Use of a Novel Active Implant Enhanced Forearm Device in the Treatment of Lateral Tendinosis

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This novel device represents a promising treatment option for patients with lateral tendinosis.

Lateral tendinosis, commonly referred to as tennis elbow, affects 1% to 2% of the population.[1] Although seen often in tennis players (with up to 50% developing this condition), it frequently occurs occupationally, as well as in those participating in baseball, javelin, golf, squash, racquetball, swimming, and weightlifting.[1-3]

Although traditionally referred to as lateral epicondylitis, acute inflammation is distinctly uncommon in pathologic specimens of this disorder. The condition is more appropriately described as tendinosis—a degenerative tendinopathy involving the common extensor tendinous origin from the lateral epicondyle. Lateral tendinosis describes a cycle of chronic tendon degeneration resulting from stress and overuse. It is thought that microtears develop in the proximal musculotendinous origins of the extensor carpi radialis brevis and occasionally the extensor digitorum communis.[2,3] A reparative response ensues, but is disrupted, resulting in the characteristic pathologic appearance of angiofibroblastic hyperplasia of the tendinous origin with a distinct absence of either inflammatory infiltrate or evidence of significant fibrous healing.[4]

Many treatment modalities have been proposed to manage this condition, and the vast majority of patients find at least some degree of relief from nonoperative interventions. The most commonly used methods include relative rest, nonsteroidal anti-inflammatory drugs (NSAIDs), and application of cold compresses. Other therapies currently in use or under investigation include acupuncture, acupressure, compressive braces, corticosteroid or botulinum toxin injections, occupational therapy, ultrasound, and laser or shock wave therapy.[5] Despite the multitude of interventions, there is a substantial persistence of symptomatology, and recurrence following resumption of normal activities is common.

This study evaluates the use of a novel elbow brace that uses tubular counter-force elements, active implants, placed over the extensor digitorum tendinous insertion and energy dampening components placed over the lateral and medial epicondyles for the treatment of lateral tendinosis.

Materials and Methods

Patients were seen in a private physician practice associated with a university affiliated teaching hospital. Forty-eight consecutive patients with lateral tendinosis were recruited between 2001 and 2003. The diagnosis of lateral tendinosis was made in patients with lateral elbow pain for >1 month's duration in whom ≥2 of the following provocative tests reproduced this pain: 1) alpation of the extensor tendon origin just distal to the lateral epicondyle, 2) resisted wrist extension with the elbow extended and the forearm pronated, and 3) passive stretching of the extensor musculature by wrist flexion and forearm pronation with the elbow in an extended position. Radiographs of the affected elbow were taken to rule out other pathology.

Patients were excluded from the study if they had had any intervention other than relative rest, moderate NSAID use (up to 600 mg ibuprofen daily) and application of cold compresses, or if they followed this conservative management for >2 weeks. Additionally, workers' compensation patients and those with arthritis and upper thoracic or shoulder pain were excluded from this study.

Patients were randomly assigned to 1 of 2 treatment groups according to a computer-generated stratified randomization schedule. Group A included 25 patients (8 women) who were treated with the energy dampening active implant elbow brace. They were instructed to wear the brace when physically active for >1 hour at a time. Patients in group A were offered only NSAIDs, cold compresses and advice on relative rest as supplemental therapy. Group B included 23 patients who received standard treatment modalities only, including NSAIDs, cold compresses and advice on relative rest. Patients in groups A and B who did not have symptomatic improvement after 10 weeks were

Figure 1: The ForeArmed Active implant (BioBrace, Los Angeles, California).

subsequently administered cortisone injections or underwent occupational therapy (adjunctive therapy). Patients were offered surgical intervention if conservative therapy failed to relieve symptoms.

The elbow brace used in group A was the ForeArmed Active implant (BioBrace, Los Angeles, California). The brace uses plastic cylindrical focal pressure transmitting elements placed directly over the proximal extensor carpi radialis brevis/extensor digitorum communis musculotendonous origin. These active implant elements are designed to place pressure onto the musculotendinous insertion site of the forearm. Additionally, the brace has shock absorbing elements placed over the lateral and medial epicondyles of the humerus (Figure 1).

Patients were followed prospectively from the time of study enrollment. They were evaluated at the time of induction and 26 weeks after initiation of therapy. Evaluation included a subjective assessment of the frequency and severity of symptoms, degree of pain based on a visual analog pain scale (VAS), and objective measurements of grip strength. The VAS ranged from 1 to 10, with 10 indicating the most severe pain. Parameters examined included the patient's assessment of pain over the lateral epicondyle, pain on resistant wrist extension, and pain on passive extension of the wrist with the elbow extended and pronated. Grip strength was measured using
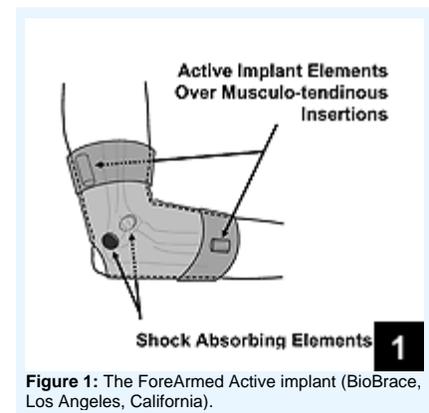
a Jamar Hydraulic Hand Dynamometer (Lafayette Instruments, Lafayette, Indiana) on the third rung with the elbow flexed at 90°. Three measurements were taken and averaged for a final score. No patients had therapy with acupuncture, acupressure, other types of compressive braces, botulinum toxin injection, ultrasound, or laser or shock wave therapy during the 6-month evaluation period.

An unpaired student's *t* test was performed to compare the mean values for VAS and grip strength between the 2 groups.

Results

Forty-eight patients (28 men and 20 women) with lateral tendinosis were enrolled in this study. Patient ages ranged from 22 to 64 years (mean: 40 years). The patients experienced symptoms for an average of 3.4 months (range, 6 weeks to 12 months) prior to enrollment in the study. The dominant extremity was affected in 92% of patients. All patients had a single elbow involved. Twenty-four patients attributed their pain to sport, 20 to work, and 4 could not ascribe an etiology to their pain. All patients were followed until study completion.

Table				
Results				
	VAS Average		Isometric Grip Force (lbs)	
	Study Induction (Week 0)	26 Weeks	Study Induction (Week 0)	26 Weeks
Group A (n=25)	6.5	2.9	41.6	58.5
Brace alone (17/25)	5.8	2.3*	40.5	59.6*
Required adjunctive therapy (5/25)	7.8	3.2	44.6	59.8
No improvement (3/25)	8.3	5.7	42.7	51.0
Group B (n=23)	7.8	4.4	42.6	54.7
Conservative treatment only (7/23)	6.9	4.3*	42.0	54.4*
Required adjunctive therapy (11/23)	8.0	3.1	43.8	57.5
No improvement (5/23)	8.6	7.2	40.8	49.2

Abbreviation: VAS=visual analog pain scale.
*$P<.05$ between groups A and B.

Patients in group A (n=25) wore the elbow brace daily for the duration of the study. No complications related to the brace were observed, and no patient discontinued its use during the study period. Seventeen patients reported subjective improvement of their symptoms and were found to have diminished VAS score (average decrease, 3.5 points) and improved grip strength (average improvement, 46.9%) at 26-week follow-up (Table). Five patients in group A had moderate symptomatic resolution with the brace alone but required occupational therapy or cortisone injection in addition to the assigned protocol. These patients subsequently had diminished VAS and improved grip strength at the conclusion of the study (26 weeks). Three patients in group A did not have improvement of symptoms with the brace or with subsequent occupational therapy or cortisone injection. They underwent surgical intervention at the conclusion of the study period. Overall for patients in group A, the average VAS score decreased by 3.6 points and grip strength increased 40.6% during the study period.

Seven patients in group B reported improvement of their symptoms and exhibited diminished VAS score (average decrease, 2.6 points) and improved grip strength (average improvement, 29.5%) with standard conservative treatment alone (NSAIDs, cold application, and relative rest). This improvement was significantly less (*P*<.05) than the improvement seen in group A patients who did not require adjunctive therapy or surgery. Eleven of 23 patients in group B had moderate symptomatic resolution with the brace alone but required adjunctive occupational therapy or cortisone injection in addition to the assigned protocol. Five of the patients in group B did not have improvement of symptoms with the brace or with subsequent occupational therapy or cortisone injection. They ultimately underwent surgical intervention at the end of the study period. Overall for patients in group B, the average VAS score decreased by 3.5 points and grip strength increased 28.4% during the study period.

Discussion

Elbow pain is a common clinical condition with many potential etiologies. While tendinosis is the most common cause, the differential diagnosis is broad and must be considered. Other causes of elbow pain include posterior interosseous nerve entrapment, cervical root compression, radiocapitellar osteoarthritis, synovitis, plica, chondromalacia, adolescent osteochondral defect, ulnar nerve compression, extra-articular olecranon exostosis, bursitis, and olecranon fossa synovitis.[3,6] A careful history and physical examination most often differentiates tendinosis from these conditions, but further investigation with electromyography and radiographic modalities may be needed. Additionally, tendinosis may occur coincident with these conditions.[6]

Lateral tendinosis most often represents an injury of repetitive stress and overuse.[3,6] The initial pathological derangement is microtearing of the proximal musculotendinous origins of the extensor carpi radialis brevis and extensor digitorum communis followed by disorganized or disrupted healing. Persistent activity leads to continued microtearing, which combined with poor tendon vascularity, prevents proper healing of the injury. Pathologic specimens of excised tendon rarely reveal either acute or chronic inflammatory infiltrates. Rather, normal collagen architecture of tendon fibers is disrupted by an invasion of fibroblasts and immature vascular granulation-type tissue, termed angiofibroblastic hyperplasia.[7] Adjacent to these areas of proliferating vascular reparative tissue, the tendon appears hypercellular, degenerative, and microfragmented.[4] A similar appearance has been described for degenerative lesions of the rotator cuff, patellar, and Achilles tendons. Thus the commonly used terms tendinitis and epicondylitis are misnomers in describing tennis elbow, as the pathology is most consistent with a chronic, degeneration rather than an inflammatory lesion.

A proper understanding of the pathopysiology of tendinosis is essential to developing and providing adequate treatment. Although multiple treatment modalities are available for patients with this condition, little evidence exists that any particular intervention has long term efficacy. Initial management includes relative rest and NSAID analgesia to promote uninterrupted healing of the affected tendinous insertions. This "wait and see" policy often is as effective as other more invasive and costly treatments. However, persistence or recurrence of symptoms, particularly with the resumption of normal activity, commonly leads patients to seek alternative treatment strategies. Evidence exists for the short term effectiveness of a variety of interventions that have been sponsored to help prevent further tissue damage.[1,6,8] Corticosteroid injections

generally are effective in short term management of lateral tendinosis, however rarely provide long term resolution of symptoms and are associated with complications when performed repeatedly, including skin hypopigmentation, subcutaneous fat atrophy, infection, and tendon rupture.[4,5,8-11] Other treatments currently being used or investigated include acupuncture, acupressure, compressive braces, corticosteroid or botulinum toxin injections, occupational therapy, copper bracelets, proliferant therapy, ultrasound, and laser or shock wave therapy.[5,12] Many are effective acutely, but further research is needed to determine if any long term superiority exists over more conservative measures.

The device used in this study was conceived and designed to optimize the benefits of counterforce dampening elements for the treatment of lateral tendinosis. Counterforce bracing is a potentially effective mechanism of dissipating traumatic forces concentrated on the tendinous origin.[13,14] By limiting full contractile expansion of the musculotendinous unit, it decreases the intrinsic muscle force that is transmitted to the tendinous origin.[6] In the ForeArmed implant, the placement of active implant pressure transmitting elements overlying the extensor and triceps tendon insertion sites has been optimized to dampen incoming energy forces to the elbow. This pressure over the insertion may prevent the repetitive pathological insults of tendinosis by dissipating the energy wave traveling proximally to the insertion site. Placement of counterforce elements over the wrist extensors has been shown to have the most significant reduction of impact induced acceleration amplitudes in the forearm, and may translate to the ideal location for dampening elements, as used in this device.[13]

Shock-absorbing elements over the medial and lateral epicondyles were placed with the intent of further reducing effect of vibratory energy in the elbow by directly counteracting and dissipating shock vibrations ending at these points. The brace may function effectively to both prevent further injury to the elbow and promote healing by protecting and isolating the epicondyles from pathological repetitive stress. Furthermore, in treatment protocols using acupressure and acupuncture, stimulation over the extensor carpi radialis brevis insertion has been suggested to mediate neurohumoral release and result in pain relief.[15-19] The active implant tubes used in the ForeArmed device may stimulate these acupuncture meridians and partially account for the favorable performance observed.

A favorable outcome for patients with lateral tendinosis treated with the Active Implant Device brace was seen in the present study. Eighty-eight percent of patients using this device during the study period reported relief of symptoms. A significantly greater number of patients (17 [68%] of 25 patients) reported symptomatic relief and gain of strength without the need for adjunctive therapy when using the Active Implant Device compared to those who received conservative therapy alone (7 [28%] of 25 patients) ($P<.05$). Three (8.8%) patients in the former compared to 5 (17%) patients in the latter treatment arm were considered treatment failures, ultimately requiring surgical intervention.

Additional advantages of this device for the treatment of lateral tendinosis stem from its ease of use and relative low cost. All patients in Group A finished treatment with the brace. Patients generally reported the brace as comfortable to wear while performing activities of daily living, and reported that it did not interfere with their ability to engage in sports or perform menial tasks. Range of motion limitation from the brace was negligible, with no patients reporting

limitation of arm motion. Importantly, no adverse events were reported such as nerve damage, neuropathy, edema, hypersensitivity, or arm pain from the device (Figure 2). The brace used in this study is relatively inexpensive ($50-$70), especially when compared to physical therapy.[20]

Figure 2: Range of motion in extension (A) and flexion (B) with the ForeArmed Active implant.

Although the patients seen in this tertiary referral center often presented at a more advanced stage of injury, most responded well to conservative treatment and did not need surgical intervention. Adherence to the treatment regimen was relatively high, and results were similar to published standards.[2-6,8] This device represents a promising treatment option for patients with lateral tendinosis, and studies are ongoing to further define its role in the management of this condition.

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