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Collagen's New Age: fColl(h), a Wild Plant-based Fragment of Collagen I

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**Sustainable and Versatile Additive
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Frankincense, an “Old Fashioned” Active Ingredient

G. Blume

Frankincense has been used for thousands of years in Ayurvedic medicine to treat a variety of suffering. Now, the research group of Prof. Oliver Werz from the University of Jena (Germany), together with his American colleagues, has demonstrated that the highly effective boswellic acid AKBA from the resin of the Indian frankincense tree (*Boswellia serrata*) also has a healing effect in addition to the already known anti-inflammatory properties [1].

“InflammAging” refers to a chronic silent inflammatory process (inflammation) that develops with advanced age. In addition to the externally visible aging of the skin, painful signs of age-related diseases such as osteoarthritis and rheumatoid arthritis often occur over time. This is the main field of application of the natural active ingredient AKBA from *Boswellia serrata* extract with extensive no side effects.

However, the promising therapeutic potential of the extract is limited by the insufficient solubility and bioavailability of the main active ingredient, whose water solubility is below 0.00045 mg/ml. By encapsulating the frankincense extract into Sopharcos’ nanoemulsion “Lipo-Tops”, the solubility can be increased by a factor of 22,000! In general, such formulations have shown that they can promote the absorption of lipophilic active ingredients and improve their bioavailability [2].

By using only natural edible raw materials, “Lipo-Tops Boswellin” can be used both for dermal application as well as for oral uptake.

Frankincense – *Boswellia serrata* Extract (BSE)

The effect of Indian frankincense resin (**Figure 1**) is mainly attributed to the boswellic acids (pentacyclic triterpenes) and triterpenic acids (tetracyclic triterpenes) it contains. In studies, the boswellic acid 3-O-acetyl-11-keto-β-boswellic acid (AKBA) showed the strongest effect as a highly effective anti-inflammatory natural substance [3].

During acute inflammation (**Figure 2**) as well as relapses of chronic inflammatory diseases, arachidonic acid is released from the cell membrane, which then forms the starting component for two enzymes. Cyclooxygenase (COX) leads to the formation of prostaglandins (pain, redness, heat) and 5-lipoxygenase (5-LOX) to the synthesis of leukotrienes (edema, formation of oxygen radicals).

Prof. O. Werz and his research group (University of Jena) were able to demonstrate new mechanisms of action for the boswellic acid AKBA in 2020, namely [5]:

- AKBA, on the one hand, inhibits the formation of the pro-inflammatory 5-LOX products, the pro-inflammatory messengers, and thus reduces the acute phase
- AKBA also promotes the formation of the anti-inflammatory 12-LOX products, the inflammation-dissolving mediators, thus initiating the decay phase of the inflammation.



Fig.1 Frankincense tree

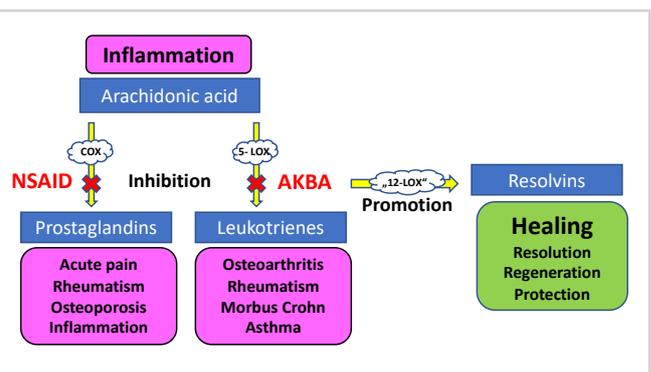


Fig.2 Inflammatory Cascade (according to Serhan & Chiang) [4]

“In this process, the normally pro-inflammatory enzyme 5-LOX is reprogrammed by the natural product to an anti-inflammatory enzyme 12-LOX” [6].

In addition, the application of the boswellic acid AKBA inhibits the activity of other enzymes; e.g., the enzyme cathepsin G, which can destroy connective tissue and articular cartilage, as well as elastase and the metalloprotease MMP-3, which can damage the extracellular matrix (collagen, elastin) [7,8].

Since naturally occurring frankincense extract (BSE) generally has limited side effects compared to other anti-inflammatory ingredients, its usage can be seen in many physical vulnerabilities e.g., skin (senile skin, psoriasis), musculoskeletal (osteoarthritis and rheumatoid arthritis), respiratory (asthma) and gastrointestinal (ulcers, Crohn’s disease) [9].

On the other hand, the high lipophilicity of boswellic acid AKBA (log P = 8), which is associated with poor solubility in water [10], and its insufficient membrane permeability are disadvantageous. Thus, the efficacy of this bioactive plant ingredient is hampered by its insufficient bioavailability after both oral and dermal application of the extract [9].

Distribution and uptake of the active ingredient can be achieved either only by changing the solubility properties of

the active ingredient or by using vehicles (carrier systems) with high permeation capacity.

“Lipo-Tops”, an Oil-in-Water Nanoemulsion

Oil-in-water (O/W) nanoemulsions consist of tiny lipid vesicles dispersed in water. These particles contain an oil droplet in their inner core in which lipophilic active ingredients like frankincense extract are completely dissolved. Thus, they act as a water-dispersed carrier system for lipophilic active ingredients and can effectively increase their bioavailability.

Lipo-Tops: Based on plant-derived raw materials, this oil-in-water nanoemulsion provides a powerful delivery system for lipophilic components/oils - both for dermal application and oral absorption [10].

In contrast to thermodynamically stable transparent microemulsions, Lipo-Tops are milky with homogeneous droplet sizes of 150-250 nm. However, they are characterized by high encapsulation efficiency of lipophilic, poorly soluble ingredients and can contain up to 20% of oils. This fact is explained by the different ratio of emulsifier to oil (1:5 for Lipo-Tops and 5:1 for microemulsions). The stable Lipo-Tops are formulated using non-PEGylated emulsifiers from sunflower based on unsaturated C18 fatty acids.



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STEP 3:
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SPRAY
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IS-CE-A



STEP 4:
MOISTURIZE

RICH & FRESH
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GE-IS

Lipo-Tops Boswellin: Since the boswellic acid AKBA has shown the highest efficacy when used against inflammatory processes, an Indian *Boswellia serrata* extract (BSE) from Sabinsa Europe GmbH with a boswellic acid content >75% was used for encapsulation. Thereby, the concentration of AKBA was higher than 30% in this frankincense extract, thus far higher than in most extracts on the market (< 10% AKBA).

The inhibition of the enzyme 5-lipoxygenase by the applied BSE extract was demonstrated in the research group of Prof. O. Werz (University of Jena) *in vitro*.

Lipo-Tops Boswellin have the following composition:

- 3-8% plant-derived, eatable emulsifiers (no PEG)
- 3-5% *Boswellia serrata* extract (>1% AKBA)
- 0-5% other active ingredients (e.g., CBD, Ibuprofen)
- 5-19% natural oils (e.g., rich in omega-3 fatty acids)
- 10-15% alcohol or propylenglycol
- Ad 100% water
- Sizes of the vesicles between 150 and 250 nm depending on composition
- pH-value between 5.5 – 6.5

Stability studies of Lipo-Tops Boswellin over a 30-days period under storage conditions of 4°C, RT, and 32°C yielded the following data [11]:

- Particle size exhibited constant values of 150 nm over this period. The measurement also showed a homogeneous distribution of vesicles, indicating good physical stability of the colloidal nanoemulsion without agglomeration or aggregation. (Laser scattered light technique).
- The amount of active ingredient AKBA, measured by HPLC (high performance liquid chromatography), showed a clear peak at the characteristic retention time, which could be assigned to AKBA (no decomposition of the active ingredient). Stability tests were performed up to 150 days without detecting any kind of change.

Usage of Lipo-Tops Boswellin in Cosmetics

Premature aging of the skin can be attributed to both external causes such as negative environmental influences (UV radiation, pollutants, chemical irritants) and internal causes such as silent inflammatory processes.

Especially aging but also inflamed skin shows a loss of elasticity, wrinkling, dryness and vulnerability, which leads to frequent or localized redness and discomfort with the sensation of stressed or burning skin.

The main disadvantage of dermal administration of the poorly water-soluble active ingredient AKBA and the

boswellic acid KBA is its low penetration behavior into the deeper skin due to its high lipophilicity. By the encapsulation of BSE into the flexible Lipo-Tops (Figure 3), whose small vesicle sizes favor a high interaction with the skin, AKBA was also detected in the viable skin layers by HPLC 6 hours after application [13].

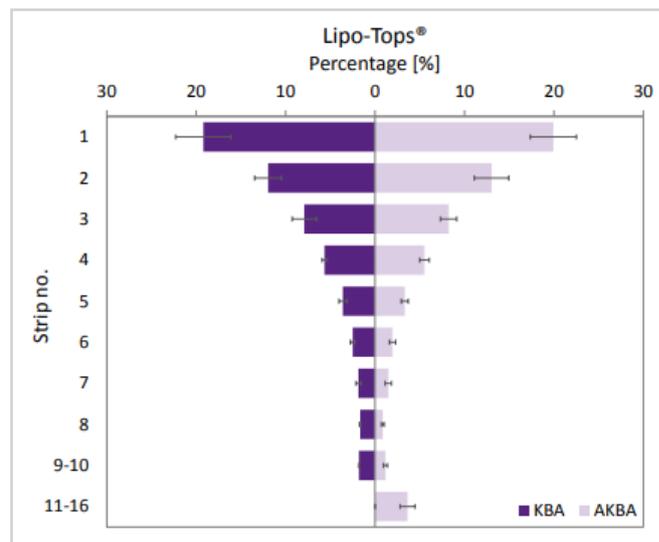


Fig. 3 Skin penetration studies using tape stripping experiments on porcine skin of Lipo-Tops Boswellin after an application time of 6 h (n=3).

Furthermore, Lipo-Tops containing the lipophilic active ingredients boswellin and tocopherol, respectively, have been incorporated into masks/nonwovens (hydrogels) made of bacterial nanocellulose (BNC), which can be used in cosmetics as well as for wound healing [13,14].

Loading this hydrophilic material with lipophilic substances is a major challenge. In the BNC fleeces, 10% of the added Lipo-Tops Tocopherol distributed homogeneously; which corresponds to a concentration of 1% of the lipophilic vitamin in the hydrogel (Figure 4). These vesicles were released intact from the masks [12] and the contained tocopherol showed after penetration a high and also long-lasting anti-oxidative capacity in the deeper skin layers as in the applied pure nanoemulsion [14].

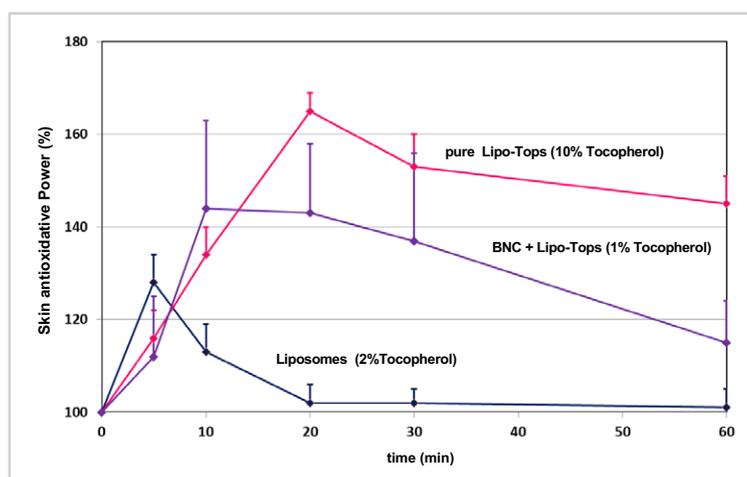


Fig. 4 Antioxidative Capacity of Tocopherol in the Skin

Liposomes show here a completely different behavior, both in terms of the anti-oxidative effect and with only a low release from the BNC [15].

Numerous studies indicate an exceptionally wide range of applications for frankincense extract enriched with AKBA. Thus, *Togni's* studies showed that the use of a cream containing an encapsulated extract of frankincense exerted a preventive effect in patients against damage caused by radiotherapy [16]. However, significant effects such as increased skin elasticity, wrinkle reduction and tactile skin softness in aged skin were also demonstrated in a human study after UV exposure [17].

After application of AKBA in cell experiments with human keratinocytes, the formation of reactive oxygen radicals (ROS) was significantly prevented after UV-A irradiation [18]. Furthermore, AKBA can inhibit elastase as well as hyaluronidase - two enzymes that damage the function of connective tissue [19,20].

Usage of Lipo-Tops Boswellin in COSMETICS

InflammAging (elder skin care)

- Loss of elasticity due to degradation of hyaluronic acid
- Thin skin (strengthening of the skin barrier)
- Dry skin

Inflammation

- Couperose and skin redness
- Oxidative stress

Exceptional skin stress

- Radiological treatments
- Laser-Therapy (Tattoo removing)
- Tattoo stitching
- UV-radiation

Medical skin care

- Neurodermatitis
- Psoriasis
- Diabetic foot syndrome

Usage in chronic inflammation (rheumatoid arthritis and osteoarthritis)

For about 5,000 years, frankincense has been used in traditional Indian medicine (Ayurveda) in the treatment of rheumatic diseases and joint complaints.

Rheumatoid arthritis (RA) affects about 1% of adults around the world, with symptoms 2-3 times more common in women than men. RA is a chronic inflammatory autoimmune disease characterized by increased levels of inflammatory biomarkers and oxidative stress. The mucosa of the joints is attacked and cartilage destruction occurs in the long term, accompanied by painful restriction of movement [9].

Osteoarthritis, on the other hand, is a degeneration of the joints that progresses with age and affects approximately 350 million people worldwide. Osteoarthritis is now the number one of painful physical impairments. It is characterized by attrition till complete loss of cartilage tissue, deformity of the joint bone, and chronic inflammation with severe pain [9,21].

Non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen are mainly used for the treatment of these joint inflammations. This prevents the synthesis of prostaglandins by inhibiting COX-2, which provides rapid pain relief. However, prolonged oral use of these products can lead to severe undesirable side effects in the gastrointestinal tract. Also, to date, there is no effective curative therapy to stop progression of symptoms.

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Due to the suitable frankincense extract with its not only anti-inflammatory but also inflammation dissolving effect, a unique natural substance can be used to treat chronic inflammation [1].

Oral Application:

However, frankincense extract, and especially the effective boswellic acid AKBA, exhibits insufficient bioavailability in the body after oral administration due to its hydrophobic, non-water-soluble property (< 0.00045 mg/ml).

Only sufficiently soluble substances are absorbed in the aqueous lumen of the intestine. Therefore, hardly any lipophilic active substance enters the organism and most of it is excreted. The absorption of AKBA (Figure 5) can be slightly improved by a meal with a higher fat content [22]. However, even large fat droplets / particles are not absorbed by the body in sufficient quantity [23].

“Based on these findings, the use of lipid-based oral formulations that allow better aqueous solubility/dispersity of the lipophilic boswellic acid AKBA is a good strategy to increase the systemic bioavailability of these substance” [24].

The nanoemulsion “Lipo-Tops Boswellin” shows all the necessary conditions for an efficient absorption of the liposoluble *Boswellia serrata* extract in the intestine. The extract is completely dissolved in small oil droplets, which in turn are in water. This results in a significant increase in the water solubility of AKBA by a factor of >22,000 and thus enables improved bioavailability after oral ingestion.

After a single application of a tocopherol-containing nanoemulsion comparable to Lipo-Tops, significantly higher concentrations of the lipophilic vitamin E were detected in the blood of the test persons over the period of 12 hours than in those who had ingested the tocopherol in gelatine capsules (Figure 6). Thus, administration of the nanoemulsion provides up to 3 times higher bioavailability of the very lipophilic vitamin compared to application of capsules [25].

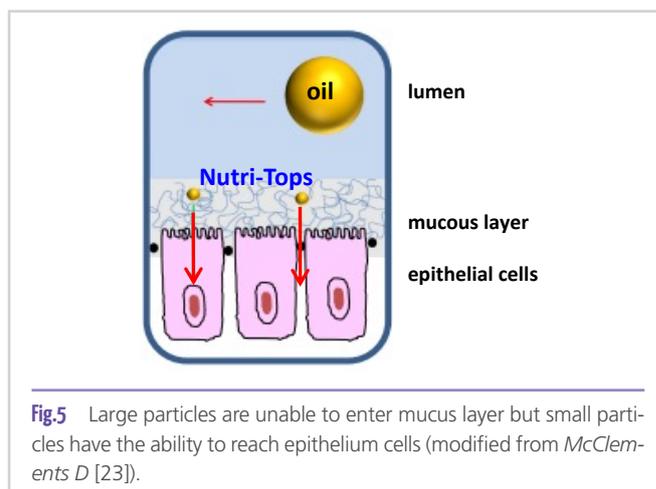


Fig.5 Large particles are unable to enter mucus layer but small particles have the ability to reach epithelium cells (modified from *McClements D* [23]).

Elderly people often have problems taking tablets because of their size or a too dry mouth. This can be solved by presenting a drink with Lipo-Tops Boswellin.

In a placebo-controlled clinical trial, patients with osteoarthritis of the knee received 50 mg of the drug aflapine (= 10 mg AKBA) or placebo 2 times daily for a period of one month. Here, aflapine resulted in a statistically significant improvement in pain scores and functional abilities of the knee, which occurred after only 7 days [26].

Based on these data, the following dosage is recommended: 1 ml of Lipo-Tops boswellin should be taken orally in the morning and evening (pure or diluted), which corresponds to a daily dosage of 20mg AKBA. Since the half-life of this boswellic acid in the blood is 15 hours, this maintains as constant a level of this substance as possible.

Dermal Application:

Dermal application of the *Boswellia serrata* extract should be considered as a good alternative and supplement to the oral form of administration, especially when the active substance is applied at the site of inflammation. Thus, the frequency of administration can be reduced but the efficiency of AKBA is increased at the target site.

In an approach for the treatment of inflammation, the penetration depth of the lipophilic nonsteroidal anti-inflammatory drug ibuprofen encapsulated in Lipo-Tops as well as in the form of a commercially available gel after dermal application was investigated by the Franz cell method (Figure 7).

The highest concentrations of ibuprofen were detected by HPLC 24 hours after application of the active ingredient encapsulated in Lipo-Tops- both in the living skin and in the underlying area (fluid) [11].

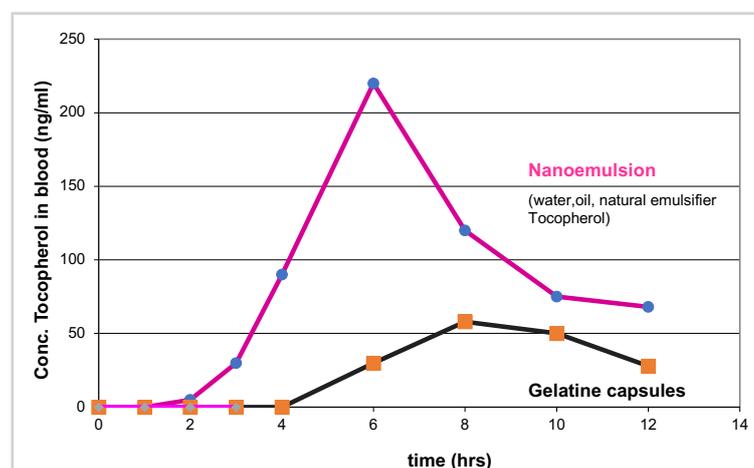
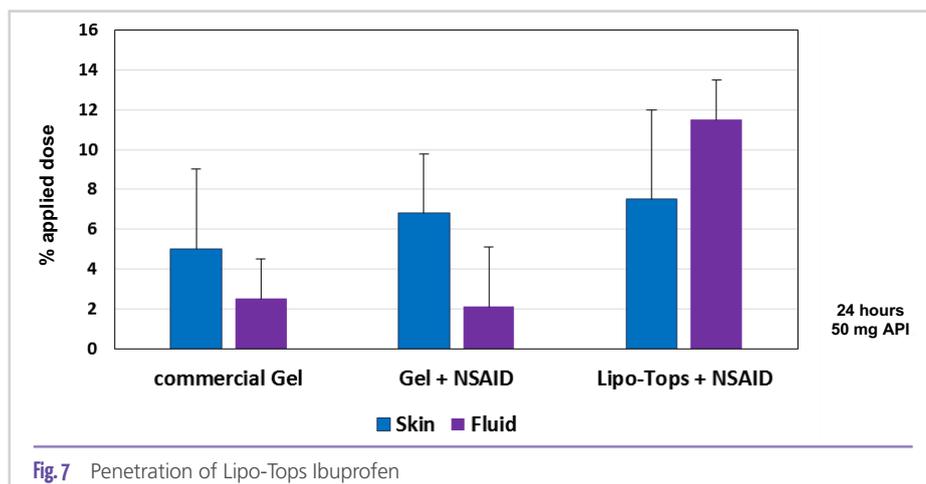


Fig.6 Oral application of Tocopherol (200 mg) *Cavallo I.* [25]



Conclusion

Lipo-Tops contain the natural, active boswellic acid AKBA of the frankincense extract, which can have a wide range of effects:

- *Inhibition of 5-LOX*
=> reduction of the pro-inflammatory messenger substances (leukotrienes)
- *Generation of 12-LOX*
=> formation of inflammation-resolving mediators (resolvins)
=> attenuation of inflammation (resolution) [5]
- *Inhibition of cathepsin G*
=> reduction of articular cartilage destruction [7]
- *Inhibition of hyaluronidase*
=> suppression of degradation of hyaluronic acid in synovial fluid [27]

Lipo-Tops Boswellin are suitable for efficient use in age-related complaints due to the potential increase in the bioavailability of AKBA and its comprehensive effect. These “silent inflammations” occur particularly frequently in joints associated with physical impairment.

Lipo-Tops Boswellin are suitable for a variety of cosmetic applications, such as care of aging skin, oxidative stress, exceptional skin stress and also in medical skin care.

Lipo-Tops Boswellin can be taken orally or applied topically.

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