



# The Patient's View at Basic Clinical Principles

*Christian Seebauer,  
Hans-Robert Metelmann,  
and Philine H. Doberschütz*

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## Core Messages

- An innovative treatment opportunity like cold atmospheric plasma (CAP) requires extended information of the patient.
- The personal medical consultation should be accompanied by a written document.
- Since the document is targeted at the patient, the wording speaks to the patient.

## 6.1 Introduction

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As in every medical specialty, successful plasma medicine requires the understanding and cooperation between the medical practitioner and the patient. The basis for patient compliance is informed consent. An innovative treatment like cold atmospheric plasma (CAP) medicine requires extended information of the patient.

This part of the textbook is intended to serve the medical practitioner as a template for medical briefing of patients. The personal medical consultation should be accompanied by a written document. The line of thoughts adopts the patient's perspective and provides text modules to facilitate the preparation of a consent form. Since such documents are targeted at the patient, the wording speaks to the patient:

» “Dear Patient,

You are consulting your doctor because of a medical or aesthetical problem, and the key term *plasma medicine* has been mentioned. It became obvious to you, that plasma medicine has nothing to do with blood plasma. Now, you are interested to learn about plasma medicine and why it makes sense to consider it for treating your problem.

The purpose of this document is to make you familiar with the basic clinical principles of plasma medicine. Please read this information carefully. Your doctor will inform you about treatment options with cold atmospheric plasma, typical risks and possible consequences, and the details of the medical intervention regarding your case. When you feel adequately informed and expressly wish to undergo plasma medicine treatment, please confirm your consent with your signature.

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## 6.2 General Aspects of Plasma Medicine

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“Colloquially, the term “plasma medicine” often refers to tools that generate physical plasma or to products activated by physical plasma, mainly used for cosmetic purposes and by laypersons. Your doctor, on the other hand, is talking about cold physical atmospheric pressure plasma, abbreviated to CAP, generated by officially approved medical devices, and indicated with particular relevance for the medical therapy of chronic wounds and infected skin.

If you suffer from a severe skin infection or wound that is not healing, you have experienced the heavy burden on your health and well-being. These problems can sometimes be difficult to handle by established therapeutic procedures, calling for innovative treatment like CAP medicine.

A wound by itself is not a disease, and wound healing is just a natural process that does not require a targeted treatment. However, problems may arise due to the following reasons:

- When open wounds become severely infected by pathogens
- When wound healing is retarded and the risk of infection is rapidly increasing
- When wounds cannot heal because of consuming illness and show massive infection
- When pain or general risk prevention require rapid healing of open wounds and infected skin
- When wounds and skin infections are health-threatening skin abscesses
- When infected wounds contaminated with certain bacteria are causing smell and odor

CAP medicine covers all of these indications.

You might be interested to learn that CAP is ionized gas, generated by physical energy. CAP induces biochemical reactions and releases molecules that interact with human wound cells and with microbial cells, such as infectious bacteria and viruses. CAP therefore accelerates wound healing in two ways: by killing harmful germs at the wound surface (antisepsis) and by promoting the growth of healing cells (tissue regeneration and microcirculation). This double effect is a unique advantage of CAP treatment compared to conventional and established wound care measures.

CAP may look, if visible, like bluish little flames, but with a temperature not higher than 40 °C, it works on the cells without causing thermal damage, ensuring a painless treatment.

Moreover, jet-plasma application is a touch-free treatment that avoids unpleasant contact of the device with your wound or irritated skin and prevents the risk of unintentionally injuring numb wounds.”

### 6.3 Selection of Patients

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“You have learned that CAP treatment is useful for you, in case you are suffering from problematic wounds or infected skin and mucosa. This includes patients with the following:

- Chronic and infected wounds
- Wounds with standstill of healing but without infection
- Skin and mucosa lesions at risk of serious progression
- Non-healing wounds by other reasons
- Skin and mucosa with certain local infections and purulent focuses

Patients suffering from infective and inflammatory skin and mucosa diseases like herpes zoster, atopic eczema, or acne may soon benefit from CAP application.

You may also belong to a group of patients considered at risk of poor wound healing, who benefit from CAP treatment as preventive measure. This includes patients with the following criteria:

- With wounds that are not closing within 28 days
- Aged 60 years or older
- After menopause
- Under systemic steroid medication
- With cancer or a history of previous impaired wound healing

You see that CAP application can be used to support the healing of lesions and acute surgical wounds in cases where the patient's difficult health-status, biographic condition, or medication pushes the risk of problematic wounds. Accelerating the wound healing can also help to reduce scar formation. Together with the potential to prevent wound infection, CAP treatment is a promising option to control the risk of surgical site infections in the field of plastic surgery and aesthetic medicine."

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## 6.4 Choice of Plasma Device

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"Your individual medical problem calls for individual treatment, and your doctor will propose and choose the most appropriate CAP device for your treatment task. You might be interested to learn that there are two types of medical devices in use, approved by the competent authorities since 2013.

One type is called plasma jet or plasma torch device: CAP is generated by electrical tension within a slim tubular handpiece or a cylindrical tube located at the end of a flexible arm. The resulting ionized gas is driven out by a propellant gas and looks like a flame. This "plasma cocktail" consists of atmospheric air, noble gases (argon, helium), and gas mixtures of the working gases.

The other type of medical device is based upon dielectric barrier discharges (DBD): CAP is generated either within a small gap between the large surface of a flat handpiece and the surface to be treated (e.g., skin, wound), or on the surface of a specifically designed electrode structure which is positioned in close vicinity to the surface to be treated. This "plasma cocktail" looks like a carpet and consists of atmospheric air.

Jet plasma devices with plasma flames shaped like the tip of a lancet are very suitable for precise interventional procedures under visual inspection. They are used on wound craters and rugged tissue, on regions with undercut, and for intra-oral application. Torch-like as well as DBD plasma devices with larger flames or plasma carpets are very convenient for the quick treatment of large and flat wounds and infected skin areas.

Rest assured that your doctor is only using CAP devices with CE certification as medical devices class-IIa according to the European Council Directive 93/42/EEC. These devices work with plasma sources that have been extensively examined

for their biological and physical properties and have been tested in detailed pre-clinical and clinical investigations.”

## 6.5 Handling of Complications

“You might have experienced that standard treatment of wounds and skin infections does not succeed in some cases. This is also true for CAP therapy. Even with well-proven healing effectiveness of CAP medicine, there are some patients with insufficient treatment results. Especially in chronic wounds, plasma medicine plays an important role – but it is not the only player. Continuous debridement, proper wound dressings, and keeping relevant co-morbidities and current medication under control are important as well.

First CAP medical devices had been approved in 2013 and still there are no known serious side effects or complications of therapy. Any enhanced risk of genotoxic and mutagenic effects of CAP treatment has been excluded by well-established in vitro tests as well as by a long-term animal trial and long-term clinical observations.

In principle, complications in medical procedures are due to the general health and medical condition of the patient. Please help your doctor to identify any risk of complications by carefully reporting your health status and medical history.”

### Conclusion

“Dear Patient,

To sum up this information, we would like to answer some of the frequently asked questions:

Is the clinical efficacy of CAP treatment proven?

Yes, there is a number of plasma sources with comprehensive physical and biological characterization and detailed preclinical and clinical investigations to prove efficacy. The application for treatment purposes is authorized by CE certification as medical devices class-IIa according to the European Council Directive 93/42/EEC. These devices are approved for the treatment of chronic wounds and pathogen-associated skin diseases.

This statement does not include several other plasma tools on the market that claim to be suitable for “plasma medicine” but have no or very inadequate physical, technical, biological, or clinical references to prove this.

How is the risk of local or systemic side effects and complications?

Approved plasma devices are in clinical use since 2013. There are no case observations or clinical studies in the literature that report severe side effects of any kind, including carcinogenesis or genetic damage.

Slight local effects have to be considered, such as minor pinprick or irritation related to the tip of the plasma plume when using plasma jets. In very rare cases and unclear connection, a brief and mild redness of the skin following unintended touch might occur.

Is the medical effect in my case reliable?

The effectiveness of CAP in wound healing and treatment of infected skin is well documented. However, there are always a couple of patients without positive treatment results for unknown reasons. Plasma medicine plays an important role in wound healing – but it is not the only player. Steady debridement, proper wound dressings, restoration and perfusion of vessels, lymphatic drainage, and keeping relevant co-morbidities under control are important as well. This is especially true for chronic wounds.

Is the medical effect well controllable?

In wound healing, the medical effect can easily be controlled by measuring the regain of skin cover and the shrinking of the wound surface. On-going photo documentation is important. Documents will include scale and date and follow the very basic requirements of scientific medical photography.

Will I see a quick medical effect?

Wound healing is never quick. You have to know that it takes stamina by all persons involved and sometimes many weeks of repeated treatment to reach a reasonable result.

Can bacteria become resistant when treated by plasma?

One of the significant advantages of plasma medicine compared to other antimicrobial therapies is its effectiveness against multi-resistant skin and wound germs. From the opposite point of view, the development of new resistances when treating germs with plasma has never been described – neither in clinical cases and studies, nor in pre-clinical and basic research.

Is there an inhibitory effect on my normal flora?

There are no case reports or pre-clinical and basic research studies mentioning problematic effects on the normal flora in clinical plasma medicine.

Is plasma therapy cost-effective?

Currently, there are no thorough treatment-related economic or organizational studies available that compare the cost of plasma therapy to standard procedures.

Clinical experience shows that personnel costs are a greater factor than the costs of material consumption. Depending on the complexity and size of the wound and the optimal number of treatments, plasma therapy can be a time-consuming process. Several case reports, however, mention a faster overall healing and a shortened time of hospitalization when plasma therapy is conducted. The purchase price of medical plasma devices varies considerably but is well below medical laser devices.

Could it be done easier? Are there no alternative solutions?

Patients suffering from problematic wounds usually have experience with many alternative but fruitless solutions. The crucial point should therefore not be whether there is a simpler option, but which option is the most effective.

How is the acceptance of plasma therapy and compliance?

By common clinical experience, most patients are appreciative for plasma medicine as an innovative and pleasant treatment procedure. The compliance usually is extraordinarily high because of the burden of suffering that problematic wounds pose. However, there are no studies available in present literature that investigate the acceptance of CAP therapy from a socio-medical and health-economic perspective.

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**Concluding Remark**

The text modules proposed in this chapter make no claim to provide all the information that might be necessary for the patient to reach a decision. This chapter does not provide a legally guaranteed information sheet but aims to serve as orientation and support as to how the patient's information can be structured.