

Leorex Derma-Ceuticals: Acne Treatment Products

Dr Michael Ziv

Elisha Hospital Haifa Israel

Objectives:

Feasibility testing for treatment of acne sufferers with Leorex Derma-Ceutical products..

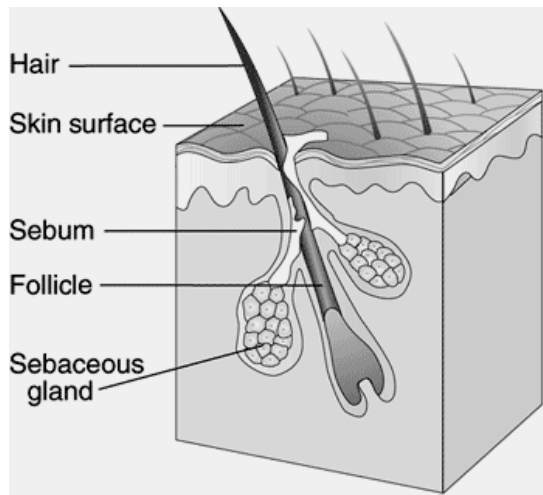
Patients and methods

Both female and male patients were treated, all of whom had no other organic diseases. The only limitation on selection of patients was that only mild acne, up to level 6 was treated. The age range of patients was from young to 30 plus and various skin types were treated.

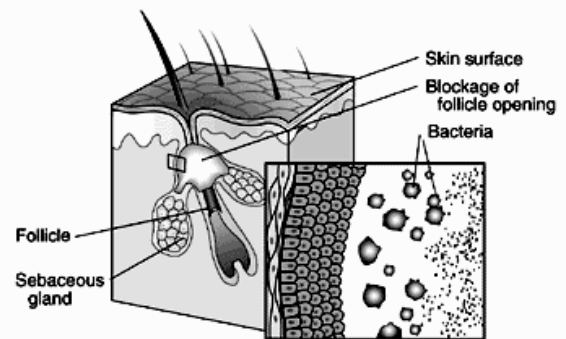
Results and Conclusions: The Leorex acne products based on nano silica physical action show a significant potential in treatment of acne of most types. A typical period in which the condition improves is 30 days and even after the use of the products is interrupted we continued to see further improvement over the next 30 days.

1 What is Acne?

Acne is a disease or disorder resulting from the interaction of hormones on the skin's oil glands, which leads to plugged pores and outbreaks of lesions commonly called pimples or zits. Acne can occur anywhere on the skin. The bumps can be large or small, different colours (red, black, white), tender or dull, hard or soft.



The following diagram, shows a reason for the pore to become blocked. This results in an excess of oil accumulating below the surface of the skin. Bacteria begin to form and grow in this “blocked” oil that would normally rise to the surface of your skin.



As this bacterium multiplies and grows, a small (or large) bump appears on the skin. This is a pimple, a collection of bacteria and trapped oil (or sebum).

2 Types of Acne

There are generally five different types of acne. The first one is the form experienced by the majority of acne sufferers in the world. The others are rare but serious forms that afflict a relatively small percentage of the population.

2.1 *Acne Vulgaris*

This is the most common form of acne. The mild to moderate versions of this type of acne include whiteheads, blackheads, papules, and pustules. Pustules are very common and are what most people think of when they say they have a pimple or zit. It is an inflamed bump with a white or yellow centre.

The severe version of acne vulgaris includes nodules and cysts. Both of these are large blemishes that may (cysts) or may not (nodules) be filled with pus. These are the forms of acne that can lead to scarring and disfigurement.

2.2 *Acne Rosacea*

Acne rosacea appears as a red rash covered intermittently by pimples and blemishes. It occurs more frequently in women than men and requires a specialized treatment routine often prescribed by a doctor.

2.3 *Acne Conglobata*

This is a very severe form of acne vulgaris. It appears as very large, interconnected lesions often dotted with whiteheads and blackheads. It frequently leads to scarring.

2.4 *Acne Fulminans*

Acne fulminans is a form of acne conglobata that appears very suddenly. The acne bumps usually ooze and other problems occur such as aching joints. A

doctor will normally prescribe Accutane for this condition mainly observed in young males.

2.5 *Pyoderma Faciale*

This condition usually afflicts women between the ages of 20 and 40. The acne from pyoderma faciale is very severe and includes nodules, sores, and pustules. If contained, it rarely lasts longer than a year or so.

3 Leorex Derma-Ceuticals – The principle of action

The phenomena of acne occur due to improper drainage of the hair follicle opening. The hair follicle opening range is approximately 50 μ to 100 μ . The opening of any other pore on the skin is substantially smaller than that. In particular the openings of sweat pores are less than 30 μ in diameter.

Leorex Derma-Ceutical products are based on the same technological/scientific platform as Leorex Cosmetic products, but with an essential difference – these products include a significant amount of electrolytes in their structures. Some of the products contain in addition oil ingredients beneficial for skin care, Sea Buckthorn Oil in Vital, and Tea Tree Oil in Bio.

The Structure of the Products used

The compositions of these products practically represent a structure consisting of a huge number of tiny particles, specifically arranged in aggregates, partially interconnected with soluble ions, which in the monophase state contains either shells encapsulating gas and/or vaporized water (an emulsion structure or phase), or it contains shells encapsulating aqueous solution droplets (a powder structure or phase) and in the bi-phase state it contains both emulsion and powder

structures (or phases), represented by the corresponding types of shells.

- The electrolytes play a triple role: in stabilization of specifically designed emulsion or powder structure of the mono-phase cosmetic composition and in formation of the characteristic structure of bi-phase cosmetic composition which comprises simultaneously, side by side, both emulsion and powder structures ;

- in facilitating and enhancing the favorable effects of ions on skin functions and appearance. Consequently, these compositions are highly effective as skin cleansers that remove dead cells and toxins from the skin, nourishes and polishes, and in many cases, repairs damage to skin functions and appearance originated from the accumulation of dead cells and/or toxins, and

- in creating a “smart” buffered pH hypertonic media.

The Biophysical Action – Bio Stimulation

The electrolytes present in the composition of present invention, play an important role in stimulating biological processes leading to renewal and/or recovery of damaged skin functions and/or appearance. The ions derived from the electrolyte, are involved with, and enhance a wide range of, biological processes associated with the recovery of damaged skin, such as restoring capillary blood flow, cleansing, reinforcing and self-healing. In addition, said ions are associated with other skin care activities, such as:

- Maintaining buffering environment for keeping unchanged the desired pH on the treated skin surface.

- Redistributing electrolytes and/or ions between skin pores, capillaries, wounds and regular tissue surface to renew the desired net of typical periodic

electric potential that is characteristic to normal healthy skin.

- Maintaining electric polarization effect which accelerates skin cellular activity.

- Facilitating the transformation of the composition of their structures, which consists of a 3-dimensional colloidal nanoparticles system into a stable, long lasting, self-organised 2-dimensional network tightly anchored to the skin surface. Such transformation occurs when the composition is applied onto the skin surface and it is followed by the release into the skin of valuable skin-care ingredients. It should be mentioned that the ions present in the 2-dimensional network play a key role in controlling the release of skin-care ingredients and nutritional factors and in their penetration into the skin. Thus, the ions derived from the electrolyte play a significant role in the stabilization of the 2-dimensional network that covers and coats the skin. Consequently, they directly affect and control the prolonged release process of components and ingredients from the composition of present invention, when it is applied onto the skin surface.

Resulting Effects

The electrolytes in the compositions are further associated in facilitating the important antioxidant effect of such composition.

The ions released from the electrolyte may restore the electrical balance of damaged skin cells. Said ions may further act in a process of neutralization of free radicals and other harmful materials, such as toxins.

The electrolytes used in the topical composition release ions that play an important role in protecting the **treated skin from bacterial and/or viral attack.** In this respect, these products may be

considered as an anti-viral, anti-bacterial composition.

The hypertonic nature of the products composition, when applied to the acne zone successively, causes a flow of water from the treated skin towards the composition layer removing from the treated acne zone dead cells, toxins and other undesired impurities. It should be noted that this procedure is very effective for opening and cleaning both the blackheads and whiteheads.

The effects of these products result in increasing, enhancing and facilitating one or more of the following biological effects associated with skin care activity. In particular, it was found highly effective in treating oily, acne-prone skin due to its prominent role in elimination of secondary infections, softening of the skin, peeling the contaminated epidermis and improving blood circulation. It is further highly active in preventing or treating seborrhea, in absorbing infected secretions and drying up pimples. Acne is a product of inflamed sebaceous glands forming a plaque of fatty materials that prevent free flow of fluids. When the composition is applied onto the acne region, it provides ions associated-hydrophobic and hydrophilic (when present) nanoparticles that may favorably affect the damaged skin – as follows:

- ◇ Opening and/or removing the plaque of fatty materials from follicles (pores) to allow free flow of sebum oil to the surface. More specifically, in view of the high affinity existing between ions associated hydrophobic nanoparticles provided by the composition of present invention and the fatty materials forming the plaque, the latter are removed from the plaque. As a result, the plaque disintegrates and disappears. Consequently, this operation keeps the follicles (pores) open and prevents the bacterial growth

(resulted in inflammation) and subsequently the development of whiteheads and blackheads on the skin surface.

- ◇ The ions associated-hydrophobic nanoparticles provided by any of the compositions may function in exchanging ions associated with fatty materials, resulting in inflammation suppression.
- ◇ The electrolyte presence reduces the comedones oil's melting point and thus plays a key role in decreasing its viscosity.

Additional Effects

- ◇ Skin reinforcement and rejuvenation:

- Due to the presence of electrolyte in these compositions, it forms a stable layer when applied onto the skin surface. Said layer which consists of a stabilized nanoparticles network is strongly anchored to the skin and may be effective for several hours. The relatively long lasting, stable network structure reinforces the treated skin area, inter alia, by unfolding the folded intracellular capillary vessels resulting in an enhancement and/or increase of blood supply to the treated skin region, thus providing the important rejuvenation effect.

- ◇ Moisturizing skin
- ◇ Antioxidant effect
- ◇ Skin cleaning (cleansers)
- ◇ Soft peeling :

- Soft peeling function of the composition of present invention result in removing impurities, scales and dead cells from treated skin surface, thus eliminating the favored natural environment required for fungi and bacteria growth.

- ◇ Anti-inflammatory effect
- ◇ Soothing of irritated skin:

- The electrolyte which is present in the composition of present invention provides ions that upon application of the composition onto the skin surface produce a net of electric potentials causing the skin surface nerves to reduce their sensitivity. At the same time, some anti-inflammatory agents such as, Sea Buckthorn Oil (in Vital) and/or Tea Tree Oil (in Bio), are slowly released to provide long lasting skin soothing and anti-irritation effects. Thus, the composition of present invention when applied onto the skin surface produce a thin coating layer (which may be invisible, if so desired) which functions as a bandage having, inter alia, skin soothing and anti-irritation properties.

◇ Anti-ageing effect :

- The anti-oxidation activity of the composition of present invention, as well as its function in deactivation of free radicals plays a critical role in forming a prominent anti-ageing effect. More specifically, the composition found highly effective in removing from the treated skin zone dead cells, free radicals, toxins and other impurities all of which have an ageing effect.

It should be emphasized that the Leorex Derma-Ceuticals may be used for restoring the natural body healing resources in a procedure of skin treatment following disorders such as, crankier scores; hives; picking; rosacea; scratching; shingles; warts; burns; dermatoses; itching and cholestasis.

Summary of the Leorex Derma-Ceutical Products Performance Effects:

- ◇ Opening the glands passages
- ◇ Highly efficient skin and passages cleansing

- ◇ Protection from environmental and bacteria contamination of affected area
- ◇ Instant halt of inflammation factors by extensive removal of irritants and pollutants causing the inflammation
- ◇ Prevention of acne induced scars
- ◇ All these in a single product

4 Final Test Results

4.1 Patient Questionnaire Results

- Leorex Pure and Leorex Vital Treatment of Acne Disorders

Questions

- 1 Tests were performed with 20 subjects with various severities of acne.
- 2 Subjects were asked the following five questions.
 - a) Procedures of Leorex application to skin was:

Sensation	Grade
Very unpleasant	1
Unpleasant	2
Neutral	3
Pleasant	4
Very Pleasant	5

- b) Aroma of Leorex Vital and/or Leorex Pure was:

Aroma	Grade
Very unpleasant	1
Unpleasant	2
Neutral	3
Pleasant	4
Very Pleasant	5

- c) Efficiency against acne disorders:

Efficacy	Grade
Very low	1
Low	2
Medium	3
High	4
Very High	5

d) Overall Products Estimation

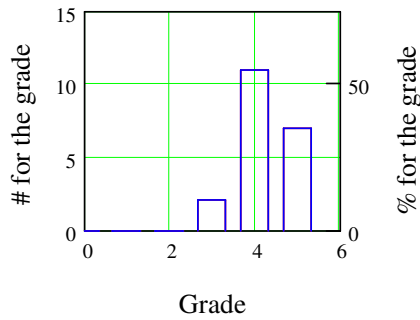
Estimation	Grade
Very low	1
Low	2
Medium	3
High	4
Very High	5

Answers

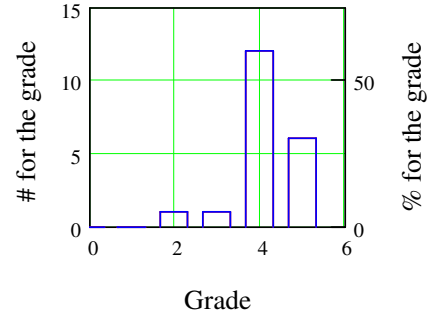
Question A		Question B		Question C		Question D	
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Distribution of Answers

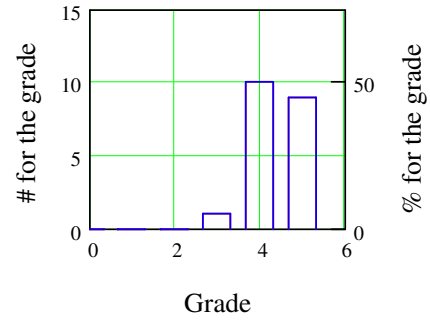
Question A



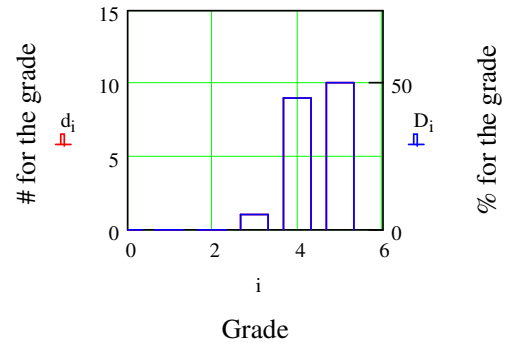
Question B



Question C



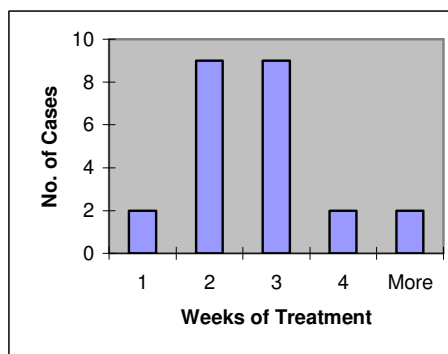
Question D



Acne Symptoms Dynamics

Pustules Dynamics Test Results Summary

Patient and sex	Age	Pustules Location	# of Pustules		Treatment Period weeks
			Bef-ore	Af-ter	
1F	14	Face	30	12	3
1F	14	Back	10	0	4
2F	18	Face	15	1	4
3F	25	Face	10	3	3
4F	18	Face	10	1	1
5F	29	Face	4	0	2
6M	15	Face	20	8	2
7F	41	Face	8	1	2
8M	34	Face	10	1	2
9F	28	Face	18	1	2
10F	32	Face	19	2	5
11F	18	Face	9	0	3
11F	18	Back	18	2	2
12M	16	Face	9	0	3
13M	17	Face	16	3	1
14M	17	Face	28	5	5
15F	22	Face	15	7	3
16F	22	Face	6	1	2
17M	15	Face	15	3	3
17M	15	Face	10	1	3
18F	17	Face	11	2	2
19F	15	Face	8	2	2
21F	18	Face	8	2	3
21F	18	Back	5	0	3

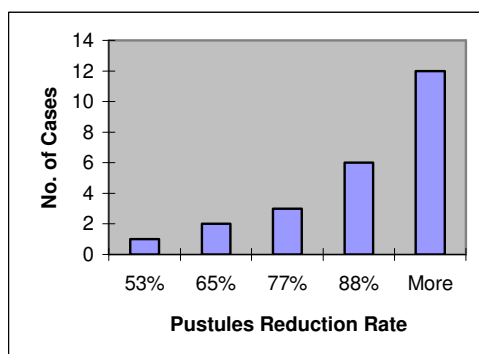


Good Treatment Practice (GTP) for Dermatologists/Cosmetologist

It is common knowledge, that the skin characteristics and skin diseases have an enormous number of combinations, which can be classified into number of categories and treatment schemes. Therefore, the above recommendations for combined treatments should be considered as basic general-type approaches to the treatment process carried out by professionals only. Individual product usage by patients “at home” is recommended. Nevertheless, some general recommendations have been given to enhance the Leorex treatment scheme.

1 During the treatment patients avoided using Cosmetic and Make-up products containing the following ingredients, which are known as acne worsening components (see the product label) :

- Isopropyl Isosterate
- Butyl Stereate
- Myristyl Myristate
- Isopropyl Palmitate
- Isocetyl Palmitate
- Decyl Oleate
- Isosteryl Neopentanoate
- Octyl Palmitate
- Octyl Stearate
- Iodoptopyl Lanolate
- Acetol Acetulan
- Amberate P
- Crude coal tar



- Lanosterin
- Laugogene
- Sterolan
- PG 2 Myristyl Propionate
- Acetylated Lanolin
- Ethylated Lanolin

2 Reduce expose to sun.

Sometimes, acne sufferers feel that their acne improves in the summer, leading to the belief that the sun has a modifying effect. Typically, patients experiencing improvement after exposure to sun are those who are in Northern countries with mild climate and with very limited dose of the sun exposure. The medical fact though, is that high-dose sun exposures increases oil production, which is why people tend to have oilier skin in the summer. It is especially crucial for hot, humid climate zones. In addition to common skin damage caused by UV, there is an additional factor of photo-chemical decomposition of sweat and sebum on the skin. Products of this decomposition irritate and are inflammatory. This, combined with the “optimal” climate for bacteria growth, obviously worsens the disease state. Despite our recommendation, should the patient be exposed to the sun then,:

- Sun block application if within 2-3 hours after Leorex Derma-Ceutical treatment
- Leorex HNWB, Leorex Daycare of Leorex Daycare Plus procedure followed by Sun-block application.

3 Oily, Comedones Affected Skin – Use Leorex Pure. Wash with hot water the comedones affected area to be treated to increase the size of passages of sebaceous glands and to “soften” the sebum in the plaque. In a case of open pustules (purulent area), it is recommended washing with warm (not hot) water.

4 Washing the treated comedones affected area after the procedure with hot water, increases comedone removal by Leorex. In case of open pustules (purulent area), we recommend washing with warm (not hot) water.

5 Another way to increase comedones (not for purulent area) cleansing is sequential hot-cold washing the area, for example 1 minute hot water, 1 minute cold water – wash 3 times.

6. Comedones cleansing effect – comedones removal can be even more enhanced by pre and post vapor treatment or sauna (not recommended for treatment of purulent area/pustules).

7 Dermatologist and cosmetologists should be encouraged to try combining treatment schemes. With accumulating experience in Leorex products use, it will be much easier to evaluate which combination and treatment scheme is optimal for a certain case and skin condition. For example, use the following combinations of Leorex derma-ceuticals :

- ◇ Stubborn Pustulous purulent face and neck areas and other non-oily acne affect areas. Night-treatment scheme.

- apply Leorex Vital especially to areas affected by pustules zones

- Dust away surplus powder when the applied layer dries

- Apply Leorex Bio all over the face

- Dust away surplus powder when the applied layer dries

Other stubborn oily and pustulous/purulent body area. Night-treatment scheme

- Apply Leorex Vital especially to areas affected by pustules zones

- Dust away surplus powder when the applied layer dries

- Apply Leorex Pure all over area

- Dust away surplus powder when the applied layer dries.

For an extremely oily skin the use of Leorex HNWB every morning in addition to the acne treatment is suggested.

8 Leorex treatment (being based on a physical action) is compatible with other types of treatment and can in our view can be efficiently combined with the laser anti-acne treatment or with system-level drugs treatments, for example R-Accutane. Combined treatment has a synergetic effect and is extremely efficient, especially for sever acne cases.

5 Conclusions

Leorex derma-cosmetics for acne treatment currently consist of three formulations :

- Leorex Pure
- Leorex Vital
- Leorex Bio

Each of these products has been developed to fit the needs of the skin at different stages of acne and, correspondingly, different stages of the treatment.

- **After treatment maintenance**

Use Leorex Bio – 2-4 times a week

- **Light State: white and backheads**

At this stage the only treatment needed is deep cleansing of comedones (white and black heads) to prevent acne-to-be state. Using Leorex Pure 1-2 times a weeks with

everyday use of Leorex Bio solves the problem. Treatment 1-3 weeks.

- **Mild State: papules, small red bumps**

Everyday use of Leorex Pure. After 1-3 weeks it is anticipated a reduction to the Light State will occur, and correspondingly the treatment moves to that recommended for the Light state.

- **Moderate State: Pustules – full-blown pimples with ripe, yellow centres**

At this stage Leorex Vital should be used every day for 2-4 weeks, as this is usually still located in the superficial layers of the skin there is a good chance that Leorex treatment will help to heal without leaving any permanent scars. As the disease severity gets to the lower states, the treatment has to be switched to one (see previous) corresponding to the actual disease state.

- **Severe Acne: Scars, nodules and cysts in the deeper layers of the skin**

Even at these stages Leorex Vital can help, but the treatment and its procedures have to be performed under tight dermatologist supervision.

After reduction of the harsh symptoms the treatment can be performed to the actual severity stage.

State	Signs	Product	Treatment Frequency	Period
Maintenance		Bio	2-4 uses a week	constant
Light	Whiteblack heads, comedones	Pure Bio	1-2 uses week Everyday	1-3 weeks
Mild	Papules small red bumps	Pure	Everyday	1-3 weeks
Moderate	Pustules	Vital	Everyday	2-4 weeks
Severe	Scars, nodules and cysts	Vital	Everyday	To be defined by doctor

