

PTT-6™, a novel topical hair serum with stem cell growth factors significantly increases hair growth in patients with hair loss- a 12-week prospective, open-label Case series

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Background

Hair loss is a common problem affecting millions of people worldwide that causes significant psychological distress.^{1,2} The advent of stem cell-derived topical cosmetics means new treatments have become available. In this case series, a topical hair serum containing PTT-6™ from CellResearch Consumer Health is used. Derived from mesenchymal stem cells of the umbilical cord lining, which is the richest source of stem cells in the body, PTT-6™ signals cells to regenerate, increase cell turnover and stimulate the natural production of collagen, elastin and hyaluronic acid. Furthermore, PTT-6™ causes prolongation of the anagen phase, thus, restoration of a normal hair follicle cycle, stimulation of hair follicle development and suppression of apoptotic cues. A topical product like this might help patients to reduce hair loss and improve hair quality with an easily accessible over-the-counter product, without the need to see a dermatologist or face the cost of hair transplantation.

Material and Methods

Hair serum

PTT-6™ is a topical hair serum, which contains over 3,000 proteins, including growth factors and cytokines derived from ethically harvested red deer umbilical cord lining stem cells. Important growth factors within PTT-6™ are Hepatocyte Growth Factor (HGF), Basic-Fibroblast Growth Factors (b-FGF), Vascular Endothelial Growth Factor (VEGF), Transforming Growth Factor-β (TGF-β), IGF-1 and Platelet-derived Growth Factor (PDGF) – among many others.

Participants

Study participants (female n=5, male n=5) with mean age of 34.1±14.2 years were recruited and enrolled in one site located in Vienna, Austria (Yuvell®). Patients with manifestation and subjective sensation of hair thinning/hair loss were primarily recruited over social media and study recruitment platforms (Probando®).

An on-site screening was performed to identify eligible subjects according to Ex- and Inclusion criteria, presented in **Table 1**, the latter including the Hamilton-Norwood Scale and the Ludwig scale for male and female hair loss patients, respectively.³ All subjects consented to the use of their demographic as well as study-outcome data for scientific and marketing purposes.

Treatment protocol

Each of the 10 patients disinfected their scalp with 0.5% Chlorhexidine prior to application. The treatment areas were subjectively chosen according to patient's area of interest and varied slightly from patient to patient. 2.5ml of PTT-6™ was applied onto the treatment area. Afterwards, the respective zone was treated with micro-needling using a 0.5 mm needle length derma stamp, including 3 passes in alternating directions and an additional 2.5ml PTT-6™ was applied and gently rubbed into the scalp. The investigator advised the patients not to wash their hair following the treatment for at least 24 hours and optimally 48 hours.

This treatment cycle was repeated weekly for 12 weeks in total. The patients continued with this weekly treatment at home, they were given a derma stamp and product for each week and returned to the clinic at weeks 4, 6, 7, 10 and 12 for on-site assessments. The assessments included subject reported outcomes such as psychological questionnaires, as well as objective measurement of hair growth using the HairMetrix® software by Canfield Scientific.

Measurements

Phototrichograms for the assessment of hair changes during the treatment period were documented for all patients by 2 trained evaluators by means of the HairMetrix® D200-evo System, using the HairMetrix® software by Canfield Scientific Inc (4 Wood Hollow Road, Parsippany, NJ 07054, USA). Canfield's non-invasive hair consultation tool provides results immediately during the consultation without cutting the hair. HairMetrix® ensures objective data, and the photographs can be taken by study personnel, no extra laboratory assessment is needed. (Canfield, 2020)

Standardized questionnaires

For the assessment of the patients' quality of life and subjective treatment experience standardized questionnaires have been used (lit), presented in **Supplement 1 and 2**.

Results

10 patients, mean age of 34.1 ± 14.2 y, 50% female, as presented in **table 2**, applied the PTT-6™ according to a treatment protocol, as described in the method section. After 12 weeks of treatment, a significant amplification of the follicular units per square centimeter (sqcm) ($P < .05$) with an associated decreased intra-follicular distance ($P < .05$) was detected, as illustrated in **Figure 1a** and **b**. Likewise, the total hair count per sqcm increased ($P < .05$) and thus, the sum of hair width per sqcm ($P < .05$), as shown in **table 3** and **Figure 1c** and **d**. Notably, there was neither change in the number of hairs per FU nor in the average hair width. No adverse effects were reported. Subjectively, the standardized questionnaires demonstrated a significant improvement of hair growth, less need to hide hair and an increased quality of life associated with hair loss, as presented in **table 4** and **Figure 2a-c**. 9 out of 10 patients said they would recommend the product.

Discussion

Hair loss is a common condition affecting many patients causing significant distress. Finasteride might be used in men, yet, side effects include loss of libido, reduced sperm count and motility. Postmenopausal women may also be treated, but long-term side effects cannot be excluded. Topical hair treatment with Minoxidil is efficient, but sometimes leads to irritation, must be applied daily and its action is lost immediately with cease of the treatment. Also, it must be prescribed by a doctor, which is associated with additional efforts and costs. Hair transplantation is an expensive and very burdensome surgical intervention, which many patients cannot afford, nor are willing to undergo. With the advent of topical cosmetics consisting of stem cell factors, new treatments are available. Our results clearly demonstrate a significant improvement of hair growth with this novel hair serum containing PTT-6™, which was further stressed by the fact, that on average, 9 out of 10 patients would recommend the product.

References

1. Aukerman, E.L. & Jafferany, M. The psychological consequences of androgenetic alopecia: A systematic review. *J Cosmet Dermatol* (2022).
2. Huang, C.H., Fu, Y. & Chi, C.C. Health-Related Quality of Life, Depression, and Self-esteem in Patients With Androgenetic Alopecia: A Systematic Review and Meta-analysis. *JAMA Dermatol* **157**, 963-970 (2021).
3. Gupta, M. & Mysore, V. Classifications of Patterned Hair Loss: A Review. *J Cutan Aesthet Surg* **9**, 3-12 (2016).

Tables

Table 1. Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none">• Male or female subjects (ratio 1:1)• Manifestation of hair thinning/hair loss. Individual sensation of having less hair, suffering from hair loss and thinning hair• Age 18-60 years inclusive	<ul style="list-style-type: none">• Patients, who do not return for follow-up review as scheduled.• Patients, who display any adverse reaction to the CALECIM® product.• Known Thyroid dysfunction• Known deficiencies of vitamins and iron• Smokers• Pregnancy and breastfeeding women

Table 2. Basic demographics of patients with hairloss (n=10) applying PTT-6 for 12 weeks on their capillitium according to the treatment protocol, as presented in the method section.

Patient	Sex	Age (years)	Norwood-Hamilton/Ludwig classification stage for hair loss
1	w	23	0-1
2	w	31	1-2
3	m	24	1
4	w	57	1
5	w	19	1
6	m	52	5
7	w	51	1
8	m	23	6
9	m	25	3-4
10	m	35	6

Table 3. Objective Assessment (Hairmetrix ®) of Capllitium. Main outcome parameters (Mean values with standard deviations). P values for linear regression model.

Week	wk 1		wk4		wk6		wk7		wk10		wk12		p value
Values	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD	
Intrafollicular distance (mm)	1,29	0,37	1,29	0,21	1,26	0,29	1,24	0,26	1,15	0,14	1,14	0,16	<0.05
T.V Ratio	2485	27,24	2006	23,58	2185	23,88	1509	24,77	23,27	33,10	25,64	31,54	n.s.
Follicular Units (FU) per sqcm	9288	38,39	8581	25,85	8876	43,85	9188	35,44	103,12	28,45	106,88	31,28	<0.05
Average hairs per FU	1,23	0,11	1,24	0,13	1,22	0,10	1,24	0,14	1,25	0,10	1,22	0,10	n.s.
Average hair width (microm)	54,35	8,11	54,16	6,75	56,23	8,48	54,19	8,58	55,20	8,02	55,36	7,49	n.s.
Terminal hair count per sqcm	107,38	49,87	94,76	39,07	100,94	52,55	102,18	45,12	116,85	40,84	121,09	44,55	<0.05
Total hair count per sqcm TOTAL	115,00	49,17	104,50	38,69	109,62	52,98	114,68	46,38	129,35	36,42	131,82	40,85	<0.05
Sum of terminal hair width (microm) per sqcm	6211,32	3127,65	5490,12	2441,03	5945,38	3310,71	5888,65	2817,05	6900,44	2842,75	7176,06	2992,96	<0.05
Sum of total hair width (microm) per sqcm	6402,03	3082,74	5732,71	2397,07	6156,88	3277,53	6199,65	2800,32	7202,50	2499,78	7433,09	2878,35	<0.05

Table 4. Patients' Subjective Assessment by standardized questionnaires. Main outcome parameters (Mean values with standard deviations). P-values for linear regression model.

Week (wk) number	wk 1		wk4		wk6		wk7		wk10		wk12		p-value
Values	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD	
Satisfaction with hair growth	1,4	0,7	1,7	0,82	2,6	0,52	2,5	0,71	2,4	0,7	2,4	0,84	<.001
Satisfaction with hair density	1,2	0,63	1,5	0,71	2,1	0,57	2,1	0,57	2,2	0,42	2,3	0,67	<.001
Satisfaction with hair thickness	1,8	0,79	1,9	0,74	2,6	0,52	2,3	0,48	2,3	0,48	2,3	0,67	<.05
Satisfaction with hair quality	2,6	0,97	2,5	0,85	2,7	0,82	2,7	0,67	2,6	0,84	2,8	0,79	n.s.
Satisfaction with result	-	-	2,22	0,97	3,1	0,32	3	0,67	2,8	0,63	2,9	0,57	n.s.
Comfortable with hair	1,8	0,79	1,8	0,79	2,7	0,67	2,2	0,63	2,3	0,48	2,7	0,67	<.005
Confidence	2,5	0,53	2,5	0,53	2,9	0,57	2,7	0,48	2,7	0,48	2,9	0,32	n.s.
Friends/Family admiring hair quality	2,5	0,97	2,2	1,03	2,4	0,97	2,4	1,17	2,2	1,03	2,1	0,88	n.s.
Thinking of how hair looks like	3,1	0,74	2,9	0,74	2,9	0,57	2,8	0,63	2,9	0,74	2,9	0,74	n.s.
Hiding hair	3,2	1,03	2,2	1,14	2,4	1,07	2,1	0,99	1,9	0,99	1,9	0,99	<.01
Rearrange hair	3,2	1,03	2,6	0,97	2,5	1,18	2,3	1,06	2,1	1,1	2,5	1,08	n.s.
Affection quality of life	3,2	1,03	2,1	0,99	1,9	0,88	2,1	0,99	1,9	0,74	1,8	0,79	<.005

Graphs

Figure 1a-d. Objective assessment (Hairmetrix ®) of 10 patients who suffer from hair loss applying PTT-6 on their capillitium.

Figure 1.a

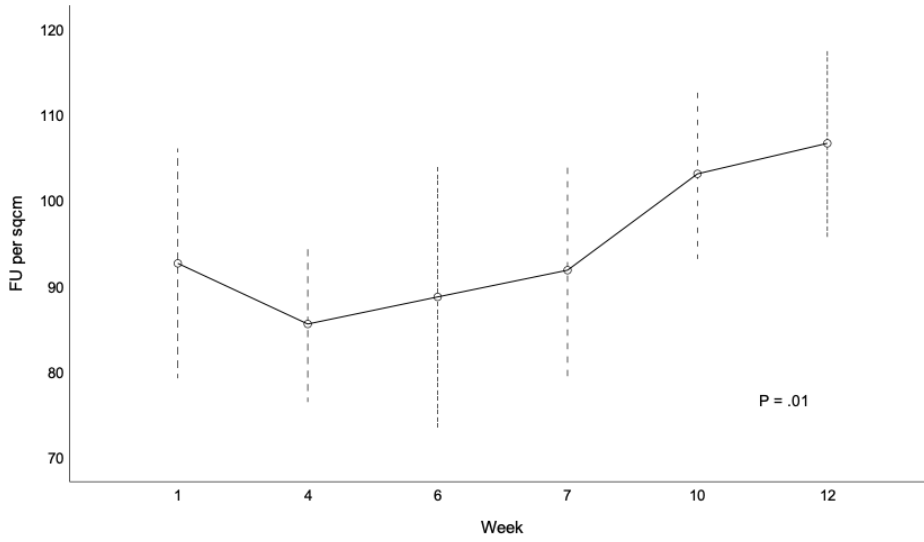


Figure 1.b

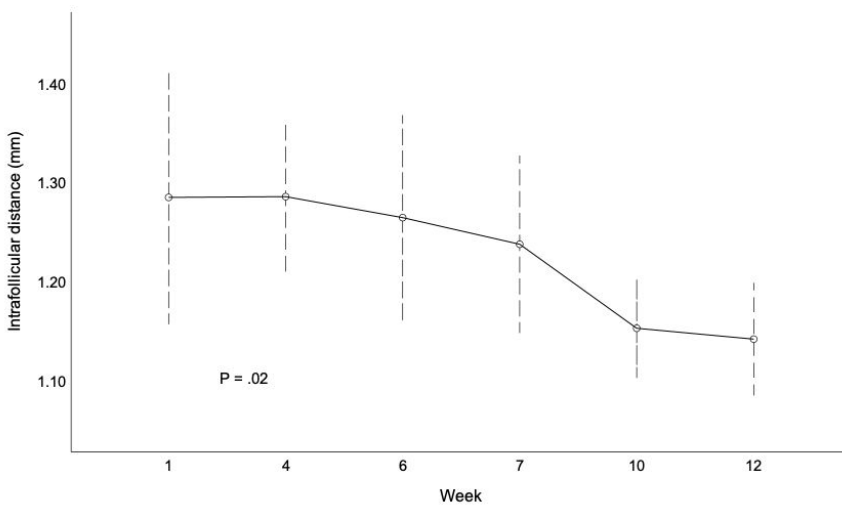


Figure 1.c

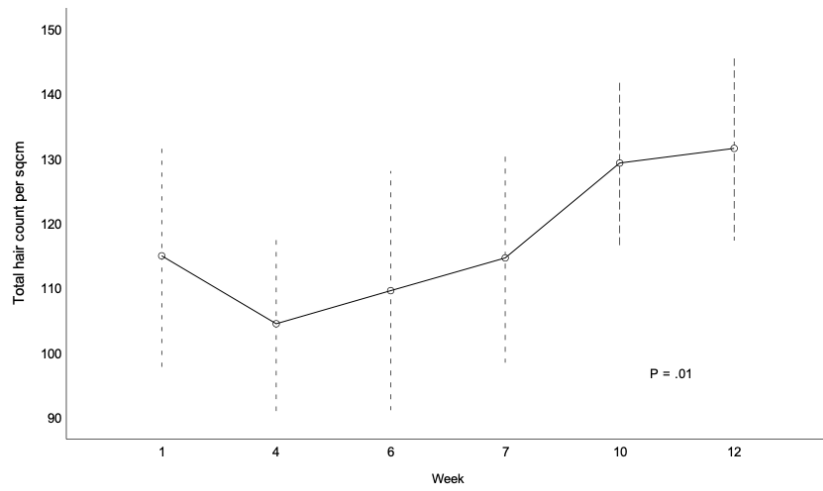


Figure 1.d

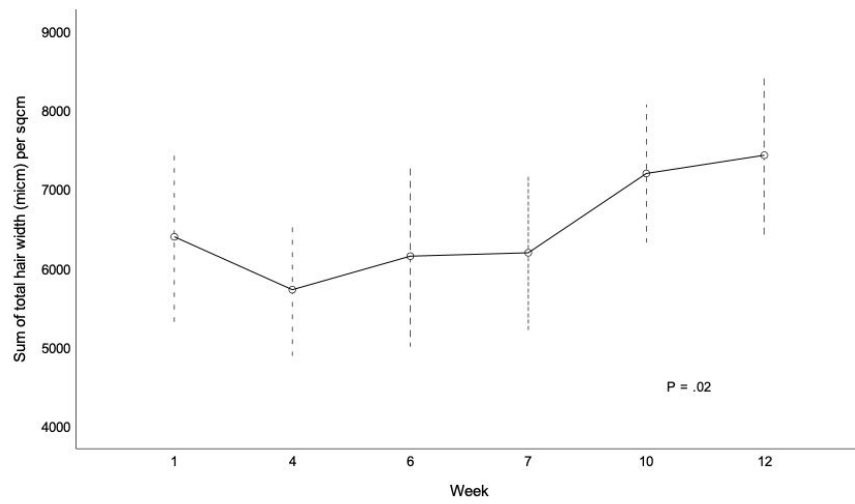


Figure 2 a-c. Patients' subjective assessment by standardized questionnaires.

Figure 2a. Patients satisfaction with hairgrowth

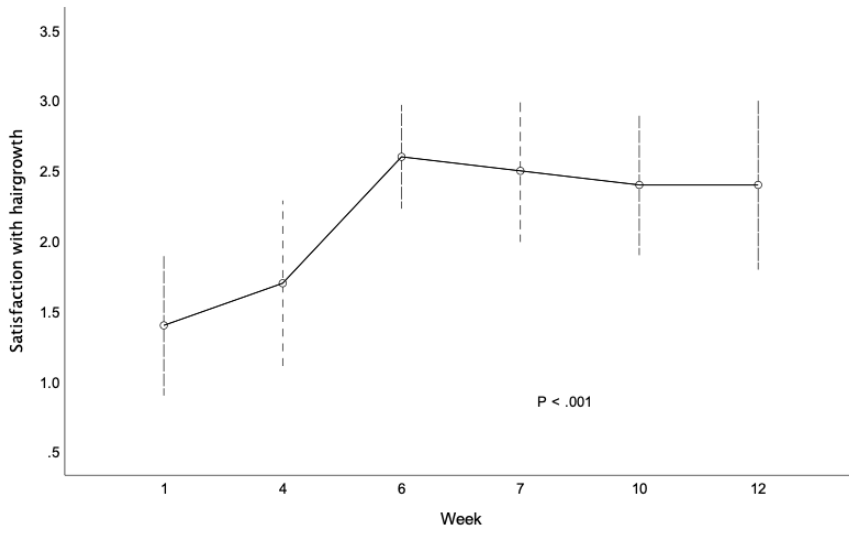


Figure 2b. Patients' likelihood of hiding hair

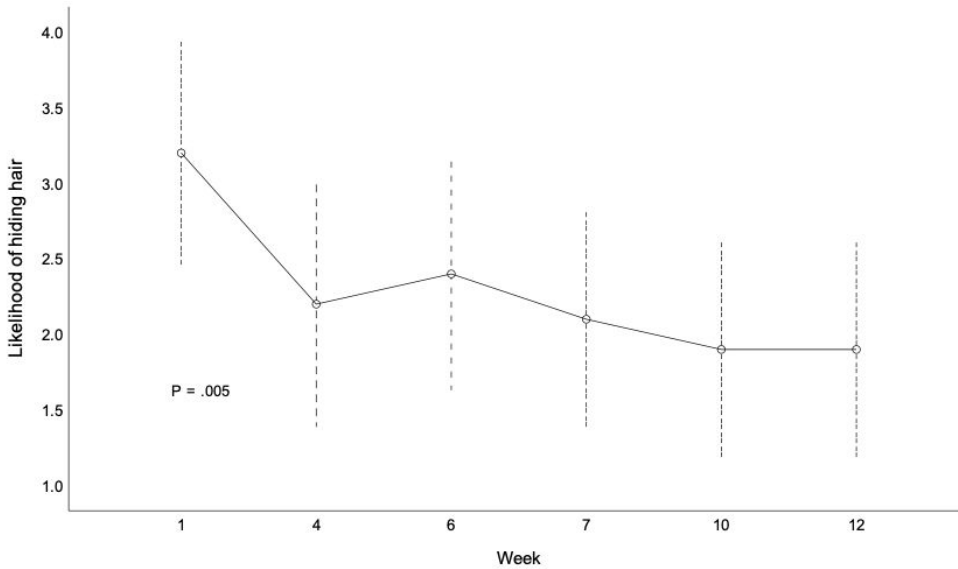
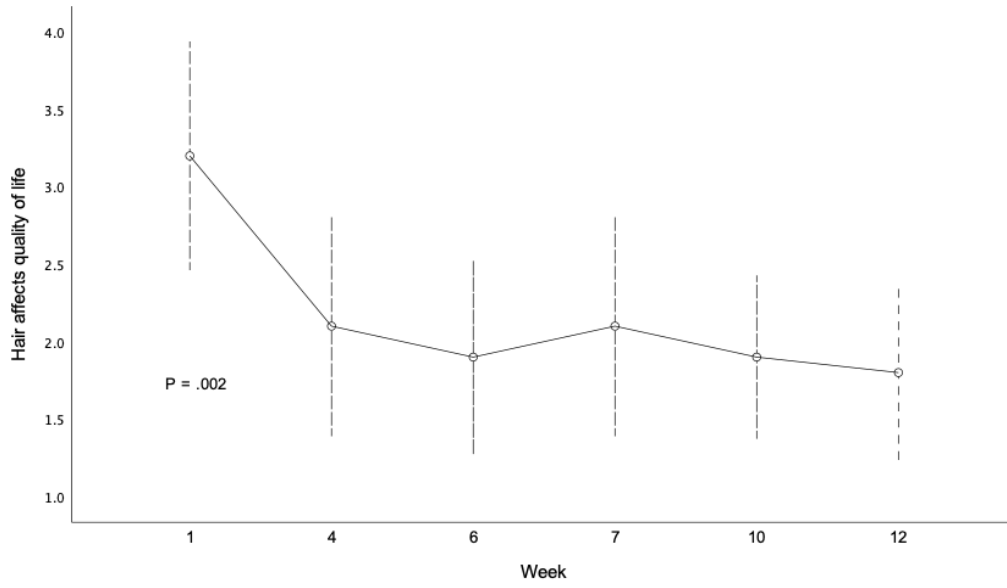


Figure 2c. Patients' quality of life affected by their hair loss



Supplement

Supplement 1. Standardized questionnaires for the assessment of patients' quality of life during the treatment period.

Visit Nr. _____

Date: _____

For each statement, circle one answer. Please assess today's situation.

Hair

	Strongly disagree	Disagree	Agree	Strongly agree
1. I am satisfied with my hair growth	1	2	3	4
2. I am satisfied with my hair density	1	2	3	4
3. I am satisfied with my hair thickness	1	2	3	4
4. I am satisfied with my overall hair quality	1	2	3	4
5. I am satisfied with the result	1	2	3	4

Psychological

	Strongly disagree	Disagree	Agree	Strongly agree
1. I feel comfortable with my hair	1	2	3	4
2. I feel confident	1	2	3	4
3. Family and friends address my hair quality often	1	2	3	4
4. I think about how my hair looks like often	1	2	3	4
5. I think about hiding my hair often	1	2	3	4
6. I try to re-arrange my hair often to make it look thicker	1	2	3	4
7. The state of my hair affects my quality of life	1	2	3	4

Please return the questionnaire to the person who gave it to you.
Thank you.

(Date and signature of patient)

Supplement 2. Standardized questionnaire for the assessment of patients' experience with the product.

Visit Nr. _____

Date: _____

For each statement, circle one answer. Please assess today's situation.

Product

	Strongly disagree	Disagree	Agree	Strongly agree
1. The application of the product is easy	1	2	3	4
2. The application of the product is painless	1	2	3	4
3. The product absorbs easily and quickly	1	2	3	4
4. I would recommend the product	1	2	3	4
5. I would rebuy/reuse the product again	1	2	3	4
6. I am willing to use this product as part of a maintenance regimen and as a treatment	1	2	3	4

7. Have you ever tried other products against hair loss (e.g. Minoxidil or Finasteride) before?

no yes

If yes, which products? _____

8. If you have ever tried other products, please rate them and compare them to Calecim Advanced Hair System according to Austrian school grades (1= very well – 5= insufficient)

Product: Calecim Advanced Hair System Grade: _____

Product: _____ Grade: _____

Product: _____ Grade: _____

Product: _____ Grade: _____

Other comments: _____

Please return the questionnaire to the person who gave it to you.

Thank you.

(Date and signature of patient)

