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WHAT ABOUT MEDICAL DEVICE TRIALS?

Medical device developers looking for a rapid, cost effective means of gaining early proof of concept for their products should consider conducting their initial clinical trials in New Zealand. The simple, one ethical committee, approval process here does not require U.S FDA Investigational Device Exemption (IDE) filing prior to the start of the study.

Safety is paramount and the ethic committee will want to see preclinical data in animals, depending on the device.

Medical Device developers can gain the necessary in vivo information for investor and FDA submission decision making about their products quickly by collaborating with internationally recognized investigators.

Our medical device sector is characterized by outstanding research capabilities with clinical expertise to contribute in areas like cardiovascular disease, diabetes, orthopedics, and surgical (e.g wound healing)

HOW LONG DOES REGULATORY APPROVAL TAKE AND WHAT DOES IT COST?

[The Ministry of Health's \(Medsafe\) Standing Committee On Therapeutic Trials \(SCOTT\) approval process takes a maximum of 45 days, usually less.](#) This is required for non-registered drug formulations, but not for medical devices, nor new indications of NZ registered formulations.

ABOUT US



Ultrasonic Pain Relief LTD
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INVESTING IN STATE OF THE ART ULTRASONIC PAIN MANAGEMENT TECHNOLOGY

For the past several years, we have been building and successfully testing our prototype. For instance, one person suffered from a severe tennis elbow for seven years. Despite many visits to sports doctors, physiotherapists, acupuncturists etc., nothing ever really worked or the pain came back. This patient ended up using medicaments to kill the pain.

We treated him only 5 minutes with our low frequency uniformly waved technology. After 24 hours, the pain was **completely** gone. What happens is that only a very highly dense acoustic pressure is able to signal healing pathways.

We are going to focuss on two target groups:

- Professional tennis players, golf players, soccer and football players, rugby players, athletes etc. These professionals will be treated in Napier.
- Selling the equipment to professional care takers such as physiotherapists, chiropractors, hospitals and so on.

Before we start, we are going to apply in New Zealand to get our device registered and do clinical trials. We need an investment for this of approximately 500,000 NZD.



Our solution:

We apply a low frequency -low intensity acoustic pressure to the tennis arm. Because of the low frequency, the sound is able to travel several centimeters (if needed) into the tissue. After approximately five minutes of treatment (water acts as the bonding medium between sonotrode and tissue), the inflammation is slowly being loosened and the scar tissue has also been softened. This channel signaling process of healing will take place within 24 hours.

Please contact [Nico van Dongen](#) to get a copy of the business plan.

We look forward to hearing from you.

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CAUSES RUNNER'S KNEE OR PATELLOFEMORAL PAIN SYNDROME (PFPS)

Patellofemoral pain syndrome (PFPS), or runner's knee, got its nickname for an obvious and very unfortunate reason—it's common among runners. The stress of running can cause irritation where the kneecap (patella) rests on the thighbone.

The resulting pain can be sharp and sudden or dull and chronic, and it may disappear while you're running, only to return again afterward. While biomechanical issues may be to blame, the cause can often be traced back to poorly conditioned quadriceps and tight hamstrings. Weak quads aren't able to support the patella, leading it to track out of alignment, and inflexible hamstrings can put pressure on the knee. If you want to treat and avoid another bout with runner's knee, add strengthening and stretching to your routine.

Causes of runner's knee

Pinpointing a single cause of runner's knee is difficult. It could be a biomechanical problem—the patella may be larger on the outside than it is on the inside, it may sit too high in the femoral groove, or it may dislocate easily. Also, worn cartilage in the knee joint reduces shock absorption, high-arched feet provide less cushioning, and flat feet or knees that turn in or out excessively can pull the patella



Image copyright of BodyHeal.com.au

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sideways.

There are also muscular causes. Tight hamstring and calf muscles put pressure on the knee, and weak quadriceps muscles can cause the patella to track out of alignment. Just the repetitive force of a normal running stride alone can be enough to provoke an attack.

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CAUSES TENNIS ELBOW - LATERAL EPICONDYLITIS

OVERUSE

Recent studies show that tennis elbow is often due to damage to a specific forearm muscle. The extensor carpi radialis brevis (ECRB) muscle helps stabilize the wrist when the elbow is straight. This occurs during a tennis groundstroke, for example. When the ECRB is weakened from overuse, microscopic tears form in the tendon where it attaches to the lateral epicondyle. This leads to inflammation and pain.

The ECRB may also be at increased risk for damage because of its position. As the elbow bends and straightens, the muscle rubs against bony bumps. This can cause gradual wear and tear of the muscle over time.

ACTIVITIES

Athletes are not the only people who get tennis elbow. Many people with tennis elbow participate in work or recreational activities that require repetitive and vigorous use of the forearm muscle.

Painters, plumbers, and carpenters are particularly prone to developing tennis elbow. Studies have shown that auto workers, cooks, and even butchers get tennis elbow more often than the rest of the population. It is thought that the repetition and weight lifting required in these occupations leads to injury.

AGE



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Most people who get tennis elbow are between the ages of 30 and 50, although anyone can get tennis elbow if they have the risk factors. In racquet sports like tennis, improper stroke technique and improper equipment may be risk factors.

UNKNOWN

Lateral epicondylitis can occur without any recognized repetitive injury. This occurrence is called "insidious" or of an unknown cause.

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CAUSES GOLFER'S ELBOW – MEDIAL EPICONDYLITIS

Golfers elbow injury explained

Golfers Elbow (Medial Epicondylitis) is characterised by pain over the inner elbow, which may radiate down the forearm. Despite the name, Golfers Elbow does not just affect golfers. In fact, this painful elbow problem is most often associated with work-related activities. Golfers Elbow is equally common in men and women, peaking in prevalence between the ages of 30 and 50.

Golfers Elbow begins as inflammation of the flexor tendons of the forearm (located on the inner side of the arm), as they attach to the Humerus (upper arm) bone. This inflammation is usually caused by prolonged gripping activities such as hammering, driving screws, weight lifting, playing certain musical instruments, canoeing, digging in the garden and driving.

If these activities are continued, then the inflammatory nature of Golfers Elbow can give rise to a chronic tendon problem that is characterized by pain, weakness and degeneration of the tendon. This elbow problem can then be very persistent and much more difficult to treat.

Golfers Elbow Signs & Symptoms

Golfer's Elbow (Medial Epicondylitis)



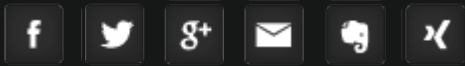
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Golfers Elbow is very easy to diagnose. There is pain when the medial epicondyle (innermost part of the elbow) is touched. There is pain if the elbow is straight and the hand is moved forward and back at the wrist. The pain is made worse by gripping activities and, in some cases, simple things like turning a door handle can cause intense pain.



Golfers Elbow can be differentiated from a fracture of the elbow and osteoarthritis of the elbow joint by x-ray investigation. Rheumatoid disease would usually affect more than one joint and is confirmed by blood tests. Pain in the elbow region can be referred from a problem in the neck or shoulder and all of these possibilities should be thoroughly examined by a doctor or a physiotherapist in order to eliminate them before a diagnosis of Golfers Elbow is made.

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CAUSES ANKLE SPRAIN OR TUMEFACTION ANKLE

Causes:

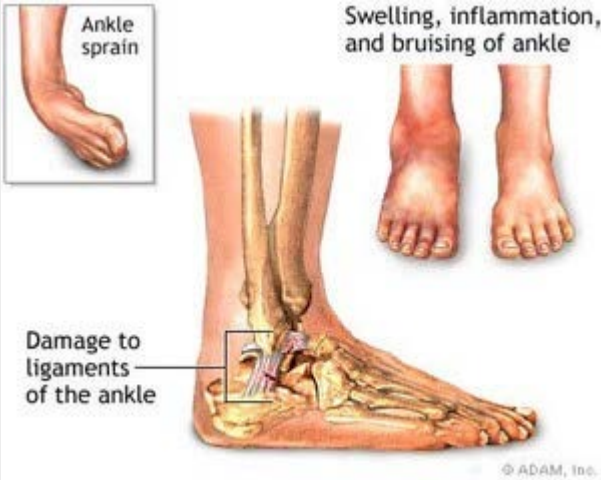
Ankle sprains typically occur on uneven walking surfaces--while stepping off a curb, for example, or while strolling across a grassy lawn that has unexpected dips or holes. Making a misstep during an athletic event or while exercising can also lead to a sprain. An ankle can get sprained while a foot is firmly planted on the ground if the body gets twisted in a way that puts abnormal pressure on the ankle.

A sprained ankle is usually the result of an inward roll (inversion) injury.

This injury occurs when the foot is forced to "roll in" (invert), putting abnormal pressure onto the outside edge of the foot. The pressure then stretches or tears one or more of the lateral, or outside, ligaments of the joint.

A much less common cause of a sprained ankle is an outward roll (eversion) injury. With this injury, the foot is suddenly turned outward, causing the medial, or inner ligaments of the ankle to be stretched or torn.

An eversion injury sometimes results in what is known as a high



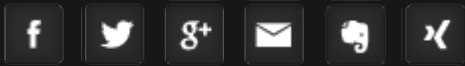
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(syndesmotomic) ankle sprain. This type of sprain occurs just above the ankle joint to the ligaments between the two major lower leg bones (tibia and fibula). High ankle sprains are treated in a similar manner to other sprains, but they tend to be more severe and take longer to heal.


This injury occurs when the foot “rolls in” (inverts), stretching or tearing one or more of the lateral, or outside, ligaments of the joint.

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CAUSES RUNNERS FOOT OR ENDONITIS AND PLANTAR FASCIITIS

Unfortunately, the root causes of plantar fasciitis are still not fully understood. There are, however, some clues.

Some studies have found a connection between poor ankle range of motion, especially in dorsiflexion, which implies that calf tightness plays a role in the development of plantar fasciitis. Indeed, the plantar fascia itself is in many ways simply a continuation of the Achilles tendon, which anchors the calf muscles to the heel bone. Like a cable that angles around a corner, tight calves could put excessive tension on the plantar fascia, increasing the risk of injury.

As mentioned earlier, obesity and time spent on your feet are risk factors as well,² though these are not as often a problem for runners. However, they do indicate that putting high strains on the foot is problematic, and new research out of the University of Delaware has connected high impact loading rates with plantar fasciitis.

The plantar fascia is also forced to absorb significantly more strain when you wear hard, flat shoes or walk around barefoot. While the dynamics of “arch support” are not fully understood from a bio mechanical perspective, it's fairly obvious to most sufferers of arch



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pain that a cushioned, supportive surface feels better on the foot than a hard, flat one.

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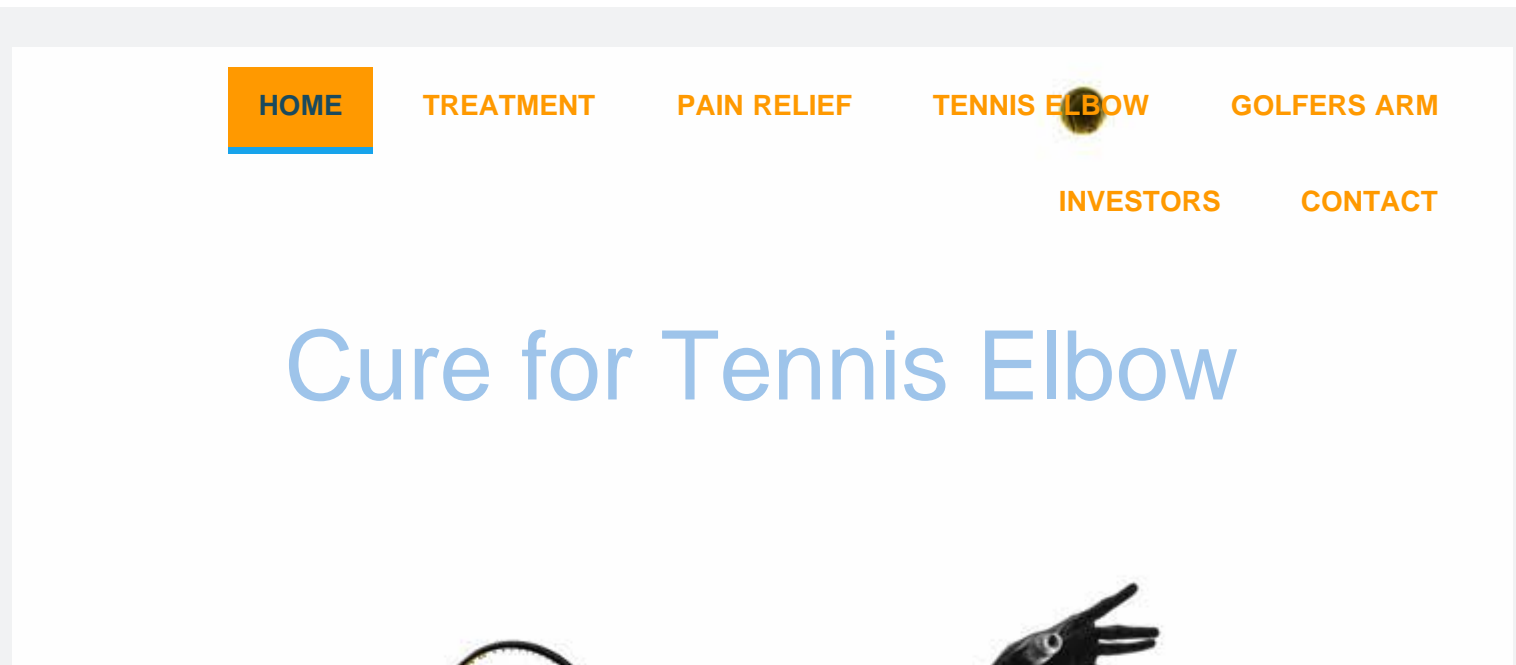
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TENNIS ELBOW FAST PAIN RELIEF

Tennis elbow is usually caused by excessive strain on the tendons and muscles of the forearm, which attach at the elbow. These tendons and muscles produce forward and backward movement at the wrist. The pain is usually felt at the side of the elbow and is experienced suddenly in about 25 percent of cases. The remaining 75 percent experience pain gradually. As the pain progresses, sufferers usually seek sports-medical attention in six to eight weeks.

Rod Laver, Tony Roche, and Arthur Ashe all ended up with tennis elbow. They hit the ball primarily with their wrists. This puts tremendous force on the elbow. Pancho Gonzales, Ken Rosewall, and Pancho Segura were immune to tennis elbow. They hit the ball from the shoulder down.

Tennis plays suffer from two types of tennis elbow. Forehand tennis elbow is common in professional tennis players as a result of wrist snapping in booming serves. Forceful serves strain the tendons and muscles that bend the wrist. These tendons and muscles attach on the inner side of the elbow and consequently the pain occurs at this site. Backhand tennis elbow is frequently seen in novice or weekend players. The pain arises from hitting backhand strokes incorrectly. A backhand stroke stresses the tendons and muscles that straighten the wrist. These tendons and muscles attach to the outer side of the elbow.



Tennis elbow pain relief

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LOW FREQUENCY - LOW INTENSITY ULTRASOUND PROVOKES STEM CELLS

NEW ULTRASONIC PAIN RELIEF

Your regular physiotherapist uses a 1 MHz device which gets locally hot when he cranks up the intensity. This phenomenon is called, standing waves, which prevents to 'scare' certain stem cells in order to channel processes in your body to restore functionality. Our technique has overcome this standing waves phenomenon and is able to produce uniform waves on any part of the body, even at 7 cm. This uniform very strong acoustic signal is thus able to provoke stem cells. The result is a very fast pain relief of any inflammatory injury. Usually within 24 hours!

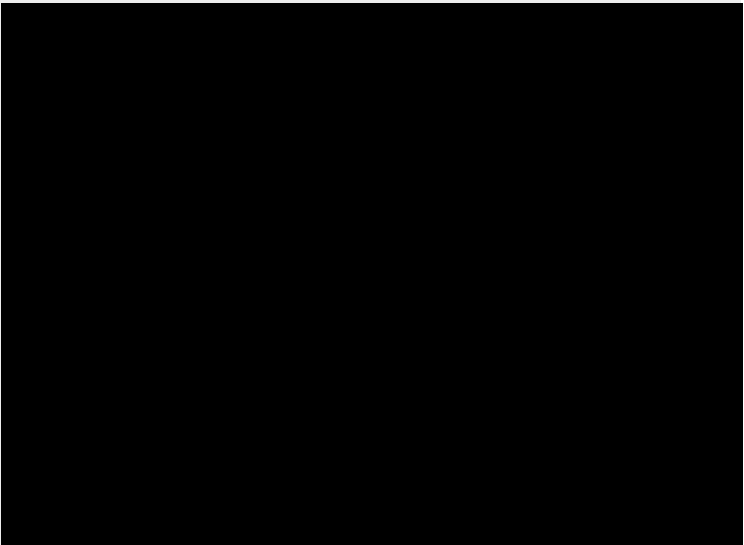
Old treatment options:

ICE PAIN RELIEF

Ice can sometimes be a good pain relief if you have tennis elbow. Try using an ice-pack (such as a pack of frozen peas wrapped in a towel) on the tender area twice a day for ten minutes.

PHYSIOTHERAPY

Physiotherapy has been shown to be helpful in the treatment of



In the movie above, the patient suffered from a Runner's knee or Chondromalacia patellae. After two days of just a five minute treatment, both swelling and injury had completely gone.

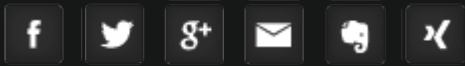
tennis elbow. Your physiotherapist may be able to use techniques such as massage, laser therapy and ultrasound therapy as well as exercises to treat your tennis elbow. It is not certain if any one of these physiotherapy treatments is better than others.

Studies have shown that physiotherapy may not be as good as a steroid injection at relieving pain in the short term (that is, within the first six weeks). But, it may be superior to steroid injections in the long term. However, there may be a wait for your physiotherapy appointment.

SUPPORTS AND SPLINTS

These can include wearing a special elbow armband or bandage. This may help to give support and protection to your elbow until symptoms ease. Another option may be to wear a wrist splint which may ease pain by helping to rest the muscles that pull on your elbow. Wearing supports such as these and having physiotherapy at the same time may give you better symptom relief in the long term.

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WORKS ULTRA FAST ON ALL INFLAMMATORY SPORTS INJURIES.

Many sports injuries result in pain, swelling and restricted movement or stiffness in the affected area.

Sprains and strains are the most common type of sports injury. A sprain happens when one or more of the ligaments is stretched, twisted or torn. A muscle strain ('pulling a muscle') happens when muscle tissues or fibres are stretched or torn.

Most sprains and strains usually heal with rest and don't require specialist treatment, although physiotherapy may speed up your recovery. Completely torn ligaments or muscle may need to be surgically repaired.

Other sports injuries include:

- back pain
- hamstring injury
- head injuries
- heel pain
- joint inflammation
- knee pain, including knee ligament damage
- shoulder pain



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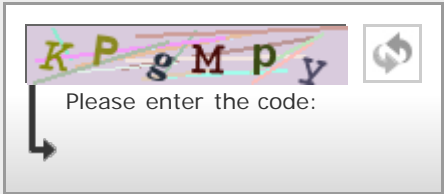
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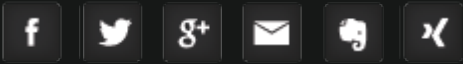
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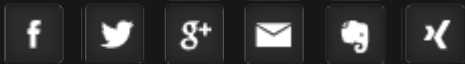


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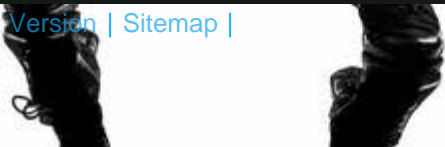
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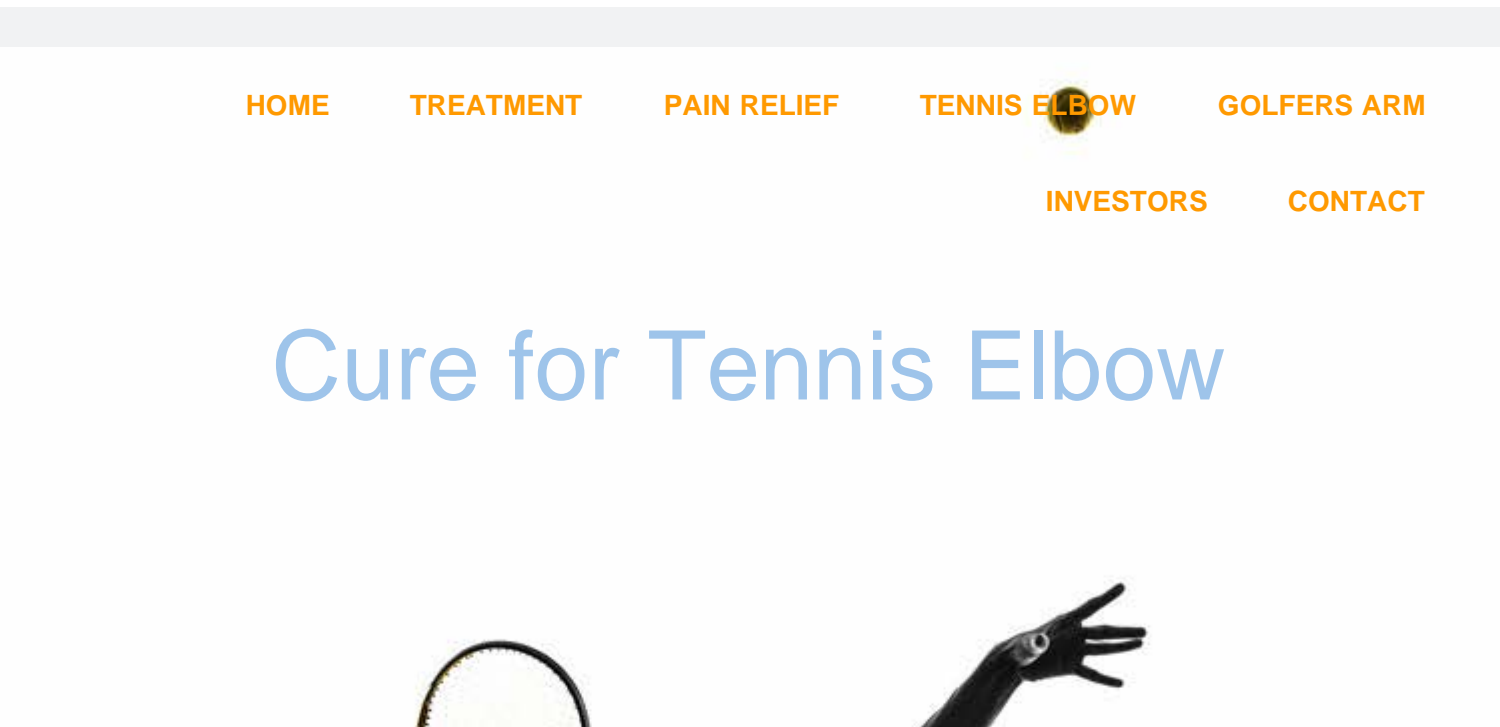


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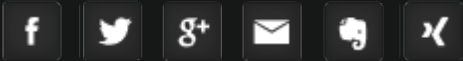




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