CQ HAND + UPPER LIMB
SPECIALIST ORTHOPAEDIC SURGEON

PATIENT INFORMATION — IN DEPTH

Autologous Tenocyte Implantation (ATI)

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.

In more depth

This section goes further than you need for your own treatment decision. Autologous tenocyte implantation is worth the extra reading because it is an unusually clean example of a problem that runs through the whole of regenerative orthopaedics: a treatment can be biologically sensible, consistently followed by improvement, entirely safe, and still not shown to work — and the reason is almost never the biology. It is the design of the studies.

WHY ANYONE THOUGHT PUTTING TENDON CELLS BACK WOULD HELP

Chronic tendon pain is not tendonitis. When the degenerate tissue is examined, there is very little inflammation in it. What there is instead is disorganised collagen, ingrowth of new vessels and nerves, and a resident cell population in trouble. In the extensor carpi radialis brevis origin of chronic tennis elbow, both **apoptosis and autophagic cell death** are demonstrable in the tenocytes themselves [1]. Ageing tenocytes drift towards the tendinotic phenotype through oxygen-tension-dependent Rac1 signalling [2]. On that picture the lesion is not inflamed, it is **depopulated** — and restocking it with healthy collagen-producing cells is a coherent thing to try.

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The cells used in ATI are characterised rather than merely harvested. In the index elbow study the cultured cells were profiled by flow cytometry and quantitative real-time PCR and shown to carry a tendon cell signature distinguishable from mesenchymal stem cells, and roughly 2 mL at 2–5 × 10^6 cells/mL in 10% autologous serum was delivered through an 18-gauge needle into the lesion on one or two passes — expressly not a peppering technique, since the object was to deposit cells rather than to provoke bleeding [3].

One assumption inside that design is rarely examined. The donor tendon is the patellar tendon; the target is the common extensor origin. Tendon cells are not interchangeable between sites — human flexor and extensor tendon cells differ measurably in vitro in their growth and matrix behaviour [4] — so the premise that a knee-derived tenocyte will behave as an elbow tenocyte once injected is an assumption the clinical studies inherit rather than test. The manufacturer's own laboratory work reports that donor age and donor site do not degrade cell growth or bioactivity, which addresses part of this, but it is a culture-dish endpoint from the group that sells the product.

WHAT FIFTY PATIENTS ACTUALLY SHOWED

An independent systematic review published in 2025 — no external funding, no declared conflicts — searched 174 records and found **five includable studies containing 50 patients between them: three case series and two case reports, all conducted in Australia between 2013 and 2018** [5]. That is the entire published clinical evidence base for the technology, at every anatomical site combined.

Within it, the elbow data are the strongest. Sixteen patients with severe chronic tennis elbow, mean symptom duration 29 months, all previously listed for surgery, improved maximum-pain VAS from 5.94 by **86% at 12 months** and QuickDASH from 45.88 by **91%**, with the combined MRI tendinopathy-and-tear score falling from 4.31 to 2.88 on a 2-to-6 scale [3]. Re-examined at a mean of 4.51 years, pain remained **78%** better and QuickDASH **84%** better, grip strength had continued to climb past its one-year value (19.85 kg → 37.38 kg at one year → 46.60 kg at final review), and the MRI score sat at 2.87 against 2.88 at one year, with all but two patients scoring identically [6]. The precursor technique, using **skin**-derived tenocyte-like cells rather than tendon-derived ones, moved median PRTEE from 78 to 12 at six months in 12 patients [7].

Two findings inside that literature deserve more weight than they usually get. First, in the gluteal tendinopathy series clinical scores improved and held to 24 months, but **tendon appearance on MRI did not significantly change** [8] — so the structural repair story does not reproduce away from the elbow. Second, in a controlled animal model, tenocyte-seeded scaffolds improved rotator cuff healing in juvenile and in aged animals but **had no effect at all in adult animals** [9]. A treatment whose preclinical benefit disappears in the age group that actually gets tendinopathy is not a comfortable finding, and it does not appear in any promotional account of the technology.

It is also not obvious that the cell has to be a cultured tenocyte. Dermal fibroblasts — vastly cheaper to obtain — reduced the retear rate after arthroscopic repair of rotator cuff tears larger than 2 cm in a randomised human trial [10]. If cell delivery is the active ingredient, the expensive cell may not be the necessary one.

HOW TO READ A TRIAL YOU CANNOT READ

The result most often cited for ATI is a 48-patient randomised comparison against surgery for severe chronic tennis elbow, announced by Orthocell to the ASX on 14 November 2023 (https://announcements.asx.com.au/

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asxpdf/20231114/pdf/05x9jhkpjfmzbp.pdf) and presented at the Australian Orthopaedic Association annual meeting. It reported a **15.7-point QuickDASH advantage over surgery at 12 months (p = 0.0028)** and return to work at 19 versus 51 days. Nearly three years later it is not indexed in PubMed or Europe PMC. Four specific problems follow, and none of them depends on doubting anyone's honesty.

The design tested one thing and the headline claims another. It was a non-inferiority trial with a 15-point QuickDASH margin — meaning it was built to conclude "not meaningfully worse", and would have returned a successful verdict even if ATI had been up to 15 points inferior. Fifteen points is approximately the whole minimal clinically important difference for QuickDASH. Reporting superiority from that architecture is a different inference from the one the sample size was calculated to support.

Everything measured was subjective, and nobody was blinded. QuickDASH and VAS are patient-completed, and every participant knew whether they had received an operation or a novel cell injection. Tennis elbow is precisely the wrong condition in which to accept that: in a prospective, randomised, **double-blinded, placebo-controlled** trial, surgical excision of the degenerate ECRB produced no additional benefit over sham surgery [11]. An open-label comparison against an operation that does not beat placebo cannot demonstrate biological activity in the injection; it can only show that two treatment trajectories look similar in a condition where **about 90% of untreated people recover within a year** [12].

Forty-eight patients is thin in a literature that is known to be fragile. A fragility analysis of randomised trials of non-operative management of lateral epicondylitis found that reversing as few as **three patient outcomes** would overturn the reported statistical significance [13].

The sponsor ran it, and sponsorship measurably moves results in this exact indication. Industry affiliation is associated with more favourable findings in randomised trials of platelet-rich plasma for lateral epicondylitis [14]. In the closely analogous mesenchymal stromal cell literature, spin is present in most trials [15], and abstracts report a significantly higher proportion of statistically significant p-values than the main texts of the same papers [16]. Reporting standards for orthopaedic biologics are poorly adhered to in general [17], which is why cell dose, viability and passage number usually cannot be recovered from what is published — and cannot be recovered from a stock-exchange release at all.

THE TRIAL THAT WOULD HAVE ANSWERED THE QUESTION

Registered as NCT01343836 (https://clinicaltrials.gov/study/NCT01343836), it was investigator-initiated at Erasmus Medical Center, **quadruple-blinded** across participant, care provider, investigator and outcomes assessor, and randomised 90 patients with chronic Achilles tendinopathy to autologous tenocyte implantation or **intratendinous saline**, both with eccentric loading. The primary endpoint was VISA-A at 24 weeks. It completed in June 2014.

No results have been posted. The registration was last updated in February 2015. No publication is indexed in PubMed or Europe PMC; the only papers that cite the registration are reviews noting its existence.

Twelve years of silence from the only placebo-controlled test of a technology is itself information. It is not proof of a negative result — trials fail to report for funding, staffing and thesis-completion reasons as often as for embarrassing ones — but the asymmetry is hard to ignore: the sponsor-run open-label trial was announced within weeks of completion, and the independent blinded trial has never been heard from.

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WHAT WOULD ACTUALLY SETTLE IT

A trial of ATI against a sham injection, with the assessor blinded, in a single tendon site, with a patient-reported primary endpoint at 12 months and an imaging co-primary read by a blinded radiologist. Roughly 130 patients per arm to detect a genuine 15-point QuickDASH difference. Registered prospectively, reported to CONSORT, with cell dose and viability disclosed to the MIBO standard. Nothing about that is technically difficult; it has simply not been done in the seventeen years since the first pilot. Until it is, cell therapy for tendon disease remains what the independent reviews describe: safe at every tendon site studied so far [18], and — in the words of the 2025 systematic review — a reasonable second-line option for resistant tendinopathy that cannot yet be said to work, because nobody has included a control group [5].

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