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Regenera activa AMT to treat androgenetic alopecia

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Abstract

To determine the effect of using Regenera ActivaAMT to treat Androgenetic Alopecia. Interventional study. Single centre study in Basrah/Iraq. Twenty-three patients whose age ranged between 20-65years, 7males and 16 females. Patient satisfaction rate, hair classification score, trichoscopy, lesion measurements, hair fall, and hair length after treatment. Among the 23 patients treated, 14 (60.9%) were satisfied with the treatment results. All other indicators used showed statistically significant differences for the favor of the use of Regenera ActivaAMT to treat Androgenetic Alopecia. The percentage of normal hair classification score increased from 4.3% before to 35% after treatment (p=0.042). The percentage of higher trichoscopy scores (7 and 8) increased from 0.0% and 5% to 43.5% and 21.7 respectively (p=0.001). The percentage of normal hair fall significantly increased from 8.7% to 80% (p=0.0001). Regarding women hair length, the difference was statistically significant for the favor of treatment (p=0.002). Regenera ActivaAMT is an effective procedure to treat Androgenetic Alopecia in both males and females at any age and in their early stages of baldness. Moreover, it is simple, painless and cannot take more than 1 hour without any restrictions post the procedure. Therefore, it can replace the hair transplant in the future.

Keywords: Androgenetic alopecia, Autologous micrografting technology (AMT), Hair loss treatment, Hair regeneration therapy. Regenera activa.

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1. Introduction

Androgenetic Alopecia (AGA) is the progressive loss of terminal hair in the scalp. It is a common disease affecting more than 50% of men and women over fifties. Kinky or whisker hair can be the first sign of AGA. The most common sites to have AGA are temple "the professor angle", mid side of anterior hair lines, mid frontal and vertex [1]. AGA has multifactorial causes such as genetic inheritance, familial tendency, hormonal, and muscular causes. It had limited

treatment options in the past and it has psychological impacts on the affected persons. AGA can happen at any age but it usually affects 50% of males and females above 50 years old, 13% in menopausal women [2] and 55.6% in patient with hirsutism in Iraq [3].

The multiple factors lead to shortening of the anagenic phase and prolong telogenic and catagenic phase with miniaturizing of the hair follicle and inflammation [1].

Genetically, fine mapping showed defects in androgen receptor genes, which is most probably caused by genetic mutation. Osborne,1916 suggested autosomal dominant inheritance in male and autosomal recessive inheritance in female while Happle and Kuster suggested it is the autosomal dominance, that explained a poly genetic inheritance play a role. Some examples of affected genes are 5-alpha reductase gene SRD5A1 on chromosome 5 and SRD5A2 on chromosome 2 which cause high level of 5-alpha reductase enzyme. In females, the gene CYP19A1 affects P450 aromatase enzyme that catalyzes the conversion of testosterone into estradiol and decreases the intrafollicular testosterone [4].

From familial point of view, 80% of population with normal testosterone have AGA due to family history. Furthermore, people with strong genetic predisposition will get baldness in early teens, while people with weak predisposition will bald in late 60-70s [5].

Hormonally, many hormones can activate the enzyme 5-alpha reductase such as S. androgen, testosterone, DHEA, free testosterone, cortisol and androstenedione [6].

Muscularly, erector pili muscle detaches from secondary follicle so the primary follicle undergoes miniaturization and detachment [7].

AGA can be diagnosed using clinical and histopathological techniques to see the hallmark miniaturization of the hair follicle.

There is a risk of arterial stiffness, cardio vascular diseases, and benign prostatic hyperplasia in patient with AGA [8].

The old treatment was used topical minoxidil and oral finasteride as antagonist to the action of 5-alpha reductase enzyme [1].

The newer treatment, Botox, has been used in order to relax the erector pili muscle. This can be achieved by injecting 20units of Botox intramuscularly once weekly for 4 weeks [9].

The newest revolutionary option is Regenera ActivaAMT. It is new technology, which has a promising solution to AGA. It can replace hair transplant in the future. Regenera ActivaAMT is a simple effective method, uses autologous micrografting in one session, which does not take more than 60minutes and can see the results within 3-12months. This procedure has no side effects with very good outcomes [10].

AMT is an autologous micrografting, which means the patient is the recipient and the donor at the same time. Native progenitor cells SVF are taken from the skin behind mastoid because this area is highly vascular and not affected by genetic predisposition to AGA. The micrograft composition includes progenitor cells CD90-CD105-CD73, extracellular matrix, and growth factors. This mixture is injected into bald area to cause tissue regeneration via:

1. increase matrix production and growth factor.
2. increase tissue neogenesis.
3. modulation of inflammation.
4. activation of tissue remodeling through biological pathways [11].

The limitations of this procedure are:

1. expensive in compare to the cost of hair transplant as an alternative option.
2. it takes long time to see the results.
3. over expectation of the patient

This maneuver has had approval from the FDA, CE FMA Japan, and IQNET [11].

Aim: Our study aimed to treat androgenetic alopecia by Regenera ActivaAMT as new effective modality treatment.

2. Method

This study is an experimental one, in which 23 participants were enrolled. It was conducted through 1 year, from June 2022 to June 2023. The participants' age range was 20-65years, and according to sex, they were 7 males and 16 females. Inclusion criteria involved that the participant patients were those who had collected 6 or more points by Trichoscopy score [12]; type 1-4 Hamilton-Norwood scale male pattern or type 1 and 2 Ludwig and Savin scale female pattern [13] even those with diseases such as hypertension, diabetes or thyroid. Excluded individuals were those who had collected 5 points or less by Trichoscopy score, type 5-7 Norwood -Hamilton scale male pattern or type 3 Ludwig and Savin scale female pattern, cancer or auto immune diseases or on chemo/radio therapy or biological agents, and types of baldness other than AGA.

The patients were evaluated according to the above criteria via Trichoscope examination, photos, width and length measurements to the bald areas, in centimeter, and hair length in females only.

Each participant patient was prepared by using antiseptic, 70% alcohol, to the area. This was for shaving the donor area and take 3 punch biopsies of about 2.5mm depth. Then the area was dressed and the biopsies were put in Regenera cons to have robotic and automated 2 cycles, 1 minute each at 80rpm. The AMT device causes mechanical controlled degradation which means there was no chemical, enzymatic, nor manual degradation.

The matrix, which was about 5ml, was collected and injected by 13mm needle at 45 angle at a rate of 0.1ml per point. The injection technique was intradermal to sub-cutaneous.

This procedure is painless with no side effects and the patient can return to normal life immediately. It takes about 45 minutes to 1 hour from A-Z, including the use of IGrow helmet post injection for better results.

Follow-up visits on regular basis had been conducted; the first one was 1-month post procedure, then 3 months, 6 months, 9 months and 1 year.

The results were evaluated through:

1. asking the patient about satisfaction rate.
2. asking the patient about hair fall.
3. photos
4. Trichoscopy exam
5. measurements the bald area.
6. measuring the hair length in females only.

The results could be seen into 2 forms:

1. stop hair fall within the first few weeks after the procedure.
2. a new baby-hair growth within 3 months to be completed at 1 year post the procedure.

3. Results

The median age of participant patients was 35.5 years. Table 1 shows that their sex distribution included 30.43% males and 69.56% females giving male: female ratio of 1:2.3. Marital status involved 60.87% patients were married.

Table 1.
Sex and marital status distribution of the participant patients.

Characteristic	No.	Percentage
Sex:		
Male	7	30.43
Female	16	69.56
Marital status:		
Single	9	39.13
Married	14	60.87
Total	23	100.00

When subjective satisfaction was measured using a 10-point scale [10] the percentage of satisfied treated patients, with the results of Regenera ActivaAMT, was 60.9% (Table 2).

Table 2.
Satisfaction levels of the treated patients.

Satisfaction score	Satisfaction level	Frequency	Percent
Pending	Still no opinion	1	4.3
Low (≤4)	Unsatisfied	6	26.1
Intermediate (5-6)	Borderline	2	8.7
High (≥7)	Satisfied	14	60.9
Total		23	100.0

When hair classification score grades before treatment, with Regenera ActivaAMT, were compared to the grades after treatment, the difference was found statistically significant (Table 3). It is clear that the percentage of those with normal grade of hair classification increased from 4.3% to 35%. This change was found to be statistically significant.

Table 3.
Comparison hair classification score grades before with after treatment.

Grade	Hair classification score before		Hair classification score after	
	Frequency	Percent	Frequency	Percent
Normal	1	4.3	7	35.0
I-Iva	16	69.6	10	50.0
V-VI	6	26.1	3	15.0
Total	23	100.0	20*	100.0
P-value**	0.042			

Note: * Three had not attended.
** Wilcoxon Signed Ranks Test.

In Table 4, higher trichoscopy scores percentage were more after intervention. The percentages of patients who showed cores 7 and 8 increased from 21.7% and 0.0% to 43.5% and 21.7% respectively. Again, these changes were statistically significant.

Table 4.
Changes in trichoscopy scores after intervention.

Score	Trichoscopy before		Trichoscopy after	
	Frequency	Percent	Frequency	Percent
4-5	8	34.8	2	10.0
6-7	15	65.2	13	65.0
8	0	0.0	5	25.0
Total	23	100.0	20	
P-value**	0.011			

Note: * Three had not attended.
** Wilcoxon Signed Ranks Test.

Table 5 clarifies that after treatment normal hair fall, among participant patients, increased significantly from 8.7% to 80% (p=0.0001)

Table 5.
Changes in the pattern of hair fall after treatment.

Hair fall	Before		After	
	Frequency	Percent	Frequency	Percent
Normal	2	8.7	16	80.0
3-6	12	52.1	3	15.0
7-10	9	39.2	1	5.0
Total	23	100.0	20	100.0
P-value**	0.0001			

Note:* Three had not attended.
** Wilcoxon Signed Ranks Test.

After the treatment course, it is clear that participant female patients' hair became significantly taller (Table 6).

Table 6.
Changes in participant women hair length (cm) after treatment.

Women hair length (cm)	Before		After	
	Frequency	Percent	Frequency	Percent
38-50	4	25.0	3	21.3
51-60	9	56.25	8	57.0
61-70	0	0.0	1	7.1
71-80	2	12.5	0	0.0
81-90	0	0.0	1	7.1
>90	1	6.25	1	7.1
Total*	16**	100.0	14***	100.0
P-value£	0.002			

Note: * One male.
** Six had been missed.
*** Eight had been missed.
£ Wilcoxon Signed Ranks Test.

4. Discussion

Women number was double than men and this could be explained by one of the following facts or both. The first one is that women are more looking for beauty. The other is that men are more aware toward hair transplant rather than Regenera ActivaAMT. The median age reflects AGA in Iraq is more obvious around thirties. AGA is more common in married rather than single and this could be explained by genetic cause [1].

Satisfaction rate was classified into three grades. The measurements represented good results; however, about 26.1% of the patients were not satisfied and in about 8.7% the satisfaction level was borderline. Álvarez, et al. [10] found that about 5.88% of the treated patients were very satisfied, about 29.41% of them were quite satisfied, 47.05% were satisfied, 5.88% were somewhat satisfied and 11.76% were unsatisfied. The higher non-satisfaction rate in the current study could be attributed to the high level of expectations among them regarding the treatment.

Hair classification according to Hamilton-Norwood and Ludwig and Savin scale showed that the proportion of those with normal hair classification increased from 4.3% before the treatment course to 35%, while the percentages of those with higher grades decrease dramatically after the treatment course. A study conducted by Zari [14] on patients whom, all, were classified between grade II and III, when the results were promising. However, up to the best of the current study researcher's knowledge, we could not find a research studied cases of AGA classified behind classification III, to compare their results to this study's ones.

Regenera had dramatic effect in stopping hair falling in all cases, even in those who were not satisfied about the outcome. This meant Regenera had positive impact on telegenic phase. Moreover, all cases had reduction in the

measurements from the least 2*2cm to the maximum 10*4, which means Regenera, had direct effect on stimulating anagenic phase. This goes with what was stated by Álvarez, et al. [10] that after Regenra course, there was a reduction in hair fall, which suggested an improvement of AGA together with increase in the mean of hair thickness after application of one single therapeutic session has been objectified.

All female cases got increase in the length of their hair from 2-5 cm regardless duration post Regenera (1 month or 1 year), which meant reduction in the resting phase and encourage anagenic phase.

Generally, anagen could last 3-5 years and hair will be elongated from 45-50cm. Therefore, in Regenera cases hair increase in length by 2cm in 1 month, which means that there will be about 12-20cm length increase in a year and this is considered as super anagenic effect.

Factors that might be affected the success of Regenera were diabetes which prolongs the duration. Also, one case was wrongly involved as the diagnose was lichen planopilaris and not AGA. One case had history of two failed trials of hair transplant before being enrolled in the current study, which gave him good results but not too much satisfaction because of the high expectation.

AMT was new technology with good outcomes. it was safe, effective, without side effects. combined treatment was essential for better outcomes such as home treatment, IGrow helmet, PRP or mesotherapy injection.

5. Conclusion

Regenera Activa AMT is effective technology to treat AGA in both males and females at any age and in their early stages of baldness.

Its concept is autologous micrografting which causes tissue regeneration and activation by increase the matrix production, growth factor, tissue neogenesis, modulation of inflammation and tissue remodeling activation.

It is simple, painless and cannot take more than 1 hour without any restrictions after the procedure.

It can replace the hair transplant in the future.

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