

TRX2[®] : Effects and Tolerability in Men and Women with Hair Loss

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Data show statistical significance at four major efficacy parameters

Oxford, October 7, 2011 – Oxford Biolabs Ltd., a UK based company focusing on the research and development of novel health & beauty therapies, presents the results of the company's preliminary clinical research study of TRX2[®] Molecular Hair Growth Supplement. TRX2[®] is a patent-pending food supplement containing nutrients that help promote and sustain healthy hair growth. Click [here](#) for more information.



Baseline



9 months



18 months

9 months (active treatment group)

1. Hair count (Mean number of hair in an area of 2×2 cm): +35.1%
2. Hair Thickness (Mean weight of hair – bundle of 30 strands): +22.5%
3. Terminal hair change (% change from vellus to non-vellus): +23.2%
4. Self-evaluation of satisfaction (score between 0-10 cm with 10 being the most satisfied): 7.8 ± 2.0 cm

18 months (active treatment group)

1. Hair count (Mean number of hair in an area 2×2 cm): +49.2%
2. Hair Thickness (Mean Weight of hair – bundle of 30 strands): +38.7%
3. Terminal hair change (% change from vellus to non-vellus): +36.4%
4. Self-evaluation of satisfaction(score between 0-10 cm with 10 being the most satisfied): 8.6 ± 1.6 cm

KEYWORDS: HAIR LOSS, ALOPECIA, ANDROGENETIC ALOPECIA, FOOD SUPPLEMENT

1 INCLUSION CRITERIA & SUBJECTS

Male and Female volunteers of 18 years of age or older and demonstrating good general health were recruited into the study. Alopecia must have been present for at least 6 months and in the areas affected by alopecia no sign of new hair growth must have been visible. Volunteers previously exposed to minoxidil and/or finasteride were not eligible to participate in the study, as were patients who have used any synthetic drug, such as antihypertensives, steroids, spironolactone, ketokonazole, cimetidine, cytotoxic compounds, anticonvulsant drugs, b-blockers, estrogens or progesterone within the previous six months. Patients who were experiencing hair loss as a consequence of scalp or hair trauma, adverse drug reactions, structural hair shaft anomalies and lichen planus were not admitted to participate in the study.

59 participants (47 men and 12 women) entered the study and completed 18 months of therapy. The ages ranged from 18 to 51 years for Men and 19 to 58 years for Women, respectively (Table 1).

2 STUDY DESIGN

The randomized, double-blind, placebo-controlled study was focused on evaluation of efficacy and safety of TRX2[®] Molecular Hair Growth Supplement (in short “TRX2[®]”) and consisted of two legs:

- A **blinded phase** lasting for 9 months; participants were receiving either TRX2[®] formulation supplementation (active treatment group) or placebo (placebo group)
- An **open phase**; participants who had taken TRX2[®] were continuing treatment for a further 9 months (active treatment group); participants who had been taken placebo during the blinded phase were switched to active TRX2[®] treatment for 9 months (switched group).

3 TREATMENT

The formulation was manufactured as 500 mg vegetable capsules. Serving Size was 3 capsules per day, to be taken with food. It was up to the volunteers to take all capsules together or at separate times.

The amount per serving (per three capsules) was as follows: Potassium chloride (191 mg), Biotin (151 µg), Carnipure™ tartrate (L-carnitine-L-tartrate) (800 mg), L-leucine (150 mg), Isoleucine (75 mg), Valine (75 mg) and Nicotinic acid (40 mg).

4 EFFICACY PARAMETERS

The efficacy of TRX2[®] was evaluated by four key parameters:

1. Hair count (primary efficacy measure). For each patient an area of 2×2 cm was selected within the area affected by hair loss (usually frontal area or crown) – the two opposing corners of the 2×2 cm square were permanently marked using a 4 cm² wire frame to ensure consistency in measurements for the participant’s following intervals.
2. Terminal hair % change. At each interval the percentage terminal hair count change (% change from vellus to non-vellus hair) was determined
3. Hair weight. At each of the intervals a small bundle of hair (ca. 30 strands) within the marked zone was clipped. 30 strands were then randomly chosen and normalized by cutting them into 1 cm in length. The total weight was measured by using a microbalance and the mean weight was recorded.
4. Self-evaluation of satisfaction on a visual analogue scale (0-10 cm). At each interval the subjects were asked about their satisfaction with the treatment by scoring their degree of satisfaction on a visual analogue scale between 0 and 10 cm (with 0 being “not at all satisfied” and 10 being “very satisfied”). The measured distance between the zero point to the subject’s mark on the visual analogue scale was used during statistical evaluation. All participants were asked if they had positive or negative comments from their hairdresser, friends and family members. Each participant was also asked for any side-effects they may have encountered as a result of the treatment.

All parameters were recorded at baseline and every 3 months thereafter during the duration of the study.

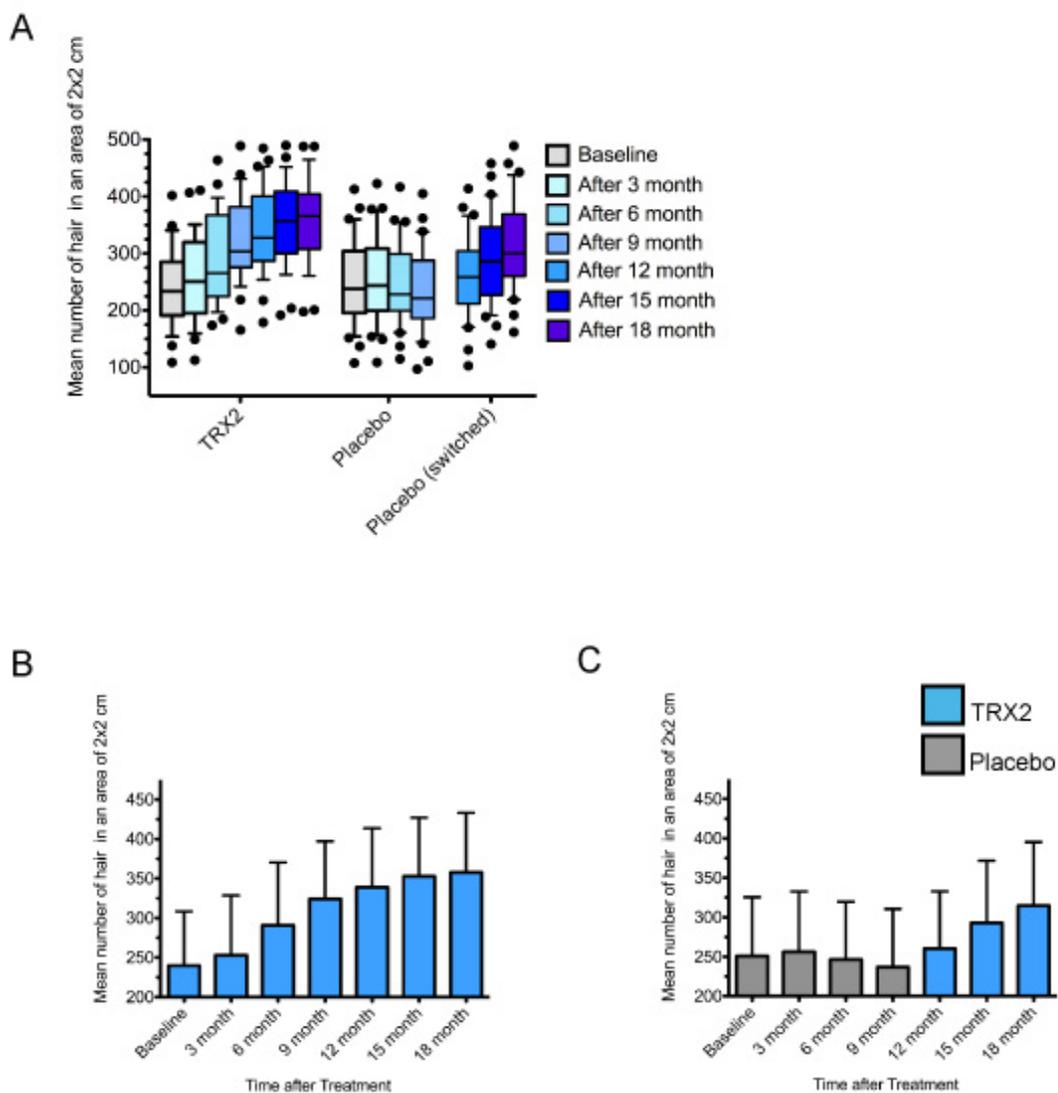


FIGURE 1: Graphical representation of total hair count as a result of TRX2[®] and placebo. A) Total hair count change of TRX2[®] in the active treatment group (left), placebo in the placebo group (middle) and TRX2[®] in the group that was switched from placebo to TRX2[®] after 9 months (switched group) (right). Time intervals are indicated in different colors (blue coloring). Each box represents the mean number of hair in a defined area of 2×2 cm. The black bar within the boxes indicates the mean. Each box has whiskers attached, which indicate the 10-90-percentile range of the data points collected (black dots). B) Total hair count change in the active treatment group with standard deviation (SD) indicated by the black bars. C) Total hair count change in the placebo group (grey color) and switched group (blue color) with standard deviation (SD) indicated by the black bars.

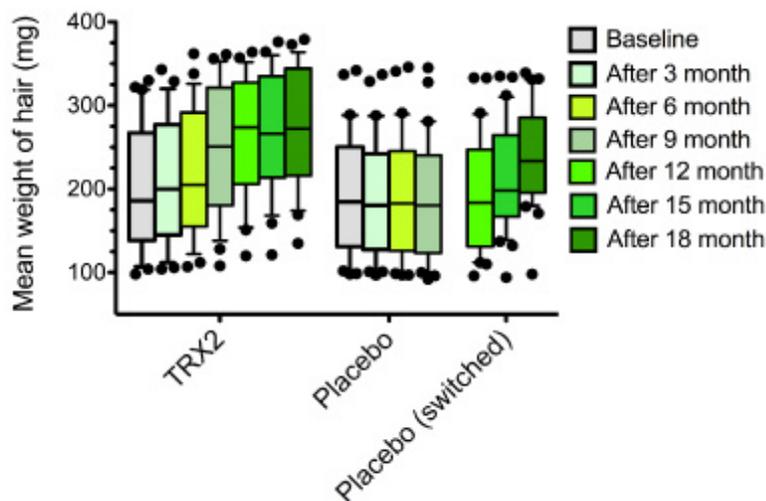
5 RESULTS

29 volunteers were randomized to receive the above mentioned formulation supplementation while 30 volunteers have been assigned to the placebo group (Table 1). The groups who received either TRX2[®] or the placebo control have been assessed for comparability with respect

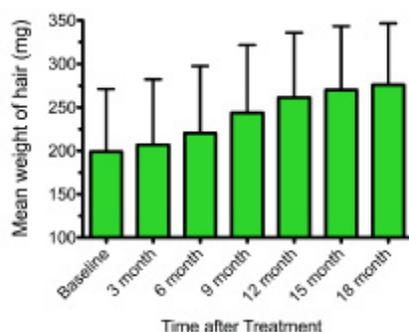
to initial hair count, the weight of hair and their affected area of hair loss. No statistically significant difference has been detected for the above characteristics between the treatment groups.

At the end of the 9-months open phase, 26 (out of a total of 29) participants in the formulation supplementation group had shown positive results, i.e. recording an

A



B



C

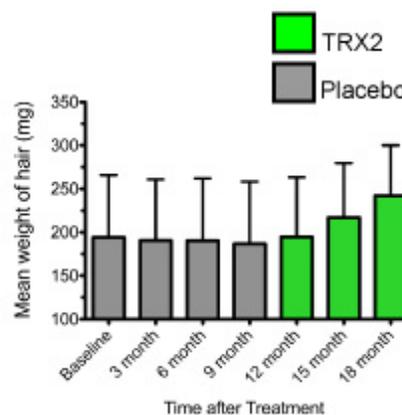


FIGURE 2: Graphical representation of hair weight as a result of TRX2[®] and placebo. A) Hair weight change of TRX2[®] formulation supplementation in the active treatment group (left), placebo in the placebo group (middle) and TRX2[®] formulation supplementation in the group that was switched from placebo to TRX2[®] after 9 months (switched group) (right). Time intervals are indicated in different colors (green coloring). Each box represents the mean hair weight of a bundle of 30 normalized hair strands. The black bar within the boxes indicates the mean. Each box has whiskers attached, which indicate the 10-90-percentile range of the data points collected (black dots). B) Hair weight change in the active treatment group with standard deviation (SD) indicated by the black bars. C) Hair weight change in the placebo group (grey color) and switched group (green color) with standard deviation (SD) indicated by the black bars.

increase of at least 10% in terms of the number of hair strands in the evaluation area and/or a 10% increase in hair weight.

The mean percentage of increase in the number of hair was 35.1 ± 6.2 (mean \pm SD) after 9 months and 49.2 ± 9.4 (mean \pm SD) after 18 months of TRX2[®] supplementation,

respectively (Figure 1; Table 2). Comparatively, the mean percentage of increase in the weight of hair (normalized bundle of 30 hair strands) was 22.5 ± 7.5 (mean \pm SD) after 9 months and 38.7 ± 6.4 (mean \pm SD) after 18 months of TRX2[®] supplementation, respectively (Figure 2). The increase of both number of hair as well as hair weight is

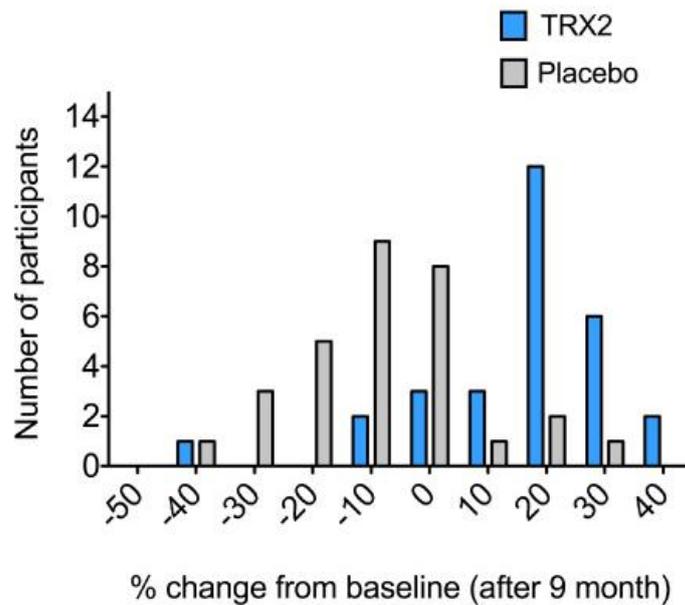


FIGURE 3: Graphical representation of percentage terminal hair count change (change from non-vellus to vellus hair) achieved by TRX2[®] formulation supplementation and placebo after 9 months.

statistically significant ($p < 0.001$) when analyzed using paired sample t-test.

On the other hand, of the total 30 volunteers in the placebo group, 3 showed slight hair re-growth (5-10% increase), 13 had hair loss (>5% decrease) while the other 14 did not show any significant changes in the number of hair ($< \pm 5\%$). After 9 months the mean percentage of increase in the number of hair across all participants in the placebo group was -5.5 ± 1.6 (mean \pm SD) (Figure 1; Table 2). Comparatively, the mean percentage of weight increment in the placebo group after 9 months was -3.9 ± 0.9 (mean \pm SD) (Figure 2). No statistically significant difference ($p > 0.05$) in the number of hairs was detected between baseline and post-supplementation, thus indicating that the placebo effect did not occur during this study.

After 9 months the placebo group was switched to TRX2[®] (switched group) in order to determine if this group would benefit from TRX2[®] formulation supplementation. The mean percentage of increase in the number of hair after 9 months was 32.7 ± 9.8 (mean \pm SD) (Figure 1; Table 2). Comparatively, the mean percentage of increase in the weight of hair (normalized bundle of 30

hair strands) was 29.7 ± 1.9 (mean \pm SD) after 9 months of TRX2[®] supplementation, respectively (Figure 2). The increase is statistically significant ($p < 0.05$) when analyzed using paired sample t-test.

After 9 months 79.3% of the participants receiving TRX2[®] showed an increase in terminal hair (>5% increase), with a mean percentage change of non-vellus to vellus hair of 23.2 ± 7.4 (mean \pm SD) (Figure 3). 10.3% of participants receiving TRX2[®] showed a decrease and 10.3% showed no statistically relevant change in terminal hair. On the other hand, 60.0% of participants in the placebo group showed a decrease in terminal hair (% decrease >5%), with a mean percentage change of non-vellus to vellus hair of -18.8 ± 9.9 (mean \pm SD). 13.3% of participants receiving placebo showed an increase and 26.7% showed no statistically relevant change in terminal hair.

The results of the self-evaluation score performed by the three groups are shown in Table 3. At the end of the blinded phase a statistically relevant difference ($P < 0.001$) between the active treatment and the placebo group was recorded, with the active treatment group showing a significantly higher score of satisfaction (7.8 ± 2.0 compared

to 0.9 ± 1.7). After 18 months the mean score of satisfaction in the active treatment group increased by 10%, compared to 9 months, with a mean score of 8.6 ± 1.6 (mean \pm SD). On the other hand, the mean score of satisfaction in the switched group also increased compared to placebo (7.4 ± 1.1 compared to 0.9 ± 1.7), clearly indicating a correlation of the participant's satisfaction with active TRX2[®] treatment ($P < 0.001$).

There were no adverse reactions recorded in any of the treated participants during the course of the study.

6 DISCUSSION

The results of this study show that participants who have received TRX2[®] formulation supplementation exhibited an increase in the number of hair, hair weight and terminal hair compared to placebo. The same effect was recorded in the long-term open phase of the study.

These objective efficacy data positively correlated with the self-evaluation score of the participants who have received either TRX2[®] or placebo.

Based on the results of this study long-term treatment of TRX2[®] is desirable in order to achieve positive results. Depending on the individual metabolism of the participant it took up to 12 months for positive changes to be detectable. However, for the majority of participants visible improvements were recorded after 6 months of treatment.

While additional scientific evaluation is required to further examine product efficacy and specification, the results of this study point at a potentially significant new option for the treatment of hair loss. The efficacy of TRX2[®] combined with its safety and excellent tolerability may make this product a viable and attractive alternative or addition to common treatments such as finasteride and minoxidil.

The detailed mechanism of action of TRX2[®] is still under investigation by various research groups, but early results indicated that efficacy is related to the stimulation and de-novo synthesis of potassium channels in hair follicles. Further studies are currently under investigation to illuminate this aspect.

TABLE 1: Baseline characteristics of the study participants in the two groups, who were given either TRX2[®] or placebo (3 capsules).

Treatment	Gender		Age (years)	Duration of hair loss (years)
	Male	Female		
TRX2 [®]	23	6	35 ± 9.6	5.3 ± 3.1
Placebo	24	6	36 ± 8.2	4.7 ± 2.3

Values are number (gender) or mean \pm SD

TABLE 2: Mean number of hair (in an area of 2×2 cm)^a, at baseline and at the end of the 9-months blinded phase as well as 9-months open phase of study participants given either TRX2[®] or placebo (3 capsules a day).

Treatment	Baseline	After 9 months	% change	After 18 months	% change
TRX2 [®]	239.9 ± 68.7	324.2 ± 73.0	+35.1 ^b	357.9 ± 75.2	+49.2 ^b
Placebo	250.8 ± 74.7	237.0 ± 73.6	-5.5 ± 1.6	N/A	N/A
Placebo (switched)	237.0 ± 73.6	314.6 ± 80.7	+32.7	N/A	N/A

^a For each patient an area of 2×2 cm was selected within the area affected by hair loss (usually frontal area or crown) – the two opposing corners of the 2×2 square were permanently marked using a 4 cm² wire frame to ensure consistency in measurements for the participant's following intervals

^b p<0.001 versus placebo

TABLE 3: Self-evaluation of satisfaction on a visual scale (0-10 with 10 being the most satisfied) with treatment (TRX2[®] or placebo) by the participants during the 9-months blinded phase in both groups and during the 9-months open phase in the active treatment group.

Treatment	Blinded phase			Open phase		
	3 months	6 months	9 months	12 months	15 months	18 months
TRX2 [®]	2.2 ± 1.9	5.2 ± 2.3	7.8 ± 2.0 ^a	8.1 ± 1.3	8.5 ± 1.3	8.6 ± 1.6 ^b
Placebo	0.8 ± 1.2	0.7 ± 1.6	0.9 ± 1.7	N/A	N/A	N/A
Placebo (switched)	N/A	N/A	N/A	2.7 ± 1.6	6.1 ± 2.0	7.4 ± 1.1

Values are mean ± SD

^a p<0.001 versus placebo after 9 months;

^b p<0.01 versus 9 months of TRX2[®] supplementation (blinded phase).

During the blinded phase, participants were given either placebo (n= 30) or TRX2[®] (n=29) over a period of 9 months. During the open phase, participants who had been taking TRX2[®] during the blinded phase, continued with this treatment for a further 9 months. Participants who had been taking placebo during the blinded phase were switched to TRX2[®] for 9 months.