LASE®
Efficacy and Safety

More Effective
Less Costly
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LASE
A Product and a Technique for Arthroscopic Lumbar Discectomy of Contained Herniations

Overview:

LASE has been used in over 20,000 procedures. It has proven to be more effective than other percutaneous procedures and to be more effective than conventional microdiscectomy for treatment of sciatica caused by a contained disc herniation.

LASE is an outpatient procedure done under local anesthetic and has proven to be safe and relatively free of complications.

LASE has clear and specific patient selection requirements.

LASE is a next step in conservative therapy that is cost effective.

LASE is much less costly than conventional surgery.

LASE is a minimally invasive therapy available and does not put the patient on a tract of potentially worsening spine pathologies.

LASE uses a combination of endoscopic visualization, continuous irrigation, the proven Ho: YAG laser, and specially designed surgical instrumentation to maintain patient safety and to achieve a high level of efficacy.
LASE
A Product and a Technique for Arthroscopic Lumbar Discectomy of Contained Herniations

FDA cleared since 1991, with over 20,000 procedures done worldwide since 1992 with the majority done in the United States.

Approved by Medicare for Hospital and Ambulatory Surgical Center (ASC) and by the Veterans Administration.

LASE is effective. Studies consistently report 80 to 90% success, for percutaneous laser discectomy using the Ho: YAG laser. (1)(4)(5)(6)(7)(8)(9)

LASE has a low complication rate. (1)(4)(5)(7)(9)

LASE is a next step in conservative therapy for indicated patients. It does not burn bridges or put the patient on a track of recurring and worsening back pathologies.

LASE is a substantial improvement in safety and efficacy over other, earlier percutaneous therapies. It uses a Ho: YAG laser with continuous endoscopic visualization with constant saline irrigation for flushing, cooling and safety.

Numerous studies have established the Ho: YAG laser to be the safest and most effective laser modality for percutaneous discectomy. Ho: YAG lasers, in general, have a long history of safety and efficacy. (1)(4)(5)(6)(7)(8)(9)(24)(25)(26)

The use of arthroscopy has been proven to be effective and safe when compared to conventional microdiscectomy and laminectomy. Recovery and return to work times can be shortened by using an endoscopic technique. (10)

Continuous irrigation flushes the disc repeatedly during the procedure. Among other things, this irrigation keeps the disc within a very few degrees of normal temperature, and prevents temperature rise in surrounding tissue. (25)

LASE is more successful than conventional surgery for contained herniations. (LASE is indicated only for contained herniations).

Conventional surgery (laminectomy/discectomy and microdiscectomy) is significantly less effective for contained vs. non-contained herniations. (29)(11)(12)(13)(15)(16)(17)(18)(20)

There is significant evidence that conventional spine surgery as opposed to percutaneous spine therapy causes a decrease in spinal stability and may put the patient on a cascade of ever worsening spine pathologies. (21)(22)(23)

Conventional surgery including microdiscectomy has a consistently reported complication rate of 4 to 5% compared to less than a 1% complication rate for precutaneous discectomy. (12)(14)(16)(19)(29)
LASE has clear patient indications (See Appendix F)

**Indications (from the LASE labeling)**

LASE is indicated for patients with contained lumbar disc herniations or bulges. Patients should have a clinical and radiologic evidence of nerve root impingement.

Patient selection criteria should include:
- Unilateral leg pain greater than back pain
- Positive straight leg raising test, crossover pain, or positive bowstring sign
- Possible neurologic finding including weakness, sensory alteration, and reflex alteration.
- Positive CT, MRI, or discography study showing a subligamentous herniation at a location consistent with clinical findings

The potential population for LASE according to its narrow patient selection criteria, is only 12% to 15% of herniated disc patients. But for that patient group, LASE is effective, safe and economical compared to all other potential modes of care.

LASE uses laser ablation to treat primary leg pain caused by a contained herniation that is affecting a nerve root.

LASE has been used since 1992, has long follow-up and has been marketed carefully to well-trained physicians. (1)

LASE success rate is consistently reported over 80%, with a one to two week recovery period. Patients frequently report relief of pain during the procedure.

There is a lot of solid science behind LASE, the use of the Ho: YAG laser in the disc and percutaneous disc decompression. (24)(25)(26)(27)(28)

LASE is indicated for patients with radicular pain caused by a contained disc herniation. These are not good candidates for convention microdiscectomy or any other invasive procedure. It is believed by many that excessively invasive procedures can start patients on a slippery slope to a lifetime of spine pathologies. (29)(21)(22)(23)

LASE has been successfully performed by surgeons (Neurosurgeons and Orthopedic surgeons) since 1992. In recent years, Pain Management Specialists (often Interventional Anesthesiologists) have also adopted the LASE therapy. Frequently this meets with opposition from surgeons who do not understand the patient selection criteria or therapy.

Many surgeons do an excellent job at utilizing LASE, but because it is more like a “needle” procedure than surgery it’s clinical technique fits very well with the skill, training and experience of the Pain Management Specialist. The most challenging aspect of the LASE procedure is achieving needle access to the targeted disc, something Pain Management Specialists do routinely.

In 20,000 procedures there are no known complications that would have benefited by immediate surgical intervention.

LASE is best coded by CPT 62287.
Patients Prefer Percutaneous Procedures
Laser discectomy, performed as a percutaneous procedure, offers many more advantages over conventional discectomy/microdiscectomy than simply a higher success rate. Laser discectomy is performed under local, rather than general, anesthetic. Patients thus recover faster, and are not at risk of the complications associated with general anesthesia. The tiny incision used for laser discectomy compared to open surgery means that the patient has less post-operative pain. Since a laminectomy/laminotomy is not performed, the risk of spinal instability is lessened.

Clarus Medical would be happy to participate in any carefully constructed study of LASE versus other treatment modalities.
Reference List
### Appendix B

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<td>Meriwether, 02, Journal Minimally Invasive Spinal Technology, Dec, 2002</td>
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<td>6</td>
<td>Meriwether, Presented at various Physician Society meetings worldwide, 1997</td>
</tr>
<tr>
<td>7</td>
<td>Nishijima, Presented at various Physician Society meetings worldwide, 1996</td>
</tr>
<tr>
<td>8</td>
<td>Sachs, Presented at various Physician Society meetings worldwide, 1996</td>
</tr>
<tr>
<td>9</td>
<td>Malberg, Malberg, Percutaneous Lumbar Laser Disc Surgery, Presented at the Annual Meeting of the New Jersey Medical Specialties Society, April 6, 2000, and is being prepared for publication.</td>
</tr>
<tr>
<td>10</td>
<td>Hermantin, A Prospective, Randomized Study Comparing the results of Open Discectomy with those of Video Assisted Arthroscopic Microdiscectomy. 1999</td>
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### Appendix C

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<td>16</td>
<td>Kotilainen 93, Kotilainen, Valtonen, Carlson, Acta Neurochir (Wien), Vol. 120, 1993, pp 143-149.</td>
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### Appendix D

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<td>24</td>
<td>Lane, 93, Lane, SPINE: State of the Art Reviews – Vol. 7, No. 1, January 1993</td>
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<td>28</td>
<td>Trost, 91, Trost, Laser Physics, 1991</td>
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Appendix A

Illustrations of Disc Herniations
Appendix B

Review Studies of Arthroscopic Discectomy
Appendix B

Review of studies for Arthroscopic Discectomy with Success and Complication Rates

The following articles establish a success rate for percutaneous laser discectomy that is higher than conventional surgery on contained herniations and a complication rate for percutaneous laser discectomy under 1% vs. about 5% for microdiscectomy.

The Ho: YAG laser produces the highest success rate and the lowest complications rate of all percutaneous modalities.

Arthroscopic discectomy has been shown to be as effective and safe as conventional microdiscectomy and laminectomy with shorter recovery and return to work times.
1. Results of a clinical trial of the holmium:YAG laser in disc decompression utilizing a side-firing fiber: a two-year follow-up
   G. David Casper MD

   100 patients were treated with a non-endoscopic holmium:YAG laser for percutaneous discectomy. 
   The follow-up was at two years, and was performed by an independent observer. 
   Using modified MacNab's criteria, 87% had a good or excellent result.

   Five patients had recurrent disc at the same level (5%, consistent with open surgery). 
   There were no complications. 
   Two observations were interesting:
   1. Repeat percutaneous procedures or open procedures were both effective for cases where the first procedure failed. 
   2. The percutaneous procedure also worked well on patients who had previously undergone an invasive procedure.

   This study was performed without any support from Clarus.

2. Functional results of Percutaneous Laser Discectomy 
   SJ Bosacco MD et al.

   Sixty-six patents were treated for contained discs using a non-endoscopic KTP laser. 
   Mean follow-up of 2.7 yr; (range 1.7 - 3.8 yr). 
   Good or excellent results were 72% for radicular pain. 
   Excluding worker's compensation patients, good or excellent results overall (leg and back pain) were obtained in 76%. 
   There was 1 minor complication.

3. Percutaneous Laser Disc Decompression (PLDD): twelve years' experience with 752 procedures in 518 patients. 
   Daniel SJ Choy

   This paper reports on 518 patients treated with non-endoscopic Nd: YAG laser discectomy. 
   Follow-up was ranged from 1 month to 4.8 years. 
   Results, using MacNab's criteria, were good or excellent in 75% of cases. 
   There were four complications, (less than 1%) all discitis. This complication was eliminated with the use of IV antibiotics. 
   The paper is the only paper included in this section that treated non-contained discs.
4. **Chui, 2001**  
**Multicenter study of Precutaneous Endoscopic Discectomy**  
(Lumbar, cervical and thoracic)  

This article gathers the work done by forty spine surgeons from nineteen centers around the world. The statistics for 26,860 operations were analyzed and tabulated. The incidence of serious surgical complication – such as discitis, wound infection, transient CSF leak, motor or sensory loss and dysesthesia was less than 1% in each series. Patient satisfaction was over 90%.  

All procedures were percutaneous and endoscopic. The Ho: YAG laser was the most commonly used therapy. Six of the centers used LASE.

5. **Meriwether, 2002, December**  
**Laser Endoscopy for Lumbar Disc Decompression**  

This study of 2000 LASE patients reports a success rate of 83.5% with an average follow up of 36 months. There were no infections and no nerve root injuries.

6. **Meriwether, 1997**  
**Determining the Efficacy of Laser Assisted Spinal Endoscopy**  

This study also of 74 patients reports an 84% success rate with stringent requirements. Complications are not reported.

7. **Nishijima, 1996**  
**Endoscopic Percutaneous Holmium: YAG Laser Lumbar Disc Decompression – One Year Follow Up**  

This study includes 436 patients who are ranked using the Japanese Orthopedic Association score for low back pain. The authors report an 80% success rate and zero complications. They recommend that the LASE procedure should be considered instead of laminectomy with discectomy on patients with contained herniations.

8. **Sachs, 1996**  
**Endoscopic Percutaneous Holmium Laser Lumbar Disc Decompression A Prospective Study of 74 Patients**  

This study reports 80.5% success with 65% of workers compensation patients working at one-year follow-up. Complications are not reported.
9. Percutaneous Lumbar Laser Disc Surgery
   Marc I Malberg MD

   This study reports on 55 patients treated with a Ho: YAG system under endoscopic control (LASE). The median follow-up was 59 months; range 16-81 mos. Using Prolo's criteria results were Satisfactory (good or excellent) 82%; Unsatisfactory (Fair or poor) 18%. Throughout the study, Dr Malberg learned to use more total energy and hence achieve a more complete discectomy. In the last group of patients he used 15 kilojoules or more total energy and achieved a 94% success rate. Most LASE physicians now use 15 kilojoules in a normal procedure.

   There were 0/55 complications. There were three recurrent discs (5%), a rate consistent with open surgery.

   This work was presented at the Annual Meeting of the New Jersey Medical Specialties Society, April 6, 2000, and is to be submitted for publication.

   This study was performed without any support from Clarus.

10. A Prospective, Randomized Study Comparing the Results of Open Discectomy with Those of Video-Assisted Arthroscopic Microdiscectomy
    Frank U Hermantin, M.D.

   Background: The usefulness of video-assisted arthroscopic microdiscectomy for the treatment of a herniated lumbar disc has been studied previously. In the current prospective, randomized study, the results of this procedure were compared with those of conventional open laminotomy and discectomy.

   Methods: Sixty patients who had objective evidence of a single intracanalicular herniation of a lumbar disc caudad to the first lumbar vertebra were randomized into two groups consisting of thirty patients each; Group 1 was managed with open laminotomy and discectomy, and Group 2 was managed with video-assisted arthroscopic micro-discectomy. None of the patients had had a previous operation on the low back, and all had failed to respond to nonoperative measures. Analysis of the outcomes of both procedures was based on the patient’s self-evaluation before and after the operation, the preoperative and postoperative clinical findings, and the patient’s ability to return to a functional status. The patients were followed for nineteen to forty-two months postoperatively.

   Results: On the basis of the patient’s preoperative and postoperative self-evaluation, the findings on physical examination, and the patient’s ability to return to work or to normal activity, twenty-eight patients (93 percent) in Group 1 and twenty-nine patients (97 percent) in Group 2 were considered to have had a satisfactory outcome. The mean duration of postoperative disability before the patients were able to return to work was considerably longer in Group 1 than in Group 2 (forty-nine compared to twenty-seven days). The patients in Group 1 used narcotics for a longer duration postoperatively. No neurovascular complications or infections were encountered in either group.
Conclusions: Although the rate of satisfactory outcomes was approximately the same in both groups, the patients who had had an arthroscopic microdiscectomy had a shorter duration of postoperative disability and used narcotics for a shorter period. These findings suggest that arthroscopic microdiscectomy may be useful for the operative treatment of specific symptoms, including radiculopathy, that are caused by lumbar disc herniation, provided that patients are properly selected - that is, they must have a herniated disc at a single level as confirmed on imaging studies, have failed to respond to nonoperative management, have no evidence of spinal stenosis, and have a herniation not exceeding one half of the anteroposterior diameter of the spinal canal. Moreover, the surgeon must be familiar with this technique and must have received training in its use.
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Appendix C

Conventional Surgery has a 4-5% Complication Rate and is Less Effective than LASE
Appendix C

A thorough investigation of published articles supplying information relating to success ratios for contained vs. non-contained herniation was done.

Although each article reports results in different ways, the following clear patterns are well supported.

1. Conventional spine surgery including microdiscectomy is significantly less effective for contained herniations than for non-contained herniations.
2. Conventional spine surgery has a complication rate of around 5%.
3. Conventional spine surgery has a recurrence rate of around 5%.

Percutaneous laser disc therapy is indicated for contained disc herniations, the type of herniation that is less effectively treated by conventional surgery.

Articles from Appendix B establish a higher success rate with percutaneous laser disc therapy than conventional surgery.

Complication rates from laser disc therapy are under 1% when all types are combined and almost non-existent with the irrigated HO:YAG laser. This is far fewer than the 5% consistently reported for microdiscectomy.

Recurrence rates are similar for percutaneous and conventional surgery.

An article-by-article summary follows.

Copies of the complete articles are available from Clarus.
This prospective study verifies that patients with No Fragment-Contained disc herniations get very poor results from open discectomy. These same patients are the indicated candidates for percutaneous discectomy procedures using LASE or Nucleotome.

During single-level lumbar discectomy on 187 consecutive patients Dr. Carragee observed the annular deficiency and presence of disc fragments. From his intraoperative findings he classified disc herniations into four categories:

1. Fragment-Defect (disc herniation with a large or massive annular defect and an extruded or sequestrated fragment).

2. Fragment-Fissure (disc herniation with minimal annular defect and an extruded or sequestrated fragment).

3. Fragment-Contained (disc herniation with an intact annulus and one or more sub annular detached fragments).

4. No Fragment-Contained (disc herniation with an intact annulus and no sub annular fragment).

An independent examiner evaluated 180 of the patients two or more years after surgery. Results are:

NOTE: A low number on the Oswestry score is better. A high number on the Stanford score is better.

1. Patients in the Fragment-Defect group had a 27.3% rate of recurrent or persistent sciatica, a 27.3% rate of reherniation and a 21.2% rate of reoperation. Postoperative Oswestry score is 16.4, Stanford score is 8.0 (second worst outcome in this study).

2. Patients in the Fragment-Fissure group had a 1.1% rate of recurrent or persistent sciatica, 1.1% rate of reherniation and a 1.1% rate of reoperation. Postoperative Oswestry score is 11.6, Stanford score is 9.0 (best outcome in this study).

3. Patients in the Fragment-Contained group had an 11.9% rate of recurrent or persistent sciatica, 9.5% rate of reherniation and a 4.8% rate of reoperation. Postoperative Oswestry score is 9.2, Stanford score is 8.8 (second best outcome in this study).

4. Patients in the No Fragment-Contained group had a 37.5% rate of recurrent or persistent sciatica, a 12.5% rate of reherniation and a 6.3% rate reoperation. Postoperative Oswestry score is 20.1, Stanford score is 6.0 (worst outcome in this study).

The following statements are directly from the article:

...patients who had extruded fragments with large or massive anular defects (Fragment-Defect herniations) accounted for most of the clinically important reherniations and reoperations over time.
Patients who had extruded disc herniations with largely intact annuli (Fragment-Fissure herniations) did exceptionally well, with only one recurrence after a mean of five years.

Patients with disc fragments contained within an intact annulus (Fragment-Contained herniations) tended to do well...

The patients in the No Fragment-Contained group had the highest rate of persistent and recurrent sciatica (p<0.001) and the second highest rate of reoperation.

The treatment of anular prolapses with no discrete fragments (No Fragment-Contained herniations) by means of conventional anulotomy and limited discectomy was unsatisfactory.

The limitations of conventional discectomy were demonstrated in patients with massive anular loss and those with anular proprolapse without herniation of fragments.

The present study shows that certain subsets of herniated discs likely represent different clinical syndromes.

Conclusions:

1. Patients with a Fragment-Defect disc herniation do not get good results from an open discectomy.

2. Patients with a Fragment-Fissure disc herniation get excellent results from an open discectomy.

3. Patients with a Fragment-Contained disc herniation get marginal results from an open discectomy. These patients are good candidates for percutaneous discectomy. These patients should be offered percutaneous discectomy before an open discectomy if conservative therapy has failed.

4. Patients with a No Fragment-Contained disc herniation get very poor results from an open discectomy. These patients are excellent candidates for percutaneous discectomy.

11. Spangfort, 1972
“The Lumbar Disc Herniation”

In this computer-aided analysis of 2,504 operations, Spangfort reports success rates of 90.3% for “Complete Herniation” (non-contained) and 63.3% for bulging discs (contained).

He also reports 82% success for “incomplete herniations”, but does not further define that term.

Since these operations were done before the advent of Microdiscectomy, recurrence and complication rates are probably not relevant.
12. Hurme, 1987
“Factors Predicting the Result of Surgery for Lumbar Intervertebral Disc Herniation”

This prospective study of 357 consecutive lumbar disc surgery patients concludes, “The operative finding graded as a protrusion predicted poor results”.

Complications were reported as bleeding, 4%, superficial infections, 0.9% and discitis 2.3%.

Repeat surgery was performed on 2.7% in the first six months after surgery.

13. Lewis, 1987
“Long Term Prospective Study of Lumbosacral Discectomy”

This 10-year study of 100 patients classified herniations as protrusion (bulge, contained) or sequestrations, extrusions or free fragments (non-contained). The average rate for complete relief of pain was 55% for contained herniations versus 69% for non-contained herniations.

Recurrence rate was reported as 18%.

The authors reported “no major-surgical complications, such as death, paralysis, etc”.

14. Quigley, 1988
“Outcome After Microdiscectomy: Results of a Prospective Single Institutional Study”

This prospective study of 374 surgical patients results in an overall success rate of 74% for microdiscectomy. This study did not identify contained vs. non-contained hernias but rather used CT or MRI to determine herniation size pre-op. No correlation with herniation size and outcome was found in this study.

Complication rate was 3.7%.

15. Abramovitz 1991
“Lumbar Disc Surgery”

This prospective Lumbar Discectomy Study enrolled 740 patients in a multi physician, multicenter, consecutive patient protocol to evaluate the indications and efficacy of lumbar discectomy. The study was developed and undertaken by a joint section of the AANS & CNS, and published in Neurosurgery, 1991.

Twelve hypotheses were tested.

An analysis of unsatisfactory outcomes showed two patterns: one of failure as a result of mechanical back pain and one of failure as a result of radiculopathy. The likelihood of a good outcome was significantly less when the only radiographic abnormality was a central bulge. A radiologically detected free fragment significantly increased the likelihood of a good outcome.

One year follow-up results were reported as 73% good by patients and 77% good by physicians.

Complication results were not given.
“Microsurgical Treatment of Lumbar Disc Herniation: Follow-up at 237 Patients”

This retrospective study compared postoperative results of patients by classification of disc herniation. The patients operated on for a prolapse or a sequestrum recovered better than those who underwent surgery for a protrusion (bulge). Of the patients operated on for a protrusion, 68% returned to work, while 76% of those operated on for a sequestrum and 85% of those operated on for a prolapse returned to work during the mean 2-year follow-up period.

Recurrence rate was 4%.

Complication rate was 4% duval tears and 1.7% discitis.

17. Hirabayashi 1993
“Microdiscectomy and Second Operation for Lumbar Disc Herniation”

In this study 214 patients underwent microdiscectomy and were followed for an average of 4 years, 5 months. Results were 76% successful with disc protrusions (contained bulge) and 88% successful with an extruded fragment.

The authors also report a significantly higher incidence of second operation in patients with protrusion-type herniations.

Recurrence rate was reported as 4.2%

Complication results were not given.

18. Jonsson, 1996
“Clinical Appearance of Contained and Noncontained Lumbar Disc Herniation”

A prospective study of 200 patients operated on for lumbar disc herniation. At surgery disc herniations were classified as extruded/sequestered, prolapse or focal protrusion (bulge).

Results for prolapse or bulge herniations were 79% and 60% respectively.

At four-month follow-up, 92% of the patients with sequestrum had excellent outcome compared with only 65% with a protruding disc.

Recurrence and complication results are not given.
“A 10-year Follow Up of the Outcome of Lumbar Microdiscectomy”

A retrospective analysis of the outcome of lumbar microdiscectomy, with independent assessment of outcome.

Results were 91% success at 6 months post-op and 83% success at 10 year post-op. These authors did not find a statistically significant difference between contained vs. non-contained disc but they do not state the values for each group. Pre-op sciatica (radiculopathy) was not recorded.

Recurrence rate was reported at 6.3%.

20. Vucetic, 1999
“Diagnosis and Prognosis in Lumbar Disc Herniation”

This prospective 2-year follow-up of 160 consecutive patients found that the most important factor predicting success was complete rupture of the annulus. A bulging disc predicted a poorer outcome.

The authors do not give success rate numbers but rather conclude that the odds for relief of leg pain was 2.5 better comparing ruptured annulus (non-contained) to intact annulus (contained herniation).

Complication and recurrence rates are not given.
Appendix D

Evidence that Conventional Surgery and Micro-Discectomy may lead to Spinal Instability
Appendix D

There is evidence that conventional spine surgery as opposed to percutaneous spine therapy causes a decrease in spinal stability. Summaries of the three available articles on this topic follow. Copies of the complete articles are available from Clarus.

“Clinical Instability of the Lumbar Spine After Microsurgery”

In a study of 190 patients, followed for a mean period of 3 years, clinical examination revealed various signs and symptoms of segmental instability of the lumbar spine in 22% of the surgical patients. There was a significant association between post-operative instability and unsatisfactory long-term outcome.

“Long–term Outcome of Patients Suffering from Clinical Instability after Microsurgical Treatment of Lumbar Disc Herniation”

This follow-up study confirms earlier observation finding that patients with post-operative lumbar instability have a poor prognosis.

23. Kambin, 1995
“Development of Degenerative Spondylosis of the Lumbar Spine After Partial Discectomy”

This study of 100 patients compares the rates of post-operative instability between laminatomy/discectomy patients and percutaneous discectomy patients and found the open discectomy patients had twice as high a rate of degenerative spondylosis as the percutaneous patients.
Appendix E

Scientific Basis for Laser Discectomy
Appendix E

These three articles lay a solid scientific basis for the safety and efficacy of percutaneous spinal disc decompression using the Ho: YAG laser.

24. Lane, 1993
“An Experimental Comparison of CO2, Argon, Nd:YAG and Ho:YAG Laser Ablation of Intervertebral Discs”

Four laser types are evaluated in this very important cadaveric study of tissue ablation and thermal affects on surrounding tissue. The study concludes that HO: YAG is most efficiently absorbed by disc material, that HO: YAG causes the lowest temperature rise in tissue outside the disc (1°C in the PLL) and that Ho: YAG causes the lowest amount of thermal necrosis.

This study was done without irrigation. LASE with continuous irrigation increases the safety of the Ho: YAG laser one step farther.

25. Min, 1996
“Quantitative Determination of Ablation in Weight of Lumbar Intervertebral Discs with Holmium: YAG Laser”

This science article produces very useful data on the amount of disc tissue removed with the Ho: YAG laser. The results agree very well with the results obtained in actual clinical practice and as verified by other means.

“Circumferential Measurement of Annulus Deviation After Laser Nucleotomy”

This study of ten cadavers concludes:
“ In pathologic discs it might be expected that by reducing the intradiscal pressure over the total circumference of the annulus, peak pressure in the prolapse region can be considerably reduced”.
“The linear negative correlation observed between energy and stiffness suggests a good therapeutic correlation with laser treatment.”

This helps explain why disc decompression via laser works, the authors in fact used LASE for this experiment.
27. Prodoehl, 1993
“The Effect of Lasers on Intervertebral Disc Pressures”

This study of five human cadavers documents an abrupt drop in intradiscal pressure achieved by laser nucleotomy. It also reports that “animal experiments have suggested that healing of the laser defect occurs by fibrosis which in conjunction with the decompression of the intervertebral disc, would lead to a hastening of the process of restabilization, an event which leads to symptomatic relief in patients with back pain and sciatica associated with disc degeneration and shortens the period of time that such individuals would be subject to recurrent episodes of discomfort”.

“Surgical Laser Properties and Their Tissue Interaction”

This comprehensive and detailed article on laser physics documents the tissue penetration characteristics of laser energy throughout a wide spectrum. It establishes a high absorption rate in water for the Ho:YAG laser wavelength. Because body tissue and particularly disc nuclear tissue is mostly water (80%) the Ho:YAG laser has a very shallow penetration depth (0.4mm) and a very high thermal diffusion time resulting in great safety and effectiveness within the spinal disc.
Appendix F

Directions for Use, LASE