

ANALYSES OF BIOPSIED TISSUES IN AUTOLOGOUS TENOCYTE THERAPY FOR TREATMENT OF TENDINOPATHY

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BACKGROUND

Chronic degenerative tendon injury is a significant unmet clinical need with considerable socio-economic consequences. First-line treatment is conservative and includes rest, physiotherapy, corticosteroid injection, and bracing.^[1-3] Patients who do not recover after 6-months of conservative treatment often require surgical intervention.^[4-6] In the context of an aging population, there is demand for new treatments that are safe, minimally invasive (non-surgical), effective and cost efficient.

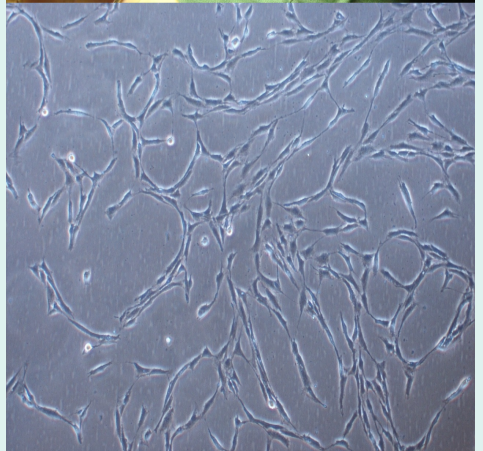
Autologous tendon cell injection (ATI) is a promising novel non-surgical treatment for tendinopathies. ATI

- Prevents progression to surgery by restoring tendon structure and function
- Replenishes degenerative tissue with patients' own healthy tendon cells
- Clinical studies^[7-11] demonstrate significant improvements in pain, strength and functional outcome measures.
- **Podium presentation (Sunday 18 June 14:15)** RCT study using ATI for treatment of rotator cuff tendinopathy.

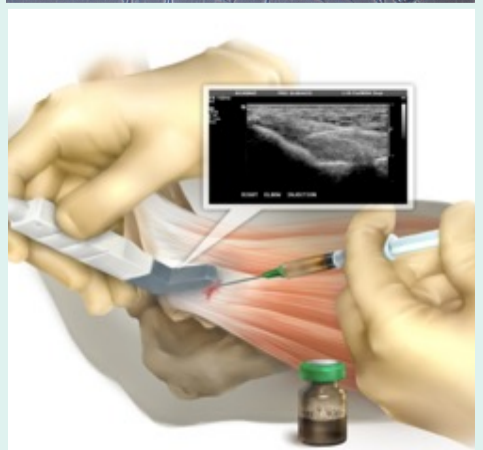
ATI – Two-stage, Minimally Invasive Outpatient Procedure⁷



1. Tendon biopsy
Healthy tendon tissue biopsy via minimally invasive procedure.



2. Tendon cell cultivation
Healthy tendon cells extracted and expanded in GMP facility.



3. Tendon cell injection
Ultrasound guided injection of healthy tendon cells to tendon injury.

Good Manufacturing Practice (GMP)

4-5 week end-to-end process

OBJECTIVES

The objectives of this study were to compare the differences between tendons cells isolated from patella (PT) and palmaris longus (PL) tendons:

- Tendon cell morphology
- Tendon cell growth characteristics
- Purity, Potency, and Identity (PPI) quality attributes of tendon cells
- Age effect on tendon cell growth characteristics and quality attributes.

Purity ensures the product doesn't contain impurities which may lead to adverse reactions and does not contain undesirable cell type(s).

Potency ensure the project performs the function for which it is intended.

Identity ensures that the product contains cells of the desired phenotype i.e. tendon-derived cells

PATIENT COHORT

The cohort (N=149) included patients who underwent biopsy of PT or PL, and underwent ATI between 2020 and 2022.

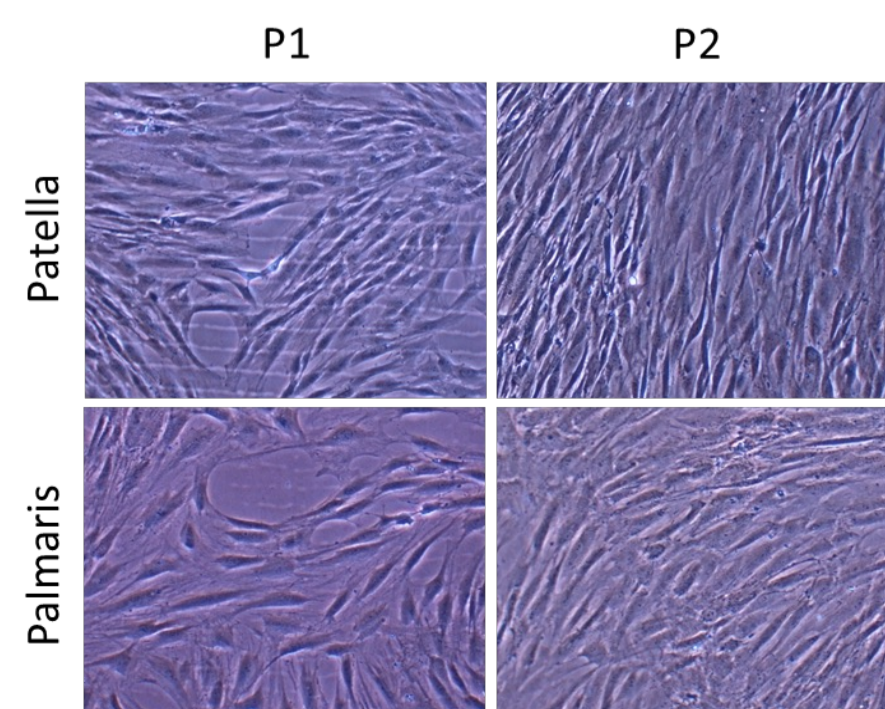
	PT (N=63)	PL (N=86)	P-value
*Gender			
Female	28 (44.4%)	28 (32.6%)	P=0.139
§Age (years)			
Mean±SD	48.89±11.13	47.12±8.39	P=0.085
Median (IQR)	50.0 (11)	47.5 (13)	
Range	22-75	31-64	

*Independent samples proportion test
§Two-sided Student's T-test (parametric) or Mann-Whitney U (non-parametric)

RESULTS

Morphology

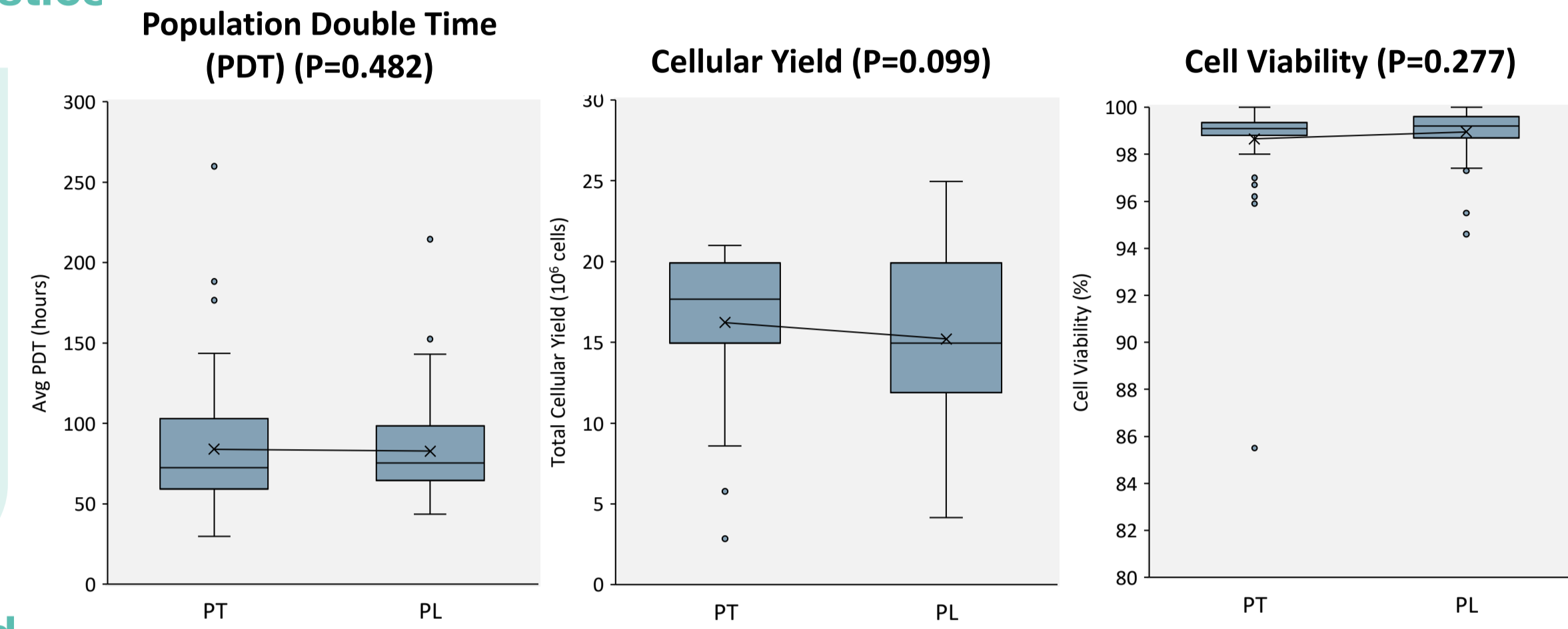
No observable difference in morphology in tendon cells from PT and PL. Both exhibited same spindle-shaped morphology.



RESULTS

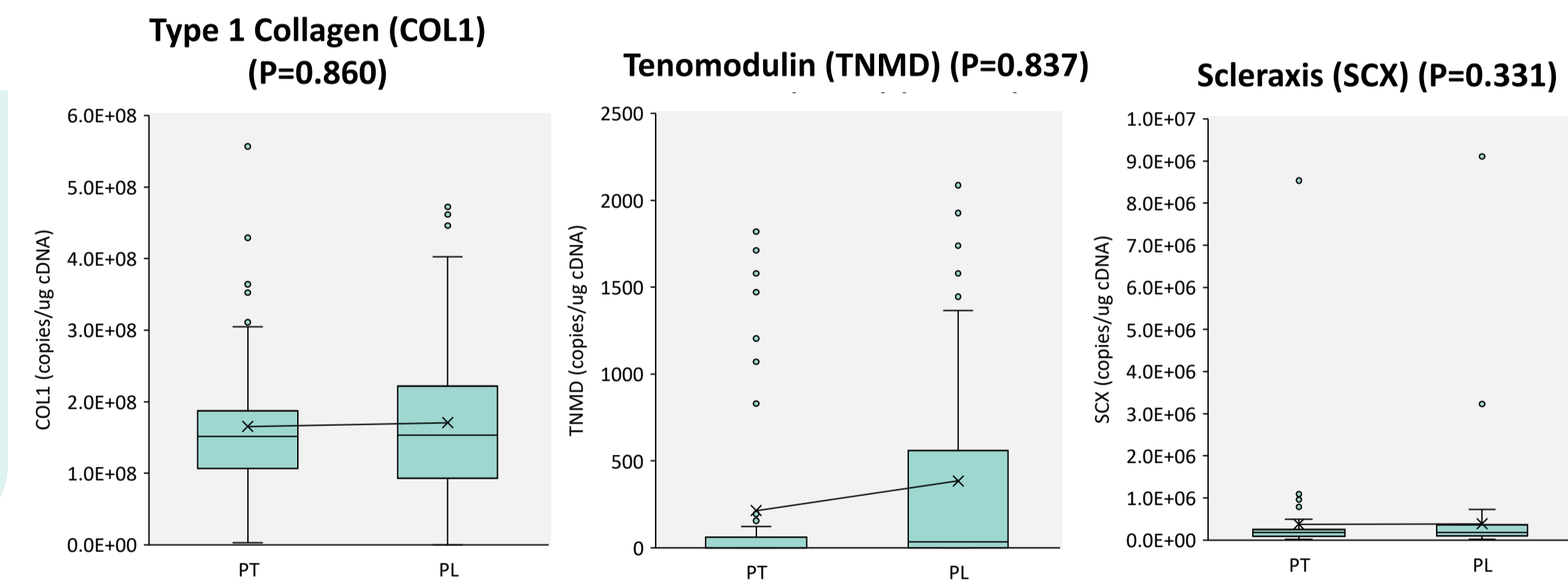
Growth Characteristics

No statistical difference in growth characteristics between tendon cells derived from PT and PL.



Purity, Potency and Identity of cells

No statistical difference in PPI quality attributes between tendon cells derived from PT and PL.



Impact of age

An age stratification analysis was completed: <35 (N=12), 35-45 (N=41), 45-60 (N=57), >60-years-old (N=39). There was no statistically significant effect between age groups for growth characteristics and PPI quality attributes of tendon cells isolated from PT and PL.

Statistical Analysis			
Growth parameters	P-value	Quality parameters	P-value
ψAverage PDT	0.879	ψCOL1	0.125
ψTotal Cell Yield	0.814	ψSCX	0.505
ψCell Viability	0.388	ψTNMD	0.419
ψOne-way ANOVA		ψOne-way ANOVA	

CONCLUSION

- The PT or PL tendons are both suitable sources for the isolation of tendon cells for ATI.
- Tendon cells isolated from PT and PL were comparable in growth characteristics and PPI quality attributes.
- Age did not effect the growth characteristics and PPI quality attributes of tendon cells isolated from PT and PL.

REFERENCE LIST:

<https://docs.google.com/document/d/1tjGp5qeK1kSIIsgvhiERpkWArm0DwsoCoORBy3GIKyM/edit?usp=sharing>