DERMA

plasma care®

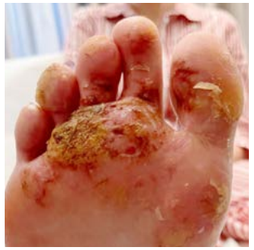
Cold plasma therapy

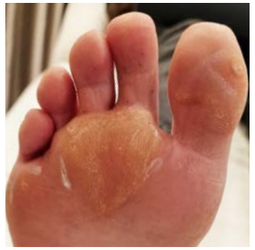
CAP for treatment of bacterial/fungal skin infections

SAVE AND RELIABLE

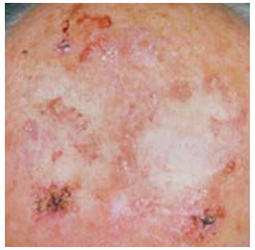
SUITABLE FOR PATIENTS WITH PACEMAKERS

PORTABLE AND EASY-TO-USE

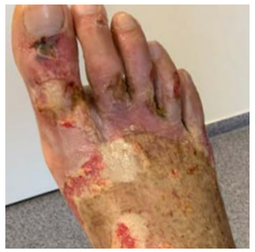


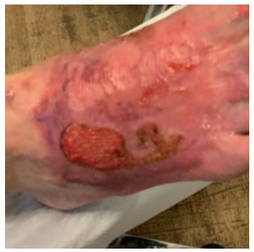


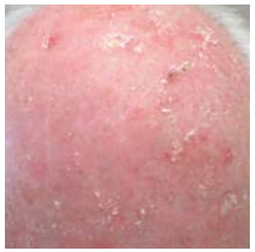
NAIL MYCOSIS
initial situation &
end of treatment

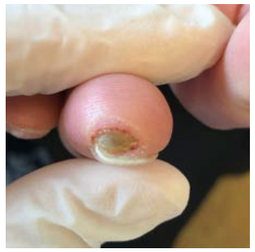


BURNS
initial situation & after
5 CAP treatments





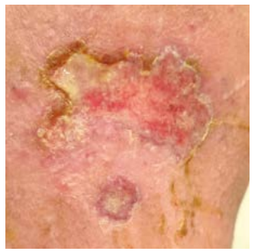


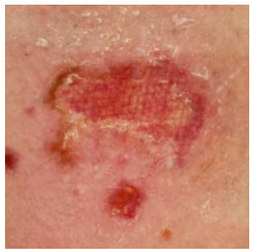


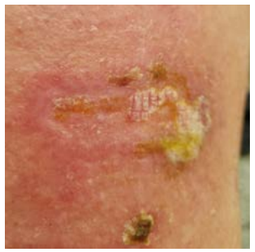
FINGERTIP NECROSIS
initial situation &
end of treatment

ACTINIC KERATOSIS
initial situation &
end of treatment

LEG ULCER
initial situation &
end of treatment







plasma derma care –
new chances in dermatology

The plasma derma care is a mobile medical device for the treatment of acute and chronic bacterial or fungal skin diseases or certain skin dysplasias/neoplasias such as actinic keratosis.

This portable device generates cold atmospheric plasma (CAP) by supplying high energy to the ambient air. CAP effectively inactivates bacteria (independent of type and level of antibiotic resistance) and human pathogenic fungi.

Furthermore, CAP has other positive effects that promote healing of dermatological diseases – e.g. an antipruritic (anti-itch)[1] effect. By stimulating the immune system locally, CAP is potentially effective for treatment of precancerous skin, too.[2,3]

Most dermatological diseases are caused by pathogens such as bacteria and fungi or are associated with those. Patients often suffer from a high level of psychological strain. Apart from this, various pathogens can also lead to a more severe course of disease.
Thus, early and effective treatment of bacterial/fungal skin diseases is extremely important for a successful therapy.

The use of **plasma derma care** provides a completely new dermatological therapy approach for the effective treatment of skin diseases without side effects.

Cover picture shows female patient ▲
with severe atopic dermatitis on both hands and wrists.

Our vision of cold plasma in medicine

Terraplasma medical GmbH looks back on many years of experience in the development of plasma technologies and their application in various fields.

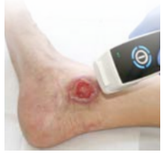
As a spin-off of Max Planck Institute for Extraterrestrial Physics headed by Prof. Dr. Dr. Gregor Morfill and Dr. Julia Zimmermann, **terraplasma GmbH** was founded in 2011.
Terraplasma GmbH still focuses on the development of various plasma technologies for applications in medical technology, hygiene and air pollution control.
In 2016, **terraplasma medical GmbH** was founded as an independent subsidiary which since has developed and researched medical devices based on plasma technology.
The **plasma derma care®** uses cold atmospheric plasma designed by terraplasma medical GmbH and already applied in various medical devices to inactivate microorganisms (bacteria incl. MRE and human pathogenic fungi).

For years, plasma technology has already been established in wound treatment through the use of **plasma care®**.

Apart from this, another medical device – the **plasma intensive care®** – was pre-launched at the beginning of 2021 for treatment of ventilated COVID-19 patients.

The main goal of terraplasma medical GmbH is to convince the medical world of the innovative and promising plasma technology and to support patients in activating the body's own healing processes through a modern therapeutic approach - and this against the background of increasing antibiotic resistances and allergies.

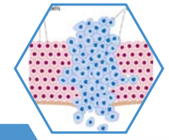
DERMA plasma care®



plasma care®

DERMA plasma care®

Oncology:
Early stage tumor treatment



2016 terraplasma MEDICAL

2019

2020 INTENSIVE* plasma care®

*currently in approval process

2021

2022

Dental medicine:
Periodontal treatment

Effects of cold plasma on bacteria and viruses

Cold atmospheric plasma (CAP) is known to have a strong antimicrobial and antiviral effect while preserving human tissues and cells.

The active components (reactive species) generated by CAP can interact with cells in various ways. The effects are physical (e. g. recombination or de-excitation of excited molecules/atoms at the surface) as well as chemical (e. g. hydrogen denaturation by reactions of hydroxyl radicals).

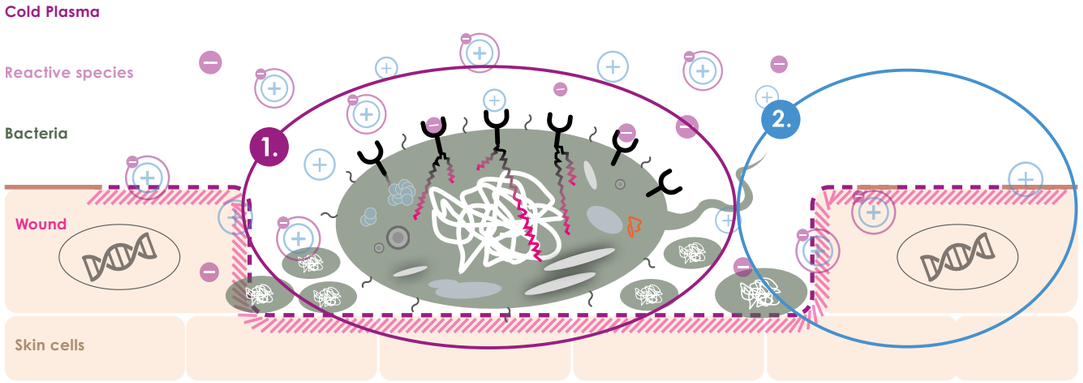
In bacteria (prokaryotic cells) – or more precisely their cellular macro-molecules (including DNA) – a direct destruction takes place.
This effect also applies for bacteria with antibiotic resistance.[4,5,6] Furthermore, an antiviral effect of the reactive oxygen species produced by cold atmospheric plasma has been observed.[7] This is presumably based on a modification of viral proteins leading to the inactivation of the viruses. In eukaryotic cells, such as human cells, DNA is protected by nucleus and its membrane as well as cytological repair mechanisms. In addition, those cells are protected within cell compounds. This means that there is no risk of cell damage.

Quite the opposite, **in human cells a local immune response is triggered and cell growth and division are stimulated**, thus promoting the regeneration of skin or mucous membrane.[8,9,10]
This effect is locally limited to the uppermost cell layer. Among other reasons, this is due to a very short half-life of the reactive species, which will have already completely reacted by interacting with the upper cells or surrounding cell milieu.[11,12]

Cold atmospheric plasma (CAP) does not cause any unspecific cell damage due to its low temperature and therefore is generally suitable for medical application.

1. **INACTIVATION OF BACTERIA + VIRUSES**
CAP interacts with microorganisms (e.g. bacteria + viruses), inactivates the cell and prevents cell proliferation by destroying the DNA.

2. **ACTIVATION OF (WOUND) HEALING**
Cell separation in healthy cells **is stimulated by CAP.** Subsequent intracellular processes: release of cytokines, activation of angiogenesis and metabolism.



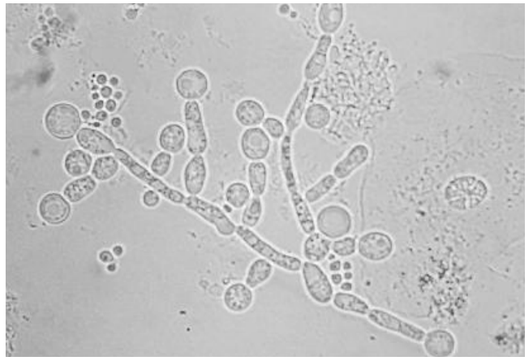
▲ *Figure 3: eeffects of cold plasma*

Effects of cold plasma on fungi

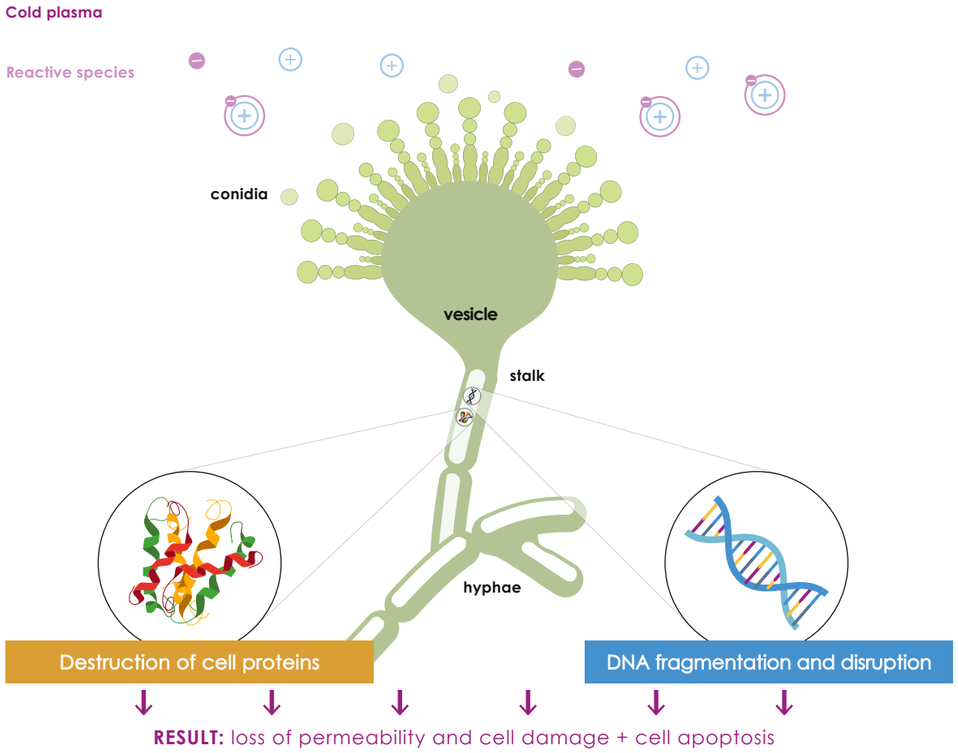
Fungal infections are also a common cause for skin diseases. Some types of fungi, such as Candida albicans, are already naturally present on the skin, but can cause an infection, if the immune system is weakened.

Apart from inactivating bacteria (including multi-drug-resistant pathogens)[13,14,15,16], CAP can also kill fungi.[17,18,19] Like human cells, fungi belong to the eukaryotes, in contrast to bacteria. They thus possess a nucleus in which the DNA is located.
Nevertheless, fungi can be killed by reactive oxygen species (ROS) – a mechanism that is also used by the immune system to fight Candida albicans infections (fig.4).[20]

Treatment with CAP causes deformation of fungal spores, which leads to their rupture, flattening and shrinkage. Also, the DNA within the spores can be destroyed. Reactive oxygen species (ROS) trigger various reactions in fungi. Depending on the dose, these can lead to the oxidation of intracellular membranes and proteins, to structural changes within the cell, and finally to apoptosis (programmed cell death).[21]



▲ Figure 4: Candida albicans under a microscope



▲ Figure 5: effects of CAP on fungi

Recent study results confirm high effectivness

Preclinical evaluations prove the antimicrobial and antifungal effectiveness of the **plasma derma care®** (see table).

Most of the tested microorganisms are resident on our skin and thus are predestined to cause certain infections. The development of perioral dermatitis, for example, is mostly triggered by *fusobacteriales*.[22,23] Acne, on the other hand, is mainly caused by *propionibacterium acnes*.[24] *Staphylococcus aureus* is a highly resistant bacterial strain that causes nosocomial infections[25] and is often identifiable in bacterial superinfections in atopic dermatitis as well as many other skin diseases.[26]

The following table (table 1) clearly reflects the high effectiveness of CAP produced by **plasma derma care** device against human pathogenic bacteria and fungi. On agar, 99.999 % of tested bacteria and of the yeast C. *albicans* were killed within 60 seconds.
Moreover, the **plasma derma care® was effective upon application to biofilms** of *E. faecalis* (99.9 % reduction within 1 minute). Under more life-like conditions in ex vivo models of pig skin and human skin, 69 to 83 % of bacteria were killed within the same period.

Apart from the described studies of effectiveness, **plasma derma care®** has also been thoroughly tested with regard to its safe use and the occurrence of side effects. However, plasma treatments of up to 3 minutes had no impact on vitality, viability or migration behavior of primary fibroblasts and keratinocytes. Nor did "normal" or "sensitive" skin from healthy donor biopsies display any histological or pro-apoptotic changes. Mutagenicity studies (HGPRT test using V79 cells) provided no evidence of any genotoxic potential of CAP, too.
The results of these preclinical studies by **terraplasma group** also correspond to the study results of recent publications.

	pathogenes	achieved log reduction after 1 min plasma treatment	associated skin diseases
bacteria	Fusobacterium Nucleatum	4,4	perioral dermatitis
	s. aureus / MRSA	5,6 / 6,0	acne, neurodermatitis
	p. acnes	.....	acne
	p. aeruginosa	5,9	acne
	s. agalactiae	6,5	Various superficial skin infections, wound infections, bacterial superinfections
	s. constellatus	5,8	
	e. coli	5,8	
	s. constellatus	5,7	
fungi	c.albicans	4,6	candidiasis
	t. rubrum	.....	dermatophytoses
	m. furfur	.....	tinea versicolor

▲ *Table 1: Investigated human pathogens with achieved log reduction*

Acne and actinic keratosis have already successfully been treated with cold atmospheric plasma.[27,28] CAP therapy was found to be an extraordinary effective treatment for patients with actinic keratosis – a non-bacterial/fungal associated skin disease. This effect is presumably based on the activation of local immune processes and the destruction of degenerated cells by the plasma – as already mentioned on left page.

Reports about tissue sensitivity or side effects caused by plasma treatment have not yet occurred in studies.[29] Moreover, the **effectiveness of plasma treatment in bacteria appears to be independent from their level of resistance to antibiotics or the species type**.[30,31,32]

A wide range of indications: from acne to atopic dermatitis

The multiple mechanism of plasma action provides treatment for a wide range of dermatological diseases (see table 2). Due to its flexible biocompatible foam layer, even hard-to-reach treatment areas could be easily accessed by plasma derma care® spacer.

Mycoses and **bacteriosis** are some of the most common dermatological diseases and – in case of delayed or inadequate therapy – they may develop severe clinical symptoms.
It is also worth to emphasize that **acne vulgaris**, with a prevalence of about 70-95%, is among adolescents[33] the most frequent dermatological disease worldwide.

Currently, **bacterial infections** are mainly treated with antibiotics. However, prolonged antibiotic treatment is not recommended due to the risk of developing resistances.
Mycoses are usually treated with topical antifungal agents. Therapy may cause side effects such as skin irritation, redness or hypersensitivity reactions; recurrences are very common.

Due to its antibacterial and antifungal effect, treatment with **plasma derma care®** is a suitable alternative for the local therapy of mycoses and bacteriosis.
The treatment of **atopic dermatitis** as a chronic constitutional disease is difficult. The usual therapies with glucocorticoids or antibiotics should not be continued for a longer time. In contrast, treatment with cold plasma is also possible in the long term, since no development of resistances or further side effects are to be expected.

Actinic keratosis can be treated well in early stages with current treatment methods such as photodynamic therapy (PDT). However these methods are often associated with recurrences and side effects such as severe pain symptoms[34]
These treatment methods are often used in combination to have synergistic effects in combating the disease.
At this point, **plasma derma care®** can be used as an add-on therapy.

	INDICATIONS	ESTABLISHED THERAPIES	**plasma derma care**
bacterial infections (bacteriosis)	akne vulgaris	antibiotics, antiseptics, glucocorticoids, retinoids, azelaic acid & benzoyl peroxide (for acne vulgaris) ⊖ retinoids with strong tetratogenic effect ⊖ antibiotics involve the risk of resistances ⊖ glucocorticoids can only be used for short periods	antibacterial, promotes wound healing, prevents superinfection and progression of inflammatory reactions ⊕ no resistances ⊕ long-term use possible
	perioral dermatitis		
	soft-tissue infections (folliculitis, boils, abscesses)		
	impetigo contagiosa		
fungal infections (mycosis)	pityriasis versicolor (tinea versicolor)	antifungal agents (azoles, polyenes, allylamines, etc.) – when used locally often associated with skin redness and irritations	antimycotic alternative/ combination therapies ⊕ prevention of recurrences and superinfection
	dermatophytosis (tinea)		
other skin diseases	atopic dermatitis (neurodermatitis)	calcineurin antagonists, glucocorticoids, antibiotics, hyposensitization	antipruritic, antibacterial, wound healing (in case of excoriations (skin-picking))
	actinic keratosis	cryotherapy, 5-fluorouracil, laser therapy, photodynamic therapy (PDT) ⊖ severe pain symptoms especially with PDT	activation of local immune processes, destruction of degenerated cells ⊕ without side effects, treatment painless
	viral skin diseases with bacterial superinfection (e.g. herpes labiales)	antivirals (aciclovir, ganciclovir, etc.), antibiotics (for bacterial superinfections)	in combination therapy: for the prevention/ treament of bacterial superinfections (antipruritic and analgetic effect)

▲ *Table 2: Indications for* **plasma derma care**

How to use –
simple, effective and painless*

The **plasma derma care** is a portable, battery-operated and therefore mobile medical device. Accordingly, it can easily be used in the clinical or practice sector, but also by outpatient care services. Treatment with the **plasma derma care** only requires a few minutes and its´ use is very intuitive.

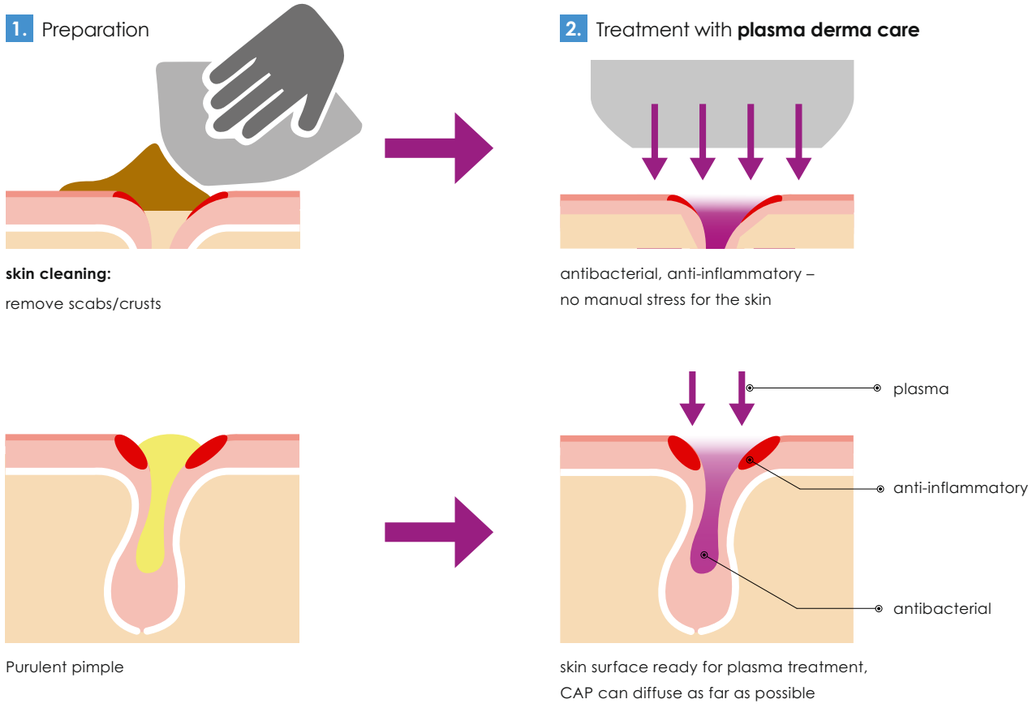
Plasma therapy does not exclude treatment with other therapeutic agents. Topical/systemic glucocorticoids, retinoids, phototherapy, etc. remain an effective add-on and may also be used depending on the individual patient profile. However, topically applied preparations should be removed prior to plasma treatment so that CAP can freely react.

In general, the use of the device is similar for all indications listed in table 2.
The affected skin area is cleaned prior to treatment and any existing crusts or pus are removed before the flexible biocompatible foam spacer is placed on the skin. The gaseous plasma can perfectly diffuse to the affected areas and unfold its effects on the skin surface (see figure 4).

An antiseptic can then be applied to provide a long-term antibacterial effect. The recommended treatment time is 1 -3 minutes per affected area.

The affected skin area is only exposed to minimal contact (application of the spacer), which means a reduced pain potential compared to other topical treatment options.
Areas close to eyes and mouth/nose openings should be treated very cautiously.
Plasma should not enter the respiratory tract or get into direct contact with the eyes; if necessary, aids such as nasal plugs and protective glasses can be used.

Patients described treatment with the* ***plasma derma care* *as free of pain.*



▲ Figure 4: treatment process with the **plasma derma care**

The advantages at a glance

Treatment with **plasma derma care** represents a completely new therapeutic approach for diverse chronic and acute skin diseases and offers a lot of advantages in comparison to conventional therapeutics.
In particular, there are no contraindications, the application is free of side effects, and at the same time treatment is highly effective.

Due to the 2-fold effect, i. e. activation of a local immune response and antimicrobial as well as antipruriginous effects, CAP can contribute in different ways to symptomatic relief or recovery.

Treatment with **plasma derma care** is quick and easy to perform, painless, cost effective and economical. Thus it may effectively be added to or even replace conventional therapies.

- high antiseptic efficacy
- wide range of indications for dermatology – from acne to neurodermatitis
- broad spectrum of effects – inactivation of all bacteria on skin
- no adverse events, skin intolerances and long-term risks [29]
- no resistances [6] or allergies
- treatment with minimum wound contact (spacer) and thus considerable reduction of pain potential in comparison to topical antiseptics.
- CAP inactivates bacteria - independent from their resistance to antibiotica or their species [30,31,32]
- also hard-to-reach or facial skin can be easily treated with flexible foam spacer

Case report

WOUND HEALING DISORDER – BASAL CELL CARCINOMA

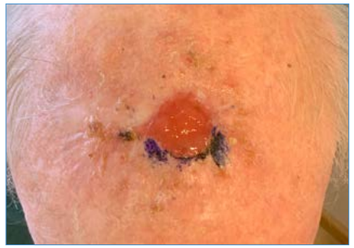
82-year-old male patient suffers from basal cell carcinoma on parietal bone: removal of basal cell carcinoma in a doctor´s practice. Delay in wound healing and occurence of first signs of infection. Formation of necrosis at front wound edge. Wound with pain sensitivity to pressure.

Treatment:

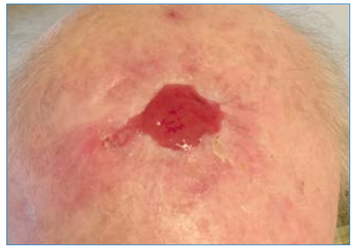
Picture 1: Start of CAP therapy on April 28th, 2022 in order to avoid further complications. After debridement with a physiological saline solution wound was treated 2 min with CAP 2 times per week.

Picture 2: Visible improvement of wound healing during 2nd treatment week. Wound edges no longer necrotic and no more visible signs of infection. Patient is free of pain.

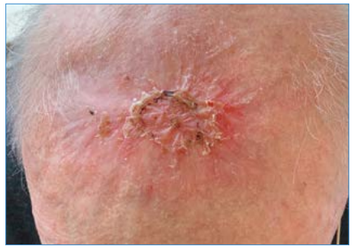
Picture 3: Complete epithelization of wound on June 14th, 2022 after 11 CAP treatments within 6 weeks.



Initial situation: first CAP treatment



Course of treatment



After 11 CAP treatments

SYMPTOMATIC TREATMENT OF PSORIASIS

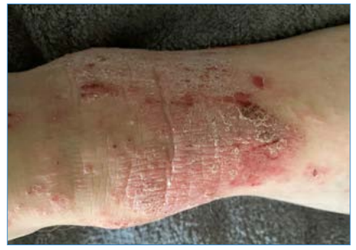
52-year-old male patient suffering from psoriasis for 6 months.
Psoriasis was initially treated with cortisone ointment with short-term improvement of symptoms. The skin soon became itchy, inflammatory and scaly again.
Skin care products used: urea ointment 10% and salicylic acid patch.

Treatment:

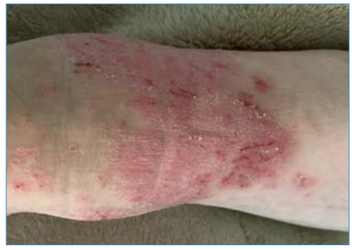
Picture 1: Heavy symptoms with bleeding contact dermatitis at right ankle. Skin areas were treated with 1 min of CAP-therapy each.

Picture 2: Patient reported a clear, subjective improvement of symptoms. The itching was reduced and the strained feeling of skin decreased. The open, scratched skin areas were found to be almost completely closed. Skin redness was visibly reduced.

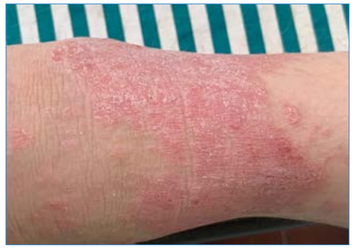
Picture 3: After only 1 week and 4 KAP treatments, the patient's subjective sensation turned out to be very positive: no pain, hardly any itching, no more feeling of skin tension on the ankle. Objectively, there was a significant reduction of inflammation, skin condition improved and contact dermatitis was almost gone.



Initial situation: 1st CAP treatment



Course of treatment



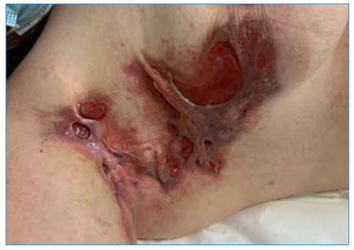
After one week/ 4 CAP treatments

AKNE INVERSA

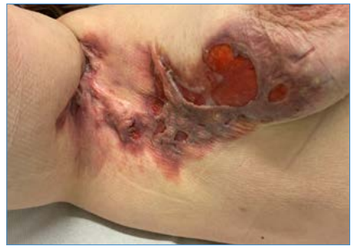
44-year-old female patient suffering from acne inversa.
Severe wound defect in patient with acne inversa around right axilla. Large wound areas up to 4.5 cm in diameter with multiple fistula tracts and undermined wound edges. Heavily exuding wounds on scar tissue due to multiple recurrences.

Treatment:

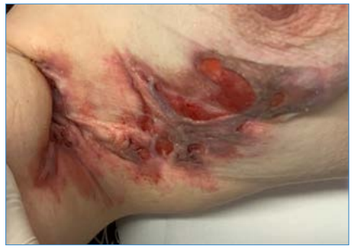
15 CAP treatments within 8 weeks. The complete wound area was divided into sections. Each section was treated with CAP for 1 minute each (6 x 1 minute). Wounds dried out significantly after 10 CAP treatments and wound edges smoothened.
After 15 CAP treatments, there was hardly any wound exudate and no more wound edge undermining. The wounds closed gradually.
The therapeutic intervals were reduced to 1 treatment per week. A final result is still pending.



Initial situation: 1st CAP treatment



After 10 CAP treatments



After 15 CAP treatments

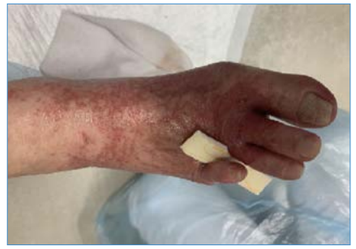
Case report

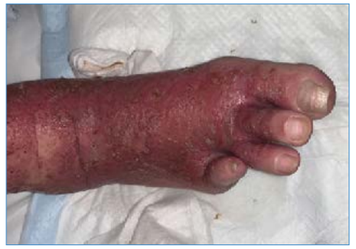
EXTRACT FROM
"DERMATOLOGIC THERAPY", WILEY, AUGUST 27TH, 2021

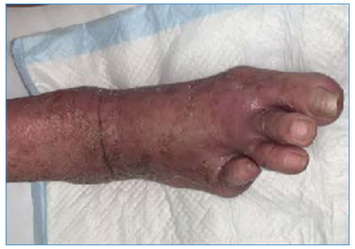
80-year old female patient suffering from diabetis mellitus (HbA1c 8,5%)
Past medical history: amputation of left foot below the knee and amputation of the right fourth toe, 3 years ago.
The patient developed an onychomycosis on the skin and toenails of right foot.
After 4 weeks of non-successful antifungal and antibiotic treatment, the patient was treated with CAP for 10 min on a daily basis. After only one week a clear improvement could be observed.

2 weeks later topical therapy was changed from an antifungal ointment to a moisturizing ointment with supplemental plasma therapy (fig. B).
Patient finished plasma therapy after 3 weeks in total (fig.C).

Read the whole article:


(A) Before treatment

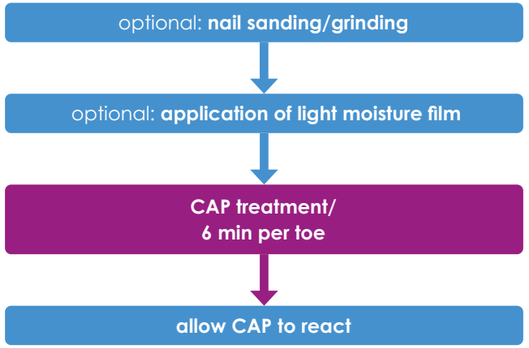

(B) After two weeks of CAP treatment


(C) After three weeks of CAP treatment

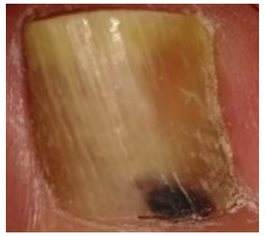
Excursus: NAIL MYCOSIS

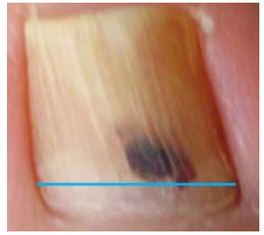
First reports about treatment of nail mycosis

Those who suffer from nail mycosis are often ashamed and hide their nails in shoes and socks. Medically, a therapy of nail mycosis is advisable to prevent a bacterial superinfection (e.g. erysipelas) and a spreading skin mycosis.
In case of diabetic foot syndrome early nail mycosis therapy is indispensable!
In more severe cases, patients must also receive a systemic antimycotic therapy. The side effects of this therapy are often described by patients as very uncomfortable. Treatment with CAP can not only eliminate the fungal disease, but also prevent its spread and reinfection.
The advantages in comparison to conventional therapies are quite obvious.

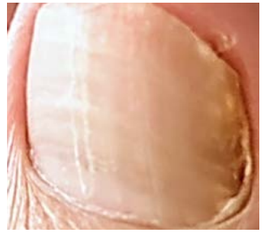


Frequency of treatment:
Every toenail is different: basically, a nail should be retreated until a completely healthy nail has been re-grown. In previous case reports, patients have been treated at least 1 to 2 times per week.
Once the healthy nail progresses to re-grow, the frequency of therapy sessions can be reduced while monitoring.


Initial situation


4 weeks/ 6 CAP treatments


Initial situation


End of CAP therapy

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terraplasma MEDICAL

terraplasma medical GmbH
Parkring 32
85748 Garching | Germany

Phone + 49 89 588 055 30
eFax + 49 89 588 055 99

Let's stay in touch:

Linked terraplasma-medical
Mail info@terraplasma-medical.com
Web www.terraplasma-medical.com

Jens Kirsch | Chief Executive Officer (CEO)
PD Dr. rer. nat. habil. med. Julia Zimmermann | Chief Medical Officer (CMO)
Prof. Dr. Dr. h.c. Gregor Morfill | Scientific advisory board

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