Evidence in Practice

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Clinical question: Is low-level laser therapy effective in the management of lateral epicondylitis?

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The purpose of "Evidence in Practice" is to illustrate how evidence is gathered and used to guide clinical decision making. This article is not a case report. The examination, evaluation, and intervention sections are purposely abbreviated.

55-year-old woman, who was right-hand dominant, was referred to my physical therapy clinic with a 6-month history of pain in her left lateral elbow. The patient was an assembly-line worker in an automotive factory. She worked 40 to 50 hours per week in a rotating 9-job "loop" manufacturing diesel engines. Each day she would perform a different job in the loop for the duration of her shift, until she had performed all 9 job functions, at which point the "loop" would repeat.

The initial examination revealed normal active range of motion of the left elbow and wrist (using techniques described by Norkin and White¹), with pain when moving into active wrist extension. The patient's grip strength was assessed using a Jamar hydraulic hand dynamometer.* Compared with her right upper extremity, the patient had decreased grip strength in her left upper extremity of approximately 40 lb. Passive range of motion was painful when moving into wrist flexion. Tenderness to palpation was noted in the lateral epicondyle and in the proximal one third of the extensor tendons. Joint play testing of the humeroradial and humeroulnar joints, using techniques described by Kaltenborn and Evjenth,² was within normal limits. Varus and valgus stress tests, cervical screening, and neurological screens did not reproduce symptoms at the elbow.

The patient reported that her pain developed during one specific job in her loop—lifting oil pans out of a cardboard box and placing them on the line. She demonstrated how she lifted the oil pans from their packaging. The patient performed a 2-handed lift, using her wrist extensors to pull the oil pans up and toward herself. Each oil pan weighed between 4.1 kg and 7.2 kg (9 lb–16 lb), depending on the size of the engine being assembled. I immediately taught the patient proper lifting techniques using her biceps brachii muscles instead of her wrist extensors to lift and pull the oil pans, and she was advised to use this technique whenever lifting objects toward herself. The patient continued to work without restrictions at her job, and she was provided with a lateral counter-force brace to redistribute muscular forces away from her lateral epicondyle. The brace consisted of an inelastic cuff worn against the forearm extensors to diminish tension along the tendons proximal to the brace placement.

I had recently been contacted by a vendor about purchasing a low-level laser as a new intervention for musculoskeletal disorders. The vendor discussed common diagnoses, such as lateral epicondylitis, seen in the workers' compensation setting and provided literature in support of low-level laser therapy (LLLT) with these diagnoses. Lateral epicondylitis is a very common diagnosis at my clinic; at any time, as many as 25% to 40% of the patients are being treated for this condition. The repetitive nature of lifting engine parts, the use of power tools, and the force required to twist parts onto engines leads to the referral of numerous patients with this condition for physical therapy each month.

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I reviewed the vendor's literature in an attempt to gain a better understanding about types of lasers and their effectiveness with patients commonly seen in my clinic. The laser being promoted was a combination laser package that included: pulse laser (900±50 nm), infrared radiation (740 nm–860 nm), and visible red light (600 nm–740 nm). The clinician could choose between 5 programs that had been preset by the manufacturer. The programs varied in the treatment time (from 3 to 5 minutes) and pulse frequency (between 50 Hz/s and 3,000 Hz/s). The preset programs were titled: "Pain Syndrome, "Chronic Pain Syndrome," "Skin & Wound Care," "Anti-Aging & Cosmetics," and "Specific Treatment Programs." In addition, a sixth program could be personalized by the clinician providing treatment.

The company provided a document supporting LLLT titled "Clinical Data." Twenty-seven abstracts were included in this document. My cursory look at these abstracts revealed that 13 were papers that were not published in a journal, and 4 were repeated twice in the document. For these reasons, my selection of abstracts was limited to 10 articles (Fig. 1). Of the remaining articles, I did not review 8 articles: 3 articles were published more than 10 years previously (Yamaya et al, Ceccherelli et al, Beckerman et al) and therefore were not likely to reflect current practice, 2 studies reported on articular cartilage repair in animals (Akai et al, Calatrava et al), 2 abstracts described the use of lasers in treating nerve pain (Hashimoto et al, Eckerdal and Bastian), and another study described general responses to treatment with low-level lasers (Navratil and Dylevsky). The remaining 2 articles (Logdberg-Anderssont et al, Wong et al) seemed to be pertinent to patient populations commonly seen in my workers' compensation clinic.

In order to locate the remaining 2 abstracts provided by the vendor, I chose to access several databases through FirstSearch[†] (http://www.oclc.org), which is available for free at my academic institution where I am a DScPT student. I began my search through the MEDLINE database. At the main screen, I typed in laser therapy, and selected source phrase from the pulldown menu. "Source phrase" is a method of locating articles by phrases seen in the title of the journal. For example, typing the words physical therapy and selecting source phrase from the pulldown menu retrieves a list of 4,364 references, all from the journal *Physical Therapy*. I chose "laser therapy" as my source phrase, because the 2 articles I was trying to locate (Log-dberg-Anderssont et al and Wong et al) were found in a journal titled *Laser Therapy*. My search produced no results.

I believed that I was unable to retrieve these citations because *Laser Therapy* was not indexed in MEDLINE. To verify that this was the case, I went to the PubMed Web site (http://www.ncbi.nih.gov/PubMed) and clicked on **Journals Database**. In the next screen, I typed **laser therapy** in the query box. Two journals were retrieved, but neither was titled *Laser Therapy*. I next decided to try to locate this journal in the Cumulative Index to Nursing and Allied Health Literature (CINAHL) database, which includes journals not indexed through MED-LINE. Using "laser therapy" as my source phrase and CINAHL

- 1. Hashimoto T, Kemmotsu O, Otsuka H, et al. Efficacy of laser irradiation on the area near the stellate ganglion is dose-dependent: double-blind crossover placebo-controlled study. Laser Ther. 1997;9:7-12.
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- Eckerdal A, Bastian L. Can low reactive-level laser therapy be used in the treatment of neurogenic facial pain? A double-blind, placebo controlled investigation of patients with trigeminal neuralgia. Laser Ther. 1996;8:247-252.
- 5. Yamaya M, Shiroto C, Kobayashi H, et al. Mechanistic approach to GaAlAs diode laser effects on production of reactive oxygen species from human neutrophils as a model for therapeutic modality at cellular level. Laser Ther. 1993;5:111-116.
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Figure 1. Abstracts in the vendor's "Clinical Data" handout.

[†]OCLC, Online Computer Library Center Inc, 6565 Frantz Rd, Dublin, OH 43017-3395.

as my database, I once again attempted to retrieve citations for Logdberg-Anderssont et al and Wong et al. This search also produced no results.

Although the vendor had provided literature in support of their product, I was not able to access the articles I had selected for critical analysis through 2 of the most common databases available to clinicians. Other databases that might contain citations to *Laser Therapy*, such as Allied and Complementary Medicine Database or Biological Abstracts, were not available through my institution's FirstSearch subscription. I decided to conduct my own search of the literature to determine whether there was evidence, not provided by a vendor, to support the use of a low-level laser in the treatment of lateral epicondylitis.

Database used for search: MEDLINE

I decided to access MEDLINE, because this database contains more than 11 million citations from more than 4,800 journals. I accessed MEDLINE through FirstSearch and performed the search on March 19, 2006.

■ Initial keywords: laser therapy and lateral elbow

I started this search with 2 keywords: laser therapy and lateral elbow. I chose "laser therapy" because it was the primary intervention I was exploring. I chose the term "lateral elbow" because it reflected the location of the patient's pain. I wanted the term to be broad enough to include a multitude of terms used to name this condition, including lateral epicondylitis, tennis elbow, and so on.

Limits: English language and the past 10 years

I chose to limit my search to those studies written in English, and only articles published from 1996 to 2006. I felt that older studies might not reflect the most current practices regarding low-level laser as an intervention. With technology changing so rapidly, I wanted articles that reflected "state of the art" laser treatment. If my search did not produce enough studies, I could always go back and change my search parameters to include older articles.

■ Selection of articles for review: This search retrieved 9 citations (Fig. 2). I decided not to review 5 of the articles: 1 study (which was identified as a "pilot study") included only 25 patients and had no control group (Stasinopoulos), 2 studies made only brief mention of laser as a new treatment modality (Sevier and Wilson, Green et al), 1 study discussed laser as an examination technique comparable to Doppler ultrasound (Ferrell et al), and the other study did not include an abstract and may have been a "Journal Club" article that was not a description of original research (Hoens). I deemed the remaining studies appropriate to include in my review because they described controlled trials (Simunovic et al, Basford et al) or systematic reviews (Trudel et al, Stasinopoulos and Johnson).

- 1. Stasinopoulos DI, Johnson MI. Effectiveness of low-level laser therapy for lateral elbow tendinopathy. Photomed Laser Surg. 2005;23:425-430.
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Figure 2. Abstracts obtained from MEDLINE search.

Although systematic reviews are treated as higher levels of evidence,³ I chose to start my search with the controlled trials. Because I had no exposure to laser as an intervention, I wanted to gain a better understanding of treatment parameters, dosing levels, and so on when using LLLT. I thought the methods section of the controlled trials would contain this information, whereas such specific information might not be present in the systematic reviews.

Simunovic Z, Trobonjaca T, Trobonjaca Z. Treatment of medial and lateral epicondylitis—tennis and golfer's elbow—with low lever laser therapy: a multicenter, double blind, placebo-controlled clinical study on 324 patients. J Clin Laser Med Surg. 1998;16:145–151.

This study included a brief introduction to laser therapy, providing an explanation of effects mediated by low-level laser. Three distinct lasers were used in the study, and 3 different treatment parameters were compared. The first laser was an infrared, gallium-aluminum-arsenide (GaAlAs), continuous-wave laser with a wavelength of 830 nm (0.830 μ m). The output power was 120 mW, with a dosage of 10 J/cm^2 . The GaAlAs laser used direct skin contact, irradiating previously identified trigger points (TPs) specific to each patient. The second laser used in the study was a helium-neon (HeNe) continuous-wave laser. Its wavelength was 632.8 nm (0.632 μ m), with output power of 10 mW. This laser has most often been used to treat wounds and mucous membranes.⁴ The HeNe laser was coupled with a second infrared laser, which had a wavelength of 904 nm (0.904 μ m) and an output power of 30 mW. Together, these lasers were combined to create a scanning method of treatment. This second treatment involved irradiating the skin with a probe held 5 cm above the skin. The probe emitted beams containing light particles from both the HeNe laser and the infrared diode. The maximum dosage for this treatment was determined to be 12 J/cm². The third and final treatment method involved a combination of direct skin contact and the scanning technique, using all of the aforementioned lasers.

The study was conducted at 2 independent laser centers in Croatia and Switzerland. Subjects were required to have a definitive diagnosis of epicondylitis made by an orthopedist. The subjects ranged in age from 16 to 70 years old and represented a variety of occupational and socioeconomic groups (eg, athletes, butchers, drivers, hairdressers, painters, musicians, tailors, typists). The number of female and male subjects was not identified. The authors classified this study as a double-blind, placebocontrolled clinical study; however, a true control group did not exist. Subjects with unilateral symptoms were treated with either the scanning or combination methods. These subjects did not have a control group and were not treated with direct laser over TPs. Subjects with bilateral symptoms received only direct laser to the TP and "sham" irradiation. In particular, all subjects with bilateral symptoms underwent direct TP treatment to the most painful side first, whereas the other side received only "sham" irradiation. After 60% improvement was noted in the more painful side, the treatments were switched, resulting in "sham" laser on the painful side and direct TP contact over the less painful side.

In addition to the lack of a control group, this study had several other weaknesses. A total of 324 subjects participated in the study, 50 with medial epicondylitis and 274 with lateral epicondylitis. However, the responses of the 2 diagnoses to treatment were not compared. A second weakness involved the lack of structured treatment regimes. Subjects with acute conditions received 5 treatments during the first week, compared with 3 treatments for subjects with chronic conditions. In addition, the number of treatments ranged from a minimum of 6 to a maximum of 24. Although patients with acute conditions were found to respond significantly better than patients with chronic conditions, it is unclear whether the results were affected because the patients with acute conditions had more treatments initially, or because they received more total treatments.

The lack of a true control group for patients with unilateral symptoms, the choice to not use random-order treatment for subjects with bilateral symptoms, and the inconsistent treatment frequencies and duration make it difficult to evaluate the effectiveness of the treatment provided. For these reasons, the results of this study did not provide evidence to either affirm or refute the use of laser therapy in the treatment of lateral epicondylitis.

Basford JR, Sheffield CG, Cieslak KR. Laser therapy: a randomized, controlled trial of the effects of low intensity Nd:YAG laser irradiation on lateral epicondylitis. Arch Phys Med Rehabil. 2000;81:1504–1510.

This study began with a brief literature review identifying some of the treatment parameters currently being used in laser therapy. According to the authors, visible red lasers have a wavelength of 0.630 μ m, whereas infrared lasers are in the range of 0.78 μ m to 1.06 μ m. Treatment doses vary from 1 to 4 J/cm² for wound treatment to 10 to 15+ J/cm² for deeper musculoskeletal conditions. Laser intensities are fairly consistent, approximately 200 mW/cm².

The study was designed as a randomized controlled trial (RCT) with random block assignment of subjects to treatment and control groups. The subjects, therapists, and statistician were masked to the type of treatment provided. A total of 62 subjects were recruited for participation in the study; however, only 47 were eligible and completed the study in its entirety. The subjects ranged in age from 18 to 70 years, with 28 (60%) of the population being female. All subjects had a diagnosis of lateral epicondylitis made by a physician experienced in musculoskeletal disease.

The laser used in the study was a $1.06 \ \mu m$ (infrared), neodymium: yttrium-aluminum-garnet (Nd:YAG), continuous-wave laser. The intensity was approximately $204 \ W/cm^2$ with a maximum dosage of $12.24 \ J/cm^2$. This laser was most similar to the GaAlAs infrared diode used with direct skin contact in the study by Simunovic et al. Both the wavelength and maximal dosage in the laser in the study by Basford et al, however, were larger. Because the laser did not use visible light, neither the subject nor the therapist could determine whether the subject was receiving laser irradiation or a "sham," inactive probe for treatment. Each subject was treated with 60 seconds of irradiation at 7 points along the forearm and wrist: 3 points at and around the lateral epicondyle, 1 point at the distal wrist, 1 point at the volar wrist, and 2 points along the medial epicondyle. The authors selected these points based on a manufacturer's report.

According to the results of the study, subjects in both groups did not differ in terms of treatment outcomes. There were no statistical differences between the groups in terms of pain, ten-

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derness to palpation, or the subject's perceived benefit from the treatment (all measured with visual analog scales). In addition, there were no statistical differences in relation to function (as measured by grip and pinch strength tests). The authors made 2 contradictory points in their results section. In the body of the article, the authors stated that subjects who received treatment were somewhat weaker and had more pain than the control subjects. In a table located on the same page, however, the authors indicated that the treated group was minimally *stronger* than the control group.

Weaknesses of the study included the use of a 1.06- μ m laser, identified by the authors as an atypical choice for the treatment of musculoskeletal conditions (typically the wavelengths are in the 0.830 μ m to 0.904 μ m region). In addition, because previous studies have not identified efficacy or parameters of lasers, this study could only make the determination that this particular laser, at these particular parameters, was not effective in the treatment of lateral epicondylitis.

Despite these (small) weaknesses, the overall study design seemed appropriate. The subjects, therapists, and statistician were blinded to the treatment technique. Laser treatment was compared with placebo, with no significant differences observed in outcomes. However, because my search had retrieved systematic reviews, which are considered one of the highest forms of evidence, I wanted to review those articles prior to making my decision. In addition, because several treatment parameters were described in the 2 studies I had reviewed, I wanted to examine other studies for similarities or differences in the treatment parameters for low-level laser.

Trudel D, Duley J, Zastrow I, et al. Rehabilitation for patients with lateral epicondylitis: a systematic review. J Hand Ther. 2004;17:243–266.

The authors of this systematic review began with a search of MEDLINE, CINAHL, Excerpta Medica Database (EMBASE), Physiotherapy Evidence Database (PEDro), and the Cochrane Database of Systematic Reviews. Search terms included diagnostic categories (tennis elbow, elbow, lateral epicondylitis, epicondylalgia) and a variety of treatment interventions (laser, acupuncture, ultrasound, and so on). Articles were limited to those written in the English language, those conducted on adults over the age of 18, and studies using RCTs or quasi-RCTs (a term the authors did not define).

The search retrieved 209 abstracts. Five independent reviewers examined the titles and abstracts of the 209 studies. Any study classified as relevant by even one reviewer underwent additional scrutiny. Thirty-eight articles were identified as relevant. Two independent evaluators then critically appraised each article. A consensus was reached by either the 2 evaluators or a third independent evaluator who was brought in to settle the difference. Each article was assessed using an appraisal form based on Sackett's levels of evidence.³ Seven studies did not meet the

inclusion criteria after analysis by the independent evaluators, leaving only 31 articles to be included in the systematic review.

A total of 9 studies that used laser therapy in the treatment of lateral epicondylitis were identified. The authors reported that 6 studies found no difference between laser and placebo, 1 study found that pain or grip strength did not change with the addition of laser to "traditional physical therapy" (a term that was not defined by the authors), and the other 2 studies indicated significant short- and long-term improvement in pain, grip strength, and incremental lifting when using LLLT. Although the authors of this systematic review reported that, overall, laser therapy is ineffective in the treatment of lateral epicondylitis, they made an additional statement that many of the studies reviewed had methodological limitations. In addition, treatment parameters and dosing for all treatment interventions were often missing.

A previous *Evidence in Practice* article by Hoppenrath and Ciccone⁵ identified several limitations of the Trudel et al review, including no statement about the credentials of the reviewers, no definition of the term "quasi-RCT," no qualitative judgments about reviewed articles despite using a rating scale to assess the articles, and results that were confusing and misleading regarding lateral epicondylitis and ultrasound. For these reasons, I decided to conduct an independent evaluation of the studies included in this review. Of the 9 studies related to laser therapy in the treatment of lateral epicondylitis, 7 were more than 10 years old. Of the remaining 2 articles, Basford et al (the first article analyzed in my search for evidence) received the highest score (44 out of 48) of all 31 studies reviewed based on Sackett's rating system. This study determined that a Nd:YAG laser was not effective in the treatment of lateral epicondylitis.

The second article (Papadopoulos et al⁶) was retrieved for additional analysis. This study received a score of 37, slightly weaker than the Basford et al study, but still among the top one third of the 31 reviewed articles. The Papadopoulos et al study used a GaAlAs laser unit with the following parameters: 820 nm wavelength, power of 50 mW, and power density of 0.4 W/cm². Subjects were placed into 2 groups: a placebo group (n=15) that received "sham laser" and an experimental group (n=14) that received treatment by the GaAlAs laser. Treatment involved direct irradiation over the most tender spot on the elbow for 60 seconds. Subjects were treated 3 times weekly for 2 weeks. Both the subject and the therapist were blinded to the type of treatment being provided. The authors found no significant differences between the 2 groups in both pain measurements with a visual analog scale or a Marcy Wedge-Pro exerciser.⁷ The authors did not identify how the Marcy Wedge-Pro exerciser was used as an assessment tool. The authors asked subjects to use the device to exercise their forearm muscles and to stop immediately when pain was experienced.

The study did have several weaknesses. The control group began with lower pain scores (attributed to chance by the authors), and there was a discrepancy in the total number of treatment sessions offered. One table shown in the article displayed 7

treatment sessions, whereas the remainder of the tables and the text mentioned only 6 treatment sessions. In addition, the use of the Marcy Wedge Pro as an assessment tool was not clearly identified.

Despite being a systematic review, the 9 studies included in the review were not described in great enough detail to support or refute the effectiveness of laser therapy. However, the 2 studies examined in greater detail (Basford et al, Papadopoulos et al) did not support the use of laser therapy in the treatment of lateral epicondylitis.

Stasinopoulos DI, Johnson MI. Effectiveness of low-level laser therapy for lateral elbow tendinopathy. Photomed Laser Surg. 2005;23:425–430.

This article was categorized as a systematic review that is specifically focused on the use of LLLT in lateral epicondylitis. Although 2 authors are listed for the study, the methods section does not indicate whether the reviewed studies were analyzed by one or both authors. Furthermore, the credentials of the authors in this area were not identified. The databases utilized in the authors' search were identified as MEDLINE, EMBASE, CINAHL, Index to Chiropractic Literature, Chirolura, and SPORTSDiscus. The search keywords included a variety of terms used to describe lateral elbow pain (lateral epicondylitis, lateral epicondylalgia, tennis elbow), treatment interventions (rehabilitation, laser, low power laser, low level laser therapy, light, laser light), and study descriptions (clinical trials, randomized control trials). The search was limited to studies in the English language, with subjects over the age of 18. The authors selected only studies comparing LLLT with: placebo, no treatment, or another conservative or surgical treatment option. Randomized controlled trials in which LLLT was given as part of another treatment (eg, in combination with nonsteroidal anti-inflammatory drugs, ultrasound) were excluded.

Ten studies were selected based on the study's inclusion criteria. However, only 9 studies were included in the systematic review after the authors read the full text of the articles. Each study was examined using a system designed by Chalmers et al.⁸ The Chalmers system scores each article on both the study design and the quality of data analysis, with a maximum score of 100. In this systematic review, one study received a score below 40, indicating a study design of low quality. The remaining 8 studies had scores from 40 to 64, considered satisfactory by the Chalmers' system.

A closer look at the 8 studies determined to have "satisfactory design," revealed that only 2 of them were written in the last 10 years (Papadopoulos et al, Basford et al). The Basford et al study received the highest score (64) using the Chalmers evaluation. This rating was consistent with the scoring utilized in the Trudel et al study. The study by Papadopoulos et al, however, received a ranking of only 48, making it the third weakest study reviewed. Because I had critically reviewed both of these studies already, I decided that no further analysis was necessary.

The authors of this systematic review reported poor results for the effectiveness of LLLT in the treatment of lateral epicondylitis. However, they indicated that additional RCTs need to be conducted utilizing this intervention. The authors thought that their systematic review had many methodological shortcomings, including (1) a lack of masking because the full text of many of the articles had to be retrieved to obtain missing information and (2) the fact that a meta-analysis could not be conducted because the reviewed studies had different types of treatment, different types of comparison groups, and different clinical characteristics among the patients studied. Although the authors identified a scale to assess the quality of the articles studied, they did not use the results of this analysis to make judgments about the content of the articles.

This systematic review, despite its methodological limitations, supported my choice to include both the studies by Basford et al and Papadopoulos et al in my decision. In addition, this review validated that definitive treatment parameters have not been established for interventions with low-level laser.

■ **Clinical decision:** Based on the available evidence, especially the studies by Basford et al and Papadopoulos et al, I decided that LLLT would not be an effective intervention for my patient with lateral epicondylitis. Although one study (Simunovic et al) reported that laser therapy significantly improved outcomes for patients with acute cases of lateral epicondylitis, the methods of this study had many weaknesses. Furthermore, although the systematic reviews were not conclusive, both reviews identified the Basford et al article as having one of the strongest methods and data analysis sections of all the studies evaluated. These results enabled me to have further confidence in making my decision based on the results of the study by Basford et al.

I discussed the results of my findings with my patient, and I began a "traditional" approach of physical therapy (ultrasound, iontophoresis, functional massage, and strengthening of the proximal upper-extremity stabilizers). In addition, the patient was advised to loosen her grip during functional activities and to rest her wrist and elbow as often as possible, until her symptoms began to subside.

I spoke to the vendor regarding the results of my literature review. I stated that, in addition to providing abstracts in their literature, full-text articles or links to such articles should be provided to clinicians to allow for independent critical analysis. The research should come from practitioners who are independent of the companies selling the equipment and should include studies published in scholarly journals. My own literature search identified methodological flaws in current studies using low-level laser in the treatment of lateral epicondylitis. Although direct irradiation to TPs was the most frequently used treatment, issues regarding laser wavelength, location of irradiation sites, and most effective method of treatment (scanning, direct contact, and so on) need to be established before efficacy of LLLT can be determined.

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