further evaluation in a randomized controlled trial to assess its efficacy as an alternative treatment for symptomatic lumbar disc herniation.

RECOMMENDATION

It is recommended that percutaneous laser disc decompression (laser discectomy) for the treatment of symptomatic lumbar disc prolapse does not meet CTAF TA criteria 2-5 for safety, efficacy and improvement in health outcomes.

The California Technology Assessment Forum panel voted unanimously to accept the recommendation as written.

June 18, 2008

This topic was reviewed in 2001 and did not meet CTAF TA criteria.

RECOMMENDATIONS OF OTHERS

BLUE CROSS BLUE SHIELD ASSOCIATION (BCBSA)

The BCBSA Technology Evaluation Center has not conducted a review of this technology.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

CMS is silent on the use of this technology.

CALIFORNIA ORTHOPAEDIC ASSOCIATION (COA)

The COA agrees with the assessment and recommendation. A COA representative was not available to attend the meeting.

CALIFORNIA ASSOCIATION OF NEUROLOGICAL SURGEONS (CANS)

The CANS has provided the following opinion statement:

"Percutaneous laser disc decompression is not a widely accepted procedure and the efficacy of using this procedure to treat or manage disc disorders has not been scientifically proven. It is considered an investigational procedure at this time.

In light of potential significant morbidity to the spine and to the spinal cord, only surgeons with experience and competency in spine surgery should perform the procedure if and when it is performed."

A CANS representative was not available to attend the meeting.

ABBREVIATIONS USED

AF	Annulus fibrosis
NP	Nucleus pulposus
IDET [®]	Intradiscal electrothermal annuloplasty
PELD	Percutaneous endoscopic laser discectomy
PLDD	Percutaneous laser disc decompression
CT	CAT scan
Ho:YAG	Holmium:yttrium-aluminum-garnet laser
Nd	Neodymium
MR	Magnetic resonance
DARE	Database of Abstracts of Reviews of Effects
APLD	Automated percutaneous lateral discectomy
AMD	Arthroscopic microdiscectomy
VAS	Visual Analog Scale

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