

# A Case Report on Umbilical Cord Connective Tissue Allograft Application in Combination with Other Modalities for Defects of the Achilles Tendon

Robert G. Parker, DPM\*  
Naomi Lambert, BS†  
John J. Shou, PharmD†  
Crislyn G. Woods, BS†  
Tyler C. Barrett†

Damaged connective tissues between the bone and tendons or ligaments are common among adults regardless of activity level. Achilles tendinosis is one of the most common tissue defects and enthesopathies. This case report presents the novel application of Wharton's jelly to supplement tissue defects in the Achilles tendon and its insertion. The patient in this study is a 54-year-old female with slow-onset chronic Achilles tendinosis from chronic enthesopathy at the Achilles tendon insertion with a retrocalcaneal exostosis progressively worsening for 3 years, who failed standard-of-care practices for more than 3 years. Her previous care included rest, one successful inferior calcaneal osteotomy, and one minimally successful retrocalcaneal resection of the contralateral foot, both performed by prior surgeons. The patient received extracorporeal pulsed-activated therapy (EPAT) before applying 2 mL of CryoText, a Wharton's jelly tissue allograft. The patient then received class IV laser therapy treatments. The patient started with a 10/10 visual analog scale (VAS) at the initial visit, and by week 13, the patient rated her pain as 0/10 VAS. The improvement in patient-reported pain and functionality reported in this study after the application of Wharton's Jelly, EPAT, and class IV laser therapy warrants future research studying the safety and efficacy of these patient care modalities together as an alternative intervention for patients with Achilles Tendinosis who have failed other standard-of-care treatments. Future research will help identify additional application sites and solidify application and dosage protocols. (J Am Podiatr Med Assoc 115(5), 2025; doi:10.7547/23-225)

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The locations where tendons, ligaments, fasciae, and joint capsules attach to the bone are called entheses. Enthesopathies, pathologies of the entheses, are characterized by inflammation or degenerative changes at the entheses.<sup>1</sup> Enthesopathy of the Achilles tendon is located where the Achilles tendon attaches to the heel bone and can further be diagnosed as Achilles tendinosis when pain approaches a chronic state.<sup>2</sup> There are approximately 2.35 per 1,000 adults between the ages of 21 and 60 years who have Achilles tendinosis.<sup>3</sup> Nearly 6% of the general population will experience Achilles tendinosis in their lifetime.<sup>4</sup> The high

incidence rate of Achilles tendinosis emphasizes the significance of the condition and the need for effective treatment options.

Achilles tendinosis is a combination of localized pain, swelling of the Achilles tendon, and loss of function. While Achilles tendonitis is rampant among athletes, it is not an exclusive pathology to athletes. Approximately 65% of Achilles injuries diagnosed in general practice are not sport related.<sup>5</sup> Factors leading to Achilles tendinosis include mechanical stress, poor blood supply from the calcaneal insertion, diminished collagen density, age, and trauma. Diagnostic measures typically include assessing the history of the symptoms, physical exam focusing on tenderness and decreased range of motion, and imaging modalities including ultrasound and magnetic resonance imaging.<sup>6</sup> This report focuses on addressing the loss and damage of structural tissues associated with Achilles

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\*Parker Foot and Ankle, Houston, TX.

†Regenerative Labs, Pensacola, FL.

*Corresponding author:* Naomi Lambert, BS, Regenerative Labs Research 1700 W Main St, Pensacola, FL 32502. (E-mail: naomi@regenerativelabs.com)

tendinosis with a Wharton's jelly tissue allograft in combination with extracorporeal pulse wave therapy (EPAT) and laser therapy.

Standard care practices for Achilles tendinosis vary from over-the-counter anti-inflammatories or corticosteroid injections with functional rehabilitation therapy to surgical intervention in severe cases. Standard noninvasive treatment options include activity modification, orthotics, heel lifts, massage, hot and cold compresses, strengthening exercises, ultrasound, and nonsteroidal anti-inflammatory medications (NSAIDs) or oral corticosteroids. However, given that there are no prostaglandin inflammatory mediators in Achilles tendonitis, the efficacy of NSAIDs is questionable.<sup>7</sup> Despite several conservative treatment options, one in four patients will require surgery.<sup>8</sup> Between 24% and 45.5% of patients with Achilles tendinosis have failed conservative treatment, leading to the need for surgical intervention. However, poor postoperative results require a greater reoperation risk as the condition progresses. Best practices are still widely debated as the Achilles tendon's pain mechanisms are poorly understood.<sup>9</sup> Without the sensation of pain, promptly identifying Achilles tendinopathy may be difficult for some patients, resulting in further complications.

Symptom improvement with the standard of care typically occurs between 3 and 12 months but not beyond 12 months and incurs the need for research to find an optimal treatment.<sup>10</sup> Recent literature has demonstrated promising alternative interventions, including EPAT, laser therapy, and regenerative tissue allograft supplementation.<sup>11,12</sup> To stimulate neovascularization, EPAT creates microtraumas; laser therapy enhances adenosine triphosphate production, cell function, and protein synthesis; and Wharton's jelly contains growth factors, cytokines, and a collagen matrix that aids in the repair of musculoskeletal injuries.<sup>7,13</sup> This retrospective case study aims to present novel application techniques and preliminary evidence of the efficacy and safety of the combination of EPAT, Wharton's jelly, and laser therapy on a patient who has failed standard-of-care practices for more than 3 years.

## Materials and Methods

All methods complied with the US Food and Drug Administration (FDA) and American Association of Tissue Banks standards. This study was conducted under an Institute of Regenerative and Cellular Medicine IRB-approved protocol (RL-UCT-001), and informed consent was obtained from the study

participant. Wharton's jelly tissue allograft was processed and distributed by Regenerative Labs. Patient recruitment, allograft application, and patient tracking were performed at Parker Foot and Ankle.

Human umbilical cords were obtained from consenting mothers following full-term Cesarean section deliveries. Prior to delivery, birth mothers underwent comprehensive medical, social, and blood testing. An independent certified laboratory tested all of the donations for infectious disease in accordance with Clinical Laboratory Improvement Amendments of 1988, 42 CFR part 493, and FDA regulations. Each birth mother was tested for hepatitis B core antibody (HBcAb), hepatitis B surface antigen (HBsAg), hepatitis C antibody (HCV), human immunodeficiency virus antibody (HIV-1/HIV-2 Plus O), human T-lymphotropic virus antibody (HTLV-I/II), syphilis (RPR), HIV-1/HCV/hepatitis B virus (HBV), nucleic acid amplification test (NAT), and West Nile virus (WNV). Each test was performed with an FDA-approved testing kit (Table 1). All test results were required to be negative or nonreactive before processing the umbilical cord tissue.

Wharton's jelly was aseptically dissociated from the rinsed umbilical cord. After dissociation, 150 mg of Wharton's Jelly was suspended in approximately 2 mL of sterile sodium chloride 0.9% solution (normal saline). Dimethyl sulfoxide was added to the suspension as a cryoprotectant. The volume of dimethyl sulfoxide was calculated as 5% of the total suspension volume. The cryoprotectant functions to preserve the integrity of the fibroblasts, pericytes, immune cells, and growth factors of the allograft while being stored in freezers at  $-40^{\circ}\text{C}$ .<sup>16</sup> The sample was not combined with cells, tissues, or articles other than the exceptions outlined in 21 CFR Part

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**Table 1. Test Kits Used in the Study**

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1. HBcAb: Catalog number: 06P06, Abbott Laboratories, Abbott Park, IL, USA 223
  2. HbsAg: Catalog number: 06P02, Abbott Laboratories, Abbott Park, IL, USA 224
  3. HCV: Catalog number: 06P04, Abbott Laboratories, Abbott Park, IL, USA 225
  4. HIV1, HIV2, plus O: Catalog number: 06P01, Abbott Laboratories, Abbott Park, IL, 226 USA 227
  5. HTLV-I/II: Catalog number: 06P07, Abbott Laboratories, Abbott Park, IL, USA 228
  6. RPR: Catalog number: 900025, Arlington Scientific, Springville, UT, USA 229
  7. HIV1, HCV, HBV, NAT: Catalog number: 303330, 303331, 303719, 303334, 303344 230
  8. WNV: Catalog number: 07001061190, Roche Diagnostics, Indianapolis, IN, USA
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## Case Presentation

The patient in this study is a 54-year-old female with slow-onset chronic Achilles tendinosis, enthesopathy at the insertion, and retrocalcaneal exostosis. She has been suffering from her condition for 3 years, and it was progressively worsening. She has failed several standard care treatment modalities, including rest and two procedures. She presented with a retrocalcaneal exostosis of the right leg, severe pain, and declining surgical intervention (Fig. 1). Previously, the patient underwent two procedures performed by previous surgeons: one successful inferior calcaneal exostectomy and one minimally successful retrocalcaneal resection of the contralateral foot (Fig. 2). Her work requires her to be on her feet 75% of the time, further aggravating the disorder and causing sharp burning pain. Exacerbating factors include walking and standing. To avoid surgery and loss of productive time at work, she sought alternative options. She was offered conservative Wharton's Jelly structural connective tissue to supplement the structural defects in conjunction with EPAT and class IV laser therapy to promote her body's own repair processes. This study aims to report pain alleviation secondary to supplementing damaged tendon tissue with Wharton's jelly and priming the local tendon with EPAT and lasers.

## Patient Care Procedures

The procedure included the application of an umbilical cord tissue matrix, also known as Wharton's Jelly, EPAT, and class IV laser therapy. The patient was placed in the prone position without a

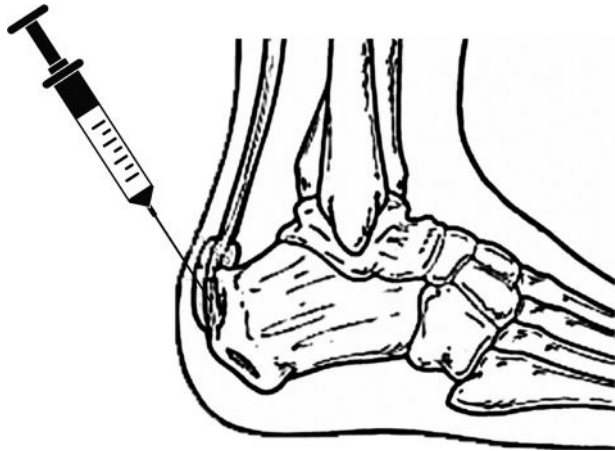


**Figure 1.** Lateral radiograph taken March 21, 2023, showing the retrocalcaneal exostosis.



**Figure 2.** Anteroposterior radiograph taken March 21, 2023, showing the remains of the retrocalcaneal exostosis after surgery.

tourniquet. It is essential to place the local anesthetic of choice more proximal away from the area to be treated. Lidocaine, 1% plain, was used to block the retrocalcaneal nerves, including the posterior tibial and sural nerves. The lower extremity was prepped and draped in the standard sterile technique. Prior to the application of the tissue allografts, the patient received EPAT at 11 Hz, 1.4 bars, for 3521 pulses to the affected tissue. While the above EPAT was performed, 2 mL of cryotext, a minimally manipulated tissue allograft, was thawed slowly per laboratory guidelines in a 35°C bath. Under real-time ultrasound guidance using Esoate My Labs (Esoate, Genoa, Italy) 15.0 MHz with a 4-cm transducer head (Figs. 3-5), the Wharton's jelly allograft was transplanted along the insertion (entheses) in the frontal plane in a fanning-like technique as well as fanning in the sagittal plane. This application was accomplished just proximal within the intratendinous area beneath the paratenon around the tendon proper by strategic supplementation, as well as between the paratenon and circumferentially around the tendon proper. Further "needling" with a 22-gauge needle was performed to encourage neovascularization. The patient was



**Figure 3.** Diagram of Wharton's jelly application at the tendon insertion.

instructed not to take NSAIDs or steroids and to refrain from high-impact activities. The patient was given acetaminophen to take as needed. The patient was scheduled for biweekly class IV laser treatments for the next 3 weeks to provide photobiomodulation. A pneumatic boot was fitted for 2 weeks.

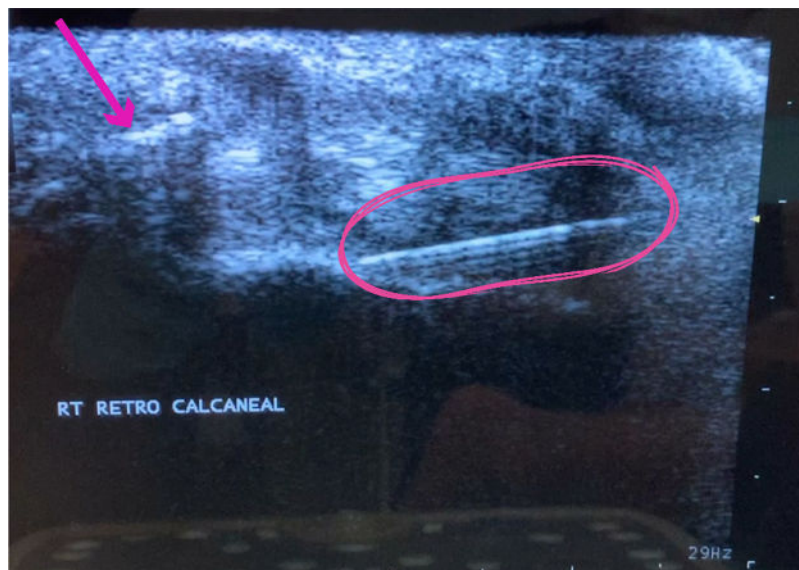
## Results

The patient began treatment on March 21, 2023, reporting a VAS pain involvement of 10/10. Upon follow-up examination on week 5 (April 25, 2023), the patient reported an 80% improvement in functionality with VAS pain involvement of 2/10, noting

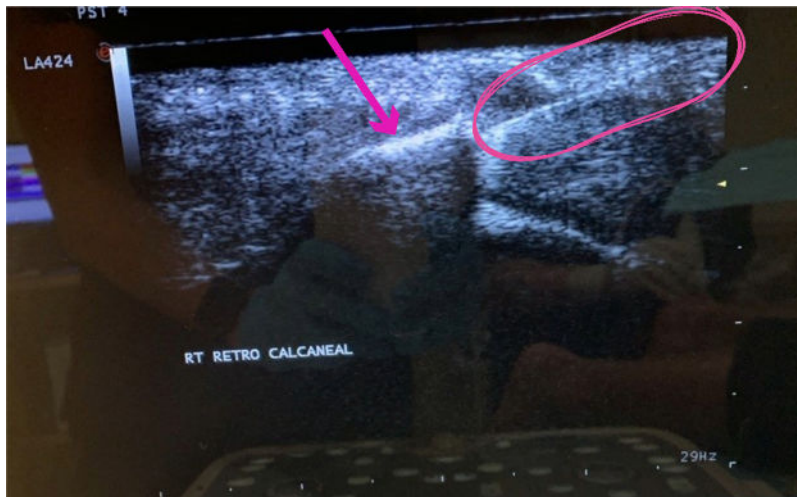
most residual pain presented in the mornings. At the final exam on week 13 (June 20, 2023), the patient reported VAS pain involvement of 0/10, with her only complaint being that the 2 weeks of wearing the pneumatic boot caused acute hip pain. The use of an equivalent height heel or "level up" device was advised on the contralateral foot to relieve the stress on her hip. The patient will be tracked for any recurrence of pain over the next 6 months.

## Discussion

These preliminary observations on using umbilical cord structural tissue allografts as a tissue supplementation in combination with EPAT and class IV laser therapy show promising improvement in patient-reported pain and functionality. By sending acoustic waves through the tissue to promote the regenerative growth factors secreted by the body, EPAT prepares the tissue for allograft incorporation. The Wharton's jelly allograft, applied in a fanning technique to agitate the surrounding tissue and distribute the allograft evenly, supplements the damaged tissues of the tendon. In addition, the contact the needle makes in the tissue stimulates new blood vessels in the tissue, allowing for accelerated blood flow to deliver nutrients and oxygen to catalyze the process of tissue regrowth. The follow-up with laser therapy has been shown to increase microcirculation, adenosine triphosphate production, and lower inflammatory markers. With each modality providing independent



**Figure 4.** Ultrasound showing the retrocalcaneal exostosis (arrow), and the needle dispensing Wharton's jelly into the peritendon (circle).



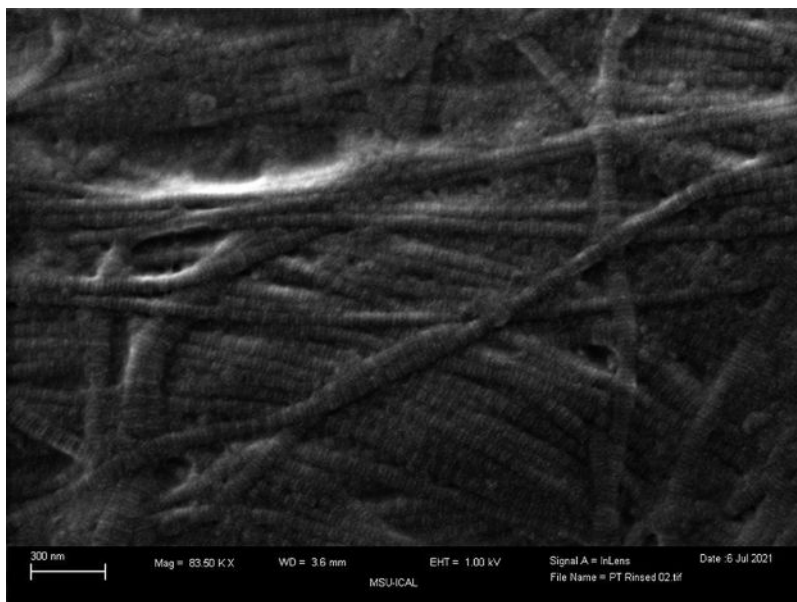
**Figure 5.** The arrow points to the retrocalcaneal exostosis, and the needle dispensing Wharton’s jelly into the tendon insertion is circled.

improvement, combining the three modalities has excellent potential for success.

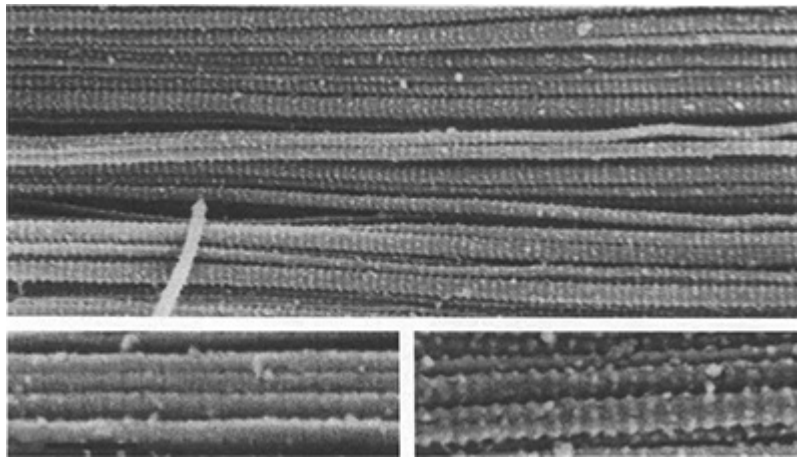
Figures 6 and 7 compare a scanning electron microscope (SEM) image of the preserved cross-linked collagen structure in a Wharton’s jelly tissue product to an SEM image of an Achilles tendon specimen from individuals aged 77 to 80 years.<sup>14</sup> The images show the structural similarity of the collagen matrix in Wharton’s jelly compared to the Achilles tendon. With such structural similarity, the homologous implementation of Wharton’s jelly provides significant results in supplementing degenerated tissue associated with

Achilles tendinosis and supports the regeneration process. With these images, Wharton’s jelly showcases the ability to function as an architectural scaffold for extracellular matrix supplementation in the Achilles tendon. Comparing SEM images of various tissue types to Wharton’s jelly helps confirm consistent structural characteristics. These structural similarities between Wharton’s jelly and different tissue types support its homologous use in various anatomical locations.

The outcomes for this patient, 100% pain reduction after 90 days, align with and exceed the positive results presented in other literature regarding



**Figure 6.** Scanning electron microscope (SEM) image of preserved cross-linked collagen structures of Wharton’s jelly tissue product. (Scale bar: 300 nm)



**Figure 7.** Achilles tendon specimens from 77- to 80-year-old individuals were incubated with monoclonal antibody (mAb-IH) and examined by SEM (top and bottom right); Unincubated control tendon (bottom left) is not decorated with IgM when examined. (Scale bar 250 nm)

each separate element used in the care procedure as stand-alone applications. After using Wharton's Jelly alone, positive results have been found for applications in the sacroiliac joint and osteoarthritis. A Wharton's jelly product was applied to the structural defect in these studies and produced statistically significant improvements. The sacroiliac joint study reported an 84% reduction in Numeric Pain Rating Scale scores and a 76% reduction in Western Ontario and McMaster University Arthritis Index scores from the initial application to the 90-day follow-up.<sup>15</sup> In comparison, the degenerated knee study reported statistically significant patient-reported outcome improvements with an overall 20.52% improvement in pain, joint stiffness, and physical function.<sup>16</sup> Throughout current literature, Wharton's jelly has been proven effective in supplementing structural defects in multiple anatomical locations.

Laser therapy is another minimally invasive and affordable option for patients with persistent pain who want an alternative to surgery. High-intensity laser therapy of class IV laser diodes delivering at least 500 mW of power has shown promising results. High-intensity laser therapy functions to decrease erythrocyte deformability and platelet aggregation, resulting in membrane revitalization, viscosity reduction, and erythrocyte stress adaptation.<sup>17</sup> After using infrared thermography, skin thermal changes were recorded to increase significantly by 9.45°C.<sup>17</sup> The increase in more effective blood flow allows for the body's natural healing factors to be delivered to the defective area at a quicker rate.

Additionally, EPAT has been tested as an independent treatment option for patients suffering from

Achilles tendinosis. A study by Saxena<sup>11</sup> found that 78.38% of tendons showed clinically significant improvement by at least 1-year posttreatment. Given that no adverse reactions were recorded, EPAT exists as a safe, viable, and practical option for the treatment of Achilles tendinosis. This study has shown that by combining Wharton's jelly allografts, EPAT, and class IV laser therapy, these treatments work in conjunction to significantly relieve chronic pain from structural defects of the Achilles tendon. The patient in this study showed 100% improvement in just 3 months after receiving a unique combination of Wharton's jelly, class IV laser therapy, and EPAT. Future research with a larger cohort will further evaluate the efficacy and safety of Wharton's jelly alongside EPAT and class IV laser therapies and assist in defining dosage protocols.

## Conclusions

In conclusion, the application of Wharton's Jelly in combination with EPAT and class IV laser therapy showed improvement in pain and functionality in a patient who suffered from structural defects of the tissue, leading to chronic Achilles tendinosis. After failing 3 years of conservative treatment, she achieved total relief in just 13 weeks. The unique Wharton's jelly application technique, including EPAT and laser therapy, showcases the functionality of Wharton's jelly and highlights an alternative treatment option for Achilles tendinosis. Additional randomized controlled trials are necessary to warrant Wharton's jelly allograft, EPAT, and laser therapy application to degenerative tissue associated with Achilles tendinosis as a standardized treatment and an alternative option to

surgery. Continued research involving larger sample sizes will further evaluate the efficacy and safety of the combination of Wharton's jelly, EPAT, and class IV laser therapies in assisting and defining dosage protocols.

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**Acknowledgments:** The authors would like to thank Desiree Hornung, administrator, and the staff Stacy, Laura, and Greta at Parker Foot and Ankle for their contribution to data collection and filing.

**Financial Disclosure:** None reported.

**Conflict of Interest:** Regenerative Labs has a research department responsible for running an observational IRB-approved study. Naomi Lambert and Crislyn Woods are employees of this company in the research department. There is no other funding or support associated with this publication.

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