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Rebalancing the Excessive Sebum Production in the Scalp

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An oily scalp is caused by over-reactive sebaceous glands on the scalp. The oil or sebum attracts dirt more easily, produces even dandruff, and makes the hair stick together. To reduce the sebum and enhance the barrier efficacy on oily scalp, Mibelle Biochemistry has developed an active ingredient based on the Chinese medicinal herb *Astragalus membranaceus*. AstraForce is a liposomal preparation of *Astragalus membranaceus* root extract. This plant is one of the most important Chinese medicinal herbs and its roots have been used for more than 2500 years in Chinese medicine to strengthen qi, the body's life force. This liposomal form facilitates the penetration of actives into the sebaceous duct allowing the active components to target the sebaceous gland more straightforwardly. The sebum-reducing effect of AstraForce has been proven on volunteers having oily scalp and hair while maintaining the barrier effectiveness. *In vitro* the active ingredient has reduced the activity of enzymes involved in sebum lipid metabolism. AstraForce thereby has a positive effect on scalp purification and hydration as well as reducing sebum production in the context of oily hair.

Introduction

The scalp is, as any other skin body area, an epithelium generating a *stratum corneum*. It is continuously renewed by a desquamation process forming an effective barrier against external attacks and minimising water loss from the body [1] (Fig. 1). It is a very complex assembly whose composition ensures its unique properties. The living keratinocytes are transformed into small enucleated flat bricks; proteins such as involucrin, loricrin, filaggrin etc reinforce the cornified envelope and rule hardness, force and flexibility properties. The corneocytes are strongly interconnected by corneodesmosomes and sealed by organised layers of extracellular complex lipids: cholesterol, ceramides and neutral lipids [2]. Healthy hair produces a certain amount of sebum, or oil, as a way to hydrate the scalp and protect the hair itself. The amount of oil produced varies depending on the hair type, the hygiene habits and other lifestyle factors. Sebum is involved in the development of the epidermal structure

and maintenance of the epidermal permeability barrier [3], carrying anti-oxidants to the skin surface, protection from microbial colonization, generation of body odor and pheromone generation. Sebum is directly involved in skin-specific hormonal signaling, epidermal differentiation and protection of the skin from ultraviolet irradiation [4]. Sebum level on the scalp is primarily governed by the production and excretion by holocrine glands: sebaceous glands that are associated with hair follicles. As soon as excreted from the pilo-sebaceous duct, the oily human sebum naturally flows, spreads and later migrates onto the hair shaft surface by capillary forces. In fact, this sebum benefits the hair, but excessive sebum production is the cause for oily scalp and hair. Coated with sebum, hairs become greasy at root, progressively stuck together, trapping external dirt and dust and pollutants particles. Moreover, sebum components become progressively oxidized [5]. With time, the head of hair takes a dull and heavy appearance, generally perceived more as dirt than oil. Additionally, excessive scalp sebum privileges a disbalanced growth of the scalp resident microflora, for example yeasts of the *Malassezia* species (major causal factor of dandruff in prone people) [6]. Causes of excess sebum secretion include genes, hormonal imbalances,

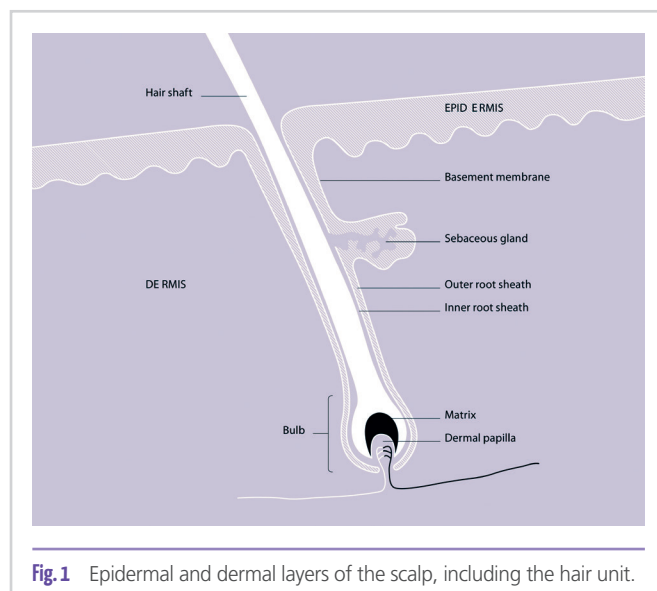


Fig. 1 Epidermal and dermal layers of the scalp, including the hair unit.

humidity, diet, etc. Hormonal imbalances as found during pregnancy, menopause, or puberty can trigger an oily scalp. Some internal diseases can cause increased sebum secretion too [7].

A Traditional Chinese herb to rebalance the scalp sebum production

Mibelle Biochemistry has developed the active ingredient AstraForce based on a traditional Chinese herb (INCI Astragalus Membranaceus Root Extract (and) Dipropylene Glycol (and) Glycerin (and) Lecithin (and) Phenoxyethanol (and) Aqua/Water) to rebalance the sebum production on oily scalp and hair. *Astragalus membranaceus* root extract fraction was incorporated into liposomes formed with lecithin. This liposomal form facilitates the penetration of actives into the sebaceous duct, which allows the actives to target the sebaceous gland more easily. AstraForce thereby has a positive effect on skin purification and hydration as well as on sebum production in the context of oily hair.

Astragalus membranaceus is a plant native to China and capable of growing in extreme habitats. Its roots strengthen the immune system and stimulate metabolism. This sweet tonic herb is known to be adaptogen: it helps the body to cope with stress and to maintain optimal homeostasis. In addition, it has anti-bacterial, anti-inflammatory and antiviral effects; properties that make it one of the most frequently used medicinal herb in food supplements and remedies.

Astragalus membranaceus contains a high percentage of astragalans, medicinally active polysaccharides known for enhancing specific immune functions such as the improvement of white blood cell response. Its composition includes also formononetin, an isoflavone with antioxidant effects on lipid peroxidation, and saponins (called astragalosides) which have the property of reducing inflammation.

Among the activities of *Astragalus Membranaceus* roots can be found that it enhances the immune system by increasing the production of interferon (an antiviral and anti-tumor agent naturally produced by the body) and stimulates natural killer cells. It also boosts T-cell production and stimulates macrophages, which in turn help other immune cells to fight bacteria, viruses, parasites, fungi, toxins, and diseased cells. As a general tonic, it regulates water circulation and helps the body to adapt to external influences by encouraging blood flow to the surface.

Study Results

Inhibition of the lipase activity

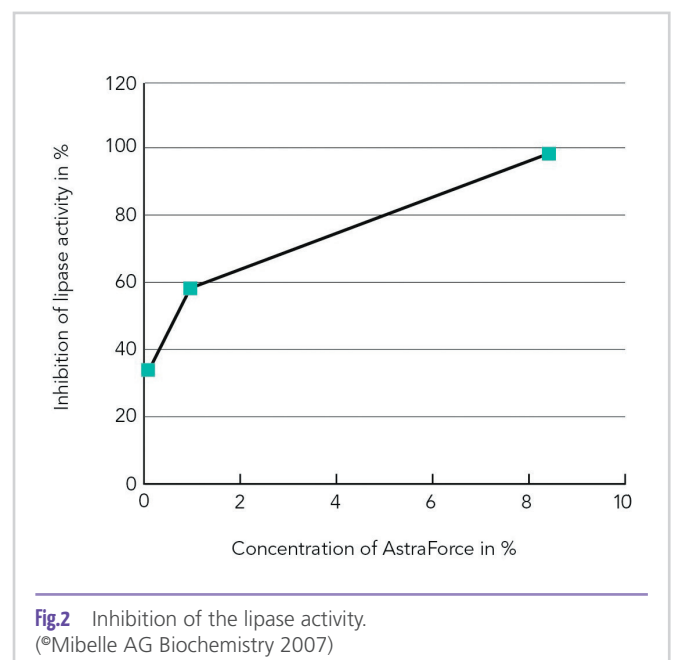
Lipase is an enzyme that converts sebum lipids into free fatty acids which are subsequently released onto the skin surface.

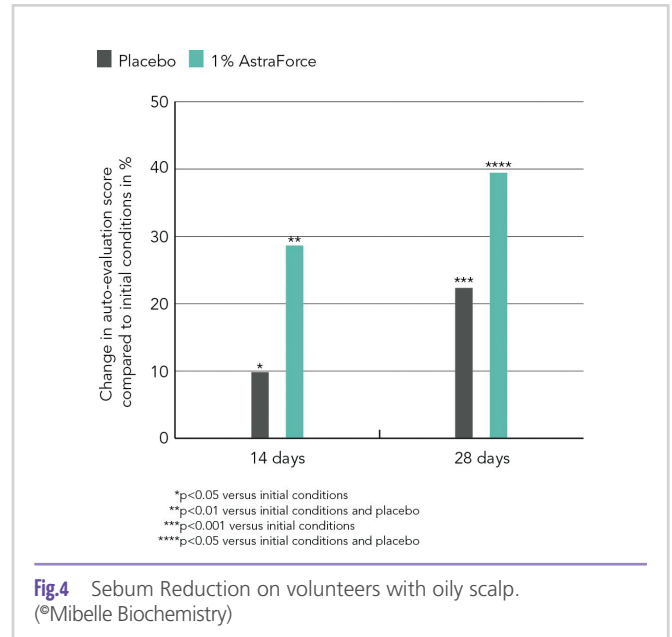
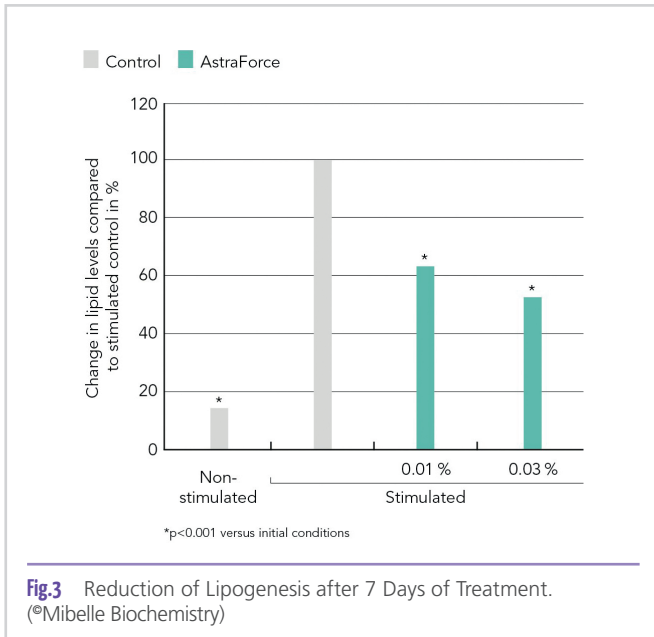
A higher concentration of free fatty acids on the scalp can lead to bacterial growth and inflammation. Therefore, the reduction of the lipase activity of AstraForce was evaluated. For this assay, AstraForce was diluted in buffer at different concentrations (0.083%, 0.83%, 8.3%) and Miglyol was used as substrate for the lipase enzyme. After mixing and 1-hour incubation the optical density (OD) was determined at 340 nm (UV Spectrophotometer Shimadzu) and measurements showed the concentration of fatty acids produced by the lipase. Results showed that AstraForce was able to inhibit the formation of fatty acids (lipase activity) in a dose-dependent manner (Fig. 2). Thus, AstraForce is able to reduce the local inflammation caused by the over-production of free fatty acids secreted to the scalp.

Lipogenesis

The effect of AstraForce on lipogenesis was investigated in human sebocytes. These cells are in the sebaceous glands close to the hair follicles and secrete the oily liquid termed sebum. During the process of lipogenesis, the metabolite acetyl-CoA is converted to fatty acids which can subsequently be secreted in the sebum. Lipogenesis is increased in acne-prone skin and often excess sebum oils can clog pores, also in the scalp.

The sebocytes were seeded in 96-well plates and cultured for 24 hours in culture medium. The medium was then removed and replaced by assay medium containing or not (control) the test compound (0.01 % and 0.03 % AstraForce) or the reference (Cerulenin, 10 μ M) and cells were pre-incubated for 4 hours. Then, the seborrheic mix was added to stimulate sebum production, and the cells were incubated for 7 days. At mid-term, i.e. after 3 days of incubation, half of the medium was removed, and the treatments were renewed (including seborrheic mix stimulation). Non-stim-





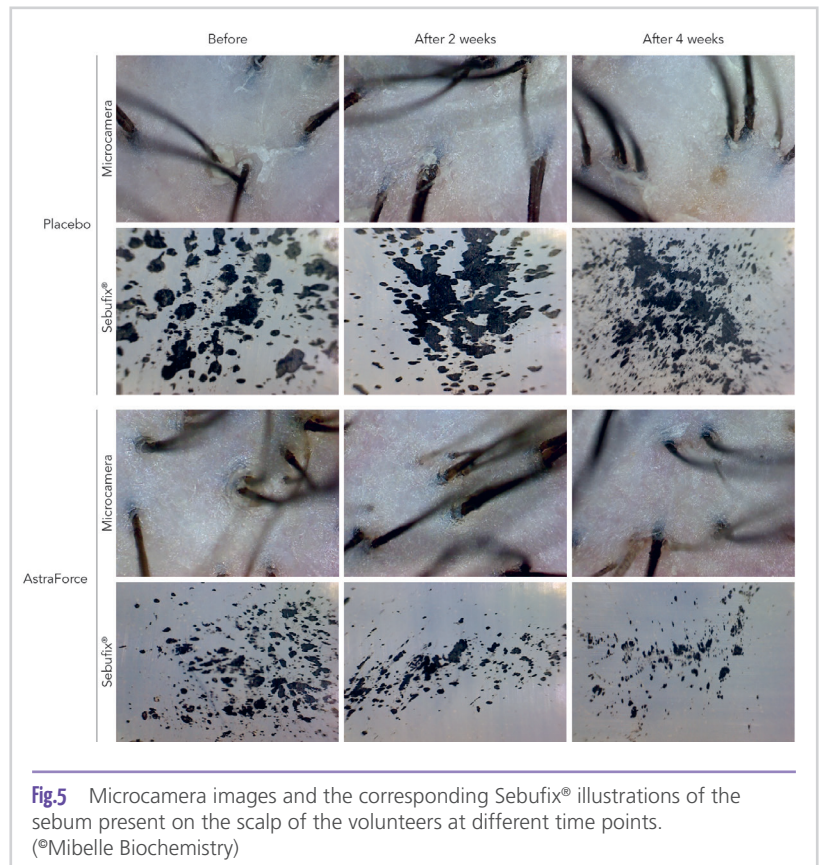
ulated control conditions were also performed in parallel. At the end of incubation, the cells were rinsed, fixed and permeabilized. The lipid droplets contained in the cells were then labeled using a specific Bodipy® fluorescent lipid probe labeling mainly neutral lipids. In parallel, the cell nuclei were stained using a Hoechst solution. The fluorescence intensity was analyzed exclusively in the lipid droplets via image analysis. Therefore, non-specific fluorescent background signal was not considered in the image analysis. Results showed that AstraForce tested at 0.01 % and 0.03 % inhibited lipid droplet formation and accumulation in a concentration-dependent manner (Fig. 3).

Sebum-reducing efficacy of AstraForce on oily scalp and hair

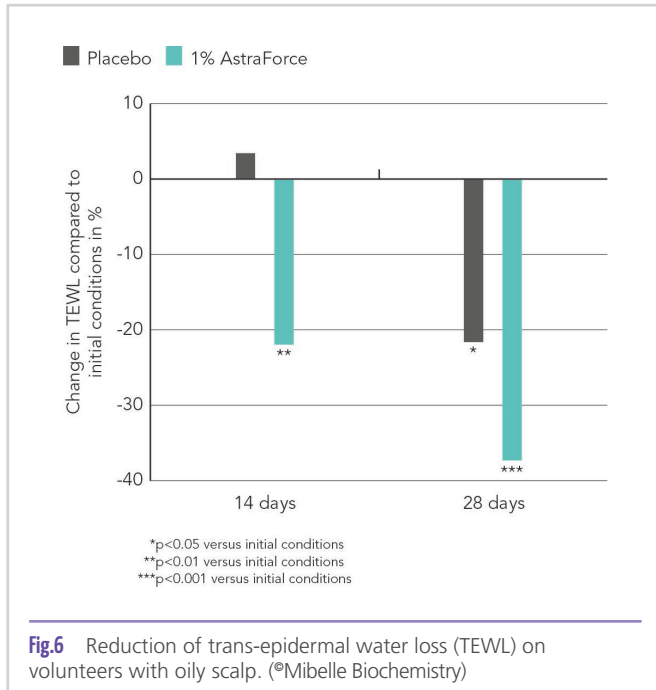
In a randomized, placebo controlled clinical study, the sebum-reducing and barrier-enhancing efficacy of AstraForce on oily hair and scalp was investigated. Sixty volunteers (46 women and 14 men) with oily scalp and aged between 18 and 65 years washed their hair either with a shampoo containing 1 % AstraForce or the corresponding placebo 3 times per week for a period of 28 days. The measured parameters were sebum amount (by scoring of pictures taken with I-scope microcamera and Sebifix® illustrations), trans-epidermal water loss (TEWL, Nano Tewameter®) and auto perception of hair oiliness.

After 14 and 28 days of treatment with a shampoo containing 1 % AstraForce, the sebum amount observed on the scalp was significantly reduced by up to 38.4 % compared to initial conditions (Fig. 4). The mi-

crocamera images and the corresponding Sebifix® illustrations displayed the visible oil reduction on the scalp of volunteers that have applied the shampoo with AstraForce compared to initial conditions and to the placebo (Fig. 5). The sebum-reducing efficacy of AstraForce on the scalp was confirmed by the score given by the volunteers on the self-evaluation: an increased by 28.6 % after 14 and by 39.4 % after 28 days. This was significant compared to initial conditions and to the treatment with the placebo.



The treatment with the shampoo containing 1 % AstraForce also reduced TEWL by 21.8 % after 14 days and by 37.1 % after 28 days (Fig. 6). Taken together these results showed the noticeable ability of AstraForce to reduce the sebum production without impairing the barrier function of the scalp.



Summary

The liposomal preparation of *Astragalus membranaceus* root extract (AstraForce), a traditional Chinese medicinal herb, was shown both in clinical studies and *in vitro* to reduce the sebum lipid production and the sebocytes activity while reducing the transepidermal water loss. Overall, the use of AstraForce lead to the rebalance of the excess of oil present on the scalp while improving the barrier function.

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