CQ HAND + UPPER LIMB
SPECIALIST ORTHOPAEDIC SURGEON

PATIENT INFORMATION

Autologous Tenocyte Implantation (ATI)

Esta página foi traduzida automaticamente e ainda não foi verificada por um médico. A **versão em inglês** é a versão oficial.

What it is

Autologous tenocyte implantation — usually shortened to ATI, and sold in Australia under the brand name OrthoATI — is an injection of your own tendon cells into a tendon that has not healed.

"Autologous" means the cells come from you. "Tenocytes" are the cells that live inside a tendon and make the collagen that gives it its strength. The idea behind the treatment is that a long-standing tendon problem is not really an inflammation — it is a patch of tendon where the repair process has stalled and the cells that should be rebuilding it have died off. ATI aims to restock that patch with healthy tendon cells taken from somewhere else in your body.

It takes two visits, several weeks apart.

- **First, a biopsy.** Under local anaesthetic, a needle takes a very small sample of tendon, usually from the patellar tendon just below the kneecap. You will also have a blood test, because the laboratory is required to screen for hepatitis and HIV before it can grow your cells.
- **Then the laboratory grows the cells.** Your sample goes to a licensed cell-culture facility, where the tendon cells are separated out and multiplied over about three to five weeks until there are several million of them.
- **Then the injection.** Your own cells come back as a small volume of fluid, and a doctor injects them directly into the damaged part of the tendon using ultrasound to guide the needle. This is done under local anaesthetic. There is no operation and no cut.

Afterwards, the published studies asked people to rest for two days, stick to light household or office work for four weeks, and do simple stretches four times a day. They did not use a formal physiotherapy strengthening programme, and restrictions on work and sport came off at four weeks.

The treatment has been used for tennis elbow, rotator cuff (shoulder) tendon problems, gluteal (hip) tendon problems and Achilles tendon problems. Nearly all of the published research is on tennis elbow.

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Does it work?

This is the part that deserves a careful answer rather than a short one, because what is claimed for ATI and what has actually been demonstrated are not the same thing.

What has been published is genuinely encouraging, but it is small and uncontrolled. An independent review published in 2025 searched the world literature and found **five studies containing 50 patients in total** – three small case series and two single-patient reports, all of them carried out in Australia. In the main tennis elbow study, 16 people with severe, long-standing tennis elbow who had already failed everything else improved their worst pain by 86% and their arm-function score by 91% over 12 months, and the appearance of the tendon on MRI improved as well. When the same group was re-examined an average of 4.5 years later, those gains were still there.

But none of those studies had a comparison group. Nobody received a dummy injection, and nobody was left untreated for comparison. That matters more than it might sound, for two reasons. Tendon pain responds strongly to the expectation of treatment – in tennis elbow, a trial that compared real surgery with fake surgery, with neither the patient nor the assessor knowing which they had, found no advantage for the real operation. And tennis elbow gets better on its own: across the untreated and placebo groups of randomised trials, **about 90% of people are better within a year**.

The trial most often quoted in favour of ATI has never been published. In November 2023 the company that makes OrthoATI announced to the stock exchange the results of a 48-person trial comparing ATI with surgery for severe tennis elbow, reporting that the injection did better than the operation and got people back to work about a month sooner. Nearly three years later that trial has not appeared in any medical journal, so no independent doctor has been able to check how it was done. Everyone in it knew which treatment they were getting, the main measurement was a questionnaire the patients filled in themselves, and the company that sells the product ran the trial. None of that means the result is wrong. It means it has not yet been tested by the people whose job it is to test it.

There is one trial that could have settled the question, and it has gone silent. A hospital in the Netherlands ran the only properly blinded study of ATI ever registered: 90 people with Achilles tendon pain, half getting tendon cells and half getting a salt-water injection, with neither the patients nor the doctors assessing them knowing which was which. It finished in 2014. Its results have never been published, anywhere, in the twelve years since.

So the honest summary is: **safe, plausible, consistently positive in uncontrolled studies, and still unproven.** The 2025 review's own conclusion was that ATI may be a reasonable second-line option for stubborn tendon problems, but that a comparison group is essential before anyone can say it works.

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What are the risks?

The safety record is the strongest part of the evidence, and it is reassuring as far as it goes.

- **At the elbow or tendon being treated**, the published series report no infections, no tendon ruptures, no bleeding into the tendon, no nerve injuries and no unwanted bone formation.
- **At the knee where the biopsy is taken**, discomfort has been mild and short-lived. In the main tennis elbow study, average knee pain was under 2 out of 10 four hours after the biopsy and had settled by four weeks, with no lasting problems. In the hip study, 3 of 12 people had mild soreness at the biopsy site that settled with an anti-inflammatory gel.
- **The commonest disappointment is not a complication but a non-response.** One person in the main tennis elbow study was no better at three months, after re-injuring the elbow lifting at work, and went on to have surgery.

Two honest qualifications. First, with only 50 patients in the entire published literature, an uncommon complication would not yet have shown up — an unblemished record in 50 people cannot rule out a problem that happens in 1 in 100. Second, two of the five published studies did not formally look for side effects at all, so "none reported" is not quite the same as "none occurred".

There is also a risk that is not medical. This is an unapproved product, the treatment is paid for privately, and the biopsy commits you to the process before anyone knows whether your cells will grow well or whether the injection will help you.

Is it right for you?

ATI is not a first step, and nobody sensible offers it as one. It has only ever been studied in people whose tendon problem had lasted at least six months and who had already been through the usual treatments without success. In the tennis elbow studies, that meant bracing, physiotherapy and at least one cortisone injection.

It is worth understanding where it sits legally in Australia, because this shapes the decision. OrthoATI is **not registered on the Australian Register of Therapeutic Goods**. It is supplied under the Therapeutic Goods Administration's Special Access Scheme, which is the pathway that allows a doctor to obtain an unapproved product for an individual patient. That is a legitimate and commonly used route, but it carries two consequences: your doctor takes personal responsibility for the decision and must tell you the product is unapproved, and it is not a Medicare-funded treatment, so the cell-processing part is paid for by you. Ask for that in writing before the biopsy, not after.

It may be worth discussing if all of the following are true.

- Your tendon problem has been going for well over six months and is genuinely disabling.
- You have properly completed a loading and strengthening programme with a physiotherapist — not just tried one — and it has not worked.
- The diagnosis has been confirmed on ultrasound or MRI, so it is clear the pain is coming from the tendon.

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- You accept that you are choosing an unproven treatment, and you would rather do that than have an operation or keep waiting.

It is probably not the right choice if your symptoms are recent, if you have not yet done a proper rehabilitation programme, if there is another explanation for the pain such as a trapped nerve, or if being told "we don't yet know if this works" is not something you can sit with comfortably.

Dr Kieran Hirpara will go through the alternatives with you before any of this is considered — continuing with a structured loading programme, a brace, further injections such as cortisone or PRP, and where appropriate an operation — and will be straightforward with you about the fact that none of the treatments for stubborn tennis elbow, including surgery, has a strong evidence base.

The bottom line

ATI is a well-tolerated injection of your own cultured tendon cells, with a clean safety record and a consistent, durable pattern of improvement in the small number of people who have been studied.

It is also, at present, an unapproved product supported by five published studies and 50 patients, none of them controlled. The trial that is used to promote it has never been published; the one blinded trial that could have tested it properly has never reported. Against a condition in which most people recover within a year on their own, and in which even surgery has not outperformed a placebo operation, that is not enough to say it works.

If you are considering it, the useful question is not "does the science look promising" — it does. The useful question is whether you are comfortable paying for, and committing to, a treatment whose benefit has not yet been separated from the natural course of the condition and the expectation of being treated. That is a reasonable thing for a well-informed person to choose. It is not something anyone should be talked into.

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