Pre-clinical Device Evaluation

Jett Plasma Lift Medical

Contents

1. Theoretical Introduction

1.1. Principle

1.1.1. Basic terms

At a normal temperature, gas is comprised of neutral atoms or molecules. There are no particles conducting electric current and gas is therefore considered as a good insulant. Inside the gas, collisions of atoms, ions and electrons appear. They are considered as non-flexible, because their inner energy changes.

Non-flexible collisions cause ionization, excitation, deexcitation and recombination of ions and atoms in the gas and they are cause by hits of free electrons, or sometimes ions as well. [1]

The aforementioned collisions can be described by the Townsend avalanche theory which explains independent ionization mechanism of electric discharges.

1.1.2. Townsend avalanche theory

If there is a DC voltage *U* between two metal plate electrodes, the electric field affects free electrons that are naturally present in the air. Homogeneous electrical field accelerates these electrons to the positively charged plate (anode) and collisions with neutral atoms or molecules appear. These accelerated electrons transmit a part of its kinetic energy to the electrons in neutral atoms. When the neutral particle is ionized with a sufficient amount of energy, the free electron is torn off, which leads to the formation of the pair electron-hole. The hole is a place where there is lack of electrons and therefore a positive charge prevails. The number of free electrons increases exponentially with the trajectory of the electron. Electrons then flow towards the positive plate and positive ions towards the negative plate (cathode), where electrons are burst from the surface of the cathode by non-flexible collisions. If the number of the free electrons between the cathode and the anode increases, a spontaneous discharge appears. In fact, the number of electrons should increase continually, but due to the recombination of the electron-hole pairs, the electric field between the electrodes decreases and it is eventually stabilized.

The aforementioned ionization of gases would be possible only by adding energy with the help of electric field, ultraviolet light, X-ray radiation or cosmic radiation. It means that for the conducting of electric current in gas, there has to be sufficiently large electric field to be able to call the discharge non-independent. In sufficiently strong electric fields, the number of ions and electrons suitable for the independent maintenance of current are created and these discharges are called independent. [2]

1.1.3. Independent electric discharges in gas

In the atmospheric or decreased pressure, these discharges may appear [11]:

1) Arc discharge

Its typical characteristics is a high current density and lower voltage, in the order of magnitude of tens of Volts, and also thermos-emissions of electrons from the incandescent electrode. If the electrodes move away from each other to several millimeters, the surrounding air is thermally ionized.

2) Corona discharge

Corona discharge is created in a strong non-homogenous electric field. The overall current of the corona is insignificant. The flammable voltage depends on the sharpness of an electrode. It is most commonly created in the DC voltage and it can burn at the border of sparkle discharge.[1]

3) Sparkle discharge

Sparkle discharge transmits high currents through a smaller section ~ mm^2, however it has a short lasting 10^{-7}-10^{-3} s. The sparkle discharge is formed by very quick, dynamic and non-stationary energetic transformations and it is accompanied by light flashes and acoustic manifestations. It is mostly realized in the atmospheric pressure but a high intensity of electric field is required $E \sim 10^6$ V/m.

4) Smoldering electric discharge

In case of this kind of discharge, the electrons and ions are accelerated by the electrostatic force between the electrodes. It is necessary to have a sufficient intensity of the electric field $E \sim 3.10^6$ V/m. If electrodes are placed into a closed space of a discharge tube in which the pressure is decreased, the smoldering discharge can be observed. Compared to the arc discharge, this kind of discharge has a low current and low temperature of the electrodes and the tube.

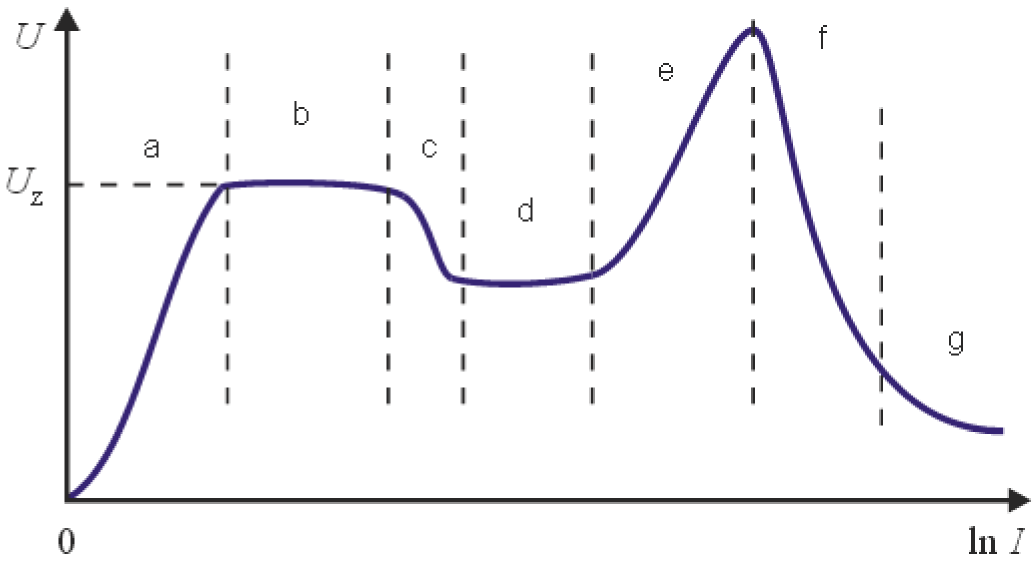

Fig. 1.1: Kinds of electric discharges [2]

Fig. 1.1 shows various kinds of electric discharges. In the first part of the curve (a), a non-independent discharge at a low output current is shown. When the flammable voltage U_z is exceeded, the electric field is big enough to accelerate electrons and it is sufficient to maintain independent discharge. This is shown in the second part of the curve and it is called Townsend discharge. Every discharge is accompanied by so-called corona, which is represented by the (c) part of the curve. The fact is that the corona is present on the surface of every sparkle discharge [3]. Another part of the curve, part (d), represents the smoldering discharge and part (e) represents an anomalous smoldering discharge at higher current densities and temperature than the preceding one. Then, in an electric field of a high intensity ($E \sim 10^6$ V/m), the sparkle discharge is ignited and if the source of the current is strong enough, the discharge is called arc (g). Sparkle channel is highly conductive and it has a very small cross-section (app. 1 mm^2). [2]

1.1.4. Plasma

Now, we are going to focus on the plasma - the ionized gas, which is created in any discharge in the gas. Plasma was discovered and diagnosed by Lagmuir in 1923. [10] Lagmuir researched this state of matter because he wanted to design a tube able to conduct current in a very low pressure and so it had to be filled with ionized gas.

Plasma can be defined as an ionized gas comprising of ions, electrons and neutral particles and molecule. It is created by the unbounding of electrons from the electron shell of atoms of gas or by the tearing of molecules (ionization). [3]

The temperature of electrons in plasma is much higher that the temperature of ions and neutral particles, so this kind of plasma is called non-isothermal and it must be maintained artificially. On the other hand, if the temperature of all particles in plasma is identical, the plasma is isothermal. [10] If we have a circuit with two conductive plates and the voltage is be increased continually, the circuit behaves according to Ohm´s law in the first phase, so the current is proportional to the voltage. In the following phase the current gets saturated, which means that the current is constant. In case of further increase of the voltage, ionizing collision cascade appears and the voltage grows exponentially. The last phase is caused by the exceeding of threshold voltage U_d, when the influence of secondary electrons from the cathode is manifested [4]. Because plasma contains free electric charges, it is conductive. [10]

1.1.5. Paschen´s law

The Paschen´s law shows that the breakdown voltage U_{pr} depends only on the product of pressure and the distance between the cathode and anode. [4]

Paschen´s law: $U_{pr}=f(p.d)$

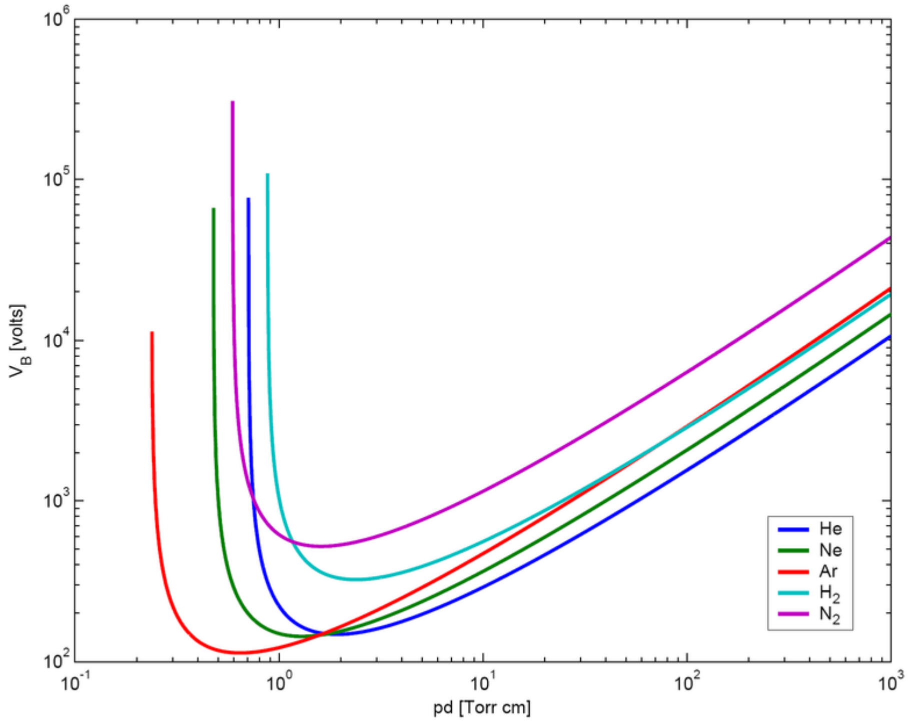

Fig. 1. 2: Dependence of voltage on the product of the distance between electrodes and pressure in various gases.

All functions of respective gases have their minimum, which was experimentally proven in 1889. See Fig. 1.2. [5]

If we use AC instead on DC voltage, the formula is modified into this form:

$$U_{pr}=f(p\times d,f\times d)$$

In the modified formula for the AC, the frequency dependency can be observed. Generally, it can be stated that the breakdown voltage in AC current is lower than in the DC current.

1.2. Application of discharges in electro-surgery

1.2.1. The history of Cautery

In the distant past, 3000 years BC, the use of cautery for the treatment of ulcers was described in the ancient Egypt. Hippocrates described the method of a tumor destruction by the use of heat. Later, hot iron was used for coagulation. The first use of thermal effects of DC was described in the half of the 18th century by Benjamin Franklin and John Wesley. It included indirect effect, when the DC current helped to heat the object that was applied on skin. [7]

At the beginning of the 19th century, DC current conducted through a conductor to effectively cauterize the tissues in the place of contact was used. [9]

In the second half of the 19th century, the experiments with biological effects of the AC on tissues were started. A French physiologist Arsené D´Arsonva was he first to apply the sparkle discharge on the tissue to destroy it thermally and he called this process "fulguration" (from Latin fulgur –flash). It is also a general fact that plasma (ionized gas) must be present in the fulguration.

1.2.2 AC electrocautery

AC electrocauters using discharges have been used for the same or similar indications as our evaluated DC electrocauter for decades. Only AC excitation causes sparkle shower, i.e. the flow of sparkles falling to the area of app. 1 cm^2. AC electrocauters are used also for surgeries, however they have much higher input powers (about 20W), yet, they are adjustable by 0.1 W. Manufacturers of the aforementioned electrocauters have clinical studies for similar indications as the evaluated device and they work with similar input powers. If small warts are burnt with these electrocauters, the clinical study for the output set to 1.8 W. During the whole time AC electrocauters are used, there appeared no side effects and therefore the method of fulguration with the output 1.8 W is considered safe and it is possible to make a comparison of the evaluated DC cautery with the AC one.

1.2.3 The effects of the heat on the tissues

Physiological body temperature is 36-37°C. During an illness, the body temperature can raise up to 40°C without the destruction of cells or tissues.

In the following chart, intracellular temperatures are stated and they are matched with corresponding reactions of organism. (See Chart 1)

Chart 1: Reactions of organism to temperature changes

50 – 60 °C	Cell death in approximately 1-6 minutes
60 °C	Immediate cell death
60-65 °C	Coagulation appears
65-90 °C	Denaturation of proteins
90-100 °C	Drying (desiccation) appears
Over 100 °C	Leads to vaporization

In the temperature range of 60-65°C, hydrothermal bounds between protein molecules are destroyed and homogeneous coagulate is created. That is why the process is called coagulation.

In his article The Fundamentals of Electrosurgery [7], M. G. Murdo describes that at the temperature lower than 60°C, hydrothermal bounds are renewable, if the temperature decreases locally. Another process is dehydration and desiccation when cells lose water through a membrane disrupted by a high temperature. It was proven that protein bounds become homogenous and they have gelatin structure. This effect on the tissue brings about a possibility of the tube structure closures, for example the closures of vessels in order to stop bleeding.

In case that intracellular temperature raises over 100°C, the water in the intracellular space starts to evaporate. Subsequently, due to a high temperature, cells expand and explode and their content pours into intracellular space.

If the temperature exceeds 200°C in a certain place, organic molecules are carbonized and so called red coagulation occurs.

If DC or AC current flows through cells, which have a certain electric resistance, the cells are heated due to the flow of the electric current. Electric energy is changed into heat, which was first described by an English physicist James Prescot Joule. The bigger the electric resistance of the tissue is, the higher the generated heat. For example, the resistance of palmar skin is 100 kΩ, the resistance of fat is 2 kΩ and resistance of muscle tissues is 0,8 kΩ.

1.2.4 Heating of tissues by sparkle discharge

By the use of both DC and AC current, a sequence of sparkle discharges that have a thermal effect on skin can be achieved. The falling sparkles carry thermal energy, which leads to the increase of intracellular cell temperature. This process is called fulguration. By the adjustment of the intensity of the sequence of sparkle discharges, also various thermal effects on cells including their carbonization can be achieved.

1) Coagulation

During the flow of the current, blood and tissues are heated quickly, which leads to the denaturation of proteins and subsequent halting of bleeding.

2) Desiccation

Desiccation is a process in which intracellular liquid inside cells is heated, which leads to the evaporation of water inside cells and to the drying of cells.

3) Fulguration

Fulguration is therefore a process, in which tissues are destroyed without incision. These tissues coagulate superficially with a continually repeating high-voltage sparkles, yet, these sparkles have a low current force. If the fulguration appears, the active electric wave is present only in 10% of the overall time of activation. In the majority of cases, the process of fluctuation is performed by a high-voltage AC electric current, which is modulated with a low working cycle of 6%.

4) Vaporization

Vaporization means that the water from cells is vaporized due to the passage of electric current.

1.2.5 Examples of the application of the DC current in medicine

In a recent past, fulguration by high-voltage DC current was used. In 1982 the 1st catheterization ablation of the AV node was performed with the use of the DC current to control the supraventricular tachycardia. A quadripolar catheter was inserted directly into the hearth through the Inferior vena cava and the tissue was burnt by the energy ranging from 300 – 500 J. [8] In 1984 the 1st ablation of posteroseptal pathways was performed also by the discharge of the DC current. Following the example of American doctors, these ablations of the AV node by the DC current were performed also in the Czech Republic in 1983 – 1992 [12].

The next ones were Japanese doctors who performed ablations of the AV node by the use of the DC current to treat supraventricular tachycardia and also to the ablation of posteroseptal accessory pathways to treat patients with Wold – Parkinson – White Syndrome. The article also mentions the use of fulguration with the energy of about 100 J to myocardial lesions. [14]

In his article on clinical experience with fulguration, Guy Fontaine states that during fulguration procedures treating the chamber tachycardia, they used the voltage of approximately 4kV with the use of the DC current [15]. Further, in his another article „Catheter Design for Successful Fulguration Procedure“, he deals with the most suitable values of current and voltage used in fulguration procedures. He states the 4-6 s time of the treatment with the discharge voltage of 2 – 3 kV and DC current of 40 – 50 mA. It implies that from the output point of view, these fulgurations ranged from 0.08 to 0.9 W during the treatment of the chamber tachycardia. Later these parameters had to be adjusted to 60 – 80 mA of the DC current due to technical problems and their output got to approximately 1,44 W [17].

Another collective of doctors mentions the use of low-energy cautery (0,1 mV) with the output of 20-36 W and with the use of the DC current for 15 – 30 seconds for the ablation of the AV node from the left chamber [16].

2. Application of the DC fulguration, i.e. sparkle discharges excited by the DC current.

The flow of the sparkles falling on skin causes an increase of intracellular temperatures. This process is described in the preceding chapter and it is called fulguration. The carrier of the heat is an electric arc (flow of sparkle discharges with a corona created on their edge). The generated heat of the sparkle discharge sequence is proportional to the input power of the exciting electric current, where a high exciting voltage causes a breakdown of air and its ionization with a subsequent creation of electric discharge. The generated heat is proportional to the input power of the exciting current and time. In this case it is not important, whether the sequence of sparkle discharges is excited by the DC or AC sinusoid current. In case of other than sinusoid course, a crumb would have to be taken into consideration. This is the reason why it is possible to compare electrocauters or other electrosurgical devices working in the regime of fulguration by applied exciting input power, for the purpose of clinical evaluation and it is not important whether it is an AC or DC excitement with a sinusoid course. The original scientific descriptions are based on the AC excited electric discharges (see Chapter 1. 2. 4.).

Paschen´s law determines the dependence of the breakdown voltage of gas $U_{pr}=f(p,d)$, which means that for the formation of an independent discharge, the breakdown voltage of gas depends only on the product of the pressure and distance between cathode and anode. Individual gases vary in functional dependence of breakdown voltage on the pressure of gas. All curves $U_{pr}/p\times d$ have their minimums. Paschan´s law was experimentally proven in 1889 [5].

If other than DC excitation is used for the excitation of discharges, the Paschen´s law is transformed into the form $U_{pr}=f(p\times d, f\times d)$, in which the f stands for the frequency of the AC source [4].

DC current discharges were first used in 1982 for catheterization ablation of an UV node (palliative performance). Then, catheterization ablation by the DC discharge was realized in 1984.

In 1982, a method of catheterization ablation of AV node using the DC current discharge was first applied on 5 patients with repetitive fits of supraventricular tachycardia. The use of the electric discharge led to the destruction of cells (ablation). This method showed that it is possible to vaporize cells safely and reliably with a relatively precise targeting protecting surrounding tissues by the use of the DC discharge. This was possible due to the fact that the sparkle charge of arch discharge generated by the DC current has a cross-section of 1 mm^2.

In 1986, the team of doctors led by G. Fontaine MD presented the effects of DC fulguration application tested on 31 patients to remove or reduce serious ventricular tachycardia.

2.1 Thermal effects of current

Thermal effects of DC and sinusoid current able to generate sparkle discharge are the same. Electric work done by the DC current between two places in electric circuit in a certain time equals the work necessary to transmit electric charge Q in this time t. For a constant current running through a circuit, there is a relation: $W_e = Q.\ t = U.\ I.\ t.$

Electric current running through the circuit is generated by the movement of electric charges performing a work. In metals, free electrons are carriers of these charges. Thanks to the interaction (collisions) of electrons with a grid, their kinetic energy is transformed into heat, which increases the temperature of the material. This heat, called Joule´s, is equal to the energy of the electric current running through the conductor.

The relation between the Joule´s heat Q_j, the current I and the resistance of the conductor R is called Joul-Lenz Law: $Q_j = U.I.t = R.I^2.t = (U^2/R).t = P.t$

For power dissipation on the conductor or on the resistor, there is therefore this rule (if considering a constant current): $P = U.I = U^2/R = R.I^2$

In case of the AC output, the calculation is more difficult, as the values of voltage and current are changing constantly and there is a mutual phase shift between them. That is why multiplying by an element cos {Ѳ}, so called power factor, is added into the equation

Manufacturers state averaged values of voltage and current and their corresponding outputs on their devices. That means that the work of the exciting sparkle discharge equals to the heat generated by the flow of sparkles which approximately equals to the input in the given time, as it has been already described above. Because of that the thermal effects of AC and DC current can be considered equal. [13]

DC fulguration is used in the evaluated device Jett Plasma Lift Medical as well. It is a mono-polar DC fulguration, during which a patient is conductively connected to the device by a disposable grounding electrode. Maximal voltage is 7000 V, maximal current is 1 mA and maximal power is 1,8 W. This volt-ampere characteristic shows that the best outcome is reached in the 50-60% of current (see Fig. 1.3.)

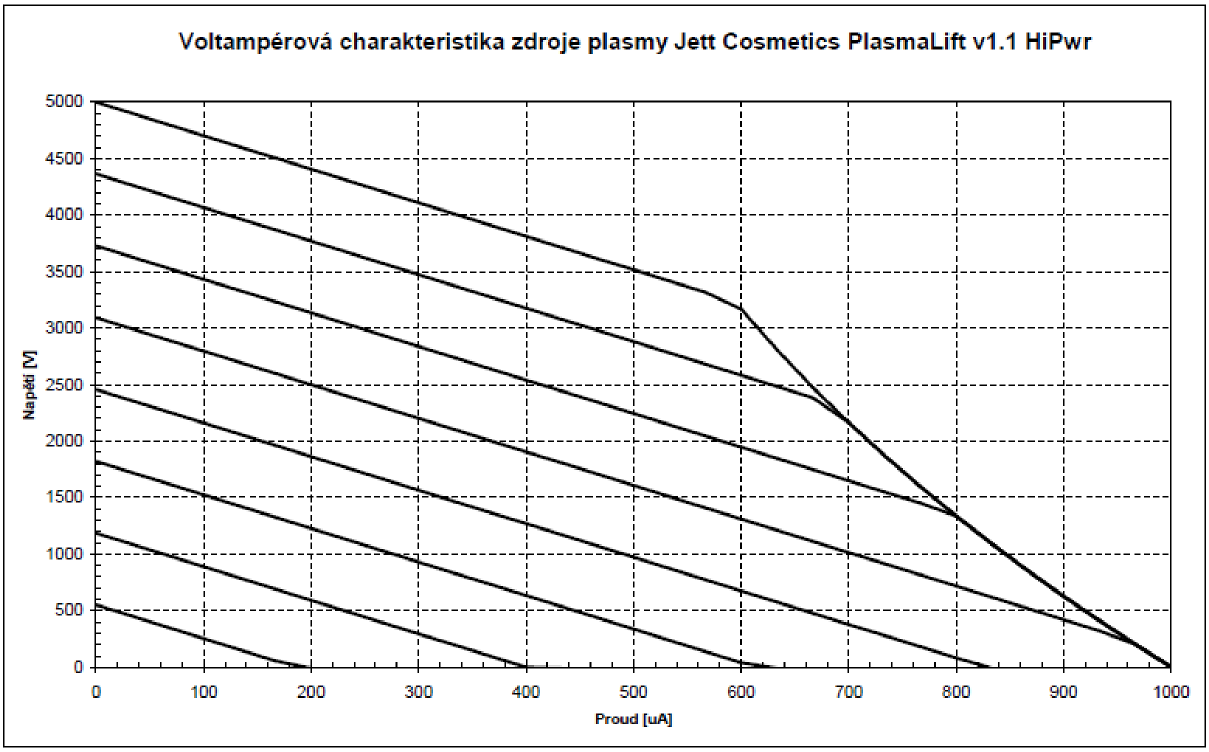

Fig. 1.3: Volt-ampere characteristics of the plasma source

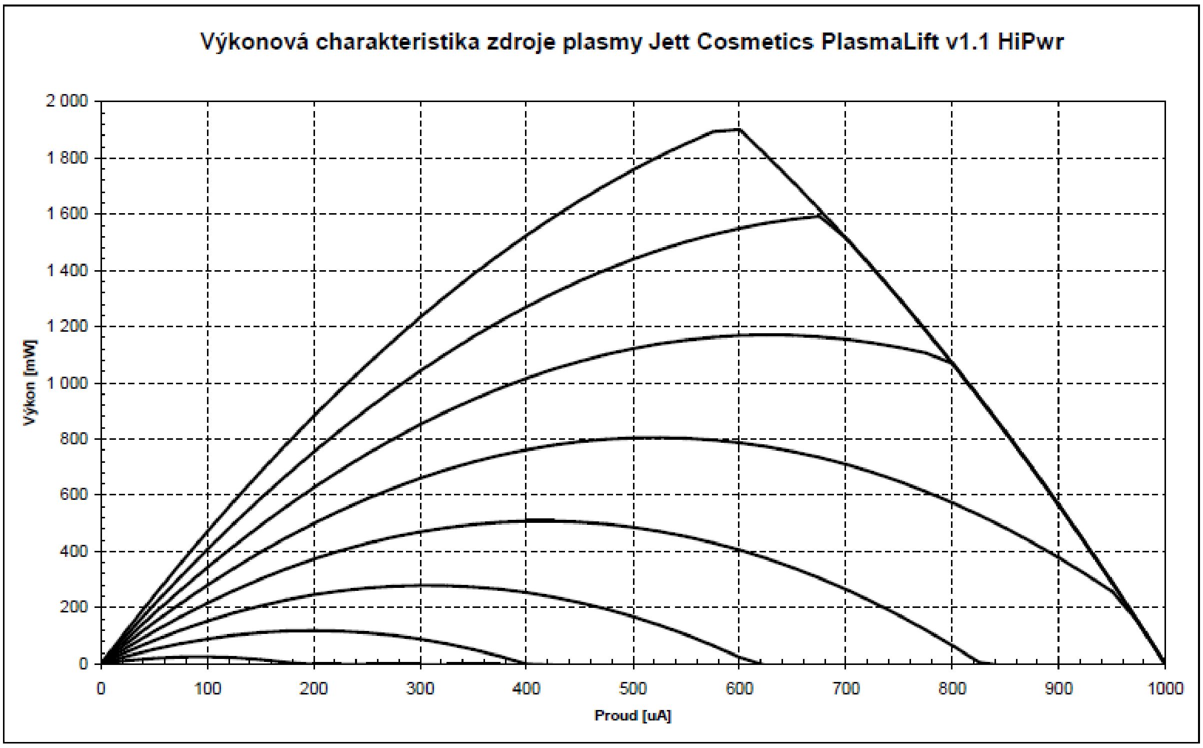

Fig.. 1.4: Output characteristics of the plasma source

Outputs 0 – 1.0 W are not able to cause a permanent damage to cells, however, at higher output intensities, i.e. 1.0 – 1.8 W, coagulation, desiccation, fulguration and vaporization can be achieved. The intensities of these outcomes are stages 6, 7 and 8. The output characteristic shows the outcome of individual stages.

Chart 2: Matching of the output with the stage

Stage	Output (W)
6	1,2
7	1,6
8	1,8

2.2. Indications

Following bullet points state indications for the treatment with Jett Plasma Lift Medical device. In case of basal-cell carcinomas and carcinomas, the treatment can be done only after the preceding histologic examination.

- angioma senilis
- verruca seborrhoica
- verruca plane
- angiokeratoma
- teleangiektasie
- lentigo
- fibroma molle
- keratocanthoma
- conydolamata accuminatum
- moluscum contagiosum
- verrucae vulgaris
- verrucae filitormes
- pulpitis
- naveus capillaris
- naveus araneus
- basalioma superficiale
- carcinoma spinocellularis
- lymphangioma
- keratosis actinica
- keratosis senilis
- kerstosis sebborhoica

2.3 Parameters of Jett Plasma Lift Medical Device

In the following Chart 3, the parameters of Jett Plasma Lift Medical are stated.

Chart 3: Parameters of Jett Plasma Lift Medical device

Manufacturer	Compex ltd.
Country of origin	Czech Republic
Type of device	Jett Plasma Lift Medical
Therapeutic principle of the device	Plasma discharge in combination with thermal energy, contactless application (electrode does not touch tissues)
Aim of use	Minor dermatological and surgery interventions
Working voltage	0,8 – 7 kV
Mechanical design of the device	Compact design, everything in one device, the size of a pencil electrode
Voltage of the plasma discharge generator	0,4 to 1,8 W 1 pencil electrode covers the whole range of the plasma discharge generator voltage
Detection of the grounding functioning	SCS System
Power supply	Power source – Power adapter
Size of handle	Length 24,5 cm, diameter 4,5 cm
Weight	Approx. 350 g

A great advantage of the evaluated device is that due to the use of DC, instead of AC voltage, the tissues are not damaged compared to high-frequency cauters, which thanks to its “spray” function affects also the surrounding tissues, i.e. healthy tissues, around the area of application.

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