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**A new method of treatment for skin basal cell carcinoma and squamous cell carcinoma**

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**INTRODUCTION** .Advances in dermato-oncology depend upon communication and dissemination of new information among specialists.

This report is devoted to significant and important problems of contemporary dermato-oncology: effective treatment of

- a) Basal Cell Carcinoma (BCC)
- b) Squamous Cell Carcinoma (SCC)

**Basal Cell Carcinoma (BCC)** is the most common malignant nonmelanoma tumor of the skin (80% of all skin cancers). It is also the most common cancer in humans in some countries. Frequency of BCC has been increased in many countries around the world.

The American Cancer Society reports that it is the most common cancer in the United States. Approximately 1 million new cases diagnosed in a year and more than 10,000 deaths occur (2% of all cancer deaths).

Because of its high frequency, the disease has been accepted to be a public issue. Despite low mortality rates and rare occurrence of metastases, the tumor may be locally invasive and relapse after treatment, causing significant morbidity.

BCC is seen in all skin types, but dark-skinned individuals are rarely affected, and more common in fair-skinned individuals (type 1 or type 2 skin types). Among to gender men are effected twice as women. BCC is rarely found in patients younger than 40 years.

Almost all BCCs occur in parts of body excessively exposed to UV-radiation especially the face, ears, neck, scalp, shoulders, and back.

Basal Cell Carcinoma patients often present with a slowly growing, non-healing sore of varying duration. Mild trauma initially can cause bleeding.

The early tumors are commonly small, translucent or pearly, raised and rounded areas located on a few dilated, superficial vessels. There are six subtypes of BCC that include nodular, superficial, pigmented, morpheaform, cystic and fibroepithelioma.

For BCC the goal of treatment is elimination of the tumor with maximal preservation of function and physical apperance according to the 2011 National Comprehensive Cancer Network clinical practice guidelines in oncology. The treatment methods include: Mohs Micrographic Surgery,

Standard surgical excision, Chemotherapy, Curettage and desiccation, Cryosurgery, Radiatin therapy, Photodynamic therapy and Immunotherapy. Most of the mentioned above treatments are performed in hospital accommodations and are expensive.

Among topical treatment approaches are: Imiquimod cream (complete histological clearance from 52% to 87% depending on lesion size and depth of infiltration), topical 5-Fluorouracil (90% clearance rate with 21% 5-year recurrence rate). The topical treatments are considered not satisfactory effective and need further unification.

All the above-mentioned facts prove the necessity for continuation of scientific research to develop simple, cheap, effective and free of side effects method of treatment for Basal Call Carcinoma.

**Squamous Cell Carcinoma (SCC)** is the second-most common cancer of the skin (after basal cell carcinoma but more common than melanoma. It usually occurs in areas exposed to the sun. Sunlight exposure and immunosuppression are risk factors for SCC of the skin, with chronic sun exposure being the strongest environmental risk factor. There is a risk of metastasis starting more than 10 years after diagnosable appearance of squamous cell carcinoma, but the risk is low, though much higher than with basal cell carcinoma. Squamous cell cancers of the lip and ears have high rates of local recurrence and distant metastasis (20–50%). Squamous cell cancers of the skin in individuals on immunotherapy or suffering from lymphoproliferative disorders (i.e. leukemia) tend to be much more aggressive, regardless of their location.

SCCs represent about 20% of the non-melanoma skin cancers, but due to their more obvious nature and growth rates, they represent 90% of all head and neck cancers that are initially presented. The vast majority of SCCs are those of the skin, and like all skin cancers, are the result of ultraviolet exposure. SCCs usually occur on portions of the body commonly exposed to the Sun; the face, ears, neck, hands, or arm. The main symptom is a growing bump that may have a rough, scaly surface and flat reddish patches. Unlike basal cell carcinomas, SCCs carry a significant risk of metastasis, often spreading to the lymph nodes, and are thus more dangerous. During its earliest stages, it is sometimes known as Bowen's disease.

An estimated 700,000 cases of SCC are diagnosed each year in the US, resulting in approximately 2,500 deaths.

Squamous cell carcinoma are generally treated by surgical excision or Mohs surgery. Non-surgical options for the treatment of cutaneous SCC include topical chemotherapy, topical immune response modifiers, photodynamic

therapy (PDT), radiotherapy, and systemic chemotherapy. The use of topical therapy, such as Imiquimod cream and PDT is generally limited to premalignant and in situ lesions. Radiation therapy is a primary treatment option for patients in whom surgery is not feasible and is an adjuvant therapy for those with metastatic or high-risk cutaneous SCC. At this time, systemic chemotherapy is used exclusively for patients with metastatic disease.

## TREATMENT – GENERAL CONSIDERATIONS

Years of extensive scientific research and clinical studies have led us to the development of complex of various preparations for the treatment of Basal Cell Carcinoma and Squamous Cell Carcinoma.

The treatment solutions are the series of proprietary preparations applied in a controlled accurate manner with a pointed applicator so as to bring the active ingredients into close contact only with affected tissue to be removed, resulting in prompt devitalization limited to the lesion and healing of affected skin.

In general the proposed method is characterized as follows:

1. High efficiency
2. Simplicity and economical attractiveness
3. The absence of side effects and complications
4. The absence of the formation of keloid scars
5. The relative cheapness and high revenue
6. No need for expensive facility set up
7. No need to purchase expensive equipment
8. The relatively short duration of the procedure and the high rotation of patients (in one business day, you can treat 15-20 patients)
9. The stability and reproducibility of the preparations used
10. The mobility of the service and the possibility of creating a network of offices employing this technique
11. The patient feels no discomfort and in 1-2 hours after the procedure can follow the working or common regime (take a shower, use makeup, continue the usual diet, etc.).

## DESCRIPTION OF TREATMENT SOLUTIONS

**Part 1** of the treatment is a multi-component formula that contains proprietary complex of halogenated and polymerized carboxylic acids incorporated into the primary liquid delivery system and the certain complex of microelements.

Mechanism of action of Part 1 is based largely on oxidation and other chemical reactions of carboxylic acids and their intermediate reduction products used in balanced ratios in relatively low concentrations.

Part 1 shows more rapid and effective destruction of skin lesion to which it is applied in the form of in-vivo fixation with the basic architecture of the lesion preserved rather than dissolution of the hydrolysis of protein peptide bonds.

This fact may contribute to the lesser damage of surrounding normal skin tissue because its aggressive potential is more effectively neutralized or its penetration into surrounding normal tissue is more effectively blocked.

The formulation of Part 1 is a subject of provisional and non-provisional patent application. At present time it is kept as a company's trade secret.

**Part 2** is a technologically advanced formula of Lipid Conjugated Microelements. This part is a result of complex technological process of incorporation of Bivalent-Negative Microelement into the double bonds of lipid media taken in a certain proportions.

The technology of this part is a subject of provisional and non-provisional patent application. It requires simultaneous application and careful control of complex of factors like concentration and sequence of addition of active ingredients, a certain level of oxygenation, maintenance of specific narrow range of temperature, pH, energy of share mixing, cool-down cycles etc.

**Part 3** is a liquid formula that consists of the following major parts:

- Anti-microbial part contains six anti-microbial agents, combined into one discrete bacteriostatic/bacteriolytic complex. It ensures the strong anti-microbial effect, since ingredients act simultaneously on the pathogenic strains of microorganisms through the following mechanisms:

- a) The achievement of bactericidal effect due to the action on the bacterial cellular wall
  - b) Inhibition of microbial growth through action on bacterial respiration and/or metabolism
  - c) Destruction of virulent microorganisms by affecting the system of bacterial replication
- Detoxifying part contains four specific antioxidant compounds. It ensures purification of the skin from bacterial debris and neutralization of bacterial toxins which together with microorganisms themselves can manifest the expressed destructive effect. At the same time active ingredients composing this part considerably increase the capability of the skin for self-healing due to the correction of cellular metabolism, strengthening of skin microcirculation and increase of its immunoresistance.
- Barrier part contains substances that form the organic barrier on the surface of the skin. That prevents penetration and direct contact of biological agents with the skin. Barrier “film” does not disrupt skin respiration and its basic functions, does not cause irritation and easily washes off by water.

## APPLICATION OF TREATMENT SOLUTIONS

- 1) Clean and degrease the lesion and the surrounding skin with alcohol or ether.
- 2) With Q-tip apply small amount of petrolatum ointment to the skin around the lesion to protect the skin from possible destructive effect of the treatment composition.
- 3) Carefully apply the composition strictly to the skin lesion by means of special capillary applicator. The composition is applied to the lesion just in quantity 0.1-0.25 ml. Moisten the surface of treated lesion once. The number of cycles of applications is determined by the specialist performing procedure who passed the appropriate training. In 10-20 seconds after the first application the lesion begins to acquire a whitish-grayish color and

becomes dense. After 2-3 minutes the delivered solution penetrates the lesion and a color change develops reflecting intra-vital fixation of the lesion. The lesion darkens step-by-step from gray to dark gray.

In some cases (especially at small sizes of lesions) one cycle is sufficient to initiate the devitalization of the lesion. The number of applications, the time and intensity of the discoloration are dependent on the type, size and pigmentation of the lesion.

- 4) No more than 5-6 lesions should be treated at one time and their total area should not be more than 4.0 square cm.
- 5) The treatment is essentially painless except for mild burning sensation, which can last 10-15 minutes.
- 6) A mild transient erythema of the surrounding skin and development of blanched (vasoconstricted) ring is expected in 5-10 minutes and requires no particular treatment.
- 7) In a few days the lesion becomes a desiccated dark brown scab and appears mummified. If mummification is judged to be unsatisfactory in several days the procedure may be repeated.
- 8) Duration of scab formation and its rejection depends on several factors such as the age of the patient, localization of tumor, common skin condition and the body in general, the presence of concomitant diseases (e.g. diabetes).
- 9) In general, this period lasts from 7 to 10 days. After the rejection of the scab on the spot of intervention remains unobtrusive pinkish spot which in the next 20-30 days covered by normal epidermis.

- 10) In compliance with proper procedure, scar tissue usually is not appearing. In case of infection application of antibiotic ointment is desirable.
- 11) As soon as mummification of the lesion begins to form, start Part 2 solution applications over the affected area. 2-3 applications per day are enough to ensure the anti-cancerous effect. Continue Part 2 applications during 15-20 days. Part 2 composition does not irritate the area of intervention and supports scab formation.
- 12) After scab rejection start to apply Part 3 solution. Part 3 provides anti-inflammatory effect and helps to quickly restore skin tissue. Continue applications of Part 3 during 5-7 days.

## **EFFICACY OF TREATMENT**

The goal of this clinical observation was to determine the effectiveness of a new treatment in patients with Basal Cell Carcinoma, and Squamous Cell Carcinoma and Common Viral Warts.

## **STUDY MATERIAL**

This study material summarizes treatment results of 33 patients that agree to participate in this study during 2007 – 2015 year period

Two (2) groups of patients were analyzed.

The First Group (I) comprised of 24 patients with Basal Cell Carcinoma, The Second Group (II) – 9 patients with Squamous Cell Carcinoma and Distribution of patients by skin lesion localization is shown in Table 1.

Table 1.

Distribution of patients by skin lesion localization

Localization of Lesion	Basal Cell Carcinoma	Squamous Cell Carcinoma	Total
Scalp	0	2	2
Forehead	5	2	7
Chin	3	0	3
Neck	7	1	8
Arms	2	1	3
Chest	7	3	10
Total	24	9	33

As shown in Table 1 the most prevailed localizations among patient with Basal Cell Carcinoma were forehead area, chest area, and neck, in patients with Squamous Cell Carcinoma – forehead, and neck. All these areas are extensively exposed to UVA and UVB radiation, so it is not surprising that skin cancer and other lesions developed at these locations. Table 2 shows distribution of patients by skin lesion size:

Table 2. Distribution of patients by skin lesion size

Size of Skin Lesion	Basal Cell Carcinoma	Squamous Cell Carcinoma	Total
2-5 mm	2	1	3
6-10 mm	8	2	10
More than 10 mm	14	6	20
Total	24	9	33

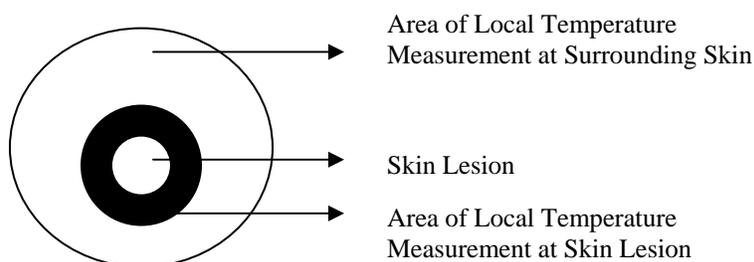
Table 3 shows distribution of patients by clinical manifestations:

Table 3. Distribution of patients by clinical manifestations

Clinical Manifestation	Basal Cell Carcinoma	Squamous Cell	Total
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		Carcinoma	
<b>Assessment of Skin Lesion:</b>			
integrity of skin lesion (cracks, etc.)	24	9	33
existence of inflammation (redness)	8	6	14
existence of hemorrhages	2	1	3
existence of dispigmentation	9	2	11
pain or excessive sensitivity of lesion	8	4	12
<b>Assessment of Surrounding Skin:</b>			
integrity of the surrounding skin	7	3	10
existence of inflammation (redness)	2	2	4
existence of hemorrhages	2	1	3
existence of dispigmentation areas	4	2	6

As an additional diagnostic and treatment effectiveness test we performed the measurements of local temperature in area of skin lesion and surrounding skin with interpretation of values of T°C before the treatment and during the first and second follow-up check-ups (see the Diagram bellow):



△ T°C Before Treatment	△ T°C at First Follow-up	△ T°C at Second Follow-up

## TREATMENT RESULTS

### I) BASAL CELL CARCINOMA

After cleaning and degreasing the lesion and the surrounding skin with alcohol small amount of petrolatum ointment was applied to the skin around the lesion. Part 1 of the treatment was strictly applied to the skin lesion with capillary applicator. After 3 minutes the lesion became whitish and then darkens step-by-step from gray to dark gray. The number of applications, the time and intensity of the discoloration depended on the type, size and pigmentation of the lesion (in average 3 applications). A mild burning sensation lasted about 10-15 minutes. A mild transient erythema of the surrounding skin developed in 10 minutes and lasted approximately 1-1.5 hours. In 2 days the lesions became dark brown and appeared to be mummified. In 3 cases mummification was judged as unsatisfactory and in 2 days the procedure was repeated.

Part 2 of the treatment was applied by patients themselves over the lesion and surrounding skin in 3-4 hours after Part 1 application 3-4 times a day during 10-15 days. Part 3 of the treatment was applied over the affected area after desiccated dark brown scab (mummification) is removed 2 times a day during 7-10 days.

**In all 24 cases of Basal Cell Carcinoma the treatment was effective with full removal of malignant process.**

In data analysis, the special attention was paid to mummified scab shedding features since this factor determines the effectiveness and the length and hence the cost of treatment. Table 4 shows day of Basal Cell Carcinoma mummified scab shedding depending on lesion location.

Table 4.

Basal Cell Carcinoma mummified scab shedding depending on lesion location.

Localization	Mummified Scab Shedding (days)							Total
	8	9	10	11	12	13	14	
Forehead	1	1	1	2	0	0	0	5
Chin	0	0	0	1	2	0	0	3
Neck	0	1	1	1	2	2	0	7
Arms	0	0	0	1	1	0	0	2
Chest	0	0	1	1	2	2	1	7

Table 5 shows day of Basal Cell Carcinoma mummified scab shedding depending on lesion size.

Table 5. Basal Cell Carcinoma mummified scab shedding depending on lesion size.

Size of Skin Lesion	Mummified Scab Shedding (days)							Total
	8	9	10	11	12	13	14	
2-5 mm	0	0	0	1	1	0	0	2
6-10 mm	4	11	15	61	44	12	7	159
More than 10 mm	0	0	1	2	2	2	1	8
Total	1	1	2	3	3	2	2	14

As we can see in Tables 4 and 5 the pick of Mummified Scab Shedding Time in Basal Cell Carcinoma in most cases (67.4%) was between days 11 and 12.

The mummified scab shedding features depend on numerous of factors:

- a) size of lesion - the larger the tumor size the longer the Mummified Scab Shedding Time. For example tumors from 1 to 5 mm shed approximately in 8 – 10 days while tumors more than 10 mm shed in average in 11 – 14 days,
- b) depth of growth into the skin – the deeper the growth of tumor, the longer is time of Mummified Scab Shedding,
- c) intensity of local blood circulation,
- d) grade of accompanying reactive inflammation etc.

In general, the Mummified Scab shed spontaneously without any pain or bleeding. Localization of the skin lesion did not appear to influence a shedding time. After-procedure inflammation was rare. Part 2 of the treatment was used by majority of patients during 3-5 days and did not cause any skin sensitivity reaction. Part 3 of the treatment was used according to

recommendations during 7-10 days..Table 6 shows the dynamics of T°C before the treatment and during two following c  
 As shown in Table 6 the initial diagnostic T°C fluctuated in range 1.5-2.5 is an indicator of malignant growth process. After treatment T°C gradually decreased up to 1.0-1.3 and 0.5-0.7 indicating to normal healing process. In two (2) cases of inflammation developed in one day after treatment procedure the T°C increased up to 3,5 which was the clear indication of inflammation and required longer (up to 10 days) use of Part 3 treatment solution.

**Basal Cell Carcinoma Case Study:**

Patient “P.M.”, 62 years old man, approached us with already established and morphologically proved diagnose of Basal Cell Carcinoma at chest area with the following data:

Table 6.

<b>LESION 1</b>		
Location:	Chest	
Size:	50x50 mm	
Lesion color:	Pinc-Brown	
Lesion cracks:	Yes	
Lesion ulceration:	Yes	
Lesion inflammation:	Aseptic Inflammation	
Lesion hemorrhage:	Yes	
Lesion maceration:	Yes	
Lesion pigmentation:		No
Lesion pain:	Moderate	
Surrounding Skin:	Clear	



**Picture 1.**

Before Treatment.

There is a big, 50x50 mm necrotized tumor with spots of hemorrhages at chest area.

Moderate inflammatory reaction of surrounding skin is clearly visualized.



**Picture 2.**

3 minutes after the first application of Part 1 Treatment Solution

During in-vivo fixation the lesion became whitish.

There is the reaction of the surrounding skin as a transient redness.

Moderate burning sensation was noted.



**Picture 3.**

10 minutes after first application of Part 1 Treatment Solution .

During in-vivo fixation the lesion became more whitish.

The reaction of the surrounding skin (redness) is more prominent.

Burning sensation continues.



**Picture 4.**

20 minutes after second application of Part 1 Solution.

In-vivo fixation (the lesion became grayish).

The reaction of the surrounding skin shows a more intense redness.

Burning sensation continues.



**Picture 5.**

45 minutes after second application of Part 1 Solution.  
In-vivo fixation - the lesion became uneven.  
The reaction of the surrounding skin as an intensive swelling and redness.  
Burning sensation is less intensive



**Picture 6.**

6 Hours After Treatment  
In-vivo fixation (the uneven brownish mummified scab started to form).  
The reaction of the surrounding skin is less intensive.  
There is minor swelling around the



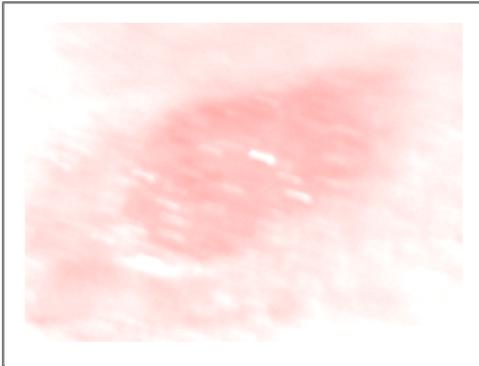
**Picture 7.**

3 Days After Treatment  
In-vivo fixation - the uneven brownish mummified scab completely formed.  
The reaction of the surrounding skin is minimal.  
Surrounding swelling is absent.  
There is no pain in affected area



**Picture 8.**

10 Days After Treatment  
In-vivo fixation - the brownish mummified scab decreased in size and started to shed.  
A granulation of new tissue is noticed.  
The reaction of the surrounding skin is minimal.  
Surrounding swelling is absent.  
There is no pain in affected area.



**Picture 9.**  
 30 Days After Treatment  
 The mummified scab shed completely.  
 Soft, pinkish new skin is growing.  
 There is no reaction of the surrounding skin.

The healing process is in progress.

## II) SQUAMOUS CELL CARCINOMA

The treatment procedure for Squamous Cell Carcinoma resembled the one used for Basal Cell Carcinoma lesions.

In all 9 cases of Squamous Cell Carcinoma the treatment was effective with full removal of malignant process.

Table 7 shows day of Squamous Cell Carcinoma mummified scab shedding depending on lesion location.

Table 7.

Squamous Cell Carcinoma mummified scab shedding depending on lesion location.

Localization	Mummified Scab Shedding (days)					Total
	10	11	12	13	14	
Forehead	0	0	0	1	1	2
Scalp	0	0	1	1	0	2
Neck	0	0	0	1	0	1
Arms	0	1	0	0	0	1

Chest	1	1	7	3	2	3
Total	1	1	1	0	0	9

Table 8 shows day of Squamous Cell Carcinoma mummified scab shedding depending on lesion size.

Size of Skin Lesion	Mummified Scab Shedding (days)						Total
	9	10	11	12	13	14	
2-5 mm	0	0	1	0	0	0	1
6-10 mm	0	0	0	1	1	0	2
More than 10 mm	0	1	1	1	2	1	6
Total	0	1	2	2	3	1	9

Dynamics of mummified scab shedding in Squamous Cell Carcinoma and the dynamics of T°C was approximately the same as in Basal Cell Carcinoma.

**Squamous Cell Carcinoma Case Study:**

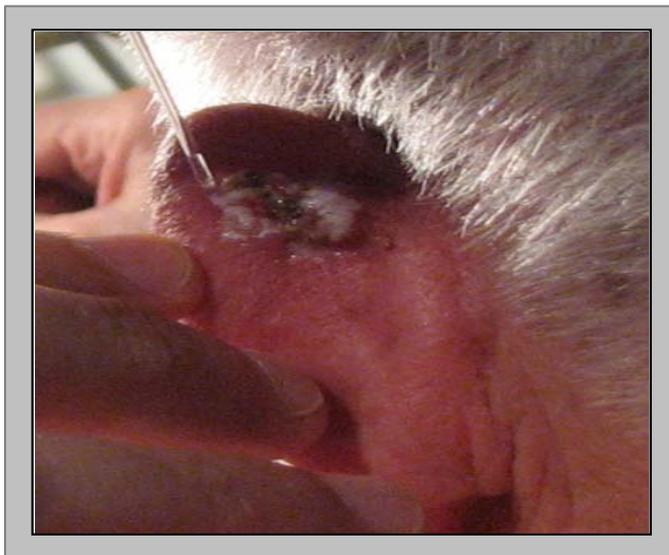
Patient “S.Y.”, 78 years old man, approached us with already established and morphologically proved diagnose of Squamous Cell Carcinoma at right ear area with the following data:

<b>LESION 1</b>	Moderat	
Location:	Right Ear	
Size:	20x30 mm	
Surrounding Skin:	Clear	
Lesion color:	Pinc-Brown	
Lesion cracks:	Yes	
Lesion ulceration:	Yes	
Lesion inflammation:	Aseptic Inflammation	
Lesion hemorrhage:	Yes	
Lesion maceration:	Yes	
Lesion pigmentation:		No

Lesion $\Delta$ T°C	2.3		
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**Picture 1.**  
Initially – Before Treatment



**Picture 2.**  
3 minutes after first application.  
Part 1 Treatment Solution was applied with glass capillary.  
During in-vivo fixation the lesion became whitish.  
It was the reaction of the surrounding skin as a transient redness.  
Slight burning sensation was noted.



**Picture 3.**  
6 Days After Treatment  
The mummified scab became brown.  
The reaction of the surrounding skin was not noticed.



**Picture 4.**

12 Days After Treatment

The mummified scab shed off.

The size of lesion decreased up to 80%.

The reaction of the surrounding skin was not noticed.

There are no signs of inflammation.

No pain.



**Picture 5.**

30 Days After Treatment

The mummified scab completely shed off.

No signs of tumor.

No pain.

The soft small scab was formed.

We were able to fulfill 3, 6 and 12 month follow-up in all 24 patients with Basal Cell Carcinoma, and all 9 patients with Squamous Cell Carcinoma (altogether 33 patients). The condition of treated area in all follow-up patients was rated as 'Normal'. Recurrence of skin tumor during 1-year period was not diagnosed.

The Mummified Scab Shedding in Basal Cell Carcinoma and Squamous Cell Carcinoma takes more days than in Common Viral Warts – 11-13 days and 7 days respectively. We explain this with considerably more aggressive process occurring in the skin in Basal Cell Carcinoma and Squamous Cell Carcinoma that takes approximately twice more time for tissue regeneration and restoration of skin cell metabolism and skin blood circulation.

**Conclusion:** The studied method is a new trend and a significant contribution to the outpatient treatment of skin malignant tumors, in connection with:

- 100% efficiency,
- affordability and simplicity,
- relatively low cost and
- the possibility of using in a doctor's office.

ა.სეპუერი, ა.პიანა, დ.ტაბიანი

კანის ბაზალურ-ბრტყელუჯრედოვანი კიბოს მკურნალობის ახალი მეთოდი.

ნიუ-იორკი, აშშ

შექმნილია კანის ბაზალურ-უჯრედოვანი კიბოს მკურნალობის ორგინალური მეთოდი. გადმოცემულია ამ მეთოდის არსი, აგრეთვე მისი გამოყენების ჩვენებები და უპირატესობა. მითითებულია, რომ ეს არის მარტივი, იაფი და ეფექტური მეთოდი. გარკვეული მოდიფიცირების შემდეგ ის შესაძლებელია გამოყენებული იქნეს კრიტიკულ მედიცინაშიც, კანის იმ მრავალფეროვანი გართულებების

სამკურნალოდ, რომლებიც საკმაოდ ხშირად აღენიშნებათ  
კრიტიკულ ავადმყოფებს.